



Prior Authorization Approval Criteria
Department of Pharmacy Services

Generic Name: Infliximab

Brand Name: Remicade

FDA Approved Uses: Ankylosing spondylitis
Crohn's disease
Fistulizing Crohn's Disease
Plaque Psoriasis
Psoriatic Arthritis
Rheumatoid arthritis
Ulcerative Colitis

Usual Doses: **Ankylosing spondylitis:** induction, 5 mg/kg IV over 2 hr given at week 0, 2, and 6 maintenance, 5 mg/kg IV over 2 hr every 6 weeks
Crohn's disease: 5mg/kg infused at week 0, 2 and 6 and then every 8 weeks thereafter (the dose may be increased up to 10mg/kg for patients who do not respond)
Fistulizing Crohn's disease: 5mg/kg infused at 0, 2 and 6 weeks.
Plaque Psoriasis: 5mg/kg IV infusion, followed by additional doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter.
Psoriatic Arthritis: 5 mg/kg IV over 2 hr given at week 0, 2 and 6 then every 8 weeks; with or without methotrexate
Rheumatoid arthritis: 3mg/kg infused at week 0, 2 and 6 and then every 8 weeks thereafter. (The dose may be increased to 10mg/kg and infused every 4 weeks for patients who don't respond)
Ulcerative Colitis: 5mg/kg infused at week 0, 2 and 6 and then every 8 weeks thereafter.

Duration of Therapy: **Ankylosing spondylitis:** Indefinite
Crohn's disease: indefinite, unless the patient doesn't respond after 14 weeks it is recommended that Remicade treatment be discontinued.
Fistulizing Crohn's disease: safety and efficacy of therapy continued after 3 doses have not been established.
Plaque Psoriasis: Indefinite.
Psoriatic Arthritis: Indefinite
RA: indefinite
Ulcerative Colitis: indefinite, unless the patient doesn't respond after 14 weeks it is recommended that Remicade treatment be discontinued.



Criteria for Use: (bullet points below are all inclusive unless otherwise noted)

- Ankylosing Spondylitis
 - Clinically diagnosed ankylosing spondylitis.
 - Failed/ intolerant to Enbrel or Humira

- Crohn's Disease/Fistulizing Crohn's disease
 - Clinically diagnosed Crohn's disease.
 - Failed/Intolerant to Enbrel or Humira

- Plaque Psoriasis:
 - Clinically diagnosed plaque psoriasis.
 - Failed/ intolerant to Enbrel or Humira

- Psoriatic Arthritis:
 - Clinically diagnosed psoriatic arthritis.
 - Failed/ intolerant to Enbrel or Humira.

- Rheumatoid Arthritis:
 - Clinically diagnosed rheumatoid arthritis.
 - Failed/ intolerant to Enbrel or Humira.

- Ulcerative Colitis:
 - Clinically diagnosed ulcerative colitis
 - Failed/intolerant to mesalamine, corticosteroids

Contraindications:

- Moderate or severe (NYHA Class III/IV) congestive heart failure.
- Hypersensitivity to murine proteins or any other component of infliximab.

Not approved if:

- Patient has any contraindications to the use of infliximab.
- Infection is present at time of use.

Special considerations (drug interactions, lab tests, adverse effects, precautions ect.)

- Tuberculosis, invasive fungal infections, and other opportunistic infections have been observed in patients receiving Remicade. Some of which have been fatal.
- Patients should be evaluated for latent tuberculosis infection with a tuberculin skin test.
- Treatment of latent tuberculosis infection should be initiated prior to therapy with Remicade.



- Concomitant immunosuppressive therapy could predispose patients to serious infections including sepsis. Some of these infections that have been reported have been fatal.

P&T Approval: _____ Date: _____