Pharmacy Prior Authorization
Clinical Guideline – Cytokines and Cell Adhesion Molecule (CAM) Antagonists

Actemra (tocilizumab)
Arcalyst (rilonacept)
Avsola (infliximab)
Cimzia (certolizumab)
Cosentyx (secukinumab)
Enbrel (etanercept)
Entyvio (vedolizumab)
Humira (adalimumab)
Ilaris (canakinumab)
Ilumya (tildrakizumab)
Inflectra (infliximab-dyyb)
Kevzara (sarilumab)
Kineret (anakinra)
Olumiant (baricitinib)
Orencia (abatacept)
Otezla (apremilast)
Remicade (infliximab)
Renflexis (infliximab-adba)
Siliq (brodalumab)
Stelara (ustekinumab)
Simponi Aria (golimumab)
Simponi (golimumab)
Taltz (ixekizumab)
Tremfya (guselkumab)
Tysabri (natalizumab)
Xeljanz (tofacitinib)
Xeljanz XR (tofacitinib)

Preferred Agents: Avsola, Enbrel, Otezla, Xeljanz (IR only), and Humira are the preferred agents.

Non-Preferred agents: Require trial and failure of ALL preferred agents (where indicated), in addition to all other clinical criteria.

Remicade requires trial and failure with Avsola, (where indicated).

NOTE: The authorization criteria for Tysabri in multiple sclerosis are included in the Multiple Sclerosis agents PA guideline.

General Authorization Guidelines for All Medications and Indications:

- Member is NOT on another cytokine or cell adhesion molecule (CAM) antagonist
- Prescribed by an appropriate specialist based on indication
- Member has been evaluated for and given the appropriate vaccinations as recommended per the Centers for Disease Control (CDC) for his/her risk factors
- Member has been screened for tuberculosis . If screening was positive for latent tuberculosis, member has received treatment for latent tuberculosis.
- The prescribed dose is Food and Drug Administration (FDA)-approved for the indication. Doses above the Food and Drug Administration (FDA)-approved labeling will not be authorized. Quantity limits exist.
- Anti-tumor necrosis factors (TNFs) only: Member does NOT have New York Heart Association (NYHA) class III or IV Congestive Heart Failure
- Anti- tumor necrosis factors (TNFs), Stelara, Xeljanz, Kineret, Actemra, Ilaris, and Orencia: Member has been screened for hepatitis B. If Member has active or chronic hepatitis B, the member is receiving appropriate antiviral treatment
- Entyvio and Tysabri: Will be used as monotherapy and NOT in combination with antineoplastic, immunosuppressive, or immunomodulating agents (for example, azathioprine, 6-mercaptopurine cyclosporine, methotrexate, tumor necrosis factors inhibitors)

Additional Criteria Based on Indication:

- Rheumatoid Arthritis: **Avsola, Enbrel, Humira, Cimzia, Remicade, Renflexis, Inflectra, Simponi, Simponi Aria, Kineret, Olumiant, Orencia, Xeljanz, Actemra, Kevzara**
    - Member is at least 18 years old
    - Member has active moderate to severe active rheumatoid arthritis (for example, swollen, tender joints with limited range of motion); AND an inadequate response to a three month trial of 2

different non-biologic disease-modifying antirheumatic drug (DMARD) regimens (1 of which must include methotrexate (MTX); If intolerance or contraindication to methotrexate (MTX), sulfasalazine (SSZ), or leflunomide (LEF) for 3 months).
  - Monotherapy: methotrexate (MTX), sulfasalazine (SSZ), or leflunomide (LEF)
  - Combination: methotrexate (MTX)+ sulfasalazine (SSZ)+hydroxychloroquine (HCQ), methotrexate (MTX)+ hydroxychloroquine (HCQ), methotrexate (MTX)+ leflunomide (LEF), methotrexate (MTX)+ sulfasalazine (SSZ), sulfasalazine (SSZ)+ hydroxychloroquine (HCQ)

- **Systemic Juvenile Idiopathic Arthritis: Enbrel, Humira, Orencia IV**
  - Age Restriction (Enbrel and Humira): Member is at least 2 years old
  - Age Restriction (Orencia): Member is at least 6 years old
  - Member does NOT have currently ACTIVE systemic features (i.e., fever, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, or serositis) but has continued synovitis in greater than or equal to 1 joint despite treatment for 3 months with methotrexate (MTX) or leflunomide (LEF)
- **Systemic Juvenile Idiopathic Arthritis: Kineret and Actemra IV**
  - Member is at least 2 years old
  - Member does NOT have currently ACTIVE systemic features (i.e., fever, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, or serositis) but has continued synovitis in ≥1 joint despite treatment for 3 months with methotrexate (MTX) or leflunomide; **OR**
  - Member currently has ACTIVE systemic features (i.e., fever, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, or serositis) AND synovitis in at least 1 joint

  NOTE: Member does not require trial of Enbrel or Humira
- **Systemic Juvenile Idiopathic Arthritis: Ilaris**
  - Member is at least 2 years old and weighs at least 7.5kg
  - Member has ACTIVE systemic features (i.e., fever, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, or serositis)
  - Member has continued synovitis in greater than 1 joint despite treatment for at least 1 month with Kineret or Actemra AND methotrexate or leflunomide (Note: both Kineret and Actemra are also non-formulary and require prior authorization (PA))

  NOTE: Member does not require trial of Enbrel or Humira
- **Polyarticular Juvenile Idiopathic Arthritis: Enbrel, Humira, Orencia IV, Actemra IV**
  - Age Restriction (Enbrel, Humira, and Actemra): Member is at least 2 years old
  - Age Restriction (Orencia): Member is at least 6 years old
  - Member had an inadequate response to a three (3) months trial of methotrexate (MTX); If intolerance or contraindication to methotrexate (MTX), sulfasalazine (SSZ), or leflunomide (LEF) for 3 months.
- **Oligoarticular Juvenile Idiopathic Arthritis: Enbrel, Humira**

  NOTE: anti- tumor necrosis factors (TNFs) are not the standard of therapy for most members as this is usually a self-limiting condition that rarely becomes chronic
  - Member is at least 2 years old
  - Member has extended Oligoarticular Juvenile Idiopathic Arthritis (JIA) (defined as disease duration greater than 6 months)

  - Member had inadequate response or intolerable side effects with 2 nonsteroidal anti-inflammatory drugs (NSAIDs) or has contraindications to nonsteroidal anti-inflammatory drugs (NSAIDs).
  - Member had inadequate response or intolerable side effects with an adequate 3-month trial of methotrexate (MTX) or has contraindications to methotrexate (MTX).
- **Cryopyrin-Associated Periodic Syndromes (CAPS): Kineret**
  - Member has diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS), including neonatal-onset multisystem inflammatory disease (NOMID), Familial cold auto inflammatory syndrome (FCAS) or Muckle-Wells syndrome (MWS)

  NOTE: Member does not require trial of Enbrel or Humira
- **Cryopyrin-Associated Periodic Syndromes (CAPS): Ilaris, Arcalyst**
  - Member is at least 4 years old and weighs at least 15kg (Ilaris)
  - Member is at least 12 years old (Arcalyst)
  - Member has one of the following subtypes of Cryopyrin-Associated Periodic Syndromes (CAPS): Familial cold auto inflammatory syndrome (FCAS) or Muckle-Wells syndrome (MWS)
  - Member has failed a 3-month minimum trial of Kineret (Note: Kineret is also non-formulary and requires PA)

  NOTE: Member does not require trial of Enbrel or Humira
- **Familial Mediterranean Fever: Ilaris**
  - Age less than 4 years
  - Member had inadequate response, intolerance or contraindication with colchicine at maximum indicated dose.
- **Giant Cell Arteritis: Actemra**
  - Member is 18 years of age or older
  - Had inadequate response, intolerance, or contraindication with glucocorticoids (e.g., prednisone, methylprednisolone). If intolerance or contraindication to glucocorticoids, methotrexate or cyclophosphamide should be tried.
  - Actemra will be used in combination with a tapering course of glucocorticoids
- **Ankylosing Spondylitis: Avsola, Enbrel, Humira, Cimzia, Remicade, Renflexis, Inflectra, Simponi, Cosentyx**
  - Member is at least 18 years old
  - Member had an inadequate response to a one (1)month trial of TWO non-steroidal anti-inflammatory drugs (NSAIDs) at an adequate dose OR has a contraindication or intolerance to oral non-steroidal anti-inflammatory drugs (NSAIDs).
- **Psoriatic Arthritis: Avsola, Enbrel, Humira, Otezla, Cimzia, Orencia, Remicade, Renflexis, Inflectra, Simponi, Cosentyx, Stelara, Taltz, Xeljanz IR**
  - Member is at least 18 years old
  - Member meets ONE of the following:
    - Has active psoriatic arthritis AND had an inadequate response to a three months trial of methotrexate (MTX); or If intolerance or contraindication to methotrexate (MTX), sulfasalazine (SSZ), or leflunomide (LEF) for 3 months.
    - Member has predominantly axial disease or active enthesitis/dactylitis AND had an inadequate response to one (1)-month trial of TWO non-steroidal anti-inflammatory drugs

(NSAIDs); or has a contraindication or intolerance to TWO oral non-steroidal anti-inflammatory drugs (NSAIDs).

Note:

- Member should continue use of non-steroidal anti-inflammatory drugs (NSAIDs) as needed as bridging or adjunctive therapy when starting disease-modifying antirheumatic drug (DMARD)
- Cosentyx and Stelara should be considered if member has contraindication to tumor necrosis factor inhibitors (for example, Heart failure, Multiple Sclerosis) but tumor necrosis factor inhibitor is indicated.

- **Plaque Psoriasis: Avsola, Enbrel, Humira, Otezla, Remicade, Renflexis, Inflectra, Ilumya, Cosentyx, Taltz, Siliq, Stelara, Tremfya**
  - Member is at least 18 years old (Avsola, Humira, Otezla, Remicade, Renflexis, Ilumya, Inflectra, Cosentyx, Taltz, Tremfya, Siliq)
  - Member is at least 4 years old (Enbrel)
  - Member is at least 12 years (Stelara)
  - Member had an inadequate response, intolerance, or contraindication to at least one oral systemic therapy such as methotrexate (MTX), cyclosporine for 3 months or more
  - Member has ONE of the following:
    - More than 10% of body surface area affected OR
    - Less than 10% BSA is affected but involves sensitive areas (i.e., hands, feet, face, or genitals) that interferes with daily activities OR
    - PASI score of more than 10
  - Phototherapy (PUVA (psoralen ultraviolet type A), UVB (ultraviolet type B)) has been ineffective
  - For Siliq: Mental health evaluation has been done by the prescriber or by a psychiatrist if member has history of prior suicide attempt, bipolar disorder or depressive disorder.
- **<u>Oral Ulcers Associated with Behçet's Disease</u>: Otezla**
  - Diagnosis of Behçet's disease with active recurrent oral ulcers
  - Age is 18 years or older
  - Documentation of previous trial and failure with at least one Non-Biologic Disease-Modifying Anti-Rheumatic Drug such as methotrexate, leflunomide, sulfasalazine or hydroxychloroquine
- **Ulcerative Colitis: Avsola, Humira, Remicade, Renflexis, Inflectra, Simponi, Entyvio, Xeljanz IR**
  - Age restriction (Simponi, , Xeljanz IR, Entyvio): At least 18 years old
  - Age restriction (Avsola, Inflectra, Renflexis, Remicade): At least 6 years old
  - Age restriction (Humira): At least 5 years old
  - <u>STEROID-DEPENDENT Ulcerative:</u>
    - Member had a relapse within three months of stopping glucocorticoids OR is unable to taper steroids to an acceptable dose after 3 months without having symptom recurrence
    - Member had inadequate response or intolerable side effects with a 3-month trial of 6-mercaptopurine (6-MP) or azathioprine (AZA) or has contraindications to both
  - <u>STEROID-REFRACTORY Ulcerative Colitis:</u>
    - Member had inadequate response or intolerable side effects to IV glucocorticoids after 7-10 days OR oral prednisone greater than or equal to 40mg/day after 30 days

- Member meets ONE of the following:
  - Member had a previous failure on mercaptopurine (6-MP) and azathioprine (AZA) or a contraindication to both medications and is therefore not a candidate for treatment with these agents for current episode
  - Member had an inadequate response or intolerable side effects to cyclosporine or there is a contraindication (NOTE: cyclosporine is used as a bridge therapy for members who will be started on the slower acting mercaptopurine (6-MP) or azathioprine (AZA))
  - Member has had surgical intervention

- **Crohn's Disease: Avsola, Humira, Remicade, Renflexis, Inflectra, Cimzia, Stelara, Entyvio, Tysabri**
  - Age restriction (Cimzia, Stelara, Entyvio, and Tysabri): At least 18 years old
  - Age restriction (Avsola, Remicade, Renflexis, Inflectra and Humira): At least 6 years old
  - STEROID-DEPENDENT CROHN'S :
    - Member had a relapse within three months of stopping glucocorticoids OR is unable to taper steroids to an acceptable dose after 3 months without having symptom recurrence
    - Member had inadequate response or intolerable side effects with a 3-month trial of 6-mercaptopurine (6-MP) or azathioprine (AZA) or injectable methotrexate (MTX) or has contraindications to all agents
  - STEROID-REFRACTORY CROHN'S:
    - Member had an inadequate response or intolerable side effects to IV glucocorticoids after 7-10 days OR oral prednisone greater than or equal to 40mg/day after 30 days (NOTE: it is recommended to switch to IV glucocorticoids for members who are not responding to oral glucocorticoids)
- **Hidradenitis Suppurative (acne inversa): Humira**
  - Member is at least 18 years old
  - Member has moderate to severe disease (Hurley stage II-III)
    - Moderate disease: Hurley stage II(recurrent abscesses, with sinus tracts and scarring, presenting as single or multiple widely separated lesions)
    - Severe disease: Hurley state III (diffuse or near-diffuse involvement presenting as multiple interconnected tracts and abscesses across an entire area
  - Member has had inadequate response or intolerable side effects with an oral antibiotic such as tetracycline, doxycycline, or minocycline OR topical antibiotics (if member has a contraindication to oral tetracyclines)
- **Uveitis: Humira**
  - Member is at least 18 years old
  - Member has intermediate, posterior, or pan uveitis that is not caused by an infection
  - Member had an inadequate response or intolerable side effects with any of the following: corticosteroids, methotrexate, azathioprine, mycophenolate, cyclosporine, tacrolimus; OR are not appropriate
- **Additional Criteria for Cytokine Release Syndrome: Actemra intravenous only**
  - Member is 2 years of age or older
  - Member has Grade 4, severe or life-threatening Cytokine Release Syndrome diagnosis due to chimeric antigen receptor-T cell therapy

mercy care

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Initial Approval:
4 months

Renewal Approval:
1 year - Requires member to have shown improvement in signs and symptoms of disease.

Dosing and administration:

- Humira:
  - Rheumatoid Arthritis, Ankylosing Spondylitis, Psoriatic Arthritis, and Juvenile Idiopathic Arthritis: 2 syringes/pens per 28 days
  - Crohn's, Ulcerative Colitis:
    - 6 syringes/pens in the initial 28 days
    - Crohn's, UC: 2 syringes/pens per 28 days after induction period; Hidradenitis: 4 syringes/pens per 28 days after induction period
  - Psoriasis and Uveitis:
    - 4 syringes/pens in the initial 28 days
    - 2 syringes/pens per 28 days after induction period
- Enbrel:
  - Rheumatoid Arthritis, Ankylosing Spondylitis, Psoriatic Arthritis, and Juvenile Idiopathic Arthritis: 4, 50mg syringes OR 8, 25mg syringes per 28 days
  - Psoriasis:
    - 8, 50mg syringes per 28 days for the initial 3 months
    - 4, 50mg syringes per 28 days after induction period
- Actemra SQ:
  - Rheumatoid Arthritis:
    - Weight <100kg: 2 syringes per 28 days. Max dose is 4 syringes per 28 days
    - Weight ≥100kg: 4 syringes per 28 days
  - Giant Cell Arteritis:
    - 162mg once weekly in combination with a tapering course of glucocorticoids
    - 162mg once every other week in combination with a tapering course of glucocorticoids may be prescribed based on clinical presentation.
- Actemra IV:
  - Rheumatoid Arthritis: 4 to 8mg/kg every 28 days
  - Polyarticular Juvenile Idiopathic Arthritis:
    - Weight <30kg: 10mg/kg every 28 days
    - Weight ≥30kg: 8mg/kg every 28 days
  - Systemic Juvenile Idiopathic Arthritis:
    - Weight <30kg: 12mg/kg every 14 days
    - Weight ≥30kg: 8mg/kg every 14 days
  - Cytokine Release Syndrome:
    - 30 kg or more: 8 mg/kg for one dose, up to 3 additional doses if no clinical improvement (max dose 800 mg)

    - Less than 30 kg: 12 mg/kg for one dose, up to 3 additional doses If no clinical improvement (max dose 800 mg)
- Cimzia:
    - 6 syringes/vials allowed in the initial 54 days
    - 2 syringes/vials per 28 days after induction period
- Cosentyx
    - Ankylosing Spondylitis and Psoriatic Arthritis:
        - 4 syringes/pens in the initial 28 days
        - 1 syringe/pen per 28 days after induction period
    - Psoriasis:
        - 8 syringes/pens in the initial 28 days
        - 2 syringes/pens per 28 days after induction period
- Entyvio
    - Crohn's and Ulcerative Colitis: 1 vial per 28 days for initial 2 months; then 1 vial per 56 days
- Ilaris:
    - Cryopyrin-Associated Periodic Syndromes (>40 kg): 150mg every 8 weeks, 1 vial per 56 days
    - Cryopyrin-Associated Periodic Syndromes (≤40 kg): 2mg/kg every 8 weeks, 1 vial per 56 days. Dose may be increased to 3mg/kg given every 8 weeks
    - Systemic Juvenile Idiopathic Arthritis: 4mg/kg (max 300mg) every 4 weeks
        - QLL for doses <180mg: 1 vial per 28 days
        - QLL for doses >180mg: 2 vials per 28 days
- Ilumya
    - Plaque Psoriasis: 100 mg (two syringes) per 28 days for the induction period; then 100 mg (one syringe) every 12 weeks after the induction period.
- Kevzara:
    - Rheumatoid Arthritis: 200mg SC every 2 weeks, 2 syringes per 28 days
- Kineret:
    - Rheumatoid Arthritis, Juvenile Idiopathic Arthritis, and Cryopyrin-Associated Periodic Syndromes: 1 syringe per day
- Olumiant
    - Rheumatoid Arthritis: One tablet (2mg) daily
- Orencia IV:
    - Rheumatoid Arthritis:
        - Weight <60kg: 2 vials per 28 days
        - Weight 60-100kg: 3 vials per 28 days
        - Weight >100kg: 4 vials per 28 days
    - Juvenile Idiopathic Arthritis:
        - Weight <75kg: 10mg/kg every 28 days
        - Weight >75kg: Follow adult Rheumatoid Arthritis dosing above
- Orencia SQ:
    - Rheumatoid Arthritis : 125 mg once a week
    - Polyarticular juvenile idiopathic arthritis:

        - Children and adolescents 2 years and older weighing greater 50 kg: 125 mg subcutaneously once a week
        - Children and adolescents 2 years and older weighing 25 kg to less than 50 kg: 87.5 mg subcutaneously once a week
        - Children and adolescents 2 years and older weighing 10kg to 25 kg: 50 mg subcutaneously once a week
    - Psoriatic Arthritis: 125 mg subcutaneously once a week

- Remicade/Inflectra:
    - Rheumatoid Arthritis: 3mg/kg at week 0, 2 and 6, then every 8 weeks thereafter. Max dose is 10mg/kg every 8 weeks or 3mg/kg every 4 weeks.
    - Crohns: 5mg/kg at week 0, 2 and 6, then every 8 weeks thereafter. Max dose is 10mg/kg every 8 weeks
    - Ulcerative Colitis, Psoriatic Arthritis and Psoriasis: 5mg/kg at week 0, 2 and 6, then every 8 weeks thereafter.
    - Ankylosing Spondylitis: 5mg/kg at week 0, 2 and 6, then every 6 weeks thereafter.
- Siliq:
    - Psoriasis: 4 (210mg) syringes for first 28 days; 2 syringes per 28 days thereafter. Treatment should be discontinued if inadequate response after 12 to 16 weeks.
- Simponi:
    - Rheumatoid Arthritis, For Ankylosing Spondylitis and Psoriatic Arthritis: 1, 50mg syringe per 28 days
    - Ulcerative Colitis:
        - 3, 100mg syringes allowed in the initial 54 days
        - 1, 100mg syringe per 28 days after induction period
- Simponi Aria:
    - Rheumatoid Arthritis: 2mg/kg at week 0 and 4, then every 8 weeks thereafter
- Stelara:
    - Psoriasis:
        - Weight ≤100kg: 1, 45mg syringe per 28 days for initial 2 months; then 1, 45mg syringe per 84 days
        - Weight >100kg: 1, 90mg syringe per 28 days for initial 2 months; then 1, 90mg syringe per 84 days
    - Psoriatic Arthritis:
        - 1, 45mg syringe per 28 days for initial 2 months; then 1, 45mg syringe per 84 days
    - Crohn's:
        - 1, 90mg syringe per 56 days
- Taltz
    - Psoriasis:
        - 3 syringes in the first 28 days
        - 2 syringes per 28 days for months 2 and 3
        - 1 syringe per 28 days after initial induction
- Tremfya
    - Psoriasis:

  - 100mg SQ at week 0 and week 4, followed by 100mg every 8 weeks.
- Tysabri:
  - Crohn's: 1 vial per 28 days
- Xeljanz:
  - Rheumatoid Arthritis: 2 tablets per day
- Xeljanz XR:
  - Rheumatoid Arthritis: 1 tablet per day

Additional information:

Examples of Contraindications to Methotrexate

- Alcoholism, alcoholic liver disease or other chronic liver disease
- Breastfeeding
- Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
- Elevated liver transaminases
- History of intolerance or adverse event
- Hypersensitivity
- Interstitial pneumonitis or clinically significant pulmonary fibrosis
- Myelodysplasia
- Pregnancy or planning pregnancy (male or female)
- Renal impairment
- Significant drug interaction

Examples of clinical reasons to avoid treatment with methotrexate, cyclosporine:

- Alcoholism, alcoholic liver disease or other chronic liver disease
- Breastfeeding
- Drug interaction
- Cannot be used due to risk of treatment-related toxicity
- Pregnancy or planning pregnancy (male or female)
- Significant comorbidity prohibits use of systemic agents (examples include liver or kidney disease, blood dyscrasias, uncontrolled hypertension)

Examples of Contraindications to the Use of NSAIDs

- Allergic-type reaction following aspirin or other NSAID administration
- Asthma
- Gastrointestinal bleeding
- History of intolerance or adverse event
- Urticaria
- Significant drug interaction

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