Pharmacy Policy

Asthma-Allergy Monoclonal Antibodies

Policy Number: 9.109
Revision Number: R1
Version Effective Date: 1/1/2021

Product Applicability	☐ **All Plan[+] Products**
Well Sense Health Plan	**Boston Medical Center HealthNet Plan**
☒ New Hampshire Medicaid	☐ MassHealth - MCO ☐ MassHealth - ACO ☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☐ Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- Cinqair (reslizumab)
- Fasenra (benralizumab)
- Nucala (mepolizumab)
- Xolair (omalizumab)

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	All FDA approved indications not otherwise excluded
Exclusion Criteria	Use for relief of acute bronchospasm or status asthmaticus Use of Cinqair and Fasenra for treatment of other eosinophilic conditions Use of Xolair for treatment of other allergic conditions or other forms of urticaria Concurrent use of any of the following: Cinqair, Fasenra, Nucala, Xolair

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Required Medical Information	**Cinqair** 1. A diagnosis of severe asthma with an eosinophil phenotype; **AND** 2. Member is symptomatic, and is compliant with use of combination controller therapy (including at least a high dose inhaled corticosteroid with either a long acting beta agonist, or leukotriene modifier); **AND** 3. The source of the allergenic asthma-triggers (if known) and underlining causes (if known) has been removed or addressed; **AND** 4. Lab documentation indicating blood eosinophil count greater than or equal to 400 cells/mcL at therapy initiation (within 3-4 weeks of dosing) **Fasenra** 1. A diagnosis of severe asthma with an eosinophil phenotype; **AND** 2. Member is symptomatic, and is compliant with use of combination controller therapy (including at least a high dose inhaled corticosteroid with either a long acting beta agonist, or leukotriene modifier); **AND** 3. The source of the allergenic asthma-triggers (if known) and underlining causes (if known) has been removed or addressed; **AND** 4. Lab documentation indicating blood eosinophil count greater than or equal to 150 cells/mcL **Nucala** 1. A diagnosis of severe asthma with an eosinophil phenotype; **AND** a. Member is symptomatic, and is compliant with use of combination controller therapy (including at least a high dose inhaled corticosteroid with either a long acting beta agonist, or leukotriene modifier); **AND** b. The source of the allergenic asthma-triggers (if known) and underlining causes (if known) has been removed or addressed; **AND** c. Lab documentation indicating blood eosinophil count greater than or equal to 150 cells/mcL, **OR** 2. A diagnosis of eosinophilic granulomatosis with polyangiitis (Churg-Strauss); **AND** a. Member is stable on oral corticosteroid for at least 4 weeks or has a contraindication to oral corticosteroid therapy; **AND** b. An inadequate response, adverse reaction, or contraindication to azathioprine or methotrexate **Xolair** 1. A diagnosis of moderate to severe persistent asthma; **AND** a. Member is symptomatic, and is compliant with use of combination controller therapy (including at least a high dose inhaled corticosteroid with either a long acting beta

	agonist, or leukotriene modifier); **AND** b. The source of the allergenic asthma-triggers (if known) and underlining causes (if known) has been removed or addressed; **AND** c. Lab documentation indicating serum IgE level: • Between 30 IU/mL and 700 IU/ml; **OR** • Over 700 IU/ml and 2 or more exacerbations requiring oral corticosteroids or hospitalizations in the past year; **AND** d. A positive skin test or in vitro reactivity to a perennial aeroallergen, **OR** 2. A diagnosis of chronic idiopathic urticaria (CIU); **AND** a. An inadequate response or contraindication or persistent adverse effect to a one-month trial each of two different H1 antagonists at the maximum tolerable dose; **AND** b. An inadequate response or contraindication or persistent adverse effect to a one-month trial of concurrent use of a histamine H1 antagonist with a histamine H2 antagonist or an antileukotriene.
Age Restrictions	Cinqair: 18 years or older Fasenra: 12 years or older Nucala for asthma: 6 years or older Nucala for eosinophilic granulomatosis with polyangiitis: 18 years or older Xolair for asthma: 6 years or older Xolair for CIU: 12 years or older
Prescriber Restriction	Asthma, Eosinophil phenotype asthma: Prescribed by or in collaboration with an allergist, immunologist or pulmonologist CIU: Prescribed by or in collaboration with an allergist, dermatologist or immunologist Eosinophilic granulomatosis with polyangiitis: Prescribed by or in collaboration with an allergist immunologist, pulmonologist or rheumatologist
Coverage Duration	Initial: 6 months Re-authorization: 12 months
Other criteria	Reauthorization: 1. Improved symptom control and/or decreased exacerbations while on Cinqair, Fasenra, Nucala or Xolair therapy evidenced by attestation that there has not been an increase in utilization of emergency services, hospitalizations, or urgent care visits due to symptom exacerbation; or 2. Reduction in total daily dose of oral corticosteroids from baseline or frequency of systemic corticosteroid use for asthma exacerbation (Cinqair, Fasenra or Nucala only)

Applicable Coding:

Code	Medication
J2786	Cinqair (reslizumab)
J0517	Fasenra (benralizumab)

Code	Medication
J2182	Nucala (mepolizumab)
J2357	Xolair (omalizumab)

Clinical Background Information and References

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3. National Asthma Education and Prevention Program Expert Panel Report 3, Guidelines for the Diagnosis and Management of Asthma. National Heart Lung and Blood Institute. NIH Publication Number 08-5846. October 2007, accessed February 2016.
4. Early Communication about an ongoing safety review of omalizumab. FDA Postmarket Drug Safety Information for Patients and Providers. July 16, 2009, accessed February 2012.
5. GINA Report: Global Strategy for Asthma Management and Prevention 2014. Ontario (Canada): National Institutes of Health: National Heart, Lung, and Blood Institute and The World health Organization: Global Initiative For Asthma (GINA); 2014. Accessed February 2015. Available from: http://www.ginasthma.org.
6. Jonathan A. Bernstein et al. The diagnosis and management of acute and chronic urticaria: 2014 update. J ALLERGY CLIN IMMUNOL VOLUME 133, NUMBER . May 2014.
7. FDA Drug Safety Communication: FDA approves label changes for asthma drug Xolair (omalizumab), including describing slightly higher risk of heart and brain adverse events. September 26, 2014, accessed February 2015.
8. Wenzel S. Treatment of severe asthma in adolescents and adults. Up to Date®. Last update Jan 11, 2016. Accessed February 2015; available from: http://www.uptodate.com
9. Khan DA. Chronic urticaria: Standard management and patient education. Up to Date®. Last updated Nov 05,2015. Accessed February 2016. Available from: http://www.uptodate.com
10. Stokes J, Casale TB. Anti-IgE Therapy. Up to Date®. Last updated Nov 17,2015. Accessed February 2016. Available from: http://www.uptodate.com
11. Product Information. Nucala®. GlaxoSmithKline. Research Triangle Park, NC. Dec 2017
12. Product Information. Cinqair®. Teva Frazer, PA. May 2016.
13. Reslizumab (Cinqair) for severe eosinophilic asthma. Med Lett Drugs Ther. 2016 Jun 20;58(1497):81-2
14. Product Information. Fasenra®. AstraZeneca Pharmaceuticals. Wilmington, DE. Nov 2017Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2017. Available from: http://www.ginasthma.org.
15. King, TE. Clinical features and diagnosis of eosinophilic granulomatosis with polyangiitis (Churg-Strauss). Up to Date®, accessed February 2018; available from: http://www.uptodate.com
16. King, TE. Treatment and prognosis of eosinophilic granulomatosis with polyangiitis (Churg-Strauss). Up to Date®, accessed February 2018; available from: http://www.uptodate.com

Original Approval Date	Original Effective Date	Policy Owner	Approved by

12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee, NH DHHS

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
12/1/2020	9.127 Asthma-Allergy Monoclonal Antibodies Policy retired, new policy created	1/1/2021	P&T Committee, NH DHHS

Next Review Date

2021

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

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