

NEW CLINICAL PA REQUIRED PREFERRED DRUGS		
THERAPEUTIC CLASS	CLINICAL CRITERIA REQUIRED PREFERRED	
Blood Formation, Coagulation, and Thrombosis	Releuko	
Agents: Colony Stimulating Factors		
Infectious Disease Agents: Antivirals – HIV	Triumeq PD	

NEW NON-PREFERRED DRUGS	
THERAPEUTIC CLASS	PA REQUIRED NON-PREFERRED
Analgesic Agents: Opioids	Seglentis
Central Nervous System (CNS) Agents: Skeletal	Fleqsuvy
Muscle Relaxants, Non-Benzodiazepine	
Dermatological: Topical Acne Products	Twyneo
Endocrine Agents: Androgens	Tlando
Gastrointestinal Agents: Unspecified GI	Ibsrela
Immunomodulator Agents for Systemic	Adbry
Inflammatory Disease	
Immunomodulator Agents for Systemic	Cibinqo
Inflammatory Disease	
Immunomodulator Agents for Systemic	Dupixent
Inflammatory Disease	
Respiratory Agents: Monoclonal Antibodies-Anti-	Tezspire
IL/Anti-IgE	

#### **REVISED THERAPEUTIC CATEGORY CRITERIA**

## **Analgesic Agents: Opioids**

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

**LENGTH OF AUTHORIZATIONS:** For the course of therapy, up to 180 days

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

#### NON-PREFERRED CRITERIA ADDITIONAL AUTHORIZATION CRITERIA:

- Must provide documentation of medical necessity beyond convenience Requests require
   reasoning for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) OR
  - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least <u>7 days</u> of at least <u>two unrelated</u>
   preferred drugs product
  - Acceptable reasons include allergies, contraindications, drug-drug interactions,



intolerance, or history of unacceptable/toxic side effects

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

## ADDITIONAL SHORT-ACTING OPIOID CRITERIA FOR NEW STARTS

- The system will defines "new start" as having no opioid claims less than a 1-day supply of opioids in the previous 90 days
- Initial short-acting requests can be authorized up to 90 days
  - Length of authorization: depending is dependent on the indication, previous patient utilization, and requested length of therapy (could be more restrictive)
  - To exceed acute opioid limits, patient must have, documentation of the following must be provided:
    - Diagnosis code must be submitted and which must should be for somatic type pain
    - Inadequate clinical response to Trialed and failed non-pharmacologic treatments and/or non-opioid analgesics ineffective or contraindicated
    - Prescriber attestation that the benefits and risks of opioid therapy have been discussed with patient (attestation documented on prior authorization form)
    - Prescriber attestation that OARRS has checked (attestation documented on prior authorization form)
  - Exemptions to the additional criteria:
    - 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, or major orthopedic surgery
    - Prescriber attestation that patient is not opioid naïve will exempt patients from these requirements, for example: (i.e., new to Medicaid or was on a higher dose in hospital)
    - If patient is newly eligible for Medicaid and there is no prior claims data
    - If patient was on a higher dose in the hospital

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.

## ADDITIONAL ALL LONG-ACTING OPIOIDS CRITERIA REQUIRE PRIOR AUTHORIZATION:

- Initial long-acting requests can be authorized up to (90 days approval)
  - Documentation of the following must should be provided: as part of prior authorization form)
    - All other causes of pain:
    - Request is a daily dose equivalent of ≤ 80 MED
    - Inadequate clinical response to documented failure of pharmacologic and non-pharmacologic treatments
    - History of short-acting opioids for ≥ 60 days



- Documented Treatment plan including risk assessment, substance abuse history, concurrent therapies, and requirements for random urine screenings (Baseline urine drug test must be submitted) and treatment plan includes requirements for random urine screens
- OARRS checked within 7 days prior to initiating long-acting therapy
- Documentation of Pain and function scores at each visit
- Opioid contract required to be in place and should be submitted with PA form
- Exemptions to the additional criteria:
  - Patients receiving long-acting opioids for a catastrophic injury or cancer pain does not require additional documentation
- Subsequent long-acting renewal requests can be authorized up to (after initial 90 days then every 180 days)
  - Documentation of the following must be provided:
    - Current treatment plan
    - Demonstrated adherence to treatment plan through progress notes, including pain and function scores, and random urine screenings results reviewed, and concerns addressed, and no serious adverse outcomes observed
- Dose escalation requests can be authorized up to 180 days
  - Documentation of the following must be provided:
    - Prescriber attestation that indicates dose escalation of is likely to result in improved function and pain control
    - Requests for a daily dose >100 MED must be prescribed by requires pain specialist or anesthesiologist consultation

### ADDITIONAL TRANSMUCOSAL FENTANYL CRITERIAFOR:

- Diagnosis of cancer pain; and
- Must be prescribed by an oncologist, pain specialist, or hospice/palliative prescriber-and
- Must currently be taking a long-acting opioid at therapeutic dose of {any of the following for at least ≥7 days without adequate pain relief}:

≥ 60 mg oral morphine/day <mark>, or</mark> ≥ 8 mg oral hydromorphone/day <mark>, or</mark>

≥ 25 mcg/hr transdermal fentanyl <del>, or</del> ≥ 25 mg oral oxymorphone/day <del>, or</del>

≥ 30 mg oral oxycodone/day <del>, or</del> Equianalgesic dose of another opioid<del>; and</del>

**QL** – Transmucosal Fentanyl: is </= 4 doses units per day

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

<u>LENGTH OF AUTHORIZATIONS</u>: <u>Approval Authorization</u> based upon diagnosis below

Diagnosis	Authorization Length
Acute Myeloid Leukemia (AML)	14 days or duration of chemotherapy regimen
Malignancy at risk for febrile neutropenia or undergoing myeloablative chemotherapy prior to allogeneic or autologous bone marrow transplantation	14 days or duration of chemotherapy regimen



Myeloid Engraftment for bone marrow transplant (BMT)	30 days
Severe, chronic neutropenia with absolute neutrophil count (ANC)	
of less than 500/mm <sup>3</sup> and have symptoms associated with	30 days
neutropenia (e.g. fever, infections, oropharyngeal ulcers).	
Hematopoietic radiation injury syndrome	30 days

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

#### **NON-PREFERRED CRITERIA:**

- Must provide documentation of medical necessity beyond convenience Requests require
   reasoning for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug
   interactions, contraindications, or intolerances) OR
  - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Acceptable reasons include allergies, contraindications, drug-drug interactions, intolerance, or history of unacceptable/toxic side effects
- Must have had an inadequate clinical response-as the patient failed a therapeutic trial of at least 14 days with one preferred drug medication?
- Will the medication be used for an approved FDA indication and duration?
  - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
  - For non-preferred brand names that have preferred generics, requests must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

#### **SUBSEQUENT AUTHORIZATION CRITERIA:**

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

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

**LENGTH OF AUTHORIZATIONS: 365 Days** 

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

## **NON-PREFERRED CRITERIA:**

- Must provide documentation of medical necessity beyond convenience Requests require
   reasoning for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug
   interactions, contraindications, or intolerances) OR
  - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of at least as there has been a 30-days with one preferred drug trial with an agent not requiring prior approval?
  - Acceptable reasons include allergies, contraindications, drug-drug interactions, intolerance, or history of unacceptable/toxic side effects
  - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
  - For non-preferred brand names that have preferred generics, requests must provide

documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

## **ADDITIONAL BACLOFEN SOLUTION CRITERIA:**

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

## **ADDITIONAL CARISOPRODOL (SOMA) CRITERIA:**

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

### **SUBSEQUENT AUTHORIZATION CRITERIA:**

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

## **Dermatological: Topical Acne Products**

**LENGTH OF AUTHORIZATIONS**: 365 Days

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

### **NON-PREFERRED CRITERIA:**

- Must provide documentation of medical necessity beyond convenience Requests require
   reasoning for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) OR
  - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response to no less than a of at least 30 days or (90 days for retinoids) trial of at least three (3) preferred drugs medications not requiring prior approva
  - Acceptable reasons include allergies, contraindications, drug-drug interactions, intolerance, or history of unacceptable/toxic side effects
  - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
  - For non-preferred brand names that have preferred generics, requests must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

#### **CLINICAL CRITERIA:**

## ADDITIONAL TRETINOIN/BENZOYL PEROXIDE (TWYNEO) CRITERIA

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

#### ADDITIONAL INFORMATION

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

#### **SUBSEQUENT AUTHORIZATION CRITERIA:**

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

**AR**- All topical retinoids: A PA is required required require prior authorization for patients aged 24 years and older

## **Endocrine Agents: Androgens**

**LENGTH OF AUTHORIZATIONS:** 365 Days

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

#### **CLINICAL PA CRITERIA:**

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

#### **NON-PREFERRED CRITERIA:**

- Must provide documentation of medical necessity beyond convenience Requests require
   reasoning for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug
   interactions, contraindications, or intolerances) OR
  - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- The requested medication may be approved if There Must have has had been a therapeutic failure an inadequate clinical response to no less than a of at least 90-days trial of with all preferred drugs medications not requiring prior approval.
  - Acceptable reasons include allergies, contraindications, drug-drug interactions, intolerance, or history of unacceptable/toxic side effects
  - o For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
  - o For non-preferred brand names that have preferred generics, requests must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

#### ADDITIONAL INFORMATION

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

## **SUBSEQUENT AUTHORIZATION CRITERIA:**

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

**Gastrointestinal Agents: Unspecified GI** 

**LENGTH OF AUTHORIZATIONS: 365 Days** 

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

## STEP THERAPY CRITERIA: all agents listed

Must have had an inadequate clinical response to preferred alternatives, including no less than a at least 14-days trial of with at least two preferred drugs medications not requiring prior approval

#### **NON-PREFERRED CRITERIA:**

- Must provide documentation of medical necessity beyond convenience Requests require
   reasoning for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug
   interactions, contraindications, or intolerances) OR
  - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response of to preferred alternatives, including no less than a at least 14-days trial of with at least three preferred drugs medications not requiring prior approval, if indicated for diagnosis
  - Acceptable reasons include allergies, contraindications, drug-drug interactions, intolerance, or history of unacceptable/toxic side effects
  - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
  - For non-preferred brand names that have preferred generics, requests must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

#### **ADDITIONAL INFORMATION:**

1. Patient must be 18 years or older

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

RELISTOR and SYMPROIC requires Must have a history of chronic pain requiring continuous opioid therapy for ≥84 days 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

#### ADDITIONAL RIFAMYCIN DELAYED-RELEASE (AEMCOLO) CRITERIA:

- AEMCOLO initial approval criteria for Travelers' Diarrhea (TD) (must meet all):
  - → Diagnosis of TD
  - Maximum authorization approval duration is will be for 3 days
  - Must have the inability to take, or failure of, any of the following:
    - Azithromycin (generic Zithromax)
    - Ciprofloxacin (generic Cipro)
    - Levofloxacin (generic Levaquin)
    - Ofloxacin (generic Floxin)
    - Xifaxan Rifaximin (Xifaxan)

## ADDITIONAL SOMATROPIN INJECTION (ZORBITIVE) AND TEDLOGLUTIDE (GATTEX) CRITERIA:

ZORBTIVE and GATTEX require a diagnosis of short bowel syndrome (SBS) and evidence of specialized parenteral nutritional support



- GATTEX requires evidence of parenteral nutrition support at least three times per 7 days and
  Must have documentation of appropriate colonoscopy and lab assessment (bilirubin, alkaline phosphatase, lipase, and amylase) at least 180 days prior to initiation
- MYTESI requires a diagnosis of non-infectious diarrhea and evidence of concurrent HIV antiviral therapy
  - MYTESI will be limited to no more than 2 tablets per day

### **SUBSEQUENT AUTHORIZATION CRITERIA:**

Re-authorization of these therapies requires Must provide documentation evidence of patient's clinical response to treatment improved condition and ongoing safety monitoring (i.e. measured by total volume, total calories, or decreased frequency of specialized parenteral nutrition support, improvement in symptoms)

## Immunomodulator Agents for Systemic Inflammatory Disease

LENGTH OF AUTHORIZATIONS: Initial: 90 days; Subsequent: 365 days Dependent on diagnosis

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

#### **CLINICAL PA CRITERIA:**

- Must have been an inadequate clinical response of at least <u>90 days</u> with <u>two applicable</u> firstline drugs indicated for diagnosis – provide documentation of the trialed drugs, dosages, dates, and duration
- Authorization of dosing regimens (loading/maintenance) will be based upon diagnosis.
   Document the requested loading and maintenance dosing on PA form, if applicable
- Must not have a No current, active infection; and
- Must provide evidence of a negative TB test prior to initiation of biologic therapy, if required by labeling

### **STEP THERAPY CRITERIA:**

• For a drug requiring step therapy, Must have had therebeen an inadequate clinical response of at least to a preferred alternative, including a trial of no less than 9030 days with of at least one preferred TNF inhibitor indicated for diagnosis

#### **NON-PREFERRED CRITERIA: ADDITIONAL INFORMATION**

- Must provide documentation of medical necessity beyond convenience Requests require
   reasoning for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances) OR
  - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- The requested non-preferred medication may be approved if the following is true: there
   Must have If there has had been an inadequate clinical response a therapeutic failure to no
   less than a of at least 90 days with trial of at least two preferred drugs medications, if
   indicated for diagnosis
  - Acceptable reasons include allergies, contraindications, drug-drug interactions, intolerance, or history of unacceptable/toxic side effects
  - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)

 For non-preferred brand names that have preferred generics, requests must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

### **ADDITIONAL CRITERIA:**

### All products in this class require Clinical Prior Authorization:

- Prior first-generation therapy appropriate for diagnosis; and
- Diagnosis of one of the following: 365 days approval
  - o Rheumatoid Arthritis
  - o Plaque Psoriasis
  - Psoriatic Arthritis
  - o Polyarticular Juvenile Idiopathic Arthritis
  - o Crohn's Disease
  - o Ankylosing Spondylitis
  - o Psoriasis
  - o Uveitis
  - o Cryopyrin-Associated Periodic Syndrome
  - o Giant Cell Arteritis
  - o Hidradenitis Suppurativa

#### **ADDITIONAL ATOPIC DERMATITIS CRITERIA:**

### Clinical Criteria for Moderate to Severe Atopic Dermatitis

- Patient must have a diagnosis of moderate to severe atopic dermatitis AND
- Must be prescribed by or in consultation with a dermatologist or allergist/immunologist-AND
- Patient has Must have at least 10% body surface area (BSA) involvement AND-with
- Prescribed in accordance with its FDA approved labeling AND
- Patient has had inadequate clinical 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 OR atopic dermatitis is severe and involves greater than > 25% of BSA
- Initial authorization is limited to 180 days with re-authorization of up to 365 days granted following demonstration of improvement in patient condition with therapy (e.g. reduced BSA affected).

## **ADDITIONAL PLAQUE PSORIASIS CRITERIA:**

 For patients with a diagnosis of moderate to severe plaque psoriasis currently receiving phototherapy, an inadequate clinical response of at least <u>90 days</u> must be shown prior to initial authorization for preferred drugs <u>Humira or Enbrel will only be approved if there is an</u>

## **ADDITIONAL ULCERATIVE COLITIS CRITERIA:**

 Diagnosis of Moderate to Severe Ulcerative Colitis (UC) (Humira, Simponi, and Xeljanz-only): initial authorization 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 an inadequate clinical response after 90 is not seen in 56 days with one TNF inhibitor, further TNF inhibitors will not be approved authorized. 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.

o Quantity limits for UC diagnosis:

Humira – 7 pens/syringes during the first 30 days, then 2 pens/syringes per 30 days Simponi – 3 pens/syringes during the first 30 days, then 1 pen/syringe per 30 days Xeljanz – 60 pills per 30 days

#### **SUBSEQUENT AUTHORIZATION CRITERIA:**

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

Infectious Disease Agents: Antivirals – HIV\*

#### **LENGTH OF AUTHORIZATIONS:**

365 Days

#### **GRANDFATHERING\*:**

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

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

## ABACAVIR/DOLUTEGRAVIR/LAMIVUDINE (TRIUMEQ PD) CRITERIA:

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

### **FOSTEMSAVIR** (RUKOBIA ER) CRITERIA:

 Patient has been diagnosed with Must provide documentation of a multidrug-resistant HIV-1 infection

### **NON-PREFERRED CRITERIA:**

- Must provide documentation of medical necessity beyond convenience Requests require
   reasoning for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug
   interactions, contraindications, or intolerances) OR
  - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- Must have had an inadequate clinical response as the patient had a therapeutic trial of at least
  30 days with at least one preferred drug medication not requiring prior approval. If applicable,
  the request must address the inability to use the individual components.
  - Acceptable reasons include allergies, contraindications, drug-drug interactions, intolerance, or history of unacceptable/toxic side effects
  - For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
  - For non-preferred brand names that have preferred generics, requests must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

## ADDITIONAL DARUNAVIR/COBICISTAT/EMTRICITABINE/TENOFOVIR (SYMTUZA) CRITERIA:

• Symtuza request Must provide clinical justification documentation for patient's inability to use the individual drugs (Prezcobix and Descovy)

#### **SUBSEQUENT AUTHORIZATION CRITERIA:**

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

AR - Isentress chewable tablet: a PA is required for patients over 11 years old 12 years and older

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

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

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

#### **CLINICAL PA CRITERIA:**

- Must be prescribed by or in consultation with an applicable specialist (i.e., allergist/ immunologist, pulmonologist, or otolaryngologist)
- For Asthma Must have had uncontrolled asthma symptoms and/or exacerbations despite at least 30 days adherence to therapy with:
  - Medium dose preferred ICS/LABA inhaler for 6 years and older (patients 6-11 years old)
     OR Medium dose preferred ICS/LABA inhaler medium dose preferred ICS/LABA inhaler with tiotropium or high dose ICS/LABA inhaler for (patients)
     years and older)
- For Chronic Rhinosinusitis with Nasal Polyposis Must have Patient had an inadequate clinical response, intolerance or contraindication of at least 30 days to one oral corticosteroid AND 30-day trial to one nasal corticosteroid spray
- For Chronic Urticaria Patient has Must have had an inadequate clinical response of at least tried and failed two
   14-days with two different antihistamines

#### NON-PREFERRED MEDICATION CRITERIA:

- Must provide documentation of medical necessity beyond convenience Requests require
   reasoning for why the patient cannot be changed to a preferred drug (i.e., allergies, drug-drug
   interactions, contraindications, or intolerances) OR
  - For any nonsolid oral dosage formulation: must provide documentation of medical necessity for why patient cannot be changed to a solid oral dosage formulation
- There Must have had been an inadequate clinical response of Non-preferred medications will be approved for patients with uncontrolled asthma symptoms and/or exacerbations despite at least 90 days adherence to therapy with one a preferred drug agent
  - Acceptable reasons include allergies, contraindications, drug-drug interactions, intolerance, or history of unacceptable/toxic side effects
  - o For non-preferred extended-release formulations: must provide documentation of an inadequate clinical response with its immediate release formulation (if available)
  - For non-preferred brand names that have preferred generics, requests must provide documentation of an inadequate clinical response or allergy to two or more generic labelers (if available)

## ADDITIONAL ASTHMA CRITERIA Clinical for

- Patient must have a diagnosis of moderate to severe asthma AND
- Prescribed by or in consultation with an allergist/immunologist or pulmonologist AND
- Prescribed in accordance with its FDA approved labeling AND
- Preferred medications will be approved for patients with

## **SUBSEQUENT AUTHORIZATION CRITERIA:**

- Initial authorization is limited to 180 days
- Re-authorization of up to 365 days granted following Must provide documentation of demonstration of patient's clinical response to treatment improvement in patient condition with therapy and ongoing safety monitoring (i.e. PFT improvement, reduced affected BSA)

## ADDITIONAL CHRONIC RHINOSINUSITIS WITH NASAL POLYPOSIS CRITERIA: Clinical for

- Patient must have a diagnosis of chronic rhinosinusitis with nasal polyposis AND
- Prescribed by or in consultation with an allergist/immunologist, pulmonologist, or otolaryngologist AND
- Prescribed in accordance with its FDA approved labeling AND

#### CHRONIC URTICARIA CRITERIA Clinical for

- Patient must have a diagnosis of chronic urticaria AND
- Prescribed by or in consultation with a dermatologist or allergist/immunologist AND
- Prescribed in accordance with its FDA approved labeling AND

#### Clinical Criteria for Moderate to Severe Atopic Dermatitis

- Patient must have a diagnosis of moderate to severe atopic dermatitis AND
- Patient has minimum body surface area (BSA) involvement of at least 10% AND
- Prescribed by or in consultation with a dermatologist or allergist/immunologist AND
- Prescribed in accordance with its FDA approved labeling AND
- 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 180 days with re-authorization of up to 365 days granted following demonstration of improvement in patient condition with therapy (e.g. reduced BSA affected).