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: 03/26/2026

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

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, ustekinumab.

CURRENT INFLAMMATORY CONDITIONS CRPA RX AND MEDICAL DRUGS:

DRUG NAME – generic name (Medical/Rx Benefit)
Authorization Criteria
Actemra - tocilizumab (Medical or Rx) **Avtozma -tocilizumab-anoh (Medical or Rx)** **Tofidence tocilizumab-bavi (Medical)** **Tyenne – tocilizumab-aazg (Medical or Rx)**
1. The patient must have a diagnosis of moderately to severely active **Rheumatoid Arthritis** a. Must be prescribed by or in consultation with a Rheumatologist **AND** b. The patient must be at least 18 years of age **AND** c. Must have failed to respond to and/or is intolerant to approved disease-modifying antirheumatic drug (DMARD) agents, such as methotrexate, azathioprine, sulfasalazine, or hydroxychloroquine, either alone or in combination for a 3-month period i. Patients starting on Actemra concurrently with methotrexate, sulfasalazine, or leflunomide will not be subject to the above requirement. **AND** d. The patient must meet one of the following: i. Treatment with **IV tocilizumab (Actemra, Actozma, Tofidence or Tyenne)** 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 tocilizumab 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 **Actemra SC or Tyenne SC** will require failure or serious side effects with Humira/Simlandi/Hadlima

iv. Treatment with **Avtozma SC** will require failure or serious side effects with Humira/Simlandi/Hadlima AND either Actemra SC or Tyenne SC

v. **SC tocilizumab** 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 Active **Systemic Juvenile Idiopathic Arthritis (sJIA) or** moderately to severely active **Polyarticular Juvenile Idiopathic Arthritis (pJIA)** in children 2 years of age or older
   a. Must be prescribed by or in consultation with a Rheumatologist **AND**
   b. Must have a contraindication to have failed to respond to, or must be intolerant to treatment with a disease-modifying antirheumatic drug (DMARD) (such as methotrexate, leflunomide, sulfasalazine), NSAID, analgesic, or corticosteroid
      i. Patients starting on SC tocilizumab (Actemra or Tyenne) concurrently with methotrexate, sulfasalazine, or leflunomide will not be subject to the above requirement
   c. The patient must meet one of the following:
      i. Treatment with **Actemra SC or Tyenne SC** will require failure or serious side effects with Humira/Simlandi/Hadlima
      ii. Treatment with **Avtozma SC** will require failure or serious side effects with Humira/Simlandi/Hadlima AND either Actemra SC or Tyenne SC
      iii. Treatment with **IV tocilizumab (Actemra, Actozma, Tofidence or Tyenne)** 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 Simponi Aria for a diagnosis of pJIA
            I. Applies to New Starts of all lines of business
   d. IV tocilizumab 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
   e. SC tocilizumab 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
   f. IV tocilizumab 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
   g. SC tocilizumab 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 or in consultation with an Ophthalmologist, Neurologist, or Rheumatologist
b. SC tocilizumab 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 tocilizumab 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. Must be prescribed by or in consultation with a Rheumatologist or Pulmonologist **AND**
    c. The patient must have lung fibrosis based on a HRCT scan from within the last 12 months **AND**
    d. Forced vital capacity (FVC) is > 55% of the predicted value; **AND**
    e. The patient must have been treated with mycophenolate mofetil (MMF)
    f. SC tocilizumab dosing for adults with SSc-ILD is 162 mg given once every week as a subcutaneous injection
    g. IV tocilizumab is not approved for SSc-ILD with declining pulmonary function
    h. Quantity Limit of 4 syringes per 28 days
5. IV tocilizumab (Actemra, Actozma, Tofidence or Tyenne) will be covered for use with chimeric antigen receptor (CAR) T-Cell therapy for potential severe or life-threatening cytokine-release syndrome (CRS)
6. IV tocilizumab (Actemra, Actozma, Tofidence or Tyenne) will be covered for use with chimeric antigen receptor (CAR) T-Cell therapy for potential severe or life-threatening cytokine-release syndrome (CRS)
7. IV tocilizumab, Actemra, Actozma, Tofidence and Tyenne, have been FDA approved for the treatment of hospitalized adult patients, and **Actemra** with additional indication for 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) for inpatient use only; therefore, coverage in the outpatient setting will not be authorized.

HCPCS: J3262 (Actemra), J3590 and Q5135 (Tyenne), J3590 (Tofidence)

Bimzelx - bimekizumab (Rx)

1. The patient must be at least 18 years of age **AND**
    a. 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**
        i. Must be prescribed by or in consultation with a Dermatologist or Rheumatologist **AND**
            a) The patient must be a candidate for systemic therapy or phototherapy and meet for **ONE** of the following (**A or B**)
                A. The patient must have had a 3-month trial of systemic therapy (i.e., acitretin, methotrexate, or cyclosporine) 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 aforementioned agents **OR**

B. The patient must have had a 3-month trial of Ultraviolet B (UVB) Phototherapy or Psoralen Ultraviolet A (PUVA) Phototherapy that resulted in an inadequate response (failure) **AND**

b) The patient must also have a documented drug failure or serious side effects to **TWO** of the following: Humira/Simlandi/Hadlima, Otezla/XR, Sotyktu, Selarsdi/Yesintek SC, Skyrizi, Tremfya, Cosentyx, Enbrel

c) Documentation of a baseline Psoriasis Area Severity Index (PASI) score is required

d) Coverage for Bimzelx will only be authorized under the pharmacy benefit

e) 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.

f) 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

1. 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

b. The patient must have a diagnosis of active **Psoriatic Arthritis**

i. Must be prescribed by or in consultation with a Rheumatologist or Dermatologist

ii. The patient must also have a documentation drug failure or serious side effects with **TWO** of the following: Enbrel, Humira/Simlandi/Hadlima, Selarsdi/Yesintek SC, Cosentyx, Otezla/XR, Tremfya, Skyrizi, Rinvoq and Xeljanz/XR

iii. Approved dosing is 160 mg once every 4 weeks

iv. Initial approval will be for 1 year. Recertification will require documentation confirming clinical improvement in signs and symptoms of Psoriatic Arthritis and will be approved for 2 years.

c. The patient must have a diagnosis of **Ankylosing Spondylitis**

i. Must be prescribed by or in consultation with a Rheumatologist **AND**

ii. Must have refractory disease defined by failure of or intolerance to at least **TWO** different NSAIDS at maximum strength for at least 1 month each **AND**

iii. The patient must also have a documentation drug failure or serious side effects with **TWO** of the following: Cosentyx, Enbrel, Humira/Simlandi/Hadlima, Rinvoq and Xeljanz/XR

iv. Approved dosing is 160 mg SC once every 4 weeks

v. Initial approval will be for 1 year. Recertification will require documentation confirming clinical improvement in signs and symptoms of Ankylosing Spondylitis and will be approved for 2 years.

d. The patient must have a diagnosis of **Non-Radiographic Axial Spondylitis (nr-axSpA)**

i. Must be prescribed by or in consultation with a Rheumatologist **AND**

ii. Must have refractory disease defined by failure of or intolerance to at least **TWO** different NSAIDS at maximum strength for at least 1 month each **AND**

iii. The patient must also have a documentation drug failure or serious side effects with **TWO** of the following: Rinvoq, Cimzia and Cosentyx

iv. Approved dosing is 160 mg SC once every 4 weeks

v. Initial approval will be for 1 year. Recertification will require documentation confirming clinical improvement in signs and symptoms of nr-axSpA and will be approved for 2 years

e. The patient must have a diagnosis of **Hidradenitis Suppurativa**
   i. Must be prescribed by or in consultation with a Dermatologist
   ii. Must be at least 18 years old
   iii. Must have a diagnosis of stage II, stage III, or severe refractory hidradenitis suppurativa with recurrent abscesses
   iv. 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
      b) Must have had serious side effects or drug failure of **TWO** of the following: Humira/Simlandi/Hadlima, Cosentyx

f. Coverage for Bimzelx will only be authorized under the pharmacy benefit

g. Quantity Limit: 1 mL (160 mg/mL injectors/syringes)/28 days

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, 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 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. Must be prescribed by or in consultation with a Dermatologist or Rheumatologist **AND**
ii. The patient must be a candidate for systemic therapy or phototherapy and meet for **ONE** of the following (**A or B**)
A. The patient must have had a 3-month trial of systemic therapy (i.e., acitretin, methotrexate, or cyclosporine) 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 aforementioned agents **OR**
B. The patient must have had a 3-month trial of Ultraviolet B (UVB) Phototherapy or Psoralen Ultraviolet A (PUVA) Phototherapy that resulted in an inadequate response (failure)

b. The patient must be at least 2 years of age and have a diagnosis of active **Psoriatic Arthritis AND**
i. Must be prescribed by or in consultation with a Rheumatologist or Dermatologist
ii. The patient must be at least 2 years of age for coverage of Cosentyx SC under the pharmacy benefit
iii. 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. Must be prescribed by or in consultation with a Rheumatologist **AND**
ii. Must have refractory disease defined by failure of or intolerance to at least **TWO** different 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. Must be prescribed by or in consultation with a Rheumatologist **AND**
ii. Must have refractory disease defined by failure of or intolerance to at least **TWO** different NSAIDS at maximum strength 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 prescribed by or in consultation with a Rheumatologist **AND**
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. Must be prescribed by or in consultation with a Dermatologist **AND**
ii. Must have a diagnosis of stage II, stage III, or severe refractory hidradenitis suppurativa with recurrent abscesses **AND**
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. Adult patients 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

HCPCS: J3247

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

1. Must be prescribed by or in consultation with a Gastroenterologist **AND**
2. The patient must be at least 18 years of age **AND**
3. The patient must have one of the following diagnoses **(I or II):**
   I. The patient must have a diagnosis of moderately to severely active **Crohn's Disease AND**
      i. There must be documentation that azathioprine, 6-mercaptopurine, or methotrexate is not effective, contraindicated, or not tolerated
         a) 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 (such as but not limited to enterocutaneous [perianal or abdominal] fistulas, rectovaginal fistulas, ileocolonic resection) **OR**
   II. The patient must have a diagnosis of moderately to severely active **Ulcerative Colitis**
      i. Must meet for **ONE** of the following **(A or B):**
         A. Must have tried and failed or has documented 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. IV or oral steroids - note, a 3-month trial of systemic steroid therapy will not be required
         B. The patient has been diagnosed with pouchitis and has tried an antibiotic, corticosteroid enema, or mesalamine enema **AND**
4. 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.), there must be serious side effects or drug failure with **TWO** of the following: Humira/Simlandi/Hadlima, Selarsdi/Yesintek, Skyrizi, Tremfya
   B. For patients <u>currently</u> treated with IV Entyvio, provider must attest that patient is a clinical responder to the IV Entyvio induction therapy
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 starting at week 6 with 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)

1. Must be prescribed by or in consultation with 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 be a candidate for systemic therapy or phototherapy and meet for **ONE** of the following (**A or B**)
    - **A.** The patient must have had a 3-month trial of systemic therapy (i.e., acitretin, methotrexate, or cyclosporine) 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 aforementioned agents **OR**
    - **B.** The patient must have had a 3-month trial of Ultraviolet B (UVB) Phototherapy or Psoralen Ultraviolet A (PUVA) Phototherapy that resulted in an inadequate response (failure)
5. Coverage for Ilumya will only be authorized under the medical benefit

HCPCS: J3245

Kevzara – sarilumab (Rx)

1. The patient must have a diagnosis of moderately to severely active **Rheumatoid Arthritis**
    a. Must be prescribed by or in consultation with a Rheumatologist **AND**
    b. The patient must be at least 18 years of age **AND**
    c. Must have failed to respond to and/or is intolerant to approved disease-modifying antirheumatic drug (DMARD) agents, such as methotrexate, azathioprine, sulfasalazine, or hydroxychloroquine, either alone or in combination for a 3-month period **AND**
    d. The patient must also have a drug failure or serious side effects to **TWO** of the following agents: Actemra SC/Tyenne SC, Enbrel, Humira/Simlandi/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. Must be prescribed by or in consultation with 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. The patient must have a diagnosis of moderately to severely active **Polyarticular Juvenile Idiopathic Arthritis (pJIA)**
   a. Must be prescribed by or in consultation with a Rheumatologist **AND**
   b. The patient must be at least 2 years of age **AND**
   c. The patient must weigh at least 63kg **AND**
   d. Must have a contraindication to, have failed to respond to, or must be intolerant to treatment with a disease-modifying antirheumatic drug (DMARD) (such as methotrexate, leflunomide, sulfasalazine), NSAID, analgesic, or corticosteroid
      i. Patients starting on Kevzara concurrently with methotrexate, sulfasalazine, or leflunomide will not be subject to the above requirement
   e. The patient must also have a documented drug failure or serious side effects to TWO of the following agents: Actemra SC/Tyenne SC, Enbrel, Humira/Simlandi/Hadlima, Xeljanz, Rinvoq
   f. Kevzara can be used as monotherapy or in combination with conventional DMARDs.
   g. Approved dosing is 200 mg SC once every two weeks.
4. 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 moderately to severely active **Rheumatoid Arthritis**
   a. The patient must be at least 18 years of age **AND**
   b. Must be prescribed by or in consultation with a Rheumatologist **AND**
   c. Must have failed to respond to and/or is intolerant to approved disease-modifying antirheumatic drug (DMARD) agents, such as methotrexate, azathioprine, sulfasalazine, or hydroxychloroquine, either alone or in combination for a 3-month period **AND**
   d. The patient must have had drug failure or serious side effects with **TWO** of the following: Actemra SC/Tyenne SC, Enbrel, Humira/Simlandi/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. Must be prescribed by or in consultation with 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 or in consultation with 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. Must be prescribed by or in consultation with a Rheumatologist **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 **Rheumatoid Arthritis AND**
    a. Must have failed to respond to and/or is intolerant to approved disease-modifying antirheumatic drug (DMARD) agents, such as methotrexate, azathioprine, sulfasalazine, or hydroxychloroquine, either alone or in combination for a 3-month period **AND**
    b. The patient must have had failure or had serious side effects to **TWO** of the following: Actemra SC//Tyenne SC, Enbrel, Humira/Simlandi/Hadlima, Xeljanz/XR, Rinvoq
    c. Approved dosage is 2 mg once daily

4. The use of Olumiant for the treatment of **alopecia** (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/Essential Plan/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. 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. Must be prescribed by or in consultation with a Gastroenterologist **AND**
2. The patient must be at least 18 years of age **AND**
   a. The patient must have a diagnosis of moderately to severely active **Ulcerative Colitis AND**
      i. Must meet for **ONE** of the following **(A or B):**
         A. Must have tried and failed or has documented 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. IV or oral steroids - note, a 3-month trial of systemic steroid therapy will not be required
         B. The patient has been diagnosed with pouchitis and has tried an antibiotic, corticosteroid enema, or mesalamine enema **AND**
      ii. The patient must have had serious side effects or drug failure of **TWO** of the following: Humira/Simlandi/Hadlima, Selarsdi/Yesintek, Skyrizi, Tremfya
      iii. 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
   b. The patient must have a diagnosis of moderately to severely active **Crohn's Disease AND**
      i. There must be documentation that azathioprine, 6-mercaptopurine, or methotrexate is not effective, contraindicated, or not tolerated
      ii. 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 (such as but not limited to enterocutaneous [perianal or abdominal] fistulas, rectovaginal fistulas, ileocolonic resection)
      iii. The patient must have had serious side effects or drug failure of **TWO** of the following: Humira/Simlandi/Hadlima, Selarsdi/Yesintek, Skyrizi, Tremfya
      iv. Approved Dosing:
         a) Induction: Week 0, Week 4, and Week 8: Infuse 900 mg intravenously over at least 90 minutes.
            I. Prior Authorization of the IV induction dose is required for all lines of business under the medical benefit except Managed Medicaid

b) Maintenance: Week 12 and every 4 weeks thereafter: 300 mg subcutaneous (SC) injection (given as two consecutive injections of 100 mg and 200 mg in any order).
I. The 200 mg/2 mL prefilled pen and prefilled syringe are only for maintenance treatment of Crohn's disease.

3. Quantity Limit (Pharmacy Benefit): 2 mL (2-100 mg/mL pens or 1- 200mg/2mL pen/syringe)/28 days

HCPCS: J2267

Orencia - abatacept (Medical or Rx)

1. The patient must have a diagnosis of moderately to severely active **Rheumatoid Arthritis**
   a. The patient must be at least 18 years of age **AND**
   b. Must be prescribed by or in consultation with a Rheumatologist **AND**
   c. Must have failed to respond to and/or is intolerant to approved disease-modifying antirheumatic drug (DMARD) agents, such as methotrexate, azathioprine, sulfasalazine, or hydroxychloroquine, either alone or in combination for a 3-month period **AND**
   d. The patient must meet **ONE** of the following:
      i. **If healthcare provider administered**, treatment with IV Orencia will require failure or serious side effects with of Inflectra/Avsola or Simponi Aria
         a) Applies to all lines of business
      ii. **If self-administered**
         a) Treatment with SC Orencia will require documentation of drug failure or serious side effects of **TWO** of the following agents: Actemra SC/Tyenne SC, Enbrel, Humira/Simlandi/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 moderately to severely active **polyarticular Juvenile Idiopathic Arthritis (pJIA)**
   a. Must be prescribed by or in consultation with a Rheumatologist **AND**
   b. Must be at least 2 years old
   c. Must have a contraindication to, have failed to respond to, or must be intolerant to treatment with a disease-modifying antirheumatic drug (DMARD) (such as methotrexate, leflunomide, sulfasalazine), NSAID, analgesic, or corticosteroid
      i. Patients starting on Orencia concurrently with methotrexate, sulfasalazine, or leflunomide will not be subject to the above requirement
   d. The patient must meet one of the following:
      i. **If self-administered**
         a) Treatment with SC Orencia will require drug failure or serious side effects with **TWO** of the following: Enbrel, Humira/Simlandi/Hadlima, Actemra SC/Tyenne SC, Xeljanz, Rinvoq/LQ
      ii. **If healthcare provider administered**, treatment with IV Orencia will require drug failure or serious side effects with Simponi Aria

a) Applies to all lines of business

e. 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

f. 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 active **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. Must be prescribed by or in consultation with a Rheumatologist or Dermatologist **AND**
   c. The patient must meet one of the following:
      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, Selarsdi/Yesintek, 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/Simlandi/Hadlima, Selarsdi/Yesintek SC, Xeljanz/XR, Cosentyx, Otezla/XR, Tremfya, Rinvoq/LQ, Skyrizi
         b) Approved dosing for psoriatic arthritis
            I. For adult patients - 125 mg once weekly with or without an IV loading dose
            II. 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 and Otezla XR- apremilast and apremilast ER (Rx)

1. For the treatment of **Plaque Psoriasis**, the patient must meet **(A + B)**
   - **A.** The patient must meet for **ONE** of the following diagnoses (**a or b**)
     - **a.** Must have a diagnosis of ***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**
       - i. The patient must be at least 6 years of age **AND**
       - ii. Must be prescribed by or in consultation with a Dermatologist or Rheumatologist **OR**
     - **b.** 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. The patient must be at least 18 years of age **AND**
   - **B.** The patient must be a candidate for systemic therapy or phototherapy and meet for **ONE** of the following (**a or b**)
     - **a.** The patient must have had a 3-month trial of systemic therapy (i.e., acitretin, methotrexate, or cyclosporine) 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 aforementioned agents **OR**
     - **b.** The patient must have had a 3-month trial of Ultraviolet B (UVB) Phototherapy or Psoralen Ultraviolet A (PUVA) Phototherapy that resulted in an inadequate response (failure)
   - **C.** Approved dosing: Initial titration over 5 days followed by the maintenance dosing below:
     - i. Age ≥ 6 years of age with weight ≥ 20 to <50 kg: 20 mg orally twice daily.
     - ii. Age ≥ 6 years of age with weight ≥ 50 kg: 30 mg orally twice daily **OR** Otezla XR 75mg once daily.
     - iii. Adult ≥ 18 years of age: 30 mg orally twice daily **OR** Otezla XR 75mg once daily
2. For the treatment of **Psoriatic Arthritis**
   - a. Must be prescribed by or in consultation with a Dermatologist or Rheumatologist
   - b. The patient must be at least 6 years of age **AND**
   - c. Must have a diagnosis of definitive Psoriatic Arthritis **AND**
   - d. Approved dosing: Initial titration over 5 days followed by the maintenance dosing below:
     - i. Age ≥ 6 years of age with weight ≥ 20 to <50 kg: 20 mg orally twice daily.
     - ii. Age ≥ 6 years of age with weight ≥ 50 kg: 30 mg orally twice daily **OR** Otezla XR 75mg once daily
     - iii. Adult ≥ 18 years of age: 30 mg orally twice daily **OR** Otezla XR 75mg once daily
3. For the treatment of **Behcet's Disease**
   - a. The patient must have a diagnosis of **oral ulcers associated with Behcet's Disease**
   - b. Patient must be at least 18 years of age **AND**
   - c. Approved dosing: Initial titration over 5 days followed by the maintenance dosing below:
     - i. 30 mg orally twice daily **OR** Otezla XR 75mg once daily
4. Coverage or Otezla/Otezla XR will be limited to Otezla 60 tablets/30 days **OR** Otezla XR 75mg 30 tablets/ 30days
5. Otezla or Otezla XR in combination with biologic DMARD therapy (such as Humira/Simlandi/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.

Rhapsido (remibrutinib)-Rx

1. Must be requested by or in consultation with an allergist/immunologist or dermatologist **AND**
2. Patients must be at least 18 years old with the diagnosis of chronic spontaneous urticaria (CSU) defined as at least a 6-week history of urticaria characterized by the development of wheals (hives), angioedema, or both, despite adequate trials (minimum of four weeks each) of:
   a. A second generation H1-antihistamine at standard dosing **AND** a second-generation H1-antihistamine trialed at 2-4 times the standard dose
   b. These criteria may be satisfied by using either the same second generation H1-antihistamine at standard dosing and 2-4 times standard dosing OR using two different second generation H1-antihistamines with at least one agent being at 2-4 times standard dosing
3. Approved Dosing: Rhapsido 25 mg tablet twice daily
4. Initial approval is for 6 months
   a. All recertifications will be for 2 years and will require documentation that the patient has responded to or continues to benefit from therapy (i.e., decreased severity of itching, or size/number of hives).
5. Rhapsido will not be approved for use in combination with Dupixent, Xolair, Cinqair, Fasenra, Nucala, or Tezspire for Chronic Spontaneous Urticaria

Rinvoq/LQ – upadacitinib (Rx)

1. The patient must have a diagnosis of moderately to severely active **Rheumatoid Arthritis**
   a. Must be prescribed by or in consultation with a Rheumatologist **AND**
   b. The patient must be at least 18 years of age **AND**
   c. Must have failed to respond to and/or is intolerant to approved disease-modifying antirheumatic drug (DMARD) agents, such as methotrexate, azathioprine, sulfasalazine, or hydroxychloroquine, either alone or in combination for a 3-month period **AND**
   d. The patient must have had serious side effects or drug failure of Humira/Simlandi/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 active **Psoriatic Arthritis**
   a. Must be prescribed by or in consultation with a Rheumatologist or Dermatologist **AND**
   b. The patient must be at least 2 years of age **AND**
   c. The patient must have had serious side effects or drug failure of Humira/Simlandi/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
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
I. 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 moderately to severely active **Crohn's Disease**
a. Must be prescribed by or in consultation with a Gastroenterologist **AND**
b. The patient must be at least 18 years of age **AND**
c. There must be documentation that azathioprine, 6-mercaptopurine, or methotrexate is not effective, contraindicated, or not tolerated **AND**
d. Must have tried and failed or has documented intolerance to at least ONE of the FDA approved systemic therapies for CD
e. 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

5. The patient must have a diagnosis of moderately to severely active **Ulcerative Colitis**
a. Must be prescribed by or in consultation with a Gastroenterologist **AND**
b. The patient must be at least 18 years of age **AND**
c. Must meet for ONE of the following **(A or B):**
A. Must have tried and failed or has documented intolerance to at least ONE of the FDA approved systemic therapies for UC
B. The patient has been diagnosed with pouchitis and has tried an antibiotic, corticosteroid enema, or mesalamine enema **AND**
d. 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

6. The patient must have a diagnosis of **Ankylosing Spondylitis**
a. The patient must be at least 18 years of age **AND**
b. Must be prescribed by or in consultation with a Rheumatologist **AND**
c. Must have refractory disease defined by failure of or intolerance to at least TWO different NSAIDS at maximum strength for at least 1 month each **AND**
d. The patient must have had serious side effects or drug failure of Humira/Simlandi/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

7. 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. Must be prescribed by or in consultation with a Rheumatologist **AND**
   c. Must have refractory disease defined by failure of or intolerance to at least **TWO** different NSAIDS at maximum strength for at least 1 month each **AND**
   d. The patient must have documentation of serious side effects or drug failure of Cimzia
   e. Approved dosing is 15 mg once daily
8. The patient must have a diagnosis of moderately to severely active **polyarticular Juvenile Idiopathic Arthritis (pJIA)**
   a. Must be prescribed by or in consultation with a Rheumatologist **AND**
   b. The patient must be at least 2 years old **AND**
   c. Must have a contraindication to have failed to respond to, or must be intolerant to treatment with a disease-modifying antirheumatic drug (DMARD) (such as methotrexate, leflunomide, sulfasalazine), NSAID, analgesic, or corticosteroid
      a) Patients starting on Rinvoq/LQ concurrently with methotrexate, sulfasalazine, or leflunomide will not be subject to the above requirement
   d. The patient must have had serious side effects or drug failure of Humira/Simlandi/Hadlima or Enbrel for anti-tumor necrosis factor (TNF) naïve patients or with any anti-TNF for anti-TNF experienced patients
9. The patient must have a diagnosis of Giant Cell Arteritis
   a. Must be at least 18 years of age
   b. Must be prescribed by or in consultation with an Ophthalmologist, Neurologist, or Rheumatologist
   c. Approved dosing: Rinvoq 15mg once daily in combination with a tapering course of corticosteroid, or as a monotherapy following discontinuation of corticosteroids
10. 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)
11. Rinvoq LQ is a new formulation of Rinvoq and is only approved for PsA and pJIA

Siliq – brodalumab (Rx)

1. Must be prescribed by or in consultation with 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 or phototherapy and meet for **ONE** of the following (**A or B**)
   A. The patient must have had a 3-month trial of systemic therapy (i.e., acitretin, methotrexate, or cyclosporine) 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 aforementioned agents **OR**
   B. The patient must have had a 3-month trial of Ultraviolet B (UVB) Phototherapy or Psoralen Ultraviolet A (PUVA) Phototherapy that resulted in an inadequate response (failure)

5. The patient must also have a documented drug failure or serious side effects to **ALL** the following: Humira/Simlandi/Hadlima, Otezla/XR, Selarsdi/Yesintek, Skyrizi, Tremfya, Enbrel, Cosentyx, Cimzia, Taltz, Sotyktu, and Bimzelx
6. Siliq is contraindicated in patients with Crohn's Disease
7. 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 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. Must be prescribed by or in consultation with a Dermatologist or Rheumatologist **AND**
    b. The patient must be at least 18 years of age **AND**
    c. The patient must be a candidate for systemic therapy or phototherapy and meet for **ONE** of the following (**A or B**)
        A. The patient must have had a 3-month trial of systemic therapy (i.e., acitretin, methotrexate, or cyclosporine) 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 aforementioned agents **OR**
        B. The patient must have had a 3-month trial of Ultraviolet B (UVB) Phototherapy or Psoralen Ultraviolet A (PUVA) Phototherapy that resulted in an inadequate response (failure)
2. The patient must have a diagnosis of active **Psoriatic Arthritis AND**
    a. The patient must be at least 18 years of age **AND**
    b. Must be prescribed by or in consultation with a Dermatologist or Rheumatologist **OR**
3. The patient must have a diagnosis of moderately to severely active **Crohn's Disease**
    a. The patient must be at least 18 years of age **AND**
    b. Must be prescribed by or in consultation with a Gastroenterologist **AND**
    c. There must be documentation that azathioprine, 6-mercaptopurine, or methotrexate is not effective, contraindicated, or not tolerated
    d. 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 (such as but not limited to enterocutaneous [perianal or abdominal] fistulas, rectovaginal fistulas, ileocolonic resection)
4. The patient must have a diagnosis of moderately to severely active **Ulcerative Colitis**
    a. Must be prescribed by or in consultation with a Gastroenterologist
    b. Must be at least 18 years old
    c. Must meet for ONE of the following **(A or B):**
        A. Must have tried and failed or has documented 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. IV or oral steroids - note, a 3-month trial of systemic steroid therapy will not be required
        B. The patient has been diagnosed with pouchitis and has tried an antibiotic, corticosteroid enema, or mesalamine enema
5. 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
c. For **Ulcerative Colitis**: induction therapy of 1200 mg given by intravenous (IV) infusion at weeks 0, 4 and 8, followed by maintenance therapy of 180 mg or 360 mg administered subcutaneously every 8 weeks thereafter

6. Skyrizi is available as a:
   a. 150 mg single-dose prefilled pen
   b. 150 mg single-dose prefilled syringe
   c. 180 mg/1.2 mL single-dose prefilled cartridge with on-body injector
   d. 360 mg/2.4 mL single-dose prefilled cartridge with on-body injector
   e. 600 mg/10 mL single-dose vial for intravenous infusion
7. 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 and Ulcerative Colitis:
      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 moderately to severely active **Rheumatoid Arthritis**
   a. The patient must be at least 18 years of age **AND**
   b. Must be prescribed by or in consultation with a Rheumatologist **AND**
   c. Must have failed to respond to and/or is intolerant to approved disease-modifying antirheumatic drug (DMARD) agents, such as methotrexate, azathioprine, sulfasalazine, or hydroxychloroquine, either alone or in combination for a 3-month period **AND**
   d. Simponi/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 **AND**
   e. Treatment with SC Simponi (self-administered) will require documentation of drug failure or serious side effects of **TWO** of the following: Actemra SC/Tyenne SC, Enbrel, Humira/Simlandi/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 active **Psoriatic Arthritis**
   a. Must be prescribed by or in consultation with a Dermatologist or Rheumatologist **AND**
   b. The patient must be 2 years of age or older
   c. Treatment with SC Simponi (self-administered) will require documentation of drug failure or serious side effects of **TWO** of the following: Enbrel, Humira/Simlandi/Hadlima, Selarsdi/Yesintek SC, Xeljanz/XR, Cosentyx, Otezla/XR, Tremfya, Rinvoq, Skyrizi
   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. SC Simponi dosing for adult patients with PsA is as follows:
      i. 50mg once monthly

f. 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. Must be prescribed by or in consultation with a Rheumatologist **AND**
   c. Must have refractory disease defined by failure of or intolerance to at least **TWO** different NSAIDS at maximum strength for at least 1 month each
   d. Treatment with SC Simponi (self-administered) will require documentation of drug failure or serious side effects of **TWO** of the following: Enbrel, Humira/Simlandi/Hadlima, Cosentyx, Xeljanz/XR, Rinvoq
   e. 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
   f. SC Simponi dosing for adults with AS is as follows:
      i. 50mg once monthly
4. The patient must have a diagnosis of moderately to severely active **Ulcerative Colitis**
   a. Must be adult or pediatric patient weighing at least 15kg **AND**
   b. Must be prescribed by or in consultation with a Gastroenterologist **AND**
   c. Must meet for ONE of the following **(A or B):**
      A. Must have tried and failed or has documented 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. IV or oral steroids - note, a 3-month trial of systemic steroid therapy will not be required
      B. The patient has been diagnosed with pouchitis and has tried an antibiotic, corticosteroid enema, or mesalamine enema
   d. Treatment with SC Simponi (self-administered) will require drug failure or serious side effects with Humira/Simlandi/Hadlima
   e. SC Simponi dosing for adults and pediatric patients with UC is as follows:

Weight for Patients with UC	Week 0	Week 2	Week 6 and every 4 weeks thereafter
Adults and pediatric patients 40kg and greater	200mg	100mg	100mg
Pediatric patients at least 15 kg to less than 40kg	100mg	50mg	50mg

   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 moderately to severely active **polyarticular Juvenile Idiopathic Arthritis (pJIA)**
   a. Must be prescribed by or in consultation with a Rheumatologist **AND**
   b. The patient must be at least 2 years old **AND**
   c. Must have a contraindication to, have failed to respond to, or must be intolerant to treatment with a disease-modifying antirheumatic drug (DMARD) (such as methotrexate, leflunomide, sulfasalazine), NSAID, analgesic, or corticosteroid
      i. Patients starting on Simponi/Simponi Aria concurrently with methotrexate, sulfasalazine, or leflunomide will not be subject to the above requirement
   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

Sotyktu – deucravacitinib (Rx)

1. The patient must be at least 18 years of age **AND**
2. Must be prescribed by or in consultation with a Dermatologist or Rheumatologist **AND (I OR II)**
    I. 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 or phototherapy and meet for **ONE** of the following (**A or B**)
            A. The patient must have had a 3-month trial of systemic therapy (i.e., acitretin, methotrexate, or cyclosporine) 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 aforementioned agents **OR**
            B. The patient must have had a 3-month trial of Ultraviolet B (UVB) Phototherapy or Psoralen Ultraviolet A (PUVA) Phototherapy that resulted in an inadequate response (failure)
    II. The patient must have a diagnosis of **active Psoriatic Arthritis AND**
3. There must be documentation of drug failure or serious side effects to **ONE** of the following: Humira/Simlandi/Hadlima, Otezla/XR, Selarsdi/Yesintek, Skyrizi, Tremfya, Cosentyx, Enbrel
4. Approved Dosing: 6 mg by mouth once daily

Quantity Limit: 30 tablets/30 days

Spevigo – spesolimab-sbzo (Medical or Rx)

1. The patient must be at least 12 years of age **AND**
2. The patient must weigh at least 40 kilograms (kg) **AND**
3. Must be prescribed by a dermatologist or a physician specializing in the treatment of autoinflammatory conditions **AND**
4. 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**
5. Must meet ONE of the following **(A or B):**
    A. Must be used for the treatment of a generalized pustular psoriasis (GPP) moderate to severe flare in patients with a history of at least 2 moderate to severe GPP flares 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 **OR**
    B. Must be used for the treatment of generalized pustular psoriasis (GPP) as ongoing therapy **AND**
        a. The patient must have a history of at least 1 moderate to severe GPP flares (as defined above)
6. 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 sub score of 2 or higher at the end of week 1 (range, 0 [no visible pustules] to 4 [severe pustulation])

7. Requests for **Recertification**
   a. Individuals that have previously received at least 1 dose of Spevigo for the treatment of a prior GPP flare will be covered for a **recurrent flare** if the patient achieved a Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) score of 0 or 1 after previous treatment **AND** had an increase of at least 2 points in both GPPGA total score and pustulation subscore after previous treatment
   b. Ongoing maintenance treatment recertification will require attestation of disease improvement such as a decrease in the number of flares per year or a decrease in the severity of symptoms experiences during flares.
8. Medical and Pharmacy Benefit Coverage
   a. Spevigo IV
      i. Covered under the Medical Benefit for the treatment of GPP flares
      ii. Spevigo IV will not be covered for the ongoing treatment of GPP (as a one-time loading dose or as maintenance treatment)
   b. Spevigo SC
      i. For Commercial/Exchange/Essential Plan/Child Health Plus, Spevigo SC will be covered under the Pharmacy Benefit for the treatment of GPP when not experiencing a flare as the loading dose and ongoing treatment of GPP as maintenance therapy
      ii. For all lines of business except Medicare Advantage, Spevigo SC will **not** be covered under the Medical Benefit for the loading dose and the ongoing treatment of GPP as maintenance therapy unless the patient has an inability to self-inject. For pediatric patients less than 18 years of age, documentation must also include the inability of a caregiver to administer the medication.
      iii. Spevigo SC will not be covered for the treatment of GPP flares
9. Approval Timeframe:
   a. Treatment of a flare with intravenous (IV) Spevigo: 1 week per request (new, additional, and recertification)
   b. One-time Loading Dose: 1 month
   c. Ongoing subcutaneous (SC) Treatment
      i. New Starts: 6 months
      ii. Recertification: 1 year
10. Approved Dosing:
   a. Experiencing a flare: 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 6 must be met for coverage for an additional dose)
   b. Initiating ongoing treatment
      i. After experiencing a flare treated with Spevigo: 300 mg administered subcutaneously (SC) 4 weeks after treatment of the flare and every 4 weeks thereafter
      ii. Without experiencing a flare: a one-time 600 mg loading dose administered subcutaneously (SC) followed by 300 mg maintenance dose 4 weeks later and every 4 weeks thereafter
      iii. The one-time 600 mg SC loading dose will **NOT** be covered for patients initiating ongoing treatment within 4 weeks of receiving Spevigo 900 mg for treatment of a GPP flare
   c. Reinitiating ongoing treatment after experiencing a flare treated with Spevigo: 300 mg administered subcutaneously (SC) 4 weeks after treatment of the flare and every 4 weeks thereafter
11. 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)
12. Spevigo will not be covered for patients currently on biologic therapy
13. Patients currently treated with Spevigo as ongoing SC maintenance treatment will require prior authorization of Spevigo IV for the treatment of NEW flares and must satisfy the criteria above
14. Quantity Limit
    a. Pharmacy Benefit: 2 mL/28 days
15. Coverage of an additional quantity will not be granted; the 600 mg one-time loading dose is covered under the Medical Benefit

HCPCS: J1747

Taltz – ixekizumab (Rx)

1. The patient must have a diagnosis of **Ankylosing Spondylitis**
   a. Must be prescribed by or in consultation with a Rheumatologist
   b. The patient must be at least 18 years of age
   c. Must have refractory disease defined by failure of or intolerance to at least **TWO** different NSAIDS at maximum strength for at least 1 month each **AND**
   d. There must be documentation of drug failure or serious side effects to **TWO** of the following: Enbrel, Humira/Simlandi/Hadlima, Cosentyx, Xeljanz/XR, Rinvoq
2. 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. Must be prescribed by or in consultation with a Dermatologist or Rheumatologist
   b. The patient must be at least 6 years of age
      I. The patient must be a candidate for systemic therapy or phototherapy and meet for **ONE** of the following (**A or B**)
         A. The patient must have had a 3-month trial of systemic therapy (i.e., acitretin, methotrexate, or cyclosporine) 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 aforementioned agents **OR**
         B. The patient must have had a 3-month trial of Ultraviolet B (UVB) Phototherapy or Psoralen Ultraviolet A (PUVA) Phototherapy that resulted in an inadequate response (failure)
   c. The patient must also have a documented drug failure or serious side effects to **TWO** of the following: Humira/Simlandi/Hadlima, Otezla/XR, Sotyktu, Selarsdi/Yesintek SC, Skyrizi, Tremfya, Cosentyx, Enbrel
3. Must have a diagnosis of active **Psoriatic Arthritis**
   a. The patient must be at least 18 years old **AND**
   b. Must be prescribed by or in consultation with a Rheumatologist or Dermatologist **AND**
   c. The patient must also have a documentation drug failure or serious side effects with **TWO** of the following: Enbrel, Humira/Simlandi/Hadlima, Selarsdi/Yesintek SC, Xeljanz/XR, Cosentyx, Otezla/XR, Tremfya, Skyrizi, Rinvoq
4. Must have a diagnosis of **Non-Radiographic Axial Spondylitis (nr-axSpA)**
   a. The patient must be at least 18 years of age **AND**
   b. Must be prescribed by or in consultation with a Rheumatologist **AND**
   c. Must have refractory disease defined by failure of or intolerance to at least **TWO** different NSAIDS at maximum strength for at least 1 month each **AND**
   d. The patient must also have a documentation drug failure or serious side effects with **TWO** of the following: Rinvoq, Cimzia, Cosentyx

5. Individuals are excluded from coverage if they have an active TB infection
6. 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 adults with **Plaque Psoriasis** and **Psoriatic arthritis with comorbid Plaque Psoriasis**
      i. For pediatric patients 6 years or older with **Plaque Psoriasis**:
         a) Body weight less than 25kg: 40 mg SC at week 0, followed by 20 mg every 4 weeks thereafter
         b) Body weight 25 kg to 50 kg: 80 mg SC at week 0, followed by 40 mg every 4 weeks thereafter
         c) Body weight greater than 50 kg: 160 mg SC at week 0, followed by 80 mg every 4 weeks thereafter
   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 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. Must be prescribed by or in consultation with a Dermatologist or Rheumatologist **AND**
   b. The patient must be at least 6 years of age who also weighs at least 40kg **AND**
   c. The patient must be a candidate for systemic therapy or phototherapy and meet for **ONE** of the following (**A or B**)
      A. The patient must have had a 3-month trial of systemic therapy (i.e., acitretin, methotrexate, or cyclosporine) 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 aforementioned agents **OR**
      B. The patient must have had a 3-month trial of Ultraviolet B (UVB) Phototherapy or Psoralen Ultraviolet A (PUVA) Phototherapy that resulted in an inadequate response (failure)
2. The patient must have a diagnosis of active **Psoriatic Arthritis AND**
   a. The patient must be at least 6 years of age who also weighs at least 40kg **AND**
   b. Must be prescribed by or in consultation with a Rheumatologist or Dermatologist
3. Coverage of Tremfya for **Plaque Psoriasis** and **Psoriatic Arthritis** 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
4. The patient must have a diagnosis of moderately to severely active **Ulcerative Colitis**
   a. Must be prescribed by or in consultation with a Gastroenterologist
   b. Must be at least 18 years old
   c. Must meet for ONE of the following **(A or B):**
      A. Must have tried and failed or has documented 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. IV or oral steroids - note, a 3-month trial of systemic steroid therapy will not be required
      B. The patient has been diagnosed with pouchitis and has tried an antibiotic, corticosteroid enema, or mesalamine enema
   d. Coverage of Tremfya for **Ulcerative Colitis** will be limited to the following:
      i. **Induction**: **(A or B)**

A. 200 mg administered by intravenous infusion at Week 0, 4 and 8.
I. Approval is for 3 induction doses in 12 weeks as medical benefit. **OR**
B. 400 mg (Induction Pack for UC or CD: 2 x 200mg/2mL single-dose prefilled pens) administered by subcutaneous injection at Week 0, 4, and 8.
I. Approval is for 3 induction doses in 12 weeks

ii. **Maintenance: (A or B)**
A. 100 mg administered by subcutaneous injection at Week 16, and every 8 weeks thereafter **OR**
B. 200 mg administered by subcutaneous injection at Week 12, and every 4 weeks thereafter.

*Use the lowest effective recommended dosage to maintain therapeutic response

5. The patient must have a diagnosis of moderately to severely active **Crohn's Disease**
   a. Must be prescribed by or in consultation with a Gastroenterologist
   b. Must be at least 18 years of age
   c. 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 (such as but not limited to enterocutaneous [perianal or abdominal] fistulas, rectovaginal fistulas, ileocolonic resection)
   d. Coverage of Tremfya for Crohn's Disease will be limited to the following:
      i. **Induction**: **(A or B)**
A. 200 mg administered by intravenous infusion at Week 0, 4 and 8.
I. Approval is for 3 induction doses in 12 weeks as medical benefit. **OR**
B. 400 mg (Induction Pack for UC or CD: 2 x 200mg/2mL single-dose prefilled pens) administered by subcutaneous injection at Week 0, 4, and 8.
I. Approval is for 3 induction doses in 12 weeks

      ii. **Maintenance**: **(A or B)**
A. 100 mg administered by subcutaneous injection at Week 16, and every 8 weeks thereafter **OR**
B. 200 mg administered by subcutaneous injection at Week 12, and every 4 weeks thereafter.

*Use the lowest effective recommended dosage to maintain therapeutic response

6. **Quantity limit**:
   a. 100mg/mL (autoinjector, prefilled syringe) 1mL per 56 days
   b. 200mg/2mL (autoinjector, prefilled syringe) 2mL per 28 days
   c. Induction Pack for UC or CD (2 x 200 mg/2 mL single-dose prefilled pens): 4 mL/365 days
      i. A maximum of 12 mL/56 days will be granted to allow for completion of induction dosing during the first 8 weeks of treatment

HCPCS: J1628

Velsipity – etrasimod (Rx)

1. Must be prescribed by or in consultation with 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 **Ulcerative Colitis AND**
4. Must meet for **ONE** of the following **(A or B):**
   A. Must have tried and failed or has documented 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. IV or oral steroids - note, a 3-month trial of systemic steroid therapy will not be required

B. The patient has been diagnosed with pouchitis and has tried an antibiotic, corticosteroid enema, or mesalamine enema **AND**

5. The patient must have had serious side effects or drug failure of **TWO** of the following: Humira/Simlandi/Hadlima, Selarsdi/Yesintek, Skyrizi, Tremfya
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 moderately to severely active **Rheumatoid Arthritis**
   a. The patient must be at least 18 years of age **AND**
   b. Must be prescribed by or in consultation with a Rheumatologist **AND**
   c. Must have failed to respond to and/or is intolerant to approved disease-modifying antirheumatic drug (DMARD) agents, such as methotrexate, azathioprine, sulfasalazine, or hydroxychloroquine, either alone or in combination for a 3-month period **AND**
   d. The patient must have had serious side effects or drug failure of Humira/Simlandi/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 active **Psoriatic Arthritis**
   a. The patient must be at least 18 years of age **AND**
   b. Must be prescribed by or in consultation with a Rheumatologist or Dermatologist **AND**
   c. The patient must have had serious side effects or drug failure of Humira/Simlandi/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 moderately to severely active **Ulcerative Colitis**
   a. The patient must be at least 18 years of age **AND**
   b. Must be prescribed by or in consultation with a Gastroenterologist **AND**
   c. Must meet for **ONE** of the following **(A or B):**
      A. Must have tried and failed or has documented 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. IV or oral steroids - note, a 3-month trial of systemic steroid therapy will not be required
      B. The patient has been diagnosed with pouchitis and has tried an antibiotic, corticosteroid enema, or mesalamine enema **AND**
   d. The patient must have had serious side effects or drug failure of Humira/Simlandi/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 moderately to severely active **polyarticular Juvenile Idiopathic Arthritis (pJIA)**
   a. Must be prescribed by or in consultation with a Rheumatologist **AND**
   b. The patient must be at least 2 years old **AND**
   c. Must have a contraindication to, have failed to respond to, or must be intolerant to treatment with a disease-modifying antirheumatic drug (DMARD) (such as methotrexate, leflunomide, sulfasalazine), NSAID, analgesic, or corticosteroid
      i. Patients starting on Xeljanz concurrently with methotrexate, sulfasalazine, or leflunomide will not be subject to the above requirement

d. The patient must have had serious side effects or drug failure of Humira/Simlandi/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. Must be prescribed by or in consultation with a Rheumatologist **AND**
    c. Must have refractory disease defined by failure of or intolerance to at least **TWO** different NSAIDS at maximum strength for at least 1 month each **AND**
    d. The patient must have had serious side effects or drug failure of Humira/Simlandi/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 (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. 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
8. 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

Zymfentra - infliximab-dyyb (Rx)

1. Based on comparable indications, efficacy, safety profile, and affordability of Avsola and Inflectra, the member will be required to use Avsola and Inflectra and as such, the use of Zymfentra for FDA approved indications (Crohn's Disease and Ulcerative Colitis) is considered not medically necessary.
2. For all non-FDA approved indications, the use of Zymfentra is considered not medically necessary

HCPCS: J1748 (effective 7/1/24)

Zeposia- ozanimod (Rx)

1. The patient must have a diagnosis of **Multiple Sclerosis OR**
2. The patient must have a diagnosis of moderately to severely active **Ulcerative Colitis**
    a. The patient must be at least 18 years of age **AND**
    b. Must be prescribed by or in consultation with a Gastroenterologist **AND**
    c. Must meet for **ONE** of the following **(A or B):**
        A. Must have tried and failed or has documented 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. IV or oral steroids - note, a 3-month trial of systemic steroid therapy will not be required
        B. The patient has been diagnosed with pouchitis and has tried an antibiotic, corticosteroid enema, or mesalamine enema **AND**

d. The patient must have had drug failure or serious side effects with **TWO** of the following: Humira/Simlandi/Hadlima, Selarsdi/Yesintek, Skyrizi, Tremfya

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:
      i. NDC 59572-0890-91 = 37 capsules/30 days
      ii. 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/Tyenne/Avtozma (Rx/Medical), Tofidence (Medical ONLY), 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 *Does not apply to Medicaid and HARP)	1 year *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.
5. Clinical documentation must be submitted for each request (initial and recertification) unless otherwise specified (e.g., provider attestation required). Supporting documentation includes, but is not limited to, progress notes documenting previous treatments/treatment history, diagnostic testing, laboratory test results, genetic testing/biomarker results, imaging and other objective or subjective measures of benefit which support 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).

6. Utilization Management is 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.
7. Not all contracts cover all Medical Infusible drugs. Refer to specific contract/benefit plan language for exclusions of Injectable Medications.
8. This policy does not apply to Medicare Part D and D-SNP pharmacy benefits. The drugs in this policy may apply to all other lines of business including Medicare Advantage.
9. For members with Medicare Advantage, medications with a National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) will be covered pursuant to the criteria outlined by the NCD and/or LCD. NCDs/LCDs for applicable medications can be found on the CMS website at https://www.cms.gov/medicare-coverage-database/search.aspx. Indications that have not been addressed by the applicable medication's LCD/NCD will be covered in accordance with criteria determined by the Health Plan (which may include review per the Health Plan's Off-Label Use of FDA Approved Drugs policy). Step therapy requirements may be imposed in addition to LCD/NCD requirements.
10. 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.
11. 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).
12. All requests will be reviewed to ensure they are being used for an appropriate indication and may be subject to an off-label review in accordance with our Off-Label Use of FDA Approved Drugs Policy (Pharmacy-32).
13. **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, ustekinumab, 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/XR 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.

14. All utilization management requirements outlined in this policy are compliant with applicable New York State insurance laws and regulations. Policies will be reviewed and updated as necessary to ensure ongoing compliance with all state and federally mandated coverage requirements.
15. Manufacturers may either discontinue participation in, or may not participate in, the Medicaid Drug Rebate Program (MDRP). Under New York State Medicaid requirements, physician-administered drugs must be produced by manufacturers that participate in the MDRP. Products made by manufacturers that do not participate in the MDRP will not be covered under Medicaid Managed Care/HARP lines of business. Drug coverage will not be available for any product from a non-participating manufacturer. For a complete list of New/Reinstated & Terminated Labelers please visit: https://www.medicaid.gov/medicaid/prescriptiondrugs/medicaid-drug-rebate-program/newreinstated-terminated-labeler-information/index.html

UPDATES:

Date	Revision
03/26/2026	Revised
03/20/2026	Revised
02/12/2026	Reviewed & P&T Committee Approval
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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