Approval Criteria Department of Pharmacy Services

Generic Name: Infliximab

Brand Name: Remicade

Medication Class: Immunomodulator

FDA Approved Uses
- Ankylosing spondylitis
- Crohn’s disease
- Plaque psoriasis
- Psoriatic arthritis
- Rheumatoid arthritis
- Ulcerative colitis

Criteria for use
- Ankylosing spondylitis
  - Clinically diagnosed ankylosing spondylitis
  - Failed / intolerant to at least one DMARD
  - Failed / intolerant to methotrexate
  - Failed / intolerant to Enbrel
- Crohn’s disease
  - Clinically diagnosed Crohn’s disease
  - Failed / intolerant to at least one corticosteroid
  - Failed / intolerant to at least one of the following:
    - Sulfasalazine (Azulfidine)
    - Mesalamine (Asacol, Pentasa)
  - 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
- Psoriatic arthritis
  - Clinically diagnosed Psoriatic arthritis
  - Failed / intolerant to corticosteroids
  - Failed / intolerant to Methotrexate
  - Failed / intolerant to Enbrel
- Rheumatoid Arthritis
  - Clinically diagnosed rheumatoid arthritis
  - Failed / intolerant to at least one DMARD
  - Failed / intolerant to Methotrexate
  - Failed / intolerant to Enbrel or Humira if pt is < 65 years old
• Ulcerative colitis
  o Clinically diagnosed with ulcerative colitis
  o Failed / intolerant to one aminosalicylate; oral mesalamine (Asacol, Pentasa), topical mesalamine (Rowasa enema, suppository and Canasa suppository), sulfasalazine (Azulfidine), osalazine (Dipentum), or balsalazide (Colazal)
  o Failed / intolerant to corticosteroids

Required Medical Information
• Documentation of dose, dates of therapy, and clinical outcomes as appropriate (ie, DMARD, corticosteroids, topicals, Enbrel, Humira)
• Laboratory tests as appropriate for diagnosis
• Appropriate documentation to support above, chart notes, statement of medical necessity

Contraindications
• Patients with a history of a severe reaction to infliximab
• Moderate of severe (NYHA Class III/IV) congestive heart failure
• Infection present at time of use

Not Approved if
• Pt dose not meet criteria above

Dosing
• Ankylosing spondylitis
  o Induction, 5mg/kg IV weeks 0, 2, and 6
  o Maintenance, 5mg/kr IV every 6 weeks
• Crohn’s disease
  o 5mg/kg at week 0, 2 and 6, then every 8 weeks thereafter
  o Fistulizing Crohn’s disease – only week 0, 2 and 6 (no maintenance)
• Plaque psoriasis
  o 5mg/kg at week 0, 2 and 6, then every 8 weeks thereafter
• Psoriatic arthritis
  o 5mg/kg at week 0, 2 and 6, then every 8 weeks thereafter
• Rheumatoid arthritis
  o 3mg/kg at week 0, 2 and 6, then every 8 weeks thereafter
  o May increase to 10mg/kg every 4 weeks if no response
• Ulcerative Colitis
  o 5mg/kg at week 0, 2, and 6, then every 8 weeks thereafter

Authorization
• Ankylosing spondylitis
  o 1 year
• Crohn’s disease
  o Initial 14 weeks, if no response – discontinue
  o Remainder of year if positive response
• Plaque psoriasis
  o 1 year
• Psoriatic arthritis
  o 1 year
• Rheumatoid arthritis
  o 1 year
• Ulcerative Colitis
  o Initial 14 weeks, if no response – discontinue
  o Remainder of year if positive response

Criteria for continuation of therapy
• Initial therapy was tolerated
• Demonstrated improvement in disease
References

33. Smith, RJ, Chin, JE, Sam, LM, et al. Biologic effects of an interleukin-1 receptor antagonist protein on