



**PHARMACY PRIOR AUTHORIZATION  
Clinical Guideline  
Tumor Necrosis Factor (TNF) Inhibitor  
Humira® (adalimumab)**

### FDA Indications

- **Ankylosing spondylitis:** May be used alone or in combination with DMARDs
- **Crohn's Disease:**
  - For reducing the signs and symptoms and inducing and maintaining clinical remission of moderate to severe Crohn's disease in patients who have had an inadequate response to conventional therapy, or
  - For reducing the signs and symptoms and inducing clinical remission in these patients if they have also lost response to or are intolerant to infliximab.
- **Plaque psoriasis**
- **Psoriatic arthritis:** May be used alone or in combination with DMARDs.
- **Rheumatoid arthritis (RA):** May be used in combination with methotrexate (MTX) or other DMARDs
- **Polyarticular-course juvenile idiopathic rheumatoid arthritis (JIA):** in patients 4 yrs of age and older. May be used alone or in combination with methotrexate

### Dosage Forms

40 mg/0.8 mL in single-use prefilled pen  
 40 mg/0.8 mL in single-use prefilled glass syringe  
 40mg/0.8ml Crohns Disease Starter Package Prefilled Pen Kit  
 40mg/0.8ml Psoriasis Starter Package Prefilled Pen Kit  
 20 mg/0.4 mL in a single-dose prefilled glass syringe (Pediatric)

### Dosage

- **Ankylosing spondylitis (adults):** 40 mg SC every other week
- **Crohn's Disease (adults):** 160 mg SC initially at week 0, 80 mg at week 2, followed by a maintenance dose of 40 mg SC every other week beginning at week 4. Initial dose may be given as 4 injections on 1 day, or divided over 2 days.
- **Plaque Psoriasis (adults):** 80 mg SC initial dose, followed by 40 mg SC every other week starting one week after initial dose.
- **Psoriatic Arthritis (adults):** 40 mg SC every other week
- **RA (adults):** 40 mg SC every other week. Some patients with RA not receiving MTX may benefit from increasing the frequency to 40 mg SC every week.
- **JIA (children ≥ 4 years):** 15 kg (33 lbs) to <30 kg (66 lbs): 20 mg SC every other week; >30 kg (66 lbs): 40 mg SC every other week

### Authorization Guidelines

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines to assess the medical necessity of the request for a prescription for Humira. If the guidelines are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the

**recipient.**

**For patients who meet all of the following:**

- **Medical records to support medication will be administered in provider's office. Self-administered injectables are available through the Delaware Medicaid pharmacy benefit. Members should be directed to Delaware retail pharmacies with prescriptions to obtain these drugs.**
- No hypersensitivity to adalimumab or any of its components
- No evidence of malignancy within the last 5 years per medical records
- No evidence of sepsis per medical records
- No active infections as documented in medical records for patients with a history of recurrent infections or an underlying condition that may predispose them to infections (i.e., advanced or uncontrolled diabetes mellitus, malignancy, immunosuppression [including long term corticosteroid therapy])
- No active or latent tuberculosis infection per medical records
- Not concurrently receiving live vaccines, other TNF-inhibitors or Kineret
- If under 21 years of age, is up to date on immunizations in accordance with current Early and Periodic Screening Diagnosis and Treatment (EPSDT) immunization guidelines prior to initiating therapy

**In Addition:**

**For treatment of ankylosing spondylitis in adults:**

- Medical records documenting diagnosis **AND**
- Trial and failure of two different formulary NSAIDs within the last 60 days **OR**
- Documented contraindication or intolerance to NSAIDs

**For patients with documented diagnosis of moderate to severe active Crohn's Disease in adults who meet all of the following:**

- Trial and failure of a compliant regimen of oral corticosteroids (moderate to severe CD) or intravenous corticosteroids (severe and fulminant CD) for at least one month (or documented contraindication or intolerance to corticosteroids); **AND**
- Trial and failure of a compliant regimen of azathioprine or mercaptopurine for at least 3 consecutive months (or documented contraindication or intolerance to azathioprine and mercaptopurine) **AND**
- Trial and failure of a compliant regimen of parenteral methotrexate for at least 3 consecutive months (or documented contraindication or intolerance to parenteral methotrexate).

**For treatment of chronic moderate to severe plaque psoriasis in adults:**

- Medical records document a diagnosis of plaque psoriasis with at least 10% body surface area (BSA) affected, **OR** involvement of < 10% in critical areas (palms, soles, genitals or face) that interferes with daily activities; **AND**
- Trial and failure of UVB therapy or documentation showing contraindication to therapy; **AND**
- Trial and failure of a compliant regimen of methotrexate for at least 3 consecutive months **OR** documentation showing contraindication to therapy

**For treatment of diagnosis of moderate to severe psoriatic arthritis in adults:**

- Medical records document a diagnosis of moderate to severe psoriatic arthritis **AND**
- Trial and failure of a compliant regimen of at least two DMARDs (i.e., methotrexate, sulfasalazine,

leflunomide) one of which should be methotrexate for at least 3 consecutive months, **OR** documentation showing contraindication to therapy

**For treatment of moderate to severe RA in adults:**

- 18 years of age, or older **AND**
- Trial and failure of a compliant regimen of one DMARD in combination with methotrexate for at least 3 consecutive months: sulfasalazine, leflunomide, or hydroxychloroquine + methotrexate (unless methotrexate is contraindicated) **OR**
- Trial and failure of a compliant regimen of 2 DMARDs as sequential monotherapy (i.e., methotrexate, sulfasalazine, hydroxychloroquine, leflunomide) one of which should be methotrexate for at least 3 consecutive months (unless methotrexate is contraindicated) **OR**
- Documented intolerance to methotrexate or other DMARDs (for any length of time)

**For treatment of JIA:**

- Age ≥4 years of age **AND**
- Medical records documenting diagnosis **AND**
- Trial and failure of a compliant regimen (3 consecutive months) of methotrexate

**Prior Authorization Requirements**

**Initial Approval**

**6 months**

**Renewal**

- **1 year**
- **Medical records supporting response to therapy**

**Additional Information**

**Black Box Warning:**

**SERIOUS INFECTIONS**

- Increased risk of serious infections leading to hospitalization or death, including tuberculosis (TB), bacterial sepsis, invasive fungal infections (such as histoplasmosis), and infections due to other opportunistic pathogens.
- Humira should be discontinued if a patient develops a serious infection or sepsis during treatment.
- Perform test for latent TB; if positive, start treatment for TB prior to starting Humira.
- Monitor all patients for active TB during treatment, even if initial latent TB test is negative.

**MALIGNANCIES**

- Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, including Humira.

**Table 1. Live Vaccines**

BCG VACCINE, LIVE  
 INFLUENZA VIRUS VACCINE LIVE, INTRANASAL  
 MEASLES, MUMPS AND RUBELLA VIRUS VACCINE, LIVE  
 MEASLES, MUMPS, RUBELLA, AND VARICELLA VIRUS VACCINE, LIVE, ATTENUATED  
 ROTAVIRUS VACCINE, LIVE, ORAL  
 TYPHOID VACCINE, LIVE, ORAL  
 VARICELLA VIRUS VACCINE, LIVE  
 YELLOW FEVER VACCINE, LIVE  
 ZOSTER VACCINE, LIVE

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