Remicade (Infliximab)

I. Description

Infliximab (Remicade) is an infused antibody that blocks the activity of tumor necrosis factor (TNF). TNF plays an important role in the inflammatory process and although infliximab is not a cure, it helps reduce symptoms. Infliximab is indicated for the treatment of the following conditions:

**Rheumatoid Arthritis**

Infliximab, 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.

**Crohn's Disease**

Infliximab is indicated for reducing signs and symptoms and inducing and maintaining clinical remission in adult and pediatric patients with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy. Also, infliximab is indicated for reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing Crohn's disease.

**Ankylosing Spondylitis**

Infliximab is indicated for reducing signs and symptoms in patients with active ankylosing spondylitis.

**Psoriatic arthritis**

Infliximab 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.
Plaque psoriasis
Infliximab 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.

Ulcerative colitis
Infliximab 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.

II. Criteria/Guidelines

For Initial Treatment

A. Rheumatoid Arthritis
Infliximab is covered (subject to Limitations/Exclusions and Administrative Guidelines) for patients with moderately to severely active rheumatoid arthritis who meet all of the following criteria:

1. The patient has a diagnosis of rheumatoid arthritis as defined by the American College of Rheumatology classification criteria in Appendix 1; AND
2. The patient's disease is currently active as established by the presence of one or more of the following:
   a. Six or more persistently (six weeks or longer) painful/tender joints;
   b. Erosions or progressive erosions on radiologic exams;
   c. A persistent increase in inflammatory markers (two readings over six weeks);
      i. Elevated serum C-reactive protein concentration (compared against the normal range of lab values for this test), or
      ii. Erythrocyte sedimentation rate of at least 28 mm per hour;
3. Infliximab will be used in combination with methotrexate at a dose of at least 10 mg per week to prevent antibody development.

B. Crohn's Disease, Fistulizing Crohn's Disease and Ulcerative Colitis
Infliximab is covered (subject to Limitations/Exclusions and Administrative Guidelines) for patients with moderately to severely active Crohn’s disease or fistulizing Crohn’s disease or ulcerative colitis who meet all of the following criteria.

1. The patient must be experiencing a flare-up of the disease; and
2. Previous treatment was not effective or was not tolerated by the patient. Previous treatments should include at least one agent from two of the three drug classes listed below, unless clinically contraindicated:
   a. Corticosteroids (e.g., prednisone)
   b. Aminosalicylates (e.g., sulfasalazine, olsalazine, mesalamine)
   c. Immunomodulatory drugs (e.g., azathioprine, mercaptopurine, cyclosporine, methotrexate)
C. Ankylosing Spondylitis
Infliximab is covered (subject to Limitations/Exclusions and Administrative Guidelines) for patients with ankylosing spondylitis when all of the following criteria are met:
1. Patient has been diagnosed with ankylosing spondylitis as defined by the Modified New York criteria.*
2. Patient has active disease as evidenced by a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score greater than 4.*
3. Patient has spinal pain on a Visual Analog Scale (VAS) score greater than 4.*

*See Appendices

D. Psoriatic Arthritis
Infliximab is covered (subject to Limitations/Exclusions and Administrative Guidelines) for patients with psoriatic arthritis when all of the following are met:
1. Patients with active psoriatic arthritis despite disease modifying anti-rheumatic drug (DMARD) or non-steroidal anti-inflammatory drug (NSAID) therapy (five or more tender and swollen joints) with one or more of the following subtypes:
   a. Arthritis involving DIP joints
   b. Arthritis mutilans
   c. Asymmetric peripheral arthritis
   d. Polyarticular arthritis
   e. Spondylitis with peripheral arthritis

E. Plaque Psoriasis
Infliximab is covered (subject to Limitations/Exclusions and Administrative Guidelines) for patients with plaque psoriasis when all of the following are met:
1. The use of infliximab is recommended by a dermatologist.
2. Patient is 18 years of age or older and has a diagnosis of chronic plaque psoriasis involving more than 10 percent body surface area.
3. The patient has tried methotrexate for at least three months at a therapeutic dose and found it to be ineffective, or the patient exhibited intolerance or allergy, or the use of methotrexate is contraindicated.
   - 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.
   - Intolerance is defined as having a recognized and reproducible or repeated adverse reaction that is clearly associated with taking the medication.
   - 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.
4. The patient cannot be on concomitant anti-psoriatic therapy with the exception of low potency topical corticosteroids on the face or groin.
For Extension of Treatment

A. Rheumatoid Arthritis
   1. Rheumatoid arthritis is stable or improved.
   2. Infliximab is being used in combination with methotrexate at a dose of at least 10 mg per week to prevent antibody development.

B. All other conditions
   1. The patient has responded to infliximab therapy.

III. Limitations/Exclusions

A. For rheumatoid arthritis, if methotrexate is contraindicated or not tolerated, other tumor necrosis factor (TNF) drugs (e.g., etanercept, adalimumab) should be considered.

B. Infliximab is not covered for the treatment of guttate, pustular, or erythrodermic psoriasis as it has not been shown to improve health outcomes.

IV. Administrative Guidelines

Precertification is not required. Documentation supporting the medical necessity should be legible, maintained in the patient’s medical record and must be made available to HMSA upon request. HMSA reserves the right to perform retrospective review using the above criteria to validate if services rendered met payment determination criteria.

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<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
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<td>J1745</td>
<td>Injection, infliximab, 10 mg</td>
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V. 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 HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.
VI. References


Appendix 1

Classification Criteria for Establishing the Diagnosis of Rheumatoid Arthritis

The American College of Rheumatology

Diagnosis of rheumatoid arthritis requires the presence of at least four of seven criteria listed below:

- Morning stiffness in and around joints lasting more than one hour
- Arthritis in at least one area in a wrist, metacarpophalangeal (MCP), or proximal interphalangeal (PIP) joint (hands or fingers) for more than six weeks
- Simultaneous swelling or fluid accumulation in three or more joints for more than six weeks
- Symmetric (bilateral joint) involvement for more than six weeks
- Presence of rheumatoid nodules
- Positive serum rheumatoid factor
- Radiographic changes typical of rheumatoid arthritis (e.g., erosion or unequivocal bony decalcification in or adjacent to the involved joint) on hand and wrist are present.

Appendix 2

Assessment Components for Improvement

The American College of Rheumatology

- Painful joint count
- Swollen joint count
- Patient pain assessment
- Patient global assessment (e.g., overall assessment of rheumatoid arthritis, activities of daily living, activity/functional levels)
- Patient disability self-assessment
- ESR or C-reactive protein levels (acute phase reactants)

Appendix 3

New York Criteria

- Low back pain with inflammatory characteristics
- Limitations of lumbar spine motion in sagittal and frontal plans
- Decreased chest expansion
- Bilateral sacroiliitis grade 2 or higher
- Unilateral sacroiliitis grade 3 or higher
Appendix 4

Visual Analog Scale (VAS)

How severe is your pain today? Place a vertical mark on the line below to indicate how bad you feel your pain is today.
No pain /__________________________/ Very severe pain

Appendix 5

The Bath Ankylosing Spondylitis Functional Index (BASFI)

Please draw a mark on each line below to indicate your level of ability with each of the following activities during the last week.

1. Putting on your socks or tights without help or aids (e.g., sock aid)
   EASY ___________________ IMPOSSIBLE

2. Bending forward from the waist to pick up a pen from the floor without an aid
   EASY ___________________ IMPOSSIBLE

3. Reaching up to a high shelf without help or aids (e.g., helping hand)
   EASY ___________________ IMPOSSIBLE

4. Getting up out of an armless dining room chair without using your hand or any other help
   EASY ___________________ IMPOSSIBLE

5. Getting up off the floor from lying on your back without help
   EASY ___________________ IMPOSSIBLE

6. Standing unsupported for 10 minutes without discomfort
   EASY ___________________ IMPOSSIBLE

7. Climbing 12-15 steps without using a handrail or walking aid (one foot on each step)
   EASY ___________________ IMPOSSIBLE

8. Looking over your shoulder without turning your body
   EASY ___________________ IMPOSSIBLE

9. Doing physically demanding activities (e.g., physiotherapy exercises, gardening or sports)
   EASY ___________________ IMPOSSIBLE

10. Doing a full day's activities whether at home or at work
    EASY ___________________ IMPOSSIBLE