MASSACHUSETTS

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Pharmacy Medical Policy

Injectable Asthma Medications

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Policy Number: 017

BCBSA Reference Number: None

Related Policies

Dupixent (dupilumab) resides in Medical policy 033

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.

Cinqair ®*^ (reslizumab) is indicated for the add-on maintenance treatment of patients with severe asthma when **ALL** of the following criteria must be met:

- Patient is ≥ 18 years old, **And**
- Patient is diagnosed with an eosinophilic phenotype, **And**
- CINQAIR is **NOT** indicated for treatment of other eosinophilic conditions, **And**
- CINQAIR is **NOT** indicated for the relief of acute bronchospasm or status asthmaticus.

Fasenra ™*^** (benralizumab) is indicated for the add-on maintenance treatment of patients with severe asthma when **ALL** of the following criteria must be met:

- Patient is ≥ 12 years old, **And**
- Patient is diagnosed with an eosinophilic phenotype, **And**
- **Fasenra™** is **NOT** indicated for treatment of other eosinophilic conditions, **And**
- **Fasenra™** is **NOT** indicated for the relief of acute bronchospasm or status asthmaticus.

Nucala ®*^** (mepolizumab) may be covered when **ALL** of the following criteria must be met:

- add-on maintenance treatment of patients with severe asthma, **And**
- Patient is ≥ 6 years old, **And**
- Patient is diagnosed with an eosinophilic phenotype

Or

- An adult patient is diagnosed with an eosinophilic granulomatosis with polyangiitis (EGPA).

Or

- For adult and pediatric patients aged 12 years and older with hypereosinophilic syndrome (HES) for ≥6 months without an identifiable non-hematologic secondary cause.

Or

- For the add-on maintenance treatment of chronic rhinosinusitis with nasal polyps (CRSwNP) in adult patients 18 years of age and older with inadequate response to nasal corticosteroids.

Tezspire ™*^** (tezepelumab) is indicated for the add-on maintenance treatment of patients with severe asthma when **ALL** of the following criteria must be met:

- Patient is ≥ 12 years old, **AND**
- Patient is diagnosed with severe asthma, **AND**
- **Tezspire ™** is **NOT** indicated for the relief of acute bronchospasm or status asthmaticus.

Xolair ™*^ (omalizumab), a recombinant humanized monoclonal anti-immunoglobulin E (IgE) antibody, may be 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 ≥ 6 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
- For pediatric patients between 6 years old and 12 years old recent IgE levels are within the range of 30 to 1300 IU/ml ("recent" is defined as any time prior to treatment but within 6 months)
- For Patients 12 years and older 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 ™*^ (omalizumab) also may be covered if **ALL** of the following are met:

- Patient is ≥ 12 years old[1]
- Patient has a diagnosis of chronic idiopathic urticaria (CIU) with at least a 6 week history of urticaria and presence of hives
- Documented failure, contraindication, or intolerance to a four-week trial of one second-generation non-sedating histamine receptor type 1 (H1) antihistamine
  - **AND**
- Documented failure, contraindication, or intolerance to at least a two-week trial of **ANY ONE** of the following medications:
  - Leukotriene receptor antagonist **OR**
  - Histamine H2-receptor antagonist **OR**
  - First-generation (sedating) H1 antihistamine **OR**
  - Substitution to a different second-generation non-sedating H1 antihistamine
- Only when prescribed by a Dermatologist or Allergist.

Xolair ™*^ (omalizumab) also may be covered if ALL of the following are met:

- Patient is ≥ 18 years old[1]
- is indicated for treatment of nasal polyps
- Concurrent therapy with nasal corticosteroids

Xolair ™*^ (omalizumab) is not covered except for the condition listed above.

*^ - This medication is Part of the Med UM Program.
Note: If approved the Prior Authorization will be granted for up to one (1) year.

** - This Drug is part of Medications covered only under the pharmacy benefit only program. This program does not apply when the medication is administered: in the emergency room, as an inpatient, at a surgical day care facility, in an ambulatory surgery-center, or through home infusion therapy or dialysis.

CPT Codes / HCPCS Codes / ICD Codes

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.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:

HCPCS Codes

HCPCS codes:	Code Description
J0517	Injection, benralizumab, 1 mg
J2182	Injection, mepolizumab, 1 mg (**Nucala** ®)
J2357	Injection, omalizumab, 5 mg (**Xolair** ™)
J2786	Injection, reslizumab, 1 mg (**Cinqair** ®)

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
Pharmacy Operations Department
25 Technology Place
Hingham, MA 02043
Tel: 1-800-366-7778
Fax: 1-800-583-6289

Prior Authorization Information

Outpatient

For services described in this policy, see below for products where prior authorization **IS REQUIRED** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is **required**.
Commercial PPO and Indemnity	Prior authorization is **required**.

Policy History

Date	Action
4/2022	Updated to add Tezspire ™ to the policy.
8/2021	Updated to add New indication for Nucala ®.
1/2021	Updated to add new indication for Xolair ®.
10/2020	Updated to add new indication for Nucala ®. Removed deleted codes
4/2020	Updated criteria for Xolair on CIU diagnosis
11/2019	Updated age requirements for Nucala ®.
7/2019	Updated to add CinQair®, Nucala ®, and Fasenra™ to the Med UM program.
1/2019	Clarified coding information.
4/2018	Clarified coding information.
2/2018	Updated to include Fasenra™ and a new indication for Nucala ®.
10/2017	Updated to clarify pediatric IgE levels.
6/2017	Update address for Pharmacy Operations.
1/2017	Updated to include New HCPCS/CPT codes.
10/2016	Updated to include CinQair® and allow all three medications to be billed on both Medical & Pharmacy.
6/2016	Updated to include Nucala® to Medical Only and changed the Policy Name.
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. 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.
8. Nucala ® [package insert]. Philadelphia, PA: GlaxoSmithKline LLC; Nov 2015.
9. Cinqair ® [package insert]. Frazer, PA: Teva Pharmaceutical Industries Ltd; Mar 2016.
10. Faserna ™ [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; Nov 2017.
11. Bernstein JA, Lang DM, Khan DA, et al. The diagnosis and management of acute and chronic urticaria: 2014 update. *J Allergy Clin Immunol.* 2014 May;133(5):1270-7.

To request prior authorization using the Massachusetts Standard Form for Medication Prior Authorization Requests (eForm), click the link below:
http://www.bluecrossma.org/medical-policies/sites/g/files/csphws2091/files/acquiadam-assets/023%20E%20Form%20medication%20prior%20auth%20instruction%20prn.pdf