Pharmacy Medical Necessity Guidelines: Anti-Inflammatory Conditions

Effective: January 1, 2019

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These pharmacy medical necessity guidelines apply to the following:

**Commercial Products**

- Tufts Health Plan Commercial products – large group plans
- Tufts Health Plan Commercial products – small group and individual plans
- Tufts Health Freedom Plan products – large group plans
- Tufts Health Freedom Plan products – small group plans
- CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

**Tufts Health Public Plans Products**

- Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
- Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
- Tufts Health RTTogether – A Rhode Island Medicaid Plan

**Fax Numbers:**

- Intravenous injection: All plans except Tufts Health Direct – Health Connector: PRECERT: 617.972.9409
- Tufts Health Direct – Health Connector only: MM: 888.415.9055
- Self-administered formulations (oral, subcutaneous injection): RXUM: 617.673.0988

**Note:** This guideline does not apply to Medicare Members (includes dual eligible Members).

**OVERVIEW**

**FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS**

The biologics for the treatment of anti-inflammatory conditions bolded in the table below are preferred.

**Actemra (tocilizumab)**

In addition to the conditions in the table below, Actemra (tocilizumab) is also indicated for the treatment of:

- **Cytokine release syndrome**
  Chimeric antigen receptor T cell-induced severe or life-threatening cytokine release syndrome in adults and pediatric patients 2 years of age and older
- **Giant cell arteritis**
  Giant cell arteritis in adult patients

**Humira (adalimumab)**

In addition to the conditions in the table below, Humira (adalimumab) is also indicated for the treatment of:

- **Hidradenitis Suppurativa**
  Moderate to severe hidradenitis suppurativa
- **Uveitis:**
  Non-infectious intermediate, posterior and panuveitis in adult patients

**Kineret (anakinra)**

In addition to the conditions in the table below, Kineret (anakinra) is also indicated for the treatment of **Neonatal-Onset Multisystem Inflammatory Disease (NOMID)**
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<th>AS</th>
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AS=ankylosing spondylitis, CD=Crohn's disease, JAKI=Janus kinase inhibitor, IL=interleukin, IRA=integrin receptor antagonist, IV=intravenous, MB=medical benefit, MOA=mechanism of action, PDE4I=phosphodiesterase, pJIA=polyarticular juvenile idiopathic arthritis, PsA=psoriatic arthritis, PsO=plaque psoriasis, RA=rheumatoid arthritis, RX=pharmacy benefit, SC=subcutaneous, sJIA=systemic juvenile idiopathic arthritis, TNF=tumor necrosis factor, UC=ulcerative colitis
1. **Enbrel (etanercept)**

The plan may authorize coverage of Enbrel for Members when all of the following criteria are met:

**Ankylosing spondylitis**
1. Documented diagnosis of ankylosing spondylitis
   AND
2. Documentation of one of the following:
   a. The prescribing physician is a rheumatologist
   b. The Member has tried and failed treatment with another biological agent indicated for the treatment of ankylosing spondylitis
   c. The Member is new to the plan and has been stable on Enbrel prior to enrollment

**Plaque psoriasis**
1. Documented diagnosis of plaque psoriasis
   AND
2. The prescribing physician is a dermatologist
   AND
3. The Member is 4 years of age or older
   AND
4. Documentation of one of the following:
   a. The Member has demonstrated an inadequate response to phototherapy and $\geq 1$ of the following agents or the provider has indicated clinical inappropriateness with all of the following:
      i. Soriatane (acitretin)
      ii. Methotrexate
      iii. Cyclosporine
   b. The Member has tried and failed treatment with another biological agent indicated for the treatment of plaque psoriasis
   c. The Member is new to the plan and has been stable on Enbrel prior to enrollment

**Polyarticular juvenile idiopathic arthritis**
1. Documented diagnosis of polyarticular juvenile idiopathic arthritis
   AND
2. The Member is a rheumatologist
   AND
3. The Member is 2 years of age or older
   AND
4. Documentation of one of the following:
   a. The Member has demonstrated an inadequate response to optimal doses of methotrexate for $\geq 3$ months or the provider has indicated clinical inappropriateness with methotrexate and sulfasalazine
   b. The Member has tried and failed treatment with another biological agent indicated for the treatment of polyarticular juvenile idiopathic arthritis
   c. The Member is new to the plan and has been stable on Enbrel prior to enrollment

**Psoriatic arthritis**
1. Documented diagnosis of psoriatic arthritis
   AND
2. The prescribing physician is a rheumatologist
   AND
3. Documentation of one of the following:
   a. The Member has demonstrated an inadequate response to optimal doses of methotrexate or sulfasalazine for $\geq 3$ months or the provider has indicated clinical inappropriateness with methotrexate and sulfasalazine
   b. The Member has tried and failed treatment with another biological agent indicated for the treatment of psoriatic arthritis
   c. The Member is new to the plan and has been stable on Enbrel prior to enrollment
Rheumatoid arthritis
1. Documented diagnosis of rheumatoid arthritis
2. The prescribing physician is a rheumatologist
3. Documentation of one of the following:
   a. The Member has demonstrated an inadequate response to optimal doses of methotrexate for ≥3 months or the provider has indicated clinical inappropriateness with methotrexate
   b. The Member has tried and failed treatment with another biological agent indicated for the treatment of rheumatoid arthritis
   c. The Member is new to the plan and has been stable on Enbrel prior to enrollment

2. Humira (adalimumab)
The plan may authorize coverage of Humira for Members when all of the following criteria are met:
   Ankylosing spondylitis
   1. Documented diagnosis of ankylosing spondylitis
   2. Documentation of one of the following:
      a. The prescribing physician is a rheumatologist
      b. The Member has tried and failed treatment with another biological agent indicated for the treatment of ankylosing spondylitis
      c. The Member is new to the plan and has been stable on Humira prior to enrollment

Crohn’s disease and Ulcerative colitis
1. Documented diagnosis of one of the following:
   a. Crohn’s disease
   b. Ulcerative colitis
2. The prescribing physician is a gastroenterologist
3. Documentation of one of the following:
   a. The Member has demonstrated an inadequate response to an appropriate trial with ≥2 of the following or the provider has indicated clinical inappropriateness of all of the following:
      i. Corticosteroids (e.g., prednisone)
      ii. 5-Aminosalicylates (e.g., sulfasalazine)
      iii. 6-mercaptopurine (6-MP) and/or azathioprine
      iv. Methotrexate
   b. The Member has tried and failed treatment with another biological agent indicated for the treatment of Crohn’s disease or ulcerative colitis
   c. The Member is new to the plan and has been stable on Humira prior to enrollment
**Hidradenitis suppurativa**
1. Documented diagnosis of hidradenitis suppurativa **AND**
2. Documentation of Hurley Stage II or III disease with ≥3 abscesses or inflammatory nodules **AND**
3. The prescribing physician is a dermatologist **AND**
4. Documentation of one of the following:
   a. The Member has demonstrated an inadequate response to ≥3 of the following conventional treatments:
      i. Local hygiene and ordinary hygiene
      ii. Weight reduction in patients who are obese
      iii. Use of ordinary soaps and antiseptic and antiperspirant agents (e.g., aluminum chloride hexahydrate)
      iv. Application of warm compresses with sodium chloride solution or Burow’s solution
      v. Laser hair removal
      vi. Cessation of cigarette smoking
      vii. Medical anti-inflammatory or antiandrogen therapy such as oral or topical antibiotics, intralesional triamcinolone, spironolactone, or finasteride
   b. The Member has tried and failed treatment with another biological agent indicated for the treatment of hidradenitis suppurativa
   c. The Member is new to the plan and has been stable on Humira prior to enrollment

**Plaque psoriasis**
1. Documented diagnosis of plaque psoriasis **AND**
2. The prescribing physician is a dermatologist **AND**
3. The Member is 18 years of age or older **AND**
4. Documentation of one of the following:
   a. The Member has demonstrated an inadequate response to phototherapy and ≥1 of the following agents or the provider has indicated clinical inappropriateness of all of the following:
      i. Soriatane (acitretin)
      ii. Methotrexate
      iii. Cyclosporine
   b. The Member has tried and failed treatment with another biological agent indicated for the treatment of plaque psoriasis
   c. The Member is new to the plan and has been stable on Humira prior to enrollment

**Polyarticular juvenile idiopathic arthritis**
1. Documented diagnosis of polyarticular juvenile idiopathic arthritis **AND**
2. The prescribing physician is a rheumatologist **AND**
3. The Member is 2 years of age or older **AND**
4. Documentation of one of the following:
   a. The Member has demonstrated an inadequate response to optimal doses of methotrexate for ≥3 months or the provider has indicated clinical inappropriateness with methotrexate
   b. The Member has tried and failed treatment with another biological agent indicated for the treatment of polyarticular juvenile idiopathic arthritis
   c. The Member is new to the plan and has been stable on Humira prior to enrollment
Psoriatic arthritis
1. Documented diagnosis of psoriatic arthritis
2. The prescribing physician is a rheumatologist
3. Documentation of one of the following:
   a. The Member has demonstrated an inadequate response to optimal doses of methotrexate or sulfasalazine for ≥3 months or the provider has indicated clinical inappropriateness with methotrexate and sulfasalazine
   b. The Member has tried and failed treatment with another biological agent indicated for the treatment of psoriatic arthritis
   c. The Member is new to the plan and has been stable on Humira prior to enrollment

Rheumatoid arthritis
1. Documented diagnosis of rheumatoid arthritis
2. The prescribing physician is a rheumatologist
3. Documentation of one of the following:
   a. The Member has demonstrated an inadequate response to optimal doses of methotrexate for ≥3 months or the provider has indicated clinical inappropriateness with methotrexate
   b. The Member has tried and failed treatment with another biological agent indicated for the treatment of rheumatoid arthritis
   c. The Member is new to the plan and has been stable on Humira prior to enrollment

Uveitis
1. Documented diagnosis of non-infectious intermediate, posterior or panuveitis
2. The prescribing physician is a uveitis specialist (e.g., ophthalmologist, ocular immunologist)
3. Documentation of one of the following:
   a. The Member has demonstrated an inadequate response or inability to tolerate conventional therapy (e.g., periocular, intraocular, or systemic corticosteroids; immunosuppressants)
   b. The Member has tried and failed treatment with another biological agent indicated for the treatment of non-infectious intermediate, posterior and panuveitis
   c. The Member is new to the plan and has been stable on Humira prior to enrollment

3. Remicade (infliximab)
The plan may authorize coverage of Remicade for Members when the following criteria are met:

Ankylosing spondylitis
1. Documented diagnosis of ankylosing spondylitis
2. Documentation of one of the following:
   a. The prescribing physician is a rheumatologist
   b. The Member has tried and failed treatment with another biological agent indicated for the treatment of ankylosing spondylitis
   c. The Member is new to the plan and has been stable on Remicade prior to enrollment
Crohn’s disease and Ulcerative colitis
1. Documented diagnosis of one of the following:
   a. Crohn’s disease
   b. Ulcerative colitis
2. The prescribing physician is a gastroenterologist
3. The Member is 6 years of age or older
4. Documentation of one of the following:
   a. The Member has demonstrated an inadequate response to an appropriate trial with ≥2 of the following or the provider has indicated clinical inappropriateness with all of the following:
      i. Corticosteroids (e.g., prednisone)
      ii. 5-Aminosalicylates (e.g., sulfasalazine)
      iii. 6-mercaptopurine (6-MP) and/or azathioprine
      iv. Methotrexate
   b. The Member has tried and failed treatment with another biological agent indicated for the treatment of Crohn’s disease or ulcerative colitis
   c. The Member is new to the plan and has been stable on Remicade prior to enrollment

Plaque psoriasis
1. Documented diagnosis of plaque psoriasis
2. The prescribing physician is a dermatologist
3. The Member is 18 years of age or older
4. Documentation of one of the following:
   a. The Member has demonstrated an inadequate response to phototherapy and ≥1 of the following agents or the provider has indicated clinical inappropriateness with all of the following:
      i. Soriatane (acitretin)
      ii. Methotrexate
      iii. Cyclosporine
   b. The Member has tried and failed treatment with another biological agent indicated for the treatment of plaque psoriasis
   c. The Member is new to the plan and has been stable on Remicade prior to enrollment

Psoriatic arthritis
1. Documented diagnosis of psoriatic arthritis
2. The prescribing physician is a rheumatologist
3. Documentation of one of the following:
   a. The Member has demonstrated an inadequate response to optimal doses of methotrexate or sulfasalazine for ≥3 months or the provider has indicated clinical inappropriateness with methotrexate and sulfasalazine
   b. The Member has tried and failed treatment with another biological agent indicated for the treatment of psoriatic arthritis
   c. The Member is new to the plan and has been stable on Remicade prior to enrollment

Rheumatoid arthritis
1. Documented diagnosis of rheumatoid arthritis
2. The prescribing physician is a rheumatologist
3. Documentation of one of the following:
   a. The Member has demonstrated an inadequate response to optimal doses of methotrexate for ≥3 months or the provider has indicated clinical inappropriateness with methotrexate
   b. The Member has tried and failed treatment with another biological agent indicated for the treatment of rheumatoid arthritis
   c. The Member is new to the plan and has been stable on Remicade prior to enrollment
4. Simponi and Simponi Aria (golimumab)

Ankylosing spondylitis
The plan may authorize coverage of Simponi and Simponi Aria for Members when all of the following criteria are met:
1. Documented diagnosis of ankylosing spondylitis
2. Documentation of one of the following:
   a. The prescribing physician is a rheumatologist
   b. The Member has tried and failed treatment with another biological agent indicated for the treatment of ankylosing spondylitis
   c. The Member is new to the plan and has been stable on a golimumab product prior to enrollment

Psoriatic arthritis
The plan may authorize coverage of Simponi and Simponi Aria for Members when all of the following criteria are met:
1. Documented diagnosis of psoriatic arthritis
2. The prescribing physician is a rheumatologist
3. Documentation of one of the following:
   a. The Member has demonstrated an inadequate response to optimal doses of methotrexate or sulfasalazine for ≥3 months or the provider has indicated clinical inappropriateness with methotrexate or sulfasalazine
   b. The Member has tried and failed treatment with another biological agent indicated for the treatment of psoriatic arthritis
   c. The Member is new to the plan and has been stable on a golimumab product prior to enrollment

Rheumatoid arthritis
The plan may authorize coverage of Simponi and Simponi Aria for Members when all of the following criteria are met:
1. Documented diagnosis of rheumatoid arthritis
2. The prescribing physician is a rheumatologist
3. Documentation of one of the following:
   a. The Member has demonstrated an inadequate response to optimal doses of methotrexate for ≥3 months or the provider has indicated clinical inappropriateness with methotrexate
   b. The Member has tried and failed treatment with another biological agent indicated for the treatment of rheumatoid arthritis
   c. The Member is new to the plan and has been stable on Simponi/Simponi Aria prior to enrollment
5. Simponi (golimumab)
The plan may authorize coverage of Simponi for Members when all of the following criteria are met:

**Ulcerative colitis**
1. Documented diagnosis of ulcerative colitis
2. The prescribing physician is a gastroenterologist
3. The Member is 18 years of age or older
4. Documentation of one of the following:
   a. The Member has demonstrated an inadequate response to an appropriate trial with two or more of the following agents or the provider has indicated clinical inappropriateness with all of the following:
      i. Corticosteroids (e.g., prednisone)
      ii. 5-Aminosalicylates (e.g., sulfasalazine)
      iii. 6-mercaptopurine (6-MP and/or azathioprine)
      iv. Methotrexate
   b. The Member has tried and failed treatment with another biological agent indicated for the treatment of ulcerative colitis
   c. The Member is new to the plan and has been stable on Simponi prior to enrollment

6. Stelara (ustekinumab) (intravenous and subcutaneous)
**Crohn’s disease**
The plan may authorize coverage of Stelara intravenous and subcutaneous injections for Members when all of the following criteria are met:
1. Documented diagnosis of Crohn’s disease
2. The prescribing physician is a gastroenterologist
3. The Member is 18 years of age or older
4. Documentation of one of the following:
   a. The Member has demonstrated an inadequate response to an appropriate trial with ≥2 of the following or the provider has indicated clinical inappropriateness with all of the following:
      i. Corticosteroids (e.g., prednisone)
      ii. 5-Aminosalicylates (e.g., sulfasalazine)
      iii. 6-mercaptopurine (6-MP and/or azathioprine)
      iv. Methotrexate
   b. The Member has tried and failed treatment with another biological agent indicated for the treatment of Crohn’s disease
   c. The Member is new to the plan and has been stable on Stelara prior to enrollment

**Plaque psoriasis**
The plan may authorize coverage of Stelara subcutaneous injection for Member when all of the following criteria are met:
1. Documented diagnosis of plaque psoriasis
2. The prescribing physician is a dermatologist
3. The Member is 12 years of age or older
4. Documentation of one of the following:
   a. The Member has demonstrated an inadequate response to phototherapy and ≥1 of the following agents or the provider has indicated clinical inappropriateness with all of the following:
      i. Soriatane (acitretin)
      ii. Methotrexate
      iii. Cyclosporine
   b. The Member has tried and failed treatment with another biological agent indicated for the treatment of plaque psoriasis
   c. The Member is new to the plan and has been stable on Stelara prior to enrollment
Psoriatic arthritis
The plan may authorize coverage of Stelara subcutaneous injection for Member when all of the following criteria are met:
1. Documented diagnosis of psoriatic arthritis
   AND
2. The prescribing physician is a rheumatologist
   AND
3. Documentation of one of the following:
   a. The Member has a documented inadequate response to optimal doses of methotrexate or sulfasalazine for 3 months or the provider has indicated clinical inappropriateness with methotrexate and sulfasalazine
   b. The Member has tried and failed treatment with another biological agent indicated for the treatment of psoriatic arthritis
   c. The Member is new to the plan and has been stable on Stelara prior to enrollment

NON-PREFERRED PRODUCTS

1. Actemra (tocilizumab) – intravenous
The plan may authorize coverage of Actemra intravenous injection for Members when all of the following criteria are met:
Cytokine release syndrome
The plan may authorize coverage of Actemra intravenous injection for Members when all of the following criteria are met:
1. Documented diagnosis of severe or life-threatening chimeric antigen receptor T cell-induced cytokine release syndrome

Polyarticular juvenile idiopathic arthritis
1. Documented diagnosis of polyarticular juvenile idiopathic arthritis
   AND
2. The prescribing physician is a rheumatologist
   AND
3. The Member is 2 years of age or older
   AND
4. The Member has demonstrated an inadequate response to optimal doses of methotrexate for ≥3 months or the provider has indicated clinical inappropriateness with methotrexate

Rheumatoid arthritis
1. Documented diagnosis of rheumatoid arthritis
   AND
2. The prescribing physician is a rheumatologist
   AND
3. Documentation of one of the following:
   a. The Member has tried and failed treatment with ≥1 of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
      i. Remicade
      ii. Simponi Aria
   b. The Member is new to the plan and stable on Actemra and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

Systemic juvenile idiopathic arthritis
1. Documented diagnosis of systemic juvenile idiopathic arthritis
   AND
2. The prescribing physician is a rheumatologist
   AND
3. The Member has demonstrated an inadequate response to optimal doses of methotrexate for ≥3 months or the provider has indicated clinical inappropriateness with methotrexate
2. Actemra (tocilizumab) – subcutaneous
The plan may authorize coverage of Acterma subcutaneous injection for Members when all of the following criteria are met:

**Giant cell arteritis**
1. Documented diagnosis of giant cell arteritis
   AND
2. The prescribing physician is a rheumatologist or neurologist
   AND
3. The Member has demonstrated an inadequate response to ≥1 of the following agents or the provider has indicated clinical inappropriateness with corticosteroids:
   a. Corticosteroids (e.g., prednisone)
   b. Immunosuppressants (e.g., methotrexate)

**Rheumatoid arthritis**
1. Documented diagnosis of rheumatoid arthritis
   AND
2. The prescribing physician is a rheumatologist
   AND
3. Documentation of one of the following:
   a. The Member has tried and failed treatment with ≥2 of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
      i. Enbrel
      ii. Humira
      iii. Simponi
   b. The Member is new to the plan and stable on Actemra and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

**Systemic juvenile idiopathic arthritis**
1. Documented diagnosis of systemic juvenile idiopathic arthritis
   AND
2. The prescribing physician is a rheumatologist
   AND
3. The Member has demonstrated an inadequate response to optimal doses of methotrexate for ≥3 months or the provider has indicated clinical inappropriateness with methotrexate

3. Cimzia (certolizumab)
The plan may authorize coverage of Cimzia for Members when all of the following criteria are met:

**Ankylosing spondylitis**
1. Documented diagnosis of ankylosing spondylitis
   AND
2. The prescribing physician is a rheumatologist
   AND
3. Documentation of one of the following:
   a. The Member has tried and failed treatment with ≥2 of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
      i. Enbrel
      ii. Humira
      iii. Simponi
   b. The Member is new to the plan and stable on Cimzia and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes
Pharmacy Medical Necessity Guidelines: Anti-inflammatory Conditions

**Crohn’s disease**
1. Documented diagnosis of Crohn’s disease
2. The prescribing physician is a gastroenterologist
3. The Member is 18 years of age or older
4. Documentation of one of the following:
   a. The Member has tried and failed treatment with the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
      i. Humira
   b. The Member is new to the plan and stable on Cimzia and the prescribing physician has documented that changing to the preferred product would result in adverse clinical outcomes

**Plaque psoriasis**
1. Documented diagnosis of plaque psoriasis
2. The prescribing physician is a dermatologist
3. The Member is 18 years of age or older
4. Documentation of one of the following:
   a. The Member has tried and failed treatment with ≥2 of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
      i. Enbrel
      ii. Humira
      iii. Stelara
   b. The Member is new to the plan and stable on Cimzia and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

**Psoriatic arthritis**
1. Documented diagnosis of psoriatic arthritis
2. The prescribing physician is a rheumatologist
3. Documentation of one of the following:
   a. The Member has tried and failed treatment with ≥2 of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
      i. Enbrel
      ii. Humira
      iii. Simponi
      iv. Stelara
   b. The Member is new to the plan and stable on Cimzia and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

**Rheumatoid arthritis**
1. Documented diagnosis of rheumatoid arthritis
2. The prescribing physician is a rheumatologist
3. Documentation of one of the following:
   a. The Member has tried and failed treatment with ≥2 of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
      i. Enbrel
      ii. Humira
      iii. Simponi
   b. The Member is new to the plan and stable on Cimzia and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes
4. Cosentyx (secukinumab)
The plan may authorize coverage of Cosentyx for Members when all of the following criteria are met:

**Ankylosing spondylitis**
1. Documented diagnosis of ankylosing spondylitis  \text{AND}
2. The prescribing physician is a rheumatologist  \text{AND}
3. Documentation of one of the following:
   a. The Member has tried and failed treatment with ≥2 of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
      i. Enbrel
      ii. Humira
      iii. Simponi
   b. The Member is new to the plan and stable on Cosentyx and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

**Plaque psoriasis**
1. Documented diagnosis of plaque psoriasis  \text{AND}
2. The prescribing physician is a dermatologist  \text{AND}
3. The Member is 18 years of age or older  \text{AND}
4. Documentation of one of the following:
   a. The Member has tried and failed treatment with ≥2 of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
      i. Enbrel
      ii. Humira
      iii. Simponi
      iv. Stelara
   b. The Member is new to the plan and stable on Cosentyx and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

**Psoriatic arthritis**
1. Documented diagnosis of psoriatic arthritis  \text{AND}
2. The prescribing physician is a rheumatologist  \text{AND}
3. Documentation of one of the following:
   a. The Member has tried and failed treatment with ≥2 of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
      i. Enbrel
      ii. Humira
      iii. Simponi
      iv. Stelara
   b. The Member is new to the plan and stable on Cosentyx and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes
5. **Entyvio (vedolizumab)**
The plan may authorize coverage of Entyvio for Members when all of the following criteria are met:

**Crohn’s disease and Ulcerative colitis**
1. Documented diagnosis of one of the following:
   a. Crohn’s disease
   b. Ulcerative colitis

2. The prescribing physician is a gastroenterologist

3. The Member is 18 years of age or older

4. Documentation of one of the following:
   a. The Member has tried and failed treatment with the following agent or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
      i. Remicade
   b. The Member is new to the plan and stable on Entyvio and the prescribing physician has documented that changing to the preferred product would result in adverse clinical outcomes

6. **Inflectra (infliximab-dyyb) and Renflexis (infliximab-adba)**
In addition to the coverage criteria for Remicade, the plan may authorize coverage of Inflectra or Renflexis for Members when the following criteria are met:

1. Documentation of one of the following:
   a. For Crohn's disease, plaque psoriasis, and ulcerative colitis:
      i. The Member has tried and failed treatment with the following agent or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
         1. Remicade
   OR
   b. For ankylosing spondylitis, psoriatic arthritis or rheumatoid arthritis:
      i. The Member has tried and failed treatment with ≥1 of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
         1. Remicade
         2. Simponi Aria
   OR
   c. The Member is new to the plan and stable on the requested agent (Inflectra or Renflexis) and the prescribing physician has documented that changing to the preferred product(s) would result in adverse clinical outcomes

7. **Kevzara (sarilumab)**
The plan may authorize coverage of Kevzara for Members when all of the following criteria are met:

**Rheumatoid arthritis**
1. Documented diagnosis of rheumatoid arthritis

2. The prescribing physician is a rheumatologist

3. Documentation of one of the following:
   a. The Member has tried and failed treatment with ≥2 of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
      i. Enbrel
      ii. Humira
      iii. Simponi
   b. The Member is new to the plan and stable on Kevzara and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes
8. Kineret (anakinra)
The plan may authorize coverage of Kineret for Members when all of the following criteria are met:

**Neonatal-Onset Multisystem Inflammatory Disease (NOMID)**
1. Documented diagnosis of neonatal-onset multisystem inflammatory disease

**Rheumatoid arthritis**
1. Documented diagnosis of rheumatoid arthritis

2. The prescribing physician is a rheumatologist

AND

3. Documentation of one of the following:
   a. The Member has tried and failed treatment with ≥2 of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
      i. Enbrel
      ii. Humira
      iii. Simponi
   b. The Member is new to the plan and stable on Kineret and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

9. Olumiant (baricitinib)
The plan may authorize coverage of Olumiant for Members when all of the following criteria are met:

1. Documented diagnosis of rheumatoid arthritis

AND

2. The prescribing physician is a rheumatologist

AND

3. Documentation of one of the following:
   a. The Member has tried and failed treatment with ≥2 of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
      i. Enbrel
      ii. Humira
      iii. Simponi
   b. The Member is new to the plan and stable on Kineret and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

10. Orencia (abatacept) – intravenous
The plan may authorize coverage of Orencia intravenous for Members when all of the following criteria are met:

**Polyarticular juvenile idiopathic arthritis**
1. Documented diagnosis of polyarticular juvenile idiopathic arthritis

AND

2. The prescribing physician is a rheumatologist

AND

3. The Member is 2 years of age or older

AND

4. The Member has demonstrated an inadequate response to optimal doses of methotrexate for ≥3 months or the provider has indicated clinical inappropriateness with methotrexate
Psoriatic arthritis and Rheumatoid arthritis
1. Documented diagnosis of one of the following:
   a. Psoriatic arthritis  
   b. Rheumatoid arthritis  
   AND
2. The prescribing physician is a rheumatologist  
   AND
3. Documentation of one of the following:
   a. The Member has tried and failed treatment with ≥1 of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
      i. Remicade
      ii. Simponi Aria
   b. The Member is new to the plan and stable on Orencia and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

11. Orencia (abatacept) – subcutaneous
The plan may authorize coverage of Orencia subcutaneous for Members when all of the following criteria are met:
Polyarticular juvenile idiopathic arthritis
1. Documented diagnosis of juvenile idiopathic arthritis  
   AND
2. The prescribing physician is a rheumatologist  
   AND
3. The Member is 2 years of age or older  
   AND
4. Documentation of one of the following:
   a. The Member has tried and failed treatment with ≥2 of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
      i. Enbrel
      ii. Humira
   b. The Member is new to the plan and stable on Orencia and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes
Psoriatic arthritis
1. Documented diagnosis of psoriatic arthritis  
   AND
2. The prescribing physician is a rheumatologist  
   AND
3. Documentation of one of the following:
   a. The Member has tried and failed treatment with ≥2 of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
      i. Enbrel
      ii. Humira
      iii. Simponi
      iv. Stelara
   b. The Member is new to the plan and stable on Orencia and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes
**Rheumatoid arthritis**

1. Documented diagnosis of rheumatoid arthritis AND
2. The prescribing physician is a rheumatologist AND
3. Documentation of one of the following:
   a. The Member has tried and failed treatment with ≥2 of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
      i. Enbrel
      ii. Humira
      iii. Simponi
   b. The Member is new to the plan and stable on Orencia and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

**12. Otezla (apremilast)**

The plan may authorize coverage of Otezla for Members when all of the following criteria are met:

**Plaque psoriasis**

1. Documented diagnosis of plaque psoriasis AND
2. The prescribing physician is a dermatologist AND
3. The Member is 18 years of age or older AND
4. Documentation of one of the following:
   a. The Member has tried and failed treatment with ≥2 of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
      i. Enbrel
      ii. Humira
      iii. Stelara
   b. The Member is new to the plan and stable on Otezla and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

**Psoriatic arthritis**

1. Documented diagnosis of psoriatic arthritis AND
2. The prescribing physician is a rheumatologist AND
3. Documentation of one of the following:
   a. The Member has tried and failed treatment with ≥2 of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
      i. Enbrel
      ii. Humira
      iii. Simponi
      iv. Stelara
   b. The Member is new to the plan and stable on Otezla and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes
13. Siliq (brodalumab)
The plan may authorize coverage of Siliq for Members when all of the following criteria are met:

Plaque psoriasis
1. Documented diagnosis of plaque psoriasis  AND
2. The prescribing physician is a dermatologist  AND
3. The Member is 18 years of age or older  AND
4. Documentation of one of the following:
   a. The Member has tried and failed treatment with ≥2 of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
      i. Enbrel
      ii. Humira
      iii. Stelara
   b. The Member is new to the plan and stable on Siliq and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

Psoriatic arthritis
1. Documented diagnosis of psoriatic arthritis AND
2. The prescribing physician is a rheumatologist AND
3. Documentation of one of the following:
   a. The Member has tried and failed treatment with ≥2 of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
      i. Enbrel
      ii. Humira
      iii. Simponi
      iv. Stelara
   b. The Member is new to the plan and stable on Taltz and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

14. Taltz (ixekizumab)
The plan may authorize coverage of Taltz for Members when all of the following criteria are met:

Plaque psoriasis
1. Documented diagnosis of plaque psoriasis  AND
2. The prescribing physician is a dermatologist  AND
3. The Member is 18 years of age or older  AND
4. Documentation of one of the following:
   a. The Member has tried and failed treatment with ≥2 of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
      i. Enbrel
      ii. Humira
      iii. Stelara
   b. The Member is new to the plan and stable on Taltz and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes
15. Tremfya (guselkumab)
The plan may authorize coverage of Tremfya for Members when all of the following criteria are met:

**Plaque psoriasis**
1. Documented diagnosis of plaque psoriasis **AND**
2. The prescribing physician is a dermatologist **AND**
3. The Member is 18 years of age or older **AND**
4. Documentation of one of the following:
   a. The Member has tried and failed treatment with ≥2 of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
      i. Enbrel
      ii. Humira
      iii. Stelara
   b. The Member is new to the plan and stable on Tremfya and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

16. Xeljanz (tofacitinib)

**Psoriatic arthritis**
The plan may authorize coverage of Xeljanz extended- or immediate-release for Members when all of the following criteria are met:
1. Documented diagnosis of psoriatic arthritis **AND**
2. The prescribing physician is a rheumatologist **AND**
3. Documentation of one of the following:
   a. The Member has tried and failed treatment with ≥2 of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
      i. Enbrel
      ii. Humira
      iii. Simponi
      iv. Stelara
   b. The Member is new to the plan and stable on a tofacitinib product and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

**Rheumatoid arthritis**
The plan may authorize coverage of Xeljanz extended- or immediate-release for Members when all of the following criteria are met:
1. Documented diagnosis of rheumatoid arthritis **AND**
2. The prescribing physician is a rheumatologist **AND**
3. Documentation of one of the following:
   a. The Member has tried and failed treatment with ≥2 of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
      i. Enbrel
      ii. Humira
      iii. Simponi
   b. The Member is new to the plan and stable on a tofacitinib product and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes
**Ulcerative colitis**
The plan may authorize coverage of **Xeljanz immediate-release** for Members when all of the following criteria are met:

1. Documented diagnosis of ulcerative colitis
2. The prescribing physician is a gastroenterologist
3. The Member is 18 years of age or older
4. Documentation of one of the following:
   a. The Member has tried and failed treatment with ≥2 of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
      i. Humira
      ii. Simponi
   b. The Member is new to the plan and stable on a Xeljanz immediate release and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

**LIMITATIONS**

1. Samples, free goods, or similar offerings of the requested medication do not qualify for an established clinical response and will not be considered for prior authorization.
2. Maximal doses of methotrexate are defined as 15 to 25 mg per week depending on the patient’s tolerance.
3. For the diagnosis of plaque psoriasis, inconvenience does not qualify as a contraindication to phototherapy.
4. Documentation of a Member being a social drinker does not qualify as a medically acceptable contraindication or clinically inappropriateness to methotrexate therapy.
5. Duration of approvals
   a. Approval of Actemra intravenous injection for cytokine release syndrome will be limited to 1 month.
   b. Initial approval of Entyvio will be limited to 6 months. For continued coverage authorization for 12 month intervals, documentation of evidence of clinical efficacy must be submitted.
   c. Initial approval of Humira, Simponi, and Xeljanz for the diagnosis of ulcerative colitis will be limited to 8 weeks. For continued coverage authorization, documentation of evidence of clinical remission must be submitted.
6. Quantity limitations – coverage of the requested medication will be limited as follows:
<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Indication</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Actemra SC</td>
<td>Giant cell arteritis, RA, sJIA</td>
<td>4 syringes per 28 days</td>
</tr>
<tr>
<td>Cimzia</td>
<td>All</td>
<td>2 syringes per 28 days</td>
</tr>
<tr>
<td>Cosentyx</td>
<td>AS*, PsA*</td>
<td>150 mg: 1 syringe per 28 days</td>
</tr>
<tr>
<td></td>
<td>PsO*</td>
<td>300 mg dose pack: 1 per 28 days (total of two 150 mg syringes)</td>
</tr>
<tr>
<td>Enbrel</td>
<td>AS, pJIA, PsA, PsO*, RA</td>
<td>25 mg: 8 syringes per 28 days</td>
</tr>
<tr>
<td></td>
<td></td>
<td>50 mg: 4 auto-injectors, cartridges, or syringes per 28 days</td>
</tr>
<tr>
<td>Humira</td>
<td>AS, CD, HS, pJIA, PsA, PsO, RA, uveitis</td>
<td>2 per 28 days</td>
</tr>
<tr>
<td></td>
<td>CD, HS, psoriasis, UC, uveitis</td>
<td>Starter pack: One time fill</td>
</tr>
<tr>
<td>Kevzara</td>
<td>All</td>
<td>2 pens or syringes per 28 days</td>
</tr>
<tr>
<td>Kinere</td>
<td>All</td>
<td>28 syringes per 28 days</td>
</tr>
<tr>
<td>Otezla</td>
<td>All</td>
<td>60 tablets per 30 days</td>
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<tr>
<td></td>
<td></td>
<td>Starter pack: One time fill</td>
</tr>
<tr>
<td>Siliq*</td>
<td>All</td>
<td>2 syringes per 28 days</td>
</tr>
<tr>
<td>Simponi SC</td>
<td>All (UC*)</td>
<td>1 auto-injector or syringe per 28 days</td>
</tr>
<tr>
<td>Stelara SC</td>
<td>PsA*, PsO*</td>
<td>45 mg syringes or vials: 1 per 84 days</td>
</tr>
<tr>
<td></td>
<td>CD</td>
<td>90 mg syringes: 1 per 54 days</td>
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<tr>
<td></td>
<td>PsA*, PsO*</td>
<td>90 mg syringes: 1 per 84 days</td>
</tr>
<tr>
<td>Taltz*</td>
<td>All*</td>
<td>1 auto-injector or syringe per 28 days</td>
</tr>
<tr>
<td>Tremfya*</td>
<td>All</td>
<td>1 per 54 days</td>
</tr>
<tr>
<td>Xeljanz*</td>
<td>All</td>
<td>5, 10 mg: 60 tablets per 30 days</td>
</tr>
<tr>
<td></td>
<td></td>
<td>11 mg: 30 tablets per 30 days</td>
</tr>
</tbody>
</table>

*Loading dose required
AS=ankylosing spondylitis, CD=Crohn’s disease, HS=hidradenitis suppurativa, pJIA=polypartricular juvenile idiopathic arthritis, PsA=psoriatic arthritis, PsO=plaque psoriasis, RA=rheumatoid arthritis, SC=subcutaneous, sJIA=systemic juvenile idiopathic arthritis, UC=ulcerative colitis

CODES
The following HCPC/CPT code(s) are:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>J0129</td>
<td>Injection, abatacept, per 10 mg</td>
</tr>
<tr>
<td>J1602</td>
<td>Injection, golimumab, 1 mg, for intravenous use</td>
</tr>
<tr>
<td>J1745</td>
<td>Injection, infliximab, excludes biosimilar, 10mg</td>
</tr>
<tr>
<td>J262</td>
<td>Injection, tocilizumab, 1 mg</td>
</tr>
<tr>
<td>J358</td>
<td>Ustekinumab, for intravenous injection, 1 mg</td>
</tr>
<tr>
<td>J380</td>
<td>Injection, vedolizumab, 1 mg</td>
</tr>
<tr>
<td>Q5103</td>
<td>Injection, infliximab-dyyb, biosimilar, (Inflixtra), 10 mg</td>
</tr>
<tr>
<td>Q5104</td>
<td>Injection, infliximab-adba-biosimilar, (Renflexis), 10 mg</td>
</tr>
</tbody>
</table>

Note: Medical billing codes may not be used for Actemra, Orencia, Simponi, or Stelara injections for subcutaneous use. These formulations must be obtained via the Member’s pharmacy benefit.

REFERENCES


73. Hunder GG. Treatment of giant cell (temporal) arteritis. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on September 7, 2018).


189. Ungprasert P, Thongprayoon C, Davis JM 3rd. Indirect comparisons of the efficacy of biological agents in patients with psoriatic arthritis with an inadequate response to traditional disease-


### APPROVAL HISTORY

May 8, 2007: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. May 13, 2008: No changes
2. May 12, 2009: No changes
3. January 1, 2010: Removal of Tufts Health Plan Medicare Preferred language (separate criteria have been created specifically for Tufts Health Plan Medicare Preferred)
4. May 11, 2010: Added note for the diagnosis of chronic plaque psoriasis to refer to the Injectable Drugs for the Treatment of Psoriasis Pharmacy Medical Necessity Guidelines
5. May 10, 2011: No changes
8. October 15, 2013: No changes.
9. October 7, 2014: Changed age limit for polyarticular juvenile idiopathic arthritis from 4 years of age and older to 2 years of age and older.
10. December 9, 2014: Added coverage of Humira 10 mg strength and Humira Pediatric Crohn's Disease Starter Package to Limitations section.
13. February 9, 2016: Updated quantity limitation for the indication of hidradenitis suppurativa.
14. September 13, 2016: Clarified that members who are already stable on Humira upon initial authorization will not receive authorization for a loading dose. Added pharmacy coverage guidelines and quantity limitations for the treatment of uveitis. Added exception language for Members new to the plan and stable on Humira prior to enrollment. Changed failure of intolerance to Remicade to trial and failure of another biological agent for Crohn’s disease and ulcerative colitis. Added trial and failure with another biological agent indicated for the same condition.
17. November 14, 2017: Administrative update adding a limitation to clarify that for plaque psoriasis, inconvenience does not qualify as a contraindication to phototherapy.
18. April 10, 2018: Effective 6/12/18, added the limitation that documentation of a Member being a social drinker does not qualify as a medically acceptable contraindication or clinically inappropriateness to methotrexate therapy.
19. September 18, 2018: Effective January 1, 2019, created therapeutic class Medical Necessity Guideline and changed name of Medical Necessity Guideline from “Humira (adalimumab)” to “Anti-inflammatory Conditions.” Non-biologic prerequisite requirements removed for all non-preferred products. Updated stability language for non-preferred products to “The Member is new to the plan and stable on the requested product and the prescribing physician has documented that changing to the preferred product(s) would result in adverse clinical outcomes.” The Criteria for Orencia IV for polyarticular juvenile idiopathic arthritis was updated to no longer require a trial and failure on both Humira and Enbrel. Criteria for available first-line biologic medications for polyarticular juvenile idiopathic arthritis was made consistent across the pharmacy and medical benefit. Removed the following two limitations: “Entyvio (vedolizumab) will not be approved if administered concomitantly with a tumor necrosis factor antagonist or Tysabri (natalizumab)” and “Orencia will not be approved if administered concomitantly with another tumor necrosis factor antagonist or Kineret (anakinra).” Added Xeljanz to the Limitation allowing for an initial 8 week authorization for the treatment of ulcerative colitis. Removed age requirements for all drugs indicated for the following indications: ankylosing spondylitis, rheumatoid arthritis, psoriatic arthritis, hidradenitis suppurativa, uveitis, and systemic juvenile idiopathic arthritis. Added FDA label supported age requirements for all drugs indicated for the following indications: plaque psoriasis, polyarticular juvenile idiopathic arthritis, ulcerative colitis, and Crohn’s disease. Added coverage criteria for cytokine release syndrome for Actemra intravenous injection.
20. October 16, 2018: Effective January 1, 2019, added Actemra subcutaneous injection to the approval criteria for systemic juvenile idiopathic arthritis and added Olumiant to the medical necessity guideline.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member’s health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.