

LCD for Infliximab (Remicade™) (L29198)

Contractor Information

Contractor Name

First Coast Service Options, Inc.

Contractor Number

09102

Contractor Type

MAC - Part B

LCD Information

LCD ID Number

L29198

LCD Title

Infliximab (Remicade™)

Contractor's Determination Number

J1745

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CMS National Coverage Policy

Language quoted from CMS National Coverage Determinations (NCDs) and coverage provisions in interpretive manuals are italicized throughout the Local Coverage Determination (LCD). NCDs and coverage provisions in interpretive manuals are not subject to the LCD Review Process (42 CFR 405.860[b] and 42 CFR 426 [Subpart D]). In addition, an administrative law judge may not review an NCD. See §1869(f)(1)(A)(i) of the Social Security Act.

Unless otherwise specified, *italicized* text represents quotation from one or more of the following CMS sources:

CMS Manual System, Pub 100-2, Medicare Benefit Policy, Chapter 1, Section 30; Chapter 15, Section 50

Primary Geographic Jurisdiction

Florida

Oversight Region

Region I

Original Determination Effective Date

For services performed on or after 02/02/2009

Original Determination Ending Date

Revision Effective Date

Revision Ending Date

Indications and Limitations of Coverage and/or Medical Necessity

Infliximab (Remicade™) is a chimeric monoclonal antibody that binds specifically to tumor necrosis factor alpha (TNFα) and blocks its activity. Overproduction of tumor necrosis factor alpha, which is a key inflammatory mediator, leads to inflammation in conditions such as Crohn's disease, rheumatoid arthritis and other autoimmune diseases.

Medicare will consider the use of Infliximab to be medically reasonable and necessary in the following circumstances:

- To reduce the signs and symptoms and induce and maintain clinical remission in adult and pediatric patients with moderately to severely active Crohn's disease in patients who have had an inadequate response to conventional therapy (e.g., corticosteroids, aminosalicylates, and immunosuppressive agents).
- To reduce the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure for patients with fistulizing Crohn's disease. Normally, the patient receives an infusion for this indication at weeks 0, 2, & 6. Subsequent treatments will be covered if the patient responds to the initial treatment as demonstrated by a reduction in signs and symptoms.
- To reduce the signs and symptoms of active arthritis, inhibiting the progression of structural damage and improving physical function, in patients with psoriatic arthritis. Normally, the patient receives an infusion for this indication at weeks 0, 2, and 6. Subsequent treatments will be covered if the patient responds to the initial treatment as demonstrated by a reduction in signs and symptoms.
- When used in combination with methotrexate, to reduce the signs and symptoms, inhibit the progression of structural damage and improve physical function in patients with moderately to severely active rheumatoid arthritis. Normally, the patient receives an infusion of Infliximab for this indication at weeks 0, 2, & 6 and then approximately every eight (8) weeks.
- To reduce signs and symptoms, achieve clinical remission and mucosal healing, and eliminate corticosteroids use in patients with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy. Normally, the patient receives an infusion for this indication at 0, 2 and 6 weeks, and every 8 weeks thereafter.

· To reduce the signs and symptoms in patients with active ankylosing spondylitis. Normally the patient receives an infusion for this indication at 0, 2 and 6 weeks. Subsequent treatment will be covered if the patient responds to the initial treatment as demonstrated by a reduction in signs and symptoms.

· 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. Remicade should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician. Normally the patient receives an infusion at 0, 2 and 6 weeks and every 8 weeks thereafter.

Note: For patients, who are unable to tolerate methotrexate or in the rare instance that Methotrexate is contraindicated for a patient, treatment with Infliximab alone will be covered only if documentation is maintained in the patient's record that clearly indicates the reason that the patient cannot take methotrexate.

Coding Information

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

99999

Not Applicable

CPT/HCPCS Codes

J1745

INJECTION INFLIXIMAB, 10 MG

ICD-9 Codes that Support Medical Necessity

555.0

REGIONAL ENTERITIS OF SMALL INTESTINE

555.1	REGIONAL ENTERITIS OF LARGE INTESTINE
555.2	REGIONAL ENTERITIS OF SMALL INTESTINE WITH LARGE INTESTINE
555.9	REGIONAL ENTERITIS OF UNSPECIFIED SITE
556.0	ULCERATIVE (CHRONIC) ENTEROCOLITIS
556.1	ULCERATIVE (CHRONIC) ILEOCOLITIS
556.2	ULCERATIVE (CHRONIC) PROCTITIS
556.3	ULCERATIVE (CHRONIC) PROCTOSIGMOIDITIS
556.5	LEFT-SIDED ULCERATIVE (CHRONIC) COLITIS
556.6	UNIVERSAL ULCERATIVE (CHRONIC) COLITIS
556.8	OTHER ULCERATIVE COLITIS
556.9	ULCERATIVE COLITIS UNSPECIFIED
565.1	ANAL FISTULA
569.81	FISTULA OF INTESTINE EXCLUDING RECTUM AND ANUS
696.0	PSORIATIC ARTHROPATHY
696.1	OTHER PSORIASIS AND SIMILAR DISORDERS
714.0	RHEUMATOID ARTHRITIS
714.2	OTHER RHEUMATOID ARTHRITIS WITH VISCERAL OR SYSTEMIC INVOLVEMENT
720.0	ANKYLOSING SPONDYLITIS

Diagnoses that Support Medical Necessity

N/A

ICD-9 Codes that DO NOT Support Medical Necessity

N/A

ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation

Diagnoses that DO NOT Support Medical Necessity

N/A

General Information

Documentation Requirements

Medical record documentation that is maintained by the performing physician must substantiate the medical necessity for the use of Infliximab by clearly indicating the relevant clinical signs and symptoms related to the medical condition for which this drug is indicated. The documentation must also include all prior treatment regimes and the patient's response to that therapy.

For fistulizing Crohn's disease, episodic retreatment will be covered if the medical record substantiates that the patient had a reduction in the clinical signs and symptoms of the disease after the initial treatment.

For rheumatoid arthritis, the medical record must clearly indicate:

- the patient is receiving Infliximab in combination with Methotrexate; or
- the patient is intolerant of methotrexate; or
- the patient has a medical condition that contraindicates the use of methotrexate.

Appendices

Utilization Guidelines

N/A

Sources of Information and Basis for Decision

Gottlieb, A; Evans, R., et al (2004). Infliximab induction therapy for patients with severe plaque-type psoriasis: A randomized, double blind, placebo-controlled trial. *Journal of the American academy of Dermatology* 51(4). Retrieved from <http://www.home.mdconsult.com> on August 11, 2005.

Infliximab Injection (2004). Medline Plus Drug information. Retrieved from <http://www.nlm.nih.gov/medlineplus/druginfo/medmaster> on August 11, 2005.

Lipsky, P.E., Van der Heijde, D., St. Clair, E.W., Furst, D.E., Breeveld, F.C., Kalden, J.R., Smolen, J.S., Weisman, M., Emery, P., Feldman, M., Harriman, G.R., & Maini, R.N. (2000). Infliximab and methotrexate in the treatment of rheumatoid arthritis. *The New England Journal of Medicine*, 343, 1594-1602.

Medical News Today (2004). Remicade Lowers Spinal Inflammation in Patients with Ankylosing Spondylitis. Retrieved from <http://www.medicalnewstoday.com> on August 11, 2005.

Ogilvie, A., Antoni, C., Dechant, C., et al. (2001). Treatment of psoriatic arthritis with antitumor necrosis factor antibody clears skin lesions of psoriasis resistant to treatment with methotrexate. *British Journal of Dermatology*, 144, 1932-1939. This article supports the use of this drug for psoriatic arthritis.

Pharmaceutical News (2004). Analysis shows Remicade reduces pain associated with Chron's disease. Retrieved from <http://www.news-medical.net> on August 11, 2005.

Remicade™ package insert, 1999-2002.

Remicade Package insert revised September 2005.

Remicade Package insert revised September 2006.

Rutgeerts, P., Feagan, A., Olson, J. et al (2005). A randomized Placebo-Controlled Trial of Infliximab Therapy for Active Ulcerative Colitis: Act I Trial. Gastroenterology, 128 (4) (2). The American Gastroenterological Association.

Sandborn, W., Rachmilewitz, D., Hanauer, S., et al (2005). Infliximab Induction and Maintenance Therapy for Ulcerative Colitis: the Act 2 Trial. Gastroenterology, 128 (4) (2). The American Gastroenterological Association.

Vanden Bosch, F., Kruithof, E., Baeten, D., et al. (2002). Randomized double-blind comparison of chimeric monoclonal antibody to tumor necrosis factor a (Infliximab) versus placebo in active spondylarthropathy. Arthritis & Rheumatism, 46(3), 755-765. This article supports the use of this drug for ankylosing spondylarthropathy.

Advisory Committee Meeting Notes

This Local Coverage Determination (LCD) does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this LCD was developed in cooperation with advisory groups, which includes representatives from numerous societies.

Start Date of Comment Period

End Date of Comment Period

Start Date of Notice Period

12/04/2008

Revision History Number

Original

Revision History Explanation

Revision Number:Original

Start Date of Comment Period:N/A

Start Date of Notice Period:12/04/2008

Revised Effective Date:02/02/2009

LCR B2009-
December 2008 Bulletin

This LCD consolidates and replaces all previous policies and publications on this subject by the carrier predecessors of First Coast Service Options, Inc. (Triple S and FCSO).

For Florida (00590) this LCD (L29198) replaces LCD L5672 as the policy in notice. This document (L29198) is effective on 02/02/2009.

Reason for Change**Last Reviewed On Date****Related Documents**

This LCD has no Related Documents.

LCD Attachments

There are no attachments for this LCD.

All Versions

Updated on 11/30/2008 with effective dates 02/02/2009 - N/A