**Infliximab**

**Remicade (infliximab)**
**Inflectra (infliximab-dyyb)**
**Renflexis (infliximab-abda)**

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**POLICY**

**A. 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.

**REMICADE**

**FDA-Approved Indications**

- Moderately to severely active Crohn’s disease in adults and pediatric patients
- Moderately to severely active ulcerative colitis in adults and pediatric patients
- Moderately to severely active rheumatoid arthritis in combination with methotrexate
- Active ankylosing spondylitis
- Active psoriatic arthritis
- Chronic severe plaque psoriasis in adults

**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

**INFLECTRA AND RENFLEXIS**

**FDA-Approved Indications**

- Moderately to severely active Crohn’s disease in adults and pediatric patients
• Moderately to severely active ulcerative colitis in adults
• Moderately to severely active rheumatoid arthritis in combination with methotrexate
• Active ankylosing spondylitis
• Active psoriatic arthritis
• Chronic severe plaque psoriasis in adults

Compendial Uses
• None

B. REQUIRED DOCUMENTATION
The following information is necessary to initiate the prior authorization review:
• For psoriasis, the following documentation is required:
  o For new starts on therapy
    ▪ Documentation supporting a history of plaque psoriasis for longer than six months
    ▪ Percent of body surface area involvement
    ▪ Results of treatment with methotrexate such as ineffective treatment or intolerance, or documentation that methotrexate is contraindicated
  o For continuation of therapy, documentation in member’s chart or medical record supporting a decrease in percent of body surface area involvement when compared to baseline must be submitted
• For Crohn’s disease, prescribers will be asked to fill in the member’s Crohn’s Disease Activity Index (CDAI) at baseline and after 6 months of therapy

C. CRITERIA FOR INITIAL APPROVAL
1. Moderately to severely active Crohn’s disease (CD)
   Initial authorization for 6 months may be granted for members who meet the following criteria:
   i. Member has a pre-treatment Crohn’s Disease Activity Index (CDAI) score ≥ 220, OR
   ii. Member has fistulizing disease, AND
   iii. Member has tried any of the following conventional therapies for CD: mesalamine, sulfasalazine, ciprofloxacin, metronidazole, azathioprine, mercaptopurine, methotrexate, methylprednisolone, or prednisone.

2. Moderately to severely active ulcerative colitis (UC)
   Initial authorization for 6 months may be granted for members who meet both of the following criteria:
   i. Member has moderately to severely active UC
   ii. Member has tried any of the following conventional therapies for UC: mesalamine, sulfasalazine, azathioprine, mercaptopurine, methylprednisolone, prednisone, cyclosporine, tacrolimus (or antibiotics for pouchitis only).

3. Moderately to severely active rheumatoid arthritis (RA)
   Initial authorization of 6 months may be granted for members with RA who meet the following criteria:
   i. Member has tried a disease modifying anti-rheumatic drug (DMARD)
   ii. Remicade®/Infliximab must be prescribed in combination with methotrexate or leflunomide unless the member has a clinical reason not to use methotrexate or leflunomide
4. **Moderate to severe chronic plaque psoriasis**
   Initial authorization of 6 months may be granted for members who meet ALL of the following criteria:
   i. Treatment with Remicade/infliximab was recommended by a dermatologist
   ii. Member has been diagnosed with moderate to severe chronic plaque psoriasis defined as the following
      a) At least 10% of body surface area (BSA) is affected, or crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected, and
      b) History of psoriasis 6 months or longer
   iii. Plaque psoriasis is characterized by well-defined patches of red and raised skin
   iv. Member has tried methotrexate for at least 3 months at a therapeutic dose and found it to be ineffective, or the member exhibited intolerance or allergy, or the use of methotrexate is contraindicated.
      a) Ineffective treatment is defined as symptoms and/or signs that are not resolved after completion of treatment at the recommended therapeutic dose and duration. If there is no recommended treatment time, the member must have had a meaningful trial.
      b) Intolerance is defined as having a recognized and reproducible or repeated adverse reaction that is clearly associated with taking the medication.
      c) Allergy is defined as a state of hypersensitivity produced by exposure to a particular antigen resulting in harmful immunologic reactions on subsequent exposures. The most common symptoms are skin rash or anaphylaxis.

5. **Active psoriatic arthritis (PsA)**
   Initial authorization of 6 months may be granted for members who meet the following criteria:
   i. Member has been diagnosed with active PsA, and meets ANY of the following:
      a) Member experienced an inadequate response to methotrexate.
      b) Member has a history of intolerance to methotrexate.
      c) Member has a contraindication to methotrexate.

6. **Active ankylosing spondylitis (AS) and axial spondyloarthritis**
   Initial authorization of 6 months may be granted for members with active AS/axial spondyloarthritis who meet ANY of the following criteria:
   i. Member has experienced an inadequate response to treatment with an NSAID over a 4-week period in total at the maximum recommended or tolerated anti-inflammatory dose
   ii. Member has experienced intolerance to NSAID therapy
   iii. Member has a contraindication to all NSAIDs
   * Axial spondyloarthritis is a covered indication for Remicade only.

7. **Active polyarticular juvenile idiopathic arthritis (pJIA)** (covered indication for Remicade only)
   Initial authorization of 6 months may be granted for members with active pJIA who have tried a disease modifying anti-rheumatic drug (DMARD).

8. **Hidradenitis suppurativa** (covered indication for Remicade only)
   Initial authorization of 6 months may be granted for members who have severe hidradenitis suppurative that is refractory to standard first-line treatment (e.g., antibiotics).

9. **Behçet’s syndrome** (covered indication for Remicade only)
Initial authorization of 6 months may be granted for members who are prescribed Remicade for the treatment of Behçet’s syndrome.

10. **Granulomatosis with polyangiitis (Wegener’s granulomatosis)** *(covered indication for Remicade only)*
    Initial authorization of 6 months may be granted for members who are prescribed Remicade for the treatment of granulomatosis with polyangiitis.

11. **Pyoderma gangrenosum** *(covered indication for Remicade only)*
    Initial authorization of 6 months may be granted for members who are prescribed Remicade for the treatment of pyoderma gangrenosum.

12. **Sarcoidosis** *(covered indication for Remicade only)*
    Initial authorization of 6 months may be granted for members who are prescribed Remicade for the treatment of sarcoidosis.

13. **Takayasu’s arteritis** *(covered indication for Remicade only)*
    Initial authorization of 6 months may be granted for members who are prescribed Remicade for the treatment of Takayasu’s arteritis.

14. **Uveitis** *(covered indication for Remicade only)*
    Initial authorization of 6 months may be granted for members who are prescribed Remicade for the treatment of uveitis.

D. **CONTINUATION OF THERAPY**

   - **No previous authorization/precertification:**
     All members (including members currently receiving treatment without prior authorization) must meet criteria for initial approval in section C.
     Members who are continuing with Remicade treatment are subject to the continuation criteria below for approval. Members who are starting treatment with Remicade are required to meet criteria for initial authorization in section C. above.

   - **Reauthorization:**
     Authorization may be granted to members requesting authorization for continuation of therapy if infliximab was previously authorized by HMSA/CVS and the criteria below are met.

**Chronic plaque psoriasis**
To receive authorization for an additional 6 months of therapy for chronic plaque psoriasis, documentation supporting a decrease in percent of body surface area involvement when compared to baseline must be submitted. Thereafter, authorization of 12 months may be granted.

**Crohn’s disease**
For members receiving 6 to 12 months of treatment with Remicade/Infliximab, a positive clinical response to treatment as evidenced by a decreased or stable CDAI score compared with baseline is required. Thereafter, authorization of 12 months may be granted.

**All other indications**
Authorization of 12 months may be granted for members who achieve or maintain positive clinical response as evidenced by low disease activity, improvement in signs and symptoms or maintenance of improvement in signs and symptoms.

E. DOSAGE AND ADMINISTRATION
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

F. ADMINISTRATIVE GUIDELINES
Prior authorization is required. Please refer to the HMSA medical policy web site for the fax form.

G. IMPORTANT REMINDER
The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that CVS/caremark reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

H. REFERENCES