
Ohio Medicaid

Pharmacy Benefit Management Program



**Department of
Medicaid**

Unified Preferred Drug List

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

Effective April 1, 2021

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Analgesic Agents: NSAIDs

LENGTH OF AUTHORIZATIONS:

Dependent on medication request

NSAID Type	Approval Criteria	Approval Length
Non-Gastroprotective NSAIDs	no less than a <u>30-day</u> trial of at least <u>two</u> non-gastroprotective NSAID medications	365 days
Gastroprotective	patient is undergoing surgical or other medical procedures that may predispose them to potential bleeding complications.	60 days
Gastroprotective	patient is being treated for H. pylori.	30 days
Transdermal/Topical	diclofenac solution: no less than a <u>30-day</u> trial of at least <u>one</u> preferred topical NSAID medications within the past 180 days	90 days

PDL CRITERIA:

Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:

- ☐ Allergy to all medications not requiring prior approval
- ☐ Contraindication to or drug-to-drug interaction with medications not requiring prior approval. Acceptable contraindications for GASTROPROTECTIVE NSAIDs include:
 - Concurrent or history of a GI event (perforation, ulcer, bleed)
 - Other risks for treatment with NON-GASTROPROTECTIVE NSAIDs:
 - Coagulation disorders (i.e. hemophilia, chronic liver disease), erosive esophagitis
 - Documented NSAID-induced ulcer
 - Peptic ulcer disease (PUD)
 - Patient on warfarin or heparin
 - Patient on oral corticosteroids
 - Patient on methotrexate
- ☐ History of unacceptable/toxic side effects to medications not requiring prior approval

ADDITIONAL INFORMATION

The requested medication may be approved if the following is true:

1. The medication is prescribed for an approved indication
2. There has been a therapeutic failure as defined as:
 - NON-GASTROPROTECTIVE NSAIDS:
 - no less than a 30-day trial of at least two non-gastroprotective NSAID medications

OR
 - GASTROPROTECTIVE NSAIDS:
 - no less than a 30-day trial of a non-gastroprotective NSAID medication.

OR

- patient is undergoing surgical or other medical procedures that may predispose them to potential bleeding complications.

OR

- patient is being treated for H. pylori.
- TRANSDERMAL/TOPICAL:
- no less than a 30-day trial of at least one preferred topical NSAID medications within the past 180 days

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

AR – Celecoxib: a PA is required for patients younger than 60 years old

Analgesic Agents: Gout

LENGTH OF AUTHORIZATIONS: 365 Days

Is there any reason the patient cannot be changed to an agent not requiring prior approval?

Acceptable reasons include:

- ☐ Allergy to medications not requiring prior approval
- ☐ Contraindication to or drug-to-drug interaction with medications not requiring prior approval.
- ☐ History of unacceptable/toxic side effects to medications not requiring prior approval

ADDITIONAL INFORMATION

The requested medication may be approved if the following is true:

- ☐ Febuxostat will be approved after 30-day trial of maximum allopurinol dose, or intolerance/contraindication to allopurinol.
 - ☐ Colchicine will be approved if any one of the following is true:
 - Diagnosis of Familial Mediterranean Fever (FMF) (180-day approval); OR
 - Trial of one of the following within the last 30 days:
 - NSAID (i.e., indomethacin, naproxen, ibuprofen, sulindac, ketoprofen)
 - Oral corticosteroid
 - ☐ Gloperba will be approved if the member is unable to swallow colchicine tablets or capsules and if all of following are met:
 - Member is using Gloperba for the prevention of gout flares
 - Trial of one of the following within the last 30 days:
 - NSAID (i.e., indomethacin, naproxen, ibuprofen, sulindac, ketoprofen)
 - Oral corticosteroid
- * Colchicine quantity limit 6/claim for acute gout, 60/30 days for chronic gout after trial on xanthine oxidase inhibitor, 120/30 days for FMF
- * Gloperba quantity limit is 1.2 mg per day

Analgesic Agents: Opioids

LENGTH OF AUTHORIZATIONS:

For the course of therapy, up to 180 days

- ☐ There must have been an inadequate clinical response to preferred alternatives, including a trial of no less than 7 days of one preferred product.

OTHER APPROVAL CRITERIA:

Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:

- ☐ Allergy to at least two unrelated medications not requiring prior approval
- ☐ Contraindication to or drug-to-drug interaction with medications not requiring prior approval
- ☐ History of unacceptable/toxic side effects to medications not requiring prior approval
- ☐ Patient must have failed the generic product (if covered by the state) before brand is authorized, in addition to the above.

ADDITIONAL CRITERIA FOR EXCEEDING SHORT-ACTING OPIOID NEW START CRITERIA

- ☐ System will define “new start” as having less than a 1-day supply of opioids in the previous 90 days
- ☐ Patients receiving short-acting opioids for certain conditions are exempt from these requirements: active cancer treatment, palliative care, and end-of-life/hospice care, sickle cell, severe burn, traumatic crushing of tissue, amputation, major orthopedic surgery
- ☐ Attestation that patient is not opioid naïve will exempt patients from these requirements, for example:
 - If patient is newly eligible for Medicaid and there is no prior claims data
 - If patient was on a higher dose in the hospital
- ☐ To exceed acute opioid limits patient must have:
 - Tried and failed non-pharmacologic treatments and/or non-opioid analgesics ineffective or contraindicated
 - Diagnosis code must be submitted and should be for somatic type pain
 - Benefits and risks of opioid therapy have been discussed with patient (attestation documented on prior authorization form)
 - Prescriber has checked OARRS (attestation documented on prior authorization form)
- Length of authorization: Up to 90 days, depending on the indication, previous patient utilization, and requested length of therapy (could be more restrictive)

ADDITIONAL CRITERIA FOR TRANSMUCOSAL FENTANYL:

- ☐ Diagnosis of cancer pain; and
- ☐ Prescription is from oncologist or pain specialist; and
- ☐ Concurrently taking a long-acting opioid at therapeutic dose (any of the following for ≥ 1 week without adequate pain relief):
 - ☐ ≥ 60 mg oral morphine/day, or
 - ☐ ≥ 25 mcg/hr transdermal fentanyl, or
 - ☐ ≥ 30 mg oral oxycodone/day, or
 - ☐ ≥ 8 mg oral hydromorphone/day, or
 - ☐ ≥ 25 mg oral oxymorphone/day, or
 - ☐ Equianalgesic dose of another opioid; and
- ☐ Dose is ≤ 4 units per day

ALL LONG-ACTING OPIOIDS REQUIRE PRIOR AUTHORIZATION:

- ☐ Initial request (90-day approval)
 - ☐ Catastrophic injury or cancer pain does not require additional documentation (documentation should be provided as part of prior authorization form)
 - ☐ All other causes of pain:
 - Documented treatment plan including risk assessment, substance abuse history, concurrent therapies
 - OARRS checked within 7 days prior to initiating long-acting therapy
 - Documentation of pain and function scores at each visit
 - Baseline urine drug test submitted and treatment plan includes requirements for random urine screens
 - Opioid contract required to be in place and should be submitted with prior authorization form
 - Documented failure of both non-opioid pharmacologic and non-pharmacologic treatments
 - History of short-acting opioids for ≥ 60 days
 - Daily Dose ≤ 80 MED
- ☐ Renewal requests (after initial 90 days then every 180 days)
 - ☐ Current treatment plan
 - ☐ Demonstrated adherence to treatment plan through progress notes including pain and function scores and random urine screens results reviewed and concerns addressed, no serious adverse outcomes observed
- ☐ Dose escalation requests
 - ☐ Prescriber indicates escalation of dose is likely to result in improved function and pain control
 - ☐ Daily Dose >100 MED requires pain specialist or anesthesiologist consultation

Effective July 1, 2018, patients with short acting opioid therapy will be limited to 30 MED per prescription and a maximum of 7 days per prescription. Prior authorization will be required to exceed these limits

Blood Formation, Coagulation, and Thrombosis Agents: Hematopoietic Agents

LENGTH OF AUTHORIZATIONS:

Dependent on diagnosis

ALL PRODUCTS IN THIS CLASS REQUIRE CLINICAL PRIOR AUTHORIZATION:

Approval of epoetin alfa or darbepoetin:

Diagnosis	Hemoglobin Level	Approval 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

Approval of epoetin alfa only (not darbepoetin):

Diagnosis	Hemoglobin Level	Approval Length
Autologous blood donation, patient will require blood transfusions	>10, <=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

PDL CRITERIA:

- Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
 - ☐ Allergy to medications not requiring prior approval
 - ☐ Contraindication to all medications not requiring prior approval
 - ☐ History of unacceptable/toxic side effects to medications not requiring prior approval
- Has the patient failed a therapeutic trial of 14 days with one preferred medication?

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

LENGTH OF AUTHORIZATIONS:

Approval based upon diagnosis:

Diagnosis	Approval 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 PRODUCTS IN THIS CLASS REQUIRE CLINICAL PRIOR AUTHORIZATION:

Requested medication must be used for an approved FDA indication and duration

CRITERIA:

- Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
 - ☐ Allergy to medications not requiring prior approval
 - ☐ Contraindication to all medications not requiring prior approval
 - ☐ History of unacceptable/toxic side effects to medications not requiring prior approval
- Has the patient failed a therapeutic trial of 14 days with one preferred medication?

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 approved to continue the drug through the automated PA system. Patients who have taken the drug previously, but do not have claims history (e.g. new to Medicaid), will be approved for PA after prescriber contact.

ALL PRODUCTS IN THIS CLASS REQUIRE CLINICAL PRIOR AUTHORIZATION:

Approval based upon diagnosis and dosage appropriate to weight, patient pharmacokinetic factors, and presence of inhibitors.

PDL CRITERIA:

1. Is there any reason the patient cannot use a medication not requiring prior approval?
Acceptable reasons include:
 - ☐ Allergy to medications not requiring prior approval
 - ☐ Contraindication to all medications not requiring prior approval
 - ☐ History of unacceptable/toxic side effects to medications not requiring prior approval
2. Has the patient trialed one preferred medication?
3. For extended half-life factors, prescribing physician attests that patient is not a suitable candidate for treatment with shorter-acting half-life product.
4. If Rebinyn is requested, confirmation that it is not being used for routine prophylaxis

ADDITIONAL CRITERIA FOR EMICIZUMAB-KXWH (HEMLIBRA)

- ☐ Indicated for hemophilia A (factor VIII deficiency):
 - Patient has factor VIII inhibitors or hemophilia A without inhibitors with documented failure to meet clinical goals (e.g., continuation of spontaneous bleeds, inability to achieve appropriate trough level previous history of inhibitors) after a trial of prophylactic factor VIII replacement products.
 - Patient will not use concurrently with activated prothrombin complex concentrate (aPCC).
 - Dose not exceed no more than 6 mg/kg per month in aggregate.

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

LENGTH OF AUTHORIZATIONS:

Varies based on criteria below

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
 - ☐ Allergy to medications not requiring prior approval
 - ☐ Contraindication to all medications not requiring prior approval
 - ☐ History of unacceptable/toxic side effects to medications not requiring prior approval
2. Has the patient failed a therapeutic trial of 14 days with a medication not requiring prior approval?

DURATION OF THERAPY LIMIT:

35 days

Guidelines from the American College of Chest Physicians limit duration of therapy in the outpatient setting for most indications to less than five weeks. Patients should be transitioned to oral warfarin as soon as possible.

Is there any reason the patient cannot be changed to oral warfarin? Acceptable reasons include:

- ☐ patients with cancer (approved up to 180 days),
- ☐ pregnant women (approved up to 280 days), or
- ☐ patients unable to take warfarin (approved up to 180 days).

Blood Formation, Coagulation, and Thrombosis Agents: Oral Anticoagulants

INDICATION AND LENGTH OF AUTHORIZATION:

Requested medication must be used for an approved FDA indication and duration

APPROVAL CRITERIA:

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
 - ☐ Allergy to medications not requiring prior approval
 - ☐ Contraindication to all medications not requiring prior approval
 - ☐ History of unacceptable/toxic side effects to medications not requiring prior approval
2. Has the patient failed a therapeutic trial of 14 days with two medications in the same class not requiring prior approval?

Cardiovascular Agents: Angina, Hypertension & Heart Failure

LENGTH OF AUTHORIZATIONS: 365 Days

HYPERPOLARIZATION-ACTIVATED CYCLE NUCLEOTIDE-GATED CHANNEL INHIBITOR CLINICAL PRIOR AUTHORIZATION CRITERIA:

Ivabradine (Corlanor) may be approved if all of the following are met:

1. Diagnosis of stable, symptomatic heart failure, and
2. Left ventricular ejection fraction less than or equal to 35%, and
3. Resting heart rate 70 bpm or higher, and
4. Patient in sinus rhythm, and
5. Heart failure symptoms persisting with maximally tolerated doses of beta blockers, or patient has a contraindication to beta blocker therapy.

ARB/ NEPRILYSIN INHIBITOR COMBINATION CLINICAL PRIOR AUTHORIZATION CRITERIA:

Valsartan/sacubitril (Entresto™) may be approved if all the following are met:

1. Diagnosis of chronic heart failure (NYHA Class II-IV), and
2. Left ventricular ejection fraction less than or equal to 40%

ALISKIREN AND TEKTRINA HCT CRITERIA:

Aliskiren and Tekturna HCT may be approved if all the following are met:

1. A 30-day trial of any one preferred anti-hypertensive agent

OTHER APPROVAL CRITERIA:

1. Is there any reason the patient cannot be changed to a preferred medication? Acceptable reasons include:
 - ☐ Allergy to medications not requiring prior approval
 - ☐ Contraindication to or drug interaction with preferred medications
 - ☐ History of unacceptable/toxic side effects to preferred medications
2. The requested medication may be approved if both of the following are true:
 - ☐ If there has been a therapeutic failure to no less than a 30-day trial of at least two medication within the same class not requiring prior approval
 - ☐ The requested medication's corresponding generic (if covered by the state) has been attempted and failed or is contraindicated
3. If there is a specific indication for a medication requiring prior approval, for which medications not requiring prior approval are not indicated, then may approve the requested medication. This medication should be reviewed for need at each request for reauthorization.
4. Nimodipine only approvable for 21 days after subarachnoid hemorrhage

Cardiovascular Agents: Antiarrhythmics

LENGTH OF AUTHORIZATIONS:

365 Days

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
 - ☐ Allergy to medications not requiring prior approval
 - ☐ Contraindication to all medications not requiring prior approval
 - ☐ History of unacceptable/toxic side effects to medications not requiring prior approval
2. Has the patient failed a therapeutic trial of 30 days with one medication not requiring prior approval?

Cardiovascular Agents: Lipotropics

LENGTH OF AUTHORIZATIONS: 365 days all Lipotropics except Omega-3 Fatty Acid 60 days for Omega-3 Polyunsaturated Fatty Acid

Trial period	30 days for HMG-CoA Reductase Inhibitors, Niacin derivatives, ezetimibe (Zetia), 90 days for Fibrates, 12 weeks for PCSK9 Inhibitors and 12 weeks for ATP Citrate Lyase (ACL) Inhibitors
Number of non-PA agents	1 medication – The assumption is that the medication must be in the same class of the medication requested, if available, except for HMG-CoA reductase inhibitors- see specific criteria

GENERAL GUIDELINES:

- ☐ Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
 - ☐ Allergy to medications not requiring prior approval
 - ☐ Contraindication to or drug-to-drug interaction with medications not requiring prior approval (pravastatin is the only HMG-CoA not metabolized by the cytochrome P450 liver enzyme system)
 - ☐ History of unacceptable/toxic side effects to medications not requiring prior approval
- ☐ If there has been a therapeutic failure to no less than two of the HMG-CoA preferred products for a 30-day trial, then a non-preferred HMG-CoA agent will be authorized.

ADDITIONAL CRITERIA FOR OMEGA-3 POLYUNSATURATED FATTY ACID AND ICOSAPENT ETHYL (LOVAZA, VASCEPA):

- ☐ Prescription-only omega-3 polyunsaturated fatty acid and icosapent ethyl are approvable only for adult patients with triglyceride levels equal to or greater than 500 mg/dL who have been unable to lower triglyceride levels with fibrates, niacin, or lifestyle changes including diet and exercise.
- ☐ Medications known to increase triglycerides (beta blockers, thiazides, and estrogens) must be discontinued or changed, if clinically appropriate, before the drug is approved. Initial approval will be for 60 days, with evidence of reduced triglycerides required for re-approval.

ADDITIONAL CRITERIA FOR COLESEVELAM (WELCHOL):

- ☐ Colesevelam may be approved as first-line therapy if there is a diagnosis of diabetes
- ☐ Will be approved through systematic PA if there is a history of an oral hypoglycemic or insulin in the previous 120 days

ADDITIONAL CRITERIA FOR PCSK9 INHIBITORS:

- ☐ All products in this class require clinical prior authorization:
 - ☐ Age ≥ 18 years or Age ≥ 13 years and Homozygous Familial Hypercholesterolemia (HoFH)
 - ☐ Documented adherence to prescribed lipid lowering medications for previous 90 days

Baseline lab results are required, and approvals will be limited to 12 weeks initially and then annually thereafter. Subsequent approvals will require additional levels being done to assess changes.

- Lipid profile required at week 8 for HeFH or ASCVD
- Lipid profile required after 3rd dose for HoFH

Diagnosis of Heterozygous Familial Hypercholesterolemia (HeFH): must meet both:

1. Total Cholesterol > 290 mg/dL or LDL-C > 190 mg/dL and one of the following:
 - Presence of tendon xanthomas or 1st or 2nd degree relative with documented tendon xanthomas, MI at age ≤ 60 years or TC > 290 mg/dL**OR**
 - Confirmation of diagnosis by gene or receptor testing
2. Unable to reach goal LDL-C with maximally tolerated dose of statin
 - A trial of 2 or more statins, at least one must be atorvastatin

Diagnosis of Clinical Atherosclerotic Cardiovascular Disease: must meet both:

1. History of MI, angina, coronary or other arterial revascularization, stroke, TIA or PVD of atherosclerotic origin and
2. Unable to reach goal LDL-C with maximally tolerated dose of statin
 - A trial of 2 or more statins, at least one must be atorvastatin

Diagnosis of Homozygous Familial Hypercholesterolemia (HoFH): must meet all:

1. Total cholesterol and LDL-C > 600 mg/dL and TG within reference range or confirmation of diagnosis by gene or receptor testing
2. Unable to reach goal LDL-C with maximally tolerated dose of statin plus ezetimibe (Zetia) 10 mg daily with at least 1 other concurrently administered lipid lowering agent
3. Age ≥ 13 years old

ADDITIONAL CRITERIA FOR ATP Citrate Lyase (ACL) Inhibitor:

- All products in this class require clinical prior authorization:
 - Age ≥ 18 years
 - A trial and failure with one PCSK9 inhibitor
 - Unable to reach goal LDL-C after a trial of 2 or more statins (one must be atorvastatin) at the maximally tolerated dose
 - Nexlizet™ (bempedoic acid and ezetimibe tablet) approval requires one of the previous statin trials to be in combination with ezetimibe (Zetia)
 - Documented adherence to prescribed lipid lowering medications for previous 90 days
 - Baseline lab results are required, and approvals will be limited to 12 weeks initially and then annually thereafter. Subsequent approvals will require additional levels being done to assess changes
 - Lipid profile required at week 8 for HeFH or ASCVD

Diagnosis of Heterozygous Familial Hypercholesterolemia (HeFH): must meet both:

1. Total Cholesterol > 290 mg/dL or LDL-C > 190 mg/dL and one of the following:
 - o Presence of tendon xanthomas or 1st or 2nd degree relative with documented tendon xanthomas, MI at age \leq 60 years or TC > 290 mg/dL
- OR**
- o Confirmation of diagnosis by gene or receptor testing

Diagnosis of Clinical Atherosclerotic Cardiovascular Disease:

1. History of MI, angina, coronary or other arterial revascularization, stroke, TIA or PVD of atherosclerotic origin

Cardiovascular Agents: Pulmonary Arterial Hypertension

LENGTH OF AUTHORIZATIONS:

365 Days

All products in this class require clinical prior authorization: Diagnosis of pulmonary arterial hypertension

GRANDFATHERING:

Patients who have a claim for a non-preferred drug in the previous 120 days will be automatically approved to continue the drug through the automated PA system. Patients who have taken the drug in the previous 120 days, but do not have claims history (e.g. new to Medicaid), will be approved for PA after prescriber contact.

GENERAL GUIDELINES:

1. Patients who have class 3 or 4 symptoms defined by the NYHA Functional Class for Pulmonary Hypertension may be approved for inhalation or intravenous agents
2. Riociguat (Adempas) may be approved for patients with persistent/recurrent Chronic Thromboembolic Pulmonary Hypertension (CTEPH) (WHO Group 4) who have had surgical treatment or have inoperable CTEPH.
3. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
 - ☐ Allergy to medications not requiring prior approval
 - ☐ Contraindication to all medications not requiring prior approval
 - ☐ History of unacceptable/toxic side effects to medications not requiring prior approval
4. Has the patient failed a therapeutic trial of at least 30 days with at least two medications, one of which is a Phosphodiesterase-5 Inhibitor, not requiring prior approval?

AR - Sildenafil oral solution: a PA is required for patients over 6 years old

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 through the automated PA system. Patients who have taken the drug in the previous 120 days, but do not have claims history (e.g. new to Medicaid), will be approved for PA after prescriber contact.

OTHER APPROVAL CRITERIA:

Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:

- ☐ Allergy to medications not requiring prior approval
- ☐ Contraindication to or drug-to-drug interaction with medications not requiring prior approval
- ☐ History of unacceptable/toxic side effects to medications not requiring prior approval
- ☐ Has the patient failed a therapeutic trial of at least 30 days with at least two medications not requiring prior approval?

ADDITIONAL CRITERIA FOR DONEPEZIL ODT (ARICEPT) & RIVASTIGMINE PATCH (EXELON):

May be approved first-line for a patient who is unable to swallow.

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

LENGTH OF AUTHORIZATIONS: 180 Days

APPROVAL CRITERIA:

- Is there any reason the patient cannot be changed to a medication not requiring prior approval?
Acceptable reasons include:
 - Allergy to preferred medications
 - Contraindication to all preferred medications
 - History of unacceptable/toxic side effects to at least two preferred medications
- **STEP THERAPY APPROVAL CRITERIA:**
 - For a drug requiring step therapy, there must have been inadequate clinical response to preferred alternatives, including a trial of at least two weeks with at least two medications not requiring prior approval
 - For a non-preferred drug, there must have been inadequate clinical response to preferred alternatives, including a trial of at least two weeks with at least one medication requiring step therapy

ADDITIONAL INFORMATION

In addition to utilizing a preferred agent when applicable, the number of tablets/doses allowed per month is restricted based on the manufacturer's package insert.

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

LENGTH OF AUTHORIZATIONS:

180 Days

APPROVAL CRITERIA:

- Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
 - Allergy to preferred medications
 - Contraindication to all preferred medications
 - History of unacceptable/toxic side effects to at least one preferred medication

ADDITIONAL CRITERIA FOR EPISODIC CLUSTER HEADACHE

1. At least 5 attacks within 30 days
2. Attacks characterized by severe or very severe unilateral orbital, supraorbital and/or temporal pain lasting 15 to 180 minutes when untreated; during part (but less than half) of the time-course of cluster headache, attacks may be less severe and/or of shorter or longer duration
3. Patient must have one or more of the following symptoms:
 - a) At least one of the following ipsilateral to the headache:
 - I. Conjunctival injection and/or lacrimation
 - II. Nasal congestion and/or rhinorrhea
 - III. Eyelid edema
 - IV. Forehead and facial sweating
 - V. Miosis and/or ptosis
 - b) A sense of restlessness or agitation
4. Attacks have a frequency between one every other day and eight per day; during part (but less than half) of the active time-course of cluster headache, attacks may be less frequent
5. Not better accounted for by another ICHD-3 diagnosis
6. At least two cluster periods lasting from seven days to one year (when untreated) and separated by pain-free remission periods of 90 days or more
7. Failure or intolerance to verapamil titrated at least to a dose of 480 mg daily (may need to be combined with glucocorticoids as adjunctive therapy for more rapid relief until verapamil is titrated)

ADDITIONAL INFORMATION

In addition to utilizing a preferred agent when applicable, the number of tablets/doses allowed per month is restricted based on the manufacturer's package insert.

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

LENGTH OF AUTHORIZATIONS:

Initial Authorization 180 days

Subsequent Authorizations 365 days

APPROVAL CRITERIA:

- Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
 - Allergy to preferred medications
 - Contraindication to three preferred medications
 - History of unacceptable/toxic side effects to at least three preferred medications

STEP THERAPY REQUIRED PREFERRED MEDICATION:

- For a drug requiring step therapy, there must have been inadequate clinical response to a trial of at least 30 days each to at least 3 controller migraine medications or has experienced contraindications or intolerance to them (i.e., beta-blockers, anticonvulsants, tricyclic antidepressants, and/or serotonin-norepinephrine reuptake inhibitors).

NON-PREFERRED MEDICATION:

- For a non-preferred medication drug there must have been inadequate clinical response to a trial of at least 30 days each to at least 3 controller migraine medications or has experienced contraindications or intolerance to them (i.e., beta-blockers, anticonvulsants, tricyclic antidepressants, and/or serotonin-norepinephrine reuptake inhibitors) AND an inadequate clinical response to a trial of at least 30 days of one step therapy required preferred medication

ADDITIONAL CRITERIA FOR MIGRAINE PROPHYLAXIS:

1. Patient must have one of the following diagnoses:
 - a. **Episodic** migraine with the following frequencies of migraine:
 - I. 4-15 headaches per 30 days measured over 90 consecutive days and headache duration of longer than 4 hours per day or longer during an attack on average.
 - b. **Chronic** migraine with the following frequencies of migraine:
 - I. 15 or more headaches per 30 days measured over 90 consecutive days and headache duration of longer than 4 hours per day or longer during an attack on average
2. Prior Authorization may be approved if the patient has failed a trial of at least 30 days each to at least 3 controller migraine medications or has experienced contraindications or intolerance to them (i.e., beta-blockers, anticonvulsants, tricyclic antidepressants, and/or serotonin-norepinephrine reuptake inhibitors).
3. Initial authorization will be limited to 180 days. Re-authorization for 365 days will be allowed based upon evidence of improved headache control.

ADDITIONAL INFORMATION

In addition to utilizing a preferred agent when applicable, the number of tablets/doses allowed per month is restricted based on the manufacturer's package insert.

*Aimovig Initial Dose is limited to 70mg once monthly; may request dose increase if 70mg fails to provide adequate relief over two consecutive months.

* Ajoovy 675mg doses (quarterly administration) will not be authorized until patient has demonstrated efficacy of medication for at least 90 days.

Central Nervous System (CNS) Agents: Anticonvulsants

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 through the automated PA system. Patients who have taken the drug in the previous 120 days, but do not have claims history (e.g. new to Medicaid), will be approved for PA after prescriber contact.

STEP THERAPY: all agents listed

1. For a drug requiring step therapy, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than 30 days of at least one preferred product.

OTHER APPROVAL CRITERIA:

1. Is there any reason the patient cannot be changed to a preferred medication?
Acceptable reasons include:
 - ☐ Allergy to two preferred medications
 - ☐ Contraindication to or drug interaction with two preferred medications
 - ☐ History of unacceptable/toxic side effects to two preferred medications
 - ☐ The requested medication's corresponding generic (if covered by the state) has been attempted and failed or is contraindicated
2. If there has been a therapeutic failure to no less than two preferred products for a 30 days trial each. Prescriptions submitted with the prescriber NPI of a physician who has registered a neurology specialty with Ohio Medicaid, for products that are used only for seizures, require a trial of one preferred product for 30 days. This provision applies only to the standard tablet/capsule dosage form and does not apply to brand products with available generic alternatives.

ADDITIONAL CRITERIA FOR CANNABINOID

LENGTH OF AUTHORIZATIONS: Initial Authorization 180 days
Subsequent Authorizations 365 days

- ☐ Patient has a diagnosis of Lennox-Gastaut syndrome, Dravet syndrome or tuberous sclerosis complex
- ☐ Patient has trialed and failed (inadequate seizure control or intolerance) 3 prior anticonvulsant therapies for 30 days each (**Note:** not required to be met for a diagnosis of Dravet Syndrome)
- ☐ Prescriber has obtained serum transaminases (ALT and AST) and total bilirubin levels prior to starting therapy

- ❑ Prescriber must submit documented average number of seizure days per month (measured monthly or quarterly)
 - ❑ Maximum daily dose (QL) not to exceed 20 mg/kg/day (titration based on response/tolerability) for Lennox-Gastaut syndrome or Dravet syndrome and not to exceed 25 mg/kg/day (titration based on response/tolerability) for tuberous sclerosis complex

Epidiolex excluded from Grandfathering. Re-authorization requires documented reduction in average number of seizure days per month (measured monthly or quarterly).

ADDITIONAL CRITERIA FOR STIRIPENTOL

LENGTH OF AUTHORIZATIONS:

Initial Authorization 180 days

Subsequent Authorizations 365 days

- ❑ Medication is prescribed by a neurologist or in consultation with a neurologist
- ❑ Patient has Dravet Syndrome
- ❑ Patient has baseline hematologic testing (CBC)
 - Prescribers must include management plans for patients with neutrophil counts <1500 cells/mm³ or platelet count less than 150,000/ μ L
- ❑ Address any co-morbid conditions
 - Patients with phenylketonuria (PKU) will not be authorized for suspension dosage form without evidence of total daily amount of phenylalanine
- ❑ Patient must be concurrently managed with clobazam.
- ❑ Dose will be restricted based upon patient weight to 50 mg/kg/day. Requested dose not to exceed 3,000mg/day
- ❑ Prescriber must submit documented average number of seizure days per month (measured monthly or quarterly)

Diacomit excluded from Grandfathering. Re-authorization requires documented reduction in average number of seizure days per month (measured monthly or quarterly).

AR - Vigabatrin Powder: a PA is required for patients over 2 years old

Central Nervous System (CNS) Agents: Antidepressants

GRANDFATHERING:

Patients who have a claim for a non-preferred drug, in the previous 120 days will be automatically approved to continue the drug through the automated PA system. Patients who have taken the drug in the previous 120 days, but do not have claims history (e.g. new to Medicaid), will be approved for PA after prescriber contact.

PSYCHIATRIST EXEMPTION:

Providers (as identified below) are exempt from prior authorization of any non-preferred antidepressant, or step therapy of any preferred brand, 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 provider.

- ☐ **FFS:** Physicians who are registered with Ohio Medicaid as having a specialty in psychiatry
- ☐ **MCOs:** 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 via the Medicaid managed care plan

LENGTH OF AUTHORIZATIONS:

365 Days

1. If there has been a therapeutic failure to no less than two preferred products for a 30-day trial each.
2. Is there any reason the patient cannot be changed to a preferred medication? Acceptable reasons include:
 - ☐ Allergy to preferred medications
 - ☐ Contraindication to or drug interaction with preferred medications
 - ☐ History of unacceptable/toxic side effects to preferred medications
 - ☐ For orally disintegrating tablet dosage forms, the patient is unable or unwilling to swallow the standard tablet/capsule dosage form.
 - ☐ The requested medication's corresponding generic (if covered by the state) has been attempted and failed or is contraindicated.

Central Nervous System (CNS) Agents: Atypical Antipsychotics

GRANDFATHERING:

Patients who have a claim for a non-preferred drug, or drug requiring step therapy, in the previous 120 days will be automatically approved to continue the drug through the automated PA system. Patients who have taken the drug in the previous 120 days, but do not have claims history (e.g. new to Medicaid), will be approved for PA after prescriber contact.

PSYCHIATRIST EXEMPTION:

Providers (as identified below) are exempt from prior authorization of any non-preferred second-generation antipsychotic, or step therapy of any preferred brand, 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 provider.

- ❑ **FFS:** Physicians who are registered with Ohio Medicaid as having a specialty in psychiatry
- ❑ **MCOs:** 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 via the Medicaid managed care plan

LENGTH OF AUTHORIZATIONS: 365 Days

STEP THERAPY: all agents listed

1. For a drug requiring step therapy, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than 30 days of at least one preferred product
2. For a non-preferred drug, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than 30 days each of at least two preferred or step therapy products

ADDITIONAL CRITERIA FOR AGENTS FOR PARKINSON'S DISEASE PSYCHOSIS (NUPLAZID™):

Pimavanserin (Nuplazid™) may be approved if all the following are met:

1. Patient is diagnosed with Parkinson's disease and has psychotic symptoms (hallucinations and/or delusions) that started after Parkinson's diagnosis
2. These psychotic symptoms are severe and frequent enough to warrant treatment with an antipsychotic AND are not related to dementia or delirium
3. The patient's other medications for Parkinson's Disease have been reduce or adjusted and psychotic symptoms remain OR patient is unable to tolerate adjustment of these other medications
4. There has been inadequate clinical response to a trial of no less than 30 days of either quetiapine or clozapine OR these therapies cannot be utilized
5. An exemption to the criteria will be granted for prescribing doctors with a neurology specialty to a patient with a history of an anti-Parkinson's agent

OTHER APPROVAL CRITERIA:

Is there any reason the patient cannot be changed to a preferred medication?

Acceptable reasons include:

- ☐ Allergy to preferred medications
- ☐ Contraindication to or drug interaction with preferred medications
- ☐ History of unacceptable/toxic side effects to preferred medications
- ☐ For orally disintegrating tablet dosage forms, the patient is unable or unwilling to swallow the standard tablet/capsule dosage form.
- ☐ The requested medication's corresponding generic (if covered by the state) has been attempted and failed or is contraindicated.
- ☐ Lurasidone (pregnancy category B) may be approved if a patient is pregnant
- ☐ Abilify Mycite will be restricted to prescribing by a psychiatrist following an aripiprazole serum blood level draw indicating need for further investigation of adherence.

ANTIPSYCHOTICS, SECOND GENERATION and SSRI COMBINATION

NO PA REQUIRED "PREFERRED"	STEP THERAPY REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
	A trial of no less than 30 days each of at least two preferred second-generation oral antipsychotics or step therapy products	FLUOXETINE/OLANZAPINE (generic of Symbyax®)

* 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.

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

LENGTH OF AUTHORIZATIONS: 365 Days

Short Acting considered separately from Long Acting products

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
 - ☐ Allergy to at least two medications not requiring prior approval
 - ☐ Contraindication to all medications not requiring prior approval
 - ☐ History of unacceptable/toxic side effects to at least two medications not requiring prior approval
 - ☐ Preferred long-acting non-solid dosage forms may be approved for a patient over age 12 if the patient is unable to swallow pills
 - ☐ Has the patient failed a therapeutic trial of at least 14 days with at least two medications not requiring prior approval?

AR - Quillichew ER: a PA is required for patients over 12 years old

AR – Vyvanse Chewable: a PA is required for patients over 12 years old

Central Nervous System (CNS) Agents: Fibromyalgia Agents

LENGTH OF AUTHORIZATIONS: 365 Days

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
 - ☐ Allergy to at least two medications in different classes (see below) not requiring prior approval
 - ☐ Contraindication to all medications not requiring prior approval
 - ☐ History of unacceptable/toxic side effects to at least two medications in different classes (see below) not requiring prior approval
2. Non-preferred medications will be approved for fibromyalgia after trial of agents from no less than two of the following drug classes for at least 14 days each in the past 90 days (guidelines suggest use of multiple agents concurrently to manage the signs of fibromyalgia):
 - ☐ Gabapentin
 - ☐ Pregabalin
 - ☐ Short- and/or long-acting opioids**
 - ☐ Skeletal muscle relaxants
 - ☐ SNRIs
 - ☐ SSRIs
 - ☐ Trazodone
 - ☐ Tricyclic antidepressants

**** The P&T Committee does not recommend the use of opioids for treatment of fibromyalgia**

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

LENGTH OF AUTHORIZATIONS:

No PA required for short-acting, buprenorphine containing, oral agents
30 days for initial authorization of injectable not to exceed 180 days for subsequent authorizations of injectable; length depending upon patient status and compliance to treatment plan
14-day authorization for Lucemyra® (lofexidine)

Criteria for Lucemyra (lofexidine)

- Indicated for Opioid Withdrawal, must meet all the following criteria:
 - Diagnosis of opioid dependence or opioid use disorder
 - Age ≥ 18 years
 - Patient is currently undergoing or is scheduled to undergo abrupt opioid discontinuation
 - Medical justification supports why an opioid taper (such as with buprenorphine or methadone) cannot be used
 - Does the patient meet one or more of the following criteria:
 - Therapeutic failure of clonidine due to intolerable adverse effects or inability to reach maximal doses of clonidine due to adverse effects
 - Documented history of intolerance to clonidine (ex: hypotension, bradycardia)
 - Contraindication to clonidine as specified in FDA labeling
 - Lofexidine has already been initiated in an inpatient setting
 - Dose will not exceed 2.88 mg (16 tablets) per day

Prescribing for buprenorphine products must follow the requirements of Ohio Administrative Code rule 4731-33-03 *Office based treatment for opioid addiction*.

BUPRENORPHINE SAFETY EDITS AND DRUG UTILIZATION REVIEW CRITERIA:

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.

Buprenorphine SL tablets (Generic of Subutex) Use restricted to pregnancy or breastfeeding; or contraindication to preferred products.

Vivitrol 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.

Criteria for SUBCUTANEOUS BUPRENORPHINE INJECTION (SUBLOCADE™)

- Indicated for opioid dependence:
 - Patient ≥18 years
 - Currently established on a dose of at least 8mg of oral buprenorphine for at least 7 days
 - Medical justification supports inability to continue to use oral formulation
 - Urine drug screen result obtained within the last 7 days with no illicit substances or non-prescribed therapies detected (initially). Subsequent authorization dependent upon UDS results indicating compliance to treatment plan.
 - Patient is actively participating in counseling. Prescriber should retain documentation of meeting attendance and submit with PA request.
 - The physician has reviewed OARRS within 7 days prior to the PA request. If the patient has received controlled substances since the previous authorization:
 - The physician has coordinated with all other prescribers of controlled substances and has determined that the patient should continue treatment;
AND
 - If the patient has received other controlled substances for 12 or more continuous weeks, the physician has consulted with a board-certified addictionologist or addiction psychiatrist who has recommended the patient receive substance abuse treatment (consultation not necessary if the prescriber is a board-certified addictionologist or addiction psychiatrist).
 - Dose does not exceed 300mg per month in the first two months and 100mg thereafter. Providers may request a maintenance dose increase beyond 100mg by submitting additional clinical documentation supporting the need for a higher dose
- Re-authorization requires adherence to specified treatment plan inclusive of adherence to counseling, OARRS and urine drug screening requirements

Sublocade may be billed by the pharmacy if it is not dispensed directly to the patient. If not administered at the pharmacy, the drug must be released only to the administering provider or administering provider's staff, following all applicable regulations.

Central Nervous System (CNS) Agents: Movement Disorders

LENGTH OF AUTHORIZATIONS: 365 Days

ADDITIONAL CRITERIA FOR THE TREATMENT OF TARDIVE DYSKINESIA:

Prescribed by a Neurologist or Psychiatrist

Ingrezza is ONLY indicated for the treatment of Tardive Dyskinesia

ADDITIONAL CRITERIA FOR AUSTEDO FOR THE TREATMENT OF HUNTINGTON'S DISEASE:

The member must have a failure to respond to maximally tolerated dose of tetrabenazine

Austedo quantity limit of 4 tablets per day

Central Nervous System (CNS) Agents: Multiple Sclerosis

DISEASE MODIFYING 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 through the automated PA system. Patients who have taken the drug in the previous 120 days, but do not have claims history (e.g. new to Medicaid), will be approved for PA after prescriber contact.

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
 - ☐ Allergy to medications not requiring prior approval
 - ☐ Contraindication to or drug interaction with medications not requiring prior approval
 - ☐ History of unacceptable/toxic side effects to medications not requiring prior approval
2. The requested medication may be approved if there has been a therapeutic failure to no less than a 30-day trial on at least one medication not requiring prior approval.

Additional Mayzent Requirements: Must review liver function tests (LFTS) complete blood count (CBC), ophthalmic examination, varicella zoster virus antibodies, and electrocardiogram (ECG) prior to initiation. Must confirm patient is not CYP2C9*3*3 genotype. Dose limited to 2mg/day.

Central Nervous System (CNS) Agents: Neuropathic Pain

LENGTH OF AUTHORIZATIONS: 365 Days

Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:

- ☐ Allergy to medications not requiring prior approval
- ☐ Contraindication to or drug interaction with medications not requiring prior approval
- ☐ History of unacceptable/toxic side effects to medications not requiring prior approval

ADDITIONAL INFORMATION

- ☐ The requested medication may be approved if there has been a therapeutic failure to no less than a 30-day trial of at least two medications in separate pharmacologic classes not requiring prior authorization

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

LENGTH OF AUTHORIZATIONS: 365 Days

Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:

- ☐ Allergy to medications not requiring prior approval
- ☐ Contraindication to or drug interaction with medications not requiring prior approval
- ☐ History of unacceptable/toxic side effects to medications not requiring prior approval

ADDITIONAL INFORMATION

The requested medication may be approved if both of the following are true:

1. If there has been a therapeutic failure to no less than a 30-day trial of at least one medication not requiring prior approval
2. The requested medication's corresponding generic (if covered by the state) has been attempted and failed or is contraindicated.
3. Neupro may be approved if the patient is unable to swallow.
4. Requests for Apokyn, Inbrija, Kynmobi and Nourianz must have documentation of a trial of at least one other medication for the treatment of "off episodes" (dopamine agonist, COMT inhibitor, or MAO-B inhibitor).

Central Nervous System (CNS) Agents: Restless Legs Syndrome

LENGTH OF AUTHORIZATIONS:

365 Days

Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:

- ☐ Allergy to medications not requiring prior approval
- ☐ Contraindication to or drug interaction with medications not requiring prior approval
- ☐ History of unacceptable/toxic side effects to medications not requiring prior approval

ADDITIONAL INFORMATION

The requested medication may be approved if there has been a therapeutic failure to no less than a 30-day trial of at least one medication not requiring prior approval

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

LENGTH OF AUTHORIZATIONS: 180 Days

1. The requested medication may be approved if there has been a therapeutic failure to no less than a 10-day trial of at least two medications not requiring prior approval
2. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
 - ☐ Allergy to medications not requiring prior approval
 - ☐ Contraindication to or drug interaction with medications not requiring prior approval
 - ☐ History of unacceptable/toxic side effects to medications not requiring prior approval
3. If the prescriber indicates the patient has a history of addiction, then may approve a requested non-controlled medication.
4. The P&T Committee does not recommend use of flurazepam (Dalmane) or triazolam (Halcion)

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

LENGTH OF AUTHORIZATIONS: 365 Days

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
 - ☐ Allergy to medications not requiring prior approval
 - ☐ Contraindication to or drug interaction with medications not requiring prior approval
 - ☐ History of unacceptable/toxic side effects to medications not requiring prior approval
2. If there has been a therapeutic failure to a 30-day trial an agent not requiring prior approval, then may approve the requested medication.

Clinical criteria must be met for Soma/Carisoprodol products—approvable only if no other muscle relaxant or agent to treat fibromyalgia, or any musculoskeletal condition, would serve the clinical needs of the patient.

Central Nervous System (CNS) Agents: Smoking Deterrents

All products covered

Dermatological: Topical Acne Products

LENGTH OF AUTHORIZATIONS: 365 Days

CLINICAL CRITERIA:

AR- All topical retinoids require prior authorization for patients age 24 and older:

- ☐ Patient diagnosis psoriasis – may approve tazarotene (Tazorac)
- ☐ Patient diagnosis acne vulgaris – may approve retinoid if the patient has a history of at least 30 days of therapy with alternative therapy (benzoyl peroxide, sodium sulfacetamide or antibiotic) in the previous 90 days
- ☐ Patient diagnosis skin cancer – may approve retinoid

PDL CRITERIA:

Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:

- ☐ Allergy to medications not requiring prior approval
- ☐ Contraindication to or drug interaction with medications not requiring prior approval
- ☐ History of unacceptable/toxic side effects to medications not requiring prior approval

ADDITIONAL INFORMATION

The requested medication may be approved if the following is true:

- ☐ If there has been a therapeutic failure to no less than a 30-day trial of at least one medication in the same class not requiring prior approval

Endocrine Agents: Androgens

LENGTH OF AUTHORIZATIONS:

365 Days

All products within this category require submission of lab work to support the need for testosterone supplementation

The requested medication may be approved if there has been a therapeutic failure to no less than a 90-day trial of all medications not requiring prior approval.

Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:

- ☐ Allergy to all medications not requiring prior approval
- ☐ Contraindication to or drug interaction with all medications not requiring prior approval
- ☐ History of unacceptable/toxic side effects to all medications not requiring prior approval

ADDITIONAL INFORMATION

Use limited to FDA approved indications in those 18 years and older.

Endocrine Agents: Diabetes – Hypoglycemia Treatments

LENGTH OF AUTHORIZATIONS: 365 DAYS

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval within the same class and formulation? Acceptable reasons include:
 - ☐ Allergy to medications not requiring prior approval
 - ☐ Contraindication to or drug interaction with medications not requiring prior approval
 - ☐ History of unacceptable/toxic side effects to medications not requiring prior approval

PA REQUIRED NON-PREFERRED:

A non-preferred medication will be approved after a trial with a preferred medication or the inability of the member and/or caregiver to administer a preferred glucagon product in a timely fashion.

Quantity limit of 2 per month

Endocrine Agents: Diabetes – Insulin

LENGTH OF AUTHORIZATIONS: 365 Days

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
 - ☐ Allergy to medications not requiring prior approval
 - ☐ Contraindication to or drug interaction with medications not requiring prior approval
 - ☐ History of unacceptable/toxic side effects to medications not requiring prior approval
 - ☐ Condition is difficult to control (i.e. prone to ketoacidosis, hypoglycemia)
2. For a medication requiring step therapy, there must have been an inadequate clinical response to at least one preferred medication within the same class not requiring prior authorization. A therapeutic failure is the inability to reach A1C goal after at least 120 days of current regimen with documented adherence and appropriate dose escalation.
3. The requested non-preferred medication may be approved if there has been a therapeutic failure to at least two medications within the same class not requiring prior authorization. A therapeutic failure is the inability to reach A1C goal after at least 120 days of current regimen with documented adherence and appropriate dose escalation.

ADDITIONAL CLINICAL CRITERIA FOR INHALED INSULIN:

- ☐ Patient has a claim for a long-acting insulin in the previous 120 days, or patient has type 2 diabetes; and
- ☐ Patient has not been diagnosed with asthma or COPD; and
- ☐ Spirometry shows FEV1 > / = 70% predicted; and
- ☐ Patient has not smoked for at least 180 days

Endocrine Agents: Diabetes – Non-Insulin

LENGTH OF AUTHORIZATIONS: 365 Days

STEP THERAPY:

1. For a drug requiring step therapy, there must have been inadequate clinical response to metformin products (either single-ingredient or in a sulfonylurea/ metformin or TZD/metformin combination), including a trial of no less than 60 days of at least one preferred metformin product
2. For a non-preferred drug, there must have been inadequate clinical response to preferred alternatives, including metformin and a trial of no less than 60 days of at least one preferred or step therapy product

Note: Inadequate clinical response after at least 60 days of recommended therapeutic dose with documented adherence to the regimen.

OTHER APPROVAL CRITERIA:

Is there any reason the patient cannot be changed to a medication within the same class not requiring prior approval? Acceptable reasons include:

- ☐ Allergy to medications not requiring prior approval
- ☐ Contraindication to or drug interaction with medications not requiring prior approval
- ☐ History of unacceptable/toxic side effects to medications not requiring prior approval

Farxiga Step Therapy Requirements are waived for members with a diagnosis of Heart Failure, Chronic Kidney Disease, Cardiovascular Disease or with multiple Cardiovascular Disease risk factors

DIABETES – ORAL HYPOGLYCEMICS, SODIUM-GLUCOSE COTRANSPORTER 2 (SGLT2) INHIBITOR AND DPP-4 COMBINATIONS

PREFERRED	NON-PREFERRED
No less than <u>90 days</u> of at least <u>one</u> preferred DPP-4 and SGLT product	GLYXAMBI (empagliflozin/ linagliptin) QTERN (dapagliflozin-saxagliptin) STEGLUJAN™ (ertugliflozin/sitagliptin)

ENDOCRINE AGENTS: DIABETES – AMYLIN ANALOGS

NO PA REQUIRED “PREFERRED”	STEP THERAPY REQUIRED “PREFERRED”	PA REQUIRED “NON-PREFERRED”
No less than <u>90 days</u> of at least <u>one</u> preferred insulin product	SYMLIN® (pramlintide)	

Soliqua and Xultophy Request must address inability to use the individual components.

Endocrine Agents: Endometriosis

LENGTH OF AUTHORIZATIONS: 365 Days

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:

- ☐ Allergy to medications not requiring prior approval
- ☐ Contraindication to or drug interaction with medications not requiring prior approval
- ☐ History of unacceptable/toxic side effects to medications not requiring prior approval

STEP THERAPY:

For a drug requiring step therapy, there must have been a therapeutic failure of at least a 30-day trial with both a NSAID and an oral contraceptive

NON-PREFERRED:

There must have been a therapeutic failure of at least a 30-day trial with both a NSAID and an oral contraceptive and a trial and a therapeutic failure of no less than 3-months on at least one step therapy required “preferred”

Endocrine Agents: Estrogenic Agents

LENGTH OF AUTHORIZATIONS: 365 Days

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
 - ☐ Allergy to medications not requiring prior approval
 - ☐ Contraindication to or drug interaction with medications not requiring prior approval
 - ☐ History of unacceptable/toxic side effects to medications not requiring prior approval
2. The requested medication may be approved if there has been a therapeutic failure of at least two trials of 30 days each with medications not requiring prior approval

Endocrine Agents: Progestin Agents

All products covered without a PA

Endocrine Agents: Growth Hormone

LENGTH OF AUTHORIZATIONS: varies as listed below.

- ☐ All products in this class require clinical prior authorization
- ☐ Must be treated and followed by a pediatric endocrinologist, pediatric nephrologist, clinical geneticist, endocrinologist or gastroenterologist (as appropriate for diagnosis)
- ☐ All information and documentation requested on the prior authorization form to justify criteria being met, including height, weight, bone age (children), date of most current x-ray, stimulus test results, IGF-1 levels and a growth chart (children) must be supplied.

PDL CRITERIA:

Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:

- ☐ Allergy to medications not requiring prior approval
- ☐ Contraindication to or drug interaction with medications not requiring prior approval
- ☐ History of unacceptable/toxic side effects to medications not requiring prior approval

The requested medication may be approved if the following is true:

- ☐ If there has been a therapeutic failure to no less than a 90-day trial of at least one preferred medication

CLINICAL CRITERIA

Children - initial approval for the following diagnoses:

1. Growth Hormone Deficiency (GHD) – 180-day approval:
 - 1) Standard deviation of 2.0 or more below mean height for chronological age; AND
 - 2) No expanding intracranial lesion or tumor diagnosed; AND
 - 3) Growth rate is:
 1. Below five (5) centimeters per year; OR
 2. Below ten (10) centimeters per year in children under 3 years of age; OR
 3. Below ten (10) centimeters per year during puberty AND
 - 4) Failure of any two stimuli test to raise the serum growth hormone level above 10 nanograms/milliliter; AND
 - 5) Epiphyses must be open; AND
 - 6) Bone age 15-16 years or less in females and 16-17 years or less in males
 - 7) Females with bone age >16 and males with bone age >17 may be approved for maintenance therapy (approval for 365 days) upon request by an endocrinologist. (Maintenance dose is typically 50% of dose used to improve height)
2. Growth Retardation of Chronic Kidney Disease – 365-day approval:
 - 1) Standard deviation of 2.0 or more below mean height for chronological age; AND
 - 2) No expanding intracranial lesion or tumor diagnosed; AND
 - 3) Growth rate below five (5) centimeters per year; AND
 - 4) Irreversible renal insufficiency with a glomerular filtration rate less than 75 ml/min per 1.73m² but pre-renal transplant; AND
 - 5) Bone age 14-15 years or less in females and 15-16 years or less in males; AND
 - 6) Epiphyses open.
3. Genetic diagnosis – 365-day approval:

- 1) One of the following:
 1. Krause-Kivlin Syndrome; or
 2. Turner Syndrome; or
 3. Prader-Willi Syndrome; or
 4. Noonan Syndrome
- 2) Bone age between 14-15 years; **AND**
- 3) Epiphyses open; **AND**
- 4) Growth rate below five (5) centimeters per year
4. Neurosecretory Growth Retardation – 180-day approval
 - 1) Standard deviation of 2.0 or more below mean height for chronological age; AND
 - 2) No expanding intracranial lesion or tumor diagnosed; AND
 - 3) Growth rate below five (5) centimeters per year; AND
 - 4) Bone age 14-15 years or less in females and 15-16 years or less in males; AND
 - 5) Epiphyses open; AND
 - 6) Mixed or normal response to any two (2) stimuli test in raising serum growth hormone above 10 nanograms/milliliter.
5. Idiopathic Short Stature – 180-day approval
 - 1) A standard deviation of 2.25 or more below mean height for chronological age; AND
 - 2) No expanding intracranial lesion or tumor diagnosed; AND
 - 3) Growth rate is below five (5) centimeters per year; AND
 - 4) Bone age is 14-15 years or less in females and 15-16 years or less in males and epiphyses are open; AND
 - 5) A mixed or normal response to any two stimuli tests in raising serum growth hormone above 10 nanograms/milliliter; AND
 - 6) The child is proportionally shorter than the predicted rate of growth from the parent's height; AND
 - 7) Requests must come from a pediatric endocrinologist.
6. Small for Gestational Age (SGA) – 365-day approval
 - 1) Request must come from a pediatric endocrinologist; AND
 - 2) Documentation to support diagnosis defined as birth weight or length 2 or more standard deviations below the mean for gestational age.
 - 3) Child fails to manifest catch up growth before 2 years of age, defined as height 2 or more standard deviations below the mean for age and gender.
 - 4) Note: Review must include evaluation of growth curves from birth

Reauthorization: The patient health status has improved since last approval (weight gain, improved body composition) 1-year approval

Adults - initial approval for 180 days:

Adult patients with growth hormone deficiency may be approved for replacement of endogenous growth hormone upon documentation of medical necessity from an endocrinologist. Requests will be reviewed and approved based upon the following conditions:

- 1) Childhood Onset - Patients who were growth hormone deficient during childhood and who have a continued deficiency which is confirmed by provocative testing.
- 2) Adult Onset - Patients who have growth hormone deficiency, either alone or with multiple pituitary hormone deficiencies, such as hypopituitarism, as a result of pituitary disease, surgery, hypothalamic disease, radiation therapy, or trauma.

Criteria for Approval for both conditions listed above:

- 1) Biochemical diagnosis of growth hormone deficiency by means of a negative response to an appropriate stimulation test ordered by the endocrinologist (Clonidine test is not acceptable for adults.); AND
- 2) No evidence of malignancy or other contraindication; AND
- 3) Other hormonal deficiencies addressed with adequate replacement therapy; AND
- 4) Base-line evaluation of the following clinical indicators
 - a. Insulin-like growth factor-1 (IGF-1)-also required following dosage change
 - b. Fasting lipid profile
 - c. BUN
 - d. Fasting glucose
 - e. Electrolyte levels
 - f. Evaluation of any new osteoarthritis and joint pain
 - g. Bone density test

Maximum dose – less than or equal to 0.025mg/kg daily (up 35 years of age)

Maximum dose – less than or equal to 0.0125mg/kg daily (35 years of age or older)

Reauthorization: documentation by endocrinologist that for the indication, discontinuing GH would have a detrimental effect on body composition or other metabolic parameters 1-year approval

Endocrine Agents: Osteoporosis – Bone Ossification Enhancers

LENGTH OF AUTHORIZATIONS: 365 Days

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
 - ☐ Allergy to medications not requiring prior approval
 - ☐ Contraindication to or drug interaction with medications not requiring prior approval
 - ☐ History of unacceptable/toxic side effects to medications not requiring prior approval
2. The requested medication may be approved if there has been a therapeutic failure to no less than a 90-day trial of at least one preferred medication within the same class of the requested medication

CRITICAL INFORMATION

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

ADDITIONAL CRITERIA FOR ABALOPARATIDE (TYMLOS™)

Abaloparatide is indicated in postmenopausal women with osteoporosis at high risk for fracture.

1. Patient is female and postmenopausal
2. Diagnosis of osteoporosis
3. Trial of bisphosphonates for greater than 365 days
4. Total lifetime therapy of parathyroid hormone analogs does not exceed 730 days (2 years)

Endocrine Agents: Uterine Fibroids

LENGTH OF AUTHORIZATIONS: 180 Days

Members who have been treated with Oriahnn for 24 months or more are not eligible for additional authorizations
Members who have been treated with Lupron Depot for 6 months or more are not eligible for additional authorizations

The requested medication may be approved if the member has a diagnosis of uterine leiomyomas (fibroids) and has failed a 90 day or more trial with an oral contraceptive

Gastrointestinal Agents: Anti-Emetics

LENGTH OF AUTHORIZATIONS:

365 Days

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
 - ☐ Allergy to medications not requiring prior approval
 - ☐ Contraindication to or drug interaction with medications not requiring prior approval
 - ☐ History of unacceptable/toxic side effects to medications not requiring prior approval
2. The requested medication may be approved if there has been a therapeutic failure to no less than a 7-day trial on at least one medication not requiring prior approval.

Gastrointestinal Agents: Irritable Bowel Syndrome (IBS) / Selected GI

LENGTH OF AUTHORIZATIONS:

365 Days

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
 - ☐ Allergy to medications not requiring prior approval
 - ☐ Contraindication to or drug interaction with medications not requiring prior approval
 - ☐ History of unacceptable/toxic side effects to medications not requiring prior approval
2. The requested medication may be approved if there has been a therapeutic failure to no less than a two-week trial of at least two medications not requiring prior approval

STEP THERAPY: all agents listed

1. For a drug requiring step therapy, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than 14-day trial of at least two medications not requiring prior approval
2. For a non-preferred drug, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than 14-day trial of at least two step therapy products

ADDITIONAL INFORMATION:

1. Patient must be 18 years or older
2. NUTRESTORE™, ZORBTIVE, and GATTEX require a diagnosis of short bowel syndrome (SBS) and evidence of specialized nutritional support
 - a. NUTRESTORE™ requires evidence of concurrent use of recombinant growth hormone
 - b. GATTEX requires evidence of parenteral nutrition support at least three times per week and appropriate colonoscopy and lab assessment (bilirubin, alkaline phosphatase, lipase, and amylase) 180 days prior to initiation
 - c. Re-authorization of these therapies requires evidence of improved condition (i.e. as measured by total volume, total calories, or decreased frequency of specialized nutrition support)
3. MYTESI™ requires a diagnosis of non-infectious diarrhea and evidence of concurrent HIV antiviral therapy
 - a. MYTESI™ will be limited to no more than 2 tablets per day

Gastrointestinal Agents: Opioid-Induced Constipation

LENGTH OF AUTHORIZATIONS:

365 Days

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
 - ☐ Allergy to medications not requiring prior approval
 - ☐ Contraindication to or drug interaction with medications not requiring prior approval
 - ☐ History of unacceptable/toxic side effects to medications not requiring prior approval
2. **Step Therapy:** ALL AGENTS LISTED
 1. For a drug requiring step therapy, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than 14-day trial of at least two medications not requiring prior approval
 2. For a non-preferred drug, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than 14-day trial of at least two step therapy products

ADDITIONAL INFORMATION:

1. Patient must be 18 years or older
2. Approval requires a history of chronic pain requiring continuous opioid therapy for 12 weeks or longer. Electronic PA will approve with a history of 90 days of opioid therapy in the previous 90 days, in addition to trials of preferred products.

Gastrointestinal Agents: Pancreatic Enzymes

LENGTH OF AUTHORIZATIONS: 365 Days

Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:

- ☐ Allergy to medications not requiring prior approval
- ☐ Contraindication to or drug interaction with medications not requiring prior approval
- ☐ History of unacceptable/toxic side effects to medications not requiring prior approval

ADDITIONAL INFORMATION

The requested medication may be approved if the following is true:

- ☐ If there has been a therapeutic failure to no less than a 14-day trial of at least one medication not requiring prior approval

Gastrointestinal Agents: Proton Pump Inhibitors

LENGTH OF AUTHORIZATIONS:

180 days, except as listed under clinical criteria

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
 - ☐ Allergy to medications not requiring prior approval
 - ☐ Contraindication to or drug interaction with medications not requiring prior approval
 - ☐ Presence of a gastrostomy and/or jejunostomy tube (G-, GJ-, J-tube)
 - ☐ History of unacceptable/toxic side effects to medications not requiring prior approval
2. If there has been a therapeutic failure to no less than a 30 days trial of at least two medications not requiring prior approval, then may approve the requested medication.
3. If a medication requiring prior approval was initiated in the hospital for the treatment of a condition such as a GI bleed, may approve the requested medication.

ADDITIONAL INFORMATION

- ☐ No PA needed for preferred PPI at once-daily dosing
- ☐ No PA needed for preferred PPI at any dose for age under 21
- ☐ Must have therapeutic failure on preferred agent before PA of non-preferred

CLINICAL CRITERIA FOR PPI DOSES GREATER THAN ONCE DAILY

1. For diagnosis of H. Pylori, BID dosing may be authorized for 30 days
2. For diagnosis of COPD, Dyspepsia, Gastritis, Gastroparesis, Symptomatic Uncomplicated Barrett's Esophagus, Carcinoma of GI tract, Crest Syndrome, Esophageal Varices, Scleroderma, Systemic Mastocytosis, Zollinger Ellison Syndrome:
 - ☐ Length of authorization: 365 days
 - ☐ Criteria for approval: Must have failed QD dosing

AR - Protonix Pak: a PA is required for patients over 6 years old

AR - Protonix Suspension: a PA is required for patients over 6 years old

Gastrointestinal Agents: Ulcerative Colitis Agents

LENGTH OF AUTHORIZATIONS: 365 Days

For a non-preferred agent, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than 30 days each of at least two preferred products.

OTHER APPROVAL CRITERIA:

Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:

- ☐ Allergy to medications not requiring prior approval
- ☐ Contraindication to or drug interaction with medications not requiring prior approval
- ☐ History of unacceptable/toxic side effects to medications not requiring prior approval

ADDITIONAL INFORMATION

1. Ulcerative Colitis Agents are available in both oral (IR, ER) and rectal (enema, suppository) formulations. Patients with mild or moderate disease may be treated with either rectal or oral agents.
2. The efficacy among the different 5-ASA derivatives appears to be comparable.

Genitourinary Agents: Benign Prostatic Hyperplasia

LENGTH OF AUTHORIZATIONS: 365 Days

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
 - ☐ Allergy to medications not requiring prior approval
 - ☐ Contraindications to or drug interaction with medications not requiring prior approval
 - ☐ History of unacceptable/toxic side effects to medications not requiring prior approval
2. Patient must have a therapeutic failure to no less than a 30-day trial on at least two medications that are preferred.

ADDITIONAL CRITERIA FOR APPROVAL OF TADALAFIL (CIALIS):

Patient must have diagnosis of benign prostatic hyperplasia and have a therapeutic failure to no less than a 30-day trial on at least one alpha-1 adrenergic blocker and a 90-day trial of finasteride.

Genitourinary Agents: Electrolyte Depleter Agents

LENGTH OF AUTHORIZATIONS: 365 Days

Non-Preferred Agent:

For a non-preferred agent, there must have been an inadequate clinical response during a trial of no less than 7 days of at least two preferred medications

OTHER APPROVAL CRITERIA:

Is there any reason the patient cannot be changed to a medication not requiring prior approval?

Acceptable reasons include:

- ☐ Allergy to medications not requiring prior approval
- ☐ Contraindication to or drug interaction with medications not requiring prior approval
- ☐ History of unacceptable/toxic side effects to medications not requiring prior approval

CLINICAL INFORMATION

Calcium acetate products may lead to hypercalcemia. This agent is recommended in patients with normal serum calcium levels.

Genitourinary Agents: Urinary Antispasmodics

LENGTH OF AUTHORIZATIONS:

365 Days

1. Patients under age 18 may be approved for tolterodine SR or Gelnique if there was inadequate clinical response to a trial of no less than 30 days of oxybutynin (IR or ER).
2. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
 - ☐ Allergy to medications not requiring prior approval
 - ☐ Contraindications to or drug interaction with medications not requiring prior approval
 - ☐ History of unacceptable/toxic side effects to medications not requiring prior approval
3. For a medication requiring step therapy, there must have been a therapeutic failure to a trial of no less than 30 days to at least one preferred medication with a different active ingredient
4. The requested non-preferred medication may be approved if there has been a therapeutic failure to a trial of no less than 30 days of at least two preferred medications with different active ingredients not requiring a prior authorization

Immunomodulator Agents for Systemic Inflammatory Disease

LENGTH OF AUTHORIZATIONS:

Dependent on diagnosis

All products in this class require Clinical Prior Authorization:

- ☐ No current infection; and
- ☐ Prior first-generation therapy appropriate for diagnosis; and
- ☐ Diagnosis of one of the following: 365 days approval
 - Rheumatoid Arthritis
 - Plaque Psoriasis
 - Psoriatic Arthritis
 - Polyarticular Juvenile Idiopathic Arthritis
 - Crohn's Disease
 - Ankylosing Spondylitis
 - Psoriasis
 - Uveitis
 - Cryopyrin-Associated Periodic Syndrome
 - Giant Cell Arteritis
 - Hidradenitis Suppurativa
- ☐ Diagnosis of Moderate to Severe Ulcerative Colitis (UC) (Humira, Simponi, and Xeljanz only): initial approval 56 days, reapprovals 365 days
Humira may be approved if there is an inadequate clinical response to at least 90 days of therapy with both 5-ASA and immunosuppressants.
Initial approval for Humira will be for 56 days. If clinical response is not seen in 56 days, further therapy with TNF inhibitors will not be approved. If there is an initial clinical response to Humira after 56 days of therapy, but no improvement in the progression of ulcerative colitis symptoms after 180 days, Simponi or Xeljanz may be approved.
 - Quantity limits for UC diagnosis:
Humira – 7 pens/syringes during month one, then 2 pens/syringes per month
Simponi – 3 pens/syringes during month one, then 1 pen/syringe per month
Xeljanz – 60 pills per month

PDL CRITERIA:

Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:

- ☐ Allergy to medications not requiring prior approval
- ☐ Contraindication to or drug interaction with medications not requiring prior approval
- ☐ History of unacceptable/toxic side effects to medications not requiring prior approval

ADDITIONAL INFORMATION

The requested medication may be approved if the following is true:

- If there has been a therapeutic failure to no less than a 90-day trial of at least two preferred medications
- For patients with a diagnosis of moderate to severe plaque psoriasis receiving phototherapy, initial authorization for Humira or Enbrel will only be approved if there is inadequate clinical response to at least 90 days of phototherapy.

Infectious Disease Agents: Antibiotics – Cephalosporins

LENGTH OF AUTHORIZATIONS: for the date of service only; no refills

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
 - ☐ Allergy to medications not requiring prior approval
 - ☐ Contraindication to or drug interaction with medications not requiring prior approval
 - ☐ History of unacceptable/toxic side effects to medications not requiring prior approval
2. If the infection is caused by an organism resistant to medications not requiring prior approval, then may approve the requested medication.
 - ☐ Note diagnosis and any culture and sensitivity reports
3. If there have been therapeutic failures to no less than a 3-day trial of at least one medication not requiring prior approval, then may approve the requested medication.

ADDITIONAL INFORMATION TO AID IN THE FINAL DECISION

If the patient is completing a course of therapy with a medication requiring prior approval, which was initiated in the hospital, then may approve the requested medication to complete the course of therapy.

AR - Cefaclor Suspension: a PA is required for patients over 12 years old

AR - Cefprozil Suspension: a PA is required for patients over 12 years old

Infectious Disease Agents: Antibiotics – Macrolides

LENGTH OF AUTHORIZATIONS: for the date of service only; no refills

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
 - ☐ Allergy to medications not requiring prior approval
 - ☐ Contraindication to or drug interaction with medications not requiring prior approval
 - ☐ History of unacceptable/toxic side effects to medications not requiring prior approval
2. If the infection is caused by an organism resistant to medications not requiring prior approval, then may approve the requested medication.
 - ☐ Note diagnosis and any culture and sensitivity reports
3. If there has been a therapeutic failure to no less than a 3-day trial of at least one medication not requiring prior approval, then may approve the requested medication.

ADDITIONAL INFORMATION TO AID IN THE FINAL DECISION

If the patient is completing a course of therapy with a medication requiring prior approval, which was initiated in the hospital, then may approve the requested medication to complete the course of therapy.

Infectious Disease Agents: Antibiotics – Quinolones

LENGTH OF AUTHORIZATIONS: for the date of service only; no refills

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
 - ☐ Allergy to medications not requiring prior approval
 - ☐ Contraindication to or drug interaction with medications not requiring prior approval
 - ☐ History of unacceptable/toxic side effects to medications not requiring prior approval
2. If the infection is caused by an organism resistant to medications not requiring prior approval, then may approve the requested medication.
 - ☐ Note diagnosis and any culture and sensitivity reports
3. If there has been a therapeutic failure to at least a 3-day trial of at least one medication not requiring prior approval, then may approve the requested medication.

ADDITIONAL INFORMATION TO AID IN THE FINAL DECISION

1. If the patient is completing a course of therapy with a medication requiring prior approval, which was initiated in the hospital, then may approve the requested medication to complete the course of therapy.
2. If the prescriber expresses concern over safety issues of a preferred agent, a non-preferred agent may be approved.

AR - Ciprofloxacin Suspension: a PA is required for patients over 12 years old

Infectious Disease Agents: Antibiotics – Inhaled

LENGTH OF AUTHORIZATIONS: 28 days

All products in this class require clinical prior authorization:

- ☐ Diagnosis of cystic fibrosis with pseudomonas-related infection
- ☐ Age limit of 6 and older for tobramycin products
- ☐ Age limit of 7 and older for aztreonam
- ☐ “Pulse” dosing cycles of 28 days on drug, followed by 28 days off drug

PDL CRITERIA:

Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:

- ☐ Allergy to medications not requiring prior approval
- ☐ Contraindication to or drug interaction with medications not requiring prior approval
- ☐ History of unacceptable/toxic side effects to medications not requiring prior approval

ADDITIONAL INFORMATION

The requested medication may be approved if the following is true:

- ☐ If there has been no less than a 28-day trial of at least one preferred medication

ADDITIONAL CRITERIA FOR AMIKACIN

LENGTH OF AUTHORIZATIONS: Initial authorization 180 days
Subsequent authorizations 365 days

1. Clinical criteria for initial authorization:

- ☐ Diagnosis of *Mycobacterium avium* complex (MAC) lung disease; and
- ☐ Patient has not achieved negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy (e.g. macrolide, rifampin, & ethambutol)

2. Criteria for subsequent authorizations

- ☐ Evidence of culture conversion (negative sputum culture)

3. Dose will be limited to 1 dose per day

Infectious Disease Agents: Antibiotics – Tetracyclines

LENGTH OF AUTHORIZATIONS: for the date of service only; no refills

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
 - ☐ Allergy to medications not requiring prior approval
 - ☐ Contraindication to or drug interaction with medications not requiring prior approval
 - ☐ History of unacceptable/toxic side effects to medications not requiring prior approval
2. If the infection is caused by an organism resistant to medications not requiring prior approval, then may approve the requested medication.
 - ☐ Note diagnosis and any culture and sensitivity reports
3. If there have been therapeutic failures to no less than a 3-day trial of at least one medication not requiring prior approval, then may approve the requested medication.

ADDITIONAL INFORMATION TO AID IN THE FINAL DECISION

If the patient is completing a course of therapy with a medication requiring prior approval, which was initiated in the hospital, then may approve the requested medication to complete the course of therapy.

AR - Vibramycin Suspension: a PA is required for patients over 12 years old

ADDITIONAL CRITERIA FOR OMADACYCLINE

LENGTH OF AUTHORIZATIONS: 14 Days

1. Clinical criteria for initial authorization:
 - ☐ Diagnosis of Community-Acquired Bacterial Pneumonia (CABP) with prior failure of other first line agent OR
 - ☐ Diagnosis of Acute Bacterial Skin and Skin Structure Infection (ABSSSI) with prior failure of other first line agent
- 2) Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
 - ☐ Allergy to medications not requiring prior approval
 - ☐ Contraindication to or drug interaction with medications not requiring prior approval
 - ☐ History of unacceptable/toxic side effects to medications not requiring prior approval
- 3) If the infection is caused by an organism resistant to medications not requiring prior approval, then may approve the requested medication.
 - ☐ Note diagnosis and any culture and sensitivity reports

ADDITIONAL INFORMATION TO AID IN THE FINAL DECISION

If the patient is completing a course of therapy with a medication requiring prior approval, which was initiated in the hospital, then may approve the requested medication to complete the course of therapy.

Infectious Disease Agents: Antifungals for Onychomycosis & Systemic Infections

LENGTH OF AUTHORIZATIONS:

For the duration of the prescription (up to 180 days)

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
 - ☐ Allergy to medications not requiring prior approval
 - ☐ Contraindication to or drug-to-drug interaction with medications not requiring prior approval:
Drug interactions (inhibition of CYP450 system)
Ketoconazole > Itraconazole > Voriconazole > Fluconazole
 - ☐ History of unacceptable/toxic side effects to medications not requiring prior approval
2. If the patient has a serious illness that causes them to be immunocompromised [i.e. AIDS, cancer, organ (solid or non-solid) transplant] then may approve the requested medication.
3. If there have been therapeutic failures to no less than a 7-day trial of at least one medication not requiring prior approval, then may approve the requested medication.

ADDITIONAL INFORMATION TO AID IN THE FINAL DECISION

1. If the patient is completing a course of therapy with a medication requiring prior approval, which was initiated in the hospital or other similar location, or if the patient has just become Medicaid eligible and is already on a course of treatment with a medication requiring prior approval, then may approve the requested medication.
2. If the request is for a diagnosis other than fungal infection, please refer the case to a pharmacist. An off-label use may be approvable for a medication such as Nizoral for advanced prostate cancer or for Cushing's Syndrome when standard treatments have failed.

Infectious Disease Agents: Antivirals – Hepatitis C Agents

LENGTH OF AUTHORIZATIONS:

365 days except simeprevir and direct acting antivirals (DAAs), see below

Is there any reason the patient cannot be changed to a medication within the same class that does not require prior approval? Acceptable reasons include:

- ☐ Allergy to medications not requiring prior approval
- ☐ Contraindication to or drug interaction with medications not requiring prior approval
- ☐ History of unacceptable/toxic side effects to medications not requiring prior approval
- ☐ Patients established on current therapy with prior payer (i.e. Commercial, Fee-for-Service, Managed Care Plan, etc).

ADDITIONAL CRITERIA FOR DAAs:

All HCV DAAs require clinical prior authorization. Only regimens recommended by the American Association for the Study of Liver Diseases (AASLD) will be approved.

Please see the [Hepatitis C Direct Acting Antiviral Prior Authorization Form](#) for criteria and the most recent regimens recommended by the American Association for the Study of Liver Diseases (AASLD)

ADDITIONAL INFORMATION TO AID IN THE FINAL DECISION

- ☐ Pegylated Interferons have a Black Box Warning which indicates that a patient should be monitored closely with periodic clinical and laboratory evaluations.
- ☐ Ribavirins are contraindicated in women who are pregnant and in their male partner(s). At least two reliable forms of contraception must be used during therapy.

Infectious Disease Agents: Antivirals – Herpes

LENGTH OF AUTHORIZATIONS:

For the duration of the prescription (up to 180 days)

Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:

- ☐ Allergy to medications not requiring prior approval
- ☐ Contraindication to or drug interaction with medications not requiring prior approval
- ☐ History of unacceptable/toxic side effects to medications not requiring prior approval

If there has been a therapeutic failure to at least a 3-day trial of at least one medication not requiring prior approval, then may approve the requested medication.

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 through the automated PA system. Patients who have taken the drug in the previous 120 days, but do not have claims history (e.g. new to Medicaid), will be approved for PA after prescriber contact.

APPROVAL CRITERIA:

Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:

1. Allergy to medications not requiring prior approval
2. Contraindication to recommended regimens not requiring prior approval
3. History of unacceptable/toxic side effects to medications not requiring prior approval
4. Has the patient had a therapeutic trial of at least 30 days with at least one medication not requiring prior approval? If applicable, the request must address the inability to use the individual components.

Symtuza request must document clinical justification for patient inability to use the individual components (Prezcobix and Descovy)

Ophthalmic Agents: Ophthalmic Steroids

LENGTH OF AUTHORIZATIONS: 30 Days

For a non-preferred drug, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than 14 days each of at least two preferred products

OTHER APPROVAL CRITERIA:

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
 - ☐ Allergy to medications not requiring prior approval
 - ☐ Contraindication to or drug interaction with medications not requiring prior approval
 - ☐ History of unacceptable/toxic side effects to medications not requiring prior approval

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

LENGTH OF AUTHORIZATIONS:

for the date of service only; no refills for acute infection. Refills for up to 14 days may be authorized for quinolones only for patients undergoing surgery.

For a non-preferred agent, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than 3 days each of at least two preferred products

OTHER APPROVAL CRITERIA:

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
 - ☐ Allergy to medications not requiring prior approval
 - ☐ Contraindication to or drug interaction with medications not requiring prior approval
 - ☐ History of unacceptable/toxic side effects to medications not requiring prior approval
2. If the infection is caused by an organism resistant to medications not requiring prior approval, then may approve the requested medication.
 - ☐ Note diagnosis and any culture and sensitivity reports

Ophthalmic Agents: Antihistamines & Mast Cell Stabilizers

LENGTH OF AUTHORIZATIONS:

365 Days

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
 - ☐ Allergy to medications not requiring prior approval
 - ☐ Contraindications to or drug interaction with medications not requiring prior approval
 - ☐ History of unacceptable/toxic side effects to medications not requiring prior approval
2. Patient must have a therapeutic failure to at least 14 days of one of the preferred agents.

Ophthalmic Agents: Dry Eye Treatments

LENGTH OF AUTHORIZATIONS: 365 Days

All drugs in this class require step therapy: Patient must have a claim for an artificial tear or OTC dry eye drop in the previous 120 days.

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
 - ☐ Allergy to medications not requiring prior approval
 - ☐ Contraindications to or drug interaction with medications not requiring prior approval
 - ☐ History of unacceptable/toxic side effects to medications not requiring prior approval
2. Patient must have a therapeutic failure to at least 30 days of one of the preferred agents.

Ophthalmic Agents: Glaucoma Agents

LENGTH OF AUTHORIZATIONS:

365 Days

STEP THERAPY:

1. For a product requiring step therapy, there must have been inadequate clinical response to preferred alternatives for glaucoma, including a trial of no less than 30 days of at least one preferred product
2. For a non-preferred agent for glaucoma, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than 30 days each of at least two preferred or step therapy products

OTHER APPROVAL CRITERIA:

Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:

- ☐ Allergy to medications not requiring prior approval
- ☐ Contraindications to or drug interaction with medications not requiring prior approval
- ☐ History of unacceptable/toxic side effects to medications not requiring prior approval

Ophthalmic Agents: NSAIDs

LENGTH OF AUTHORIZATIONS:

For the date of service only; no refills for acute use.
Refills for up to 14 days may be authorized for patients undergoing surgery.

Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:

- ☐ Allergy to medications not requiring prior approval
- ☐ Contraindication to or drug interaction with medications not requiring prior approval
- ☐ History of unacceptable/toxic side effects to medications not requiring prior approval

ADDITIONAL INFORMATION

The requested medication may be approved if both of the following are true:

1. If there has been a therapeutic failure to no less than a 3-day trial of at least one medication not requiring prior approval
2. The requested medication's corresponding generic (if covered by the state) has been attempted and failed or is contraindicated.

Otic Agents: Antibacterial and Antibacterial/Steroid Combinations

LENGTH OF AUTHORIZATIONS:

For the date of service only; no refills for acute infection.

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
 - ☐ Allergy to medications not requiring prior approval
 - ☐ Contraindication to or drug interaction with medications not requiring prior approval
 - ☐ History of unacceptable/toxic side effects to medications not requiring prior approval
2. If the infection is caused by an organism resistant to medications not requiring prior approval, then may approve the requested medication.
 - ☐ Note diagnosis and any culture and sensitivity reports

The requested medication may be approved if both of the following are true:

- ☐ If there has been a therapeutic failure to no less than a 7-day trial of at least one medication not requiring prior approval
- ☐ The requested medication's corresponding generic (if covered by the state) has been attempted and failed or is contraindicated.

Respiratory Agents: Antihistamines – Second Generation

LENGTH OF AUTHORIZATIONS: 365 Days

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
 - ☐ Allergy to medications not requiring prior approval
 - ☐ Contraindication to or drug interaction with medications not requiring prior approval
 - ☐ History of unacceptable/toxic side effects to medications not requiring prior approval
2. If there have been therapeutic failures after courses of treatment (e.g., 30 days for allergic rhinitis) with medication not requiring prior approval, then may approve the requested medication.

ADDITIONAL INFORMATION

- ☐ Fexofenadine is indicated for patients 6 years of age and older
- ☐ Loratadine is indicated for patients 2 years of age and older
- ☐ Cetirizine and desloratadine are indicated for patients 6 months of age and older

AR - Cetirizine Chewable: a PA is required for patients over 6 years old

AR - Cetirizine Syrup: a PA is required for patients over 6 years old

Respiratory Agents: Cystic Fibrosis

LENGTH OF AUTHORIZATIONS:

Initial authorization 90 days

Subsequent authorization 365 days

Initial Authorization

□ KALYDECO (ivacaftor), ORKAMBI (lumacaftor/ivacaftor), SYMDEKO (tezacaftor/ivacaftor) and TRIKAFTA (elexacaftor/tezacaftor/ivacaftor and ivacaftor) may be approved if the patient meets all the following criteria:

- Diagnosis of cystic fibrosis
- The prescriber is, or has consulted with a pulmonologist or infectious disease specialist
- Patient has documentation (must include with PA request) of the genetic mutation(s) that the FDA approved the requested medication to treat
- Patient meets the FDA-approved age minimum for the requested medication

Reauthorization Criteria:

□ Patient may be approved for reauthorization if they meet all the following criteria:

- Patient must meet all initial criteria
- Patient's adherence to medication is confirmed by claim history
- Chart notes submitted with one or more of the following:

Stabilization OR improvement of FEV1 coupled with one of the following:

- Stabilization or improvement of weight gain
- Stabilization or improvement in sweat chloride
- Decrease in the number of pulmonary exacerbations or their severity
- Decrease in the number or severity of pulmonary infections
- Decrease in the number of hospitalizations
- Increased Cystic Fibrosis Questionnaire-Revised (CFQ-R) respiratory domain score
- Other documentation by the physician clearly explaining the ongoing benefit of continuing the drug based on stated and documented objective evidence of improvement or a clear stabilization in a previous decline in one of the above parameters

Respiratory Agents: Epinephrine Auto-Injectors

LENGTH OF AUTHORIZATIONS:

365 DAYS

The requested medication may be approved if there has been therapeutic failure using the product(s) not requiring prior approval.

Is there any reason the patient cannot be changed to a medication not requiring prior approval?

Acceptable reasons include:

- ☐ Intolerance to medication(s) not requiring prior approval
- ☐ Contraindication to or drug interaction with medication(s) not requiring prior approval
- ☐ History of unacceptable/toxic side effects to medication(s) not requiring prior approval

Respiratory Agents: Hereditary Angioedema

LENGTH OF AUTHORIZATIONS: 365 Days

All products in this class require clinical prior authorization:

- ☐ Diagnosis of hereditary angioedema
- ☐ History of recurrent angioedema (without urticaria) within the past 6 months
- ☐ History of recurrent episodes of abdominal pain and vomiting within the past 6 months
- ☐ History of laryngeal edema within the past 180 days
- ☐ Positive family history of angioedema

PDL CRITERIA:

Is there any reason the patient cannot be changed to a medication not requiring prior approval?

Acceptable reasons include:

- ☐ Allergy to medications not requiring prior approval
- ☐ Contraindication to or drug interaction with medications not requiring prior approval
- ☐ History of unacceptable/toxic side effects to medications not requiring prior approval

ADDITIONAL INFORMATION

The requested medication may be approved if the following is true:

- ☐ There has been one episode of angioedema during use of a preferred medication

Respiratory Agents: Inhaled Agents

LENGTH OF AUTHORIZATIONS: 365 DAYS

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval within the same class and formulation? Acceptable reasons include:
 - ☐ Allergy to medications not requiring prior approval
 - ☐ Contraindication to or drug interaction with medications not requiring prior approval
 - ☐ History of unacceptable/toxic side effects to medications not requiring prior approval
2. The requested medication may be approved if there has been a therapeutic failure to no less than a 14-day trial of at least one medication not requiring prior approval within the same class and formulation (must try two medications if anticholinergic).

ADDITIONAL INFORMATION TO AID IN THE FINAL PA DECISION- GLUCOCORTICOIDS

If there have been therapeutic failures to no less than 30-day trials of at least two medications not requiring prior approval, then may approve the requested medication.

Requested medication may be approved if the patient is:

- ☐ Under 13 years old and is unable to use an inhaler not requiring prior approval
- ☐ Disabled and unable to use a preferred inhaler
- ☐ Non-compliant on a preferred inhaler due to taste, dry mouth, or infection
- ☐ Clinically unstable, as defined in current guidelines in terms of oral steroid use or patient's current symptomatology

AR - Albuterol Nebulizer Solution 0.42mg/ml, 0.63mg/ml: a PA is required for patients over 12 years

AR - Budesonide Nebulizer Solution: a PA is required for patients over 6 years

Respiratory Agents: Leukotriene Receptor Modifiers & Inhibitors

LENGTH OF AUTHORIZATIONS: 365 Days

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
 - ☐ Allergy to medications not requiring prior approval
 - ☐ Contraindication to or drug interaction with medications not requiring prior approval
 - ☐ History of unacceptable/toxic side effects to medications not requiring prior approval
2. For a product requiring step therapy, there must have been therapeutic failure to a 90-day trial of a preferred alternative.
3. For a non-preferred product, there must have been a therapeutic failure to a 90-day trial of two preferred agents

Respiratory Agents: Monoclonal Antibodies-Anti-IL/Anti-IgE (Self-Administered)

LENGTH OF AUTHORIZATIONS:

365 DAYS

Clinical Criteria for Asthma

- Indicated for **moderate to severe asthma** if:
 - Prescribed by or in consultation with an allergist/immunologist or pulmonologist
 - Preferred medications will be approved for patients with uncontrolled eosinophilic asthma symptoms and/or exacerbations despite at least one-month adherence to therapy with:
 - Medium dose preferred ICS/LABA inhaler (members 6-11 years old) – Nucala only
 - Medium dose preferred ICS/LABA inhaler with tiotropium or high dose preferred ICS/LABA inhaler (members 12 years and older) – Nucala or Fasenra
 - Non-preferred medications will be approved for patients with uncontrolled eosinophilic asthma symptoms and/or exacerbations despite at least three months adherence to therapy with a preferred agent

ADDITIONAL CRITERIA FOR DUPILUMAB (DUPIXENT)

- Indicated for **moderate to severe atopic dermatitis** if:
 - Patient has minimum body surface area (BSA) involvement of at least 10%
 - Prescribed by or in consultation with a dermatologist or allergist/immunologist
 - Patient is 6 years of age or older
 - Patient has had inadequate response or contraindication to two of the following: topical corticosteroids, topical calcineurin inhibitors [e.g. Elidel], or topical PDE-4 inhibitors [e.g. Eucrisa™] unless atopic dermatitis is severe and involves greater than 25% of BSA.
 - Initial authorization is limited to 112 days with re-authorization of up to 365 days granted following demonstration of improvement in patient condition with therapy (e.g. reduced BSA affected).
- Indicated for **chronic rhinosinusitis with nasal polyposis** if:
 - Patient is 18 years of age or older
 - Patient had an inadequate response, intolerance or contraindication to one oral corticosteroid
 - Patient had a 30-day trial and experienced an inadequate response, intolerance or contraindication to one nasal corticosteroid spray

Respiratory Agents: Nasal Preparations

LENGTH OF AUTHORIZATIONS: 365 days

For a non-preferred drug, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than 30 days each of at least two preferred or step therapy products

OTHER APPROVAL CRITERIA:

Is there any reason the patient cannot be changed to a medication not requiring prior approval?

Acceptable reasons include:

- ☐ Allergy to medications not requiring prior approval
- ☐ Contraindication to or drug interaction with medications not requiring prior approval
- ☐ History of unacceptable/toxic side effects to medications not requiring prior approval

Respiratory Agents: Other Agents

LENGTH OF AUTHORIZATIONS: 365 Days

DALIRESP EVALUATED WITH EACH REFILL

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval within the same class and formulation? Acceptable reasons include:
 - ☐ Allergy to medications not requiring prior approval
 - ☐ Contraindication to or drug interaction with medications not requiring prior approval
 - ☐ History of unacceptable/toxic side effects to medications not requiring prior approval
2. Daliresp must be used with a long-acting beta agonist or long-acting muscarinic antagonists

Topical Agents: Anti-Fungals

LENGTH OF AUTHORIZATIONS:

Duration of the prescription (up to 180 days)

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
 - ☐ Allergy to at least two medications not requiring prior approval
 - ☐ Contraindication to all medications not requiring prior approval
 - ☐ History of unacceptable/toxic side effects to at least two medications not requiring prior approval
2. Is the infection caused or presumed to be caused by an organism resistant to medications not requiring prior approval?
3. Has the patient failed therapeutic trials of 14 days with two medications not requiring prior approval?

Topical Agents: Anti-Parasitics

LENGTH OF AUTHORIZATIONS:

14 Days

Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:

- ☐ Allergy to medications not requiring prior approval
- ☐ Contraindication to or drug interaction with medications not requiring prior approval
- ☐ History of unacceptable/toxic side effects to medications not requiring prior approval

ADDITIONAL INFORMATION

The requested medication may be approved if the following is true:

- ☐ If there has been a therapeutic failure to no less than a 30-day trial of at least one medication not requiring prior approval
- ☐ The requested medication's corresponding generic (if covered by the state) has been attempted and failed or is contraindicated.

INDICATIONS AS APPROVED BY FDA

- ☐ Benzyl alcohol lotion is indicated for patients 6 months of age and older
- ☐ Crothamiton is indicated for adults
- ☐ Ivermectin is indicated for age 6 months and older
- ☐ Lindane lotion and shampoo are indicated only in patients who cannot tolerate or who have failed other treatments. **The P&T Committee does not recommend use of lindane.**
- ☐ Malathion is indicated for patients 6 years of age and older
- ☐ Permethrin cream and lotion are indicated for patients 2 months of age and older
- ☐ Spinosad is indicated for patients 6 months of age and older
- ☐ Package labeling does not list age for permethrin or piperonyl butoxide-pyrethrins

Topical Agents: Corticosteroids

LENGTH OF AUTHORIZATIONS:

365 days for low and medium potency

90 days for high and very high potency

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
 - ☐ Allergy to at least two medications not requiring prior approval
 - ☐ Contraindication to all medications not requiring prior approval
 - ☐ History of unacceptable/toxic side effects to at least two medications not requiring prior approval
2. Has the patient failed therapeutic trials of 14 days with two medications not requiring prior approval in the same category?

Topical Agents: Immunomodulators

LENGTH OF AUTHORIZATIONS: 365 Days

STEP THERAPY:

1. For a product requiring step therapy, there must have been an inadequate clinical response to no less than two 30-day trials of topical corticosteroids
2. For a non-preferred medication, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than 30 days of the preferred medication

OTHER APPROVAL CRITERIA:

Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:

- ☐ Allergy to medications not requiring prior approval
- ☐ Contraindication to or drug interaction with medications not requiring prior approval
- ☐ History of unacceptable/toxic side effects to medications not requiring prior approval

CLINICAL INFORMATION

- ☐ Indicated for short-term and intermittent long-term treatment of atopic dermatitis if:
 - Alternative, conventional therapies (such as topical corticosteroids) are deemed inadvisable because of potential risks, or
 - There has been inadequate response or intolerance to alternative, conventional therapies (such as topical corticosteroids)
 - ☐ Elidel and Protopic 0.03% are indicated in patients 2 years old or older. Protopic 0.1% is indicated in adults only.
- AR - pimecrolimus and tacrolimus: a PA is required for patients younger than 2 years old