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 ≥4g 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 stage 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

References:
2. Humira (adalimumab) [package insert]. North Chicago, IL; AbbVie Inc; Revised September 2015.
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.
13. National Institute for Health and Clinical Excellence (NICE). Infliximab, adalimumab and golimumab for treating moderately to severely active ulcerative colitis after the failure of conventional therapy (including a review of TA140


