# Pharmacy Management Drug Policy

**SUBJECT: Inflammatory Conditions Clinical Review Prior Authorization (CRPA) Rx & Medical Drugs**
**POLICY NUMBER: PHARMACY-73**
**EFFECTIVE DATE: 01/01/2018**
**LAST REVIEW DATE: 12/06/2023**

*If the member's subscriber contract excludes coverage for a specific service or prescription drug, it is not covered under that contract. In such cases, medical or drug policy criteria are not applied. This drug policy applies to the following line/s of business:*

**Policy Application**

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|---|---|---|
| **Category**: | ☒ Commercial Group (e.g., EPO, HMO, POS, PPO) | ☒ Medicare Advantage |
| | ☒ On Exchange Qualified Health Plans (QHP) | ☐ Medicare Part D |
| | ☒ Off Exchange Direct Pay | ☒ Essential Plan (EP) |
| | ☒ Medicaid & Health and Recovery Plans (MMC/HARP) | ☒ Child Health Plus (CHP) |
| | ☐ Federal Employee Program (FEP) | ☐ Ancillary Services |
| | ☒ Dual Eligible Special Needs Plan (D-SNP) | |

## DESCRIPTION:

The Inflammatory Conditions Clinical Review Prior Authorization (CRPA) is designed to ensure that newly approved (FDA) prescription drugs are used appropriately in cases where a drug poses potential efficacy, quality, toxicity, or utilization concerns for members of the Health Plan. In addition, this policy may be used for medications that have significant concerns about safety or inappropriate use, but do not warrant a stand-alone policy. The Pharmacy Management clinical team reviews the drugs falling into these categories under the process of Clinical Review Prior Authorization (CRPA). A Letter of Medical Necessity (LOMN), Exception Form, or Prior Authorization Form completion is required for consideration of drug coverage under this policy.

Please note that certain medications to treat inflammatory conditions that have multiple indications are not contained within this policy and have a stand-alone policy: Cimzia, Enbrel, adalimumab, infliximab products, Stelara.

## CURRENT INFLAMMATORY CONDITIONS CRPA RX AND MEDICAL DRUGS:

**DRUG NAME – generic name (Medical/Rx Benefit)**

**Authorization Criteria**

### Actemra - tocilizumab (Medical or Rx)

1. The patient must have a diagnosis of **Rheumatoid Arthritis**
    a. The patient must be actively followed by, and the drug prescribed by a rheumatologist **AND**
    b. The patient must be at least 18 years of age **AND**
    c. There must be documentation of drug failure or serious side effects to a disease-modifying anti-rheumatic drug (DMARD) agent, such as methotrexate, azathioprine, sulfasalazine, or hydroxychloroquine, either alone or in combination for a 3-month period **AND**
    d. Step Therapy Applies -
        i. Treatment with **IV Actemra** will require:
            a) Documentation of an inability to self-inject
                i. Applies to New Starts of all lines of business
                ii. Applies to Existing Users for all non-Medicare Part B lines of business **AND**
            b) Failure or serious side effects with Inflectra/Avsola or Simponi Aria
                i. Applies to New Starts of all lines of business
        ii. IV Actemra dosing for adults with rheumatoid arthritis is:

i. Initial dosing will be limited to 4 mg/kg every 4 weeks
ii. After 12 weeks, based on clinical response, dose can be increased to 8 mg/kg but the total dose cannot exceed 800 mg

iii. Treatment with **SC Actemra** will require failure or serious side effects with Humira/Cyltezo/Hadlima
a) SC Actemra dosing for adults with rheumatoid arthritis is:
i. Patients less than 100 kg should receive 162 mg every other week. Dosing can be increased to weekly based on clinical response.
ii. Patients at or above 100 kg should receive 162 mg every week
iii. Quantity limit of 4 syringes per 28 days

2. The patient must have a diagnosis of **Systemic Juvenile Idiopathic Arthritis (sJIA) or Polyarticular Juvenile Idiopathic Arthritis (pJIA)** in children 2 years of age or older
   a. Must have failed to respond to and/or is intolerant to approved disease- modifying antirheumatic drugs (DMARDs) agents, such as methotrexate, NSAIDs, analgesics or corticosteroids either alone or in combination
      i. Step Therapy Applies –
         a) Treatment with **SC Actemra** will require failure or serious side effects with Humira/Cyltezo/Hadlima for a diagnosis of pJIA
         b) Treatment with **IV Actemra** will require:
            i. Documentation of an inability to self-inject
               a. Applies to New Starts of all lines of business
               b. Applies to Existing Users for all non-Medicare Part B lines of business **AND**
            ii. Failure or serious side effects with Simponi Aria for a diagnosis of pJIA
               a. Applies to New Starts of all lines of business
   b. IV Actemra dosing for children with PJIA is:
      i. Patients less than 30kg should receive 10mg/kg every 4 weeks
      ii. Patients at or above 30kg should receive 8mg/kg every 4 weeks
   c. SC Actemra dosing for children with PJIA is:
      i Patients less than 30kg should receive 162mg every 3 weeks
      ii Patients at or above 30kg should receive 162mg every 2 weeks
   d. IV Actemra dosing for children with SJIA is:
      i. Patients less than 30kg should receive 12mg/kg every 2 weeks
      ii. Patients at or above 30kg should receive 8mg/kg every 2 weeks
   e. SC Actemra dosing for children with SJIA is:
      i. Patients less than 30kg should receive 162mg every 2 weeks
      ii. Patients at or above 30kg should receive 162mg once every week
3. The patient must have a diagnosis of **giant cell arteritis (GCA)**
   a. The patient must be at least 18 years of age and have a confirmed diagnosis of giant cell arteritis and the drug prescribed by an ophthalmologist, neurologist, or rheumatologist
   b. SC Actemra dosing for adults with GCA is:
      i. 162mg given once every week as a subcutaneous injection, in combination with a tapering course of glucocorticoids
      ii. A dose of 162 mg given SC every other week, in combination with a tapering course of glucocorticoids, may be prescribed based on clinical considerations
      iii. Quantity limit of 4 syringes per 28 days
   c. IV Actemra dosing for adults with GCA is:
      i. 6 mg/kg every 4 weeks as an intravenous infusion, in combination with a tapering course of glucocorticoids
      ii. Doses exceeding 600 mg per infusions are not recommended in GCA patients

4. The patient must have a diagnosis of **systemic sclerosis- associated interstitial lung disease (SSc-ILD) with declining pulmonary function**
    a. The patient must be ≥ 18 years of age **AND**
    b. The patient must be actively followed by, and the drug prescribed by a rheumatologist or pulmonologist **AND**
    c. The patient must have fibrosis affecting at least 10% of the lung based on a HRCT scan from within the last 12 months **AND**
    d. The patient must have been treated with azathioprine, mycophenolate mofetil (MMF), or prednisone **AND**
    e. The patient must be a non-smoker (defined as someone who has not smoked in the past month)
    f. SC Actemra dosing for adults with SSc-ILD is 162 mg given once every week as a subcutaneous injection
    g. IV Actemra is not approved for SSc-ILD with declining pulmonary function
    h. Quantity Limit of 4 syringes per 28 days
5. IV Actemra will be covered for use with chimeric antigen receptor (CAR) T-Cell therapy for potential severe or life-threatening cytokine-release syndrome (CRS)
6. The use of Actemra (tocilizumab) for the treatment of hospitalized adults and pediatric patients (2 years of age or older) with COVID-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO) is intended for inpatient use only; therefore, coverage in the outpatient setting will not be authorized. Please note, this indication has not been approved by the Food and Drug Administration (FDA) for patients 2 years of age to less than 18 years of age and is only available for use under an emergency use authorization (EUA).

**HCPCS**: J3262

## Bimzelx - bimekizumab (Rx)

1. The patient must be followed by a dermatologist or rheumatologist **AND**
2. The patient must be at least 18 years of age **AND**
3. Must have moderate to severe chronic **plaque psoriasis** that involves at least 10% of their body surface area. Consideration will be given to those who have less than 10% body surface area involvement but have severe disease of sensitive areas or areas causing significant disruption in normal activities (such as the hands, feet, face, genitalia) **AND**
4. The patient must meet one of the following criteria:
    a. The patient must be a candidate for systemic therapy (i.e., acitretin, methotrexate, or cyclosporine) with a trial period of at least 3 months that resulted in an inadequate response (failure). A 3-month trial will not be required if the member experienced serious side effects during a trial of one of the above-mentioned agents
    b. If systemic therapy is contraindicated, then one of the following must be attempted for a reasonable period of time (at least 3 months):
        i. UVB in combination with a topical therapy such as coal tar, steroids or tazarotene **OR**
        ii. PUVA in combination with topical corticosteroids **OR**
        iii. Medium/High potency topical steroids in combination with anthralin, calcipotriene, or tazarotene **AND**
5. Step Therapy Applies
    a. The patient must also have a documented drug failure or serious side effects to **THREE** of the following: Humira/Cyltezo/Hadlima, Otezla, Stelara SC, Skyrizi, Tremfya, Cosentyx, Enbrel
6. Documentation of a baseline Psoriasis Area Severity Index (PASI) score is required
7. Coverage for Bimzelx will only be authorized under the pharmacy benefit

8. Initial approval will be for 1 year. Initial recertification will require documentation that the patient achieved PASI 90 (almost clear skin) after the 16-week induction dosing was complete AND has maintained PASI 90. Initial recertification will be approved for 1 year. Ongoing recertifications will require documentation that the patient has maintained PASI 90 and will be approved for 1 year.
9. Quantity Limit: 2 mL (2-160 mg/mL injectors/syringes)/56 days
    a. Approved Dosing:
        i. Induction: 320 mg at week 0, week 4, week 8, week 12, and week 16
        ii. Maintenance: 320 mg every 8 weeks starting at week 24
            a) For patients that weigh 120 kilograms (kg) or more, a dose of 320 mg every 4 weeks (2 mL/28 days) may be considered after at least 32 weeks of treatment (including 16 weeks induction and at least 16 weeks of maintenance treatment) if the patient achieved PASI 90 (almost clear skin) after the 16-week induction dosing **AND** failed to maintain PASI 90 after 16 weeks (2-doses) of maintenance treatment

## Cibinqo - abrocitinib (Rx)

1. Must be prescribed by or in consultation with an allergist, immunologist, or dermatologist **AND**
2. Must be at least 12 years of age **AND**
3. Must have a diagnosis of moderate to severe atopic dermatitis
    a. Must involve at least 10% body surface area
        i. Consideration will be given to those who have less than 10% body surface area involvement but have severe disease of the hands, feet, or other sensitive areas **OR** severe itch that has been unresponsive to topical therapies **AND**
    b. Must have evidence of functional impact on everyday activities **AND**
4. Must have had a trial and failure or contraindication to:
    a. Medium to higher potency prescription topical corticosteroid therapy **AND**
        i. Adequate trial is defined as ≥ 28 days or for the maximum duration recommended by the product prescribing information (i.e., 14 days for super-potent topical corticosteroids), whichever is shorter **AND**
    b. Tacrolimus or pimecrolimus
        i. Adequate trial is defined as ≥ 6 weeks based on prescribing information **AND**
    c. Treatment with at least one of the above therapies must have occurred within the previous 6 months **AND**
5. Must have had serious side effects or drug failure of Dupixent **AND** Rinvoq
6. Initial approval will be for 6-months. Recertification will require documentation confirming clinical improvement in signs and symptoms of Atopic Dermatitis and will be approved for 2 years.
7. Cibinqo will not be approved in combination with Opzelura, Rinvoq, Dupixent, or Adbry
8. Approved dosing:
    a. 100 mg by mouth once daily
        i. If an adequate response is not achieved after 12 weeks, consider increasing to 200 mg orally once daily. Discontinue if inadequate response after dosage increase.

## Cosentyx IV & SC - secukinumab IV (Medical), SC (Rx)

1. The patient must meet for ONE of the following (a,b,c,d,e):
    a. The patient must be at least 6 years of age and have a diagnosis of moderate to severe chronic **Plaque Psoriasis** that involves at least 10% of the body surface area. Consideration will be given to those who have less than 10% body surface area involvement but have severe disease of sensitive areas or areas causing significant disruption in normal activities (such as the hands, feet, face, genitalia) **AND**
        i. The patient must be followed by a dermatologist or rheumatologist **AND**

ii. The patient must be a candidate for systemic therapy (i.e., acitretin, methotrexate, or cyclosporine) with a trial period of at least 3 months that resulted in an inadequate response (failure). A 3-month trial will not be required if the member experienced serious side effects during a trial of one of the above-mentioned agents
iii. If systemic therapy is contraindicated, then one of the following must be attempted for a reasonable period of time (at least 3 months):
a. UVB in combination with a topical therapy such as coal tar, steroids or tazarotene **OR**
b. PUVA in combination with topical corticosteroids **OR**
c. Medium/High potency topical steroids in combination with anthralin, calcipotriene, or tazarotene

b. The patient must be at least 2 years of age and have a diagnosis of **Psoriatic Arthritis**
i. The patient must be actively followed by, and drug prescribed by a rheumatologist or dermatologist **AND**
ii. The patient must have some clinical features of psoriatic arthritis such as: involvement of the DIP joints, an asymmetric distribution of joint disease, Spondyloarthritis, sausage digits, new bone formation on radiographs, cutaneous findings, and the characteristic nail manifestations of psoriatic arthritis (nail pitting, onycholysis & other lesions, which include leukonychia, red spots in the lunula, and nail plate crumbling) all may be present
iii. The patient must be at least 2 years of age for coverage of Cosentyx SC under the pharmacy benefit
iv. The patient must be at least 18 years of age for coverage of Cosentyx IV under the medical benefit

c. The patient must be at least 18 years of age and have a diagnosis of **Ankylosing Spondylitis**
i. The patient must be actively followed by, and the drug prescribed by a rheumatologist **AND**
ii. There must be presence of refractory disease defined by failure of at least two NSAIDs at maximum strength for at least 1 month each

d. The patient must be at least 18 years of age and have a diagnosis of **Non-Radiographic Axial Spondylitis (nr-axSpA)**
i. A diagnosis of non-radiographic axial spondylitis established by a rheumatologist
ii. Must be actively followed by and the drug prescribed by a rheumatologist
iii. Presence of refractory disease defined by failure of at least TWO different NSAIDs given as maximum dosage for at least 1 month each

e. The patient must be at least 4 years of age and have a diagnosis of **Enthesitis-Related Arthritis (ERA)**
i. Must be followed by a rheumatologist
ii. Must have failed to respond to and/or is intolerant to approved disease- modifying antirheumatic drugs (DMARDs) agents, such as methotrexate, NSAIDs, analgesics or corticosteroids either alone or in combination

f. The patient must be at least 18 years of age and have a diagnosis of **Hidradenitis Suppurativa (HS)**
i. the patient must be actively followed by, and drug prescribed by a dermatologist
ii. Must have a diagnosis of stage II, stage III, or severe refractory hidradenitis suppurativa with recurrent abscesses
iii. Must have had a minimum of a three-month trial of systemic antibiotics (such as minocycline, doxycycline, clindamycin, or rifampin) which failed to provide clinical improvement
a. A 3-month trial will not be required if the member experienced serious side effects during a trial of one of the above-mentioned agents

2. Intravenous (IV) Cosentyx will only be covered for the treatment of Psoriatic Arthritis, Ankylosing Spondylitis, and Non-Radiographic Axial Spondylitis
3. Approved Dosing:
    a. Pharmacy Benefit (SC): an initial loading dose of 75 mg, 150mg, 300mg subcutaneous injection at weeks 0,1,2,3, and 4, and then maintenance dosing of 75 mg, 150mg, or 300mg every 4 weeks depending on the diagnosis (please refer to the prescribing information)
        i. Treatment of Psoriatic Arthritis, Ankylosing Spondylitis, and Non-Radiographic Axial Spondylitis may be initiated with or without a loading dose
        ii. For patients with Hidradenitis Suppurativa who have not adequately responded to 300 mg every 4 weeks, the dose maybe increased to 300 mg every 2 weeks
    b. Medical Benefit (IV): an initial loading dose of 6 mg/kg given by intravenous infusion at week 0, followed by a 1.75 mg/kg intravenous maintenance (max 300 mg per infusion) dose given every 4 weeks thereafter.
        i. Treatment of Psoriatic Arthritis, Ankylosing Spondylitis, and Non-Radiographic Axial Spondylitis may be initiated with or without a loading dose
4. Quantity limit (Pharmacy Benefit):
    a. 300 mg UnoReady® autoinjector pen (contains 1-300 mg pen) is 1 mL per 28 days
    b. 300 mg package (contains 2-150 mg pens/syringes) is 2 mL per 28 days
    c. 150 mg pen/syringe (contains 1-150 mg pen/syringe) is 1 mL per 28 days
    d. 75 mg syringe (contains 1-75 mg syringe) is 0.5 mL per 28 days

## Entyvio IV and SC – vedolizumab IV (Medical), SC (Rx)

1. The patient must be actively followed by, and the drug prescribed by a gastroenterologist **AND**
2. The patient must be at least 18 years of age **AND**
3. The patient must have a diagnosis of moderately to severely active **Crohn's Disease**
    a. Crohn's Disease Activity Index (CDAI) score of 220-450. Typically described as having more prominent symptoms of fever, significant weight loss, abdominal pain or tenderness, intermittent nausea or vomiting or significant anemia **AND**
    b. There must be documentation that azathioprine, 6-mercaptopurine, or methotrexate is not effective, contraindicated, or not tolerated
        i. Treatment with a biologic medication as first-line therapy will be assessed on a case-by-case basis through a letter of medical necessity and clinical progress notes based on severity of the disease **OR**
    c. Only Entyvio IV will be considered for a diagnosis of Crohn's Disease. Entyvio Pen, for subcutaneous (SC) injection, is not approved by the Food and Drug Administration (FDA) for Crohn's Disease and therefore will not be authorized.
4. The patient must have a diagnosis of moderate to severe **Ulcerative Colitis**
    a. The patient must have had drug failure or serious side effects to at least ONE of the following conventional therapies for at least 3 months:
        i. Thiopurines: Azathioprine/6-mercaptopurine (6-MP)
        ii. 5-Aminosalicylates: Sulfasalazine, Mesalamine, Olsalazine
        iii. Cyclosporine
        iv. IV or oral steroids - note, a 3-month trial of systemic steroid therapy will not be required
    b. The following requirements apply to only requests for Entyvio Pen (Pharmacy Benefit)
        a. For patients <u>not currently</u> on treatment with IV Entyvio (i.e., treatment naïve, etc.), Step Therapy Applies: there must be serious side effects or drug failure of Humira/Cyltezo/Hadlima **AND** Stelara
        b. For patients <u>currently</u> treated with IV Entyvio, there must be adequate medical justification as to why the IV formulation cannot be continued

i. Convenience of administration will not be considered medically necessary and will not be authorized

5. Approved Dosing:
   a. Intravenous (IV) Infusion: Initial dosing is 300 mg intravenously at weeks 0, 2, and 6 with maintenance dosing of 300 mg IV every 8 weeks. More frequent dosing will be considered on a case-by-case basis.
   b. Subcutaneous (SC) Injection: Initial dosing is 300 mg intravenously at weeks 0 and 2 with maintenance dosing of 108 mg SC every 2 weeks.
6. Entyvio Pen will be covered under the Pharmacy Benefit as it is FDA approved for self-administration.
7. Entyvio IV will be covered under the Medical Benefit as it is FDA approved to be administered by a healthcare provider

**HCPCS:** J3380

## Ilumya – tildrakizumab-asmn (Medical)

10. The patient must be followed by a dermatologist or rheumatologist **AND**
11. The patient must be at least 18 years of age **AND**
12. Must have moderate to severe chronic **plaque psoriasis** that involves at least 10% of their body surface area. Consideration will be given to those who have less than 10% body surface area involvement but have severe disease of sensitive areas or areas causing significant disruption in normal activities (such as the hands, feet, face, genitalia) **AND**
13. The patient must meet one of the following criteria:
    c. The patient must be a candidate for systemic therapy (i.e., acitretin, methotrexate, or cyclosporine) with a trial period of at least 3 months that resulted in an inadequate response (failure). A 3-month trial will not be required if the member experienced serious side effects during a trial of one of the above-mentioned agents
    d. If systemic therapy is contraindicated, then one of the following must be attempted for a reasonable period of time (at least 3 months):
       iv. UVB in combination with a topical therapy such as coal tar, steroids or tazarotene **OR**
       v. PUVA in combination with topical corticosteroids **OR**
       vi. Medium/High potency topical steroids in combination with anthralin, calcipotriene, or tazarotene **AND**
14. Coverage for Ilumya will only be authorized under the medical benefit

**HCPCS:** J3245

## Kevzara – sarilumab (Rx)

1. The patient must have a diagnosis of active moderate to severe **Rheumatoid Arthritis**
   a. The patient must be actively followed by, and the drug prescribed by a rheumatologist **AND**
   b. The patient must be at least 18 years of age **AND**
   c. There must be documentation of drug failure or serious side effects to a disease-modifying anti- rheumatic drug (DMARD) agent, such as methotrexate, azathioprine, sulfasalazine, or hydroxychloroquine, either alone or in combination for a 3-month period **AND**
   d. Step Therapy Applies –
      i. The patient must also have a documented drug failure or serious side effects to **TWO** of the following agents: Actemra SC, Enbrel, Humira/Cyltezo/Hadlima, Xeljanz/XR, Rinvoq
   e. Approved dosing is 200 mg SC once every two weeks. The weekly dose may be decreased to 150mg in patients who experience neutropenia, elevated LFTs, and/or elevated cholesterol levels on Kevzara.
2. The patient must have a diagnosis of **Polymyalgia Rheumatica (PMR)**
   a. The patient must be actively followed by, and the drug prescribed by a rheumatologist **AND**

b. The patient must be at least 18 years of age **AND**
c. The patient must use Kevzara in combination with a tapering course of systemic corticosteroids (applicable to New Starts only) **AND**
d. The patient must have had one of the following:
    i. An inadequate response to corticosteroids (defined as an inability to achieve remission [resolution of signs and symptoms of PMR, and normalization of CRP (<10 mg/L)] after 12 weeks of therapy) **OR**
    ii. An inability to tolerate a corticosteroid taper (defined as a recurrence of signs and symptoms of PMR during a taper attempt)
e. Approved dosing is 200 mg SC once every two weeks

3. Coverage for Kevzara will be limited to 2 syringes/28 days (2.28 mL/28 days)

## Kineret - anakinra (Rx)

1. The patient must have a diagnosis of **Rheumatoid Arthritis**
    a. The patient must be at least 18 years of age **AND**
    b. The patient must be actively followed by, and the drug prescribed by a rheumatologist **AND**
    c. There must be documentation of drug failure or serious side effects to a disease-modifying anti-rheumatic drug (DMARD) agent, such as methotrexate, azathioprine, sulfasalazine, or hydroxychloroquine, either alone or in combination for a 3-month period **AND**
    d. Step Therapy Applies –
        i. The patient must have had drug failure or serious side effects with **TWO** of the following: Actemra SC, Enbrel, Humira/Cyltezo/Hadlima, Xeljanz/XR, Rinvoq
    e. Dosing is limited to daily subcutaneous injections (100 mg/day) **OR**
2. Kineret is also indicated for the treatment of **neonatal-onset multisystem inflammatory disease (NOMID)** as initial therapy
    a. The patient must be followed by, and the drug prescribed by a rheumatologist, geneticist, or a dermatologist
    b. Initial dosing of 1mg/kg/day, maintenance dosing of 3-4 mg/kg/day and maximum dosing of 8 mg/kg/day
3. Must be used to treat patients with **deficiency of the interleukin-1 receptor antagonist (DIRA)**
    a. Must be prescribed by a rheumatologist, geneticist, dermatologist, or a physician who specializes in the treatment of inflammatory conditions **AND**
    b. Deficiency of the interleukin-1 receptor antagonist (DIRA) must be confirmed by a mutation in the IL1RN gene **AND**
    c. Documentation of one or more of the following must be submitted:
        i Increased levels of erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP)
        ii Inflammatory bone disease
        iii Skin biopsy showing neutrophilic pustulosis
    d. Approval timeframe:
        i. Initial approval will be for 6 months. Recertification will require documentation of a response to treatment and will be approved for 2 years. A response to treatment is defined as any of the following:
            a. normalization of ESR and CRP
            b. resolution of inflammatory bone disease
            c. resolution of neutrophilic pustulosis
            d. reduction in the use of corticosteroids
        ii. Continued approval will require provider attestation that the patient has maintained a response to treatment and will be approved for 2 years
    e. The approved starting dose is 1 to 2 mg/kg/day with a maximum daily dose of 8 mg/kg.

i. The allowed quantity will be reviewed in accordance with FDA-approved weight-based dosing and, as such, will be limited to the minimum number of syringes required to obtain the maximum daily dose of 8 mg/kg at the patient's current weight.

f. Kineret should not be used in combination with Arcalyst or any other biologic product

4. Must have diagnosis of **recurrent pericarditis (RP)** defined as a subsequent pericarditis episode after a symptom-free interval of at least 4-6 weeks
   a. Must be prescribed by or in consultation with a cardiologist **AND**
   b. Patient must be > 12 years or older **AND**
   c. Patient must be presenting with at least a second pericarditis recurrence (third pericarditis episode at minimum) despite treatment with NSAIDs, colchicine or corticosteroids, in any combination
      i. The current episode is characterized by pericardial pain for > 1 day with a numerical rating scale (NRS) pain score of > 4 **AND** a C-reactive protein level of at least of at least 1 mg/dL **OR**
      ii. The current episode must have met <u>two or more</u> of the following:
         A. Pericarditis chest pain (typically sharp chest pain, improved with sitting up and leaning forward)
         B. Pericardial rubs (superficial scratchy or squeaking sound heard with the diaphragm of a stethoscope over the left sternal border)
         C. New widespread ST-elevation or PR depression on ECG
         D. Pericardial effusion (new or worsening) **AND**
   d. Provider must attest that the patient will attempt to taper and discontinue NSAIDs, colchicine and/or corticosteroids while on Kineret **AND**
   e. Kineret will not be approved for patients with pericarditis secondary to tuberculosis, post-thoracic blunt trauma, myocarditis, systemic autoimmune diseases (excluding Still's disease), or neoplastic, purulent, or radiation etiologies **AND**
   f. Kineret will not be approved for patients with incessant or chronic pericarditis **AND**
   g. Patient is not on concurrent therapy with any of the following – Ilaris, Arcalyst, or any other biologic product
   h. The maximum dose is 100 mg/day based on currently available literature
   i. Approval timeframes:
      i. Initial approval of Kineret for recurrent pericarditis will be for 3 months.
      ii. Initial and subsequent recertification will require documentation that the patient has had no pericarditis recurrence while using Kineret **AND** documentation that NSAIDs, colchicine and/or corticosteroid doses have been reduced or discontinued. Initial and subsequent recertifications will be approved for 6 months at a time.
5. Quantity Limit: 30 syringes per 30 days

## Olumiant – baricitinib (Rx)

1. The patient must be actively followed by, and the drug prescribed by a rheumatologist **AND**
2. The patient must be at least 18 years of age **AND**
3. The patient must have active moderate to severe **Rheumatoid Arthritis AND**
   a. There must be documentation of drug failure or serious side effects to a disease-modifying anti-rheumatic drug (DMARD) agent, such as methotrexate, azathioprine, sulfasalazine, or hydroxychloroquine, either alone or in combination for a 3-month period **AND**
   b. Step Therapy Applies –
      i. The patient must have had failure or had serious side effects to **TWO** of the following: Actemra, Enbrel, Humira/Cyltezo/Hadlima, Xeljanz/XR, Rinvoq
   c. Approved dosage is 2 mg once daily

4. The use of Olumiant for the treatment of **alopecia** areata (including but not limited to alopecia areata, alopecia universalis) is considered a cosmetic use (defined as use to improve a patient's appearance and/or self-esteem).
   a. For Commercial/Exchange/Child Health Plus, the use of a drug, whether it is for a Food and Drug Administration (FDA) approved or off-label indication, for a cosmetic use is considered not medically necessary
5. Quantity Limit: 30 tablets per 30 days.
6. The use of Olumiant (baricitinib) for the treatment of hospitalized adults and pediatric patients (2 years of age or older) with COVID-19 who require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO) is intended for inpatient use only; therefore, coverage in the outpatient setting will not be authorized. Please note, this indication has not been approved by the Food and Drug Administration (FDA) for patients 2 years of age to less than 18 years of age and is only available for use under an emergency use authorization (EUA).

## Omvoh - mirikizumab-mrkz (Rx)

1. The patient must be actively followed by, and the drug prescribed by a gastroenterologist **AND**
2. The patient must be at least 18 years of age **AND**
3. The patient must have a diagnosis of moderate to severe active Ulcerative Colitis **AND**
4. The patient must have tried and failed or has documented intolerance to at least **ONE** of the following conventional therapies for at least 3 months:
   a. Thiopurines: Azathioprine/6-mercaptopurine (6-MP)
   b. 5-Aminosalicylates: Sulfasalazine, Mesalamine, Olsalazine
   c. Cyclosporine
   d. IV or oral steroids - note, a 3-month trial of systemic steroid therapy will not be required **AND**
5. Step Therapy Applies:
   a. The patient must have had serious side effects or drug failure of Humira/Cyltezo/Hadlima **AND** Stelara
6. Approved Dosing:
   a. Induction: 300 mg administered by intravenous (IV) infusion at week 0, week 4, and week 8
      i. Prior Authorization of the IV induction dose is required for all lines of business under the medical benefit except Managed Medicaid
   b. Maintenance: 200 mg administered by subcutaneous (SC) injection (given as two consecutive injections of 100 mg each) every 4 weeks starting at week 12
7. Quantity Limit (Pharmacy Benefit): 2 mL (2-100 mg/mL pens)/28 days

## Orencia - abatacept (Medical or Rx)

1. The patient must have a diagnosis of **Rheumatoid Arthritis**
   a. The patient must be at least 18 years of age **AND**
   b. The patient must be actively followed by, and the drug prescribed by a rheumatologist **AND**
   c. There must be documentation of drug failure or serious side effects to a disease-modifying anti-rheumatic drug (DMARD) agent, such as methotrexate, azathioprine, sulfasalazine, or hydroxychloroquine, either alone or in combination for a 3-month period **AND**
   d. Step Therapy Applies –
      I. **If healthcare provider administered**, treatment with IV Orencia will require failure or serious side effects with of Inflectra/Avsola or Simponi Aria
         i. Applies to all lines of business
      II. **If self-administered**

i. Treatment with SC Orencia will require documentation of drug failure or serious side effects of **TWO** of the following agents: Actemra SC, Enbrel, Humira/Cyltezo/Hadlima, Xeljanz/XR, Rinvoq

e. Approved Dosing:
   i. IV
      a. Dosing is based on body weight. Following the initial administration, abatacept should be given at 2 and 4 weeks after the first infusion, then every 4 weeks thereafter
         i. < 60kg: 500mg dose
         ii. 60 – 100kg: 750mg dose
         iii. > 100kg: 1,000mg dose
   ii. SC
      a. Dosing for adult rheumatoid arthritis is 125mg once weekly. SC dosing may be initiated with or without a loading dose.
      b. If initiating with an IV loading dose, administer the initial IV infusion then administer 125 mg subcutaneously within 24 hours of the infusion, followed by 125 mg subcutaneously once weekly thereafter

2. The patient must have a diagnosis of **polyarticular Juvenile Idiopathic Arthritis (pJIA)**
   a. The patient must be actively followed by, and the drug prescribed by a rheumatologist **AND**
   b. The patient must have failed to respond to and/or is intolerant to approved disease- modifying antirheumatic drugs (DMARDs) agents, such as methotrexate, NSAIDs, analgesics or corticosteroids either alone or in combination **AND**
      i. Step Therapy Applies –
         a) **If self-administered**
            i. Treatment with SC Orencia will require drug failure or serious side effects with **TWO** of the following: Enbrel, Humira/Cyltezo/Hadlima, Actemra SC, Xeljanz
         b) **If healthcare provider administered**, treatment with IV Orencia will require drug failure or serious side effects with Simponi Aria
            i. Applies to all lines of business
   c. IV Orencia dosing for children 6 years or older with JIA is:
      i. Dosing is based on body weight. Following the initial administration, abatacept should be given at 2 and 4 weeks after the first infusion, then every 4 weeks thereafter
         - < 75kg: 10mg/kg dose
         - > 75kg: administer based on adult dosing
   d. SC Orencia dosing for children 2 years or older with JIA is:
      i. Subcutaneous dosing for juvenile idiopathic arthritis should be initiated at 50mg to 125mg once weekly (weight range-based dosing) without an intravenous loading dose
3. The patient must have a diagnosis of **Psoriatic Arthritis**
   a. The patient must be at least 18 years of age for treatment with Orencia IV **OR** at least 2 years of age for treatment with Orencia SC **AND**
   b. The patient must be actively followed by, and the drug prescribed by a rheumatologist or dermatologist **AND**
   c. The patient must have some clinical features of psoriatic arthritis such as: involvement of the DIP joints, an asymmetric distribution of joint disease, spondylarthritis, sausage digits, new bone formation on radiographs, cutaneous findings, and the characteristic nail manifestations of psoriatic arthritis (nail pitting, onycholysis & other lesions, which include leukonychia, red spots in the lunula, and nail plate crumbling). All may be present.
   d. Step Therapy Applies –

i. **If healthcare provider administered**, treatment with IV Orencia will require documentation of drug failure or serious side effects to **ONE** of the following: Inflectra/Avsola, Stelara, Simponi Aria, Tremfya
   a) Applies to all lines of business
   b) IV Orencia dosing is based on body weight. Following the initial administration, abatacept should be given at 2 and 4 weeks after the first infusion, then every 4 weeks thereafter.
      - < 60kg: 500 mg dose
      - 60 – 100kg: 750 mg dose
      - > 100kg: 1,000 mg dose

ii. **If self-administered**
   a) Treatment with SC Orencia will require documentation of drug failure or serious side effects of **TWO** of the following: Enbrel, Humira/Cyltezo/Hadlima, Stelara SC, Xeljanz/XR, Cosentyx, Otezla, Tremfya, Rinvoq, Skyrizi
      - For pediatric patients ages 2 to less than 6 years, only a trial of Cosentyx is required
   b) Approved dosing for psoriatic arthritis
      - For adult patients - 125 mg once weekly with or without an IV loading dose
      - For pediatric patients - 50 mg to 125 mg once weekly (weight range-based dosing) without an intravenous loading dose

4. The patient must have a diagnosis of **acute Graft versus Host Disease (aGvHD)**
   a. The patient must be at least 2 years of age **AND**
   b. Must be used for the prophylaxis of acute GvHD **AND**
   c. Must be undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated-donor **AND**
   d. Must be used in combination with a calcineurin inhibitor and methotrexate
   e. Approved Dose:
      i. For patients 6 years of age and older: 10 mg/kg IV the day before transplantation and on days 5,14, and 28 after transplantation
      ii. For patients 2 years of age to < 6 years of age: 12 mg/kg IV the day before transplantation and on days 5,14, and 28 after transplantation
   f. SC Orencia is NOT FDA approved for the treatment of aGvHD
5. Do not co-administer abatacept with TNF antagonists or any other biologic therapy
6. Quantity limit for subcutaneous (SC) administration:
   a. 125 mg syringe: 4 mL per 28 days (4 syringes)
   b. 87.5 mg syringe: 2.8 mL per 28 days (4 syringes)
   c. 50 mg syringe: 1.6 mL per 28 days (4 syringes)

**HCPCS**: J0129

## Otezla - apremilast (Rx)

1. The patient must be at least 18 years of age **AND**
2. The patient must meet ONE of the following (a, b, c):
   a. Must have a diagnosis of definitive **psoriatic arthritis** established by a rheumatologist or dermatologist **AND**
      i. The patient must have some clinical features of psoriatic arthritis such as: involvement of the DIP joints, an asymmetric distribution of joint disease, Spondyloarthritis, sausage digits, new bone formation on radiographs, cutaneous findings, and the characteristic nail manifestations of psoriatic arthritis (nail pitting, onycholysis & other lesions, which include leukonychia, red spots in the lunula, and nail plate crumbling). All may be present.

ii. The patient must be actively followed by, and the drug prescribed by a Rheumatologist or Dermatologist

b. The patient must be followed by a dermatologist or rheumatologist and the patient must have moderate to severe chronic **plaque psoriasis** that involves at least 10% of the body surface area. Consideration will be given to those who have less than 10% body surface area involvement but have severe disease of sensitive areas or areas causing significant disruption in normal activities (such as the hands, feet, face, genitalia) **OR** must have a diagnosis of mild plaque psoriasis that involves less than 10% of the body surface area without severe disease of the hands or feet or other areas causing disruption in normal activities **AND**
   i. Step Therapy Applies –
      a) For moderate to severe chronic plaque psoriasis (or those with severe disease of the hands or feet or other areas causing disruption in normal activities but have less than 10% body surface area involvement), the patient must be a candidate for systemic therapy (i.e., acitretin, methotrexate, or cyclosporine) with a trial period of at least 3 months that resulted in an inadequate response (failure). A 3-month trial will not be required if the member experienced serious side effects during a trial of one of the above-mentioned agents
      b) For mild plaque psoriasis or for individuals with moderate to severe chronic plaque psoriasis that have contraindications to systemic therapy, one of the following must be attempted for a reasonable period of time (at least 3 months):
         i. UVB in combination with a topical therapy such as coal tar, steroids or tazarotene **OR**
         ii. PUVA in combination with topical corticosteroids **OR**
         iii. Medium/High potency topical steroids in combination with anthralin, calcipotriene, or tazarotene

c. The patient must have a diagnosis of **oral ulcers associated with Behcet's Disease**.

3. Otezla in combination with biologic DMARD therapy (such as Humira/Cyltezo/Hadlima, Enbrel, Cosentyx, etc.) is not FDA approved or supported with a high level of clinically valid medical evidence for the treatment of plaque psoriasis or psoriatic arthritis. Therefore, these requests are considered combination therapy and are considered not medically necessary.
4. Coverage or Otezla will be limited to 60 tablets/30 days

## Rinvoq – upadacitinib (Rx)

1. The patient must have a diagnosis of **Rheumatoid Arthritis**
   a. The patient must be followed by, and the drug prescribed by a rheumatologist **AND**
   b. The patient must be at least 18 years of age **AND**
   c. The patient must have had failure or serious side effects to methotrexate
      i. For patients who have a contraindication to methotrexate, trial of an alternate DMARD in appropriate dosages will be required **AND**
   d. The patient must have had serious side effects or drug failure of Humira/Cyltezo/Hadlima or Enbrel for anti-tumor necrosis factor (TNF) naïve patients or with any anti-TNF for anti-TNF experienced patients
   e. Approved dosing is 15 mg once daily
2. The patient must have a diagnosis of definitive **Psoriatic Arthritis** established by a Rheumatologist or Dermatologist **AND**
   a. The patient must be actively followed by, and the drug prescribed by a rheumatologist or dermatologist **AND**
   b. The patient must be at least 18 years of age **AND**
   c. The patient must have some clinical features of psoriatic arthritis such as: involvement of the DIP joints, an asymmetric distribution of joint disease, Spondyloarthritis, sausage digits, new bone formation on radiographs, cutaneous findings, and the characteristic nail manifestations

of psoriatic arthritis (nail pitting, onycholysis & other lesions, which include leukonychia, red spots in the lunula, and nail plate crumbling). All may be present **AND**

d. The patient must have had serious side effects or drug failure of Humira/Cyltezo/Hadlima or Enbrel for anti-tumor necrosis factor (TNF) naïve patients or with any anti-TNF for anti-TNF experienced patients
e. Approved dosing is 15 mg once daily

3. The patient must have a diagnosis of **moderate to severe Atopic Dermatitis**
   a. Must be prescribed by or in consultation with an allergist, immunologist, or dermatologist **AND**
   b. The patient must be at least 12 years of age **AND**
   c. The patient must have a diagnosis of moderate to severe Atopic Dermatitis
      i. Must involve at least 10% body surface area
         a) Consideration will be given to those who have less than 10% body surface area involvement but have severe disease of the hands, feet, or other sensitive areas **OR** severe itch that has been unresponsive to topical therapies
      ii. Must have evidence of functional impact on everyday activities **AND**
   d. Must have had a trial and failure or contraindication to:
      i. Medium to higher potency prescription topical corticosteroid therapy
         a) Adequate trial is defined as ≥ 28 days or for the maximum duration recommended by the product prescribing information (i.e., 14 days for super-potent topical corticosteroids), whichever is shorter **AND**
      ii. Tacrolimus or pimecrolimus
         a) Adequate trial is defined as ≥ 6 weeks based on prescribing information **AND**
      iii. Treatment with at least one of the above therapies must have occurred within the previous 6 months **AND**
   e. Must have had serious side effects or drug failure of systemic therapy that is FDA approved to treat moderate to severe Atopic Dermatitis
   f. Approved dosing:
      i. Pediatric Patients 12 years of age or older weighing at least 40 kg **AND** Adults less than 65 years of age
         a) 15 mg once daily
            A. If an adequate response is not achieved, consider increasing the dosage to 30 mg once daily. Discontinue if an adequate response is not achieved with the 30 mg dose. Use the lowest effective dose needed to maintain response
      ii. Adults 65 years of age or older
         a) 15 mg once daily
   g. Rinvoq will not be approved in combination with Opzelura, Cibinqo, Dupixent, or Adbry
   h. Initial and subsequent approval duration is 2 years

4. The patient must have a diagnosis of moderate to severe **Ulcerative Colitis**
   a. The patient must be at least 18 years of age **AND**
   b. The patient must be actively followed by, and the drug prescribed by a gastroenterologist **AND**
   c. There must be documentation of failure or intolerance to at least ONE of the following conventional therapies for at least 3 months:
      i. Thiopurines: azathioprine/6-mercaptopurine (6-MP)
      ii. 5-Aminosalicylates: sulfasalazine, mesalamine, olsalazine
      iii. Cyclosporine
      iv. IV or oral steroids - note, a 3-month trial of systemic steroid therapy will not be required **AND**
   d. The patient must have had serious side effects or drug failure of Humira/Cyltezo/Hadlima for anti-tumor necrosis factor (TNF) naïve patients or with any anti-TNF for anti-TNF experienced patients
   e. Approved dosing:

i. Induction: 45 mg once daily for 8 weeks
ii. Maintenance: 15 mg once daily
a) A dose of 30 mg once daily may be considered for patients with refractory, severe, or extensive disease

5. The patient must have a diagnosis of **Ankylosing Spondylitis**
   a. The patient must be at least 18 years of age **AND**
   b. There must be documentation of refractory disease as defined by failure of two different NSAIDs given as maximum doses for at least 1 month each **AND**
   c. The patient must have had serious side effects or drug failure of Humira/Cyltezo/Hadlima or Enbrel for anti-tumor necrosis factor (TNF) naïve patients or with any anti-TNF for anti-TNF experienced patients
   d. Approved dosing is 15 mg once daily
6. The patient must have a diagnosis of **Non-Radiographic Axial Spondylitis (nr-axSpA)**
   a. The patient must be at least 18 years of age **AND**
   b. The patient must have a diagnosis of non-radiographic axial spondylitis established by a rheumatologist **AND**
   c. The patient must be actively followed by, and the drug prescribed by a rheumatologist **AND**
   d. The patient must have the presence of refractory disease defined by failure of at least TWO different NSAIDs given as maximum dosage for at least 1 month each **AND**
      i. Step Therapy Applies –
         a) The patient must have documentation of serious side effects or drug failure of Cimzia
   e. Approved dosing is 15 mg once daily
7. The patient must have a diagnosis of moderately to severely active **Crohn's Disease**
   a. Crohn's Disease Activity Index (CDAI) score of 220-450. Typically described as having more prominent symptoms of fever, significant weight loss, abdominal pain or tenderness, intermittent nausea or vomiting or significant anemia **AND**
   b. There must be documentation that azathioprine, 6-mercaptopurine, or methotrexate is not effective, contraindicated, or not tolerated **AND**
   c. The patient must have had serious side effects or drug failure of Humira/Cyltezo/Hadlima for anti-tumor necrosis factor (TNF) naïve patients or with any anti-TNF for anti-TNF experienced patients
   d. Approved dosing:
      i. Induction: 45 mg once daily for 12 weeks
      ii. Maintenance: 15 mg once daily
         a) A dose of 30 mg once daily may be considered for patients with refractory, severe, or extensive disease
8. Rinvoq is available as 15 mg, 30 mg, 45 mg tablets and the quantity will be limited to 30 tablets per 30 days for each strength
   a. Rinvoq 45 mg will be over for a max of 84 tablets/365 days to allow for the induction dosing applicable to Crohn's Disease (12 weeks) and Ulcerative Colitis (8 weeks)

## Siliq – brodalumab (Rx)

1. The patient must be followed by a dermatologist or rheumatologist **AND**
2. The patient must be at least 18 years of age **AND**
3. Must have moderate to severe chronic **plaque psoriasis** that involves at least 10% of the body surface area. Consideration will be given to those who have less than 10% body surface area involvement but have severe disease of sensitive areas or areas causing significant disruption in normal activities (such as the hands, feet, face, genitalia) **AND**
4. The patient must be a candidate for systemic therapy (i.e., acitretin, methotrexate, or cyclosporine) with a trial period of at least 3 months that resulted in an inadequate response (failure). A 3-month

trial will not be required if the member experienced serious side effects during a trial of one of the above-mentioned agents
    a. If systemic therapy is contraindicated, then one of the following must be attempted for a reasonable period of time (at least 3 months):
        i. UVB in combination with a topical therapy such as coal tar, steroids or tazarotene **OR**
        ii. PUVA in combination with topical corticosteroids **OR**
        iii. Medium/High potency topical steroids in combination with anthralin, calcipotriene, or tazarotene **AND**
5. The patient must also have a documented drug failure or serious side effects to **ALL** the following: Humira/Cyltezo/Hadlima, Otezla, Stelara, Skyrizi, Tremfya, Enbrel, Cosentyx, Cimzia, Taltz, Sotyktu, and Bimzelx
6. Siliq is contraindicated in patients with Crohn's Disease
7. Siliq has a black box warning for suicidal ideation, including completed suicide
8. Individuals are excluded from coverage if they have an active TB infection.
9. Coverage of Siliq will be limited to an initial induction dose of 210 mg subcutaneous injection at weeks 0, 1, and 2 followed by 210 mg every 2 weeks

## Skyrizi – risankizumab-rzaa (Rx)

1. The patient must be followed by a dermatologist or rheumatologist **AND**
2. The patient must be at least 18 years of age **AND**
3. The patient must have moderate to severe chronic **Plaque Psoriasis** that involves at least 10% of the body surface area. Consideration will be given to those who have less than 10% body surface area involvement but have severe disease of sensitive areas or areas causing significant disruption in normal activities (such as the hands, feet, face, genitalia) **AND**
    a. The patient must be a candidate for systemic therapy (i.e., acitretin, methotrexate, or cyclosporine) with a trial period of at least 3 months that resulted in an inadequate response (failure). A 3-month trial will not be required if the member experienced serious side effects during a trial of one of the above-mentioned agents
        i. If systemic therapy is contraindicated, then one of the following must be attempted for a reasonable period of time (at least 3 months):
            a) UVB in combination with a topical therapy such as coal tar, steroids, or tazarotene **OR**
            b) PUVA in combination with topical steroids in combination with anthralin, calcipotriene, or tazarotene **OR**
            c) Medium/High potency topical steroids in combination with anthralin, calcipotriene, or tazarotene **OR**
4. The patient must have a diagnosis of definitive **Psoriatic Arthritis** established by a Rheumatologist or Dermatologist
    a. The patient must have some clinical features of psoriatic arthritis such as: involvement of the DIP joints, an asymmetric distribution of joint disease, spondyloarthritis, sausage digits, new bone formation on radiographs, cutaneous findings, and the characteristic nail manifestations of psoriatic arthritis (nail pitting, onycholysis & other lesions, which include leukonychia, red spots in the lunula, and nail plate crumbling). All may be present
    b. The patient must be actively followed by, and the drug prescribed by a Rheumatologist or Dermatologist **OR**
5. The patient must have a diagnosis of moderately to severely active **Crohn's Disease**
    a. Crohn's Disease Activity Index (CDAI) score of 220-450. Typically described as having more prominent symptoms of fever, significant weight loss, abdominal pain or tenderness, intermittent nausea or vomiting or significant anemia **AND**

   b. There must be documentation that azathioprine, 6-mercaptopurine, or methotrexate is not effective, contraindicated, or not tolerated
      i. Treatment with a biologic medication as first-line therapy will be assessed on a case-by-case basis through a letter of medical necessity and clinical progress notes based on severity of the disease
6. Approved Dose:
   a. For Psoriatic Arthritis and Plaque Psoriasis: 150 mg at weeks 0, 4, and then every 12 weeks thereafter
   b. For Crohn's Disease: 600 mg given by intravenous (IV) infusion at weeks 0, 4, and 8, followed by 180 mg or 360 mg administered subcutaneously at week 12, and every 8 weeks thereafter
7. Skyrizi is available as a:
   a. 150 mg kit (containing 2-75 mg prefilled syringes)
   b. 150 mg single-dose prefilled pen
   c. 150 mg single-dose prefilled syringe
   d. 180 mg/1.2 mL single-dose prefilled cartridge with on-body injector
   e. 360 mg/2.4 mL single-dose prefilled cartridge with on-body injector
   f. 600 mg/10 mL single-dose vial for intravenous infusion
8. Quantity limit
   a. For Psoriatic Arthritis and Plaque Psoriasis:
      i. Coverage of the initial loading dose will be limited to 2 kits/pens/syringes for the first month of therapy and is covered under the pharmacy benefit
      ii. Coverage of ongoing maintenance therapy will be limited to 1 kit/pen/syringe per 84 days
   b. For Crohn's Disease:
      i. The initial loading dose will be covered under the medical benefit (if applicable)
      ii. Coverage of ongoing maintenance therapy will be limited to 1 prefilled cartridge with on-body injector per 56 days

**HCPCS**: J2327

## Simponi/Simponi Aria - golimumab (Medical or Rx)

1. The patient must have a diagnosis of **Rheumatoid Arthritis**
   a. The patient must be at least 18 years of age **AND**
   b. The patient must be actively followed by, and the drug prescribed by a rheumatologist **AND**
   c. There must be documentation of clinical failure or intolerance to a disease-modifying anti-rheumatic drug (DMARD) agent, such as methotrexate, azathioprine, sulfasalazine, or hydroxychloroquine, either alone or in combination for a 3-month period **AND**
   d. Simponi Aria must be used in combination with methotrexate. Consideration for the use without concurrent methotrexate may be given to patients who have a previous intolerance or contraindication to methotrexate therapy
   e. Step Therapy Applies –
      i. Treatment with SC Simponi (self-administered) will require documentation of drug failure or serious side effects of **TWO** of the following: Actemra SC, Enbrel, Humira/Cyltezo/Hadlima, Xeljanz/XR, Rinvoq
   f. Simponi Aria dosing for adults with RA is as follows:
      i. Dosing is 2mg/kg IV infusion at week 0 and 4 and then every 8 weeks thereafter
   g. SC Simponi dosing for adults with RA is as follows:
      i. 50mg once monthly
2. The patient must have a diagnosis of definitive **Psoriatic Arthritis** established by a Rheumatologist or Dermatologist

   a. The patient must be actively followed by, and the drug prescribed by a rheumatologist or dermatologist **AND**
   b. The patient must be 2 years of age or older
   c. The patient must have some clinical features of psoriatic arthritis such as: involvement of the DIP joints, an asymmetric distribution of joint disease, spondyloarthritis, sausage digits, new bone formation on radiographs, cutaneous findings, and the characteristic nail manifestations of psoriatic arthritis (nail pitting, onycholysis & other lesions, which include leukonychia, red spots in the lunula, and nail plate crumbling). All may be present.
   d. Simponi Aria dosing for patients with PsA is as follows:
      i. Adult patients: 2 mg/kg IV at weeks 0, 4, and then every 8 weeks thereafter
      ii. Pediatric patients: 80 mg/m$^2$ at weeks 0, 4, and then every 8 weeks thereafter
   e. Step Therapy Applies –
      i. Treatment with SC Simponi (self-administered) will require documentation of drug failure or serious side effects of **TWO** of the following: Enbrel, Humira/Cyltezo/Hadlima, Stelara SC, Xeljanz/XR, Cosentyx, Otezla, Tremfya, Rinvoq, Skyrizi
   f. SC Simponi dosing for adult patients with PsA is as follows:
      i. 50mg once monthly
   g. SC Simponi is not FDA approved to treat PsA in pediatric patients
3. The patient must have a diagnosis of **Ankylosing Spondylitis**
   a. The patient must be at least 18 years of age **AND**
   b. The patient must be actively followed by, and the drug prescribed by a rheumatologist **AND**
   c. There must be documentation of refractory disease as defined by failure of two different NSAIDs given as maximum dose for at least 1 month each
   d. Simponi Aria dosing for adults with AS is as follows:
      i. 2 mg/kg IV at weeks 0, 4, and then every 8 weeks thereafter
   e. Step Therapy Applies –
      i. Treatment with SC Simponi (self-administered) will require documentation of drug failure or serious side effects of **TWO** of the following: Enbrel, Humira/Cyltezo/Hadlima, Cosentyx, Xeljanz/XR, Rinvoq
   f. SC Simponi dosing for adults with AS is as follows:
      i. 50mg once monthly
4. The patient must have a diagnosis of moderate to severe **Ulcerative Colitis**
   a. The patient must be at least 18 years of age **AND**
   b. The patient must be actively followed by, and the drug prescribed by a gastroenterologist **AND**
   c. There must be documentation of failure or intolerance to at least ONE of the following conventional therapies for at least 3 months:
      i. Thiopurines: azathioprine/6-mercaptopurine (6-MP)
      ii. 5-Aminosalicylates: sulfasalazine, mesalamine, olsalazine
      iii. Cyclosporine
      iv. IV or oral steroids - note, a 3-month trial of systemic steroid therapy will not be required
   d. Step Therapy Applies –
      i. Treatment with SC Simponi (self-administered) will require drug failure or serious side effects with Humira/Cyltezo/Hadlima
   e. SC Simponi dosing for adults with UC is as follows:
      i. 200mg initially, followed by 100mg at Week 2, and then 100mg every 4 weeks
   f. Simponi Aria is not FDA approved for the treatment of Ulcerative Colitis
5. A diagnosis of **irritable bowel disease associated arthritis** will be evaluated using criteria for ankylosing spondylitis
6. The patient must have a diagnosis of **polyarticular Juvenile Idiopathic Arthritis (pJIA)**

a. The patient must be actively followed by, and the drug prescribed by a rheumatologist
b. The patient must be at least 2 years old
c. The patient must have failed to respond to and/or is intolerant to approved disease-modifying antirheumatic drugs (DMARDs) agents, such as methotrexate, NSAIDs, analgesics or corticosteroids either alone or in combination
d. Simponi Aria dosing for pediatric patients with pJIA is 80 mg/m2 IV at weeks 0 and 4 followed by 80 mg/m2 IV every 8 weeks thereafter
e. SC Simponi is not FDA approved for the treatment of pJIA

7. Simponi Aria is intended for coverage under the medical benefit (healthcare provider administered)
8. Simoni SC is intended for coverage under the pharmacy benefit (self-administered)
9. Quantity Limit under the pharmacy benefit:
   a. Simponi 50 mg: 0.5 mL per 30 days
   b. Simponi 100 mg: 1 mL per 30 days

**HCPCS**: J1602

## Spevigo – spesolimab-sbzo (Medical)

1. The patient must be at least 18 years of age **AND**
2. Must be prescribed by a dermatologist or a physician specializing in the treatment of autoinflammatory conditions **AND**
3. The patient must have a confirmed diagnosis of generalized pustular psoriasis (GPP) defined as the presence of primary, sterile, macroscopically visible pustules on non-acral skin (excluding cases where pustulation is restricted to psoriatic plaques) **AND**
4. Must be used for the treatment of a generalized pustular psoriasis (GPP) flare defined as:
   a. A Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) score of ≥ 3 **AND**
   b. New appearance or worsening of existing pustules **AND**
   c. A GPPGA pustulation sub score of ≥ 2 **AND**
   d. ≥ 5% body surface covered with erythema and the presence of pustules
5. Coverage will not be granted for any non-Food and Drug Administration indications (such as acute generalized exanthematous pustulosis [AGEP], acrodermatitis continua of Hallopeau [ACH], palmoplantar pustulosis [PPP], chronic plaque psoriasis, guttate psoriasis, and erythrodermic psoriasis)
6. Patients with a concurrent inflammatory diagnosis (such as plaque psoriasis) may not receive treatment with Spevigo if they are currently on biologic therapy
7. Approval will be for 1 week per request (new, additional, and recertification)
8. Requests for **an additional dose** used to treat the **same flare** will be covered if the patient meets the following criteria:
   a. The additional dose will be used no sooner than 1 week after the initial dose **AND**
   b. The patient has a Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) total score of 2 or higher at the end of week 1 (range, 0 [clear skin] to 4 [severe disease]) **AND**
   c. The patient has a GPPGA pustulation subscore of 2 or higher at the end of week 1 (range, 0 [no visible pustules] to 4 [severe pustulation])
9. Requests for **recertification**, defined as previously receiving at least 1 dose of Spevigo approved by the Health Plan using the criteria listed above, for the treatment of a **NEW flare** will be covered if the patient achieved a Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) score of 0 or 1 after previous treatment
10. Approved Dosing:
    a. 900 mg dose by intravenous (IV) infusion over 90 minutes

i. If GPP flare symptoms persist, an additional intravenous (IV) 900 mg dose (over 90 minutes) may be administered one week after the initial dose (the criteria listed in 8 must be met for coverage for an additional dose)

## Sotyktu – deucravacitinib (Rx)

1. The patient must be at least 18 years of age **AND**
2. The patient must be followed by a dermatologist or rheumatologist **AND**
3. The patient must have moderate to severe chronic **plaque psoriasis** that involves at least 10% of the body surface area. Consideration will be given to those who have less than 10% body surface area involvement but have severe disease of sensitive areas or areas causing significant disruption in normal activities (such as the hands, feet, face, genitalia) **AND**
   a. The patient must be a candidate for systemic therapy (i.e., acitretin, methotrexate, or cyclosporine) with a trial period of at least 3 months that resulted in an inadequate response (failure). A 3-month trial will not be required if the member experienced serious side effects during a trial of one of the above-mentioned agents
   b. If systemic therapy is contraindicated, one of the following must be attempted for a reasonable period of time (at least 3 months):
      i. UVB in combination with a topical therapy such as coal tar, steroids or tazarotene **OR**
      ii. PUVA in combination with topical corticosteroids **OR**
      iii. Medium/High potency topical steroids in combination with anthralin, calcipotriene, or tazarotene **AND**
4. Step Therapy Applies –
   a. There must be documentation of drug failure or serious side effects to **THREE** of the following: Humira/Cyltezo/Hadlima, Otezla, Stelara, Skyrizi, Tremfya, Cosentyx, Enbrel
5. Approved Dosing: 6 mg by mouth once daily
6. Quantity Limit: 30 tablets/30 days

## Taltz – ixekizumab (Rx)

1. The patient must be followed by a dermatologist or rheumatologist **AND**
2. The patient must have a diagnosis of **Ankylosing Spondylitis**
   a. The patient must be at least 18 years of age
   b. There must be documentation of refractory disease as defined by failure of two different NSAIDs given as maximum doses for at least 1 month each **AND**
   c. Step Therapy Applies –
      i. There must be documentation of drug failure or serious side effects to **TWO** of the following: Enbrel, Humira/Cyltezo/Hadlima, Cosentyx, Xeljanz/XR, Rinvoq
3. The patient must have moderate to severe chronic **Plaque Psoriasis** that involves at least 10% of the body surface area. Consideration will be given to those who have less than 10% body surface area involvement but have severe disease of sensitive areas or areas causing significant disruption in normal activities (such as the hands, feet, face, genitalia) **AND**
   a. The patient must be at least 6 years of age
   b. The patient must be a candidate for systemic therapy (i.e., acitretin, methotrexate, or cyclosporine) with a trial period of at least 3 months that resulted in an inadequate response (failure). A 3-month trial will not be required if the member experienced serious side effects during a trial of one of the above-mentioned agents
   c. If systemic therapy is contraindicated, then one of the following must be attempted for a reasonable period of time (at least 3 months):
      i. UVB in combination with a topical therapy such as coal tar, steroids, or tazarotene **OR**
      ii. PUVA in combination with topical steroids **OR**
      iii. Medium/High potency topical steroids in combination with anthralin, calcipotriene, or tazarotene **AND**

   d. Step Therapy Applies –
      i. The patient must also have a documented drug failure or serious side effects to **THREE** of the following: Humira/Cyltezo/Hadlima, Otezla, Stelara SC, Skyrizi, Tremfya, Cosentyx, Enbrel
4. Must have a diagnosis of definitive **Psoriatic Arthritis** established by a Rheumatologist or Dermatologist
   a. The patient must be at least 18 years old **AND**
   b. The patient must have some clinical features of psoriatic arthritis such as: involvement of the DIP joints, an asymmetric distribution of joint disease, Spondyloarthritis, sausage digits, new bone formation on radiographs, cutaneous findings, and the characteristic nail manifestations of psoriatic arthritis (nail pitting, onycholysis & other lesions, which include leukonychia, red spots in the lunula, and nail plate crumbling) all may be present **AND**
   c. The patient must be actively followed by, and the drug prescribed by a Rheumatologist or Dermatologist **AND**
   d. Step Therapy Applies –
      i. The patient must also have a documentation drug failure or serious side effects with **TWO** of the following: Enbrel, Humira/Cyltezo/Hadlima, Stelara SC, Xeljanz/XR, Cosentyx, Otezla, Tremfya, Skyrizi, Rinvoq
5. Must have a diagnosis of **Non-Radiographic Axial Spondylitis (nr-axSpA)**
   a. The patient must be at least 18 years of age **AND**
   b. The patient must have a diagnosis of non-radiographic axial spondylitis established by a rheumatologist **AND**
   c. Must be actively followed by and the drug prescribed by a rheumatologist **AND**
   d. Presence of refractory disease defined by failure of at least TWO different NSAIDs given as maximum dosage for at least 1 month each
   e. Step Therapy Applies –
      i. The patient must also have a documentation drug failure or serious side effects with **TWO** of the following: Rinvoq, Cimzia, Cosentyx
6. Individuals are excluded from coverage if they have an active TB infection
7. Coverage of Taltz will be limited to:
   a. an initial induction dose of 160mg subcutaneous injection at week 0, then 80mg SC weeks 2,4,6,8,10 and 12 and then maintenance dosing of 80mg every 4 weeks for **Plaque Psoriasis** and **Psoriatic arthritis with comorbid Plaque Psoriasis**
   b. an initial induction dose of 160mg subcutaneous injection at week 0, followed by a maintenance dose of 80mg every 4 weeks for **Ankylosing Spondylitis** and **Psoriatic Arthritis**
   c. 80mg subcutaneously every 4 weeks for **Non-Radiographic Axial Spondyloarthritis**

## Tremfya – guselkumab (Medical or Rx)

1. The patient must be followed by a dermatologist or rheumatologist **AND**
2. The patient must be at least 18 years of age **AND**
3. Must have moderate to severe chronic **plaque psoriasis** that involves at least 10% of their body surface area. Consideration will be given to those who have less than 10% body surface area involvement but have severe disease of sensitive areas or areas causing significant disruption in normal activities (such as the hands, feet, face, genitalia) **AND**
   a. The patient must be a candidate for systemic therapy (i.e., acitretin, methotrexate, or cyclosporine) with a trial period of at least 3 months that resulted in an inadequate response (failure). A 3-month trial will not be required if the member experienced serious side effects during a trial of one of the above-mentioned agents

b. If systemic therapy is contraindicated, then one of the following must be attempted for a reasonable period of time (at least 3 months):
   i. UVB in combination with a topical therapy such as coal tar, steroids or tazarotene **OR**
   ii. PUVA in combination with topical corticosteroids **OR**
   iii. Medium/High potency topical steroids in combination with anthralin, calcipotriene, or tazarotene **OR**

4. The patient must have a diagnosis of definitive **Psoriatic Arthritis** established by a Rheumatologist or Dermatologist
   a. The patient must have some clinical features or psoriatic arthritis such as involvement of the DIP joints, an asymmetric distribution of joint disease, spondyloarthritis, sausage digits, new bone formation on radiographs, cutaneous findings, and the characteristic nail manifestations of psoriatic arthritis (nail pitting, onycholysis & other lesions, which include leukonychia, red spots in the lunula, and nail plate crumbling). All may be present **AND**
   b. The patient must be actively followed by, and the drug prescribed by a Rheumatologist or Dermatologist
5. Individuals are excluded from coverage if they have an active TB infection
6. Coverage of Tremfya will be limited to an initial induction dose of 100 mg subcutaneous injection at weeks 0 and 4, and then maintenance dosing of 100mg every 8 weeks thereafter

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## Velsipity – etrasimod (Rx)

1. The patient must be actively followed by, and the drug prescribed by a gastroenterologist **AND**
2. The patient must be at least 18 years of age **AND**
3. The patient must have a diagnosis of moderate to severe active Ulcerative Colitis **AND**
4. The patient must have tried and failed or has documented intolerance to at least **ONE** of the following conventional therapies for at least 3 months:
   a. Thiopurines: Azathioprine/6-mercaptopurine (6-MP)
   b. 5-Aminosalicylates: Sulfasalazine, Mesalamine, Olsalazine
   c. Cyclosporine
   d. IV or oral steroids - note, a 3-month trial of systemic steroid therapy will not be required **AND**
5. Step Therapy Applies:
   a. The patient must have had serious side effects or drug failure of Humira/Cyltezo/Hadlima **AND** Stelara
6. Approved dosing: 2 mg by mouth once daily
7. Quantity Limit: 30 tablets/30 days

## Xeljanz and Xeljanz XR- tofacitinib and tofacitinib ER (Rx)

1. The patient must have a diagnosis of moderate to severe **Rheumatoid Arthritis**
   a. The patient must be at least 18 years of age **AND**
   b. The patient must be actively followed by, and the drug prescribed by a rheumatologist **AND**
   c. The patient must have had serious side effects or drug failure of methotrexate
      i. For patients who have a contraindication to methotrexate, trial of an alternative DMARD in appropriate dosages will be required prior to approval **AND**
   d. The patient must have had serious side effects or drug failure of Humira/Cyltezo/Hadlima or Enbrel for anti-tumor necrosis factor (TNF) naïve patients or with any anti-TNF for anti-TNF experienced patients
2. The patient must have a diagnosis of definitive **Psoriatic Arthritis** established by a Rheumatologist or Dermatologist
   a. The patient must be at least 18 years of age **AND**

b. The patient must have some clinical features or psoriatic arthritis such as involvement of the DIP joints, an asymmetric distribution of joint disease, spondyloarthritis, sausage digits, new bone formation on radiographs, cutaneous findings, and the characteristic nail manifestations of psoriatic arthritis (nail pitting, onycholysis & other lesions, which include leukonychia, red spots in the lunula, and nail plate crumbling) all may be present **AND**
c. The patient must be actively followed by, and the drug prescribed by a Rheumatologist or Dermatologist **AND**
d. The patient must have had serious side effects or drug failure of Humira/Cyltezo/Hadlima or Enbrel for anti-tumor necrosis factor (TNF) naïve patients or with any anti-TNF for anti-TNF experienced patients

3. The patient must have a diagnosis of **Ulcerative Colitis**
   a. The patient must be at least 18 years of age **AND**
   b. The patient must be actively followed by, and the drug prescribed by a gastroenterologist **AND**
   c. There must be documentation of failure or intolerance to at least **ONE** of the following conventional therapies for at least 3 months:
      i. Thiopurines: azathioprine/6-mercaptopurine (6-MP)
      ii. 5-Aminosalicylates: sulfasalazine, mesalamine, olsalazine
      iii. Cyclosporine
      iv. IV or oral steroids - note, a 3-month trial of systemic steroid therapy will not be required **AND**
   d. The patient must have had serious side effects or drug failure of Humira/Cyltezo/Hadlima for anti-tumor necrosis factor (TNF) naïve patients or with any anti-TNF for anti-TNF experienced patients
4. The patient must have a diagnosis of **polyarticular Juvenile Idiopathic Arthritis (pJIA)**
   a. The patient must be actively followed by, and the drug prescribed by a rheumatologist **AND**
   b. The patient must be at least 2 years old **AND**
   c. The patient must have failed to respond to and/or is intolerant to approved disease-modifying antirheumatic drugs (DMARDs) agents, such as methotrexate, NSAIDs, analgesics or corticosteroids either alone or in combination **AND**
   d. The patient must have had serious side effects or drug failure of Humira/Cyltezo/Hadlima or Enbrel for anti-tumor necrosis factor (TNF) naïve patients or with any anti-TNF for anti-TNF experienced patients
   e. The approved dose of Xeljanz for pJIA is as follows:
      i. 10 to < 20 kg: 3.2 mg oral solution twice daily
      ii. 20 kg to < 40 kg: 4 mg oral solution twice daily
      iii. ≥ 40 kg: 5 mg oral tablet or oral solution twice daily
   f. Xeljanz XR is not FDA approved for the treatment of pJIA
5. The patient must have a diagnosis of **Ankylosing Spondylitis**
   a. The patient must be at least 18 years of age **AND**
   b. There must be documentation of refractory disease as defined by failure of two different NSAIDs given as maximum doses for at least 1 month each **AND**
   c. The patient must have had serious side effects or drug failure of Humira/Cyltezo/Hadlima or Enbrel for anti-tumor necrosis factor (TNF) naïve patients or with any anti-TNF for anti-TNF experienced patients
6. Xeljanz has not been found to be safe and effective for and is not FDA approved for the treatment of alopecia areata (including but not limited to alopecia areata, alopecia universalis) and will be subject to off label review and policy criteria. In addition, the use of Xeljanz for the treatment of alopecia is considered a cosmetic use (defined as use to improve a patient's appearance and/or

self-esteem). The use of a drug, whether it is for a Food and Drug Administration (FDA) approved or off-label indication, for a cosmetic use is considered not medically necessary.
7. Serious infections, active tuberculosis, lymphoma, and other malignancies have been observed in patients treated with Xeljanz.
8. Xeljanz has been given a black box warning for increased risk of blood clots and death with 10mg twice daily dosing, which is used for patients with ulcerative colitis.
9. Xeljanz oral solution is supplied in a 240 mL bottle with a concentration of 1 mg/mL and is only FDA approved for the treatment of pJIA
10. Coverage will be limited to:
    a. 60 tablets/30 days for Xeljanz
    b. 30 tablets/30 days for Xeljanz XR
    c. 300 mL/30 days for Xeljanz oral solution

**Zeposia- ozanimod (Rx)**

1. The patient must have a diagnosis of **Multiple Sclerosis OR**
2. The patient must have a diagnosis of **Ulcerative Colitis**
    a. The patient must be at least 18 years of age **AND**
    b. The patient must be actively followed by, and the drug prescribed by a gastroenterologist **AND**
    c. There must be documentation of failure or intolerance to at least **ONE** of the following conventional therapies for at least 3 months:
        i. Thiopurines: azathioprine/6-mercaptopurine (6-MP)
        ii. 5-Aminosalicylates: sulfasalazine, mesalamine, olsalazine
        iii. Cyclosporine
        iv. IV or oral steroids - note, a 3-month trial of systemic steroid therapy will not be required **AND**
    d. Step Therapy Applies –
        i. The patient must have had drug failure or serious side effects with:
            a) Humira/Cyltezo/Hadlima **AND** Stelara for Commercial and Exchange formularies
3. Coverage of Zeposia will be limited to:
    a. 30 capsules/30 days for Zeposia 0.92 mg capsules
    b. 7 capsules/30 days for Zeposia 7-Day Starter Pack
    c. Zeposia Starter Kit:
        a. NDC 59572-0890-91 = 37 capsules/30 days
        b. NDC 59572-0890-28 = 28 capsules/28 days

## APPROVAL TIME PERIODS:

For drugs that can be both self-administered (pharmacy benefit [Rx]) or administered by a healthcare professional (medical benefit) **OR** only administered by a healthcare professional (medical benefit), approval time frames are as follows (please refer to Policy Guidelines [#4] for approval time periods of other drugs within this policy):

**Actemra (Rx/Medical), Cosentyx (Rx/Medical), Entyvio (Rx/Medical), Ilumya (Medical ONLY), Orencia (Rx/Medical), Simponi/Simponi Aria(Rx/Medical), Tremfya(Rx/Medical),**

| Line of Business | Rx Initial approval | Rx Recertification | Medical Initial approval | Medical Recertification |
|---|---|---|---|---|
| **Commercial, Exchange, and Safety Net** (Medicaid, HARP, CHP, Essential Plan) | 1 year<br><br>*Does not apply to Medicaid and HARP) | 1 year<br><br>*Does not apply to Medicaid and HARP | All sites of service: 1 year | All sites of service: 1 year |
| **Medicare** | Already defined in policy | Already defined in policy | All sites of service: 2 years | All sites of service: 2 years |

**POLICY GUIDELINES:**

1. This policy is subject to frequent revisions as new medications come onto the market. Some drugs will require prior authorization prior to approved language being added to the policy
2. Supportive documentation of previous drug use must be submitted for any criteria that requires trial of a preferred agent if the preferred drug is not found in claims history
3. Dose and frequency should be in accordance with the FDA label or recognized compendia (for off-label uses). When services are performed in excess of established parameters, they may be subject to review for medical necessity
4. Unless otherwise stated above within the approval time-period section or drug/diagnosis specific criteria, approval time periods will be for 1 year.
   - Continued approval at time of recertification will require documentation that the drug is providing ongoing benefit to the patient in terms of improvement or stability in disease state or condition. Such documentation may include progress notes, imaging or laboratory findings, and other objective or subjective measures of benefit which support that continued use of the requested product is medically necessary. Also, ongoing use of the requested product must continue to reflect the current policy's preferred formulary. Recertification reviews may result in the requirement to try more cost-effective treatment alternatives as they become available (i.e., generics, biosimilars, or other guideline-supported treatment options). Requested dosing must continue to be consistent with FDA-approved or off-label/guideline-supported dosing recommendations.
5. Utilization Management are contract dependent and coverage criteria may be dependent on the contract renewal date. Additionally, coverage of drugs listed in this policy are contract dependent. Refer to specific contract/benefit language for exclusions.
6. Not all contracts cover all Medical Infusible drugs. Refer to specific contract/benefit plan language for exclusions of Injectable Medications.
7. For contracts where Insurance Law § 4903(c-1), and Public Health Law § 4903(3-a) are applicable, if trial of preferred drug(s) is the only criterion that is not met for a given condition, and one of the following circumstances can be substantiated by the requesting provider, then trial of the preferred drug(s) will not be required.
   a. The required prescription drug(s) is (are) contraindicated or will likely cause an adverse reaction or physical or mental harm to the member;
   b. The required prescription drug is expected to be ineffective based on the known clinical history and conditions and concurrent drug regimen;
   c. The required prescription drug(s) was (were) previously tried while under the current or a previous health plan, or another prescription drug or drugs in the same pharmacologic class or with the same mechanism of action was (were) previously tried and such prescription drug(s) was (were) discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;
   d. The required prescription drug(s) is (are) not in the patient’s best interest because it will likely cause a significant barrier to adherence to or compliance with the plan of care, will likely worsen a comorbid condition, or will likely decrease the ability to achieve or maintain reasonable functional ability in performing daily activities;
   e. The individual is stable on the requested prescription drug. The medical profile of the individual (age, disease state, comorbidities), along with the rational for deeming stability as it relates to standard medical practice and evidence-based practice protocols for the disease state will be taken into consideration.

f. The above criteria are not applicable to requests for brand name medications that have an AB rated generic. We can require a trial of an AB-rated generic equivalent prior to providing coverage for the equivalent brand name prescription drug.

8. This policy is applicable to drugs that are included on a specific drug formulary. If a drug referenced in this policy is non-formulary, please reference the Non-Formulary Medication Exception Review Policy for all Lines of Business (Pharmacy-69).
9. **Concurrent use of Inflammatory Agents**
   a. Drugs listed in this policy as well as other immunomodulating therapies or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs) not listed in this policy (Adalimumab, Enbrel, Stelara, Cimzia, Remicade, biosimilars, etc.) should not be administered in combination with another biologic or targeted synthetic DMARD used for an inflammatory condition. Combination therapy is generally not recommended due to the added risk of immunosuppression, potential for a higher rate of adverse effects, and lack of evidence for additive therapy. NOTE: This does NOT exclude the use of conventional synthetic DMARDs (e.g., MTX, leflunomide, hydroxychloroquine, and sulfasalazine) in combination with biologics and targeted synthetic DMARDs.
   b. Requests for the concurrent use of inflammatory agents will be evaluated for safety and efficacy and subject to off-label review.
   c. Otezla in combination with biologic DMARD therapy (such as adalimumab, Enbrel, Cosentyx, etc.) is not FDA approved or supported with a high level of clinically valid medical evidence for the treatment of plaque psoriasis or psoriatic arthritis. Therefore, these requests are considered combination therapy and are considered not medically necessary.

**UPDATES:**

| Date | Revision |
|---|---|
| 12/06/2023 | Revised |
| 11/30/2023 | Revised |
| 10/25/2023 | Revised |
| 09/01/2023 | Revised |
| 08/24/2023 | P&T Committee Approval |
| 06/23/2023 | Revised |
| 04/01/2023 | Revised |
| 03/15/2023 | Revised |
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| 09/2022 | Revised / P&T Committee Approval |
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| 07/2022 | Revised |
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| 08/2021 | Revised |
| 07/2021 | Revised |
| 06/2021 | Revised |
| 05/2021 | Revised |
| 04/2021 | Revised |

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|---|---|
| 01/2021 | Revised |
| 11/2020 | Revised |
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| 8/2020 | Revised |
| 6/2020 | Revised |
| 5/2020 | Revised |
| 4/2020 | Revised |
| 2/2020 | Revised |
| 1/2020 | Revised |
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| 8/2019 | Revised |
| 5/2019 | Revised |
| 1/2019 | Revised |
| 10/2018 | Revised |
| 7/2018 | Revised |
| 6/2018 | Revised |
| 2/2018 | Revised |
| 1/2018 | Created |

## APPENDIX:

**Table 1:** Generalized Pustular Psoriasis Physician Global Assessment (GPPGA)

| Score | Erythema | Pustules | Scaling |
|---|---|---|---|
| 0 (Clear) | Normal or post-inflammatory hyperpigmentation | No visible pustules | No scaling or crusting |
| 1 (Almost Clear) | Faint, diffuse pink or slight red | Low density occasional small discrete pustules (noncoalescent) | Superficial focal scaling or crusting restricted to periphery of lesions |
| 2 (Mild) | Light red | Moderate density grouped discrete small pustules (noncoalescent) | Predominantly fine scaling or crusting |
| 3 (Moderate) | Bright red | High density pustules with some coalescence | Moderate scaling or crusting covering most or all lesions |
| 4 (Severe) | Deep fiery red | Very high-density pustules with pustular lakes | Severe scaling or crusting covering most or all lesions |

Each component is graded separately, the average is calculated and the final GPPGA is determined from this composite score*. A lower score indicates a lesser severity, with 0 being clear and 1 being almost clear. To receive a score of 0 or 1, the patient should be afebrile in addition to the skin presentation requirements.

*Composite mean score = (erythema + pustules + scaling)/3; total GPPGA score given is 0 if mean = 0 for all three components, 1 if mean 0 to <1.5, 2 if mean 1.5 to <2.5, 3 if mean 2.5 to <3.5, 4 if mean ≥3.5.

## REFERENCES:

In addition to the full prescribing information for each individual drug, the following references have been utilized in creating drug specific criteria:

**Orencia** –
1. Weinblatt M. et al. Safety of the selective costimulation modulator abatacept in rheumatoid arthritis patients receiving background biologic and nonbiologic disease-modifying antirheumatic drugs: A one-year randomized, placebo-controlled study. Arthritis & Rheumatism. August 2006; 54(9):2807-2816.

2. Kremer JM et al. Effects of abatacept in patients with methotrexate-resistant active rheumatoid arthritis: a randomized trial. Annals of Internal Medicine. June 2006; 144(12):865-876.
3. Emery P. Kosinski M. Li T. Martin M. Williams GR. Becker JC. Blaisdell B. Ware JE Jr. Birbara C. Russell AS. Treatment of rheumatoid arthritis patients with abatacept and methotrexate