

**PHARMACY PRIOR AUTHORIZATION
Clinical Guideline – Anti-TNF AGENTS**

**Cimzia[®] (certolizumab)
Enbrel[®] (etanercept)**

**Humira[®] (adalimumab)
Remicade[®] (infliximab)**

Simponi[®] (golimumab)

Authorization Guidelines:

General Criteria for All Medications and All Indications:

- Patient is NOT on another biological DMARD or other anti-TNF agent
- Patient does NOT have NYHA class III or IV CHF
- Patient does NOT have untreated chronic hepatitis B
- Patient does NOT have treated chronic hepatitis B with Child-Pugh class B and C
- Patient does NOT have acute Hepatitis C infection
- Patient does NOT have chronic hepatitis C infection with severe liver disease Child Pugh Class B or C (Enbrel may be considered cautiously)
- Prescribed by an appropriate specialist based on indication
- Patient is up to date with all recommended vaccinations
- Patient has been screened for latent TB and hepatitis B
- Request is for a formulary preferred agent. Requests for non-preferred anti-TNF's require trial and failure of TWO formulary anti-TNF's in addition to all other criteria.

Additional Criteria for Rheumatoid Arthritis (RA): (Enbrel, Humira, Cimzia, Remicade, Simponi)

- Patient is at least 18 years old
- Patient meets ONE of the following:
 - Diagnosed with Early RA (defined as disease duration < 6 months) AND has high disease activity and poor prognostic factors (i.e., functional limitation, extra-articular disease, positive rheumatoid factor or anti-cyclic citrullinated peptide antibodies or bony erosions by radiograph)
 - Diagnosed with Established RA (defined as disease duration > 6 months) AND has moderate or high disease activity despite an adequate 3-month trial of 2 different non-biologic DMARD regimens (1 of which must include methotrexate (MTX) unless contraindicated)
 - Monotherapy: MTX, sulfasalazine (SSZ), or leflunomide (LEF)
 - Combination: MTX+SSZ+hydroxychloroquine (HCQ), MTX+HCQ, MTX+LEF, MTX+SSZ, SSZ+HCQ
- NOTE: Patient should be continued on an oral DMARD when anti-TNF is initiated unless significant side effects limit use

Additional Criteria for Systemic Juvenile Idiopathic Arthritis: (Enbrel, Humira)

- Patient is at least 2 years old
- Patient 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 MTX or leflunomide
- NOTE: anti-TNF's are not as effective for systemic features and are not commonly used for that phenotype of systemic JIA.

Additional Criteria for Polyarticular Juvenile Idiopathic Arthritis: (Enbrel, Humira)

- Patient is at least 2 years old
- Prescribed by a rheumatologist
- Patient has severe disease OR moderate to severe disease despite an adequate 3-month trial of MTX

Additional Criteria for Oligoarticular Juvenile Idiopathic Arthritis: (Enbrel, Humira)

- NOTE: anti-TNF's are not the standard of therapy for most patients as this is usually a self-limiting condition that rarely becomes chronic
- Patient is at least 2 years old
- Prescribed by a rheumatologist
- Patient has extended oligoarticular JIA (defined as disease duration > 6 months)
- Failed therapy with 2 NSAIDs
- Failed an adequate 3-month trial of MTX

Additional Criteria for Ankylosing Spondylitis (AS): (Enbrel, Humira, Cimzia, Remicade, Simponi)

- Patient is at least 18 years old
- Patient is currently on an NSAID and will be continued when anti-TNF is initiated OR has a contraindication to NSAID use
- Patient meets ONE of the following:
 - Has peripheral arthritis AND high disease activity despite a 3-month trial of adequately dosed sulfasalazine
 - Has predominantly axial disease AND high disease activity despite a 3-month trial of TWO different NSAIDs at an adequate dose OR has a contraindication to NSAID use

Additional Criteria for Psoriatic Arthritis (PsA): (Enbrel, Humira, Cimzia, Remicade, Simponi)

- Patient is at least 18 years old
- Patient is currently on an NSAID and will be continued when anti-TNF is initiated OR has a contraindication to NSAID use
- Patient meets ONE of the following:
 - Has active PsA despite a 3-month trial of adequate dose MTX (or leflunomide or sulfasalazine if MTX is contraindicated)
 - Patient has predominantly axial disease AND active PsA despite a 3-month trial of TWO different NSAIDs at an adequate dose OR has a contraindication to NSAID use

Additional Criteria for Plaque Psoriasis: (Enbrel, Humira, Remicade)

- Patient is at least 18 years old
- Symptoms are not controlled with topical therapy
- Disease has a significant impact on physical, psychological or social wellbeing
- Patient has failed a 3-month compliant trial with MTX or cyclosporine or has a true contraindication to both
- Psoriasis is severe and extensive (for example, more than 10% of body surface area affected or a PASI score of more than 10)
- Phototherapy has been ineffective, cannot be used or has resulted in rapid relapse (rapid relapse is defined as greater than 50% of baseline disease severity within 3 months)

Additional Criteria for Ulcerative Colitis (UC): (Humira, Remicade, Simponi)

- Age restriction (Humira and Simponi): At least 18 years old
- Age restriction (Remicade): At least 6 years old

STEROID-DEPENDENT UC:

- Patient meets ONE of the following:
 - Relapse occurs within three months of stopping glucocorticoids
 - ADULTS: Glucocorticoids cannot be tapered to <10 mg/day within three months without symptom recurrence
 - CHILDREN/ADOLESCENTS: Patient requires prednisone ≥ 10 mg/day for ≥ 3 months OR daily low dose prednisone for ≥ 4 months to prevent symptom recurrence
- Patient has failed a compliant, 3-month trial of ONE of the following:
 - 6-mercaptopurine(6-MP) or azathioprine (AZA)
 - Sulfasalazine ≥ 4 g per day, mesalamine 4.8g per day, or balsalazide 6.75g per day (for patients with a contraindication to 6-MP and AZA)

STEROID-REFRACTORY UC:

- Inadequate response to IV glucocorticoids within 7-10 days (NOTE: it is recommended to switch to IV glucocorticoids for patients who are not responding to oral glucocorticoids)
- Patient meets ONE of the following:
 - Patient had a previous failure on 6-MP and AZA or a contraindication to both medications and is therefore not a candidate for treatment with these agents for current episode
 - Patient has symptoms after surgical intervention
 - Patient had an inadequate response to cyclosporine AND Patient is not a surgical candidate or refuses surgery (NOTE: Switching to anti-TNF's after cyclosporine failure is NOT recommended by clinical practice guidelines, therefore surgery is the best option)
 - Patient has a contraindication to cyclosporine (NOTE: cyclosporine is used as a bridge therapy for patients who will be started on the slower acting 6-MP or AZA)

Additional Criteria for Crohn's: (Humira, Remicade, Cimzia)

- Age restriction (Cimzia): At least 18 years old
- Age restriction (Remicade and Humira): At least 6 years old

STEROID-DEPENDENT CROHN'S:

- Patient meets ONE of the following:
 - Relapse occurs within three months of stopping glucocorticoids
 - ADULTS: Glucocorticoids cannot be tapered to <10 mg/day within three months without symptom recurrence
 - CHILDREN/ADOLESCENTS: Patient requires prednisone ≥ 10 mg/day for ≥ 3 months OR daily low dose prednisone for ≥ 4 months to prevent symptom recurrence
- Patient has failed a compliant, 3-month trial of ONE of the following:
 - 6-MP or AZA
 - Injectable MTX (for patients with a contraindication to 6-MP and AZA)

STEROID-REFRACTORY CROHN'S:

- Inadequate response to IV glucocorticoids within 7-10 days (NOTE: it is recommended to switch to IV glucocorticoids for patients who are not responding to oral glucocorticoids)

Additional Criteria for Hidradenitis Suppurative (acne inversa): (Humira)

- Patient is at least 18 years old
- Patient has ≥ 3 abscesses or inflammatory nodules
- Patient meets ONE of the following:
 - Has severe disease (Hurley stage III)
 - Has moderate disease (Hurley state II) despite treatment with an oral formulary tetracycline (i.e., doxycycline)

Initial Approval:

- 4 months

Renewal:

- Indefinite
- UC and Crohn's: Patient should be in remission without need for daily prednisone >5 mg per day
- RA, JIA, AS, PsA: At least 20% symptom improvement
- Psoriasis: At least 20% improvement. Enbrel dose should be reduced to 50mcg per week
- Hidradenitis: At least 20% symptom improvement

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3. Cimzia (certolizumab) [package insert]. Smyrna, GA; UCB Inc; Revised October 2013.
4. Remicade (infliximab) [package insert]. Horsham, PA; Janssen Biotech Inc; Revised September 2015.
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