Policy and Procedure	
PHARMACY PRIOR AUTHORIZATION POLICY AND CRITERIA ORPTCOTH016.0426	**MISCELLANEOUS PRODUCTS** **THERAPEUTIC IMMUNOMODULATORS (TIMs)** See Table 1 for Applicable Medications
Effective Date: 5/1/2026	**Review/Revised Date**: 01/17, 02/17, 03/17, 09/17, 01/18, 05/18, 07/18, 08/18, 01/19, 03/19, 04/19, 09/19, 12/19, 08/20, 11/20, 12/20, 01/21, 03/21, 05/21, 09/21, 03/22, 09/22, 04/23, 05/23, 08/23, 09/23, 12/23, 02/24, 04/24, 05/24, 06/24, 07/24, 08/24, 11/24, 02/25, 04/25, 05/25, 08/25, 11/25, 01/26, 04/26 (snm)
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SCOPE:
Providence Health Plan and Providence Health Assurance as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:
Commercial

POLICY CRITERIA:

COVERED USES:
All Food and Drug Administration (FDA)-approved indications not otherwise excluded from the benefit. Drug Compendia supported indications may be covered.

If medication is being requested for coverage under the medical benefit, please refer to the Medically Infused Therapeutic Immunomodulators (TIMs) policy.

REQUIRED MEDICAL INFORMATION:
1. For **all requests**, the patient must have an FDA-labeled indication for the requested product or use to treat the indication is supported in drug compendia (e.g., the American Hospital Formulary Service-Drug Information (AHFS-DI) or Truven Health Analytics’ DRUGDEX System). Exception: biosimilar products may be covered for all FDA-approved indications that the innovator product has been granted
   AND
2. The requested product will not be given concurrently with another therapeutic immunomodulator product unless there is no product which covers all indications
   AND
3. Requests for non-preferred products will require inadequate response (after three months), intolerance, or FDA-labeled contraindication to all the preferred products as outlined below in addition to any indication-specific criteria, if applicable. Accepted contraindications include contraindications listed in the

package insert or an allergic reaction to an ingredient found only in the preferred product(s).

a. Non-preferred adalimumab products will require inadequate response (after three months), intolerance, or FDA-labeled contraindication to all preferred adalimumab products (Simlandi, Hadlima, adalimumab-adaz, and adalimumab-aaty)
b. Non-preferred tocilizumab products will require inadequate response (after three months), intolerance, or FDA-labeled contraindication to Tyenne
c. Non-preferred ustekinumab products will require inadequate response (after three months), intolerance, or FDA-labeled contraindication to all preferred ustekinumab products (Selarsdi, Steqeyma, and Yesintek)

AND

4. The following indication-specific criteria*:

Alopecia Areata (AA)
Ankylosing Spondylitis (AS)/Radiographic Axial Spondyloarthritis (r-axSpA)
Asthma
Atopic Dermatitis (AD)
Behcet's Disease with Active Oral Ulcers (BD)
Bullous Pemphigoid (BP)
Chronic Obstructive Pulmonary Disease (COPD)
Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)
Chronic Spontaneous Urticaria (CSU)
Crohn's Disease (CD)
Enthesitis Related Arthritis (ERA)
Eosinophilic Esophagitis (EoE)
Eosinophilic Granulomatosis with Polyangiitis (EGPA)
Giant Cell Arteritis (GCA)
Hidradenitis Suppurativa (HS)
Hypereosinophilic Syndrome (HES)
IgE-Mediated Food Allergy
Non-Radiographic Axial Spondyloarthritis (nr-axSpA)
Plaque Psoriasis (Ps)
Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Polymyalgia Rheumatica (PMR)
Prurigo Nodularis (PN)
Psoriatic Arthritis (PsA)
Rheumatoid Arthritis (RA)
Systemic Juvenile Idiopathic Arthritis (SJIA)
Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)
Ulcerative Colitis (UC)
Uveitis

*If indication is not listed, the requested drug may be covered if it is an FDA-approved medication for the indication and age of the patient

Notes:

- Conventional therapy requirements may be waived if the patient has previously used another therapeutic immunomodulator product or apremilast (Otezla) for the same indication
- Conventional therapy and preferred product requirements may be waived with clinically appropriate medical rationale

For quantity limit exception requests (See Table 2 for specific quantity limits)

1. For patients already established on the requested dose and frequency, the following criteria must be met: Response to therapy with increased dosing
   Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are not considered established on therapy
2. For patients not established on requested dose and frequency (e.g., requesting dose escalation or previous dose escalation sponsored by manufacturer not previously approved by a health plan), one of the following must be met:
   a. Requested dose is FDA-labeled for the indication (Exception: Dosing for biosimilar products may be covered for all FDA-approved labeled dosing that the innovator product has been granted)
   b. For dose escalation requests in inflammatory bowel disease (e.g., Crohn's disease or ulcerative colitis), adalimumab 40 mg once weekly or ustekinumab 90 mg every six weeks may be covered if all the following criteria are met:
      i. Patient initially responded to the medication, but has experienced an inadequate response, or waning of response, to the medication
      ii. Patient has used the medication at the FDA-labeled dosing for at least six months
      iii. Current and active inflammation on endoscopy or imaging [e.g., computed tomography enterography (CTE) or magnetic resonance enterography (MRE)] obtained after at least six months of treatment on the FDA-approved dosing outlined above. Results must have been obtained within the last six months prior to this request
   c. For other disease states: requests for dose escalation are considered experimental/investigational and are not covered

Requests for indications that were approved by the FDA within the previous six (6) months may not have been reviewed by the health plan for safety and effectiveness and inclusion on this policy

document. These requests will be reviewed using the New Drug and or Indication Awaiting P&T Review; Prior Authorization Request ORPTCOPS047.

Requests for a non-FDA approved (off-label) indication requires the proposed indication be listed in either the American Hospital Formulary System (AHFS), Drugdex, or the National Comprehensive Cancer Network (NCCN) and is considered subject to evaluation of the prescriber's medical rationale, formulary alternatives, the available published evidence-based research and whether the proposed use is determined to be experimental/investigational.

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.

Alopecia Areata

REQUIRED MEDICAL INFORMATION:
For initial authorization:

1. Member's benefit covers treatment for hair loss or alopecia areata
2. Severe disease, defined as current episode of alopecia areata lasting more than six months with at least 50% scalp hair loss at baseline
3. Other causes of hair loss have been ruled out (e.g., androgenetic alopecia)

For patients established on therapy:
Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are not considered established on therapy

1. Response to therapy (e.g., slowing of disease progression or decrease in symptom severity and/or frequency)
2. Member's benefit covers treatment for hair loss or alopecia areata

EXCLUSION CRITERIA: N/A

AGE RESTRICTIONS:
Age must be appropriate based on FDA-approved indication (see Table 1)

PRESCRIBER RESTRICTIONS:
Must be prescribed by, or in consultation with, a dermatologist

COVERAGE DURATION:
Initial authorization will be approved for one year. Reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes.

QUANTITY LIMITS: See Table 2

Back to Top

Ankylosing Spondylitis/ Radiographic Axial Spondyloarthritis

REQUIRED MEDICAL INFORMATION:
For initial authorization:

1. Inadequate response (after four weeks of total therapy) or intolerance to two different nonsteroidal anti-inflammatory drugs (NSAIDs) or FDA-labeled contraindication to all NSAIDs
2. Preferred and non-preferred TIMs products may be covered as outlined below when criterion 1 is met:
    a. Preferred products may be covered: preferred adalimumab products (Simlandi, Hadlima, adalimumab-adaz and adalimumab-aaty), etanercept (Enbrel), and secukinumab (Cosentyx)
    b. Tofacitinib (Xeljanz/Xeljanz XR) and upadacitinib (Rinvoq) require inadequate response (after three months of therapy), intolerance, or FDA-labeled contraindication to one TNF inhibitor
    c. Certolizumab (Cimzia), golimumab (Simponi), ixekizumab (Taltz) and bimekizumab (Bimzelx) require inadequate response (after three months of therapy), intolerance, or FDA-labeled contraindication to two products listed in criteria 2a and/or 2b
    d. All other therapies require inadequate response (after three months of therapy), intolerance, or FDA-labeled contraindication to three products listed in criteria 2a and/or 2b

For patients established on therapy:
Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are not considered established on therapy

1. Response to therapy (e.g., slowing of disease progression or decrease in symptom severity and/or frequency)

EXCLUSION CRITERIA: N/A

AGE RESTRICTIONS:
Age must be appropriate based on FDA-approved indication (see Table 1)

PRESCRIBER RESTRICTIONS:
Must be prescribed by, or in consultation with, a rheumatologist

COVERAGE DURATION:

Initial authorization will be approved for one year. Reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

QUANTITY LIMITS: See Table 2

Back to Top

Asthma

REQUIRED MEDICAL INFORMATION:
For initial authorization:

1. Indication-specific diagnostic criteria are met as outlined below:
    a. Eosinophilic asthma, defined as one of the following while on high-dose inhaled corticosteroids or daily corticosteroids:
        i. Blood eosinophil count of at least 150 cells/microliter
        ii. Fraction of exhaled nitric oxide (FeNO) of at least 20 parts per billion
        iii. Sputum eosinophils of at least 2%
    b. Corticosteroid dependent asthma
    c. Moderate to severe persistent allergic asthma with both of the following:
        i. One of the following:
            1) The patient is 6 to less than 12 years of age and BOTH of the following:
                a) Pretreatment IgE baseline level is 30 IU/mL to 1300 IU/mL
                b) Weight is 20 kg to 150 kg
            2) The patient is 12 years of age or over and BOTH of the following:
                a) Pretreatment IgE baseline level is 30 IU/mL to 700 IU/mL
                b) Weight is 30 kg to 150 kg
        ii. Positive skin test or in vitro reactivity test to a perennial aeroallergen
2. Adherence to treatment (for three months) with maximally tolerated doses of a combination of the following, unless patient has an intolerance or FDA-labeled contraindication to all therapies (This may be verified by pharmacy claims information):
    a. Inhaled corticosteroid
    b. One of the following:
        i. Long-acting inhaled beta 2-agonist (LABA)
        ii. Leukotriene receptor antagonist (LTRA)
        iii. Long-acting muscarinic antagonist (LAMA)
3. Inadequate asthma control despite above therapy, defined as one of the following:
    a. Asthma Control Test (ACT) score less than 20 or Asthma Control Questionnaire (ACQ) score greater than or equal to 1.5
    b. At least one asthma exacerbation in the last 12 months

   c. Controlled asthma that worsens when the doses of inhaled and/or systemic corticosteroids are tapered
   d. Baseline (prior to therapy with the requested product) Forced Expiratory Volume (FEV1) that is less than 80% of predicted
4. Patient must be using medication with standard maintenance therapy

For patients established on therapy:
Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are not considered established on therapy

1. Response to therapy indicating improvement or stabilization of condition as defined by one of the following:
   a. Increase in percent predicted Forced Expiratory Volume (FEV1)
   b. Decrease in the dose of inhaled corticosteroid required to control the patient's asthma
   c. Decrease in need for treatment with systemic corticosteroids due to exacerbations of asthma
   d. Decrease in the number of hospitalizations, need for mechanical ventilation, or visits to the emergency room or urgent care due to exacerbations of asthma
2. Patient is currently treated within the past 90 days and is compliant with asthma control therapy

EXCLUSION CRITERIA: N/A

AGE RESTRICTIONS:
Age must be appropriate based on FDA-approved indication (see Table 1)

PRESCRIBER RESTRICTIONS:
Must be prescribed by, or in consultation with, a pulmonologist, immunologist, or allergist

COVERAGE DURATION:
Initial authorization will be approved for six months. Reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

QUANTITY LIMITS: See Table 2

Back to Top

Atopic Dermatitis

REQUIRED MEDICAL INFORMATION:
For initial authorization:

1. One of the following:
    a. Patient has a body surface area (BSA) involvement of at least 40%
    b. Patient has a BSA involvement of 10-39% or involvement of the hands, feet, face, neck, scalp, genitals/groin or skin folds, and meets both of the following criteria:
        i. Inadequate response (after four weeks of therapy) or intolerance to at least a moderate potency topical corticosteroid[22] or FDA-labeled contraindication to all topical corticosteroids
        ii. Inadequate response (after six weeks of therapy) or intolerance to a topical calcineurin inhibitor (e.g., tacrolimus ointment) or FDA-labeled contraindication to all topical calcineurin inhibitors (May be waived with trial of systemic immunosuppressant [e.g., methotrexate, azathioprine, mycophenolate, cyclosporine])
2. For abrocitinib (Cibinqo): Inadequate response (after three months of therapy), intolerance, or FDA-labeled contraindication to dupilumab

For patients established on therapy:
Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are not considered established on therapy

1. Response to therapy (e.g., slowing of disease progression or decrease in symptom severity and/or frequency)
2. For Adbry/Ebglyss: If the request is for four mL per 28 days, one of the following must be met:
    a. For Adbry: Patient has not achieved clear or almost clear skin in the last six months OR individual weighs greater than 100 kg
    b. For Ebglyss: Patient has not achieved an adequate clinical response
3. For Nemluvio: A request for 1 mL per 28 days may be approved if patient has not achieved clear or almost clear skin in the last six months

EXCLUSION CRITERIA: N/A

AGE RESTRICTIONS:
Age must be appropriate based on FDA-approved indication (see Table 1)

PHARMACY PRIOR AUTHORIZATION POLICY AND CRITERIA ORPTCOTH016	MISCELLANEOUS PRODUCTS THERAPEUTIC IMMUNOMODULATORS (TIMs) See Table 1 for Applicable Medications

PRESCRIBER RESTRICTIONS:
Must be prescribed by, or in consultation with, a dermatologist, allergist, or immunologist

COVERAGE DURATION:
Initial authorization will be approved for six months. Reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

QUANTITY LIMITS: See Table 2

Back to Top

Behcet's Disease with Active Oral Ulcers

REQUIRED MEDICAL INFORMATION:
For initial authorization:

1. Patient has had three occurrences of active oral ulcers within the previous 12 months
2. Inadequate response (after three months of therapy), intolerance, or FDA-labeled contraindication to one conventional therapy (e.g., corticosteroids)

For patients established on therapy:
Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are not considered established on therapy

1. Response to therapy (e.g., slowing of disease progression or decrease in symptom severity and/or frequency)

EXCLUSION CRITERIA: N/A

AGE RESTRICTIONS:
Age must be appropriate based on FDA-approved indication (see Table 1)

PRESCRIBER RESTRICTIONS:
Must be prescribed by, or in consultation with, a dermatologist or rheumatologist

COVERAGE DURATION:
Initial authorization will be approved for one year. Reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

QUANTITY LIMITS: See Table 2

Back to Top

Bullous Pemphigoid

REQUIRED MEDICAL INFORMATION:
For initial authorization:

1. One of the following:
   a. Mild disease, defined as BPDAI (Bullous Pemphigoid Disease Area Index) of less than 20, and inadequate response (after four weeks of therapy), intolerance, or FDA-labeled contraindication to one topical corticosteroid
   b. Moderate to severe disease

For patients established on therapy:
Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are not considered established on therapy

1. Response to therapy (e.g., slowing of disease progression or decrease in symptom severity and/or frequency)

EXCLUSION CRITERIA: N/A

AGE RESTRICTIONS:
Age must be appropriate based on FDA-approved indication (see Table 1)

PRESCRIBER RESTRICTIONS:
Must be prescribed by, or in consultation with, a dermatologist

COVERAGE DURATION:
Initial authorization will be approved for one year. Reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

QUANTITY LIMITS: See Table 2

Back to Top

Chronic Obstructive Pulmonary Disease

REQUIRED MEDICAL INFORMATION:
For initial authorization:

1. Diagnosis confirmed by spirometry with a post-bronchodilator FEV1/FVC ratio less than 0.7
2. Post-bronchodilator FEV1 between 20% to 80% predicted
3. Baseline (prior to therapy with the requested product) blood eosinophil count of at least 300 cells/microliter
4. Adherence to treatment (for three months) with maximally tolerated doses of the following, unless patient has an intolerance or FDA-labeled contraindication to all therapies (This may be verified by pharmacy claims information):
    a. Inhaled corticosteroid (ICS)
    b. Long-acting inhaled beta 2-agonist (LABA)
    c. Long-acting muscarinic antagonist (LAMA)
5. History of inadequately controlled COPD while on COPD inhaled maintenance therapy as demonstrated by one of the following:
    a. Frequent COPD exacerbations requiring one or more courses of systemic corticosteroids within the past 12 months
    b. Severe COPD exacerbation requiring hospitalization, mechanical ventilation, or visit to the emergency room or urgent care within the past 12 months
6. Patient will continue standard maintenance therapy for COPD

For patients established on therapy:
Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are not considered established on therapy

1. Response to therapy (e.g., slowing of disease progression or decrease in symptom severity and/or frequency)
2. Patient is currently treated within the past 90 days and is compliant with COPD maintenance therapy

EXCLUSION CRITERIA: N/A

AGE RESTRICTIONS:
Age must be appropriate based on FDA-approved indication (see Table 1)

PRESCRIBER RESTRICTIONS:

Must be prescribed by, or in consultation with, an allergist, immunologist, or pulmonologist

COVERAGE DURATION:
Initial authorization will be approved for one year. Reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

QUANTITY LIMITS: See Table 2

Back to Top

Chronic Rhinosinusitis with Nasal Polyps

For initial authorization:

1. Evidence of nasal polyposis by direct examination, endoscopy or sinus computed tomography (CT) scan
2. At least two of the following symptoms consistent with CRS:
    a. Nasal discharge (rhinorrhea or post-nasal drainage)
    b. Nasal obstruction or congestion
    c. Loss or decreased sense of smell (hyposmia)
    d. Facial pressure or pain
3. Symptoms consistent with CRS for at least 12 consecutive weeks
4. Inadequate response (after four weeks of therapy) or intolerance to intranasal corticosteroids (e.g., fluticasone) or FDA-labeled contraindication to all intranasal corticosteroids
5. Patient will continue standard maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) in combination with medication

For patients established on therapy:

Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are not considered established on therapy

1. Response to therapy (e.g., slowing of disease progression or decrease in symptom severity and/or frequency)
2. Patient will continue standard maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) in combination with medication

EXCLUSION CRITERIA: N/A

AGE RESTRICTIONS:

Age must be appropriate based on FDA-approved indication (see Table 1)

PRESCRIBER RESTRICTIONS:

Must be prescribed by, or in consultation with, an otolaryngologist, allergist, or pulmonologist

COVERAGE DURATION:

Initial authorization will be approved for six months. Reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

QUANTITY LIMITS: See Table 2

PHARMACY PRIOR AUTHORIZATION POLICY AND CRITERIA ORPTCOTH016	MISCELLANEOUS PRODUCTS THERAPEUTIC IMMUNOMODULATORS (TIMs) See Table 1 for Applicable Medications

Back to Top

Chronic Spontaneous Urticaria

REQUIRED MEDICAL INFORMATION:
For initial authorization:

1. Symptoms of hives and itching, angioedema, or both for over six weeks
2. Inadequate response (after two weeks of therapy) or intolerance to a scheduled second-generation non-sedating H1 antihistamine (e.g., levocetirizine, loratadine, cetirizine, fexofenadine) at four times the standard dosing or FDA-labeled contraindication to all second-generation non-sedating H1 antihistamines
3. For Rhapsido: Inadequate response, intolerance, or contraindication to omalizumab

For patients established on therapy:
Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are not considered established on therapy

1. Response to therapy (e.g., slowing of disease progression or decrease in symptom severity and/or frequency)

EXCLUSION CRITERIA: N/A

AGE RESTRICTIONS:
Age must be appropriate based on FDA-approved indication (see Table 1)

PRESCRIBER RESTRICTIONS:
Must be prescribed by, or in consultation with, an allergist, immunologist, or dermatologist

COVERAGE DURATION:
Initial authorization will be approved for six months. Reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

QUANTITY LIMITS: See Table 2

Back to Top

Crohn's Disease

REQUIRED MEDICAL INFORMATION:
For initial authorization:

1. Diagnosis of moderate to severe Crohn's disease
2. Preferred and non-preferred TIMs products may be covered as outlined below if criterion 1 is met:
    a. Preferred products may be covered: preferred adalimumab products (Simlandi, Hadlima, adalimumab-adaz and adalimumab-aaty), preferred ustekinumab products (Selarsdi, Steqeyma, and Yesintek), guselkumab (Tremfya), risankizumab-rzaa (Skyrizi), and subcutaneous vedolizumab (Entyvio Pen)
    b. Mirikizumab (Omvoh) and upadacitinib (Rinvoq) require inadequate response (after three months of therapy), intolerance, or FDA-labeled contraindication to one product listed in criteria 2a
    c. Infliximab-dyyb (Zymfentra) requires one of the following:
        i. Inadequate response (after three months of therapy), intolerance, or FDA-labeled contraindication to two products listed in criteria 2a
        ii. Established on intravenous infliximab
    d. All other therapies (including certolizumab [Cimzia]) require inadequate response (after three months of therapy), intolerance, or FDA-labeled contraindication to two products listed in criteria 2a

For patients established on therapy:
Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are not considered established on therapy

1. Response to therapy (e.g., slowing of disease progression or decrease in symptom severity and/or frequency)

EXCLUSION CRITERIA: N/A

AGE RESTRICTIONS:
Age must be appropriate based on FDA-approved indication (see Table 1)

PRESCRIBER RESTRICTIONS:
Must be prescribed by, or in consultation with, a gastroenterologist

COVERAGE DURATION:

Initial authorization will be approved for one year. Reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

QUANTITY LIMITS: See Table 2

Back to Top

Enthesitis Related Arthritis

REQUIRED MEDICAL INFORMATION:
For initial authorization:

1. Inadequate response (after four weeks of total therapy) or intolerance to two different non-steroidal anti-inflammatory drugs (NSAIDs) or FDA-labeled contraindication to all NSAIDs
2. Preferred and non-preferred TIMs products may be covered as outlined below when criterion 1 is met:
    a. Preferred products may be covered: secukinumab (Cosentyx)
    b. All other therapies require inadequate response (after three months of therapy), intolerance, or FDA-labeled contraindication to secukinumab (Cosentyx)

For patients established on therapy:
Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are not considered established on therapy

1. Response to therapy (e.g., slowing of disease progression or decrease in symptom severity and/or frequency)

EXCLUSION CRITERIA: N/A

AGE RESTRICTIONS:
Age must be appropriate based on FDA-approved indication (see Table 1)

PRESCRIBER RESTRICTIONS:
Must be prescribed by, or in consultation with, a rheumatologist

COVERAGE DURATION:
Initial authorization will be approved for one year. Reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

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QUANTITY LIMITS: See Table 2

Back to Top

Eosinophilic Esophagitis

REQUIRED MEDICAL INFORMATION:
For initial authorization:

1. Eosinophil-predominant inflammation on esophageal biopsy with at least 15 eosinophils per high power field (HPF)
2. Patient weighs at least 15 kg
3. Inadequate response (after eight weeks of therapy) or intolerance to one of the following therapies, or FDA-labeled contraindication to all the following therapies:
    a. Proton pump inhibitor
    b. Topical glucocorticoid (e.g., fluticasone inhaler, swallowed budesonide)

For patients established on therapy:
Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are not considered established on therapy

1. Response to therapy (e.g., slowing of disease progression or decrease in symptom severity and/or frequency)

EXCLUSION CRITERIA: N/A

AGE RESTRICTIONS:
Age must be appropriate based on FDA-approved indication (see Table 1)

PRESCRIBER RESTRICTIONS:
Must be prescribed by, or in consultation with, an allergist, gastroenterologist, or immunologist

COVERAGE DURATION:
Initial authorization will be approved for six months. Reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

QUANTITY LIMITS: See Table 2

Back to Top

Eosinophilic Granulomatosis with Polyangiitis

REQUIRED MEDICAL INFORMATION:
For initial authorization:

1. Confirmed diagnosis of EGPA defined as one of the following at baseline (prior to therapy for the requested indication):
   a. Blood eosinophilia greater of at least 1000 cells/microliter
   b. Blood eosinophil level of at least 10% eosinophils on white blood cell differential count
2. History or presence of asthma
3. No severe disease with organ- or life-threatening manifestations (e.g., alveolar hemorrhage, glomerulonephritis, central nervous system vasculitis, mononeuritis multiplex, cardiac involvement, mesenteric ischemia, limb/digit ischemia)
4. Inadequate response (after four weeks of therapy) or intolerance to oral corticosteroid therapy, or FDA-labeled contraindication to all oral corticosteroids
5. One of the following:
   a. Relapsing or refractory disease
   b. Maintenance of disease remission

For patients established on therapy:
Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are not considered established on therapy

1. One of the following:
   a. Remission achieved with the requested product
   b. Decrease in oral corticosteroid maintenance dose required for control of symptoms related to EGPA
   c. Decrease in hospitalization due to symptoms of EGPA
   d. Dose of maintenance corticosteroid therapy and/or immunosuppressant therapy was not increased

EXCLUSION CRITERIA: N/A

AGE RESTRICTIONS:
Age must be appropriate based on FDA-approved indication (see Table 1)

PRESCRIBER RESTRICTIONS:

Must be prescribed by, or in consultation with, an allergist, pulmonologist, rheumatologist, immunologist, or nephrologist

COVERAGE DURATION:
Initial authorization will be for one year. Reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

QUANTITY LIMITS: See Table 2

Back to Top

Giant Cell Arteritis

REQUIRED MEDICAL INFORMATION:
For initial authorization:

1. Inadequate response, intolerance, or FDA-labeled contraindication to systemic corticosteroid therapy
2. Preferred and non-preferred TIMs products may be covered as outlined below if criterion 1 is met:
    a. Preferred products may be covered: preferred tocilizumab product (Tyenne) and upadacitinib (Rinvoq)
    b. Non-preferred tocilizumab products require inadequate response (after three months of therapy), intolerance, or contraindication to all preferred tocilizumab products (Tyenne)
    c. All other therapies require inadequate response (after three months of therapy), intolerance, or FDA-labeled contraindication to one product listed in criteria 2a

For patients established on therapy:
Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are not considered established on therapy

1. Response to therapy (e.g., slowing of disease progression or decrease in symptom severity and/or frequency)

EXCLUSION CRITERIA: N/A

AGE RESTRICTIONS:
Age must be appropriate based on FDA-approved indication (see Table 1)

PRESCRIBER RESTRICTIONS:
Must be prescribed by, or in consultation with, a rheumatologist or neurologist

COVERAGE DURATION:
Initial authorization will be approved for one year. Reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

QUANTITY LIMITS: See Table 2

Back to Top

Hidradenitis Suppurativa

REQUIRED MEDICAL INFORMATION:
For initial authorization:

1. Diagnosis of moderate to severe HS
2. Inadequate response (after three months of therapy) or intolerance to one conventional therapy (i.e., oral tetracyclines [doxycycline, minocycline, tetracycline], oral contraceptives, metformin, finasteride, spironolactone, intralesional corticosteroids [triamcinolone], clindamycin + rifampin, rifampin + moxifloxacin + metronidazole, cyclosporine, oral retinoids) or FDA-labeled contraindication to all conventional therapies
3. Preferred and non-preferred TIMs products may be covered as outlined below when criteria 1 and 2 are met:
    a. Preferred products may be covered: preferred adalimumab products (Simlandi, Hadlima, adalimumab-adaz and adalimumab-aaty) and secukinumab (Cosentyx)
    b. All other therapies (including bimekizumab [Bimzelx]) require inadequate response (after three months of therapy), intolerance, or FDA-labeled contraindication to both products listed in criterion 3a

For patients established on therapy:
Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are not considered established on therapy

1. Response to therapy (e.g., slowing of disease progression or decrease in symptom severity and/or frequency)

EXCLUSION CRITERIA: N/A

AGE RESTRICTIONS:
Age must be appropriate based on FDA-approved indication (see Table 1)

PRESCRIBER RESTRICTIONS:
Must be prescribed by, or in consultation with, a dermatologist

COVERAGE DURATION:
Initial authorization will be approved for one year. Reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

QUANTITY LIMITS: See Table 2

PHARMACY PRIOR AUTHORIZATION POLICY AND CRITERIA ORPTCOTH016	MISCELLANEOUS PRODUCTS THERAPEUTIC IMMUNOMODULATORS (TIMs) See Table 1 for Applicable Medications

Back to Top

Hypereosinophilic Syndrome

REQUIRED MEDICAL INFORMATION:
For initial authorization:

1. Diagnosis of HES for at least six months confirmed by both of the following:
    a. One of the following:
        i. Peripheral blood eosinophil count of at least 1,000 cells/microliter
        ii. Percentage of eosinophils in bone marrow section exceeding 20% of all nucleated cells
        iii. Marked deposition of eosinophil granule proteins found
        iv. Tissue infiltration by eosinophils that is extensive in the opinion of a pathologist
    b. There has been evaluation of hypereosinophilia-related organ involvement (e.g., fibrosis of lung, heart, digestive tract, skin; thrombosis with or without thromboembolism; cutaneous erythema, edema/angioedema, ulceration, pruritus, or eczema; peripheral or central neuropathy with chronic or recurrent neurologic deficit; other organ system involvement [e.g., liver, pancreas, kidney])
2. No identifiable non-hematologic secondary (reactive) cause of HES (e.g., infection [e.g., HIV infection or parasitic helminth infection], allergy/atopy, medications [e.g., drug hypersensitivity], collagen vascular disease, metabolic [e.g., adrenal insufficiency], solid tumor/lymphoma [e.g., non-hematologic malignancy])
3. No FIP1L1-PDGFRA-positive disease
4. History of at least two HES flares in the 12 months prior to initiation of therapy (defined as HES-related worsening of clinical symptoms and/or blood eosinophil counts requiring an escalation in therapy)
5. Inadequate response or intolerance to one of the following or FDA-labeled contraindication to all the following:
    a. Oral corticosteroid therapy
    b. Hydroxyurea
    c. Interferon-a
    d. Another immunosuppressive product (e.g., cyclosporine, methotrexate)
6. Patient will continue existing HES therapy (e.g., oral corticosteroids, hydroxyurea, interferon-a, immunosuppressant)

For patients established on therapy:

Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are not considered established on therapy

1. Response to therapy indicating improvement or stabilization of condition as indicated by one of the following:
    a. Decrease in incidence of HES flares
    b. Escalation of therapy (due to HES-related worsening of clinical symptoms or increased blood eosinophil counts) has not been required
2. Patient will continue existing HES therapy (e.g., oral corticosteroids, hydroxyurea, interferon-a, immunosuppressant)

EXCLUSION CRITERIA: N/A

AGE RESTRICTIONS:
Age must be appropriate based on FDA-approved indication (see Table 1)

PRESCRIBER RESTRICTIONS:
Must be prescribed by, or in consultation with, an allergist, immunologist, otolaryngologist, pulmonologist, or rheumatologist

COVERAGE DURATION:
Initial authorization will be approved for one year. Reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

QUANTITY LIMITS: See Table 2

Back to Top

IgE-Mediated Food Allergy

REQUIRED MEDICAL INFORMATION:
For initial authorization:

1. Both of the following:
    a. Pretreatment IgE level is 30 IU/mL to 1850 IU/mL
    b. Weight is 10 kg to 150 kg
2. IgE-mediated food allergy confirmed by an allergy diagnostic test (e.g., skin prick test, serum specific IgE test, oral food challenge)
3. Patient will avoid known food allergens while treated with the requested product
4. Requested product will not be used for the emergency treatment of allergic reactions, including anaphylaxis

For patients established on therapy:
Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are not considered established on therapy

1. Response to therapy (e.g., slowing of disease progression or decrease in symptom severity and/or frequency)
2. Patient will continue to avoid known food allergens while treated with the requested product
3. Requested product will not be used for the emergency treatment of allergic reactions, including anaphylaxis

EXCLUSION CRITERIA: N/A

AGE RESTRICTIONS:
Age must be appropriate based on FDA-approved indication (see Table 1)

PRESCRIBER RESTRICTIONS:
Must be prescribed by, or in consultation with, an allergist or immunologist

COVERAGE DURATION:
Initial authorization will be approved for one year. Reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

QUANTITY LIMITS: See Table 2

Back to Top

Non-Radiographic Axial Spondyloarthritis

REQUIRED MEDICAL INFORMATION:
For initial authorization:

1. Preferred and non-preferred TIMs products may be covered as outlined below:
    a. Preferred products may be covered: certolizumab (Cimzia) and secukinumab (Cosentyx)
    b. Upadacitinib (Rinvoq) may be covered with inadequate response (after three months of therapy), intolerance, or FDA-labeled contraindication to one TNF inhibitor
    c. Ixekizumab (Taltz) and bimekizumab (Bimzelx) may be covered with inadequate response (after three months of therapy), intolerance, or FDA-labeled contraindication to two products listed in criteria 1a and/or 1b
    d. All other therapies require inadequate response (after three months of therapy), intolerance, or FDA-labeled contraindication to three products listed in criteria 1a and/or 1b

For patients established on therapy:
Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are not considered established on therapy

1. Response to therapy (e.g., slowing of disease progression or decrease in symptom severity and/or frequency)

EXCLUSION CRITERIA: N/A

AGE RESTRICTIONS:
Age must be appropriate based on FDA-approved indication (see Table 1)

PRESCRIBER RESTRICTIONS:
Must be prescribed by, or in consultation with, a rheumatologist

COVERAGE DURATION:
Initial authorization will be approved for one year. Reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

QUANTITY LIMITS: See Table 2

PHARMACY PRIOR AUTHORIZATION POLICY AND CRITERIA ORPTCOTH016	MISCELLANEOUS PRODUCTS THERAPEUTIC IMMUNOMODULATORS (TIMs) See Table 1 for Applicable Medications

Back to Top

Plaque Psoriasis

REQUIRED MEDICAL INFORMATION:
For initial authorization:

1. Diagnosis of moderate to severe plaque psoriasis
2. One of the following:
    a. Inadequate response (after three months of therapy) or intolerance to one of the following conventional therapies: acitretin, anthralin, calcipotriene, calcitriol, coal tar products, cyclosporine, methotrexate, pimecrolimus, PUVA (phototherapy), tazarotene, topical corticosteroids or FDA-labeled contraindication to all conventional products
    b. Severe active plaque psoriasis (e.g., greater than 10% body surface area involvement, occurring on select locations [i.e., hands, feet, scalp, face, genitals], intractable pruritis, serious emotional complications)
    c. Concomitant severe psoriatic arthritis (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable to psoriatic arthritis, long-term damage that interferes with function [i.e., joint deformities, vision loss, rapidly progressive])
3. Preferred and non-preferred TIMs products may be covered as outlined below when criteria 1 and 2 are met:
    a. Preferred products may be covered: Preferred adalimumab products (Simlandi, Hadlima, adalimumab-adaz and adalimumab-aaty), preferred ustekinumab products (Selarsdi, Steqeyma, and Yesintek), risankizumab-rzaa (Skyrizi), apremilast (Otezla), etanercept (Enbrel), guselkumab (Tremfya), secukinumab (Cosentyx), and deucravacitinib (Sotyktu)
    b. Certolizumab (Cimzia) and bimekizumab (Bimzelx) require inadequate response (after three months of therapy), intolerance, or FDA-labeled contraindication to two products listed in criterion 3a
    c. All other therapies require inadequate response (after three months of therapy), intolerance, or FDA-labeled contraindication to three products listed in criterion 3a

For patients established on therapy:
Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are not considered established on therapy

1. Response to therapy (e.g., slowing of disease progression or decrease in symptom severity and/or frequency)

EXCLUSION CRITERIA: N/A

AGE RESTRICTIONS:
Age must be appropriate based on FDA-approved indication (see Table 1)

PRESCRIBER RESTRICTIONS:
Must be prescribed by, or in consultation with, a dermatologist

COVERAGE DURATION:
Initial authorization will be approved for one year. Reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

QUANTITY LIMITS: See Table 2

Back to Top

Polyarticular Juvenile Idiopathic Arthritis

REQUIRED MEDICAL INFORMATION:
For initial authorization:

1. Inadequate response (after one month of therapy) or intolerance to either an oral non-steroidal anti-inflammatory drug (NSAID) or an oral disease-modifying anti-rheumatic product (DMARD) (e.g., methotrexate, leflunomide, sulfasalazine) or FDA-labeled contraindication to both therapies
2. Preferred and non-preferred TIMs products may be covered as outlined below when criterion 1 is met:
    a. Preferred products may be covered: etanercept (Enbrel) and preferred adalimumab products (Simlandi, Hadlima, adalimumab-adaz and adalimumab-aaty)
    b. Tofacitinib (Xeljanz) and upadacitinib (Rinvoq/Rinvoq LQ) require inadequate response (after three months of therapy), intolerance, or FDA-labeled contraindication to one TNF inhibitor
    c. Preferred tocilizumab product (Tyenne) requires inadequate response (after three months of therapy), intolerance, or FDA-labeled contraindication to an adalimumab product
    d. Certolizumab (Cimzia) requires inadequate response (after three months of therapy), intolerance, or FDA-labeled contraindication to two products listed in criteria 2a and/or 2b
    e. Non-preferred tocilizumab products require inadequate response (after three months of therapy), intolerance, or FDA-labeled contraindication to an adalimumab product (preferred products are Simlandi, Hadlima, adalimumab-adaz and adalimumab-aaty) and a tocilizumab product (preferred product is Tyenne)
    f. Abatacept (Orencia) requires inadequate response (after three months of therapy), intolerance, or FDA-labeled contraindication to two products listed in criteria 2a, 2b, and/or 2c
    g. All other therapies (including sarilumab [Kevzara]) require inadequate response (after three months of therapy), intolerance, or FDA-labeled contraindication to three products listed in criteria 2a and/or 2b

For patients established on therapy:
Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are not considered established on therapy

1. Response to therapy (e.g., slowing of disease progression or decrease in symptom severity and/or frequency)

EXCLUSION CRITERIA: N/A

AGE RESTRICTIONS:
Age must be appropriate based on FDA-approved indication (see Table 1)

PRESCRIBER RESTRICTIONS:
Must be prescribed by, or in consultation with, a rheumatologist

COVERAGE DURATION:
Initial authorization will be approved for one year. Reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

QUANTITY LIMITS: See Table 2

Back to Top

Polymyalgia Rheumatica

REQUIRED MEDICAL INFORMATION:
For initial authorization:

1. One of the following:
    a. Age 50 years or older at disease onset and bilateral shoulder or pelvic aching or stiffness lasting longer than 45 minutes and persisting for at least two weeks
    b. Age less than 50 years with asymmetric shoulder or pelvic pain and PMR with atypical features
2. Similar disorders have been ruled out (e.g., giant cell arteritis rheumatoid arthritis, drug-induced myalgias, fibromyalgia, other musculoskeletal disease, or other bone disease)
3. One of the following:
    a. Inadequate response (after eight weeks) or intolerance to one systemic corticosteroid at a dose equivalent to at least 7.5 mg/day of prednisone or FDA-labeled contraindication to systemic corticosteroids
    b. PMR flare while attempting to taper systemic corticosteroid

For patients established on therapy:
Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are not considered established on therapy

1. Response to therapy (e.g., slowing of disease progression or decrease in symptom severity and/or frequency)

EXCLUSION CRITERIA: N/A

AGE RESTRICTIONS:
Age must be appropriate based on FDA-approved indication (see Table 1)

PRESCRIBER RESTRICTIONS:
Must be prescribed by, or in consultation with, a rheumatologist

COVERAGE DURATION:
Initial authorization will be approved for one year. Reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

QUANTITY LIMITS: See Table 2

PHARMACY PRIOR AUTHORIZATION POLICY AND CRITERIA ORPTCOTH016	MISCELLANEOUS PRODUCTS THERAPEUTIC IMMUNOMODULATORS (TIMs) See Table 1 for Applicable Medications

Back to Top

Prurigo Nodularis

REQUIRED MEDICAL INFORMATION:
For initial authorization:

1. Diagnosis of prurigo nodularis with the following features:
    a. Presence of greater than or equal to 20 firm, nodular lesions
    b. Itching which has lasted for at least six weeks
    c. History and/or signs of repeated scratching, picking, or rubbing
2. Inadequate response (after two weeks of therapy) or intolerance to at least a moderate potency topical corticosteroid[22], or FDA-labeled contraindication to all topical corticosteroids of moderate or higher potency
3. For Nemluvio: A request for 2 mL per 28 days may be approved if patient weighs at least 90 kg

For patients established on therapy:
Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are not considered established on therapy

1. Response to therapy (e.g., slowing of disease progression or decrease in symptom severity and/or frequency)
2. For Nemluvio: A request for 2 mL per 28 days may be approved if patient weighs at least 90 kg

EXCLUSION CRITERIA: N/A

AGE RESTRICTIONS:
Age must be appropriate based on FDA-approved indication (see Table 1)

PRESCRIBER RESTRICTIONS:
Must be prescribed by, or in consultation with, a dermatologist, allergist, or immunologist

COVERAGE DURATION:
Initial authorization will be approved for six months. Reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

QUANTITY LIMITS: See Table 2

Back to Top

Psoriatic Arthritis

REQUIRED MEDICAL INFORMATION:
For initial authorization:

1. One of the following:
    a. Inadequate response (after three months of therapy) or intolerance to one conventional therapy (e.g., non-steroidal anti-inflammatory drug (NSAID), cyclosporine, methotrexate, leflunomide, or sulfasalazine) or FDA-labeled contraindication to all conventional products
    b. Severe active psoriatic arthritis (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable to psoriatic arthritis, long-term damage that interferes with function [i.e., joint deformities, vision loss, rapidly progressive])
    c. Concomitant severe psoriasis (e.g., greater than 10% body surface area involvement, occurring on select locations [i.e., hands, feet, scalp, face, genitals], intractable pruritis, serious emotional complications)
2. Preferred and non-preferred TIMs products may be covered as outlined below when criterion 1 is met:
    a. Preferred products may be covered: preferred adalimumab products (Simlandi, Hadlima, adalimumab-adaz and adalimumab-aaty), etanercept (Enbrel), guselkumab (Tremfya), secukinumab (Cosentyx), preferred ustekinumab product (Selarsdi, Steqeyma, and Yesintek), risankizumab-rzaa (Skyrizi), and apremilast (Otezla)
    b. Upadacitinib (Rinvoq/Rinvoq LQ) and tofacitinib (Xeljanz/Xeljanz XR) require inadequate response (after three months of therapy), intolerance, or FDA-labeled contraindication to one TNF inhibitor
    c. Certolizumab (Cimzia), abatacept (Orencia), golimumab (Simponi), ixekizumab (Taltz), and bimekizumab (Bimzelx) may be covered with inadequate response (after three months of therapy), intolerance, or FDA-labeled contraindication to two products listed in criteria 2a and/or 2b
    d. All other therapies require inadequate response (after three months of therapy), intolerance, or FDA-labeled contraindication to three products listed in criteria 2a and/or 2b

For patients established on therapy:
Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are not considered established on therapy

1. Response to therapy (e.g., slowing of disease progression or decrease in symptom severity and/or frequency)

EXCLUSION CRITERIA: N/A

AGE RESTRICTIONS:
Age must be appropriate based on FDA-approved indication (see Table 1)

PRESCRIBER RESTRICTIONS:
Must be prescribed by, or in consultation with, a rheumatologist

COVERAGE DURATION:
Initial authorization will be approved for one year. Reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

QUANTITY LIMITS: See Table 2

Back to Top

Rheumatoid Arthritis

REQUIRED MEDICAL INFORMATION:
For initial authorization:

1. Diagnosis of moderate to severe active rheumatoid arthritis
2. Inadequate response (after three months of therapy) or intolerance to one oral disease modifying anti-rheumatic product (DMARD) (e.g., methotrexate, azathioprine, auranofin, hydroxychloroquine, penicillamine, sulfasalazine, leflunomide) or FDA-labeled contraindication to all oral DMARDs
3. Preferred and non-preferred TIMs products may be covered as outlined below when criteria 1 and 2 are met:
    a. Preferred products may be covered: etanercept (Enbrel) and preferred adalimumab products (Simlandi, Hadlima, adalimumab-adaz and adalimumab-aaty)
    b. Tofacitinib (Xeljanz/Xeljanz XR) and upadacitinib (Rinvoq) require inadequate response (after three months of therapy), intolerance, or FDA-labeled contraindication to one TNF inhibitor
    c. Preferred tocilizumab product (Tyenne) requires inadequate response (after three months of therapy), intolerance, or FDA-labeled contraindication to an adalimumab product (preferred products are Simlandi, Hadlima, adalimumab-adaz and adalimumab-aaty)
    d. Certolizumab (Cimzia), sarilumab (Kevzara), abatacept (Orencia), golimumab (Simponi), and baricitinib (Olumiant) require inadequate response (after three months of therapy), intolerance, or FDA-labeled contraindication to two products listed in criteria 3a and/or 3b
    e. Non-preferred tocilizumab products require inadequate response (after three months of therapy), intolerance, or FDA-labeled contraindication to an adalimumab product (preferred products are Simlandi, Hadlima, adalimumab-adaz and adalimumab-aaty) and a tocilizumab product (preferred product is Tyenne)
    f. All other therapies (e.g., anakinra [Kineret]) require inadequate response (after three months of therapy), intolerance, or FDA-labeled contraindication to three products listed in criteria 3a and/or 3b

For patients established on therapy:
Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are not considered established on therapy

1. Response to therapy (e.g., slowing of disease progression or decrease in symptom severity and/or frequency)

EXCLUSION CRITERIA: N/A

AGE RESTRICTIONS:
Age must be appropriate based on FDA-approved indication (see Table 1)

PRESCRIBER RESTRICTIONS:
Must be prescribed by, or in consultation with, a rheumatologist

COVERAGE DURATION:
Initial authorization will be approved for one year. Reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

QUANTITY LIMITS: See Table 2

Back to Top

Systemic Juvenile Idiopathic Arthritis

REQUIRED MEDICAL INFORMATION:
For initial authorization:

1. Preferred and non-preferred TIMs products may be covered as outlined below:
    a. Preferred products may be covered: preferred tocilizumab products (Tyenne)
    b. All other therapies require inadequate response (after three months of therapy), intolerance, or FDA-labeled contraindication to all preferred tocilizumab products (Tyenne)

For patients established on therapy:
Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are not considered established on therapy

1. Response to therapy (e.g., slowing of disease progression or decrease in symptom severity and/or frequency)

EXCLUSION CRITERIA: N/A

AGE RESTRICTIONS:
Age must be appropriate based on FDA-approved indication (see Table 1)

PRESCRIBER RESTRICTIONS:
Must be prescribed by, or in consultation with, a rheumatologist

COVERAGE DURATION:
Initial authorization will be approved for one year. Reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

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QUANTITY LIMITS: See Table 2

Back to Top

Systemic-Sclerosis Associated Interstitial Lung Disease

REQUIRED MEDICAL INFORMATION:
For initial authorization:

1. Patient has interstitial lung disease, as evidence by high-resolution computed tomography (HRCT) or chest radiography scans
2. Preferred and non-preferred TIMs products may be covered as outlined below when criterion 1 is met:
    a. Preferred products may be covered: preferred tocilizumab product (Tyenne)
    b. All other therapies require inadequate response (after three months of therapy), intolerance, or FDA-labeled contraindication to all preferred tocilizumab products (Tyenne)

For patients established on therapy:
Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are not considered established on therapy

1. Response to therapy (e.g., slowing of disease progression or decrease in symptom severity and/or frequency)

EXCLUSION CRITERIA: N/A

AGE RESTRICTIONS:
Age must be appropriate based on FDA-approved indication (see Table 1)

PRESCRIBER RESTRICTIONS:
Must be prescribed by, or in consultation with, a rheumatologist, pulmonologist, radiologist, or pathologist

COVERAGE DURATION:
Initial authorization will be approved for one year. Reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

QUANTITY LIMITS: See Table 2

Back to Top

Ulcerative Colitis

REQUIRED MEDICAL INFORMATION:
For initial authorization:

1. Diagnosis of moderate to severe ulcerative colitis
2. Preferred and non-preferred TIMs products may be covered as outlined below when criterion 1 is met:
   a. Preferred products may be covered: preferred adalimumab products (Simlandi, Hadlima, adalimumab-adaz, and adalimumab-aaty), risankizumab (Skyrizi), preferred ustekinumab products (Selarsdi, Steqeyma, and Yesintek), guselkumab (Tremfya), and subcutaneous vedolizumab (Entyvio Pen)
   b. Tofacitinib (Xeljanz/Xeljanz XR) requires inadequate response (after three months of therapy), intolerance, or FDA-labeled contraindication to one TNF inhibitor
   c. Golimumab (Simponi) requires inadequate response (after three months of therapy), intolerance, or FDA-labeled contraindication to one adalimumab product (preferred products are Simlandi, Hadlima, adalimumab-adaz, and adalimumab-aaty)
   d. Mirikizumab (Omvoh) and upadacitinib (Rinvoq requires inadequate response (after three months of therapy), intolerance, or FDA-labeled contraindication to one product listed in criteria 2a and/or 2b
   e. Infliximab-dyyb (Zymfentra) requires one of the following:
      i. Inadequate response (after three months of therapy), intolerance, or FDA-labeled contraindication to two products listed in criteria 2a and/or 2b
      ii. Established on intravenous infliximab
   f. Etrasimod (Velsipity) requires inadequate response (after three months of therapy), intolerance, or FDA-labeled contraindication to three products listed in criteria 2a and/or 2b

For patients established on therapy:
Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are not considered established on therapy

1. Response to therapy (e.g., slowing of disease progression or decrease in symptom severity and/or frequency)

EXCLUSION CRITERIA: N/A

AGE RESTRICTIONS:

Age must be appropriate based on FDA-approved indication (see Table 1)

PRESCRIBER RESTRICTIONS:
Must be prescribed by, or in consultation with, a gastroenterologist

COVERAGE DURATION:
Initial authorization will be approved for one year. Reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

QUANTITY LIMITS: See Table 2

Back to Top

Uveitis

REQUIRED MEDICAL INFORMATION:
For initial authorization:

1. Inadequate response to one periocular/intravitreal corticosteroid injection or a two-week trial of one oral corticosteroid
2. Preferred and non-preferred TIMs products may be covered as outlined below when criterion 1 is met:
    a. Preferred products may be covered: preferred adalimumab products (Simlandi, Hadlima, adalimumab-adaz, and adalimumab-aaty)
    b. All other therapies require inadequate response (after three months of therapy), intolerance, or FDA-labeled contraindication to all preferred adalimumab products (Simlandi, Hadlima, adalimumab-adaz, and adalimumab-aaty)

For patients established on therapy:
Note: Medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are not considered established on therapy

1. Response to therapy indicating improvement or stabilization of condition

EXCLUSION CRITERIA: N/A

AGE RESTRICTIONS:
Age must be appropriate based on FDA-approved indication (see Table 1)

PRESCRIBER RESTRICTIONS:
Must be prescribed by, or in consultation with, an ophthalmologist

COVERAGE DURATION:
Initial authorization will be approved for one year. Reauthorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

QUANTITY LIMITS: See Table 2

Back to Top

INTRODUCTION:
Therapeutic Immunomodulators (TIMs) have become standard of care in patients with moderate to severe, chronic inflammatory diseases where conventional therapies have not been adequate. These products work by targeting specific steps in the inflammatory and immune cascade.

FDA APPROVED INDICATIONS: see Table 1

POSITION STATEMENT:
Due to the lack of extensive comparative clinical trials with TIMs products, comparisons between products are typically based on indirect comparative evidence.

Preferred use of biosimilar therapeutic immunomodulators
Biosimilars have been approved for use in the United States for several disease states that are currently treated with therapeutic immunomodulators. The United States Food and Drug Administration (FDA) defines a biosimilar as a "biological product that is highly similar to and had no clinically meaningful differences from an existing FDA-approved reference product." The Companies have chosen to favor the use of biosimilar products to provide quality clinical care to our members in the most cost-effective manner.

Alopecia Areata (AA):
Alopecia areata (AA) is an inflammatory autoimmune condition that causes non-scarring hair loss. The clinical presentation can vary significantly including age of onset (typically between 20-50 years of age), type of hair loss (well demarcated patch or multiple patches of hair loss, extensive hair loss on scalp only or of entire scalp and body), and other manifestations (e.g., nail involvement). AA is often associated with spontaneous remission (hair regrowth within one year), so treatment is not typically warranted. However, this is a relapsing condition with most patients experiencing more than one episode. This indication is not covered by the health plan, as the treatment of alopecia areata (AA) is considered cosmetic in nature and has "no direct impact on general health that justifies the use of hazardous treatments." While there are limited treatment options for AA, no treatment has been shown to improve function or reduce morbidity/mortality.[11,12]

The British Association of Dermatologists published a living clinical guideline in 2024 which provides the following recommendations for pharmacological therapy in adults[36]:

- For scalp hair loss with AA:
    - potent or very potent topical corticosteroid once daily for 3-6 months

- For limited mild to moderate AA (less than 50% hair loss):
  - intralesional triamcinolone acetonide
- For rapidly progressing AA:
  - oral corticosteroids over 6-12 weeks
  - cyclosporine for a limited course of 3-6 months
- For moderate to severe AA (at least 21% hair loss):
  - oral corticosteroids over 6-12 weeks with/without topical minoxidil treatment or corticosteroid-sparing products (azathioprine, methotrexate, cyclosporine)
  - corticosteroid-sparing products (azathioprine, methotrexate, cyclosporine)
  - mycophenolate mofetil
- For severe AA (at least 50% hair loss):
  - oral Janus kinase inhibitor

The Severity of Alopecia Tool (SALT) score defines severe AA as at least 50% scalp hair loss. The Alopecia Areata Scale (AAS) score defines severe AA as at least 50% scalp hair loss or at least 21% scalp hair loss plus one of the following[37]:

- noticeable involvement of eyebrows or eyelashes
- inadequate response after at least 6 months of treatment
- diffuse (multifocal) positive pull test consistent with rapidly progressive AA
- negative impact on psychosocial functioning resulting from AA

Guidelines:

- British Association of Dermatologists: https://academic.oup.com/bjd/article/192/2/190/7829170

Axial Spondyloarthritis (includes Ankylosing Spondylitis (AS)/Radiographic Axial Spondyloarthritis (r-axSpA) and Non-Radiographic Axial Spondyloarthritis (nr-axSpA):

Axial spondyloarthritis is a chronic inflammatory rheumatic musculoskeletal condition primarily impacting the axial skeleton. The spectrum of disease includes patients with radiographic sacroiliitis (AS/r-axSpA) and without radiographic sacroiliitis (nr-axSpA). The primary goal in the management of axial spondyloarthritis is to reduce symptoms, inflammation, and progressive structural damage and improve quality of life. Non-pharmacological therapies which are recommended include exercise, smoking cessation, and physiotherapy. First-line pharmacological therapy for pain and stiffness is non-steroidal anti-inflammatory drugs (NSAIDs). Glucocorticoid injections may be considered for local musculoskeletal inflammation. Sulfasalazine may be considered for peripheral arthritis. Patients with highly active disease despite conventional treatments may benefit from treatment with biological therapies [e.g.,

tumor necrosis factor (TNF) inhibitors, interleukin (IL) inhibitors, and Janus Kinase (JAK) inhibitors][38].

The two strongest predictors of TNF inhibitor efficacy are an elevated C-reactive protein (CRP) and the presence of inflammation on magnetic resonance imaging of the sacroiliac joints (MRI-SIJ). While there are no head-to-head trials to compare biological products, current practice is to start with a TNF inhibitor or an IL-17A inhibitor due to more extensive experience with the drugs including more evidence regarding their safety and efficacy. Treatment should be reviewed for continuation after at least 12 weeks. A taper may be considered after at least 6 months in remission[38].

Guidelines:

- Assessment of SpondyloArthritis International Society (ASAS)-European Alliance of Associations for Rheumatology (EULAR): https://ard.bmj.com/content/82/1/19

Asthma:

The Global Initiative for Asthma (GINA) guidelines are evidence-based international guidelines that are updated annually. The current guidelines include add-on biologic Type 2 inflammation targeted therapies if available and affordable in patients with exacerbations or poor symptom control despite the use of high dose inhaled corticosteroid (ICS) and long-acting beta agonist (LABA), and who have allergic or eosinophilic biomarkers or need maintenance oral corticosteroid (OCS).[23]

Guidelines:

- Global Initiative for Asthma (2025): https://ginasthma.org/reports/

Atopic Dermatitis (AD):

The 2023 American Academy of Dermatology (AAD) guidelines for the management of atopic dermatitis (AD) recommend topical therapies as first-line treatment options due to their efficacy and safety profiles, starting with moisturizers. For patients with uncontrolled AD despite the use of moisturizers, topical corticosteroids (TCSs) and topical calcineurin inhibitors (TCIs) are recommended for both adults and children[14].

The 2023 guidelines released by AAD were focused on the systemic treatment of AD in adults and included strong recommendations for both dupilumab and tralokinumab. While no head-to-head trials have been performed, a meta-analysis indicated that dupilumab was more effective than tralokinumab at 16 weeks. Lebrikizumab and nemolizumab were not addressed in these guidelines[15]. A focused

guideline, however, was published in 2025 to address the use of tapinarof cream, roflumilast cream, lebrikizumab, and nemolizumab in adults. Lebrikizumab and nemolizumab received strong recommendations with high-certainty evidence for use in moderate to severe AD.[35]

The 2023 American Academy of Allergy, Asthma and Immunology/American College of Allergy, Asthma and Immunology Joint Task Force on Practice Parameters GRADE – and Institute of Medicine-based recommendations support the AAD guidelines with recommendations on topical products as well as systemic products. Lebrikizumab is noted in these guidelines under the discussion of tralokinumab. Guidelines note that there is no recommendation for dupilumab over tralokinumab, however there is currently more support for dupilumab. It is noted that revision or adaptation of the guidelines may occur once a formal assessment has been made of lebrikizumab. Nemolizumab was not addressed in these guidelines. Second-line systemic options include the JAK inhibitors.[16]

Ninety-seven studies were included in a living systematic review and network meta-analysis of seven databases which indicated that lebrikizumab had similar efficacy to dupilumab[17]. A second systematic review and network meta-analysis of five databases included 149 studies and found greater efficacy of dupilumab versus tralokinumab or lebrikizumab. All three had favorable safety profiles.[18]

Guidelines:

- American Academy of Allergy, Asthma and Immunology/American College of Allergy, Asthma and Immunology Joint Task Force: https://www.annallergy.org/article/S1081-1206(23)01455-2/fulltext
- American Academy of Dermatology: https://www.aad.org/member/clinical-quality/guidelines/atopic-dermatitis

Behcet's Disease (BD):

Behcet's Disease/Syndrome is a chronic inflammatory disorder of blood vessels throughout the body which requires different therapies depending on the organs/systems involved. The British Association of Dermatologists and British Society for Rheumatology living guideline from 2024 recommends the following pharmacological options for oral ulcers[39]:

- First line: Topical corticosteroids, triple mouthwash (betamethasone, doxycycline, nystatin)
- Second line: Colchicine
- Third line: Azathioprine or mycophenolate mofetil, tumor necrosis factor (TNF) inhibitor

- Fourth line: Apremilast (Otezla), secukinumab (Cosentyx)
- Dapsone

The European Alliance of Associations for Rheumatology (EULAR) guidelines from 2018 recommend topical corticosteroids, colchicine, azathioprine, thalidomide, interferon-alpha, tumor necrosis factor-alpha inhibitors, and apremilast[40].

Guidelines:

- British Association of Dermatologists and British Society for Rheumatology: https://academic.oup.com/bjd/article/191/5/e8/7754287
- European Alliance of Associations for Rheumatology (EULAR): https://ard.bmj.com/content/77/6/808

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP):

Chronic rhinosinusitis (CRS) is defined as inflammation of the nasal cavity and presence of at least two other symptoms (e.g., facial pressure, nasal discharge) for more than 12 weeks. To diagnose CRS, inflammation must be documented by examination and/or computerized tomography (CT) imaging.

The 2023 Joint Task Force, consisting of members from the American Academy of Allergy, Asthma & Immunology, American College of Allergy, Asthma, and Immunology and the American Academy of Otolaryngology-Head and Neck Surgery (2025), recommend the following: (1) In people with CRSwNP, the guideline panel suggests intranasal corticosteroids (INCS) rather than no INCS (conditional recommendation, low certainty of evidence). (2) In people with CRSwNP, the guideline panel suggests biologics rather than no biologics (conditional recommendation, moderate certainty of evidence).[33]

Guidelines:

- American Academy of Otolaryngology-Head and Neck Surgery: https://aao-hnsfjournals.onlinelibrary.wiley.com/doi/10.1002/ohn.1344
- Allergy-Immunology Joint Task Force: https://www.sciencedirect.com/science/article/pii/S0091674922014841?via%3Dihub

Chronic Spontaneous Urticaria (CSU):

Urticaria is a primarily mast-cell driven condition characterized by wheals and/or angioedema. The activation of mast cells leads to the release of mediators e.g., histamine, platelet-activating factor (PAF), and cytokines which results in the activation of sensory nerves, vasodilatation and plasma extravasation. Additional

cells are also recruited to the location of the urticarial lesions. The diagnostic work-up for CSU involves both confirming the diagnosis and ruling out other causes[28].

The EAACI/GA2LEN/EDF/AAAAI/WAO 2021 Guideline for the Management of Urticaria provides the following pharmacological recommendations[28]:

- First line therapy: Second generation H_1-antihistamines – scheduled standard dosing
- Second line therapy: Second generation H_1-antihistamines – up to fourfold increase from scheduled standard dosing
- Third line therapy: Add-on therapy with omalizumab 300 mg every 4 weeks
- Fourth line therapy: Off-label increase in omalizumab to doses up to 600 mg every 2 weeks
- Fifth line therapy: Cyclosporine

Efficacy should be assessed every 3-6 months for continuation/step down or alternative drug therapy.[28].

Guidelines:

- European Academy of Allergology and Clinical Immunology (EEACI)/Global Allergy and Asthma European Network (GA^{2}LEN)/European Dermatology Forum (EuroGuiDerm)/Asia Pacific Association of Allergy (APAACI): https://onlinelibrary.wiley.com/doi/10.1111/all.15090

Crohn's Disease (CD):

Based on the available evidence and national practice guidelines, TIMs are effective products in inducing and maintaining remission in severe, active CD. These products are typically used when conventional therapies (e.g., corticosteroids, mesalamine, 6-MP and azathioprine) have failed to induce remission. Some systematic reviews and meta-analyses suggest that infliximab and adalimumab may have superior efficacy over other TIMs products from indirect comparisons. Overall, there is insufficient direct comparative evidence for the efficacy of TIMs in the treatment of severe, active CD; all FDA approved products have shown to be superior to placebo and are considered to have comparable efficacy.

Dose escalation requests are common for this disease state. Adalimumab maintenance dosing is every other week, but evidence suggests that once weekly dosing can be helpful for patients that have not achieved a full response to every other week dosing (this dosing regimen is covered per policy). Ustekinumab (Stelara) is covered at every eight weeks for CD. Two retrospective evaluations of patients that were dose escalated to every four weeks have been published.[2,3] However, these studies are of low-quality; retrospective in nature (non-standardized treatment protocols and follow-up procedures) and did not adequately compare

changes seen with dose escalation to that of standard therapy. In addition, surrogate markers were used for determining disease activity (lack of robust endoscopic evaluations). Endoscopy/colonoscopy and/or imaging are used to measure active inflammation and can be useful in determining whether dose escalation is reasonable. Per the American College of Gastroenterology (ACG) 2018 Clinical Guideline on the Management of Crohn's Disease in Adults, endoscopy/colonoscopy may show evidence of ulcerations and granulomatous inflammation. Common forms of imaging in Crohn's disease are computed tomography enterography (CTE) and magnetic resonance enterography (MRE). Signs of active inflammation through on CTE consist of mucosal enhancement, mesenteric hypervascularity, and mesenteric fat stranding. In MRE, the signs are similar to CTE, but also can detect wall enhancement, mucosal lesions, and T2 hypersensitivity.

The American Gastroenterological Association (AGA), in their 2021 guidelines, defines moderate to severe luminal Crohn's disease as any of the following:

- CDAI score of at least 220
- High risk of adverse disease-related complications, e.g., surgery, hospitalizations, and disability based on a combination of structural damage, inflammatory burden, and impact on quality of life

The AGA recommends the use of infliximab, adalimumab, ustekinumab, or vedolizumab over certolizumab for the induction of remission in patients without previous use of TIMs products. In primary non-responders to TNF products, they recommend use of ustekinumab to induce remission (vedolizumab may be considered). For those that loss response to infliximab, they recommend adalimumab or ustekinumab to induce remission (vedolizumab may be considered). For patients with moderate to severe disease, biologic therapy is recommended to induce remission instead of 5-aminosalicylates and/or corticosteroids.[8]

Guidelines:

- ACG Clinical Guideline Management of Crohn's Disease in Adults (2018): https://journals.lww.com/ajg/Fulltext/2018/04000/ACG_Clinical_Guideline__Management_of_Crohn_s.10.aspx
- AGA Medical management of moderate to severe luminal and perianal fistulizing Crohn's disease (2021): https://gastro.org/clinical-guidance/medical-management-of-moderate-to-severe-luminal-and-perianal-fistulizing-crohns-disease/

Eosinophilic Esophagitis (EoE):

Eosinophilic esophagitis is a chronic atopic inflammatory disorder limited to the esophagitis that is diagnosed using all of the following:

- Presence of symptoms of esophageal dysfunction (including dysphagia, food impaction, abdominal pain, heartburn, regurgitation, chest pain, vomiting)
- Esophageal biopsy consisting of ≥15 eosinophils per high-power field (eos/hpf)
- Evaluation showing no other significant causes of esophageal dysfunction (e.g., Barrett's esophagus) and/or esophageal eosinophilia (Crohn's disease with esophageal eosinophilia, infection, connective tissue disorder, drug hypersensitivity)[30]

PPIs are an effective first-line option. Topical glucocorticoids, including fluticasone inhaler or swallowed budesonide, are off-label options which may effectively decrease eosinophil counts. These options can be used for long-term therapy and have fewer side effects than systemic glucocorticoids, which have been shown to improve symptoms in 95% of pediatric EoE patients in short-term use, yet 90% of patients experienced recurrence of symptoms upon discontinuation of therapy.[30,31]

Dupilumab is a treatment option which targets drivers of type 2 inflammation and is recommended in patients who are unresponsive to other treatments e.g., PPIs or glucocorticoids. Recommended dosing for dupilumab in EoE is 300 mg given every week for adult and pediatric patients weighing at least 40 kg.[1]

Guidelines:

- ACG Clinical Guideline Diagnosis and Management of Eosinophilic Esophagitis (2025): https://journals.lww.com/ajg/fulltext/2025/01000/acg_clinical_guideline__diagnosis_and_management.16.aspx

Eosinophilic Granulomatosis with Polyangiitis (EGPA):

Per the EULAR algorithm for treatment of EGPA, in patients with relapsing or refractory EGPA without organ-threatening manifestations at the time of relapse, mepolizumab is preferred for maintenance of remission, and azathioprine, methotrexate or rituximab can be used as alternatives if mepolizumab is not tolerated or ineffective.[34]

The approval of mepolizumab for eosinophilic granulomatosis with polyangiitis (EGPA) was based on a placebo-controlled, multicenter, 52-week trial. In this trial, mepolizumab led to significantly more accrued weeks of remission (Birmingham Vasculitis Activity Score 0 and prednisone less than or equal to 4mg/day), than placebo (odds ratio [OR] 5.91; 95% CI 2.68-13.03) and a higher percentage of participants in remission at weeks 36 and 48 (OR 16.74; 95% CI 3.61-77.56). Patients had to have a diagnosis of relapsing or refractory eosinophilic

granulomatosis with polyangiitis at least six months previously, and had been taking a stable dose of prednisolone or prednisone with a majority of patients having previously taken immunosuppressive products.[24]

The approval of benralizumab for eosinophilic granulomatosis with polyangiitis (EGPA) was based on the MANDRA trial, a randomized, double-blind, active-controlled, noninferiority 52-week clinical study comparing the efficacy and safety of benralizumab to mepolizumab. The study included adult patients with asthma, eosinophilia (≥1,000 cells/uL or >10% of leukocytes), and a history of relapsing or refractory disease treated with prednisolone/prednisone with or without immunosuppressive therapy. The trial showed the noninferiority of benralizumab to mepolizumab in the induction of remission, defined as Birmingham Vasculitis Activity Score (BVAS) of 0 and prednisolone/prednisone dose of 4 mg/day or less, at weeks 36 and 48. In addition, the accrued duration of remission was similar between benralizumab and mepolizumab (odds ratio [OR] 1.36, 95% CI: 0.75-2.48).[1,25]

Guidelines:

- American College of Rheumatology/European Alliance of Associations for Rheumatology Classification Criteria for Eosinophilic Granulomatosis with Polyangiitis (2022): https://ard.bmj.com/content/81/3/309.info

Hidradenitis Suppurativa (HS):

HS (also known as acne inversa and Verneuil disease) is a chronic inflammatory skin condition involving the occlusion of hair follicles which can cause abscesses, draining skin tunnels, and fibrotic scars. Occlusion and rupture of the nodules releases keratin and bacteria which induces an immune response. HS is classified using the Hurley staging system as follows[29]:

- Hurley Stage I: Abscesses without tunneling or scars
- Hurley Stage II: Abscesses with tunneling and/or scars which are recurrent with single or multiple widely spaced lesions
- Hurley Stage III: Diffuse lesions which may include multiple tracts and large abscesses with near complete skin involvement

The 2019 North American clinical guidelines cite the level of evidence for pharmacological therapies in descending order as follows[41]:

- Adalimumab
- Rifampin + clindamycin, isotretinoin, acitretin, alitretinoin, infliximab, anakinra, ustekinumab
- Clindamycin, tetracyclines, rifampin + moxifloxacin + metronidazole, antiandrogen contraceptives, etanercept

- Zinc pyrithione, resorcinol, intralesional triamcinolone, benzoyl peroxide, dapsone, ertapenem, spironolactone, metformin, finasteride, cyclosporine, systemic steroids, golimumab

Guidelines:

- North American clinical management guidelines: https://www.sciencedirect.com/science/article/pii/S0190962219303676?via%3Dihub

Hypereosinophilic Syndrome:

The approval of mepolizumab for hypereosinophilic syndrome (HES) was based on a randomized, double-blind, placebo-controlled, multicenter 32-week study. The incidence of HES flare over the treatment period was 56% for the placebo group and 28% for the group treated with NUCALA (50% reduction) (OR 0.28, 95% CI 0.12-0.64, p-value 0.002). Treatment with mepolizumab resulted in a statistically significant 66% reduction in the annualized rate of HES flares compared with placebo. Patients had to have a diagnosis of primary HES for at least six months and been on stable HES therapy for four weeks prior to randomization (including chronic or episodic oral corticosteroids (OCS), immunosuppressive, or cytotoxic therapy).[26]

Plaque Psoriasis (Ps):

Psoriasis is a chronic, inflammatory skin condition commonly characterized by well-demarcated, erythematous plaques with silvery scales. The morphology varies, however, resulting in five primary subtypes of psoriasis[42]:

- Plaque: erythematous plaques covered in silvery scales primarily found over the extensor surfaces of the extremities (e.g., elbows, knees, scalp, and back)
- Guttate/Eruptive: erythematous raindrop-shaped plaques with silvery scales primarily found over the trunk and the back and commonly seen in children who have had an upper respiratory tract infection
- Pustular: either localized or generalized small non-infectious, pus-filled lesions surrounded by erythema
- Erythrodermic: generalized inflammation with erythema and skin exfoliation of over 90% of the body resulting from plaque psoriasis exacerbation
- Inverse/Flexural/Intertriginous: smooth, erythematous patches primarily found in areas e.g., the groin and armpits

In clinical trials, psoriasis is commonly measured utilizing the psoriasis area severity index (PASI) with a score of 0 representing no disease and 72 representing the most severe disease. In practice, severity may also be measured by body surface area (BSA) with mild as less than 3% BSA, moderate as 3-10% BSA, and severe as greater than 10% BSA. Severe disease may also be diagnosed for patients with

10% BSA or less if it results in decreased quality of life or is present in locations e.g., the hands, feet, scalp, face, or genital region[43].

The Joint American Academy of Dermatology (AAD) and National Psoriasis Foundation (NPF) guidelines from 2019 do not recommend one biologic product over another[43].

Guidelines:

- Joint American Academy of Dermatology (AAD) and National Psoriasis Foundation (NPF) 2019 guidelines: https://www.jaad.org/article/S0190-9622(18)33001-9/fulltext

Polyarticular Juvenile Idiopathic Arthritis (PJIA):

Juvenile Idiopathic Arthritis (JIA) is an umbrella term for a group of seven chronic arthritic conditions which affect children under 16 years of age. These subtypes are oligoarthritis, rheumatoid factor (RF) positive polyarthritis, RF negative polyarthritis, systemic arthritis, psoriatic arthritis, enthesitis-related arthritis, and undifferentiated arthritis. Treatment options for JIA depend on the subtype, severity, damage, and associated disease[53].

The American College of Rheumatology 2019 Guidelines recommend the following pharmacological therapy for PJIA[55]:

- Initial therapy with a disease-modifying anti-rheumatic drug (DMARD) is strongly recommended over nonsteroidal anti-inflammatory drug (NSAID) monotherapy
- Methotrexate monotherapy as initial therapy is conditionally recommended over triple DMARD therapy
- For patients without risk factors, initial therapy with a DMARD is conditionally recommended over a biologic
- For patients with risk factors, initial therapy with a DMARD is conditionally recommended over a biologic, recognizing that there are situations where initial therapy that includes a biologic may be preferred
- If low disease activity remains, escalating therapy is conditionally recommended over no escalation of therapy
- If moderate to high disease activity remains, adding a biologic to the original DMARD is conditionally recommended over:
    - switching to another DMARD
    - changing to triple DMARD therapy
- If moderate to high disease with tumor necrosis factor (TNF) inhibitor, switching to a non-TNF inhibitor biologic is conditionally recommended over switching to a second TNF inhibitor

Guidelines:

- American College of Rheumatology 2019 Guidelines: https://rheumatology.org/juvenile-idiopathic-arthritis-guideline

Polymyalgia rheumatica (PMR):

Polymyalgia rheumatica (PMR) is chronic inflammatory condition characterized by pain and morning stiffness, specifically in the shoulders and pelvic region[51]. The 2015 Guidelines for the Management of PMR, developed by the European League Against Rheumatism (EULAR) in collaboration with the American College of Rheumatology (ACR), recommends oral glucocorticoids as first-line therapy with intramuscular methylprednisolone as a potential alternative. In patients at high risk of relapse or prolonged therapy with glucocorticoids, early introduction of methotrexate should be considered[52].

Sarilumab was studied in the SAPHYR trial for use in PMR. This phase 3, multicenter, randomized, double-blind, placebo-controlled trial enrolled 118 patients with at least one PMR flare during a glucocorticoid taper. Patients with giant-cell arteritis, rheumatoid arthritis, or other inflammatory arthritis conditions were excluded. The study population was randomly assigned in a 1:1 ratio to receive 52 weeks of sarilumab 200 mg twice monthly plus a 14-week prednisone taper or placebo plus a 52-week prednisone taper. The primary outcome of sustained remission at 52 weeks occurred in 28% of patients receiving sarilumab versus 10% receiving placebo. The most common adverse effects were neutropenia, diarrhea, arthralgia, insomnia, hypertension, and osteoarthritis[51].

Guidelines:

- European League Against Rheumatism (EULAR)/American College of Rheumatology (ACR) 2015 Guidelines: https://rheumatology.org/polymyalgia-rheumatica-guideline#2015-polymyalgia-guideline

Prurigo nodularis (PN):

Prurigo nodularis is a rare chronic inflammatory skin disease where hard, extremely itchy bumps called nodules appear. The cause of the condition is unknown, but PN can either be associated with an underlying medical condition or appear on its own. PN is associated with itch that is often severe enough to interfere with sleep and mental health. Diagnosis is conducted by ruling out other skin conditions, treatment of any underlying diseases, and assessing number nodules and severity of itch. Treatments supported by compendia for prurigo include standard topical antipruritic products available over the counter e.g., menthol and camphor, oatmeal baths, pramoxine, and calamine lotion. Further treatment supported by compendia include

topical corticosteroids and, to relieve nighttime itching, sedating antihistamines or antidepressants.[19] A Japanese Dermatological Association 2020 guideline for prurigo published in the Journal of Dermatology suggests additional treatment options including vitamin D3 analogues, tacrolimus ointment, cyclosporine, and systemic corticosteroid therapy, among others. These treatment options do not have high levels of evidence to support them due to the rarity of PN. Nemolizumab and dupilumab are not mentioned in these guidelines.[49] A 2021 United States expert panel supports these recommendations and note no FDA-approved therapies for PN at the time of the guidelines[50].

The OLYMPIA 1 phase 3, double-blind, multicenter, randomized trial was a 24-week trial which enrolled 286 participants at least 18 years of age who had PN for at least 6 months with severe pruritis defined as an average PP-NRS of at least 7, 20 or more bilaterally distributed nodules, and an IGA score of 3 or 4. Patients were randomized 2:1 to receive nemolizumab (dosed according to weight) or placebo. Results showed a statistically significant benefit of nemolizumab in achieving both of the following coprimary endpoints at week 16: 4 points or greater improvement on the PP-NRS and a score of 0 or 1 plus a reduction of at least 2 points in the IGA score[20].

The OLYMPIA 2 phase 3, double-blind, multicenter, randomized trial was a 16-week trial which enrolled 274 participants with the same criteria as the OLYMPIA 1 trial. Randomization was identical and results were also significant for the same primary endpoints[21].

The LIBERTY-PN PRIME and PRIME2 trials were two phase 3 double-blind, randomized controlled trials which assessed the efficacy of dupilumab for PN in adult patients. Dupilumab 300 mg every 2 weeks for 24 weeks reduced the number of nodules from a baseline range of 20 to greater than 100 to 5 or less in 32% of patients in the PRIME trial versus 11.8% of placebo. The PRIME2 trial showed similar results with a decrease of 25.6% with dupilumab versus 12.2% with placebo. A reduction of at least 4 points in the Worst Itch Numeric Scale Rating (WI-NRS) was also achieved by 60% of patients receiving dupilumab versus 18.4% of patients receiving placebo[48].

Guidelines:

- Japanese Dermatological Association 2020 guidelines: https://onlinelibrary.wiley.com/doi/full/10.1111/1346-8138.16067
- 2021 United States Expert Panel: https://pubmed.ncbi.nlm.nih.gov/32682025/

Psoriatic Arthritis (PsA):

PsA is a chronic inflammatory arthritis with clinical features similar to other spondyloarthropathies and rheumatoid arthritis. These features are classified as either articular/periarticular or extra-articular. Articular/periarticular features include peripheral arthritis, enthesitis, dactylitis, tenosynovitis, axial disease, and spondylitis. Extra-articular features include psoriatic skin disease, nail disease, and ocular disease. Treatment is guided by the severity of disease, joint damage, extra-articular disease, comorbidities, and patient preference[44].

The European Alliance of Associations for Rheumatology (EULAR) 2023 Guidelines provide the following recommendations[45]:

- For musculoskeletal signs and symptoms: non-steroidal anti-inflammatory drugs (NSAIDs), adjunctive local injections of glucocorticoids
- For polyarthritis or monoarthritis/oligoarthritis with poor prognostic factors: conventional synthetic disease-modifying antirheumatic drug (csDMARD) with a preference for methotrexate with skin involvement
- For peripheral arthritis with an inadequate response to a csDMARD: biological disease-modifying antirheumatic drug (bDMARD)
- For peripheral arthritis with an inadequate response to a csDMARD and a bDMARD: Janus kinase inhibitor (JAKi)
- For peripheral arthritis with an inadequate response to a csDMARD, bDMARD, and JAKi: phosphodiesterase-4 (PDE4) inhibitor
- For unequivocal enthesitis with an inadequate response to NSAIDs or local glucocorticoid injections: bDMARD
- For clinically relevant axial disease with an inadequate response to NSAIDs: Interleukin (IL)-17A inhibitor, Tumor Necrosis Factor (TNF) inhibitor, IL-17A/F inhibitor, JAKi

Guidelines:

- European Alliance of Associations for Rheumatology (EULAR) 2023 Guidelines: https://ard.bmj.com/content/83/6/706

Rheumatoid arthritis (RA):

Rheumatoid arthritis (RA) is a systemic autoimmune disease which includes both inflammatory arthritis as well as extra-articular involvement. The most common symptoms are joint pain and swelling, often starting in the smaller joints and progressing to the larger joints. The most common extra-articular features are rheumatoid nodules, commonly found on pressure points. Classification of RA involves the number and size of joints involved, serological testing for rheumatoid factor or anti-citrullinated peptide/protein antibody, elevated acute phase reactants (ESR or CRP), and symptom duration of at least six weeks[46].

The 2022 European Alliance of Associations for Rheumatology (EULAR) Guidelines provide the following pharmacological recommendations[47]:

- Conventional synthetic disease-modifying antirheumatic drugs (csDMARDs) should be considered as first-line medications, specifically methotrexate. Leflunomide or sulfasalazine may be considered in patients unable to take methotrexate
- If failure of csDMARD and no poor prognostic factors, switch to another csDMARD
- If failure of csDMARD and poor prognostic factors, switch to a biological DMARD (bDMARD). A Janus kinase (JAK) inhibitor may also be considered however risk must be considered
- bDMARD and tsDMARD (targeted synthetic DMARDs), e.g., JAK inhibitors, should be combined with a csDMARD if possible
- If failure of b/tsDMARD, switch to another b/tsDMARD

In 2017, ICER published a review of the Targeted Immune Modulators for Rheumatoid Arthritis. They reviewed the following therapies[4]:

- TNFα inhibitors: adalimumab (Humira), certolizumab pegol (Cimzia), etanercept (Enbrel), golimumab (Simponi and Simponi Aria), infliximab (Remicade):
- CD20-directed cytolytic B-cell antibody: rituximab (Rituxan)
- T-cell inhibitor: abatacept (Orencia)
- IL-6 inhibitors: tocilizumab (Actemra,), sarilumab (Kevzara™)
- JAK inhibitors: tofacitinib (Xeljanz), baricitinib (Olumiant™)

Newer products, e.g., upatacitinib (rinvoq) were not included in this review.

Using a network meta-analysis, the review suggests that all products are superior to conventional DMARD monotherapy. There have been some head-to-head trials conducted between the TIMs products and adalimumab was found to be inferior to monotherapy with tocilizumab or sarilumab in terms of achieving clinical remission or ACR responses; these products were rated as B+ over adalimumab (Moderate certainty of a small or substantial net health benefit, with high certainty of at least a small net health benefit). Abatacept was given the same B+ rating over infliximab. Tofacitinib is considered more costly and less effective than adalimumab[4].

In 2019, ICER completed a review of janus kinase (JAK) inhibitors for the treatment of RA. They found that upadacitinib and tofacitinib have a high certainty of net health benefit over DMARD monotherapy in patients that have not used a TIMs product previously; the certainty of this benefit is lower when patients have already failed a TIMs product. Upadacitinib may have superior efficacy to adalimumab and may be more cost-effective but noted that adalimumab is still well above cost-effectiveness

thresholds. Additionally, there are safety concerns with JAK inhibitors medications that must be taken into consideration[7].

Guidelines:

- European Alliance of Associations for Rheumatology (EULAR) 2022 Guidelines: https://ard.bmj.com/content/82/1/3

Systemic Juvenile Idiopathic Arthritis (SJIA)

Juvenile Idiopathic Arthritis (JIA) is an umbrella term for a group of seven chronic arthritic conditions which affect children under 16 years of age. These subtypes are oligoarthritis, rheumatoid factor (RF) positive polyarthritis, RF negative polyarthritis, systemic arthritis, psoriatic arthritis, enthesitis-related arthritis, and undifferentiated arthritis. Treatment options for JIA depend on the subtype, severity, damage, and associated disease[53].

SJIA is differentiated from other forms of JIA by fever, rash, and visceral involvement and may be considered an autoimmune disorder. The pathogenesis of the disease and the involvement of cytokines differ from other forms of JIA as well. In up to 40% of cases, SJIA is associated with Macrophase Activation Syndrome (MAS) which is a life-threatening complication.

The American College of Rheumatology 2021 Guidelines recommend the following pharmacological therapy for SJIA[54]:

- For SJIA without MAS:
  - Biologic disease-modifying anti-rheumatic drugs (bDMARDs), specifically Interleukin (IL)-1 and -6 inhibitors, are conditionally recommended as initial monotherapy
  - Nonsteroidal anti-inflammatory drugs (NSAIDs) are conditionally recommended as initial monotherapy
- For SJIA with MAS:
  - bDMARDs (specifically IL-1 and IL-6 inhibitors) are conditionally recommended over calcineurin inhibitor monotherapy
  - Glucocorticoids are conditionally recommended as part of initial treatment
  - bDMARD or conventional synthetic DMARDs (csDMARDs) are strongly recommended over long-term glucocorticoids if incomplete response to bDMARD

Guidelines:

- American College of Rheumatology 2021 Guidelines: https://rheumatology.org/juvenile-idiopathic-arthritis-guideline

Ulcerative Colitis (UC):
Based on the available evidence and national practice guidelines, TIMs are effective products in inducing and maintaining remission in moderate to severe UC. These products are typically used when conventional therapies (e.g., aminosalicylates, topical mesalamine, corticosteroids, 6-mercaptopurine (6-MP) and azathioprine) have failed to induce remission. Infliximab may be more consistently efficacious for inducing remission and mucosal healing than adalimumab. Overall, there is insufficient direct comparative evidence for the efficacy of TIMs in the treatment of moderate to severe UC; all FDA approved products have shown to be superior to placebo and are considered to have comparable efficacy.

The 2025 ACG guidelines recommend the following in patients with moderate to severe ulcerative colitis to induce remission: oral budesonide, oral systemic corticosteroids, ozanimod, etrasimod, ustekinumab, guselkumab, mirikizumab, risankizumab, vedolizumab, infliximab, adalimumab, golimumab, tofacitinib, upadacitinib. Data on combination anti-TNF and immunomodulators in moderately to severely active UC only exist for infliximab and thiopurines.[56]

In 2020, the Institute for Clinical and Economic Review (ICER) published a report on TIMs for UC, assessing the following therapies: adalimumab, golimumab, infliximab and biosimilars, tofacitinib, and ustekinumab. All products were found to be clinically superior than placebo, and all were found to be comparable to adalimumab. It was noted that vedolizumab was “found to produce greater rates of clinical response and remission over adalimumab, the market leader, in both patients who had used TIMs previously (“biologic-experienced”) as well as those who did not (“biologic-naïve”).” No products were found to be cost-effective at current drug costs, but infliximab and its biosimilars represent the best value for money for UC.[9]

The AGA, in their 2020 guidelines, defines moderate to severely active UC as any of the following:
- Patients deemed to be at high-risk for colectomy
- Mayo Clinic Score 6–12, with Mayo Endoscopic Subscore 2 or 3
- Severely active endoscopic disease, with ulcers
- Patients with corticosteroid dependence, or refractory to oral corticosteroids

The AGA recommends infliximab, adalimumab, golimumab, vedolizumab, tofacitinib, or ustekinumab over no treatment; however, they suggest the use of infliximab or vedolizumab over adalimumab for the induction of remission in patients without previous use of TIMs products. They do not recommend the use of tofacitinib in this setting, unless in a clinical trial. In primary non-responders to infliximab, they suggest use of ustekinumab or tofacitinib rather than vedolizumab or adalimumab for induction of remission.[10]

Guidelines:

- American Gastroenterological Association (2020): http://www.gastro.org/guidelines
- American College of Gastroenterology (2025): https://gi.org/clinical-guidelines/clinical-guidelines-sortable-list/

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PHARMACY PRIOR AUTHORIZATION POLICY AND CRITERIA ORPTCOTH016	MISCELLANEOUS PRODUCTS THERAPEUTIC IMMUNOMODULATORS (TIMs) See Table 1 for Applicable Medications

Table 1. Self-administered TIMs and their respective FDA-approved Indications. FDA approvals listed below are for adult patients, unless otherwise indicated.

Drug	MOA	AD	AS	Asthma	CD	Ps	PsA	RA	UC	Other
Abatacept (Orencia)	T-cell inhibitor						X (age 2+)	X		PJIA (age 2+) aGVHD (age 2+)
Abrocitinib (Cibinqo)	JAK inhibitor	X (age 12+)								
Adalimumab (Humira)	Anti-TNF		X		X (age 6+)	X	X	X	X (age 5+)	PJIA (age 2+) Uveitis (age 2+) HS (age 12+)
Adalimumab-aacf (Idacio)	Anti-TNF		X		X (age 6+)	X	X	X	X	PJIA (age 2+) HS (age 12+) Uveitis (age 2+)
Adalimumab - aaty (Yuflyma)	Anti-TNF		X		X (age 6+)	X	X	X	X	PJIA (age 2+) HS (age 12+) Uveitis (age 2+)
Adalimumab-adaz (Hyrimoz)	Anti-TNF		X		X (age 6+)	X	X	X	X	PJIA (age 2+) HS (age 12+) Uveitis (age 2+)
Adalimumab-adbm (Cyltezo)	Anti-TNF		X		X (age 6+)	X	X	X	X	PJIA (age 2+) HS (age 12+)

Drug	MOA	AD	AS	Asthma	CD	Ps	PsA	RA	UC	Other
										Uveitis (age 2+)
Adalimumab-afzb (Abrilada)	Anti-TNF		X		X (age 6+)	X	X	X	X	HS PJIA (age 2+) Uveitis
Adalimumab-aqvh (Yusimry)	Anti-TNF		X		X (age 6+)	X	X	X	X	PJIA (age 2+) HS Uveitis
Adalimumab-atto (Amjevita)	Anti-TNF		X		X (age 6+)	X	X	X	X	PJIA (age 2+) HS (12+) Uveitis (age 2+)
Adalimumab-bwwd (Hadlima)	Anti-TNF		X		X (age 6+)	X	X	X	X	PJIA (age 2+) HS Uveitis
Adalimumab-fkjp (Hulio)	Anti-TNF		X		X (age 6+)	X	X	X	X	PJIA (age 2+) HS Uveitis
Adalimumab-ryvk (Simlandi)	Anti-TNF		X		X (age 6+)	X	X	X	X	PJIA (age 2+) HS (age 12+) Uveitis (age 2+)
Anakinra (Kineret)	IL-1 inhibitor							X		NOMID/CAPS DIRA (age 0+)
Apremilast (Otezla)	PDE-4 inhibitor					X (6+)	X (6+)			BD
Baricitinib (Olumiant)	JAK inhibitor							X		AA COVID-19
Benralizumab (Fasenra)	IL-5 inhibitor			X (eosinophilic type age 6+)						EGPA
Bimekizumab (Bimzelx)	IL-17 inhibitor		X			X	X			NRAS HS
Brodalumab (Siliq)	IL-17 inhibitor					X				
Certolizumab (Cimzia)	Anti-TNF		X		X	X	X	X		NRAS PJIA (age 2+)
Deucravacitinib (Sotyktu)	TYK-2 inhibitor					X				
Deuruxolitinib (Leqselvi)	JAK inhibitor									AA

Drug	MOA	AD	AS	Asthma	CD	Ps	PsA	RA	UC	Other
Dupilumab (Dupixent)	IL-4/13 inhibitor	X (age 6 mo +)		X (age 6+)						BP COPD CRSwNP (12+) CSU (12+) EoE (1+) PN
Etanercept (Enbrel)	Anti-TNF		X			X (age 4+)	X (age 2+)	X		PJIA (age 2+)
Etrasimod arginine (Velsipity)	S1PR modulator								X	
Golimumab (Simponi)	Anti-TNF		X				X	X	X (weight 15 kg+)	
Guselkumab (Tremfya)	IL-23 inhibitor				X	X (age 6+) (weight 40 kg+)	X (age 6+) (weight 40 kg+)		X	
Infliximab-dyyb (Zymfentra)	Anti-TNF				X				X	
Ixekizumab (Taltz)	IL-17 inhibitor		X			X (age 6+)	X			NRAS
Lebrikizumab (Ebglyss)	IL-13 inhibitor	X (age 12+)								
Mepolizumab (Nucala)	IL-5 inhibitor			X (eosinophilic type age 6+)						COPD CRSwNP EGPA HES (12+)
Mirikizumab-mrkz (Omvoh)	IL-23 inhibitor				X				X	
Nemolizumab (Nemluvio)	IL-31 inhibitor	X (age 12+)								PN
Omalizumab (Xolair)	IgE inhibitor			X (age 6+)						CSU (12+) CRSwNP IgE-Mediated Food Allergy (1+)
Remibrutinib (Rhapsido)	BTK inhibitor									CSU
Risankizumab-rzaa (Skyrizi)	IL-23 inhibitor				X	X	X		X	

Drug	MOA	AD	AS	Asthma	CD	Ps	PsA	RA	UC	Other
Ritlecitinib (Litfulo)	JAK inhibitor									AA (12+)
Sarilumab (Kevzara)	IL-6 inhibitor							X		PMR PJIA
Secukinumab (Cosentyx)	IL-17 inhibitor		X			X (age 6+)	X (age 2+)			NRAS ERA (age 4+) HS
Tezepelumab-ekko (Tezspire)	TSLP inhibitor			X (age 12+)						CRSwNP (12+)
Tocilizumab (Actemra)	IL-6 inhibitor							X		GCA PJIA (age 2+) SJIA (age 2+) SSc-ILD
Tocilizumab (Avtozma)	IL-6 inhibitor							X		GCA PJIA (age 2+) SJIA (age 2+)
Tocilizumab-aazg (Tyenne)	IL-6 inhibitor							X		GCA PJIA (age 2+) SJIA (age 2+)
Tofacitinib (Xeljanz)	JAK inhibitor		X				X (age 2+)	X	X	PJIA (age 2+)
Tofacitinib (Xeljanz XR)	JAK inhibitor		X				X	X	X	
Tralokinumab (Adbry)	IL-13 inhibitor	X (age 12+)								
Upadacitinib (Rinvoq)	JAK inhibitor	X (age 12+)	X		X		X (age 2+)	X	X	GCA NRAS PJIA (age 2+)
Upadacitinib (Rinvoq LQ)	JAK inhibitor						X (age 2+)			PJIA (age 2+)
Ustekinumab (Stelara)	IL-12/23 inhibitor				X	X (age 6+)	X (age 6+)		X	
Ustekinumab-aauz (Otulfi)	IL-12/23 inhibitor				X	X (age 6+)	X (age 6+)		X	
Ustekinumab-aekn (Selarsdi)	IL-12/23 inhibitor				X	X (age 6+)	X (age 6+)		X	
Ustekinumab-auub	IL-12/23 inhibitor				X	X	X		X	

Drug	MOA	AD	AS	Asthma	CD	Ps	PsA	RA	UC	Other
(Wezlana)						(age 6+)	(age 6+)			
Ustekinumab-kfce (Yesintek)	IL-12/23 inhibitor				X	X (age 6+)	X (age 6+)		X	
Ustekinumab-srlf (Imuldosa)	IL-12/23 inhibitor				X	X (age 6+)	X (age 6+)		X	
Ustekinumab-stba (Steqeyma)	IL-12/23 inhibitor				X	X (age 6+)	X (age 6+)		X	
Ustekinumab-ttwe (Pyzchiva)	IL-12/23 inhibitor				X	X (age 6+)	X (age 6+)		X	
Vedolizumab (Entyvio Pen)	α4β7 inhibitor				X**				X**	

Indications are approved in adults unless otherwise noted.
infliximab (Remicade) and infliximab biosimilars (e.g., Inflectra, Renflexis) are the only FDA approved drugs for **fistulizing** Crohn's Disease – preferred products are not FDA approved for this sub-indication and do not apply.
**vedolizumab for intravenous administration is eligible for coverage, and is considered a preferred product under the medical benefit.
Abbreviations: AA = alopecia areata; AD = atopic dermatitis; aGVHD = Prophylaxis of acute graft versus host disease; AS = ankylosing spondylitis; BD = oral ulcers associated with Behçet's Disease; BP = bullous pemphigoid; BTK = Bruton Tyrosine Kinase; CD = Crohn's disease; COPD = chronic obstructive pulmonary disease; CRS = cytokine release syndrome; CRSwNP = Chronic Rhinosinusitis with Nasal Polyps; CSU = Chronic Spontaneous Urticaria; IRA = Deficiency of Interleukin-1 Receptor Antagonist; EoE = eosinophilic esophagitis; EGPA = Eosinophilic Granulomatosis with Polyangiitis; ERA = Enthesitis-Related Arthritis; GCA = giant cell arteritis; HES = Hypereosinophilic Syndrome; HS = Hidradenitis Suppurativa; IgE = Immunoglobulin E; IL = interleukin; JAK = Janus kinase; MOA = mechanism of action; NOMID/CAPS = neonatal onset multi-systemic inflammatory disease/Cryopyrin-Associated Periodic Syndromes; NRAS = non-radiographic axial spondyloarthritis; PDE-4 = Phosphodiesterase 4; PJIA = Polyarticular Juvenile Idiopathic Arthritis; PMR = polymyalgia rheumatica; PN = prurigo nodularis; Ps = psoriasis; PsA = psoriatic arthritis; RA = rheumatoid arthritis; S1PR = sphingosine 1-phosphate receptor; SJIA = Systemic juvenile idiopathic arthritis; SSc-ILD = systemic sclerosis-associated interstitial lung disease; TSLP = Thymic Stromal Lymphopoietin; TYK-2 = Tyrosine kinase-2; UC = ulcerative colitis

Back to Top

Table 2. Quantity limitations for self-administered medications

Drug	Quantity Limit
Abatacept (Orencia)	4 doses per 28 days
Abrocitinib (Cibinqo)	30 tablets per 30 days
Adalimumab	2 doses per 28 days
Anakinra (Kineret)	30 syringes per 30 days
Apremilast (Otezla)	60 tablets per 30 days
Baricitinib (Olumiant)	30 tablets per 30 days
Benralizumab (Fasenra)	1 dose per 56 days (quantities of 1 per 28 days will be allowed for three-month initial loading dose and EGPA)
Bimekizumab (Bimzelx)	160 mg injector/syringe: 1 mL per 28 days

Drug	Quantity Limit
	320 mg injector/syringe: 2 mL/56 days
Brodalumab (Siliq)	2 injections per 28 days
Certolizumab (Cimzia)	1 kit per 28 days
Deuruxolitinib (Leqselvi)	60 tablets per 30 days
Dupilumab (Dupixent)	2 injections per 28 days
Etanercept (Enbrel)	200 mg per 28 days
Etrasimod arginine (Velsipity)	30 tablets per 30 days
Golimumab (Simponi)	1 dose per 28 days
Guselkumab (Tremfya)*	100 mg/mL: 1 dose per 56 days 200 mg/2 mL: 2 doses per 28 days
Ixekizumab (Taltz)	1 dose per 28 days
Lebrikizumab (Ebglyss)	Initial authorization: 4 mL per 28 days Reauthorization: 2 mL per 28 days
Mepolizumab (Nucala)	1 dose per 28 days (quantities of 3 per 28 days are approvable for EGPA and HES)
Mirikizumab-mrkz (Omvoh)*	100 mg/mL: 2 injections per 28 days 200 mg/2mL: 1 injection per 28 days 300 mg/3mL: 1 injection per 28 days
Nemolizumab (Nemluvio)	1 mL per 56 days
Omalizumab (Xolair)	1 dose per 28 days
Remibrutinib (Rhapsido)	60 tablets per 30 days
Risankizumab-rzaa (Skyrizi)*	1 dose per 84 days (syringe/pen) 1 dose per 56 days (on-body injector)
Ritlecitinib (Litfulo)	30 capsules per 30 days
Sarilumab (Kevzara)	2 injections per 28 days
Secukinumab (Cosentyx)	300 mg per 28 days
Tezepelumab (Tezspire)	210mg (1.91mL) per 28 days
Tocilizumab	4 doses per 28 days
Tofacitinib (Xeljanz and Xeljanz XR)	IR: 60 tablets per 30 days ER: 30 tablets per 30 days 10mL per day
Tralokinumab (Adbry)	Initial authorization: 4 mL per 28 days Reauthorization: 2 mL per 28 days
Upadacitinib (Rinvoq)	30 tablets per 30 days 12 mL per day
Ustekinumab*	1 dose per 84 days
Vedolizumab (Entyvio Pen)	2 syringes per 28 days

*intravenous guselkumab, infliximab, mirikizumab-mrkz, risankizumab-rzaa, ustekinumab are indicated for induction dosing in Crohn's disease and ulcerative colitis
Abbreviations: EGPA: Eosinophilic Granulomatosis with Polyangiitis, HES: Hypereosinophilic Syndrome

Back to Top