DESCRIPTION: Infliximab and biosimilar infliximab-dyyb both neutralize the biological activity of tumor necrosis factor (TNF) alpha, a naturally occurring cytokine involved in the body’s inflammatory and immune responses, and blocks the interaction with cell surface TNF receptors.

INDICATION(S):

**Plaque Psoriasis** REMICADE/INFLECTRA is indicated for the treatment of adult patients with chronic severe (i.e., extensive and/or disabling) plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate. REMICADE/INFLECTRA should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician.

**Rheumatoid Arthritis** REMICADE/INFLECTRA, in combination with methotrexate, is indicated for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis.

**Psoriatic Arthritis** REMICADE/INFLECTRA is indicated for reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function in patients with psoriatic arthritis.

**Adult Crohn’s Disease** REMICADE/INFLECTRA is indicated 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. REMICADE is indicated for reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing Crohn’s disease.

**Pediatric Crohn’s Disease and Pediatric Ulcerative Colitis** REMICADE/INFLECTRA is indicated for reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients with moderately to severely active Crohn’s disease who have had an inadequate response to conventional therapy.

**Ulcerative Colitis** REMICADE/INFLECTRA is indicated for reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in patients with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy.

**Ankylosing Spondylitis** REMICADE/INFLECTRA is indicated for reducing signs and symptoms in patients with active ankylosing spondylitis.

CONTRAINDICATIONS

- REMICADE/INFLECTRA at doses >5mg/kg should not be administered to patients with moderate to severe heart failure (NYHA Functional Class III/IV).
- REMICADE/INFLECTRA should not be administered to patients with known hypersensitivity to any murine proteins or other components of the product.
WARNING / PRECAUTION:

- Serious Infections including tuberculosis, invasive fungal infections & opportunistic infections.
- Evaluate for tuberculosis & latent infection prior to initiating therapy.
- Malignancies: In controlled portions of clinical trials more cases of malignancies were observed among patients receiving TNF antagonists and more cases of lymphoma have been observed.
- Hypersensitivity Reactions; Hepatitis B Reactivation; Neurological Reactions, Hematological Reactions, Hepatotoxicity
- Anakinra (Kineret®)- In clinical studies, serious infections have been seen with concurrent use of TNF antagonists and anakinra.
- Abatacept (Orencia®) – concomitant use with a TNF antagonist can increase the risk of infection and serious infections; concomitant use is not recommended.
- Heart Failure- Worsening of CHF noted with TNF antagonists.
- Vaccinations- Patients on Remicade/Inflectra should not receive live vaccines.
- Immunosuppression- may alter host defenses against infection & malignancy.

REASONS FOR PA:

- Cost
- Potential for misuse
- Toxicity

CRITERIA for APPROVAL:

1. Diagnosis is an FDA-Labeled Indication and
2. Prescribed by or in consultation with rheumatologist or gastroenterologist or dermatologist and
3. Patient has demonstrated a negative tuberculin test and
4. Patient has no contraindications to treatment and
5. Patient is at least 18 years of age or older (except for ≥ 6 years of age for inflammatory bowel diseases including Crohn’s and Ulcerative Colitis) and
6. Trial and failure of appropriate conventional therapies DMARDS (see form) and NSAIDS where applicable and
7. Trial and failure of: Humira AND Enbrel

INITIAL APPROVAL

Initial approval will be for 3 months; patient should be evaluated for response to therapy. If patient is responding to therapy, an additional 12 months will be approved annually.
Dispensed in ONLY the amount necessary to complete the infusion (temperature sensitive, contains no preservatives, to be used within 3 hrs of preparation)

REASONS for DENIAL of BENEFIT:

1. Patient has the following:
   a. Moderate to severe CHF (NYHA Class III/IV)
   b. History of hypersensitivity to infliximab/infliximab-dyyb or any of its components or murine products
2. Patient does not meet above criteria

Policy History:

Created: 10/2008
Revised: 2/2009, 11/2012, 10/2014, 10/2016 – added to include biosimilar
1. Remicade® Prescribing Information, Janssen Biotech, Inc. October 2015 Horsham, PA.
11. Inflectra® Prescribing Information, Celltrion, Inc. April 2016 Lakeforest