

Contractor's Policy Number

03-01

Contractor's Name

CareFirst of Maryland Inc., Medicare Part A

Contractor Number

00190

Contractor Type

Fiscal Intermediary

LMRP Title

Infliximab Therapy (Remicade™)

AMA CPT Copyright Statement

CPT codes, descriptions, and other data only are copyright 1999 American Medical Association (or such publication of CPT). All rights reserved. Applicable FARS/DFARS clauses apply.

CMS National Coverage Policy

- Establishment of national policy supersedes all previous contractor policy statements, including Local Medical Policy coverage guidelines
- Title XVIII of the Social Security Act, section 1861 (s) and (t). These sections relate to drugs and biologicals.
- Title XVIII of the Social Security Act, section 1862 (a) (7). This section excludes routine physical examinations.
- Title XVIII of the Social Security Act, section 1862 (a) (1) (A). This section

allows coverage and payment for only those services that are considered to be medically reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

- Title XVIII of the Social Security Act, section 1833 (e). This section prohibits Medicare payment for any claim that lacks the necessary information to process the claim.
- Medicare Hospital Manual, Section 442.7
- Medicare Intermediary Manual, Sections 3101.3, 3112.4, 3627.9, and 3627.10

Primary Geographic Jurisdiction

Maryland

Washington, DC

Secondary Geographic Jurisdiction

Alabama, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Massachusetts, Michigan, Missouri, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Wisconsin, Washington state, and Wyoming

CMS Region

Region III

CMS Consortium

Northeast

Original Policy Effective Date

06/27/2003

Original Policy Ending Date

NA

Revision Effective Date

NA

Revision Ending Date

NA

LMRP Description

Infliximab is a chimeric IgG monoclonal antibody which binds specifically to human tumor necrosis factor alpha. Infliximab neutralizes the biological activity of tumor necrosis factor alpha by binding with high affinity to the soluble and transmembrane forms of the molecule and inhibiting its binding to its receptor. The clinical result is a decrease in inflammation.

Indications and Limitations of Coverage and/or Medical Necessity

Infliximab is indicated for the following:

- In rheumatoid arthritis, 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 who have had an inadequate response to methotrexate.
- As a monotherapy in rheumatoid arthritis when methotrexate is not tolerated or contraindicated.
- In ankylosing spondylitis, when the condition has shown an inadequate response to conventional therapy.
- In Crohn's disease, for reducing signs and symptoms and inducing and

maintaining clinical remission in patients with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy.

- In fistulizing Crohn's disease, for the reduction in the number of draining enterocutaneous fistulae.
- In pyoderma gangrenosum associated with Crohn's disease when the condition has shown an inadequate response to conventional therapy.
- In psoriatic arthropathy, when the condition has shown an inadequate response to conventional therapy.
- In ulcerative colitis, when the condition has shown an inadequate response to conventional therapy.

CPT/HCPCS Section & Benefit Category

HCPCS Level II/Injections/Drugs

Medical

Type of Bill Code

13X, 22X, 23X, 74X, 75X, 83X

Revenue Codes

636

CPT/HCPCS Codes

The AMA and CMS require the use of short descriptors for policies published on the Web. Refer to the CPT book for the long description of the following code(s):

J1745 Injection, Infliximab

Not Otherwise Classified (NOC)

NA

ICD-9 Codes that Support Medical Necessity

ICD-9-CM code listings may cover a range and include truncated codes. It is the provider's responsibility to avoid truncated codes by selecting a code(s) carried out to the highest level of specificity and selected from the ICD-9-CM book appropriate to the year in which the claim is submitted.

It is not enough to link the procedure code to a correct, payable ICD-9-CM code. The diagnosis or clinical suspicion must be present for the procedure to be paid.

Covered for:

555.0	Regional enteritis, small intestine
555.1	Regional enteritis; large intestine
555.2	Regional enteritis, small intestine with large intestine
555.9	Regional enteritis,unspecified site
556.0	Ulcerative (chronic) enterocolitis
556.1	Ulcerative (chronic) ileocolitis
556.5	Left-sided ulcerative (chronic) colitis
556.6	Universal ulcerative (chronic) colitis
686.01	Pyoderma gangrenosum
696.0	Psoriatic arthropathy
714.0	Rheumatoid arthritis
720.0	Ankylosing spondylitis

Diagnoses that Support Medical Necessity

As listed in the "ICD-9 Codes that Support Medical Necessity" section of this policy

ICD-9 Codes that DO NOT Support Medical Necessity

Any diagnosis codes not listed in the "ICD-9 Codes that Support Medical Necessity" section of this policy

Diagnoses that DO NOT Support Medical Necessity

Conditions not listed in the "ICD-9 Codes that Support Medical Necessity" section of this policy.

Reasons for Denial

- Treatment of psoriasis in the absence of psoriatic arthropathy will be denied,
- All other indications not listed in the "Indications and Limitations of Coverage" section of this policy,
- The service is for screening purposes,
- The service is not medically necessary,
- The medical record does not verify that the service described by the HCPCS code was provided, and;
- The service does not follow the guidelines of this policy.

Non-covered ICD-9 Codes

Any diagnosis codes not listed in the "ICD-9 Codes that Support Medical Necessity" section of this policy.

Non-covered Diagnoses

Conditions not listed in the "ICD-9 Codes that Support Medical Necessity" section of this policy.

Coding Guidelines

- To report this service, use the appropriate HCPCS code J1745 with revenue code 636,
- To report the administration of Infliximab, use HCPCS code Q0081 with

revenue code 260,

- All of the coverage criteria must be met before this service can be reimbursed by Medicare,
- Diagnosis (es) must be present on any claim submitted, and be coded to the highest level of specificity, and;
- The diagnosis code(s) must be representative of the patient's condition.

Documentation Requirements

- Documentation supporting the medical necessity should be legible, maintained in the patient's medical record, and available to Medicare upon request.
- Documentation should include details of the patient's history that show an inadequate response to conventional therapies prior to beginning Infliximab.
- The number of milligrams used should accompany the electronic claim on page 7 under "Remarks".

Utilization Guidelines

- Infliximab should be administered in compliance with the package labeling.
- Continuation of the drug after the initial dosing should be based on a documented response to therapy.
- When given in the outpatient setting, the Infliximab should be given under the direct supervision of a physician.

Other Comments

Medicare will monitor utilization of this drug through the Medical Review Process.

Financial Responsibility:

Provider Liable

The provider of the service or the ordering physician must have notified the

patient in writing, prior to the service, and obtained a signature verifying Advance Beneficiary Notice. Without prior notice, services denied as not medically necessary cannot be billed to the beneficiary. The provider is liable.

Beneficiary Liable

If there is clear evidence that the beneficiary was issued and signed an Advanced Beneficiary Notice (ABN) prior to the service, the liability rests with the beneficiary. Claims for dates of service prior to January 1, 2003 should contain the condition code 20 and occurrence code 32, with date to signify that an ABN was issued to the beneficiary. Absence of these codes will result in a provider liable determination

Claims for dates of service beginning January 1, 2003 should contain the occurrence code 32 with date to signify that an ABN was issued to the beneficiary. Absence of this code will result in a provider liable determination.

Reference: PM AB-02-168, CR 2415

Sources of Information and Basis for Decision

TrailBlazer Infliximab Therapy (Remicade™) LMRP

Remicade™ package insert

American College of Rheumatology Subcommittee on Rheumatoid Arthritis Guidelines. Guidelines for the Management of Rheumatoid Arthritis. *Arthritis and Rheumatism*, vol. 46, No. 2, February 2002, pp 328-346.

CAC representative for Gastroenterology

Advisory Committee Notes

This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy

was developed in cooperation with advisory groups, which includes representatives from Gastroenterology and Rheumatology.

Advisory Committee Meeting Date:

Start Date of Comment Period

03/10/2003

End Date of Comment Period

04/24/2003

Start Date of Notice Period

05/13/2003

Revision History

Number	Date	Change
---------------	-------------	---------------

THIS BULLETIN SHOULD BE SHARED WITH ALL HEALTH CARE PRACTITIONERS AND MANAGERIAL MEMBERS OF THE PROVIDER/SUPPLIER STAFF. BULLETINS ISSUED AFTER OCTOBER 1, 1999 ARE AVAILABLE FROM OUR WEBSITE AT www.marylandmedicare.com

Italicized and or quoted material is excerpted from the American Medical Association *Current Procedural Terminology CPT codes*, descriptions and other data only are copyrighted 1999 American Medical Association (or such other publication of CPT). All rights reserved. Applicable FARS/DFARS apply.