Fiscal Year 2021 Print Annual Reviews
December 2021

Count	Category/Medication
1.	Alpha$_1$-Proteinase Inhibitors
2.	Amyloidosis Medications
3.	Amyotrophic Lateral Sclerosis (ALS) Medications
4.	Benign Prostatic Hyperplasia (BPH) Medications
5.	Chorionic Gonadotropin Medications
6.	Constipation and Diarrhea Medications
7.	Corticosteroid Special Formulations
8.	Crysvita® (Burosumab-twza)
9.	Erythropoietin Stimulating Agents (ESAs)
10.	Fabry Disease Medications
11.	Fibromyalgia Medications
12.	Gaucher Disease Medications
13.	Givlaari® (Givosiran) and Scenesse® (Afamelanotide)
14.	Hyperkalemia Medications
15.	Lambert-Eaton Myasthenic Syndrome (LEMS) Medications
16.	Northera® (Droxidopa)
17.	Ocaliva® (Obeticholic Acid)
18.	Pancreatic Enzymes
19.	Parathyroid Medications
20.	Pediculicide Medications
21.	Qbrexza® (Glycopyrronium)
22.	Revcovi® (Elapegademase-lvlr)
23.	Tepezza® (Teprotumumab-trbw)
24.	Thrombocytopenia Medications

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

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

Fiscal Year 2021 Annual Review of Alpha$_1$-Proteinase Inhibitors

Oklahoma Health Care Authority
Fiscal Year 2021 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 must be 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. 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 must be 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 2021

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	3	33	$229,942.88	$6,967.97	$248.86	498,184	924
2021	5	39	$331,998.16	$8,512.77	$305.99	728,343	1,085
% Change	**66.70%**	**18.20%**	**44.40%**	**22.20%**	**23.00%**	**46.20%**	**17.40%**
Change	**2**	**6**	**$102,055.28**	**$1,544.80**	**$57.13**	**230,159**	**161**

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

Fiscal Year 2021 Utilization: Medical Claims (J0256)

Fiscal Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2021	1	1	$2,372.26	$2,372.26	1

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

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

Demographics of Members Utilizing Alpha$_1$-Proteinase Inhibitors

- Due to the limited number of members utilizing alpha$_1$-proteinase inhibitors during fiscal year 2021, detailed demographic information could not be provided.

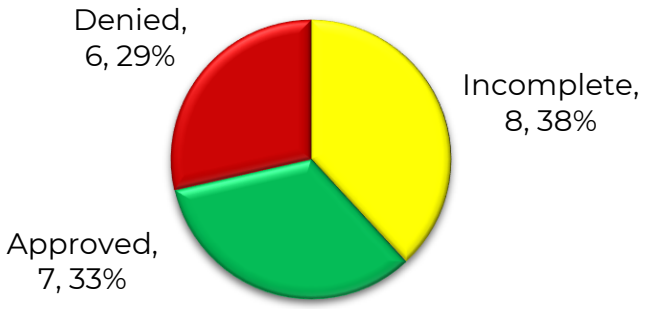
Top Prescriber Specialties of Alpha$_1$-Proteinase Inhibitors by Number of Claims

- The only prescriber specialty listed on paid pharmacy claims for alpha$_1$-proteinase inhibitors during fiscal year 2021 was pulmonary disease specialist.

Prior Authorization of Alpha$_1$-Proteinase Inhibitors

There were 21 prior authorization requests submitted for alpha$_1$-proteinase inhibitors during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021.

Status of Petitions



Recommendations

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

Utilization Details of Alpha$_1$-Proteinase Inhibitors: Fiscal Year 2021

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
PROLASTIN-C INJ 1,000MG	27	4	$245,750.72	$9,101.88	6.75	74.02%
GLASSIA INJ 1,000MG	12	1	$86,247.44	$7,187.29	12	25.98%
TOTAL	**39**	**5***	**$331,998.16**	**$8,512.77**	**7.8**	**100%**

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

Medical Claims

PRODUCT UTILIZED	†TOTAL CLAIMS	*TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
PROLASTIN C INJ 10MG J0256	1	1	$2,372.26	$2,372.26	1
TOTAL	**1**	**1**	**$2,372.26**	**$2,372.26**	**1**

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

Fiscal Year 2021 Annual Review of Amyloidosis Medications

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

Onpattro® (Patisiran) Approval Criteria:

1. An FDA approved indication for the treatment of polyneuropathy associated with hereditary transthyretin-mediated (hATTR) amyloidosis; and
2. Diagnosis confirmed by the following:
   a. Tissue (fat pad) biopsy confirming amyloid deposits; and
   b. Genetic confirmation of transthyretin (*TTR*) gene mutation (e.g., Val30Met); and
3. Onpattro® must be prescribed by, or in consultation with, a cardiologist, geneticist, or neurologist (or an advanced care practitioner with a supervising physician who is a cardiologist, geneticist, or neurologist); and
4. Prescriber must confirm the member will take the recommended daily allowance of vitamin A; and
5. Prescriber must confirm the member will be pre-medicated with intravenous (IV) corticosteroid, oral acetaminophen, IV histamine-1 (H_1) antagonist, and IV histamine-2 (H_2) antagonist 60 minutes prior to Onpattro® administration to reduce the risk of infusion-related reaction(s); and
6. Onpattro® will not be approved for concomitant use with Tegsedi® (inotersen), Vyndamax® (tafamidis), or Vyndaqel® (tafamidis meglumine); and
7. Member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
8. Onpattro® approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment.

Tegsedi® (Inotersen) Approval Criteria:

1. An FDA approved indication for the treatment of polyneuropathy associated with hereditary transthyretin-mediated (hATTR) amyloidosis; and
2. Diagnosis confirmed by the following:
   a. Tissue (fat pad) biopsy confirming amyloid deposits; and

   b. Genetic confirmation of transthyretin (*TTR*) gene mutation (e.g., Val30Met); and
3. Tegsedi® must be prescribed by, or in consultation with, a cardiologist, geneticist, or neurologist (or an advanced care practitioner with a supervising physician who is a cardiologist, geneticist, or neurologist); and
4. Prescriber must confirm the member will take the recommended daily allowance of vitamin A; and
5. Prescriber must agree to monitor ALT, AST, and total bilirubin prior to initiation of Tegsedi® and every 4 months during treatment; and
6. Prescriber must confirm the first injection of Tegsedi® administered by the member or caregiver will be performed under the guidance of a health care professional; and
7. Prescriber must confirm the member or caregiver has been trained by a health care professional on the subcutaneous (sub-Q) administration and proper storage of Tegsedi®; and
8. Tegsedi® will not be approved for concomitant use with Onpattro® (patisiran), Vyndamax® (tafamidis), or Vyndaqel® (tafamidis meglumine); and
9. Prescriber, pharmacy, and member must be enrolled in the Tegsedi® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
10. Tegsedi® 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
11. A quantity limit of 4 syringes per 28 days will apply.

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

1. An FDA approved indication for the treatment of the cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular (CV) mortality and CV-related hospitalization; and
2. Diagnosis confirmed by:
   a. Genetic confirmation of transthyretin (*TTR*) mutation (e.g., Val122Ile) or wild-type amyloidosis; and
   b. Cardiac imaging (e.g., ultrasound, MRI) confirming cardiac involvement; and
3. Presence of amyloid deposits confirmed by:
   a. Nuclear scintigraphy; or
   b. Endomyocardial biopsy; and
4. Member must have medical history of heart failure (NYHA Class I to III); and

5. Vyndamax® or Vyndaqel® must be prescribed by, or in consultation with, a cardiologist or geneticist (or an advanced care practitioner with a supervising physician who is a cardiologist or geneticist); and
6. Prescriber must verify Vyndamax® or Vyndaqel® will not be used concomitantly with Onpattro® (patisiran) or Tegsedi® (inotersen); and
7. 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
8. A quantity limit of 1 Vyndamax® capsule or 4 Vyndaqel® capsules per day will apply.

Utilization of Amyloidosis Medications: Fiscal Year 2021

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

Prior Authorization of Amyloidosis Medications

There were no prior authorization requests submitted for amyloidosis medications during fiscal year 2021 (07/01/2020 to 06/30/2021).

Market News and Updates

Anticipated Patent Expiration(s):[1]

- Vyndaqel® (tafamidis meglumine): April 2024
- Tegsedi® (inotersen): April 2031
- Onpattro® (patisiran): August 2035
- Vyndamax® (tafamidis): August 2035

Recommendations

The College of Pharmacy does not recommend any changes to the current amyloidosis 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: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 12/2021. Last accessed 12/16/2021.

Fiscal Year 2021 Annual Review of Amyotrophic Lateral Sclerosis (ALS) Medications

Oklahoma Health Care Authority
Fiscal Year 2021 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 2021

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	5	30	$51,946.87	$1,731.56	$58.24	10,360	892
2021	4	31	$139,378.79	$4,496.09	$178.23	25,108	782
% Change	**-20.00%**	**3.30%**	**168.30%**	**159.70%**	**206.00%**	**142.40%**	**-12.30%**
Change	**-1**	**1**	**$87,431.92**	**$2,764.53**	**$119.99**	**14,748**	**-110**

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

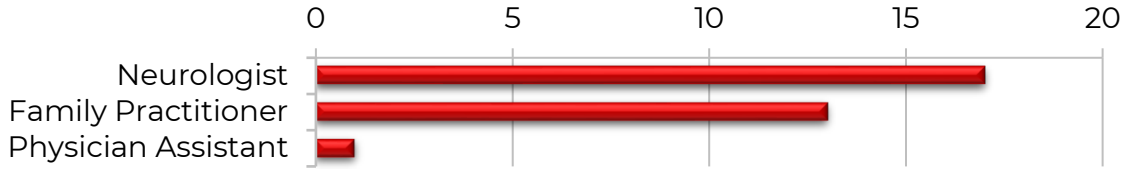
Comparison of Fiscal Years: Medical Claims

- There were no medical claims for Radicava® (edaravone) during fiscal year 2021.

Demographics of Members Utilizing ALS Medications

- There were 4 unique members utilizing ALS medications during fiscal year 2021. Due to the limited number of members utilizing ALS medications, detailed demographic information could not be provided.

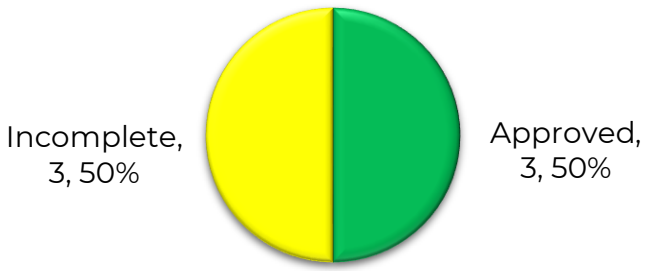
Top Prescriber Specialties of ALS Medications by Number of Claims



Prior Authorization of ALS Medications

There were 6 prior authorization requests submitted for 1 unique member for ALS medications during fiscal year 2021, all of which were for Radicava®. The following chart shows the status of the submitted petitions for fiscal year 2021.

Status of Petitions



Market News and Updates

Anticipated Patent and/or Exclusivity Expiration(s):[2]

- Exservan™ (riluzole oral film): April 2024
- Radicava® (edaravone): May 2024
- Tiglutik® (riluzole oral suspension): March 2029

News:

- **June 2021:** Mitsubishi Tanabe Pharma America announced the launch of Exservan™ (riluzole) oral films in the United States for the treatment of ALS. Exservan™ was approved by the U.S. Food and Drug Administration (FDA) in November 2019 based on a pharmacokinetic study in healthy adults that demonstrated similar bioavailability of the riluzole 50mg oral film relative to riluzole 50mg oral tablets.

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, formulated as a powder in single-use sachets for oral administration after dissolution in water. AMX0035 targets pathways originating in the mitochondria and endoplasmic reticulum leading to neuronal death and degradation. In November 2021, Amylyx announced the submission of a New Drug Application (NDA) to the FDA for AMX0035 for the treatment of ALS. The NDA is supported by data from the Phase 2 CENTAUR study in 137 patients with ALS which demonstrated a statistically significant slowing of functional decline at the end of the 6-month treatment period relative to placebo. Additionally, a long-term, open-label extension study demonstrated a 44% lower risk of death in patients treated up to 3 years with AMX0035 relative to patients who received placebo. In November 2021, Amylyx also announced the first patients have been dosed in the new Phase 3 PHOENIX study of AMX0035 which will enroll approximately 600 patients with clinically definite or clinically probable ALS within 24 months from symptom onset.[3,4]
- **BIIB067 (Tofersen):** Biogen is developing BIIB067 for the treatment of superoxide dismutase 1 (SOD1) ALS, a rare genetic form of ALS. The

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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 12/2021. Last accessed 12/02/2021.

[3] Amylyx Pharmaceuticals, Inc. Amylyx Pharmaceuticals Submits New Drug Application (NDA) for AMX0035 for the Treatment of ALS. Available online at: https://www.amylyx.com/2021/11/02/amylyx-pharmaceuticals-submits-new-drug-application-nda-for-amx0035-for-the-treatment-of-als/. Issued 11/02/2021. Last accessed 12/02/2021.

[4] Amylyx Pharmaceuticals, Inc. Amylyx Pharmaceuticals Announces Participants Dosed in the Global Phase 3 PHOENIX Study of AMX0035 in ALS. Available online at: https://www.amylyx.com/2021/11/04/amylyx-pharmaceuticals-announces-participants-dosed-in-the-global-phase-3-phoenix-study-of-amx0035-in-als/. Issued 11/04/2021. Last accessed 12/02/2021.

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 October 2021, Biogen announced topline results from the pivotal Phase 3 VALOR study evaluating BIIB067 for the treatment of SOD1 ALS. The primary endpoint, change from baseline to week 28 in the Revised Amyotrophic Lateral Sclerosis Functional Rating Scale (ALSFRS-R), was not met in the study. However, some secondary and exploratory endpoints suggested trends favoring BIIB067, particularly in patients who initiated treatment earlier in the disease process. Biogen is currently determining the potential next steps and is engaging with regulators, the medical community, and patient advocacy groups regarding future plans for BIIB067.[5]

- **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 ma-lst 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 and a confirmatory Phase 3 study was initiated. In June 2021, AB Science announced its decision to voluntarily suspend all clinical studies of masitinib worldwide, while additional safety analyses are conducted, due to a potential risk of ischemic heart disease detected in previous studies of masitinib. However, in November 2021, AB Science announced it has received authorization from the FDA to resume patient enrollment in the confirmatory Phase 3 study in patients with ALS.[6,7]
- **MN-166 (Ibudilast):** MediciNova is developing MN-166 for the treatment of ALS in patients already receiving a stable dose of riluzole. MN-166 is an oral, small molecule that inhibits phosphodiesterase type-4 (PDE-4) and inflammatory cytokines, including interleukin (IL)-1β, IL-6, and TNF-α. The Phase 2/3 COMBAT-ALS study is ongoing, and will assess the

[5] Biogen, Inc. Biogen Announces Topline Results from the Tofersen Phase 3 Study and its Open-Label Extension in SOD1-ALS. Available online at: https://investors.biogen.com/news-releases/news-release-details/biogen-announces-topline-results-tofersen-phase-3-study-and-its. Issued 10/17/2021. Last accessed 12/02/2021.

[6] AB Science. AB Science Announces a Voluntary Hold in the Clinical Studies of Masitinib Worldwide. Available online at: https://www.ab-science.com/ab-science-announces-a-voluntary-hold-in-the-clinical-studies-of-masitinib/. Issued 06/01/2021. Last accessed 12/02/2021.

[7] AB Science. AB Science Receives U.S. Food and Drug Administration (FDA) Authorization to Resume Patient Enrollment in the Phase 3 Study of Masitinib in Amyotrophic Lateral Sclerosis (ALS). Available online at: https://www.ab-science.com/ab-science-received-authorization-from-the-fda-to-resume-patient-enrollment-in-the-confirmatory-phase-3-study-of-masitinib-ab19001-in-patients-with-als/. Issued 11/18/2021. Last accessed 12/02/2021.

efficacy, safety, and tolerability of MN-166 relative to placebo over 12 months of treatment, followed by a 6-month open-label extension period.[8]

- **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. Topline results from a Phase 3 study were previously announced, indicating NurOwn® did not meet its primary efficacy endpoint. In February 2021, BrainStorm announced it had met with the FDA and received feedback regarding the Phase 3 data. The FDA indicated the current level of clinical data does not provide the threshold of substantial evidence sought by the FDA to support a Biologics License Application (BLA) for NurOwn®, although this does not preclude BrainStorm from proceeding with a BLA submission. BrainStorm plans to complete all Phase 3 studies in ALS and will conduct additional analyses of key ALS disease biomarkers before making a final decision regarding a potential BLA submission for NurOwn®.[9]
- **Ravulizumab-cwvz:** Alexion is evaluating ravulizumab for the treatment of ALS. Ravulizumab 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. It was thought that ravulizumab may inhibit complement-mediated damage in ALS patients. In March 2021, Alexion completed enrollment of patients into the Phase 3 CHAMPION-ALS study to evaluate the efficacy and safety of ravulizumab relative to placebo in adults with ALS. Results of the study were expected in the first half of 2022, however the study was stopped early in August 2021 based on a pre-specified interim analysis indicating a lack of efficacy. Ravulizumab was previously FDA approved for the treatment of paroxysmal nocturnal hemoglobinuria (PNH) or atypical hemolytic

[8] MediciNova, Inc. Clinical Development: MN-166 (Neurology Diseases). Available online at: https://medicinova.com/clinical-development/core/mn-166/als/. Last accessed 12/02/2021.
[9] BrainStorm Cell Therapeutics, Inc. BrainStorm Announces High-Level FDA Feedback on NurOwn® ALS Clinical Development Program. Available online at: https://ir.brainstorm-cell.com/2021-02-22-BrainStorm-Announces-High-Level-FDA-Feedback-on-NurOwn-R-ALS-Clinical-Development-Program. Issued 02/22/2021. Last accessed 12/02/2021.

uremic syndrome (aHUS) and is marketed under the brand name Ultomiris®.[10,11,12]

- **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 a previous Phase 2 study, reldesemtiv failed to meet its primary efficacy endpoint, but some clinically-meaningful results were observed in post-hoc analyses that supported progression to further clinical studies. In August 2021, Cytokinetics announced the initiation of the Phase 3 COURAGE-ALS study of reldesemtiv in patients with ALS. The study will enroll approximately 555 patients with ALS and will randomize patients 2:1 to receive oral reldesemtiv 300mg or placebo twice daily for 24 weeks. The primary efficacy endpoint will be the change from baseline in the ALSFRS-R at week 24.[13]
- **Verdiperstat:** Biohaven Pharmaceuticals is developing verdiperstat for the treatment of ALS. Verdiperstat is a novel, oral, brain-penetrant, irreversible myeloperoxidase (MPO) inhibitor. Verdiperstat may be able to preserve neurons by inhibiting MPO-induced pathological oxidative stress and inflammation that contribute to cellular injury in neurodegenerative diseases such as ALS. In November 2021, Biohaven announced the completion of patient enrollment into the Phase 2/3 HEALEY ALS study. Approximately 160 adults with ALS have been enrolled into the study, which will assess the efficacy and safety of verdiperstat 600mg or placebo taken orally twice daily for 24 weeks. The primary efficacy endpoint will be the change from baseline to week 24 on the ALSFRS-R.[14,15]

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[10] Alexion Pharmaceuticals, Inc. Alexion Pipeline. Available online at: https://alexion.com/our-research/pipeline. Last accessed 12/02/2021.
[11] Alexion Pharmaceuticals, Inc. Alexion Reports First Quarter 2021 Results. Available online at: https://ir.alexion.com/news-releases/news-release-details/alexion-reports-first-quarter-2021-results. Issued 04/30/2021. Last accessed 12/02/2021.
[12] Doctor V. Another ALS Hopeful Falls Short as Alexion Halts Phase III Trial. *BioSpace*. Available online at: https://www.biospace.com/article/still-no-cure-for-als-after-alexion-halts-trial-for-potential-treatment/. Issued 08/20/2021. Last accessed 12/02/2021.
[13] Cytokinetics, Inc. Cytokinetics Announces Start of COURAGE-ALS, a Phase 3 Clinical Trial of Reldesemtiv in Patients with Amyotrophic Lateral Sclerosis. Available online at: https://ir.cytokinetics.com/news-releases/news-release-details/cytokinetics-announces-start-courage-als-phase-3-clinical-trial. Issued 08/02/2021. Last accessed 12/02/2021.
[14] Biohaven Pharmaceutical Holding Company, Ltd. Science & Pipeline: Verdiperstat. Available online at: https://www.biohavenpharma.com/science-pipeline/mpo/verdiperstat. Last accessed 12/02/2021.
[15] Biohaven Pharmaceutical Holding Company, Ltd. Biohaven Completes Enrollment of Verdiperstat Arm of Pivotal Healey ALS Platform Trial Conducted by the Healey Center for ALS at Massachusetts General Hospital. Available online at: https://www.biohavenpharma.com/investors/news-events/press-releases/11-15-2021. Issued 11/15/2021. Last accessed 12/02/2021.

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 2021

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
RILUZOLE TAB 50MG	19	4	$931.97	$49.05	4.75	0.67%
RADICAVA INJ 30MG	12	1	$138,446.82	$11,537.24	12	99.33%
TOTAL	**31**	**4***	**$139,378.79**	**$4,496.09**	**7.75**	**100%**

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

Fiscal Year 2021 Annual Review of Benign Prostatic Hyperplasia (BPH) Medications

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

Benign Prostatic Hyperplasia (BPH) Medications		
Tier-1	**Tier-2**	**Tier-3**
alfuzosin (Uroxatral®)	doxazosin (Cardura XL®)	tadalafil (Cialis®) 5mg
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.

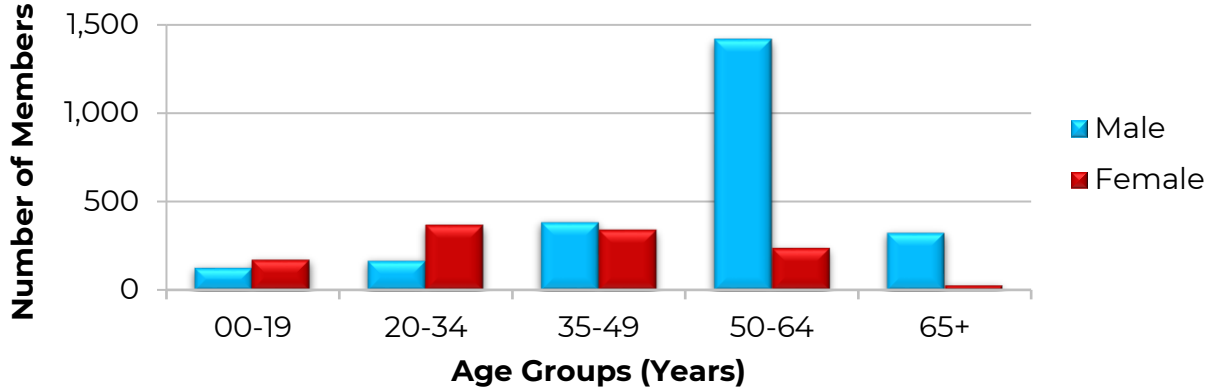
Utilization of BPH Medications: Fiscal Year 2021

Comparison of Fiscal Years

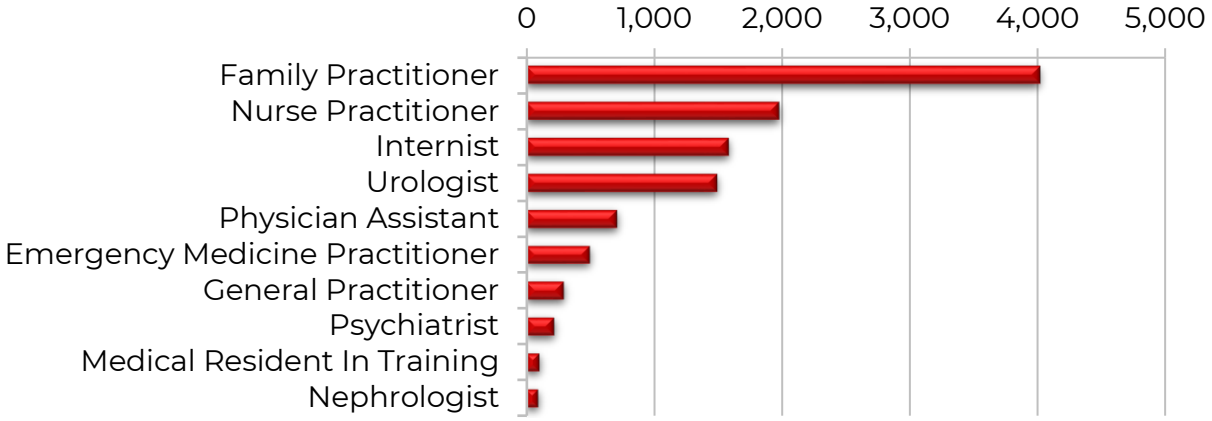
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	3,269	11,716	$162,975.83	$13.91	$0.34	533,200	483,327
2021	3,555	11,632	$157,314.79	$13.52	$0.30	576,617	516,497
% Change	**8.70%**	**-0.70%**	**-3.50%**	**-2.80%**	**-11.80%**	**8.10%**	**6.90%**
Change	**286**	**-84**	**-$5,661.04**	**-$0.39**	**-$0.04**	**43,417**	**33,170**

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

Demographics of Members Utilizing BPH Medications



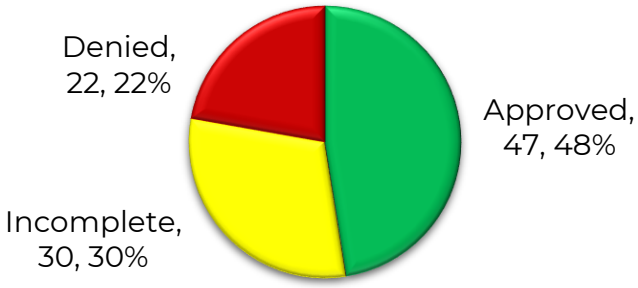
Top Prescriber Specialties of BPH Medications by Number of Claims



Prior Authorization of BPH Medications

There were 99 prior authorization requests submitted for 75 unique members for BPH medications during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021.

Status of Petitions



Market News and Updates

Pipeline:

- **Fexapotide (NX-1207):** Nymox has completed Phase 3 studies evaluating fexapotide for the treatment of BPH. The studies 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. In Phase 3 studies, patients were followed over the course of 1 year following a single fexapotide injection. The primary outcome was the change from baseline in BPH symptoms at 1 year. Additionally, patients could be enrolled into an open-label re-injection study in which patients could voluntarily elect to receive no further treatment, conventional oral BPH treatment, surgical treatment, or an additional fexapotide injection. As of October 2021, Nymox is planning to submit a New Drug Application (NDA) soon 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.[16,17,18]
- **Entadfi™ (Tadalafil 5mg/Finasteride 5mg):** Entadfi™, previously known as Tadfin®, is a fixed-dose proprietary capsule co-formulation of tadalafil and finasteride currently being evaluated for the treatment of BPH. Veru has conducted clinical studies demonstrating bioavailability and bioequivalence of Entadfi™ to tadalafil 5mg and finasteride 5mg dosed daily as separate tablets. Veru submitted an NDA to the FDA for

[16] Nymox Pharmaceutical Corp. Nymox Pipeline. Available online at: https://nymox.com/science/pipeline. Last accessed 12/06/2021.
[17] Nymox Pharmaceutical Corp. Fexapotide for BPH. Available online at: https://nymox.com/science/fexapotide-for-bph. Last accessed 12/06/2021.
[18] Nymox Pharmaceutical Corp. Nymox Provides Current Update. Available online at: https://nymox.com/files/download/8d56dcda672f48e. Issued 10/11/2021. Last accessed 12/06/2021.

Entadfi™ in February 2021. The FDA is expected to make a decision regarding the NDA in December 2021.[19,20]

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 2021

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST / CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 UTILIZATION						
TAMSULOSIN CAP 0.4MG	8,479	3,025	$107,575.39	$12.69	2.8	68.38%
FINASTERIDE TAB 5MG	887	245	$11,996.47	$13.52	3.62	7.63%
DOXAZOSIN TAB 4MG	628	130	$9,792.92	$15.59	4.83	6.23%
DOXAZOSIN TAB 2MG	434	123	$6,334.71	$14.60	3.53	4.03%
DOXAZOSIN TAB 8MG	242	48	$3,795.03	$15.68	5.04	2.41%
ALFUZOSIN TAB 10MG ER	157	51	$2,078.83	$13.24	3.08	1.32%
DOXAZOSIN TAB 1MG	156	51	$2,219.48	$14.23	3.06	1.41%
TERAZOSIN CAP 1MG	144	50	$2,400.38	$16.67	2.88	1.53%
DUTASTERIDE CAP 0.5MG	134	35	$2,361.71	$17.62	3.83	1.50%
TERAZOSIN CAP 2MG	123	38	$2,358.60	$19.18	3.24	1.50%
TERAZOSIN CAP 10MG	90	25	$1,640.86	$18.23	3.6	1.04%
TERAZOSIN CAP 5MG	78	27	$1,408.54	$18.06	2.89	0.90%
SUBTOTAL	**11,552**	**3,551***	**$153,962.92**	**$13.33**	**3.25**	**97.87%**
TIER-2 UTILIZATION						
SILODOSIN CAP 8MG	49	7	$1,540.18	$31.43	7	0.98%
SILODOSIN CAP 4MG	16	3	$674.60	$42.16	5.33	0.43%
DUTAST/TAMSU CAP 0.5-0.4MG	4	1	$908.55	$227.14	4	0.58%
SUBTOTAL	**69**	**10***	**$3,123.33**	**$45.27**	**6.9**	**1.99%**
TIER-3 UTILIZATION						
TADALAFIL TAB 5MG	11	2	$228.54	$20.78	5.5	0.15%
SUBTOTAL	**11**	**2***	**$228.54**	**$20.78**	**5.5**	**0.15%**
TOTAL	**11,632**	**3,555***	**$157,314.79**	**$13.52**	**3.27**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; DUTAST/TAMSU = dutasteride/tamsulosin; ER = extended-release; TAB = tablet
Fiscal Year 2021 = 07/01/2020 to 06/30/2021

[19] Veru, Inc. Veru Pipeline: Entadfi™. Available online at: https://verupharma.com/pipeline/entadfi/. Last accessed 12/06/2021.
[20] Veru, Inc. Veru Reports Record Fiscal 2021 Full-Year Financial Results. Available online at: https://verupharma.com/news/veru-reports-record-fiscal-2021-full-year-financial-results/. Issued 12/02/2021. Last accessed 12/06/2021.

Fiscal Year 2021 Annual Review of Chorionic Gonadotropin Medications

Oklahoma Health Care Authority
Fiscal Year 2021 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 2021

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	1	1	$142.92	$142.92	$142.92	1	1
2021	0	0	$0.00	$0.00	$0.00	0	0
% Change	**-100%**	**-100%**	**-100%**	**-100%**	**-100%**	**100%**	**-100%**
Change	**-1**	**-1**	**-$142.92**	**-$142.92**	**-$142.92**	**-1**	**-1**

*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 2021 = 07/01/2020 to 06/30/2021
Please note: There was no SoonerCare utilization of chorionic gonadotropin medications during fiscal year 2021.

Prior Authorization of Chorionic Gonadotropin Medications

There were no prior authorization requests submitted for chorionic gonadotropin medications during fiscal year 2021 (07/01/2020 to 06/30/2021).

Recommendations

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

Fiscal Year 2021 Annual Review of Constipation and Diarrhea Medications

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria: Constipation Medications

Amitiza® (Lubiprostone) Approval Criteria [Chronic Idiopathic Constipation (CIC) or Irritable Bowel Syndrome with Constipation (IBS-C) Diagnosis]:

1. An FDA approved diagnosis of CIC in members 18 years of age or older, or IBS-C in female members 18 years of age or older; and
2. Documentation that constipation-causing therapies for other disease states have been discontinued (excluding opioid pain medications for cancer patients); and
3. Documented and updated colon screening for members older than 50 years of age; and
4. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
    a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
    b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
5. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if the prescriber documents member is responding well to treatment; and
6. A quantity limit of 60 capsules per 30 days will apply.

Amitiza® (Lubiprostone) Approval Criteria [Opioid-Induced Constipation (OIC) Diagnosis]:

1. An FDA approved diagnosis of OIC in members 18 years of age or older with chronic, non-cancer pain who are currently on chronic opioid therapy, except methadone, including members with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation; and
2. Documentation of the underlying cause of chronic pain, or reason why member is on chronic opioid therapy; and
3. Documented and updated colon screening for members older than 50 years of age; and
4. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be

within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
   a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
   b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
5. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if the prescriber documents member is responding well to treatment; and
6. Amitiza® must be discontinued if treatment with the opioid pain medication is also discontinued; and
7. A quantity limit of 60 capsules per 30 days will apply.

Ibsrela® (Tenapanor) Approval Criteria:

1. An FDA approved diagnosis of irritable bowel syndrome with constipation (IBS-C) in members 18 years of age or older; and
2. Documentation that constipation-causing therapies for other disease states have been discontinued (excluding opioid pain medications for cancer patients); and
3. Documented and updated colon screening for members older than 50 years of age; and
4. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
   a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
   b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
5. A patient-specific, clinically significant reason why the member cannot use Amitiza® (lubiprostone), Linzess® (linaclotide), or Trulance® (plecanatide) must be provided; and
6. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if the prescriber documents the member is responding well to treatment; and
7. A quantity limit of 60 tablets per 30 days will apply.

Linzess® (Linaclotide) Approval Criteria:

1. An FDA approved diagnosis of chronic idiopathic constipation (CIC) or irritable bowel syndrome with constipation (IBS-C) in members 18 years of age or older; and
2. Documentation that constipation-causing therapies for other disease states have been discontinued (excluding opioid pain medications for cancer patients); and
3. Documented and updated colon screening for members older than 50 years of age; and

4. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
    a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
    b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
5. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if the prescriber documents the member is responding well to treatment; and
6. A quantity limit of 30 capsules per 30 days will apply.

Motegrity® (Prucalopride) Approval Criteria:

1. An FDA approved diagnosis of chronic idiopathic constipation (CIC) in members 18 years of age or older; and
2. Documentation that constipation-causing therapies for other disease states have been discontinued (excluding opioid pain medications for cancer patients); and
3. Documented and updated colon screening for members older than 50 years of age; and
4. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
    a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
    b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
5. A patient-specific, clinically significant reason why the member cannot use Amitiza® (lubiprostone), Linzess® (linaclotide), or Trulance® (plecanatide) must be provided; and
6. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if the prescriber documents the member is responding well to treatment; and
7. A quantity limit of 30 tablets per 30 days will apply.

Movantik® (Naloxegol) Approval Criteria:

1. An FDA approved diagnosis of opioid-induced constipation (OIC) in members 18 years of age or older with chronic, non-cancer pain who are currently on chronic opioid therapy including members with chronic pain related to prior cancer or its treatment who do not require frequent (e.g. weekly) opioid dosage escalation; and
2. Member must not have known or suspected gastrointestinal obstruction; and

3. Documentation of the underlying cause of chronic pain, or reason why member is on chronic opioid therapy; and
4. Documented and updated colon screening for members older than 50 years of age; and
5. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
    a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
    b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
6. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment; and
7. Movantik® must be discontinued if treatment with the opioid pain medication is also discontinued; and
8. A quantity limit of 30 tablets per 30 days will apply.

Pizensy™ (Lactitol) Approval Criteria:

1. An FDA approved indication for treatment of chronic idiopathic constipation (CIC) in members 18 years of age or older; and
2. Member must not have a known contraindication to Pizensy™ (i.e., suspected gastrointestinal obstruction, galactosemia); and
3. Documentation that constipation-causing therapies for other disease states have been discontinued (excluding opioid pain medications for cancer patients); and
4. Documented and updated colon screening for members older than 50 years of age; and
5. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
    a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
    b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
6. A patient-specific, clinically significant reason why the member cannot use Linzess® (linaclotide), Amitiza® (lubiprostone), or Trulance® (plecanatide) must be provided; and
7. Use of the unit-dose packets will require a patient-specific, clinically significant reason why the member cannot use the multi-dose bottle; and
8. Approval will initially be for 12 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment; and

9. A quantity limit of 560 grams per 28 days will apply.

Relistor® (Methylnaltrexone) Injection Approval Criteria [Opioid-Induced Constipation (OIC) in Chronic Non-Cancer Pain Diagnosis]:

1. An FDA approved diagnosis of OIC in members 18 years of age or older with chronic, non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation; and
2. Documentation of the underlying cause of chronic pain, or reason why the member is on chronic opioid therapy; and
3. Member must have current use of opioid medications; and
4. Documented and updated colon screening for members older than 50 years of age; and
5. Documentation of hydration attempts and trials of at least 3 different products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
    a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
    b. Members with an oncology-related diagnosis are exempt from trial requirements; and
6. Member must not have known or suspected gastrointestinal obstruction; and
7. A patient-specific, clinically significant reason why the member cannot use Amitiza® (lubiprostone), Movantik® (naloxegol), or Symproic® (naldemedine) must be provided; and
8. A patient-specific, clinically significant reason why the member cannot use the tablet formulation of Relistor® must be provided; and
9. The 12mg single-use vials, syringes, or kits will be the preferred products. Criteria for consideration of 8mg single-use syringes:
    a. Weight range of 38kg to 62kg; and/or
    b. Caregiver unable to draw up dose from vial; and
10. Approval will initially be for 12 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment; and
11. Relistor® must be discontinued if treatment with the opioid pain medication is also discontinued; and
12. A quantity limit of 30 units per month will apply.

Relistor® (Methylnaltrexone) Injection Approval Criteria [Opioid-Induced Constipation (OIC) in Terminal Disease Diagnosis]:

1. An FDA approved diagnosis of OIC in members with severe terminal disease who are receiving only palliative care (life expectancy <6 months); and
2. Member must have current use of opioid medications; and

3. Documented treatment attempts with a minimum of 3 alternative products, excluding bulk forming laxatives; and
    a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
    b. Members with an oncology-related diagnosis are exempt from trial requirements; and
4. Mechanical gastrointestinal obstruction has been ruled out; and
5. The 12mg single-use vials, syringes, or kits will be the preferred products. Criteria for consideration of 8mg single-use syringes:
    a. Weight range of 38kg to 62 kg; and/or
    b. Caregiver unable to draw up dose from vial; and
6. A quantity limit of 30 units per month will apply; and
7. Approvals will be for the duration of 16 weeks of therapy. Use of Relistor® beyond 4 months has not been studied in patients with severe terminal disease.

Relistor® (Methylnaltrexone) Tablets Approval Criteria:

1. An FDA approved diagnosis of opioid-induced constipation (OIC) in members 18 years of age or older with chronic, non-cancer pain who are currently on chronic opioid therapy, including members with chronic pain related to prior cancer or its treatment who do not require frequent (e.g. weekly) opioid dosage escalation; and
2. Member must not have known or suspected gastrointestinal obstruction; and
3. Documentation of the underlying cause of chronic pain, or reason why the member is on chronic opioid therapy; and
4. Documented and updated colon screening for members older than 50 years of age; and
5. Documentation of hydration attempts and trials of at least 3 different types of products that have failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
    a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
    b. Members with an oncology-related diagnosis are exempt from trial requirements; and
6. A patient-specific, clinically significant reason why the member cannot use Amitiza® (lubiprostone), Movantik® (naloxegol), or Symproic® (naldemedine) must be provided; and
7. Approval will initially be for 12 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment; and
8. Relistor® must be discontinued if treatment with the opioid pain medication is also discontinued; and
9. A quantity limit of 90 tablets per 30 days will apply.

Symproic® (Naldemedine) Approval Criteria:

1. An FDA approved diagnosis of opioid-induced constipation (OIC) in members 18 years of age or older with chronic, non-cancer paid who are currently on chronic opioid therapy, including members with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation; and
2. Member must not have known or suspected gastrointestinal obstruction; and
3. Documentation of the underlying cause of chronic pain, or reason why member is on chronic opioid therapy; and
4. Documented and updated colon screening for members older than 50 years of age; and
5. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
    a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
    b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
6. A patient-specific, clinically significant reason why member cannot use Amitiza® (lubiprostone) or Movantik® (naloxegol) must be provided; and
7. Approval will initially be for 12 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment; and
8. Symproic® must be discontinued if treatment with the opioid pain medication is also discontinued; and
9. A quantity limit of 30 tablets per 30 days will apply.

Trulance® (Plecanatide) Approval Criteria:

1. An FDA approved diagnosis of chronic idiopathic constipation (CIC) or irritable bowel syndrome with constipation (IBS-C) in members 18 years of age or older; and
2. Documentation that constipation-causing therapies for other disease states have been discontinued (excluding opioid pain medications for cancer patients); and
3. Documented and updated colon screening for members older than 50 years of age; and
4. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners; and
    a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
    b. Members with an oncology-related diagnosis are exempt from the trial requirements; and

5. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment; and
6. A quantity limit of 30 tablets per 30 days will apply.

Zelnorm™ (Tegaserod) Approval Criteria:

1. An FDA approved diagnosis of irritable bowel syndrome with constipation (IBS-C) in female members 18 to 64 years of age; and
2. Member must be female for authorization of Zelnorm™ (the safety and efficacy of Zelnorm™ in males with IBS-C have not been established); and
3. Member must not have any of the contraindications for use of Zelnorm™ [i.e., history of myocardial infarction (MI), stroke, transient ischemic attack (TIA), or angina; history of ischemic colitis or other forms of intestinal ischemia; severe renal impairment (estimated glomerular filtration rate {eGFR} <15mL/min/1.73m^2) or end-stage renal disease (ESRD); moderate or severe hepatic impairment (Child-Pugh B or C); history of bowel obstruction, symptomatic gallbladder disease, suspected sphincter or Oddi dysfunction, or abdominal adhesions; hypersensitivity to tegaserod]; and
4. Documentation that constipation-causing therapies for other disease states have been discontinued (excluding opioid pain medications for cancer patients); and
5. Documented and updated colon screening for members older than 50 years of age; and
6. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the counter (OTC) or prescription (does not include fiber or stool softeners); and
    a. 1 of the 3 trials must be for polyethylene glycol 3350 (PEG-3350); and
    b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
7. A patient-specific, clinically significant reason why the member cannot use Amitiza® (lubiprostone), Linzess® (linaclotide), or Trulance® (plecanatide) must be provided; and
8. Approval will initially be for 6 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment. Zelnorm™ should be discontinued in patients who have not had adequate control of symptoms after 4 to 6 weeks of treatment; and
9. A quantity limit of 60 tablets per 30 days will apply.

Current Prior Authorization Criteria: Diarrhea Medications

Aemcolo® (Rifamycin) Approval Criteria:

1. An FDA approved diagnosis of travelers' diarrhea; and
2. Member must be 18 years of age or older; and
3. Travelers' diarrhea must be due to non-invasive strains of *Escherichia coli*; and
4. A patient-specific, clinically significant reason why the member cannot use Xifaxan® (rifaximin) oral tablets must be provided; and
5. A quantity limit of 12 tablets per 3 days will apply.

Motofen® (Difenoxin/Atropine) Approval Criteria:

1. An FDA approved diagnosis of acute nonspecific diarrhea or acute exacerbations of chronic functional diarrhea; and
2. Member must not be 2 years of age or younger;
3. Member must not have diarrhea associated with organisms that penetrate the intestinal mucosa (e.g., toxigenic *Escherichia coli*, *Salmonella* species, *Shigella*) or pseudomembranous colitis associated with broad spectrum antibiotics; and
4. A patient-specific, clinically significant reason why the member cannot use Lomotil® (diphenoxylate/atropine) and loperamide must be provided; and
5. A quantity limit of 16 tablets per 2 days will apply.

Viberzi® (Eluxadoline) Approval Criteria:

1. An FDA approved diagnosis of irritable bowel syndrome with diarrhea (IBS-D); and
2. Member must be 18 years of age or older; and
3. Member must not have any of the contraindications for use of Viberzi® (i.e., removed gallbladder; biliary duct obstruction or sphincter of Oddi disease or dysfunction; alcoholism, alcohol abuse, or alcohol addiction; history of pancreatitis or structural diseases of the pancreas; severe hepatic impairment; history of chronic or severe constipation; mechanical gastrointestinal obstruction); and
4. Documentation of trials of 2 of the following 3 medications that failed to relieve diarrhea: loperamide, dicyclomine, or diphenoxylate/atropine (each trial should be for at least 10 to 14 consecutive days at the recommended dosing). Trials must be within the past 90 days. Documentation should be provided including dates, dosing, and reason for trial failure; and
5. Approval will initially be for 12 weeks of therapy. Further approval may be granted if the prescriber documents the member is responding well to treatment; and
6. A quantity limit of 60 tablets per 30 days will apply.

Xermelo® (Telotristat Ethyl) Approval Criteria:

1. An FDA approved diagnosis of carcinoid syndrome diarrhea in combination with somatostatin analog (SSA) therapy in adults inadequately controlled by SSA therapy; and
2. Member must be 18 years of age or older; and
3. Member must have been taking a stable dose of SSA therapy for the last 3 months and be inadequately controlled (4 or more bowel movements per day); and
4. Prescriber must verify member will continue taking SSA therapy in combination with Xermelo®; and
5. Approval will initially be for 12 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment; and
6. A quantity limit of 90 tablets per 30 days will apply.

Xifaxan® (Rifaximin) 200mg Approval Criteria:

1. An FDA approved diagnosis of travelers' diarrhea; and
2. Member must be 12 years of age or older; and
3. Travelers' diarrhea must be due to noninvasive strains of *Escherichia coli*; and
4. A quantity limit of 9 tablets per 3 days will apply.

Xifaxan® (Rifaximin) 550mg Approval Criteria:

1. An FDA approved indication for the reduction in risk of overt hepatic encephalopathy (HE) recurrence; or
2. An FDA approved diagnosis of irritable bowel syndrome with diarrhea (IBS-D); and
    a. For the diagnosis of IBS-D: Documentation of trials of 2 of the following 3 medications that failed to relieve diarrhea: loperamide, dicyclomine, or diphenoxylate/atropine (each trial should be for at least 10 to 14 consecutive days at the recommended dosing). Trials must be within the past 90 days. Documentation should be provided including dates, dosing, and reason for trial failure; and
    b. For the diagnosis if IBS-D: Member must be 18 years of age or older; and
3. A quantity limit of 60 tablets per 30 days will apply. Patients with the diagnosis of IBS-D needing 42 tablets for a 14-day treatment regimen (550mg 3 times daily for 14 days) will be approved for a quantity limit override upon meeting Xifaxan® approval criteria. Patients with IBS-D who experience a recurrence of symptoms can be retreated up to 2 times with the same 14-day treatment regimen (550mg 3 times daily for 14 days).

Utilization of Constipation and Diarrhea Medications: Fiscal Year 2021

Comparison of Fiscal Years: Constipation Medications

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	205	998	$395,461.58	$396.25	$13.38	38,294	29,552
2021	245	1,074	$446,861.81	$416.07	$13.89	39,299	32,165
% Change	**19.50%**	**7.60%**	**13.00%**	**5.00%**	**3.80%**	**2.60%**	**8.80%**
Change	**40**	**76**	**$51,400.23**	**$19.82**	**$0.51**	**1,005**	**2,613**

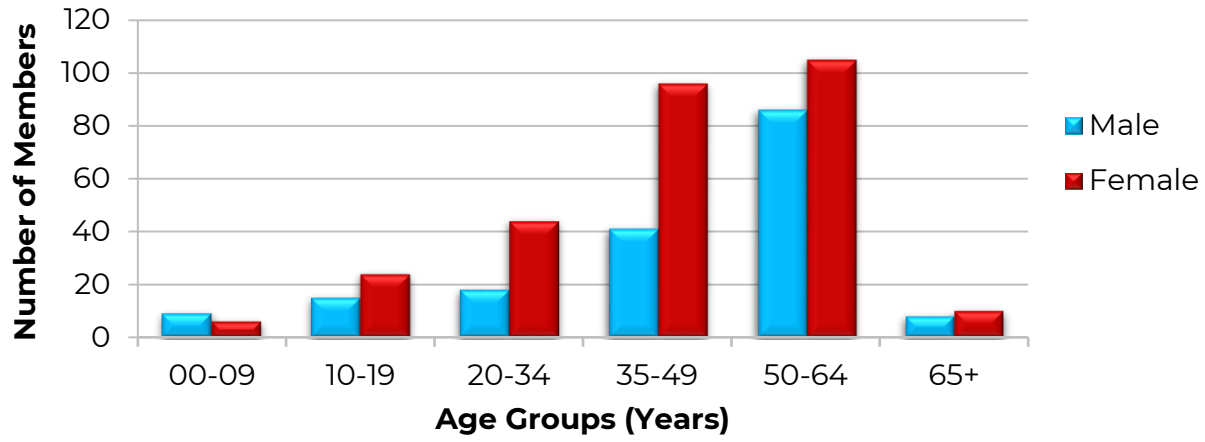
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020; Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Comparison of Fiscal Years: Diarrhea Medications

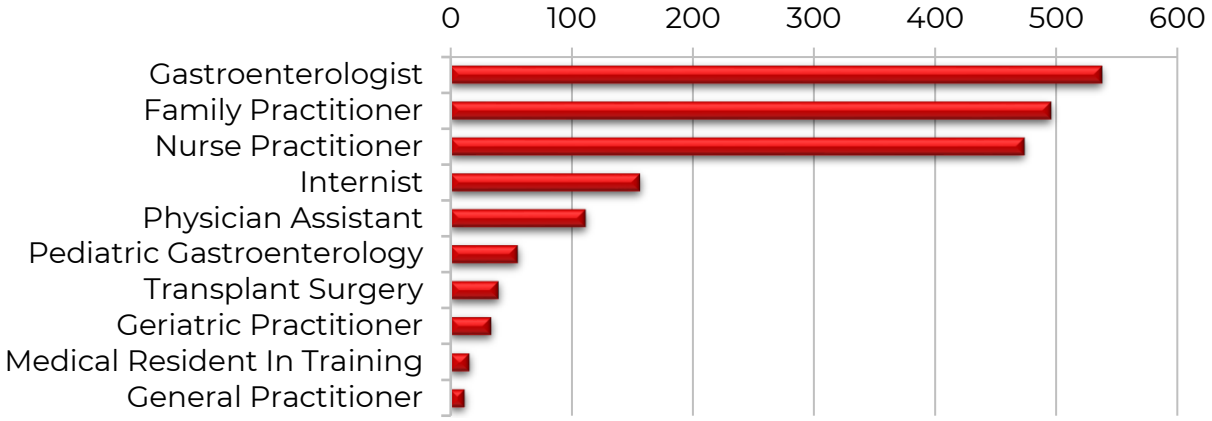
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	194	969	$2,105,369.64	$2,172.72	$76.78	54,566	27,422
2021	218	936	$2,164,010.36	$2,311.98	$82.29	52,526	26,298
% Change	**12.40%**	**-3.40%**	**2.80%**	**6.40%**	**7.20%**	**-3.70%**	**-4.10%**
Change	**24**	**-33**	**$58,640.72**	**$139.26**	**$5.51**	**-2,040**	**-1,124**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020; Fiscal Year 2021 = 07/01/2020 to 06/30/2021
The above table includes Xifaxan®, which was first FDA approved in 2004 and has a significant federal rebate. Please note, the majority of utilization of rifaximin was for the 550mg strength for the reduction in risk of overt hepatic encephalopathy (HE) recurrence.

Demographics of Members Utilizing Constipation and Diarrhea Medications



Top Prescriber Specialties of Constipation and Diarrhea Medications by Number of Claims



Prior Authorization of Constipation and Diarrhea Medications

There were 2,339 prior authorization requests submitted for constipation and diarrhea medications during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021.

Status of Petitions

Market News and Updates

Anticipated Patent Expiration(s):[21]

- Aemcolo® (rifamycin): May 2025
- Amitiza® (lubiprostone): October 2027
- Xifaxan® (rifaximin): October 2029
- Relistor® (methylnaltrexone injection): December 2030
- Xermelo® (telotristat): February 2031
- Relistor® (methylnaltrexone tablet): March 2031
- Movantik® (naloxegol): April 2032
- Viberzi® (eluxadoline): March 2033
- Symproic® (naldemedine): May 2033

[21] 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 12/2021. Last accessed 12/01/2021.

- Linzess® (linaclotide): August 2033
- Pizensy™ (lactitol): May 2037

News:

- **January 2021:** Par Pharmaceutical released the first generic formulations of Amitiza® (lubiprostone), available in 8mcg and 24mcg oral capsules. Lubiprostone is indicated for the treatment of chronic idiopathic constipation (CIC), opioid induced constipation (OIC), and irritable bowel syndrome with constipation (IBS-C) in women 18 years of age and older.[22]
- **July 2021:** Ardelyx received a Complete Response Letter (CRL) for tenapanor from the U.S. Food and Drug Administration (FDA) for the control of serum phosphorus in adults with chronic kidney disease (CKD) on dialysis. The FDA indicated the results of the clinical studies of tenapanor show it is effective in reducing serum phosphorus in CKD patients on dialysis, but the magnitude of the treatment effect was considered small and of unclear clinical significance. Additionally, the FDA indicated a new clinical study would be required to demonstrate a clinically relevant treatment effect on serum phosphorus or an effect on the clinical outcome thought to be caused by hyperphosphatemia in CKD patients on dialysis. Ardelyx disagrees with the FDA's assessment regarding clinical significance and plans to submit a Formal Dispute Resolution Request (FDRR) to appeal the CRL for tenapanor. Tenapanor is a small molecule with a unique mechanism of action that acts locally in the gut to inhibit the sodium/hydrogen exchanger 3 (NHE3), resulting in reduced permeability to phosphate and decreased phosphate absorption in the gastrointestinal tract. Tenapanor was previously FDA approved in September 2019 for the treatment of adults with IBS-C with the brand name Ibsrela®, but the product is not yet available. Ardelyx plans to launch Ibsrela® in the United States for patients with IBS-C in the second quarter of 2022.[23,24,25,26]

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[22] Ernst, D. Generic Version of Amitiza® Now Available. *MPR*. Available online at: https://www.empr.com/home/news/generics-news/amitiza-lubiprostone-authorized-generic-mallinckrodt-par-pharmaceutical/. Issued 01/04/2021. Last accessed 12/01/2021.

[23] Ardelyx, Inc. Ardelyx Receives Complete Response Letter from U.S. FDA for New Drug Application for Tenapanor for the Control of Serum Phosphorus in Adult Patients with CKD on Dialysis. Available online at: https://ir.ardelyx.com/news-releases/news-release-details/ardelyx-receives-complete-response-letter-us-fda-new-drug. Issued 07/29/2021. Last accessed 12/01/2021.

[24] Ardelyx, Inc. Products: Ibsrela® Availability. Available online at: https://ardelyx.com/products/. Last accessed 12/01/2021.

[25] Ardelyx, Inc. Ardelyx Provides Corporate Update Following Type A Meeting with FDA. Available online at: https://ir.ardelyx.com/news-releases/news-release-details/ardelyx-provides-corporate-update-following-type-meeting-fda. Issued 10/13/2021. Last accessed 12/27/2021.

[26] Ardelyx, Inc. Ardelyx to Pursue Formal Dispute Resolution for Tenapanor. Available online at: https://ir.ardelyx.com/news-releases/news-release-details/ardelyx-pursue-formal-dispute-resolution-tenapanor. Issued 11/04/2021. Last accessed 12/27/2021.

- **October 2021:** The results of a randomized controlled study evaluating the effects of prucalopride on memory in healthy adult participants were published in *Translational Psychiatry*. Prucalopride is a selective serotonin-4 (5-HT4) receptor partial agonist that had been previously identified as having pro-cognitive effects. In the study, participants were randomly assigned to receive prucalopride 1mg or placebo for 1 week. After 1 week of treatment, the prucalopride group performed significantly better on memory tests than the placebo group, and brain activity was increased in areas related to cognition in participants who received prucalopride. The investigators hope prucalopride may eventually be an option to help patients with cognitive impairment related to mental illness. Prucalopride was previously FDA approved for the treatment of adults with CIC in December 2018 and is marketed under the brand name Motegrity®.[27]

Recommendations

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

Utilization Details of Constipation Medications: Fiscal Year 2021

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
LINACLOTIDE PRODUCTS						
LINZESS CAP 290MCG	325	63	$140,409.11	$432.03	5.16	31.42%
LINZESS CAP 145MCG	217	58	$96,286.91	$443.72	3.74	21.55%
LINZESS CAP 72MCG	104	34	$45,558.99	$438.07	3.06	10.20%
SUBTOTAL	**646**	**155**	**$282,255.01**	**$436.93**	**4.17**	**63.16%**
LUBIPROSTONE PRODUCTS						
AMITIZA CAP 8MCG	108	31	$38,864.50	$359.86	3.48	8.70%
AMITIZA CAP 24MCG	96	25	$34,836.54	$362.88	3.84	7.80%
LUBIPROSTONE CAP 24MCG	21	10	$5,839.40	$278.07	2.1	1.31%
LUBIPROSTONE CAP 8MCG	17	10	$3,981.16	$234.19	1.7	0.89%
SUBTOTAL	**242**	**76**	**$83,521.60**	**$345.13**	**3.18**	**18.69%**
NALOXEGOL PRODUCTS						
MOVANTIK TAB 25MG	73	26	$25,420.13	$348.22	2.81	5.69%
MOVANTIK TAB 12.5MG	2	2	$704.76	$352.38	1	0.16%
SUBTOTAL	**75**	**28**	**$26,124.89**	**$348.33**	**2.68**	**5.85%**
PLECANATIDE PRODUCTS						
TRULANCE TAB 3MG	73	19	$32,146.48	$440.36	3.84	7.19%
SUBTOTAL	**73**	**19**	**$32,146.48**	**$440.36**	**3.84**	**7.19%**

[27] Davenport L. Constipation Med Boosts Cognitive Performance in Mental Illness. *Medscape*. Available online at: https://www.medscape.com/viewarticle/960451. Issued 10/07/2021. Last accessed 12/01/2021.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
PRUCALOPRIDE PRODUCTS						
MOTEGRITY TAB 1MG	17	3	$7,465.23	$439.13	5.67	1.67%
MOTEGRITY TAB 2MG	16	5	$5,912.92	$369.56	3.2	1.32%
SUBTOTAL	**33**	**8**	**$13,378.15**	**$405.40**	**4.13**	**2.99%**
METHYLNALTREXONE PRODUCTS						
RELISTOR INJ 12MG/0.6ML	3	2	$7,245.82	$2,415.27	1.5	1.62%
RELISTOR TAB 150MG	1	1	$1,798.56	$1,798.56	1	0.40%
SUBTOTAL	**4**	**3**	**$9,044.38**	**$2,261.10**	**1.33**	**2.02%**
NALDEMEDINE PRODUCTS						
SYMPROIC TAB 0.2MG	1	1	$391.30	$391.30	1	0.09%
SUBTOTAL	**1**	**1**	**$391.30**	**$391.30**	**1**	**0.09%**
TOTAL	**1,074**	**245***	**$446,861.81**	**$416.07**	**4.38**	**100%**

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

Utilization Details of Diarrhea Medications: Fiscal Year 2021

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
RIFAXIMIN PRODUCTS						
XIFAXAN TAB 550MG	883	207	$2,096,848.66	$2,374.69	4.27	96.90%
XIFAXAN TAB 200MG	32	8	$39,701.21	$1,240.66	4	1.83%
SUBTOTAL	**915**	**215**	**$2,136,549.87**	**$2,335.03**	**4.26**	**98.73%**
ELUXADOLINE PRODUCTS						
VIBERZI TAB 100MG	14	2	$18,284.68	$1,306.05	7	0.84%
VIBERZI TAB 75MG	7	1	$9,175.81	$1,310.83	7	0.42%
SUBTOTAL	**21**	**3**	**$27,460.49**	**$1,307.64**	**7**	**1.27%**
TOTAL	**936**	**218***	**$2,164,010.36**	**$2,311.98**	**4.29**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
TAB = tablet
Fiscal Year 2021 = 07/01/2020 to 06/30/2021
Xifaxan® was first FDA approved in 2004 and has a significant federal rebate. Please note, the majority of utilization of rifaximin was for the 550mg strength for the reduction in risk of overt hepatic encephalopathy (HE) recurrence.

Fiscal Year 2021 Annual Review of Corticosteroid Special Formulations

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

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

1. Approval 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 a 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. Approval 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 2021

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	1,314	1,661	$166,914.89	$100.49	$20.76	9,875	8,041
2021	652	862	$87,179.48	$101.14	$20.12	4,809	4,334
% Change	**-50.4%**	**-48.1%**	**-47.8%**	**0.6%**	**-3.1%**	**-51.3%**	**-46.1%**
Change	**-662**	**-799**	**-$79,735.41**	**$0.65**	**-$0.64**	**-5,066**	**-3,707**

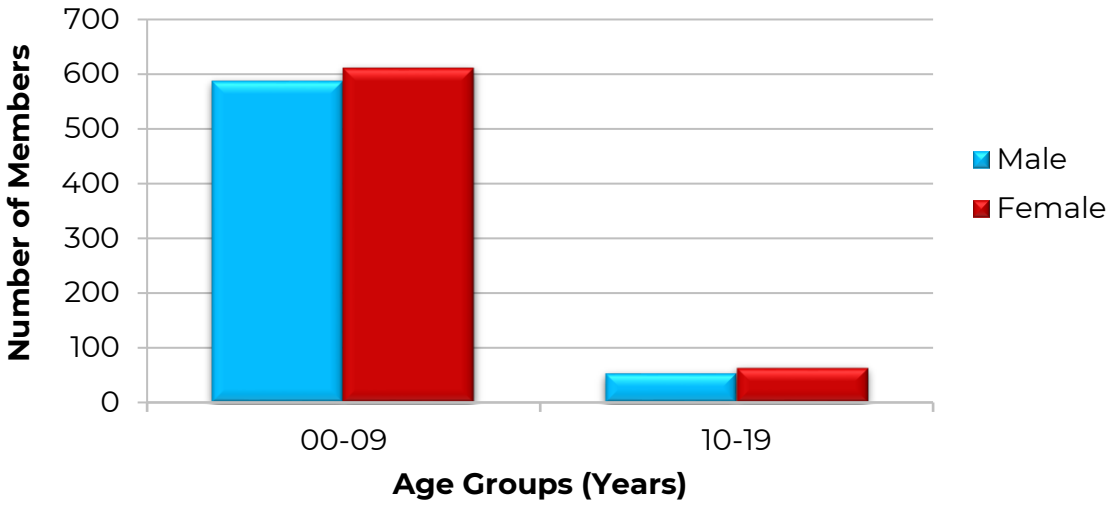
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020; Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Comparison of Fiscal Years: Medical Claims

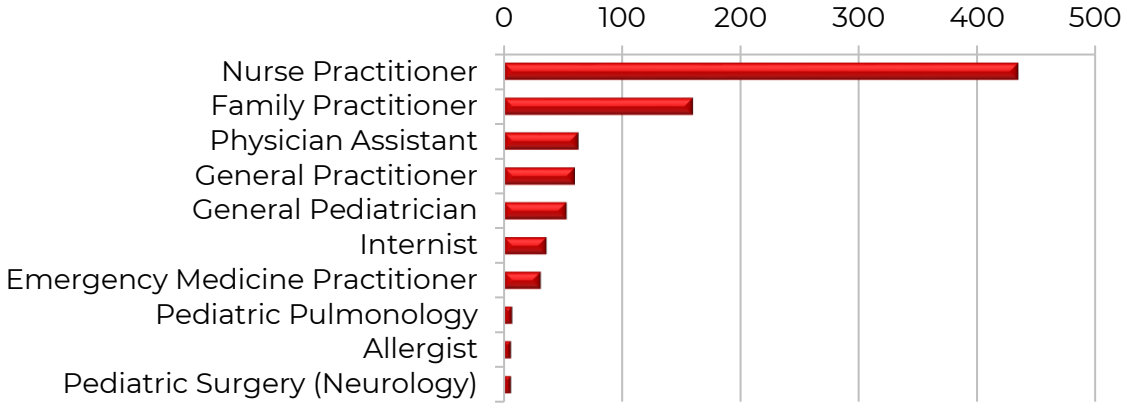
Fiscal Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Total Units
2020	8	8	$1,521.40	$190.18	289
2021	6	6	$2,894.33	$482.39	257
% Change	**-25.0%**	**-25.0%**	**90.2%**	**153.6%**	**-11.1%**
Change	**-2**	**-2**	**$1,372.93**	**$292.21**	**-32**

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

Demographics of Members Utilizing Corticosteroid Special Formulations



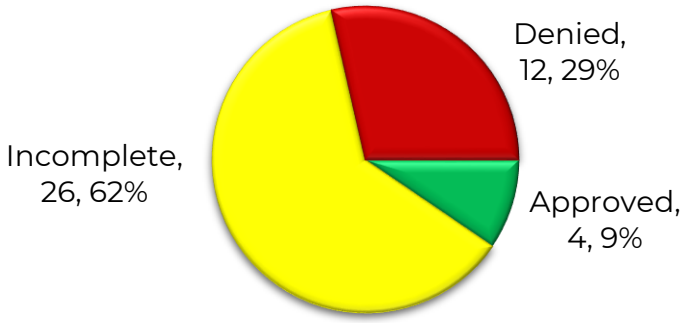
Top Prescriber Specialties of Corticosteroid Special Formulations by Number of Claims



Prior Authorization of Corticosteroid Special Formulations

There were 42 prior authorization requests submitted for corticosteroid special formulations during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[28]

- Rayos® (Prednisone Delayed-Release Tablet): January 2028
- Zilretta® [Triamcinolone Acetonide Extended-Release (ER) Injection]: August 2031

[28] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 11/2021. Last accessed 11/01/2021.

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 2021

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
PREDNISOLONE ORALLY DISINTEGRATING TABLET (ODT) PRODUCTS						
PREDNISOLONE 15MG ODT	577	439	$60,421.40	$104.72	1.31	69.31%
PREDNISOLONE 10MG ODT	193	180	$14,224.63	$73.70	1.07	16.32%
PREDNISOLONE 30MG ODT	92	80	$12,533.45	$136.23	1.15	14.38%
TOTAL	**862**	**652***	**$87,179.48**	**$101.14**	**1.32**	**100%**

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

Medical Claims

PRODUCT UTILIZED	†TOTAL CLAIMS	*TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
ZILRETTA INJ 32MG J3304	6	6	$2,894.33	$482.39	1
TOTAL	**6**	**6**	**$2,894.33**	**$482.39**	**1**

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

Fiscal Year 2021 Annual Review of Crysvita® (Burosumab-twza)

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

Crysvita® (Burosumab-twza) Approval Criteria [Tumor-Induced Osteomalacia (TIO) Diagnosis]:

1. An FDA approved indication for the treatment of fibroblast growth factor 23 (FGF23)-related hypophosphatemia in TIO associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized in members 2 years of age and older; and
2. Member's diagnosis must be confirmed by elevated serum FGF23 level that was not amendable to cure by surgical excision of the underlying tumor/lesion; and
3. Member's serum phosphorus level must be below the normal range for member age; and
4. Member must not have any contraindications to taking Crysvita® including the following:
    a. Concomitant use with oral phosphate and active vitamin D analogs; and
    b. Serum phosphorus within or above the normal range for member age; and
    c. Severe renal impairment or end-stage renal disease; and
5. Crysvita® must be administered by a health care professional. Approvals will not be granted for self-administration. Prior authorization requests must indicate how Crysvita® will be administered; and
    a. Crysvita® must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment; or
    b. Crysvita® must be shipped via cold chain supply to the member's home and administered by a home health care provider if the member's caregiver has been trained on the proper storage of Crysvita®; and
6. The prescriber must agree to assess serum phosphorus levels on a monthly basis for the first 3 months of treatment and thereafter as appropriate and follow the Crysvita® *Prescribing Information* for dose adjustments; and
7. The prescriber must agree to monitor 25-hydroxy vitamin D levels; and
8. Crysvita® must be prescribed by an endocrinologist or specialist with expertise in the treatment of TIO (or an advanced care practitioner with

a supervising physician who is an endocrinologist or specialist with expertise in treating TIO); and
9. The member's recent weight (within the last 3 months) must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
10. Initial authorizations will be for the duration of 6 months, at which time the prescriber must verify the member is responding to the medication as demonstrated by serum phosphorus levels within the normal range for member age or clinically significant improvement in bone-related symptoms; and
11. Early refill requests for dose changes more frequently than every 4 weeks will not be approved; and
12. The maximum approvable dosing regimen is 180mg every 2 weeks; and
13. A quantity limit of 12 single-dose vials per month will apply.

Crysvita® (Burosumab-twza) Approval Criteria [X-Linked Hypophosphatemia (XLH) Diagnosis]:

1. An FDA approved indication for the treatment of XLH in adult and pediatric members 6 months of age and older. Diagnosis of XLH must be confirmed by 1 of the following:
    a. Genetic testing; or
    b. Elevated serum fibroblast growth factor 23 (FGF23) level; and
2. Member's serum phosphorus level must be below the normal range for member age; and
3. Member must not have any contraindications to taking Crysvita® including the following:
    a. Concomitant use with oral phosphate and active vitamin D analogs; and
    b. Serum phosphorus within or above the normal range for member age; and
    c. Severe renal impairment or end-stage renal disease; and
4. Crysvita® must be administered by a health care professional. Approvals will not be granted for self-administration. Prior authorization requests must indicate how Crysvita® will be administered; and
    a. Crysvita® must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment; or
    b. Crysvita® must be shipped via cold chain supply to the member's home and administered by a home health care provider if the member's caregiver has been trained on the proper storage of Crysvita®; and
5. Member must have clinical signs and symptoms of XLH (symptoms beyond hypophosphatemia alone); and

6. Every 2 week dosing will not be approved for members 18 years of age or older; and
7. The prescriber must agree to assess serum phosphorus levels on a monthly basis for the first 3 months of treatment, and thereafter as appropriate; and
8. Crysvita® must be prescribed by a nephrologist, endocrinologist, or specialist with expertise in the treatment of XLH (or an advanced care practitioner with a supervising physician who is a nephrologist, endocrinologist, or specialist with expertise in the treatment of XLH); and
9. Initial authorizations will be for the duration of 6 months, at which time the prescriber must verify the member is responding to the medication as demonstrated by serum phosphorus levels within the normal range for member age or clinically significant improvement in bone-related symptoms; and
10. 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 Crysvita® (Burosumab-twza): Fiscal Year 2021

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	7	67	$914,663.59	$13,651.70	$487.56	159	1,876
2021	11	99	$1,263,578.79	$12,763.42	$462.85	210	2,730
% Change	**57.10%**	**47.80%**	**38.10%**	**-6.50%**	**-5.10%**	**32.10%**	**45.50%**
Change	**4**	**32**	**$348,915.20**	**-$888.28**	**-$24.71**	**51**	**854**

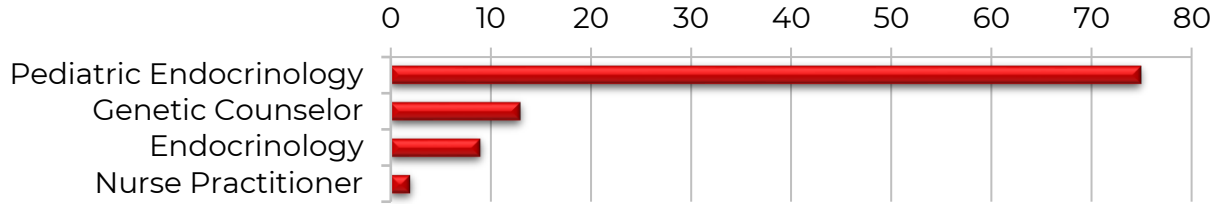
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020; Fiscal Year 2021 = 07/01/2020 to 06/30/2021

- There were no SoonerCare paid medical claims for Crysvita® (burosumab-twza) during fiscal year 2021.

Demographics of Members Utilizing Crysvita® (Burosumab-twza)

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

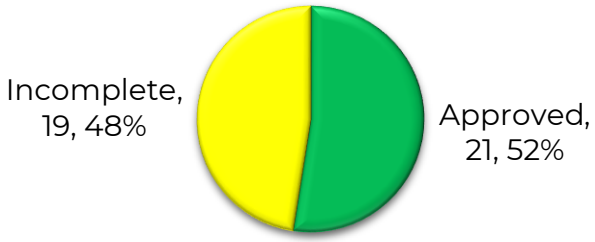
Top Prescriber Specialties of Crysvita® (Burosumab-twza) by Number of Claims



Prior Authorization of Crysvita® (Burosumab-twza)

There were 40 prior authorization requests submitted for Crysvita® (burosumab-twza) for 11 unique members during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021.

Status of Petitions



Recommendations

The College of Pharmacy does not recommend any changes to the current Crysvita® (burosumab-twza) prior authorization criteria at this time.

Utilization Details of Crysvita® (Burosumab-twza): Fiscal Year 2021

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
CRYSVITA INJ 20MG/ML	53	5	$621,853.93	$11,733.09	10.6	49.21%
CRYSVITA INJ 10MG/ML	30	7	$187,567.30	$6,252.24	4.29	14.84%
CRYSVITA INJ 30MG/ML	16	2	$454,157.56	$28,384.85	8	35.94%
TOTAL	**99**	**11***	**$1,263,578.79**	**$12,763.42**	**9**	**100%**

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

Fiscal Year 2021 Annual Review of Erythropoietin Stimulating Agents (ESAs)

Oklahoma Health Care Authority
Fiscal Year 2021 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 patients 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 2021

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	20	245	$66,693.02	$272.22	$28.28	154	2,358
2021	20	148	$55,972.87	$378.20	$30.03	159	1,864
% Change	**0.00%**	**-39.60%**	**-16.10%**	**38.90%**	**6.20%**	**3.20%**	**-20.90%**
Change	**0**	**-97**	**-$10,720.15**	**$105.98**	**$1.75**	**5**	**-494**

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

Fiscal Year 2021 Utilization of ESAs: Medical Claims

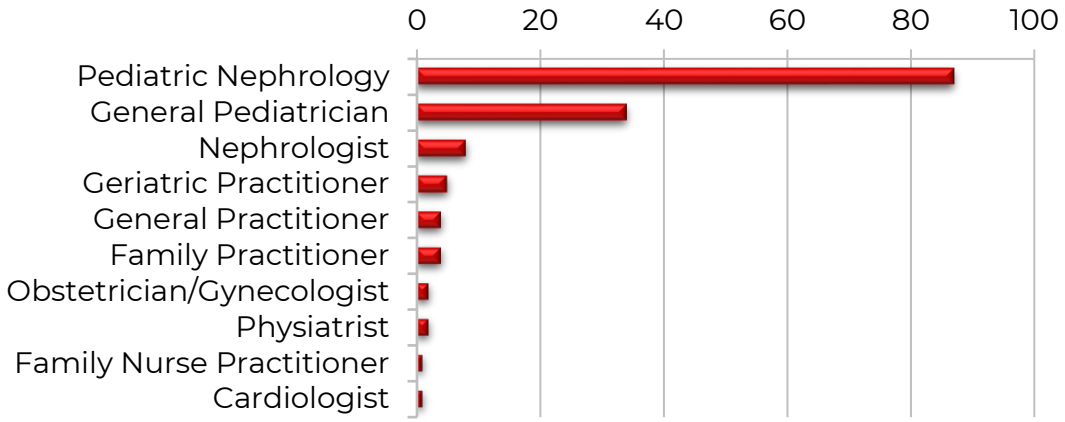
Fiscal Year	*Total Members	†Total Claims	Total Cost	Claims/ Member	Cost/ Claim
2021	18	52	$45,630.58	2.89	$877.51

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

Demographics of Members Utilizing ESAs

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

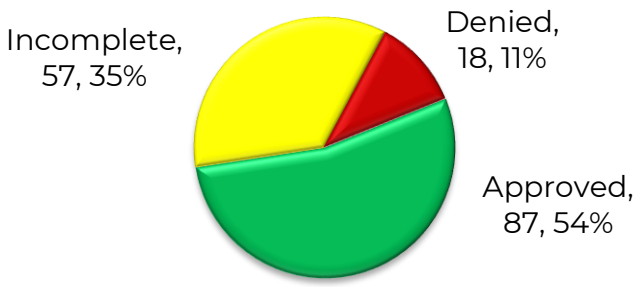
Top Prescriber Specialties of ESAs by Number of Claims



Prior Authorization of ESAs

There were 162 prior authorization requests submitted for ESAs during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021.

Status of Petitions



Recommendations

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

Utilization Details of ESAs: Fiscal Year 2021

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
EPOETIN ALFA PRODUCTS						
PROCRIT INJ 20,000/ML	88	9	$22,472.17	$255.37	9.78	40.15%
EPOGEN INJ 20,000/ML	45	6	$18,747.95	$416.62	7.5	33.49%
EPOGEN INJ 10,000/ML	6	3	$7,028.56	$1,171.43	2	12.56%
RETACRIT INJ 10,000/ML	1	1	$449.11	$449.11	1	0.80%
PROCRIT INJ 4,000/ML	1	1	$435.51	$435.51	1	0.78%
PROCRIT INJ 40,000/ML	1	1	$4,283.41	$4,283.41	1	7.65%
SUBTOTAL	**142**	**21**	**$53,416.71**	**$376.17**	**6.76**	**95.43%**
DARBEPOETIN ALFA PRODUCTS						
ARANESP INJ 40MCG	5	1	$2,468.49	$493.70	5	4.41%
ARANESP INJ 150MCG	1	1	$87.67	$87.67	1	0.16%
SUBTOTAL	**6**	**2**	**$2,556.16**	**$426.03**	**3**	**4.57%**
TOTAL	**148**	**20***	**$55,972.87**	**$378.20**	**7.4**	**100%**

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

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM	% COST
DARBEPOETIN ALFA PRODUCTS						
ARANESP INJ J0881	37	9	$39,918.38	4.11	$1,078.88	87.48%
EPOETIN ALFA PRODUCTS						
PROCRIT INJ J0885	15	9	$5,712.20	1.67	$380.81	12.52%
TOTAL	**52†**	**18***	**$45,630.58**	**2.89**	**$877.51**	**100%**

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

Fiscal Year 2021 Annual Review of Fabry Disease Medications

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

Fabrazyme® (Agalsidase Beta) Approval Criteria:

1. An FDA approved diagnosis of Fabry disease. Diagnosis must be 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 2021

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	3	51	$699,493.00	$13,715.55	$504.68	214	1,386
2021	3	42	$545,072.79	$12,977.92	$505.63	263	1,078
% Change	**0.00%**	**-17.60%**	**-22.10%**	**-5.40%**	**0.20%**	**22.90%**	**-22.20%**
Change	**0**	**-9**	**-$154,420.21**	**-737.63**	**$0.95**	**49**	**-308**

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

Comparison of Fiscal Years: Medical Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2020	1	25	$320,791.80	$12,831.67	25
2021	1	21	$277,661.30	$13,221.97	21
% Change	**0.00%**	**-16.00%**	**-13.45%**	**3.04%**	**-16.00%**
Change	**0**	**-4**	**-$43,130.50**	**$390.30**	**-4**

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

Demographics of Members Utilizing Fabry Disease Medications

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

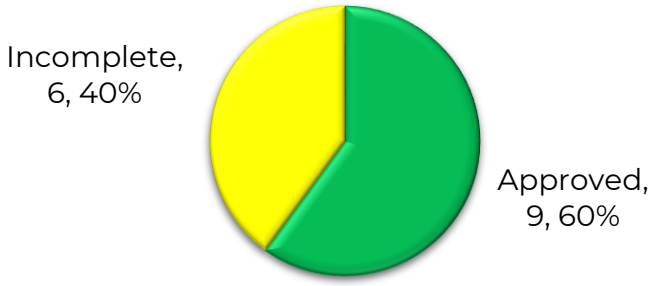
Top Prescriber Specialties of Fabry Disease Medications by Number of Claims: Pharmacy Claims

- The only prescriber specialty listed on paid pharmacy claims for Fabry disease medications during fiscal year 2021 was medical geneticist.

Prior Authorization of Fabry Disease Medications

There were 15 prior authorization requests for 4 unique members submitted for Fabry disease medications during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[29]

- Galafold® (migalastat): May 2038

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 2021

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
FABRAZYME INJ 5MG	20	3	$115,426.45	$5,771.32	6.67	21.18%
FABRAZYME INJ 35MG	15	2	$254,006.47	$16,933.76	7.5	46.60%
GALAFOLD CAP 123MG	7	1	$175,639.87	$25,091.41	7	32.22%
TOTAL	**42**	**3***	**$545,072.79**	**$12,977.92**	**14**	**100%**

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

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS†	TOTAL MEMBERS*	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
AGALSIDASE INJ J0180	21	1	$277,661.30	21	$13,221.97
TOTAL	**21**	**1**	**$277,661.30**	**21**	**$13,221.97**

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

[29] 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 12/2021. Last accessed 12/06/2021.

Fiscal Year 2021 Annual Review of Fibromyalgia Medications

Oklahoma Health Care Authority
Fiscal Year 2021 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 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 2021

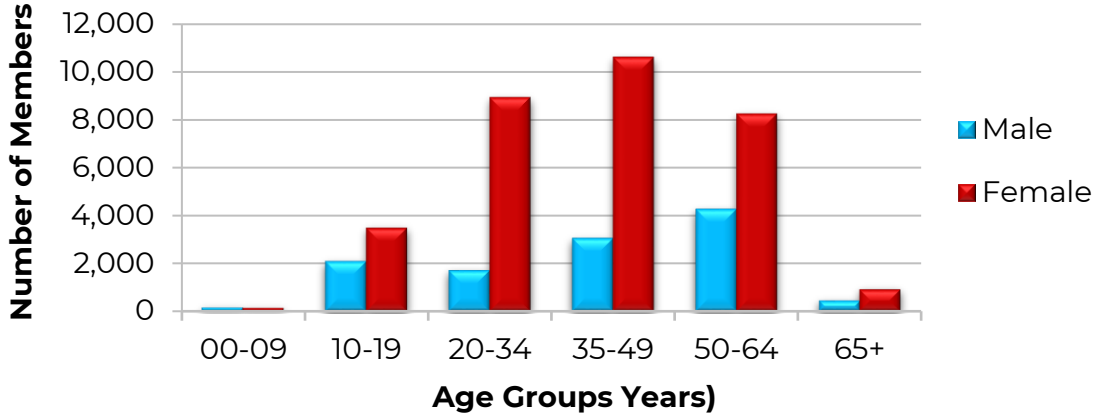
The utilization details include fibromyalgia medications used for all diagnoses and does not differentiate between fibromyalgia diagnoses and other diagnoses, for which use may be appropriate.

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	41,390	205,635	$6,677,589.16	$32.47	$1.05	16,040,599	6,374,006
2021	44,005	210,558	$3,541,204.42	$16.82	$0.51	17,193,349	6,924,810
% Change	**6.30%**	**2.40%**	**-47.00%**	**-48.20%**	**-51.40%**	**7.20%**	**8.60%**
Change	**2,615**	**4,923**	**-$3,136,384.74**	**-$15.65**	**-$0.54**	**1,152,750**	**550,804**

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

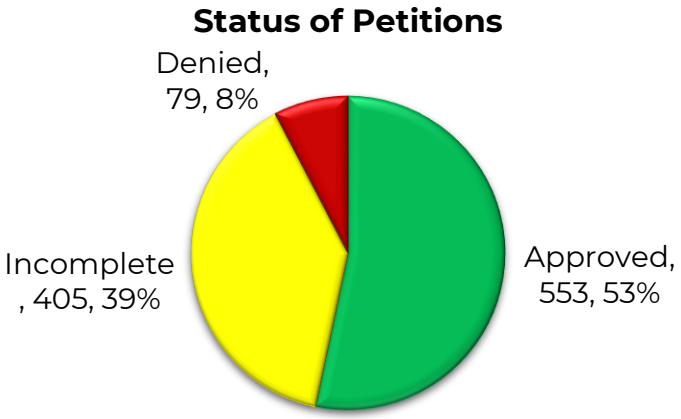
Demographics of Members Utilizing Fibromyalgia Medications



Top Prescriber Specialties of Fibromyalgia Medications by Number of Claims

Prior Authorization of Fibromyalgia Medications

There were 1,037 prior authorization requests submitted for fibromyalgia medications during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021.



Market News and Updates

Anticipated Patent Expiration(s):[30]

- Savella® (milnacipran): September 2029

Recommendations

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

Utilization Details of Fibromyalgia Medications: Fiscal Year 2021

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
GABAPENTIN PRODUCTS						
GABAPENTIN CAP 300MG	33,660	9,843	$476,616.43	$14.16	3.42	13.46%
GABAPENTIN TAB 600MG	21,341	4,437	$382,293.92	$17.91	4.81	10.80%
GABAPENTIN TAB 800MG	17,285	2,932	$385,793.20	$22.32	5.9	10.89%
GABAPENTIN CAP 100MG	11,213	4,258	$137,673.86	$12.28	2.63	3.89%
GABAPENTIN CAP 400MG	6,091	1,483	$85,505.68	$14.04	4.11	2.41%
GABAPENTIN SOL 250MG/5ML	1,328	235	$63,998.32	$48.19	5.65	1.81%
NEURONTIN CAP 300MG	9	1	$4,718.74	$524.30	9	0.13%
GABAPENTIN SOL 300MG/6ML	4	1	$365.60	$91.40	4	0.01%
SUBTOTAL	**90,931**	**23,190**	**$1,536,965.75**	**$16.90**	**3.92**	**43.40%**
CYCLOBENZAPRINE PRODUCTS						

[30] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/. Last revised 12/2021. Last accessed 12/08/2021.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
CYCLOBENZAPRINE TAB 10MG	28,109	12,133	$284,742.29	$10.13	2.32	8.05%
CYCLOBENZAPRINE TAB 5MG	7,347	4,245	$77,487.54	$10.55	1.73	2.19%
SUBTOTAL	**35,456**	**16,378**	**$362,229.83**	**$10.22**	**2.16**	**10.24%**
DULOXETINE PRODUCTS						
DULOXETINE CAP 60MG	17,021	4,313	$263,665.89	$15.49	3.95	7.45%
DULOXETINE CAP 30MG	11,172	4,168	$163,388.01	$14.62	2.68	4.61%
DULOXETINE CAP 20MG	2,645	1,051	$38,996.22	$14.74	2.52	1.10%
CYMBALTA CAP 60MG	1	1	$253.37	$253.37	1	0.01%
SUBTOTAL	**30,839**	**9,533**	**$466,303.49**	**$15.12**	**3.23**	**13.17%**
TRAMADOL PRODUCTS						
TRAMADOL HCL TAB 50MG	22,305	7,844	$239,235.44	$10.73	2.84	6.76%
SUBTOTAL	**22,305**	**7,844**	**$239,235.44**	**$10.73**	**2.84**	**6.76%**
AMITRIPTYLINE PRODUCTS						
AMITRIPTYLINE TAB 25MG	5,383	1,917	$65,434.93	$12.16	2.81	1.85%
AMITRIPTYLINE TAB 50MG	3,902	1,179	$70,079.12	$17.96	3.31	1.98%
AMITRIPTYLINE TAB 10MG	3,332	1,237	$39,487.07	$11.85	2.69	1.12%
AMITRIPTYLINE TAB 100MG	2,304	547	$68,491.02	$29.73	4.21	1.93%
AMITRIPTYLINE TAB 75MG	1,033	284	$22,465.16	$21.75	3.64	0.63%
AMITRIPTYLINE TAB 150MG	805	193	$36,371.76	$45.18	4.17	1.03%
SUBTOTAL	**16,759**	**5,357**	**$302,329.06**	**$18.04**	**3.13**	**8.54%**
PREGABALIN PRODUCTS						
PREGABALIN CAP 150MG	3,682	770	$58,484.53	$15.88	4.78	1.65%
PREGABALIN CAP 75MG	2,934	1,026	$43,938.25	$14.98	2.86	1.24%
PREGABALIN CAP 100MG	2,531	657	$40,013.99	$15.81	3.85	1.13%
PREGABALIN CAP 50MG	1,514	618	$22,981.09	$15.18	2.45	0.65%
PREGABALIN CAP 200MG	1,377	232	$22,300.04	$16.19	5.94	0.63%
PREGABALIN CAP 300MG	987	170	$15,816.98	$16.03	5.81	0.45%
PREGABALIN CAP 25MG	305	166	$4,502.92	$14.76	1.84	0.13%
PREGABALIN CAP 225MG	197	50	$3,006.02	$15.26	3.94	0.08%
LYRICA CAP 150MG	192	46	$120,431.38	$627.25	4.17	3.40%
LYRICA CAP 200MG	141	24	$86,120.79	$610.79	5.88	2.43%
LYRICA CAP 300MG	91	21	$51,809.15	$569.33	4.33	1.46%
LYRICA CAP 100MG	83	33	$49,622.15	$597.86	2.52	1.40%
LYRICA CAP 75MG	73	32	$43,751.74	$599.34	2.28	1.24%
LYRICA CAP 50MG	40	11	$23,482.04	$587.05	3.64	0.66%
LYRICA CAP 225MG	21	3	$12,163.57	$579.22	7	0.34%
PREGABALIN SOL 20MG/ML	12	1	$730.56	$60.88	12	0.02%
LYRICA CAP 25MG	3	3	$1,292.58	$430.86	1	0.04%
SUBTOTAL	**14,183**	**3,863**	**$600,447.78**	**$42.34**	**3.67**	**16.95%**
MILNACIPRAN PRODUCTS						
SAVELLA TAB 50MG	46	12	$18,231.46	$396.34	3.83	0.51%
SAVELLA TAB 100MG	34	4	$13,627.12	$400.80	8.5	0.38%
SAVELLA TITR PAK	4	4	$1,438.24	$359.56	1	0.04%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SAVELLA TAB 25MG	1	1	$396.25	$396.25	1	0.01%
SUBTOTAL	**85**	**21**	**$33,693.07**	**$396.39**	**4.05**	**0.94%**
TOTAL	**210,558**	**44,005***	**$3,541,204.42**	**$16.82**	**4.78**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; HCL = hydrochloride; SOL = solution; TAB = tablet; TITR PAK = titration pack
Fiscal Year 2021 = 07/01/2020 to 06/30/2021
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 2021 Annual Review of Gaucher Disease Medications

Oklahoma Health Care Authority
Fiscal Year 2021 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 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 member is responding well 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, 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 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 member is responding well 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 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 member is responding well to the medication.

Utilization of Gaucher Disease Medications: Fiscal Year 2021

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	3	12	$262,403.34	$21,866.94	$776.34	244	338
2021	3	30	$773,970.12	$25,799.00	$921.39	1,226	840
% Change	**0.00%**	**150.00%**	**195.00%**	**18.00%**	**18.70%**	**402.50%**	**148.50%**
Change	**0**	**18**	**$511,566.78**	**$3,932.06**	**$145.05**	**982**	**502**

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

Fiscal Year 2021 Utilization: Medical Claims

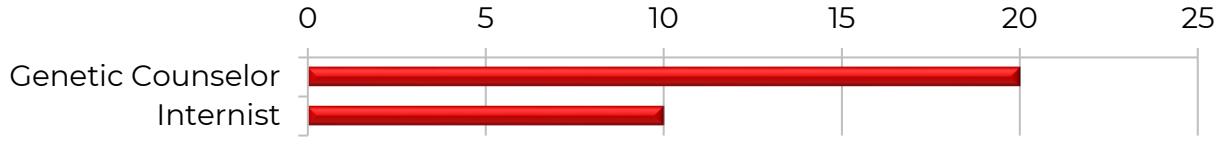
Fiscal Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Total Units
2021	2	52	$498,635.04	$9,589.14	1,440

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

Demographics of Members Utilizing Gaucher Disease Medications

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

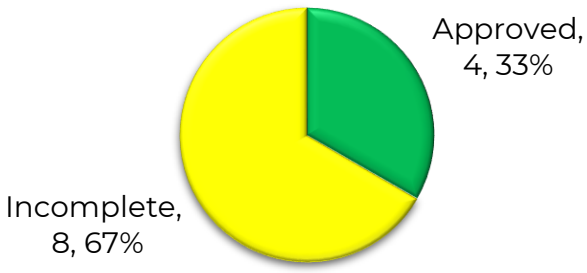
Top Prescriber Specialties of Gaucher Disease Medications by Number of Claims



Prior Authorization of Gaucher Disease Medications

There were 12 prior authorization requests submitted for Gaucher disease medications during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[31]

- Cerdelga® (eliglustat): December 2038

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 2021

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	*TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
CEREZYME INJ 400 UNIT	20	2	$550,395.96	$27,519.80	10	71.11%
MIGLUSTAT CAP 100MG	10	1	$223,574.16	$22,357.42	10	28.89%
TOTAL	**30**	**3**	**$773,970.12**	**$25,799.00**	**10**	**100%**

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

Medical Claims

PRODUCT UTILIZED	†TOTAL CLAIMS	*TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
VPRIV INJ 400 UNIT J3385	52	2	$498,635.04	$9,589.14	26
TOTAL	**52**	**2**	**$498,635.04**	**$9,589.14**	**26**

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

[31] 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 12/2021. Last accessed 12/06/2021.

Fiscal Year 2021 Annual Review of Givlaari® (Givosiran) and Scenesse® (Afamelanotide)

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

Givlaari® (Givosiran) Approval Criteria:

1. An FDA approved diagnosis of acute hepatic porphyria (AHP) confirmed by:
   a. Genetic testing; or
   b. Elevated urinary porphobilinogen (PBG) and signs/symptoms of AHP; and
2. Member must be 18 years of age or older; and
3. Givlaari® must be administered in a health care setting by a health care professional prepared to manage anaphylaxis; and
   a. Givlaari® must be shipped to the health care setting where the member is scheduled to receive treatment; and
4. The prescriber must agree to monitor liver function tests prior to initiating treatment with Givlaari®, every month during the first 6 months of treatment, and as clinically indicated thereafter; and
5. The prescriber must agree to monitor renal function during treatment with Givlaari® as clinically indicated; and
6. Member must not be taking sensitive CYP1A2 or CYP2D6 substrates (e.g., caffeine, dextromethorphan, duloxetine, amitriptyline, olanzapine, fluoxetine, paroxetine, hydrocodone, tramadol) concomitantly with Givlaari®; and
7. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
8. Initial approvals will be for the duration of 6 months. Further approval may be granted if the prescriber documents that the member is responding well to treatment as indicated by fewer porphyria attacks and that the member does not have elevated transaminase levels.

Scenesse® (Afamelanotide) Approval Criteria:

1. An FDA approved indication to increase pain-free light exposure in adult members with a history of phototoxic reactions from erythropoietic protoporphyria (EPP); and
   a. The diagnosis of EPP must be confirmed by genetic testing; and
2. Member must be 18 years of age or older; and
3. Scenesse® must be administered by a health care professional who is proficient in the subcutaneous implantation procedure and has

completed the training program provided by the manufacturer prior to administration of the Scenesse® implant; and
   a. Scenesse® must be shipped via cold chain supply shipping and delivery to the health care setting where the member is scheduled to receive the implant administration; and
   b. Scenesse® must be stored under refrigeration (36 to 46°F) and protected from light prior to implantation; and
4. The Scenesse® implant should be inserted using an SFM Implantation Cannula or other implantation device that has been determined by the manufacturer to be suitable for implantation of Scenesse®; and
5. The prescriber must agree that the member will be monitored by a health care provider for at least 30 minutes after the implant administration; and
6. The prescriber must agree that the member will have a full body skin examination performed at least twice yearly while the member is being treated with Scenesse® to monitor pre-existing and new skin pigmentary lesions; and
7. Documentation that member will maintain sun and light protection measures during treatment with Scenesse® to prevent phototoxic reactions related to EPP; and
8. A quantity limit of 1 implant per 60 days will apply. Initial approvals will be for 2 implants for the duration of 4 months. Further approval may be granted if the prescriber documents the member is responding well to treatment as indicated by increased tolerance of sunlight (i.e., fewer phototoxic reactions).

Utilization of Givlaari® (Givosiran) and Scenesse® (Afamelanotide): Fiscal Year 2021

There was no SoonerCare utilization of Givlaari® (givosiran) or Scenesse® (afamelanotide) during fiscal year 2021 (07/01/2020 to 06/30/2021).

Prior Authorization of Givlaari® (Givosiran) and Scenesse® (Afamelanotide)

There were no prior authorization requests submitted for Givlaari® (givosiran) or Scenesse® (afamelanotide) during fiscal year 2021 (07/01/2020 to 06/30/2021).

Market News and Updates

Anticipated Patent Expiration(s):[32]

- Scenesse® (afamelanotide): March 2029

[32] 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 12/2021. Last accessed 12/03/2021.

- Givlaari® (givosiran): October 2034

Pipeline:

- **Afamelanotide:** Clinuvel is currently evaluating afamelanotide for multiple additional indications, including for the treatment of vitiligo, variegate porphyria, xeroderma pigmentosum, and arterial ischemic stroke.[33]

Recommendations

The College of Pharmacy does not recommend any changes to the current Givlaari® (givosiran) and Scenesse® (afamelanotide) prior authorization criteria at this time.

[33] Clinuvel. Pharmaceutical Technology: Pipeline. Available online at: https://www.clinuvel.com/pharmaceutical-technology/#Pipeline. Last accessed 12/03/2021.

Fiscal Year 2021 Annual Review of Hyperkalemia Medications

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

Lokelma® (Sodium Zirconium Cyclosilicate) Approval Criteria:

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

Veltassa® (Patiromer) Approval Criteria:

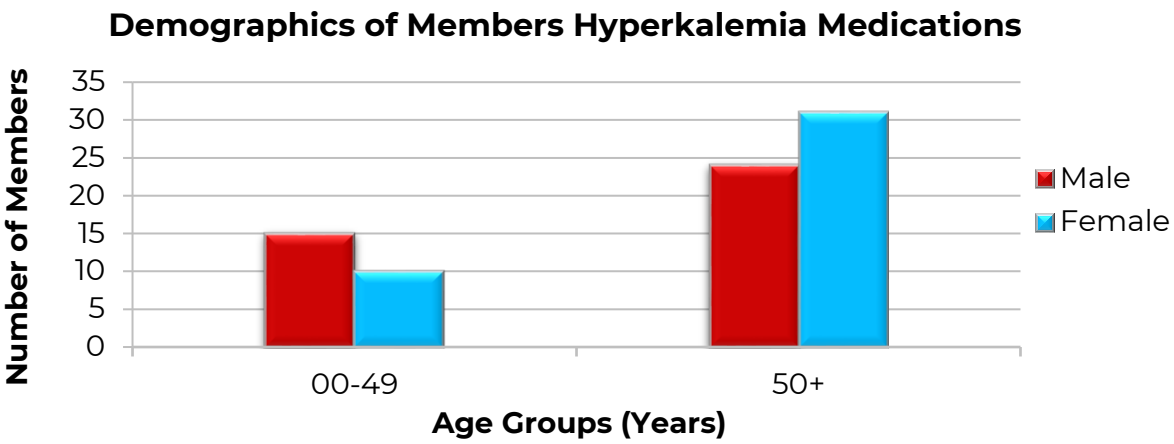
1. An FDA approved diagnosis of hyperkalemia; and
2. Medications known to cause hyperkalemia [e.g., angiotensin-converting enzyme (ACE) inhibitors, angiotensin II receptor blockers (ARBs), aldosterone antagonists, nonsteroidal anti-inflammatory drugs (NSAIDs)] have been discontinued or reduced to the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

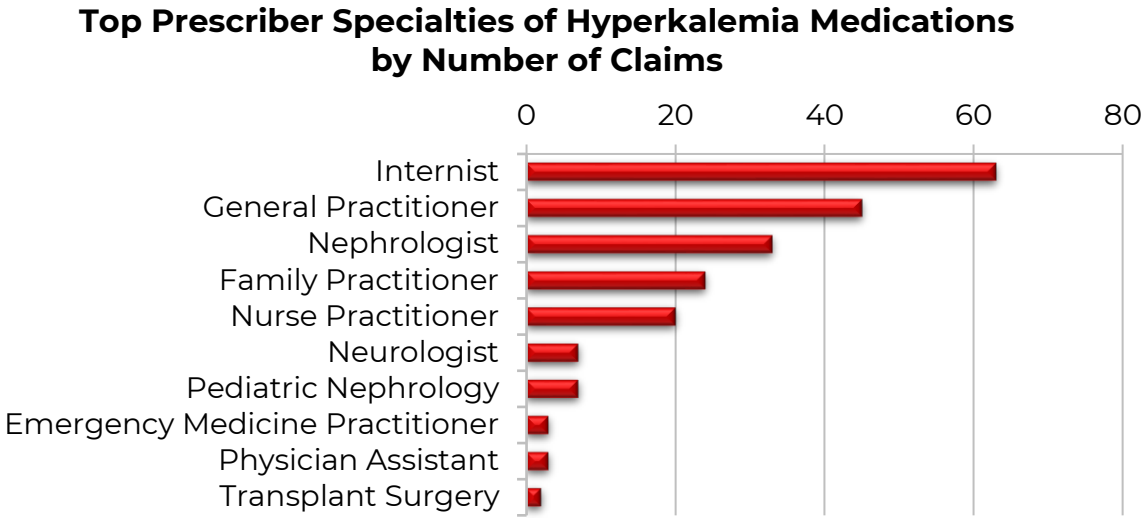
Utilization of Hyperkalemia Medications: Fiscal Year 2021

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	61	157	$32,712.40	$208.36	$13.15	33,538	2,487
2021	80	217	$62,841.19	$289.59	$16.27	40,993	3,862
% Change	**31.10%**	**38.20%**	**92.10%**	**39.00%**	**23.70%**	**22.20%**	**55.30%**
Change	**19**	**60**	**$30,128.79**	**$81.23**	**$3.12**	**7,455**	**1,375**

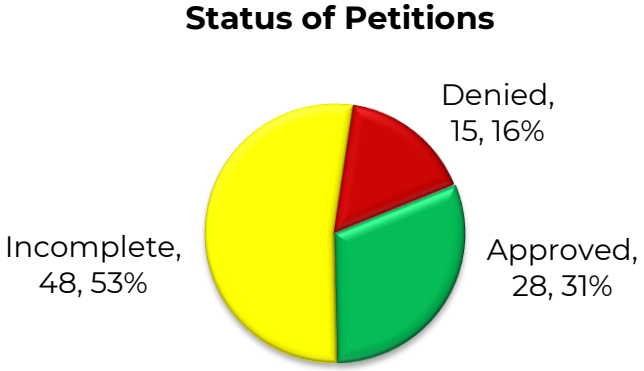
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020; Fiscal Year 2021 = 07/01/2020 to 06/30/2021





Prior Authorization of Hyperkalemia Medications

There were 91 prior authorization requests submitted for hyperkalemia medications during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021.



Market News and Updates

Anticipated Patent Expiration(s):[34]

- 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 2021

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SODIUM POLYSTYRENE SULFONATE (SPS) PRODUCTS						
SPS SUS 15GM/60ML	78	43	$4,830.29	$61.93	1.81	7.69%
SPS POW 454GM	24	16	$1,044.69	$43.53	1.5	1.66%
SUBTOTAL	**102**	**59**	**$5,874.98**	**$57.60**	**1.73**	**9.35%**
SODIUM ZIRCONIUM CYCLOSILICATE PRODUCTS						
LOKELMA PACKET 10GM	62	15	$20,797.32	$335.44	4.13	33.10%
LOKELMA PACKET 5GM	2	1	$1,341.93	$670.97	2	2.14%
SUBTOTAL	**64**	**16**	**$22,139.25**	**$345.93**	**4**	**35.23%**
PATIROMER PRODUCTS						
VELTASSA POW 8.4GM	50	10	$33,912.43	$678.25	5	53.97%
VELTASSA POW 16.8GM	1	1	$914.53	$914.53	1	1.46%
SUBTOTAL	**51**	**11**	**$34,826.96**	**$682.88**	**4.64**	**55.42%**
TOTAL	**217**	**80***	**$62,841.19**	**$289.59**	**2.71**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
POW = powder; SPS = sodium polystyrene sulfonate; SUS = suspension
Fiscal Year 2021 = 07/01/2020 to 06/30/2021

[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 12/2021. Last accessed 12/02/2021.

Fiscal Year 2021 Annual Review of Lambert-Eaton Myasthenic Syndrome (LEMS) Medications

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

Firdapse® (Amifampridine) and Ruzurgi® (Amifampridine) Approval Criteria:

1. An FDA approved diagnosis of Lambert-Eaton myasthenic syndrome (LEMS); and
2. LEMS diagnosis must be confirmed by 1 of the following:
   a. A high titer anti-P/Q-type voltage-gated calcium channel (VGCC) antibody assay; or
   b. A confirmatory electrodiagnostic study [e.g., repetitive nerve stimulation (RNS), needle electromyography (EMG), single-fiber electromyography (SFEMG)]; and
3. The requested medication must be prescribed by, or in consultation with, a neurologist or oncologist; and
4. Member must not have a history of seizures or be taking medications that lower the seizure threshold (e.g., bupropion, tramadol, amphetamines, theophylline); and
5. For Firdapse®, a patient-specific, clinically significant reason why the member cannot use Ruzurgi® must be provided; and
6. For Firdapse®, a quantity limit of 240 tablets per 30 days will apply. For Ruzurgi®, a quantity limit of 300 tablets per 30 days will apply; and
7. Initial approvals will be for 6 months. Continued authorization will require the prescriber to indicate that the member is responding well to treatment and continues to require treatment with the requested medication.

Utilization of LEMS Medications: Fiscal Year 2021

Fiscal Year 2021 Utilization

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	1	12	$118,684.95	$9,890.41	$329.68	1,470	360

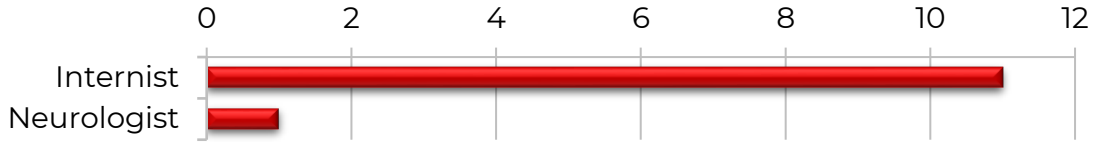
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Demographics of Members Utilizing LEMS Medications

- There was 1 unique member utilizing Firdapse® (amifampridine) during fiscal year 2021. However, due to the limited number of members

utilizing LEMS medications, detailed demographic information could not be provided.
- There was no SoonerCare utilization of Ruzurgi® (amifampridine) during fiscal year 2021.

Top Prescriber Specialties of LEMS Medications by Number of Claims

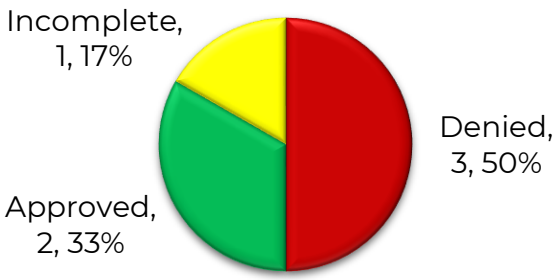


- Please note: The 11 paid claims for Firdapse® which were prescribed by an internist were prescribed in consultation with a neurologist.

Prior Authorization of LEMS Medications

There were 6 prior authorization request submitted for 1 unique member for Firdapse® (amifampridine) during fiscal year 2021. There were no prior authorization requests submitted for Ruzurgi® (amifampridine) during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021.

Status of Petitions



Market News and Updates

Anticipated Patent and/or Exclusivity Expiration(s):[35]
- Ruzurgi® (amifampridine): May 2026
- Firdapse® (amifampridine): April 2034

News:
- **September 2021:** Jacobus Pharmaceutical Company issued a voluntary worldwide recall of 3 lots of Ruzurgi® (amifampridine) 10mg tablets due to contamination with yeast, mold, and aerobic bacteria. The use of oral

[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.cf. Last revised 12/2021. Last accessed 12/01/2021.

products contaminated with yeast, mold, and aerobic bacteria in patients with immunosuppressive conditions such as LEMS increases the concern for serious infections. Jacobus has notified its distributors and customers and is arranging for the return of all recalled products. Patients who have the recalled lots of Ruzurgi® should stop using it and return the product. Additionally, patients should contact their health care provider if they have experienced any problems that may be related to taking or using the product.[36]

- **September 2021:** In an ongoing legal battle between Catalyst Pharmaceuticals, the manufacturer of Firdapse®, and Jacobus Pharmaceuticals, the manufacturer of Ruzurgi®, a United States appeals court ruled the U.S. Food and Drug Administration (FDA) should not have approved Ruzurgi® because it violates the 7-year exclusivity period awarded to Firdapse® under the Orphan Drug Act. A 3-judge panel called the FDA's approval of Ruzurgi® "arbitrary, capricious, and not in accordance with the law." This ruling overturns a previous ruling from July 2020, at which time the judge had sided with Jacobus. Prior to the FDA approval of Ruzurgi®, Catalyst's Firdapse® had been granted 7 years of exclusivity in adult patients with LEMS. However, Catalyst believes their exclusivity period is being violated by information regarding efficacy in adult patients contained in the *Prescribing Information* for Ruzurgi®, and believes this information constitutes illegal off-label marketing of Ruzurgi®, which has only been FDA approved for use in pediatric patients. As of December 2021, Ruzurgi® remains FDA approved.[37,38]

Pipeline:

- **Amifampridine:** Catalyst Pharmaceuticals is currently developing a long-acting formulation of amifampridine phosphate for the treatment of LEMS. Additionally, they have announced plans to submit a

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[36] U.S. FDA. Jacobus Pharmaceutical Company Inc. Issues Voluntary Worldwide Recall of Ruzurgi® (Amifampridine) 10mg Tablets Due to Yeast, Mold, and Bacterial Contamination. Available online at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/jacobus-pharmaceutical-company-inc-issues-voluntary-worldwide-recall-ruzurgir-amifampridine-10-mg. Issued 09/13/2021. Last accessed 12/01/2021.

[37] Catalyst Pharmaceuticals, Inc. Catalyst Pharmaceuticals Receives Positive Decision from Appeals Court that Supports Orphan Drug Exclusivity for Firdapse® for LEMS. Available online at: https://ir.catalystpharma.com/news-releases/news-release-details/catalyst-pharmaceuticals-receives-positive-decision-appeals. Issued 09/30/2021. Last accessed 12/03/2021.

[38] Dunleavy K. U.S. Appeals Court Sides with Catalyst, Calling FDA Approval of Jacobus' Ruzurgi® 'Arbitrary,' 'Capricious,' and Unlawful. *Fierce Pharma.* Available online at: https://www.fiercepharma.com/pharma/ruling-for-catalyst-u-s-appeals-court-calls-fda-approval-ruzurgi-arbirbitrary-capricious-and. Issued 10/01/2021. Last accessed 12/03/2021.

supplemental New Drug Application (sNDA) to the FDA for Firdapse® for the treatment of pediatric patients with LEMS.[39]

Recommendations

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

Utilization Details of LEMS Medications: Fiscal Year 2021

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
AMIFAMPRIDINE PRODUCTS						
FIRDAPSE TAB 10MG	12	1	$118,684.95	$9,890.41	12	100%
TOTAL	**12**	**1***	**$118,684.95**	**$9,890.41**	**12**	**100%**

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

[39] Catalyst Pharmaceuticals, Inc. Catalyst Pharmaceuticals Reports Third Quarter 2021 Financial Results. Available online at: https://ir.catalystpharma.com/news-releases/news-release-details/catalyst-pharmaceuticals-reports-third-quarter-2021-financial. Issued 11/09/2021. Last accessed 12/03/2021.

Fiscal Year 2021 Annual Review of Northera® (Droxidopa)

Oklahoma Health Care Authority
Fiscal Year 2021 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 2021

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	1	9	$145,107.00	$16,123.00	$537.43	4,860	270
2021	1	1	$58.08	$58.08	$4.15	42	14
% Change	**0.00%**	**-88.90%**	**-100.00%**	**-99.60%**	**-99.20%**	**-99.10%**	**-94.80%**
Change	**0**	**-8**	**-$145,048.92**	**-$16,064.92**	**-$533.28**	**-4,818**	**-256**

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

Demographics of Members Utilizing Northera® (Droxidopa)

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

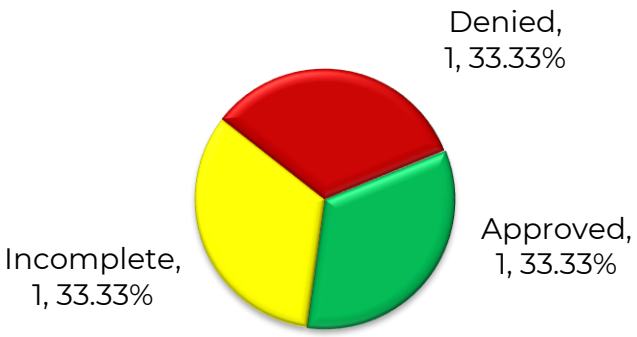
Top Prescriber Specialties of Northera® (Droxidopa) by Number of Claims

- The only prescriber specialty listed on paid pharmacy claims for Northera® (droxidopa) during fiscal year 2021 was cardiologist.

Prior Authorization of Northera® (Droxidopa)

There were 3 prior authorization requests submitted for Northera® (droxidopa) during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021.

Status of Petitions



Market News and Updates

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

- **February 2021:** The FDA approved an Abbreviated New Drug Application (ANDA) for the first generic formulation of droxidopa 100mg, 200mg, and 300mg capsules. The exclusivity period for Northera® (droxidopa) expired on February 18, 2021, and multiple manufacturers of generic formulations have been FDA approved since the exclusivity expiration.[40,41]

[40] 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 12/2021. Last accessed 12/02/2021.
[41] U.S. FDA. National Drug Code Directory. Droxidopa. Available online at: https://www.accessdata.fda.gov/scripts/cder/ndc/dsp_searchresult.cfm. Last revised 12/02/2021. Last accessed 12/02/2021.

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 2021

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
DROXIDOPA 100MG CAP	1	1	$58.08	$4.15	$58.08	100%
TOTAL	**1**	**1***	**$58.08**	**$4.15**	**$58.08**	**100%**

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

Fiscal Year 2021 Annual Review of Ocaliva® (Obeticholic Acid)

Oklahoma Health Care Authority
Fiscal Year 2021 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 daily will apply.

Utilization of Ocaliva® (Obeticholic Acid): Fiscal Year 2021

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	1	7	$48,419.60	$6,917.09	$230.57	210	210
2021	1	6	$44,578.68	$7,429.78	$247.66	180	180
% Change	**0.00%**	**-14.30%**	**-7.90%**	**7.40%**	**7.40%**	**-14.30%**	**-14.30%**
Change	**0**	**-1**	**-$3,840.92**	**$512.69**	**$17.09**	**-30**	**-30**

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

Demographics of Members Utilizing Ocaliva® (Obeticholic Acid)

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

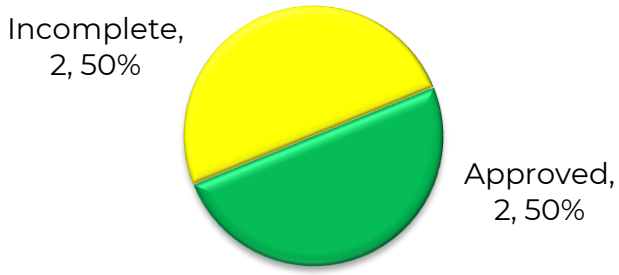
Top Prescriber Specialties Ocaliva® (Obeticholic Acid) of by Number of Claims

- The only prescriber specialty listed on paid pharmacy claims for Ocaliva® during fiscal year 2021 was nurse practitioner. The nurse practitioner is supervised by a gastroenterologist.

Prior Authorization of Ocaliva® (Obeticholic Acid)

There were 4 prior authorization requests submitted for Ocaliva® (obeticholic acid) during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[42]

- Ocaliva® (obeticholic acid): April 2036

New(s):

- **May 2021:** The U.S. Food and Drug Administration (FDA) issued a drug safety communication to restrict the use of Ocaliva® in primary biliary cholangitis (PBC) patients with advanced cirrhosis due to risk of serious liver injury. The FDA found some PBC patients with cirrhosis who took Ocaliva®, especially those with evidence of advanced cirrhosis, developed liver failure, sometimes requiring liver transplant. Based on the original clinical trials, the FDA believes the benefits of Ocaliva® outweigh the risks for PBC patients who do not have advanced cirrhosis. The FDA added a new contraindication, the FDA's strongest warning, to the Ocaliva® *Prescribing Information* and patient *Medication Guide* stating Ocaliva® should not be used in PBC patients with advanced cirrhosis. The FDA also revised the *Boxed Warning*, the FDA's most prominent warning, to include this information along with

[42] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 12/2021. Last accessed 12/06/2021.

related warnings about this risk. The FDA will continue to monitor and evaluate the clinical benefit and adverse events of Ocaliva® and will communicate any new information to the public if it becomes available.[43]

- **August 2021:** The FDA previously issued a Complete Response Letter (CRL) in June 2020 regarding a 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 determined the predicted benefit of OCA based on a surrogate histopathologic endpoint remained uncertain and did not sufficiently outweigh the potential risks to support accelerated approval for the treatment of patients with liver fibrosis due to NASH. The FDA recommended 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 histologic features of NASH, fibrosis is considered the strongest predictor of adverse clinical outcomes, including liver-related death. There is currently no approved therapy for NASH, which has become a leading cause of liver failure and resulting poor clinical outcomes. In August 2021, Intercept announced plans to have a pre-submission meeting with the FDA by the first half of 2022. Intercept will increase the number of independent pathologists to evaluate each clinical study biopsy from 1 to 3 after the FDA raised questions about using a single pathologist. This method is intended to eliminate potential bias and guarantee consensus among the experts, who will compare the biopsies at baseline and after 18 months of treatment. If 2 of the pathologists disagree on their readings, the third will break the tie. Because this change will affect the study's conclusions, Intercept will have the panel of pathologists re-review all of the biopsies from the REGENERATE study. This includes 500 biopsies that were not part of the interim analysis. The re-review process, which will be used in another Phase 3 study called REVERSE studying patients with cirrhosis, will last until the first half of 2022. Intercept will be evaluating data and

[43] U.S. FDA. FDA Drug Safety and Availability. Due to Risk of Serious Liver Injury, FDA Restricts use of Ocaliva (Obeticholic Acid) in Primary Biliary Cholangitis (PBC) Patients with Advanced Cirrhosis. Available online at: https://www.fda.gov/drugs/drug-safety-and-availability/due-risk-serious-liver-injury-fda-restricts-use-ocaliva-obeticholic-acid-primary-biliary-cholangitis. Issued 05/26/2021. Last accessed 12/06/2021.

making data-driven decisions to determine the next steps for the NASH resubmission.[44,45]

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 2021

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
OCALIVA TAB 10MG	6	1	$44,578.68	$247.66	$7,429.78	100%
TOTAL	**6**	**1***	**$44,578.68**	**$247.66**	**$7,429.78**	**100%**

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

[44] Intercept Pharmaceuticals. 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 12/06/2021.
[45] Higgins-Dunn N. Intercept Charts New Path to NASH Approval for Obeticholic Acid, as Long as Safety Holds. *Fierce Pharma*. Available online at: https://www.fiercepharma.com/pharma/intercept-still-sees-fda-approval-pathway-for-nash-hopeful-ocaliva-as-long-as-safety-holds. Issued 08/02/2021. Last accessed 12/06/2021.

Fiscal Year 2021 Annual Review of Pancreatic Enzymes

Oklahoma Health Care Authority
Fiscal Year 2021 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.

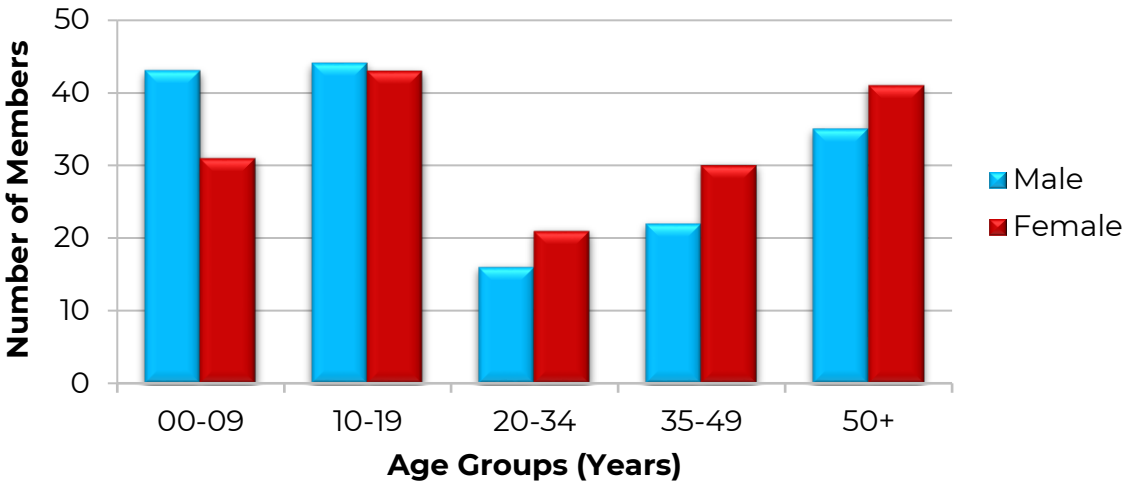
Utilization of Pancreatic Enzymes: Fiscal Year 2021

Comparison of Fiscal Years

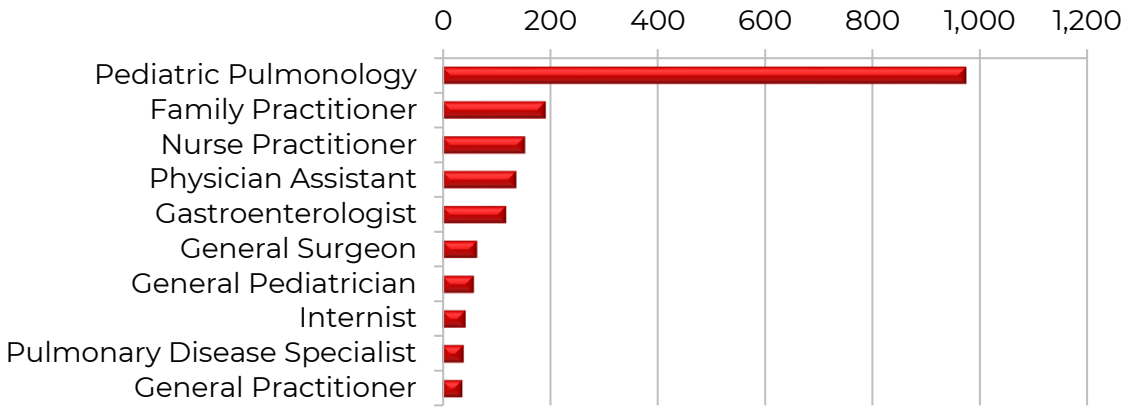
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	326	1,749	$3,259,354.28	$1,863.55	$65.51	591,434	49,754
2021	389	1,917	$3,731,482.81	$1,946.52	$68.61	660,965	54,388
% Change	**19.3%**	**9.6%**	**14.5%**	**4.5%**	**4.7%**	**11.8%**	**9.3%**
Change	**63**	**168**	**$472,128.53**	**$82.97**	**$3.10**	**69,531**	**4,634**

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

Demographics of Members Utilizing Pancreatic Enzymes



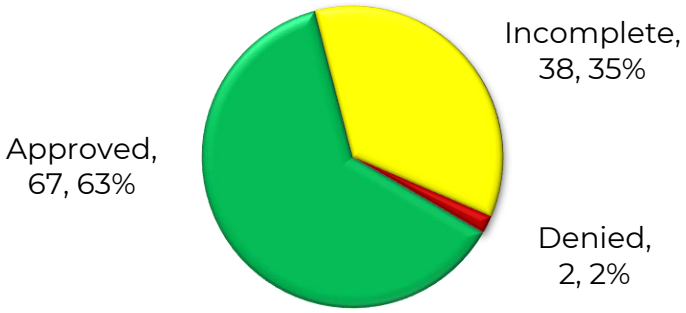
Top Prescriber Specialties of Pancreatic Enzymes by Number of Claims



Prior Authorization of Pancreatic Enzymes

There were 107 prior authorization requests submitted for pancreatic enzymes during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021.

Status of Petitions



Recommendations

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

Utilization Details of Pancreatic Enzymes: Fiscal Year 2021

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
CREON®						
CREON CAP 36,000U	332	100	$822,462.17	$2,477.30	3.32	22.04%
CREON CAP 24,000U	296	75	$659,907.48	$2,229.42	3.95	17.68%
CREON CAP 12,000U	283	65	$269,712.84	$953.05	4.35	7.23%
CREON CAP 6,000U	94	23	$58,325.48	$620.48	4.09	1.56%
CREON CAP 3,000U	35	15	$8,583.37	$245.24	2.33	0.23%
SUBTOTAL	**1,040**	**278**	**$1,818,991.34**	**$1,749.03**	**3.74**	**48.74%**
ZENPEP®						
ZENPEP CAP 25,000U	120	24	$429,121.37	$3,576.01	5	11.50%
ZENPEP CAP 40,000U	111	32	$351,812.56	$3,169.48	3.47	9.43%
ZENPEP CAP 5,000U	108	27	$103,995.46	$962.92	4	2.79%
ZENPEP CAP 10,000U	102	24	$104,975.50	$1,029.17	4.25	2.81%
ZENPEP CAP 20,000U	70	15	$133,373.59	$1,905.34	4.67	3.57%
ZENPEP CAP 15,000U	56	11	$100,487.21	$1,794.41	5.09	2.69%
ZENPEP CAP 3,000U	6	1	$213.42	$35.57	6	0.01%
SUBTOTAL	**573**	**134**	**$1,223,979.11**	**$2,136.09**	**4.28**	**32.80%**
PERTZYE®						
PERTZYE CAP 1,6000U	134	18	$307,569.14	$2,295.29	7.44	8.24%
PERTZYE CAP 24,000U	77	12	$301,360.07	$3,913.77	6.42	8.08%
PERTZYE CAP 8,000U	37	7	$24,083.42	$650.90	5.29	0.65%
SUBTOTAL	**248**	**37**	**$633,012.63**	**$2,552.47**	**6.70**	**16.97%**
VIOKACE®						
VIOKACE TAB 10,440U	29	3	$35,080.81	$1,209.68	9.67	0.94%
VIOKACE TAB 20,880U	13	2	$8,223.36	$632.57	6.5	0.22%
SUBTOTAL	**42**	**5**	**$43,304.17**	**$1,031.05**	**8.4**	**1.16%**
PANCREAZE®						
PANCREAZE CAP 10,500U	6	1	$1,822.26	$303.71	6	0.05%
PANCREAZE CAP 16,800U	5	2	$6,366.90	$1,273.38	2.5	0.17%
PANCREAZE CAP 21,000U	3	1	$4,006.40	$1,335.47	3	0.11%
SUBTOTAL	**14**	**4**	**$12,195.56**	**$871.11**	**3.5**	**0.33%**
TOTAL	**1,917**	**389***	**$3,731,482.81**	**$1,946.52**	**4.93**	**100%**

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

Fiscal Year 2021 Annual Review of Parathyroid Medications

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

Hectorol® (Doxercalciferol Capsule) Approval Criteria:

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

Natpara® (Parathyroid Hormone Injection) Approval Criteria:

1. An FDA approved indication for use as an adjunct to calcium and vitamin D to control hypocalcemia in 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 Capsule) Approval Criteria:

1. 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

2. Member must be 10 years of age or older; 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 2021

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
2020	436	1,996	$523,356.13	$262.20	$6.56	84,505	79,770
2021	416	1,807	$214,977.02	$118.97	$2.96	78,710	72,680
% Change	**-4.60%**	**-9.50%**	**-58.90%**	**-54.60%**	**-54.90%**	**-6.90%**	**-8.90%**
Change	**-20**	**-189**	**-$308,379.11**	**-$143.23**	**-$3.60**	**-5,795**	**-7,090**

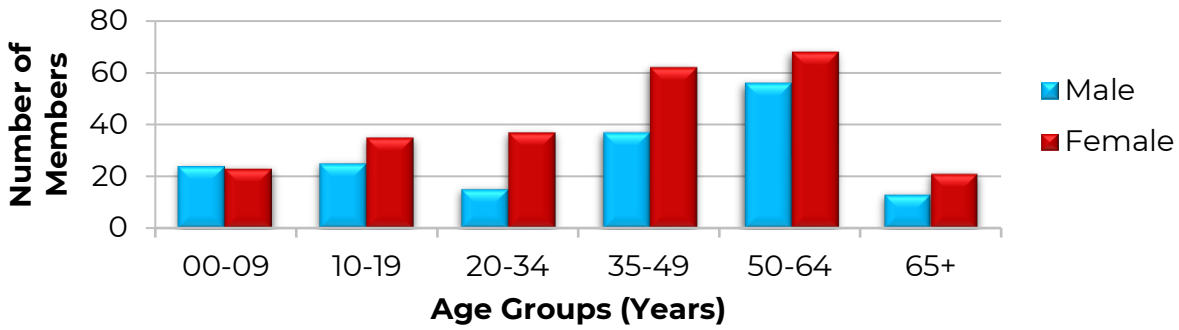
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020; Fiscal Year 2021 = 07/01/2020 to 06/30/2021

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

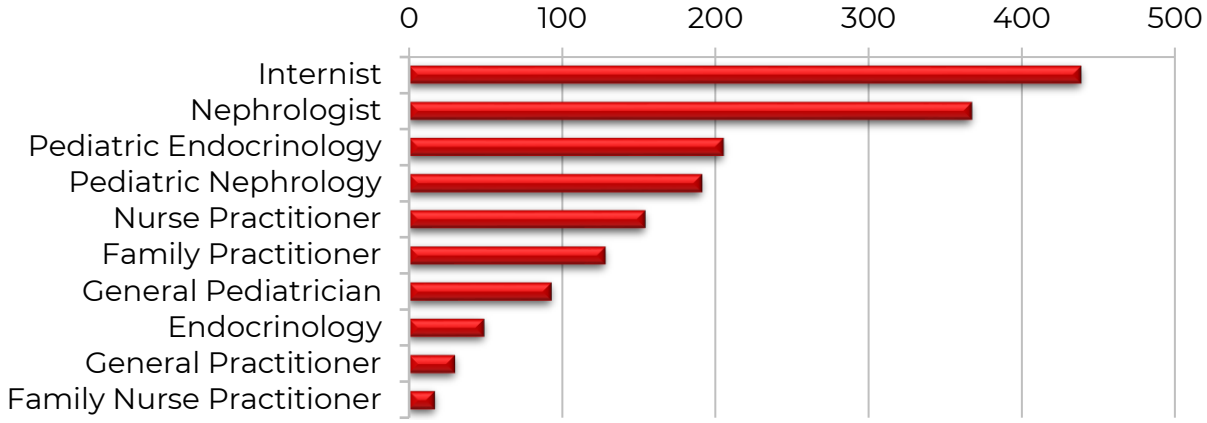
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	5	11	$119,109.37	$10,828.12	$381.76	24	312
2021	0	0	$0.00	$0.00	$0.00	0	0
% Change	**-100%**	**-100%**	**-100%**	**-100%**	**-100%**	**-100%**	**-100%**
Change	**-5**	**-11**	**-$119,109.37**	**-$10,828.12**	**-$381.76**	**-24**	**-312**

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

Demographics of Members Utilizing Parathyroid Medications



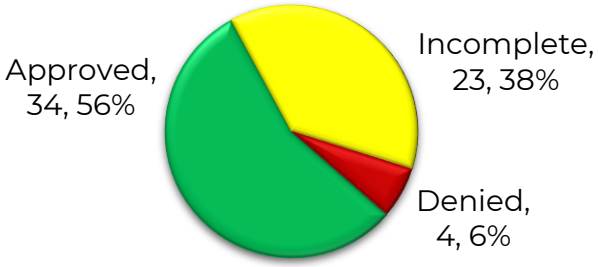
Top Prescriber Specialties of Parathyroid Medications by Number of Claims



Prior Authorization of Parathyroid Medications

There were 61 prior authorization requests submitted for parathyroid medications during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[46]

- Sensipar® (cinacalcet tablet): September 2026
- Rayaldee® [calcifediol extended-release (ER) capsule]: 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.

[46] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/. Last revised 12/2021. Last accessed 12/13/2021.

Utilization Details of Parathyroid Medications: Fiscal Year 2021

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
CALCIMIMETIC PRODUCTS						
CINACALCET PRODUCTS						
CINACALCET TAB 30MG	349	77	$58,839.99	$168.60	4.53	27.37%
CINACALCET TAB 60MG	137	32	$56,350.14	$411.31	4.28	26.21%
CINACALCET TAB 90MG	58	14	$38,069.12	$656.36	4.14	17.71%
SENSIPAR TAB 30MG	3	3	$2,377.05	$792.35	1	1.11%
SUBTOTAL	**547**	**126**	**$155,636.30**	**$284.53**	**4.34**	**72.40%**
VITAMIN-D ANALOG PRODUCTS						
CALCITRIOL PRODUCTS						
CALCITRIOL CAP 0.25MCG	668	197	$10,975.86	$16.43	3.39	5.11%
CALCITRIOL CAP 0.5MCG	342	83	$8,833.96	$25.83	4.12	4.11%
CALCITRIOL SOL 1MCG/ML	156	46	$14,357.51	$92.04	3.39	6.68%
SUBTOTAL	**1,166**	**326**	**$34,167.33**	**$29.30**	**3.58**	**15.89%**
CALCIFEDIOL PRODUCTS						
RAYALDEE CAP 30MCG	13	3	$19,503.96	$1,500.30	4.33	9.07%
SUBTOTAL	**13**	**3**	**$19,503.96**	**$1,500.30**	**4.33**	**9.07%**
PARICALCITOL PRODUCTS						
PARICALCITOL CAP 1MCG	66	10	$2,422.06	$36.70	6.6	1.13%
PARICALCITOL CAP 2MCG	10	4	$2,430.32	$243.03	2.5	1.13%
PARICALCITOL INJ 5MCG/ML	4	1	$705.64	$176.41	4	0.33%
PARICALCITOL INJ 2MCG/ML	1	1	$111.41	$111.41	1	0.05%
SUBTOTAL	**81**	**16**	**$5,669.43**	**$69.99**	**5.06**	**2.64%**
TOTAL	**1,807**	**416***	**$214,977.02**	**$118.97**	**4.34**	**100%**

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

Fiscal Year 2021 Annual Review of Pediculicide Medications

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

Pediculicide Medications		
Tier-1	**Tier-2**	**Tier-3**
Covered OTC Lice Medications	ivermectin lotion (Sklice®)	lindane shampoo
Generics with SMAC Pricing		malathion (Ovide®)
Natroba™ (spinosad) **– Brand Preferred**		

Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
OTC = over-the-counter; SMAC = State Maximum Allowable Cost

- Over-the-counter (OTC) treatments for lice (i.e., permethrin, pyrethrin) 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 recent 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 recent trial with 1 Tier-1 medication with inadequate response or adverse effect; and
3. Recent 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) approved *Prescribing Information*:

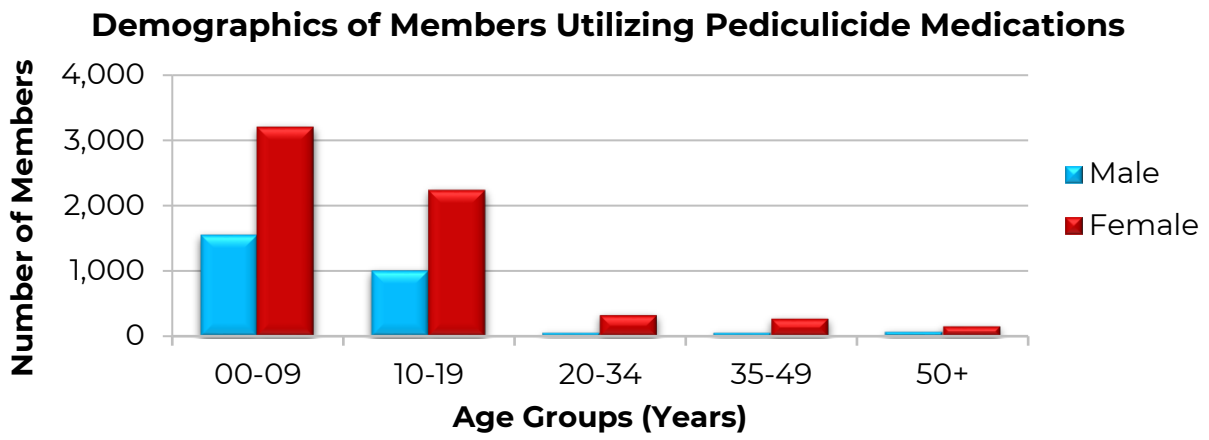
1. **Crotamiton (Eurax® and Crotan™) Cream and Lotion:**
   a. An FDA approved diagnosis of scabies or pruritic skin; and
   b. Member must be 18 years of age or older; and
   c. For a diagnosis of scabies, member must have used permethrin 5% cream in the past 7 to 14 days with inadequate results; and
   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.

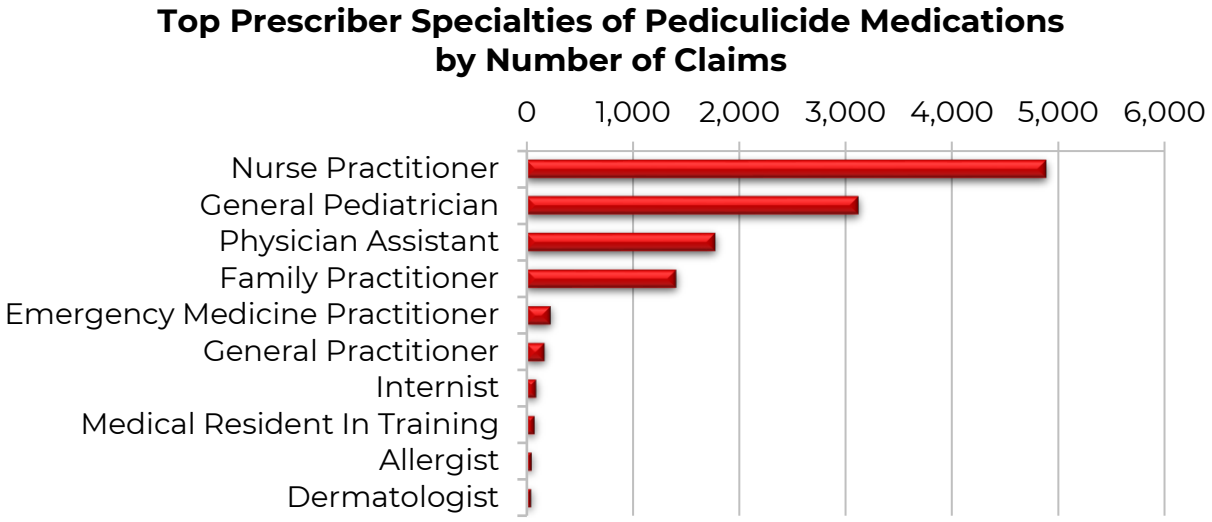
Utilization of Pediculicide Medications: Fiscal Year 2021

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	11,535	16,116	$2,737,616.96	$169.87	$16.99	1,510,392	161,172
2021	8,923	12,101	$2,034,470.19	$168.12	$15.67	1,146,743	129,802
% Change	**-22.60%**	**-24.90%**	**-25.70%**	**-1.00%**	**-7.80%**	**-24.10%**	**-19.50%**
Change	**-2,612**	**-4,015**	**-$703,146.77**	**-$1.75**	**-$1.32**	**-363,649**	**-31,370**

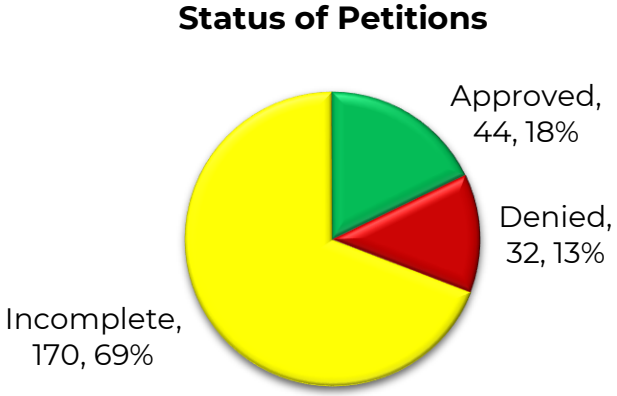
*Total number of unduplicated utilizing members.
Costs do not reflect rebated prices or net costs.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020; Fiscal Year 2021 = 07/01/2020 to 06/30/2021





Prior Authorization of Pediculicide Medications

There were 246 prior authorization requests submitted for pediculicide medications during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021.



Market News and Updates

Anticipated Patent Expiration(s):[47]

- Natroba™ (spinosad): July 2023
- Ovide® (malathion): February 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 2021

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SPINOSAD PRODUCTS						
NATROBA SUS 0.9%	6,797	5,026	$1,856,897.00	$273.19	1.35	91.27%
SPINOSAD SUS 0.9%	1	1	$229.04	$229.04	1	0.01%
SUBTOTAL	**6,798**	**5,027**	**$1,857,126.04**	**$273.19**	**1.35**	**91.28%**
PERMETHRIN AND PYRETHRIN OTC PRODUCTS						
PERMETHRIN CRE 5%	4,700	3,669	$162,784.15	$34.63	1.28	8.00%
LICE TREATMT LOT 1%	287	222	$4,190.37	$14.60	1.29	0.21%
LICE TRTMNT LIQ 1%	265	183	$4,675.20	$17.64	1.45	0.23%
VANALICE GEL 0.3-3.5%	33	33	$1,683.49	$51.01	1	0.08%
LICE TREATMT LIQ 1%	1	1	$16.91	$16.91	1	0.00%
SUBTOTAL	**5,286**	**4,108**	**$173,350.12**	**$32.79**	**1.29**	**8.52%**
IVERMECTIN PRODUCTS						
IVERMECTIN LOT 0.5%	17	15	$3,994.03	$234.94	1.13	0.20%
SUBTOTAL	**17**	**15**	**$3,994.03**	**$234.94**	**1.13**	**0.20%**
TOTAL	**12,101**	**8,923***	**$2,034,470.19**	**$168.12**	**1.36**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CRE = cream; LIQ = liquid; LOT = lotion; OTC = over-the-counter; SUS = suspension; TRTMNT = treatment
Fiscal Year 2021 = 07/01/2020 to 06/30/2021
Please note: Some Tier-1 products participate in supplemental rebates; therefore, costs shown do not reflect net costs.

[47] 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 12/2021. Last accessed 12/13/2021.

Fiscal Year 2021 Annual Review of Qbrexza® (Glycopyrronium)

Oklahoma Health Care Authority
Fiscal Year 2021 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 2021

Comparison of Fiscal Years

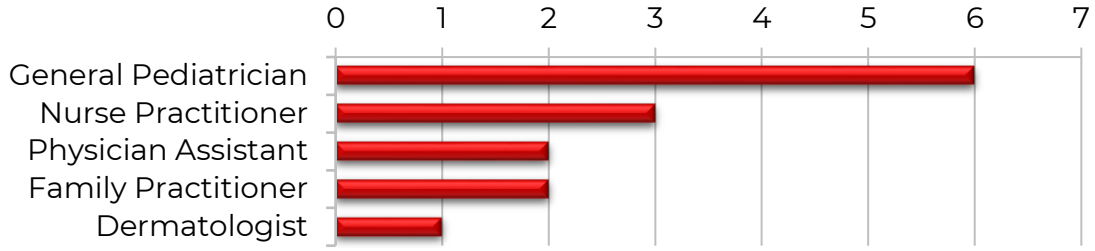
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	4	10	$5,597.15	$559.71	$18.66	300	300
2021	6	14	$8,113.72	$579.55	$19.32	420	420
% Change	**50.00%**	**40.00%**	**45.00%**	**3.50%**	**3.50%**	**40.00%**	**40.00%**
Change	**2**	**4**	**$2,516.57**	**$19.83**	**$0.66**	**120**	**120**

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

Demographics of Members Utilizing Qbrexza® (Glycopyrronium)

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

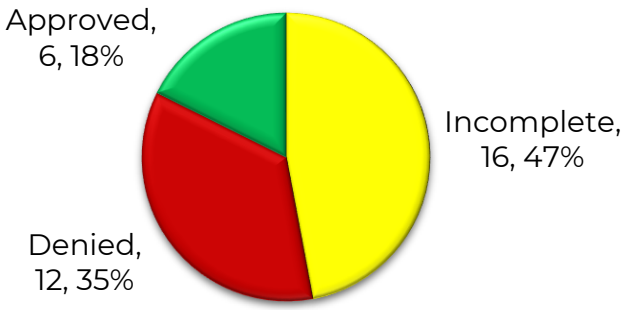
Top Prescriber Specialties of Qbrexza® (Glycopyrronium) by Number of Claims



Prior Authorization of Qbrexza® (Glycopyrronium)

There were 34 prior authorization requests submitted for Qbrexza® (glycopyrronium) during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[48]

- 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.

[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 12/2021. Last accessed 12/13/2021.

Fiscal Year 2021 Annual Review of Revcovi® (Elapegademase-lvlr)

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

Revcovi® (Elapegademase-lvlr) Approval Criteria:

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

Utilization of Revcovi® (Elapegademase-lvlr): Fiscal Year 2021

There was no SoonerCare utilization of Revcovi® (elapegademase-lvlr) during fiscal year 2021 (07/01/2020 to 06/30/2021).

Prior Authorization of Revcovi® (Elapegademase-lvlr)

There were no prior authorization requests submitted for Revcovi® (elapegademase-lvlr) during fiscal year 2021 (07/01/2020 to 06/30/2021).

Recommendations

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

Fiscal Year 2021 Annual Review of Tepezza® (Teprotumumab-trbw)

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

Tepezza® (Teprotumumab-trbw) Approval Criteria:

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

member (or the member's caregiver) must be trained on the proper storage of Tepezza®; and

8. The member's current weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
9. Approvals will be for a maximum of 8 total infusions.

Utilization of Tepezza® (Teprotumumab-trbw): Fiscal Year 2021

Fiscal Year 2021 Utilization: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	1	3	$193,734.23	$64,578.08	$3,075.15	13	63
2021	2	13	$715,340.33	$55,026.18	$2,620.29	48	273
% Change	**100.0%**	**333.3%**	**269.2%**	**-14.8%**	**-14.8%**	**269.2%**	**333.3%**
Change	**1**	**10**	**$521,606.10**	**-$9,551.90**	**-$454.86**	**35**	**210**

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

Demographics of Members Utilizing Tepezza® (Teprotumumab-trbw)

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

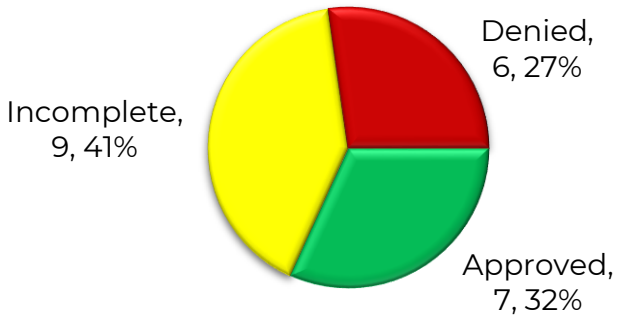
Top Prescriber Specialties of Tepezza® (Teprotumumab-trbw) by Number of Claims

- The only prescriber specialty listed on paid claims for Tepezza® during fiscal year 2021 was ophthalmologist.

Prior Authorization of Tepezza® (Teprotumumab-trbw)

There were 22 prior authorization requests submitted for Tepezza® (teprotumumab-trbw) during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021.

Status of Petitions



Recommendations

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

Utilization Details of Tepezza® (Teprotumumab-trbw): Fiscal Year 2021

PRODUCT UTILIZED	TOTAL CLAIMS	*TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
TEPEZZA INJ 500MG	13	2	$715,340.33	$55,026.18	6.5
TOTAL	**13**	**2**	**$715,340.33**	**$55,026.18**	**6.5**

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

Fiscal Year 2021 Annual Review of Thrombocytopenia Medications

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

Cablivi® (Caplacizumab-yhdp) Approval Criteria:

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

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

1. An FDA approved indication for the treatment of thrombocytopenia in adult members with chronic ITP who have had an insufficient response to a previous treatment; and
2. Member must be 18 years of age or older; and
3. Previous insufficient response with at least 1 of the following treatments:
    a. Corticosteroids; or
    b. Immunoglobulins; or
    c. Splenectomy; and
4. A patient-specific, clinically significant reason why the member cannot use an alternative thrombopoietin (TPO) receptor agonist available without a prior authorization must be provided; and
5. Prescriber must verify the degree of thrombocytopenia and clinical condition increase the risk for bleeding; and
6. Prescriber must verify platelet counts will be assessed weekly until a stable platelet count >50 x 10^9/L has been achieved, and then obtained monthly thereafter; and

7. Must be prescribed by, or in consultation with, a hematologist or oncologist; and
8. Doptelet® must not be used in an attempt to normalize platelet counts; and
9. Female members must not be pregnant and must have a negative pregnancy test prior to therapy initiation; and
10. Prescriber must verify female member is not breastfeeding; and
11. A quantity limit of 60 tablets per 30 days will apply.

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

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

Mulpleta® (Lusutrombopag) Approval Criteria:

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

Tavalisse® (Fostamatinib) Approval Criteria:

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

Utilization of Thrombocytopenia Medication: Fiscal Year 2021

Comparison of Fiscal Years

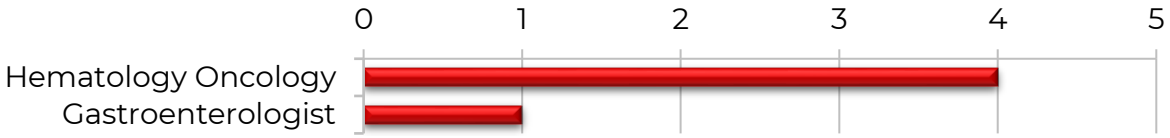
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	2	4	$38,006.14	$9,501.53	$316.72	150	120
2021	3	5	$50,541.05	$10,108.21	$404.33	250	125
% Change	**50.00%**	**25.00%**	**33.00%**	**6.40%**	**27.70%**	**66.70%**	**4.20%**
Change	**1**	**1**	**$12,534.91**	**$606.68**	**$87.61**	**100**	**5**

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

Demographics of Members Utilizing Thrombocytopenia Medications

- There was 1 unique member utilizing Doptelet® (avatrombopag) and there were 2 unique members utilizing Tavalisse® (fostamatinib) during fiscal year 2021. Due to the limited number of members utilizing thrombocytopenia medications, detailed demographic information could not be provided.

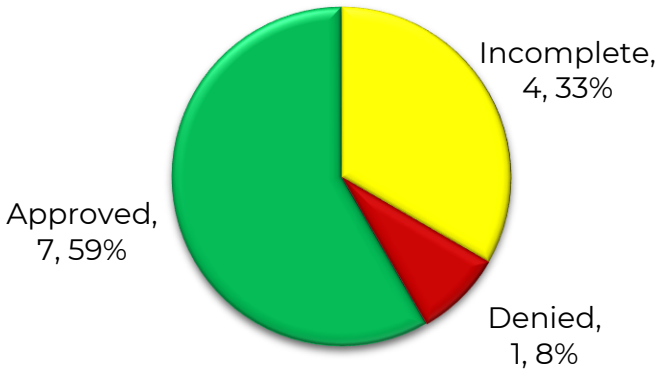
Top Prescriber Specialties of Thrombocytopenia Medications by Number of Claims



Prior Authorization of Thrombocytopenia Medications

There were 12 prior authorization requests submitted for thrombocytopenia medications during fiscal year 2021. The following chart shows the status of the submitted petitions.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[49]

- Doptelet® (avatrombopag): May 2025
- Promacta® (eltrombopag): February 2028
- Mulpleta® (lusutrombopag): September 2031
- Tavalisse® (fostamatinib): July 2032

Recommendations

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

Utilization Details of Thrombocytopenia Medications: Fiscal Year 2021

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
FOSTAMATINIB PRODUCTS						
TAVALISSE TAB 100MG	3	1	$35,452.23	$11,817.41	3	70.15%
TAVALISSE TAB 150MG	1	1	$11,817.41	$11,817.41	1	23.38%
SUBTOTAL	**4**	**2***	**$47,269.64**	**$11,817.41**	**2**	**93.53%**
AVATROMBOPAG PRODUCTS						
DOPTELET TAB 20MG	1	1	$3,271.41	$3,271.41	1	6.47%
SUBTOTAL	**1**	**1**	**$3,271.41**	**$3,271.41**	**1**	**6.47%**
TOTAL	**5**	**3***	**$50,541.05**	**$10,108.21**	**1.67**	**100%**

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

[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 12/2021. Last accessed 12/14/2021.