PHARMACY PRIOR AUTHORIZATION
Clinical Guideline
Humira® (adalimumab)

FDA Indications

- **Ankylosing spondylitis:** for reducing signs and symptoms in patients with active ankylosing spondylitis.
- **Crohn’s Disease:** for reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn’s disease who have had an inadequate response to conventional therapy. Humira is indicated for reducing signs and symptoms and inducing clinical remission in these patients if they have also lost response to or are intolerant to Remicade® (infliximab).
- **Psoriatic arthritis:** for reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving the physical function in patients with psoriatic arthritis. Humira can be used alone or in combination with DMARDs.
- **Rheumatoid arthritis (RA):** for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis. Humira can be used alone or in combination with methotrexate (MTX) or other DMARDs.
- **Juvenile Rheumatoid Arthritis (JRA):** for reducing signs and symptoms of moderately to severely active polyarticular idiopathic juvenile rheumatoid arthritis in patients 4 years of age and older.
- **Plaque psoriasis:** for the 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.

Dosage Forms

- 40 mg/0.8 mL in single-use prefilled pen
- 40 mg/0.8 mL in single-use prefilled glass syringe
- 20 mg/0.4 mL in a single-dose prefilled glass syringe

Dosage

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

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:
- No hypersensitivity to adalimumab or any of its components
- No evidence of recent malignancy 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
- Concurrently not receiving live vaccines with adalimumab
- 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 with Humira
- Not planning to use any other TNF-inhibitors with Humira
- Not planning to use with Kineret
- Use for:
  - Treatment of ankylosing spondylitis for 18 years of age and older:
    - Trial and failure of a compliant regimen of two formulary NSAIDs within the last 60 days
    - OR
    - Documented contraindication or intolerance to NSAIDs
  - Treatment of moderate to severe psoriatic arthritis for 18 years of age and older:
    - Trial and failure of a compliant regimen of at least two DMARDs (i.e., sulfasalazine, leflunomide) one of which should be methotrexate for at least three months
    - OR
    - Documented contraindication or intolerance to methotrexate or other DMARDs
  - Treatment of polyarticular-course JRA for 4 years of age and older:
    - Medical records documenting diagnosis
  - Treatment of moderate-severe RA for 18 years of age and older:
    - Trial and failure of a compliant regimen of one DMARD in combination with methotrexate for at least three 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., sulfasalazine or leflunomide) one of which should be methotrexate for at least three
• Treatment of moderate to severe active Crohn’s Disease for 18 years of age and older:
  ➢ Trial and failure of a compliant regimen of oral corticosteroids (moderate to severe CD) or intravenous corticosteroids (severe and fulminant CD or failure to respond to oral corticosteroids) for one month; OR
  ➢ Trial and failure of a compliant regimen of azathioprine or mercaptopurine for three consecutive months; AND
  ➢ Documented contraindication or intolerance to corticosteroids, azathioprine or mercaptopurine

• For patients with documented diagnosis of chronic moderate to severe plaque psoriasis who meet all of the following:
  ➢ Has a body surface area (BSA) of 10% or more that is 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 three consecutive months or documentation showing contraindication to therapy

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### Prior Authorization Requirements

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### Additional Information

- Table 1. Live Vaccines

### References

**Primary Reference Policy**
7100.07 Pharmacy Prior Authorization

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