



Status

Active

## Medical and Behavioral Health Policy

Section: Medicine

Policy Number: II-97

Effective Date: 01/22/2014

Blue Cross and Blue Shield of Minnesota medical policies do not imply that members should not receive specific services based on the recommendation of their provider. These policies govern coverage and not clinical practice. Providers are responsible for medical advice and treatment of patients. Members with specific health care needs should consult an appropriate health care professional.

## INFLIXIMAB

**Description:** Tumor necrosis factor (TNF), a cytokine produced by macrophages and T cells, is a key mediator of inflammation and is produced in response to infection and immunologic injury. Infliximab (Remicade®) is a TNF alpha blocking agent that is administered via an intravenous (IV) infusion.

Secondary loss of response to infliximab is seen in a certain percentage of patients. The development of anti-infliximab antibodies has been suggested as one reason for non-response. This has led to investigation of the clinical utility of quantitative testing of anti-infliximab antibodies, also referred to as human antichimeric antibodies (HACA) or antibodies to infliximab (ATI). Prometheus® Laboratories Inc. offers the Anser™ IFX assay for anti-infliximab antibodies.

- Policy:**
- I. Use of infliximab may be considered **MEDICALLY NECESSARY** for the following FDA-approved indications:
    - A. **Rheumatoid Arthritis**  
Used in combination with methotrexate, for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis.
    - B. **Crohn's disease**
      1. For reducing signs and symptoms and inducing and maintaining clinical remission in adult and pediatric patients who are six years of age or older with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy.
      2. For reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing Crohn's disease.
    - C. **Ankylosing Spondylitis**  
For reducing signs and symptoms in patients with active ankylosing spondylitis.

#### **D. Psoriatic Arthritis**

For reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function in patients with psoriatic arthritis.

#### **E. Plaque Psoriasis**

1. Patient has moderate to severe psoriasis with **EITHER** of the following:
  - a. Greater than 5% of body surface area with plaque psoriasis;  
**OR**
  - b. Less than or equal to 5% body surface area with plaque psoriasis involving sensitive areas or areas that would significantly impact daily functioning (e.g., palms, soles of the feet, head/neck, or genitalia).
- AND**
2. Dermatologist or physician with expertise in treating moderate to severe psoriasis prescribes the therapy;  
**AND**
3. Patient must have:
  - a. Documented failure of treatment with phototherapy (UVB or PUVA) **OR** topical and systemic therapy (methotrexate, cyclosporine, or acitretin)  
**OR**
  - b. A medical contraindication to these treatments.

#### **F. Ulcerative Colitis**

1. For reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy.
2. For reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients who are six year of age or older with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy.

**II.** Other uses of infliximab are considered **INVESTIGATIVE**, including but not limited to the following due to the lack of clinical evidence demonstrating their impact on improved health outcomes.

- Age-related macular degeneration
- Alcoholic hepatitis
- Arthritis (other than rheumatoid arthritis and psoriatic arthritis)
- Behcet syndrome
- Behcet syndrome uveitis
- Cancer cachexia
- Depression
- Diabetic macular edema
- Endometriosis
- Erythrodermic or exfoliative psoriasis
- Giant cell arteritis

- Graft-versus-host disease
- Hidradenitis suppurativa
- Intra-articular injections
- Juvenile idiopathic arthritis
- Juvenile idiopathic arthritis-associated uveitis
- Kawasaki syndrome
- Polyarteritis nodosa
- Polymyalgia rheumatica
- Renal cell carcinoma
- Sacroiliitis
- Sarcoidosis
- Sclerosing cholangitis
- Sjogren syndrome
- Systemic lupus erythematosus
- Systemic necrotizing vasculitides
- Systemic sclerosis
- Takayasu's arteritis
- Wegener's Granulomatosis

### III. Testing of Serum Antibodies to Infliximab

Testing of antibodies to infliximab, either alone or as a combination test that includes the measurement of serum infliximab levels, is considered **INVESTIGATIVE** due to the lack of clinical evidence demonstrating its impact on improved health outcomes.

#### Coverage:

Blue Cross and Blue Shield of Minnesota medical policies apply generally to all Blue Cross and Blue Plus plans and products. Benefit plans vary in coverage and some plans may not provide coverage for certain services addressed in the medical policies.

Medicaid products and some self-insured plans may have additional policies and prior authorization requirements. Receipt of benefits is subject to all terms and conditions of the member's summary plan description (SPD). As applicable, review the provisions relating to a specific coverage determination, including exclusions and limitations. Blue Cross reserves the right to revise, update and/or add to its medical policies at any time without notice.

For Medicare NCD and/or Medicare LCD, please consult CMS or National Government Services websites.

Refer to the Pre-Certification/Pre-Authorization section of the Medical Behavioral Health Policy Manual for the full list of services, procedures, prescription drugs, and medical devices that require Pre-certification/Pre-Authorization. Note that services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial of claims may result if criteria are not met.

#### Coding:

*The following codes are included below for informational purposes*

*only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.*

**CPT:**

84999 Unlisted chemistry procedure

**HCPCS:**

J1745 Injection infliximab, 10 mg

**Policy  
History:**

**Developed February 11, 2009**

**Most recent history:**

Reviewed January 12, 2011

Revised January 11, 2012

Revised January 9, 2013

Reviewed/Updated, no policy statement changes January 8, 2014

**Cross  
Reference:**

Abatacept (Orencia®), II-161

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