

## SPECIALTY GUIDELINE MANAGEMENT

### REMICADE (infliximab) INFLECTRA (infliximab-dyyb)

#### POLICY

##### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

###### A. FDA-Approved Indications

1. Moderately to severely active Crohn's disease
2. Moderately to severely active ulcerative colitis
3. Moderately to severely active rheumatoid arthritis in combination with methotrexate
4. Active ankylosing spondylitis
5. Active psoriatic arthritis
6. Chronic severe plaque psoriasis

###### B. Compendial Uses

- Axial spondyloarthritis
- Behçet's syndrome
- Granulomatosis with polyangiitis (Wegener's granulomatosis)
- Hidradenitis suppurativa
- Juvenile idiopathic arthritis
- Pyoderma gangrenosum
- Sarcoidosis
- Takayasu's arteritis
- Uveitis

All other indications are considered experimental/investigational and are not a covered benefit.

##### II. CRITERIA FOR INITIAL APPROVAL

###### A. **Moderately to severely active Crohn's disease (CD)**

1. Authorization of 24 months may be granted for members who have received Remicade, Inflectra, or any other biologic indicated for the treatment of Crohn's disease in a paid claim through a pharmacy or medical benefit within the previous 120 days of the initial request for Remicade or Inflectra.
2. Authorization of 24 months may be granted for treatment of moderately to severely active CD when any of the following criteria is met:
  - a. Member has fistulizing disease.
  - b. Member has an inadequate response, intolerance or contraindication to at least one conventional therapy option (see Appendix A).

###### B. **Moderately to severely active ulcerative colitis (UC)**

1. Authorization of 24 months may be granted for members who have received Remicade, Inflectra, or any other biologic indicated for moderately to severely active ulcerative colitis in a paid claim through a pharmacy or medical benefit within the previous 120 days of the initial request for Remicade or Inflectra.

2. Authorization of 24 months may be granted for treatment of moderately to severely active UC when the member has an inadequate response, intolerance or contraindication to at least ONE conventional therapy option (see Appendix B).

**C. Moderately to severely active rheumatoid arthritis (RA)**

1. Authorization of 24 months may be granted for members who have received Remicade, Inflectra, or any other biologic DMARD or targeted synthetic DMARD (e.g., Xeljanz) indicated for moderately to severely active rheumatoid arthritis in a paid claim through a pharmacy or medical benefit within the previous 120 days of the initial request for the medication. Remicade or Inflectra must be prescribed in combination with methotrexate or leflunomide unless the member has a clinical reason not to use methotrexate or leflunomide.
2. Authorization of 24 months may be granted for treatment of moderately to severely active RA when all of the following criteria are met:
  - a. Member is prescribed Remicade or Inflectra in combination with methotrexate or leflunomide, or has a clinical reason not to use methotrexate or leflunomide.
  - b. Member has any of the following:
    - i. Inadequate response to at least a 3-month trial of methotrexate despite adequate dosing (i.e., titrated to 20 mg/week)
    - ii. Intolerance or contraindication to methotrexate (see Appendix C)

**D. Active ankylosing spondylitis (AS) and axial spondyloarthritis**

1. Authorization of 24 months may be granted for members who have received Remicade, Inflectra, or any other biologic DMARD indicated for active ankylosing spondylitis in a paid claim through a pharmacy or medical benefit within the previous 120 days of the initial request for Remicade or Inflectra.
2. Authorization of 24 months may be granted for treatment of active ankylosing spondylitis and axial spondyloarthritis when any of the following criteria is met:
  - a. Member has experienced an inadequate response to at least two non-steroidal anti-inflammatory drugs (NSAIDs) over a 4-week period in total at maximum recommended or tolerated anti-inflammatory dose.
  - b. Member has an intolerance and/or contraindication to two or more NSAIDs (see Appendix D).

**E. Active psoriatic arthritis (PsA)**

Authorization of 24 months may be granted for treatment of active psoriatic arthritis (PsA).

**F. Chronic severe plaque psoriasis**

1. Authorization of 24 months may be granted for members who have received Remicade, Inflectra, Otezla, or any other biologic DMARD indicated for the treatment of severe psoriasis in a paid claim through a pharmacy or medical benefit within the previous 120 days of the initial request for Remicade or Inflectra.
2. Authorization of 24 months may be granted for treatment of chronic severe plaque psoriasis when all of the following criteria are met:
  - a. At least 5% of body surface area (BSA) is affected OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
  - b. Member meets any of the following criteria:
    1. Member has had an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine or acitretin.
    2. Member has a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine or acitretin (see Appendix E).
    3. Member has severe psoriasis that warrants a biologic DMARD as first-line therapy.

**G. Behçet's syndrome**

Authorization of 24 months may be granted for treatment of Behçet's syndrome.

**H. Granulomatosis with polyangiitis (Wegener's granulomatosis)**

Authorization of 24 months may be granted for treatment of granulomatosis with polyangiitis.

**I. Hidradenitis suppurativa**

Authorization of 24 months may be granted for treatment of severe, refractory hidradenitis suppurativa.

**J. Juvenile Idiopathic arthritis (JIA)**

1. Authorization of 24 months may be granted for members who have received Remicade or Inflectra in a paid claim through a pharmacy or medical benefit within the previous 120 days of the initial request for Remicade or Inflectra.
2. Authorization of 24 months may be granted for treatment of JIA when any of the following criteria is met:
  - a. Member has experienced an inadequate response to at least a 3-month trial of a self-injectable TNF inhibitor indicated for JIA (e.g., Enbrel or Humira).
  - b. Member has experienced an intolerable adverse event (e.g., hypersensitivity reaction) to a self-injectable TNF inhibitor indicated for JIA.
  - c. Member has developed antibodies against Enbrel or Humira.

**K. Pyoderma gangrenosum**

Authorization of 24 months may be granted for treatment of pyoderma gangrenosum.

**L. Sarcoidosis**

Authorization of 24 months may be granted for treatment of sarcoidosis.

**M. Takayasu's arteritis**

Authorization of 24 months may be granted for treatment of Takayasu's arteritis.

**N. Uveitis**

Authorization of 24 months may be granted for treatment of uveitis in members who have experienced an inadequate response or intolerance or have a contraindication to a trial of immunosuppressive therapy for uveitis (e.g., methotrexate, azathioprine, or mycophenolate mofetil).

**III. CONTINUATION OF THERAPY**

Authorization of 24 months may be granted for all members (including new members) who meet all initial authorization criteria and achieve or maintain positive clinical response after at least 3 months of therapy with Remicade or Inflectra as evidenced by low disease activity or improvement in signs and symptoms of the condition.

**IV. OTHER**

For all indications: Member has a pretreatment tuberculosis (TB) screening with a TB skin test or an interferon gamma release assay (e.g., QFT-GIT, T-SPOT.TB).

Note: Members who have received Remicade, Inflectra, or any other biologic DMARD or targeted synthetic DMARD (e.g., Xeljanz) in a paid claim through a pharmacy or medical benefit within the previous 120 days of the continuation request are exempt from requirements related to TB screening in this Policy.

**V. APPENDICES**

**Appendix A: Examples of Conventional Therapy Options for CD**

1. Mild to moderate disease – induction of remission:
  - a. Oral budesonide, oral mesalamine
  - b. Alternatives: metronidazole, ciprofloxacin, rifaximin
2. Mild to moderate disease – maintenance of remission:
  - a. Azathioprine, mercaptopurine
  - b. Alternatives: oral budesonide, methotrexate intramuscularly (IM)
3. Moderate to severe disease – induction of remission:
  - a. Prednisone, methylprednisolone intravenously (IV)
  - b. Alternatives: methotrexate IM
4. Moderate to severe disease – maintenance of remission:
  - a. Azathioprine, mercaptopurine
  - b. Alternative: methotrexate IM
5. Perianal and fistulizing disease – induction of remission
  - a. Metronidazole ± ciprofloxacin
6. Perianal and fistulizing disease – maintenance of remission
  - a. Azathioprine, mercaptopurine
  - b. Alternative: methotrexate IM

#### **Appendix B: Examples of Conventional Therapy Options for UC**

1. Mild to moderate disease – induction of remission:
  - a. Oral mesalamine (e.g., Asacol, Asacol HD, Lialda, Pentasa), balsalazide, olsalazine
  - b. Rectal mesalamine (e.g., Canasa, Rowasa)
  - c. Rectal hydrocortisone (e.g., Colocort, Cortifoam)
  - d. Alternatives: prednisone, azathioprine, mercaptopurine, sulfasalazine
2. Mild to moderate disease – maintenance of remission:
  - a. Oral mesalamine, balsalazide, olsalazine, rectal mesalamine
  - b. Alternatives: azathioprine, mercaptopurine, sulfasalazine
3. Severe disease – induction of remission:
  - a. Prednisone, hydrocortisone IV, methylprednisolone IV
  - b. Alternatives: cyclosporine IV, tacrolimus, sulfasalazine
4. Severe disease – maintenance of remission:
  - a. Azathioprine, mercaptopurine
  - b. Alternative: sulfasalazine
5. Pouchitis: Metronidazole, ciprofloxacin
  - a. Alternative: rectal mesalamine

#### **Appendix C: Examples of Contraindications to Methotrexate**

1. Alcoholism, alcoholic liver disease or other chronic liver disease
2. Breastfeeding
3. Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
4. Elevated liver transaminases
5. History of intolerance or adverse event
6. Hypersensitivity
7. Interstitial pneumonitis or clinically significant pulmonary fibrosis
8. Myelodysplasia
9. Pregnancy or planning pregnancy (male or female)
10. Renal impairment
11. Significant drug interaction

#### **Appendix D: Examples of Contraindications to the Use of NSAIDs**

1. Allergic-type reaction following aspirin or other NSAID administration
2. Asthma
3. Gastrointestinal bleeding

4. History of intolerance or adverse event
5. Significant drug interaction
6. Urticaria

**Appendix E: Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine or Acitretin.**

1. Alcoholism, alcoholic liver disease or other chronic liver disease
2. Breastfeeding
3. Drug interaction
4. Cannot be used due to risk of treatment-related toxicity
5. Pregnancy or planning pregnancy (male or female)
6. Significant comorbidity prohibits use of systemic agents (examples include liver or kidney disease, blood dyscrasias, uncontrolled hypertension)

**VI. REFERENCES**

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