HUMIRA® UTILIZATION MANAGEMENT CRITERIA

**DRUG CLASS:** Disease Modifying Anti-Rheumatic Drug (DMARD)  
- Tumor Necrosis Factor (TNF) Inhibitor

**DRUG NAME:** Humira (adalimumab injection)
Humira is supplied as:  
- 40 mg (0.8 ml) in pre-filled pens  
- 40 mg (0.8 ml) and 20 mg (0.4 ml) in pre-filled single-use glass syringes

**FDA INDICATIONS:**

**Rheumatoid Arthritis:**
Reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage and improving physical function in adult patients with moderately to severely active rheumatoid arthritis (RA). Humira can be used alone or in combination with methotrexate or other DMARDs.

**Juvenile Idiopathic Arthritis:**
Reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (JIA) in children 4 years of age and older. Humira can be used alone or in combination with methotrexate.

**Plaque Psoriasis:**
Treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate.

**Psoriatic Arthritis:**
Reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage and improving physical function. Humira can be used alone or in combination with DMARDs.

**Ankylosing Spondylitis:**
Reducing signs and symptoms in patients with active Ankylosing Spondylitis.

**Crohn’s Disease:** Reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn’s disease who have had inadequate response to conventional therapy.

**BENEFIT DESIGN:**

**Rheumatoid, Psoriatic Arthritis, Juvenile Idiopathic Arthritis:** Coverage is provided immediately (without initiating a coverage review) for the treatment of rheumatoid arthritis and psoriatic arthritis in the presence of a prescription within the previous 18 months for any of the following disease-modifying anti-rheumatic drugs (DMARDs):

- Methotrexate
- Leflunomide (Arava)
- Etanercept (Enbrel)
- Adalimumab (Humira)
- Anakinra (Kineret)

In situations where none of the above DMARDs exist in history or where the above does not apply, coverage for Humira is determined through the coverage authorization criteria.
Plaque Psoriasis (chronic moderate to severe): Coverage is provided immediately (without initiating a coverage review) for the treatment of plaque psoriasis in the presence of a prescription within the previous 18 months for any of the following drugs and if the prescribing physician is a dermatologist:
- Methoxsalen (Oxsoralen)
- Methotrexate
- Cyclosporine
- Acitretin (Soriatane)
- Etanercept (Enbrel)
- Adalimumab (Humira)
In situations where the above does not apply, coverage for Humira is determined through the coverage authorization criteria.

Crohn’s Disease, Ankylosing Spondylitis: Coverage determined through coverage authorization criteria.

COVERAGE AUTHORIZATION CRITERIA:
Coverage is provided for the treatment of rheumatoid arthritis, psoriatic arthritis, or juvenile idiopathic arthritis if one of the following bullets applies:
- Patient has experienced a therapeutic failure or has had an inadequate response to methotrexate, OR
- Patient is unable to receive methotrexate (e.g., use of methotrexate is contraindicated in the patient), OR
- Rheumatoid arthritis is newly diagnosed or rapidly progressive and advancing, AND
- The prescriber has considered and screened for the presence of latent tuberculosis (TB) infection.
- Coverage is not provided for use of once-weekly doses of Humira in combination with methotrexate.
- Coverage is not provided for use of Humira in combination with other biologics such as Kineret, Enbrel, Cimzia, Simponi, Orencia, Stelara or Remicade.

Coverage is provided for the treatment of plaque psoriasis if the following applies:
- Patient is being managed by a dermatologist, AND
- Body Surface Area (BSA) involvement of at least 5%, AND
- Involvement of the palms, soles, head and neck, or genitalia, causing disruption in normal daily activities and/or employment, AND
- Failure of systemic therapy (methotrexate, cyclosporine, Soriatane) or patient has contraindication to these treatments.
- The prescriber has considered and screened for the presence of latent tuberculosis (TB) infection.

Coverage is provided for Crohn’s Disease if:
- Patient has moderately to severely active Crohn’s Disease,
- Patient has had inadequate response to conventional therapy, AND
- The prescriber has considered and screened for the presence of latent tuberculosis (TB) infection.

Coverage is provided for active ankylosing spondylitis if:
- The prescriber has considered and screened for the presence of latent tuberculosis (TB)
BLACK BOX WARNINGS:

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, of which Humira is a member.

DOSAGE AND ADMINISTRATION:

Rheumatoid arthritis, psoriatic arthritis, or ankylosing spondylitis in adults: 40 mg of Humira is given by subcutaneous injection every other week. Some patients with RA not receiving methotrexate may benefit from from increasing the dosing frequency of Humira to 40 mg every week.

Juvenile Idiopathic Arthritis: The recommended dose of Humira for patients 4 to 17 years of age with polyarticular juvenile idiopathic arthritis is based on weight.
- 15 kg (33 lbs) to < 30 kg (66 lbs): 20 mg every other week
- ≥ 30 kg (66 lbs): 40 mg every other week
*Limited data are available for Humira treatment in pediatric patients with a weight below 15 kg.

Plaque Psoriasis: The recommended dose of Humira for adult patients with plaque psoriasis is an initial dose of 80 mg, followed by 40 mg given every other week starting one week after the initial dose.

Crohn’s Disease in adults: 160 mg initially on Day 1 (given as four 40 mg injections in one day, or as two 40 mg injections per day for two consecutive days), followed by 80 mg two weeks later (Day 15). Two weeks later (Day 29) begin a maintenance dose of 40 mg every other week. Aminosalicylates, corticosteroids, and/or immunomodulatory agents (e.g., 6-mercaptopurine or azathioprine) may be continued during treatment with Humira.

WARNINGS AND PRECAUTIONS:
- Serious infections – do not start Humira during an active infection. If an infection develops, monitor carefully, and stop Humira if infection becomes serious.
- Malignancies – are seen more often than in controls, and lymphoma is seen more often than in the general population.
- Anaphylaxis or serious allergic reactions may occur.
- Hepatitis B virus reactivation – monitor HBV carriers during and several months after therapy. If reactivation occurs, stop Humira and begin anti-viral therapy.
- Demyelinating disease, exacerbation or new onset, may occur.
- Cytopenias, pancytopenia – advise patients to seek immediate medical attention if symptoms develop, and consider stopping Humira.
- Heart failure, worsening or new onset, may occur.
- Lupus-like syndrome – stop Humira if syndrome develops.

REFERENCE: