Ohio | Department of Medicaid

30 Day Change Notice
Effective Date: October 1, 2022

NEW CLINICAL PA REQUIRED PREFERRED DRUGS	
THERAPEUTIC CLASS	**CLINICAL CRITERIA REQUIRED PREFERRED**
Blood Formation, Coagulation, and Thrombosis Agents: Colony Stimulating Factors	Releuko
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 Muscle Relaxants, Non-Benzodiazepine	Fleqsuvy
Dermatological: Topical Acne Products	Twyneo
Endocrine Agents: Androgens	Tlando
Gastrointestinal Agents: Unspecified GI	Ibsrela
Immunomodulator Agents for Systemic Inflammatory Disease	Adbry
Immunomodulator Agents for Systemic Inflammatory Disease	Cibinqo
Immunomodulator Agents for Systemic Inflammatory Disease	Dupixent
Respiratory Agents: Monoclonal Antibodies-Anti-IL/Anti-IgE	Tezspire

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 7 days of at least two unrelated preferred drugs ~~product~~
  - ~~Acceptable reasons include allergies, contraindications, drug-drug interactions,~~

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~~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, 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~~ both non-opioid 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 CRITERIA~~FOR~~:

- ~~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 ~~, or~~	≥ 8 mg oral hydromorphone/day ~~, or~~
≥ 25 mcg/hr transdermal fentanyl ~~, or~~	≥ 25 mg oral oxymorphone/day ~~, or~~
≥ 30 mg oral oxycodone/day ~~, or~~	Equianalgesic dose of another opioid~~; and~~

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

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

LENGTH OF AUTHORIZATIONS: ~~Approval~~ Authorization 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^3 and have symptoms associated with neutropenia (e.g. fever, infections, oropharyngeal ulcers).	30 days
Hematopoietic radiation injury syndrome	30 days

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

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 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)

~~**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 ~~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~~
  - 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**~~

~~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~~ Must have 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 90 days with two applicable first-line 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~~ 90~~30~~ 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~~
  - ~~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~~

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 90 days must be shown prior to initial authorization for preferred drugs ~~Humira or Enbrel will only be approved if there is~~ an

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.~~

- ~~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~~12 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~~
    - 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).~~