



PRIOR AUTHORIZATION CRITERIA

Generic/Brand: **Adalimumab (HUMIRA) Injection**
Therapeutic Class: Rheumatoid Immunosuppressant

CRITERIA FOR APPROVAL:

Indications:

Rheumatoid arthritis (RA): For reducing signs and symptoms and inhibiting the progression of structural damage in adult patients with moderately to severely active RA who have had an inadequate response to one or more disease-modifying antirheumatic drugs (DMARDs). Adalimumab can be used alone or in combination with methotrexate (MTX) or other DMARDs.

Humira is indicated to reduce the symptoms of active arthritis in patients with psoriatic arthritis. Humira can be used alone or in combination with DMARDs.

There are no recognized off label uses at this time.

DMARD class medications include:

- Methotrexate
- Sulfasalazine
- Azathioprine
- Hydroxychloroquine
- Penicillamine

Dose:

The recommended dose for adult patients with RA is 40 mg administered every other week as an SC injection. MTX, glucocorticoids, salicylates, nonsteroidal anti-inflammatory drugs (NSAIDs), analgesics, or other DMARDs may be continued during treatment with adalimumab. Some patients not taking concomitant MTX may derive additional benefit from increasing the dosing frequency of adalimumab to 40 mg every week. (see quantity limitation reference below).

The recommended dose of Humira for psoriatic arthritis is 40 mg every other week by subcutaneous injection.

Requirements:

1. Member must be diagnosed with moderate to severe Rheumatoid Arthritis or Psoriatic Arthritis.
2. Prescription must be written by a rheumatologist.
3. Safety and efficacy of this medication has not been established in children. Therefore, member must be at least 18 years of age.
4. For the treatment of rheumatoid Arthritis, the member should have had a previous 6 month trial of at least one disease modifying antirheumatic drug (DMARD) or present with a medical contraindication to the use of these agents.

Quantity Limitation:

Dosing for Humira will be limited to two (40mg) doses per 28 days. Approval for four (40mg) doses per 28 days may be granted for members who:

- Demonstrate treatment failure with at least a twelve week trial of Humira dosed every 14 days in combination with methotrexate **or**
- Demonstrate treatment failure with at least a twelve week trial of Humira dosed every 14 days and have a medical contraindication to the use of methotrexate

LENGTH OF APPROVAL:

As requested by physician up to 6 months.

RENEWAL OF PA:

Continued approval will be based on documentation relating to the patient's clinical response to therapy.

REFERENCES:

Clinical Pharmacology, Adalimumab, Humira, accessed on October 5, 2005.

URL:<http://cp.gsm.com>. Gold Standard.

Humira packet insert, <http://www.rxabbott.com/pdf/humira.pdf>