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## **1.0 Description of the Procedure, Product, or Service**

Remicade (infliximab) is a genetically engineered human/ mouse monoclonal antibody that binds to and inhibits the activity of tumor necrosis factor alpha (TNF-alpha). Remicade (infliximab) is a drug used as a therapy for some recipients with Crohn's disease or rheumatoid arthritis. Remicade (infliximab) is also used in the treatment of conditions such as ankylosing spondylitis, psoriatic arthritis, ulcerative colitis, and chronic severe plaque psoriasis. This drug acts by reducing inflammation. It is usually administered via intravenous infusion.

Crohn's disease is the inflammation of the ileum, where the small intestine joins the large intestine. Complications of Crohn's disease may lead to small bowel stricture or obstruction. Fistulas may form in the areas that are the most inflamed. Recipients with Crohn's disease have elevated levels of tumor necrosis factor alpha (TNF-alpha) which damages the GI tract and over time develops into extensive intestinal wall destruction causing ulcers, bleeding, weight loss, skin lesions and other problems due to nutritional deficiencies.

Rheumatoid arthritis is a chronic condition where the recipient's own immune system causes inflammation of the joints and the tissue around the joints. The body is equipped with a defense mechanism called the immune system which protects recipients from disease and infection. When a recipient has an autoimmune condition, the immune system creates antibodies that attack its own tissues by mistake. Rheumatoid arthritis usually starts between the age of 25 and 55 and the cause is unknown. Symptoms of rheumatoid arthritis (RA) are described as painful inflammation of the synovial tissue lining the joints. These recipients have elevated levels of tumor necrosis factor alpha (TNF-alpha) in their joints. Chronic joint inflammation leads to tissue break down, cell damage to the bone, edema, warmth, redness, joint stiffness, and pain. These recipients are also fatigued, weak, have a low-grade fever, and loss of appetite.

### **1.1 Medical Term Definitions**

- a. Antibody, a protein that is produced by the immune system against a specific antigen.
- b. Rheumatoid arthritis, a chronic disease considered to be autoimmune and characterized by pain, stiffness, inflammation, swelling, and sometimes destruction of joints.

## **2.0 Eligible Recipients**

### **2.1 General Provisions**

To be eligible, NCHC recipients must be enrolled on the date of service.

### 3.0 When the Procedure, Product, or Service Is Covered

#### 3.1 General Criteria

NCHC covers procedures, products, and services related to this policy when they are medically necessary and

- a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the recipient's needs;
- b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available; **AND**
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

#### 3.2 Specific Criteria

Remicade (infliximab) may be medically necessary when **BOTH** of the following criteria are met:

- a. Remicade (infliximab) is being used for one of the following indications:
  1. to reduce the number of draining enterocutaneous fistulas in recipients with fistulizing Crohn's disease;
  2. to reduce signs or symptoms or maintain clinical remission of moderately to severely active Crohn's disease;
  3. when used alone or in combination with Methotrexate to reduce the signs and symptoms of moderate to severe rheumatoid arthritis, rapidly advancing progressive rheumatoid arthritis, or psoriatic arthritis;
  4. ankylosing spondylitis refractory to conventional therapies (inadequate symptom relief from other treatments such as NSAIDs, COX-2 inhibitors, or methotrexate unless unable to take these drugs);
  5. as treatment of severe plaque type psoriasis as evidenced by psoriatic plaques covering at least 10% of the body surface and have failed prior treatment with psoralen-UVA or other systemic therapies (refractory to conventional therapies);
  6. moderate to severe ulcerative colitis; **OR**
  7. ulcerative colitis where the recipient has inadequate response to conventional treatment such as aminosalicylates, corticosteroids, or immunosuppressants (unless unable to tolerate these drugs); **AND**
- b. The recipient has no contraindications to the use of Remicade (infliximab), including:
  1. Class III or IV Congestive Heart Failure, **OR**
  2. Untreated active or latent tuberculosis.

## 4.0 When the Procedure, Product, or Service Is Not Covered

### 4.1 General Criteria

Procedures, products, and services related to this policy are not covered when

- a. the recipient does not meet the eligibility requirements listed in **Section 2.0**;
- b. the recipient does not meet the medical necessity criteria listed in **Section 3.0**;
- c. the procedure, product, or service unnecessarily duplicates another provider's procedure, product, or service; or
- d. the procedure, product, or service is experimental or investigational.

### 4.2 Specific Criteria

Remicade (infliximab) is not covered:

- a. for other off-label uses not listed in **Subsection 3.2**, including graft-versus-host disease (GVHD), juvenile rheumatoid arthritis (JRA), juvenile idiopathic arthritis-associated uveitis, polyarteritis nodosa, Bechet's syndrome, sarcoidosis, and systemic lupus erythematosus.
- b. when used in combination with other biologics such as Enbrel (etanercept), Kineret (anakinra), Orencia (abatacept), Rituxan (rituximab), or Humira (adalimumab).

## 5.0 Requirements for and Limitations on Coverage

### 5.1 Prior Approval

Prior approval is required for Remicade (infliximab).

### 5.2 Other

- a. Initial treatment is typically administered in a three-dose induction.
- b. Continued treatment may be considered when the recipient has shown biological response to treatment as evidenced by any of the disease assessment tools.
- c. Maintenance therapy is given typically every 6 - 8 weeks.

## 6.0 Providers Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for procedures, products, and services related to this policy, providers shall

- a. meet NCHC qualifications for participation;
- b. be currently enrolled with NCHC; **AND**
- c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

## 7.0 Additional Requirements

### 7.1 Compliance

Providers must comply with all applicable federal, state, and local laws and regulations, including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements.

## 8.0 Policy Implementation/Revision Information

Original Effective Date: July 1, 2010

Revision Information:

Date	Section Revised	Change
July 1, 2010		Policy Conversion: Implementation of Session Law 2009-451, Section 10.32 "NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY."
	Throughout	Policy Termination

## Attachment A: Claims-Related Information

Reimbursement requires compliance with all NCHC guidelines.

### A. Claim Type

Professional (CMS-1500/837P transaction)

Institutional (UB-04/837I transaction)

### B. Diagnosis Codes

Providers must bill the ICD-9-CM diagnosis codes(s) to the highest level of specificity that supports medical necessity.

### C. Procedure Code(s)

HCPCS Code
J1745 Claims will deny unless prior approval has been obtained.

### D. Modifiers

Providers are required to follow applicable modifier guidelines.

### E. Billing Units

The appropriate procedure code(s) used determines the billing unit(s).

### F. Place of Service

Outpatient Hospital and Office

### G. Co-payments

Co-payment(s) may apply to covered prescriptions and services.

### H. Reimbursement

Providers must bill their usual and customary charges.