MASSACHUSETTS

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Pharmacy Medical Policy

# IgE Receptor Binding Inhibitors

## Table of Contents


- Policy: Commercial
- Policy: Medicare
- Coding Information
- Policy History
- Information Pertaining to All Policies
- References
- Endnotes
- Forms


## Policy Number: 017

BCBSA Reference Number: None

## Related Policies

None

## Policy

### Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

**Note:** All requests for outpatient retail pharmacy for indications listed and not listed on the medical policy guidelines may be submitted to BCBSMA Clinical Pharmacy Operations by completing the Prior Authorization Form on the last page of this document. Physicians may also submit requests for exceptions via the web using Express PA which can be found on the BCBSMA provider portal or directly on the web at https://provider.express-path.com. ‘

This medication is not covered by the pharmacy benefit. It is covered by the Medical Benefit or as a Home Infusion Therapy.

Xolair™, a recombinant humanized monoclonal anti-immunoglobulin E (IgE) antibody, is covered for allergic mediated moderate-to-severe asthma caused by perennial aeroallergens, and in accordance with the FDA approved criteria**. ALL** of the following criteria must be met:

- Patient is ≥ 12 years old[1]
- Asthma symptoms are not adequately controlled by > 3 months of continuous therapy of high dose inhaled steroids[1,3] or oral steroids
- Patient has a positive skin test or in vitro testing for one or more perennial aeroallergen
- Recent IgE levels are within the range of 30 to 700 IU/ml (“recent” is defined as any time prior to treatment but within 6 months)
- Only when prescribed by a pulmonologist or allergist.

Xolair™ is also covered if **ALL** of the following are met:

- Patient is ≥ 12 years old[1]
- Patient has a Diagnosis of Chronic idiopathic urticaria (CIU)
- Symptomatic despite H1 antihistamine treatment

- Only when prescribed by a Dermatologist or Allergist

Xolair™ is not covered except for the condition listed above.

## CPT Codes / HCPCS Codes / ICD-9 Codes

*The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.*

*Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.*

### CPT Codes

There is no specific CPT code for this service.

### HCPCS Codes

| HCPCS codes: | Code Description |
|---|---|
| J2357 | Injection, omalizumab, 5 mg |

### ICD-9 Diagnosis Codes

| ICD-9-CM diagnosis codes: | Code Description |
|---|---|
| 493.00 | Extrinsic asthma, unspecified |
| 493.01 | Extrinsic asthma with status asthmaticus |
| 493.02 | Extrinsic asthma, with (acute) exacerbation |
| 493.10 | Intrinsic asthma, unspecified |
| 493.11 | Intrinsic asthma with status asthmaticus |
| 493.12 | Intrinsic asthma, with (acute) exacerbation |
| 493.20 | Chronic obstructive asthma, unspecified |
| 493.21 | Chronic obstructive asthma, with status asthmaticus |
| 493.22 | Chronic obstructive asthma, with (acute) exacerbation |
| 493.82 | Cough variant asthma |
| 493.90 | Asthma, unspecified |
| 493.91 | Asthma, unspecified type, with status asthmaticus |
| 493.92 | Asthma, unspecified with (acute) exacerbation |

### ICD-10 Diagnosis Codes

| ICD-10-CM Diagnosis codes: | Code Description |
|---|---|
| J45.40 | Moderate persistent asthma, uncomplicated |
| J45.41 | Moderate persistent asthma with (acute) exacerbation |
| J45.42 | Moderate persistent asthma with status asthmaticus |
| J45.50 | Severe persistent asthma, uncomplicated |
| J45.51 | Severe persistent asthma with (acute) exacerbation |
| J45.52 | Severe persistent asthma with status asthmaticus |
| J45.901 | Unspecified asthma with (acute) exacerbation |
| J45.902 | Unspecified asthma with status asthmaticus |

| | |
|---|---|
| J45.909 | Unspecified asthma, uncomplicated |
| J45.991 | Cough variant asthma |
| J45.998 | Other asthma |

## Individual Consideration

All our medical policies are written for the majority of people with a given condition. Each policy is based on medical science. For many of our medical policies, each individual's unique clinical circumstances may be considered in light of current scientific literature. Physicians may send relevant clinical information for individual patients for consideration to:

Blue Cross Blue Shield of Massachusetts
Clinical Pharmacy Department
One Enterprise Drive
Quincy, MA 02171
Tel: 1-800-366-7778
Fax: 1-800-583-6289

## Managed Care Authorization Instructions

- This medication is not covered by the pharmacy benefit. It is covered by the Medical Benefit or as a Home Infusion Therapy.
- Prior authorization is required for all out patient sites of service
- For all outpatient sites of service, physicians may fax or mail the attached form to the address above.
- For all outpatient sites of service, physicians may also submit authorization requests via the web using Express PAth which can be found on the BCBSMA provider portal or directly on the web at https://provider.express-path.com

## PPO and Indemnity Authorization Instructions

- This medication is not covered by the pharmacy benefit. It is covered by the Medical Benefit or as a Home Infusion Therapy.
- Prior authorization **is** required when this medication is processed under the home infusion therapy benefit.
- Prior authorization **is not** required when this medication is purchased by the physician and administered in the office in accordance with this medical policy.
- Physicians may also fax or mail the attached form to the address above.
- Physicians may also submit authorization requests via the web using Express PAth which can be found on the BCBSMA provider portal or directly on the web at https://provider.express-path.com

## Policy History

| Date | Action |
|---|---|
| 7/2014 | Updated to include ICD-10 and updated with new Indication CIU. |
| 1/2014 | Updated ExpressPAth language |
| 3/2012 | Reviewed – Medical Policy Group - Allergy, Asthma, Immunology and ENT/Otolaryngology. No changes to policy statements. |
| 11/2011-4/2012 | Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements. |
| 3/2011 | Reviewed - Medical Policy Group - Allergy and ENT/Otolaryngology. No changes to policy statements. |
| 3/2010 | Reviewed - Medical Policy Group - Allergy and ENT/Otolaryngology. No changes to policy statements. |
| 10/2009 | Updated to reflect UM guidelines. |
| 3/2009 | Reviewed - Medical Policy Group - Allergy and ENT/Otolaryngology. No changes to policy statements. |
| 3/2008 | Reviewed - Medical Policy Group - Allergy and ENT/Otolaryngology. No changes to policy statements. |

| | |
|---|---|
| 3/2007 | Reviewed - Medical Policy Group - Allergy and ENT/Otolaryngology.<br>No changes to policy statements. |
| 9/2003 | New policy, effective 9/2003, describing covered and non-covered indications. |

## References


1. Xolair™ subcutaneous injection [package insert]. South San Francisco, CA and East Hanover, NJ: Genentech, Inc. and Novartis Pharmaceuticals Corporation; June 2003.
2. Solèr M, Matz J, Townley R, et al. The anti-IgE antibody omalizumab reduces exacerbations and steroid requirement in allergic asthmatics. *Eur Respir J.* 2001;18:254-261.
3. Buhl R, Solèr M, Matz J, et al. Omalizumab provides long-term control in patients with moderate-to-severe allergic asthma. *Eur Respir J.* 2002;20:73-78.
4. Buhl R, Hanf G, Solèr M, et al. The anti-IgE antibody omalizumab improves asthma-related quality of life in patients with allergic asthma. *Eur Respir J.* 2002;20:1088-1094.
5. Busse W, Corren J, Lanier BQ, et al. Omalizumab, anti-IgE recombinant humanized monoclonal antibody, for the treatment of severe allergic asthma. *J Allergy Clin Immunol.* 2001;108(2):184-190.
6. Finn A, Gross G, van Bavel J, et al. Omalizumab improves asthma-related quality of life in patients with severe allergic asthma. *J Allergy Clin Immunol.* 2003;111(2):278-284.
7. Holgate S, Bousquet J, Wenzel S, Fox H, Liu J, Castellsague J. Efficacy of omalizumab, an anti-immunoglobulin E antibody, in patients with allergic asthma at high risk of serious asthma-related morbidity and mortality. *Curr Med Res Opin.* 2001;17(4):233-240.

**IgE Receptor Binding Inhibitors**
**Xolair™(omalizumab) Prior Authorization Form**
**Please complete and fax to: (888) 641-5355**
**Please contact Pharmacy Operations with questions at (800)366-7778**
If the patient is a BCBSMA employee, please fax the form to: (617)246-4013
**For Home Infusion Authorizations:**

| | | | |
|---|---|---|---|
| Company Name: | | Contact: | |
| Telephone: | | Provider #: | |
| Fax: | | | |
| Patient Name: | | Patient Address: | |
| Patient BCBSMA ID#: | | Patient DOB: | |
| Physician Name: | | Physician Telephone: | |
| Physician Address: | | Physician Fax: | |

For Outpatient Administration:

| | | | |
|---|---|---|---|
| Servicing Provider: | Name:<br>NPI #: | Requesting Provider | Name:<br>NPI #: |
| Phone:<br>Fax:<br>Contact Person: | | Phone:<br>Fax:<br>Contact Person: | |
| Patient Name: | | Patient Address: | |
| Patient BCBSMA ID#: | | Patient DOB: | |

Is this fax number 'secure' for PHI receipt/transmission per HIPAA requirements? (circle one) Yes No

Required Clinical Information:

Drug: _____ Dose: _____ Frequency: _____
Route of administration: _____ Dates of Service: ____/____/____ to ____/____/_____
Diagnosis_____ ICD-9 or 10 code_____
Weight_____

**Check and list concomitant therapies:**

- ❑ Inhaled corticosteroid
- ❑ Oral steroid
- ❑ Combination long acting β-2 agonist with inhaled corticosteroid

| ***Therapy*** | ***Drug name*** | ***Dosage*** | ***Treatment length*** |
|---|---|---|---|
| | | | |
| | | | |
| | | | |

**Lab results:**

- ❑ RAST test date: _____
- ❑ Skin test date: _____

Name of perennial aeroallergen: _____
Pre-treatment serum IgE: _____ date: _____

**Physician signature:**_____ **date:**_____
**NOTE:** Copy of signed prescription is REQUIRED for Home Infusion requests