
Ohio Medicaid

Pharmacy Benefit Management Program



**Department of
Medicaid**

Unified Preferred Drug List

**Medicaid Fee-for-Service
and Managed Care Plans**

Effective January 1, 2024

Helpful Links

Prior Authorization (PA)

[Prior Authorization \(PA\) Information | medicaid.ohio.gov](#)

- **General Prior Authorization Requirements**
- **PA and Step Therapy Frequently Asked Questions (FAQ)**

Unified Preferred Drug List (UPDL)

[Ohio Unified Preferred Drug List | medicaid.ohio.gov](#)

- **Unified Preferred Drug List (UPDL)**
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General Information

- The Statewide UPDL is not an all-inclusive list of drugs covered by Ohio Department of Medicaid.
 - Medications that are new to market will be non-preferred, PA required until reviewed by the Ohio Department of Medicaid Pharmacy and Therapeutics (P&T) Committee.
 - The document is listed in sections defined by therapeutic class. Drugs are listed by generic name if a generic is available unless the brand name of the drug is preferred. In most cases, when a generic for a brand-name drug is available, the generic drug will be preferred, and the brand name will be non-preferred. Some drugs may also require a specific manufacturer or the brand to be dispensed.
 - Ohio Department of Medicaid will only cover drugs that are part of the Medicaid Drug Rebate Program, with limited exceptions. This document may not reflect the most current rebate status of a drug (i.e., a drug may be listed on the document but is non-rebateable and therefore non-payable).
 - Some therapeutic categories are grandfathered. These categories will be denoted with an “*” next to their title on the table on contents and their place within the criteria document.
 - Some therapeutic categories may have quantity limits on specific drugs detailed in the criteria document, however this is not an all-inclusive list. For a list of the quantity limits on specific drugs, please reference the Quantity Limit Document found here: [Quantity Limits Document | medicaid.ohio.gov](#)
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Terminology/Abbreviations:

AR (Age Restriction) – An edit allowing claims for members within a defined age range to be covered without PA

BvG (Brand Preferred Over the Generic) – The brand name drug is preferred over the generic equivalent

PA (Clinical Prior Authorization) – A prior authorization (PA) is required before the drug will be covered

QL (Quantity Limit) – A limit on the quantity that will be covered within a given time frame

ST (Step Therapy) – Drug requires a trial with one or more preferred drugs before being covered

New UPDL Criteria Format

- With a few minor exceptions, all therapeutic categories have the same standardized outline format. The design of this new format is intended to have a cumulative approach bottom-to-top.

Example Category

LENGTH OF AUTHORIZATIONS: X days or Initial: X days; Subsequent: X days (if different)

GRANDFATHERING*:

Patients who have a claim for a non-preferred drug in the previous 120 days will be automatically approved to continue the drug. Patients who have taken the drug previously, but do not have claims history (e.g. new to Medicaid), will need to submit a prior authorization in order to continue coverage.

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

CLINICAL PA CRITERIA (if applicable):

“DRUG” CRITERIA (if applicable):

STEP THERAPY CRITERIA:

- Must have had an inadequate clinical response of at least X days with at least X preferred drugs

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least X days with X preferred drugs
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

ADDITIONAL “DRUG” CRITERIA (if applicable):

ADDITIONAL INFORMATION (if applicable):

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient’s response to treatment from baseline and/or attestation of clinical stabilization

QL – Drug: X doses per X days

AR – a PA is required for patients X years and older OR younger than X years

Interpretation of New UPDL Criteria Format

- Beginning January 2023 and with a few minor exceptions, all therapeutic categories have the same standardized outline format. The design of this new format is intended to have a cumulative approach bottom-to-top. The following scenarios will aid in illustrating this point:

Scenario 1: Clinical PA drug

- All Authorizations
- Clinical PA Criteria

Scenario 2: Clinical PA drug with drug-specific criteria

- All Authorizations
- Drug-Specific Criteria

Scenario 3: Step-Therapy drug

- All Authorizations
- Clinical PA Criteria (if applicable)
- Step Therapy Criteria

Scenario 4: Non-Preferred drug

- All Authorizations
- Clinical PA Criteria (if applicable)
- Step Therapy Criteria (if applicable)
- Non-Preferred Criteria

Scenario 5: Non-Preferred drug with drug-specific criteria

- All Authorizations
 - Clinical PA Criteria (if applicable)
 - Step Therapy Criteria (if applicable)
 - Non-Preferred Criteria
 - Additional Drug-Specific Criteria
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Analgesic Agents: Gout

LENGTH OF AUTHORIZATIONS: 365 days except 180 days for Familial Mediterranean Fever

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

CLINICAL PA CRITERIA:

- Must have had an inadequate clinical response with an NSAID and oral corticosteroid within the last 30 days for acute gout diagnosis **OR**
- Must have had an inadequate clinical response of at least 30 days with the maximally tolerated xanthine oxidase inhibitor dose for chronic gout diagnosis

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 30 days with at least one preferred drug
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

ADDITIONAL COLCHICINE CAPSULE (MITIGARE) CRITERIA:

- Must have had an inadequate clinical response of 30 days with colchicine tablets

ADDITIONAL COLCHICINE SOLUTION (GLOPERBA) CRITERIA:

- Must be unable to swallow tablets or capsules for authorization of colchicine solution

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

QL – All colchicine products: 6 doses per claim for acute gout; 2 doses per day for 30 days for chronic gout; 4 doses per day per 30 days for Familial Mediterranean Fever

Analgesic Agents: NSAIDs

LENGTH OF AUTHORIZATIONS: Dependent upon the table below

	Authorization Length
H. Pylori Treatment	30 days
Transdermal/Topical	90 days
All Other Treatments	365 days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 30 days with at least two preferred drugs
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

AR – Naproxen Suspension: a PA is required for patients 12 years old and older

Analgesic Agents: Opioids

Ohio law requires prescribers to request and review an OARRS report before initially prescribing or personally furnishing any controlled substance, such as an opioid analgesic or a benzodiazepine, and gabapentin

LENGTH OF AUTHORIZATIONS: For the course of therapy, up to 180 days. Initial short-acting and long-acting requests may only be authorized for up to 90 days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

BUPRENORPHINE TOPICAL (BUTRANS) CRITERIA:

- For doses greater than 5 mcg/hour must provide documentation of an inadequate clinical response with at least one opioid formulation taken for at least 60 of the last 90 days

MORPHINE SULFATE ER (KADIAN, MS CONTIN) & TAPENTADOL ER (NUCYNTA) CRITERIA:

- Unless receiving for cancer pain, palliative care, or end-of-life/hospice care, must provide documentation of an inadequate clinical response with at least one opioid formulation taken for at least 60 of the last 90 days
- Must also meet LONG-ACTING OPIOID CRITERIA

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 7 days of at least two unrelated preferred drugs of the same duration of action (SHORT-ACTING or LONG-ACTING)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)
- Must also meet applicable SHORT-ACTING or LONG-ACTING OPIOID CRITERIA

ADDITIONAL SHORT-ACTING OPIOIDS CRITERIA:

- The system defines an “initial request” as having no opioid claims in the previous 90 days
- **Initial short-acting requests** can be authorized up to 90 days
 - Length of authorization is dependent on indication, previous patient utilization, and requested length of therapy (could be more restrictive)
 - To exceed acute opioid limits, documentation of the following must be

provided:

- Diagnosis code which must be for somatic type pain
- Prescriber attestation that the benefits and risks of opioid therapy have been discussed with patient
- Exemptions to the additional criteria:
 - Patients receiving short-acting opioids for active cancer treatment, palliative care, and end-of-life/hospice care, sickle cell, severe burn, traumatic crushing of tissue, amputation, major orthopedic surgery
 - Prescriber attestation that patient is opioid tolerant (i.e., new to Medicaid or was on higher dose in hospital)
- **Subsequent short-acting requests** can be authorized up to 180 days
 - Documentation of the following must be provided:
 - Current treatment plan
 - Demonstrated adherence to treatment plan through progress notes, including pain and function scores, random urine screenings results reviewed, concerns addressed, and no serious adverse outcomes observed
- **Dose escalation requests** can be authorized up to 180 days
 - Documentation of the following must be provided:
 - Prescriber attestation that dose escalation is likely to result in improved function or pain control
 - Requests for a cumulative daily dose > 80 MED must be prescribed by or in consultation with a pain specialist, specialist in the area of the body affected by pain, or anesthesiologist

Patients with initial prescriptions for opioid therapy, defined as no rx claims for opioids in the last 90 days, will be limited to 30 MED per day and a maximum of 7 days per prescription. Prior authorization will be required to exceed these limits.

ADDITIONAL LONG-ACTING OPIOIDS CRITERIA:

- The system defines an “initial long-acting request” as having no opioid claims in the previous 90 days
- **Initial long-acting requests** can be authorized up to 90 days
 - Documentation of the following must be provided:
 - Request is a daily dose equivalent of ≤ 80 MED
 - Inadequate clinical response to both non-opioid pharmacologic and non-pharmacologic treatments
 - Current use of opioids for ≥ 60 of the last 90 days
 - Treatment plan including risk assessment, substance abuse history, concurrent therapies, and requirements for random urine screenings (baseline urine drug tests must be submitted)
 - Pain and function scores at each visit

- Opioid contract required to be in place and submitted with PA form
 - Exemptions to the additional criteria:
 - Patients receiving long-acting opioids for cancer pain, palliative care, or end-of-life/hospice care
- **Subsequent long-acting requests** can be authorized up to 180 days
 - Documentation of the following must be provided:
 - Current treatment plan
 - Demonstrated adherence to treatment plan through progress notes, including pain and function scores, random urine screenings results reviewed, concerns addressed, and no serious adverse outcomes observed
- **Dose escalation requests** can be authorized up to 180 days
 - Documentation of the following must be provided:
 - Prescriber attestation that dose escalation is likely to result in improved function or pain control
 - Requests for a cumulative daily dose > 80 MED must be prescribed by or in consultation with a pain specialist, specialist in the area of the body affected by pain, or anesthesiologist

ADDITIONAL TRANSMUCOSAL FENTANYL CRITERIA:

- Must be prescribed by an oncologist, pain specialist, or hospice/palliative prescriber
- Must be concurrently taking a long-acting opioid at a therapeutic dose of any of the following for at least 7 days without adequate pain relief:

≥ 60 mg oral morphine/day	≥ 8 mg oral hydromorphone/day
≥ 25 mcg/hr transdermal fentanyl	≥ 25 mg oral oxymorphone/day
≥ 30 mg oral oxycodone/day	Equianalgesic dose of another opioid

BUPRENORPHINE BUCCAL FILM (BELBUCA) CRITERIA:

- Must meet ADDITIONAL LONG-ACTING OPIOID Criteria

QL – Transmucosal Fentanyl: 4 doses per day

Blood Formation, Coagulation, and Thrombosis Agents: Colony Stimulating Factors

LENGTH OF AUTHORIZATIONS: Dependent upon diagnosis below

Diagnosis	Authorization Length
Acute Myeloid Leukemia (AML)	14 days or duration of chemotherapy regimen
Malignancy at risk for febrile neutropenia or undergoing myeloablative chemotherapy prior to allogeneic or autologous bone marrow transplantation	14 days or duration of chemotherapy regimen
Myeloid Engraftment for bone marrow transplant (BMT)	30 days
Severe, chronic neutropenia with absolute neutrophil count (ANC) of less than 500/mm ³ and have symptoms associated with neutropenia (e.g., fever, infections, oropharyngeal ulcers).	30 days
Hematopoietic radiation injury syndrome	30 days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

CLINICAL PA CRITERIA:

- Must provide documentation of diagnosis, patient’s weight, and duration of treatment

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 14 days with at least one preferred drug
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient’s clinical response to treatment and ongoing safety monitoring

Blood Formation, Coagulation, and Thrombosis Agents: Hematopoietic Agents

LENGTH OF AUTHORIZATIONS: Dependent upon diagnosis below

Authorization of epoetin alfa or darbepoetin:

Diagnosis	Hemoglobin Level	Authorization Length
Anemia due to chronic renal failure, patient on dialysis	≤11	365 days
Anemia due to chronic renal failure, patient not on dialysis	≤10	365 days
Chemotherapy-induced anemia	≤10	90 days
Anemia in myelodysplastic syndrome	≤11	180 days

Authorization of epoetin alfa ONLY:

Diagnosis	Hemoglobin Level	Authorization Length
Autologous blood donation, patient will require blood transfusions	>10 to ≤13	30 days
Anemia of prematurity, age ≤6 months	N/A	42 days
Anemia associated with chronic inflammatory disorders (e.g., rheumatoid arthritis)	≤11	180 days
Anemia associated with ribavirin combination therapy in hepatitis C-infected patient	≤11	180 days
Anemia in zidovudine-treated HIV-infected patients	≤11	180 days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 14 days with at least one preferred drug
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient’s clinical response to treatment and ongoing safety monitoring

Blood Formation, Coagulation, and Thrombosis Agents: Hemophilia Factors*

LENGTH OF AUTHORIZATIONS: 365 Days

GRANDFATHERING*:

Patients who have a claim for a non-preferred drug in the previous 120 days will be automatically authorized to continue the drug. Patients who have taken the drug previously, but do not have claims history (e.g., new to Medicaid), will need to submit a prior authorization in order to continue coverage.

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

CLINICAL PA CRITERIA:

- Must provide documentation of patient's body weight

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 14 days with at least one preferred drug
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

ADDITIONAL EXTENDED HALF-LIFE FACTOR CRITERIA

- Must provide attestation that the patient is not a suitable candidate for treatment with a shorter-acting half-life drug

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

Blood Formation, Coagulation, and Thrombosis Agents: Heparin-Related Preparations

LENGTH OF AUTHORIZATIONS: Dependent upon criteria below

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 14 days with at least one preferred drug
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

ADDITIONAL INFORMATION:

- For most indications: Guidelines from the American College of Chest Physicians limit duration of therapy in the outpatient setting for most indications to less than 35 days and patients should be transitioned to oral anticoagulant as soon as possible
- For requests over 35 days and/or the patient cannot be transitioned to an oral anticoagulant, prescriber must submit additional documentation for reasoning:
 - For patients with cancer – authorized up to 180 days
 - For pregnant women – authorized up to 280 days
 - For patients unable to take an oral anticoagulant – authorized up to 180 days

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

Blood Formation, Coagulation, and Thrombosis Agents: Oral Anticoagulants

LENGTH OF AUTHORIZATION: 365 days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 14 days with at least two preferred drugs
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

AR – All drugs: a PA is required for patients older than 12 years old

Blood Formation, Coagulation, and Thrombosis Agents: Oral Antiplatelet

LENGTH OF AUTHORIZATION: 365 days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 14 days with at least two preferred drugs
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

Cardiovascular Agents: Angina, Hypertension & Heart Failure

LENGTH OF AUTHORIZATIONS: 365 days except nimodipine: 21 days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

PROPRANOLOL ORAL SOLUTION (HEMANGEOL) CRITERIA:

- Must provide documentation of the patient's weight

SACUBITRIL/VALSARTAN (ENTRESTO) CRITERIA:

- Must provide documentation of chronic heart failure classified as either NYHA Class II-IV or ACC/AHA Stage B-D

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 30 days of at least two preferred drugs within the same class, if indicated for diagnosis
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

ADDITIONAL FINERENONE (KERENDIA) CRITERIA:

- Must be on a maximally tolerated dose of an angiotensin-converting enzyme inhibitor or angiotensin receptor blocker
- Must provide documentation of an inadequate clinical response to a SGLT2 Inhibitor **OR** provide documentation of medical necessity beyond convenience for why the patient cannot try a SGLT2 inhibitor (i.e., chronic kidney disease diagnosis)

ADDITIONAL MAVACAMTEN (CAMZYOS) CRITERIA:

- Must be prescribed by or in consultation with a cardiologist
- Must provide documentation of NYHA Class II-III symptoms and left ventricular ejection fraction $\geq 55\%$

ADDITIONAL SOTAGLIFLOZIN (INPEFA) CRITERIA:

- Must provide documentation of an inadequate clinical response to at least two SGLT2 Inhibitors (refer to Endocrine Agents: Diabetes – Non-Insulin class for complete list)

ADDITIONAL VERICIGUAT (VERQUVO) CRITERIA:

- Must provide documentation of ejection fraction
- Must have been hospitalized for the treatment of heart failure in the previous 180 days or needs treatment with an outpatient intravenous diuretic in the previous 90 days
- Must be treated with an agent from **ALL** the following unless contraindicated:
 - Angiotensin-converting enzyme inhibitor, angiotensin II receptor blocker, **OR** an angiotensin receptor neprilysin inhibitor
 - Beta-blocker
 - Aldosterone antagonist and/or SGLT2 inhibitor as appropriate for renal function

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

AR – Sotylize Solution: a PA is required for patients 6 years and older

Cardiovascular Agents: Antiarrhythmics

LENGTH OF AUTHORIZATIONS: 365 Days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 30 days with at least one preferred drug
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

Cardiovascular Agents: Lipotropics

LENGTH OF AUTHORIZATIONS: See below

Juxtapid (Initial)	180 days
Vascepa, Lovaza, ACL inhibitors (Initial)	84 days
All others (Initial and Subsequent)	365 days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

CLINICAL PA CRITERIA:

- Must provide documentation of baseline labs **AND** have documented adherence to 90 days of prescribed lipid lowering medications
- Must have had an inadequate clinical response of at least 90 days **AND** unable to reach goal LDL-C (see below) despite treatment with maximally tolerated dose of high-potency statin and ezetimibe (or a clinical reason that these drugs cannot be utilized)

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 30 days (or 90 days for fibrates) with at least one preferred drug in the same drug class
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

ADDITIONAL LOVASTATIN ER (ALTOPREV), PITAVASTATIN (LIVALO), FLUVASTATIN (LESCOL) CRITERIA

- Must have had an inadequate clinical response of at least 30 days with two preferred drugs in the same drug class

ADDITIONAL COLESEVELAM (WELCHOL) CRITERIA:

- Must provide documentation of a Type 2 Diabetes diagnosis

ADDITIONAL ICOSAPENT ETHYL (VASCEPA) CRITERIA:

- Must provide documentation of baseline labs indicating triglyceride levels $\geq 500\text{mg/dL}$ after an inadequate clinical response to fibrates, niacin, and diet/exercise
- Must provide documentation of discontinuation of drugs known to increase triglyceride levels (i.e., beta blockers, thiazides, and estrogens), if clinically appropriate

ADDITIONAL LOMITAPIDE (JUXTAPID) & ATP CITRATE LYASE (ACL) INHIBITOR CRITERIA:

- Must provide documentation of baseline labs **AND** have documented adherence to 90 days of prescribed lipid lowering medications
- Must have had inadequate clinical response of at least 90 days **AND** unable to reach goal LDL-C with high-potency statin, ezetimibe and PCSK9 inhibitor (or a clinical reason that these drugs cannot be utilized)

ADDITIONAL INFORMATION:

- High potency statins: atorvastatin (Lipitor) 40-80mg & rosuvastatin (Crestor) 20-40mg
- LDL goals for Familial Hypercholesterolemia (includes Heterozygous & Homozygous FH): LDL $\leq 100\text{mg/dL}$ for adults or LDL $\leq 110\text{mg/dL}$ for those < 18 years of age
- LDL goals for Clinical Atherosclerotic Cardiovascular Disease (ASCVD): LDL $\leq 70\text{mg/dL}$

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

Cardiovascular Agents: Pulmonary Arterial Hypertension*

LENGTH OF AUTHORIZATIONS: 365 Days

GRANDFATHERING*:

Patients who have a claim for a non-preferred drug in the previous 120 days will be automatically approved to continue the drug. Patients who have taken the drug previously, but do not have claims history (e.g., new to Medicaid), will need to submit a prior authorization in order to continue coverage.

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

CLINICAL PA CRITERIA:

- Must provide documentation of NYHA Functional Class for Pulmonary Hypertension and symptoms experienced by patient

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 30 days with at least two preferred drugs, one of which must be a phosphodiesterase-5 inhibitor
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

ADDITIONAL INFORMATION:

- Patients who have class III or IV symptoms defined by the NYHA Functional Class for Pulmonary Hypertension may be authorized for inhalation or intravenous agents

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

AR – Sildenafil Susp: a PA is required for patients 18 years and older

AR – Tadiq: a PA is required for patients younger than 18 years

Central Nervous System (CNS) Agents: Alzheimer's Agents*

LENGTH OF AUTHORIZATIONS: 365 Days

GRANDFATHERING*:

Patients who have a claim for a non-preferred drug in the previous 120 days will be automatically approved to continue the drug. Patients who have taken the drug previously, but do not have claims history (e.g., new to Medicaid), will need to submit a prior authorization in order to continue coverage.

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 30 days with at least two preferred drugs
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

AR – All drugs: a PA is required for patients younger than 40 years

Central Nervous System (CNS) Agents: Anti-Migraine Agents, Acute

LENGTH OF AUTHORIZATIONS: 180 Days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

STEP THERAPY CRITERIA:

- Must have had an inadequate clinical response of at least 14 days with at least two preferred drugs

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 14 days with at least two preferred drugs
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

ADDITIONAL UBROGEPANT (UBRELVY) CRITERIA

- Must have had an inadequate clinical response of at least 14 days with at least one preferred oral CGRP antagonist

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

QL – Nurtec ODT: 8 doses per 30 days for acute treatment

Central Nervous System (CNS) Agents: Anti-Migraine Agents, Cluster Headache

LENGTH OF AUTHORIZATIONS: 180 days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 60 days to at least one preferred drug
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

ADDITIONAL INFORMATION:

- An inadequate clinical response to verapamil is defined as a titration to at least 480mg daily

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

QL – Emgality: 3 doses per 30 days

Central Nervous System (CNS) Agents: Anti-Migraine Agents, Prophylaxis

LENGTH OF AUTHORIZATIONS: Initial: 180 days; Subsequent: 365 days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

STEP THERAPY CRITERIA:

- Must have had an inadequate clinical response of at least 30 days with at least three preferred controller migraine drugs
- Must include objective documentation of severity, frequency, type of migraine, and number of headache days per month (preferably a headache diary)

ERENUMAB (AIMOVIG) CRITERIA:

- Must have had an inadequate clinical response of at least 60 days with the 70mg dose to request a dose increase

FREMANEZUMAB (AJOVY) CRITERIA:

- Must have demonstrated efficacy for at least 90 days before quarterly administration will be authorized

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 30 days with at least three preferred controller migraine drugs **AND** one step therapy drug
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

ADDITIONAL INFORMATION:

- Controller migraine drug classes include beta-blockers, anticonvulsants, tricyclic antidepressants, or serotonin-norepinephrine reuptake inhibitors

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment (preferably a headache diary or other objective documentation of severity, frequency, and number of headache days per month).

QL – Nurtec ODT: 18 doses per 30 days for prophylactic treatment

QL – Aimovig, Ajovy: 1 dose per 30 days

QL – Emgality: 2 doses per 30 days (for initial loading dose only), then 1 dose per 30 days thereafter

Central Nervous System (CNS) Agents: Anticonvulsants*

LENGTH OF AUTHORIZATIONS: 365 days except Epidiolex and Diacomit – Initial: 180 days

GRANDFATHERING* (except Diacomit):

Patients who have a claim for a non-preferred drug in the previous 120 days will be automatically approved to continue the drug. Patients who have taken the drug previously, but do not have claims history (e.g., new to Medicaid), will need to submit a prior authorization in order to continue coverage.

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

STEP THERAPY CRITERIA:

- Must have had an inadequate clinical response of at least 30 days with at least one preferred drug

CANNABIDIOL (EPIDIOLEX) CRITERIA

- Must have had an inadequate clinical response of at least 30 days with any two of the following anticonvulsants: clobazam, levetiracetam, valproic acid, lamotrigine, topiramate, rufinamide, or felbamate within the past 365 days (members who meet this criterion will not require a PA)

STIRIPENTOL (DIACOMIT) CRITERIA

- Must be prescribed by or in consultation with a neurologist
- Must be concomitantly taking clobazam (Onfi)
- Must provide documentation of addressed comorbidities and baseline hematologic testing (CBC)
 - Patients with phenylketonuria (PKU) must provide evidence of total daily amount of phenylalanine
 - Prescribers must include management plans for patients with neutrophil counts <1,500 cells/mm³ or platelet count <150,000/ μ L
- Must provide documentation of patient's weight
 - Maximum daily dose does not exceed: 50 mg/kg/day or 3,000mg/day
- Must provide baseline average number of seizure days per month (measured monthly or quarterly)

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation

- Must have had an inadequate clinical response of at least 30 days with at least two preferred drugs
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)
- Prescriptions submitted from a prescriber who is credentialed as a neurology specialty with Ohio Medicaid AND for drugs that are used only for seizures, there must have been an inadequate clinical response of at least 30 days with one preferred drug. This provision applies only to the standard tablet/capsule dosage form.

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring (i.e., documented reduction in average number of seizure days per month [measured monthly or quarterly])

AR – Vigabatrin Powder: a PA is required for patients 3 years and older

AR – Eprontia Solution: a PA is required for patients 12 years and older

Central Nervous System (CNS) Agents: Anticonvulsants Rescue

LENGTH OF AUTHORIZATIONS: 365 Days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response with at least one preferred drug
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

AR – Valtoco: a PA is required for patients younger than 6 years old

AR – Nayzilam: a PA is required for patients younger than 12 years old

Central Nervous System (CNS) Agents: Antidepressants*

LENGTH OF AUTHORIZATIONS: 365 Days

GRANDFATHERING*:

Patients who have a claim for a non-preferred drug in the previous 120 days will be automatically approved to continue the drug. Patients who have taken the drug previously, but do not have claims history (e.g., new to Medicaid), will need to submit a prior authorization in order to continue coverage.

PSYCHIATRIST EXEMPTION:

Prescribers (as identified below) are exempt from prior authorization of any non-preferred antidepressant, or step therapy of any preferred drug, in the standard tablet/capsule dosage forms. Other dosage forms may still require prior authorization. The exemption will be processed by the claims system when the pharmacy has submitted the prescriber on the claim using the individual national provider identifier (NPI) for the prescriber.

Prescribers are defined as:

Physicians with a specialty in psychiatry, nurse practitioners certified in psychiatric mental health, or clinical nurse specialists certified in psychiatric mental health, who are credentialed with the Ohio Department of Medicaid.

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 30 days with at least two preferred drugs
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

ADDITIONAL DEXTROMETHORPHAN/BUPROPION (AUVELITY) CRITERIA:

- Must have an inadequate clinical response of at least 30 days with **ALL** of the following:
 - ONE dopamine/norepinephrine reuptake inhibitor (DNRI)
 - ONE selective norepinephrine reuptake inhibitor (SNRI)

- TWO selective serotonin reuptake inhibitors (SSRIs) (ONE of which must be either vilazodone (Viibryd) OR vortioxetine (Trintellix))

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

Central Nervous System (CNS) Agents: Attention Deficit Hyperactivity Disorder Agents

LENGTH OF AUTHORIZATIONS: 365 days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

STEP THERAPY CRITERIA:

- Must have had an inadequate clinical response of at least 30 days with atomoxetine **OR** at least two preferred ADHD agents.

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 30 days with at least three preferred drugs
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

ADDITIONAL INFORMATION:

- Requests for non-preferred immediate-release formulations must have all required trials with preferred immediate-release drugs, and requests for non-preferred extended-release formulations must have all required trials with preferred extended-release drugs
- For patients established on drugs that change from preferred to non-preferred on January 1, a prior authorization is **NOT** required until **after** June 30th of that year.

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

AR –Amphetamine/Dextroamphetamine, Dextroamphetamine IR, & Zenzedi: a PA is required for patients younger than 3 years

AR –Amphetamine/Dextroamphetamine XR, Atomoxetine, Cotelpla XR-ODT, Methylphenidate Patches, Dextroamphetamine ER, Dexmethylphenidate, Methylphenidate IR & ER, & Xelstrym: a PA is required for patients younger than 6 years

AR – Dextroamphetamine Solution & Dyanavel XR: a PA is required for patients 12 years and older

AR – Methylphenidate solution/suspension: a PA is required for patients younger than 6 years and 12 years and older

Central Nervous System (CNS) Agents: Atypical Antipsychotics*

LENGTH OF AUTHORIZATIONS: 365 Days

GRANDFATHERING*:

Patients who have a claim for a non-preferred drug in the previous 120 days will be automatically approved to continue the drug. Patients who have taken the drug previously, but do not have claims history (e.g., new to Medicaid), will need to submit a prior authorization in order to continue coverage.

PSYCHIATRIST EXEMPTION:

Prescribers (as identified below) are exempt from prior authorization of any non-preferred second-generation antipsychotic, or step therapy of any preferred drug, in the standard tablet/capsule and long-acting injectable dosage forms. Other dosage forms may still require prior authorization. The exemption will be processed by the claims system when the pharmacy has submitted the prescriber on the claim using the individual national provider identifier (NPI) for the prescriber.

Prescribers are defined as:

Physicians with a specialty in psychiatry, nurse practitioners certified in psychiatric mental health, or clinical nurse specialists certified in psychiatric mental health, who are credentialed with the Ohio Department of Medicaid.

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

PALIPERIDONE PALMITATE (INVEGA HAFYERA) CRITERIA:

- Must have had 4 months of treatment with Invega Sustenna or 3 months with Invega Trinza

STEP THERAPY CRITERIA:

- Must have had an inadequate clinical response of at least 30 days with at least one preferred drug

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 30 days with at least two preferred drugs
 - For non-preferred extended-release formulations: must provide documentation of

- an inadequate clinical response with its immediate release formulation (if available)
- For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

ADDITIONAL ARIPIPRAZOLE (ABILIFY MYCITE) CRITERIA:

- Must be prescribed by or in consultation with a psychiatrist following an aripiprazole serum blood level draw indicating need for further investigation of adherence

ADDITIONAL OLANZAPINE/SAMIDORPHAN (LYBALVI) CRITERIA:

- Must provide documentation that patient is not using opioids or undergoing acute opioid withdrawal

ADDITIONAL PIMAVANSERIN (NUPLAZID) CRITERIA:

- For Parkinson-related Hallucinations & Delusions **ALL** of the following must be met:
 - Psychotic symptoms are severe and frequent enough to warrant treatment with an antipsychotic **AND** are not related to dementia or delirium
 - The patient's other Parkinson's Disease drugs have been reduced or adjusted and psychotic symptoms persist **OR** patient is unable to tolerate adjustment of these other drugs
 - Must have been inadequate clinical response or contraindication to at least 30 days of either quetiapine or clozapine
- An exemption to the criteria will be authorized for prescribers with a neurology specialty to a patient with a history of the related condition

ADDITIONAL FLUOXETINE/OLANZAPINE (SYMBYAX) CRITERIA:

- Must provide documentation for patient's inability to use the individual drugs

ADDITIONAL INFORMATION:

- Long-acting injectable antipsychotics may be billed by the pharmacy if they are not dispensed directly to the patient. If not administered by the pharmacist, the drug must be released only to the administering provider or administering provider's staff, following all regulations for a Prescription Pick-Up Station as described by the Ohio Board of Pharmacy

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

Central Nervous System (CNS) Agents: Fibromyalgia Agents

LENGTH OF AUTHORIZATIONS: 365 Days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 14 days with at least two preferred drugs in different classes (see Additional Information section below)
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

ADDITIONAL INFORMATION

- Drugs and drug classes include gabapentin, pregabalin, short- and/or long-acting opioids, skeletal muscle relaxants, SNRIs, SSRIs, trazodone, and tricyclic antidepressants
- The P&T Committee does not recommend the use of opioids for treatment of fibromyalgia

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

Central Nervous System (CNS) Agents: Medication Assisted Treatment of Opioid Addiction

LENGTH OF AUTHORIZATIONS: 180 days except 14 days for Lucemyra

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 30 days with at least two preferred drugs
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

ADDITIONAL LOFEXIDINE (LUCEMYRA) CRITERIA

- May be authorized if **ALL** of the following criteria are met:
 - Must provide medical justification supporting why an opioid taper (such as with buprenorphine or methadone) cannot be used
 - Must have had an inadequate clinical response or contraindication to clonidine
- Must provide documentation that the drug was initiated in an inpatient setting to be exempt from the above criteria

BUPRENORPHINE SAFETY EDITS AND DRUG UTILIZATION REVIEW CRITERIA:

- Prescribing for buprenorphine products must follow the requirements of Ohio Administrative Code rule 4731-33-03 *Office based treatment for opioid addiction*.
- In favor of eliminating prior authorization for all forms of oral short acting buprenorphine- containing products, ODM and the Managed Care Plans will implement safety edits and a retrospective drug utilization review process for all brand and generic forms of oral short acting buprenorphine-containing products. Safety edits are in place for dosages over 24mg of buprenorphine equivalents/day.
- Buprenorphine sublingual tablets (generic Subutex) will be restricted to pregnancy, breastfeeding, or contraindication to preferred products
- Buprenorphine injection (Sublocade) dosing schedule will be limited to 300mg/30 days

ADDITIONAL INFORMATION

- Vivitrol and Sublocade may be billed by the pharmacy if it is not dispensed directly to the patient. If not administered by the pharmacist, the drug must be released only to the administering provider or administering provider's staff, following all regulations for a Prescription Pick-Up Station as described by the Ohio Board of Pharmacy.

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

Central Nervous System (CNS) Agents: Movement Disorders

LENGTH OF AUTHORIZATIONS: 365 Days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

CLINICAL PA CRITERIA:

- Must be prescribed by or in consultation with a neurologist or psychiatrist

STEP THERAPY CRITERIA:

- Must have an inadequate clinical response of at least 90 days to a maximally tolerated dose of tetrabenazine for Huntington's Disease only

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 30 days with at least two preferred drugs
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

Central Nervous System (CNS) Agents: Multiple Sclerosis*

LENGTH OF AUTHORIZATIONS: 365 Days

GRANDFATHERING*:

Patients who have a claim for a non-preferred drug in the previous 120 days will be automatically approved to continue the drug. Patients who have taken the drug previously, but do not have claims history (e.g., new to Medicaid), will need to submit a prior authorization in order to continue coverage.

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 30 days with at least one preferred drug
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

ADDITIONAL SIPONIMOD (MAYZENT) CRITERIA:

- Must provide documentation of genotype, liver function tests (LFTS) complete blood count (CBC), ophthalmic examination, varicella zoster virus antibodies, and electrocardiogram (ECG)

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

Central Nervous System (CNS) Agents: Narcolepsy

LENGTH OF AUTHORIZATIONS: 365 days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response with at least two preferred drugs - either (1) at least 30 days of modafinil or armodafinil; or (2) at least 7 days of a preferred methylphenidate or amphetamine drug
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

ADDITIONAL OXYBATE SALTS (XYWAV) CRITERIA:

- Must have documented adherence to sodium restricted diet

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

AR – Adderall IR: a PA is required for patients younger than 3 years

AR – Adderall XR, Dexedrine ER: a PA is required for patients younger than 6 years

AR – Methylphenidate: a PA is required for patients younger than 6 years

Central Nervous System (CNS) Agents: Neuropathic Pain

LENGTH OF AUTHORIZATIONS: 365 Days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

STEP THERAPY CRITERIA:

- Must have had an inadequate clinical response of at least 30 days with generic Lidocaine patch

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 30 days with at least two preferred drugs in different drug classes
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

Central Nervous System (CNS) Agents: Parkinson's Agents

LENGTH OF AUTHORIZATIONS: 365 Days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 30 days with at least one preferred drug
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

ADDITIONAL APOMORPHINE (APOKIN/KYNMOBI), LEVODOPA INHALATION (INBRIJA), & ISTRADefylline (NOURIANZ) CRITERIA:

- Must have had inadequate clinical response to at least 30 days with one other drug for the treatment of “off episodes” (dopamine agonist, COMT inhibitor, or MAO-B inhibitor)

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient’s clinical response to treatment and ongoing safety monitoring

Central Nervous System (CNS) Agents: Restless Legs Syndrome

LENGTH OF AUTHORIZATIONS: 365 Days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 30 days with at least one preferred drug
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

Central Nervous System (CNS) Agents: Sedative-Hypnotics, Non-Barbiturate

LENGTH OF AUTHORIZATIONS: 180 Days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 10 days with at least two preferred drugs
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

ADDITIONAL INFORMATION

- Non-controlled medications may be authorized if the prescriber indicates the patient has a history of addiction
- The P&T Committee does not recommend the use of flurazepam (Dalmane) or triazolam (Halcion)

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

Central Nervous System (CNS) Agents: Skeletal Muscle Relaxants, Non-Benzodiazepine

LENGTH OF AUTHORIZATIONS: 365 Days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 30 days with at least one preferred drug
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics, requests must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

ADDITIONAL BACLOFEN SOLUTION CRITERIA:

- Must provide documentation of trial with baclofen tablets or justification why a non-solid oral dosage form is indicated

ADDITIONAL CARISOPRODOL (SOMA) CRITERIA:

- Must provide medical justification that no other muscle relaxant or agent to treat fibromyalgia, or any musculoskeletal condition would serve the clinical needs of the patient

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

Central Nervous System (CNS) Agents: Smoking Deterrents

All products are covered without a PA

Dermatologic Agents: Oral Acne Products

LENGTH OF AUTHORIZATIONS: 150 days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

CLINICAL PA CRITERIA:

- Must have had an inadequate clinical response of at least 90 days with at least one preferred topical **AND** one preferred oral antibiotic for acne
- Must be absent of oral tretinoin in the past 56 days
- Prescriber attests that patient is registered and meets all of the requirements of the iPLEDGE program

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 90 days with at least two preferred drugs
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

ADDITIONAL INFORMATION

- Authorization length will be for no more than 150 days at a time then must take 56 days off

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

Dermatologic Agents: Topical Acne Products

LENGTH OF AUTHORIZATIONS: 365 Days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 30 days or (90 days for retinoids) of at least three preferred drugs
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

ADDITIONAL TRETINOIN/BENZOYL PEROXIDE (Twyneo) CRITERIA

- Must provide documentation for patient's inability to use the individual drugs

ADDITIONAL INFORMATION

- All retinoids - May be authorized with a diagnosis of skin cancer
- Tazarotene (Tazorac) - May be authorized with a diagnosis of psoriasis

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

AR - All topical retinoids: a PA is required for patients 24 years and older

Endocrine Agents: Androgens

LENGTH OF AUTHORIZATIONS: 365 Days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

CLINICAL PA CRITERIA:

- Must provide documentation of lab work to support the need for testosterone supplementation

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 90 days with **ALL preferred** drugs
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring (i.e., testosterone and hematocrit)

AR: All drugs: a PA is required for patients younger than 18 years

Endocrine Agents: Diabetes – Hypoglycemia Treatments

LENGTH OF AUTHORIZATIONS: 365 Days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least one preferred drug **OR** the inability of the member and/or caregiver to administer a preferred glucagon product in a timely fashion
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

QL – All glucagon products: 2 doses per 34 days

Endocrine Agents: Diabetes – Insulin

LENGTH OF AUTHORIZATIONS: 365 Days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

STEP THERAPY CRITERIA:

- Must have had an inadequate clinical response of at least 120 days with at least one preferred drug having a similar duration of action

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 120 days with at least two preferred drugs having a similar duration of action
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

ADDITIONAL TEMPO PEN CRITERIA

- Must have had an inadequate clinical response or documentation of medical necessity beyond convenience for why the patient cannot use the corresponding FlexPens or Kwikpens

ADDITIONAL INHALED INSULIN (AFREZZA) CRITERIA:

- Must provide documentation of spirometry testing prior to initiation with a predicted FEV1 $\geq 70\%$ - Will not be authorized for patients with asthma or COPD
- Must provide documentation of being nicotine-free for at least 180 days

ADDITIONAL INFORMATION

- An inadequate clinical response is defined as the inability to reach A1C goal after at least 120 days of current regimen with documented adherence and appropriate dose escalation.
- Requests may be authorized for patients with a condition that is difficult to control (i.e., prone to ketoacidosis, hypoglycemia)

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

Endocrine Agents: Diabetes – Non-Insulin

LENGTH OF AUTHORIZATIONS: 365 Days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 120 days with at least three preferred drugs
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

ADDITIONAL ORAL AND INJECTABLE COMBINATION DRUGS CRITERIA

- Must have had a trial of at least 120 days with the individual drugs **OR** must provide documentation of medical necessity beyond convenience for patient's inability to use the individual drugs

ADDITIONAL INFORMATION

- An inadequate clinical response is defined as the inability to reach A1C goal after at least 120 days of current regimen, with use of two or more drugs concomitantly per ADA guidelines, documented adherence, and appropriate dose escalation (must achieve maximum recommended dose or document that maximum recommended dose is not tolerated or is clinically inappropriate).
 - Must include a patient specific A1C goal if less than 7%
 - Must include current A1C (within last 6 months)
- For non-preferred drugs that have preferred drugs in the same drug class: must provide documentation that there was at least one inadequate clinical response with a drug in same drug class

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring
 - Must document A1C goal per ADA guidelines and A1C trends including current value (within last 6 months).

- Must include a patient specific A1C goal if less than 7%
 - Must include current A1C (within last 6 months)
- Must meet all initial clinical criteria for subsequent authorizations.

Endocrine Agents: Endometriosis

LENGTH OF AUTHORIZATIONS: 365 Days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

STEP THERAPY CRITERIA:

- Must have had an inadequate clinical response of at least 84 days with at least one preferred NSAID and one oral contraceptive

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 84 days with at least one preferred NSAID, one preferred oral contraceptive, **AND** one preferred step-therapy drug
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

Endocrine Agents: Estrogenic Agents

LENGTH OF AUTHORIZATIONS: 365 Days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 30 days with at least two preferred drugs
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

ADDITIONAL INFORMATION:

- Requests for non-preferred drugs must have an inadequate clinical response with preferred drugs with the same delivery method

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

Endocrine Agents: Growth Hormone

LENGTH OF AUTHORIZATIONS: Initial: 180 days; Subsequent: 365 days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

CLINICAL PA CRITERIA:

Pediatric Approvals (under 18 years of age):

- Must be treated and followed by a pediatric endocrinologist, nephrologist, clinical geneticist, endocrinologist, or gastroenterologist (or as appropriate for diagnosis)
- Must provide documentation to justify criteria being met, including height, weight, bone age (children), date and results of most current x-ray, stimulus test results, IGF-1 levels, and a growth chart (children)
- Must not be used in combination with another somatropin agent

Adult Approvals (18 years of age or older):

- Must be treated and followed by an endocrinologist
- Must provide documentation of growth hormone deficiency by means of a negative response to an appropriate stimulation test (clonidine test is not acceptable for adults)
- Must provide documentation of baseline evaluation of the following clinical indicators: (1) insulin-like growth factor (IGF-1); (2) fasting lipid profile; (3) BUN; (4) fasting glucose; (5) electrolyte levels; (6) evaluation of any new osteoarthritis and joint pain; (7) bone density test
- Must have had other hormonal deficiencies addressed with adequate replacement therapy

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 90 days with at least one preferred drug
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring (i.e., height, weight gain, improved body composition)
For adults: must provide documentation by endocrinologist that discontinuing agent would have a detrimental effect on body composition or other metabolic parameters

Endocrine Agents: Osteoporosis – Bone Ossification Enhancers

LENGTH OF AUTHORIZATIONS: 365 Days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

TERIPARATIDE (FORTEO™) CRITERIA:

- Must have had an inadequate clinical response of at least 365 days with one bisphosphonate
- A total lifetime duration of therapy of 730 days will be authorized between any parathyroid analog

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 365 days with at least one preferred drug within the same class
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

ADDITIONAL ABALOPARATIDE (TYMLOS™) CRITERIA:

- Must have had an inadequate clinical response of at least 365 days with one bisphosphonate
- A total lifetime duration of therapy of 730 days will be authorized between any parathyroid analog

ADDITIONAL INFORMATION

- Patients should only be on ONE of the therapeutic classes (bisphosphonates, calcitonin-salmon)

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

Endocrine Agents: Progestin Agents

All products are covered without a PA

Endocrine Agents: Uterine Fibroids

LENGTH OF AUTHORIZATIONS: Up to 180 Days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

CLINICAL PA CRITERIA:

- Must have had an inadequate clinical response of at least 90 days with at least one oral contraceptive

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 90 days with at least one preferred drug
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

ADDITIONAL INFORMATION:

- A total lifetime duration of therapy of 730 days between Oriahnn and Myfembree or 180 days for Lupron Depot will be authorized

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

Gastrointestinal Agents: Anti-Emetics

LENGTH OF AUTHORIZATIONS: 365 Days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 3 days with at least one preferred drug
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

Gastrointestinal Agents: Bowel Preparations

LENGTH OF AUTHORIZATIONS: 365 Days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any solid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a non-solid oral dosage formulation
- Must have had an inadequate clinical response with at least one preferred drug
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

Gastrointestinal Agents: Crohn's Disease

LENGTH OF AUTHORIZATIONS: 365 Days; Ortikos ER – based on indication

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 30 days with at least two preferred drugs
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

Gastrointestinal Agents: Hepatic Encephalopathy

LENGTH OF AUTHORIZATIONS: 365 Days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

STEP THERAPY CRITERIA:

- Must have had an inadequate clinical response of at least 14 days with at least one preferred drug

RIFAXAMIN (XIFAXAN) CRITERIA:

- Must have had an inadequate clinical response of at least 14 days to lactulose to be authorized for monotherapy or add on therapy

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 14 days with at least two preferred drugs
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

Gastrointestinal Agents: Irritable Bowel Syndrome (IBS) with Diarrhea

LENGTH OF AUTHORIZATIONS: 365 Days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

STEP THERAPY CRITERIA:

- Must have had an inadequate clinical response of at least 30 days with at least one preferred drug

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 30 days with at least two preferred drugs
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

Gastrointestinal Agents: Pancreatic Enzymes

LENGTH OF AUTHORIZATIONS: 365 Days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 14 days with at least one preferred drug
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

Gastrointestinal Agents: Proton Pump Inhibitors

LENGTH OF AUTHORIZATIONS: 180 days, except as listed under additional criteria

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 30 days with at least two preferred drugs
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

ADDITIONAL CRITERIA FOR PPI DOSES GREATER THAN ONCE DAILY

- For H. Pylori diagnosis: Must provide documentation of diagnosis
 - Authorization length: 30 days
- For any of the following diagnoses: carcinoma of GI tract, COPD, Crest Syndrome, dyspepsia, esophageal varices, gastritis, gastroparesis, scleroderma, symptomatic uncomplicated Barret's Esophagus, systemic mastocytosis, or Zollinger Ellison Syndrome: Must provide documentation of diagnosis **AND** must have failed once-daily dosing of the requested drug
 - Authorization length: 365 days

ADDITIONAL INFORMATION

- Request may be authorized if the drug was initiated in the hospital for the treatment of a condition such as a GI bleed or the presence of a gastrostomy and/or jejunostomy (G, GJ, J-tube)

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

AR – Protonix Pak/Pantoprazole Packet: a PA is required for patients 6 years and older

AR – Omeprazole & Pantoprazole Tab/Cap/ODT: a PA is required for patient 21 years and older requesting more than once daily dosing

Gastrointestinal Agents: Ulcerative Colitis

LENGTH OF AUTHORIZATIONS: 365 Days; except Uceris foam – based on indication

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 30 days with at least two preferred drugs
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

QL - Budesonide ER 9mg tablets: 56 tablets per 90 days

Gastrointestinal Agents: Unspecified GI

LENGTH OF AUTHORIZATIONS: 365 days except 3 days for Aemcolo

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

STEP THERAPY CRITERIA:

- Must have had an inadequate clinical response to at least 14 days with at least two preferred drugs

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 14 days with at least three preferred drugs, if indicated for diagnosis
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

ADDITIONAL METHYLNALTREXONE (RELISTOR) AND NALDEMEDINE (SYMPROIC) CRITERIA:

- Must have a history of chronic pain requiring continuous opioid therapy for ≥ 84 days

ADDITIONAL RIFAMYCIN DELAYED-RELEASE (AEMCOLO) CRITERIA:

- Must have the inability to take, or failure of **ALL** of the following: azithromycin, ciprofloxacin, levofloxacin, ofloxacin, or rifaximin

ADDITIONAL SOMATROPIN INJECTION (ZORBTIVE) AND TEDLOGLUTIDE (GATTEX) CRITERIA:

- Must have evidence of specialized parenteral nutritional support
- Must have documentation of appropriate lab assessment (bilirubin, alkaline phosphatase, lipase, and amylase) at least 180 days prior to initiation

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring (i.e., decreased frequency of specialized nutrition support or improvement in symptoms)

Genitourinary Agents: Benign Prostatic Hyperplasia

LENGTH OF AUTHORIZATIONS: 365 Days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

TADALAFIL (CIALIS) CRITERIA:

- Must have had an inadequate clinical response of at least 30 days with at least one alpha-1 adrenergic blocker. If prostate volume of > 30cc on imaging, a prostate specific antigen (PSA) > 1.5ng/dL, or palpable prostate enlargement on digital rectal exam (DRE), then a trial of at least 90 days of finasteride is required.

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 30 days with at least two preferred drugs
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

ADDITIONAL DUTASTERIDE/TAMSULOSIN (JALYN) & FINASTERIDE/TADALAFIL (ENTADFI) CRITERIA

- Must provide documentation for patient's inability to use the individual drugs

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

Genitourinary Agents: Electrolyte Depletor Agents

LENGTH OF AUTHORIZATIONS: 365 Days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 7 days with at least two preferred drugs
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

Genitourinary Agents: Urinary Antispasmodics

LENGTH OF AUTHORIZATIONS: 365 Days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 30 days with at least two preferred drugs with different active ingredients
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

AR – Vesicare LS: a PA is required for patients younger than 2 years old AND 5 years and older

AR – Myrbetriq Granules: a PA is required for patients younger than 3 years old AND 5 years and older

Immunomodulator Agents: Systemic Inflammatory Disease

LENGTH OF AUTHORIZATIONS: Initial: 90 days; Subsequent: 365 days

ALL AUTHORIZATIONS:

- Must be prescribed in accordance with FDA approved labeling
- First line treatment can vary based upon the severity of disease for certain diagnoses. Documentation of the patient's disease state and the criteria used to classify the severity is required.

CLINICAL PA CRITERIA:

- Must have been an inadequate clinical response of at least 90 days with at least two applicable first-line drugs indicated for diagnosis – provide documentation of the trialed drugs, dosages, dates, and durations
- Authorization of dosing regimens (loading/maintenance) will be based upon diagnosis. Document the requested loading and maintenance dosing on PA form, if applicable
- Must not have a current, active infection
- Must provide evidence of negative TB test prior to initiation of biologic therapy, if required by labeling

STEP THERAPY CRITERIA:

- Must have had an inadequate clinical response of at least 90 days with at least one preferred TNF inhibitor indicated for diagnosis

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 90 days with at least two preferred drugs, if indicated for diagnosis
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

ADDITIONAL ALOPECIA AREATA CRITERIA:

- Must be prescribed by or in consultation with a specialist (i.e., dermatologist, rheumatologist)

- Must provide documentation of an inadequate clinical response of at least 90 days with a topical steroid

ADDITIONAL ATOPIC DERMATITIS CRITERIA:

- Must have at least 10% body surface area (BSA) involvement with two of the following: topical corticosteroids or topical calcineurin inhibitors [e.g., Elidel] unless atopic dermatitis is severe and involves >25% BSA

ADDITIONAL CROHN'S DISEASE CRITERIA:

- Must provide documentation of Crohn's Disease Activity Index (CDAI) score of 220 or higher to be considered moderate to severe disease

ADDITIONAL HIDRADENTIS SUPPURATIVA CRITERIA:

- Must provide documentation of Hurley Stage III to be classified as severe disease

ADDITIONAL PLAQUE PSORIASIS CRITERIA:

- For patients currently receiving phototherapy, initial authorization for preferred drugs requires an inadequate clinical response to at least 90 days of phototherapy
- To classify as severe disease patient must present at least two of the following: Psoriasis Area and Severity Index (PASI) score ≥ 11 , BSA $\geq 10\%$, and Static Physician's Global Assessment (sPGA) ≥ 3

ADDITIONAL ULCERATIVE COLITIS CRITERIA:

- If an inadequate clinical response after 90 days with one TNF inhibitor, further TNF inhibitors will not be authorized

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

Infectious Disease Agents: Antibiotics – Cephalosporins

LENGTH OF AUTHORIZATIONS: Based on indication

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 3 days with at least one preferred antibiotic
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

ADDITIONAL INFORMATION

- Requests may be authorized if:
 - The infection is caused by an organism resistant to **ALL** preferred antibiotics (must provide diagnosis and any culture/sensitivity results)
 - The patient is completing a course of therapy that was started in the hospital or other similar location or was started before Medicaid eligibility, only the remaining course will be authorized

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment, ongoing safety monitoring, **AND** medical necessity for continued use

AR – Cefaclor Suspension: a PA is required for patients 12 years and older

AR – Cefixime Suspension: a PA is required for patients 12 years and older

AR – Cefprozil Suspension: a PA is required for patients 12 years and older

AR – Suprax Chewable Tablet: a PA is required for patients 12 years and older

Infectious Disease Agents: Antibiotics – Inhaled

LENGTH OF AUTHORIZATIONS: Initial: 180 days; Subsequent: 365 days

ALL REQUESTS: Must be prescribed in accordance with FDA approved labeling

CLINICAL PA CRITERIA:

- Must provide documentation of cultures demonstrating drug is prescribed in alignment with approved indication

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 28 days with at least one preferred drug
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring (i.e., culture conversion, symptom improvement)

QL – Tobramycin drugs: 56 doses in 56 days

Infectious Disease Agents: Antibiotics – Macrolides

LENGTH OF AUTHORIZATIONS: Based on indication

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 3 days with at least one preferred drug
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

ADDITIONAL INFORMATION

- Requests may be authorized if:
 - The infection is caused by an organism resistant to **ALL** preferred antibiotics (must provide diagnosis and any culture/sensitivity results)
 - The patient is completing a course of therapy that was started in the hospital or other similar location or was started before Medicaid eligibility, only the remaining course will be authorized

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment, ongoing safety monitoring, **AND** medical necessity for continued use

Infectious Disease Agents: Antibiotics – Quinolones

LENGTH OF AUTHORIZATIONS: Based on indication

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 3 days with at least one preferred drug
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

ADDITIONAL INFORMATION

- Requests may be authorized if:
 - The infection is caused by an organism resistant to **ALL** preferred antibiotics (must provide diagnosis and any culture/sensitivity results)
 - The patient is completing a course of therapy that was started in the hospital or other similar location or was started before Medicaid eligibility, only the remaining course will be authorized

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment, ongoing safety monitoring, **AND** medical necessity for continued use

AR – Ciprofloxacin Suspension: a PA is required for patients 12 years and older

Infectious Disease Agents: Antibiotics – Tetracyclines

LENGTH OF AUTHORIZATIONS: Based on indication for acute infections or 365 days for acne

ALL REQUESTS: Must be prescribed in accordance with FDA approved labeling

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 3 days with at least one preferred drug for acute infections **OR** at least 90 days with at least one preferred oral drug for acne
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

ADDITIONAL INFORMATION

- Requests may be authorized if:
 - The infection is caused by an organism resistant to **ALL** preferred antibiotics (must provide diagnosis and any culture/sensitivity results)
 - The patient is completing a course of therapy that was started in the hospital or other similar location or was started before Medicaid eligibility, only the remaining course will be authorized

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment, ongoing safety monitoring, **AND** medical necessity for continued use

AR – Vibramycin Suspension: a PA is required for patients 12 years and older

AR – Doxycycline Syrup: a PA is required for patients 12 years and older

Infectious Disease Agents: Antifungals

LENGTH OF AUTHORIZATIONS: Based on indication

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 7 days with at least two preferred drugs, if indicated for the diagnosis
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

ADDITIONAL OTESECONAZOLE (VIVJOA) CRITERIA:

- Must provide documentation of at least three symptomatic episodes of vulvovaginal candidiasis in the past 12 months
- Must provide documentation of non-reproductive potential (i.e., post-menopausal)
- Must have had an inadequate clinical response of at least 180 day maintenance course with oral fluconazole shown by documentation of more than one breakthrough infection

ADDITIONAL INFORMATION:

- Requests may be authorized if:
 - The infection is caused by an organism resistant to **ALL** preferred antifungals (must provide diagnosis and any culture/sensitivity results)
 - The patient is completing a course of therapy that was started in the hospital or other similar location or was started before Medicaid eligibility, only the remaining course will be authorized

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment, ongoing safety monitoring, **AND** medical necessity for continued use

Infectious Disease Agents: Antivirals – Hepatitis C Agents

LENGTH OF AUTHORIZATIONS: Dependent upon authorized course

ALL REQUESTS: Must be prescribed in accordance with FDA approved labeling.

CLINICAL PA CRITERIA:

- Only regimens recommended by the American Association for the Study of Liver Diseases (AASLD) will be authorized
- Please see the [Hepatitis C Direct Acting Antiviral Prior Authorization Form](#) for criteria

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response defined as not achieving SVR with guideline-recommended preferred drugs
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

ADDITIONAL INFORMATION:

- Requests for patients established on current therapy with prior payer (i.e., Commercial, Fee-for-Service, Managed Care Plan, etc) will be authorized with documentation
- Requests for regimens including pegylated Interferons must include close monitoring with periodic clinical and laboratory evaluations
- Requests for regimens including ribavirins must include documentation of at least two reliable forms of contraception being used during therapy

Infectious Disease Agents: Antivirals – Herpes

LENGTH OF AUTHORIZATIONS: For the duration of the prescription (up to 180 days)

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 3 days with at least one preferred drug
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

Infectious Disease Agents: Antivirals – HIV*

LENGTH OF AUTHORIZATIONS: 365 Days

GRANDFATHERING*:

Patients who have a claim for a non-preferred drug in the previous 120 days will be automatically approved to continue the drug. Patients who have taken the drug previously, but do not have claims history (e.g., new to Medicaid), will need to submit a prior authorization in order to continue coverage.

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

ABACAVIR/DOLUTEGRAVIR/LAMIVUDINE (TRIUMEQ PD) CRITERIA:

- Must provide documentation of patient's weight (only authorized for those 10 – 25 kg)

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 30 days with at least one preferred drug. If applicable, the request must address the inability to use the individual components.
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

AR – Isentress chewable tablet: a PA is required for patients 12 years and older

AR – Lamivudine solution: a PA is required for patients 3 years and older

AR – Nevirapine solution: a PA is required for patients 3 years and older

Ophthalmic Agents: Antibiotic and Antibiotic-Steroid Combination Drops and Ointments

LENGTH OF AUTHORIZATIONS: 30 days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 3 days with at least two preferred drugs
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

ADDITIONAL INFORMATION

- Requests may be authorized if:
 - The infection is caused by an organism resistant to **ALL** preferred antibiotics (must provide diagnosis and any culture/sensitivity results)
 - The patient is completing a course of therapy that was started in the hospital or other similar location or was started before Medicaid eligibility, only the remaining course will be authorized

Ophthalmic Agents: Antihistamines & Mast Cell Stabilizers

LENGTH OF AUTHORIZATIONS: 365 Days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 14 days with at least two preferred drugs
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

Ophthalmic Agents: Dry Eye Treatments

LENGTH OF AUTHORIZATIONS: 14 Days for Eysuvis; 365 Days for all other drugs

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

STEP THERAPY CRITERIA:

- Must have had an inadequate clinical response of at least 14 days with one artificial tear or OTC dry eye drop in the previous 120 days

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 14 days with at least one preferred drug
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

Ophthalmic Agents: Glaucoma Agents

LENGTH OF AUTHORIZATIONS: 365 Days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

STEP THERAPY CRITERIA:

- Must have had an inadequate clinical response of at least 30 days with at least one preferred drug in the same class, if available

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 30 days with at least two preferred drugs in the same class, if available
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

Ophthalmic Agents: NSAIDs

LENGTH OF AUTHORIZATIONS: 30 days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling_

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 3 days with at least one preferred drug
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

Ophthalmic Agents: Ophthalmic Steroids

LENGTH OF AUTHORIZATIONS: 30 days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 14 days with at least two preferred drugs
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

Otic Agents: Antibacterial and Antibacterial/Steroid Combinations

LENGTH OF AUTHORIZATIONS: 30 days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 7 days with at least one preferred drug
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

Respiratory Agents: Antihistamines – Second Generation

LENGTH OF AUTHORIZATIONS: 365 Days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 30 days with at least two different preferred drugs
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

AR – Cetirizine Chewables: a PA is required for patients 6 years and older

Respiratory Agents: Cystic Fibrosis

LENGTH OF AUTHORIZATIONS: Initial: 90 days; Subsequent: 365 days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

CLINICAL PA CRITERIA:

- Must be prescribed by or in consultation with a pulmonologist or infectious disease specialist
- Must provide documentation of the genetic mutation

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 30 days with at least one preferred drug
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

ADDITIONAL BRONCHITOL CRITERIA:

- Must be used as an add-on maintenance therapy
- Must provide documentation of a completed Bronchitol Tolerance Test

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment (adherence to treatment demonstrated by claims history **AND** one or more of the following: FEV1, weight gain, sweat chloride, pulmonary exacerbations, etc.) and ongoing safety monitoring

AR – Trikafta Pak: a PA is required for patients 6 years and older

Respiratory Agents: Epinephrine Auto-Injectors

LENGTH OF AUTHORIZATIONS: 365 Days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response to at least one preferred drug
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

Respiratory Agents: Hereditary Angioedema

LENGTH OF AUTHORIZATIONS: Initial: 90 days; Subsequent: 180 Days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

CLINICAL PA CRITERIA:

- Must provide documentation of diagnosis (i.e., C1-INH deficiency or dysfunction (Type I or II HAE)) and whether the drug will be used for prophylaxis or treatment
- Must provide documentation of at-home administration

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 60 days with at least one preferred drug
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

Respiratory Agents: Inhaled Agents

LENGTH OF AUTHORIZATIONS: 365 Days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 14 days with at least two preferred drugs within the same class and duration of action
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

ADDITIONAL STEROID-CONTAINING INHALER CRITERIA

- May be authorized if documentation of one of the following is provided:
 - Patient is 12 years or younger OR is disabled and is unable to use a preferred inhaler
 - Patient has been non-compliant on a preferred inhaler due to taste, dry mouth, or infection
 - Patient is clinically unstable, as defined by current guidelines in terms of oral steroid use or patient's current symptomatology

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

AR – Albuterol Nebulizer Solution 0.021% (0.63mg/3mL), 0.042% (1.25mg/3mL): a PA is required for patients 13 years and older

AR – Budesonide Nebulizer Solution: a PA is required for patients 7 years and older

Respiratory Agents: Leukotriene Receptor Modifiers & Inhibitors

LENGTH OF AUTHORIZATIONS: 365 Days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

STEP THERAPY CRITERIA:

- Must have had an inadequate clinical response of at least 90 days with at least one preferred drug

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 90 days with at least two preferred drugs
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

Respiratory Agents: Monoclonal Antibodies-Anti-IL/Anti-IgE

LENGTH OF AUTHORIZATIONS: Initial: 180 days; Subsequent: 365 days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

CLINICAL PA CRITERIA:

- Must be prescribed by or in consultation with an applicable specialist (i.e., allergist/immunologist, pulmonologist, or otolaryngologist)
- For **Asthma** – Must have had uncontrolled asthma symptoms and/or exacerbations despite at least 30 days with:
 - Medium dose preferred ICS/LABA inhaler for 6 years and older **OR** medium dose preferred ICS/LABA inhaler with tiotropium or high dose ICS/LABA inhaler if 12 years and older
- For **Chronic Rhinosinusitis with Nasal Polyposis** – Must have had an inadequate clinical response of at least 30 days to at least one oral corticosteroid **AND** one nasal corticosteroid spray
- For **Chronic Urticaria** – Must have had an inadequate clinical response to at least 14 days with at least two different antihistamines

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 90 days with at least one preferred drug
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics, requests must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring (i.e., PFT improvement, reduced affected BSA)

Respiratory Agents: Nasal Preparations

LENGTH OF AUTHORIZATIONS: 365 days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 30 days with at least two preferred drugs in the same class, if available
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

Respiratory Agents: Other Agents

LENGTH OF AUTHORIZATIONS: Initial: 90 days; Subsequent: 180 days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 90 days with at least one preferred long-acting beta agonist **AND** one preferred long-acting muscarinic antagonist-containing inhalers
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

ADDITIONAL ROFLUMILAST (DALIRESP) CRITERIA:

- Must be used in addition to a long-acting beta agonist **AND** a long-acting muscarinic antagonist-containing inhalers

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment, adherence to maintenance inhaler per pharmacy claims, and ongoing safety monitoring

Topical Agents: Antifungals

LENGTH OF AUTHORIZATIONS: Up to 180 days for all agents except 365 days for Jublia

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 14 days with at least two preferred drugs, if indicated for diagnosis
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

ADDITIONAL EFINACONAZOLE (JUBLIA) CRITERIA:

- Must have had an inadequate clinical response of at least 365 days with at least one preferred topical drug **AND** at least 84 days with at least one preferred oral drug indicated for diagnosis

ADDITIONAL INFORMATION

- Requests may be authorized if:
 - The infection is caused by an organism resistant to preferred antibiotics drugs (note diagnosis and any culture/sensitivity results)

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

Topical Agents: Antiparasitics

LENGTH OF AUTHORIZATIONS: 14 Days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 14 days with at least one preferred drug
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

Topical Agents: Corticosteroids

LENGTH OF AUTHORIZATIONS: 365 days for low/med potency; 90 days for high/very high potency

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 14 days with at least two preferred drugs
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

Topical Agents: Immunomodulators

LENGTH OF AUTHORIZATIONS: 365 Days

ALL AUTHORIZATIONS: Must be prescribed in accordance with FDA approved labeling

STEP THERAPY CRITERIA:

- Must have had an inadequate clinical response of at least 30 days with at least two topical corticosteroids

NON-PREFERRED CRITERIA:

- Must provide documentation of medical necessity beyond convenience for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) **OR**
 - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least 30 days with at least one preferred drug
 - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
 - For non-preferred brand names that have preferred generics: must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

SUBSEQUENT AUTHORIZATION CRITERIA:

- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring

AR – pimecrolimus and tacrolimus: a PA is required for patients younger than 2 years old