Print Annual Reviews for Fiscal Year 2020

Count	Category/Medication
1.	Actinic Keratosis Medications
2.	Aldurazyme® (Iduronidase)/Naglazyme® (Galsulfase)
3.	$Alpha_1$-Proteinase Inhibitors
4.	Amyotrophic Lateral Sclerosis (ALS) Medications
5.	Antifungal Medications (Systemic)
6.	Antihistamine Medications (Oral)
7.	Anti-Parasitic Medications
8.	Arcalyst® (Rilonacept)
9.	Benign Prostatic Hyperplasia (BPH) Medications
10.	Benzodiazepine Medications
11.	Botulinum Toxins
12.	Bowel Preparation Medications
13.	Brineura® (Cerliponase Alfa)
14.	Butalbital Medications
15.	Carbaglu® (Carglumic Acid)
16.	Cholbam® (Cholic Acid)
17.	Chorionic Gonadotropin Medications
18.	Corticosteroid Special Formulations
19.	Defitelio® (Defibrotide)
20.	Elaprase® (Idursulfase)
21.	Erythropoiesis-Stimulating Agents (ESAs)
22.	Fabry Disease Medications
23.	Fibromyalgia Medications
24.	Gamifant® (Emapalumab)
25.	Gattex® [Teduglutide (rDNA Origin)]
26.	Gaucher Disease Medications
27.	Gout Medications
28.	H.P. Acthar® Gel (Repository Corticotropin Injection)
29.	Hyperkalemia Medications
30.	Idiopathic Pulmonary Fibrosis (IPF) Medications
31.	Inhaled Anti-Infective Medications
32.	Injectable and Vaginal Progesterone Products
33.	Insomnia Medications
34.	Iron Chelating Agents
35.	Jynarque® (Tolvaptan)
36.	Kanuma® (Sebelipase Alfa)
37.	Keveyis® (Dichlorphenamide)
38.	Leukotriene Modulators
39.	Lidocaine Topical Products
40.	Lumizyme® (Alglucosidase Alfa)
41.	Luxturna® (Voretigene Neparvovec-rzyl)

Count	Category/Medication
42.	Mepsevii® (Vestronidase Alfa-vjbk)
43.	Mozobil® (Plerixafor)
44.	Muscle Relaxant Medications
45.	Myalept® (Metreleptin)
46.	Mytesi® (Crofelemer)
47.	Naloxone Medications
48.	Nasal Allergy Medications
49.	Northera® (Droxidopa)
50.	Nuedexta® (Dextromethorphan/Quinidine)
51.	Ocaliva® (Obeticholic Acid)
52.	Ophthalmic Allergy Medications
53.	Ophthalmic Antibiotic Medications
54.	Otic Anti-Infective Medications
55.	Pancreatic Enzymes
56.	Parathyroid Medications
57.	Pediculicide Medications
58.	Phenylketonuria Medications
59.	Phosphate Binders
60.	Prenatal Vitamins
61.	Procysbi® (Cysteamine Bitartrate)
62.	Pulmonary Hypertension Medications
63.	Qbrexza™ (Glycopyrronium)
64.	Qualaquin® (quinine sulfate)
65.	Ravicti® (Glycerol Phenylbutyrate)
66.	Revcovi™ (Elapegademase-lvlr)
67.	Short-Acting Beta$_2$ Agonists (SABAs)
68.	Smoking Cessation
69.	Strensiq® (Asfotase Alfa)
70.	Sylvant® (Siltuximab)
71.	Symlin® (Pramlintide)
72.	Testosterone Products
73.	Topical Antibiotic Products
74.	Topical Antifungal Products
75.	Vasomotor Symptom Medications
76.	Vesicular Monoamine Transporter 2 (VMAT2) Inhibitor Medications
77.	Vimizim® (Elosulfase Alfa)
78.	Xgeva® (Denosumab)
79.	Xiaflex® (Collagenase Clostridium Histolyticum)
80.	Xuriden® (Uridine Triacetate)
81.	Zinplava™ (Bezlotoxumab)

Fiscal Year 2020 = July 1, 2019 – June 30, 2020

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 2020 Annual Review of Actinic Keratosis Medications

Oklahoma Health Care Authority
Fiscal Year 2020 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 the 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. Size of each lesion being treated; and
   c. Anticipated duration of treatment; and
3. Approval quantity and length will be based on patient-specific information provided, in accordance with the 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 of age 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% cream) must be provided.

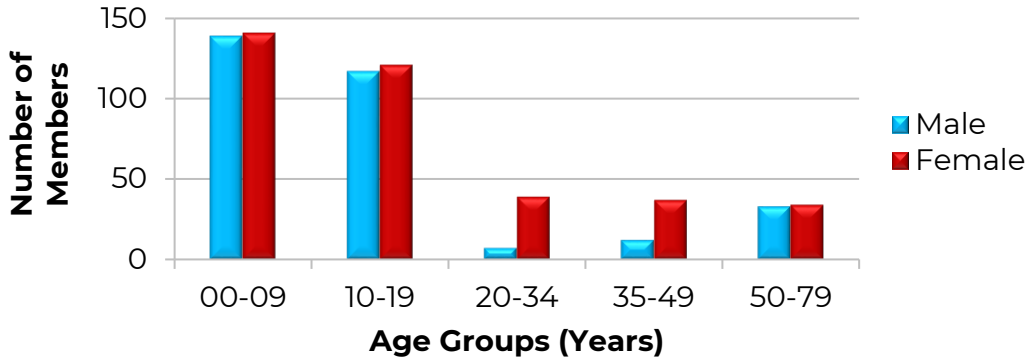
Utilization of Actinic Keratosis Medications: Fiscal Year 2020

Comparison of Fiscal Years

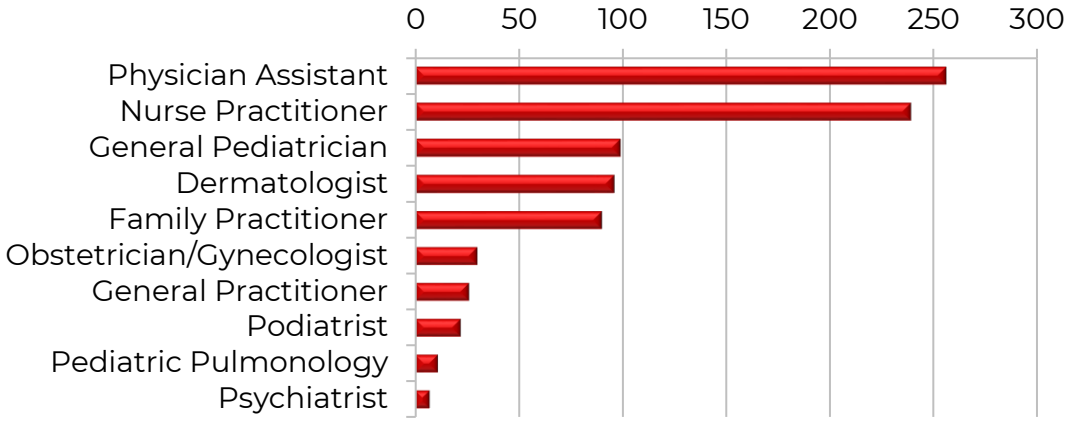
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	719	896	$34,083.70	$38.04	$1.04	15,967	32,708
2020	680	907	$32,754.90	$36.11	$1.03	15,185	31,946
% Change	**-5.40%**	**1.20%**	**-3.90%**	**-5.10%**	**-1.00%**	**-4.90%**	**-2.30%**
Change	**-39**	**11**	**-$1,328.80**	**-$1.93**	**-$0.01**	**-782**	**-762**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Demographics of Members Utilizing Actinic Keratosis Medications

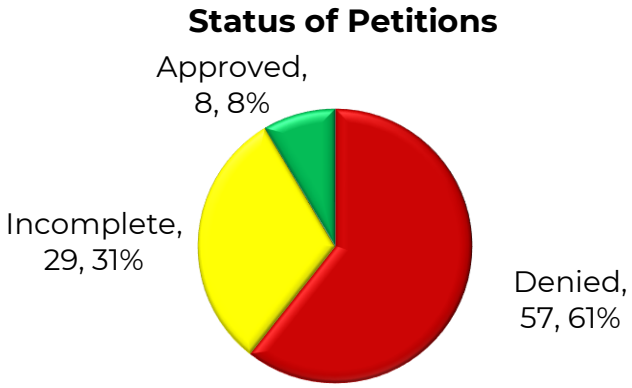


Top Prescriber Specialties of Actinic Keratosis Medications by Number of Claims



Prior Authorization of Actinic Keratosis Medications

There were 94 prior authorization requests submitted for actinic keratosis medications during fiscal year 2020. The following chart shows the status of the submitted petitions for fiscal year 2020.



Market News and Updates

Anticipated Patent Expiration(s):[1]

- Carac® (fluorouracil 0.5% cream): June 2021
- 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.

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 08/2020. Last accessed 08/31/2020.

Utilization Details of Actinic Keratosis Medications: Fiscal Year 2020

PRODUCT UTILZIED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
IMIQUIMOD PRODUCTS						
IMIQUIMOD CRE 5%	811	599	$23,531.13	$29.01	1.35	71.84%
IMIQUIMOD CRE 3.75%	2	2	$2,238.24	$1,119.12	1.00	6.83%
SUBTOTAL	**813**	**601**	**$25,769.37**	**$31.70**	**1.35**	**78.67%**
FLUOROURACIL PRODUCTS						
FLUOROURACIL CRE 5%	90	78	$6,699.36	$74.44	1.15	20.45%
FLUOROURACIL SOL 5%	1	1	$70.86	$70.86	1.00	0.22%
SUBTOTAL	**91**	**79**	**$6,770.22**	**$74.40**	**1.15**	**20.67%**
DICLOFENAC PRODUCTS						
DICLOFENAC GEL 3%	3	2	$215.31	$71.77	1.5	0.66%
SUBTOTAL	**3**	**2**	**$215.31**	**$71.77**	**1.5**	**0.66%**
TOTAL	**907**	**680***	**$32,754.90**	**$36.11**	**1.33**	**100%**

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

Fiscal Year 2020 Annual Review of Aldurazyme® (Laronidase) and Naglazyme® (Galsulfase)

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Aldurazyme® (Laronidase) Approval Criteria:

1. An FDA approved diagnosis of Hurler, Hurler-Scheie, or Scheie syndrome (mucopolysaccharidosis type I; MPS 1) confirmed by:
   a. Enzyme assay demonstrating a deficiency of alpha-L-iduronidase (IDUA) enzyme activity; or
   b. Molecular genetic testing to confirm pathogenic mutations in the *IDUA* gene; and
2. For Scheie syndrome, the provider must document that the member has moderate-to-severe symptoms; and
3. Aldurazyme® must be administered by a health care professional prepared to manage anaphylaxis; and
4. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment; and
5. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling.

Naglazyme® (Galsulfase) Approval Criteria:

1. An FDA approved diagnosis of Maroteaux-Lamy syndrome (mucopolysaccharidosis type VI; MPS VI) confirmed by:
   a. Enzyme assay demonstrating a deficiency of arylsulfatase B (ASB) enzyme activity; or
   b. Genetic testing to confirm diagnosis of MPS VI; and
2. Naglazyme® must be administered by a health care professional prepared to manage anaphylaxis; and
3. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment; 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 Aldurazyme® (Laronidase) and Naglazyme® (Galsulfase): Fiscal Year 2020

There was no SoonerCare utilization of Aldurazyme® (laronidase) or Naglazyme® (galsulfase) during fiscal year 2020 (07/01/2019 to 06/30/2020).

Prior Authorization of Aldurazyme® (Laronidase) and Naglazyme® (Galsulfase)

There were no prior authorization requests submitted for Aldurazyme® (laronidase) or Naglazyme® (galsulfase) during fiscal year 2020.

Recommendations

The College of Pharmacy does not recommend any changes to the current Aldurazyme® (laronidase) and Naglazyme® (galsulfase) prior authorization criteria at this time.

Fiscal Year 2020 Annual Review of Alpha$_1$-Proteinase Inhibitors

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Aralast NP®, Glassia®, and Zemaira® [Alpha$_1$-Proteinase Inhibitor (Human)]
Approval Criteria:

1. An FDA approved indication for augmentation and maintenance therapy of members 18 years of age or older with severe hereditary deficiency of alpha$_1$-antitrypsin (AAT) with clinical evidence of emphysema; and
2. Diagnosis confirmed by all of the following:
    a. Genetic confirmation of PiZZ, PiZ(null), or Pi(null, null) phenotype alpha$_1$-antitrypsin deficiency (AATD) or other alleles determined to increase the risk of AATD; and
    b. Serum levels of AAT <11µmol/L; and
    c. Documented emphysema with airflow obstruction; and
3. Prescriber must document that member's forced expiratory volume in 1 second (FEV_1) is ≤65% predicted; and
4. Must be prescribed by a pulmonary disease specialist (or an advanced care practitioner with a supervising physician who is a pulmonary disease specialist); and
5. The prescriber must verify the member is a non-smoker; and
6. The prescriber must verify the member does not have antibodies to IgA; and
7. A patient-specific, clinically significant reason why the member cannot use Prolastin®-C or Prolastin®-C Liquid must be provided; and
8. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling.

Prolastin®-C Liquid and Prolastin®-C [Alpha$_1$-Proteinase Inhibitor (Human)]
Approval Criteria:

1. An FDA approved indication for augmentation and maintenance therapy of members 18 years of age or older with severe hereditary deficiency of alpha$_1$-antitrypsin (AAT) with clinical evidence of emphysema; and
2. Diagnosis confirmed by all of the following:
    a. Genetic confirmation of PiZZ, PiZ(null), or Pi(null, null) phenotype alpha$_1$-antitrypsin deficiency (AATD) or other alleles determined to increase risk of AATD; and

b. Serum levels of AAT <11µmol/L; and
c. Documented emphysema with airflow obstruction; and

3. Prescriber must document that member's forced expiratory volume in 1 second (FEV_1) is ≤65% predicted; and
4. Must be prescribed by a pulmonary disease specialist (or an advanced care practitioner with a supervising physician who is a pulmonary disease specialist); and
5. The prescriber must verify the member is a non-smoker; and
6. The prescriber must verify the member does not have antibodies to IgA; and
7. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling.

Utilization of Alpha$_1$-Proteinase Inhibitors: Fiscal Year 2020

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	8	55	$434,721.42	$7,904.03	$282.29	957,656	1,540
2020	3	33	$229,942.88	$6,967.97	$248.86	498,184	924
% Change	**-62.50%**	**-40.00%**	**-47.10%**	**-11.80%**	**-11.80%**	**-48.00%**	**-40.00%**
Change	**-5**	**-22**	**-$204,778.54**	**-$936.06**	**-$33.43**	**-459,472**	**-616**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

- There were no paid medical claims for alpha$_1$-proteinase inhibitors during fiscal year 2020.

Demographics of Members Utilizing Alpha$_1$-Proteinase Inhibitors

- Due to the limited number of members utilizing alpha$_1$-proteinase inhibitors, detailed demographic information could not be provided.

Top Prescriber Specialties of Alpha$_1$-Proteinase Inhibitors by Number of Claims

- The only prescriber specialty listed on paid pharmacy claims for alpha$_1$-proteinase inhibitors during fiscal year 2020 was pulmonary disease specialist.

Prior Authorization of Alpha$_1$-Proteinase Inhibitors

There were 11 prior authorization requests submitted for alpha$_1$-proteinase inhibitors during fiscal year 2020. The following chart shows the status of the submitted petitions for fiscal year 2020.

Status of Petitions

Recommendations

The College of Pharmacy does not recommend any changes to the current alpha$_1$-proteinase inhibitors prior authorization criteria at this time.

Utilization Details of Alpha$_1$-Proteinase Inhibitors: Fiscal Year 2020

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
PROLASTIN-C INJ 1,000MG	20	2	$153,906.97	$7,695.35	10	66.93%
GLASSIA INJ 1,000MG	13	1	$76,035.91	$5,848.92	13	33.07%
TOTAL	**33**	**3***	**$229,942.88**	**$6,967.97**	**11**	**100%**

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

Fiscal Year 2020 Annual Review of Amyotrophic Lateral Sclerosis (ALS) Medications

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Exservan™ (Riluzole Oral Film) and Tiglutik® (Riluzole Oral Suspension) Approval Criteria:

1. An FDA approved diagnosis of amyotrophic lateral sclerosis (ALS); and
2. A patient-specific, clinically significant reason why the member cannot use riluzole tablets, even when tablets are crushed, must be provided; and
3. The following quantity limits apply:
    a. A quantity limit of 2 films per day or 60 films per 30 days will apply for Exservan™; or
    b. A quantity limit of 20mL per day or 600mL per 30 days will apply for Tiglutik®.

Radicava® (Edaravone) Approval Criteria:

1. An FDA approved diagnosis of amyotrophic lateral sclerosis (ALS); and
2. Member must have been evaluated by a physician specializing in the treatment of ALS within the last 3 months; and
3. Disease duration of 2 years or less (for initial approval); and
    a. A prior authorization request with patient-specific information may be submitted for consideration of edaravone for members with disease duration >2 years, including but not limited to disease progression, specific symptoms related to the disease, activities of daily living currently affected by the disease, or prognosis; and
4. Approvals will be for the duration of 6 months. For each subsequent approval, the prescriber must document that the member is responding to the medication, as indicated by a slower progression in symptoms and/or slower decline in quality of life compared to the typical ALS disease progression.

Utilization of ALS Medications: Fiscal Year 2020

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019⁺	2	14	$1,253.86	$89.56	$2.99	840	420
2020	5	30	$51,946.87	$1,731.56	$58.24	10,360	892
% Change	**150.00%**	**114.30%**	**4043.00%**	**1833.40%**	**1847.80%**	**1133.30%**	**112.40%**
Change	**3**	**16**	**$50,693.01**	**$1,642.00**	**$55.25**	**9,520**	**472**

*Total number of unduplicated utilizing members.
⁺All paid claims in fiscal year 2019 were for generic riluzole 50mg oral tablets which are available without prior authorization.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

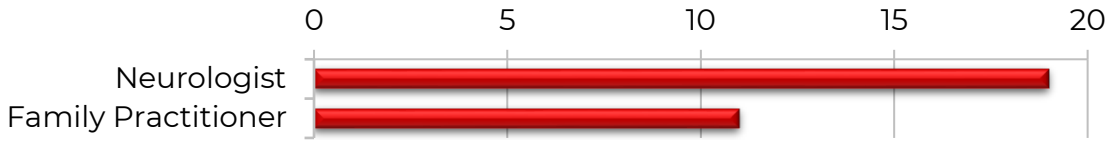
Comparison of Fiscal Years: Medical Claims

- There were no medical claims for Radicava® (edaravone) during fiscal year 2019 or fiscal year 2020.

Demographics of Members Utilizing ALS Medications

- There were 5 unique members utilizing ALS medications during fiscal year 2020. Due to the limited number of members utilizing ALS medications, detailed demographic information could not be provided.

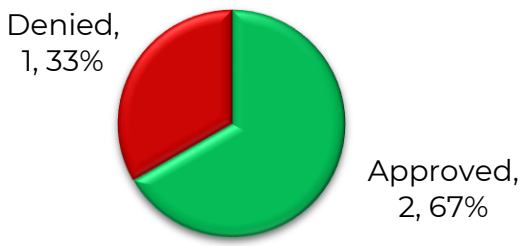
Top Prescriber Specialties of ALS Medications by Number of Claims



Prior Authorization of ALS Medications

There were 3 prior authorization requests submitted for 2 unique members for ALS medications during fiscal year 2020. The following chart shows the status of the submitted petitions for fiscal year 2020.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[2]

- Radicava® (edaravone): November 2020; however, the exclusivity period for the treatment of ALS expires May 2024
- Exservan™ (riluzole oral film): April 2024
- Tiglutik® (riluzole oral suspension): March 2029

Pipeline:

- **AMX0035:** Amylyx Pharmaceuticals is developing AMX0035 for the treatment of ALS. AMX0035 contains a co-formulation of 2 active compounds, sodium phenylbutyrate and taurursodiol, designed to target pathways originating in the mitochondria and endoplasmic reticulum leading to neuronal death and degradation. In October 2020, Amylyx announced the publication of survival data from the Phase 2/3 CENTAUR study. The time to all-cause mortality was assessed for up to 35 months after randomization. The study results showed a 44% risk reduction in death in patients treated with AMX0035 compared to placebo. Amylyx is currently conducting an open label extension study (CENTAUR-OLE) with an estimated completion date of January 2021.[3,4]
- **BIIB067 (Tofersen):** Biogen is developing BIIB067 for the treatment of superoxide dismutase 1 (SOD1) ALS, a rare genetic form of ALS. The SOD1 mutation may be responsible for approximately 2% of all ALS cases. BIIB067 is an antisense oligonucleotide that binds to SOD1 mRNA, leading to its degradation and reduced synthesis of SOD1 protein. In July 2020, Biogen announced the publication of positive results in *The New England Journal of Medicine* from the Phase 1/2 study of BIIB067 and is currently conducting the Phase 3 VALOR study in adults with ALS with a confirmed SOD1 mutation.[5,6]
- **Masitinib:** AB Science is developing masitinib for the treatment of ALS in combination with riluzole. Masitinib is an orally-administered selective tyrosine kinase inhibitor that modulates the activity of mast

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[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/index.cfm. Last revised 11/2020. Last Accessed 11/30/2020.

[3] Amylyx Pharmaceuticals, Inc. Amylyx Pipeline. Available online at: https://www.amylyx.com/pipeline. Last accessed 12/01/2020.

[4] Amylyx Pharmaceuticals, Inc. Amylyx Pharmaceuticals Announces Publication of CENTAUR Survival Data Demonstrating Statistically Significant Survival Benefit of AMX0035 for People with ALS. Available online at: https://www.amylyx.com/2020/10/16/amylyx-pharmaceuticals-announces-publication-of-centaur-survival-data-demonstrating-statistically-significant-survival-benefit-of-amx0035-for-people-with-als/. Issued 10/16/2020. Last accessed 12/01/2020.

[5] Biogen, Inc. Biogen Pipeline. Available online at: https://www.biogen.com/en_us/pipeline.html. Last accessed 12/01/2020.

[6] Biogen, Inc. The New England Journal of Medicine Publishes Final Results from Phase 1/2 Study of Tofersen for a Genetic Form of ALS. Available online at: https://investors.biogen.com/news-releases/news-release-details/new-england-journal-medicine-publishes-final-results-phase-12. Issued 07/08/2020. Last accessed 12/01/2020.

cells and microglia. In ALS, masitinib is thought to have a neuroprotective effect in both the peripheral and central nervous system by slowing microglial-related disease progression, reducing neuro-inflammation, and modulating the neuronal microenvironment. Positive results from a Phase 2B/3 study were previously published in July 2019 showing patients who received masitinib + riluzole had a statistically-significant slower decline in the ALS functional rating scale-revised (ALSFRS-R) from baseline compared to patients receiving placebo + riluzole at week 48. A confirmatory Phase 3 study is ongoing and will enroll patients at an earlier stage of disease.[7,8,9]

- **NurOwn®:** BrainStorm Cell Therapeutics is developing NurOwn® for treatment of ALS. NurOwn® cells are autologous, bone marrow-derived mesenchymal stem cells (MSCs) that have been converted ex-vivo into MSCs which secrete high levels of neurotrophic factors (NTFs). It is expected that these MSC-NTF cells can deliver NTFs and immunomodulatory cytokines directly to sites of damage to ultimately slow or stabilize disease progression in ALS. In November 2020, BrainStorm announced topline results from a Phase 3 study in ALS patients. In the study, NurOwn® did not meet its primary efficacy endpoint of a 1.25 point per month improvement in post-treatment ALSFRS-R slope compared with the pre-treatment ALSFRS-R slope. BrainStorm plans to further evaluate these results and discuss the data with the U.S. Food and Drug Administration (FDA) to see if there is a path forward to support future approval of NurOwn®.[10,11]
- **Ravulizumab-cwvz:** Alexion is currently evaluating ravulizumab-cwvz for the treatment of ALS. Ravulizumab-cwvz is a humanized monoclonal antibody that inhibits the C5 protein in the terminal complement cascade which, when activated in an uncontrolled manner, is thought to play a role in certain rare neuromuscular diseases. Ravulizumab-cwvz may be able to inhibit complement-mediated damage in ALS patients. Alexion is currently enrolling

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[7] AB Science. AB Science Pipeline: Masitinib in Neurology. Available online at: https://www.ab-science.com/masitinib-in-neurology/. Last accessed 12/01/2020.
[8] AB Science. AB Science Pipeline: Masitinib Overview – Amyotrophic Lateral Sclerosis. Available online at: https://www.ab-science.com/pipeline-overview/masitinib-overview/amyotrophic-lateral-sclerosis/. Last accessed 12/01/2020.
[9] AB Science. AB Science Announces the Publication of the Positive Phase 2/3 Clinical Trial with Masitinib in ALS in the Journal Amyotrophic Lateral Sclerosis and Frontotemporal Degeneration. *Globe Newswire*. Available online at: https://www.globenewswire.com/news-release/2019/07/08/1879227/0/en/AB-Science-announces-the-publication-of-the-positive-phase-2-3-clinical-trial-with-masitinib-in-ALS-in-the-journal-Amyotrophic-Lateral-Sclerosis-and-Frontotemporal-Degeneration.html. Issued 07/08/2019. Last accessed 12/01/2020.
[10] BrainStorm Cell Therapeutics, Inc. BrainStorm Pipeline. Available online at: https://brainstorm-cell.com/pipeline/. Last accessed 12/01/2020.
[11] BrainStorm Cell Therapeutics, Inc. BrainStorm Announces Topline Results from NurOwn® Phase 3 ALS Study. Available online at: https://ir.brainstorm-cell.com/2020-11-17-BrainStorm-Announces-Topline-Results-from-NurOwn-R-Phase-3-ALS-Study. Issued 11/17/2020. Last accessed 12/01/2020.

patients into the Phase 3 CHAMPION-ALS study to evaluate the efficacy and safety of ravulizumab-cwvz vs. placebo in adults with ALS disease onset within the past 36 months. Patients will be allowed to continue their existing ALS standard of care treatments during the study. Ravulizumab-cwvz was previously FDA approved for the treatment of adults with paroxysmal nocturnal hemoglobinuria (PNH) or atypical hemolytic uremic syndrome (aHUS) and is marketed under the brand name Ultomiris®.[12,13]

- **Reldesemtiv:** Cytokinetics is developing reldesemtiv for the treatment of ALS and spinal muscular atrophy (SMA). Reldesemtiv is a fast skeletal muscle troponin activator (FSTA) which slows the rate of calcium release from the regulatory troponin complex of fast skeletal muscle fibers. Reldesemtiv is thought to increase muscle contractility by sensitizing the sarcomere to calcium. In May 2019, Cytokinetics announced reldesemtiv had failed to meet its primary efficacy endpoint in the Phase 2 FORTITUDE-ALS study. Despite the non-statistically significant results, Cytokinetics did observe some clinically-meaningful results in post-hoc analyses and believes the results of the study support progression of reldesemtiv in further clinical trials.[14,15]

Recommendations

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

Utilization Details of ALS Medications: Fiscal Year 2020

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
RILUZOLE TAB 50MG	26	5	$2,186.95	$84.11	5.2	4.21%
RADICAVA INJ 30MG	4	1	$49,759.92	$12,439.98	4	95.79%
TOTAL	**30**	**5***	**$51,946.87**	**$1,731.56**	**6**	**100.00%**

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

[12] Alexion Pharmaceuticals, Inc. Alexion Pipeline. Available online at: https://alexion.com/our-research/pipeline. Last accessed 12/01/2020.
[13] Alexion Pharmaceuticals, Inc. Alexion Announces Planned Initiation of Pivotal Phase 3 Study of Ultomiris® (Ravulizumab) in ALS. Available online at: https://www.biospace.com/article/releases/alexion-announces-planned-initiation-of-pivotal-phase-3-study-of-ultomiris-ravulizumab-in-als/. Issued 01/14/2020. Last accessed 12/01/2020.
[14] Cytokinetics, Inc. Cytokinetics Pipeline: Reldesemtiv. Available online at: https://cytokinetics.com/reldesemtiv/. Last accessed 12/01/2020.
[15] Cytokinetics, Inc. Cytokinetics Announces Results of FORTITUDE-ALS, a Phase 2 Clinical Trial of Reldesemtiv in Patients with ALS, Presented at American Academy of Neurology Annual Meeting. Available online at: https://ir.cytokinetics.com/news-releases/news-release-details/cytokinetics-announces-results-fortitude-als-phase-2-clinical. Issued 05/06/2019. Last accessed 12/01/2020.

Fiscal Year 2020 Annual Review of Antifungal Medications (Systemic)

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Cresemba® (Isavuconazonium Sulfate) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
   a. Invasive aspergillosis; or
   b. Invasive mucormycosis; and
2. For the treatment of invasive aspergillosis, a patient-specific, clinically significant reason why voriconazole cannot be used must be provided.

Ketoconazole Oral Tablets Approval Criteria:

1. An FDA approved indication of systemic fungal infections with 1 of the following:
   a. Blastomycosis; or
   b. Coccidioidomycosis; or
   c. Histoplasmosis; or
   d. Chromomycosis; or
   e. Paracoccidioidomycosis; and
2. Member is 3 years of age or older; and
3. Member does not have underlying hepatic disease; and
4. Trials with other effective oral antifungal therapies, including fluconazole, itraconazole, and voriconazole, have failed to resolve infection; or
5. Other effective oral antifungal therapies are not tolerated or potential benefits outweigh the potential risks; and
6. Hepatic function tests must be done at baseline and weekly during treatment; and
7. A clinical exception may apply for members with a diagnosis of Cushing's disease when other modalities are not available.

Noxafil® (Posaconazole) Approval Criteria:

1. An FDA approved indication of 1 of the following:
   a. Prophylaxis of invasive *Aspergillus* and *Candida* infections in high-risk members due to being severely immunocompromised, such as hematopoietic stem cell transplant (HSCT) recipients with graft-versus-host disease (GVHD) or those with hematologic malignancies with prolonged neutropenia from chemotherapy; or
   b. Treatment of oropharyngeal candidiasis (OPC), including OPC refractory (rOPC) to itraconazole and/or fluconazole; or

2. Treatment of invasive mucormycosis; or
3. Other appropriate diagnoses for which Noxafil® is not FDA approved may be considered with submission of a manual prior authorization; and
4. For the diagnosis of OPC, only the oral suspension may be used.

Onmel® (Itraconazole Oral Tablets) Approval Criteria:

1. An FDA approved diagnosis of onychomycosis of the toenail caused by *Trichophyton rubrum* or *T. mentagrophytes;* and
2. A patient-specific, clinically significant reason why itraconazole 100mg oral capsules cannot be used in place of Onmel® 200mg tablets must be provided.

Oravig® (Miconazole Buccal Tablets) Approval Criteria:

1. An FDA-approved diagnosis of oropharyngeal candidiasis in adults 18 years of age and older; and
2. Recent trials (within the last month) of the following medications at the recommended dosing and duration of therapy:
    a. Clotrimazole troches; and
    b. Nystatin suspension; and
    c. Fluconazole tablets; or
3. Contraindication(s) to all available alternative medications.

Tolsura™ (Itraconazole Oral Capsules) Approval Criteria:

1. An FDA approved indication of 1 of the following fungal infections in immunocompromised and non-immunocompromised adult members:
    a. Blastomycosis, pulmonary and extrapulmonary; or
    b. Histoplasmosis, including chronic cavitary pulmonary disease and disseminated, non-meningeal histoplasmosis; or
    c. Aspergillosis, pulmonary and extrapulmonary, in members who are intolerant of or who are refractory to amphotericin B therapy; and
2. A patient-specific, clinically significant reason why the member cannot use itraconazole 100mg capsules, which are available without prior authorization, must be provided.

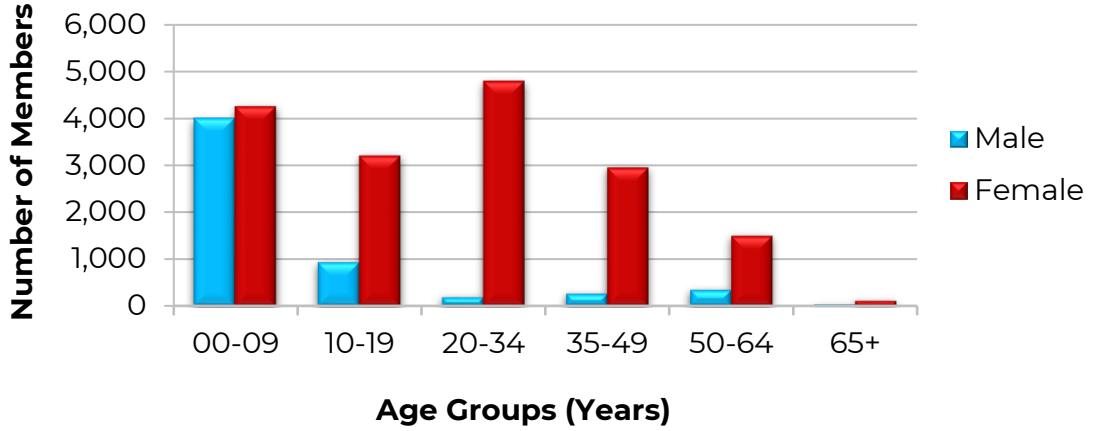
Utilization of Systemic Antifungal Medications: Fiscal Year 2020

Comparison of Fiscal Years

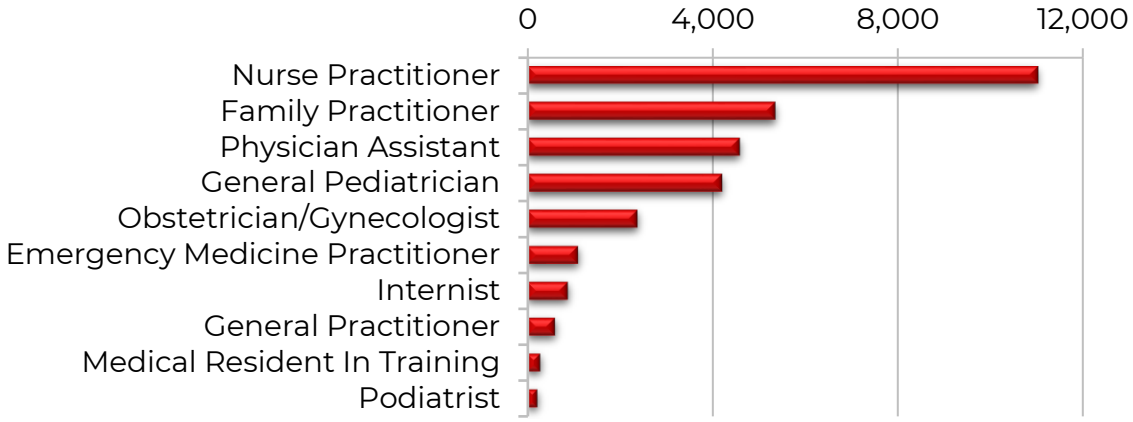
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	23,568	33,351	$2,420,382.36	$72.57	$6.51	1,845,365	372,016
2020	22,646	32,463	$1,402,791.57	$43.21	$3.97	1,675,345	353,157
% Change	**-3.90%**	**-2.70%**	**-42.00%**	**-40.50%**	**-39.00%**	**-9.20%**	**-5.10%**
Change	**-922**	**-888**	**-$1,017,590.79**	**-$29.36**	**-$2.54**	**-170,020**	**-18,859**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Demographics of Members Utilizing Systemic Antifungal Medications



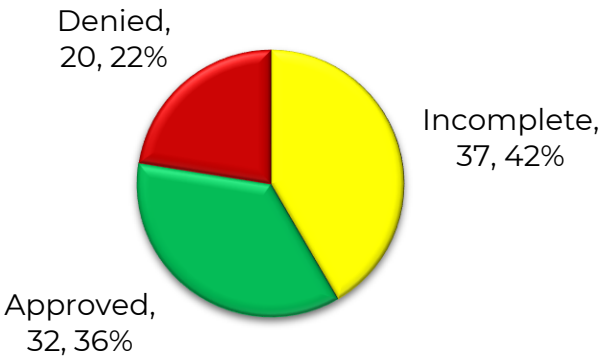
Top Prescriber Specialties of Systemic Antifungal Medications by Number of Claims



Prior Authorization of Systemic Antifungal Medications

There were 89 prior authorization requests submitted for systemic antifungal medications during fiscal year 2020. The following chart shows the status of the submitted petitions for fiscal year 2020.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[16]

- Noxafil® (posaconazole oral suspension): April 2022
- Oravig® (miconazole buccal tablet): September 2022
- Cresemba® [isavuconazonium capsule and intravenous (IV) powder for solution]: October 2025
- Onmel® (itraconazole tablet): October 2028
- Noxafil® (posaconazole IV solution): February 2033
- Tolsura™ (itraconazole capsule): June 2033

Recommendations

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

Utilization Details of Systemic Antifungal Medications: Fiscal Year 2020

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
FLUCONAZOLE PRODUCTS						
FLUCONAZOLE TAB 150MG	13,983	9,760	$174,334.06	$12.47	1.43	12.43%
FLUCONAZOLE TAB 200MG	2,101	1,473	$38,984.41	$18.56	1.43	2.78%
FLUCONAZOLE TAB 100MG	1,577	1,309	$21,074.09	$13.36	1.2	1.50%
FLUCONAZOLE SUS 40MG/ML	1,286	1,044	$47,299.35	$36.78	1.23	3.37%
FLUCONAZOLE SUS 10MG/ML	1,167	1,018	$28,819.09	$24.70	1.15	2.05%
FLUCONAZOLE TAB 50MG	19	18	$283.06	$14.90	1.06	0.02%
FLUCONAZOLE INJ 400MG	2	2	$107.99	$54.00	1	0.01%
SUBTOTAL	**20,135**	**14,624**	**$310,902.05**	**$15.44**	**1.38**	**22.16%**
NYSTATIN PRODUCTS						
NYSTATIN SUS 100,000U/ML	7,945	6,663	$145,299.34	$18.29	1.19	10.36%

[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/. Last revised 02/2021. Last accessed 02/02/2021.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
NYSTATIN TAB 500,000U	42	22	$1,275.85	$30.38	1.91	0.09%
SUBTOTAL	**7,987**	**6,685**	**$146,575.19**	**$18.35**	**1.19**	**10.45%**
TERBINAFINE PRODUCTS						
TERBINAFINE TAB 250MG	1,912	1,355	$29,238.59	$15.29	1.41	2.08%
SUBTOTAL	**1,912**	**1,355**	**$29,238.59**	**$15.29**	**1.41**	**2.08%**
GRISEOFULVIN PRODUCTS						
GRISEOFULVIN SUS 125MG/5ML	1,369	1,077	$117,199.79	$85.61	1.27	8.35%
GRISEOFULVIN TAB MICR 500MG	363	286	$84,749.67	$233.47	1.27	6.04%
GRISEOFULVIN TAB ULTR 250MG	107	87	$18,146.31	$169.59	1.23	1.29%
GRISEOFULVIN TAB ULTR 125MG	20	17	$4,936.99	$246.85	1.18	0.35%
SUBTOTAL	**1,859**	**1,467**	**$225,032.76**	**$121.05**	**1.27**	**16.03%**
ITRACONAZOLE PRODUCTS						
ITRACONAZOLE CAP 100MG	200	90	$20,318.65	$101.59	2.22	1.45%
ITRACONAZOLE SOL 10MG/ML	59	37	$40,709.90	$690.00	1.59	2.90%
SPORANOX SOL 10MG/ML	2	2	$693.48	$346.74	1	0.05%
SUBTOTAL	**261**	**129**	**$61,722.03**	**$236.48**	**2.02**	**4.40%**
VORICONAZOLE PRODUCTS						
VORICONAZOLE INJ 200MG	121	104	$444,342.77	$3,672.25	1.16	31.68%
VORICONAZOLE TAB 200MG	72	26	$18,386.15	$255.36	2.77	1.31%
VORICONAZOLE TAB 50MG	17	5	$11,128.60	$654.62	3.4	0.79%
VORICONAZOLE SUS 40MG/ML	14	5	$14,883.31	$1,063.09	2.8	1.06%
SUBTOTAL	**224**	**140**	**$488,740.83**	**$2,181.88**	**1.6**	**34.84%**
CLOTRIMAZOLE PRODUCTS						
CLOTRIMAZOLE TRO 10MG	49	48	$1,475.87	$30.12	1.02	0.11%
SUBTOTAL	**49**	**48**	**$1,475.87**	**$30.12**	**1.02**	**0.11%**
POSACONAZOLE PRODUCTS						
POSACONAZOLE TAB 100MG DR	16	7	$48,493.19	$3,030.82	2.29	3.46%
NOXAFIL TAB 100MG	9	5	$45,767.47	$5,085.27	1.8	3.27%
NOXAFIL SUS 40MG/ML	2	1	$8,443.46	$4,221.73	2	0.60%
SUBTOTAL	**27**	**13**	**$102,704.12**	**$3,803.86**	**2.08**	**7.33%**
ISAVUCONAZONIUM PRODUCTS						
CRESEMBA CAP 186MG	8	3	$36,317.72	$4,539.72	2.67	2.59%
SUBTOTAL	**8**	**3**	**$36,317.72**	**$4,539.72**	**2.67**	**2.59%**
AMPHOTERICIN B PRODUCTS						
AMPHOTERICIN INJ 50MG	1	1	$82.41	$82.41	1	0.01%
SUBTOTAL	**1**	**1**	**$82.41**	**$82.41**	**1**	**0.01%**
TOTAL	**32,463**	**22,646***	**$1,402,791.57**	**$43.21**	**1.43**	**100.00%**

CAP = capsule; DR = delayed-release; INJ = injection; MICRO = microcrystalline; SOL = solution; SUS = suspension; TAB = tablet; TRO = troche; ULTR = ultramicrocrystalline
*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Fiscal Year 2020 Annual Review of Antihistamine Medications (Oral)

Oklahoma Health Care Authority
Fiscal Year 2020 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®)¥

OTC = over-the-counter
⁺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®.

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.

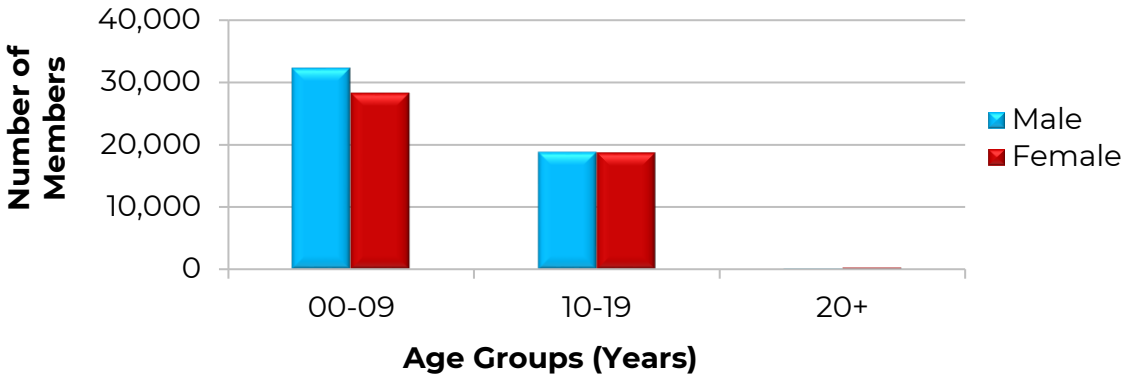
Utilization of Oral Antihistamine Medications: Fiscal Year 2020

Comparison of Fiscal Years

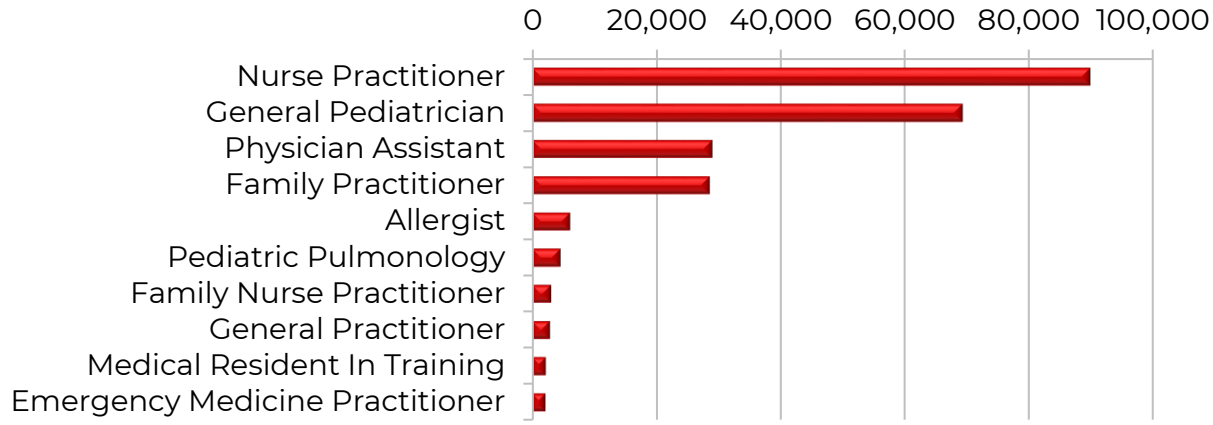
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	107,677	256,304	$2,941,412.03	$11.48	$0.36	23,868,054	8,142,077
2020	98,603	244,548	$2,836,389.55	$11.60	$0.36	23,212,489	7,952,112
% Change	**-8.40%**	**-4.60%**	**-3.60%**	**1.00%**	**0.00%**	**-2.70%**	**-2.30%**
Change	**-9,074**	**-11,756**	**-$105,022.48**	**$0.12**	**$0.00**	**-655,565**	**-189,965**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Demographics of Members Utilizing Oral Antihistamine Medications



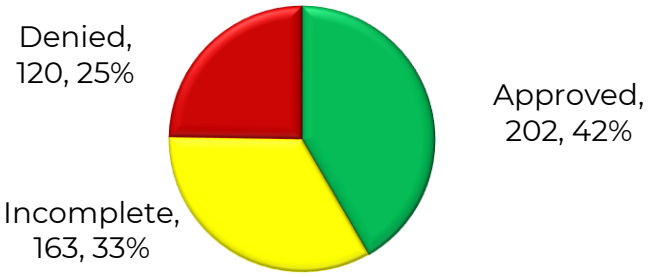
Top Prescriber Specialties of Oral Antihistamine Medications by Number of Claims



Prior Authorization of Oral Antihistamine Medications

There were 485 prior authorization requests submitted for oral antihistamine medications during fiscal year 2020. The following chart shows the status of the submitted petitions for fiscal year 2020.

Status of Petitions



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 2020

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 UTILIZATION						
CETIRIZINE PRODUCTS						
CETIRIZINE SOL 1MG/ML	95,716	43,885	$1,243,981.33	$13.00	2.18	43.86%
CETIRIZINE TAB 10MG	78,872	30,850	$727,469.33	$9.22	2.56	25.65%
CETIRIZINE SOL 5MG/5ML	19,437	10,862	$258,173.38	$13.28	1.79	9.10%
CETIRIZINE TAB 5MG	4,092	1,860	$37,837.80	$9.25	2.2	1.33%
ALL DAY ALLG SOL 5MG/5ML	1,129	650	$14,042.70	$12.44	1.74	0.50%
ALL DAY ALLG TAB 10MG	232	116	$2,754.50	$11.87	2	0.10%
ALLERGY RELI TAB 10MG	133	108	$1,629.08	$12.25	1.23	0.06%
GNP ALL DAY TAB ALLERGY 10MG	126	78	$1,548.41	$12.29	1.62	0.05%
ALL DAY ALLG SOL 1MG/ML	59	32	$776.86	$13.17	1.84	0.03%
CHILD ALLERGY SOL 5MG/5ML	2	2	$27.62	$13.81	1	0.00%
SM ALL DAY TAB ALLERGY 10MG	1	1	$12.07	$12.07	1	0.00%
SUBTOTAL	**199,799**	**88,444**	**$2,288,253.08**	**$11.44**	**2.26**	**80.68%**
LORATADINE PRODUCTS						
LORATADINE TAB 10MG	22,358	8,804	$246,005.84	$11.00	2.54	8.67%
LORATADINE SOL 5MG/5ML	17,862	8,808	$235,530.28	$13.19	2.03	8.30%
LORATADINE SYP 5MG/5ML	2,403	1,461	$33,993.16	$14.15	1.64	1.20%
ALLERGY TAB 10MG	392	185	$4,602.01	$11.74	2.12	0.16%
ALLERGY RELIEF TAB 10MG	245	121	$2,720.44	$11.10	2.02	0.10%
SM ALLERGY SYP 5MG/5ML	201	145	$1,355.84	$6.75	1.39	0.05%
ALLERGY CHILD SYP 5MG/5ML	199	109	$3,137.55	$15.77	1.83	0.11%
SM LORATADINE TAB 10MG	110	44	$571.55	$5.20	2.5	0.02%
ALLERGY CHILD SOL 5MG/5ML	29	11	$420.23	$14.49	2.64	0.01%
SUBTOTAL	**43,799**	**19,688**	**$528,336.90**	**$12.06**	**2.22**	**18.62%**
TIER-1 SUBTOTAL	**243,598**	**108,132**	**$2,816,589.98**	**$11.55**	**2.25**	**99.30%**
TIER-2 UTILIZATION						
LEVOCETIRIZINE PRODUCTS						
LEVOCETIRIZINE TAB 5MG	670	139	$8,757.14	$13.07	4.82	0.31%
LEVOCETIRIZINE SOL 2.5MG/5ML	247	53	$10,230.02	$41.42	4.66	0.36%
TIER-2 SUBTOTAL	**917**	**192**	**$18,987.16**	**$20.71**	**4.78**	**0.67%**
TIER-3 UTILIZATION						
DESLORATADINE PRODUCTS						
DESLORATADINE TAB 5MG	32	3	$787.29	$24.60	10.67	0.03%
CLEMASTINE PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
CLEMASTINE TAB 2.68MG	1	1	$25.12	$25.12	1	0.00%
TIER-3 SUBTOTAL	**33**	**4**	**$812.41**	**$24.62**	**8.25**	**0.03%**
TOTAL	**244,548**	**98,603***	**$2,836,389.55**	**$11.60**	**2.48**	**100%**

ALLG = allergy; SOL = solution; SYP = syrup; TAB = tablet
*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Fiscal Year 2020 Annual Review of Anti-Parasitic Medications

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Albenza® (Albendazole) Approval Criteria:

1. A quantity of 6 tablets will process without prior authorization.
2. For infections requiring additional doses, a prior authorization will need to be submitted and the following criteria will apply:
    a. An FDA approved indication of 1 of the following:
        i. Treatment of parenchymal neurocysticercosis due to active lesions caused by larval forms of the pork tapeworm, *Taenia solium*; or
        ii. Treatment of cystic hydatid disease of the liver, lung, and peritoneum, caused by the larval form of the dog tapeworm, *Echinococcus granulosus*.

Benznidazole Tablets Approval Criteria:

1. An FDA approved diagnosis of Chagas disease (American trypanosomiasis) caused by *Trypanosoma cruzi*; and
2. Benznidazole must be prescribed by or in consultation with an infectious disease specialist; and
3. Female members of reproductive potential must have a pregnancy test prior to treatment with benznidazole; and
4. Female members of reproductive potential must be willing to use effective contraception during treatment with benznidazole tablets and for 5 days after the last dose; and
5. Member must not have taken disulfiram within the last 2 weeks; and
6. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug. The approval duration will be for 60 days of therapy.

Daraprim® (Pyrimethamine) Approval Criteria:

1. An FDA approved indication for the treatment of toxoplasmosis; or
2. An FDA approved indication for the treatment of susceptible strains of acute malaria; and
3. Member must take Daraprim® concomitantly with a sulfonamide; and
4. Approval length will be based on recommended dosing regimen specific to the member's diagnosis.

Emverm® (Mebendazole) Approval Criteria:

1. An FDA approved indication of 1 of the following:

a. Treatment of *Enterobius vermicularis* (pinworm); or
b. Treatment of *Trichuris trichiura* (whipworm); or
c. Treatment of *Ascaris lumbricoides* (roundworm); or
d. Treatment of *Ancylostoma duodenale* (hookworm); or
e. Treatment of *Necator americanus* (hookworm); and

2. For the treatment of *Enterobius vermicularis* (pinworm), *Ascaris lumbricoides* (roundworm), *Ancylostoma duodenale* (hookworm), or *Necator americanus* (hookworm), a patient-specific, clinically significant reason why a more cost-effective anthelmintic therapy, such as albendazole or pyrantel pamoate, cannot be used must be provided; and
3. The following quantity limits will apply:
   a. *Enterobius vermicularis* (pinworm): 2 tablets per approval; or
   b. *Trichuris trichiura* (whipworm): 6 tablets per approval; or
   c. *Ascaris lumbricoides* (roundworm): 6 tablets per approval; or
   d. *Ancylostoma duodenale* (hookworm): 6 tablets per approval; or
   e. *Necator americanus* (hookworm): 6 tablets per approval.

Impavido® (Miltefosine) Approval Criteria:

1. An FDA approved indication for treatment of 1 of the following:
   a. Visceral leishmaniasis due to *Leishmania donovani*; or
   b. Cutaneous leishmaniasis due to *Leishmania braziliensis*, *Leishmania guyanensis*, or *Leishmania panamensis*; or
   c. Mucosal leishmaniasis due to *Leishmania braziliensis*; and
2. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to therapy initiation. Female members must be willing to use effective contraception while on therapy and for 5 months after completion of therapy; and
3. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
4. A quantity limit of 84 capsules per 28 days will apply.

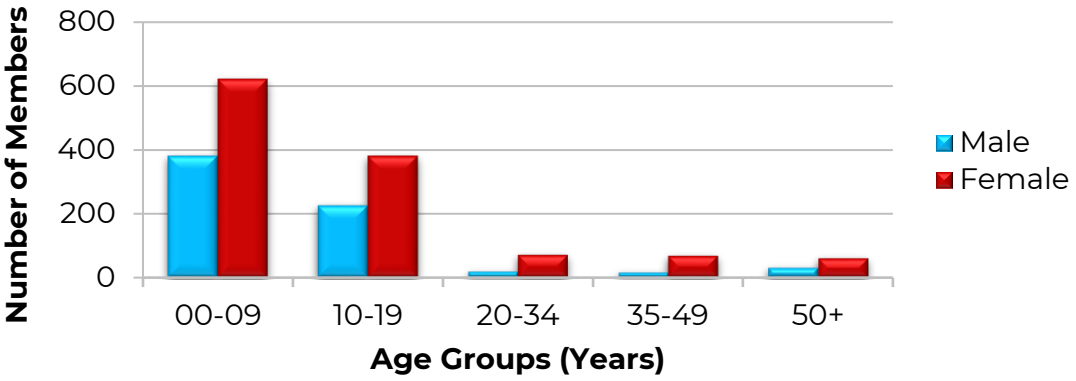
Utilization of Anti-Parasitic Medications: Fiscal Year 2020

Comparison of Fiscal Years

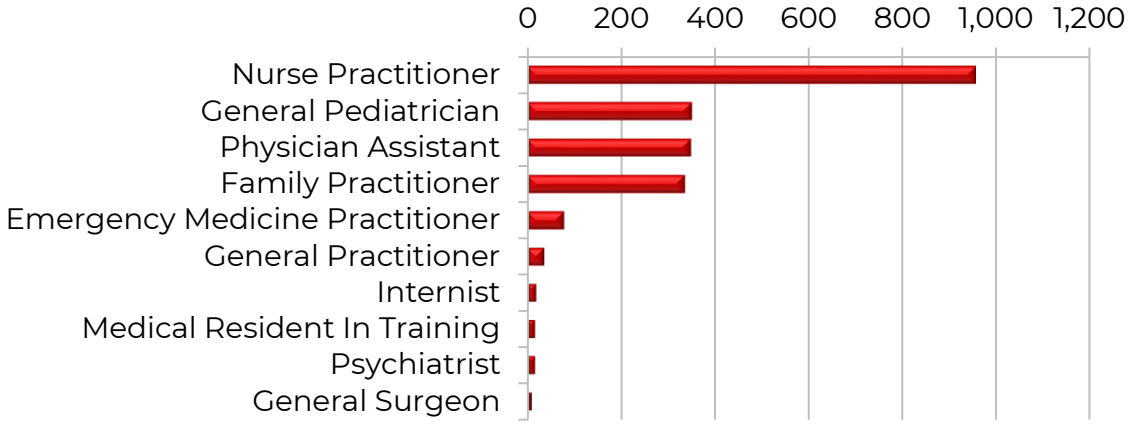
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	2,095	2,505	$975,339.00	$389.36	$47.68	9,871	20,454
2020	1,869	2,231	$419,702.39	$188.12	$22.90	9,096	18,325
% Change	**-10.8%**	**-10.9%**	**-57.0%**	**-51.7%**	**-52.0%**	**-7.9%**	**-10.4%**
Change	**-226**	**-274**	**-$555,636.61**	**-$201.24**	**-$24.78**	**-775**	**-2,129**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Demographics of Members Utilizing Anti-Parasitic Medications



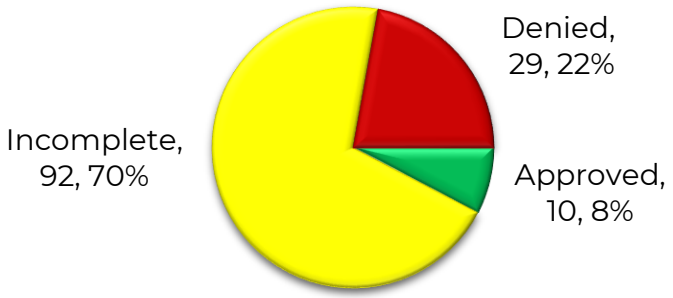
Top Prescriber Specialties of Anti-Parasitic Medications by Number of Claims



Prior Authorization of Anti-Parasitic Medications

There were 131 prior authorization requests submitted for 96 unique members for anti-parasitic medications during fiscal year 2020. The following chart shows the status of the submitted petitions for fiscal year 2020.

Status of Petitions



Market News and Updates

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

- **March 2020:** The FDA approved the first generic for Daraprim® for the treatment of toxoplasmosis when used with a sulfonamide. Daraprim® was in the headlines in 2015 when the CEO of Turing Pharmaceuticals, Martin Shkreli, increased the price of the medication from $13.50 per tablet to $750.00 per tablet.[17,18]

Recommendations

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

Utilization Details of Anti-Parasitic Medications: Fiscal Year 2020

PRODUCT UTILIZED	TOTAL CLAIMS	*TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
ALBENDAZOLE TAB 200MG	1,343	1,175	$347,171.16	$258.50	1.14
IVERMECTIN TAB 3MG	854	686	$24,138.21	$28.26	1.24
ALBENZA TAB 200MG	20	17	$19,750.85	$987.54	1.18
PRAZIQUANTEL TAB 600MG	7	7	$871.33	$124.48	1.00
EMVERM CHW 100MG	4	4	$4,412.65	$1,103.16	1.00
DARAPRIM TAB 25MG	2	1	$23,263.74	$11,631.87	2.00
BILTRICIDE TAB 600MG	1	1	$94.45	$94.45	1.00
TOTAL	**2,231**	**1,869**	**$419,702.39**	**$188.12**	**1.19**

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

[17] U.S. Food and Drug Administration (FDA). FDA Approves First Generic of Daraprim®. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-generic-daraprim. Issued 02/28/2020. Last accessed 11/30/2020.
[18] Brooks, M. FDA OKs First Generic of Daraprim® (Pyrimethamine) Tablets. *Medscape*. Available online at: https://www.medscape.com/viewarticle/925980. Issued 03/02/2020. Last accessed 11/30/2020.

Fiscal Year 2020 Annual Review of Arcalyst® (Rilonacept)

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Arcalyst® (Rilonacept) Approval Criteria:

1. An FDA approved indication of Cryopyrin-Associated Periodic Syndromes (CAPS) verified by genetic testing. This includes Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 years of age and older; and
2. The member should not be using a tumor necrosis factor blocking agent (e.g., adalimumab, etanercept, infliximab) or anakinra; and
3. Documentation that the member does not have active or chronic infection including hepatitis B, hepatitis C, human immunodeficiency virus (HIV), or tuberculosis; and
4. The following dosing restrictions will apply:
    a. Dosing should not be more often than once weekly; and
    b. Approved dosing schedule for members 18 years of age and older:
        i. Initial treatment: Loading dose of 320mg delivered as (2) 2mL subcutaneous (sub-Q) injections of 160mg each given on the same day at 2 different injection sites; and
        ii. Continued treatment: (1) 160mg injection given once weekly; or
    c. Approved dosing schedule for pediatric members 12 to 17 years of age (must have member weight in kilograms):
        i. Initial treatment: Loading dose of 4.4mg/kg, up to a maximum of 320mg, delivered as 1 or 2 sub-Q injections, with a maximum single-injection volume of 2mL (given at 2 different injection sites if administered as 2 injections); and
        ii. Continued treatment: 2.2mg/kg, up to a maximum of 160mg, given once weekly; and
5. Approvals will be for the duration of 1 year.

Utilization of Arcalyst® (Rilonacept): Fiscal Year 2020

There was no SoonerCare utilization of Arcalyst® (rilonacept) during fiscal year 2020 (07/01/2019 to 06/30/2020).

Prior Authorization of Arcalyst® (Rilonacept)

There were no prior authorization requests submitted for Arcalyst® (rilonacept) during fiscal year 2020.

Recommendations

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

Fiscal Year 2020 Annual Review of Benign Prostatic Hyperplasia (BPH) Medications

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

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

BPH Medications Tier-2 Approval Criteria:

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

BPH Medications Tier-3 Approval Criteria:

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

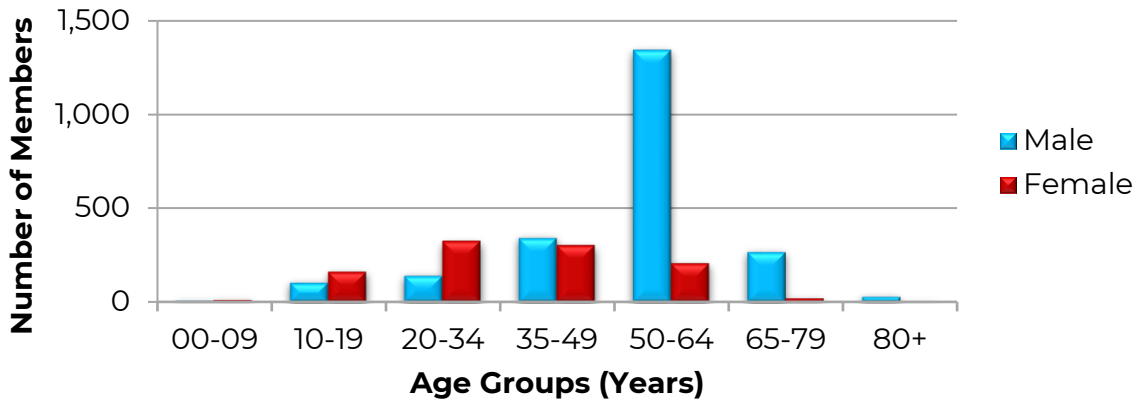
Utilization of BPH Medications: Fiscal Year 2020

Comparison of Fiscal Years

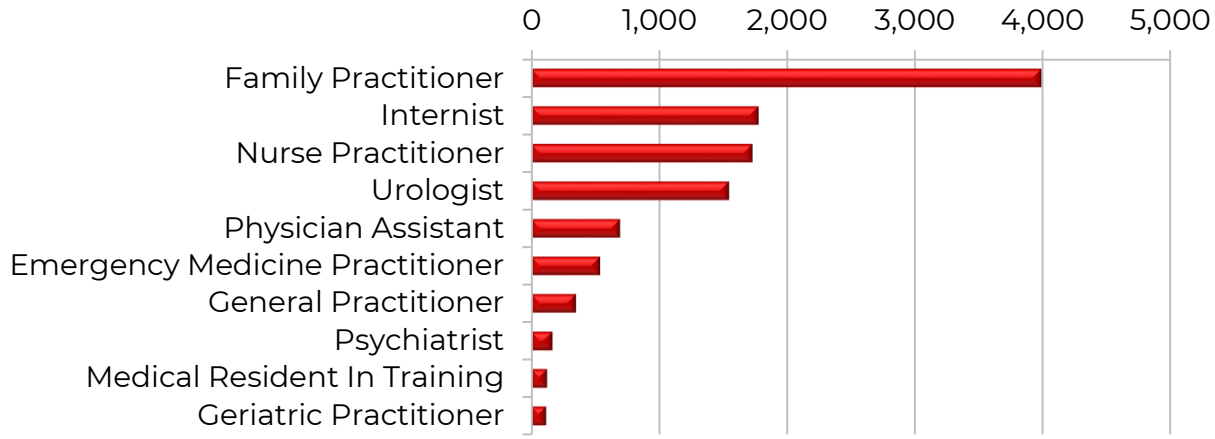
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	3,212	11,400	$166,187.27	$14.58	$0.36	504,041	458,657
2020	3,268	11,712	$162,919.37	$13.91	$0.34	533,140	483,267
% Change	**1.70%**	**2.70%**	**-2.00%**	**-4.60%**	**-5.60%**	**5.80%**	**5.40%**
Change	**56**	**312**	**-$3,267.90**	**-$0.67**	**-$0.02**	**29,099**	**24,610**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Demographics of Members Utilizing BPH Medications

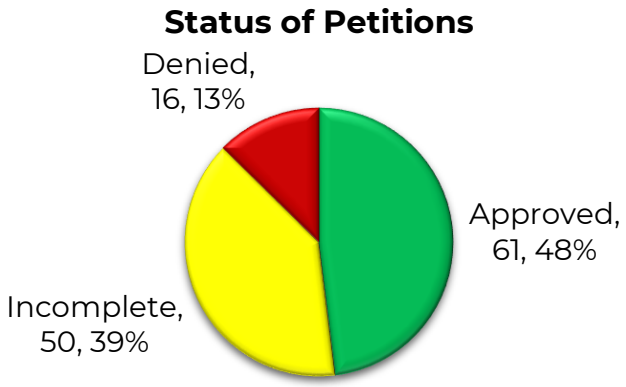


Top Prescriber Specialties of BPH Medications by Number of Claims



Prior Authorization of BPH Medications

There were 127 prior authorization requests submitted for 81 unique members for BPH medications during fiscal year 2020. The following chart shows the status of the submitted petitions for fiscal year 2020.



Market News and Updates

Pipeline:

- **Fexapotide (NX-1207):** Nymox has completed a Phase 3 study evaluating fexapotide for the treatment of BPH. The study followed patients for up to 7 years and showed statistically significant improvements in BPH symptoms compared to placebo, with a favorable safety profile. Fexapotide is a novel injectable protein administered by transrectal ultrasound guided intraprostatic injection in an office setting by a urologist and works by inducing apoptosis, selectively removing cells in the enlarged prostate gland. Nymox is planning to submit a New Drug Application (NDA) in the first quarter of 2021, seeking U.S. Food and Drug Administration (FDA) approval of fexapotide for the treatment of BPH. Nymox is also currently evaluating fexapotide for the treatment of early stage prostate cancer.[19,20,21]
- **Tadfin® (Tadalafil 5mg/Finasteride 5mg):** Tadfin® is a new fixed-dose proprietary tablet co-formulation of tadalafil and finasteride currently being evaluated for the treatment of BPH. Veru has conducted clinical studies demonstrating bioavailability and bioequivalence of Tadfin® to tadalafil 5mg and finasteride 5mg dosed daily as separate tablets. Stability testing of commercially manufactured batches of Tadfin® are currently ongoing, and Veru plans to submit an NDA to the FDA in 2021.[22]

[19] Nymox Pharmaceutical Corp. Nymox Pipeline. Available online at: https://nymox.com/science/pipeline. Last accessed 12/02/2020.
[20] Nymox Pharmaceutical Corp. Fexapotide for BPH. Available online at: https://nymox.com/science/fexapotide-for-bph. Last accessed 12/02/2020.
[21] Nymox Pharmaceutical Corp. Nymox Provides Update on Regulatory Filing Activities. Available online at: https://nymox.com/files/download/25f309fad151932. Issued 11/16/2020. Last accessed 12/02/2020.
[22] Veru, Inc. Veru Pipeline. Available online at: https://verupharma.com/pipeline/tadfin/. Last accessed 12/02/2020.

Recommendations

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

Utilization Details of BPH Medications: Fiscal Year 2020

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ CLIENT	% COST
TIER-1 UTILIZATION						
TAMSULOSIN CAP 0.4MG	8,318	2,762	$108,478.37	$13.04	3.01	66.58%
FINASTERIDE TAB 5MG	886	231	$11,920.43	$13.45	3.84	7.32%
DOXAZOSIN TAB 4MG	731	138	$12,194.27	$16.68	5.3	7.48%
DOXAZOSIN TAB 2MG	440	106	$7,118.72	$16.18	4.15	4.37%
DOXAZOSIN TAB 8MG	353	59	$6,160.56	$17.45	5.98	3.78%
ALFUZOSIN TAB 10MG ER	181	36	$2,306.41	$12.74	5.03	1.42%
DUTASTERIDE CAP 0.5MG	141	34	$2,405.64	$17.06	4.15	1.48%
TERAZOSIN CAP 1MG	140	37	$1,975.28	$14.11	3.78	1.21%
DOXAZOSIN TAB 1MG	126	45	$2,007.51	$15.93	2.8	1.23%
TERAZOSIN CAP 2MG	118	36	$1,897.00	$16.08	3.28	1.16%
TERAZOSIN CAP 10MG	102	21	$1,580.16	$15.49	4.86	0.97%
TERAZOSIN CAP 5MG	92	31	$1,448.24	$15.74	2.97	0.89%
SUBTOTAL	**11,628**	**3,263***	**$159,492.59**	**$13.72**	**3.56**	**97.90%**
TIER-2 UTILIZATION						
SILODOSIN CAP 8MG	43	3	$1,516.56	$35.27	14.33	0.93%
SILODOSIN CAP 4MG	14	3	$639.49	$45.68	4.67	0.39%
DUTAST/TAMSU CAP 0.5-0.4MG	3	2	$680.32	$226.77	1.5	0.42%
SUBTOTAL	**60**	**8***	**$2,836.37**	**$47.27**	**7.5**	**1.74%**
TIER-3 UTILIZATION						
TADALAFIL TAB 5MG	24	3	$590.41	$24.60	8	0.36%
SUBTOTAL	**24**	**3***	**$590.41**	**$24.60**	**8**	**0.36%**
TOTAL	**11,712**	**3,268***	**$162,919.37**	**$13.91**	**3.58**	**100.00%**

CAP = capsule; DUTAST/TAMSU = dutasteride/tamsulosin; ER = extended-release; TAB = tablet
*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Fiscal Year 2020 Annual Review of Benzodiazepine Medications

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

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

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

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

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

Niravam™ (Alprazolam Orally Disintegrating Tablet) Approval Criteria:

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

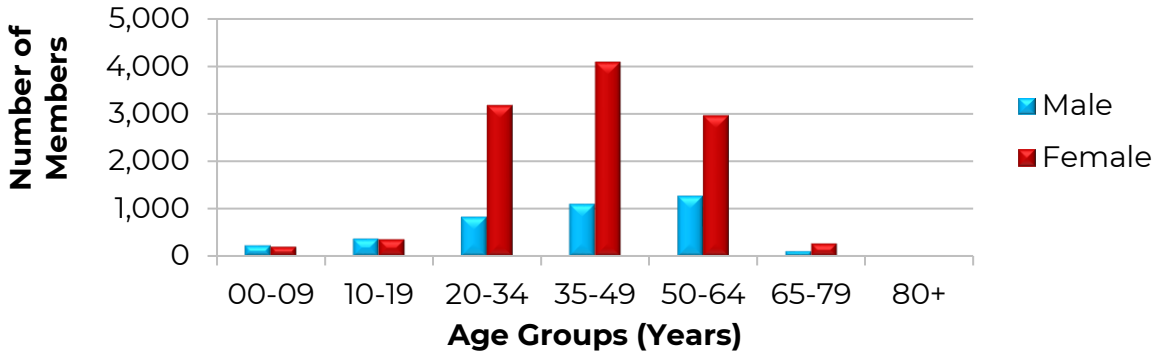
Utilization of Benzodiazepine Medications: Fiscal Year 2020

Comparison of Fiscal Years

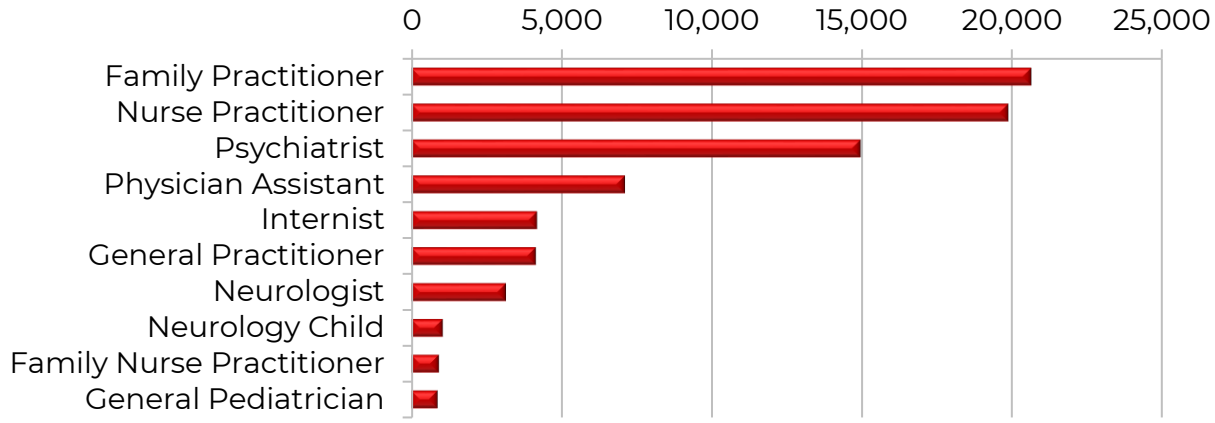
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	17,666	92,599	$1,086,957.06	$11.74	$0.43	5,528,383	2,528,265
2020	15,004	82,288	$1,002,903.36	$12.19	$0.45	4,881,770	2,239,169
% Change	**-15.10%**	**-11.10%**	**-7.70%**	**3.80%**	**4.70%**	**-11.70%**	**-11.40%**
Change	**-2,662**	**-10,311**	**-$84,053.70**	**$0.45**	**$0.02**	**-646,613**	**-289,096**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Demographics of Members Utilizing Benzodiazepine Medications

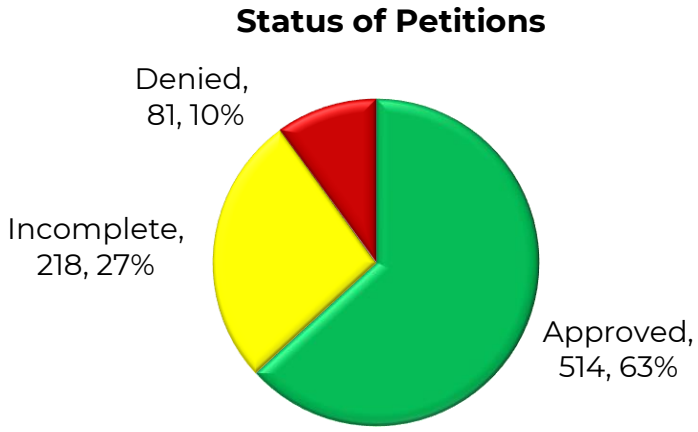


Top Prescriber Specialties of Benzodiazepine Medications by Number of Claims



Prior Authorization of Benzodiazepine Medications

There were 813 prior authorization requests submitted for benzodiazepine medications during fiscal year 2020. The following chart shows the status of the submitted petitions for fiscal year 2020.



Market News and Updates

News:

- **January 2020:** Results from a national survey concluded that despite the risk of respiratory depression, benzodiazepines and opioids continue to be co-prescribed. During the study period, 2014-2016, the rate of visits at which benzodiazepines were prescribed was 27 annual visits per 100 adults. At these benzodiazepine prescribed visits, approximately one-third had an overlapping opioid prescription for a rate of 10 annual visits per 100 adults. These rates were higher among women than men and increased with age.[23]

Recommendations

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

[23] Santo L, Rui P, Ashman JJ. Physician Office Visits at Which Benzodiazepines Were Prescribed: Findings From 2014-2016 National Ambulatory Medical Care Survey. *National Health Statistics Reports* 2020; 137.

Utilization Details of Benzodiazepine Medications: Fiscal Year 2020

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ALPRAZOLAM PRODUCTS						
ALPRAZOLAM TAB 1MG	18,358	2,998	$194,120.17	$10.57	6.12	19.36%
ALPRAZOLAM TAB 0.5MG	8,236	2,018	$86,484.46	$10.50	4.08	8.62%
ALPRAZOLAM TAB 2MG	7,671	1,130	$92,190.79	$12.02	6.79	9.19%
ALPRAZOLAM TAB 0.25MG	2,138	688	$21,881.27	$10.23	3.11	2.18%
ALPRAZOLAM TAB 2MG ER	134	31	$2,411.98	$18.00	4.32	0.24%
ALPRAZOLAM TAB 1MG ER	110	33	$1,698.26	$15.44	3.33	0.17%
ALPRAZOLAM TAB 3MG ER	81	13	$1,602.99	$19.79	6.23	0.16%
ALPRAZOLAM TAB 0.5MG ER	78	17	$1,226.45	$15.72	4.59	0.12%
ALPRAZOLAM TAB 2MG XR	56	12	$1,032.13	$18.43	4.67	0.10%
ALPRAZOLAM TAB 1MG XR	32	14	$496.55	$15.52	2.29	0.05%
ALPRAZOLAM TAB 0.5MG XR	21	4	$287.05	$13.67	5.25	0.03%
ALPRAZOLAM TAB 3MG XR	16	6	$322.71	$20.17	2.67	0.03%
ALPRAZOLAM TAB 0.5MG ODT	3	2	$282.46	$94.15	1.50	0.03%
SUBTOTAL	**36,934**	**6,966**	**$404,037.27**	**$10.94**	**5.30**	**40.28%**
CHLORDIAZEPOXIDE PRODUCTS						
CHLORDIAZEP CAP 25MG	159	96	$1,878.73	$11.82	1.66	0.19%
CHLORDIAZEP CAP 10MG	91	41	$1,221.85	$13.43	2.22	0.12%
CHLORDIAZEP CAP 5MG	19	14	$264.86	$13.94	1.36	0.03%
SUBTOTAL	**269**	**151**	**$3,365.44**	**$12.51**	**1.78**	**0.34%**
CLONAZEPAM PRODUCTS						
CLONAZEPAM TAB 1MG	11,159	2,167	$121,771.92	$10.91	5.15	12.14%
CLONAZEPAM TAB 0.5MG	9,989	2,442	$106,774.75	$10.69	4.09	10.65%
CLONAZEPAM TAB 2MG	2,784	481	$31,292.65	$11.24	5.79	3.12%
CLONAZEPAM ODT 0.25MG	1,139	339	$36,935.57	$32.43	3.36	3.68%
CLONAZEPAM ODT 0.5MG	616	209	$22,194.69	$36.03	2.95	2.21%
CLONAZEPAM ODT 0.125MG	590	210	$22,303.41	$37.80	2.81	2.22%
CLONAZEPAM ODT 1MG	359	132	$13,211.25	$36.80	2.72	1.32%
CLONAZEPAM ODT 2MG	43	19	$1,910.22	$44.42	2.26	0.19%
KLONOPIN TAB 2MG	12	1	$2,991.54	$249.30	12.00	0.30%
SUBTOTAL	**26,691**	**6,000**	**$359,386.00**	**$13.46**	**4.45**	**35.83%**
CLORAZEPATE PRODUCTS						
CLORAZ DIPOT TAB 3.75MG	163	25	$13,800.15	$84.66	6.52	1.38%
CLORAZ DIPOT TAB 7.5MG	122	24	$10,151.12	$83.21	5.08	1.01%
CLORAZ DIPOT TAB 15MG	72	11	$10,013.58	$139.08	6.55	1.00%
SUBTOTAL	**357**	**60**	**$33,964.85**	**$95.14**	**5.95**	**3.39%**
DIAZEPAM PRODUCTS						
DIAZEPAM TAB 10MG	4,670	1,243	$47,201.74	$10.11	3.76	4.71%
DIAZEPAM TAB 5MG	4,192	1,370	$42,115.49	$10.05	3.06	4.20%
DIAZEPAM TAB 2MG	865	292	$8,985.51	$10.39	2.96	0.90%
DIAZEPAM SOL 5MG/5ML	226	46	$8,598.23	$38.05	4.91	0.86%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
DIAZEPAM CON 5MG/ML	23	8	$1,173.33	$51.01	2.88	0.12%
DIAZEPAM INJ 5MG/ML	11	1	$2,177.32	$197.94	11.00	0.22%
SUBTOTAL	**9,987**	**2,960**	**$110,251.62**	**$11.04**	**3.37**	**11.01%**
LORAZEPAM PRODUCTS						
LORAZEPAM TAB 1MG	3,837	1,126	$40,872.29	$10.65	3.41	4.08%
LORAZEPAM TAB 0.5MG	2,996	908	$32,486.35	$10.84	3.30	3.24%
LORAZEPAM TAB 2MG	1,026	278	$11,493.59	$11.20	3.69	1.15%
LORAZEPAM CON 2MG/ML	113	40	$3,177.19	$28.12	2.83	0.32%
LORAZEPAM INJ 2MG/ML	18	6	$584.18	$32.45	3.00	0.06%
SUBTOTAL	**7,990**	**2,358**	**$88,613.60**	**$11.09**	**3.39**	**8.85%**
OXAZEPAM PRODUCTS						
OXAZEPAM CAP 15MG	31	6	$1,646.55	$53.11	5.17	0.16%
OXAZEPAM CAP 10MG	19	3	$829.69	$43.67	6.33	0.08%
OXAZEPAM CAP 30MG	10	3	$808.34	$80.83	3.33	0.08%
SUBTOTAL	**60**	**12**	**$3,284.58**	**$54.74**	**5.00**	**0.32%**
TOTAL	**82,288**	**15,004***	**$1,002,903.36**	**$12.19**	**5.48**	**100.0%**

CAP = capsule; CLORAZ DIPOT = clorazepate dipotassium; CON = concentrate; ER = extended-release; INJ = injection; ODT = orally disintegrating tablet; SOL = solution; TAB = tablet; XR = extended-release
*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Fiscal Year 2020 Annual Review of Botulinum Toxins

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Botulinum Toxins Approval Criteria:

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

Approval Criteria for Botox® for Neurogenic Overactive Bladder (*other botulinum toxins will not be approved for this diagnosis*):

1. Diagnosis of neurogenic bladder including underlying pathological dysfunction subtype confirmed by:
    a. Urodynamic studies to determine pathology and serve to provide objective evidence of bladder and external sphincter function; and
    b. A diary of fluid intake, incontinence, voiding, and catheterization times and amounts to provide a record of actual occurrences; and
2. Member must have a clinically significant reason why anticholinergic medications are no longer an option for the member; and
3. Member must be 18 years of age or older and have adequate hand function and sufficient cognitive ability to know when the bladder needs emptying and to self-catheterize, or have a caregiver able to catheterize the member when necessary; and
4. Botox® must be administered by a urologist.

Approval Criteria for Botox® for Non-Neurogenic Overactive Bladder (*other botulinum toxins will not be approved for this diagnosis*):

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

Approval Criteria for Botox® for Prevention of Migraine Headaches (*other botulinum toxins will not be approved for this diagnosis*):

1. Non-migraine medical conditions known to cause headache have been ruled out and/or have been treated. This includes, but is not limited to:
    a. Increased intracranial pressure (e.g., tumor, pseudotumor cerebri, central venous thrombosis); and
    b. Decreased intracranial pressure (e.g., post-lumbar puncture headache, dural tear after trauma); and
2. Migraine headache exacerbation secondary to other medical conditions or medication therapies have been ruled out and/or treated. This includes, but is not limited to:
    a. Hormone replacement therapy or hormone-based contraceptives; and
    b. Chronic insomnia; and
    c. Obstructive sleep apnea; and
3. Member has no contraindications to Botox® injections; and
4. FDA indications are met:
    a. Member is 18 years of age or older; and
    b. Member has documented chronic migraine headaches:
        i. Frequency of ≥15 headache days per month with ≥8 migraine days per month and occurring for >3 months; and
        ii. Headache duration of ≥4 hours per day; and
5. The member has failed medical migraine preventative therapy, including ≥2 agents with different mechanisms of action. This includes, but is not limited to:
    a. Select antihypertensive therapy (e.g., beta-blockers); or

b. Select anticonvulsant therapy; or
c. Select antidepressant therapy [e.g., tricyclic antidepressants (TCA), serotonin and norepinephrine reuptake inhibitors (SNRI)]; and

6. Member is not frequently taking medications which are known to cause medication overuse headaches (MOH or rebound headaches) in the absence of intractable conditions known to cause chronic pain. MOH are a frequent cause of chronic headaches. A list of prescription or non-prescription medications known to cause MOH includes, but is not limited to:
   a. Decongestants (alone or in combination products) (≥10 days/month for >3 months); and
   b. Combination analgesics containing caffeine and/or butalbital (≥10 days/month for >3 months); and
   c. Opioids (≥10 days/month for >3 months); and
   d. Analgesic medications including acetaminophen or non-steroidal anti-inflammatory drugs (NSAIDs) (≥15 days/month for >3 months); and
   e. Ergotamine-containing medications (≥10 days/month for >3 months); and
   f. Triptans (≥10 days/month for >3 months); and
7. Member is not taking any medications that are likely to be the cause of the headaches; and
8. Member must have been evaluated within the last 6 months by a neurologist for chronic migraine headaches and Botox® recommended as treatment (not necessarily prescribed or administered by a neurologist); and
9. Prescriber must verify that other aggravating factors that are contributing to the development of chronic migraine headaches are being treated when applicable (e.g., smoking); and
10. Member will not use the requested medication concurrently with a calcitonin gene-related peptide (CGRP) inhibitor for the prevention of migraine headaches.

Utilization of Botulinum Toxins: Fiscal Year 2020

Fiscal Year 2020 Utilization of Botulinum Toxins: Medical Claims

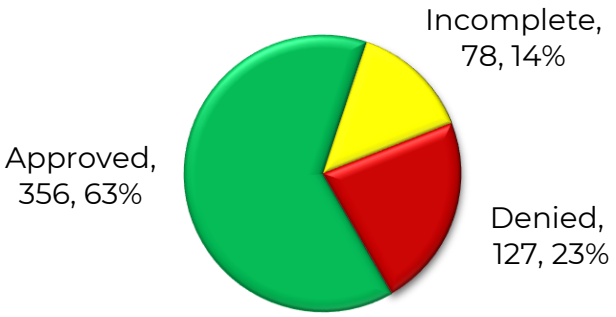
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Total Units
2020	281	479	$678,650.25	$1,416.81	112,400

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

Prior Authorization of Botulinum Toxins

There were 561 prior authorization requests submitted for botulinum toxins for 386 unique members during fiscal year 2020. The following chart shows the status of the submitted petitions for fiscal year 2020.

Status of Petitions



Market News and Updates

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

- **July 2020:** In October 2019, the FDA approved Botox® for the treatment of pediatric patients with lower limb spasticity, excluding spasticity caused by cerebral palsy (CP). Spasticity can be seen in patients with CP, multiple sclerosis, spinal cord injury, and stroke. In July 2020, the FDA approved a label expansion to include the treatment of lower limb spasticity in patients with CP. This label expansion was based on Allergan and Ispen Biopharmaceuticals selectively waiving Orphan Drug exclusivity marketing rights each company held for the use of their respective neurotoxin in the treatment of pediatric patients with spasticity caused by CP.[24]
- **July 2020**: Ispen Biopharmaceuticals announced the FDA has approved the expanded use of Dysport® for the treatment of both upper and lower limb spasticity in patients 2 years of age and older, including spasticity caused by CP. This approval was based on an agreement between Ispen Biopharmaceuticals and Allergan, the manufacturer of Botox®, to selectively waive their respective exclusivities for the treatment of spasticity due to CP.[25]

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[24] Allergan. FDA Approves Expanded Botox® (OnabotulinumtoxinA) Label for the Treatment of Pediatric Patients with Spasticity. *PR Newswire.* Available online at: https://www.prnewswire.com/news-releases/fda-approves-expanded-botox-onabotulinumtoxina-label-for-the-treatment-of-pediatric-patients-with-spasticity-301091264.html. Issued 07/09/2020. Last accessed 01/28/2021.

[25] Ipsen Biopharmaceuticals. Ipsen Announces Updated Indication for Dysport® (AbobotulinumtoxinA) for the Treatment of Spasticity in Children. *Business Wire*. Available online at: https://www.businesswire.com/news/home/20200709005981/en/Ipsen-Announces-Updated-Indication-for-Dysport%C2%AE-abobotulinumtoxinA-for-the-Treatment-of-Spasticity-in-Children. Issued 07/09/2020. Last accessed 01/28/2021.

Guideline Update(s):

- **September 2019:** The American Academy of Neurology (AAN) and the American Headache Society (AHS) released a practice guideline update regarding pharmacologic treatment for pediatric migraine prevention. This update was based on a systematic literature review from January 2003 to August 2017, in which 15 Class I-III trials of migraine prevention in children and adolescents were selected. The majority of randomized controlled trials studying the efficacy of preventive medications for pediatric migraine failed to demonstrate superiority to placebo. There was also insufficient evidence to determine if children or adolescents receiving botulinum toxin were more or less likely than those receiving placebo to have a reduction in headache frequency. For pediatric migraine prevention, the authors recommended counseling on lifestyle and behavioral factors that influence headache frequency and assessment and management of comorbid conditions associated with headache persistence. Prescribers should also engage in shared decision-making with the patients and caregivers regarding the use of preventative migraine treatments, including discussing the limitations in the evidence to support pharmacologic treatment.[26]

Recommendations

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

Utilization Details of Botulinum Toxins: Fiscal Year 2020

Medical Claims

PRODUCT UTILIZED	†TOTAL CLAIMS	*TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
BOTOX (J0585)	452	265	$659,506.81	$1,459.09	1.71	97.18%
DYSPORT (J0586)	12	9	$9,640.12	$803.34	1.33	1.42%
XEOMIN (J0588)	10	6	$4,457.01	$445.70	1.67	0.66%
MYOBLOC (J0587)	5	3	$5,046.31	$1,009.26	1.67	0.74%
TOTAL	**479**	**281**	**$678,650.25**	**$1,416.81**	**1.70**	**100.00%**

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

[26] Oskoui M, Pringsheim T, Billinghurst L, et al. Practice Guideline Update Summary: Pharmacologic Treatment for Pediatric Migraine Prevention; Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology and the American Headache Society. *Neurology* 2019; 93(11): 500-509.

Fiscal Year 2020 Annual Review of Bowel Preparation Medications

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Clenpiq®, ColPrep™ Kit, OsmoPrep®, Plenvu®, Prepopik®, and SUPREP® Approval Criteria:

1. An FDA approved indication for use in cleansing of the colon as a preparation for colonoscopy; and
2. A patient-specific, clinically significant reason other than convenience why the member cannot use other bowel preparation medications available without prior authorization must be provided; and
3. If the member requires a low volume polyethylene glycol electrolyte lavage solution, Moviprep® is available without prior authorization. Other medications currently available without prior authorization include: Colyte®, Gavilyte®, Golytely®, and Trilyte®.

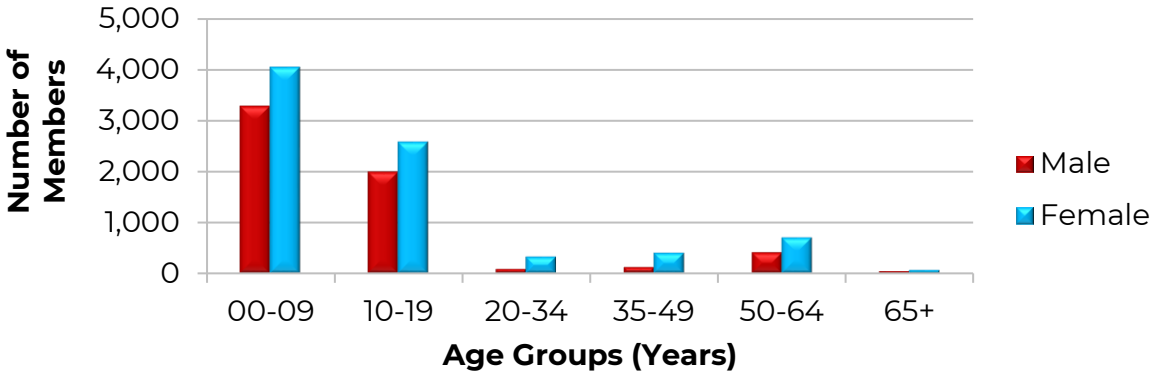
Utilization of Bowel Preparation Medications: Fiscal Year 2020

Comparison of Fiscal Years

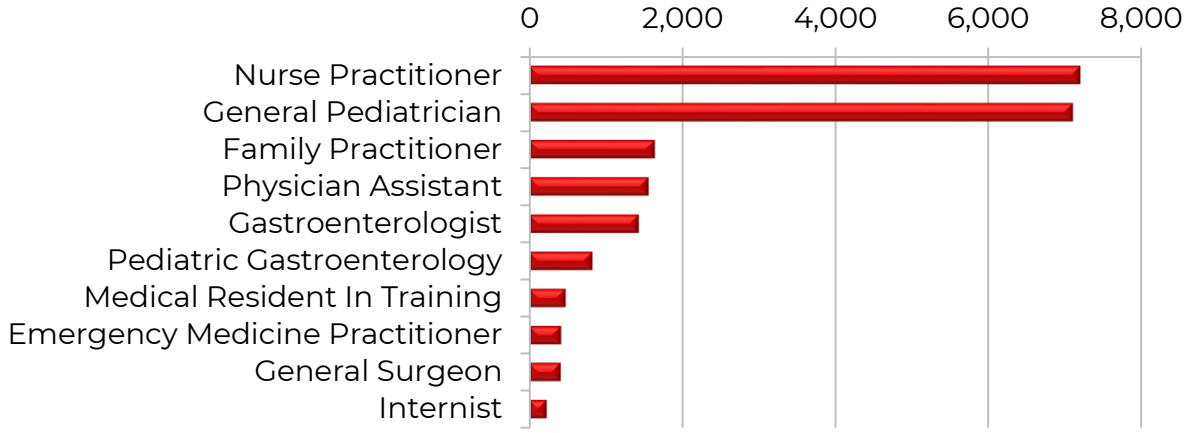
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	18,048	29,186	$610,859.20	$20.93	$0.81	21,890,773	751,364
2020	14,090	22,515	$435,905.21	$19.36	$0.76	18,245,997	570,527
% Change	**-21.90%**	**-22.90%**	**-28.60%**	**-7.50%**	**-6.20%**	**-16.60%**	**-24.10%**
Change	**-3,958**	**-6,671**	**-$174,953.99**	**-$1.57**	**-$0.05**	**-3,644,776**	**-180,837**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Demographics of Members Utilizing Bowel Preparation Medications



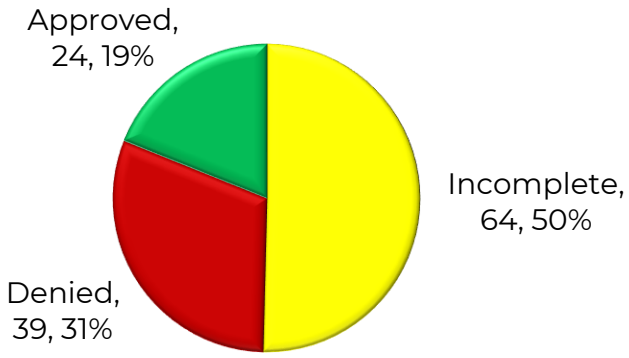
Top Prescriber Specialties of Bowel Preparation Medications by Number of Claims



Prior Authorization of Bowel Preparation Medications

There were 127 prior authorization requests submitted for bowel preparation medications during fiscal year 2020. The following chart shows the status of the submitted petitions for fiscal year 2020.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[27]

- SUPREP® (sodium sulfate/potassium sulfate/magnesium sulfate): March 2023
- OsmoPrep® (sodium phosphate dibasic/sodium phosphate monobasic): June 2028

[27] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 09/2020. Last accessed 09/17/2020.

- Prepopik® (sodium picosulfate/magnesium oxide/anhydrous citric acid): October 2028
- Plenvu® [polyethylene glycol (PEG) 3350/sodium ascorbate/sodium sulfate/ascorbic acid/sodium chloride/potassium chloride]: September 2033
- Clenpiq® (sodium picosulfate/magnesium oxide/anhydrous citric acid): June 2034

U.S. Food and Drug Administration (FDA) Label Expansion(s):[28]

- **August 2019:** The FDA approved Clenpiq® (sodium picosulfate/ magnesium oxide/anhydrous citric acid) for cleansing of the colon as a preparation for colonoscopy in pediatric patients 9 years of age and older. The approval is supported by a single study in 78 pediatric patients 9 to 16 years of age evaluating successful colon cleansing with Clenpiq® versus PEG. Successful colon cleansing was achieved in 88% [95% confidence interval (CI): 62, 98] and 81% (95% CI: 54, 96) of patients receiving Clenpiq® in the 9 to 12 years of age and 13 to 16 years of age ranges, respectively. Clenpiq® was first FDA approved in 2012 for the same indication in adults.

News:

- **March 2020:** A multicenter, randomized trial compared the bowel cleansing efficacy of 2 bowel preparation formulations available in China and Taiwan: a 300mL small-volume Bowklean (sodium picosulfate/magnesium citrate) preparation versus a larger-volume 2L Klean-Prep/Dulcolax® (PEG/bisacodyl) preparation. The study enrolled 631 individuals and found Bowklean was non-inferior to Klean-Prep/Dulcolax® in overall colon cleansing but was associated with significantly better preparation quality and greater tolerability.[29]
- **July 2020:** An article published in *Endoscopy International Open* stated that due to COVID-19 and the suspension of elective surgeries to preserve personal protective equipment (PPE), there has been a decrease in colonoscopy services. There is an urgent need to limit collateral damage associated with delaying routine endoscopy. Possible low-cost interventions that minimize the risk for spreading COVID-19 were discussed, including decreasing the number of incomplete or low-quality procedures that require rescheduling and minimizing the

[28] U.S. FDA. Supplemental Approval of Clenpiq®. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/209589Orig1s005ltr.pdf. Issued 08/08/2019. Last accessed 12/28/2020.

[29] Hung S, Chen HC, Tzu-Liang Chen W. A Randomized Trial Comparing the Bowel Cleansing Efficacy of Sodium Picosulfate/Magnesium Citrate and Polyethylene Glycol/Bisacodyl (The Bowklean Study). *Nature* 2020; 10:5604.

need for anesthesia medication and support. One possible alternative is water-aided colonoscopy (WAC).[30]

Recommendations

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

Utilization Details of Bowel Preparation Medications: Fiscal Year 2020

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
PEG POW 3350	16,719	10,133	$280,988.98	$16.80	1.65	64.45%
GAVILYTE-G SOL	1,242	1,135	$24,292.33	$19.56	1.09	5.57%
HM CLEARLAX POW	1,041	610	$18,770.90	$18.03	1.71	4.31%
PEG PACKET 3350	940	636	$45,567.66	$48.48	1.48	10.45%
CLEARLAX POW	491	294	$9,240.64	$18.82	1.67	2.12%
GNP CLEARLAX POW	431	292	$8,162.72	$18.94	1.48	1.87%
PEG-3350/KCL SOL/SODIUM	354	328	$7,562.01	$21.36	1.08	1.73%
PEG-3350 POW	322	236	$6,327.85	$19.65	1.36	1.45%
PEG-3350 SOL ELECTROL	203	184	$4,028.97	$19.85	1.1	0.92%
GAVILYTE-C-SOL	169	156	$2,904.42	$17.19	1.08	0.67%
PEG-3350 SOL ELECTROL	155	147	$2,552.83	$16.47	1.05	0.59%
MOVIPREP SOL	135	130	$15,024.17	$111.29	1.04	3.45%
PEG-3350 POW	124	66	$6,043.64	$48.74	1.88	1.39%
GAVILYTE-N-SOL FLAV PK	120	115	$2,499.94	$20.83	1.04	0.57%
TRILYTE SOL	29	29	$654.13	$22.56	1	0.15%
HEALTHYLAX POW	13	10	$573.10	$44.08	1.3	0.13%
SM CLEARLAX POW	12	9	$145.60	$12.13	1.33	0.03%
GOLYTELY SOL	8	8	$140.91	$17.61	1	0.03%
GNP CLEARLAX PAK 3350	4	2	$164.91	$41.23	2	0.04%
SUPREP BOWEL SOL PREP KIT	3	3	$292.50	$97.50	1	0.07%
TOTAL	**22,515**	**14,090**	**$435,905.21**	**$19.36**	**1.60**	**100%**

FLAV PK = flavor pack; KCL = potassium chloride; PAK = packet; PEG = polyethylene glycol;
PREP = preparation; POW = powder; SOL = solution;
*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020

[30] Cadoni S, Ishaq S, Hassan C, et al. Covid-19 Pandemic Impact on Colonoscopy Service and Suggestions for Managing Recovery. *Endosc Int Open* 2020; 8(7):E985-E989.

Fiscal Year 2020 Annual Review of Brineura® (Cerliponase Alfa)

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Brineura® (Cerliponase Alfa) Approval Criteria:

1. An FDA approved diagnosis of late infantile neuronal ceroid lipofuscinosis type 2 (CLN2) also known as tripeptidyl peptidase-1 (TPP-1) deficiency; and
2. Member must have confirmed TPP-1 enzymatic deficiency via enzyme assay, confirmed by molecular analysis; and
3. Member must be 3 years of age or older; and
4. Brineura® must be prescribed by a specialist with expertise in treatment of CLN2 (or an advanced care practitioner with a supervising physician who is a specialist with expertise in treating CLN2); and
5. Brineura® must be administered in a health care facility by a prescriber who is knowledgeable in intraventricular administration; and
6. Member must not have ventriculoperitoneal shunts or acute intraventricular access device-related complications; and
7. Member must not have documented generalized status epilepticus within 4 weeks of initiating treatment; and
8. Prescriber must verify member's blood pressure and heart rate will be monitored prior to each infusion, during infusion, and post-infusion; and
9. Prescriber must be willing to perform regular 12-lead electrocardiogram (ECG) evaluation at baseline and at least every 6 months and verify that they are acceptable to the prescriber; and
10. A baseline assessment must be performed to assess the Motor plus Language CLN2 score; and
11. Initial authorizations will be for the duration of 6 months, at which time compliance will be required for continued approval. After 12 months of utilization, the prescriber must verify the member is responding to the medication as demonstrated by a 2 point or less decline in Motor plus Language CLN2 score from baseline; and
12. Approval quantity will be based on Brineura® *Prescribing Information* and FDA approved dosing regimen.

Utilization of Brineura® (Cerliponase Alfa): Fiscal Year 2020

There was no SoonerCare utilization of Brineura® (cerliponase alfa) during fiscal year 2020 (07/01/2019 to 06/30/2020).

Prior Authorization of Brineura® (Cerliponase Alfa)

There were no prior authorization requests submitted for Brineura® (cerliponase alfa) during fiscal year 2020.

Market News and Updates

Pipeline:

- **RGX-181:** CLN2 is a rare genetic disorder caused by a mutation in the gene that makes TPP-1. RGX-181 is a novel gene therapy that will use the adeno-associated virus (AAV) vector to deliver the TPP-1 gene directly into the central nervous system for patients with CLN2. REGENXBIO is currently in the preclinical phase of development and expects to initiate enrollment in a Phase 1/2 trial in the first half of 2021.[31,32]

Recommendations

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

[31] REGENXBIO, Inc. REGENXBIO Reports Second Quarter 2020 Financial Results and Operational Highlight. *Cision PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/regenxbio-reports-second-quarter-2020-financial-results-and-operational-highlights-301107904.html. Issued 08/06/2020. Last accessed: 10/01/2020.
[32] REGENXBIO, Inc. Patients & Families: CLN2. Available online at: https://www.regenxbio.com/cln2/. Last accessed: 10/01/2020.

Fiscal Year 2020 Annual Review of Butalbital Medications

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Esgic® Capsule (Butalbital/Acetaminophen/Caffeine 50mg/325mg/40mg) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use Fioricet® tablets (butalbital/acetaminophen/caffeine 50mg/325mg/40mg) must be provided.

Fioricet with Codeine® (Butalbital/Acetaminophen/Caffeine/Codeine 50mg/300mg/40mg/30mg) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot take the 325mg acetaminophen formulation (butalbital/ acetaminophen/caffeine/codeine 50mg/325mg/40mg/30mg), which is available generically, must be provided.

Miscellaneous Butalbital Medications Approval Criteria:

1. An FDA approved indication for the treatment of tension-type headache; and
2. Member must be 12 years of age or older; and
3. Failure within the previous 60 days of the following:
    a. All available formulations of butalbital/acetaminophen medications that do not require prior authorization (medications available without prior authorization contain butalbital/acetaminophen/ caffeine in the standard 50mg/325mg/40mg dose); and
    b. At least 2 nonsteroidal anti-inflammatory drugs (NSAIDs), unless contraindicated.

Vanatol™ LQ (Butalbital/Acetaminophen/Caffeine Oral Solution) Approval Criteria:

1. An FDA approved indication for the treatment of the symptom complex of tension (or muscle contraction) headache; and
2. A patient-specific, clinically significant reason why a liquid formulation is needed in place of the generic tablets, even when the tablets are crushed, must be provided; and
3. Members with other solid dosage formulations in pharmacy claims history will not generally be approved.

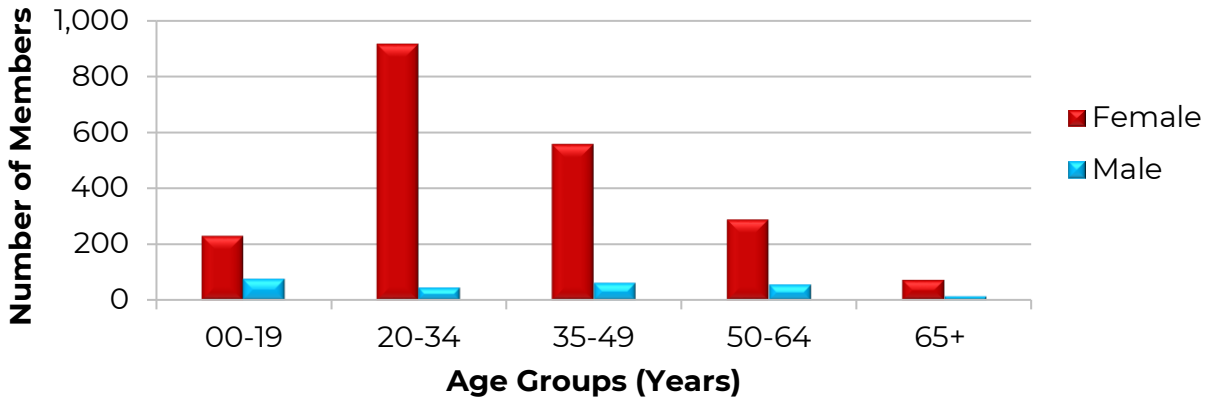
Utilization of Butalbital Medications: Fiscal Year 2020

Comparison of Fiscal Years

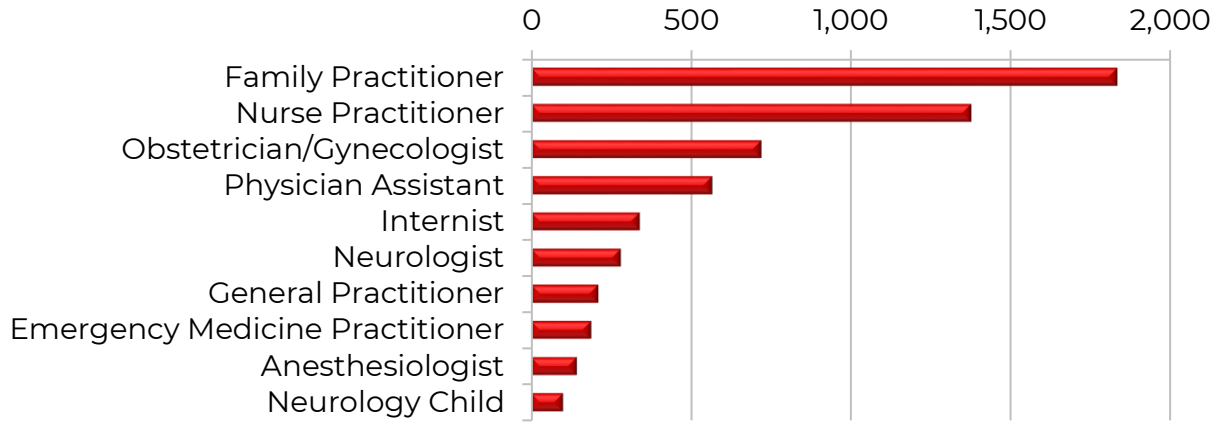
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	3,130	7,918	$237,155.15	$29.95	$1.90	378,142	124,963
2020	2,310	6,180	$155,925.43	$25.23	$1.54	292,875	101,424
% Change	**-26.20%**	**-21.90%**	**-34.30%**	**-15.80%**	**-18.90%**	**-22.50%**	**-18.80%**
Change	**-820**	**-1,738**	**-$81,229.72**	**-$4.72**	**-$0.36**	**-85,267**	**-23,539**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Demographics of Members Utilizing Butalbital Medications

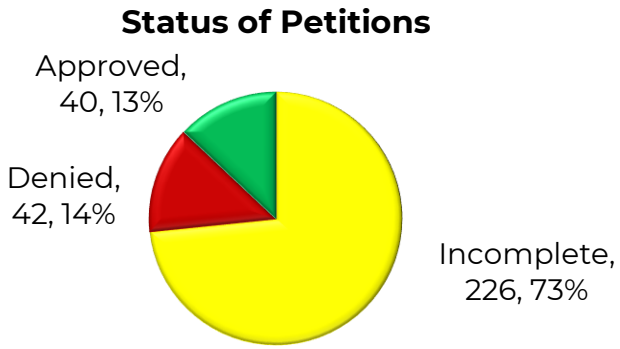


Top Prescriber Specialties of Butalbital Medications by Number of Claims



Prior Authorization of Butalbital Medications

There were 308 prior authorization requests submitted for butalbital medications during fiscal year 2020. The following chart shows the status of the submitted petitions for fiscal year 2020.



Market News and Updates

News:

- **July 2020:** The U.S Food and Drug Administration (FDA) cleared Zydus Cadila's generic formulation of Fioricet® (butalbital/acetaminophen/ caffeine) tablet in the 50mg/325mg/40mg strength for the treatment of tension headaches.[33]

Recommendations

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

Utilization Details of Butalbital Medications: Fiscal Year 2020

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
BUTALBITAL PRODUCTS						
BUT/APAP/CAF TAB 50/325/40MG	5,249	2,074	$110,831.97	$21.11	2.53	71.08%
BUT/ASA/CAF CAP 50/325/40MG	454	180	$15,909.46	$35.04	2.52	10.20%
BUT/APAP TAB 50/325MG	41	18	$2,510.39	$61.23	2.28	1.61%
BUT/APAP/CAF CAP 50/300/40MG	2	1	$95.56	$47.78	2.00	0.06%
SUBTOTAL	**5,746**	**2,273**	**$129,347.38**	**$22.51**	**2.52**	**82.95%**
BUTALBITAL/CODEINE PRODUCTS						
BUT/APAP/CAF/COD CAP 50/325/40/30MG	263	102	$13,019.39	$49.50	2.58	8.35%
BUT/ASA/CAF/COD 50/325/40/30MG	92	29	$6,893.73	$74.93	3.17	4.42%
ASCOMP/COD CAP 50/325/40/30MG	79	19	$6,664.93	$84.37	4.16	4.27%
SUBTOTAL	**434**	**150**	**$26,578.05**	**$61.24**	**2.89**	**17.04%**
TOTAL	**6,180**	**2,310***	**$155,925.43**	**$25.23**	**2.68**	**100%**

APAP = acetaminophen; ASA = aspirin; BUT = butalbital; CAF = caffeine; CAP = capsule; COD = codeine; TAB = tablet
*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020

[33] Levy S. FDA Clears Zydus Cadila's Generic Fioricet®. *Drug Store News*. Available online at: https://drugstorenews.com/fda-clears-zydus-cadilas-generic-fioricet. Issued 07/20/2020. Last accessed 09/17/2020.

Fiscal Year 2020 Annual Review of Carbaglu® (Carglumic Acid)

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Carbaglu® (Carglumic Acid) Approval Criteria:

1. An FDA approved diagnosis of N-acetylglutamate synthase (NAGS) deficiency; and
2. Carbaglu® must be prescribed by, or in consultation with, a geneticist;
3. Documentation of active management with a low protein diet; and
4. Initial approvals will be for the duration of 1 year. After that time, reauthorization will require the prescriber to verify the member is responding well to therapy.

Utilization of Carbaglu® (Carglumic Acid): Fiscal Year 2020

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	1	13	$1,031,677.53	$79,359.81	$2,714.94	5,280	380
2020	1	11	$1,165,778.14	$105,979.83	$3,784.99	5,820	308
% Change	**0.00%**	**-15.40%**	**13.00%**	**33.50%**	**39.40%**	**10.20%**	**-18.90%**
Change	**0**	**-2**	**$134,100.61**	**$26,620.02**	**$1,070.05**	**540**	**-72**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Demographics of Members Utilizing Carbaglu® (Carglumic Acid)

- There was 1 unique member utilizing Carbaglu® (carglumic acid) during fiscal year 2020. However, due to the limited number of members utilizing Carbaglu® (carglumic acid) during fiscal year 2020, detailed demographic information could not be provided.

Top Prescriber Specialties of Carbaglu® (Carglumic Acid) by Number of Claims

- The only prescriber specialty listed on paid claims for Carbaglu® (carglumic acid) during fiscal year 2020 was genetic counselor.

Prior Authorization of Carbaglu® (Carglumic Acid)

There were no prior authorization requests submitted for Carbaglu® (carglumic acid) during fiscal year 2020. The fiscal year 2020 utilization of

Carbaglu® (carglumic acid) was from prior authorization requests approved during fiscal year 2019.

Recommendations

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

Utilization Details of Carbaglu® (Carglumic Acid): Fiscal Year 2020

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
CARBAGLU TAB 200MG	11	1	$1,165,778.14	$105,979.83	11	100%
TOTAL	**11**	**1***	**$1,165,778.14**	**$105,979.83**	**11**	**100%**

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

Fiscal Year 2020 Annual Review of Cholbam® (Cholic Acid)

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Cholbam® (Cholic Acid) Approval Criteria:

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

Utilization of Cholbam® (Cholic Acid): Fiscal Year 2020

There was no SoonerCare utilization of Cholbam® (cholic acid) during fiscal year 2020 (07/01/2019 to 06/30/2020).

Prior Authorization of Cholbam® (Cholic Acid)

There were no prior authorization requests submitted for Cholbam® (cholic acid) during fiscal year 2020.

Market News and Updates

Anticipated Patent Expiration(s):[34]

- Cholbam® (cholic acid): March 2022

Recommendations

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

[34] 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 01/2021. Last accessed 01/10/2021.

Fiscal Year 2020 Annual Review of Chorionic Gonadotropin Medications

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

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

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

Utilization of Chorionic Gonadotropin Medications: Fiscal Year 2020

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	1	1	$142.92	$142.92	$142.92	1	1
2020	1	2	$287.56	$143.78	$143.78	2	2
% Change	**0.00%**	**100.00%**	**101.20%**	**0.60%**	**0.60%**	**100.00%**	**100.00%**
Change	**0**	**1**	**$144.64**	**$0.86**	**$0.86**	**1**	**1**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Demographics of Members Utilizing Chorionic Gonadotropin Medications

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

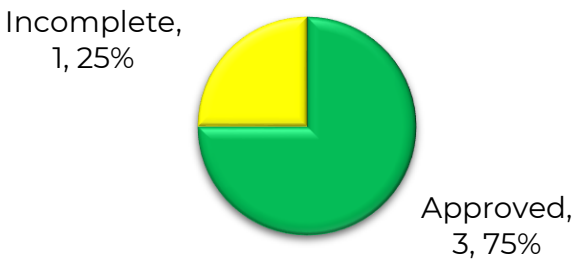
Top Prescriber Specialties of Chorionic Gonadotropin Medications by Number of Claims

- The only prescriber specialty listed on paid pharmacy claims for chorionic gonadotropin medications during fiscal year 2020 was pediatric endocrinologist.

Prior Authorization of Chorionic Gonadotropin Medications

There were 4 prior authorization requests submitted for 1 unique member for chorionic gonadotropin medications during fiscal year 2020. The following chart shows the status of the submitted petitions for fiscal year 2020.

Status of Petitions



Recommendations

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

Utilization Details of Chorionic Gonadotropin Medications: Fiscal Year 2020

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
NOVAREL INJ 5000 UNIT	2	1	$287.56	$143.78	2	100%
TOTAL	**2**	**1***	**$287.56**	**$143.78**	**2**	**100%**

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

Fiscal Year 2020 Annual Review of Corticosteroid Special Formulations

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Orapred ODT® [Prednisolone Sodium Phosphate Orally Disintegrating Tablet (ODT)] Approval Criteria:

1. Authorization requires a patient-specific, clinically significant reason why the member cannot use prednisone tablets; and
2. A quantity limit of 10 ODTs per 30 days will be available without prior authorization for members 10 years of age or younger.

Rayos® (Prednisone Delayed-Release Tablet) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use immediate-release corticosteroid medications must be provided.

TaperDex™ (Dexamethasone Tablet) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use dexamethasone 1.5mg individual tablets, which are available without prior authorization, must be provided.

Veripred™ 20 (Prednisolone Sodium Phosphate Oral Solution 20mg/5mL) and Millipred™ (Prednisolone Sodium Phosphate Oral Solution 10mg/5mL) Approval Criteria:

1. Authorization of Veripred™ 20 or Millipred™ requires a patient-specific, clinically significant reason why the member cannot use a tablet or an alternative strength liquid formulation.

Zilretta® [Triamcinolone Acetonide Extended-Release (ER) Injection] Approval Criteria:

1. An FDA approved diagnosis of osteoarthritis (OA) pain of the knee; and
2. Zilretta® will only be approvable for use in the knee(s) for OA pain; and
3. A patient-specific, clinically significant reason why the member cannot use Kenalog-40® (triamcinolone acetonide 40mg injection) and Depo-Medrol® (methylprednisolone injection) must be provided; and
4. A quantity limit of 1 injection per knee per 12 weeks will apply.

Utilization of Corticosteroid Special Formulations: Fiscal Year 2020

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	1,556	1,994	$180,342.82	$90.44	$18.55	11,530	9,722
2020	1,314	1,661	$166,914.89	$100.49	$20.76	9,875	8,041
% Change	**-15.6%**	**-16.7%**	**-7.4%**	**11.1%**	**11.9%**	**-14.4%**	**-17.3%**
Change	**-242**	**-333**	**-$13,427.93**	**$10.05**	**$2.21**	**-1,655**	**-1,681**

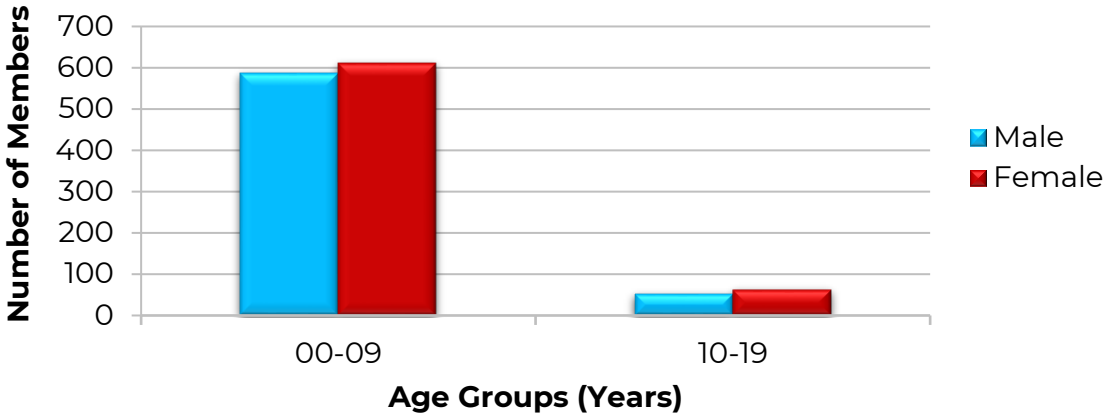
*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Comparison of Fiscal Years: Medical Claims

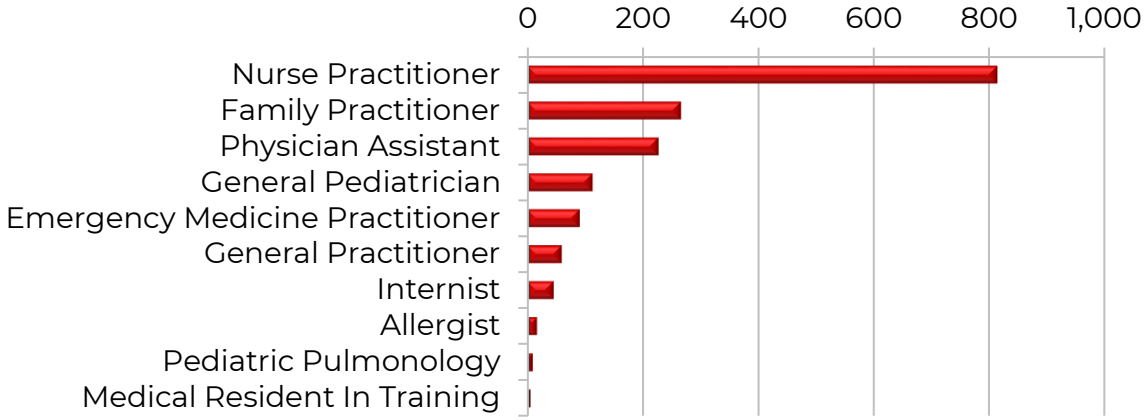
Fiscal Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Total Units
2019	1	1	$141.71	$141.71	32
2020	8	8	$1,521.40	$190.18	289
% Change	**700%**	**700%**	**973.6%**	**34.2%**	**803.1%**
Change	**7**	**7**	**$1,379.69**	**$ 48.47**	**257**

*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Demographics of Members Utilizing Corticosteroid Special Formulations: Pharmacy Claims



Top Prescriber Specialties of Corticosteroid Special Formulations by Number of Claims: Pharmacy Claims



Prior Authorization of Corticosteroid Special Formulations

There were 61 prior authorization requests for 43 unique members submitted for corticosteroid special formulations during fiscal year 2020. The following chart shows the status of the submitted petitions for fiscal year 2020.

Status of Petitions

Market News and Updates

Anticipated Patent Expiration(s):[35]

- Rayos® (Prednisone Delayed-Release Tablets): January 2028
- Zilretta® (Triamcinolone Acetonide Extended-Release Injection): August 2031

[35] 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 12/2020. Last accessed 12/01/2020.

Recommendations

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

Utilization Details of Corticosteroid Special Formulations: Fiscal Year 2020

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
PREDNISOLONE ORALLY DISINTEGRATING TABLET (ODT) PRODUCTS						
PREDNISOLONE ODT 15MG	782	683	$90,091.92	$115.21	1.14	53.97%
PREDNISOLONE ODT 10MG	683	504	$50,743.81	$74.30	1.36	30.40%
PREDNISOLONE ODT 30MG	196	180	$26,079.16	$133.06	1.09	15.62%
TOTAL	**1,661**	**1,314***	**$166,914.89**	**$100.49**	**1.26**	**100%**

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

Medical Claims

PRODUCT UTILIZED	⁺TOTAL CLAIMS	*TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
J3304 ZILRETTA INJ 1MG	8	8	$1,521.40	$190.18	1.0
TOTAL	**8**	**8**	**$1,521.40**	**$190.18**	**1.0**

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

Fiscal Year 2020 Annual Review of Defitelio® (Defibrotide)

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Defitelio® (Defibrotide) Approval Criteria:

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

Utilization of Defitelio® (Defibrotide): Fiscal Year 2020

There was no SoonerCare utilization of Defitelio® (defibrotide) during fiscal year 2020 (07/01/2019 to 06/30/2020).

Prior Authorization of Defitelio® (Defibrotide)

There were no prior authorization requests submitted for Defitelio® (defibrotide) during fiscal year 2020.

Market News and Updates

Anticipated Exclusivity Expiration(s):[36]

- Defitelio® (defibrotide): March 2023

Recommendations

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

[36] 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 12/2020. Last accessed 12/16/2020.

Fiscal Year 2020 Annual Review of Elaprase® (Idursulfase)

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Elaprase® (Idursulfase) Approval Criteria:

1. An FDA approved diagnosis of Hunter syndrome (mucopolysaccharidosis type II; MPS II) confirmed by:
   a. Enzyme assay demonstrating a deficiency of iduronate-2-sulfatase (IDS) enzyme activity; or
   b. Molecular genetic testing confirming a hemizygous pathogenic variant in the *IDS* gene; and
2. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to the Elaprase® *Prescribing Information*.

Utilization of Elaprase® (Idursulfase): Fiscal Year 2020

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	1	6	$451,624.10	$75,270.68	$2,688.24	432	168
2020	0	0	$0.00	$0.00	$0.00	0	0
% Change	**-100.00%**	**-100.00%**	**-100.00%**	**-100.00%**	**-100.00%**	**-100.00%**	**-100.00%**
Change	**-1**	**-6**	**-$451,624.10**	**-$75,270.68**	**-$2,688.24**	**-432**	**-168**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

- There was no SoonerCare utilization of Elaprase® (idursulfase) during fiscal year 2020.

Prior Authorization of Elaprase® (Idursulfase)

There were no prior authorization requests submitted for Elaprase® (idursulfase) during fiscal year 2020.

Market News and Updates

Pipeline:

- **DNL310:** Denali Therapeutics is developing DNL310 for the treatment of Hunter syndrome (mucopolysaccharidosis II or MPS II). DNL310 is a recombinant iduronate 2-sulfatase (IDS) enzyme engineered to cross the blood-brain-barrier (BBB) to replace the IDS enzyme and treat

neuropathic and systemic forms of MPS II. DNL310 is currently in the early clinical stage of development. In November 2020, Denali announced the first human biomarker proof of concept data for its proprietary Transport Vehicle (TV) technology from a Phase 1/2 study of DNL310 in 5 pediatric patients with MPS II. The TV technology is designed to effectively deliver large therapeutic molecules, such as antibodies, enzymes, proteins, and oligonucleotides, across the BBB after intravenous administration. The Phase 1/2 study is ongoing and Denali is currently planning a Phase 2/3 pivotal study. Additional safety and biomarker data should become available in the first quarter of 2021.[37,38]

- **JR-141:** JCR Pharmaceuticals is developing JR-141 for the treatment of MPS II. JR-141 is a fusion protein consisting of an antibody against the transferring receptor and IDS, the enzyme which is deficient in MPS II patients. The drug uses JCR's "J-Brain Cargo®" technology to deliver active drug molecules to the central nervous system (CNS), crossing the BBB. A Phase 3 study of JR-141 is ongoing in Japan, and JCR Pharmaceuticals is currently planning pivotal studies in the United States and Europe.[39,40,41]
- **RGX-121:** REGENXBIO is developing RGX-121 for the treatment of MPS II. RGX-121 is a one-time gene therapy that uses the adeno-associated virus serotype 9 (AAV9) vector to deliver the *IDS* gene to the CNS in an attempt to address the neurological manifestations of disease and prevent or stabilize cognitive decline. RGX-121 is administered intracisternally into the ventricles of the brain which could provide a permanent source of secreted IDS beyond the BBB. REGENXBIO is currently enrolling participants in a Phase 1/2 clinical trial of RGX-121. RGX-121 has received Orphan Drug, Rare Pediatric Disease, and Fast Track designations from the U.S. Food and Drug Administration (FDA). In September 2020, REGENXBIO released information regarding an

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[37] Denali Therapeutics, Inc. Denali Pipeline. Available online at: https://www.denalitherapeutics.com/pipeline. Last accessed 12/16/2020.

[38] Denali Therapeutics, Inc. Denali Therapeutics Announces First Human Biomarker Proof of Concept for Its Transport Vehicle (TV) Technology Achieved in Phase 1/2 Study of ETV:IDS (DNL310) in Hunter Syndrome (MPS II). *Globe Newswire*. Available online at: https://www.globenewswire.com/news-release/2020/11/10/2123675/0/en/Denali-Therapeutics-Announces-First-Human-Biomarker-Proof-of-Concept-for-Its-Transport-Vehicle-TV-Technology-Achieved-in-Phase-1-2-Study-of-ETV-IDS-DNL310-in-Hunter-Syndrome-MPS-II.html. Issued 11/10/2020. Last accessed 12/16/2020.

[39] JCR Pharmaceuticals Co., Ltd. JCR Pipeline. Available online at: https://www.jcrpharm.co.jp/en/site/en/biopharmaceutical/pdf/pipeline_0803.pdf. Last accessed 12/16/2020.

[40] JCR Pharmaceuticals Co., Ltd. R&D/Production. Available online at: https://www.jcrpharm.co.jp/en/site/en/biopharmaceutical/global.html. Last accessed 12/16/2020.

[41] JCR Pharmaceuticals Co., Ltd. JCR Pharmaceuticals announces Completion of Acquisition of ArmaGen, Inc. Available online at: https://www.prnewswire.com/news-releases/jcr-pharmaceuticals-announces-completion-of-acquisition-of-armagen-inc-301047260.html. Issued 04/27/2020. Last accessed 12/16/2020.

ongoing Phase 1/2 study in pediatric patients younger than 5 years of age with severe MPS II, stating that 6 patients have been dosed with RGX-121 across 2 dose levels. RGX-121 has been well-tolerated with no serious adverse events reported. REGENXBIO plans to initiate a second Phase 1/2 study in pediatric patients 5 to 18 years of age with severe MPS II and will provide additional updates from the ongoing studies by the end of 2020.[42,43]

Recommendations

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

[42] REGENXBIO, Inc. REGENXBIO Pipeline: RGX-121. Available online at: https://regenxbio.com/rgx-121/. Last accessed 12/16/2020.
[43] REGENXBIO, Inc. REGENXBIO Announces Continued Progress and Expansion of Clinical Development Program for RGX-121 for the Treatment of Mucopolysaccharidosis Type II (MPS II). *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/regenxbio-announces-continued-progress-and-expansion-of-clinical-development-program-for-rgx-121-for-the-treatment-of-mucopolysaccharidosis-type-ii-mps-ii-301141550.html. Issued 09/30/2020. Last accessed 12/16/2020.

Fiscal Year 2020 Annual Review of Erythropoietin Stimulating Agents (ESAs)

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Aranesp® (Darbepoetin Alfa) Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. Treatment of anemia due to chemotherapy in members with non-myeloid malignancies; or
    b. Treatment of anemia associated with chronic renal failure; and
        i. Member must not be receiving dialysis [erythropoietin stimulating agents (ESAs) are included in the bundled dialysis payment if member is on any form of dialysis and cannot be billed separately]; and
2. Recent hemoglobin levels must be provided; and
3. Approvals will be for the duration of 16 weeks of therapy. Recent hemoglobin levels must be provided with continuation requests, and further approval may be granted if the member's recent hemoglobin level is <11g/dL.

Epogen® (Epoetin Alfa), Procrit® (Epoetin Alfa), and Retacrit® (Epoetin Alfa-epbx) Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. Treatment of anemia due to chemotherapy in members with non-myeloid malignancies; or
    b. Treatment of anemia in zidovudine-treated Human Immunodeficiency Virus (HIV)-infected members; or
    c. Reduction of allogeneic blood transfusion(s) in members receiving surgery; or
    d. Treatment of anemia associated with chronic renal failure; and
        i. Member must not be receiving dialysis [erythropoietin stimulating agents (ESAs) are included in the bundled dialysis payment if member is on any form of dialysis and cannot be billed separately]; and
2. Recent hemoglobin levels must be provided; and
3. Approvals will be for the duration of 16 weeks of therapy. Recent hemoglobin levels must be provided with continuation requests, and further approval may be granted if the member's recent hemoglobin level is <11g/dL.

Utilization of ESAs: Fiscal Year 2020

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	27	304	$93,364.23	$307.12	$24.31	293	3,841
2020	20	245	$66,693.02	$272.22	$28.28	154	2,358
% Change	**-25.90%**	**-19.40%**	**-28.60%**	**-11.40%**	**16.30%**	**-47.40%**	**-38.60%**
Change	**-7**	**-59**	**-$26,671.21**	**-$34.90**	**$3.97**	**-139**	**-1,483**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Fiscal Year 2020 Utilization of ESAs: Medical Claims

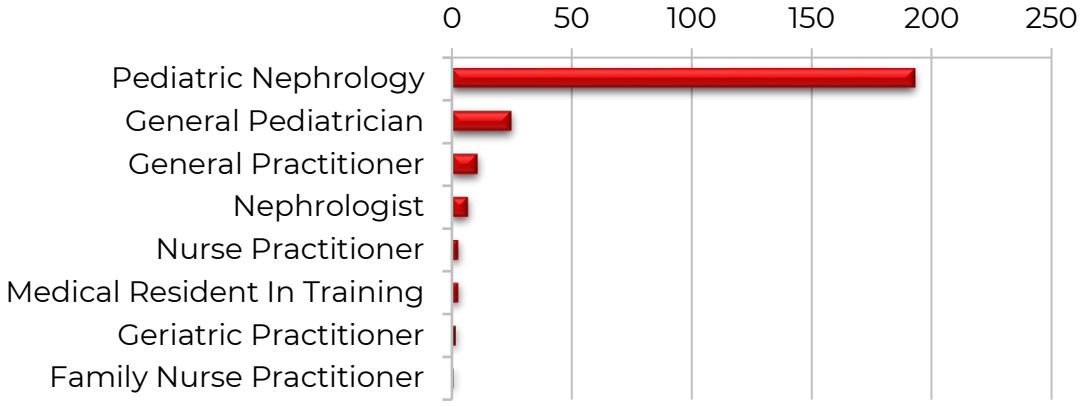
Fiscal Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Total Units
2020	63	181	$107,747.97	$595.29	23,702

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

Demographics of Members Utilizing ESAs

- Due to the limited number of members utilizing ESAs, detailed demographic information could not be provided.

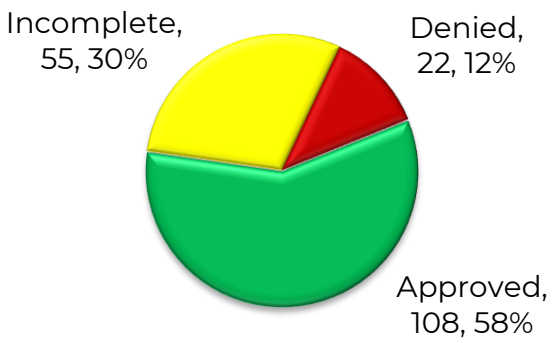
Top Prescriber Specialties of ESAs by Number of Claims



Prior Authorization of ESAs

There were 185 prior authorization requests submitted for ESAs during fiscal year 2020. The following chart shows the status of the submitted petitions for fiscal year 2020.

Status of Petitions



Recommendations

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

Utilization Details of ESAs: Fiscal Year 2020

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
DARBEPOETIN ALFA PRODUCTS						
ARANESP INJ 150MCG	5	1	$472.65	$4.50	$94.53	0.71%
ARANESP INJ 100MCG	1	1	$340.29	$24.31	$340.29	0.51%
ARANESP INJ 40MCG	1	1	$1,249.81	$44.64	$1,249.81	1.87%
SUBTOTAL	**7**	**3**	**$2,062.75**	**$14.03**	**$294.68**	**3.09%**
EPOETIN ALFA PRODUCTS						
PROCRIT INJ 20000/ML	204	12	$48,911.89	$26.80	$239.76	73.34%
EPOGEN INJ 20000/ML	25	2	$3,262.63	$17.08	$130.51	4.89%
PROCRIT INJ 10000/ML	6	3	$11,015.48	$113.56	$1,835.91	16.52%
EPOGEN INJ 10000/ML	2	1	$1,349.22	$24.09	$674.61	2.02%
PROCRIT INJ 3000/ML	1	1	$91.05	$2.17	$91.05	0.14%
SUBTOTAL	**238**	**19**	**$64,630.27**	**$29.23**	**$271.56**	**96.91%**
TOTAL	**245**	**20***	**$66,693.02**	**$28.28**	**$272.22**	**100.00%**

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

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
EPOETIN ALFA PRODUCTS					
PROCRIT INJ J0885	59	23	$25,387.48	2.57	$430.30
RETACRIT INJ Q5106	57	15	$8,711.37	3.8	$152.83
SUBTOTAL	**116**	**38**	**$34,098.85**	**3.05**	**$296.96**
DARBEPOETIN ALFA PRODUCTS					
ARANESP INJ J0881	65	25	$73,649.12	2.6	$1,133.06
SUBTOTAL	**65**	**25**	**$73,649.12**	**2.6**	**$1,133.06**
TOTAL	**181†**	**63***	**$107,747.97**	**2.87**	**$595.29**

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

Fiscal Year 2020 Annual Review of Fabry Disease Medications

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Fabrazyme® (Agalsidase Beta) Approval Criteria:

1. An FDA approved diagnosis of Fabry disease confirmed by 1 of the following:
   a. Genetic testing confirming positive galactosidase alpha (*GLA*) gene mutation; or
   b. Decreased plasma levels of alpha-galactosidase A (<5% of normal); and
2. Fabrazyme® will initially be approved for 6 months. After that time, compliance will be required for continued authorization; and
3. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling.

Galafold® (Migalastat) Approval Criteria:

1. An FDA approved diagnosis of Fabry disease with a confirmed amenable galactosidase alpha (*GLA*) gene variant based on *in vitro* assay data; and
2. Galafold® must be prescribed by a geneticist or an advanced care practitioner with a supervising physician who is a geneticist; and
3. Member must have an estimated glomerular filtration rate (eGFR) of ≥30mL/min/1.73m^2; and
4. Galafold® will initially be approved for 6 months. After that time, compliance will be required for continued authorization; and
5. A quantity limit of 14 capsules per 28 days will apply.

Utilization of Fabry Disease Medications: Fiscal Year 2020

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	3	40	$652,681.36	$16,317.03	$775.16	3,720	842
2020	3	75	$866,762.46	$11,556.83	$503.64	3,506	1,721
% Change	**0.00%**	**87.50%**	**32.80%**	**-29.20%**	**-35.00%**	**-5.80%**	**104.40%**
Change	**0**	**35**	**$214,081.10**	**-$4,760.20**	**-$271.52**	**-214**	**879**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Comparison of Fiscal Years: Medical Claims

Fiscal Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Total Units
2019	1	21	$259,557.90	$12,359.90	1,470
2020	1	25	$320,791.80	$12,831.67	1,750
% Change	**0.00%**	**19.05%**	**23.59%**	**3.82%**	**19.05%**
Change	**0**	**4**	**$61,233.9**	**$471.77**	**280**

*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Demographics of Members Utilizing Fabry Disease Medications

- Due to the limited number of members utilizing Fabry disease medications, detailed demographic information could not be provided.

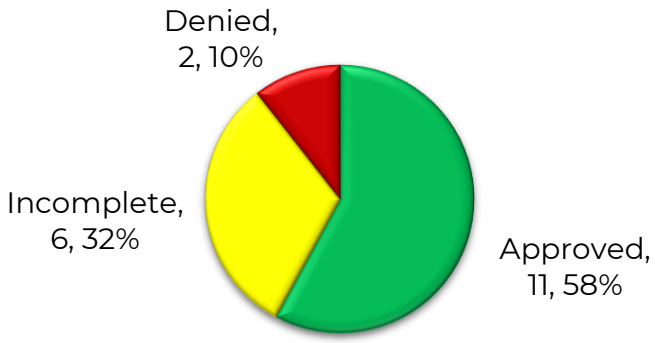
Top Prescriber Specialties of Fabry Disease Medications by Number of Claims: Pharmacy Claims

- The only prescriber specialty listed on paid pharmacy claims for Fabry disease medications during fiscal year 2020 was medical geneticist.

Prior Authorization of Fabry Disease Medications

There were 19 prior authorization requests for 5 unique members submitted for Fabry disease medications during fiscal year 2020. The following chart shows the status of the submitted petitions for fiscal year 2020.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[44]

- Galafold® (migalastat): May 2038

[44] 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 01/2021. Last accessed 01/04/2021.

Recommendations

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

Utilization Details of Fabry Disease Medications: Fiscal Year 2020

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
FABRAZYME INJ 5MG	48	3	$270,201.53	$5,629.20	16	31.17%
FABRAZYME INJ 35MG	27	2	$596,560.93	$22,094.85	13.5	68.83%
TOTAL	**75**	**3***	**$866,762.46**	**$11,556.83**	**25**	**100.00%**

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

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS[+]	TOTAL MEMBERS*	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
AGALSIDASE INJ J0180	25	1	$320,791.80	25	$12,831.67
TOTAL	**25**	**1**	**$320,791.80**	**25**	**$12,831.67**

INJ = injection
[+]Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Fiscal Year 2020 Annual Review of Fibromyalgia Medications

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Fibromyalgia Medications	
Tier-1	**Tier-2**
amitriptyline (Elavil®)	milnacipran (Savella®)
cyclobenzaprine (Flexeril®)	
duloxetine (Cymbalta®)	
pregabalin (Lyrica®)	
tramadol 50mg* (Ultram®)	

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).
*Unique criteria applies for the use of tramadol 100mg tablets.

Fibromyalgia Medications Tier-2 Approval Criteria:

1. Member must have a documented, recent (within the last 6 months) trial of 2 Tier-1 medications (must include 1 trial with duloxetine) at least 3 weeks in duration that did not provide an adequate response or resulted in intolerable adverse effects; or
2. Contraindication(s) to all available lower tiered medications; or
3. Current stabilization on a Tier-2 medication.

Tramadol 100mg Tablet Approval Criteria:

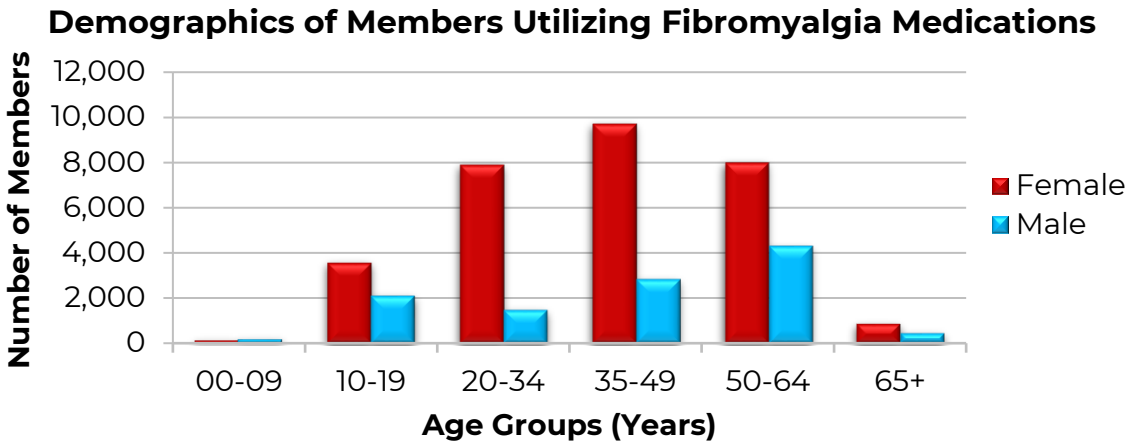
1. A patient-specific, clinically significant reason why the member cannot use 2 tramadol 50mg tablets to achieve a 100mg dose must be provided; and
2. An age restriction will apply for members younger than 12 years of age. For members younger than 12 years of age, the provider must submit patient-specific, clinically significant information supporting the use of tramadol despite the medication being contraindicated for the member's age.

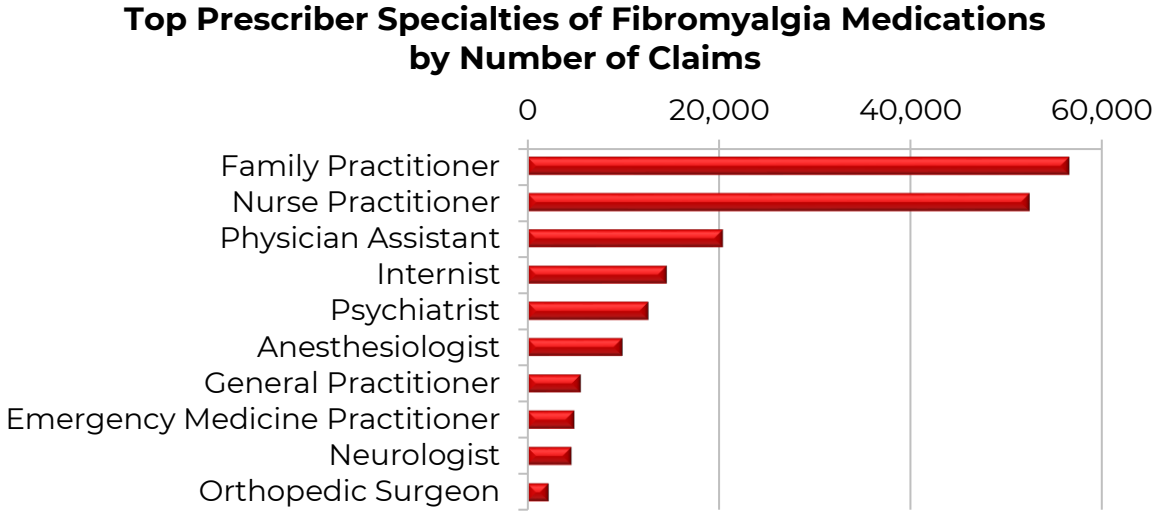
Utilization of Fibromyalgia Medications: Fiscal Year 2020

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	45,426	216,670	$7,626,767.47	$35.20	$1.19	16,439,462	6,407,897
2020	41,390	205,637	$6,677,634.97	$32.47	$1.05	16,040,959	6,374,126
% Change	**-8.90%**	**-5.10%**	**-12.40%**	**-7.80%**	**-11.80%**	**-2.40%**	**-0.50%**
Change	**-4,036**	**-11,033**	**-$949,132.50**	**-$2.73**	**-$0.14**	**-398,503**	**-33,771**

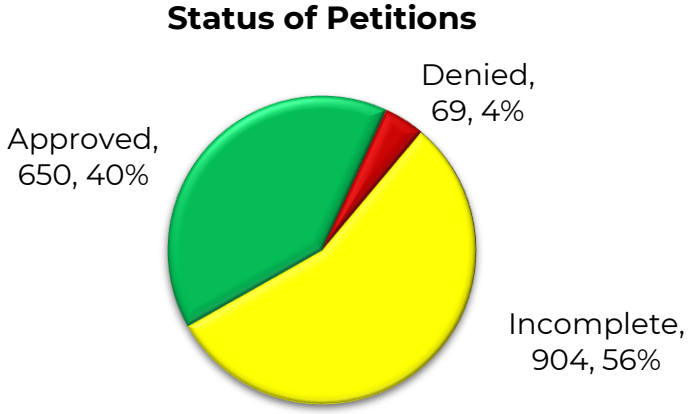
*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020





Prior Authorization of Fibromyalgia Medications

There were 1,623 prior authorization requests submitted for fibromyalgia medications during fiscal year 2020. The following chart shows the status of the submitted petitions for fiscal year 2020.



Market News and Updates

Anticipated Patent Expiration(s):[45]

- Savella® (milnacipran): September 2029

News:

- **April 2020:** The U.S. Food and Drug Administration (FDA) expanded the approval of Cymbalta® (duloxetine) to include the treatment of fibromyalgia in pediatric patients 13 to 17 years of age. The approval was based on data from a 13-week placebo-controlled trial that included 184 patients with juvenile primary fibromyalgia syndrome. Patients were randomized to receive duloxetine 30mg once daily for 1 week, then 60mg once daily for 12 weeks (based on response and tolerability) or placebo. The primary end point of the trial was reduction from baseline in average pain severity as measured by the Brief Pain Inventory (BPI)-Modified Short Form: Adolescent Version 24-hour average pain severity rating scale. Results showed treatment with duloxetine was not associated with a statistically significant improvement over placebo for the primary end point (mean change: -1.62 vs -0.97, respectively; P=0.052); however, significantly more patients had a treatment response (secondary end points defined as ≥30% and ≥50% reductions of BPI average pain severity) with duloxetine than with placebo. The mean duloxetine dosage for patients who completed the 12-week treatment phase was 49mg/day. Overall, the safety profile was found to be similar to that observed in previous clinical trials of duloxetine.[46]

Recommendations

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

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[45] 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 02/2021. Last accessed 02/04/2021.

[46] Ernst D. Cymbalta Approved for Pediatric Patients With Fibromyalgia. *MPR*. Available online at: https://www.empr.com/home/news/cymbalta-approved-for-pediatric-patients-with-fibromyalgia/. Issued 04/22/2020. Last accessed 02/04/2021.

Utilization Details of Fibromyalgia Medications: Fiscal Year 2020

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
GABAPENTIN PRODUCTS						
GABAPENTIN CAP 300MG	32,719	9,341	$445,869.51	$13.63	3.5	6.68%
GABAPENTIN TAB 600MG	23,200	4,500	$400,454.66	$17.26	5.16	6.00%
GABAPENTIN TAB 800MG	18,094	2,944	$373,265.15	$20.63	6.15	5.59%
GABAPENTIN CAP 100MG	10,101	3,523	$123,980.86	$12.27	2.87	1.86%
GABAPENTIN CAP 400MG	6,203	1,526	$86,456.07	$13.94	4.06	1.28%
GABAPENTIN SOL 250MG/5ML	1,113	222	$53,499.08	$48.07	5.01	0.80%
NEURONTIN CAP 300MG	4	1	$4,925.59	$1,231.40	4	0.07%
SUBTOTAL	**91,434**	**22,057**	**$1,488,450.92**	**$16.28**	**4.15**	**22.28%**
CYCLOBENZAPRINE PRODUCTS						
CYCLOBENZAPRINE TAB 10MG	25,974	11,050	$264,349.24	$10.18	2.35	3.96%
CYCLOBENZAPRINE TAB 5MG	6,758	3,965	$71,433.89	$10.57	1.7	1.07%
SUBTOTAL	**32,732**	**15,015**	**$335,783.13**	**$10.26**	**2.18**	**5.03%**
DULOXETINE PRODUCTS						
DULOXETINE CAP 60MG	17,030	4,190	$266,215.81	$15.63	4.06	3.99%
DULOXETINE CAP 30MG	10,245	3,661	$154,093.51	$15.04	2.8	2.30%
DULOXETINE CAP 20MG	2,159	835	$33,683.23	$15.60	2.59	0.50%
CYMBALTA CAP 60MG	6	1	$2,463.13	$410.52	6	0.04%
SUBTOTAL	**29,440**	**8,687**	**$456,455.68**	**$15.50**	**3.39**	**6.83%**
TRAMADOL PRODUCTS						
TRAMADOL HCL TAB 50MG	23,488	8,386	$252,886.61	$10.77	2.8	3.79%
SUBTOTAL	**23,488**	**8,386**	**$252,886.61**	**$10.77**	**2.8**	**3.79%**
AMITRIPTYLINE PRODUCTS						
AMITRIPTYLINE TAB 25MG	5,318	1,903	$70,810.87	$13.32	2.79	1.06%
AMITRIPTYLINE TAB 50MG	3,989	1,178	$80,086.90	$20.08	3.39	1.20%
AMITRIPTYLINE TAB 10MG	3,384	1,209	$42,121.60	$12.45	2.8	0.63%
AMITRIPTYLINE TAB 100MG	2,325	560	$81,618.38	$35.10	4.15	1.22%
AMITRIPTYLINE TAB 75MG	835	248	$22,784.00	$27.29	3.37	0.34%
AMITRIPTYLINE TAB 150MG	798	188	$45,098.23	$56.51	4.24	0.68%
SUBTOTAL	**16,649**	**5,286**	**$342,519.98**	**$20.57**	**3.15**	**5.13%**
PREGABALIN PRODUCTS						
LYRICA CAP 150MG	2,105	499	$1,169,159.27	$555.42	4.22	17.51%
PREGABALIN CAP 150MG	1,360	470	$24,195.88	$17.79	2.89	0.36%
LYRICA CAP 75MG	1,334	495	$670,216.83	$502.41	2.69	10.04%
LYRICA CAP 100MG	1,178	363	$669,711.01	$568.52	3.25	10.02%
PREGABALIN CAP 75MG	1,034	493	$17,418.43	$16.85	2.1	0.26%
PREGABALIN CAP 100MG	900	345	$15,920.59	$17.69	2.61	0.24%
LYRICA CAP 50MG	748	320	$399,995.04	$534.75	2.34	5.99%
LYRICA CAP 300MG	705	137	$322,053.65	$456.81	5.15	4.82%
LYRICA CAP 200MG	553	137	$296,444.98	$536.07	4.04	4.44%
PREGABALIN CAP 50MG	507	275	$8,420.68	$16.61	1.84	0.13%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
PREGABALIN CAP 200MG	483	137	$9,407.44	$19.48	3.53	0.14%
PREGABALIN CAP 300MG	360	106	$6,273.32	$17.43	3.4	0.09%
LYRICA CAP 25MG	146	64	$66,056.61	$452.44	2.28	0.99%
LYRICA CAP 225MG	146	37	$68,492.42	$469.13	3.95	1.03%
PREGABALIN CAP 225MG	116	32	$1,865.88	$16.09	3.63	0.03%
PREGABALIN CAP 25MG	90	61	$1,437.88	$15.98	1.48	0.02%
LYRICA SOL 20MG/ML	13	2	$12,060.83	$927.76	6.5	0.18%
PREGABALIN SOL 20MG/ML	2	1	$121.76	$60.88	2	0.01%
SUBTOTAL	**11,780**	**3,974**	**$3,759,252.50**	**$319.12**	**2.96**	**56.30%**
MILNACIPRAN PRODUCTS						
SAVELLA TAB 50MG	69	11	$25,448.49	$368.82	6.27	0.38%
SAVELLA TAB 100MG	39	6	$14,891.49	$381.83	6.5	0.22%
SAVELLA TITR PAK	5	5	$1,746.34	$349.27	1	0.03%
SAVELLA TAB 25MG	1	1	$199.83	$199.83	1	0.01%
SUBTOTAL	**114**	**23**	**$42,286.15**	**$370.93**	**4.96**	**0.64%**
TOTAL	**205,637**	**41,390***	**$6,677,634.97**	**$32.47**	**4.97**	**100.00%**

CAP = capsule; HCL = hydrochloride; SOL = solution; TAB = tablet; TITR PAK = titration pack
*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020
The utilization details include fibromyalgia medications used for all diagnoses and does not differentiate between fibromyalgia diagnoses and other diagnoses, for which use may be appropriate.

Fiscal Year 2020 Annual Review of Gamifant® (Emapalumab-lzsg)

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Gamifant® (Emapalumab-lzsg) Approval Criteria:

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

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

Utilization of Gamifant® (Emapalumab-lzsg): Fiscal Year 2020

There was no SoonerCare utilization, including pharmacy and medical claims, of Gamifant® (emapalumab-lzsg) during fiscal year 2020 (07/01/2019 to 06/30/2020).

Prior Authorization of Gamifant® (Emapalumab-lzsg)

There were no prior authorization requests submitted for Gamifant® (emapalumab-lzsg) during fiscal year 2020.

Market News and Updates

News:

- **July 2020:** Sobi announced its intent to file for a re-examination of Gamifant® (emapalumab-lzsg) in Europe following the negative opinion expressed by the European Medicines Agency's Committee for Medicinal Products for Human use (CHMP). CHMP recommended refusal of marketing authorization for the drug as treatment of primary hemophagocytic lymphohistiocytosis (HLH) in children younger than 18 years of age in Europe. Sobi also plans to initiate clinical studies with Gamifant® for potential indications such as pre-emptive treatment of patients with risk factors of hematopoietic stem-cell transplantation (HSCT) acute graft failure.[47]

Recommendations

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

[47] McKee S. Sobi to Refile Gamifant Following CHMP Rejection. *PharmaTimes*. Available online at: http://www.pharmatimes.com/news/sobi_to_refile_gamifant_following_chmp_rejection_1345560. Issued 07/27/2020. Last accessed 12/23/2020.

Fiscal Year 2020 Annual Review of Gattex® [Teduglutide (rDNA Origin)]

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Gattex® [Teduglutide (rDNA Origin)] Approval Criteria:

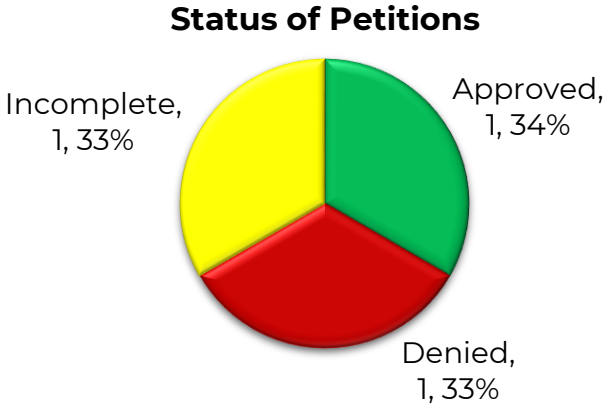
1. An FDA approved diagnosis of severe short bowel syndrome; and
2. Member must have required parenteral nutrition at least 3 times per week, every week, for the past 12 months; and
3. Documentation of all of the following:
    a. Prior use of supportive therapies (e.g., anti-motility agents, proton pump inhibitors, bile acid sequestrants, octreotide); and
    b. Colonoscopy within the previous 6 months, with removal of polyps if present; and
    c. Gastro-intestinal malignancy has been ruled out; and
4. Approval will be for the duration of 3 months, after which time, prescriber must verify benefit of medication by documented reduction of at least 20% in parenteral support. Subsequent approvals will be for the duration of 1 year.

Utilization of Gattex® [Teduglutide (rDNA Origin)]: Fiscal Year 2020

There was no SoonerCare utilization of Gattex® [teduglutide (rDNA origin)] during fiscal year 2020 (07/01/2019 to 06/30/2020).

Prior Authorization of Gattex® [Teduglutide (rDNA Origin)]

There were 3 prior authorization requests submitted for Gattex® [teduglutide (rDNA origin)] during fiscal year 2020. The following chart shows the status of the submitted petitions for fiscal year 2020. Please note, there were no paid pharmacy claims for the approved prior authorization in fiscal year 2020.



Market News and Updates

Anticipated Exclusivity Expiration(s):[48]

- Gattex® [teduglutide (rDNA origin)]: May 2026

Recommendations

The College of Pharmacy does not recommend any changes to the current Gattex® [teduglutide (rDNA origin)] prior authorization criteria at this time.

[48] 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 12/2020. Last accessed 12/22/2020.

Fiscal Year 2020 Annual Review of Gaucher Disease Medications

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Cerdelga® (Eliglustat) Approval Criteria:

1. An FDA approved indication of type 1 Gaucher disease (GD1); and
2. Member is classified as 1 of the following as detected by an FDA-cleared test:
   a. CYP2D6 extensive metabolizers (EMs); or
   b. CYP2D6 intermediate metabolizers (IMs); or
   c. CYP2D6 poor metabolizers (PMs); and
3. Prescriber must verify that the member will not take Cerdelga® concurrently with another therapy for GD1; and
4. For CYP2D6 EMs and IMs, a quantity limit of 56 capsules per 28 days will apply. For CYP2D6 PMs, a quantity limit of 28 capsules per 28 days will apply; and
5. Approvals will be for the duration of 6 months, at which time the prescriber must verify the patient is responding to the medication.

Cerezyme® (Imiglucerase), Elelyso® (Taliglucerase Alfa), and Vpriv® (Velaglucerase Alfa) Approval Criteria:

1. A diagnosis of symptomatic (e.g., anemia, thrombocytopenia, bone disease, splenomegaly, or hepatomegaly) type 1 or type 3 Gaucher disease (GD); and
2. Member's weight (kg) must be provided and must have been taken within the last 4 weeks to ensure accurate weight-based dosing; and
3. Prescriber must verify that the member will not take requested therapy concurrently with another therapy for GD; and
4. Approvals will be for the duration of 6 months, at which time the prescriber must verify the patient is responding to the medication.

Zavesca® (Miglustat) Approval Criteria:

1. An FDA approved indication of mild/moderate type 1 Gaucher disease (GD1); and
2. A patient-specific, clinically significant reason why the member cannot use 1 of the following enzyme replacement therapies must be provided:
   a. Cerezyme® (imiglucerase); or
   b. Elelyso® (taliglucerase alfa); or
   c. Vpriv® (velaglucerase alfa); and

3. Prescriber must verify that the member will not take Zavesca® concurrently with another therapy for GD1; and
4. A quantity limit of 90 capsules per 30 days will apply; and
5. Approvals will be for the duration of 6 months, at which time the prescriber must verify the patient is responding to the medication.

Utilization of Gaucher Disease Medications: Fiscal Year 2020

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	4	34	$696,776.46	$20,493.43	$725.81	636	960
2020	3	12	$262,403.34	$21,866.94	$776.34	244	338
% Change	**-25.0%**	**-64.7%**	**-62.3%**	**6.7%**	**7.0%**	**-61.6%**	**-64.8%**
Change	**-1**	**-22**	**-$434,373.12**	**$1,373.51**	**$50.53**	**-392**	**-622**

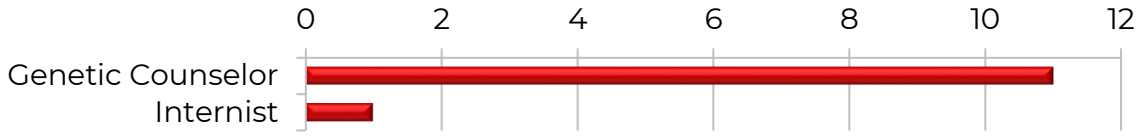
*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

- There were no pharmacy claims for Cerdelga® (eliglustat), Elelyso® (taliglucerase alfa), or Vpriv® (velaglucerase alfa) during fiscal year 2020.
- There were no medical claims for Cerezyme® (imiglucerase), Elelyso® (taliglucerase alfa) or Vpriv® (velaglucerase alfa) during fiscal year 2020.

Demographics of Members Utilizing Gaucher Disease Medications

- Due to the limited number of members utilizing Gaucher disease medications, detailed demographic information could not be provided.

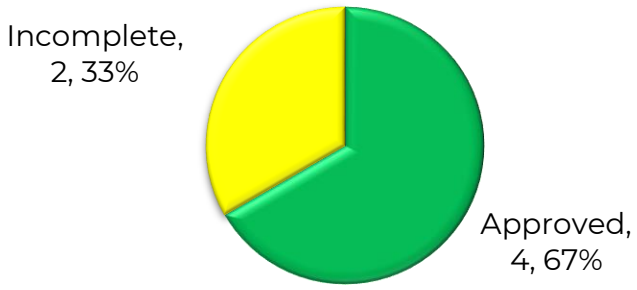
Top Prescriber Specialties of Gaucher Disease Medications by Number of Claims



Prior Authorization of Gaucher Disease Medications

There were 6 prior authorization requests submitted for 3 unique members for Gaucher disease medications during fiscal year 2020. The following chart shows the status of the submitted petitions for fiscal year 2020.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[49,50]

- Vpriv® (velaglucerase alfa): July 2022
- Elelyso® (taliglucerase alfa): June 2025
- Cerdelga® (eliglustat): June 2026

Pipeline:

- **AVR-RD-02:** AVROBIO's investigational gene therapy AVR-RD-02 for type 1 Gaucher disease (GD1) is currently in Phase 1/2 clinical trials to evaluate the safety and efficacy of the medication.[51]

Recommendations

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

Utilization Details of Gaucher Disease Medications: Fiscal Year 2020

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
CEREZYME INJ 400UNIT	11	2	$255,750.99	$23,250.09	5.5	97.46%
MIGLUSTAT CAP 100MG	1	1	$6,652.35	$6,652.35	1	2.54%
TOTAL	**12**	**3***	**$262,403.34**	**$21,866.94**	**4.00**	**100%**

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

[49] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 09/2020. Last accessed 10/01/2020.
[50] United States Patent and Trademark Office (USPTO). Patent Terms Extended Under 35 USC §156. Available online at: https://www.uspto.gov/patent/laws-and-regulations/patent-term-extension/patent-terms-extended-under-35-usc-156. Last revised 01/24/2020. Last accessed 10/02/2020.
[51] AVROBIO, Inc. Our Pipeline. Available online at: https://www.avrobio.com/our-pipeline. Last accessed 10/02/2020.

Fiscal Year 2020 Annual Review of Gout Medications

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Colcrys® (Colchicine Tablet), Gloperba® (Colchicine Oral Solution), and Mitigare® (Colchicine Capsule) Approval Criteria:

1. A quantity of 6 tablets or capsules for a 3-day supply is available without prior authorization for the treatment of acute gouty attacks; and
2. Member must have failure of allopurinol after 6 months of treatment defined by persistent gouty attacks with serum urate levels >6.0mg/dL; and
3. A patient-specific, clinically significant reason why colchicine/probenecid would not be a viable option for the member must be provided; and
4. For authorization of Gloperba®, a patient-specific, clinically significant reason why the member cannot use colchicine tablets or capsules must be provided; and
5. A quantity limit of 60 tablets or capsules per 30 days or 300mL per 30 days will apply for gout; and
6. Members with the diagnosis of Familial Mediterranean Fever verified by genetic testing will be approved for up to 2.4mg per day.

Krystexxa® (Pegloticase) Approval Criteria:

1. An FDA approved diagnosis of gout; and
2. Member must have symptomatic gout with:
   a. ≥3 gout flares in the previous 18 months; or
   b. ≥1 gout tophus; or
   c. Gouty arthritis; and
3. Member must have failure of the following urate lowering therapies: allopurinol, febuxostat, lesinurad, and probenecid titrated to the maximum tolerable dose for at least 3 months; and
4. Pegloticase must be administered in a health care setting by a health care provider prepared to manage anaphylaxis; and
5. Prescriber must attest that the member will be pre-medicated with antihistamines and corticosteroids to reduce the risk of anaphylaxis; and
6. Prescriber must document that the member does not have glucose-6-phosphate dehydrogenase (G6PD) deficiency prior to starting pegloticase; and
7. Member must continue oral urate-lowering agents prior to starting pegloticase; and

8. Member must receive gout flare prophylaxis with nonsteroidal anti-inflammatory drug(s) (NSAIDs) or colchicine at least 1 week before initiation of pegloticase therapy and continue for at least 6 months unless medically contraindicated or member is unable to tolerate therapy; and
9. Approvals will be for the duration of 6 months. Reauthorizations may be granted if the prescriber documents the member is responding well to treatment, and member has not exceeded >4 consecutive weeks without therapy.

Uloric® (Febuxostat) Approval Criteria:

1. Member must have failure of allopurinol defined by persistent gouty attacks with serum urate levels >6.5mg/dL; and
2. A patient-specific, clinically significant reason why allopurinol is not a viable option for the member must be provided; and
3. A quantity limit of 30 tablets per 30 days will apply.

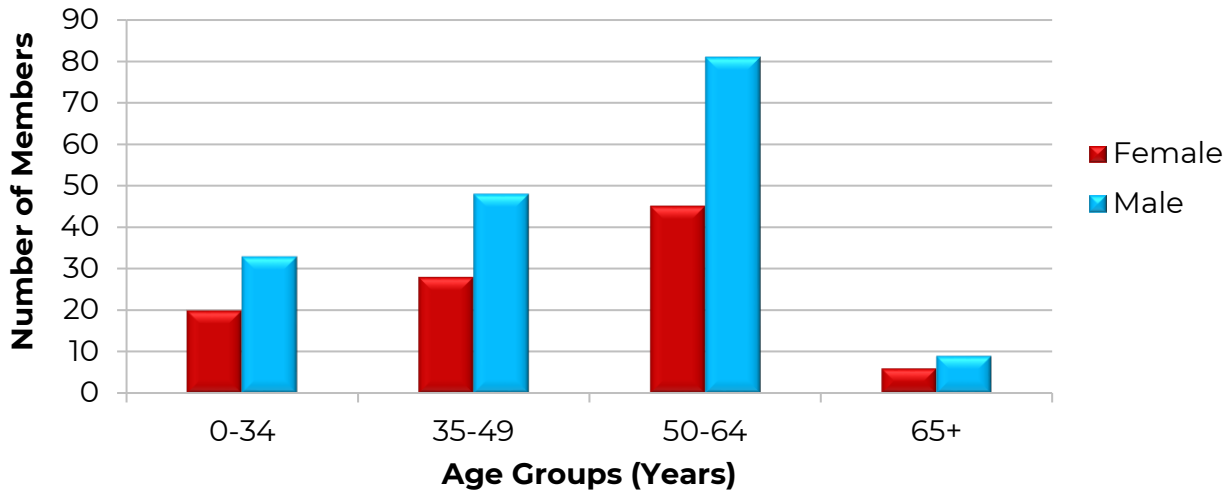
Utilization of Gout Medications: Fiscal Year 2020

Comparison of Fiscal Years: Pharmacy Claims

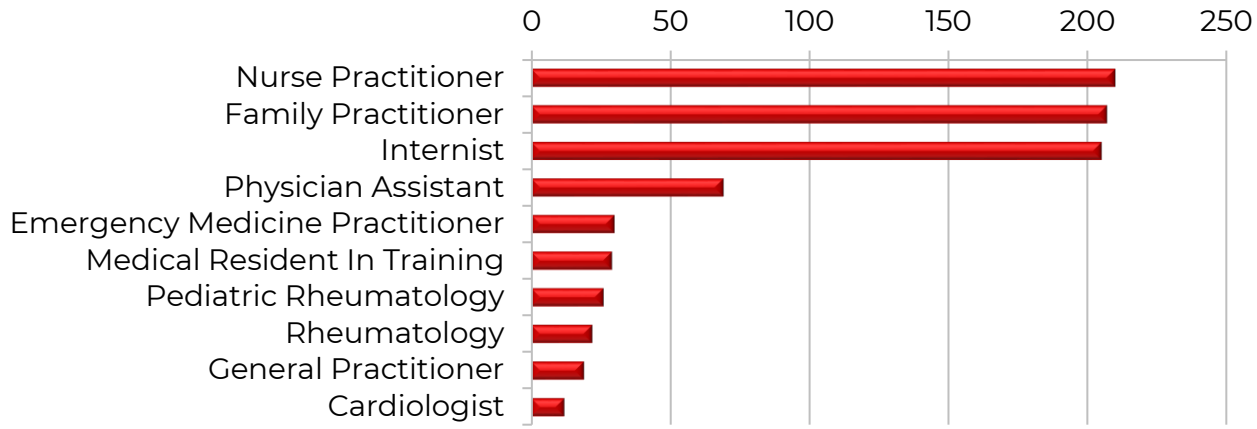
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	270	815	$107,177.49	$131.51	$9.31	12,477	11,513
2020	268	857	$70,569.79	$82.35	$6.75	10,888	10,452
% Change	**-0.70%**	**5.20%**	**-34.20%**	**-37.40%**	**-27.50%**	**-12.70%**	**-9.20%**
Change	**-2**	**42**	**-$36,607.70**	**-$49.16**	**-$2.56**	**-1,589**	**-1,061**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Demographics of Members Utilizing Gout Medications



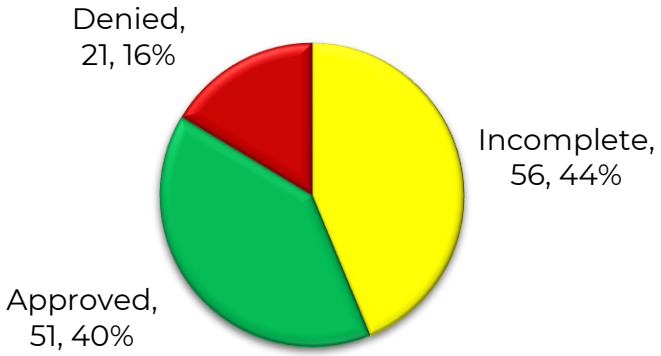
Top Prescriber Specialties of Gout Medications by Number of Claims



Prior Authorization of Gout Medications

There were 128 prior authorization requests submitted for gout medications during fiscal year 2020. The following chart shows the status of the submitted petitions.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[52]

- Colcrys® (colchicine tablet): February 2029
- Uloric® (febuxostat tablet): September 2031
- Mitigare® (colchicine capsule): August 2033
- Gloperba® (colchicine oral solution): December 2037

[52] 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 01/2021. Last accessed 01/04/2021.

News:

- **November 2020:** The xanthine oxidase inhibitors febuxostat and allopurinol are widely used urate-lowering therapies (ULT). Results of the CARES trial reported in 2018 raised concerns that febuxostat therapy was associated with an increased risk of death in patients with gout and cardiovascular (CV) disease. However, newly published results from the Febuxostat versus Allopurinol Streamlined Trial (FAST) showed the 2 treatments did not differ with respect to CV outcomes or mortality in patients with gout and CV risk factors. The FAST trial was conducted between 2011 and 2019 and included 6,128 patients treated with a lead-in phase with allopurinol at dosages to achieve a serum urate concentration <6mg/dL, then randomly assigned in a 1:1 ratio to receive treatment with febuxostat or allopurinol. At the end of follow-up (median 1,467 days), febuxostat was noninferior to allopurinol for the primary outcome, which was a composite of non-fatal stroke, hospitalization for non-fatal myocardial infarction or biomarker-positive acute coronary syndrome, or death due to a CV event [adjusted hazard ratio (HR): 0.85; 95% confidence interval (CI): 0.70-1.03; P<0.0001]. It is suggested that results from the FAST trial should lead regulators to reconsider and update their advice about febuxostat that was issued following the results of the CARES trial.[53,54]

Guideline Update(s):

- **June 2020:** The American College of Rheumatology (ACR) released the 2020 ACR Guideline for the Management of Gout, an update to the 2012 ACR guideline. The update is based on evidence from more than 130 published studies and includes a total of 42 recommendations, of which 16 are strong recommendations. A highlight of the updated guideline is a strong recommendation to use a treat-to-target strategy with ULT for all patients with gout. The guideline suggests a management strategy starting with a low-dose ULT medication and escalating the dosage to achieve and maintain a serum urate level <6mg/dL to optimize patient outcomes over a fixed-dose strategy. This strategy lowers the risk of treatment-related adverse effects, as well as flare risk accompanying ULT initiation. Other recommendations include expanded indications for starting ULT to conditionally consider patients with infrequent gout flares or after their first gout flare if they also have moderate-to-severe chronic kidney disease (CKD stage ≥3), marked hyperuricemia (serum urate >9mg/dL), or kidney stones. Additionally, a strong recommendation is made to use allopurinol as the first-line ULT,

[53] Mackenzie IS, et al. Long-Term Cardiovascular Safety of Febuxostat Compared with Allopurinol in Patients with Gout (FAST): A Multicentre, Prospective, Randomized, Open-Label, Non-Inferiority Trial. *Lancet* 2020; 396(10264):1745-1757. doi: 10.1016/S0140-6736(20)32234-0.
[54] Onuora S. Febuxostat Cardiovascular Safety Revisited. *Nat Rev Rheumatol* 2021; 17(3).

including in patients with CKD, and a strong recommendation is made to use anti-inflammatory prophylaxis (e.g., colchicine, NSAIDs, prednisone/prednisolone) when starting ULT for at least 3-6 months rather than <3 months, with ongoing evaluation and continued prophylaxis as needed if the patient continues to experience flares. Conditional recommendations include, but are not limited to, recommending against initiating ULT for patients experiencing their first gout flare without the above mentioned comorbidities, recommending HLA-B*5801 testing prior to starting allopurinol in patients of Southeast Asian descent (e.g., Han Chinese, Korean, Thai) and African American descent who have higher prevalence of HLA-B*5801, and recommending against HLA-B*5801 testing in patients of other ethnic or racial backgrounds.[55,56]

Pipeline:

- **SEL-212:** The first patient was randomized in the DISSOLVE trial, 1 of 2 Phase 3, double-blind, placebo-controlled trials evaluating SEL-212 for the treatment of chronic refractory gout. SEL-212 consists of pegadricase, a pegylated uricase, co-administered with ImmTOR™, which is designed to mitigate the formation of anti-drug antibodies. SEL-212 will potentially be a new, once-monthly treatment option and is being studied at 2 doses of ImmTOR™ (0.1mg/kg and 0.15mg/kg) and 1 dose of pegadricase (0.2mg/kg) in both studies. The primary endpoint in both studies is serum uric acid levels at 6 months. Secondary endpoints include tender and swollen joint counts, tophus burden, patient reported outcomes of activity limitation and quality of life, and gout flare incidence.[57]

Recommendations

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

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[55] FitzGerald JD, Dalbeth N, Mikuls T, et al. 2020 American College of Rheumatology Guideline for the Management of Gout. *Arthritis Care & Research* 2020; 72(6):744-760. doi: 10.1002/acr.24180.
[56] American College of Rheumatology. ACR Releases Gout Management Guidelines with Emphasis on Treat-to-Target Strategy for Urate Lowering Therapy. *Globe Newswire*. Available online at: https://www.globenewswire.com/news-release/2020/05/11/2031355/0/en/ACR-Releases-Gout-Management-Guideline-with-Emphasis-on-Treat-to-Target-Strategy-for-Urate-Lowering-Therapy.html. Issued 05/11/2020. Last accessed 01/07/2021.
[57] Selecta Biosciences, Inc. First Patient Randomised in the Phase 3 DISSOLVE Clinical Programme of SEL-212 for Chronic Refractory Gout. *La Merie Publishing*. Available online at: https://pipelinereview.com/index.php/2020092375981/Proteins-and-Peptides/First-patient-randomised-in-the-phase-3-DISSOLVE-clinical-programme-of-SEL-212-for-Chronic-Refractory-Gout.html. Issued 09/23/2020. Last accessed 01/07/2021.

Utilization Details of Gout Medications: Fiscal Year 2020

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
COLCHICINE PRODUCTS						
COLCHICINE TAB 0.6MG	559	208	$20,772.07	$37.16	2.69	29.43%
COLCHICINE CAP 0.6MG	50	36	$2,009.12	$40.18	1.39	2.85%
COLCRYS TAB 0.6MG	13	12	$663.88	$51.07	1.08	0.94%
SUBTOTAL	**622**	**256**	**$23,445.07**	**$37.69**	**2.43**	**33.22%**
FEBUXOSTAT PRODUCTS						
FEBUXOSTAT TAB 40MG	93	18	$13,406.56	$144.16	5.17	19.00%
FEBUXOSTAT TAB 80MG	66	11	$10,336.60	$156.62	6	14.65%
ULORIC TAB 40MG	44	13	$12,996.96	$295.39	3.38	18.42%
ULORIC TAB 80MG	32	8	$10,384.60	$324.52	4	14.72%
SUBTOTAL	**235**	**50**	**$47,124.72**	**$200.53**	**4.7**	**66.78%**
TOTAL	**857**	**268***	**$70,569.79**	**$82.35**	**3.19**	**100.00%**

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

Fiscal Year 2020 Annual Review of H.P. Acthar® Gel (Repository Corticotropin Injection)

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

H.P. Acthar® Gel (Repository Corticotropin Injection) Approval Criteria:

1. An FDA approved diagnosis of infantile spasms; and
    a. Member must be 2 years of age or younger; and
    b. Must be prescribed by, or in consultation with, a neurologist or an advanced care practitioner with a supervising prescriber that is a neurologist; or
2. An FDA approved diagnosis of multiple sclerosis (MS); and
    a. Member is experiencing an acute exacerbation; and
    b. Must be prescribed by, or in consultation with, a neurologist or an advanced care practitioner with a supervising prescriber that is a neurologist or a prescriber that specializes in MS; and
    c. Prescriber must rule out pseudo-exacerbation from precipitating factors (e.g., pain, stress, infection, premenstrual syndrome); and
    d. Symptoms of acute exacerbation last at least 24 hours; and
    e. Member must be currently stable within the last 30 days on an immunomodulator agent, unless contraindicated; and
    f. A patient-specific, clinically significant reason why the member cannot use alternative corticosteroid therapy [e.g., intravenous (IV) methylprednisolone, IV dexamethasone, oral prednisone] must be provided; and
    g. A quantity limit of daily doses of up to 120 units for up to 3 weeks for acute exacerbation will apply; or
3. An FDA approved diagnosis of nephrotic syndrome without uremia of the idiopathic type or that is due to lupus erythematosus to induce a diuresis or a remission of proteinuria; and
    a. Must be prescribed by, or in consultation with, a nephrologist or an advanced care practitioner with a supervising prescriber that is a nephrologist; and
    b. A patient-specific, clinically significant reason why the member cannot use alternative corticosteroid therapy (e.g., prednisone) must be provided; or
4. An FDA approved diagnosis of the following disorders or diseases: rheumatic; collagen; dermatologic; allergic states; ophthalmic; respiratory; or edematous states; and
    a. A patient-specific, clinically significant reason why the member cannot use alternative corticosteroid therapy must be provided.

Utilization of H.P. Acthar® Gel (Repository Corticotropin Injection): Fiscal Year 2020

Comparison of Fiscal Years: Pharmacy Claims

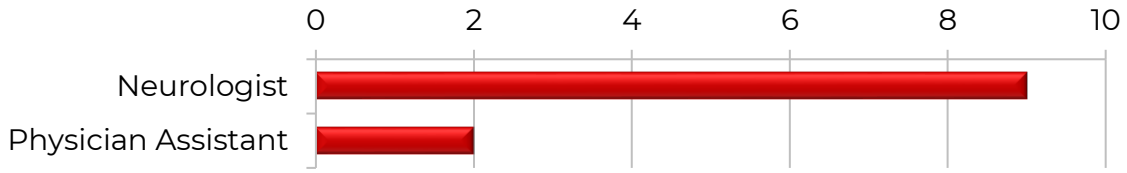
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	13	35	$2,178,310.07	$62,237.43	$3,275.65	280	665
2020	5	11	$623,556.17	$56,686.92	$3,542.93	80	176
% Change	**-61.5%**	**-68.6%**	**-71.4%**	**-8.9%**	**8.2%**	**-71.4%**	**-73.5%**
Change	**-8**	**-24**	**-$1,554,753.90**	**-$5,550.51**	**$267.28**	**-200**	**-489**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Demographics of Members Utilizing H.P. Acthar® Gel (Repository Corticotropin Injection)

- Due to the limited number of members utilizing H.P. Acthar® Gel during fiscal year 2020, detailed demographic information could not be provided.

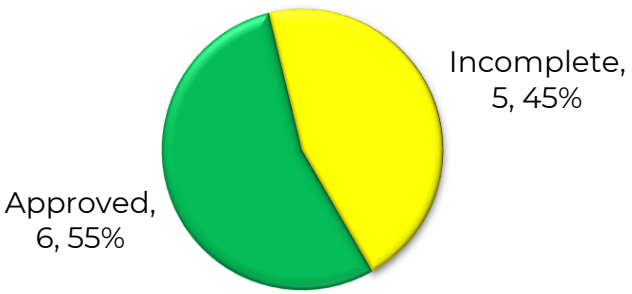
Top Prescriber Specialties of H.P. Acthar® Gel (Repository Corticotropin Injection) by Number of Claims



Prior Authorization of H.P. Acthar® Gel (Repository Corticotropin Injection)

There were 11 prior authorization requests submitted for 5 unique members for H.P. Acthar® Gel during fiscal year 2020. The following chart shows the status of the submitted petitions for fiscal year 2020.

Status of Petitions



Market News and Updates

News:

- **April 2020:** ANI Pharmaceuticals announced the U.S. Food and Drug Administration (FDA) has accepted its supplemental New Drug Application (sNDA) for Purified Cortophin® Gel (repository corticotropin injection). Currently, the only manufacturer of repository corticotropin injection is Mallinckrodt Pharmaceuticals. The FDA set a Prescription Drug User Fee Act (PDUFA) goal date of July 23, 2020.[58]
- **April 2020:** The FDA issued a Refusal to File (RTF) letter to ANI Pharmaceuticals regarding its sNDA for Cortophin® gel. Upon preliminary review, the FDA determined certain portions of the application were not sufficient to complete a substantive review. The manufacturer will seek guidance from the FDA and respond to the issues identified in the RTF letter.[59]

Recommendations

The College of Pharmacy does not recommend any changes to the current H.P. Acthar® Gel (repository corticotropin injection) prior authorization criteria at this time.

Utilization Details of H.P. Acthar® Gel (Repository Corticotropin Injection): Fiscal Year 2020

PRODUCT UTILIZED	TOTAL CLAIMS	*TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
ACTHAR INJ 80 UNIT	11	5	$623,556.17	$56,686.92	2.20
TOTAL	**11**	**5**	**$623,556.17**	**$56,686.92**	**2.20**

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

[58] ANI Pharmaceuticals, Inc. ANI Announces FDA Acceptance of Supplemental Filing for Cortrophin® Gel 80 U/mL. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/ani-announces-fda-acceptance-of-supplemental-filing-for-cortrophin-gel-80-uml-301039194.html. Issued 04/13/2020. Last Accessed 12/01/2020.
[59] ANI Pharmaceuticals, Inc. ANI Receives Refusal to File Letter from FDA for Cortrophin® Gel. *BioSpace*. Available online at: https://www.biospace.com/article/releases/ani-receives-refusal-to-file-letter-from-fda-for-cortrophin-gel/. Issued 04/29/2020. Last Accessed 12/01/2020.

Fiscal Year 2020 Annual Review of Hyperkalemia Medications

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Lokelma® (Sodium Zirconium Cyclosilicate) Approval Criteria:

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

Veltassa® (Patiromer) Approval Criteria:

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

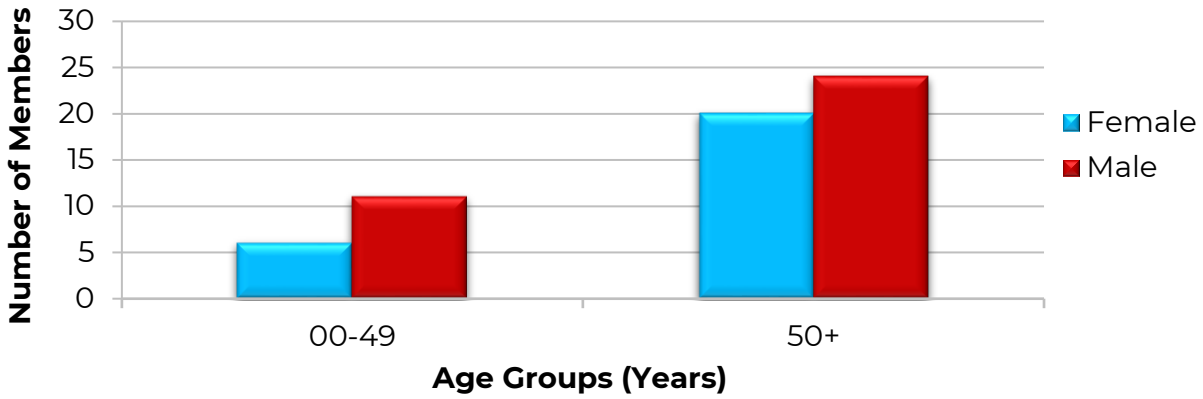
Utilization of Hyperkalemia Medications: Fiscal Year 2020

Comparison of Fiscal Years

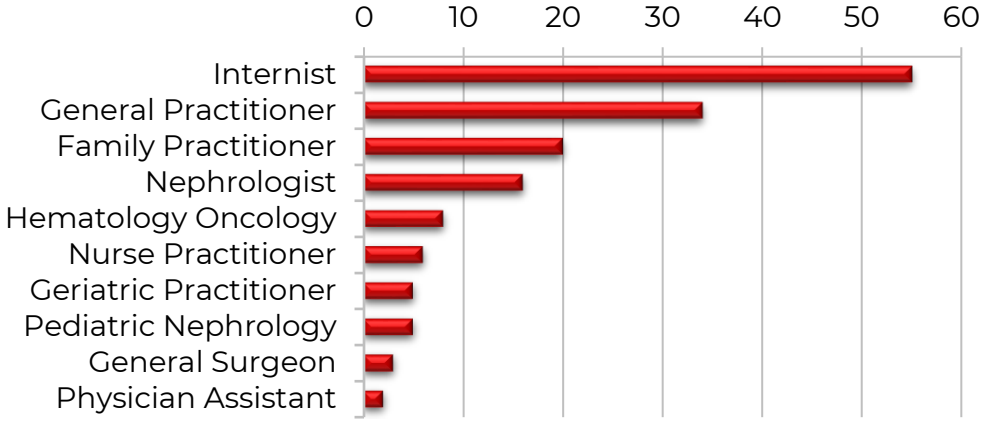
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	54	107	$26,264.95	$245.47	$14.63	19,572	1,795
2020	61	157	$32,712.40	$208.36	$13.15	33,538	2,487
% Change	**13.00%**	**46.70%**	**24.50%**	**-15.10%**	**-10.10%**	**71.40%**	**38.60%**
Change	**7**	**50**	**$6,447.45**	**-$37.11**	**-$1.48**	**13,966**	**692**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Demographics of Members Utilizing Hyperkalemia Medications



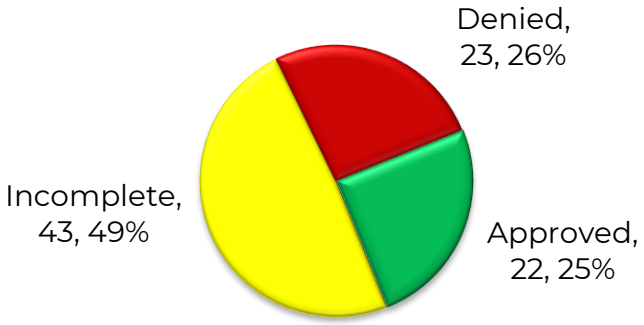
Top Prescriber Specialties of Hyperkalemia Medications by Number of Claims



Prior Authorization of Hyperkalemia Medications

There were 88 prior authorization requests submitted for hyperkalemia medications during fiscal year 2020. The following chart shows the status of the submitted petitions for fiscal year 2020.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[60]

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

Recommendations

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

Utilization Details of Hyperkalemia Medications: Fiscal Year 2020

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
SODIUM POLYSTYRENE SULFONATE (SPS) PRODUCTS						
SPS SUS 15GM/60ML	74	35	$3,349.31	$10.31	$45.26	10.24%
SOD POLY SUL POW 454GM	20	13	$1,033.63	$2.31	$51.68	3.16%
SOD POLY SUL SUS 15GM/60ML	1	1	$63.26	$2.11	$63.26	0.19%
SUBTOTAL	**95**	**49**	**$4,446.20**	**$5.54**	**$46.80**	**13.59%**
SODIUM ZIRCONIUM CYCLOSILICATE PRODUCTS						
LOKELMA PAK 10GM	38	8	$15,572.36	$15.21	$409.80	47.60%
LOKELMA PAK 5GM	3	2	$2,630.73	$29.23	$876.91	8.04%
SUBTOTAL	**41**	**10**	**$18,203.09**	**$16.34**	**$443.98**	**55.64%**
PATIROMER PRODUCTS						
VELTASSA POW 8.4GM	20	9	$9,266.61	$17.16	$463.33	28.33%
VELTASSA POW 16.8GM	1	1	$796.50	$26.55	$796.50	2.43%
SUBTOTAL	**7**	**3**	**$2,062.75**	**$14.03**	**$294.68**	**0.0309**
TOTAL	**157**	**61***	**$32,712.40**	**$13.15**	**$208.36**	**100%**

PAK = packet; POLY = polystyrene; POW = powder; SOD = sodium; SUL = sulfonate; SUS = suspension
*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020

[60] 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 01/2021. Last accessed 01/11/2021.

Fiscal Year 2020 Annual Review of Idiopathic Pulmonary Fibrosis (IPF) Medications

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Esbriet® (Pirfenidone) Approval Criteria:

1. An FDA approved diagnosis of idiopathic pulmonary fibrosis (IPF); and
2. Member must be 18 years of age or older; and
3. Prescriber must verify liver function tests (LFTs) (e.g., ALT, AST, bilirubin) will be monitored prior to the initiation of Esbriet®, monthly for the first 6 months of treatment, and every 3 months thereafter, and as clinically indicated; and
4. Medication must be prescribed by a pulmonologist or pulmonary specialist (or an advanced care practitioner with a supervising physician who is a pulmonologist or pulmonary specialist); and
5. A quantity limit of 270 capsules or tablets per 30 days will apply for the 267mg strength capsules and tablets, and a quantity limit of 90 tablets per 30 days will apply for the 801mg strength tablets.

Ofev® (Nintedanib) Approval Criteria:

1. An FDA approved indication of 1 of the following:
   a. Treatment of idiopathic pulmonary fibrosis (IPF); or
   b. Treatment of chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype; or
   c. Slowing the rate of decline in pulmonary function in patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD); and
2. Member must be 18 years of age or older; and
3. Prescriber must verify liver function tests (LFTs) (e.g., ALT, AST, bilirubin) will be monitored prior to initiation of Ofev® treatment, at regular intervals during the first 3 months of treatment, and periodically thereafter or as clinically indicated; and
4. Female members must not be pregnant and must have a negative pregnancy test immediately prior to therapy initiation. Female members of reproductive potential must be willing to use effective contraception while on therapy and for at least 3 months after therapy completion; and
5. Medication must be prescribed by, or in consultation with, a pulmonologist or pulmonary specialist (or an advanced care practitioner with a supervising physician who is a pulmonologist or pulmonary specialist); and
6. A quantity limit of 60 capsules per 30 days will apply.

Utilization of IPF Medications: Fiscal Year 2020

Comparison of Fiscal Years: Pharmacy Claims

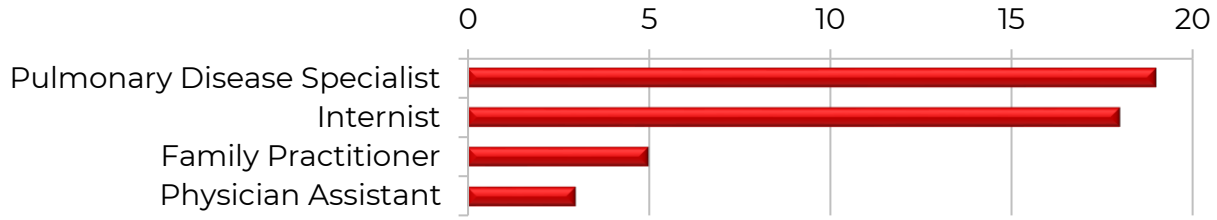
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	5	18	$138,655.04	$7,703.06	$256.77	3,801	540
2020	8	45	$390,086.57	$8,668.59	$276.66	5,547	1,410
% Change	**60.00%**	**150.00%**	**181.30%**	**12.50%**	**7.70%**	**45.90%**	**161.10%**
Change	**3**	**27**	**$251,431.53**	**$965.53**	**$19.89**	**1,746**	**870**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Demographics of Members Utilizing IPF Medications

- All members utilizing IPF medications during fiscal year 2020 were adults; however, detailed demographic information cannot be provided due to the limited number of members using IPF medications during fiscal year 2020.

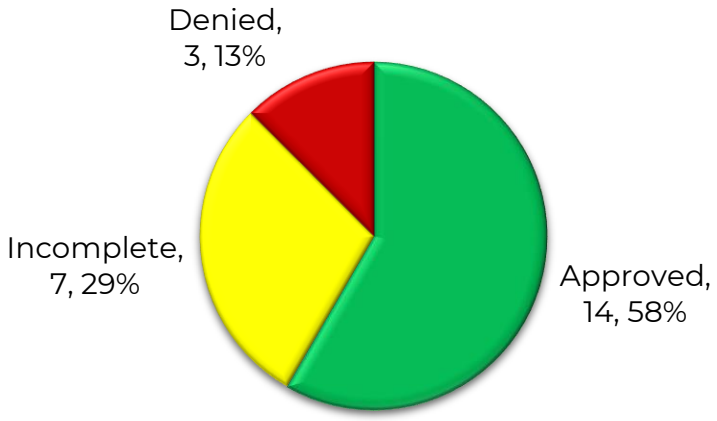
Top Prescriber Specialties of IPF Medications by Number of Claims



Prior Authorization of IPF Medications

There were 24 prior authorization requests submitted for IPF medications during fiscal year 2020. The following chart shows the status of the submitted petitions.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[61]

- Ofev® (nintedanib): June 2029
- Esbriet® (pirfenidone): March 2037

Pipeline:

- **Pamrevlumab:** Pamrevlumab is a first-in-class antibody developed by FibroGen to inhibit the activity of connective tissue growth factor (CTGF), a common factor in fibrotic and proliferative disorders characterized by persistent and excessive scarring that can lead to organ dysfunction and failure. Pamrevlumab is administered as an intravenous (IV) infusion and is currently in Phase 3 trials. The trial is evaluating the efficacy and safety of 30mg/kg IV infusions of pamrevlumab administered every 3 weeks compared to placebo in patients with IPF. Results from the Phase 2, randomized, double-blind, placebo-controlled PRAISE trial found pamrevlumab reduced the decline in percent predicted forced vital capacity (ppFVC) by 60.3% at week 48 (P=0.033). The proportion of patients with disease progression was lower in the pamrevlumab group than in the placebo group at week 48 (10.0% vs. 31.4%; P=0.013).[62,63]
- **GLPG1690:** GLPG1690 is a small molecular, selective autotaxin inhibitor being investigated in Phase 3 trials for the treatment of IPF. In the FLORA Phase 2A trial, patients receiving GLPG1690 showed improvement in FVC at 12 weeks, with an encouraging safety profile. Galapagos received Orphan Drug designation for GLPG1690 for IPF from the U.S. Food and Drug Administration (FDA) and European Commission (EC). The Phase 3 trial is investigating how GLPG1690 works together with current standard treatment on lung function and IPF disease, in general, and will also study GLPG1690 tolerability.[62]
- **PRM-151:** PRM-151 is recombinant human pentraxin-2 (rhPTX-2), a novel antifibrotic agent with activity on monocyte differentiation, being studied for the treatment of IPF. The current Phase 3 trial will evaluate the efficacy, safety and pharmacokinetics (PK) of PRM-151 compared with placebo in patients with IPF.[62]

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[61] 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 01/2021. Last accessed 01/05/2021.

[62] Pulmonary Fibrosis Foundation. Drug Development Pipeline – PF and IPF. Available online at: https://www.pulmonaryfibrosis.org/life-with-pf/clinical-trials/pipeline?drugphases=d9cff6d0-9b5d-6477-b7e4-ff000016512a&mechanismofactions=e9cff6d0-9b5d-6477-b7e4-ff000016512a. Last revised 07/2020. Last accessed 01/07/2021.

[63] Richeldi L, Fernandez Perez ER, Costabel U, et al. Pamrevlumab, an Anti-Connective Tissue Growth Factor Therapy, for Idiopathic Pulmonary Fibrosis (PRAISE): A Phase 2, Randomised, Double-Blind, Placebo-Controlled Trial. *Lancet* 2020; 8(1):25-33.

- **INOPulse:** INO, which stands for inhaled nitric oxide, is being investigated in a Phase 3, randomized, double-blind, placebo-controlled dose escalation and verification clinical trial (REBUILD). The trial will assess the safety and efficacy of pulsed inhaled nitric oxide versus placebo in patients at risk for pulmonary hypertension associated with pulmonary fibrosis on long-term oxygen therapy.[62]

Recommendations

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

Utilization Details of IPF Medications: Fiscal Year 2020

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
PIRFENIDONE PRODUCTS						
ESBRIET TAB 267MG	21	5	$147,181.69	$7,008.65	4.20	37.73%
NINTEDANIB PRODUCTS						
OFEV CAP 150MG	15	4	$151,446.34	$10,096.42	3.75	38.82%
OFEV CAP 100MG	9	1	$91,458.54	$10,162.06	9.00	23.45%
TOTAL	**45**	**8***	**$390,086.57**	**$8,668.59**	**5.63**	**100.00%**

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

Fiscal Year 2020 Annual Review of Inhaled Anti-Infective Medications

Oklahoma Health Care Authority
Fiscal Year 2020 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.

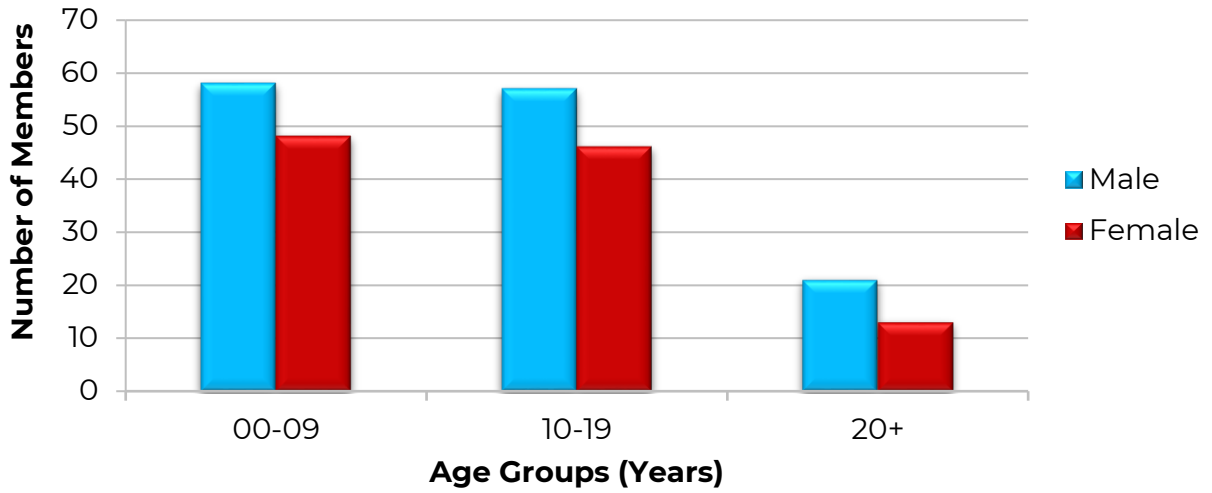
Utilization of Inhaled Anti-Infective Medications: Fiscal Year 2020

Comparison of Fiscal Years

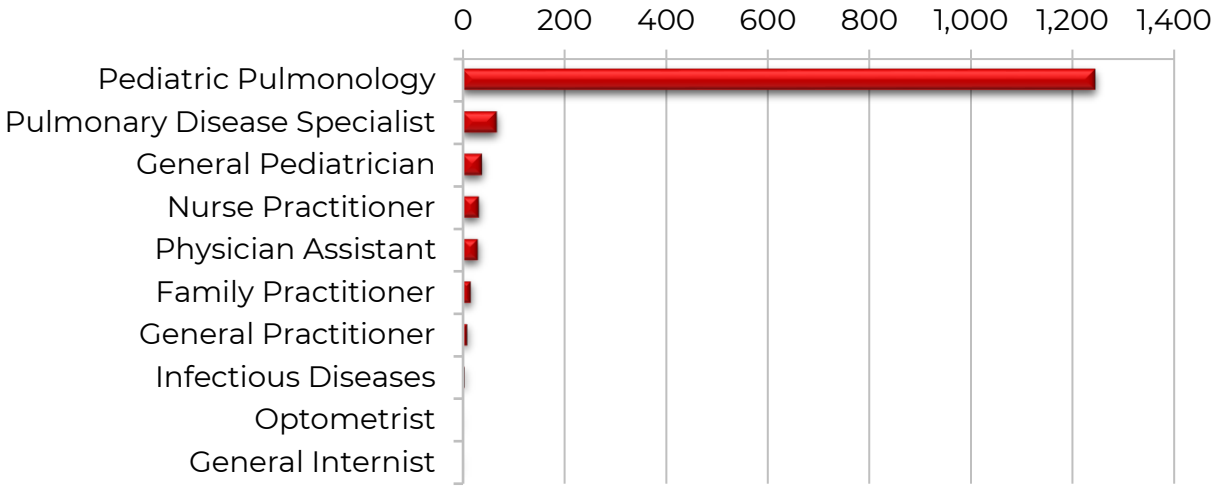
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	233	1,440	$5,000,041.36	$3,472.25	$91.10	187,892	54,884
2020	243	1,451	$5,235,977.81	$3,608.53	$94.88	190,092	55,187
% Change	**4.30%**	**0.80%**	**4.70%**	**3.90%**	**4.10%**	**1.20%**	**0.60%**
Change	**10**	**11**	**$235,936.45**	**$136.28**	**$3.78**	**2,200**	**303**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Demographics of Members Utilizing Inhaled Anti-Infective Medications



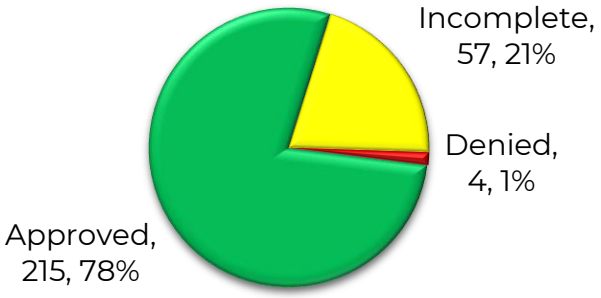
Top Prescriber Specialties of Inhaled Anti-Infective Medications by Number of Claims



Prior Authorization of Inhaled Anti-Infective Medications

There were 276 prior authorization requests submitted for inhaled anti-infective medications during fiscal year 2020. 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 2020.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[64]

- Cayston® (aztreonam inhalation solution): December 2021
- Bethkis® (tobramycin inhalation solution): September 2022
- Tobi® Podhaler® (tobramycin inhalation powder): November 2030
- Arikayce® (amikacin liposome inhalation suspension): May 2035

Pipeline:

- **Murepavadin:** Polyphor is currently in the preclinical phase of development for inhaled murepavadin for the treatment of *Pseudomonas aeruginosa* infections in patients with CF. Murepavadin is a novel outer membrane protein targeting antibiotic (OMPTA) designed to target *P. aeruginosa* specifically by binding to lipopolysaccharide transport protein D (LptD), an outer membrane protein necessary for the survival and proliferation of *P. aeruginosa*. Murepavadin appears to be highly potent and active even against multidrug resistant strains of the bacteria. In December 2020, Polyphor announced plans to initiate a first-in-human Phase 1 safety and tolerability study in healthy volunteers in 2021, with a planned Phase 1B/2A study in adults with CF to follow.[65,66]

[64] 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 01/2021. Last Accessed 01/06/2021.
[65] Polyphor. Polyphor Pipeline: Inhaled Murepavadin. Available online at: http://www.polyphor.com/pol7080/. Last accessed 01/06/2021.
[66] Polyphor. Polyphor Receives Approval to Start First-in-Human Clinical Trial of Inhaled Antibiotic Murepavadin. *Globe Newswire.* Available online at: https://www.globenewswire.com/news-release/2020/12/22/2149098/0/en/Polyphor-Receives-Approval-to-Start-First-in-Human-Clinical-Trial-of-Inhaled-Antibiotic-Murepavadin.html. Issued 12/22/2020. Last accessed 01/06/2021.

Recommendations

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

Utilization Details of Inhaled Anti-Infective Medications: Fiscal Year 2020

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ CLIENT	% COST
DORNASE ALFA PRODUCTS						
PULMOZYME SOL 1MG/ML	988	162	$3,485,384.47	$3,527.72	6.1	66.57%
SUBTOTAL	**988**	**162***	**$3,485,384.47**	**$3,527.72**	**6.1**	**66.57%**
TOBRAMYCIN NEBULIZED PRODUCTS						
TOBRAMYCIN NEB 300MG/5ML	311	111	$511,950.58	$1,646.14	2.8	9.78%
BETHKIS NEB 300MG/4ML	28	9	$164,536.35	$5,876.30	3.11	3.14%
KITABIS PAK NEB 300MG/5ML	18	9	$83,445.22	$4,635.85	2	1.59%
TOBI NEB 300MG/5ML	1	1	$7,349.22	$7,349.22	1	0.14%
SUBTOTAL	**358**	**130***	**$767,281.37**	**$2,143.24**	**2.75**	**14.65%**
AZTREONAM PRODUCTS						
CAYSTON INH 75MG	69	21	$636,802.80	$9,229.03	3.29	12.16%
SUBTOTAL	**69**	**21***	**$636,802.80**	**$9,229.03**	**3.29**	**12.16%**
TOBRAMYCIN POWDER PRODUCTS						
TOBI PODHALER CAP 28MG	32	11	$301,907.62	$9,434.61	2.91	5.77%
SUBTOTAL	**32**	**11***	**$301,907.62**	**$9,434.61**	**2.91**	**5.77%**
AMIKACIN PRODUCTS						
ARIKAYCE SUS 590MG/8.4ML	4	2	$44,601.55	$11,150.39	2	0.85%
SUBTOTAL	**4**	**2***	**$44,601.55**	**$11,150.39**	**2**	**0.85%**
TOTAL	**1,451**	**243***	**$5,235,977.81**	**$3,608.53**	**5.97**	**100.00%**

CAP = capsule; INH = inhalation; NEB = nebulized; PAK = pack; SOL = solution; SUS = suspension
*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2020 = 07/01/2016 to 06/30/2020

Fiscal Year 2020 Annual Review of Injectable and Vaginal Progesterone Products

Oklahoma Health Care Authority
Fiscal Year 2020 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).

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. Member and 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 2020

Please note, the compounded hydroxyprogesterone caproate product is billed by medical claims only and not reflected in the following pharmacy claims data. Fiscal year 2020 medical claim utilization details for the compounded hydroxyprogesterone caproate product can be found at the

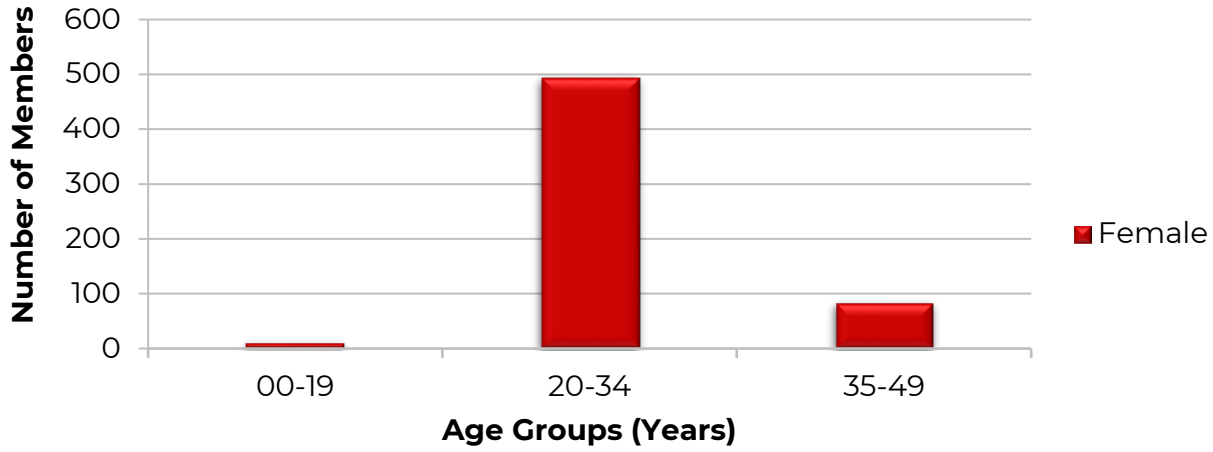
end of this report. The following utilization details include pharmacy claims data only.

Comparison of Fiscal Years: Pharmacy Claims

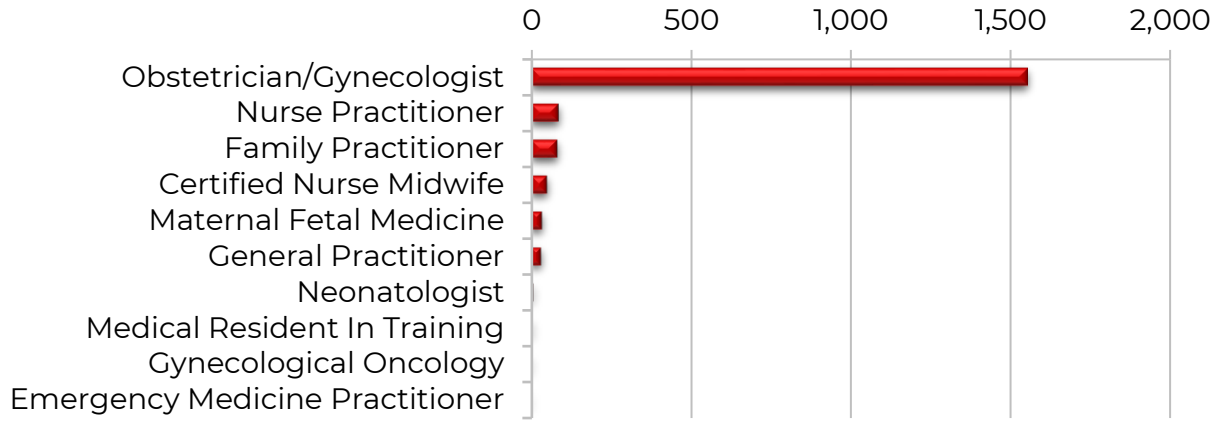
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	738	2,278	$6,645,412.03	$2,917.21	$103.51	9,618	64,201
2020	584	1,855	$5,197,176.65	$2,801.71	$101.45	7,878	51,228
% Change	**-20.90%**	**-18.60%**	**-21.80%**	**-4.00%**	**-2.00%**	**-18.10%**	**-20.20%**
Change	**-154**	**-423**	**-$1,448,235.38**	**-$115.50**	**-$2.06**	**-1,740**	**-12,973**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Demographics of Members Utilizing Injectable and Vaginal Progesterone Products

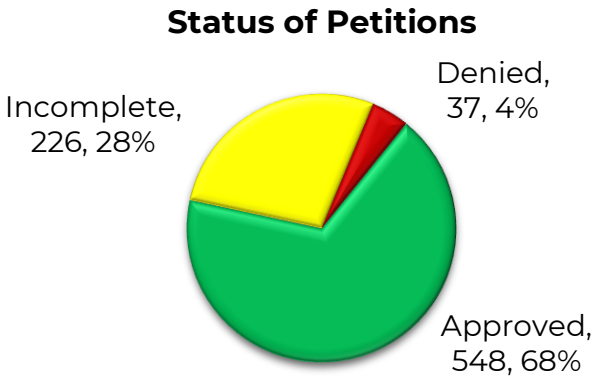


Top Prescriber Specialties of Injectable and Vaginal Progesterone Products by Number of Claims



Prior Authorization of Injectable and Vaginal Progesterone Products

There were 811 prior authorization requests submitted for 518 unique members for injectable and vaginal progesterone products during fiscal year 2020. The following chart shows the status of the submitted petitions for fiscal year 2020.



Market News and Updates

Anticipated Patent Expiration(s):[67]

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

News:

- **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. This recommendation was based on results of the PROLONG study, an FDA-required postmarketing confirmatory efficacy study of Makena® which failed to show a reduction in preterm delivery or neonatal mortality and morbidity. The withdrawal of Makena® from the market had been previously recommended by the FDA's Bone, Reproductive, and Urologic Drugs Advisory Committee in October 2019 based on these findings. 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. The American College of Obstetricians and Gynecologist (ACOG) responded to the FDA's proposal in a statement released October 2020 indicating the ACOG's recommendations regarding the use of hydroxyprogesterone caproate remain unchanged. They support the FDA's recommendation that health care professionals should discuss the benefits, risks, and

[67] 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 01/2021. Last Accessed 01/11/2021.

uncertainties related to the use of Makena® with patients until the FDA finalizes its decision.[68,69]

- **December 2020:** AMAG responded to the FDA's Notice of Opportunity for a Hearing regarding the proposed removal of Makena® from the market. AMAG requested a hearing to discuss options for additional studies to demonstrate the efficacy of Makena®. Proposed additional studies include retrospective studies using real-world data or a new randomized clinical trial focused on high-risk, principally minority patient populations. Currently, Makena® remains FDA approved and available while the FDA reviews AMAG's request.[70]

Recommendations

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

Utilization Details of Injectable and Vaginal Progesterone Products: Fiscal Year 2020

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
HYDROXYPROGESTERONE INJECTABLE PRODUCTS						
MAKENA INJ 275MG	1,267	372	$3,834,518.58	$3,026.46	3.41	73.78%
HYDROXYPROG INJ 250MG/ML	583	223	$1,361,307.61	$2,335.00	2.61	26.19%
SUBTOTAL	**1,850**	**582***	**$5,195,826.19**	**$2,808.55**	**3.18**	**99.97%**
PROGESTERONE VAGINAL PRODUCTS						
ENDOMETRIN SUP 100MG	5	2	$1,350.46	$270.09	2.5	0.03%
SUBTOTAL	**5**	**2***	**$1,350.46**	**$270.09**	**2.5**	**0.03%**
TOTAL	**1,855**	**584***	**$5,197,176.65**	**$2,801.71**	**3.18**	**100.00%**

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

[68] 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 01/11/2021.
[69] The American College of Obstetricians and Gynecologists. ACOG Statement on FDA Proposal to Withdraw 17p Hydroxyprogesterone Caproate. Available online at: https://www.acog.org/news/news-releases/2020/10/acog-statement-on-fda-proposal-to-withdraw-17p-hydroxyprogesterone-caproate. Issued 10/07/2020. Last accessed 01/11/2021.
[70] AMAG Pharmaceuticals, Inc. AMAG Pharmaceuticals Files Submission in Response to the Food and Drug Administration's notice of Opportunity for a Hearing and Proposal To Withdraw Approval of Makena® (Hydroxyprogesterone Caproate Injection). Available online at: https://www.amagpharma.com/news/amag-pharmaceuticals-files-submission-in-response-to-the-food-and-drug-administrations-notice-of-opportunity-for-a-hearing-and-proposal-to-withdraw-approval-of-makena-hydroxyprogestero/. Issued 12/14/2020. Last accessed 01/11/2021.

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS[+]	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM
S5000 HYDROXYPROGESTERONE CAPROATE INJ	2	2	$21.73	$10.87
TOTAL	**2**	**2**	**$21.73**	**$10.87**

INJ = injection
[+]Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Fiscal Year 2020 Annual Review of Insomnia Medications

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Insomnia Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA***
estazolam (ProSom®)	zolpidem CR (Ambien® CR)	lemborexant (Dayvigo®)	doxepin (Silenor®)
eszopiclone (Lunesta®)		suvorexant (Belsomra®)	tasimelteon (Hetlioz®)⁺
flurazepam (Dalmane®)			temazepam (Restoril®) 7.5mg and 22.5mg
ramelteon (Rozerem®) – *Brand preferred*			zolpidem SL tablets (Edluar®)
temazepam (Restoril®) 15mg and 30mg			zolpidem SL tablets (Intermezzo®)
triazolam (Halcion®)			zolpidem oral spray (Zolpimist®)
zaleplon (Sonata®)			
zolpidem (Ambien®)			

CR = controlled release; PA = prior authorization; SL = sublingual
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).
*Unique dosage formulations require a special reason for use in place of Tier-1 formulations.
⁺Individual criteria specific to tasimelteon applies.

- Tier-1 medications are available without a prior authorization for all members older than 18 years of age.
- Members 18 years of age or younger will be required to submit a prior authorization for consideration of all insomnia medications.
- All medications have a quantity limit of 30 units per 30 days.

Insomnia Medications Tier-2 Approval Criteria:

1. An FDA approved diagnosis; and
2. Member must have a minimum of a 30-day trial with at least 2 Tier-1 medications and clinical documentation of attempts to correct any primary cause for insomnia; and
3. No concurrent anxiolytic benzodiazepine therapy greater than 3 times daily dosing; and
4. Approvals will be granted for the duration of 6 months.

Insomnia Medications Tier-3 Approval Criteria:

1. An FDA approved diagnosis; and
2. Member must have a minimum of a 30-day trial with at least 2 Tier-1 medications and clinical documentation of attempts to correct any primary cause for insomnia; and
3. Member must have a minimum of a 30-day trial with at least 2 Tier-2 medications; and
    a. If only 1 Tier-2 medication is available, a minimum of a 30-day trial with 1 Tier-2 medication will be required; and
4. No concurrent anxiolytic benzodiazepine therapy greater than 3 times daily dosing; and
5. Approvals will be granted for the duration of 6 months.

Hetlioz® (Tasimelteon) Approval Criteria:

1. An FDA approved diagnosis of Non-24-Hour Sleep-Wake Disorder (Non-24) confirmed by a sleep specialist; and
2. Member must be 18 years of age or older; and
3. Member must have a failed trial of appropriately timed doses of melatonin; and
4. Initial approvals will be for the duration of 12 weeks. For continuation, the prescriber must include information regarding improved response/effectiveness of this medication; and
5. A quantity limit of 30 capsules for 30 days will apply.

Seconal Sodium™ (Secobarbital Sodium Capsule) Approval Criteria:

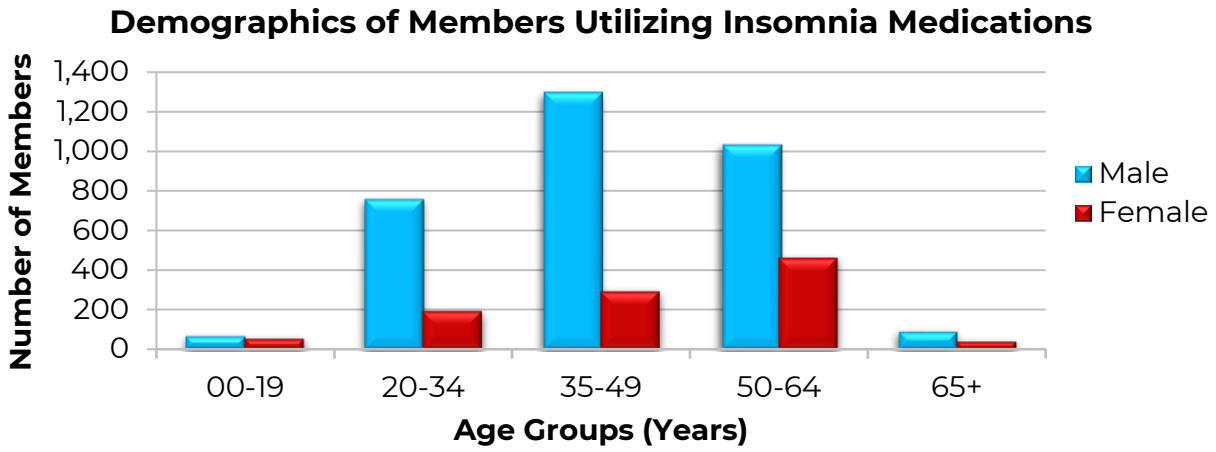
1. An FDA approved indication for 1 of the following:
    a. The short-term treatment of insomnia; or
    b. A preanesthetic; and
2. A patient-specific, clinically significant reason why the member cannot use other cost-effective therapeutic alternatives must be provided; and
3. For the short-term treatment of insomnia, a quantity limit of 1 capsule per day not to exceed 14 capsules per 30 days will apply.

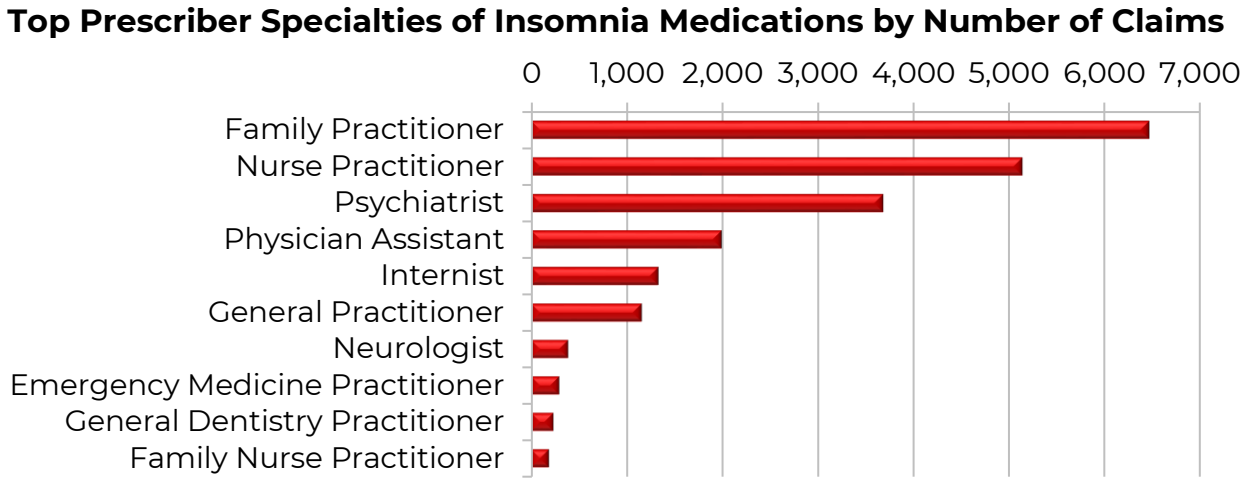
Utilization of Insomnia Medications: Fiscal Year 2020

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	5,364	25,809	$856,591.79	$33.19	$1.14	752,414	749,320
2020	4,279	21,933	$857,996.39	$39.12	$1.35	637,191	637,175
% Change	**-20.2%**	**-15.0%**	**0.2%**	**17.9%**	**18.4%**	**-15.3%**	**-15.0%**
Change	**-1,085**	**-3,876**	**$1,404.60**	**$5.93**	**$ 0.21**	**-115,223**	**-112,145**

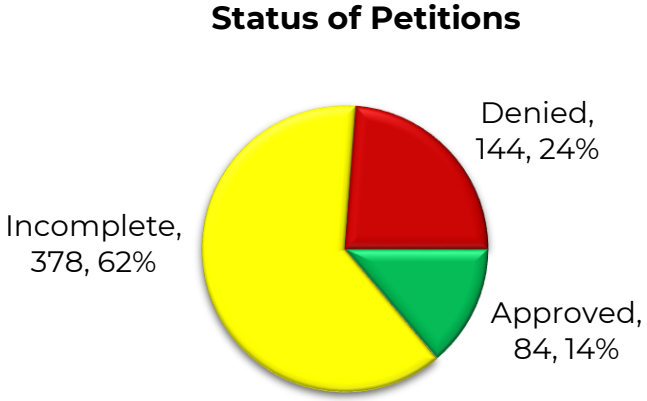
*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020





Prior Authorization of Insomnia Medications

There were 606 prior authorization requests submitted for insomnia medications during fiscal year 2020. The following chart shows the status of the submitted petitions for fiscal year 2020.



Market News and Updates

Anticipated Patent Expiration(s):[71]

- Silenor® (doxepin tablets): September 2030
- Edluar® (zolpidem sublingual tablets): February 2031
- Zolpimist® (zolpidem oral spray): August 2032
- Belsomra® (suvorexant tablets): May 2033
- Hetlioz® (tasimelteon capsules): August 2035
- Dayvigo® (lemborexant tablets): October 2035

News:

- **July 2020:** The American College of Physicians (ACP) recommends cognitive behavioral therapy as first-line treatment for chronic insomnia, followed by pharmacologic therapy if cognitive behavioral therapy is ineffective. In the clinical setting, patients often use different pharmacologic therapies before behavioral or cognitive interventions. In a randomized clinical trial published in *JAMA Psychiatry*, 211 adults with insomnia disorder were randomized to receive either behavioral therapy or zolpidem for 6 weeks, and remitters remained on maintenance therapy for the next 12 months. Non-remitters continued on to second-stage therapy that included trazodone or cognitive therapy. In total, there were 4 treatment arms. Among the patients enrolled in the trial, the proportion of patients who responded to 6 weeks of behavioral therapy as a first-line therapy was similar to the proportion of patients who responded to zolpidem as first-line therapy. The results of this study suggest patients should be treated with behavioral or cognitive therapy first, as recommended by the ACP, due to the potential risks associated with pharmacological therapies.[72]

Recommendations

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

[71] 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 01/2021. Last accessed 01/29/2021.

[72] Hlavinka E. Behavioral Therapy a Front Runner for First-Line Insomnia Tx. *MedPage Today*. Available online at: https://www.medpagetoday.com/psychiatry/sleepdisorders/87465. Issued 07/08/2020. Last Accessed 01/29/2021.

Utilization Details of Insomnia Medications: Fiscal Year 2020

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 PRODUCTS						
ZOLPIDEM TAB 10MG	10,694	1,979	$107,537.42	$10.06	5.4	12.53%
ZOLPIDEM TAB 5MG	2,492	782	$25,077.38	$10.06	3.19	2.92%
TEMAZEPAM CAP 30MG	2,156	406	$24,122.94	$11.19	5.31	2.81%
ESZOPICLONE TAB 3MG	1,682	353	$23,477.41	$13.96	4.76	2.74%
TEMAZEPAM CAP 15MG	1,325	395	$14,980.86	$11.31	3.35	1.75%
ROZEREM TAB 8MG	562	135	$202,161.27	$359.72	4.16	23.56%
ESZOPICLONE TAB 2MG	531	201	$7,872.42	$14.83	2.64	0.92%
TRIAZOLAM TAB 0.25MG	462	276	$14,319.39	$30.99	1.67	1.67%
ZALEPLON CAP 10MG	371	110	$5,523.50	$14.89	3.37	0.64%
ESZOPICLONE TAB 1MG	249	122	$4,196.80	$16.85	2.04	0.49%
ZALEPLON CAP 5MG	99	39	$1,410.29	$14.25	2.54	0.16%
ESTAZOLAM TAB 2MG	8	3	$207.58	$25.95	2.67	0.02%
TRIAZOLAM TAB 0.125MG	6	5	$203.20	$33.87	1.2	0.02%
ESTAZOLAM TAB 1MG	3	1	$81.00	$27.00	3	0.01%
FLURAZEPAM CAP 30MG	1	1	$25.62	$25.62	1	0.00%
SUBTOTAL	**20,641**	**4,808**	**$431,197.08**	**$20.89**	**4.29**	**50.24%**
TIER-2 PRODUCTS						
ZOLPIDEM ER TAB 12.5MG	1,052	160	$21,156.67	$20.11	6.58	2.47%
ZOLPIDEM ER TAB 6.25MG	78	16	$1,437.02	$18.42	4.88	0.17%
AMBIEN CR TAB 12.5MG	12	1	$6,374.28	$531.19	12	0.74%
SUBTOTAL	**1,142**	**177**	**$28,967.97**	**$25.37**	**6.45**	**3.38%**
TIER-3 PRODUCTS						
BELSOMRA TAB 10MG	29	4	$10,103.36	$348.39	7.25	1.18%
BELSOMRA TAB 20MG	23	3	$8,112.60	$352.72	7.67	0.95%
BELSOMRA TAB 15MG	1	1	$340.52	$340.52	1	0.04%
SUBTOTAL	**53**	**8**	**$18,556.48**	**$350.12**	**6.63**	**2.17%**
SPECIAL PRIOR AUTHORIZATION (PA) PRODUCTS						
TEMAZEPAM CAP 7.5MG	55	8	$3,199.81	$58.18	6.88	0.37%
HETLIOZ CAP 20MG	23	2	$372,607.74	$16,200.34	11.5	43.43%
RAMELTEON TAB 8MG	8	8	$1,202.03	$150.25	1	0.14%
ZOLPIDEM SUB 3.5MG	5	1	$894.90	$178.98	5	0.10%
DOXEPIN TAB 6MG	2	2	$518.21	$259.11	1	0.06%
TEMAZEPAM CAP 22.5MG	2	1	$178.86	$89.43	2	0.02%
EDLUAR SUB 5MG	1	1	$181.97	$181.97	1	0.02%
SILENOR TAB 6MG	1	1	$491.34	$491.34	1	0.06%
SUBTOTAL	**97**	**24**	**379,275**	**$3,910.05**	**4.04**	**44.20%**
TOTAL	**21,933**	**4,279***	**$857,996.39**	**$39.12**	**5.13**	**100.00%**

CAP = capsule; CR = controlled-release; ER = extended-release; SUB = sublingual; TAB = tablet
*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Fiscal Year 2020 Annual Review of Iron Chelating Agents

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Ferriprox® (Deferiprone), Jadenu® (Deferasirox), and Jadenu® Sprinkle (Deferasirox) 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.

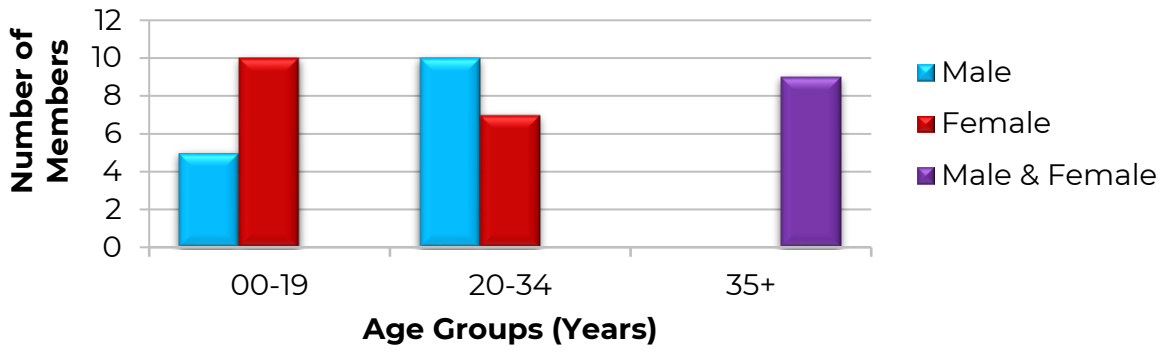
Utilization of Iron Chelating Agents: Fiscal Year 2020

Comparison of Fiscal Years

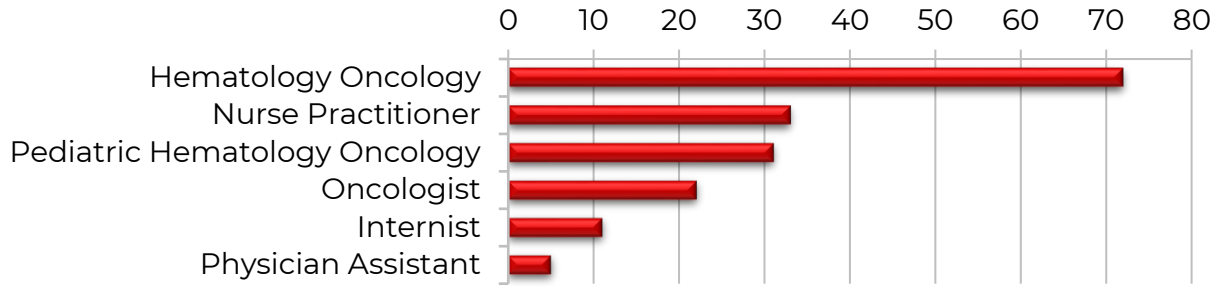
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	42	212	$2,137,740.49	$10,083.68	$321.95	16,605	6,640
2020	41	174	$1,598,308.75	$9,185.68	$303.63	13,596	5,264
% Change	**-2.40%**	**-17.90%**	**-25.20%**	**-8.90%**	**-5.70%**	**-18.10%**	**-20.70%**
Change	**-1**	**-38**	**-$539,431.74**	**-$898.00**	**-$18.32**	**-3,009**	**-1,376**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Demographics of Members Utilizing Iron Chelating Agents



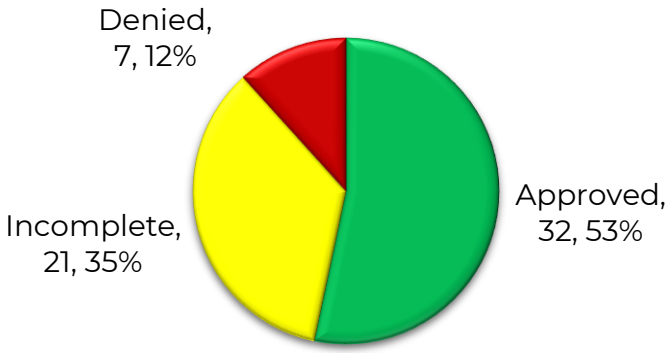
Top Prescriber Specialties of Iron Chelating Agents by Number of Claims



Prior Authorization of Iron Chelating Agents

There were 60 prior authorization requests submitted for 31 unique members for iron chelating agents during fiscal year 2020. The following chart shows the status of the submitted petitions for fiscal year 2020.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[73]

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

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

- **May 2020:** The FDA approved a new twice daily (BID) formulation of Ferriprox® (deferiprone) for the treatment of patients with transfusional iron overload due to thalassemia syndromes when current chelation therapy is inadequate. The BID formulation is available as 1,000mg oral tablets. The previous FDA approved dosing frequency for Ferriprox® was three times daily (TID). This new formulation eliminates the mid-day dose and provides for a more convenient, BID regimen. The approval of

[73] 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 01/2021. Last Accessed 01/14/2021.

the Ferriprox® BID formulation was based on reduction of serum ferritin levels. No controlled trials have been conducted to demonstrate a direct treatment benefit, such as improvement in symptoms, functioning, or survival. The Wholesale Acquisition Cost (WAC) of the Ferriprox® BID formulation is $180.39 per 1,000mg tablet, resulting in an estimated cost per day of $1,443.15 for an 80kg adult using the maximum FDA approved dosing of 99mg/kg/day. In comparison, the WAC of the Ferriprox® TID formulation is $144.31 per 1,000mg tablet, resulting in an estimated cost per day of $1,154.52 for an 80kg adult using the maximum FDA approved dosing of 99mg/kg/day.[74]

News:

- **September 2020:** The first generic formulation of Ferriprox® (deferiprone) was launched by Taro Pharmaceutical Industries in September 2020. The generic formulation is available as 500mg oral tablets and is indicated for the treatment of patients with transfusional iron overload due to thalassemia syndromes when current chelation therapy is inadequate. The generic formulation is dosed based on actual body weight and is administered TID.[75]

Pipeline:

- **SP-420:** AbFero is conducting Phase 1 studies of AP-420 for a variety of potential indications, including transfusional iron overload, retinal degeneration, Parkinson's disease, and ischemia reperfusion. SP-420 belongs to the desferrithiocin class, which is a novel class of orally active iron chelators. Local iron overload is thought to play a role in retinal and neurodegenerative diseases. SP-420 has the ability to cross the blood-brain-barrier and blood-retinal-barrier, making it a potential therapeutic option in these conditions.[76,77]

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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[74] Chiesi Global Diseases. Chiesi Group Receives FDA Approval for Ferriprox® (Deferiprone) Twice-a-Day Tablets. *Globe Newswire*. Available online at: https://www.globenewswire.com/news-release/2020/05/21/2037157/0/en/Chiesi-Group-Receives-FDA-Approval-for-Ferriprox-deferiprone-twice-a-day-tablets.html. Issued 05/21/2020. Last accessed 01/14/2021.
[75] Ernst D. Generic Version of Ferriprox® Now Available. *MPR*. Available online at: https://www.empr.com/home/news/generics-news/deferiprone-ferriprox-transfusional-iron-overload-thalassemia-syndromes/. Issued 09/29/2020. Last accessed 01/14/2021.
[76] AbFero Pharmaceuticals, Inc. AbFero Pipeline: Available online at: https://www.abferopharmaceuticals.com/pipeline/. Last accessed 01/14/2021.
[77] AbFero Pharmaceuticals, Inc. Our Technology: SP-420. Available online at: https://www.abferopharmaceuticals.com/oral-iron-chelator-technology/. Last accessed 01/14/2021.

Utilization Details of Iron Chelating Agents: Fiscal Year 2020

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
DEFERASIROX PRODUCTS						
JADENU TAB 360MG	74	20	$1,008,422.14	$13,627.33	3.7	63.09%
DEFERASIROX TAB 360MG	31	15	$152,192.15	$4,909.42	2.07	9.52%
DEFERASIROX TAB 500MG	30	10	$95,009.80	$3,166.99	3	5.94%
JADENU SPRKL GRA 180MG	18	3	$81,281.10	$4,515.62	6	5.09%
DEFERASIROX TAB 250MG	3	1	$321.93	$107.31	3	0.02%
DEFERASIROX TAB 125MG	2	1	$955.30	$477.65	2	0.06%
JADENU SPRKL GRA 360MG	2	1	$20,291.62	$10,145.81	2	1.27%
EXJADE TAB 500MG	1	1	$5,078.07	$5,078.07	1	0.32%
JADENU TAB 180MG	1	1	$2,544.52	$2,544.52	1	0.16%
SUBTOTAL	**162**	**40***	**$1,366,096.63**	**$8,432.70**	**4.05**	**85.47%**
DEFERIPRONE PRODUCTS						
FERRIPROX TAB 1000MG	10	1	$194,019.96	$19,402.00	10	12.14%
FERRIPROX TAB 500MG	2	1	$38,192.16	$19,096.08	2	2.39%
SUBTOTAL	**12**	**1***	**$232,212.12**	**$19,351.01**	**12**	**14.53%**
TOTAL	**174**	**41***	**$1,598,308.75**	**$9,185.68**	**4.24**	**100.00%**

GRA = granule; SPRKL = sprinkle; TAB = tablet
*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Please note, Exjade® was first FDA approved in 2005 and has a significant federal rebate.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Fiscal Year 2020 Annual Review of Jynarque® (Tolvaptan)

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Jynarque® (Tolvaptan) Approval Criteria:

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

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

Utilization of Jynarque® (Tolvaptan): Fiscal Year 2020

Comparison of Fiscal Years: Pharmacy Claims

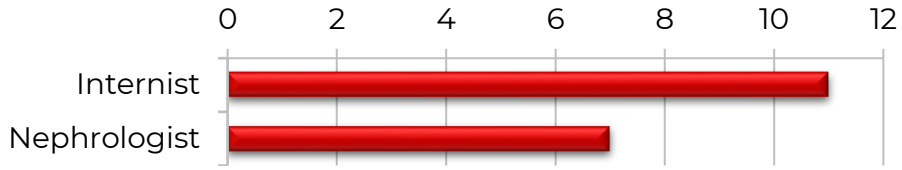
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	1	1	$13,704.03	$13,704.03	$489.43	56	28
2020	2	18	$262,780.89	$14,598.94	$521.39	1,008	504
% Change	**100.00%**	**1700.00%**	**1817.50%**	**6.50%**	**6.50%**	**1700.00%**	**1700.00%**
Change	**1**	**17**	**$249,076.86**	**$894.91**	**$31.96**	**952**	**476**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Demographics of Members Utilizing Jynarque® (Tolvaptan)

- Due to the limited number of members utilizing Jynarque® (tolvaptan) during fiscal year 2020, detailed demographic information could not be provided.

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



Prior Authorization of Jynarque® (Tolvaptan)

There were 18 prior authorization requests submitted for Jynarque® (tolvaptan) during fiscal year 2020. The following chart shows the status of the submitted petitions for fiscal year 2020.

Status of Petitions

Market News and Updates

Anticipated Patent Expiration(s):[78]

- Jynarque® (tolvaptan): September 2026

Recommendations

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

Utilization Details of Jynarque® (Tolvaptan): Fiscal Year 2020

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
JYNARQUE PAK 45-15MG	9	2	$130,316.70	$517.13	$14,479.63	49.59%
JYNARQUE PAK 90-30MG	7	1	$103,822.67	$529.71	$14,831.81	39.51%
JYNARQUE PAK 60-30MG	2	1	$28,641.52	$511.46	$14,320.76	10.90%
TOTAL	**18**	**2***	**$262,780.89**	**$521.39**	**$14,598.94**	**100.00%**

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

[78] 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 01/2021. Last accessed 01/20/2021.

Fiscal Year 2020 Annual Review of Kanuma® (Sebelipase Alfa)

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Kanuma® (Sebelipase Alfa) Approval Criteria:

1. An FDA approved diagnosis of Lysosomal Acid Lipase (LAL) deficiency; and
2. Kanuma® (sebelipase alfa) must be administered in a health care setting by a health care professional prepared to manage anaphylaxis; and
3. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to the Kanuma® *Prescribing Information*.

Utilization of Kanuma® (Sebelipase Alfa): Fiscal Year 2020

There was no SoonerCare utilization of Kanuma® (sebelipase alfa) during fiscal year 2020 (07/01/2019 to 06/30/2020).

Prior Authorization of Kanuma® (Sebelipase Alfa)

There were no prior authorization requests submitted for Kanuma® (sebelipase alfa) during fiscal year 2020.

Recommendations

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

Fiscal Year 2020 Annual Review of Keveyis® (Dichlorphenamide)

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Keveyis® (Dichlorphenamide) Approval Criteria:

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

Utilization of Keveyis® (Dichlorphenamide): Fiscal Year 2020

There has been no SoonerCare utilization of Keveyis® (dichlorphenamide) since it was approved by the U.S. Food and Drug Administration (FDA) in

August 2015 through fiscal year 2020 (fiscal year 2020 = 07/01/2019 to 06/30/2020).

Prior Authorization of Keveyis® (Dichlorphenamide)

There have been no prior authorization requests submitted for Keveyis® (dichlorphenamide) since it was FDA approved in August 2015 through fiscal year 2020.

Market News and Updates

Anticipated Exclusivity Expiration(s):[79]

- Keveyis® (dichlorphenamide): August 2022

New(s):

- **January 2021:** Strongbridge reported preliminary fourth quarter 2020 financial results which included net product sales for Keveyis® of approximately $8.2 million and full year 2020 revenue of approximately $30.7 million, a 41.5% increase over 2019 revenue of $21.7 million. Strongbridge has a target for full year 2021 revenue guidance of approximately $34 million to $36 million for Keveyis®.[80]

Recommendations

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

[79] 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 01/2021. Last accessed 01/26/2021.
[80] Strongbridge Biopharma Plc. Strongbridge Biopharma Plc Announces Preliminary Fourth Quarter and Full-Year 2020 Financial Results and Provides Corporate Update. *Globe Newswire*. Available online at: https://investors.strongbridgebio.com/news-releases/news-release-details/strongbridge-biopharma-plc-announces-preliminary-fourth-0. Issued 01/06/2021. Last accessed 01/28/2021.

Fiscal Year 2020 Annual Review of Leukotriene Modulators

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Singulair® (Montelukast) Approval Criteria:

1. Montelukast tablets and chewable tablets are available without prior authorization.
2. For Insure Oklahoma members, a prior authorization is required. This medication is not covered for a diagnosis of allergic rhinitis for those members.
3. A prior authorization is required for the granule formulation of montelukast:
    a. Use of the granule formulation requires a patient-specific, clinically significant reason why the member cannot use montelukast tablets or chewable tablets.

Zyflo CR® (Zileuton) Approval Criteria:

1. Member must be 12 years of age or older; and
2. An FDA approved diagnosis of mild or moderate persistent asthma; and
3. Member must meet the following trial requirements:
    a. A trial of an inhaled corticosteroid (ICS) and ICS/long-acting beta-2 agonist (LABA) therapy within the previous 6 months and the reason for trial failure must be provided; and
    b. A recent trial with at least 1 other available leukotriene modifier that did not yield adequate response.

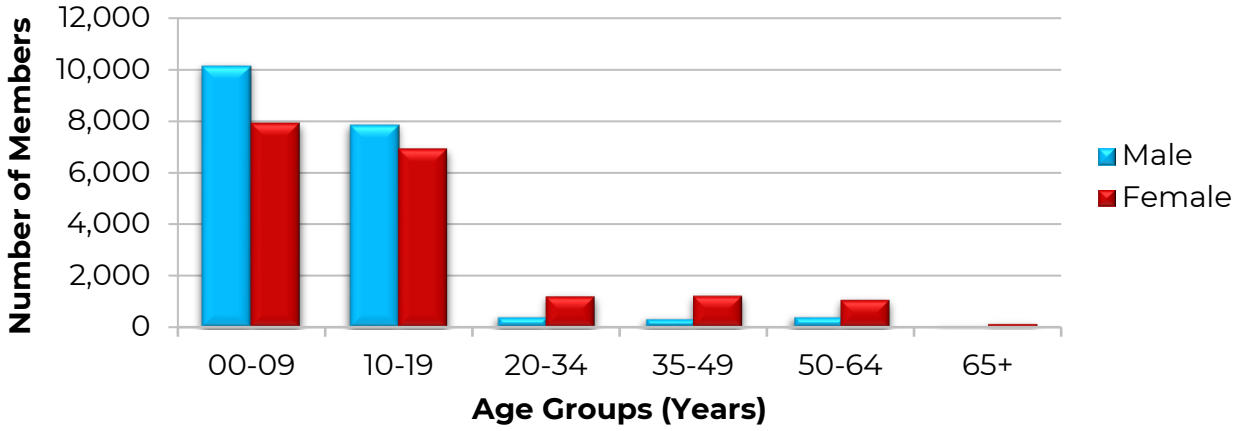
Utilization of Leukotriene Modulators: Fiscal Year 2020

Comparison of Fiscal Years: Pharmacy Claims

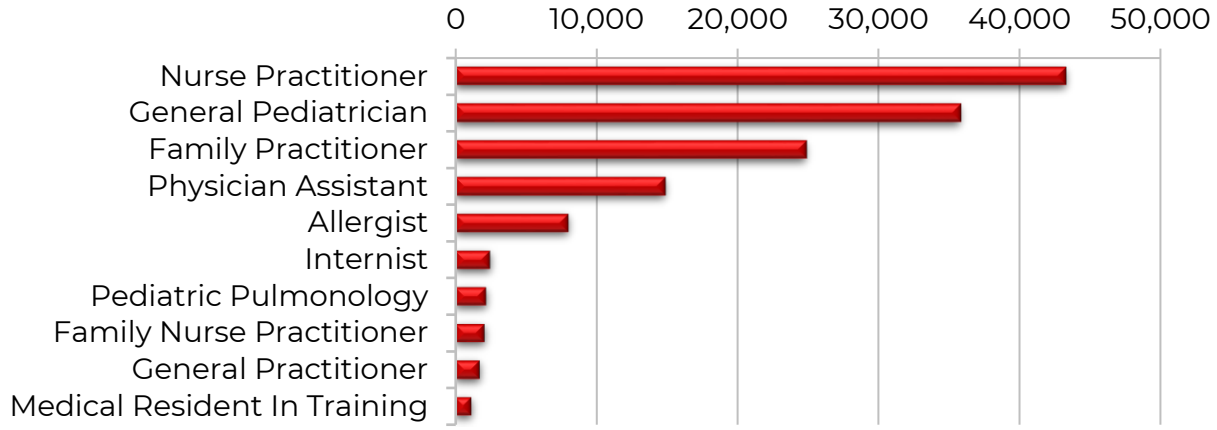
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	40,230	142,602	$2,198,268.11	$15.42	$0.51	4,266,880	4,274,871
2020	37,563	140,819	$2,081,785.77	$14.78	$0.48	4,293,925	4,301,315
% Change	**-6.60%**	**-1.30%**	**-5.30%**	**-4.20%**	**-5.90%**	**0.60%**	**0.60%**
Change	**-2,667**	**-1,783**	**-$116,482.34**	**-$0.64**	**-$0.03**	**27,045**	**26,444**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Demographics of Members Utilizing Leukotriene Modulators



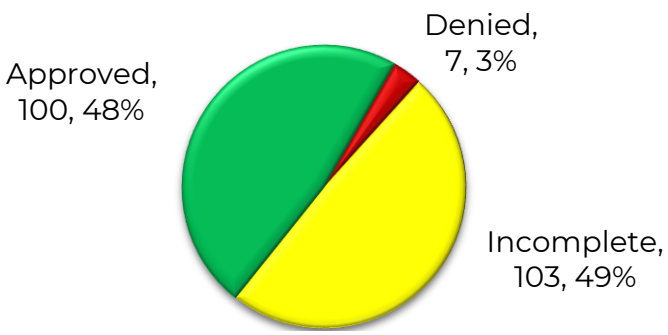
Top Prescriber Specialties of Leukotriene Modulators by Number of Claims



Prior Authorization of Leukotriene Modulators

There were 210 prior authorization requests submitted for leukotriene modulators during fiscal year 2020. The following chart shows the status of the submitted petitions.

Status of Petitions



Market News and Updates

News:

- **March 2020:** The U.S. Food and Drug Administration (FDA) released an announcement strengthening existing warnings about serious behavior and mood-related changes associated with montelukast. The FDA now requires a *Boxed Warning* to be added to the montelukast *Prescribing Information* to describe the serious mental health side effects and to recommend montelukast only be reserved to treat allergic rhinitis in patients who are not treated effectively with or cannot tolerate other allergy medications. Due to the risk of mental health side effects, the benefits of montelukast may not outweigh the risks in some patients, particularly when the symptoms of disease may be mild and adequately treated with other medications.[81]
- **December 2020:** With the emergence of COVID-19, the scientific and medical communities have tried to understand the underlying disease as well as find potential treatment. Focus has been on 4 different strategies: antiviral treatments to limit the entry of the virus into the cell and its propagation, anti-inflammatory treatment to reduce the impact of COVID-19 associated inflammation and cytokine storm, treatment using cardiovascular medication to reduce the COVID-19 associated thrombosis and vascular damage, and treatment to reduce the COVID-19 associated lung injury. Leukotrienes and their receptors have been investigated as potential drug targets since they are lipid mediators of inflammation and tissue damage and well-established targets in respiratory diseases, like asthma. Besides their role in inflammation, leukotrienes are involved in other aspects of lung pathologies like vascular damage, thrombosis, and fibrotic response. Several investigations in China and Italy looking at comorbidities or pre-existing medical conditions in laboratory-confirmed COVID-19 patients did not find asthma among the comorbidities; similarly, asthma was not reported when patients died as a result of a SARS-CoV-2 infection. Therefore, the use of an asthma medication, like montelukast, might have had a role in minimizing the clinical presentation of this comorbidity. A review article has been published recommending montelukast to be considered as a treatment modality given that there are currently minimal to no effective strategies against COVID-19.[82]

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[81] U.S. Food and Drug Administration (FDA). FDA Requires Boxed Warning about Serious Mental Health Side Effects for Asthma and Allergy Drug Montelukast (Singulair®); Advises Restricting Use for Allergic Rhinitis. Available online at: https://www.fda.gov/drugs/drug-safety-and-availability/fda-requires-boxed-warning-about-serious-mental-health-side-effects-asthma-and-allergy-drug. Issued 03/04/2020. Last accessed 01/05/2021.

[82] Aigner L, Pietrantonio F, Bessa de Sousa DM, et al. The Leukotriene Receptor Antagonist Montelukast as a Potential COVID-19 Therapeutic. *Front Mol Biosci* 2020; 7:610132.

Recommendations

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

Utilization Details of Leukotriene Modulators: Fiscal Year 2020

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
MONTELUKAST CHW 5MG	55,405	14,839	$785,903.92	$14.18	3.73	37.75%
MONTELUKAST TAB 10MG	44,511	12,094	$520,528.42	$11.69	3.68	25.00%
MONTELUKAST CHW 4MG	37,484	10,894	$553,737.78	$14.77	3.44	26.60%
MONTELUKAST GRA 4MG	3,411	1,474	$219,698.51	$64.41	2.31	10.55%
SINGULAIR CHW 5MG	8	1	$1,917.14	$239.64	8	0.09%
TOTAL	**140,819**	**37,563***	**$2,081,785.77**	**$14.78**	**3.75**	**100.00%**

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

Fiscal Year 2020 Annual Review of Lidocaine Topical Products

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

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

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

Synera® (Lidocaine/Tetracaine Patch) Approval Criteria:

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

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

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

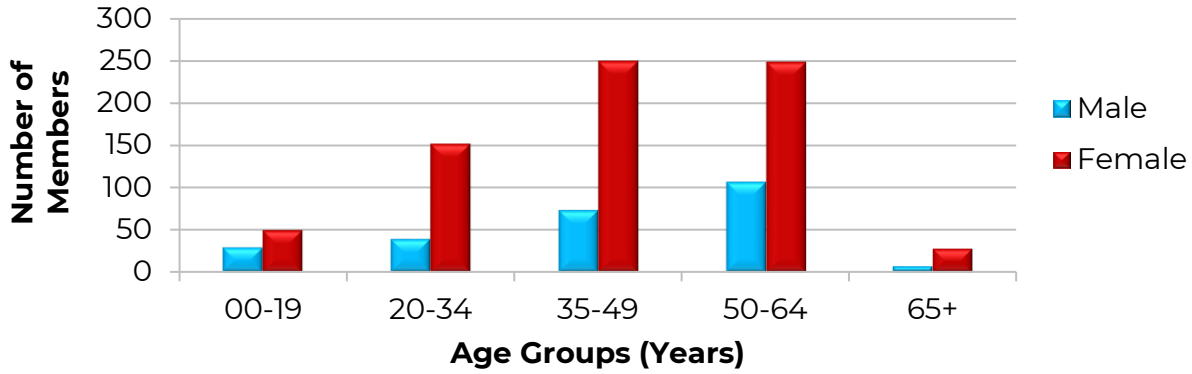
Utilization of Lidocaine Topical Products: Fiscal Year 2020

Comparison of Fiscal Years: Pharmacy Claims

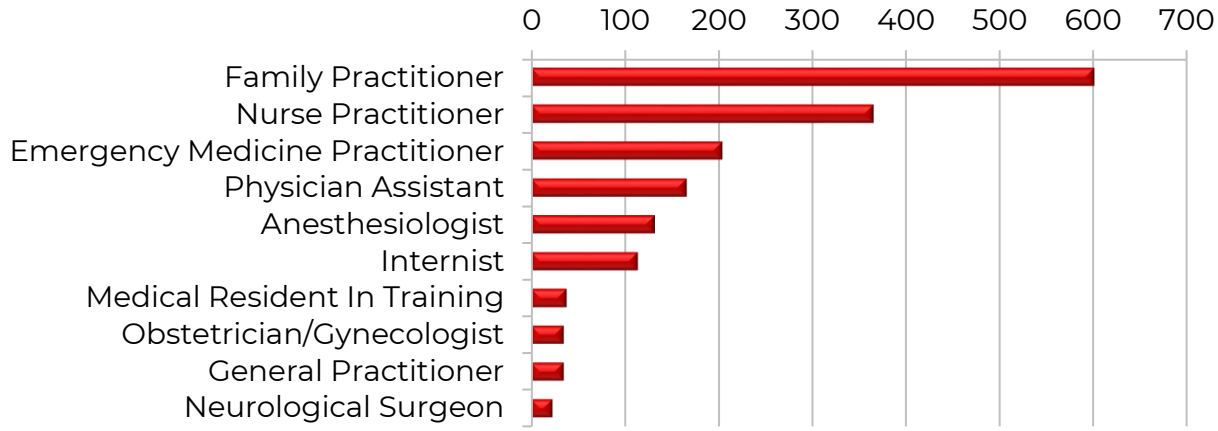
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	738	1,301	$119,258.54	$91.67	$3.57	40,333	33,403
2020	983	1,859	$167,425.70	$90.06	$3.40	56.779	49,225
% Change	**33.00%**	**42.90%**	**40.40%**	**-1.80%**	**-4.80%**	**40.80%**	**47.40%**
Change	**244**	**558**	**$48,167.16**	**-$1.61**	**-$0.17**	**16,446**	**15,822**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Demographics of Members Utilizing Lidocaine Topical Products

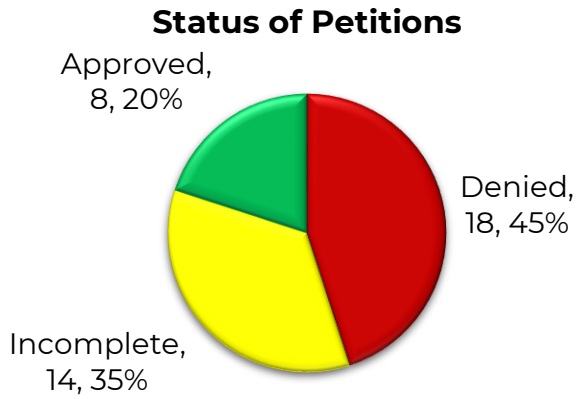


Top Prescriber Specialties of Lidocaine Topical Products by Number of Claims



Prior Authorization of Lidocaine Topical Products

There were 40 prior authorization requests submitted for lidocaine topical products during fiscal year 2020. The following chart shows the status of the submitted petitions.



Market News and Updates

Anticipated Patent Expiration(s):[83]

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

Recommendations

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

Utilization Details of Lidocaine Topical Products: Fiscal Year 2020

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
LIDOCAINE PRODUCTS						
LIDOCAINE PAD 5%	1,858	982	$166,898.66	$89.83	1.89	99.69%
ZTLIDO PAD 1.8%	1	1	$527.04	$527.04	1.00	0.31%
TOTAL	**1,859**	**983***	**$167,425.70**	**$90.06**	**1.89**	**100.00%**

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

[83] 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 01/2021. Last accessed 01/11/2021.

Fiscal Year 2020 Annual Review of Lumizyme® (Alglucosidase Alfa)

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Lumizyme® (Alglucosidase Alfa) Infantile-Onset Approval Criteria:

1. An FDA approved diagnosis of infantile-onset Pompe disease [acid alpha-glucosidase (GAA) deficiency]; and
2. Documentation of diagnosis confirmation of GAA enzyme deficiency through specific genetic laboratory test(s); and
3. Lumizyme® must be prescribed by a geneticist or a physician that specializes in the treatment of Pompe disease and/or inherited genetic disorders; and
4. Member's weight must be provided and must have been taken within the last 4 weeks to ensure accurate dosing.

Lumizyme® (Alglucosidase Alfa) Late-Onset (Non-Infantile) Approval Criteria:

1. An FDA approved diagnosis of late-onset (non-infantile) Pompe disease [acid alpha-glucosidase (GAA) deficiency]; and
2. Documentation of diagnosis confirmation of GAA enzyme deficiency through specific genetic laboratory test(s); and
3. Provider must document presence of symptoms of Pompe disease; and
4. Lumizyme® must be prescribed by a geneticist or a physician that specializes in the treatment of Pompe disease and/or inherited genetic disorders; and
5. Member's weight must be provided and must have been taken within the last 4 weeks to ensure accurate dosing; and
6. Initial approval will be for the duration of 6 months, at which time compliance and information regarding efficacy, such as improvement or stabilization in forced vital capacity (FVC) and/or 6-minute walk test (6MWT), will be required for continued approval. Additional authorizations will be for the duration of 1 year.

Utilization of Lumizyme® (Alglucosidase Alfa): Fiscal Year 2020

There was no SoonerCare utilization of Lumizyme® (alglucosidase alfa) during fiscal year 2020 (07/01/2019 to 06/30/2020).

Prior Authorization of Lumizyme® (Alglucosidase Alfa)

There were no prior authorization requests submitted for Lumizyme® (alglucosidase alfa) during fiscal year 2020.

Market News and Updates

Pipeline:

- **Avalglucosidase Alfa:** The U.S. Food and Drug Administration (FDA) has granted priority review of Sanofi's Biologics License Application (BLA) for avalglucosidase alfa with a decision date set for May 18, 2021. Avalglucosidase alfa is an investigational enzyme replacement therapy for the treatment of patients with Pompe disease and is designed to improve delivery of the acid alpha-glucosidase (GAA) enzyme to muscle cells resulting in a reduction in glycogen accumulation.[84]

Recommendations

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

[84] Sanofi. FDA Grants Priority Review for Avalglucosidase Alfa, a Potential New Therapy for Pompe Disease. Available online at: https://www.sanofi.com/en/media-room/press-releases/2020/2020-11-18-07-00-00. Issued 11/18/2020. Last accessed 12/02/2020.

Fiscal Year 2020 Annual Review of Luxturna® (Voretigene Neparvovec-rzyl)

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Luxturna® (Voretigene Neparvovec-rzyl) Approval Criteria:

1. An FDA approved diagnosis of biallelic *RPE65* mutation-associated retinal dystrophy; and
    a. Diagnosis must be confirmed by genetic testing; and
2. Member must have sufficient viable retinal cells in both eyes as determined by the treating physician(s); and
3. Member must have best corrected visual acuity of 20/60 or worse in both eyes and/or visual field <20 degrees in any meridian in both eyes; and
4. Member must be 4 years of age or older; and
5. Member must not have participated in a previous *RPE65* gene therapy study or have previously received treatment with Luxturna®; and
6. Member must not have had intraocular surgery in the past 6 months; and
7. Female members of child bearing age must not be pregnant and must have a negative pregnancy test immediately prior to administration of Luxturna®; and
8. Male and female members of child bearing age must be willing to use effective contraception during treatment with Luxturna® and for at least 4 months after administration of Luxturna®; and
9. Member must take the recommended systemic oral corticosteroid regimen, starting 3 days prior to administration of Luxturna® to each eye, and continuing after administration of Luxturna®, as per the Luxturna® *Prescribing Information*; and
10. Luxturna® must be prescribed and administered by a retinal surgeon with expertise in the treatment of biallelic *RPE65* mutation-associated retinal dystrophy and in the administration of Luxturna® at an Ocular Gene Therapy Treatment Center; and
    a. Luxturna® must be shipped via cold chain supply shipping and delivery to the Ocular Gene Therapy Treatment Center where the member is scheduled to receive treatment; and
    b. Luxturna® must be stored frozen prior to preparation for administration (Luxturna® should be administered within 4 hours of preparation); and

c. The receiving facility must have a mechanism in place to track patient-specific Luxturna® from receipt to storage to administration; and

11. Luxturna® must be administered subretinally to each eye on separate days within a close interval, but no fewer than 6 days apart; and
    a. The scheduled procedure date for each eye must be provided; and
12. Only 1 single-dose vial per eye will be approved per member per lifetime; and
    a. Each single-dose vial of Luxturna® is to be dispensed immediately prior to the scheduled procedure for the specific eye; or
13. A prior authorization request with patient-specific information may be submitted for consideration of Luxturna® for members not meeting all of the current prior authorization criteria requirements.

Utilization of Luxturna® (Voretigene Neparvovec-rzyl): Fiscal Year 2020

There was no SoonerCare utilization of Luxturna® (voretigene neparvovec-rzyl) during fiscal year 2020 (07/01/2019 to 06/30/2020).

Prior Authorization of Luxturna® (Voretigene Neparvovec-rzyl)

There were no prior authorization requests submitted for Luxturna® (voretigene neparvovec-rzyl) during fiscal year 2020.

Market News and Updates

Pipeline:

- **AAV-RPE65:** MeiraGTx is conducting Phase 1/2 studies of AAV-RPE65 in adult and pediatric patients with *RPE65* deficiency, a genetic condition that causes visual deficits progressing to eventual blindness. AAV-RPE65 has been granted Orphan Drug designation for the treatment of Leber's congenital amaurosis (LCA) and Rare Pediatric Disease designation for the treatment of inherited retinal dystrophy due to biallelic *RPE65* mutations by the U.S. Food and Drug Administration (FDA).[85]
- **AAV-RPGR:** MeiraGTx and Janssen are jointly developing AAV-RPGR, a gene therapy for the treatment of adult and pediatric patients with X-linked retinitis pigmentosa (RP) caused by mutations in the eye-specific form of the *RPGR* gene. AAV-RPGR has been granted Fast Track and Orphan Drug designations by the FDA. In November 2020, MeiraGTx announced 12-month data from a Phase 1/2 study of AAV-RPGR which demonstrated statistically significant improvement in vision that was sustained 1 year after treatment. MeiraGTx is planning to initiate the

[85] MeiraGTx. MeiraGTx Pipeline: AAV-RPE65. Available online at: https://meiragtx.com/research-development/pipeline/. Last accessed 01/15/2021.

pivotal Phase 3 Lumeos study for the treatment of patients with X-linked RP.[86,87]

- **GS030:** GenSight is developing GS030, a novel gene therapy for the treatment of RP. GS030 uses optogenetics, a biologic technique that involves the transfer of a gene that encodes for a light-sensitive protein, which in turn causes neuronal cells to respond to light stimulation. GS030 consists of 2 complementary components, a gene therapy product encoding a photoactivatable protein, delivered via a modified adeno-associated virus serotype 2 (AAV2) vector, and biomimetic goggles that stimulate the engineered retinal cells (images are projected onto the retina by a light source that uses a specific wavelength). GenSight is currently conducting the Phase 1/2 PIONEER dose-escalation study to evaluate the safety and tolerability of GS030 in patients with RP. In April 2020, GenSight announced positive safety data from the first 6 patients treated with GS030. The safety review identified no safety issues in patients who each received a single intravitreal injection of GS030 and the study is moving forward without any protocol modification. An additional cohort of 3 patients will be recruited to receive the maximal dose of GS030.[88,89]

Recommendations

The College of Pharmacy does not recommend any changes to the current Luxturna® (voretigene neparvovec-rzyl) prior authorization criteria at this time.

[86] MeiraGTx. MeiraGTx Pipeline: AAV-RPGR. Available online at: https://meiragtx.com/research-development/pipeline/. Last accessed 01/15/2021.
[87] MeiraGTx. MeiraGTx Announces Investigational Gene Therapy Continues to Demonstrate Statistically Significant Improvement in Vision in Patients with X-Linked Retinitis Pigmentosa One Year After Treatment. Available online at: https://investors.meiragtx.com/news-releases/news-release-details/meiragtx-announces-investigational-gene-therapy-continues. Issued 11/13/2020. Last accessed 01/15/2021.
[88] GenSight Biologics. GenSight Pipeline: GS030 for Retinitis Pigmentosa. Available online at: https://www.gensight-biologics.com/product/gs030-for-retinitis-pigmentosa/. Last accessed 01/15/2021.
[89] GenSight Biologics. GenSight Biologics Announces Positive Data Safety Monitoring Board Review of PIONEER Phase 1/2 Trial of GS030 Combining Gene Therapy and Optogenetics for the Treatment of Retinitis Pigmentosa. Available online at: https://www.gensight-biologics.com/2020/04/14/gensight-biologics-announces-positive-data-safety-monitoring-board-review-of-pioneer-phase-i-ii-trial-of-gs030-combining-gene-therapy-and-optogenetics-for-the-treatment-of-retinitis-pigmentosa/. Issued 04/14/2020. Last accessed 01/15/2021.

Fiscal Year 2020 Annual Review of Mepsevii® (Vestronidase Alfa-vjbk)

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Mepsevii® (Vestronidase Alfa-vjbk) Approval Criteria:

1. An FDA approved diagnosis of Sly syndrome (mucopolysaccharidosis VII; MPS VII) confirmed by:
   a. Enzyme analysis demonstrating a deficiency of beta-glucuronidase activity; or
   b. Genetic testing to confirm diagnosis of MPS VII; and
2. Mepsevii® must be administered by a health care professional prepared to manage anaphylaxis; and
3. Initial approvals will be for the duration of 12 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment; 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 the Mepsevii® *Prescribing Information.*

Utilization of Mepsevii® (Vestronidase Alfa-vjbk): Fiscal Year 2020

There was no SoonerCare utilization of Mepsevii® (vestronidase alfa-vjbk) during fiscal year 2020 (07/01/2019 to 06/30/2020).

Prior Authorization of Mepsevii™ (Vestronidase Alfa-vjbk)

There were no prior authorization requests submitted for Mepsevii® (vestronidase alfa-vjbk) during fiscal year 2020.

Recommendations

The College of Pharmacy does not recommend any changes to the current Mepsevii® (vestronidase alfa-vjbk) prior authorization criteria at this time.

Fiscal Year 2020 Annual Review of Mozobil® (Plerixafor)

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Mozobil® (Plerixafor) Approval Criteria:

1. An FDA approved indication for use in combination with a granulocyte-colony stimulating factor (G-CSF) to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with non-Hodgkin's lymphoma (NHL) or multiple myeloma (MM); and
2. Member must have a cancer diagnosis of NHL or MM. This medication is not covered for the diagnosis of leukemia; and
3. Mozobil® must be prescribed by an oncologist; and
4. Member must be 18 years of age or older; and
5. Mozobil® must be used in combination with the G-CSF Neupogen® (filgrastim); and
6. The following dosing restrictions will apply (current body weight in kilograms is required):
    a. Recommended dose is 0.24mg/kg (maximum dose is 40mg/day) administered 11 hours prior to apheresis for up to 4 consecutive days; or
    b. Dosing for renal impairment (creatinine clearance ≤50mL/min): 0.16mg/kg (maximum dose is 27mg/day); and
7. Approvals will be for the duration of 2 months.

Utilization of Mozobil® (Plerixafor): Fiscal Year 2020

Fiscal Year 2020 Utilization: Medical Claims

Fiscal Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2020	2	3	$33,383.04	$11,127.68	1.5

*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020
Please note: There was no SoonerCare utilization of Mozobil® (plerixafor) during fiscal year 2019 (07/01/2018 to 06/30/2019) to allow for a fiscal year comparison.

Demographics of Members Utilizing Mozobil® (Plerixafor)

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

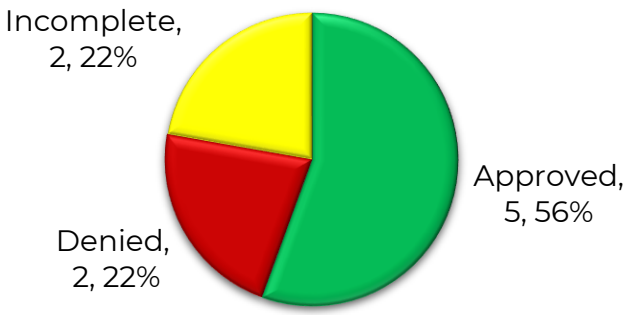
Top Prescriber Specialties of Mozobil® (Plerixafor) by Number of Claims

- The only prescriber specialty listed on approved prior authorization requests for Mozobil® (plerixafor) during fiscal year 2020 was hematologist oncologist.

Prior Authorization of Mozobil® (Plerixafor)

There were 9 prior authorization requests submitted for Mozobil® (plerixafor) during fiscal year 2020. The following chart shows the status of the submitted petitions for fiscal year 2020.

Status of Petitions



Recommendations

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

Utilization Details of Mozobil® (Plerixafor): Fiscal Year 2020

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
MOZOBIL J2562	3	2	$33,383.04	$11,127.68	1.5
TOTAL	**3⁺**	**2***	**$33,383.04**	**$11,127.68**	**1.5**

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

Fiscal Year 2020 Annual Review of Muscle Relaxant Medications

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Muscle Relaxant Medications*		
Tier-1	**Tier-2**	**Special PA**
baclofen 10mg, 20mg (Lioresal®)	metaxalone (Skelaxin®)	baclofen 5mg (Lioresal®)
chlorzoxazone (Parafon Forte®)		carisoprodol (Soma®) 250mg
cyclobenzaprine (Flexeril®)		carisoprodol (Soma®) 350mg
methocarbamol (Robaxin®)		carisoprodol/ASA
orphenadrine (Norflex®)		carisoprodol/ASA/codeine
tizanidine tabs (Zanaflex®)		chlorzoxazone (Lorzone™) tabs
		cyclobenzaprine 7.5mg (Fexmid®) tabs
		cyclobenzaprine ER (Amrix®) caps
		tizanidine (Zanaflex®) caps

ASA = aspirin; caps = capsules; ER = extended-release; PA = prior authorization; tabs = tablets
* 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).

Muscle Relaxant Medications Tier-2 Approval Criteria:

1. Member must have failure with at least 2 Tier-1 medications within the past 90 days defined as no beneficial response after at least 2 weeks of use during which time the drug has been titrated to the recommended dose; and
2. Approvals will be for the duration of 3 months, except for members with chronic diseases such as multiple sclerosis, cerebral palsy, muscular dystrophy, paralysis, or other chronic musculoskeletal diagnosis confirmed with diagnostic results, in which case authorizations will be for the duration of 1 year; and
3. For repeat authorizations, there must be documentation of a failed withdrawal attempt within the past 3 months defined as increase in pain and debilitating symptoms when medication was discontinued.

Amrix® [Cyclobenzaprine Extended-Release (ER) Capsule] and Fexmid® (Cyclobenzaprine 7.5mg Tablet) Approval Criteria:

1. Authorization requires clinical documentation of inability to take other generically available forms of cyclobenzaprine tablets; and

2. The following quantity limits apply:
    a. Amrix® 15mg and 30mg ER capsules: 30 capsules per 30 days; or
    b. Fexmid® 7.5mg tablets: 90 tablets per 30 days.

Baclofen 5mg Tablets Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use other appropriate Tier-1 products, including splitting a baclofen 10mg tablet to achieve a 5mg dose, must be provided.

Lorzone™ (Chlorzoxazone) Approval Criteria:

1. Generic chlorzoxazone 500mg tablets must be tried prior to consideration of Lorzone™; and
2. A patient-specific, clinically significant reason why the member cannot use generic chlorzoxazone 500mg tablets must be provided; and
3. The following quantity limits apply:
    a. Lorzone™ 375mg tablets: 120 tablets per 30 days; or
    b. Lorzone™ 750mg tablets: 120 tablets per 30 days.

Soma® (Carisoprodol 250mg) Approval Criteria:

1. Authorization requires detailed documentation regarding member's inability to use other skeletal muscle relaxants including carisoprodol 350mg, and patient-specific reason(s) why member cannot be drowsy for even a short time period must be provided. Member must not have other sedating medications in current claims history; and
2. For a diagnosis of acute musculoskeletal pain, the approval will be for the duration of 14 days per 365 day period. Conditions requiring chronic use will not be approved.

Soma® (Carisoprodol 350mg) or Soma® (Carisoprodol 350mg) Combination Product(s) Approval Criteria:

1. Members may receive 3 months of carisoprodol 350mg per rolling 365 days without prior authorization; and
2. After the member has received the 3 months, an additional approval for 1 month may be granted to allow titration or change to a Tier-1 muscle relaxant. This additional 1-month approval will be granted 1 time only. Further authorizations will not be granted; or
3. Clinical exceptions may be made for members with the following diagnosis and approvals will be granted for the duration of 1 year: multiple sclerosis, cerebral palsy, muscular dystrophy, paralysis, or cancer pain; and
4. A quantity limit of 120 tablets per 30 days will apply for carisoprodol and carisoprodol combination products.

Zanaflex® (Tizanidine Capsule) Approval Criteria:

1. Tizanidine tablets must be tried prior to consideration of tizanidine capsules; and
2. The capsule formulation may be considered for approval only if there is supporting information as to why the member cannot take the tablets.

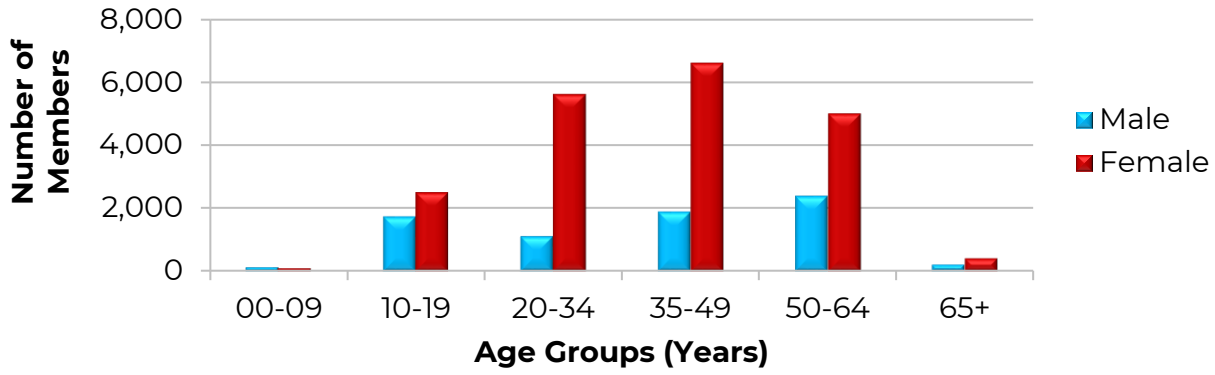
Utilization of Muscle Relaxant Medications: Fiscal Year 2020

Comparison of Fiscal Years: Pharmacy Claims

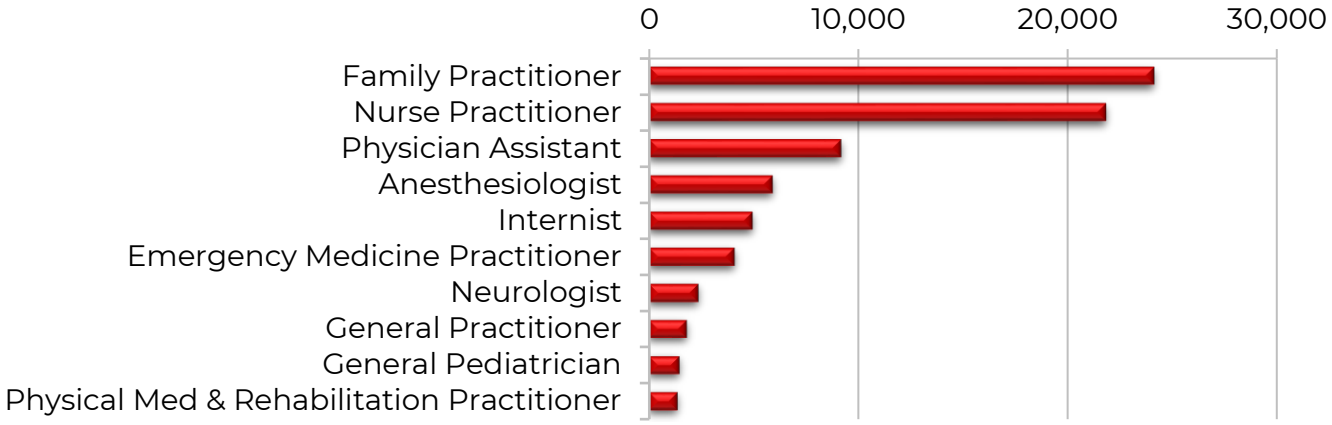
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	30,117	91,186	$1,291,228.64	$14.16	$0.57	6,086,865	2,265,189
2020	27,551	85,998	$1,220,538.11	$14.19	$0.56	5,796,873	2,161,380
% Change	**-8.50%**	**-5.70%**	**-5.50%**	**0.20%**	**-1.80%**	**-4.80%**	**-4.60%**
Change	**-2,566**	**-5,188**	**-$70,690.53**	**$0.03**	**-$0.01**	**-289,992**	**-103,809**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Demographics of Members Utilizing Muscle Relaxant Medications

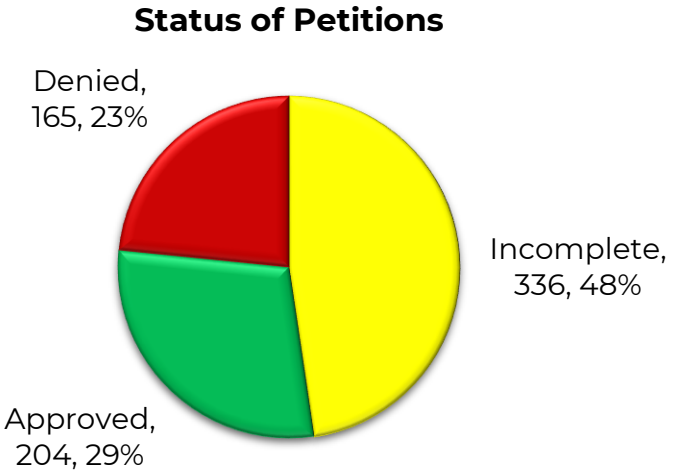


Top Prescriber Specialties of Muscle Relaxant Medications by Number of Claims



Prior Authorization of Muscle Relaxant Medications

There were 705 prior authorization requests submitted for muscle relaxant medications during fiscal year 2020. 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 2020.



Market News and Updates

Anticipated Patent Expiration(s):[90]

- Amrix® [cyclobenzaprine extended-release (ER) capsule]: February 2025
- Skelaxin® (metaxalone tablet): February 2026

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

- **June 2020:** Amphastar Pharmaceuticals received FDA approval for succinylcholine chloride injection USP 200mg/10mL multiple-dose vial as an adjunct to general anesthesia, to facilitate tracheal intubation, and to provide skeletal muscle relaxation during surgery or mechanical ventilation. Amphastar's newly approved drug product was determined by the FDA to be therapeutically equivalent to Quelicin™ (succinylcholine chloride injection USP 200mg/10mL multiple-dose vial).[91]

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[90] 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 01/2021. Last accessed 01/12/2021.

[91] Amphastar Pharmaceuticals, Inc. Amphastar Pharmaceuticals, Inc. Receives FDA Approval for Succinylcholine Chloride Injection USP, 200mg/10mL (20mg/mL) Multiple-Dose Vial. Available online at: http://ir.amphastar.com/news-releases/news-release-details/amphastar-pharmaceuticals-inc-receives-fda-approval. Issued 06/09/2020. Last accessed 01/12/2021.

Pipeline:

- **Arbaclofen ER:** The FDA is currently reviewing Osmotica's arbaclofen ER as a potential oral therapy for the treatment of multiple sclerosis (MS) spasticity. The compound is similar to the muscle relaxant baclofen that is approved to treat spasticity in patients with MS, spinal cord injuries, or other disorders involving the spinal cord. The ER formulation, which is based on Osmotica's proprietary Osmodex drug delivery technology, allows arbaclofen to be slowly released over longer periods of time, potentially reducing dosing frequency and undesirable effects. The New Drug Application (NDA) is supported by data from a Phase 3 trial and an open-label, long term extension trial which evaluated safety and efficacy of arbaclofen ER. When given as a daily 40mg or 80mg tablet, arbaclofen ER lowered patients' Total Numeric-transformed Modified Ashworth Scale for the most affected limb (TNmAS-MAL) scores, which is a well-established measure of muscle spasticity, from the study's start to day 84 compared with placebo. Results from the extension trial showed patients taking arbaclofen ER tablets daily had continued improvement in the TNmAS-MAL scores, demonstrating the long-term effectiveness at alleviating spasticity.[92]

Recommendations

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

Utilization Details of Muscle Relaxant Medications: Fiscal Year 2020

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
TIER-1 PRODUCTS					
BACLOFEN PRODUCTS					
BACLOFEN TAB 10MG	11,712	3,214	$177,513.62	$0.53	$15.16
BACLOFEN TAB 20MG	5,678	1,117	$126,947.25	$0.76	$22.36
LIORESAL INT INJ 40MG/20ML	8	1	$15,184.44	$63.27	$1,898.06
SUBTOTAL	**17,398**	**4,332**	**$319,645.31**	**$0.64**	**$18.37**
CHLORZOXAZONE PRODUCTS					
CHLORZOXAZONE TAB 500MG	895	295	$22,294.11	$0.94	$24.91
SUBTOTAL	**895**	**295**	**$22,294.11**	**$0.94**	**$24.91**
CYCLOBENZAPRINE PRODUCTS					
CYCLOBENZAPRINE TAB 10MG	25,974	11,050	$264,349.24	$0.42	$10.18

[92] Carvalho J. FDA will Review Arbaclofen ER, Potential Oral Therapy for MS Spasticity. *Multiple Sclerosis News Today*. Available online at: https://multiplesclerosisnewstoday.com/news-posts/2020/07/22/fda-agrees-to-review-arbaclofen-er-potential-ms-spasticity-treatment/. Issued 07/22/2020. Last accessed 01/12/2021.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
CYCLOBENZAPRINE TAB 5MG	6,758	3,965	$71,433.89	$0.54	$10.57
SUBTOTAL	**32,732**	**15,015**	**$335,783.13**	**$0.44**	**$10.26**
METHOCARBAMOL PRODUCTS					
METHOCARBAMOL TAB 750MG	3,659	1,513	$60,464.69	$0.68	$16.52
METHOCARBAMOL TAB 500MG	3,616	1,856	$53,643.21	$0.71	$14.83
SUBTOTAL	**7,275**	**3,369**	**$114,107.90**	**$0.69**	**$15.68**
ORPHENADRINE PRODUCTS					
ORPHENADRINE TAB 100MG ER	2,555	1,684	$48,494.33	$1.10	$18.98
SUBTOTAL	**2,555**	**1,684**	**$48,494.33**	**$1.10**	**$18.98**
TIZANIDINE PRODUCTS					
TIZANIDINE TAB 4MG	21,035	6,116	$300,893.56	$0.53	$14.30
TIZANIDINE TAB 2MG	3,036	1,224	$45,756.34	$0.61	$15.07
SUBTOTAL	**24,071**	**7,340**	**$346,649.90**	**$0.54**	**$14.40**
TIER-1 SUBTOTAL	**84,926**	**32,035**	**$1,186,975.25**	**$0.55**	**$13.98**
TIER-2 PRODUCTS					
METAXALONE PRODUCTS					
METAXALONE TAB 800MG	228	63	$14,336.50	$2.22	$62.88
METAXALONE TAB 400MG	12	1	$5,628.26	$15.63	$469.02
SUBTOTAL	**240**	**6,830**	**$19,964.76**	**$2.92**	**$83.19**
TIER-2 SUBTOTAL	**240**	**6,830**	**$19,964.76**	**$2.92**	**$83.19**
SPECIAL PA PRODUCTS					
BACLOFEN PRODUCTS					
BACLOFEN TAB 5MG	36	9	$2,318.51	$2.36	$64.40
SUBTOTAL	**36**	**9**	**$2,318.51**	**$2.36**	**$64.40**
CARISOPRODOL PRODUCTS					
CARISOPRODOL TAB 350MG	793	368	$9,583.66	$0.49	$12.09
SUBTOTAL	**793**	**368**	**$9,583.66**	**$0.49**	**$12.09**
CYCLOBENZAPRINE PRODUCTS					
CYCLOBENZAPRINE CAP 15MG ER	3	1	$1,696.50	$18.85	$565.50
SUBTOTAL	**3**	**1**	**$1,696.50**	**$18.85**	**$565.50**
SPECIAL PA SUBTOTAL	**832**	**378**	**$13,598.67**	**$0.65**	**$16.34**
TOTAL	**85,998**	**27,551***	**$1,220,538.11**	**$0.56**	**$14.19**

CAP = capsule; ER = extended-release; INJ = injection; INT = intrathecal; PA = prior authorization; TAB = tablet
*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Fiscal Year 2020 Annual Review of Myalept® (Metreleptin)

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Myalept® (Metreleptin) Approval Criteria:

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

Utilization of Myalept® (Metreleptin): Fiscal Year 2020

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	1	13	$577,263.03	$44,404.85	$1,480.16	130	390
2020	1	12	$583,703.70	$48,641.97	$1,621.40	120	360
% Change	**0.00%**	**-7.7%**	**1.1%**	**9.5%**	**9.5%**	**-7.7%**	**-7.7%**
Change	**0**	**-1**	**$6,440.67**	**$4,237.12**	**$141.24**	**-10**	**-30**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Demographics of Members Utilizing Myalept® (Metreleptin)

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

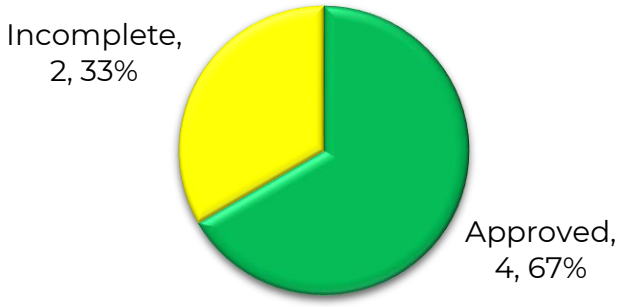
Top Prescriber Specialties of Myalept® (Metreleptin) by Number of Claims

- The only prescriber specialty listed on paid claims for Myalept® (metreleptin) during fiscal year 2020 was pediatric endocrinologist.

Prior Authorization of Myalept® (Metreleptin)

There were 6 prior authorization requests submitted for Myalept® (metreleptin) during fiscal year 2020. The following chart shows the status of the submitted petitions for fiscal year 2020.

Status of Petitions



Recommendations

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

Utilization Details of Myalept® (Metreleptin): Fiscal Year 2020

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
MYALEPT INJ 11.3MG	12	1	$583,703.70	$48,641.98	12	100.00%
TOTAL	**12**	**1***	**$583,703.70**	**$48,641.98**	**12**	**100.00%**

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

Fiscal Year 2020 Annual Review of Mytesi® (Crofelemer)

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Mytesi® (Crofelemer) Approval Criteria:

1. An FDA approved diagnosis of non-infectious diarrhea in adult members with human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS) currently on anti-retroviral therapy; and
2. Duration of diarrhea has been ≥4 weeks; and
3. Dietary modifications have failed; and
4. Prescribers must verify that infectious diarrhea has been ruled out via confirmation of all of the following:
    a. CD4 count has been measured and possible opportunistic infections have been ruled out; and
    b. Member does not have fever; and
    c. Stool studies for pathogens are negative including:
        i. Bacterial cultures; and
        ii. Ova, parasite, cryptosporidium and/or giardia; and
        iii. *Clostridium difficile* (*Clostridium difficile* testing should include a glutamate dehydrogenase screen and if positive, followed by a confirmatory test or nucleic acid amplification test in members with documented diarrhea; a toxin enzyme immunoassay should not be used as a stand-alone test); and
5. If stool study results are negative and the member has severe symptoms, particularly in the case of advanced immunodeficiency, an endoscopy with biopsy is recommended, at the prescriber's discretion, to rule out inflammatory bowel disease, cancer, cytomegalovirus (CMV) infection, microsporidium, or mycobacterium avium complex (MAC); and
6. A quantity limit of 60 tablets per 30 days will apply. Initial approvals will be for 4 weeks of therapy. An additional 6-month approval may be granted if the prescriber documents member is responding well to treatment.

Utilization of Mytesi® (Crofelemer): Fiscal Year 2020

There was no SoonerCare utilization of Mytesi® (crofelemer) during fiscal year 2020 (07/01/2019 to 06/30/2020).

Prior Authorization of Mytesi® (Crofelemer)

There were no prior authorization requests submitted for Mytesi® (crofelemer) during fiscal year 2020.

Market News and Updates

Anticipated Patent Expiration(s):[93]

- Mytesi® (crofelemer): October 2031

News:

- **July 2020:** Jaguar Health has completed the filing of an investigational new drug application (IND) with the U.S. Food and Drug Administration (FDA) for Mytesi® (crofelemer) for a new indication: prophylaxis and symptomatic relief of diarrhea in adult patients with solid tumors receiving targeted therapy with or without standard chemotherapy. Mytesi® is a novel, plant-based, chloride ion channel modulating anti-diarrhea medication previously FDA approved in 2012 for symptomatic relief of noninfectious diarrhea in adult patients with human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS) on antiretroviral therapy.[94]
- **August 2020:** Jaguar Health has 3 ongoing investigator-initiated trials for Mytesi® for the following indications: chronic idiopathic diarrhea in non-HIV adult patients, functional diarrhea in non-HIV adult patients, and diarrhea in human epidermal growth factor receptor 2 (HER2)-positive breast cancer patients. Results from these 3 trials are expected to be released in mid to late 2021.[95]

Recommendations

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

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[93] 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 12/2020. Last accessed 12/02/2020.

[94] Jaguar Health, Inc. Jaguar Health Subsidiary Napo Pharmaceuticals Completes Filing of Investigational New Drug Application for Crofelemer (Mytesi®) for Symptomatic Relief of Cancer Therapy-Related Diarrhea. *Accesswire*. Available online at: https://www.accesswire.com/596280/Jaguar-Health-Subsidiary-Napo-Pharmaceuticals-Completes-Filing-of-Investigational-New-Drug-Application-for-Crofelemer-Mytesi-for-Symptomatic-Relief-of-Cancer-TherapyRelated-Diarrhea. Issued 07/06/2020. Last Accessed 12/02/2020.

[95] Jaguar Health, Inc. Jaguar Health Provides Updates on Investigator-Initiated Trials of Crofelemer (Mytesi®). *Accesswire*. Available online at: https://www.accesswire.com/602346/Jaguar-Health-Provides-Updates-on-Investigator-Initiated-Trials-of-Crofelemer-Mytesi. Issued 08/19/2020. Last Accessed 12/02/2020.

Fiscal Year 2020 Annual Review of Naloxone Medications

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Naloxone injection and nasal spray are currently covered without prior authorization.

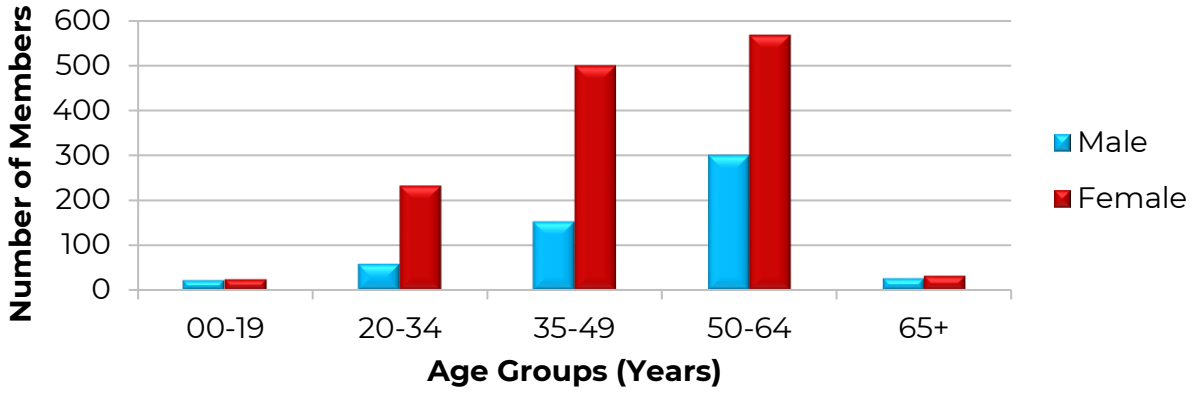
Utilization of Naloxone Medications: Fiscal Year 2020

Comparison of Fiscal Years: Pharmacy Claims

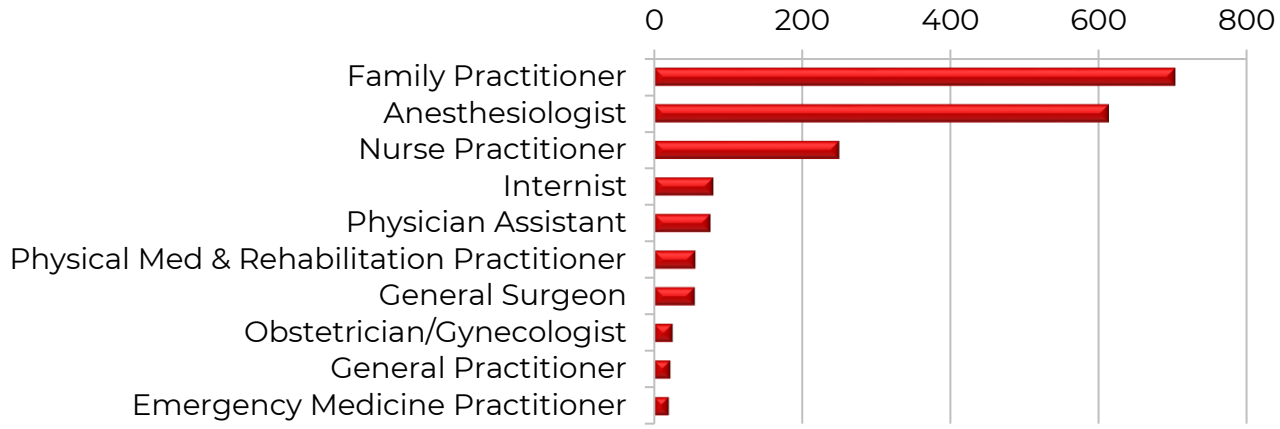
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	2,069	2,191	$273,817.98	$124.97	$4.16	4,429	65,787
2020	1,925	2,008	$260,359.68	$129.66	$4.27	4,026	60,998
% Change	**-7.0%**	**-8.4%**	**-4.9%**	**3.8%**	**2.6%**	**-9.1%**	**-7.3%**
Change	**-144**	**-183**	**-$13,458.30**	**$4.69**	**$0.11**	**-403**	**-4,789**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Demographics of Members Utilizing Naloxone Medications



Top Prescriber Specialties of Naloxone Medications by Number of Claims



Prior Authorization of Naloxone Medications

There were 5 prior authorization requests submitted for naloxone medications during fiscal year 2020. All 5 prior authorization requested were deemed incomplete, as naloxone medications currently do not require prior authorization.

Market News and Updates

Anticipated Patent Expiration(s):[96]

- Evzio® (naloxone auto-injector): March 2035
- Narcan® (naloxone nasal spray): March 2035

News:

- **July 2020:** The U.S. Food and Drug Administration (FDA) is requiring labeling changes to the *Prescribing Information* for opioid pain medications and opioid use disorder (OUD) medications regarding naloxone. The FDA recommends as a routine part of prescribing these medications, health care professionals should discuss the availability of naloxone with patients and caregivers, both when beginning and renewing treatment. The new labeling also recommends health care professionals consider prescribing naloxone when they prescribe medications to treat OUD and when prescribing opioid pain medications to those at an increased risk of opioid overdose.[97]

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[96] 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 01/2021. Last accessed 01/21/2021.

[97] U.S. FDA. FDA Requiring Labeling Changes for Opioid Pain Medicines, Opioid Use Disorder Medicines Regarding Naloxone. Available online at: https://www.fda.gov/news-events/press-announcements/fda-requiring-labeling-changes-opioid-pain-medicines-opioid-use-disorder-medicines-regarding. Issued 07/23/2020. Last accessed 01/21/2021.

Recommendations

The College of Pharmacy does not recommend any changes to the current naloxone medications coverage criteria at this time.

Utilization Details of Naloxone Medications: Fiscal Year 2020

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
NARCAN NASAL SPR 4MG	1,991	1,908	$259,477.00	$130.32	1.04	99.66%
NALOXONE INJ 1MG/ML	9	9	$515.52	$57.28	1	0.20%
NALOXONE INJ 0.4MG/ML	7	7	$201.35	$28.76	1	0.08%
NALOXONE INJ 0.4MG/ML	1	1	$165.81	$165.81	1	0.06%
TOTAL	**2,008**	**1,925***	**$260,359.68**	**$129.66**	**1.04**	**100.00%**

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

Fiscal Year 2020 Annual Review of Nasal Allergy Medications

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Nasal Allergy Medications		
Tier-1	**Tier-2**	**Tier-3**
beclomethasone (Beconase® AQ)	azelastine (Astelin®)	azelastine (Astepro®)
fluticasone (Flonase®)	beclomethasone (Qnasl® 80mcg)	azelastine/fluticasone (Dymista®)
		beclomethasone (Qnasl® 40mcg)
		ciclesonide (Omnaris®, Zetonna®)
		flunisolide (Nasalide®, Nasarel®)
		fluticasone (Veramyst®)
		fluticasone (Xhance®)*
		mometasone (Nasonex®)
		olopatadine (Patanase®)

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).
*Xhance®: Unique criteria applies.

Nasal Allergy Medications Tier-2 Approval Criteria:

1. Member must have failure with all Tier-1 medications defined as no beneficial response after at least 3 weeks use at the maximum recommended dose; or
2. Documented adverse effect or contraindication to all Tier-1 medications; and
3. For members 2 to 4 years of age, the age-appropriate, lower-tiered generic medications must be tried prior to the approval of higher tiered medications; and
4. Approvals will be for the duration of 3 months, except for members with chronic diseases such as asthma or chronic obstructive pulmonary disease (COPD), in which case authorizations will be for the duration of 1 year.

Nasal Allergy Medications Tier-3 Approval Criteria:

1. All Tier-2 criteria must be met; and

2. Member must have failure with all available Tier-2 medications defined as no beneficial response after at least 3 weeks use at the maximum recommended dose; or
3. Documented adverse effect or contraindication to all Tier-2 medications; and
4. For members 2 to 4 years of age, the age-appropriate, lower-tiered generic medications must be tried prior to the approval of higher tiered medications; and
5. Approvals will be for the duration of 3 months, except for members with chronic diseases such as asthma or COPD, in which case authorizations will be for the duration of 1 year.

Xhance® (Fluticasone Propionate Nasal Spray) Approval Criteria:

1. An FDA approved diagnosis of nasal polyps; and
2. A patient-specific, clinically significant reason why the member cannot use intranasal fluticasone, budesonide, mometasone, and/or other cost-effective therapeutic equivalent medication(s) must be provided; and
3. Current Tier structure rules will also apply.

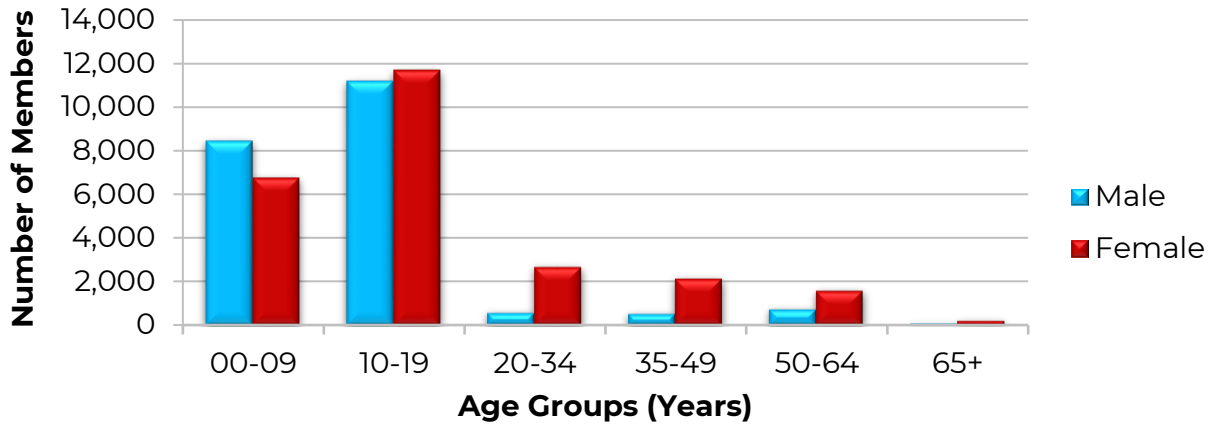
Utilization of Nasal Allergy Medications: Fiscal Year 2020

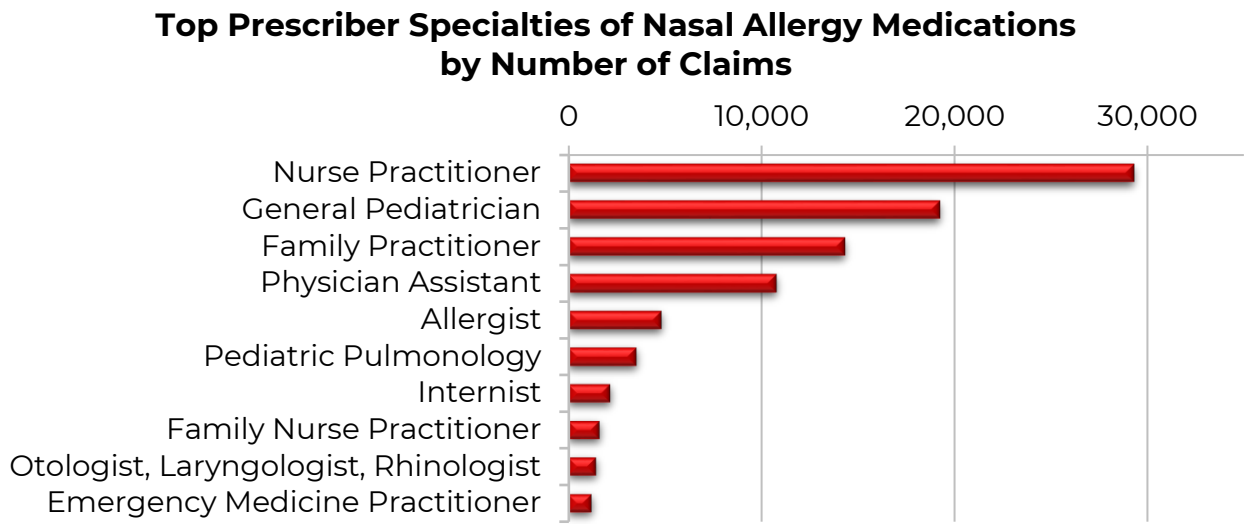
Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	51,311	96,828	$1,752,698.34	$18.10	$0.48	1,563,393	3,662,649
2020	46,607	92,367	$1,753,503.78	$18.98	$0.50	1,494,035	3,525,750
% Change	**-9.20%**	**-4.60%**	**0.00%**	**4.90%**	**4.20%**	**-4.40%**	**-3.70%**
Change	**-4,704**	**-4,461**	**$805.44**	**$0.88**	**$0.02**	**-69,358**	**-136,899**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

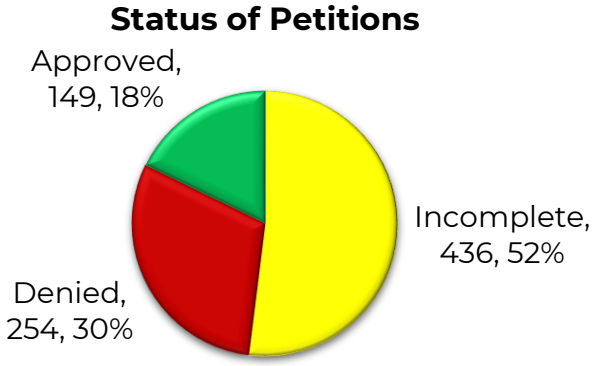
Demographics of Members Utilizing Nasal Allergy Medications





Prior Authorization of Nasal Allergy Medications

There were 839 prior authorization requests submitted for nasal allergy medications during fiscal year 2020. The following chart shows the status of the submitted petitions for fiscal year 2020.



Market News and Updates

Anticipated Patent Expiration(s):[98]

- Patanase® (olopatadine): August 2023
- Dymista® (azelastine/fluticasone): August 2026
- Omnaris® (ciclesonide): February 2028
- Zetonna® (ciclesonide): February 2028
- Astepro® (azelastine): June 2028
- Qnasl® (beclomethasone): October 2031
- Xhance® (fluticasone): July 2035

[98] 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 01/2021. Last Accessed 01/26/2021.

Recommendations

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

Utilization Details of Nasal Allergy Medications: Fiscal Year 2020

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 PRODUCTS						
FLUTICASONE SPR 50MCG	90,591	46,155	$1,332,127.26	$14.70	1.96	75.97%
BECONASE AQ SUS 0.042%	1,283	584	$376,069.41	$293.12	2.2	21.45%
SUBTOTAL	**91,874**	**46,552***	**$1,708,196.67**	**$18.59**	**1.97**	**97.42%**
TIER-2 PRODUCTS						
AZELASTINE SPR 0.1%	285	121	$5,861.30	$20.57	2.36	0.33%
QNASL AER 80MCG	65	15	$14,555.41	$223.93	4.33	0.83%
SUBTOTAL	**350**	**134***	**$20,416.71**	**$58.33**	**2.61**	**1.16%**
TIER-3 PRODUCTS						
DYMISTA SPR 137MCG/50MCG	61	13	$11,513.45	$188.75	4.69	0.66%
QNASL CHILD SPR 40MCG	25	6	$5,602.88	$224.12	4.17	0.32%
MOMETASONE SPR 50MCG	24	8	$1,333.25	$55.55	3	0.08%
AZEL/FLUTIC SPR 137MCG/50MCG	14	7	$2,360.80	$168.63	2	0.13%
XHANCE MIS 93MCG	6	2	$2,892.12	$482.02	3	0.16%
FLUNISOLIDE SPR 0.025%	6	1	$335.33	$55.89	6	0.02%
AZELASTINE SPR 0.15%	4	2	$156.54	$39.14	2	0.01%
ZETONNA AER 37MCG	2	1	$442.00	$221.00	2	0.03%
NASONEX SPR 50MCG/AC	1	1	$254.03	$254.03	1	0.01%
SUBTOTAL	**143**	**35***	**$24,890.40**	**$174.06**	**4.09**	**1.42%**
TOTAL	**92,367**	**46,607***	**$1,753,503.78**	**$18.98**	**1.98**	**100.00%**

AC = actuation; AER = aerosol; AQ = aqueous; AZEL/FLUTIC = azelastine/fluticasone; SPR = spray; SUS = suspension
*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Fiscal Year 2020 Annual Review of Northera® (Droxidopa)

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Northera® (Droxidopa) Approval Criteria:

1. An FDA approved diagnosis of symptomatic neurogenic orthostatic hypotension caused by primary autonomic failure (e.g., Parkinson's disease, multiple system atrophy, pure autonomic failure), dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy; and
2. Member must be 18 years of age or older; and
3. Member must have tried and failed 2 of the following medications at recommended dosing within the last 90 days or have a contraindication to all preferred medications:
   a. Midodrine; or
   b. Fludrocortisone; or
   c. Pyridostigmine; and
4. Initial approvals will be for the duration of 2 weeks of treatment only; and
5. Continued approvals will require the prescriber to provide information regarding improved member response/effectiveness of this medication to determine whether Northera® is continuing to provide a benefit; and
6. Continued approvals will be for the duration of 3 months. Each approval will require prescriber documentation of member response/ effectiveness to Northera®.

Utilization of Northera® (Droxidopa): Fiscal Year 2020

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	1	9	$134,578.75	$14,953.19	$498.44	4,860	270
2020	1	9	$145,107.00	$16,123.00	$537.43	4,860	270
% Change	**0.00%**	**0.00%**	**7.80%**	**7.80%**	**7.80%**	**0.00%**	**0.00%**
Change	**0**	**0**	**$10,528.25**	**$1,169.81**	**$38.99**	**0**	**0**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Demographics of Members Utilizing Northera® (Droxidopa)

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

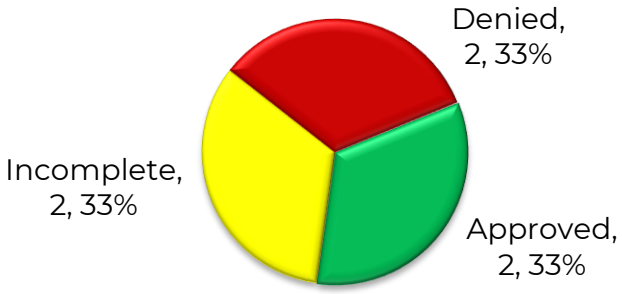
Top Prescriber Specialties of Northera® (Droxidopa) by Number of Claims

- The only prescriber specialty listed on paid pharmacy claims for Northera® (droxidopa) during fiscal year 2020 was cardiologist.

Prior Authorization of Northera® (Droxidopa)

There were 6 prior authorization requests submitted for Northera® (droxidopa) during fiscal year 2020. The following chart shows the status of the submitted petitions for fiscal year 2020.

Status of Petitions



Market News and Updates

Anticipated Exclusivity Expiration(s):[99]

- Northera® (droxidopa): February 2021

Recommendations

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

Utilization Details of Northera® (Droxidopa): Fiscal Year 2020

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
NORTHERA CAP 100MG	9	1	$145,107.00	$537.43	$16,123.00	100.00%
TOTAL	**9**	**1***	**$145,107.00**	**$537.43**	**$16,123.00**	**100.00%**

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

[99] 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 01/2021. Last accessed 01/26/2021.

Fiscal Year 2020 Annual Review of Nuedexta® (Dextromethorphan/Quinidine)

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Nuedexta® (Dextromethorphan/Quinidine) Approval Criteria:

1. An FDA approved diagnosis of pseudobulbar affect (PBA) secondary to a neurological condition (e.g., amyotrophic lateral sclerosis, multiple sclerosis, Parkinson's disease, stroke, traumatic brain injury); and
2. Documentation of the neurological condition must be submitted; and
3. Member must be 18 years of age or older; and
4. Nuedexta® must be prescribed by, or in consultation with, a neurologist or psychiatrist (or an advanced care practitioner with a supervising physician who is a neurologist or psychiatrist); and
5. Member must not have any contraindications to therapy [e.g., concomitant use with quinidine, quinine, or mefloquine; history of quinidine, quinine, or mefloquine-induced thrombocytopenia, hepatitis, or other hypersensitivity reactions; known hypersensitivity to dextromethorphan; use with a monoamine oxidase inhibitor (MAOI) or within 14 days of stopping an MAOI; prolonged QT interval, congenital long QT syndrome, history suggestive of torsades de pointes, or heart failure; complete atrioventricular (AV) block without implanted pacemaker, or at high risk of complete AV block; currently taking other drugs that both prolong QT interval and are metabolized by CYP2D6 (e.g., thioridazine, pimozide)]; and
6. Prescriber must document baseline number of PBA laughing or crying episodes per day; and
7. A quantity limit of 60 capsules per 30 days will apply; and
8. Initial approvals will be for the duration of 12 weeks. Reauthorizations may be granted if the prescriber documents the member is responding well to treatment as indicated by a reduction in the number of PBA episodes of laughing or crying per day compared to baseline. Current users must meet the revised approval criteria when reapplying for prior authorization continuation.

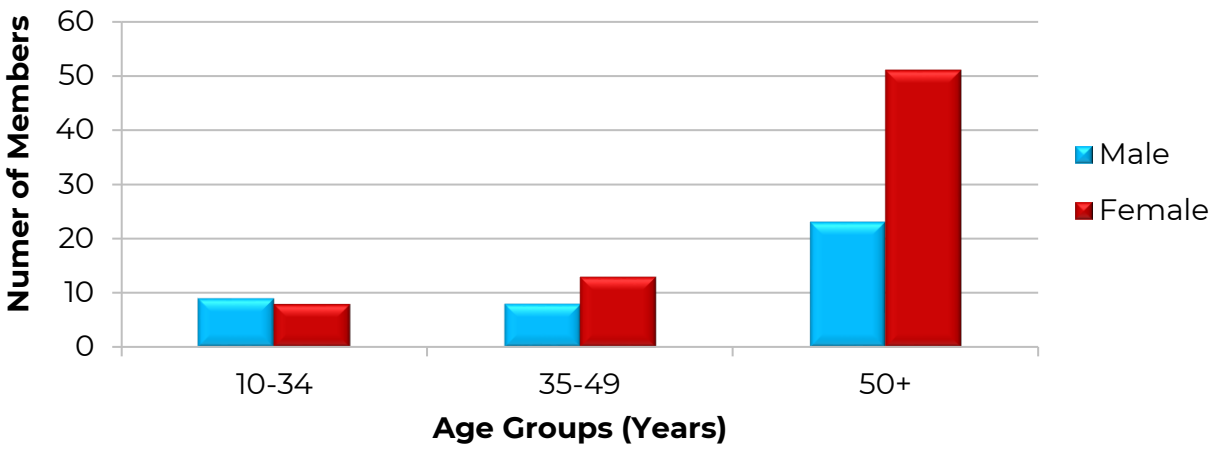
Utilization of Nuedexta® (Dextromethorphan/Quinidine): Fiscal Year 2020

Comparison of Fiscal Years: Pharmacy Claims

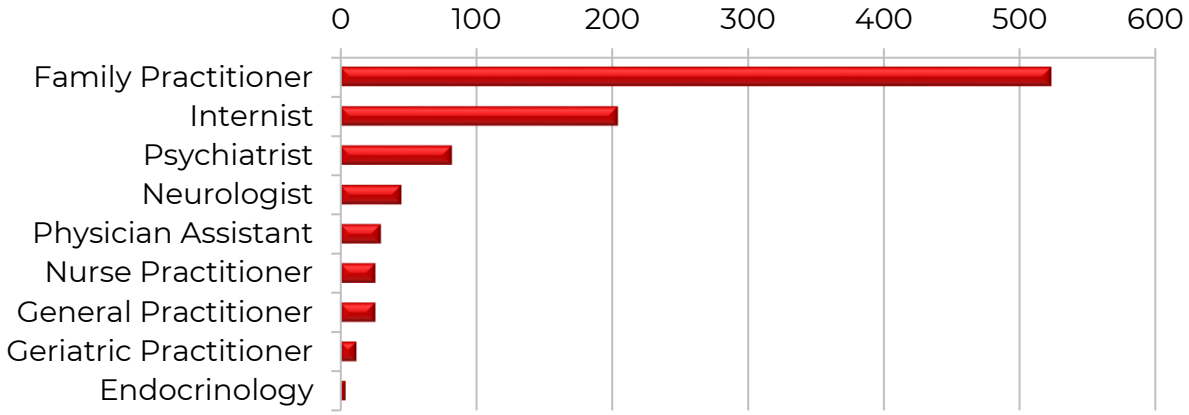
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	116	866	$827,763.95	$955.85	$34.37	46,164	24,081
2020	112	953	$991,419.23	$1,040.31	$37.00	51,278	26,796
% Change	**-3.40%**	**10.00%**	**19.80%**	**8.80%**	**7.70%**	**11.10%**	**11.30%**
Change	**-4**	**87**	**$163,655.28**	**$84.46**	**$2.63**	**5,114**	**2,715**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Demographics of Members Utilizing Nuedexta® (Dextromethorphan/Quinidine)

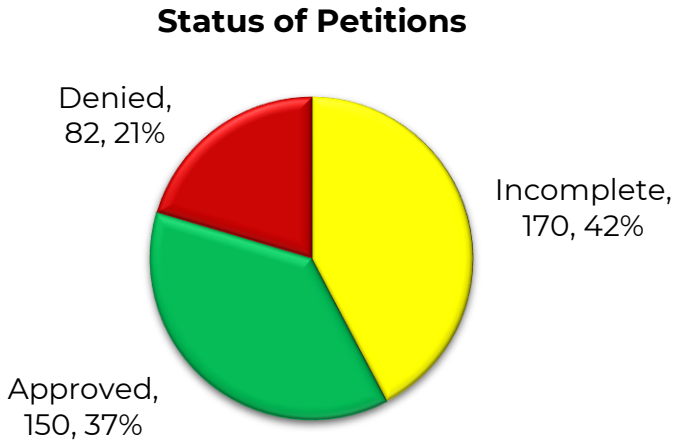


Top Prescriber Specialties of Nuedexta® (Dextromethorphan/Quinidine) by Number of Claims



Prior Authorization of Nuedexta® (Dextromethorphan/Quinidine)

There were 402 prior authorization requests submitted for Nuedexta® (dextromethorphan/quinidine) during fiscal year 2020. The following chart shows the status of the submitted petitions.



Market News and Updates

Anticipated Patent Expiration(s):[100]

- Nuedexta® (dextromethorphan/quinidine): August 2026

Recommendations

The College of Pharmacy does not recommend any changes to the current Nuedexta® (dextromethorphan/quinidine) prior authorization criteria at this time.

Utilization Details of Nuedexta® (Dextromethorphan/Quinidine): Fiscal Year 2020

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
DEXTROMETHORPHAN/QUINIDINE PRODUCTS						
NUEDEXTA CAP 20-10MG	953	112	$991,419.23	$1,040.31	8.51	100.00%
TOTAL	**953**	**112***	**$991,419.23**	**$1,040.31**	**8.51**	**100.00%**

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

[100] 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 01/2021. Last accessed 01/21/2021.

Fiscal Year 2020 Annual Review of Ocaliva® (Obeticholic Acid)

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Ocaliva® (Obeticholic Acid) Approval Criteria:

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

Utilization of Ocaliva® (Obeticholic Acid): Fiscal Year 2020

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	2	12	$79,125.24	$6,593.77	$219.79	360	360
2020	1	7	$48,419.60	$6,917.09	$230.57	210	210
% Change	**-50.00%**	**-41.70%**	**-38.80%**	**4.90%**	**4.90%**	**-41.70%**	**-41.70%**
Change	**-1**	**-5**	**-$30,705.64**	**$323.32**	**$10.78**	**-150**	**-150**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Demographics of Members Utilizing Ocaliva® (Obeticholic Acid)

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

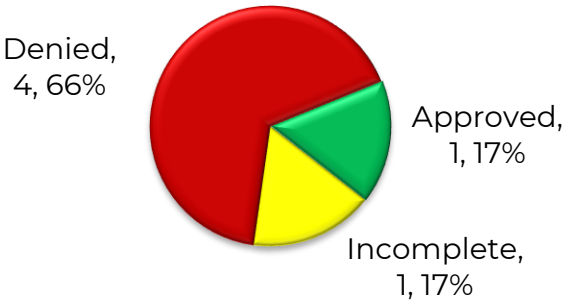
Top Prescriber Specialties of Ocaliva® (Obeticholic Acid) by Number of Claims

- The only prescriber specialty on paid pharmacy claims for Ocaliva® (obeticholic acid) during fiscal year 2020 was nurse practitioner. The nurse practitioner is supervised by a gastroenterologist.

Prior Authorization of Ocaliva® (Obeticholic Acid)

There were 6 prior authorization requests submitted for Ocaliva® (obeticholic acid) during fiscal year 2020. The following chart shows the status of the submitted petitions for fiscal year 2020.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[101]

- Ocaliva® (obeticholic acid): April 2036

News:

- **June 2020:** The U.S. Food and Drug Administration (FDA) issued a Complete Response Letter (CRL) regarding the New Drug Application (NDA) for obeticholic acid (OCA) for the treatment of fibrosis due to nonalcoholic steatohepatitis (NASH). The CRL indicated that, based on the data reviewed to date, the FDA has determined the predicted benefit of OCA based on a surrogate histopathologic endpoint remains uncertain and does not sufficiently outweigh the potential risks to support accelerated approval for the treatment of patients with liver fibrosis due to NASH. The FDA recommends Intercept submit additional post-interim analysis efficacy and safety data from the ongoing REGENERATE study in support of potential accelerated approval and that the long-term outcomes phase of the study should continue. According to the FDA draft guidance for NASH fibrosis, of the

[101] 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 01/2021. Last accessed 01/20/2021.

histologic features of NASH, fibrosis is considered the strongest predictor of adverse clinical outcomes, including liver-related death. There is currently no FDA approved therapy for NASH, which has become a leading cause of liver failure and resulting poor clinical outcomes.[102]

Recommendations

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

Utilization Details of Ocaliva® (Obeticholic Acid): Fiscal Year 2020

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
OCALIVA TAB 10MG	7	1	$48,419.60	$230.57	$6,917.09	100.00%
TOTAL	**7**	**1***	**$48,419.60**	**$230.57**	**$6,917.09**	**100.00%**

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

[102] Intercept Pharmaceuticals, Inc. Intercept Receives Complete Response Letter from FDA for Obeticholic Acid for the Treatment of Fibrosis due to NASH. *Globe Newswire*. Available online at: https://ir.interceptpharma.com/news-releases/news-release-details/intercept-receives-complete-response-letter-fda-obeticholic-acid. Issued 06/29/2020. Last accessed 01/28/2021.

Fiscal Year 2020 Annual Review of Ophthalmic Allergy Medications

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

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

OTC = over-the-counter
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).

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.

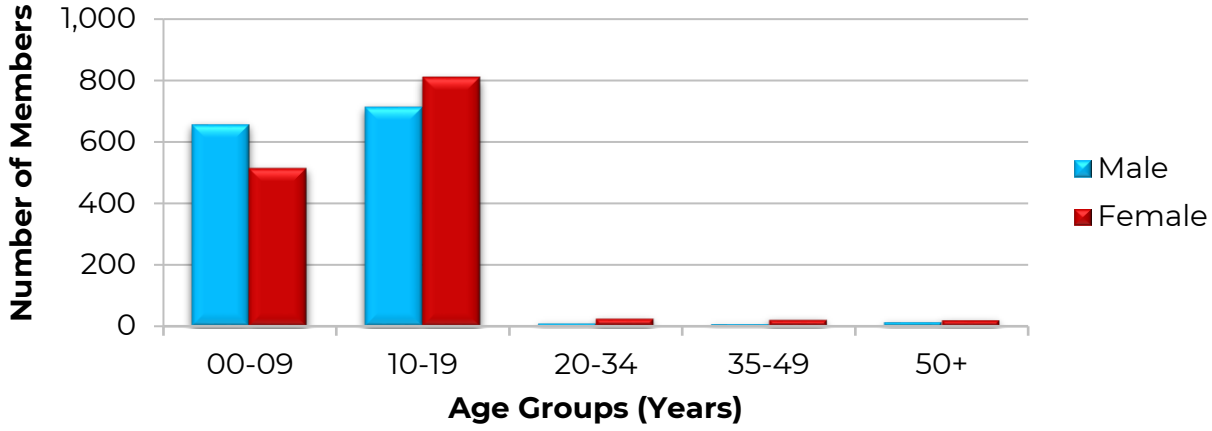
Utilization of Ophthalmic Allergy Medications: Fiscal Year 2020

Comparison of Fiscal Years

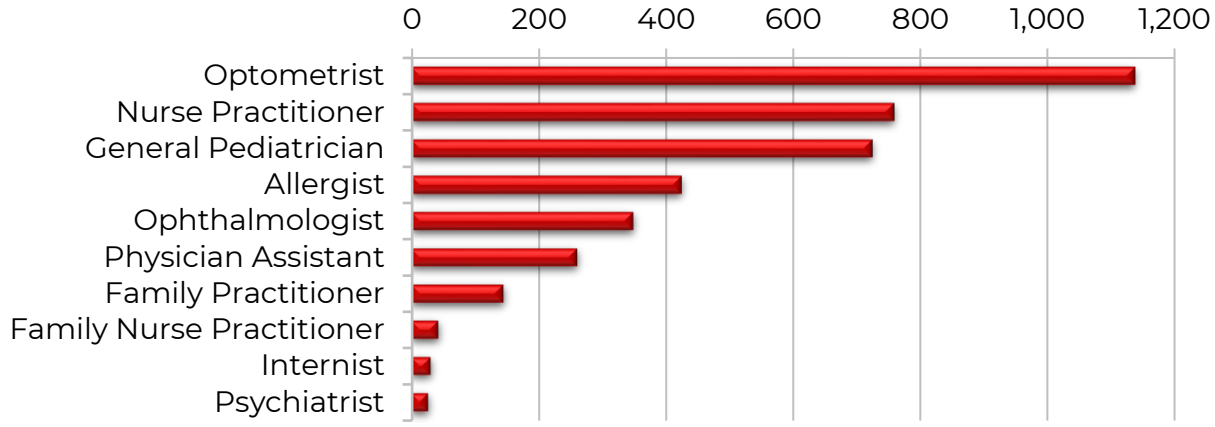
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	3,191	4,460	$81,852.53	$18.35	$0.56	29,019	145,998
2020	2,790	3,985	$70,470.19	$17.68	$0.55	25,812	128,462
% Change	**-12.60%**	**-10.70%**	**-13.90%**	**-3.70%**	**-1.80%**	**-11.10%**	**-12.00%**
Change	**-401**	**-475**	**-$11,382.34**	**-$0.67**	**-$0.01**	**-3,207**	**-17,536**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Demographics of Members Utilizing Ophthalmic Allergy Medications



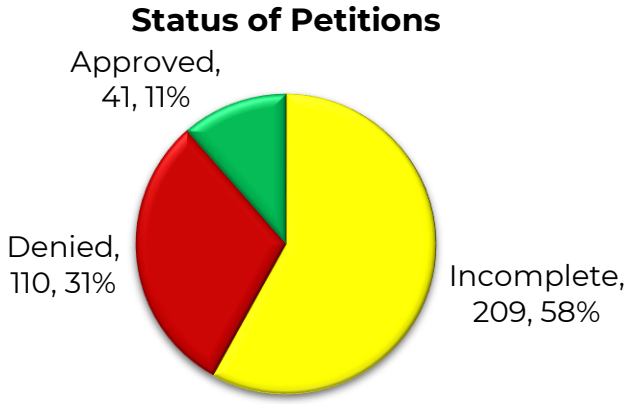
Top Prescriber Specialties of Ophthalmic Allergy Medications by Number of Claims



Prior Authorization of Ophthalmic Allergy Medications

There were 360 prior authorization requests submitted for ophthalmic allergy medications during fiscal year 2020. 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 2020.



Market News and Updates

Anticipated Patent Expiration(s):[103]

- Bepreve® (bepotastine): January 2025
- Lastacaft® (alcaftadine): December 2027
- Pataday® (olopatadine): May 2032
- Zerviate™ (cetirizine): January 2033

News:

- **February 2020:** The U.S. Food and Drug Administration (FDA) approved 2 formulations of olopatadine ophthalmic solution for over-the-counter (OTC) use through the Rx-to-OTC switch process. Pataday® Once Daily Relief (olopatadine 0.2%) and Pataday® Twice Daily Relief (olopatadine 0.1%) were marketed previously under the prescription brand names Pataday® and Patanol®, respectively. Both OTC formulations are indicated for the temporary relief of itchy eyes due to pollen, ragweed, grass, animal hair, and dander in patients 2 years of age or and older. Pataday® Twice Daily Relief is also indicated for the temporary relief of red eyes.[104]
- **March 2020:** Zerviate™ (cetirizine 0.24% ophthalmic solution) was launched by Eyevance Pharmaceuticals in March 2020. Zerviate™ was previously FDA approved in May 2017 for the treatment of ocular

[103] 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 01/2021. Last Accessed 01/26/2021.
[104] Alcon. Alcon to Launch Pataday®, the Eye Allergy Drop with the #1 Doctor-Prescribed Active Ingredient, Following FDA Approval of OTC Switch. Available online at: https://www.alcon.com/media-release/alcon-launch-pataday-eye-allergy-drop-1-doctor-prescribed-active-ingredient-following. Issued 02/17/2020. Last accessed 01/26/2021.

itching associated with allergic conjunctivitis in patients 2 years of age and older.[105]

- **July 2020:** The FDA approved Pataday® Once Daily Relief *Extra Strength* (olopatadine 0.7% ophthalmic solution) for OTC use through the Rx-to-OTC switch process. Formerly marketed under the prescription brand name Pazeo®, the OTC product is indicated for the temporary relief of itchy eyes due to pollen, ragweed, grass, animal hair, and dander. National retail availability for the OTC formulation is expected in February 2021.[106]

Pipeline:

- **Reproxalap:** Aldeyra 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 are elevated in ocular and systemic inflammatory diseases. In January 2021, Aldeyra announced positive top-line results from the Phase 3 TRANQUILITY study of reproxalap for dry eye disease. The Phase 3 ALLEVIATE study in patients with allergic conjunctivitis is also ongoing.[107,108]

Recommendations

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

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[105] Park B. Zerviate™ Ophthalmic Solution Now Available for Allergic Conjunctivitis. *MPR*. Available online at: https://www.empr.com/home/news/zerviate-ophthalmic-solution-now-available-for-allergic-conjunctivitis/. Issued 03/31/2020. Last accessed 01/26/2021.

[106] Park B. Olopatadine 0.7% Eye Drops Approved for Sale Over-the-Counter. *MPR*. Available online at: https://www.empr.com/home/news/olopatadine-pataday-ophthalmic-solution-pazeo-over-the-counter-otc/. Issued 07/14/2020. Last accessed 01/28/2021.

[107] Aldeyra Therapeutics, Inc. Aldeyra Pipeline. Available online at: https://www.aldeyra.com/pipeline-disease-areas/. Last accessed 01/26/2021.

[108] Aldeyra Therapeutics, Inc. Aldeyra Therapeutics Announces Positive Top-Line Symptom and Sign Results from Run-In Cohort of Phase 3 TRANQUILITY Trial in Dry Eye Disease. Available online at: https://ir.aldeyra.com/news-releases/news-release-details/aldeyra-therapeutics-announces-positive-top-line-symptom-and. Issued 01/07/2021. Last accessed 01/26/2021.

Utilization Details of Ophthalmic Allergy Medications: Fiscal Year 2020

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 PRODUCTS						
KETOTIFEN PRODUCTS						
KETOTIFEN FUM DRO 0.025% OP	2,571	1,966	$39,056.91	$15.19	1.31	55.42%
ALAWAY DRO 0.025% OP	870	545	$12,438.05	$14.30	1.6	17.65%
EYE ITCH RELIEF DRO 0.025% OP	8	8	$113.25	$14.16	1	0.16%
ALAWAY CHILD DRO 0.025% OP	7	7	$108.27	$15.47	1	0.15%
EYE ITCH SOL RELIEF 0.025% OP	7	7	$120.73	$17.25	1	0.17%
SUBTOTAL	**3,463**	**2,533**	**$51,837.21**	**$14.97**	**1.37**	**73.56%**
CROMOLYN PRODUCTS						
CROMOLYN SOD SOL 4% OP	324	240	$5,299.37	$16.36	1.35	7.52%
SUBTOTAL	**324**	**240**	**$5,299.37**	**$16.36**	**1.35**	**7.52%**
TIER-1 SUBTOTAL	**3,787**	**2,747***	**$57,136.58**	**$15.09**	**1.38**	**81.08%**
TIER-2 PRODUCTS						
OLOPATADINE PRODUCTS						
OLOPATADINE DRO 0.1%	108	31	$2,436.90	$22.56	3.48	3.46%
PAZEO DRO 0.7%	46	11	$9,646.72	$209.71	4.18	13.69%
SUBTOTAL	**154**	**42**	**$12,083.62**	**$78.47**	**3.67**	**17.15%**
AZELASTINE PRODUCTS						
AZELASTINE DRO 0.05%	39	13	$718.56	$18.42	3	1.02%
SUBTOTAL	**39**	**13**	**$718.56**	**$18.42**	**3**	**1.02%**
EPINASTINE PRODUCTS						
EPINASTINE DRO 0.05%	1	1	$39.66	$39.66	1	0.06%
SUBTOTAL	**1**	**1**	**$39.66**	**$39.66**	**1**	**0.06%**
TIER-2 SUBTOTAL	**194**	**53***	**$12,841.84**	**$66.20**	**3.66**	**18.22%**
TIER-3 PRODUCTS						
OLOPATADINE PRODUCTS						
OLOPATADINE SOL 0.2%	3	3	$63.93	$21.31	1	0.09%
SUBTOTAL	**3**	**3**	**$63.93**	**$21.31**	**1**	**0.09%**
BEPOTASTINE PRODUCTS						
BEPREVE DRO 1.5%	1	1	$427.84	$427.84	1	0.61%
SUBTOTAL	**1**	**1**	**$427.84**	**$427.84**	**1**	**0.61%**
TIER-3 SUBTOTAL	**4**	**4***	**$491.77**	**$122.94**	**1**	**0.70%**
TOTAL	**3,985**	**2,790***	**$70,470.19**	**$17.68**	**1.43**	**100.00%**

DRO = drops; FUM = fumarate; OP = ophthalmic; SOD = sodium; SOL = solution
*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Fiscal Year 2020 Annual Review of Ophthalmic Antibiotic Medications

Oklahoma Health Care Authority
Fiscal Year 2020 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*	neomycin/polymyxin B/hydrocortisone (Cortisporin®) susp
	sulfacetamide/prednisolone (Blephamide®) susp & oint
	tobramycin/dexamethasone (Tobradex®) oint
	tobramycin/dexamethasone (Tobradex® ST) oint
	tobramycin/loteprednol (Zylet®) susp

HC= hydrocortisone; oint= ointment; susp= suspension
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).
*Brand preferred

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 optometrists/ophthalmologists; or
4. When 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 optometrists/ophthalmologists; or
4. When requested medication is being used for pre/post-operative prophylaxis.

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

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

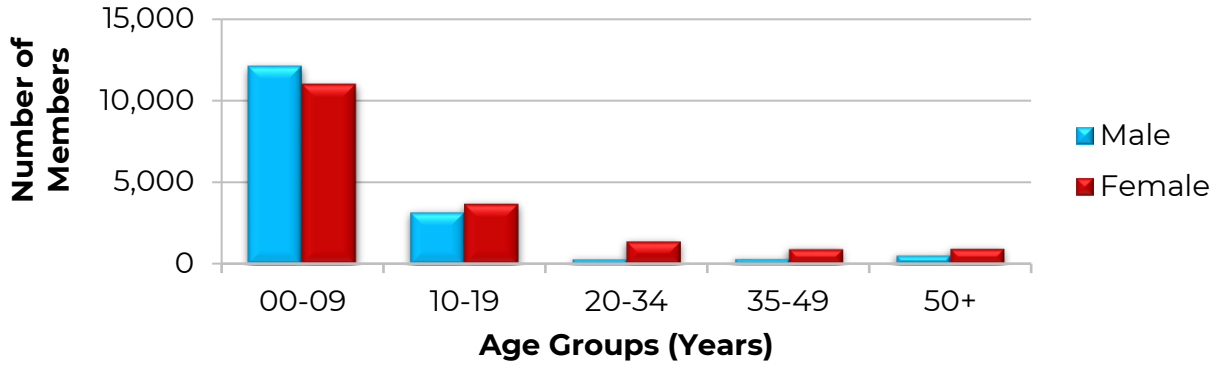
Utilization of Ophthalmic Antibiotic Medications: Fiscal Year 2020

Comparison of Fiscal Years

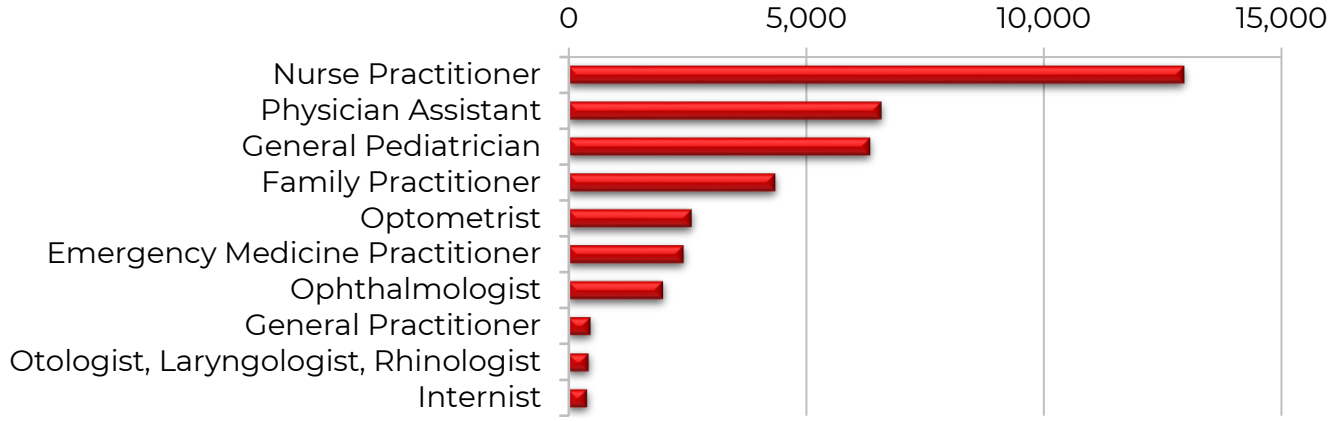
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	37,903	44,263	$937,306.34	$21.18	$1.61	297,843	581,393
2020	34,496	40,095	$891,990.76	$22.25	$1.67	268,575	535,431
% Change	**-9.00%**	**-9.40%**	**-4.80%**	**5.10%**	**3.70%**	**-9.80%**	**-7.90%**
Change	**-3,407**	**-4,168**	**-$45,315.58**	**$1.07**	**$0.06**	**-29,268**	**-45,962**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Demographics of Members Utilizing Ophthalmic Antibiotic Medications



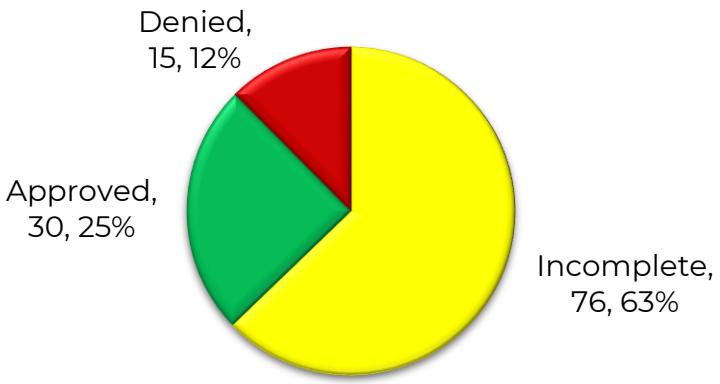
Top Prescriber Specialties of Ophthalmic Antibiotic Medications by Number of Claims



Prior Authorization of Ophthalmic Antibiotic Medications

There were 121 prior authorization requests submitted for ophthalmic antibiotic medications during fiscal year 2020. The following chart shows the status of the submitted petitions for fiscal year 2020.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[109]

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

[109] 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 01/2021. Last Accessed 01/28/2021.

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 2020

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
OPHTHALMIC ANTIBIOTIC LIQUIDS						
TIER-1 PRODUCTS						
POLYMYXIN B/TRIMETHOPRIM SOL	11,770	11,271	$195,436.89	$16.60	1.04	21.91%
OFLOXACIN DRO 0.3% OP	7,293	6,735	$173,249.72	$23.76	1.08	19.42%
TOBRAMYCIN SOL 0.3% OP	2,970	2,822	$48,951.87	$16.48	1.05	5.49%
GENTAMICIN SOL 0.3% OP	2,924	2,768	$45,023.36	$15.40	1.06	5.05%
CIPROFLOXACIN SOL 0.3% OP	1,432	1,351	$24,175.10	$16.88	1.06	2.71%
SULFACETAMIDE SOD SOL 10% OP	921	889	$36,647.86	$39.79	1.04	4.11%
SOD SULFACETAMIDE SOL 10% OP	246	240	$11,248.16	$45.72	1.03	1.26%
TRIMETHOPRIM SOL POLYMYXIN	88	87	$1,393.75	$15.84	1.01	0.16%
NEO/POLY/GRAMICIDIN SOL OP	55	51	$2,838.66	$51.61	1.08	0.32%
BLEPH-10 SOL 10% OP	22	22	$680.52	$30.93	1	0.08%
TIER-1 SUBTOTAL	**27,721**	**25,244***	**$539,645.89**	**$19.47**	**1.10**	**60.50%**
TIER-3 PRODUCTS						
MOXIFLOXACIN SOL HCL 0.5%	378	261	$11,259.71	$29.79	1.45	1.26%
BESIVANCE SUS 0.6%	66	57	$11,581.68	$175.48	1.16	1.30%
GATIFLOXACIN SOL 0.5%	35	29	$1,855.41	$53.01	1.21	0.21%
AZASITE SOL 1%	3	3	$627.38	$209.13	1	0.07%
MOXEZA SOL 0.5%	3	1	$477.09	$159.03	3	0.05%
TIER-3 SUBTOTAL	**485**	**344***	**$25,801.27**	**$53.20**	**1.41**	**2.89%**
LIQUID SUBTOTAL	**28,206**	**25,516***	**$565,447.16**	**$20.05**	**1.11**	**63.39%**
OPHTHALMIC ANTIBIOTIC OINTMENTS						
TIER-1 PRODUCTS						
ERYTHROMYCIN OIN 5MG/GM	8,523	7,783	$176,273.13	$20.68	1.1	19.76%
BACITRACIN/POLYMYXIN OIN OP	131	122	$2,896.60	$22.11	1.07	0.32%
TOBREX OIN 0.3% OP	62	50	$13,308.25	$214.65	1.24	1.49%
GENTAK OIN 0.3% OP	46	45	$1,203.18	$26.16	1.02	0.13%
NEO/BACITRACIN/POLY OIN OP	24	24	$1,001.98	$41.75	1	0.11%
POLYCIN OIN OP	13	13	$289.69	$22.28	1	0.03%
AK-POLY-BAC OIN OP	3	3	$67.94	$22.65	1	0.01%
NEO-POLYCIN OIN OP	2	2	$81.20	$40.60	1	0.01%
TIER-1 SUBTOTAL	**8,804**	**8,018***	**$195,121.97**	**$22.16**	**1.10**	**21.87%**
TIER-2 PRODUCTS						
BACITRACIN OIN OP	25	15	$2,571.23	$102.85	1.67	0.29%
CILOXAN OIN 0.3% OP	2	2	$434.24	$217.12	1	0.05%
TIER-2 SUBTOTAL	**27**	**17***	**$3,005.47**	**$111.31**	**1.59**	**0.34%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
OINTMENT SUBTOTAL	**8,831**	**8,030***	**$198,127.44**	**$22.44**	**1.10**	**22.21%**
OPHTHALMIC ANTIBIOTIC/STEROID COMBINATION PRODUCTS						
TIER-1 PRODUCTS						
NEO/POLYMYXIN/DEX SUS 0.1% OP	1,733	1,598	$36,829.93	$21.25	1.08	4.13%
TOBRAMYCIN/DEX SUS 0.3-0.1%	602	552	$46,160.27	$76.68	1.09	5.17%
NEO/POLY/DEX OIN 0.1% OP	547	470	$11,980.91	$21.90	1.16	1.34%
TOBRADEX SUS 0.3-0.1%	41	30	$6,733.04	$164.22	1.37	0.75%
SULFACETAMIDE/PRED NA SOL OP	13	10	$278.03	$21.39	1.3	0.03%
TIER-1 SUBTOTAL	**2,936**	**2,584***	**$101,982.18**	**$34.74**	**1.14**	**11.43%**
TIER-2 PRODUCTS						
TOBRADEX OIN 0.3-0.1%	94	81	$20,329.97	$216.28	1.16	2.28%
ZYLET SUS 0.5-0.3%	17	17	$4,400.30	$258.84	1	0.49%
TOBRADEX ST SUS 0.3-0.05	5	5	$1,052.58	$210.52	1	0.12%
NEO/POLY/HC SUS OP	4	4	$553.91	$138.48	1	0.06%
NEO/POLY/BAC/HC OIN OP	2	2	$97.22	$48.61	1	0.01%
TIER-2 SUBTOTAL	**122**	**109***	**$26,433.98**	**$216.67**	**1.12**	**2.96%**
COMBINATION SUBTOTAL	**3,058**	**2,669***	**$128,416.16**	**$41.99**	**1.15**	**14.40%**
TOTAL	**40,095**	**34,496***	**$891,990.76**	**$22.25**	**1.16**	**100.00%**

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

Fiscal Year 2020 Annual Review of Otic Anti-Infective Medications

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Otic Anti-Infective Medications		
Tier-1	**Tier-2**	**Special PA**
acetic acid (VoSol®, Acetasol®)	ciprofloxacin 0.2% (Cetraxal®)	acetic acid/HC (Acetasol® HC, VoSol® HC)
ciprofloxacin/dexamethasone (Ciprodex®)	ciprofloxacin/fluocinolone (Otovel®)	ciprofloxacin 6% (Otiprio®)
ciprofloxacin/HC (Cipro® HC)	finafloxacin (Xtoro™)	
neomycin/colistin/HC/ thonzonium (Coly-Mycin® S)	neomycin/polymyxin B/HC (Cortisporin®, Pediotic®)	
	ofloxacin (Floxin® Otic)	

HC = hydrocortisone; PA = prior authorization
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).

Otic Anti-Infective Medications Tier-2 Approval Criteria:

1. Member must have an adequate 14-day trial of at least 2 Tier-1 medications; or
2. Approval may be granted if there is a unique FDA approved indication not covered by Tier-1 medications or infection by an organism not known to be covered by any of the Tier-1 medications.

Acetasol® HC and VoSol® HC (Acetic Acid/Hydrocortisone) Approval Criteria:

1. Diagnosis of acute otitis externa; and
2. Member must have recent trials (within the last 6 months) with all other commonly used topical otic anti-infectives that have failed to resolve infection; or
3. Allergy to all available products and failure of acetic acid alone.

Otiprio® (Ciprofloxacin 6% Otic Suspension) Approval Criteria:

1. An FDA approved indication of 1 of the following:
   a. For the treatment of bilateral otitis media with effusion in members undergoing tympanostomy tube placement; or
   b. For the treatment of acute otitis externa due to *Pseudomonas aeruginosa (P. aeruginosa)* or *Staphylococcus aureus (S. aureus)*; and
2. Member must be 6 months of age or older; and
3. Otiprio® must be administered by a health care professional; and

4. A patient-specific, clinically significant reason why appropriate lower tiered otic anti-infective medications cannot be used must be provided; and
5. A quantity limit of 1 vial per treatment course will apply.

Utilization of Otic Anti-Infective Medications: Fiscal Year 2020

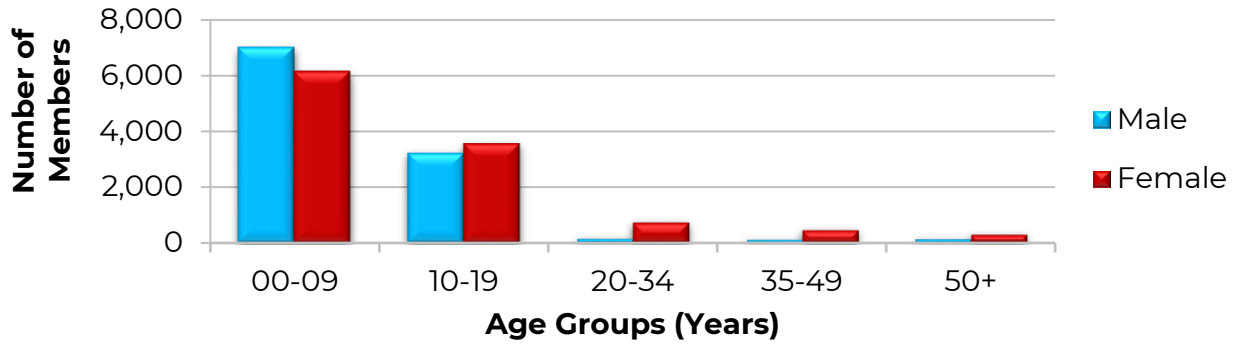
Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	22,270	27,447	$5,975,573.16	$217.71	$19.99	209,205	298,880
2020	21,829	26,435	$6,161,353.31	$233.08	$21.09	200,980	292,133
% Change	**-2.00%**	**-3.70%**	**3.10%**	**7.10%**	**5.50%**	**-3.90%**	**-2.30%**
Change	**-441**	**-1,012**	**$185,780.15**	**$15.37**	**$1.10**	**-8,225**	**-6,747**

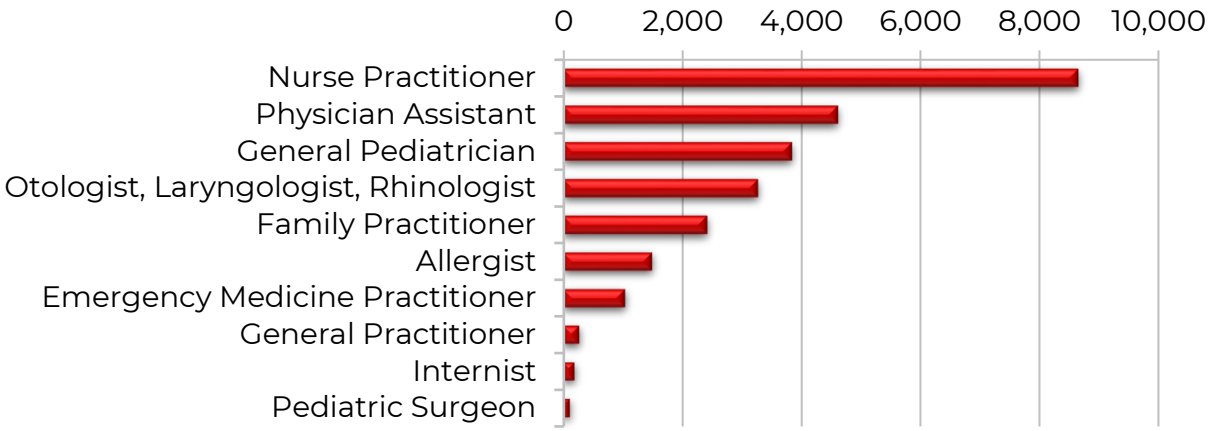
*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

- Please note: Some Tier-1 products participate in supplemental rebates; therefore, costs shown do not reflect net costs.

Demographics of Members Utilizing Otic Anti-Infective Medications

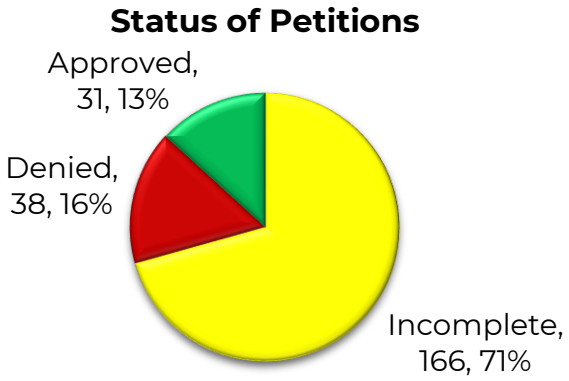


Top Prescriber Specialties of Otic Anti-Infective Medications by Number of Claims



Prior Authorization of Otic Anti-Infective Medications

There were 235 prior authorization requests submitted for otic anti-infective medications during fiscal year 2020. The following chart shows the status of the submitted petitions for fiscal year 2020.



Market News and Updates

Anticipated Patent Expiration(s):[110]

- Ciprodex® (ciprofloxacin/dexamethasone): June 2025
- Otovel® (ciprofloxacin/fluocinolone): March 2030
- Xtoro™ (finafloxacin): November 2033
- Otiprio® (ciprofloxacin): July 2035

News:

- **August 2020:** The first generic equivalents of Ciprodex® (ciprofloxacin 0.3%/dexamethasone 0.1%) were launched in August 2020 by Dr. Reddy's Laboratories and Sandoz. The generic formulations are available as 7.5mL otic suspensions for the treatment of middle and outer ear bacterial infections.[111,112]

Recommendations

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

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[110] 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 01/2021. Last Accessed 01/29/2021.

[111] Sandoz, Inc. Sandoz Launches Ciprofloxacin + Dexamethasone Otic Suspension in U.S. for Treatment of Middle and Outer Ear Bacterial Infections. Available online at: https://www.us.sandoz.com/news/media-releases/sandoz-launches-ciprofloxacin-dexamethasone-otic-suspension-us-treatment-middle. Issued 08/10/2020. Last accessed 01/29/2021.

[112] Park B. Generic Version of Ciprodex® Otic Suspension Now Available. *MPR*. Available online at: https://www.empr.com/home/news/ciprofloxacin-ciprodex-generic-otic-suspension-fluoroquinolone-antibacterial/. Issued 08/12/2020. Last accessed 01/29/2021.

Utilization Details of Otic Anti-Infective Medications: Fiscal Year 2020

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 PRODUCTS						
CIPRODEX SUS 0.3-0.1%	25,701	21,267	$6,009,599.13	$233.83	1.21	97.54%
CIPRO HC SUS OTIC 0.2-1%	344	326	$105,369.96	$306.31	1.06	1.71%
ACETIC ACID SOL 2% OTIC	188	177	$4,743.39	$25.23	1.06	0.08%
CORTISPORIN SUS-TC 0.33-0.3-1-0.05%	153	141	$35,185.01	$229.97	1.09	0.57%
COLY-MYCIN S SUS 0.33-0.3-1-0.05%	21	18	$4,921.92	$234.38	1.17	0.08%
SUBTOTAL	**26,407**	**21,827***	**$6,159,819.41**	**$233.26**	**1.21**	**99.98%**
TIER-2 PRODUCTS						
OFLOXACIN DRO 0.3% OTIC	11	10	$354.63	$32.24	1.1	0.01%
NEO/POLY/HC SOL 1% OTIC	8	4	$554.82	$69.35	2	0.01%
NEO/POLY/HC SUS 1% OTIC	8	7	$519.41	$64.93	1.14	0.01%
CIPROFLOXACIN SOL 0.2%	1	1	$105.04	$105.04	1	0.00%
SUBTOTAL	**28**	**22***	**$1,533.90**	**$54.78**	**1.27**	**0.02%**
TOTAL	**26,435**	**21,829***	**$6,161,353.31**	**$233.08**	**1.21**	**100.00%**

DRO = drops; HC = hydrocortisone; NEO = neomycin; POLY = polymyxin; SOL = solution; SUS = suspension

*Total number of unduplicated utilizing members.

Please note: Tier-1 products may participate in supplemental rebates; therefore, costs shown do not reflect net costs.

Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Fiscal Year 2020 Annual Review of Pancreatic Enzymes

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Pancreaze®, Pertzye®, and Viokace® Approval Criteria:

1. An FDA approved diagnosis of pancreatic insufficiency; and
2. Documented trials of inadequate response to Creon® and Zenpep® or a patient-specific, clinically significant reason why the member cannot use Creon® and Zenpep® must be provided.

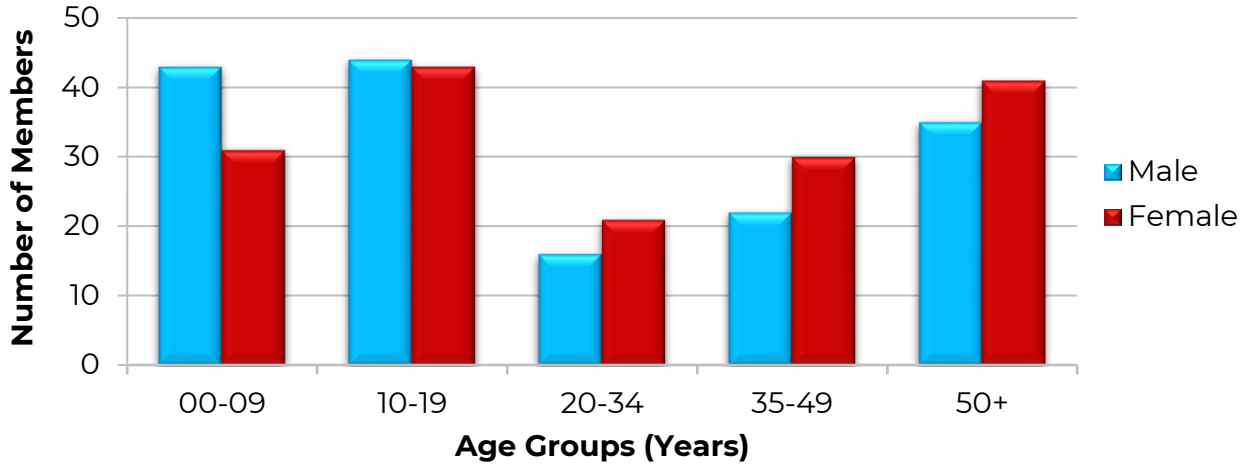
Utilization of Pancreatic Enzymes: Fiscal Year 2020

Comparison of Fiscal Years

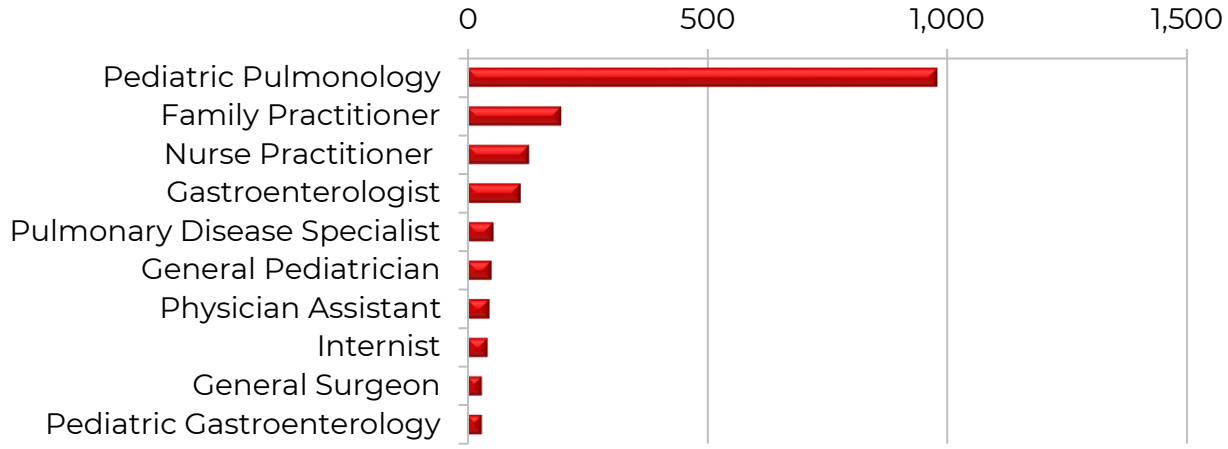
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	310	1,689	$3,029,521.15	$1,793.68	$62.61	577,898	48,391
2020	326	1,749	$3,259,354.28	$1,863.55	$65.51	591,434	49,754
% Change	**5.2%**	**3.6%**	**7.6%**	**3.9%**	**4.6%**	**2.3%**	**2.8%**
Change	**16**	**60**	**$229,833.13**	**$69.87**	**$ 2.90**	**13,536**	**1,363**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Demographics of Members Utilizing Pancreatic Enzymes



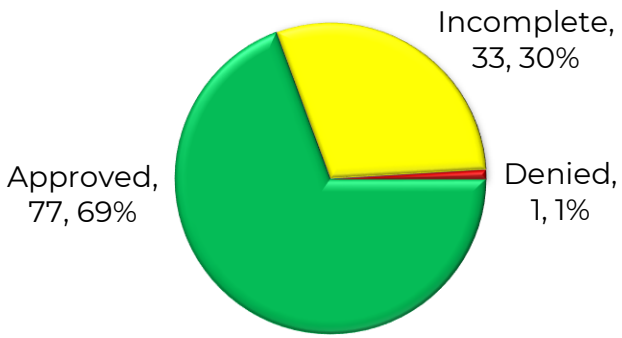
Top Prescriber Specialties of Pancreatic Enzymes by Number of Claims



Prior Authorization of Pancreatic Enzymes

There were 111 prior authorization requests submitted for pancreatic enzymes during fiscal year 2020. The following chart shows the status of the submitted petitions for fiscal year 2020.

Status of Petitions



Market News and Updates

News:

- **April 2020:** The U.S Food and Drug Administration (FDA) has the authority to approve drugs and biological products under the Federal Food, Drug, and Cosmetic (FD&C) Act and the Public Health Service (PHS) Act. The FD&C Act pertains to prescription drugs and over-the-counter (OTC) products, while the PHS Act applies to biologic products, such as therapeutic protein products. Historically, pancreatic enzymes have been approved through a New Drug Application (NDA) under the FD&C Act. In the Biologics Price Competition and Innovation (BPCI) Act of 2009, there was a provision that required these products to transition

from the FD&C Act to the PHS Act. Pancreatic enzymes products will now need to be submitted under a biologic license application (BLA) under the PHS Act for approvals.[113]

Recommendations

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

[113] U.S. Food and Drug Administration (FDA). Information for Patients About Regulatory Changes for Certain Biological Product Medications. Available online at: https://www.fda.gov/media/135341/download. Last Accessed 01/26/2021.

Utilization Details of Pancreatic Enzymes: Fiscal Year 2020

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
CREON®						
CREON CAP 24000U	312	61	$774,841.37	$2,483.47	5.11	23.77%
CREON CAP 36000U	294	78	$672,598.06	$2,287.75	3.77	20.64%
CREON CAP 12000U	256	51	$207,306.21	$809.79	5.02	6.36%
CREON CAP 6000U	67	17	$49,621.28	$740.62	3.94	1.52%
CREON CAP 3000U	20	8	$4,639.31	$231.97	2.50	0.14%
SUBTOTAL	**949**	**215**	**$1,709,006.23**	**$1,800.85**	**4.41**	**52.43%**
ZENPEP®						
ZENPEP CAP 25000U	116	22	$376,357.63	$3,244.46	5.27	11.55%
ZENPEP CAP 5000U	95	19	$82,778.09	$871.35	5.00	2.54%
ZENPEP CAP 40000U	90	22	$286,239.78	$3,180.44	4.09	8.78%
ZENPEP CAP 10000U	86	17	$64,263.36	$747.25	5.06	1.97%
ZENPEP CAP 20000U	84	18	$119,485.91	$1,422.45	4.67	3.67%
ZENPEP CAP 15000U	45	10	$70,928.63	$1,576.19	4.50	2.18%
ZENPEP CAP 3000U	4	3	$1,442.09	$360.52	1.33	0.04%
SUBTOTAL	**520**	**111**	**$1,001,495.49**	**$1,925.95**	**4.68**	**30.73%**
PERTZYE®						
PERTZYE CAP 16000U	113	19	$210,827.03	$1,865.73	5.95	6.47%
PERTZYE CAP 24000U	74	14	$278,506.74	$3,763.60	5.29	8.54%
PERTZYE CAP 8000U	53	8	$28,822.79	$543.83	6.63	0.88%
PERTZYE CAP 4000U	6	2	$8,088.72	$1,348.12	3.00	0.25%
SUBTOTAL	**246**	**43**	**$526,245.28**	**$2,139.21**	**5.72**	**16.14%**
VIOKACE®						
VIOKACE TAB 10440U	15	3	$12,572.36	$838.16	5.00	0.39%
VIOKACE TAB 20880U	3	2	$2,353.39	$784.46	1.50	0.07%
SUBTOTAL	**18**	**5**	**$14,925.75**	**$829.21**	**3.60**	**0.46%**
PANCREAZE®						
PANCREAZE CAP 10500U	10	1	$3,040.56	$304.06	10	0.09%
PANCREAZE CAP 4200U	3	1	$959.01	$319.67	3	0.03%
PANCREAZE CAP 21000U	3	1	$3,681.96	$1,227.32	3	0.11%
SUBTOTAL	**16**	**3**	**$7,681.53**	**$480.10**	**5.33**	**0.23%**
TOTAL	**1,749**	**326***	**$3,259,354.28**	**$1,863.55**	**5.37**	**100.00%**

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

Fiscal Year 2020 Annual Review of Parathyroid Medications

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Hectorol® (Doxercalciferol Capsule) Approval Criteria:

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

Natpara® (Parathyroid Hormone) Approval Criteria:

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

Parsabiv® (Etelcalcetide Injection) Approval Criteria:

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

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

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

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

Zemplar® (Paricalcitol Capsules) Approval Criteria:

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

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

Utilization of Parathyroid Medications: Fiscal Year 2020

Comparison of Fiscal Years: Calcimimetics and Vitamin D Analogs

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	459	2,071	$841,981.31	$406.56	$10.71	82,888	78,640
2020	436	1,996	$523,356.13	$262.20	$6.56	84,505	79,770
% Change	**-5.00%**	**-3.60%**	**-37.80%**	**-35.50%**	**-38.70%**	**2.00%**	**1.40%**
Change	**-23**	**-75**	**-$318,625.18**	**-$144.36**	**-$4.15**	**1,617**	**1,130**

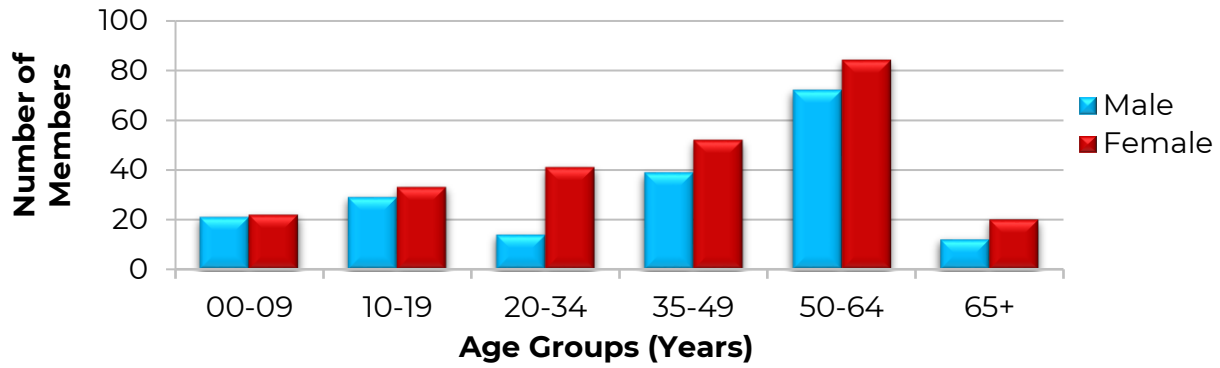
*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Comparison of Fiscal Years: Natpara® (Parathyroid Hormone Injection)

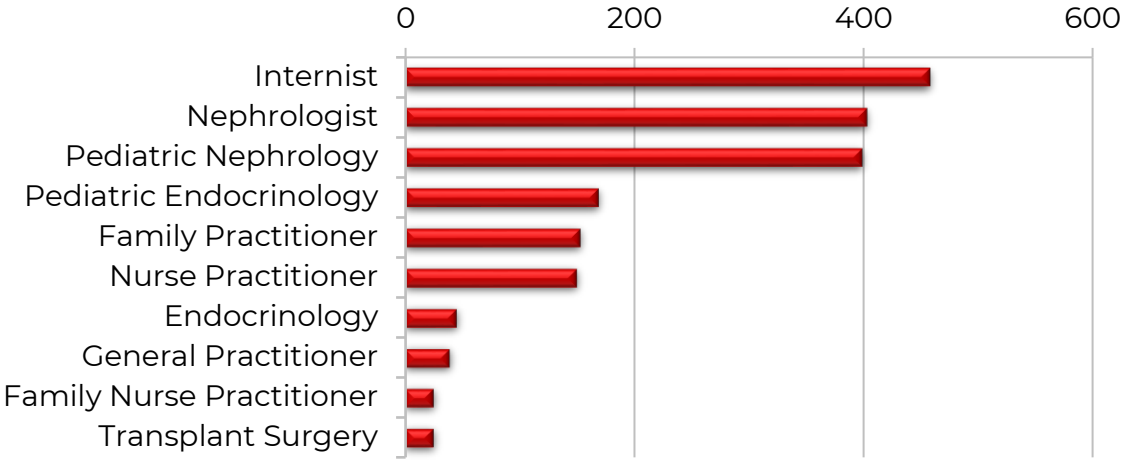
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	5	52	$503,454.29	$9,681.81	$342.02	104	1,472
2020	5	11	$119,109.37	$10,828.12	$381.76	24	312
% Change	**0.00%**	**-78.80%**	**-76.30%**	**11.80%**	**11.60%**	**-76.90%**	**-78.80%**
Change	**0**	**-41**	**-$384,344.92**	**$1,146.31**	**$39.74**	**-80**	**-1,160**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Demographics of Members Utilizing Parathyroid Medications



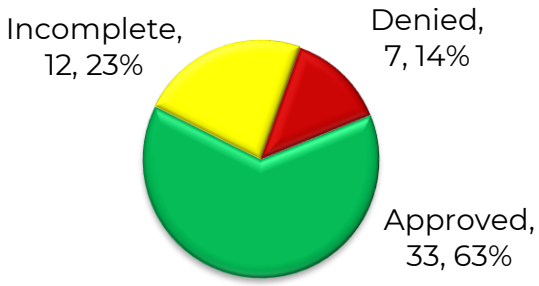
Top Prescriber Specialties of Parathyroid Medications by Number of Claims



Prior Authorization of Parathyroid Medications

There were 52 prior authorization requests submitted for parathyroid medications during fiscal year 2020. The following chart shows the status of the submitted petitions for fiscal year 2020.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[114]

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

Recommendations

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

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[114] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/. Last revised 01/2021. Last accessed 01/29/2021.

Utilization Details of Calcimimetics and Vitamin D Analogs: Fiscal Year 2020

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
CALCIMIMETIC PRODUCTS						
CINACALCET PRODUCTS						
CINACALCET TAB 30MG	261	59	$98,736.63	$11.57	$378.30	18.87%
CINACALCET TAB 60MG	124	27	$131,465.93	$30.90	$1,060.21	25.12%
SENSIPAR TAB 30MG	89	32	$90,780.64	$27.47	$1,020.01	17.35%
CINACALCET TAB 90MG	40	11	$47,083.39	$35.67	$1,177.08	9.00%
SENSIPAR TAB 60MG	38	17	$76,420.77	$55.38	$2,011.07	14.60%
SENSIPAR TAB 90MG	7	4	$16,773.96	$79.88	$2,396.28	3.21%
SUBTOTAL	**559**	**150**	**$461,261.32**	**$24.27**	**$825.15**	**88.15%**
VITAMIN-D ANALOG PRODUCTS						
CALCIFEDIOL PRODUCTS						
RAYALDEE CAP 30MCG	7	2	$7,321.30	$34.86	$1,045.90	1.40%
SUBTOTAL	**7**	**2**	**$7,321.30**	**$34.86**	**$1,045.90**	**1.40%**
CALCITRIOL PRODUCTS						
CALCITRIOL CAP 0.25MCG	784	206	$13,292.45	$0.38	$16.95	2.54%
CALCITRIOL CAP 0.5MCG	360	91	$9,725.14	$0.70	$27.01	1.86%
CALCITRIOL SOL 1MCG/ML	168	44	$19,131.84	$2.42	$113.88	3.66%
SUBTOTAL	**1,312**	**341**	**$42,149.43**	**$0.74**	**$32.13**	**8.06%**
PARICALCITOL PRODUCTS						
PARICALCITOL CAP 1MCG	69	10	$2,619.80	$1.21	$37.97	0.50%
PARICALCITOL CAP 2MCG	40	8	$7,743.67	$6.61	$193.59	1.48%
PARICALCITOL CAP 4MCG	9	1	$2,260.61	$8.37	$251.18	0.43%
SUBTOTAL	**118**	**19**	**$12,624.08**	**$3.51**	**$106.98**	**2.41%**
TOTAL	**1,996**	**436***	**$523,356.13**	**$6.56**	**$262.20**	**100%**

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

Utilization Details of Natpara® (Parathyroid Hormone Injection): Fiscal Year 2020

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
PARATHYROID HORMONE ANALOG PRODUCTS						
PARATHYROID HORMONE PRODUCTS						
NATPARA INJ 100MCG	6	3	$59,564.12	$354.55	$9,927.35	50.01%
NATPARA INJ 75MCG	4	2	$39,700.08	$342.24	$9,925.02	33.33%
NATPARA INJ 50MCG	1	1	$19,845.17	$708.76	$19,845.17	16.66%
TOTAL	**11**	**5***	**$119,109.37**	**$381.76**	**$10,828.12**	**100%**

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

Fiscal Year 2020 Annual Review of Pediculicide Medications

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Pediculicide Medications		
Tier-1	**Tier-2**	**Tier-3**
covered OTC lice medications	Sklice® (ivermectin lotion)	lindane shampoo
generics with SMAC pricing		Ovide® (malathion)
Natroba™ (spinosad)*		

OTC = over-the-counter; SMAC = State Maximum Allowable Cost
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).
*Brand preferred

- Over-the-counter (OTC) treatments for lice are a covered benefit for pediatric members. A prescription is required for coverage, and prescriptions are limited to 1 individual package size for a 7-day supply.

Pediculicide Medications Tier-2 Approval Criteria:

1. An FDA approved diagnosis; and
2. A trial with 1 Tier-1 medication with inadequate response or adverse effect; and
3. Requested medication must be age-appropriate; and
4. A clinical exception to Tier-1 medications applies if there is known resistance to OTC permethrin and pyrethrin.

Pediculicide Medications Tier-3 Approval Criteria:

1. An FDA approved diagnosis; and
2. A trial with 1 Tier-1 medication with inadequate response or adverse effect; and
3. Trials with all available Tier-2 medication(s) with inadequate response or adverse effect; and
4. If no Tier-2 medications are available, then a trial with all Tier-1 medications will be required prior to authorization of a Tier-3 medication; and
5. Requested medication must be age-appropriate; and
6. A clinical exception to Tier-1 medications applies if there is known resistance to OTC permethrin and pyrethrin.

The following restrictions also apply for each individual product based on U.S. Food and Drug Administration (FDA) approval information:

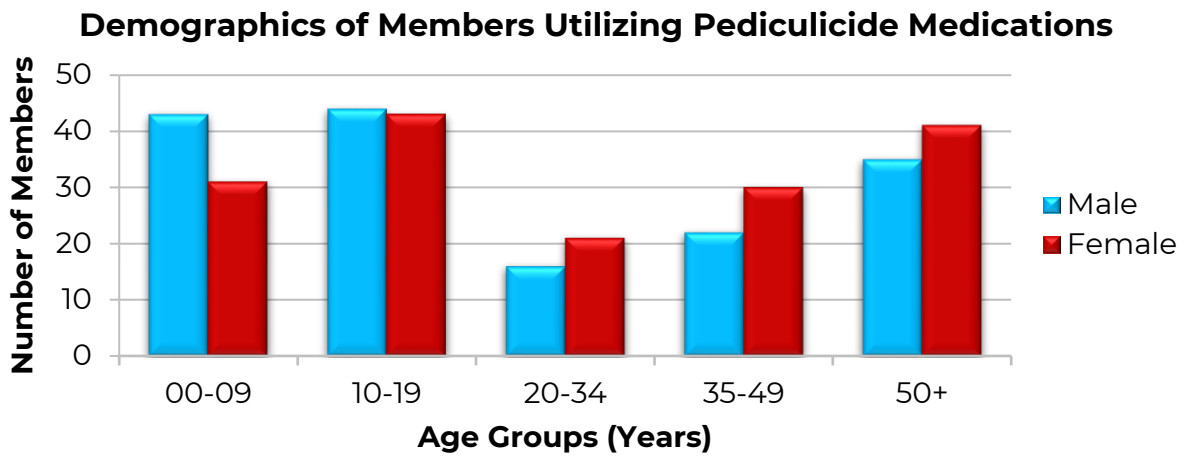
1. **Crotamiton (Eurax® and Crotan™) Cream and Lotion:**
   a. An FDA approved diagnosis of scabies or pruritic skin; and
   b. Member must be 18 years of age or older; and
   c. For a diagnosis of scabies, member must have used permethrin 5% cream in the past 7 to 14 days with inadequate results; and
   d. For a diagnosis of pruritic skin, a patient-specific, clinically significant reason why the member cannot use other available topical treatments used for pruritic skin must be provided; and
   e. For authorization of Crotan™, a patient-specific, clinically significant reason why the member cannot use Eurax® must be provided; and
   f. A quantity limit of 1 tube or bottle per 30 days will apply.
2. **Ivermectin (Sklice®) Lotion:**
   a. Member must be 6 months of age or older; and
   b. A quantity limit of 117mL per 7 days will apply.
3. **Lindane Shampoo:**
   a. Member must be 13 years of age or older or weigh ≥110 pounds; and
   b. A quantity limit of 60mL per 7 days will apply; and
   c. A maximum quantity of one 7-day supply per 30 days will apply.
4. **Malathion (Ovide®) Lotion:**
   a. Member must be 6 years of age or older; and
   b. A quantity limit of 60mL per 7 days will apply; treatment may be repeated once if needed for current infestation after 7 days from original fill date.
5. **Spinosad (Natroba™) Suspension:**
   a. Member must be 6 months of age or older; and
   b. A quantity limit of 120mL per 7 days will apply; treatment may be repeated once if needed for current infestation after 7 days from original fill date; and
   c. The brand formulation of Natroba™ is preferred. Requests for the generic formulation of spinosad require a patient-specific, clinically significant reason why the brand formulation cannot be used.

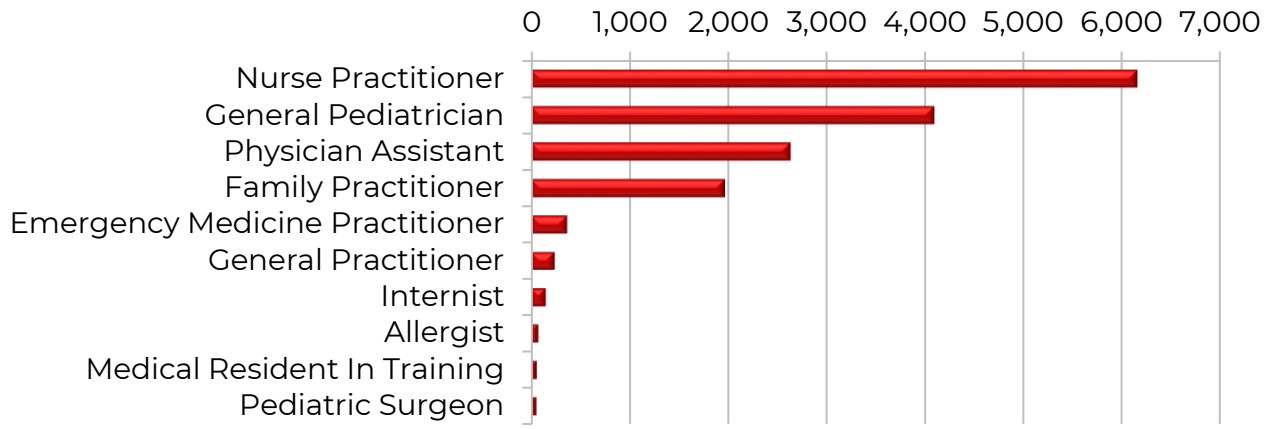
Utilization of Pediculicide Medications: Fiscal Year 2020

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	14,882	21,502	$4,316,069.00	$200.73	$21.77	2,055,403	198,234
2020	11,535	16,116	$2,737,616.96	$169.87	$16.99	1,510,392	161,172
% Change	**-22.5%**	**-25.0%**	**-36.6%**	**-15.4%**	**-22.0%**	**-26.5%**	**-18.7%**
Change	**-3,347**	**-5,386**	**-$1,578,452.04**	**-$30.86**	**-$4.78**	**-545,011**	**-37,062**

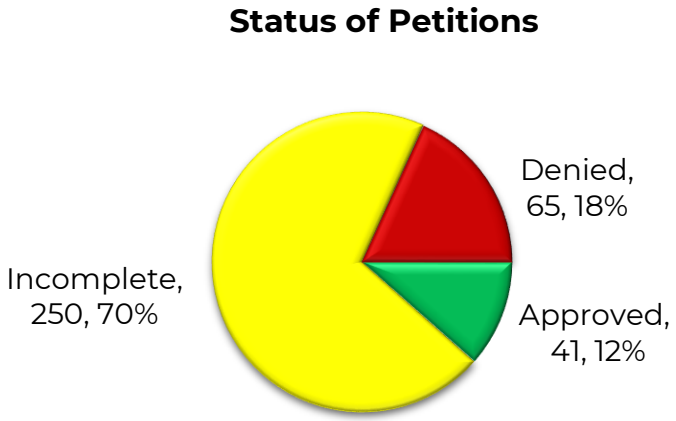
*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020





Prior Authorization of Pediculicide Medications

There were 356 prior authorization requests submitted for pediculicide medications during fiscal year 2020. The following chart shows the status of the submitted petitions for fiscal year 2020.



Market News and Updates

Anticipated Patent Expiration(s):[115]

- Natroba™ (spinosad): July 2023
- Ovide® (malathion): February 2027
- Sklice® (ivermectin): October 2027

Recommendations

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

Utilization Details of Pediculicide Medications: Fiscal Year 2020

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SPINOSAD PRODUCTS						
NATROBA SUS 0.9%	8,435	6,056	$2,304,012.75	$273.15	1.39	84.16%
SPINOSAD SUS 0.9%	3	3	$687.12	$229.04	1	0.03%
SUBTOTAL	**8,438**	**6,059**	**$2,304,699.87**	**$273.13**	**1.39**	**84.19%**
PERMETHRIN PRODUCTS						
PERMETHRIN CRE 5%	6,169	4,776	$239,382.17	$38.80	1.29	8.74%
LICE TRTMNT LOT 1%	532	419	$7,585.92	$14.26	1.27	0.28%
LICE TRTMNT LIQ 1%	435	343	$7,368.24	$16.94	1.27	0.27%
SUBTOTAL	**7,136**	**5,538**	**$254,336.33**	**$35.64**	**1.29**	**9.29%**
IVERMECTIN PRODUCTS						
SKLICE LOT 0.5%	538	506	$177,677.81	$330.26	1.06	6.49%
SUBTOTAL	**538**	**506**	**$177,677.81**	**$330.26**	**1.06**	**6.49%**
MALATHION PRODUCTS						
MALATHION LOT 0.5%	4	4	$902.95	$225.74	1	0.03%
SUBTOTAL	**4**	**4**	**$902.95**	**$225.74**	**1**	**0.03%**
TOTAL	**16,116**	**11,535***	**$2,737,616.96**	**$169.87**	**1.40**	**100.00%**

CRE = ream; LIQ = liquid; LOT = lotion; SUS = suspension, TRTMNT = treatment
*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020
Please note: Some Tier-1 products participate in supplemental rebates; therefore, costs shown do not reflect net costs.

[115] 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 01/2021. Last accessed 01/26/2021.

Fiscal Year 2020 Annual Review of Phenylketonuria Medications

Oklahoma Health Care Authority
Fiscal Year 2020 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 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 members 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.

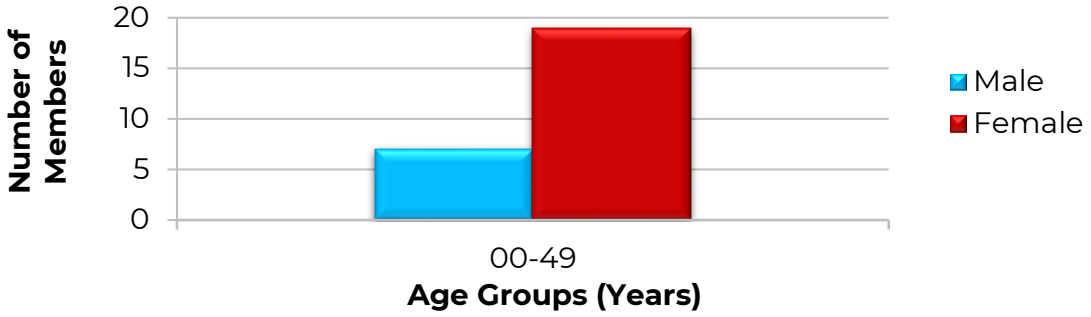
Utilization of Phenylketonuria Medications: Fiscal Year 2020

Comparison of Fiscal Years: Pharmacy Claims

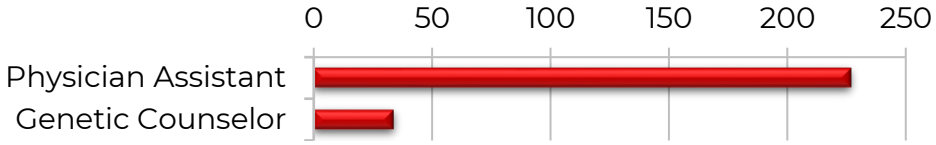
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	27	255	$2,252,871.50	$8,834.79	$292.77	49,890	7,695
2020	26	261	$2,393,331.53	$9,169.85	$307.63	51,347	7,780
% Change	**-3.70%**	**2.40%**	**6.20%**	**3.80%**	**5.10%**	**2.90%**	**1.10%**
Change	**-1**	**6**	**$140,460.03**	**$335.06**	**$14.86**	**1,457**	**85**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Demographics of Members Utilizing Phenylketonuria Medications



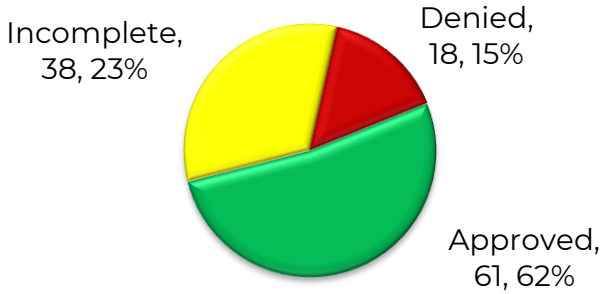
Top Prescriber Specialties of Phenylketonuria Medications by Number of Claims



Prior Authorization of Phenylketonuria Medications

There were 117 prior authorization requests submitted for phenylketonuria medications during fiscal year 2020. The following chart shows the status of the submitted petitions for fiscal year 2020.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[116]

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

Recommendations

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

Utilization Details of Phenylketonuria Medications: Fiscal Year 2020

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
SAPROPTERIN PRODUCTS						
KUVAN TAB 100MG	140	16	$1,746,274.66	$415.78	$12,473.39	72.96%
KUVAN POW 100MG	64	10	$206,092.06	$107.34	$3,220.19	8.61%
KUVAN POW 500MG	45	7	$348,003.93	$257.78	$7,733.42	14.54%
SUBTOTAL	**249**	**33**	**$2,300,370.65**	**$307.95**	**$9,238.44**	**96.11%**
PEGVALIASE-PQPZ PRODUCTS						
PALYNZIQ INJ 2.5MG/0.5ML	6	3	$9,581.42	$72.59	$1,596.90	0.40%
PALYNZIQ INJ 20MG/ML	5	1	$76,539.55	$510.26	$15,307.91	3.20%
PALYNZIQ INJ 10MG/0.5ML	1	1	$6,839.91	$244.28	$6,839.91	0.29%
SUBTOTAL	**12**	**5**	**$92,960.88**	**$299.87**	**$7,746.74**	**3.89%**
TOTAL	**261**	**26***	**$2,393,331.53**	**$307.63**	**$9,169.85**	**100.00%**

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

[116] 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 02/2021. Last accessed 02/03/2021.

Fiscal Year 2020 Annual Review of Phosphate Binders

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Generic calcium acetate containing products, Fosrenol® (lanthanum carbonate 500mg and 750mg chewable tablet), PhosLo® (calcium acetate gel cap), Phoslyra® (calcium acetate oral solution), Renagel® (sevelamer hydrochloride tablet), and Renvela® (sevelamer carbonate tablet and packet for suspension) are currently available without prior authorization.

Auryxia® (Ferric Citrate) Approval Criteria:

1. An FDA approved diagnosis of hyperphosphatemia in members with chronic kidney disease (CKD) on dialysis; and
    a. Documented trials of inadequate response to at least 2 of the phosphate binders available without prior authorization or a patient-specific, clinically significant reason why the member cannot use a phosphate binder available without prior authorization must be provided; or
2. An FDA approved diagnosis of iron deficiency anemia (IDA) in members with CKD not on dialysis; and
    a. Documented lab results verifying IDA; and
    b. Documented intolerance or inadequate response to prior treatment with oral iron; and
3. A quantity limit of 12 tablets per day will apply based on the maximum recommended dose.

Fosrenol® (Lanthanum Carbonate) 1,000mg Chewable Tablets, 750mg Oral Powder, and 1,000mg Oral Powder Approval Criteria:

1. An FDA approved diagnosis of hyperphosphatemia in members with end stage renal disease (ESRD); and
2. Documented trials of inadequate response to at least 2 of the phosphate binders available without prior authorization or a patient-specific, clinically significant reason why the member cannot use a phosphate binder available without prior authorization must be provided; and
3. For the approval of Fosrenol® oral powder, a patient-specific, clinically significant reason why a special formulation is needed over a phosphate binder available without prior authorization, such as brand Fosrenol® 500mg or 750mg chewable tablets which can be crushed, must be provided; and
4. For the approval of Fosrenol® 1,000mg chewable tablets, a patient-specific, clinically significant reason why the member cannot use a

phosphate binder available without a prior authorization, such as brand Fosrenol® 500mg or 750mg chewable tablets, must be provided; and
5. Fosrenol® 500mg or 750mg chewable tablets are brand preferred. Authorization of the generic formulation requires a patient-specific, clinically significant reason why the member cannot use the brand formulation.

Velphoro® (Sucroferric Oxyhydroxide) Approval Criteria:

1. An FDA approved diagnosis of hyperphosphatemia in members with chronic kidney disease (CKD) on dialysis; and
2. Documented trials of inadequate response to at least 2 of the phosphate binders available without prior authorization or a patient-specific, clinically significant reason why the member cannot use a phosphate binder available without prior authorization must be provided.

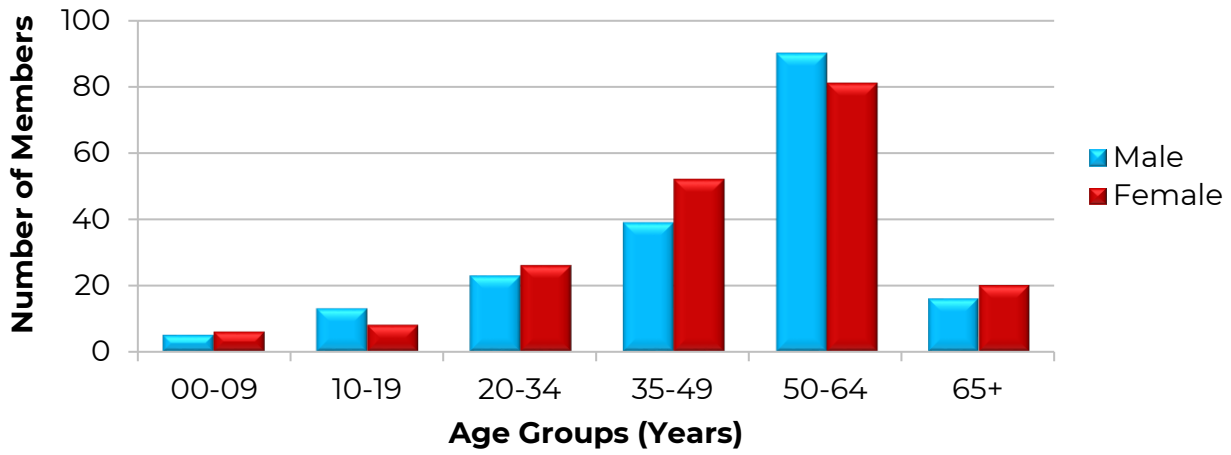
Utilization of Phosphate Binders: Fiscal Year 2020

Comparison of Fiscal Years: Pharmacy Claims

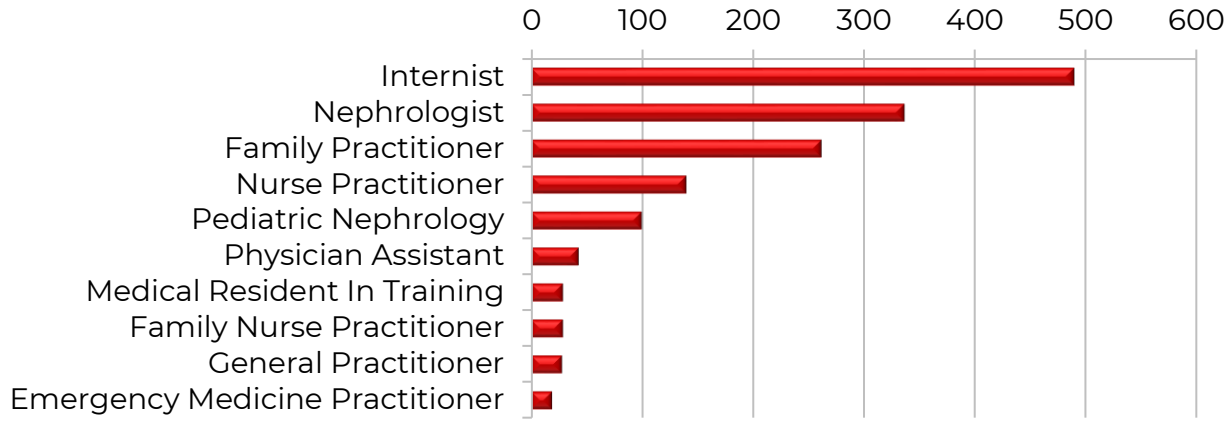
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	361	1,466	$534,312.42	$364.47	$12.45	312,756	42,911
2020	379	1,524	$541,793.22	$355.51	$12.21	311,608	44,355
% Change	**5.0%**	**4.0%**	**1.4%**	**-2.5%**	**-1.9%**	**-0.4%**	**3.4%**
Change	**18**	**58**	**$7,480.80**	**-$8.96**	**-$0.24**	**-1,148**	**1,444**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Demographics of Members Utilizing Phosphate Binders



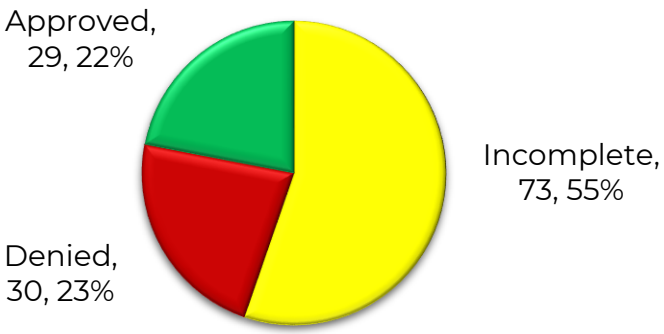
Top Prescriber Specialties of Phosphate Binders by Number of Claims



Prior Authorization of Phosphate Binders

There were 132 prior authorization requests submitted for phosphate binders during fiscal year 2020. The following chart shows the status of the submitted petitions for fiscal year 2020.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[117]

- PhosLo® (calcium acetate): July 2021
- Fosrenol® (lanthanum carbonate): August 2024
- Renvela® (sevelamer carbonate tablet): October 2025
- Phoslyra® (calcium acetate): February 2030
- Auryxia® (ferric citrate): July 2030
- Renvela® (sevelamer carbonate packet for suspension): December 2030

[117] 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 01/2021. Last accessed 01/22/2021.

- Velphoro® (sucroferric oxyhydroxide): November 2034

Pipeline:

- **Tenapanor:** Ardelyx announced tenapanor, a first-in-class therapy, is under review by the U.S. Food and Drug Administration (FDA) for the control of serum phosphorus in adult patients with chronic kidney disease (CKD) on dialysis. Tenapanor is a phosphate absorption inhibitor with a unique mechanism of action that acts locally in the gut to inhibitor the sodium hydrogen exchanger 3 (NHE3). This results in a conformational change of the epithelial cell junctions, thereby significantly reducing paracellular uptake of phosphate at the primary pathway of phosphate absorption. Tenapanor has been studied in 3 Phase 3 clinical trials in the United States, all of which have met their primary endpoint.[118]
- **PT20:** PT20 is an iron-based phosphate binder for the treatment of hyperphosphatemia in patients with hemodialysis-dependent CKD. Results were recently published from a Phase 2b double-blind, parallel-group, placebo-controlled, dose-ranging trial evaluating the efficacy and safety of 28 days of oral PT20 treatment. Among the 153 patients, 129 completed treatment. PT20 treatment for 28 days resulted in a statistically significant and dose-dependent reduction in serum phosphate concentration. The most common PT20 treatment-related adverse events were diarrhea and discolored feces. There were no serious adverse events.[119]

Recommendations

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

[118] Ardelyx, Inc. Ardelyx Announces Data Supporting Efficacy and Safety of Tenapanor, a First-in-Class Phosphate Absorption Inhibitor, to be Presented at ASN's Kidney Week 2020. *PRNewswire*. Available online at: https://www.prnewswire.com/news-releases/ardelyx-announces-data-supporting-efficacy-and-safety-of-tenapanor-a-first-in-class-phosphate-absorption-inhibitor-to-be-presented-at-asns-kidney-week-2020-301149661.html. Issued 10/12/2020. Last accessed 01/22/2021.

[119] Sampson M, Faria N, Powell JJ. Efficacy and Safety of PT20, an Iron-Based Phosphate Binder, for the Treatment of Hyperphosphataemia: A Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging, Phase IIb Study in Patients with Haemodialysis-Dependent Chronic Kidney Disease. *Nephrol Dial Transplant* 2020; doi: 10.1093/ndt/gfaa116.

Utilization Details of Phosphate Binders: Fiscal Year 2020

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
SEVELAMER CARBONATE PRODUCTS					
SEVELAMER TAB 800MG	670	185	$70,104.99	$3.57	$104.63
SEVELAMER POW 0.8GM	50	14	$69,871.23	$49.03	$1,397.42
SEVELAMER POW 2.4GM	12	5	$23,510.48	$65.31	$1,959.21
RENVELA TAB 800MG	7	3	$9,058.12	$49.50	$1,294.02
RENVELA POW 2.4 GM	7	1	$1,531.38	$51.05	$1,531.38
SUBTOTAL	**17,398**	**208**	**$174,076.20**	**$8.05**	**$235.24**
CALCIUM ACETATE PRODUCTS					
CALCIUM ACETATE CAP 667MG	546	182	$18,095.80	$1.15	$33.14
CALCIUM ACETATE TAB 667MG	18	11	$1,380.40	$2.58	$76.69
PHOSLYRA SOL 667MG/5ML	2	2	$1,384.80	$23.47	$692.40
SUBTOTAL	**566**	**195**	**$20,861.00**	**$1.27**	**$36.86**
SUCROFERRIC OXYHYDROXIDE PRODUCTS					
VELPHORO CHW 500MG	103	26	$206,040.73	$67.05	$2,000.40
SUBTOTAL	**103**	**26**	**$206,040.73**	**$67.05**	**$2,000.40**
FERRIC CITRATE PRODUCTS					
AURYXIA TAB 210MG	49	11	$55,268.78	$41.09	$1,127.93
SUBTOTAL	**49**	**11**	**$55,268.78**	**$41.09**	**$1,127.93**
LANTHANUM CARBONATE PRODUCTS					
FOSRENOL CHW 750MG	14	8	$28,935.11	$68.89	$2,066.79
LANTHANUM CHW 500MG	12	4	$17,637.96	$48.99	$1,469.83
FOSRENOL CHW 500MG	9	4	$11,241.09	$41.63	$1,249.01
LANTHANUM CHW 750MG	9	5	$12,539.90	$46.44	$1,393.32
SUBTOTAL	**44**	**21**	**$70,354.06**	**$53.30**	**$1,598.96**
SEVELAMER HYDROCHLORIDE PRODUCTS					
SEVELAMER TAB 800MG	13	11	$8,871.02	$26.17	$682.39
RENAGEL TAB 800MG	9	2	$6,321.43	$23.41	$702.38
SUBTOTAL	**22**	**13**	**$15,192.45**	**$24.95**	**$690.57**
TOTAL	**1,524**	**379***	**$541,793.22**	**$12.21**	**$355.51**

CAP = capsule; CHW = chewable; POW = powder; SOL = solution; TAB = tablet
*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Fiscal Year 2020 Annual Review of Prenatal Vitamins

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Prenatal Vitamins Approval Criteria:

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

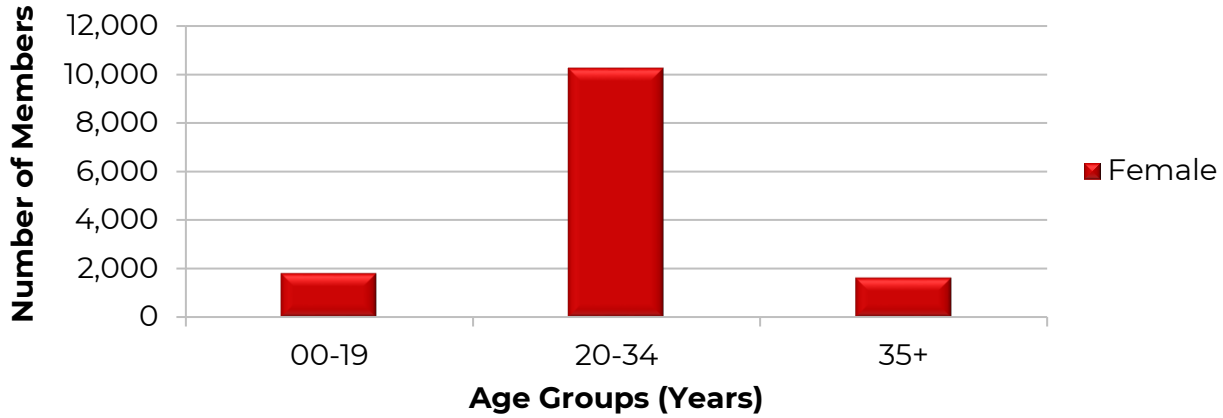
Utilization of Prenatal Vitamins: Fiscal Year 2020

Comparison of Fiscal Years: Pharmacy Claims

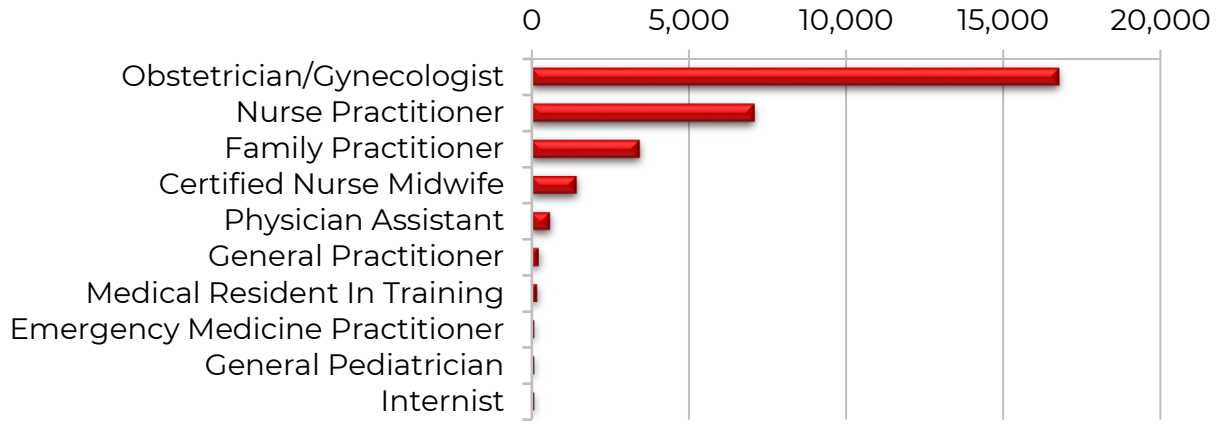
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	15,010	32,301	$2,989,959.33	$92.57	$2.16	1,646,516	1,386,300
2020	13,742	30,250	$3,003,849.11	$99.30	$2.32	1,596,575	1,293,087
% Change	**-8.40%**	**-6.30%**	**0.50%**	**7.30%**	**7.40%**	**-3.00%**	**-6.70%**
Change	**-1,268**	**-2,051**	**$13,889.78**	**$6.73**	**$0.16**	**-49,941**	**-93,213**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Demographics of Members Utilizing Prenatal Vitamins

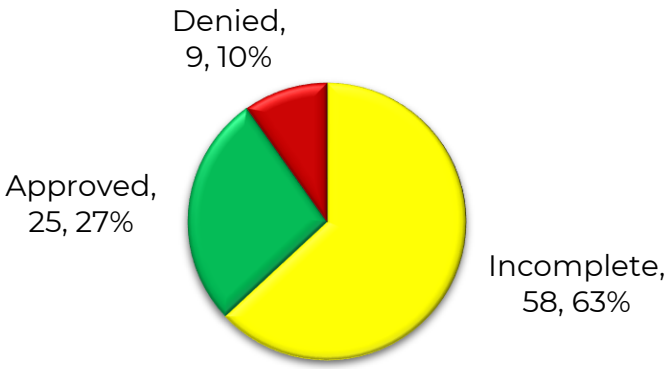


Top Prescriber Specialties of Prenatal Vitamins by Number of Claims



Prior Authorization of Prenatal Vitamins

There were 92 prior authorization requests submitted for prenatal vitamins during fiscal year 2020. The following chart shows the status of the submitted petitions for fiscal year 2020.



Recommendations

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

Utilization Details of Prenatal Vitamins: Fiscal Year 2020

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
VITAFOL CAP ULTRA	6,570	2,857	$1,039,865.55	$158.27	2.30	34.62%
CONCEPT DHA CAP	4,157	2,072	$184,834.49	$44.46	2.01	6.15%
VITAFOL CHW GUMMIES	3,748	1,674	$468,163.72	$124.91	2.24	15.59%
CITRANATAL CAP HARMONY	2,736	1,266	$482.290.65	$176.28	2.16	16.06%
FOLIVANE-OB CAP	1,805	1,118	$72,723.79	$40.29	1.61	2.42%
CITRANATAL MIS 90 DHA	1,656	720	$189,832.89	$114.63	2.30	6.32%
PRENATAL TAB 27-1MG	1,389	734	$21,365.77	$15.38	1.89	0.71%
CONCEPT OB CAP	1,226	743	$56,736.61	$46.28	1.65	1.89%
PRENATAL VIT TAB LOW	1,033	694	$14,313.32	$13.86	1.49	0.48%
TARON-C DHA CAP	742	441	$27,905.63	$37.61	1.68	0.93%
VOL-PLUS TAB	741	590	$17,801.02	$24.02	1.26	0.59%
VIRT-C DHA CAP	630	375	$24,102.04	$38.26	1.68	0.80%
CITRANATAL PAK ASSURE	556	218	$67,686.98	$121.74	2.55	2.25%
CITRANATAL PAK DHA	509	249	$59,775.89	$117.44	2.04	1.99%
VITAFOL-NANO TAB	373	160	$57,439.47	$153.99	2.33	1.91%
VITAFOL FE+ CAP	372	182	$44,856.28	$120.58	2.04	1.49%
CITRANATAL TAB BLOOM	358	167	$60,396.92	$168.71	2.14	2.01%
M-NATAL PLUS TAB	336	287	$6,765.42	$20.14	1.17	0.23%
SE-NATAL 19 TAB	289	172	$7,632.70	$26.41	1.68	0.25%
VITAFOL-OB TAB 65-1MG	143	75	$29,129.68	$203.70	1.91	0.97%
CITRANATAL MIS B-CALM	132	84	$13,813.47	$104.65	1.57	0.46%
PROVIDA OB CAP	129	85	$7,907.14	$61.30	1.52	0.26%
VITAFOL-OB PAK+DHA	128	48	$16,745.43	$130.82	2.67	0.56%
COMPLETE NAT PAK DHA	114	35	$3,440.91	$30.18	3.26	0.11%
VITAFOL-ONE CAP	69	39	$12,095.15	$175.29	1.77	0.40%
NIVA-PLUS TAB	63	49	$1,359.26	$21.58	1.29	0.05%
TRINATAL RX TAB 1	58	30	$1,034.45	$17.84	1.93	0.03%
CITRANATAL TAB RX	56	28	$9,051.93	$161.64	2.00	0.30%
SE-NATAL 19 CHW	54	41	$1,828.67	$33.86	1.32	0.06%
COMPLETENATE CHW	42	26	$1,254.68	$29.87	1.62	0.04%
ELITE-OB TAB	19	7	$471.32	$24.81	2.71	0.02%
SELECT-OB+ PAK DHA	6	3	$726.02	$121.00	2.00	0.02%
TRICARE TAB PRENATAL	4	4	$87.29	$21.82	1.00	0.00%
PRENAISSANCE CAP PLUS	4	1	$225.24	$56.31	4.00	0.01%
VITAFOL FE+ CAP	1	1	$135.16	$135.16	1.00	0.00%
PNV TABS 29-1MG	1	1	$33.65	$33.65	1.00	0.00%
OB COMPLETE TAB	1	1	$20.52	$20.52	1.00	0.00%
TOTAL	**30,250**	**13,742***	**$3,003,849.11**	**$99.30**	**2.20**	**100%**

CAP = capsule; CHW = chewable; DHA = omega-3 fatty acid; FE = iron; PNV = prenatal vitamin; TAB = tablet

*Total number of unduplicated utilizing members.

Costs do not reflect rebated prices or net costs.

Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Fiscal Year 2020 Annual Review of Procysbi® (Cysteamine Bitartrate)

Oklahoma Health Care Authority
Fiscal Year 2020 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 2020

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	1	2	$5,865.90	$2,932.95	$97.77	360	60
2020	1	2	$1,740.00	$870.00	$29.00	360	60
% Change	**0.00%**	**0.00%**	**-70.30%**	**-70.30%**	**-70.30%**	**0.00%**	**0.00%**
Change	**0**	**0**	**-$4,125.90**	**-$2,062.95**	**-$68.77**	**0**	**0**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Demographics of Members Utilizing Procysbi® (Cysteamine Bitartrate)

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

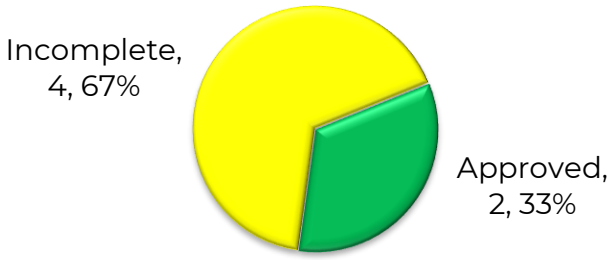
Top Prescriber Specialties of Procysbi® (Cysteamine Bitartrate) by Number of Claims

- The only prescriber specialty listed on paid pharmacy claims for Procysbi® (cysteamine bitartrate) during fiscal year 2020 was pediatric nephrologist.

Prior Authorization of Procysbi® (Cysteamine Bitartrate)

There were 6 prior authorization requests submitted for Procysbi® (cysteamine bitartrate) during fiscal year 2020. The following chart shows the status of the submitted petitions for fiscal year 2020.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[120]

- 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.

Utilization Details of Procysbi® (Cysteamine Bitartrate): Fiscal Year 2020

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
PROCYSBI CAP 75MG	1	1	$940.49	$31.35	$940.49	54.05%
PROCYSBI CAP 25MG	1	1	$799.51	$26.65	$799.51	45.95%
TOTAL	**2**	**1***	**$1,740.00**	**$29.00**	**$870.00**	**100.00%**

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

[120] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/. Last revised 01/2021. Last accessed 01/29/2021.

Fiscal Year 2020 Annual Review of Pulmonary Hypertension Medications

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Adcirca® (Tadalafil) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension; and
2. Medical supervision by a pulmonary specialist or cardiologist; and
3. A patient-specific, clinically significant reason why the member cannot use generic sildenafil oral tablets must be provided; or
4. A clinical exception for use as initial combination therapy with Letairis® (ambrisentan) applies; and
5. A quantity limit of 60 tablets per 30 days will apply.

Adempas® (Riociguat) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension or chronic thromboembolic pulmonary hypertension (CTEPH); and
    a. Members with a diagnosis of pulmonary arterial hypertension must have previous failed trials of at least 1 medication in each of the following categories:
        i. Revatio® (sildenafil) or Adcirca® (tadalafil); and
        ii. Letairis® (ambrisentan) or Tracleer® (bosentan); and
    b. Members with a diagnosis of CTEPH must currently be on anticoagulation therapy; and
2. Medical supervision by a pulmonary specialist or cardiologist; and
3. Member must not be on any concurrent phosphodiesterase (PDE) inhibitor therapy; and
4. Member must not have a diagnosis of pulmonary hypertension associated with idiopathic interstitial pneumonias (PH-IIP); and
5. Female members and all health care professionals (prescribers and dispensing pharmacies) must be enrolled in the Adempas® REMS program; and
6. A quantity limit of 90 tablets per 30 days will apply.

Opsumit® (Macitentan) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension; and
2. Member must have previous failed trials of at least 1 medication in each of the following categories:
    a. Revatio® (sildenafil) or Adcirca® (tadalafil); and
    b. Letairis® (ambrisentan) or Tracleer® (bosentan); and
3. Medical supervision by a pulmonary specialist or cardiologist; and

4. Female members and all health care professionals (prescribers and dispensing pharmacies) must be enrolled in the Opsumit® REMS program; and
5. A quantity limit of 30 tablets per 30 days will apply.

Orenitram® (Treprostinil) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension; and
2. Member must have previous failed trials of at least 1 medication in each of the following categories:
   a. Revatio® (sildenafil) or Adcirca® (tadalafil); and
   b. Letairis® (ambrisentan) or Tracleer® (bosentan); and
3. Medical supervision by a pulmonary specialist or cardiologist; and
4. A quantity limit of 90 tablets per 30 days will apply.

Revatio® (Sildenafil Tablets) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension; and
2. Medical supervision by a pulmonary specialist or cardiologist; and
3. A quantity limit of 90 tablets per 30 days will apply.

Revatio® (Sildenafil Suspension) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension; and
2. Medical supervision by a pulmonary specialist or cardiologist; and
3. An age restriction will apply. The oral suspension formulation may be approvable for members 6 years of age and younger. Members 7 years of age and older must have a patient-specific, clinically significant reason why the member is not able to use the oral tablet formulation; and
4. A quantity limit of 224mL per 30 days (2 bottles) will apply.

Uptravi® (Selexipag) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension; and
2. Member must be 18 years of age or older; and
3. Member must have previous failed trials of at least 1 medication in each of the following categories (alone or in combination):
   a. Revatio® (sildenafil), Adcirca® (tadalafil), or Adempas® (riociguat); and
   b. Letairis® (ambrisentan) or Tracleer® (bosentan); and
   c. Orenitram® (treprostinil); and
4. Medical supervision by a pulmonary specialist and/or cardiologist; and
5. A quantity limit of 2 tablets daily will apply for all strengths with an upper dose limit of 1,600mcg twice daily.

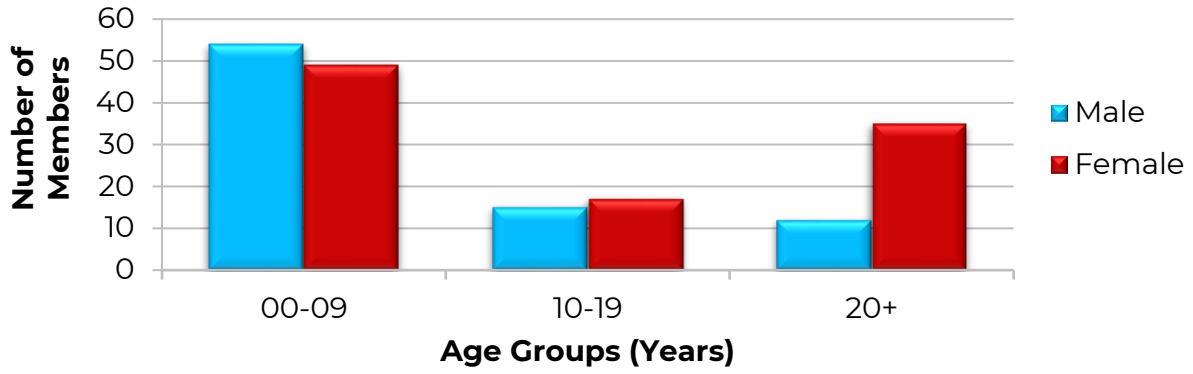
Utilization of Pulmonary Hypertension Medications: Fiscal Year 2020

Comparison of Fiscal Years

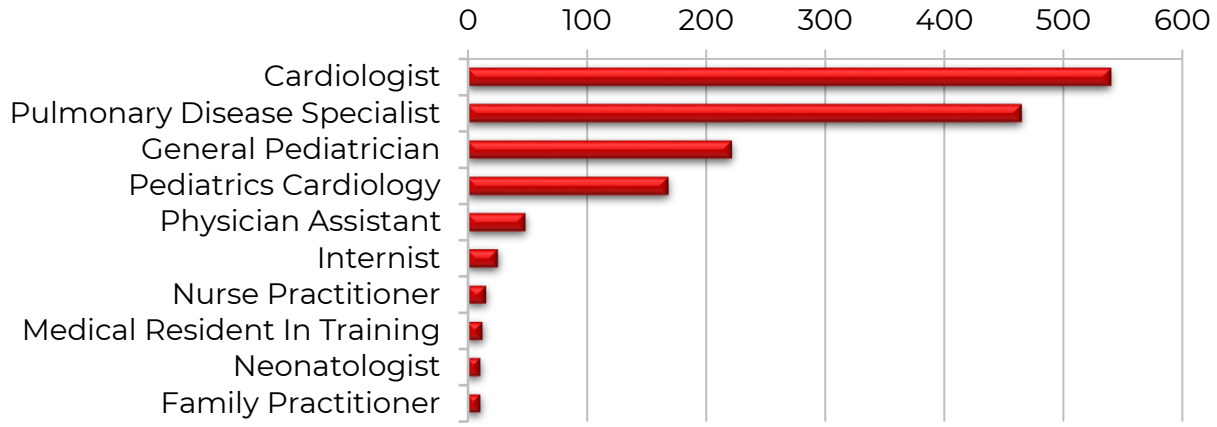
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	177	1,400	$9,176,780.73	$6,554.84	$218.72	115,011	41,956
2020	182	1,538	$8,243,847.08	$5,360.11	$175.56	112,754	46,958
% Change	**2.80%**	**9.90%**	**-10.20%**	**-18.20%**	**-19.70%**	**-2.00%**	**11.90%**
Change	**5**	**138**	**-$932,933.65**	**-$1,194.73**	**-$43.16**	**-2,257**	**5,002**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Demographics of Members Utilizing Pulmonary Hypertension Medications

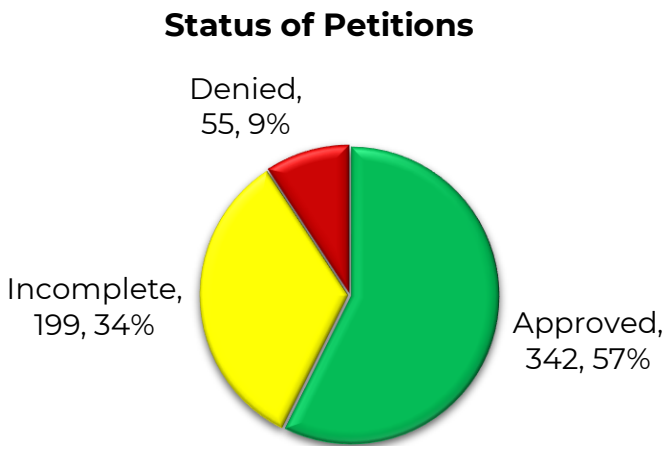


Top Prescriber Specialties of Pulmonary Hypertension Medications by Number of Claims



Prior Authorization of Pulmonary Hypertension Medications

There were 596 prior authorization requests submitted for pulmonary hypertension medications during fiscal year 2020. The following chart shows the status of the submitted petitions for fiscal year 2020.



Market News and Updates

Anticipated Patent Expiration(s):[121]

- Opsumit® (macitentan): April 2029
- Orenitram® (treprostinil): August 2031
- Letairis® (ambrisentan): October 2031
- Adempas® (riociguat): February 2034
- Uptravi® (selexipag): December 2036

Pipeline:

- **Levosimendan:** Tenax Therapeutics is developing levosimendan for the treatment of pulmonary hypertension associated with heart failure with preserved ejection fraction (PH-HFpEF). Levosimendan is a calcium sensitizer that improves the contraction of the heart muscles by increasing its sensitivity to calcium, and helps dilate blood vessels. In June 2020, Tenax reported positive results from the Phase 2 HELP study in which levosimendan reduced right atrial and pulmonary capillary wedge pressures and demonstrated a significant improvement in 6-minute walk distance (6MWD) in patients with PH-HFpEF.[122,123]
- **Ralinepag:** United Therapeutics is conducting Phase 3 studies of ralinepag for the treatment of pulmonary arterial hypertension (PAH). Ralinepag is a novel, once daily prostacyclin (IP) receptor agonist. The Phase 3 ADVANCE OUTCOMES and ADVANCE CAPACITY studies are

[121] 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 01/2021. Last accessed 02/01/2021.
[122] Tenax Therapeutics, Inc. Tenax Pipeline. Available online at: http://www.tenaxthera.com/pipeline/levosimendan/. Last accessed 02/01/2021.
[123] Tenax Therapeutics, Inc. Tenax Therapeutics Reports Positive Results from Phase 2 Trial of Levosimendan in Patients with Pulmonary Hypertension and Heart Failure with Preserved Ejection Fraction (PH-HFpEF). Available online at: http://investors.tenaxthera.com/prviewer/release_only/id/4342198. Issued 06/02/2020. Last accessed 02/01/2021.

currently ongoing and will evaluate time to clinical worsening and exercise capacity, respectively, in patients with PAH.[124]

- **Rodatristat Ethyl:** Altavant is conducting Phase 2 studies of rodatristat ethyl for the treatment of PAH. Rodatristat ethyl is a prodrug of a tryptophan hydroxylase inhibitor which blocks peripheral serotonin production. Excessive serotonin signaling is thought to play a role in the pathophysiology of PAH. Because rodatristat ethyl does not cross the blood-brain-barrier, its effects are restricted to the periphery without negatively affecting serotonin production in the central nervous system. The Phase 2A ELEVATE 1 study of rodatristat ethyl in patients with PAH is currently ongoing.[125,126]
- **Tyvaso® (Treprostinil):** In August 2020, United Therapeutics announced that the U.S. Food and Drug Administration (FDA) has accepted their supplemental New Drug Application (sNDA) for Tyvaso® (treprostinil) for a new indication for the treatment of pulmonary hypertension associated with interstitial lung disease (PH-ILD). The sNDA submission is based on data from the Phase 3 INCREASE study in 326 adult patients with PH-ILD. The primary efficacy end point was change in 6MWD at peak exposure from baseline to week 16. The results shows a statistically significant increase in 6MWD with inhaled treprostinil compared to placebo. If approved, Tyvaso® would become the first medication to be FDA approved for the treatment of PH-ILD. The FDA is expected to complete its review of the sNDA by April 2021.[127]
- **Uptravi® (Selexipag):** Janssen is developing an injectable formulation of selexipag for intravenous (IV) administration for the treatment of PAH in adults who are currently prescribed oral Uptravi® but are temporarily unable to take oral therapy. In September 2020, Janssen submitted a New Drug Application (NDA) to the FDA for the IV formulation. The NDA submission is based on data from a Phase 3 study in patients with PAH who temporarily switched from the oral to the IV formulation, and then transitioned back to the original oral dose.

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[124] United Therapeutics Corporation. United Therapeutics Pipeline: ADVANCE Studies Ralinepag (IP Receptor Agonist). Available online at: https://pipeline.unither.com/product/advance-studies-ralinepag-ip-receptor-agonist/description/. Last accessed 02/01/2021.
[125] Altavant Sciences. Altavant Pipeline: Rodatristat Ethyl. Available online at: https://altavant.com/pipeline/. Last accessed 02/01/2021.
[126] Altavant Sciences. Altavant Sciences Presents Data at CHEST 2019 Supporting Once-Daily Dosing of Rodatristat Ethyl for the Treatment of Pulmonary Arterial Hypertension. Available online at: https://altavant.com/altavant-sciences-presents-data-at-chest-2019-supporting-once-daily-dosing-of-rodatristat-ethyl-for-the-treatment-of-pulmonary-arterial-hypertension/. Issued 10/22/2019. Last accessed 02/01/2021.
[127] Park B. Treprostinil Under Review for Pulmonary HTN with Interstitial Lung Disease. *MPR*. Available online at: https://www.empr.com/home/news/drugs-in-the-pipeline/treprostinil-tyvaso-supplemental-nda-pulmonary-hypertension/. Issued 08/17/2020. Last accessed 02/01/2021.

The IV formulation was able to maintain continuous dosing for short periods of time when oral administration was not feasible.[128]

Recommendations

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

Utilization Details of Pulmonary Hypertension Medications: Fiscal Year 2020

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
PHOSPHODIESTERASE-5 (PDE-5) INHIBITORS						
SILDENAFIL TAB 20MG	304	63	$6,438.15	$21.18	4.83	0.08%
TADALAFIL TAB 20MG	262	38	$12,683.94	$48.41	6.89	0.15%
SILDENAFIL SUS 10MG/ML	257	58	$1,307,465.53	$5,087.41	4.43	15.86%
REVATIO SUS 10MG/ML	73	26	$742,123.59	$10,166.08	2.81	9.00%
ALYQ TAB 20MG+	7	1	$0.00	$0.00	7	0.00%
ADCIRCA TAB 20MG	2	1	$2,029.00	$1,014.50	2	0.02%
SUBTOTAL	**905**	**159***	**$2,070,740.21**	**$2,288.11**	**5.69**	**25.12%**
ENDOTHELIN RECEPTOR ANTAGONISTS (ERA)						
TRACLEER TAB 32MG	119	20	$787,792.58	$6,620.11	5.95	9.56%
OPSUMIT TAB 10MG	71	9	$695,829.39	$9,800.41	7.89	8.44%
LETAIRIS TAB 10MG	66	14	$640,113.01	$9,698.68	4.71	7.76%
BOSENTAN TAB 62.5MG	59	10	$93,297.97	$1,581.32	5.9	1.13%
AMBRISENTAN TAB 10MG	40	8	$46,439.74	$1,160.99	5	0.56%
AMBRISENTAN TAB 5MG	24	9	$32,934.88	$1,372.29	2.67	0.40%
LETAIRIS TAB 5MG	19	5	$232,786.66	$12,251.93	3.8	2.82%
BOSENTAN TAB 125MG	10	2	$87,644.70	$8,764.47	5	1.06%
TRACLEER TAB 125MG	5	1	$58,195.05	$11,639.01	5	0.71%
SUBTOTAL	**413**	**58***	**$2,675,033.98**	**$6,477.08**	**7.12**	**32.45%**
PROSTACYCLIN VASODILATORS						
REMODULIN INJ 5MG/ML	36	7	$565,232.48	$15,700.90	5.14	6.86%
REMODULIN INJ 10MG/ML	34	3	$1,108,685.80	$32,608.41	11.33	13.45%
ORENITRAM TAB 1MG	19	4	$197,961.40	$10,419.02	4.75	2.40%
ORENITRAM TAB 0.25MG	12	5	$19,799.36	$1,649.95	2.4	0.24%
UPTRAVI TAB 1000MCG	12	1	$201,677.61	$16,806.47	12	2.45%
ORENITRAM TAB 5MG	11	3	$355,295.44	$32,299.59	3.67	4.31%
UPTRAVI TAB 1400MCG	11	1	$195,991.97	$17,817.45	11	2.38%
REMODULIN INJ 2.5MG/ML	11	2	$122,831.54	$11,166.50	5.5	1.49%

[128] Janssen Pharmaceutical Company. Janssen Submits New Drug Application (NDA) to U.S. FDA for Uptravi® (Selexipag) Injection for Intravenous Use to Treat Pulmonary Arterial Hypertension (PAH). *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/janssen-submits-new-drug-application-nda-to-us-fda-for-uptravi-selexipag-injection-for-intravenous-use-to-treat-pulmonary-arterial-hypertension-pah-301140441.html. Issued 09/30/2020. Last accessed 02/01/2021.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
REMODULIN INJ 1MG/ML	10	2	$17,680.60	$1,768.06	5	0.21%
UPTRAVI TAB 600MCG	9	1	$146,054.63	$16,228.29	9	1.77%
ORENITRAM TAB 0.125MG	8	4	$9,279.25	$1,159.91	2	0.11%
TREPROSTINIL INJ 5MG/ML	7	3	$80,276.43	$11,468.06	2.33	0.97%
UPTRAVI TAB 200MCG	6	3	$102,655.51	$17,109.25	2	1.25%
FLOLAN INJ 0.5MG	4	1	$1,987.42	$496.86	4	0.02%
UPTRAVI TAB 200MCG/800MCG	3	2	$82,647.55	$27,549.18	1.5	1.00%
UPTRAVI TAB 800MCG	2	1	$18,378.64	$9,189.32	2	0.22%
UPTRAVI TAB 400MCG	2	1	$36,727.46	$18,363.73	2	0.45%
SUBTOTAL	**197**	**25***	**$3,263,163.09**	**$16,564.28**	**7.88**	**39.58%**
SOLUBLE GUANYLATE CYCLASE (sGC) STIMULATORS						
ADEMPAS TAB 2.5MG	21	3	$220,899.99	$10,519.05	7	2.68%
ADEMPAS TAB 1MG	1	1	$10,345.71	$10,345.71	1	0.13%
ADEMPAS TAB 0.5MG	1	1	$3,664.10	$3,664.10	1	0.04%
SUBTOTAL	**23**	**5***	**$234,909.80**	**$10,213.47**	**4.6**	**2.85%**
TOTAL	**1,538**	**182***	**$8,243,847.08**	**$5,360.11**	**8.45**	**100.00%**

INJ = injection; SUS = suspension; TAB = tablet
*Total number of unduplicated utilizing members.
⁺Claims for Alyq™ in FY20 consist of claims for 1 member for which SoonerCare was not the primary payer; therefore, the reimbursed amount is not a true reflection of the cost of the medication for SoonerCare.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Fiscal Year 2020 Annual Review of Qbrexza® (Glycopyrronium)

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Qbrexza® (Glycopyrronium) Approval Criteria:

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

Utilization of Qbrexza® (Glycopyrronium): Fiscal Year 2020

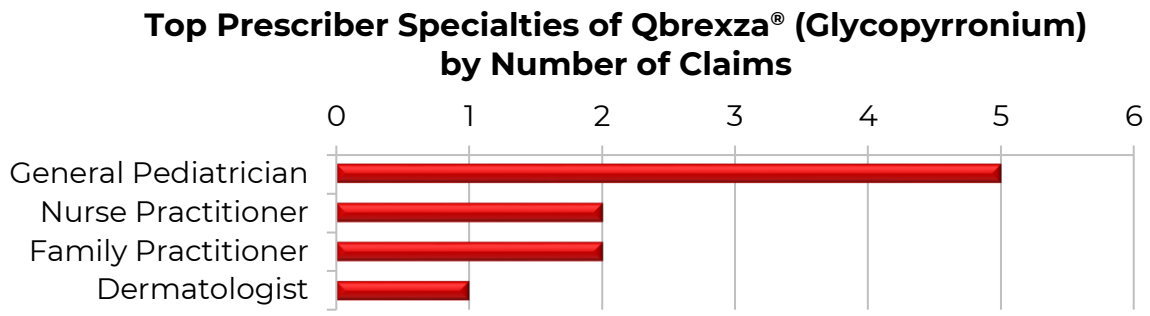
Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	1	2	$1,075.09	$537.55	$17.92	60	60
2020	4	10	$5,597.15	$559.71	$18.66	300	300
% Change	**300.00%**	**400.00%**	**420.60%**	**4.10%**	**4.10%**	**400.00%**	**400.00%**
Change	**3**	**8**	**$4,522.06**	**$22.16**	**$0.74**	**240**	**240**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

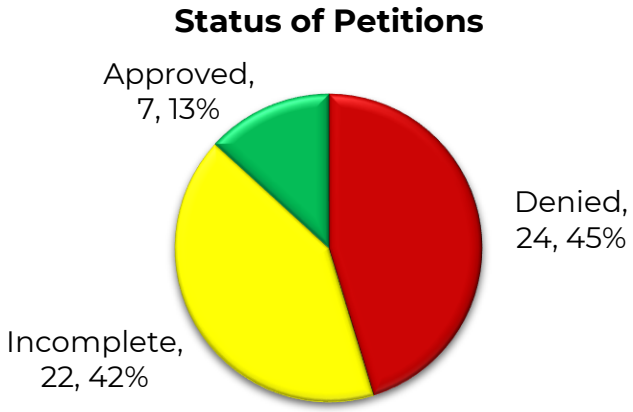
Demographics of Members Utilizing Qbrexza® (Glycopyrronium)

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



Prior Authorization of Qbrexza® (Glycopyrronium)

There were 53 prior authorization requests submitted for Qbrexza® (glycopyrronium) during fiscal year 2020. The following chart shows the status of the submitted petitions for fiscal year 2020.



Market News and Updates

Anticipated Patent Expiration(s):[129]

- Qbrexza® (glycopyrronium): February 2033

Recommendations

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

[129] 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 01/2021. Last accessed 01/04/2021.

Fiscal Year 2020 Annual Review of Qualaquin® (Quinine Sulfate)

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Qualaquin® (Quinine Sulfate) Approval Criteria:

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

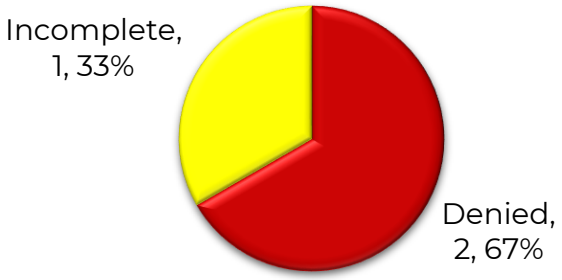
Utilization of Qualaquin® (Quinine Sulfate): Fiscal Year 2020

There was no SoonerCare utilization of Qualaquin® (quinine sulfate) during fiscal year 2020 (07/01/2019 to 06/30/2020).

Prior Authorization of Qualaquin® (Quinine Sulfate)

There were 3 prior authorization requests submitted for Qualaquin® (quinine sulfate) during fiscal year 2020. The following chart shows the status of the submitted petitions for fiscal year 2020.

Status of Petitions



Recommendations

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

Fiscal Year 2020 Annual Review of Ravicti® (Glycerol Phenylbutyrate)

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Ravicti® (Glycerol Phenylbutyrate) Approval Criteria:

1. An FDA approved diagnosis of urea cycle disorder (UCD); and
2. Active management with a protein restricted diet; and
3. A patient-specific, clinically significant reason why member cannot use Buphenyl® (sodium phenylbutyrate) must be provided.

Utilization of Ravicti® (Glycerol Phenylbutyrate): Fiscal Year 2020

Comparison of Fiscal Years

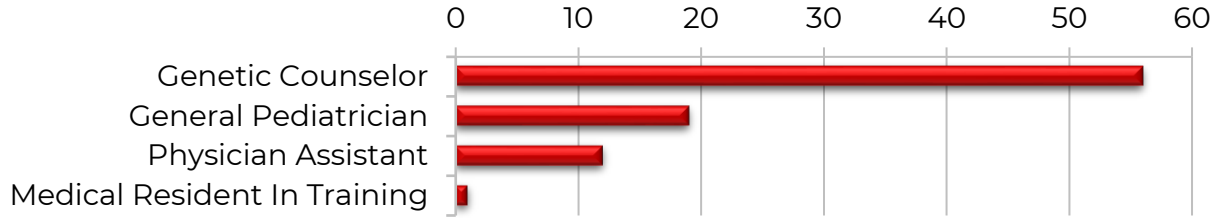
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	8	73	$1,962,374.79	$26,881.85	$929.59	10,475	2,111
2020	9	88	$2,456,664.28	$27,916.64	$914.96	12,525	2,685
% Change	**12.50%**	**20.50%**	**25.20%**	**3.80%**	**-1.60%**	**19.60%**	**27.20%**
Change	**1**	**15**	**$494,289.49**	**$1,034.79**	**-$14.63**	**2,050**	**574**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Demographics of Members Utilizing Ravicti® (Glycerol Phenylbutyrate)

- There were 9 unique pediatric members utilizing Ravicti® (glycerol phenylbutyrate) during fiscal year 2020; however, due to the limited number of members utilizing Ravicti® (glycerol phenylbutyrate), detailed demographic information could not be provided.

Top Prescriber Specialties of Ravicti® (Glycerol Phenylbutyrate) by Number of Claims

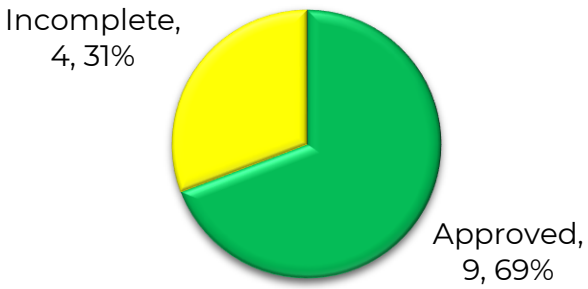


- Upon further research, all members utilizing Ravicti® (glycerol phenylbutyrate) during fiscal year 2020 were originally prescribed this medication by physicians specializing in medical or clinical genetics.

Prior Authorization of Ravicti® (Glycerol Phenylbutyrate)

There were 13 prior authorization requests submitted for 8 unique members for Ravicti® (glycerol phenylbutyrate) during fiscal year 2020. The following chart shows the status of the submitted petitions for fiscal year 2020.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[130]

- Ravicti® (glycerol phenylbutyrate): March 2032

Pipeline:

- **ACER-001:** Acer Therapeutics is developing ACER-001 for the treatment of urea cycle disorders (UCD). ACER-001 is a fully taste-masked, immediate release formulation of sodium phenylbutyrate developed using a microencapsulation process which was designed with the goal of improving patient compliance. Acer is currently conducting a bioequivalence study comparing the pharmacokinetics of ACER-001 to Buphenyl® (sodium phenylbutyrate) under fed conditions. Once the bioequivalence study is complete, Acer plans to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) under the Section 505(b)(2) regulatory pathway for ACER-001 for the treatment of UCD in mid-2021.[131]

Recommendations

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

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[130] 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 01/2021. Last accessed 01/28/2021.

[131] Acer Therapeutics, Inc. Acer Pipeline: ACER-001 for UCD. Available online at: https://www.acertx.com/rare-disease-research/acer-001-for-urea-cycle-disorders-ucds/. Last accessed 01/28/2021.

Utilization Details of Ravicti® (Glycerol Phenylbutyrate): Fiscal Year 2020

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
RAVICTI LIQ 1.1GM/ML	88	9	$2,456,664.28	$27,916.64	9.78	100.00%
TOTAL	**88**	**9***	**$2,456,664.28**	**$27,916.64**	**9.78**	**100.00%**

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

Fiscal Year 2020 Annual Review of Revcovi™ (Elapegademase-lvlr)

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Revcovi™ (Elapegademase-lvlr) Approval Criteria:

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

Utilization of Revcovi™ (Elapegademase-lvlr): Fiscal Year 2020

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	1	2	$394,261.74	$197,130.87	$7,040.39	60	56
2020	0	0	$0.00	$0.00	$0.00	0	0
% Change	**-100%**	**-100%**	**-100%**	**-100%**	**-100%**	**-100%**	**-100%**
Change	**-1**	**-2**	**-$394,261.74**	**-$197,130.87**	**-$7,040.39**	**-60**	**-56**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020
Please note: There was no SoonerCare utilization of Revcovi™ (elapegademase-lvlr) during fiscal year 2020.

Prior Authorization of Revcovi™ (Elapegademase-lvlr)

There were no prior authorization requests submitted for Revcovi™ (elapegademase-lvlr) during fiscal year 2020.

Recommendations

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

Fiscal Year 2020 Annual Review of Short-Acting Beta$_2$ Agonists (SABAs)

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Tier-1 products are covered with no prior authorization necessary.

Short-Acting Beta$_2$ Agonists Tier-2 Approval Criteria:

1. A 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 levalbuterol HFA requires a patient-specific, clinically significant reason the member cannot use the brand formulation.

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

*Brand preferred.
¥Additional criteria applies.
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).

ProAir® Digihaler® (Albuterol Sulfate Inhalation Powder) Approval Criteria:

1. A 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 bronchodilators and/or inhaled corticosteroids (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 clients with chronic obstructive pulmonary disease (COPD); and
5. A quantity limit of 288mL per 30 days will apply.

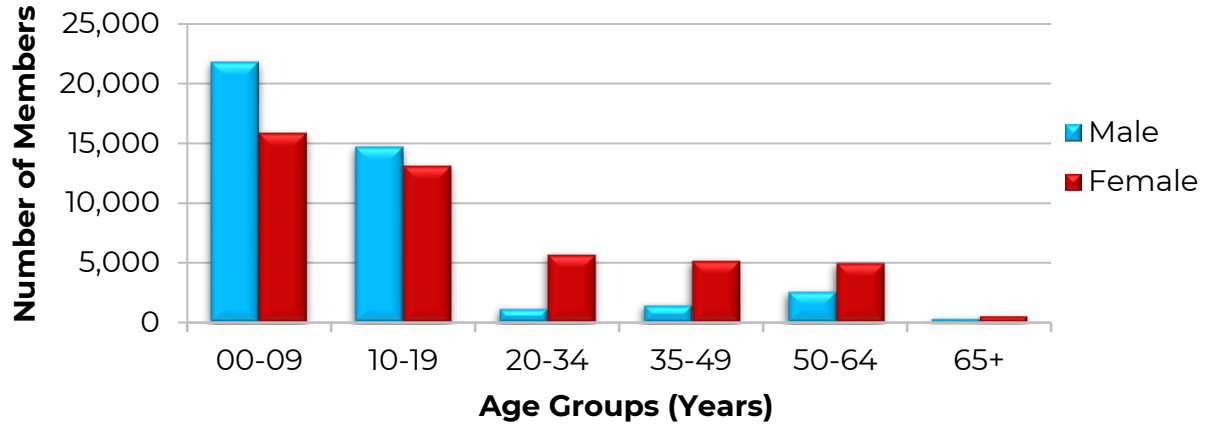
Utilization of SABAs: Fiscal Year 2020

Comparison of Fiscal Years: Pharmacy Claims

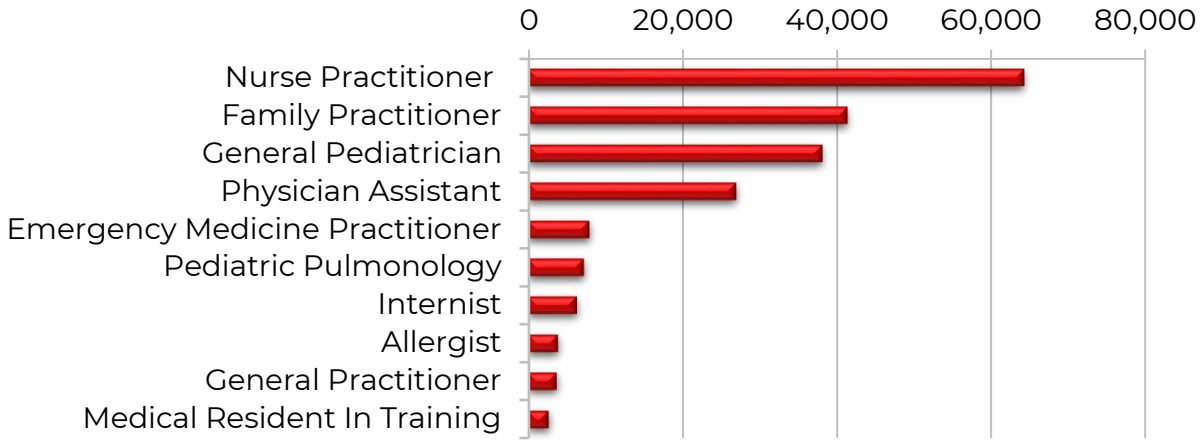
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	89,980	212,798	$14,529,323.38	$68.28	$3.20	9,940,593	4,546,218
2020	87,169	211,243	$13,807,557.10	$65.36	$3.03	10,026,690	4,556,731
% Change	**-3.10%**	**-0.70%**	**-5.00%**	**-4.30%**	**-5.30%**	**0.90%**	**0.20%**
Change	**-2,811**	**-1,555**	**-$721,766.28**	**-$2.92**	**-$0.17**	**86,097**	**10,513**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Demographics of Members Utilizing SABAs



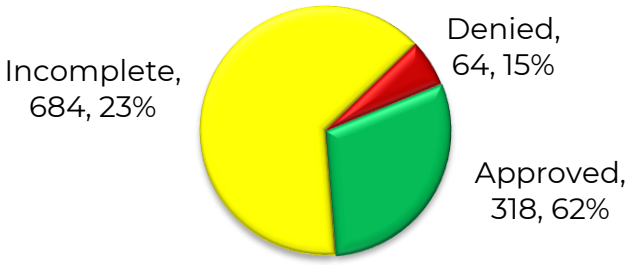
Top Prescriber Specialties of SABAs by Number of Claims



Prior Authorization of SABAs

There were 1,066 prior authorization requests submitted for SABAs during fiscal year 2020. The following chart shows the status of the submitted petitions for fiscal year 2020.

Status of Petitions



Market News and Updates[132]

Anticipated Patent Expiration(s):

- Ventolin® (albuterol HFA): August 2026; however, an authorized generic is currently available
- ProAir® (albuterol HFA): January 2032; however, an authorized generic is currently available
- ProAir RespiClick® (albuterol sulfate inhalation powder): January 2032
- ProAir® Digihaler® (albuterol sulfate inhalation powder): August 2036

[132] 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 02/2021. Last accessed 02/05/2021.

Recommendations

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

Utilization Details of SABAs: Fiscal Year 2020

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
TIER-1 PRODUCTS						
PROAIR HFA 90MCG/ACT	116,519	53,739	$9,980,424.43	$3.54	$85.65	72.28%
VENTOLIN HFA 90MCG/ACT	6,934	4,175	$465,023.58	$2.72	$67.06	3.37%
PROVENTIL HFA 90MCG/ACT	4,906	2,655	$505,545.06	$4.20	$103.05	3.66%
XOPENEX HFA 45MCG/ACT	619	248	$54,335.63	$3.44	$87.78	0.39%
PROAIR RESPICLICK 90MCG/ACT	531	384	$38,260.37	$2.78	$72.05	0.28%
SUBTOTAL	**129,509**	**61,201**	**$11,043,589.07**	**$3.52**	**$85.27**	**79.98%**
TIER-2 PRODUCTS						
ALBUTEROL HFA 90MCG/ACT	27,522	19,508	$1,352,728.82	$2.06	$49.15	9.80%
LEVALBUTEROL AER 45MCG/ACT	6	2	$446.91	$2.09	$74.49	0.00%
SUBTOTAL	**27,528**	**19,510**	**$1,353,175.73**	**$2.06**	**$49.16**	**9.80%**
NEBULIZER SOLUTION PRODUCTS						
ALBUTEROL NEB 0.083%	34,470	21,192	$576,038.32	$1.15	$16.71	4.17%
ALBUTEROL NEB 1.25MG/3ML	10,552	7,770	$409,631.85	$3.24	$38.82	2.97%
ALBUTEROL NEB 0.63MG/3ML	6,376	4,656	$262,084.15	$3.20	$41.10	1.90%
LEVALBUTEROL NEB 0.63MG	1,367	813	$74,967.74	$3.07	$54.84	0.54%
LEVALBUTEROL NEB 1.25MG	740	368	$30,545.34	$2.18	$41.28	0.22%
ALBUTEROL NEB 0.5%	395	268	$19,064.98	$2.98	$48.27	0.14%
LEVALBUTEROL NEB 0.31MG	276	209	$16,021.87	$3.65	$58.05	0.12%
LEVALBUTEROL NEB 1.25MG/0.5ML	20	10	$14,845.63	$34.36	$742.28	0.11%
XOPENEX NEB 1.25MG/3ML	10	1	$7,592.42	$28.65	$759.24	0.05%
SUBTOTAL	**54,206**	**35,287**	**$1,410,792.30**	**$1.86**	**$26.03**	**10.22%**
TOTAL	**211,243**	**87,169***	**$13,807,557.10**	**$3.03**	**$65.36**	**100.00%**

ACT = actuation; AER = aerosol; HFA = hydrofluoroalkane inhaler; NEB = nebulizer
*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Fiscal Year 2020 Annual Review of Smoking Cessation Products

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Smoking Cessation Products Coverage Criteria:

1. All nicotine replacement products (patches, gum, lozenges, and inhalers), Zyban® (bupropion), and Chantix® (varenicline) do not require prior authorization.
2. Chantix® (varenicline) may be used for up to 180 days per calendar year. Varenicline is not covered for members younger than 16 years of age.
3. Nicotine replacement patches have a quantity limit of 30 patches per 30 days.
4. Smoking cessation products do not count against the 6 prescription limit per month.
5. Smoking cessation products are available without a co-pay.

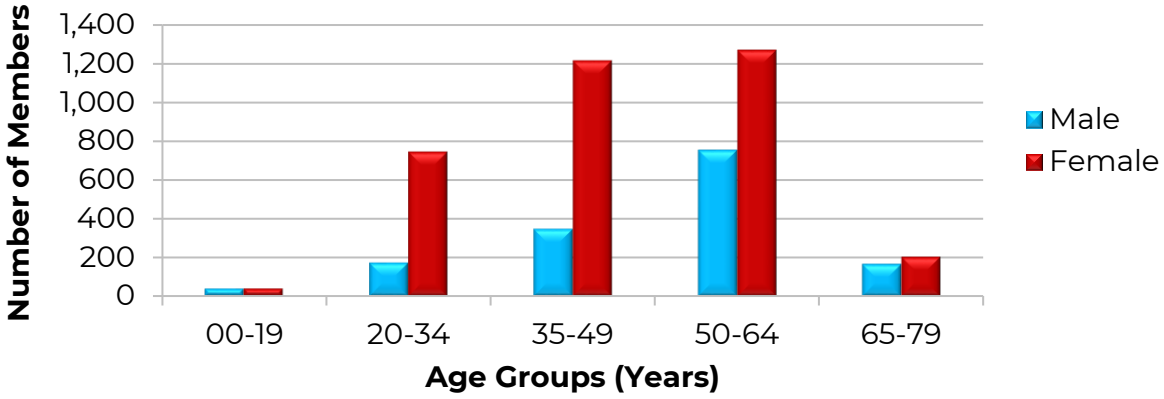
Utilization of Smoking Cessation Products: Fiscal Year 2020

Comparison of Fiscal Years: Pharmacy Claims

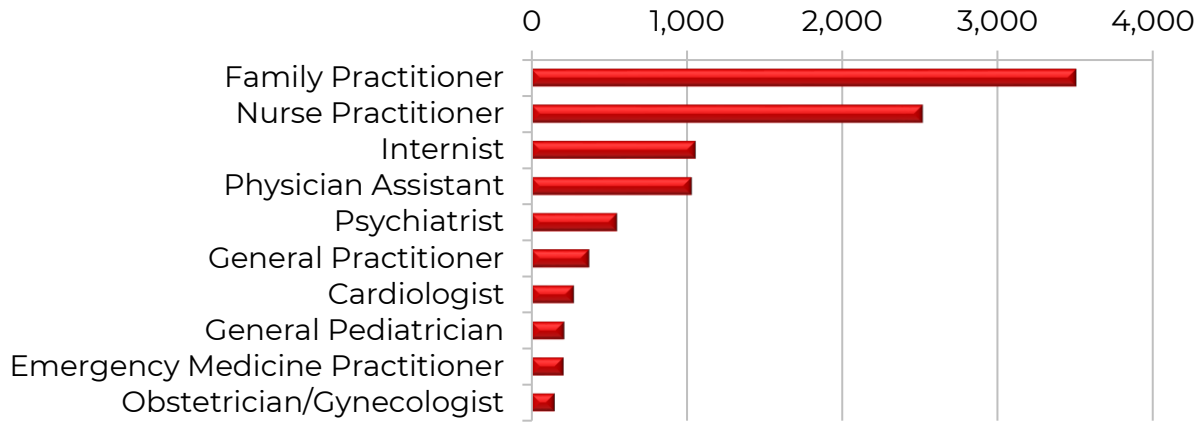
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	5,610	12,034	$2,558,726.21	$212.62	$8.78	595,038	291,460
2020	4,958	10,492	$2,337,875.93	$222.82	$9.10	519,470	256,858
% Change	**-11.60%**	**-12.80%**	**-8.60%**	**4.80%**	**3.60%**	**-12.70%**	**-11.90%**
Change	**-652**	**-1,542**	**-$220,850.28**	**$10.20**	**$0.32**	**-75,568**	**-34,602**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Demographics of Members Utilizing Smoking Cessation Products



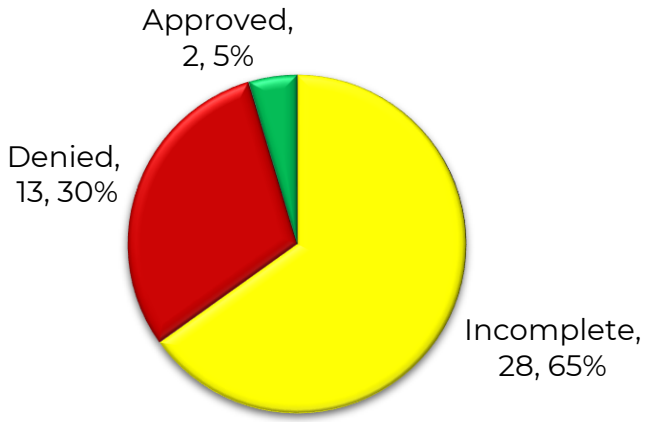
Top Prescriber Specialties of Smoking Cessation Products by Number of Claims



Prior Authorization of Smoking Cessation Products

There were 43 prior authorization requests submitted for smoking cessation products during fiscal year 2020. The following chart shows the status of the submitted petitions for fiscal year 2020.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[133]

- Chantix® (varenicline tablets): February 2023

[133] 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 01/2021. Last accessed 01/27/2021.

News:

- **July 2020:** According to a survey for the charity Action on Smoking and Health (ASH), more than 1 million people have given up smoking since the COVID-19 pandemic hit. Of those who had quit in the previous 4 months, 41% said it was in direct response to the coronavirus. In a separate survey, the University College London found more people quit smoking in the year to June 2020 than in any year since its survey began in 2007.[134]
- **July 2020:** A new initiative led by the World Health Organization (WHO), Access Initiative for Quitting Tobacco, aims to help the world's 1.3 tobacco users to quit. Smoking cessation is more important than even as evidence reveals smokers are more likely than non-smokers to have severe outcomes from COVID-19. The project gives people free access to nicotine replacement therapy and to Florence, a digital health worker, based on artificial intelligence, that dispels myths around COVID-19 and tobacco and helps people develop a personalized plan to quit tobacco.[135]

Recommendations

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

Utilization Details of Smoking Cessation Products: Fiscal Year 2020

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
VARENICLINE PRODUCTS						
CHANTIX PAK 0.5MG & 1MG	2,147	1,896	$904,524.87	$421.30	1.13	38.69%
CHANTIX PAK 1MG	1,302	678	$551,108.49	$423.28	1.92	23.57%
CHANTIX TAB 1MG	1,182	564	$500,738.09	$423.64	2.10	21.42%
CHANTIX TAB 0.5MG	120	71	$41,807.40	$348.40	1.69	1.79%
SUBTOTAL	**4,751**	**3,209**	**$1,998,178.85**	**$420.58**	**1.48**	**85.47%**
NICOTINE REPLACEMENT PRODUCTS						
NICOTINE TD DIS	1,929	1,231	$94,564.64	$49.02	1.57	4.04%
NICOTINE TD DIS	1,068	710	$51,117.70	$47.92	1.50	2.19%
NICOTINE TD DIS	509	350	$22,082.60	$43.38	1.45	0.94%
NICOTINE POL LOZ 4MG	214	67	$10,730.32	$50.14	3.19	1.46%
NICODERM CQ DIS	194	111	$13,346.64	$68.80	1.75	0.57%

[134] Schraer R. Coronavirus: Smokers Quit in Highest Numbers in a Decade. *BBC*. Available online at: https://www.bbc.com/news/health-53403610. Issued 07/14/2020. Last accessed 01/27/2021.
[135] WHO and Partners to Help More than 1 Billion People Quit Tobacco to Reduce Risk of COVID-19. *WHO*. Available online at: https://www.who.int/news/item/10-07-2020-who-and-partners-to-help-more-than-1-billion-people-quit-tobacco-to-reduce-risk-of-covid-19. Issued 07/10/2020. Last accessed 01/27/2021.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
NICOTINE POL GUM 4MG	146	41	$5,817.54	$39.85	3.56	0.25%
NICODERM CQ DIS	126	87	$5,634.65	$45.81	1.41	0.24%
NICOTINE POL GUM 4MG	95	32	$3,951.53	$41.60	2.97	0.17%
SM NICOTINE DIS	93	75	$4,897.29	$52.66	1.24	0.21%
NICOTROL INH	92	67	$41,943.78	$455.91	1.37	1.79%
NICODERM CQ DIS	89	60	$5,067.19	$56.93	1.48	0.22%
NICORETTE LOZ 4MG	84	26	$5,878.55	$69.98	3.23	0.25%
NICOTINE POL LOZ 2MG	75	32	$3,258.20	$43.44	2.34	0.14%
NICORETTE GUM 4MG	71	15	$2,579.80	$36.34	4.73	0.11%
NICOTINE POL GUM 2MG	59	30	$1,895.27	$32.12	1.97	0.08%
HM NICOTINE DIS	55	29	$2,429.71	$44.18	1.90	0.10%
SM NICOTINE DIS	49	42	$2,372.78	$48.42	1.17	0.10%
NICOTROL NS SPR	39	14	$28,363.36	$727.27	2.79	0.12%
GNP NICOTINE DIS	38	35	$1,790.33	$47.11	1.09	0.08%
HM NICOTINE DIS	35	25	$1,690.43	$48.30	1.40	0.07%
HM NICOTINE GUM 2MG	33	12	$1,159.10	$35.12	2.75	0.05%
GNP NICOTINE DIS	31	13	$1,186.29	$38.27	2.38	0.05%
NICOTINE POL GUM 2MG	30	21	$925.34	$30.84	1.43	0.04%
NICOTINE POL GUM 4MG	27	17	$1,095.43	$40.57	1.59	0.05%
HM NICOTINE LOZ 4MG	27	18	$1,957.40	$72.50	1.50	0.08%
HM NICOTINE LOZ 2MG	26	10	$1,458.90	$56.11	2.60	0.06%
NICOTINE POL GUM 2MG	23	17	$818.17	$35.57	1.35	0.03%
NICORETTE GUM	22	10	$1,259.89	$57.27	2.20	0.05%
SM NICOTINE GUM 4MG	21	13	$765.25	$36.44	1.62	0.03%
HM NICOTINE GUM 4MG	20	9	$2,087.44	$104.37	2.22	0.09%
SM NICOTINE LOZ 2MG	19	8	$713.86	$37.57	2.38	0.03%
HM NICOTINE DIS	18	12	$988.02	$54.89	1.50	0.04%
NICOTINE LOZ 2MG MINT	16	9	$1,283.72	$80.23	1.78	0.05%
SM NICOTINE LOZ 4MG	15	7	$757.77	$50.52	2.14	0.03%
GNP NICOTINE LOZ 4MG	15	8	$765.34	$51.02	1.88	0.03%
NICOTINE POL GUM 2MG	15	13	$505.63	$33.71	1.15	0.02%
SM NICOTINE DIS	13	11	$566.77	$43.60	1.18	0.02%
SM NICOTINE GUM 4MG	12	7	$939.36	$78.28	1.71	0.04%
NICORETTE LOZ 2MG	11	9	$616.05	$56.00	1.22	0.03%
GNP NICOTINE DIS	10	8	$396.13	$39.61	1.25	0.02%
NICORETTE GUM 2MG	8	8	$410.41	$51.30	1.00	0.02%
NICORETTE GUM	8	5	$426.07	$53.26	1.60	0.02%
SM NICOTINE GUM 2MG	8	8	$186.03	$23.25	1.00	0.01%
NICORETTE GUM 2MG	7	7	$394.30	$56.33	1.00	0.02%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
NICOTINE LOZ 4MG MINT	5	1	$190.09	$38.02	5.00	0.01%
NICORETTE GUM 4MG	5	3	$239.55	$47.91	1.67	0.01%
NICORETTE GUM 2MG	5	4	$285.63	$57.13	1.25	0.01%
SM NICOTINE GUM 2MG	4	4	$142.75	$35.69	1.00	0.01%
GNP NICOTINE LOZ MINI	3	3	$225.42	$75.14	1.00	0.01%
GNP NICOTINE GUM 4MG	3	2	$68.84	$22.95	1.50	0.00%
NICORETTE GUM 2MG	2	2	$146.55	$73.28	1.00	0.01%
NICORETTE GUM 4MG	2	2	$147.39	$73.70	1.00	0.01%
NICORETTE ST GUM 2MG	1	1	$53.61	$53.61	1.00	0.00%
GNP NICOTINE GUM 2MG	1	1	$46.48	$46.48	1.00	0.00%
NICORETTE ST GUM 4MG	1	1	$45.61	$45.61	1.00	0.00%
NICOTINE GUM 4MG	1	1	$21.75	$21.75	1.00	0.00%
GNP NICOTINE GUM 2MG	1	1	$34.71	$34.71	1.00	0.00%
SUBTOTAL	**5,526**	**3,365**	**$332,783.36**	**$60.22**	**1.64**	**14.20%**
BUPROPION PRODUCTS						
BUPROPION TAB 150MG	215	109	$6,913.72	$32.16	1.97	0.30%
SUBTOTAL	**215**	**109**	**$6,913.72**	**$32.16**	**1.97**	**0.30%**
TOTAL	**10,492**	**4,958***	**$2,337,875.93**	**$222.82**	**2.12**	**100%**

DIS = patch; INH = inhaler; LOZ = lozenge; NS = nasal spray; SPR = spray; TAB = tablet
*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Fiscal Year 2020 Annual Review of Strensiq® (Asfotase Alfa)

Oklahoma Health Care Authority
Fiscal Year 2020 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 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 2020

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	4	34	$1,187,822.70	$34,935.96	$1,247.71	401	952
2020	2	24	$731,286.60	$30,470.28	$1,088.22	256	672
% Change	**-50.00%**	**-29.40%**	**-38.40%**	**-12.80%**	**-12.80%**	**-36.20%**	**-29.40%**
Change	**-2**	**-10**	**-$456,536.10**	**-$4,465.68**	**-$159.49**	**-145**	**-280**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Demographics of Members Utilizing Strensiq® (Asfotase Alfa)

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

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

- The only prescriber specialty listed on paid pharmacy claims for Strensiq® (asfotase alfa) during fiscal year 2020 was general pediatrician.

Prior Authorization of Strensiq® (Asfotase Alfa)

There were 3 prior authorization requests submitted for Strensiq® (asfotase alfa) during fiscal year 2020, all of which were approved.

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 2020

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
STRENSIQ INJ 40MG/ML	15	2	$514,969.53	$1,226.12	$34,331.30	70.42%
STRENSIQ INJ 28MG/0.7ML	9	1	$216,317.07	$858.40	$24,035.23	29.58%
TOTAL	**24**	**2***	**$731,286.60**	**$1,088.22**	**$30,470.28**	**100.00%**

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

Fiscal Year 2020 Annual Review of Sylvant® (Siltuximab)

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Sylvant® (Siltuximab) Approval Criteria:

1. An FDA approved diagnosis of Multicentric Castleman's Disease (also known as giant lymph node hyperplasia); and
2. Member must be Human Immunodeficiency Virus (HIV) and Human Herpesvirus-8 (HHV-8) negative; and
3. Member must be 18 years of age or older; and
4. The following FDA approved dosing restrictions will apply:
    a. 11mg/kg via intravenous (IV) infusion every 3 weeks until treatment failure (defined as disease progression based on increase in symptoms, radiologic progression, or deterioration in performance status); and
5. Sylvant® must be administered in a clinical setting able to provide resuscitation equipment, medications, and trained personnel; and
6. The prescriber must verify that a complete blood count (CBC) will be done prior to each dose for the first 12 months and for an additional 3 doses thereafter; and
7. Approvals will be for the duration of 6 months.

Utilization of Sylvant® (Siltuximab): Fiscal Year 2020

There was no SoonerCare utilization, including pharmacy and medical claims, of Sylvant® (siltuximab) during fiscal year 2020 (07/01/2019 to 06/30/2020).

Prior Authorization of Sylvant® (Siltuximab)

There were no prior authorization requests submitted for Sylvant® (siltuximab) during fiscal year 2020.

Market News and Updates

Pipeline:

- **Sirolimus:** A Phase 2, single-arm, open-label, multi-center study of sirolimus in previously treated idiopathic Multicentric Castleman's Disease (iMCD) is currently being conducted. Blockade of interleukin 6 (IL-6) signaling with siltuximab or tocilizumab stops symptoms and improves lymphadenopathy in a portion of patients. However, 66% of patients in the siltuximab Phase 2 clinical study did not meet response criteria, and recent studies found that IL-6 is not significantly elevated

in many iMCD patients. Recent research has suggested a key role for the phosphoinositide 3-kinase (PI3K)/Akt/mechanistic target of rapamycin (mTOR) pathway in iMCD pathogenesis and off-label administration of sirolimus, an mTOR inhibitor, has shown clinical activity. Based on these experiences, the current study is evaluating the efficacy of sirolimus as a therapy for iMCD patients who are either unable to tolerate IL-6 blockade therapy (siltuximab or tocilizumab), or who fail, relapse, or are refractory to such treatment. The estimated study enrollment is 24 male or female adults 18 to 80 years of age. Patients with iMCD who have failed previous therapy will take daily oral sirolimus (loading dose of 7.5mg/m^2 on day 1 and 2.5mg/m^2/day starting on day 2) for 12 months. The primary outcome measure is the proportion of patients achieving a positive clinical benefit response after 12 months.[136]

Recommendations

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

[136] Sirolimus in Previously Treated Idiopathic Multicentric Castleman Disease. *Clinicaltrials.gov*. Available online at: https://clinicaltrials.gov/ct2/show/study/NCT03933904. Last revised 07/20/2020. Last accessed 12/23/2020.

Fiscal Year 2020 Annual Review of Symlin® (Pramlintide)

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Symlin® (Pramlintide) Approval Criteria:

1. An FDA approved diagnosis of type 1 or type 2 diabetes; and
2. Member must be using a basal-bolus insulin regimen; and
3. Member must have failed to achieve adequate glycemic control on basal-bolus insulin regimen or are gaining excessive weight on basal-bolus insulin regimen; and
4. Member must be receiving ongoing care under the guidance of a health care professional; and
5. Members meeting any of the following criteria should not be considered for Symlin® (pramlintide) therapy:
    a. Poor compliance with insulin regimen; or
    b. Poor compliance with self-blood glucose monitoring; or
    c. Hemoglobin A1C (HbA1c) >9%; or
    d. Recurrent severe hypoglycemia requiring assistance in the past 6 months; or
    e. Presence of hypoglycemia unawareness; or
    f. Diagnosis of gastroparesis; or
    g. Required use of medications that stimulate gastrointestinal motility; or
    h. Pediatric members 15 years of age or younger.

Utilization of Symlin® (Pramlintide): Fiscal Year 2020

There was no SoonerCare utilization of Symlin® (pramlintide) during fiscal year 2019 (07/01/2018 to 06/30/2019) or fiscal year 2020 (07/01/2019 to 06/30/2020).

Prior Authorization of Symlin® (Pramlintide)

There were no prior authorization requests submitted for Symlin® (pramlintide) during fiscal year 2020.

Recommendations

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

Fiscal Year 2020 Annual Review of Testosterone Products

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Testosterone Products		
Tier-1*	**Tier-2**	**Special PA**
methyltestosterone powder	testosterone enanthate sub-Q auto-injector (Xyosted®)	fluoxymesterone oral tab (Androxy®)
testosterone cypionate IM inj (Depo-Testosterone®)	testosterone nasal gel (Natesto®)	methyltestosterone oral tab/cap (Android®, Methitest®, Testred®)
testosterone enanthate IM inj (Delatestryl®)	testosterone patch (Androderm®)	testosterone buccal tab (Striant®)
testosterone topical gel (Androgel® 1%, 1.62%)+	testosterone topical gel (Fortesta®, Testim®, Vogelxo®)	testosterone pellets (Testopel®)
	testosterone topical solution (Axiron®)	testosterone undecanoate oral cap (Jatenzo®)
	testosterone undecanoate IM inj (Aveed®)	

cap = capsule; IM = intramuscular; inj = injection; PA = prior authorization; sub-Q = subcutaneous; tab = tablet
*Tier-1 products include generic injectable products and supplementally rebated topical products.
+Brand name preferred

Initial Approval Criteria for All Testosterone Products:

1. An FDA approved diagnosis of 1 of the following:
   a. Testicular failure due to cryptorchidism, bilateral torsions, orchitis, vanishing testis syndrome, or orchiectomy; or
   b. Idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency, or pituitary hypothalamic injury from tumors, trauma, or radiation; or
   c. Delayed puberty; or
   d. Advanced inoperable metastatic mammary cancer in females 1 to 5 years postmenopausal, or premenopausal females with breast cancer benefitting from oophorectomy and have been determined to have a hormone-responsive tumor; and
2. Must include 2 labs showing pre-medication, morning testosterone (total testosterone) levels <300ng/dL; and
3. Must include 1 lab showing abnormal gonadotropins and/or other information necessary to demonstrate diagnosis; or
4. Testosterone and gonadotropin labs are not required for authorization of testosterone therapy if documentation is provided for established hypothalamic pituitary or gonadal disease, if the pituitary gland or testes has/have been removed, or for postmenopausal females with

advanced inoperable metastatic mammary cancer or premenopausal females with breast cancer benefitting from oophorectomy and that have been determined to have a hormone-responsive tumor.

Testosterone Products Tier-2 Approval Criteria:

1. All diagnoses and laboratory requirements listed in the initial approval criteria for all testosterone products must be met; and
2. Member must have a trial of at least 2 Tier-1 products (must include at least 1 injectable and 1 topical formulation) at least 12 weeks in duration; or
3. A patient-specific, clinically significant reason why member cannot use all available Tier-1 products must be provided; or
4. Prior stabilization on a Tier-2 product (within the past 180 days); and
5. Approvals will be for the duration of 1 year; and
6. For Xyosted® [testosterone enanthate subcutaneous (sub-Q) auto-injector]:
    a. Member must be trained by a health care professional on sub-Q administration and storage of Xyosted® sub-Q auto-injector.

Testosterone Products Special Prior Authorization (PA) Approval Criteria:

1. All diagnoses and laboratory requirements listed in the initial approval criteria for all testosterone products must be met; and
2. A patient-specific, clinically significant reason why member cannot use all other available formulations of testosterone must be provided; and
3. Approvals will be for the duration of 1 year.

Utilization of Testosterone Products: Fiscal Year 2020

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	171	671	$135,158.35	$201.43	$4.54	22,707	29,745
2020	163	715	$110,511.93	$154.56	$3.94	17,607	28,030
% Change	**-4.70%**	**6.60%**	**-18.20%**	**-23.30%**	**-13.20%**	**-22.50%**	**-5.80%**
Change	**-8**	**44**	**-$24,646.42**	**-$46.87**	**-$0.60**	**-5,100**	**-1,715**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

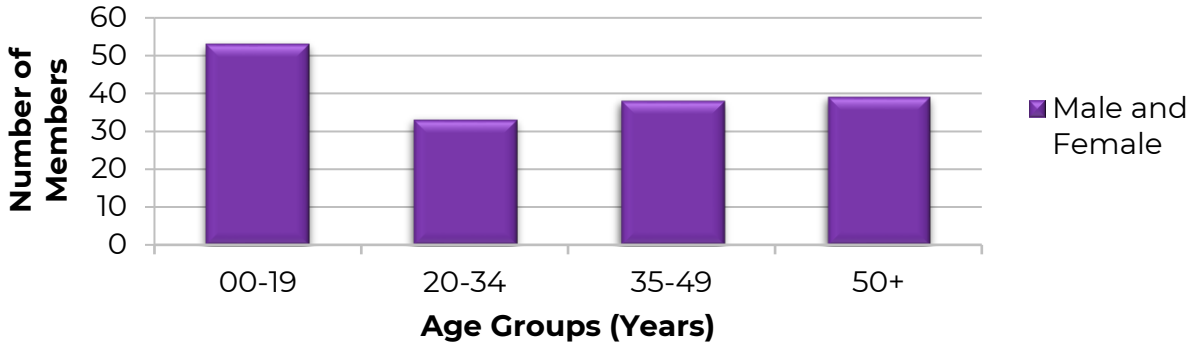
Comparison of Fiscal Years: Medical Claims

Fiscal Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2019	29	170	$716.45	$4.21	5.86
2020	271	1,749	$4,602.25	$2.63	6.45
% Change	**834.48%**	**928.82%**	**542.37%**	**-37.53%**	**10.07%**
Change	**242**	**1,579**	**$3,885.80**	**-$1.58**	**0.59**

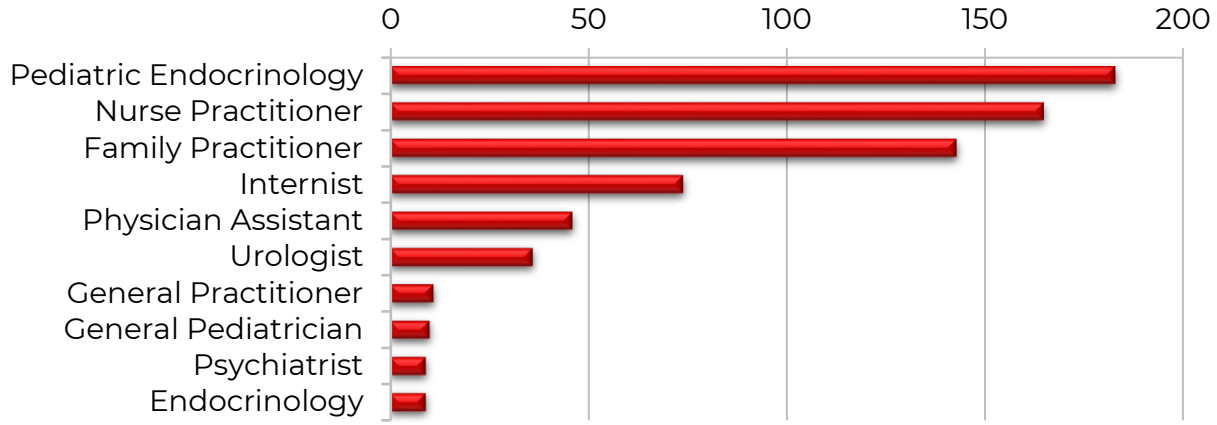
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

- Due to increased medical claims utilization, a prior authorization was implemented on 10/23/2019 for J1071 (testosterone cypionate injection) with the same approval criteria required for pharmacy claims. During fiscal year 2020, 1,674 (95.7%) of the paid claims were from dates of service 07/01/2019 to 10/22/2019, before the prior authorization requirement was implemented.

Demographics of Members Utilizing Testosterone Products: Pharmacy Claims

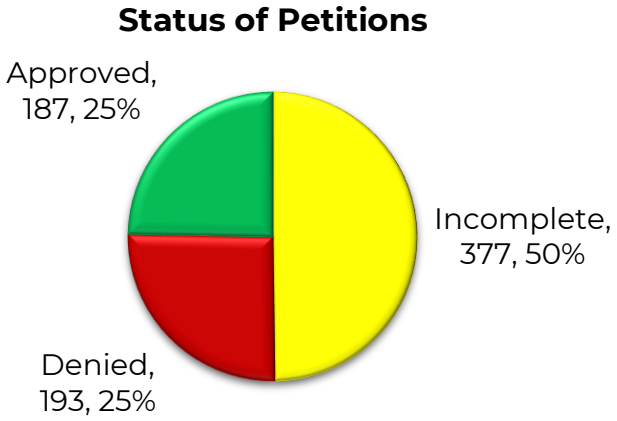


Top Prescriber Specialties of Testosterone Products by Number of Claims: Pharmacy Claims



Prior Authorization of Testosterone Products

There were 757 prior authorization requests submitted for 369 unique members for testosterone products during fiscal year 2020. All testosterone products require prior authorization regardless of tier status in order to evaluate diagnosis and submitted labs. The following chart shows the status of the submitted petitions for fiscal year 2020.



Market News and Updates

Anticipated Patent Expiration(s):[137]

- Natesto® (testosterone nasal gel): February 2024
- Testim® (testosterone topical gel): January 2025
- Androgel® (testosterone topical gel): October 2026
- Aveed® [testosterone undecanoate intramuscular (IM) injection]: May 2027
- Axiron® (testosterone topical solution): September 2027
- Jatenzo® (testosterone undecanoate oral capsule): December 2030
- Vogelxo® (testosterone topical gel): February 2034
- Xyosted® [testosterone enanthate subcutaneous (sub-Q) auto-injector]: August 2038

News:

- **February 2020:** Clarus Therapeutics launched Jatenzo® (testosterone undecanoate) oral capsules in February 2020. Jatenzo® was previously approved by the U.S. Food and Drug Administration (FDA) in March 2019 as testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. In

[137] 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 02/2021. Last Accessed 02/04/2021.

August 2019, Jatenzo® was granted 3-year market exclusivity by the FDA.[138,139]

Pipeline:

- **Tlando™ (Testosterone Undecanoate):** Lipocine is currently developing Tlando™, an oral testosterone undecanoate product, for the replacement of endogenous testosterone in both primary and secondary hypogonadism. In November 2019, the FDA rejected Lipocine's New Drug Application (NDA) for Tlando™, stating the trial establishing efficacy of the product did not meet the 3 secondary end points for maximal testosterone concentrations. In March 2020, Lipocine announced the resubmission of a NDA for Tlando™ based on a reanalysis of existing data and a new Prescription Drug User Fee Act (PDUFA) date of August 28, 2020 was set. In August 2020, Lipocine announced the FDA had informed the company additional time would be required to complete the review of the NDA for Tlando™. No additional data was requested by the FDA and no timeline or new PDUFA action date was provided. In December 2020, Lipocine again announced the FDA was still reviewing the NDA for Tlando™, but an updated PDUFA action date has still not been provided.[140,141,142,143,144]

Recommendations

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

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[138] Duffy S. Jatenzo®, an Oral Testosterone Replacement Therapy, Now Available. Available online at: https://www.empr.com/home/news/jatenzo-an-oral-testosterone-replacement-therapy-now-available/. Issued 02/11/2020. Last accessed 02/19/2021.

[139] Clarus Therapeutics, Inc. Clarus Therapeutics Announces FDA Award of 3-Year Market Exclusivity for Jatenzo®. Available online at: https://www.clarustherapeutics.com/clarus-therapeutics-announces-fda-award-of-3-year-market-exclusivity-for-jatenzo/. Issued 08/19/2019. Last accessed 02/19/2021.

[140] Lipocine, Inc. Lipocine Pipeline: Tlando™. Available online at: https://www.lipocine.com/pipeline/tlando/. Last accessed 02/19/2021.

[141] Ernst D. FDA Again Rejects NDA for Oral Testosterone Product Candidate. *MPR*. Available online at: https://www.empr.com/home/news/fda-again-rejects-nda-for-oral-testosterone-product-candidate/. Issued 11/12/2019. Last accessed 02/19/2021.

[142] Lipocine, Inc. Lipocine Announces Tlando™ PDUFA Date of August 28, 2020. Available online at: https://www.lipocine.com/news-article/lipocine-announces-tlando-pdufa-date-of-august-28-2020/. Issued 03/04/2020. Last accessed 02/19/2021.

[143] Lipocine, Inc. Lipocine Provides Regulatory Update for Tlando™. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/lipocine-provides-regulatory-update-for-tlando-301120513.html. Issued 08/28/2020. Last accessed 02/19/2021.

[144] Lipocine, Inc. Lipocine Provides New Regulatory Update of Tlando™. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/lipocine-provides-new-regulatory-update-on-tlando-301186755.html. Issued 12/04/2020. Last accessed 02/19/2021.

Utilization Details of Testosterone Products: Fiscal Year 2020

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TESTOSTERONE INJECTABLE PRODUCTS						
TESTOST CYP INJ 200MG/ML	534	124	$23,531.95	$44.07	4.31	21.29%
DEPO-TESTOST INJ 200MG/ML	28	18	$1,472.76	$52.60	1.56	1.33%
TESTOST ENAN INJ 200MG/ML	10	6	$785.09	$78.51	1.67	0.71%
TESTOST CYP INJ 100MG/ML	8	5	$373.02	$46.63	1.6	0.34%
DEPO-TESTOST INJ 100MG/ML	7	4	$494.41	$70.63	1.75	0.45%
XYOSTED INJ 75MG/0.5ML	2	1	$969.66	$484.83	2	0.88%
SUBTOTAL	**589**	**136***	**$27,626.89**	**$46.90**	**4.33**	**25.00%**
TESTOSTERONE TOPICAL PRODUCTS						
ANDROGEL GEL 1.62%	79	20	$51,944.22	$657.52	3.95	47.00%
ANDROGEL GEL 1% (50MG)	25	4	$24,893.97	$995.76	6.25	22.53%
TESTOSTERONE GEL 1% (50MG)	16	2	$3,401.19	$212.57	8	3.08%
TESTOSTERONE GEL 1.62%	3	1	$236.83	$78.94	3	0.21%
TESTOSTERONE GEL 1.62%	1	1	$1,454.49	$1,454.49	1	1.32%
ANDROGEL GEL 1% (25MG)	1	1	$629.94	$629.94	1	0.57%
TESTOSTERONE GEL 10MG/ACT	1	1	$324.40	$324.40	1	0.29%
SUBTOTAL	**126**	**30***	**$82,885.04**	**$657.82**	**4.2**	**75.00%**
TOTAL	**715**	**163***	**$110,511.93**	**$154.56**	**4.39**	**100.00%**

ACT = actuation; CYP = cypionate; ENAN = enanthate; INJ = injection; TESTOST = testosterone
*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Medical Claims

PRODUCT UTILIZED	†TOTAL CLAIMS	*TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
TESTOSTERONE CYPIONATE INJ J1071	1,749	271	$4,602.25	$2.63	6.45
TOTAL	**1,749**	**271**	**$4,602.25**	**$2.63**	**6.45**

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

Fiscal Year 2020 Annual Review of Topical Antibiotic Products

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Topical Antibiotic Products	
Tier-1	**Tier-2**
gentamicin 0.1% cream (Garamycin®)	mupirocin 2% cream (Bactroban®)
gentamicin 0.1% ointment (Garamycin®)	mupirocin 2% kit (Centany®)
gentamicin powder	mupirocin 2% nasal ointment (Bactroban®)
mupirocin 2% ointment (Bactroban®)	ozenoxacin 1% cream (Xepi™)
neomycin/polymyxin B sulfates/ bacitracin zinc/HC 1% ointment (Cortisporin®)	retapamulin ointment 2% (Altabax®)
neomycin/polymyxin B sulfates/HC 0.5% cream (Cortisporin®)	

HC = hydrocortisone
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).

Topical Antibiotic Products Tier-2 Approval Criteria:

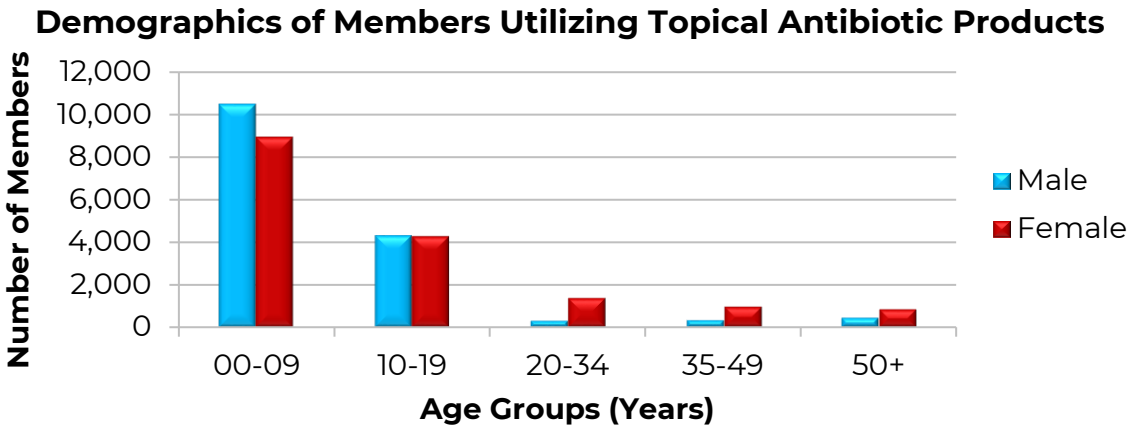
1. A documented 5-day trial of a Tier-1 product within the last 30 days; or
2. Clinical exceptions apply for adverse effects with all Tier-1 products or for a unique indication not covered by Tier-1 products; and
3. Approvals will be for the duration of 10 days.

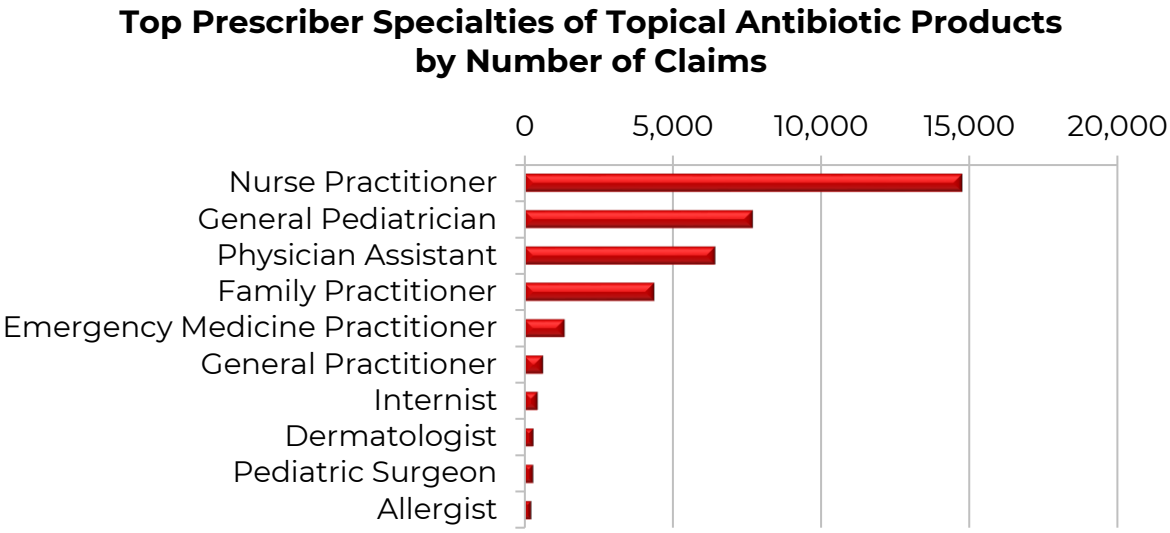
Utilization of Topical Antibiotic Products: Fiscal Year 2020

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	35,158	41,195	$665,450.16	$16.15	$1.53	991,462	435,637
2020	32,320	38,238	$626,655.03	$16.39	$1.54	967,063	406,947
%	**-8.10%**	**-7.20%**	**-5.80%**	**1.50%**	**0.70%**	**-2.50%**	**-6.60%**
Change	**-2,838**	**-2,957**	**-$38,795.13**	**$0.24**	**$0.01**	**-24,399**	**-28,690**

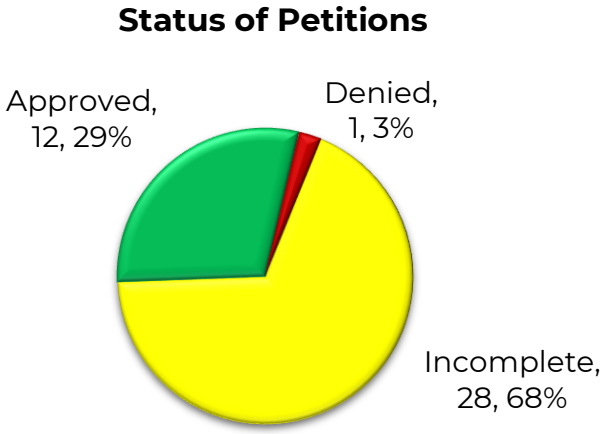
*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020





Prior Authorization of Topical Antibiotic Products

There were 41 prior authorization requests submitted for topical antibiotic products during fiscal year 2020. The following chart shows the status of the submitted petitions for fiscal year 2020.



Market News and Updates

Anticipated Patent Expiration(s):[145]

- Altabax® (retapamulin 1% ointment): February 2027
- Xepi™ (ozenoxacin 1% cream): January 2032

Recommendations

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

Utilization Details of Topical Antibiotic Products: Fiscal Year 2020

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
TIER-1 PRODUCTS					
MUPIROCIN OIN 2%	37,848	32,157	$591,226.79	$1.47	$15.62
GENTAMICIN OIN 0.1%	270	136	$23,865.44	$6.53	$88.39
GENTAMICIN CRE 0.1%	103	72	$9,787.02	$4.52	$95.02
TIER-1 SUBTOTAL	**38,221**	**32,365**	**$624,879.25**	**$1.54**	**$16.35**
TIER-2 PRODUCTS					
MUPIROCIN CRE 2%	9	8	$1,639.29	$14.38	$182.14
CENTANY OIN 2%	8	8	$136.49	$1.24	$17.06
TIER-2 SUBTOTAL	**17**	**16**	**$1,775.78**	**$7.93**	**$104.46**
TOTAL	**38,238**	**32,320***	**$626,655.03**	**$1.54**	**$16.39**

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

[145] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 02/2021. Last accessed 02/07/2021.

Fiscal Year 2020 Annual Review of Topical Antifungal Products

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Topical Antifungal Products		
Tier-1	**Tier-2**	**Special PA**
ciclopirox cream, suspension	butenafine (Mentax®)	efinaconazole (Jublia®)
clotrimazole (Rx) cream	ciclopirox solution, shampoo, gel (Penlac® and Loprox®)	tavaborole (Kerydin®)
clotrimazole (OTC)* cream	clotrimazole solution	
clotrimazole/betamethasone cream	clotrimazole/betamethasone lotion	
econazole cream	ketoconazole foam (Extina®)	
ketoconazole cream, shampoo	ketoconazole gel (Xolegel®)	
nystatin cream, ointment, powder	luliconazole cream (Luzu®)	
terbinafine (OTC)* cream	miconazole/zinc oxide/white petrolatum (Vusion®)	
tolnaftate (OTC)* cream	naftifine (Naftin®)	
	nystatin/triamcinolone cream, ointment	
	oxiconazole (Oxistat®)	
	salicylic acid (Bensal HP®)	
	sertaconazole nitrate (Ertaczo®)	
	sulconazole (Exelderm®)	

OTC = over-the-counter; PA = prior authorization; Rx = prescription
*OTC antifungal medications are covered for pediatric members 0 to 20 years of age without prior authorization; OTC antifungal medications require a prescription to be covered at the pharmacy.
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).

Topical Antifungal Products Tier-2 Approval Criteria:

1. Documented, recent trials with at least 2 Tier-1 topical antifungal products for at least 90 days each; and
2. When the same medication is available in Tier-1, a patient-specific, clinically significant reason must be provided for using a special dosage form of that medication in Tier-2 (e.g., foams, shampoos, spray, kit); and
3. Authorization of combination products nystatin/triamcinolone or clotrimazole/betamethasone lotion requires a patient-specific, clinically significant reason why the member cannot use the individual

components separately, or in the case of clotrimazole/betamethasone lotion, why the Tier-1 cream cannot be used; and

4. For treatment of onychomycosis, a trial of oral antifungals (6 weeks for fingernails and 12 weeks for toenails) will be required for consideration of approval of Penlac® (ciclopirox solution).

Jublia® (Efinaconazole) and Kerydin® (Tavaborole) Approval Criteria:

1. An FDA approved diagnosis of onychomycosis of the toenails due to *Trichophyton rubrum* or *Trichophyton mentagrophytes*; and
2. Member must have a documented trial of oral antifungals (12 weeks for toenails); and
3. A patient-specific, clinically significant reason why the member cannot use Penlac® (ciclopirox solution) must be provided; and
4. A clinically significant reason why the member requires treatment for onychomycosis must be provided (cosmetic reasons will not be approved).

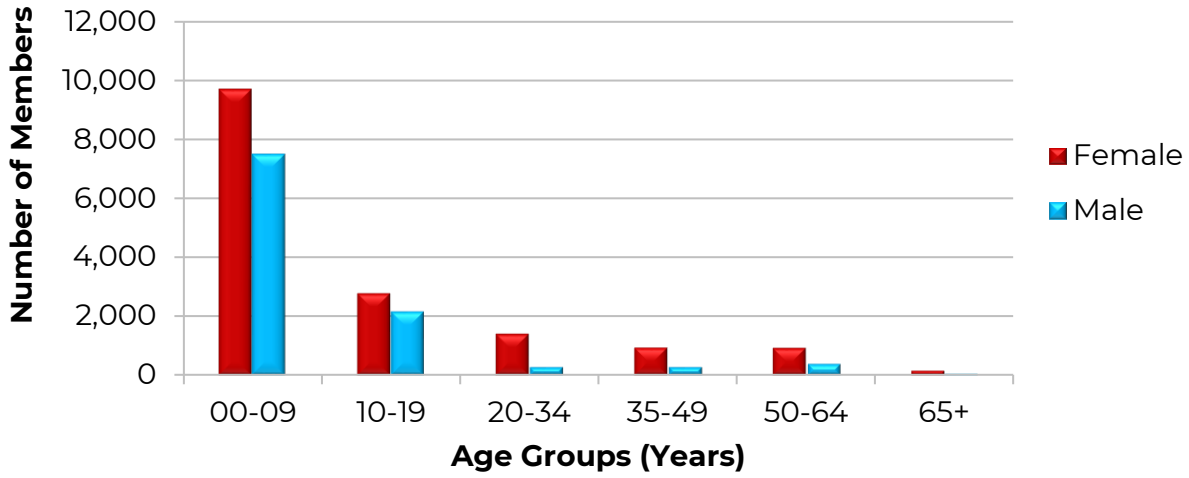
Utilization of Topical Antifungal Products: Fiscal Year 2020

Comparison of Fiscal Years: Pharmacy Claims

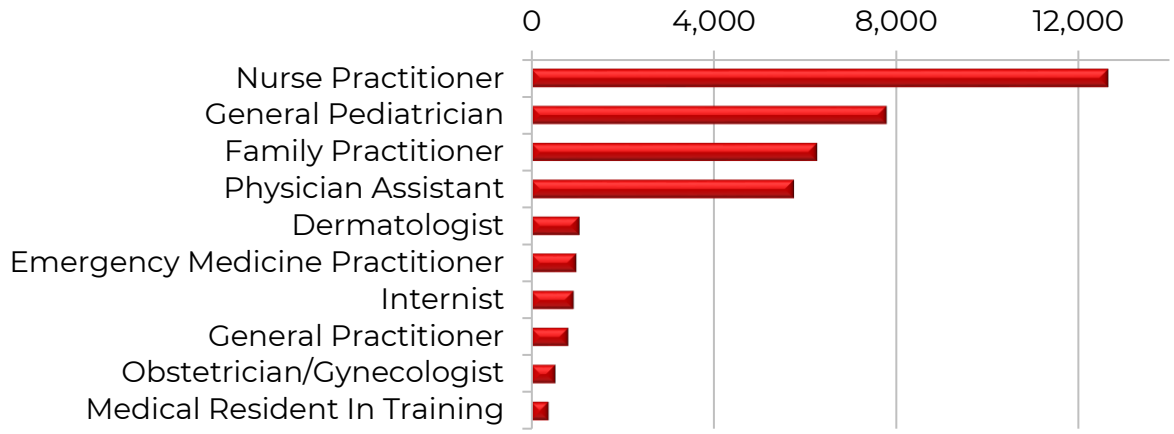
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	28,027	39,927	$814,491.11	$20.40	$1.32	1,617,190	615,460
2020	26,570	38,312	$801,802.03	$20.93	$1.31	1,612,773	612,448
% Change	**-5.20%**	**-4.00%**	**-1.60%**	**2.60%**	**-0.80%**	**-0.30%**	**-0.50%**
Change	**-1,457**	**-1,615**	**-$12,689.08**	**$0.53**	**-$0.01**	**-4,417**	**-3,012**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Demographics of Members Utilizing Topical Antifungal Products



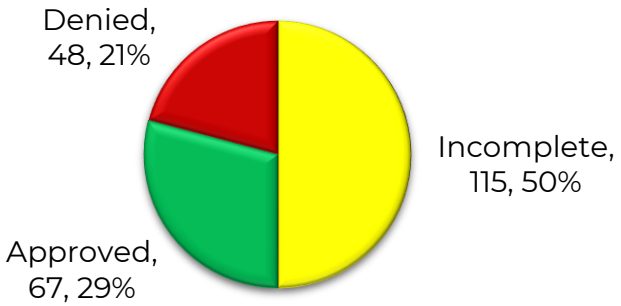
Top Prescriber Specialties of Topical Antifungal Products by Number of Claims



Prior Authorization of Topical Antifungal Products

There were 230 prior authorization requests submitted for antifungal medications during fiscal year 2020. The following chart shows the status of the submitted petitions for fiscal year 2020.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[146]

- Kerydin® (tavaborole solution): November 2027
- Vusion® (miconazole/zinc oxide/white petrolatum ointment): March 2028
- Naftin® (naftifine gel): January 2033
- Luzu® (luliconazole cream): April 2034
- Jublia® (efinaconazole solution): April 2035

[146] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 02/2021. Last accessed 02/07/2021.

Recommendations

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

Utilization Details of Topical Antifungal Products: Fiscal Year 2020

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
TIER-1 PRODUCTS					
NYSTATIN PRODUCTS					
NYSTATIN CRE 100000	11,733	9,278	$212,592.51	$1.37	$18.12
NYSTATIN OIN 100000	5,417	4,385	$99,429.31	$1.49	$18.36
NYSTOP POW 100000	1,959	1,371	$37,288.40	$1.27	$19.03
NYSTATIN POW 100000	1,026	588	$20,832.98	$1.33	$20.31
NYSTATIN POW 100000	692	326	$13,475.03	$1.54	$19.47
SUBTOTAL	**20,827**	**15,948**	**$383,618.23**	**$1.39**	**$18.42**
CLOTRIMAZOLE PRODUCTS					
CLOTRIMAZOLE CRE 1%	5,730	4,836	$96,663.62	$1.22	$16.87
ATHLETE FOOT CRE 1%	7	6	$95.88	$0.73	$13.70
SUBTOTAL	**5,737**	**4,842**	**$96,759.50**	**$1.22**	**$16.87**
KETOCONAZOLE PRODUCTS					
KETOCONAZOLE CRE 2%	4,449	3,687	$165,189.00	$2.09	$37.13
KETOCONAZOLE SHA 2%	4,289	2,527	$88,265.27	$0.67	$20.58
SUBTOTAL	**8,738**	**6,214**	**$253,454.27**	**$1.21**	**$29.01**
CLOTRIMAZOLE/BETAMETHASONE PRODUCTS					
CLOTRIM/BETA CRE DIPROP	1,506	1,210	$31,597.62	$1.35	$20.98
CLOTRIM/BETA CRE 1-0.05%	391	293	$8,754.54	$1.46	$22.39
SUBTOTAL	**1,897**	**1,503**	**$40,352.16**	**$1.38**	**$21.27**
TERBINAFINE PRODUCTS					
TERBINAFINE CRE 1%	411	355	$6,707.94	$1.12	$16.32
ATHLETE FOOT CRE 1%	40	36	$823.10	$1.03	$20.58
LAMISIL CRE 1%	10	9	$152.78	$1.22	$15.28
ATHLETE FOOT CRE AF 1%	6	6	$91.92	$1.24	$15.32
SUBTOTAL	**467**	**406**	**$7,775.74**	**$1.12**	**$16.65**
CICLOPIROX PRODUCTS					
CICLOPIROX CRE 0.77%	342	274	$6,673.98	$1.20	$19.51
SUBTOTAL	**342**	**274**	**$6,673.98**	**$1.20**	**$19.51**
TOLNAFTATE PRODUCTS					
TOLNAFTATE CRE 1%	8	8	$100.52	$0.82	$12.57
ANTIFUNGAL CRE 1%	7	6	$79.23	$0.70	$11.32
SM ANTIFUNGAL CRE 1%	1	1	$13.57	$1.36	$13.57
SUBTOTAL	**16**	**15**	**$193.32**	**$0.78**	**$12.08**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
ECONAZOLE PRODUCTS					
ECONAZOLE CRE 1%	222	184	$5,848.29	$1.60	$26.34
SUBTOTAL	**222**	**6,830**	**$5,848.29**	**$1.60**	**$26.34**
TIER-1 SUBTOTAL	**38,246**	**29,386**	**$794,675.49**	**$1.32**	**$20.78**
TIER-2 PRODUCTS					
CICLOPIROX PRODUCTS					
CICLOPIROX SUS 0.77%	17	8	$738.49	$1.64	$43.44
CICLOPIROX SOL 8%	9	6	$198.15	$0.40	$22.02
CICLOPIROX GEL 0.77%	4	2	$204.26	$3.29	$51.07
CICLOPIROX SHA 1%	2	2	$103.52	$1.73	$51.76
SUBTOTAL	**32**	**18**	**$1,244.42**	**$1.17**	**$38.89**
CLOTRIMAZOLE PRODUCTS					
CLOTRIMAZOLE SOL 1%	26	24	$1,398.94	$2.71	$53.81
SUBTOTAL	**26**	**24**	**$1,398.94**	**$2.71**	**$53.81**
TIER-2 SUBTOTAL	**58**	**42**	**$2,643.36**	**$1.67**	**$45.58**
SPECIAL PA PRODUCTS					
EFINACONAZOLE PRODUCTS					
JUBLIA SOL 10%	8	1	$4,483.18	$18.68	$560.40
SUBTOTAL	**8**	**1**	**$4,483.18**	**$18.68**	**$560.40**
SPECIAL PA SUBTOTAL	**8**	**1**	**$4,483.18**	**$18.68**	**$560.40**
TOTAL	**38,312**	**26,570***	**$801,802.03**	**$1.31**	**$20.93**

CLOTRIM/BETA = clotrimazole/betamethasone; CRE = cream; DIPROP = dipropionate; OIN = ointment; PA = prior authorization; POW = powder; SHA = shampoo; SOL = solution; SUS = suspension
*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Fiscal Year 2020 Annual Review of Vasomotor Symptom Medications

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Bijuva® (Estradiol/Progesterone Capsule) Approval Criteria:

1. An FDA approved indication for the treatment of moderate-to-severe vasomotor symptoms due to menopause in women with an intact uterus; and
2. A patient-specific, clinically significant reason why the member cannot use all other available estrogen/progestin products indicated for vasomotor symptoms of menopause must be provided; and
3. A quantity limit of 30 capsules (1 pack) per 30 days will apply.

Brisdelle® (Paroxetine Mesylate 7.5mg) Approval Criteria:

1. An FDA approved indication for the treatment of moderate-to-severe vasomotor symptoms associated with menopause; and
2. Approvals for Brisdelle® will not be granted for psychiatric indications; and
3. Members must not have any of the contraindications for use of Brisdelle®; and
4. Two previous trials with either a selective serotonin reuptake inhibitor (SSRI) or a selective serotonin norepinephrine reuptake inhibitor (SNRI) or both, or a patient-specific, clinically significant reason why a SSRI or SNRI is not appropriate for the member must be provided; and
5. Authorization requires a patient-specific, clinically significant reason why paroxetine 10mg is not appropriate for the member; and
6. A quantity limit of 30 capsules per 30 days will apply.

Duavee® (Conjugated Estrogens/Bazedoxifene) Approval Criteria:

1. An FDA approved indication for the treatment of moderate-to-severe vasomotor symptoms associated with menopause or for prevention of postmenopausal osteoporosis; and
2. Member must be a female with an intact uterus; and
3. For the treatment of moderate-to-severe vasomotor symptoms associated with menopause:
    a. Member must have at least 7 moderate-to-severe hot flushes per day or at least 50 per week prior to treatment; and
4. For the prevention of postmenopausal osteoporosis:
    a. A trial of Fosamax® (alendronate), Actonel® (risedronate), Boniva® (ibandronate) or Reclast® (zoledronic acid) used compliantly for at

least 6 months concomitantly with calcium and vitamin D, that failed to prevent fracture or improve bone mineral density (BMD) scores; or

b. Contraindication to, hypersensitivity to, or intolerable adverse effects with all bisphosphonates indicated for prevention of postmenopausal osteoporosis; and

5. Member must not have any of the contraindications for use of Duavee®; and
6. Members older than 65 years of age will generally not be approved without supporting information; and
7. Approvals will be for the duration of 6 months to ensure the need for continued therapy is reassessed periodically and the medication is being used for the shortest duration possible; and
8. A quantity limit of 30 tablets per 30 days will apply.

Elestrin® (Estradiol 0.06% Gel) Approval Criteria:

1. An FDA approved indication for the treatment of moderate-to-severe vasomotor symptoms due to menopause; and
2. Member must not have any contraindications for use of Elestrin®; and
3. A patient-specific, clinically significant reason why other topical estradiol formulations (e.g., Divigel®) are not appropriate for the member must be provided; and
4. Members older than 65 years of age will generally not be approved without supporting information; and
5. Approvals will be for the duration of 6 months to ensure the need for continued therapy is reassessed periodically and the medication is being used for the shortest duration possible; and
6. A quantity limit of 52 grams per 30 days will apply.

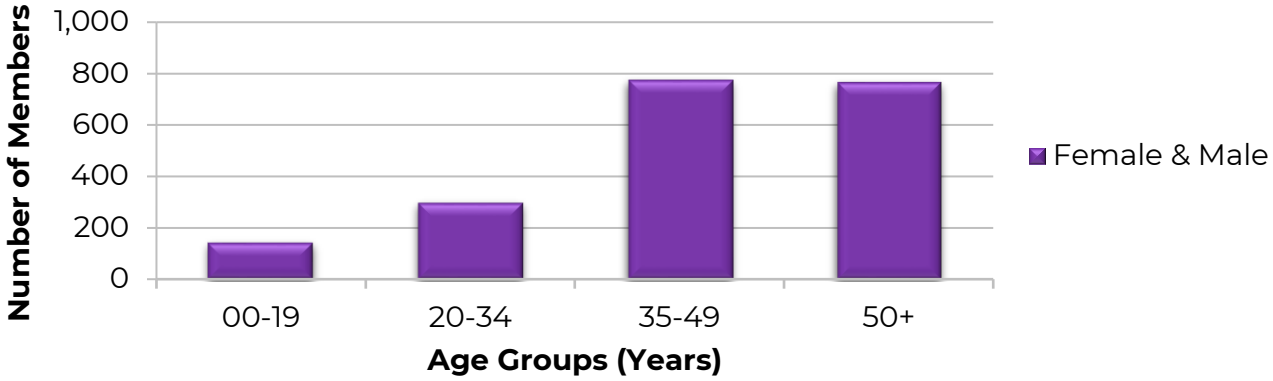
Utilization of Vasomotor Symptom Medications: Fiscal Year 2020

Comparison of Fiscal Years: Pharmacy Claims

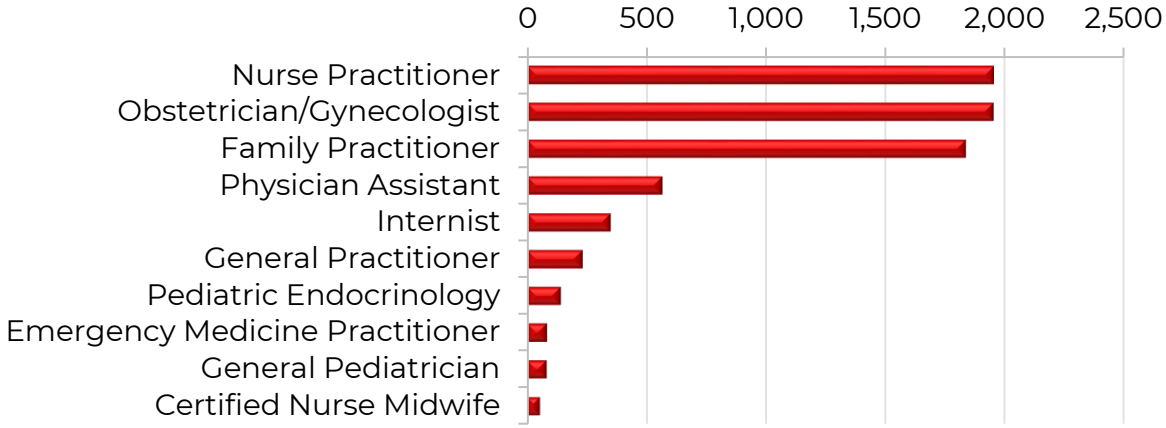
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	2,243	8,210	$798,404.95	$97.25	$2.22	324,874	359,791
2020	1,977	7,504	$712,408.24	$94.94	$2.10	310,791	338,907
% Change	**-11.90%**	**-8.60%**	**-10.80%**	**-2.40%**	**-5.40%**	**-4.30%**	**-5.80%**
Change	**-266**	**-706**	**-$85,996.71**	**-$2.31**	**-$0.12**	**-14,083**	**-20,884**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Demographics of Members Utilizing Vasomotor Symptoms Medications



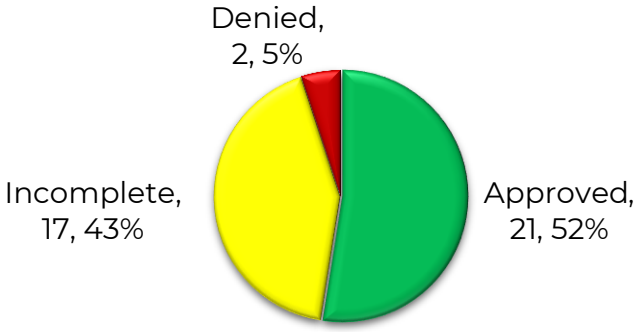
Top Prescriber Specialties of Vasomotor Symptom Medications by Number of Claims



Prior Authorization of Vasomotor Symptom Medications

There were 40 prior authorization requests submitted for vasomotor symptom medications during fiscal year 2020. The following chart shows the status of the submitted petitions for fiscal year 2020.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[147]

- Elestrin® (estradiol gel): June 2022
- Evamist® (estradiol transdermal spray): July 2022
- Duavee® (conjugated estrogens/bazedoxifene tablet): March 2027
- Brisdelle® (paroxetine capsule): April 2029
- Minivelle® (estradiol transdermal system): July 2030
- Angeliq® (drospirenone/estradiol tablet): October 2031
- Bijuva® (estradiol/progesterone capsule): November 2032

Pipeline:

- **Fezolinetant:** Astellas is currently investigating fezolinetant, an oral, non-hormonal compound for the treatment of moderate-to-severe vasomotor symptoms. Fezolinetant is a selective neurokinin-3 (NK3) receptor antagonist. The first trials of the BRIGHT SKY clinical development program will evaluate the safety and efficacy of 30mg and 45mg once daily fezolinetant in reducing the frequency and severity of vasomotor symptoms. The BRIGHT SKY program will launch 3 Phase 3 clinical trials (SKYLIGHT 1, SKYLIGHT 2 and SKYLIGHT 4) that are double-blinded and placebo-controlled for the first 12 weeks followed by non-controlled 40-week extension periods. The Phase 3 trials are still underway and results have yet to be released.[148]

News:

- **October 2020:** A new group of non-hormonal drugs, selective NK3 antagonists, are currently in clinical trials and show strong promise for treating menopausal hot flashes as effectively as hormones. Potential therapies were discussed by researchers at the virtual North American Menopause Society (NAMS) 2020 Annual Meeting. While several non-hormonal drugs are already used to treat vasomotor symptoms in menopausal women with and without breast cancer, none are as effective as hormone treatment. However, women still need more non-hormonal options that are at least as effective as hormonal options, as some women are unable to take hormonal medications if they are at risk for blood clots or breast cancer.[149]

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[147] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 02/2021. Last accessed 02/15/2021.

[148] Astellas Pharma, Inc. Astellas Initiates Phase 3 Clinical Trials for Fezolinetant in Postmenopausal Women with Vasomotor Symptoms. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/astellas-initiates-phase-3-clinical-trials-for-fezolinetant-in-postmenopausal-women-with-vasomotor-symptoms-300896688.html. Issued 08/06/2019. Last accessed 02/15/2021.

[149] Haelle, T. New Nonhormonal Hot Flash Treatments on the Way. *Medscape*. Available online at: https://www.medscape.com/viewarticle/938693. Issued 10/06/2020. Last accessed 02/15/2021.

- **October 2020:** New naturally occurring estrogens are on the horizon and may provide safer options with similar efficacy for treating hot flashed and other symptoms of menopause. Those naturally occurring estrogens are the fetal estrogens, estetrol and estriol, which are produced almost exclusively during pregnancy. Only estetrol has been investigated in clinical trials, and it does show some promise. Hormone therapy is still the most effective for postmenopausal symptoms, but as women age, particularly past 70 years of age, the risk of stroke, heart disease and breast cancer associated with hormone therapy begin to outweigh the benefits.[150]

Recommendations

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

Utilization Details of Vasomotor Symptom Medications: Fiscal Year 2020

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
ORAL ESTROGEN PRODUCTS					
ESTRADIOL TAB 1MG	1,889	635	$25,593.76	$0.28	$13.55
ESTRADIOL TAB 2MG	1,471	405	$22,948.78	$0.35	$15.60
ESTRADIOL TAB 0.5MG	671	237	$8,716.54	$0.27	$12.99
PREMARIN TAB 1.25MG	529	135	$159,168.78	$5.80	$300.89
PREMARIN TAB 0.625MG	470	132	$142,174.34	$5.92	$302.50
PREMARIN TAB 0.3MG	202	61	$53,551.05	$5.80	$265.10
PREMARIN TAB 0.9MG	120	28	$32,457.37	$5.68	$270.48
PREMARIN TAB 0.45MG	95	21	$21,069.33	$5.58	$221.78
MENEST TAB 0.625MG	5	2	$21,069.33	$5.58	$221.78
MENEST TAB 1.25MG	1	1	$21,069.33	$5.58	$221.78
SUBTOTAL	**5,453**	**1,657**	**$466,884.40**	**$1.79**	**$85.62**
TOPICAL ESTROGEN PRODUCTS					
ESTRADIOL DIS 0.1MG	249	55	$16,003.04	$2.22	$64.27
ESTRADIOL DIS 0.1MG	195	53	$11,420.95	$2.06	$58.57
ESTRADIOL DIS 0.05MG	134	36	$8,073.69	$2.13	$60.25
ESTRADIOL DIS 0.05MG	130	29	$9,219.71	$2.45	$70.92
ESTRADIOL DIS 0.0375MG	90	22	$5,964.42	$2.35	$66.27
ESTRADIOL DIS 0.025MG	86	22	$4,969.90	$2.06	$57.79
ESTRADIOL DIS 0.075MG	63	15	$4,579.64	$2.51	$72.69
ESTRADIOL DIS 0.025MG	57	24	$3,815.16	$1.80	$66.93
ESTRADIOL DIS 0.0375MG	49	11	$2,534.76	$1.82	$51.73

[150] Haelle, T. Fetal Estrogens Show Promise for Safer Therapy for Menopause. *Medscape*. Available online at: https://www.medscape.com/viewarticle/939095. Issued 10/14/2020. Last accessed 02/15/2021.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
DIVIGEL GEL 1MG/GM	48	8	$7,342.23	$5.10	$152.96
DOTTI DIS 0.0375MG	25	11	$1,650.62	$2.35	$66.02
DOTTI DIS 0.05MG	25	6	$1,719.28	$2.44	$68.77
DOTTI DIS 0.025MG	24	7	$1,614.54	$2.13	$67.27
DOTTI DIS 0.1MG	17	8	$1,088.98	$2.26	$64.06
ESTRADIOL DIS 0.075MG	16	8	$911.02	$2.02	$56.94
EVAMIST SPR 1.53MG	16	2	$2,768.10	$3.86	$173.01
DOTTI DIS 0.075MG	15	6	$1,099.77	$2.56	$73.32
ESTRADIOL DIS 0.06MG	13	4	$561.16	$1.54	$43.17
DIVIGEL GEL 0.5MG	11	4	$1,577.38	$4.78	$143.40
DIVIGEL GEL 0.25MG	7	3	$1,577.38	$4.78	$143.40
VIVELLE-DOT DIS 0.05MG	4	1	$1,577.38	$4.78	$143.40
DIVIGEL GEL 0.75MG	1	1	$1,577.38	$4.78	$143.40
SUBTOTAL	**1,275**	**336**	**$88,047.65**	**$2.36**	**$69.06**
ORAL ESTROGEN/PROGESTIN PRODUCTS					
PREMPRO TAB 0.3-1.5MG	142	35	$35,046.75	$7.02	$246.81
PREMPRO TAB 0.625-2.5MG	139	35	$42,023.15	$6.85	$302.32
ESTRA/NORETH TAB 1-0.5MG	62	11	$3,727.07	$1.71	$60.11
PREMPRO TAB 0.45-1.5MG	43	13	$9,683.74	$7.05	$225.20
ESTRA/NORETH TAB 0.5-0.1MG	39	16	$3,145.36	$1.84	$80.65
PREMPRO TAB 0.625-5MG	33	11	$10,285.37	$6.68	$311.68
NORETH/ETHIN TAB 0.5MG-2.5MCG	13	3	$882.67	$2.42	$67.90
AMABELZ TAB 0.5-0.1MG	9	1	$557.58	$2.21	$61.95
FYAVOLV TAB 0.5-2.5MG	7	4	$722.60	$2.87	$103.23
NORETH/ETHIN TAB 1MG-5MCG	6	1	$298.26	$1.78	$49.71
PREMPHASE TAB 0.625-5MG	6	2	$2,653.26	$6.77	$442.21
MIMVEY TAB 1-0.5MG	5	2	$757.72	$2.08	$151.54
JINTELI TAB 1MG-5MCG	4	2	$527.34	$1.49	$131.84
FYAVOLV TAB 1-5MG	2	1	$89.60	$1.60	$44.80
PREFEST TAB 1-0.09MG	1	1	$157.08	$5.24	$157.08
ANGELIQ TAB 0.5-1MG	1	1	$565.93	$6.74	$565.93
ANGELIQ TAB 0.25-0.5MG	1	1	$569.39	$6.78	$569.39
SUBTOTAL	**513**	**140**	**$111,692.87**	**$5.49**	**$217.72**
INJECTABLE ESTROGEN PRODUCTS					
DEPO-ESTRADIOL INJ 5MG/ML	135	76	$16,226.96	$1.13	$120.20
ESTRADIOL VAL INJ 20MG/ML	19	8	$1,965.57	$1.53	$103.45
ESTRADIOL VAL INJ 200MG/5ML	6	3	$1,023.40	$1.66	$170.57
DELESTROGEN INJ 10MG/ML	3	3	$422.80	$1.36	$140.93
DELESTROGEN INJ 40MG/ML	3	1	$953.16	$2.27	$317.72
SUBTOTAL	**166**	**91**	**$20,591.89**	**$1.21**	**$124.05**
TOPICAL ESTROGEN/PROGESTIN PRODUCTS					
CLIMARA PRO DIS 0.045MG-0.015MG/DAY	40	8	$8,587.22	$7.67	$214.68
COMBIPATCH DIS 0.05MG-0.14MG/DAY	20	12	$4,070.15	$7.14	$203.51

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
COMBIPATCH DIS 0.05MG-0.25MG/DAY	11	5	$2,227.09	$7.18	$202.46
SUBTOTAL	**71**	**25**	**$14,884.46**	**$7.44**	**$209.64**
ORAL ESTROGEN/SERM PRODUCTS					
DUAVEE TAB 0.45-20MG	9	1	$1,589.48	$5.89	$176.61
SUBTOTAL	**9**	**1**	**$1,589.48**	**$5.89**	**$176.61**
VAGINAL ESTROGEN PRODUCTS					
FEMRING MIS 0.1MG/24HR	14	5	$7,255.92	$5.79	$518.28
FEMRING MIS 0.05MG/24HR	3	1	$1,461.57	$5.41	$487.19
SUBTOTAL	**17**	**6**	**$8,717.49**	**$5.72**	**$512.79**
TOTAL	**7,504**	**1,977***	**$712,408.24**	**$2.10**	**$94.94**

DIS = patch; ESTRA/NORETH = estradiol/norethindrone; INJ = injection; MIS = insert;
NORETH/ETHIN = norethindrone/ethinyl estradiol; SERM = selective estrogen receptor modulator;
SPR = spray; TAB = tablet; VAL = valerate
*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Fiscal Year 2020 Annual Review of Vesicular Monoamine Transporter 2 (VMAT2) Inhibitor Medications

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Austedo® (Deutetrabenazine) Approval Criteria [Huntington's Disease Diagnosis]:

1. An FDA approved diagnosis of chorea associated with Huntington's disease; and
2. Austedo® must be prescribed by a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
3. A previous trial of Xenazine® (tetrabenazine) or a patient-specific, clinically significant reason why the member cannot use Xenazine® (tetrabenazine) must be provided; and
4. Member must not be actively suicidal or have uncontrolled depression and prescriber must verify member will be monitored for depression prior to starting Austedo® therapy and throughout treatment; and
5. Member must not have hepatic impairment; and
6. Member must not be taking monoamine oxidase inhibitors (MAOIs) or have taken an MAOI within the last 14 days; and
7. Member must not be taking reserpine or have taken reserpine within the last 20 days; and
8. Member must not use another vesicular monoamine transport 2 (VMAT2) inhibitor (e.g., tetrabenazine, valbenazine) concurrently with Austedo®; and
9. For members requiring doses of Austedo® >24mg per day or who are using Austedo® concomitantly with other medications that are known to prolong the QTc interval [antipsychotic medications (e.g., chlorpromazine, haloperidol, thioridazine, ziprasidone), antibiotics (e.g., moxifloxacin), Class 1A (e.g., quinidine, procainamide) and Class III (e.g., amiodarone, sotalol) antiarrhythmic medications, or any other medications known to prolong the QTc interval], the prescriber must agree to assess the QTc interval before and after increasing the dose of Austedo® or other medications that are known to prolong the QTc interval; and
10. The member must not have congenital long QT syndrome or a history of cardiac arrhythmias; and
11. The daily dose of Austedo® must not exceed 36mg per day if the member is taking strong CYP2D6 inhibitors (e.g., paroxetine, fluoxetine,

quinidine, bupropion) or if the member is a known poor CYP2D6 metabolizer; and
12. Approvals will be for the duration of 6 months at which time the prescriber must document that the signs and symptoms of chorea have decreased and the member is not showing worsening signs of depression.

Austedo® (Deutetrabenazine) Approval Criteria [Tardive Dyskinesia Diagnosis]:

1. An FDA approved diagnosis of tardive dyskinesia meeting the following DSM-5 criteria:
    a. Involuntary athetoid or choreiform movements; and
    b. History of treatment with dopamine receptor blocking agent (DRBA); and
    c. Symptom duration lasting longer than 4 to 8 weeks; and
2. Member must be 18 years of age or older; and
3. Austedo® must be prescribed by a neurologist or psychiatrist (or an advanced care practitioner with a supervising physician who is a neurologist or psychiatrist); and
4. Member must not be actively suicidal or have uncontrolled depression and prescriber must verify member will be monitored for depression prior to starting Austedo® therapy and throughout treatment; and
5. Member must not have hepatic impairment; and
6. Member must not be taking monoamine oxidase inhibitors (MAOIs) or have taken an MAOI within the last 14 days; and
7. Member must not be taking reserpine or have taken reserpine within the last 20 days; and
8. Member must not use another vesicular monoamine transport 2 (VMAT2) inhibitor (e.g., tetrabenazine, valbenazine) concurrently with Austedo®; and
9. For members requiring doses of Austedo® >24mg per day or who are using Austedo® concomitantly with other medications that are known to prolong the QTc interval [antipsychotic medications (e.g., chlorpromazine, haloperidol, thioridazine, ziprasidone), antibiotics (e.g., moxifloxacin), Class 1A (e.g., quinidine, procainamide) and Class III (e.g., amiodarone, sotalol) antiarrhythmic medications, or any other medications known to prolong the QTc interval], the prescriber must agree to assess the QTc interval before and after increasing the dose of Austedo® or other medications that are known to prolong the QTc interval; and
10. The member must not have congenital long QT syndrome or a history of cardiac arrhythmias; and
11. The daily dose of Austedo® must not exceed 36mg per day if the member is taking strong CYP2D6 inhibitors (e.g., paroxetine, fluoxetine,

quinidine, bupropion) or if the member is a known poor CYP2D6 metabolizer; and
12. Female members must not be pregnant or breastfeeding; and
13. Prescriber must document a baseline evaluation using the Abnormal Involuntary Movement Scale (AIMS); and
14. Approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment as indicated by an improvement from baseline in the AIMS total score (a negative change in score indicates improvement) or documentation of a positive clinical response to therapy.

Ingrezza® (Valbenazine) Approval Criteria:

1. An FDA approved diagnosis of tardive dyskinesia meeting the following DSM-5 criteria:
    a. Voluntary athetoid or choreiform movements; and
    b. History of treatment with dopamine receptor blocking agent (DRBA); and
    c. Symptom duration lasting longer than 4 to 8 weeks; and
2. Member must be 18 years of age or older; and
3. Ingrezza® must be prescribed by a neurologist or psychiatrist (or an advanced care practitioner with a supervising physician who is a neurologist or psychiatrist); and
4. The daily dose of Ingrezza® must not exceed 40mg per day if the member is taking strong CYP2D6 inhibitors (e.g., paroxetine, fluoxetine, quinidine); and
5. The daily dose of Ingrezza® must not exceed 40mg per day if the member is taking strong CYP3A4 inhibitors (e.g., itraconazole, ketoconazole, clarithromycin); and
6. Member must not be taking strong CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's wort); and
7. Member must not be taking monoamine oxidase inhibitors (MAOIs); and
8. Member must not be taking other vesicular monoamine transporter 2 (VMAT2) inhibitors (e.g., tetrabenazine, deutetrabenazine); and
9. The daily dose of Ingrezza® must not exceed 40mg per day for members with moderate or severe hepatic impairment (Child-Pugh score 7 to 15); and
10. The member must not have congenital long QT syndrome or a history of arrhythmias associated with a prolonged QT interval; and
11. Female members must not be pregnant or breastfeeding; and
12. Prescriber must agree to monitor digoxin concentration when co-administering Ingrezza® with digoxin; and
13. Prescriber must document a baseline evaluation using the Abnormal Involuntary Movement Scale (AIMS); and

14. A quantity limit of 1 capsule per day will apply; and
15. Approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment as indicated by an improvement from baseline in the AIMS total score (a negative change in score indicates improvement) or documentation of a positive clinical response to therapy.

Xenazine® (Tetrabenazine) Approval Criteria:

1. A diagnosis of 1 of the following:
    a. Chorea associated with Huntington's disease; or
    b. Tardive dyskinesia; or
    c. Tourette syndrome; and
2. Xenazine® must be prescribed by a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
3. Member must not be actively suicidal or have uncontrolled depression and prescriber must verify member will be monitored for depression prior to starting Xenazine® therapy and throughout treatment; and
4. Member must not have hepatic impairment; and
5. Member must not be taking monoamine oxidase inhibitors (MAOIs) or have taken an MAOI within the last 14 days; and
6. Member must not be taking reserpine or have taken reserpine within the last 20 days; and
7. Member must not use another vesicular monoamine transporter 2 (VMAT2) inhibitor (e.g., deutetrabenazine, valbenazine) concurrently with Xenazine®; and
8. Member must not be taking medications that are known to prolong the QTc interval concomitantly with Xenazine® [antipsychotic medications (e.g., chlorpromazine, haloperidol, thioridazine, ziprasidone), antibiotics (e.g., moxifloxacin), Class 1A (e.g., quinidine, procainamide) and Class III (e.g. amiodarone, sotalol) antiarrhythmic medications, or any other medications known to prolong the QTc interval]; and
9. Patients who require doses of tetrabenazine >50mg per day must be tested and genotyped to determine if they are poor metabolizers (PMs), intermediate metabolizers (IMs), or extensive metabolizers (EMs) by their ability to express the drug metabolizing enzyme, CYP2D6. The following dose limits will apply based on patient metabolizer status:
    a. Extensive and Intermediate CYP2D6 Metabolizers: 100mg divided daily; or
    b. Poor CYP2D6 Metabolizers: 50mg divided daily; and
10. The daily dose of Xenazine® must not exceed 50mg per day if the member is taking strong CYP2D6 inhibitors (e.g., paroxetine, fluoxetine, quinidine, bupropion); and

11. Approvals will be for the duration of 6 months at which time the prescriber must document that the signs and symptoms of chorea, tardive dyskinesia, or Tourette syndrome have decreased and the member is not showing worsening signs of depression.

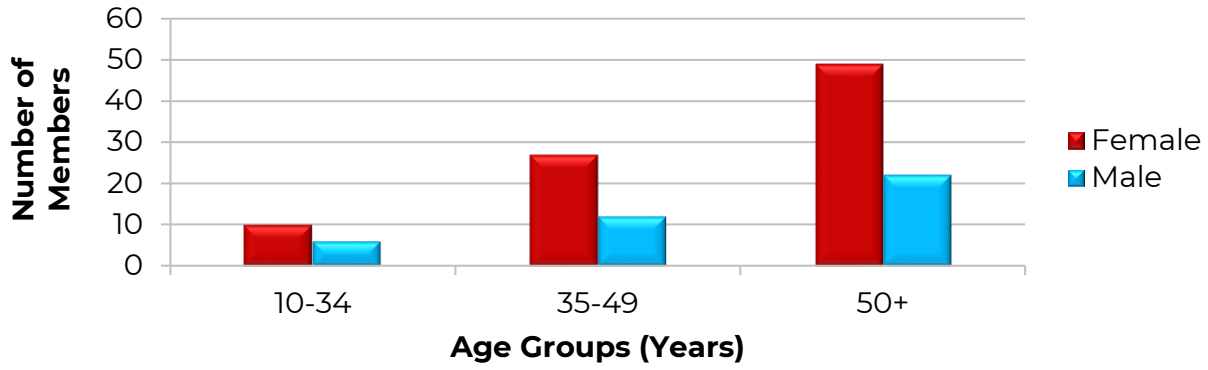
Utilization of VMAT2 Inhibitor Medications: Fiscal Year 2020

Comparison of Fiscal Years: Pharmacy Claims

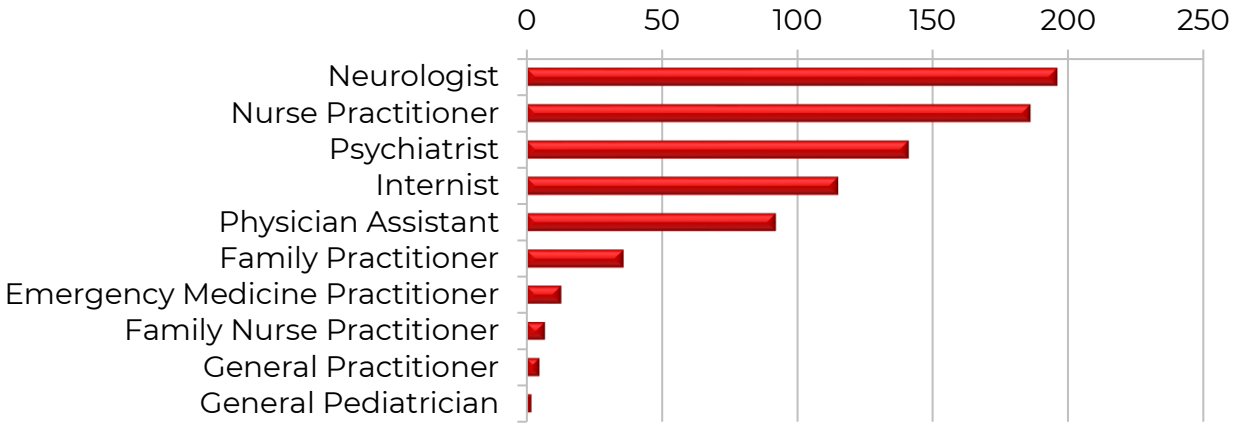
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2019	85	423	$2,788,354.40	$6,591.85	$228.72	19,130	12,191
2020	126	794	$5,044,769.01	$6,353.61	$215.53	36,256	23,406
% Change	**48.20%**	**87.70%**	**80.90%**	**-3.60%**	**-5.80%**	**89.50%**	**92.00%**
Change	**41**	**371**	**$2,256,414.61**	**-$238.24**	**-$13.19**	**17,126**	**11,215**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Demographics of Members Utilizing VMAT2 Inhibitor Medications

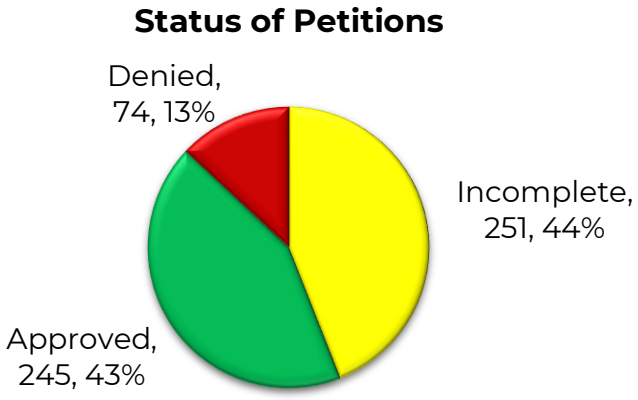


Top Prescriber Specialties of VMAT2 Inhibitor Medications by Number of Claims



Prior Authorization of VMAT2 Inhibitor Medications

There were 570 prior authorization requests submitted for VMAT2 inhibitor medications during fiscal year 2020. The following chart shows the status of the submitted petitions for fiscal year 2020.



Market News and Updates

Anticipated Patent Expiration(s):[151]

- Austedo® (deutetrabenazine): September 2033
- Ingrezza® (valbenazine): October 2037

News:

- **February 2020:** Teva announced results of their clinical trials of deutetrabenazine for the treatment of tics in children with moderate-to-severe Tourette syndrome. In the Phase 2/3 ARTISTS 1 and Phase 3 ARTISTS 2 trials, the results showed treatment with deutetrabenazine was not better than placebo in these patients.[152]

Recommendations

The College of Pharmacy does not recommend any changes to the current VMAT2 inhibitor medications prior authorization criteria at this time.

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[151] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 02/2021. Last accessed 02/10/2021.

[152] Taylor P. Teva's Weak Pipeline Hit by Tourette's Drug Trial Failure. *PMLive*. Available online at: http://www.pmlive.com/pharma_news/tevas_weak_pipeline_hit_by_tourettes_drug_trial_failure_1326565. Issued 02/20/2020. Last accessed 02/10/2021.

Utilization Details of VMAT2 Inhibitor Medications: Fiscal Year 2020

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM
VALBENAZINE PRODUCTS					
INGREZZA CAP 80MG	249	47	$1,653,870.97	$221.40	$6,642.05
INGREZZA CAP 40MG	167	40	$983,307.31	$205.07	$5,888.07
INGREZZA CAP 40-80MG	4	4	$26,965.64	$240.76	$6,741.41
SUBTOTAL	**420**	**91**	**$2,664,143.92**	**$215.25**	**$6,343.20**
DEUTETRABENAZINE PRODUCTS					
AUSTEDO TAB 12MG	227	42	$1,379,179.48	$204.14	$6,075.68
AUSTEDO TAB 9MG	55	17	$227,774.44	$145.54	$4,141.35
AUSTEDO TAB 6MG	54	17	$185,749.20	$118.69	$3,439.80
SUBTOTAL	**336**	**76**	**$1,792,703.12**	**$181.34**	**$5,335.43**
TETRABENAZINE PRODUCTS					
XENAZINE TAB 25MG	31	3	$538,174.94	$578.68	$17,360.48
XENAZINE TAB 12.5MG	6	2	$48,950.81	$271.95	$8,158.47
TETRABENAZINE TAB 12.5MG	1	1	$796.22	$24.13	$796.22
SUBTOTAL	**38**	**6**	**$587,921.97**	**$514.37**	**$15,471.63**
TOTAL	**794**	**126***	**$5,044,769.01**	**$215.53**	**$6,353.61**

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

Fiscal Year 2020 Annual Review of Vimizim® (Elosulfase Alfa)

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Vimizim® (Elosulfase Alfa) Approval Criteria:

1. An FDA approved diagnosis of Morquio A syndrome (mucopolysaccharidosis type IVA; MPS IVA) confirmed by:
   a. Enzyme assay demonstrating a deficiency of N-acetylgalactosamine-6-sulfatase (GALNS) enzyme activity; or
   b. Molecular genetic testing to confirm biallelic pathogenic variants in GALNS; and
2. Vimizim® must be administered by a health care professional prepared to manage anaphylaxis; and
3. Initial approvals will be for the duration of 12 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment; 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 Vimizim® (Elosulfase Alfa): Fiscal Year 2020

There was no SoonerCare utilization, including pharmacy and medical claims, of Vimizim® (elosulfase alfa) during fiscal year 2020 (07/01/2019 to 06/30/2020).

Prior Authorization of Vimizim® (Elosulfase Alfa)

There were no prior authorization requests submitted for Vimizim® (elosulfase alfa) during fiscal year 2020.

Market News and Updates

News:

- **September 2020:** A deficiency of N-acetylgalactosamine-6-sulfatase (GALNS) causes mucopolysaccharidosis (MPS) type IVA which is characterized by systemic skeletal dysplasia. Adeno-associated virus 8 (AAV8) vectors expressing different forms of human GALNS under a liver-specific promoter were evaluated in mice. The vectors were delivered intravenously (IV) into 4-week-old MPS IVA knockout (KO) and immune tolerant (MTOL) mice at a dose of 5×10^{13} genome copies (GC)/kg. The mice were monitored for 12 weeks post-injection. GALNS

enzyme activity was elevated significantly in the plasma of all treated mice at 2 weeks post-injection. Treatment with AAV8 vectors resulted in a reduction of keratan sulfate (KS) levels in plasma to normal levels 2 weeks post-injection, which were maintained until necropsy. Vectors reduced the storage of KS in articular cartilage, ligaments, and meniscus surrounding articular cartilage and growth plate region, as well as in heart muscle and valves. These results suggest the continuous presence of high levels of circulating enzyme increases the penetration into bone and heart and reduces the KS level, thereby improving storage in these regions. The current data support a strategy for developing a novel treatment to address the bone and heart disease in MPS IVA using AAV8 gene therapy.[153]

Recommendations

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

[153] Sawamoto K, Karumuthil-Melethil S, Khan S, et al. Liver-Targeted AAV8 Gene Therapy Ameliorates Skeletal and Cardiovascular Pathology in a Mucopolysaccharidosis IVA Murine Model. *Mol Ther Methods Clin Dev* 2020; 18:50-61. doi: 10.1016/j.omtm.2020.05.015.

Fiscal Year 2020 Annual Review of Xgeva® (Denosumab)

Oklahoma Health Care Authority
Fiscal Year 2020 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 >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 2020

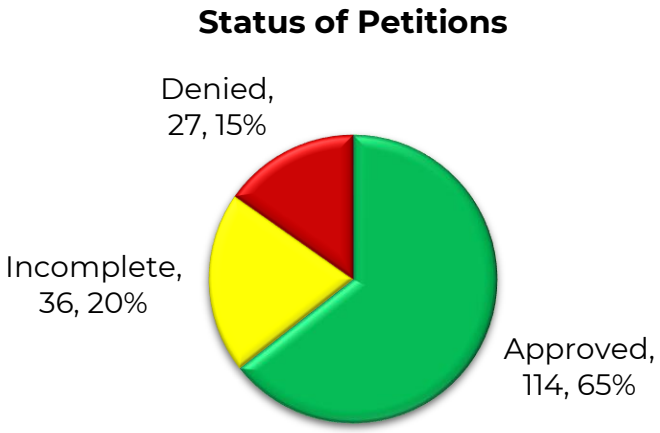
Comparison of Fiscal Years: Medical Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Total Units
2019	55	286	$619,024.92	$2,164.42	34,212
2020	66	282	$640,169.69	$2,270.11	33,542
% Change	**20.00%**	**-1.40%**	**3.42%**	**4.88%**	**-1.96%**
Change	**11**	**-4**	**$21,144.77**	**$105.69**	**-670**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Prior Authorization of Xgeva® (Denosumab)

There were 177 prior authorization requests submitted for Xgeva® (denosumab) during fiscal year 2020. The following chart shows the status of the submitted petitions for fiscal year 2020.



Recommendations

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

Fiscal Year 2020 Annual Review of Xiaflex® (Collagenase Clostridium Histolyticum)

Oklahoma Health Care Authority
Fiscal Year 2020 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 2020

Comparison of Fiscal Years: Medical Claims

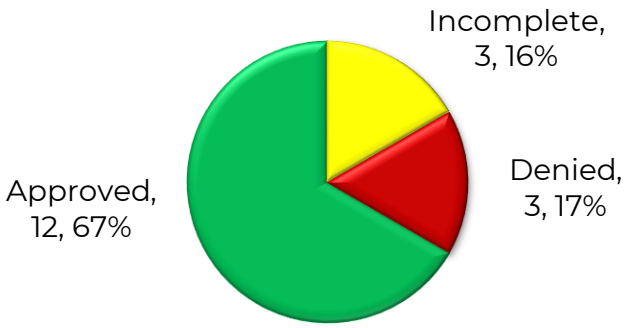
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Total Units
2019	1	2	$4,115.00	$2,057.50	148
2020	4	15	$53,961.42	$3,597.43	1,094
% Change	**300%**	**650%**	**1,211.3%**	**74.8%**	**639.2%**
Change	**3**	**13**	**$49,846.42**	**$1,539.93**	**946**

*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2019 = 07/01/2018 to 06/30/2019; Fiscal Year 2020 = 07/01/2019 to 06/30/2020

Prior Authorization of Xiaflex® (Collagenase Clostridium Histolyticum)

There were 18 prior authorization requests submitted for 4 unique members for Xiaflex® (collagenase clostridium histolyticum) during fiscal year 2020. The following chart shows the status of the submitted petitions for fiscal year 2020.

Status of Petitions



Market News and Updates

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

- **July 2020:** Endo International announced the FDA has approved Qwo™ (collagenase clostridium histolyticum-aaes) for the treatment of moderate-to-severe cellulite in the buttocks of adult women. Qwo™ is the first FDA approved injectable treatment for cellulite and is expected to be available in the spring of 2021.[154]

[154] Endo International PLC. U.S. FDA Approves Qwo™ (Collagenase Clostridium Histolyticum-aaes), the First Injectable Treatment for Cellulite. *PR Newswire*. Available online at: https://investor.endo.com/news-releases/news-release-details/us-fda-approves-qwotm-collagenase-clostridium-histolyticum-aaes. Issued 07/06/2020. Last Accessed 12/15/2020.

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 2020

PRODUCT UTILIZED	TOTAL CLAIMS	*TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
XIAFLEX INJ 0.9MG	15	4	$53,961.42	$3,597.43	3.75
TOTAL	**15**	**4**	**$53,961.42**	**$3,597.43**	**3.75**

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

Fiscal Year 2020 Annual Review of Xuriden® (Uridine Triacetate)

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Xuriden® (Uridine Triacetate) Approval Criteria:

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

Utilization of Xuriden® (Uridine Triacetate): Fiscal Year 2020

There was no SoonerCare utilization of Xuriden® (uridine triacetate) during fiscal year 2020 (07/01/2019 to 06/30/2020).

Prior Authorization of Xuriden® (Uridine Triacetate)

There were no prior authorization requests submitted for Xuriden® (uridine triacetate) during fiscal year 2020.

Market News and Updates

Anticipated Patent Expiration(s):[155]

- Xuriden® (uridine triacetate): July 2023

Recommendations

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

[155] 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 01/2021. Last accessed 01/28/2021.

Fiscal Year 2020 Annual Review of Zinplava™ (Bezlotoxumab)

Oklahoma Health Care Authority
Fiscal Year 2020 Print Report

Current Prior Authorization Criteria

Zinplava™ (Bezlotoxumab) Approval Criteria:

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

Utilization of Zinplava™ (Bezlotoxumab): Fiscal Year 2020

There was no SoonerCare utilization of Zinplava™ (bezlotoxumab) during fiscal year 2020 (07/01/2019 to 06/30/2020).

Prior Authorization of Zinplava™ (Bezlotoxumab)

There were no prior authorization requests submitted for Zinplava™ (bezlotoxumab) during fiscal year 2020.

Market News and Updates

Pipeline:

- **CP101:** In June 2020, Finch Therapeutics announced positive topline results from PRISM3, its multi-center, randomized, double-blind, placebo-controlled Phase 2 study of CP101, an investigational oral microbiome drug, for the prevention of recurrent *Clostridium difficile* infection (CDI). In the PRISM3 study, CP101 met the primary efficacy endpoint, with 74.5% of recurrent CDI patients who received a single administration of CP101 achieving a sustained clinical cure through week 8, a statistically significant improvement in comparison to 61.5% of patients in the control group who received standard-of-care antibiotic therapy alone ($P<0.05$). CP101 was well tolerated in the study at 8 weeks post treatment, with no treatment-related serious adverse events. CP101 has been granted Fast Track and Breakthrough Therapy designations by the U.S. Food and Drug Administration (FDA) for the prevention of recurrent CDI.[156]
- **SER-109:** In August 2020, Seres Therapeutics reported positive topline results from the pivotal Phase 3 ECOSPOR III study evaluating its investigational oral microbiome therapeutic, SER-109, for recurrent CDI. The study showed SER-109 administration resulted in a highly statistically significant absolute decrease of 30.2% in the proportion of patients who experienced a recurrence of CDI within 8 weeks of administration versus placebo, the study's primary endpoint. Of the patients administered SER-109, 11.1% experienced a CDI recurrence, versus 41.3% of placebo patients. The study's efficacy results exceeded the statistical threshold previously provided in consultation with the FDA, which may allow this single clinical study to fulfill the efficacy requirements for a Biologics License Application (BLA). Additionally, the SER-109 safety results were favorable, with an adverse event profile comparable to placebo.[157]

Recommendations

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

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