Pharmacy Management Drug Policy

SUBJECT: Inflammatory Conditions Clinical Review Prior Authorization (CRPA) Rx and Medical Drugs
POLICY NUMBER: PHARMACY-73
EFFECTIVE DATE: 01/01/2018
LAST REVIEW DATE: 1/20/2020

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. Medical or drug policies apply to commercial and Health Care Reform products only when a contract benefit for the specific service exists.

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 FLRx 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, Humira, infliximab products, Stelara.

POLICY GUIDELINES:

1. 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 Coverage Exception Evaluation Policy for All Lines of Business Formularies policy for review guidelines.
2. 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.
3. 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.
4. 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.

CURRENT INFLAMMATORY CONDITIONS CRPA RX AND MEDICAL DRUGS:

DRUG NAME – generic name (Medical/Rx Benefit) **Authorization Criteria**
Actemra - tocilizumab (Medical or Rx)

1. Member must have a diagnosis of **rheumatoid arthritis**
   a. Member must be actively followed by and the drug prescribed by a rheumatologist **AND**
   b. There must be documentation of drug failure or serious side effects to a disease-modifying anti-rheumatic drug (DMARD) agent, such as methotrexate, azathioprine, sulfasalazine, or hydroxychloroquine, either alone or in combination for a 3-month period **AND**
   c. Treatment with **IV Actemra** will require failure or serious side effects with Inflectra or Simponi Aria
      i. IV Actemra dosing for adults with rheumatoid arthritis is:
         a. Initial dosing will be limited to 4mg/kg every 4 weeks
         b. After 12 weeks, based on clinical response, dose can be increased to 8mg/kg but the total dose cannot exceed 800mg
      d. SC Actemra dosing for adults with rheumatoid arthritis is:
         i. Patients less than 100kg should receive 162 mg every other week. Dosing can be increased to weekly based on clinical response.
         ii. Patients at or above 100kg should receive 162mg every week
         iii. Quantity limit of 4 syringes per 28 days
2. Member must have a diagnosis of **systemic juvenile idiopathic arthritis (SJIA) or polyarticular juvenile idiopathic arthritis (PJIA)** in children 2 years of age or older
   a. There must be documentation of drug failure or serious side effects to an adequate trial (12 weeks) of glucocorticoids or methotrexate
   b. Treatment with **SC Actemra** will require failure or serious side effects with Humira
   c. IV Actemra dosing for children with PJIA is:
      i. Patients less than 30kg should receive 10mg/kg every 4 weeks
      ii. Patients at or above 30kg should receive 8mg/kg every 4 weeks
   c. SC Actemra dosing for children with PJIA is:
      i Patients less than 30kg should receive 162mg every 3 weeks
      ii Patients at or above 30kg should receive 162mg every 2 weeks
   d. IV Actemra dosing for children with SJIA is:
      i. Patients less than 30kg should receive 12mg/kg every 2 weeks
      ii. Patients at or above 30kg should receive 8mg/kg every 2 weeks
   e. SC Actemra dosing for children with SJIA is:
      i. Patients less than 30kg should receive 162mg every 2 weeks
      ii. Patients at or above 30kg should receive 162mg once every week
3. Member must have a diagnosis of **giant cell arteritis (GCA)**
   a. Member must have a confirmed diagnosis of giant cell arteritis and the drug prescribed by an ophthalmologist, neurologist, or rheumatologist
   b. SC Actemra dosing for adults with GCA is:
      i. 162mg given once every week as a subcutaneous injection, in combination with a tapering course of glucocorticoids
      ii. A dose of 162 mg given SC every other week, in combination with a tapering course of glucocorticoids, may be prescribed based on clinical considerations
      iii. IV Actemra is not approved for GCA
      iv. Quantity limit of 4 syringes per 28 days
4. IV Actemra will be covered for use with chimeric antigen receptor (CAR) T-Cell therapy for

potential severe or life-threatening cytokine-release syndrome (CRS)
HCPCS: J3262

Cosentyx - secukinumab (Rx)

1. Member must be followed by a dermatologist or rheumatologist **AND**
2. Member must be at least 18 years of age **AND**
3. Member must have ONE of the following disease states:
   a. Must 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 severe disease of the hands or feet or other areas causing disruption in normal activities, but have less than 10% body surface area involvement **AND**
      i. Member must be a candidate for systemic therapy (i.e., acitretin, methotrexate, or cyclosporine therapy) **AND** had a trial period of at least 3 months or had developed serious side effects or have a contraindication (medical reason to avoid the drug) to the above-mentioned agents
      ii. If systemic therapy is contraindicated, then one of the following must be attempted for a reasonable period of time (at least 3 months):
         a. UVB in combination with a topical therapy such as coal tar, steroids or tazarotene **OR**
         b. PUVA in combination with topical corticosteroids **OR**
         c. Medium/High potency topical steroids in combination with anthralin, calcipotriene, or tazarotene **AND**
      iii. Member must also have a documented failure or serious side effects to **ONE** of the following preferred agents: Humira, Otezla, Stelara, Skyrizi, Tremfya
   b. Must have a diagnosis of **psoriatic arthritis**
      i. Member must be actively followed by and drug prescribed by a rheumatologist or dermatologist **AND**
      ii. Member must have some clinical features of psoriatic arthritis such as: involvement of the DIP joints, an asymmetric distribution of joint disease, spondyloarthritis, sausage digits, new bone formation on radiographs, cutaneous findings, and the characteristic nail manifestations of psoriatic arthritis (nail pitting, onycholysis & other lesions, which include leukonychia, red spots in the lunula, and nail plate crumbling) all may be present
   c. Must have a diagnosis of **ankylosing spondylitis**
      i. Member must be actively followed by and the drug prescribed by a rheumatologist **AND**
      ii. There must be presence of refractory disease defined by failure of at least two NSAIDs at maximum strength for at least 1 month each **AND**
4. Coverage of Cosentyx will be limited to an initial induction dose of 300mg subcutaneous injection at weeks 0,1,2,3, and 4, and then maintenance dosing of 150mg or 300mg every 4 weeks
5. Quantity limit for maintenance phase:
   a. 300 mg package is 2 ml per 28 days
   b. 150 mg package is 1 ml per 28 days

Entyvio – vedolizumab (Medical)

1. Member must be actively followed by and the drug prescribed by a gastroenterologist **AND**
2. Member must have a diagnosis of moderate to severe **Crohn's Disease**
   a. Crohn's Disease Activity Index (CDAI) score of 220-450. Typically described as having more prominent symptoms of fever, significant weight loss, abdominal pain or tenderness,

intermittent nausea or vomiting or significant anemia **AND**
   b. Member must meet at least ONE of the following criteria:
      i. Continues to experience disease flare despite complete and adequate therapy with a corticosteroid (such as prednisone or budesonide)
      ii. Treatment with an immunomodulator (such as azathioprine or 6-mercaptopurine) fails to maintain remission in a case of steroid dependent or steroid refractory disease
      iii. Documentation is provided that azathioprine, 6-mercaptopurine, or methotrexate is not effective, contraindicated, or not tolerated
3. Member must have a diagnosis of moderate to severe **ulcerative colitis**
   a. Member must have had drug failure or serious side effects to at least 2 of the following conventional therapies for at least 3 months:
      i. Thiopurines: Azathioprine/6-mercaptopurine (6-MP)
      ii. 5-Aminosalicylates: Sulfasalazine, Mesalamine-Asacol, Colazol, Olsalazine, Cyclosporine
      iii. IV or oral steroids
4. Initial dosing is 300 mg intravenously at weeks 0, 2, and 6 with maintenance dosing of 300 mg every 8 weeks. More frequent dosing will be considered on a case by case basis.
5. Entyvio is administered by a health care professional and will be covered under the medical benefit

HCPCS: J3380

Ilumya – tildrakizumab-asmn (Medical)

1. Member must be followed by a dermatologist or rheumatologist **AND**
2. Member 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 severe disease of the hands or feet or other areas causing disruption in normal activities, but have less than 10% body surface area involvement **AND**
4. Member must meet one of the following criteria:
   a. Member must be a candidate for systemic therapy (i.e., acitretin, methotrexate, or cyclosporine therapy) **AND** had a trial period of at least a 3 months or had developed serious side effects or have a contraindication (medical reason to avoid the drug) to the above mentioned agents
   b. If systemic therapy is contraindicated, then one of the following must be attempted for a reasonable period of time (at least 3 months):
      i. UVB in combination with a topical therapy such as coal tar, steroids or tazarotene **OR**
      ii. PUVA in combination with topical corticosteroids **OR**
      iii. Medium/High potency topical steroids in combination with anthralin, calcipotriene, or tazarotene **AND**
5. Coverage for Ilumya will only be authorized under the medical benefit
6. There must be documentation of drug failure or serious side effects to TWO of the following: Inflectra, Stelara, or Tremfya

HCPCS: J3245

Kevzara – sarilumab (Rx)

1. Member must be actively followed by and the drug prescribed by a rheumatologist **AND**
2. Member must have a diagnosis of active moderate to severe **rheumatoid arthritis**
   a. There must be documentation of drug failure or serious side effects to a disease-modifying anti- rheumatic drug (DMARD) agents, such as methotrexate, azathioprine, sulfasalazine, or hydroxychloroquine, either alone or in combination for a 3-month period **AND**
3. Member must also have a documented drug failure or serious side effects to **TWO** of the

following agents: Actemra SC, Enbrel, Humira, Xeljanz/XR, Rinvoq
4. Kevzara has not been studied in combination with TNF inhibitors. Concurrent use of Kevzara and a TNF inhibitor will not be authorized.
5. Approved dosing is 200mg 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.
6. Coverage for Kevzara will be limited to 2 syringes/28 days (2.28ml/28 days)

Kineret - anakinra (Rx)

1. Member must be actively followed by and the drug prescribed by a rheumatologist **AND**
2. Member must have a diagnosis of **rheumatoid arthritis**
   a. There must be documentation of drug failure or serious side effects to a disease-modifying anti-rheumatic drug (DMARD) agents, such as methotrexate, azathioprine, sulfasalazine, or hydroxychloroquine, either alone or in combination for a 3-month period **AND**
   b. Member must also have a documented drug failure or serious side effects to **TWO** of the following preferred agents: Actemra SC, Enbrel, Humira, Xeljanz/XR, Rinvoq
   c. Dosing is limited to daily subcutaneous injections (100 mg/day)
3. Kineret is also indicated for the treatment of **neonatal-onset multisystem inflammatory disease** (NOMID) as initial therapy
   a. Initial dosing of 1mg/kg, maintenance dosing of 3-4mg/kg and maximum dosing of 8mg/kg

Olumiant – baracitinib (Rx)

1. Member must be actively followed by and the drug prescribed by a rheumatologist **AND**
2. Member must have active moderate to severe **rheumatoid arthritis AND**
   a. There must be documentation of drug failure or serious side effects to a disease-modifying anti-rheumatic drug (DMARD) agents, such as methotrexate, azathioprine, sulfasalazine, or hydroxychloroquine, either alone or in combination for a 3-month period **AND**
   b. Member must have had failure or had serious side effects to TWO of the following: Actemra, Enbrel, Humira, Xeljanz/XR, Rinvoq
3. Coverage for Olumiant will be limited to 30 tablets per 30 days

Orencia - abatacept (Medical or Rx)

1. Member must have a diagnosis of **rheumatoid arthritis**
   a. Member must be actively followed by and the drug prescribed by a rheumatologist **AND**
   b. There must be documentation of drug failure or serious side effects to a disease-modifying anti-rheumatic drug (DMARD) agent, such as methotrexate, azathioprine, sulfasalazine, or hydroxychloroquine, either alone or in combination for a 3-month period **AND**
   c. Treatment with IV Orencia will require failure or serious side effects with of Inflectra or Simponi Aria
      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
         - < 60kg: 500mg dose
         - 60 – 100kg: 750mg dose
         - > 100kg: 1,000mg dose
   d. Treatment with SC Orencia will require a trial of TWO of the following preferred agents: Actemra SC, Enbrel, Humira, Xeljanz/XR, Rinvoq
      i. Dosing for adult rheumatoid arthritis is 125mg once weekly. SC dosing may be initiated with or without a loading dose.
      ii. 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. Member must have a diagnosis of **juvenile idiopathic arthritis (JIA)**
   a. Member must be actively followed by and the drug prescribed by a rheumatologist **AND**
   b. There must be documentation of clinical failure or intolerance to a disease-modifying anti-rheumatic drug (DMARD) agent, such as methotrexate, azathioprine, sulfasalazine, or hydroxychloroquine, either alone or in combination for a 3-month period **AND**
   c. Treatment with SC Orencia will require drug failure or serious side effects with TWO of the following: Enbrel, Humira, Actemra
   d. 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
   e. 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. Member must have a diagnosis of **psoriatic arthritis**
   a. Member must be actively followed by and the drug prescribed by a rheumatologist or dermatologist **AND**
   b. The member must have some clinical features of psoriatic arthritis such as: involvement of the DIP joints, an asymmetric distribution of joint disease, spondyloarthritis, sausage digits, new bone formation on radiographs, cutaneous findings, and the characteristic nail manifestations of psoriatic arthritis (nail pitting, onycholysis & other lesions, which include leukonychia, red spots in the lunula, and nail plate crumbling). All may be present.
   c. Treatment with IV Orencia will require documentation of drug failure or serious side effects to Inflectra.
      i. 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: 500mg dose
         - 60 – 100kg: 750mg dose
         - > 100kg: 1,000mg dose
   d. Treatment with SC Orencia will require a trial of TWO of the following preferred agents: Enbrel, Humira, Stelara SC, Xeljanz/XR, Cosentyx
      i. Dosing for psoriatic arthritis is 125mg once weekly. SC dosing may be initiated without an IV loading dose
4. Do not co-administer abatacept with TNF antagonists or any other biologic therapy
5. Quantity limit of 4/28 days for the 125mg syringe, 2.8/28 days for the 87.5mg syringe and 6/28 days for the 50mg syringe

HCPCS: J0490

Otezla - apremilast (Rx)

1. Must be prescribed by a dermatologist or rheumatologist
2. Member must have **ONE** of the following disease states:
   a. Must have a diagnosis of **psoriatic arthritis** established by a rheumatologist or dermatologist **AND**
      i. The member must have some clinical features of psoriatic arthritis such as: involvement of the DIP joints, an asymmetric distribution of joint disease, spondyloarthritis,

sausage digits, new bone formation on radiographs, cutaneous findings, and the characteristic nail manifestations of psoriatic arthritis (nail pitting, onycholysis & other lesions, which include leukonychia, red spots in the lunula, and nail plate crumbling). All may be present.

ii. Member must have had drug failure or serious side effects with one of the following preferred agents: Enbrel, Humira, Stelara, Xeljanz/XR, Cosentyx

b. 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 severe disease of the hands or feet or other areas causing disruption in normal activities, but have less than 10% body surface area involvement **AND**

i. Member must be a candidate for systemic therapy (i.e. acitretin, methotrexate, or cyclosporine therapy) **AND** had a trial period of at least 3 months or had developed serious side effects or have a contraindication (medical reason to avoid the drug) to the above-mentioned agents

ii. If systemic therapy is contraindicated, then one of the following must be attempted for a reasonable period of time (at least 3 months):

a. UVB in combination with a topical therapy such as coal tar, steroids or tazarotene **OR**

b. PUVA in combination with topical corticosteroids **OR**

c. Medium/High potency topical steroids in combination with anthralin, calcipotriene, or tazarotene

3. Member must have a diagnosis of oral ulcers associated with Behcet's Disease.
4. Coverage of Otezla will be limited to 60 tablets/30 days

Rinvoq – upadacitinib (Rx)

1. Member must be followed by and the drug prescribed by a rheumatologist **AND**
2. Must have a diagnosis of **rheumatoid arthritis AND**
3. Member must have had failure or serious side effects to methotrexate
   a. For patients who have a contraindication to methotrexate, trial of an alternate DMARD in appropriate dosages will be required.
4. Rinvoq is available as 15mg tablets and quantity will be limited to 30 tablets per 30 days.

Siliq – brodalumab (Rx)

1. Member must be followed by a dermatologist or rheumatologist **AND**
2. Member 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 severe disease of the hands or feet or other areas causing disruption in normal activities, but have less than 10% body surface area involvement **AND**
4. Member must be a candidate for systemic therapy (i.e., acitretin, methotrexate, or cyclosporine therapy) **AND** had a trial period of at least 3 months or had developed serious side effects or contraindications (medical reason to avoid the drugs) to the above-mentioned agents
   a. If systemic therapy is contraindicated, then one of the following must be attempted for a reasonable period of time (at least 3 months):
      i. UVB in combination with a topical therapy such as coal tar, steroids or tazarotene **OR**
      ii. PUVA in combination with topical corticosteroids **OR**
      iii. Medium/High potency topical steroids in combination with anthralin, calcipotriene, or tazarotene **AND**
5. Member must also have a documented drug failure or serious side effects to **ALL** of the

following: Humira, Otezla, Stelara, Skyrizi, Tremfya, Enbrel, Cosentyx, Cimzia, Taltz
6. Siliq is contraindicated in patients with Crohn's Disease
7. Siliq has a black box warning for suicidal ideation, including completed suicide
8. Individuals are excluded from coverage if they have an active TB infection.
9. Coverage of Siliq will be limited to an initial induction dose of 210 mg subcutaneous injection at weeks 0, 1, and 2 followed by 210 mg every 2 weeks

Skyrizi – risankizumab-rzaa (Rx)

1. Member must be followed by a dermatologist or rheumatologist **AND**
2. Member must be at least 18 years of age **AND**
3. Member 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 severe disease of the hands or feet or other areas causing disruption in normal activities, but have less than 10% body surface area involvement **AND**
4. Member must be a candidate for systemic therapy (i.e., acitretin, methotrexate, or cyclosporine therapy) **AND** had a trial period of at least 3 months or had developed serious side effects or contraindications to the above-mentioned agents
   a. If systemic therapy is contraindication, then one of the following must be attempted for a reasonable period of time (at least 3 months):
      i. UVB in combination with a topical therapy such as coal tar, steroids, or tazarotene **OR**
      ii. PUVA in combination with topical steroids in combination with anthralin, calcipotriene, or tazarotene.
      iii. Medium/High potency topical steroids in combination with anthralin, calcipotriene, or tazarotene
5. Two consecutive subcutaneous injections (75 mg each) for a total dose of 150 mg at weeks 0, 4, and then every 12 weeks thereafter.
6. Quantity limit:
   a. Loading dose: 2 kits (4 syringes/month) for 1 month
   b. Maintenance dose: 1 kit (2 syringes) per 84 days

Simponi - golimumab (Medical or Rx)

1. Member must have a diagnosis of **rheumatoid arthritis**
   a. Member must be actively followed by and the drug prescribed by a rheumatologist **AND**
   b. There must be documentation of clinical failure or intolerance to a disease-modifying anti-rheumatic drug (DMARD) agent, such as methotrexate, azathioprine, sulfasalazine, or hydroxychloroquine, either alone or in combination for a 3-month period **AND**
   c. 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
   d. Simponi Aria dosing for adults with RA is as follows:
      a. Dosing is 2mg/kg IV infusion at week 0 and 4 and then every 8 weeks thereafter
   e. Treatment with SC Simponi will require a trial of **TWO** of the following preferred agents: Actemra SC, Enbrel, Humira, Xeljanz/XR, Rinvoq
      i. SC Simponi dosing for adults with RA is as follows:
         a. 50mg once monthly
2. Member must have a diagnosis of **psoriatic arthritis**
   a. Member must be actively followed by and the drug prescribed by a rheumatologist or dermatologist **AND**
   b. The member must have some clinical features of psoriatic arthritis such as: involvement of the DIP joints, an asymmetric distribution of joint disease, spondyloarthritis, sausage digits,

new bone formation on radiographs, cutaneous findings, and the characteristic nail manifestations of psoriatic arthritis (nail pitting, onycholysis & other lesions, which include leukonychia, red spots in the lunula, and nail plate crumbling). All may be present.

c. Simponi Aria dosing for adults with PsA is as follows:
    a. 2 mg/kg IV at weeks 0, 4, and then every 8 weeks thereafter
d. Treatment with SC Simponi will require a trial of **TWO** of the following preferred agents: Enbrel, Humira, Stelara SC, Xeljanz/XR, Cosentyx
    i. SC Simponi dosing for adults with PsA is as follows:
        a. 50mg once monthly

3. Member must have a diagnosis of **ankylosing spondylitis**
    a. Member must be actively followed by and the drug prescribed by a rheumatologist **AND**
    b. There must be documentation of refractory disease as defined by failure of two different NSAIDs given as maximum dose for at least 1 month each
    c. Simponi Aria dosing for adults with AS is as follows:
        a. 2 mg/kg IV at weeks 0, 4, and then every 8 weeks thereafter
    d. Treatment with SC Simponi will require a trial of **TWO** of the following preferred agents: Enbrel, Humira, Cosentyx
        i. SC Simponi dosing for adults with AS is as follows:
            a. 50mg once monthly
4. Member must have a diagnosis of ulcerative colitis
    a. Member must be actively followed by and the drug prescribed by a gastroenterologist **AND**
    b. There must be documentation of failure or intolerance to at least 2 of the following conventional therapies for at least 3 months:
        i. Thiopurines: azathioprine/6-mercaptopurine (6-MP)
        ii. 5-Aminosalicylates: sulfasalazine, mesalamine, olsalazine
        iii. Cyclosporine
        iv. IV or oral steroids
    c. Treatment with SC Simponi will require drug failure or serious side effects with Humira
        i. SC Simponi dosing for adults with UC is as follows:
            a. 200mg initially, followed by 100mg at Week 2, and then 100mg every 4 weeks
    d. 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

HCPCS: J1602

Taltz – ixekizumab (Rx)

1. Member must be followed by a dermatologist or rheumatologist **AND**
2. Member must be at least 18 years of age **AND**
3. Member must have a diagnosis of **ankylosing spondylitis**
    a. Member must be actively followed by and the drug prescribed by a rheumatologist **AND**
    b. There must be documentation of refractory disease as defined by failure of two different NSAIDs given as maximum doses for at least 1 month each
    c. There must be documentation of drug failure or serious side effects to **TWO** of the following preferred agents: Enbrel, Humira, Cosentyx.
4. 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 severe disease of the hands or feet or other areas causing disruption in normal activities, but have less than 10% body surface area involvement **AND**
    a. Member must be a candidate for systemic therapy (i.e., acitretin, methotrexate, or

cyclosporine therapy) **AND** had a trial period of at least a 3 months or had developed serious side effects or have a contraindication (medical reason to avoid the drug) to the above mentioned agents

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

c. Member must also have a documented drug failure or serious side effects to **TWO** of the following preferred agents: Humira, Otezla, Stelara, Skyrizi, Tremfya

5. Must have a diagnosis of **psoriatic arthritis**
   a. Member must be actively followed by and the drug prescribed by a rheumatologist or dermatologist **AND**
   b. Member must have some clinical features of psoriatic arthritis such as: involvement of the DIP joints, an asymmetric distribution of joint disease, spondyloarthritis, sausage digits, new bone formation on radiographs, cutaneous findings, and the characteristic nail manifestations of psoriatic arthritis (nail pitting, onycholysis & other lesions, which include leukonychia, red spots in the lunula, and nail plate crumbling) all may be present **AND**
   c. Member must also have a documented drug failure or serious side effects to **TWO** of the following preferred agents: Enbrel, Humira, Stelara SC, Xeljanz/XR, Cosentyx
   d. Individuals are excluded from coverage if they have an active TB infection
   e. Coverage of Taltz will be limited to an initial induction dose of 160mg subcutaneous injection at week 0, then 80mg SQ weeks 2,4,6,8,10 and 12 and then maintenance dosing of 80mg every 4 weeks

Tremfya – guselkumab (Medical or Rx)

1. Member must be followed by a dermatologist or rheumatologist **AND**
2. Member 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 severe disease of the hands or feet or other areas causing disruption in normal activities, but have less than 10% body surface area involvement **AND**
4. Member must meet one of the following criteria:
   c. Member must be a candidate for systemic therapy (i.e., acitretin, methotrexate, or cyclosporine therapy) **AND** had a trial period of at least a 3 months or had developed serious side effects or have a contraindication (medical reason to avoid the drug) to the above mentioned agents
   d. If systemic therapy is contraindicated, then one of the following must be attempted for a reasonable period of time (at least 3 months):
      iv. UVB in combination with a topical therapy such as coal tar, steroids or tazarotene **OR**
      v. PUVA in combination with topical corticosteroids **OR**
      vi. Medium/High potency topical steroids in combination with anthralin, calcipotriene, or tazarotene **AND**
5. Individuals are excluded from coverage if they have an active TB infection
6. Coverage of Tremfya will be limited to an initial induction dose of 100 mg subcutaneous injection at weeks 0 and 4, and then maintenance dosing of 100mg every 8 weeks thereafter

HCPCS: J1628

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

1. Member must have active moderate to severe **rheumatoid arthritis**
   a. Member must be actively followed by and the drug prescribed by a rheumatologist
   b. Member must have had failure or had serious side effects to methotrexate
   c. For patients who have a contraindication to methotrexate, trial of an alternative DMARD in appropriate dosages will be required prior to approval of Xeljanz/XR
2. Member must have a diagnosis of **psoriatic arthritis**
   a. Member must have some clinical features of psoriatic arthritis such as: involvement of the DIP joints, an asymmetric distribution of joint disease, spondyloarthritis, sausage digits, new bone formation on radiographs, cutaneous findings, and the characteristic nail manifestations of psoriatic arthritis (nail pitting, onycholysis & other lesions, which include leukonychia, red spots in the lunula, and nail plate crumbling) all may be present
3. Member must have a diagnosis of **ulcerative colitis**
   a. Member must be actively followed by and the drug prescribed by a gastroenterologist **AND**
   b. There must be documentation of failure or intolerance to at least 2 of the following conventional therapies for at least 3 months:
      v. Thiopurines: azathioprine/6-mercaptopurine (6-MP)
      vi. 5-Aminosalicylates: sulfasalazine, mesalamine, olsalazine
      vii. Cyclosporine
      viii. IV or oral steroids
   c. Member must have had drug failure or serious side effects with Humira
4. Serious infections, active tuberculosis, lymphoma, and other malignancies have been observed in patients treated with Xeljanz
5. Xeljanz has been given a black box warning for an increased risk of blood cloths and death with the 10mg twice daily dosing of tofacitinib, which is used in patients with ulcerative colitis.
6. Coverage will be limited to 60 tablets/30 days for Xeljanz and 30 tablets /30 days for Xeljanz XR

APPROVAL TIME PERIODS:

For drugs that can be both self-administered (pharmacy benefit) or administered by a healthcare professional (medical benefit) OR only administered by a healthcare professional (medical benefit), approval time frames are as follows:

Actemra

Line of Business	Rx Initial approval (SC)	Rx Recertification (SC)	Medical Initial approval (IV)	Medical Recertification (IV)
Medicaid Managed Care (MMC)/Child Health Plus (CHP)	2 years	2 years	6 months	12 months
Commercial/Exchange	2 years	2 years	Outpatient hospital: 6 months	Outpatient hospital: 6 months

			Home Care/Office Based: 2 years	Home Care/Office Based: 2 years
Medicare	Already defined in policy	Already defined in policy	Outpatient hospital: 6 months	Outpatient hospital: 6 months
			Home Care/Office Based: 2 years	Home Care/Office Based: 2 years

Entyvio

Line of Business	Medical Initial approval (IV)	Medical Recertification (IV)
Medicaid Managed Care (MMC)/Child Health Plus (CHP)	6 months	12 months
Commercial/Exchange	Outpatient hospital: 1 year	Outpatient hospital: 1 year
	Home Care/Office based: 2 years	Home Care/Office based: 2 years
Medicare	Outpatient hospital: 2 years	Outpatient hospital: 2 years
	Home Care/Office based: 2 years	Home Care/Office based: 2 years

Orencia

Line of Business	Rx Initial approval (SC)	Rx Recertification (SC)	Medical Initial approval (IV)	Medical Recertification (IV)
Medicaid Managed Care (MMC)/Child Health Plus (CHP)	2 years	2 years	6 months	12 months
Commercial/Exchange	2 years	2 years	Outpatient hospital: 6 months	Outpatient hospital: 6 months
			Home Care/Office Based: 2 years	Home Care/Office Based: 2 years
Medicare	Already defined in policy	Already defined in policy	Outpatient hospital: 6 months	Outpatient hospital: 6 months
			Home Care/Office Based: 2 years	Home Care/Office Based: 2 years

Simponi

Line of Business	Rx Initial approval (SC)	Rx Recertification (SC)	Medical Initial approval (IV)	Medical Recertification (IV)
Medicaid Managed Care (MMC)/Child Health Plus (CHP)	2 years	2 years	6 months	12 months

Commercial/Exchange	2 years	2 years	Outpatient hospital: 6 months	Outpatient hospital: 6 months
			Home Care/Office Based: 2 years	Home Care/Office Based: 2 years
Medicare	Already defined in policy	Already defined in policy	Outpatient hospital: 6 months	Outpatient hospital: 6 months
			Home Care/Office Based: 2 years	Home Care/Office Based: 2 years

Tremfya

Line of Business	**Rx Initial approval**	**Rx Recertification**	**Medical Initial approval**	**Medical Recertification**
Medicaid Managed Care (MMC)/Child Health Plus (CHP)	2 years	2 years	6 months	12 months
Commercial/Exchange	2 years	2 years	Outpatient hospital: 6 months	Outpatient hospital: 6 months
			Home Care/Office Based: 2 years	Home Care/Office Based: 2 years
Medicare	Already defined in policy	Already defined in policy	Outpatient hospital: 6 months	Outpatient hospital: 6 months
			Home Care/Office Based: 2 years	Home Care/Office Based: 2 years

POLICY GUIDELINES:

1. Unless otherwise stated above within the approval time period section, approval time periods will be for 2 years.

- Continued approval at time of recertification will require documentation that the drug is providing ongoing benefit to the patient in terms of improvement or stability in disease state or condition. Such documentation may include progress notes, imaging or laboratory findings, and other objective or subjective measures of benefit which support that continued use of the requested product is medically necessary. Also, ongoing use of the requested product must continue to reflect the current policy's preferred formulary. Recertification reviews may result in the requirement to try more cost-effective treatment alternatives as they become available (i.e.; generics, biosimilars, or other guideline-supported treatment options). Requested dosing must continue to be consistent with FDA-approved or off-label/guideline-supported dosing recommendations.

2. Prior authorization is contract dependent.
3. 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.

- The required prescription drug(s) is (are) contraindicated or will likely cause an adverse reaction or physical or mental harm to the member;
- The required prescription drug is expected to be ineffective based on the known clinical history and conditions and concurrent drug regimen;
- 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;
- 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;
- 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.
- 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.

4. 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 Coverage Exception Evaluation Policy for All Lines of Business Formularies policy for review guidelines.
5. Requests for biologics to used in combination with other drugs listed in this policy will be evaluated for safety and efficacy and subject to off label review.

UPDATES:

Date	Revision
1/2020	Updated
9/2019	Updated
8/2019	Updated
5/2019	Updated
1/2019	Updated
10/2018	Updated
7/2018	Updated
6/2018	Updated
2/2018	Revised
1/2018	Created

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