Approval Criteria Department of Pharmacy Services

Generic Name: adalimumab

Brand Name: Humira®

Medication Class: TNF Inhibitor

FDA Approved Uses
- Ankylosing spondylitis – for reducing signs and symptoms in patients with active ankylosing spondylitis
- Crohn disease – for reducing signs and symptoms, as well as inducing and maintaining clinical remission, in adults with moderately to severely active Crohn disease who have had an inadequate response to conventional therapy; for reducing signs and symptoms, as well as inducing clinical remission, in these patients if they have also lost response to or are intolerant to infliximab
- Plaque psoriasis – for the treatment of adults with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate
- Polyarticular juvenile idiopathic arthritis – for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients 4 years and older
- Psoriatic arthritis – for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adults with active psoriatic arthritis, alone or in combination with non-biologic disease-modifying antirheumatic drugs (DMARDs)
- Rheumatoid arthritis – for reducing the 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 (RA). Etanercept can be initiated in combination with methotrexate or used alone
- Ulcerative colitis – for inducing and sustaining clinical remission in adults with moderately to severely active ulcerative colitis who have had an inadequate response to immunosuppressants such as corticosteroids, azathioprine, or 6-mercaptopyrurine.

Criteria for use
- Rheumatoid Arthritis (RA)
  o Must be 18 years of age or older
  o Clinical diagnosis of moderately to severely active RA
  o Trial and failure, or contraindication to, one or more non-biologic disease modifying antirheumatic agent (DMARDs) [azathioprine, 6-mercaptopurine, methotrexate]
- Plaque psoriasis
  o Must be 18 years of age or older
  o Clinical diagnosis of chronic moderate to severe plaque psoriasis with EITHER of the following:
    • Plaque psoriasis involving greater than 5% of body surface area (BSA)
    • Plaque psoriasis involving less than 5% of BSA involving sensitive areas or areas that would significantly impact daily function (palms, soles of feet, head/neck, or genitalia)
  o Trial and failure, or contraindication to, phototherapy or other systemic therapies (methotrexate, acitretin, or cyclosporine)
- Ankylosing spondylitis
  - Must be 18 years of age or older
  - Clinical diagnosis of active Ankylosing spondylitis
  - Trial and failure, or contraindication to, conventional therapy (NSAIDs or non-biologic DMARDs)

- Juvenile idiopathic arthritis
  - Age 4 and older
  - Clinical diagnosis of moderate to severely active polyarticular juvenile idiopathic arthritis (JIA)
  - Trial and failure, intolerance to, or contraindication to, one or more non-biologic disease modifying anti-rheumatic agents (DMARDs)

- Psoriatic arthritis
  - Must be age 18 years and older
  - Clinical diagnosis of active psoriatic arthritis
  - Trial and failure to, intolerance to, or contraindication to one or more non-biologic DMARD

- Crohn’s disease
  - Must be age 18 years and older
  - Clinical diagnosis of moderately to severely active CD
  - Trial and failure of, intolerance to, or contraindication to conventional therapy (5-ASA products, sulfasalazine, systemic corticosteroids, or immunosuppressants, or other TNF antagonists (infliximab))

- Ulcerative colitis
  - Must be age 18 years and older
  - Clinically diagnosed with moderately to severely active UC
  - Trial and failure of, intolerance to, or contraindication to conventional therapy (5-ASA products, sulfasalazine, systemic corticosteroids, or immunosuppressive drugs)

Not Approved For
- Any indication or criteria not met above
- If used in combination with any other TNF agent
- If used in combination with the following non-TNF immunomodulatory drugs: abatacept or anakinra
- Tuberculosis, invasive fungal infection, other serious infection, or a history of recurrent infections
- Individuals who have not had a tuberculin skin test, or CDC-recommended equivalent, to evaluate for latent tuberculosis

Required Medical Information
- Clinical documentation of diagnosis (medical record)
- Clinical documentation of past medical history with dates of treatments and response to therapy
- Pharmacy claims history to support previous treatment

Contraindications
- Sepsis
- Active or latent tuberculosis

Dosing
- Ankylosing spondylitis
  - 40mg every other week subcutaneously

- Crohn’s disease
  - Initial – 160mg subcutaneously on day 1 (4 x 40mg injections) or 2 x 40mg injection for 2 consecutive days, followed by 80mg subcutaneously 2 weeks later
  - Maintenance – Two weeks later (day 29), begin maintenance dosage of 40mg subcutaneously every other week

- Plaque psoriasis
  - Initial - 80 mg subcutaneously
  - Maintenance – 40 mg subcutaneously every other week starting one week after initial dose
- Psoriatic arthritis
  - 40mg every other week subcutaneously
- Rheumatoid arthritis
  - 40mg every other week subcutaneously
  - May be increased to 40mg weekly in patients not taking methotrexate
- Ulcerative colitis
  - Initial – 160mg subcutaneously on day 1 (4 x 40mg injections) or 2 x 40mg injection for 2 consecutive days, followed by 80mg subcutaneously 2 weeks later
  - Maintenance – Two weeks later (day 29) continue with a dosage of 30mg subcutaneously every other week
  - Duration of therapy – Discontinue after 8 weeks if no clinical improvement

Authorization
- RA / PA / JIA / AS
  - 1 year (2 injections / 28 days)
- Crohn’s disease / Ulcerative colitis
  - Initial – Crohn’s disease Starter pack (6 injections) one time only
  - Maintenance – 2 syringes every 30 days x 1 year

References

hap.org/midwest
HAP Midwest Health Plan is a wholly owned subsidiary of HAP.


