

ADALIMUMAB (Humira®) UTILIZATION MANAGEMENT CRITERIA

DRUG CLASS:	Disease Modifying Anti-Rheumatic Drug (DMARD) - Tumor Necrosis Factor (TNF) Inhibitor
DRUG NAME:	Humira (adalimumab injection) - 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-APPROVED INDICATIONS:

Rheumatoid Arthritis (RA):

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).

Juvenile Idiopathic Arthritis (JIA):

Reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (JIA) in children 4 years of age and older.

Plaque Psoriasis (Ps):

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 (PsA):

Reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage and improving physical function.

Ankylosing Spondylitis (AS):

Reducing signs and symptoms in patients with active Ankylosing Spondylitis.

Crohn's Disease (CD): 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[®], Oencia[®], 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, **AND**
- Patient has had inadequate response to conventional therapy (e.g., corticosteroid, 5-aminosalicylate, azathioprine, 6-mercaptopurine, metronidazole, methotrexate), **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)

QUANTITY LIMITATIONS (effective 10/1/11)

The allowed quantity for maintenance doses of Humira is two 40 mg injections every 28 days. This corresponds to maintenance doses of 40 mg every other week. (Maintenance quantity limits will not take effect until 30 days after initiation of therapy.)

For patients with rheumatoid arthritis who are not taking concurrent methotrexate, four 40 mg injections every 28 days are allowed.

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.

MALIGNANCY

- Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, of which Humira is a member.
- Post-marketing cases of hepatosplenic T-cell lymphoma (HSTCL), a rare type of T-cell lymphoma, have occurred in adolescent and young adults with inflammatory bowel disease treated with TNF blockers including Humira.

DOSAGE AND ADMINISTRATION:

Humira is administered by subcutaneous injection.

Rheumatoid Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis

- 40 mg every other week. Some patients with RA not receiving methotrexate may benefit from increasing the frequency to 40 mg every week.

Juvenile Idiopathic Arthritis

- 15 kg (33 lbs) to <30 kg (66 lbs): 20 mg every other week
- ≥30 kg (66 lbs): 40 mg every other week

Crohn's Disease

- Initial dose (Day 1) is 160 mg (four 40 mg injections in one day or 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 and/or corticosteroids may be continued during treatment with Humira. Azathioprine, 6-mercaptopurine (6-MP) or MTX may be continued during treatment with Humira if necessary.

Plaque Psoriasis

- 80 mg initial dose, followed by 40 mg every other week starting one week after initial dose.

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.
- Invasive fungal infections – For patients who develop a systemic illness on Humira, consider empiric antifungal therapy for those who reside or travel to regions where mycoses are endemic.
- Malignancies – The incidence of malignancies was greater in Humira treated patients than in controls.
- 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 antiviral 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:

Humira (adalimumab). Product Information. Abbott Laboratories. March 2011.