**Pharmacy Policy**

# Asthma-Allergy Monoclonal Antibodies

**Policy Number:** 9.109
**Version Number:** 2
**Version Effective Date:** 1/1/2022

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

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

## Prior Authorization Policy

**Products Affected:**

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

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

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| **Covered Use** | All FDA approved indications not otherwise excluded |
| **Exclusion Criteria** | Use for relief of acute bronchospasm or status asthmaticus<br>Use of Fasenra for treatment of other eosinophilic conditions<br>Use of Xolair for treatment of other allergic conditions or other forms of urticaria<br>Concurrent use of any of the following: Fasenra, Nucala, Xolair |
| **Required Medical Information** | **Fasenra**<br>1. A diagnosis of severe asthma with an eosinophil phenotype; **AND** |

[+] *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

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
3. A diagnosis of hypereosinophilic syndrome (HES); **AND**
    a. Condition has been present for 6 months or more; **AND**
    b. Documentation that secondary causes have been ruled out (e.g., drug sensitivity, parasite helminth infection, HIV infection, non-hematological malignancy); **AND**
        a. Inadequate response, adverse reaction or contrainidication to a systemic glucocorticoid; **AND**
        b. Documented inadequate response, adverse reaction to ONE or contraindication to ALL of the following:
            i. Methotrexate
            ii. Cyclophosphamide
            iii. Cyclosporine
            iv. Azathioprine
            v. Hydroxyurea
            vi. Interferon alpha
4. A diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP); **AND**
    a. An inadequate response, adverse reaction or contraindication to an oral

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| | corticosteroid; **AND**<br>b. An inadequate response, adverse reaction or contraindication to an intranasal corticosteroid; **AND**<br>c. An inadequate response, adverse reaction or contraindication to a leukotriene modifier; **AND**<br>d. Nucala will be used as adjunctive therapy<br>**Xolair**<br>1. A diagnosis of moderate to severe persistent asthma; **AND**<br>Documentation of all of the following:<br>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**<br>b. The source of the allergenic asthma-triggers (if known) and underlining causes (if known) has been removed or addressed; **AND**<br>c. Lab documentation indicating serum IgE level:<br>• Between 30 IU/mL and 700 IU/ml; **OR**<br>• Over 700 IU/ml and 2 or more exacerbations requiring oral corticosteroids or hospitalizations in the past year; **AND**<br>d. A positive skin test or in vitro reactivity to a perennial aeroallergen, **OR**<br>2. A diagnosis of chronic idiopathic urticaria (CIU); **AND**<br>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**<br>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.<br>3. A diagnosis of nasal polyps; **AND**<br>a. An inadequate response, adverse reaction or contraindication to an oral corticosteroid; **AND**<br>b. An inadequate response, adverse reaction or contraindication to an intranasal corticosteroid; **AND**<br>c. An inadequate response, adverse reaction or contraindication to a leukotriene modifier; **AND**<br>d. Xolair will be used as adjunctive therapy |
| **Age Restrictions** | Fasenra: 12 years or older<br>Nucala for asthma: 6 years or older<br>Nucala for eosinophilic granulomatosis with polyangiitis/CRSwNP: 18 years or older |

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| | Nucala for HES: 12 years or older<br>Xolair for asthma: 6 years or older<br>Xolair for CIU: 12 years or older<br>Xolair for nasal polyps: 18 years or older |
| **Prescriber Restriction** | Asthma, Eosinophil phenotype asthma: Prescribed by or in collaboration with an allergist, immunologist or pulmonologist<br>CIU: Prescribed by or in collaboration with an allergist, dermatologist or immunologist<br>Eosinophilic granulomatosis with polyangiitis: Prescribed by or in collaboration with an allergist immunologist, pulmonologist or rheumatologist |
| **Coverage Duration** | Initial: 6 months<br>Re-authorization: 12 months |
| **Other criteria** | Reauthorization:<br>1. Improved symptom control and/or decreased exacerbations while on 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<br>Reduction in total daily dose of oral corticosteroids from baseline or frequency of systemic corticosteroid use for asthma exacerbation (Fasenra or Nucala only) |

**Applicable Coding:**

| Code | Medication |
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| J0517 | Fasenra (benralizumab) |
| J2182 | Nucala (mepolizumab) |
| J2357 | Xolair (omalizumab) |

## Clinical Background Information and References


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| Original Approval Date | Original Effective Date | Policy Owner | Approved by |
|---|---|---|---|
| 12/1/2020 | 1/1/2021 | Pharmacy Services | Pharmacy & Therapeutics (P&T) Committee |

| Policy Revisions History | | | |
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| **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 |
| 8/12/2021 | Annual P&T Review: Added diagnoses of HES and CRSwNP to criteria for Nucala. Added diagnosis of nasal polyps for Xolair. Updated age restrictions for new indications. Removed references to Cinqair as it was removed from formulary previously | 1/1/2022 | P&T Committee |

## Next Review Date

8/2022

## 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.