

Medicare Part B Prior Authorization Form

Last Reviewed: Sept 11

For Prior Authorization please fax to: (877)974-4411 toll free, or (616)942-8206

This form applies to: Commercial Plan Medicaid Plan Medicare Plan

Xolair™ (omalizumab)

Urgent

Non-urgent

Member Name:	Member #:
DOB:	Gender:
Provider Name:	Provider Phone:
Provider Office Address:	
Provider Office Contact Name:	Provider Fax:
Provider Signature:	Provider NPI:
Date:	Member's PCP:

Product:

Xolair injection 150 mg

Dose: _____ Start date: _____ Frequency: _____

Patient's weight: _____

List the ICD9 code: _____

Place of administration:

Self-administered

Provider's Office

Outpatient Infusion Center

Name of center: _____

Home Infusion

Name of agency: _____

Billing options:

Physician buy and bill (J2357)

Preferred Specialty Vendor

Other: _____

Please Complete the Following Information:

Diagnosis:

Moderate to severe persistent asthma– ICD code: _____

Other: _____ – ICD code: _____ Please provide rationale for use:

Patient has had a positive skin test or in-vitro reactivity to a perennial aeroallergen (please fax results):

Yes

No – Rationale for use: _____

Patient's symptoms are inadequately controlled with inhaled corticosteroids:

Yes

No – Rationale for use: _____

Note: Priority Health Medicare applies CMS local coverage determination criteria when available for Part B drugs. If no local coverage determination criteria is available for the state in which the member is receiving the services, the above prior authorization criteria must be met.

***** All fields must be complete and legible for Prior Authorization Review*****

**Please fax this request to: (877)974-4411 toll free or (616)942-8206
YOUR OFFICE WILL RECEIVE A RESPONSE VIA FAX**

The following Local Coverage Determination (LCD) information was obtained from the US Department of Health & Human Services Center for Medicare & Medicaid Services (available www.cms.hhs.gov). The primary jurisdiction for coverage outlined in this LCD is Michigan. For Priority Health Medicare members receiving this service outside the state of Michigan, please refer to the LCD for that state for coverage requirements. If no LCD is available for the state in which this service is being provided, coverage will be determined as outlined in this prior authorization document.

Article for OMALIZUMAB (e.g. Xolair) – Related to LCD L25820 (A46088)

Indications:

- Omalizumab is approved by the Food and Drug Administration (FDA) for patients (12 years of age or above) with moderate to severe persistent asthma who have had a positive skin test or in-vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids.

Moderate persistent asthma

Moderate persistent asthma is defined by the National Heart, Lung, and Blood Institute (NHLBI) as:

- Daily symptoms
- Daily use of inhaled short-acting beta2-agonist
- Exacerbations affect activity
- Exacerbations greater than or equal to 2 times a week; may last days
- Nighttime symptoms greater than 1 time a week

Severe persistent asthma

Severe persistent asthma is defined by the National Heart, Lung, and Blood Institute (NHLBI) as:

- Continual symptoms
- Limited physical symptoms
- Frequent exacerbations
- Nighttime symptoms are frequent

The presence of one of these features of severity (moderate or severe) is sufficient to place a patient in that category. These clinical features are based on pre-treatment symptoms and measurements.

- Allergy to peanuts
- Latex allergy

Limitations:

Because of the chance of anaphylaxis with omalizumab, patients should receive omalizumab treatment in a doctor's office or clinic setting and be observed for an appropriate period of time after each treatment. Omalizumab should only be administered in a healthcare setting by healthcare providers prepared to manage anaphylaxis that can be life-threatening.

Omalizumab has not been shown to alleviate asthma exacerbations acutely and should not be used for the treatment of acute bronchospasm or status asthmaticus.

Utilization:

Omalizumab 150 to 375 mg is administered subcutaneously every 2 or 4 weeks.

Omalizumab is covered when the drug is administered by a physician or incident to a physician's service in a clinic or office setting and used in accordance with FDA-approved indications.

Omalizumab is not covered if self-administered by the patient.

Coding Guidelines:

For claims submitted to the carrier or Part B MAC:

Claims for omalizumab should be billed using chemotherapy administration codes and is payable in the following places of service: office (11), home (12), assisted living facility (13), group home (14), **nursing facility for patients not in a Part A stay (32)**, custodial care facility (33), independent clinic (49) only when supplied as an "incident to" service by the physician and state or local public health clinic

(71), only when supplied as an "incident to" service by the physician.

Coding Information

Bill Type Codes: [back to top](#)

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 article does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the article should be assumed to apply equally to all claims.

11x Hospital-inpatient (including Part A)

13x Hospital-outpatient (HHA-A also) (under OPPS 13X must be used for ASC claims submitted for OPPS payment -- eff. 7/00)

85x Special facility or ASC surgery-rural primary care hospital (eff 10/94)

CPT/HCPCS Codes [back to top](#)

J2357 INJECTION, OMALIZUMAB, 5 MG

ICD-9 Codes that are Covered [back to top](#)

493.00 EXTRINSIC ASTHMA UNSPECIFIED

493.10 INTRINSIC ASTHMA UNSPECIFIED

493.20 CHRONIC OBSTRUCTIVE ASTHMA UNSPECIFIED

493.90 ASTHMA UNSPECIFIED

995.3 ALLERGY UNSPECIFIED NOT ELSEWHERE CLASSIFIED

V15.01 PERSONAL HISTORY OF ALLERGY TO PEANUTS

V15.07 PERSONAL HISTORY OF ALLERGY TO LATEX

ICD-9 Codes that are Not Covered [back to top](#)

Not Applicable

Other Information

Other Comments [back to top](#)

Sources of Information

American Society of Health-System Pharmacists, Inc. AHFS Drug Information®. Bethesda, MD: 2007.

Clinical Pharmacology Web site. <http://www.clinicalpharmacology.com/>. Accessed 04/30/2009.

National Comprehensive Cancer Network Web site. <http://www.nccn.org/index.asp>. Accessed 04/30/2009.

Thomson Micromedex DrugDex®. Thomson Web site. <http://www.thomsonhc.com/home/dispatch>. Accessed 04/30/2009.

U.S. Food and Drug Administration label approved 06/20/2003. Drugs@FDA Web site. <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/>. Accessed 11/19/2007.

United States Pharmacopoeia (USP), Volume I; Drug Information for the Health Care Professional, 2007.

06/05/2009 - In accordance with Section 911 of the Medicare Modernization Act of 2003, fiscal intermediary number 00270 was removed from this article as the claims processing for New Hampshire and Vermont was transitioned to NHIC, the Part A/Part B MAC contractor in these states.

Revision History Explanation [back to top](#)

Article published June 2009: Source of revision – External/internal: Based on an external comment, the coding guidelines for claims submitted to the carrier or Part B MAC have been revised to state that omalizumab should be billed using chemotherapy administration codes. The places of service have been revised to add the following place of service: nursing facility for patients not in a Part A stay (32). In the "Sources of Information" section, the formatting of the Web sites for Clinical Pharmacology, National Comprehensive Cancer Network, Micromedex DrugDex® and U. S. Food and Drug Administration has been revised.

05/15/2009 - In accordance with Section 911 of the Medicare Modernization Act of 2003, fiscal intermediary numbers 00180 and 00181 were removed from this article as the claims processing for Maine and Massachusetts was transitioned to NHIC. the Part A/Part B MAC contractor in these states.

Other Information

Correction (published 01/29/2009): the description for ICD-9-CM code 995.3 has been corrected on the Web site version to match what is listed in the CMS Medicare Coverage Database.

Article published January 2009: Source of revision – Internal – ICD-9-CM code 995.3 has been added to the "ICD-9-CM Codes That Support Medical Necessity" section of the article effective for dates of service on or after 07/18/2008. This was inadvertently omitted in the previous revision of the article. The "Article Text" and "Sources of Information" have been revised to include compendia recognized by CMS based on Change Request 6191 (Compendia as Authoritative Sources for Use in the Determination of a Medically Accepted Indication of Drugs and Biologicals Used Off-Label in an Anti-Cancer Chemotherapeutic Regimen, effective 11/25/2008). This article has been reviewed using all listed compendia and is up to date. Minor changes were made to reflect current template language.

This revised article is effective for all National Government Services jurisdictions on July 18, 2008 with these exceptions: for Connecticut – Part B the article is effective on August 1, 2008; for Upstate New York – Part B, the article is effective on September 1, 2008; and for New York and Connecticut – Part A, the article is effective on November 14, 2008. For New York – Part A (contract 00308), the content of this article is currently in effect but the article will be transferred to the J-13 contract number 13201 on November 14, 2008.

This article was revised to add the Jurisdiction 13 (J-13) MAC contractor numbers and to retain the most clinically appropriate medical policy information within the jurisdiction, including off-label indications and approved indications from DrugPoints®.

The indications have been revised to include: moderate and severe asthma, allergy to peanuts and latex allergy. The following ICD-9-CM code have been added: V15.01 and V15.07. Thomson Healthcare DrugPoints® has been added to the "Article Text" paragraph and "Sources of Information". Bill type codes have been added. Places of service for claims submitted to the carrier has been revised.

Article published December 2007: Original version of article.

The original version of the corresponding LCD became effective on 12/01/2007.

Other Information

08/18/2008 - In accordance with Section 911 of the Medicare Modernization Act of 2003, fiscal intermediary number 00454 was removed from this article as the claims processing for American Samoa, California, Guam, Hawaii, Nevada and Northern Mariana Islands was transitioned to Palmetto GBA, the Part A/Part B MAC contractor in these states.

11/14/2008 - In accordance with Section 911 of the Medicare Modernization Act of 2003, fiscal intermediary number 00308 is removed from this article. Effective on this date, claims processing for Delaware is performed by Highmark Medicare Services, the Part A/Part B MAC contractor for this state, and the claims processing for New York and Connecticut is performed by National Government Services under the J-13 MAC contract; carrier number 00805 is removed, and claims processing for New Jersey is performed by Highmark Medicare Services, the Part A/Part B MAC contractor for this state.

06/05/2009 - In accordance with Section 911 of the Medicare Modernization Act of 2003, fiscal intermediary number 00270 was removed from this article as the claims processing for New Hampshire and Vermont was transitioned to NHIC, the Part A/Part B MAC contractor in these states.

Related Documents [back to top](#)

LMRP(s)

Article(s)

[A44930 - Drugs and Biologicals, Coverage of, for Label and Off-Label Uses - Supplemental Instructions Article](#)

LCD(s)

[L25820 - Drugs and Biologicals, Coverage of, for Label and Off-Label Uses](#)

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Updated on 05/29/2009 with effective dates 06/05/2009 - N/A

[Updated on 05/28/2009 with effective dates 05/15/2009 - 06/04/2009](#)

[Updated on 05/07/2009 with effective dates 05/15/2009 - N/A](#)

[Updated on 01/23/2009 with effective dates 01/01/2009 - 05/14/2009](#)

[Updated on 12/23/2008 with effective dates 01/01/2009 - N/A](#)

[Updated on 11/07/2008 with effective dates 11/14/2008 - N/A](#)

[Updated on 08/06/2008 with effective dates 08/18/2008 - 11/13/2008](#)

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[Updated on 11/21/2007 with effective dates 12/01/2007 - N/A](#)