



Prior Authorization Approval Criteria

Remicade (infliximab)

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:* 5 mg/kg IV over 2 hr given at weeks 0, 2, and 6 followed by a maintenance dose of 5 mg/kg IV over 2 hr every 6 weeks
Crohn's disease and fistulizing Crohn's disease: 5 mg/kg IV over 2 hr given at weeks 0, 2, and 6 followed by a maintenance dose of 5 mg/kg IV over 2 hr every 8 weeks. In patients who respond and subsequently lose response, the dose may be increased to 10 mg/kg.
Plaque psoriasis: 5 mg/kg IV over 2 hr given at weeks 0, 2, and 6 followed by a maintenance dose of 5 mg/kg IV over 2 hr every 8 weeks.
Psoriatic arthritis: 5 mg/kg IV over 2 hr given at weeks 0, 2, and 6 followed by a maintenance dose of 5 mg/kg IV over 2 hr every 8 weeks; with or without methotrexate
Rheumatoid arthritis: 3 mg/kg IV over 2 hr given at weeks 0, 2, and 6 followed by a maintenance dose of 3 mg/kg IV over 2 hr every 8 weeks. In patients experiencing an incomplete response, the dose may be increased up to 10 mg/kg OR 3 mg/kg IV may be administered every 4 weeks
Ulcerative colitis: 5 mg/kg IV over 2 hr given at weeks 0, 2, and 6 followed by a maintenance dose of 5 mg/kg IV over 2 hr every 8 weeks.

Cost (based on AWP 2009): (based on 5mg/kg at weeks 0, 2, 6, then every 8 weeks, 70kg patient): *Induction* (weeks 0, 2, and 6): \$1050;
Maintenance (every 8 weeks): \$2275/year

Duration of therapy: *Ankylosing spondylitis:* Indefinite
Crohn's disease and fistulizing Crohn's disease: indefinite, unless the patient doesn't respond after 14 weeks it is recommended that Remicade treatment be discontinued.
Plaque psoriasis: Indefinite.
Psoriatic arthritis: Indefinite
RA: indefinite
Ulcerative colitis: indefinite

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

- The indicated diagnosis (including any applicable labs and/or tests) and

medication usage must be supported by documentation from the patient's medical records.

- Note: Medication will be approved for FDA-approved dosing regimen as stated in "Usual Doses" section above. To meet the criteria for increased dose (for Crohn's disease, Fistulizing Crohn's disease, or Rheumatoid arthritis) or more frequent dosing (for Rheumatoid arthritis), patient must have tried and failed standard FDA-approved dosing and frequency as documented in the patient's medical records.
- Medical services must meet nationally recognized standard for quality care and are provided at the appropriate level of care and place of service. The first 3 doses may be given at the facility of choice by the physician, all subsequent doses will be given by home infusion. The following are some exceptions that may be acceptable for services outside the home:
 - Documented history of a severe reaction to Remicade. Severe reaction is defined as anaphylactic reaction. The patient should have a history of reactions and not be based on the potential of Remicade to induce such reactions.
 - Documented intolerance to Remicade requiring constant telemetry monitoring of vitals.
 - Unsafe home environment.
 - No access to 911 services.
 - Patient is severely decompensated e.g. respiratory failure in a myasthenic crisis.
- *Ankylosing spondylitis*
 - Clinically diagnosed ankylosing spondylitis.
 - Failed/ intolerant to at least one DMARD.
 - Failed/ intolerant to Methotrexate.
 - Failed/ intolerant to Enbrel and Humira.
- *Crohn's Disease/fistulizing Crohn's disease*
 - Clinically diagnosed Crohn's disease.
 - Failed/Intolerant to at least one corticosteroid.
 - Failed/Intolerant to at least of the following:
 - sulfasalazine (Azulfidine)
 - mesalazine (Asacol, Pentasa).
 - Failed/Intolerant to Humira.
 - Failed/Intolerant to at least one of the following:
 - azathioprine (Imuran)
 - 6-mercaptopurine (Purinethol)
 - methotrexate.
- *Plaque psoriasis:*
 - Clinically diagnosed plaque psoriasis.
 - Failed/ intolerant to corticosteroids.
 - Failed/ intolerant to Methotrexate.
 - Failed/ intolerant to Enbrel and Humira.
- *Psoriatic arthritis:*
 - Clinically diagnosed psoriatic arthritis.
 - Failed/ intolerant to corticosteroids.
 - Failed/ intolerant to Methotrexate.
 - Failed/ intolerant to Enbrel and Humira.
- *Rheumatoid arthritis:*

- Clinically diagnosed rheumatoid arthritis.
- Failed/ intolerant to at least one DMARD.
- Failed/ intolerant to Methotrexate.
- Failed/ intolerant to Enbrel and Humira.
- *Ulcerative colitis:*
 - Clinically diagnosed ulcerative colitis
 - Failed/intolerant to one aminosalicylate; oral mesalamine (Asacol, Pentasa), topical mesalamine (Rowasa enema, suppository and Canasa suppository), sulfasalazine (Azulfidine), olsalazine (Dipentum), or balsalazide (Colazal)
 - Failed/intolerant to corticosteroids
 - Failed/intolerant to azathioprine and mercaptopurine.

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 etc.)

- 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.
- Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, including REMICADE. (See WARNINGS, MALIGNANCY.)
- Postmarketing cases of hepatosplenic T-cell lymphoma, a rare type of T-cell lymphoma, have been reported in patients treated with TNF blockers including REMICADE. These cases have had a very aggressive disease course and have been fatal. All reported REMICADE cases have occurred in patients with Crohn's disease or ulcerative colitis and the majority were in adolescent and young adult males. All of these patients received treatment with azathioprine or 6-mercaptopurine concomitantly with REMICADE at or prior to diagnosis.

P&T Approval: _____ Date: _____

Approved: 11/18/04

Revised: 09/12/07, 06/2010, 12/08/2010, 03/14/12