I. Medication Description

Remicade® (infliximab) is a chimeric monoclonal antibody that neutralizes the biological activity of tumor necrosis factor-α (TNF-α) by binding with high affinity to the soluble and transmembrane forms of TNF-α, which subsequently inhibits binding of TNF-α with its receptors. Biological activities attributed to TNF-α include the following: induction of proinflammatory cytokines such as interleukins 1 and 6; enhancement of leukocyte migration by increasing endothelial layer permeability and expression of adhesion molecules by endothelial cells and leukocytes; activation of neutrophil and eosinophil functional activity; and induction of acute phase reactants and other liver proteins, as well as tissue-degrading enzymes produced by synoviocytes and/or chondrocytes. The clinical result of inhibiting TNF-α activity includes reduction in inflammatory processes associated with specific autoimmune disorders.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage of Remicade is provided for the following conditions when the listed criteria are met:

- Ankylosing spondylitis (active disease):
  - Prescribed by a rheumatologist AND
  - The patient has had inadequate results with at least two NSAIDs (unless NSAIDs are contraindicated)

- Crohn’s disease (moderate to severe):
  - Prescribed by a gastroenterologist AND
  - One of the following:
    - The patient has experienced treatment failure or intolerable side effects with an immune modulator such as azathioprine, 6MP, methotrexate (unless contraindicated) OR
    - The severity of the condition requires rapid improvement not attainable with immune modulators OR
    - The patient has fistulizing disease

- Plaque psoriasis (moderate to severe disease):
  - Prescribed by a rheumatologist or dermatologist AND
• At least 10% of BSA affected or less than 10% BSA affected but with palmar, plantar, head/neck, or genitalia involvement **AND**
• Patient has had an inadequate response to PUVA or UVB therapy unless contraindicated **AND**
• Patient has had an inadequate response to non-biologic systemic therapy (i.e. methotrexate, cyclosporine, acitretin) unless contraindicated

**Psoriatic arthritis (active disease):**
• Prescribed by a rheumatologist or dermatologist **AND**
• One of the following:
  - Patient has tried therapy with at least one non-biologic DMARD with either treatment failure after 12 weeks or intolerable side effects (unless DMARDs are contraindicated) **OR**
  - If predominantly axial disease is documented, the patient has experienced treatment failure with at least two oral NSAIDs (unless NSAIDs are contraindicated)

**Rheumatoid arthritis (moderate to severe disease):**
• Prescribed by a rheumatologist **AND**
• Patient has tried therapy with at least one non-biologic DMARD with either treatment failure after 12 weeks or intolerable side effects (unless DMARDs are contraindicated)

**Ulcerative colitis (moderate to severe disease):**
• Prescribed by a gastroenterologist **AND**
• One of the following:
  - The patient has experienced treatment failure or intolerable side effects with an immune modulator such as azathioprine, 6MP, methotrexate (unless contraindicated) **OR**
  - The severity of the condition requires rapid improvement not attainable with immune modulators

### IV. Quantity Limits

• **For Rheumatoid Arthritis**
  - Month 1 (induction dosing): no more than 100 billable units (1,000mg)
  - Month 2 (induction dosing): no more than 60 billable units (600mg)
  - Month 3 and after (maintenance dosing): no more than 100 billable units every 4 weeks

• **For Crohn’s Disease**
  - Month 1 (induction dosing): no more than 100 billable units (1,000mg)
  - Month 2 (induction dosing): no more than 60 billable units (600mg)
  - Month 3 and after (maintenance dosing): no more than 100 billable units every 8 weeks

• **For Ankylosing Spondylitis**
  - Month 1 (induction dosing): no more than 100 billable units (1,000mg)
  - Month 2 (induction dosing): no more than 60 billable units (600mg)
  - Month 3 and after (maintenance dosing): no more than 60 billable units every 6 weeks

• **For all other indications:**
  - Month 1 (induction dosing): no more than 100 billable units (1,000mg)
  - Month 2 (induction dosing): no more than 60 billable units (600mg)
Month 3 and after (maintenance dosing): no more than 60 billable units every 8 weeks

V. **Coverage Duration**

Coverage is available for 1 year and may be renewed.

VI. **Coverage Renewal Criteria**

Coverage can be renewed based upon the following criteria:
- Clinical response or remission of disease is maintained with continued use **AND**
- Absence of unacceptable toxicity from the drug

VII. **Billing/Coding Information**

- **Remicade (infliximab) J1745** – 1 billable unit is 10mg
- Pertinent Indications:
  - Rheumatoid Arthritis – M06.9, M05.00, M05.30, M05.60, M06.1, M06.4, M08.00, M12.00
  - Ankylosing Spondylitis – M45.9
  - Crohn’s Disease – K50.00, K50.10, K50.80, K50.90
  - Plaque psoriasis – L40.0-L40.4, L40.8
  - Psoriatic arthritis – L40.54, L40.59
  - Ulcerative Colitis – K51.00, K51.20, K51.30, K51.50, K51.80, K51.90

VIII. **Summary of Policy Changes**

- 4/1/11: Clarification of prior DMARD use requirements
- 6/15/12: Addition of pediatric Crohn’s diagnosis; Revision of DMARD and steroid requirements for Crohn’s and Ulcerative Colitis; Addition of opportunistic infections to Black Box (Listeria, Legionella); Revision of systemic or phototherapy requirements for Plaque Psoriasis
- 3/15/13: no policy changes
- 3/15/14: no policy changes
- 3/15/15: no policy changes
- 7/1/15: formulary distinctions made, removal of need for Tb testing on patients not at high risk
- 3/15/16: updated quantity limits to including induction dosing

IX. **References**

1. UpToDate Online, retrieved November 2010
3. Facts and Comparisons Online, retrieved November 2010
5. Rutgeerts P; Sandborn WJ; Feagan BG; Reinisch W; Olson A; Johanss J; Travers S; Rachmilewitz D; Hanauer SB; Lichtenstein GR; de Villiers WJ; Present D; Sands BE; Colombel JF. Infliximab for induction and maintenance therapy for ulcerative colitis. N Engl J Med. 2005 Dec 8;353(23):2462-76.


The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

Drug therapy initiated with samples will not be considered as meeting medical necessity for coverage for non-preferred or prior authorized medications.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.