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

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

Preferred Agents:
HUMIRA, ENBREL, OTEZLA, and XELJANZ (IR ONLY)

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

Remicade requires trial and failure of Inflectra and Renflexis (where indicated).

NOTE: 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 appropriate vaccinations as recommended per Centers for Disease Control (CDC) for member risk factors
- Member has been screened for tuberculosis. If screening was positive for latent tuberculosis (TB), member has received treatment for latent tuberculosis - excluding Otezla.
- Prescribed dose is Food and Drug Administration (FDA)-approved for indication. Doses above Food and Drug Administration (FDA)-approved labeling will not be authorized. Quantity limits exist.
- For anti-tumor necrosis factors only: Member does NOT have New York Heart Association (NYHA) class III or IV Congestive Heart Failure
- For anti-tumor necrosis factors, Stelara, Xeljanz, Kineret, Actemra, Ilaris, and Orencia: Member has been screened for hepatitis B. If Member has active or chronic hepatitis B, member is receiving appropriate antiviral treatment
- For 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 (TNF)-inhibitors)

Additional Criteria Based on Indication:

- **Rheumatoid Arthritis: Enbrel, Humira, Xeljanz IR, Actemra, Cimzia, Inflectra, Kevzara, Kineret, Olumiant, Orencia, Remicade, Renflexis, Simponi, Simponi Aria, Xeljanz XR**

- Member is 18 years of age or older
- Diagnosis of active moderate to severe rheumatoid arthritis (for example, swollen, tender joints with limited range of motion);
- Documented inadequate response to a three-month trial of methotrexate; If there is an intolerance or contraindication to methotrexate, member can use sulfasalazine, leflunomide, or hydroxychloroquine for 3 months).
- Medication will be used concurrently with methotrexate or another non-biologic disease-modifying antirheumatic drug (DMARD) such as sulfasalazine, leflunomide, or hydroxychloroquine

- **Systemic Juvenile Idiopathic Arthritis: Enbrel, Humira, Orencia (subcutaneous/intravenous)**
  - Member is 2 years of age or older - Enbrel, Humira, and Orencia (subcutaneous)
  - Member is 6 years of age or older - Orencia intravenous
  - Documentation of the following:
    - Member does not have active systemic features (for example, fever, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, or serositis)
    - Synovitis is in one or more joints despite a 3 months treatment with methotrexate or leflunomide
- **Systemic Juvenile Idiopathic Arthritis: Kineret and Actemra**
  - Member is 2 years of age or older
  - Documentation of one of the following:
    - Member does not have current active systemic features (for example, fever, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, or serositis) and synovitis is in one or more joints despite treatment for 3 months with methotrexate or leflunomide
    - Member has current active systemic features (for example, fever, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, or serositis) and synovitis is in at least 1 joint
  - NOTE: Member does not require trial of formulary agents
- **Systemic Juvenile Idiopathic Arthritis: Ilaris**
  - Member is 2 years of age or older and weighs at least 7.5kilograms
  - Documentation of the following:
    - Member has active systemic features (for example, fever, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, or serositis)
    - Synovitis is in one or more joints despite a one-month treatment with Kineret or Actemra, and methotrexate or leflunomide (Kineret and Actemra are non-formulary and require prior authorization)
  - NOTE: Member does not require trial of formulary agents
- **Polyarticular Juvenile Idiopathic Arthritis: Enbrel, Humira, Orencia (subcutaneous/intravenous), Actemra**
  - Member is 2 years of age or older - Enbrel, Humira, Orencia subcutaneous, and Actemra
  - Member is 6 years of age or older -Orencia (intravenous)
  - Documented inadequate response to a three months trial of methotrexate
  - If member has an intolerance or contraindication to methotrexate, a documented trial of sulfasalazine, or leflunomide for 3 months is required.

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- **Oligoarticular Juvenile Idiopathic Arthritis: Enbrel, Humira**
  NOTE: anti- tumor necrosis factors are not the standard of therapy for most members as this is usually a self-limiting condition that rarely becomes chronic
  - Member is 2 years of age or older
  - Member has extended Oligoarticular Juvenile Idiopathic Arthritis, defined as disease duration greater than 6 months
  - Documented inadequate response, or intolerable side effects with 2 Nonsteroidal Anti-Inflammatory drugs (NSAIDs), or member has a contraindication to Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)
  - Documented inadequate response, or intolerable side effect to a 3-month trial of methotrexate
  - If member has an intolerance, or contraindication to methotrexate, a documented trial of leflunomide or sulfasalazine for 3 months is required
- **Cryopyrin-Associated Periodic Syndromes: Kineret**
  - Diagnosis of Cryopyrin-Associated Periodic Syndromes, including neonatal-onset multisystem inflammatory disease, Familial cold auto inflammatory syndrome, or Muckle-Wells syndrome
  - NOTE: Member does not require trial of formulary agents
- **Cryopyrin-Associated Periodic Syndromes: Ilaris, Arcalyst**
  - Member is 4 years of age or older and weighs at least 15kilograms - Ilaris
  - Member is 12 years of age or older - Arcalyst
  - Diagnosis of Cryopyrin-Associated Periodic Syndromes with one of the following subtypes
    - Familial cold auto inflammatory syndrome
    - Muckle-Wells syndrome
  - Member had a 3-month trial of Kineret (Kineret is non-formulary and will require a Prior Authorization)
  - NOTE: Member does not require trial of formulary agents
- **Familial Mediterranean Fever: Ilaris**
  - Member is 4 years of age or older
  - Documented inadequate response, intolerance or contraindication to colchicine at maximum indicated dose (Claims history to support compliance or adherence)
  - NOTE: Member does not require trial of formulary agents
- **Giant Cell Arteritis: Actemra subcutaneous**
  - Member is 18 years of age or older
  - Documented inadequate response, intolerance, or contraindication with glucocorticoids (for example, prednisone, methylprednisolone)
  - If member has an intolerance, or contraindication to glucocorticoids, a trial of methotrexate or cyclophosphamide is required
  - Actemra will be used in combination with a tapering course of glucocorticoids
  - NOTE: Member does not require trial of formulary agents
- **Ankylosing Spondylitis: Enbrel, Humira, Cimzia, Cosentyx, Inflectra, Remicade, Renflexis, Simponi, Simponi Aria, Taltz**
  - Member is 18 years of age or older

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- Documented inadequate response to a one-month trial of 2 Non-Steroidal Anti-Inflammatory Drugs, or member has a contraindication or intolerance to 2 oral Non-Steroidal Anti-Inflammatory Drugs

- **Psoriatic Arthritis: Enbrel, Humira, Otezla, Cimzia, Cosentyx, Inflectra, Orencia, Remicade, Renflexis, Simponi, Simponi Aria, Stelara, Taltz, Xeljanz, Xeljanz XR**
  - Member is 18 years of age or older
  - Documentation of one of the following:
    - Member has active Psoriatic Arthritis, and an inadequate response to a three months trial of methotrexate, or if member has intolerance, or contraindication to methotrexate, there was a three months trial of sulfasalazine, or leflunomide
    - Member has predominantly axial disease or active enthesitis/dactylitis and inadequate response to one-month trial of two Non-Steroidal Anti-Inflammatory Drugs, or member has a contraindication or intolerance to oral non-steroidal anti-inflammatory drugs

  Note:
  - Member should continue use of Non-Steroidal anti-inflammatory drugs as needed as bridging or adjunctive therapy when starting disease-modifying antirheumatic drug
  - Cosentyx and Stelara should be considered if member has contraindication to Tumor Necrosis Factor inhibitors (for example, Heart failure, Multiple Sclerosis), where Tumor Necrosis Factor inhibitor is indicated

- **Plaque Psoriasis: Enbrel, Humira, Otezla, Cimzia, Ilumya, Inflectra, Cosentyx, Remicade, Renflexis, Taltz, Siliq, Stelara, Tremfya, Skyrizi**
  - Member is 18 years of age or older - Humira, Otezla, Cimzia, Cosentyx, Ilumya, Inflectra, Remicade, Renflexis, Siliq, Skyrizi, Taltz, Tremfya
  - Member is 4 years of age or older - Enbrel
  - Member is 12 years of age or older - Stelara
  - Documented inadequate response, intolerance, or contraindication, to at least one oral systemic therapy such as methotrexate, or cyclosporine for 3 months or more
  - Member has one of the following:
    - More than 10% of body surface area is affected
    - Less than 10% Body Surface Area is affected, but involves sensitive areas (for example, hands, feet, face or genitals) that interferes with daily activities
    - Psoriasis Area and Severity Index score 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 prescriber or psychiatrist, if member has history of prior suicide attempt, bipolar disorder or depressive disorder

- **Oral Ulcers Associated with Behçet's Disease: Otezla**
  - Diagnosis of Behçet's disease with active recurrent oral ulcers
  - Member is 18 years of age 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: Humira, Xeljanz IR, Remicade, Renflexis, Inflectra, Simponi, Stelara, Entyvio,**
  - Member is 18 years of age or older - Humira, Entyvio, Inflectra, Simponi, Renflexis, Xeljanz

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- Member is 6 years of age or older - Remicade
- Steroid Dependent:
  - Documented relapse within three months of stopping glucocorticoids, or is unable to taper steroids to an acceptable dose after 3 months, without having symptom recurrence
- Steroid Refractory:
  - Documented inadequate response, or intolerable side effects to intravenous glucocorticoids after 7-10 days, or oral prednisone greater than or equal to 40mg per day after 30 days

- **Crohn's Disease: Humira, Cimzia, Entyvio, Remicade, Renflexis, Inflectra, Stelara, Tysabri**
  - Member is 18 years of age or older - Cimzia, Entyvio, Stelara, Tysabri
  - Member is 6 years of age or older - Humira, Inflectra, Remicade, Renflexis
  - Steroid Dependent:
    - Documented relapse within three months of stopping glucocorticoids, or is unable to taper steroids to an acceptable dose after 3 months without having symptom recurrence
    - Documented inadequate response, or intolerable side effects, with a 3-month trial of mercaptopurine, or azathioprine, or injectable methotrexate, or member has contraindications to all agents
  - Steroid Refractory:
    - Documented inadequate response, or intolerable side effects, to intravenous glucocorticoids after 7-10 days, or oral prednisone greater than or equal to 40mg per day after 30 days
    - NOTE: it is recommended to switch to intravenous glucocorticoids for members that are not responding to oral glucocorticoids
- **Hidradenitis Suppurative (Acne Inversa): Humira**
  - Member is 12 years of age or older
  - Member has moderate to severe disease (Hurley stage II-III)
  - Documentation of trial and failure of a 90-day treatment with oral antibiotics (for example, doxycycline, minocycline, or clindamycin with rifampin)
- **Uveitis: Humira**
  - Member is 2 years of age or older
  - Intermediate, posterior, or pan uveitis is not caused by infection
  - Documented inadequate response, or intolerable side effects with any of the following:
    - Corticosteroids, methotrexate, azathioprine, mycophenolate, cyclosporine, tacrolimus, or medications are not appropriate
- **Cytokine Release Syndrome: Actemra Intravenous Only**
  - Member is 2 years of age or older
  - Member has Grade three or four, of severe or life-threatening diagnosis due to chimeric antigen receptor-T cell therapy
  - NOTE: Member does not require trial of formulary agents

Initial Approval:

6 months

Renewal:

6 months
Requires documentation indicating member has 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 Subcutaneous:**
  - 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 Intravenous:**
  - 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)

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- **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:
    - 10 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:**
  - For 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:**
  - For Rheumatoid Arthritis: 200mg SC every 2 weeks, 2 syringes per 28 days
- **Kineret:**
  - For Rheumatoid Arthritis, Juvenile Idiopathic Arthritis, and Cryopyrin-Associated Periodic Syndromes: 1 syringe per day
- **Olumiant:**
  - For Rheumatoid Arthritis: One tablet (2mg) daily
- **Orencia Intravenous:**
  - 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

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  - 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
- **Skyrizi:**
  - Plaque psoriasis:
    - 4 syringes in the initial 28 days
    - 2 syringes per 84 days after induction period
- **Stelara:**
  - For 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
  - For Psoriatic Arthritis:
    - One 45mg syringe per 28 days for initial 2 months; then 1, 45mg syringe per 84 days
  - For Crohn's:
    - One 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 (for example, 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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