**Pharmacy Policy**

# Asthma and Allergy Monoclonal Antibodies – Unified Formulary

**Policy Number:** 9.143
**Version Number:** 1.2
**Version Effective Date:** 9/1/2021

Product Applicability ☐ **All Plan+ Products**

**Well Sense Health Plan**
☐ New Hampshire Medicaid

**Boston Medical Center HealthNet Plan**
☒ 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

**Reference Table:**

| Drugs that require PA | No PA |
|---|---|
| Cinqair® (reslizumab) | |
| Dupixent® (dupilumab) | |
| Fasenra® (benralizumab) | |
| Nucala® (mepolizumab) | |
| Xolair® (omalizumab) | |

**Procedure:**

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| **Approval Diagnosis:** | • **Chronic Idiopathic Urticaria (CIU)**<br>• **Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP)**<br>• **Eosinophilic Granulomatosis with Polyangiitis (EGPA)**<br>• **Hypereosinophilic Syndrome (HES)** |

+ *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.

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| | • **Moderate to Severe Allergy-Related Asthma**<br>• **Moderate to Severe Eosinophilic Asthma**<br>• **Moderate to Severe Atopic Dermatitis**<br>• **Nasal Polyps**<br>• **OCS-Dependent Asthma**<br><br>*Requests for all other indications will be evaluated on a case-by-case basis with consideration for less costly alternatives and current medical evidence.* |
| **Approval Criteria:**<br><br>***CIU***<br><br>**Xolair®**<br>(omalizumab) | Prescriber provides documentation of **ALL** of the following:<br>1. Appropriate diagnosis<br>2. Member is ≥ 12 years of age<br>3. Inadequate response (defined as ≥14 days of therapy), adverse reaction or contraindication to at least **TWO** different histamine$_1$ antihistamines *(history of claims is sufficient)* (See appendix for examples)<br>4. Inadequate response (defined as ≥14 days of therapy), adverse reaction or contraindication to a histamine$_1$ antihistamine in combination with a leukotriene antagonist* (See appendix for examples)<br>5. Inadequate response (defined as ≥14 days of therapy), adverse reaction or contraindication to a histamine$_1$ antihistamine in combination with a histamine$_2$ antihistamine* (See appendix for examples)<br>6. Dosing is appropriate (150 mg **or** 300 mg every 28 days. See Appendix for dosing requests > 300 mg every 28 days)<br>7. **ONE** of the following:<br>a. Prescriber is an allergist/immunologist or dermatologist<br>b. Prescriber provides consultation notes from an allergist/immunologist or dermatologist regarding the diagnosis and treatment recommendations<br>8. If request is for the 150 mg syringe, medical necessity for the 150 mg syringe instead of the 150 mg vial (e.g., member will be self-administering)<br><br>*Notes:*<br>*- Previous prior authorizations for monoclonal antibodies should be end-dated if member is switched to an alternate asthma/allergy monoclonal antibody.*<br>***See Appendix for off-label requests for children < 12 years of age and for higher or more frequent dosing of omalizumab* |
| **Approval Criteria:**<br><br>***CRSwNP***<br><br>**Dupixent®**<br>(dupilumab) | Prescriber provides documentation of **ALL** of the following:<br>1. Appropriate diagnosis<br>2. Member is ≥ 18 years of age<br>3. Prescriber is a specialist (i.e., allergist, immunologist, pulmonologist)<br>4. Inadequate response, adverse reaction or contraindication to **ONE** oral corticosteroid *(history of claims is sufficient)*<br>5. Inadequate response, adverse reaction or contraindication to **ONE** intranasal corticosteroid *(history of claims is sufficient)*<br>6. Inadequate response, adverse reaction or contraindication to **ONE** leukotriene antagonist *(history of claims is sufficient)*<br>7. Dosing is appropriate (300 mg subcutaneosuly every 2 weeks)<br>8. Documentation that dupilumab will be used as adjunctive therapy |

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| **Approval Criteria:**<br><br>***EGPA***<br><br>**Nucala®**<br>(mepolizumab) | Prescriber provides documentation of **ALL** of the following:<br>1. Appropriate diagnosis<br>2. Member is ≥ 18 years of age<br>3. Inadequate response (defined as ≥ 30 days of therapy), adverse reaction or contraindication to **ONE** systemic glucocorticoid *(history of claims is sufficient)*<br>4. Inadequate response (defined as ≥ 30 days of therapy)or adverse reaction to **ONE** of the following *(history of claims is sufficient)* or contraindication to **BOTH** of the following*:*<br>a. azathioprine<br>b. methotrexate<br>5. Prescriber is a specialist (i.e., allergist, cardiologist, hematologist, immunologist, pulmonologist, rheumatologist, etc.)<br>6. Dosing is appropriate (300 mg subcutaneously every 28 days)<br><br>*Notes:*<br>*- Previous prior authorizations for monoclonal antibodies should be end-dated if member is switched to an alternate asthma/allergy monoclonal antibody.* |
| **Approval Criteria:**<br><br>**HES**<br><br>**Nucala®**<br>(mepolizumab) | Prescriber provides documentation of **ALL** of the following:<br>1. Diagnosis of hypereosinophilic syndrome (HES)<br>2. Documentation of diagnosis without an identifiable non-hematologic secondary cause<br>3. Member is ≥12 years of age<br>4. Inadequate response (defined as ≥ 30 days of therapy), adverse reaction or contraindication to ONE systemic glucocorticoid *(history of claims in POPS is sufficient)*<br>5. Inadequate response (defined as ≥ 30 days of therapy) or adverse reaction to **ONE** of the following *(history of claims in POPS is sufficient)* or contraindication to **ALL** of the following:<br>a. hydroxyurea<br>b. methotrexate<br>c. interferon alfa<br>6. Prescriber is a specialist (i.e., allergist, cardiologist, GI, hematologist, immunologist, pulmonologist, etc)<br>7. Dosing is appropriate (300 mg subcutaneously every 28 days) |
| **Approval Criteria:**<br><br>***Moderate to Severe Allergy-Related Asthma***<br><br>**Xolair®**<br>(omalizumab) | Prescriber provides documentation of **ALL** of the following:<br>1. Appropriate diagnosis<br>2. Member is ≥ 6 years of age<br>3. Member is symptomatic despite receiving **ONE** of the following *(history of claims is sufficient)*:<br>a. Combination inhaler (Advair®, Breo®, Dulera®, fluticasone/salmeterol [Airduo®], or Symbicort®)<br>b. Combination of an inhaled corticosteroid (Alvesco®, ArmonAir®, Arnuity®, Asmanex®, Flovent®, Pulmicort® or Qvar®) **AND** a long-acting β-agonist inhaler (Foradil® or Serevent®)<br>c. Chronic oral corticosteroids (defined as ≥ 90 days of therapy within the last 120 days)<br>4. Baseline serum IgE between 30 IU/mL to 700 IU/mL ***see Appendix for higher IgE levels*** |

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| | 5. Evidence of specific allergic sensitivity (i.e. positive skin test or blood test [radioallergosorbent test or RAST] for IgE) (MD documentation on prior authorization form is sufficient to meet this criterion)<br>6. Prescriber is an asthma specialist (i.e., allergist, immunologist, pulmonologist)<br>7. Dosing is appropriate (Dosing range is 75 to 375 mg subcutaneously every 14 to 28 days [not exceeding 6 units/28 days for the 150 mg vial, 4 units/28 days for the 150 mg syringe, and 2 units/28 days for the 75 mg syringe])†<br>8. If request is for the 150 mg syringe, medical necessity for the 150 mg syringe instead of the 150 mg vial (e.g., member will be self-administering)<br><br>*Notes:*<br>*†Please refer to appendix for examples of dispensing*<br>*- Table 1 in the Appendix Section is provided as a reference point for dosing. As long as the requested dosing range is between 75 to 375 mg every 2 to 4 weeks, reviewers do not have to verify dosing from table based on current weight and IgE level.*<br>*- Previous prior authorizations for monoclonal antibodies should be end-dated if member is switched to an alternate asthma/allergy monoclonal antibody.* |
| **Approval Criteria:**<br><br>***Moderate-severe atopic dermatitis***<br><br>**Dupixent®** (dupilumab) | Prescriber provides documentation of **ALL** of the following:<br>1. Appropriate diagnosis<br>2. Member is ≥6 years of age<br>3. Prescriber is an allergist/immunologist or dermatologist, or provides consultation notes from an allergist/immunologist or dermatologist<br>4. Inadequate response or adverse reaction to **ONE** superpotent or potent topical corticosteroid *(History of claims within last two years is sufficient)*, or contraindication to **ALL** superpotent or potent topical corticosteroids*<br>5. Inadequate response or adverse reaction to topical tacrolimus or Eucrisa® (crisaborole) *(History of claims is sufficient)*, or contraindication to both topical tacrolimus and Eucrisa® (crisaborole)<br>6. Inadequate response or adverse reaction to **ONE** systemic immunomodulatory agent† (e.g. azathioprine, cyclosporine, methotrexate, mycophenolate mofetil, mycophenolic acid) *(History of claims within last two years is sufficient)*, or contraindication to **ALL** systemic immunomodulatory agents<br><br>7. Appropriate dosing<br><br>*Notes:*<br>• *Requests for members less than 6 years of age will be reviewed on a case-by-case basis.*<br>• *If member has tried lower potency corticosteroid, prescriber must provide clinical rationale for not utilizing superpotent/potent corticosteroid*<br>• **Trials with topical corticosteroids may be bypassed if the request clearly states that the treatment area is a sensitive area (facial/groin) or the affected area is too widespread.*<br>• †*If member has tried systemic immunomodulatory therapy and trial with a superpotent or potent topical corticosteroid has not been documented, the* |

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| | *trial may be bypassed* |
| **Approval Criteria:**<br><br>***Moderate-severe eosinophilic asthma or oral corticosteroid-dependent asthma***<br><br>**Dupixent®** (dupilumab) | Prescriber provides documentation of **ALL** of the following:<br>1. Appropriate diagnosis<br>2. Member is ≥ 12 years of age<br>3. Member is symptomatic despite receiving **ONE** of the following *(history of claims is sufficient)*:<br>a. Combination inhaler (Advair®, Breo®, Dulera®, fluticasone/salmeterol [Airduo®], or Symbicort®)<br>b. Combination of an inhaled corticosteroid (Alvesco®, ArmonAir®, Arnuity®, Asmanex®, Flovent®, Pulmicort® or Qvar®) **AND** a long-acting β-agonist inhaler (Foradil® or Serevent®)*<br>c. Chronic oral corticosteroids (defined as ≥ 90 days of therapy within the last 120 days)<br>4. **ONE** of the following:<br>a. Evidence of an eosinophilic phenotype (i.e. peripheral blood eosinophil count ≥ 150 cells/µL, elevated sputum eosinophils or FeNO) (MD documentation on prior authorization form is sufficient to meet this criterion)<br>b. Member is receiving chronic oral corticosteroids (defined as ≥ 90 days of therapy within the last 120 days)<br>c. Member has documented concomitant diagnosis of atopic dermatitis or CRSwNP and either moderate-to-severe eosinophilic asthma or OCS-dependent asthma<br>5. Prescriber is an asthma specialist (i.e., allergist, immunologist, pulmonologist)<br>6. Dosing is appropriate<br><br>*Notes:*<br>• *Previous prior authorizations for monoclonal antibodies should be end-dated if member is switched to an alternate asthma/allergy monoclonal antibody.* |
| **Approval Criteria:**<br><br>**Nasal Polyps**<br><br>**Dupixent® (dupilumab)**<br><br>**Xolair® (omalizumab)** | Prescriber provides documentation of ALL of the following:<br>1. Appropriate diagnosis<br>2. Member is ≥ 18 years of age<br>3. Prescriber is a specialist (i.e., allergist, immunologist, **otolaryngologist** pulmonologist)<br>4. Inadequate response, adverse reaction or contraindication to ONE oral corticosteroid (history of claims is sufficient)<br>5. Inadequate response, adverse reaction or contraindication to ONE intranasal corticosteroid (history of claims is sufficient)<br>6. Inadequate response, adverse reaction or contraindication to ONE leukotriene antagonist (history of claims is sufficient)<br>7. Dosing is appropriate (Dupixent: 300 mg subcutaneously every 14 days; Xolair: based on weight and serum total IgE level: 75 to 600 mg every 14 to 28 days)<br>8. If request is for Xolair 150 mg syringe, medical necessity for the 150 mg syringe instead of the 150 mg vial (e.g., member will be self-administering) |

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| | 9. Requested agent will be used as adjunctive therapy |
| **Approval Criteria:**<br><br>***Severe Eosinophilic Asthma***<br><br>**Cinqair®** (reslizumab), **Fasenra®** (benralizumab), **Nucala®** (mepolizumab) | Prescriber provides documentation of **ALL** of the following:<br>1. Appropriate diagnosis<br>2. Member is ≥ 6 years of age (for Nucala®), ≥ 12 years of age (for Fasenra®) or ≥ 18 years of age (for Cinqair®)<br>3. Member is symptomatic despite receiving **ONE** of the following *(history of claims is sufficient)*:<br>a. Combination inhaler (Advair®, Breo®, Dulera®, fluticasone/salmeterol [Airduo®], or Symbicort®)<br>b. Combination of an inhaled corticosteroid (Alvesco®, ArmonAir®, Arnuity®, Asmanex®, Flovent®, Pulmicort® or Qvar®) **AND** a long-acting β-agonist inhaler (Foradil® or Serevent®)<br>c. Chronic oral corticosteroids (defined as ≥ 90 days of therapy within the last 120 days)<br>4. Evidence of an eosinophilic phenotype (i.e. peripheral blood eosinophil count ≥ 150 cells/µL [for Nucala® and for Fasenra®], or ≥ 400 cells/µL [for Cinqair®]†, elevated sputum eosinophils or FeNO) (MD documentation on prior authorization form is sufficient to meet this criterion)<br>5. Prescriber is an asthma specialist (i.e., allergist, immunologist, pulmonologist)<br>6. Dosing is appropriate (3 mg/kg intravenously every 14 days [for Cinqair®], 30 mg every 28 days for 3 doses, then 30 mg every 56 days [for Fasenra®], or 100 mg subcutaneously every 28 days in those ≥ 12 years of age and 40 mg subcutaneously every 28 days in those 6 to 11 years of age [for Nucala®])<br><br>*Notes:*<br>*- Previous prior authorizations for monoclonal antibodies should be end-dated if member is switched to an alternate asthma/allergy monoclonal antibody.*<br>† *Please see Appendix for information on interpreting peripheral blood eosinophil counts that fall outside of this range.* |
| **Denial Criteria:** | Cases that do not meet the approval criteria will be denied. |
| | If a request is denied and the prescriber has additional clinical documentation, a **new** prior authorization request must be submitted. |
| **Duration of Authorization:** | CIU: Initial approval may be issued for **4 months.**<br>All others: Initial approval may be issued for **6 months**. |
| **Recertification Criteria:** | CIU: Resubmission by prescriber will infer a positive response to therapy and request may be recertified for **4 months.**<br>All others: Resubmission by prescriber will infer a positive response to therapy and request may be recertified for **1 year.**<br><br>Handling recertifications with change in criteria:<br>Requests for **Xolair 150 mg syringes** that were approved prior to 08/26/2019 must now meet the new criteria of medical necessity for the syringe instead of the vial. |

**Appendix:**

## Stability

Requests for members new to the Plan and previously covered on another insurance plan for an FDA-approved dosing regimen of Cinqair® (reslizumab), Dupixent® (dupilumab), Fasenra® (benralizumab), Nucala® (mepolizumab), or Xolair® (omalizumab) can be approved without documentation of failed trials with the conventional therapies for that diagnosis.

## Grandfathering

Information is not applicable.

## Additional Information

## Examples of Traditional Therapies for CIU

**$H_1$-Antihistamines (first generation):**
Brompheniramine, carbinoxamine, chlorpheniramine, clemastine, cyproheptadine, diphenhydramine, hydroxyzine, promethazine

**$H_1$-Antihistamines (second generation):**
acrivastine/pseudoephedrine, cetirizine, desloratadine, fexofenadine, levocetirizine, loratadine

**$H_2$-Antihistamines:**
cimetidine, famotidine, nizatidine, ranitidine

**Leukotriene Modifiers:**
montelukast, zafirlukast, zileuton

## Omalizumab dispensing chart

If member is approved for the 150 mg vial, please approve appropriate quantity as highlighted in table below (assuming office does not specify on PA to use in combination with the 75 mg syringe). If member is approved for medical necessity of the 150 mg syringe, consolidate to the lowest mL to achieve requested dose, which might mean using both the 150 mg syringe and the 75 mg syringe (see table below).
For Xolair **vials** enter as number of **vials** needed.
For Xolair **syringes** enter as number of **mL** needed.

| Requested Dose | Approved Formulation | Approved Quantity per Dose | Total Approved Quantity for dosing every 2 weeks for 6 months | Total Approved Quantity for dosing every 4 weeks for 6 months |
|---|---|---|---|---|
| 75 mg | 75 mg/0.5 mL syringe | 0.5 mL | 6 mL | 3 mL |
| 150 mg | 150 mg single-use vial OR<br>150 mg/mL syringe | 1 vial OR<br>1 mL | 12 vials OR<br>12 mL | 6 vials OR<br>6 mL |
| 225 mg | 150 mg single-use vial | 2 vials | 24 vials | 12 vials |
| 225 mg* | 150 mg/mL syringe + | 1.5 mL | 18 mL | 9 mL |

| | | | | |
|---|---|---|---|---|
| | 75 mg/0.5mL syringe | | | |
| 300 mg | 150 mg single-use vial OR<br>150 mg/mL syringe | 2 vials OR<br>2 mL | 24 vials OR<br>24 mL | 12 vials OR<br>12 mL |
| 375 mg | 150 mg single-use vial | 3 vials | 36 vials | 18 vials |
| 375 mg* | 150 mg/mL syringe +<br>75 mg/0.5mL syringe | 2.5 mL | 30 mL | 15 mL |

* If approving both the 150 mg syringe and the 75 mg syringe, enter one PA with the GSN range of 067907-067908 and indicate on external message that both strengths are approved.

**Moderate to Severe Allergy-Related Asthma: Omalizumab requests for members < 6 years of age**

- Members < 6 years of age
    - Please approve or deny based on your professional clinical judgment
- According to the 2011 Global Initiative for Asthma guideline, omalizumab has proven efficacy in children age 6-12 years with moderate-severe and severe persistent allergic asthma. A few published studies support the safety and efficacy of omalizumab in children age 6-12, with uncontrolled asthma despite the use of ICS.
- Consider alternatives such as theophylline, leukotriene receptor antagonists and high dose ICS since they are recommended by the 2007 NHLBI asthma guidelines in children between the ages of 5 and 11. Furthermore, the guidelines recommend considering subcutaneous allergen immunotherapy for children with allergic asthma.

**Moderate to Severe Allergy-Related Asthma: Omalizumab requests for members with high (>700 IU/mL) IgE levels or weight (<30 kg or >150 kg)**

- If the member meets current clinical criteria with the exception of having IgE>700 IU/mL **AND** the requested dose is ≤ 375 mg every 2 weeks
    - **Approve for 6 months**
- Omalizumab has been studied in patients (including children ages of 6 and 12) with baseline IgE levels of up to 1,300 IU/mL. In addition, 2 retrospective reviews of patients with much higher IgE levels (mean ~2,371 IU/L and ~12,239 IU/L, respectively) demonstrated similar outcomes compared to patients with IgE<700 IU/L. The maximum dose of omalizumab in patients with IgE levels >700 IU/mL is 375 mg every 2 weeks.
- While there is no published data on the use of omalizumab in patients weighing <30 kg or >150 kg, if the member meets current clinical criteria **AND** the requested dose is ≤ 375 mg every 2 weeks
    - **Approve for 6 months**

**Moderate to Severe Allergy-Related Asthma: Omalizumab requests for members with low (<30 IU/mL) IgE levels**

- IgE<30 IU/mL
    - Please approve or deny based on your professional clinical judgment
- Early studies of omalizumab suggested clinical benefit when serum free IgE levels were suppressed to <10.4 IU/mL. As such, patients with baseline serum IgE levels <30 IU/mL may have little potential for benefit when treated with omalizumab.
- A small number of patients with baseline serum total IgE<30 IU/mL were enrolled in the pivotal trials of omalizumab in patients (≥12 years old) with moderate-to-severe asthma. No specific details on the safety or efficacy of omalizumab in these patients are available.

**Moderate to Severe Allergy-Related Asthma: Omalizumab requests for quantities > 4 vials or syringes (150 mg strength) and > 2 syringes (75 mg strength)/28 days**

- Based on the FDA-approved dosing, **>** 4 vials or syringes (150 mg strength) and > 2 syringes (75 mg strength)/28 days are unnecessary for the treatment of moderate to severe allergic asthma. Requests for larger amounts should be **denied-** requesting clinical rationale for exceeding FDA-approved doses.

**Monitoring omalizumab therapy**

Total serum IgE levels increase 3 to 6 fold in all individuals on omalizumab therapy due to the presence of omalizumab-IgE immune complexes. Therefore, no specific laboratory monitoring is recommended for patients who are responding clinically to omalizumab therapy.

**CIU: Initial Dosing Omalizumab requests for > 150 mg every 4 Weeks**

- If prescriber documents (either in medical records or on the PA form) that member has had an IR to a trial of the 150 mg dose in the past, request for the 300 mg dose can be approved.
- For the majority of requests, prescriber will be asked to initiate a trial dose of 150 mg in their members. The initial request should be denied and the prescriber can resubmit with additional information for the higher dose or a request for a starting dose of 150mg every 4 weeks. If after this initial dose, no apparent effect is seen, the prescriber can re-submit another PA documenting this IR and request a trial with 300 mg every four weeks. If there is no response after the second higher dose, the member is unlikely to benefit from this agent.

**CIU: Omalizumab requests for > 300 mg every 4 Weeks**

For individuals with only partial responses to the FDA-approved dosing of 300 mg every four weeks following three to six months of therapy, there is evidence to support a short-term trial of higher doses (using a step-wise approach to 450 mg and potentially 600 mg every four weeks) or more frequent dosing of 150 mg every two weeks. The response to these trials should be evident after three doses.

Requests for 450 mg every four weeks or 150 mg every two weeks can be approved for three months. If member has not achieved adequate response to this dosing, an allowance to 600 mg every four weeks or 300 mg every two weeks can be considered for a three-month approval if provider submits request. Recertification with either dosing will require documentation of positive response. If none is achieved after the three-month trial, outreach will be made to office regarding medical necessity of continuing omalizumab and inform them of discontinuation of therapy.

**CIU: Omalizumab requests for children < 12 years of age**

Although Xolair® (omalizumab) is only FDA-approved for individuals ≥ 12 years of age with CIU, it does have labeling for use in children ≥ six years of age with moderate to severe persistent allergic asthma that is inadequately controlled with ICS. There have also been various case studies highlighting a positive response for treatment of urticaria with omalizumab with no new safety concerns in children as young as four years of age at traditional dosing of 150 mg every four weeks.

Requests for children four years of age and older who have met the standard approval criteria can be approved for the standard four-month trial.

**Severe Eosinophilic Asthma: Mepolizumab requests for members < 6 years of age**

- Members <6 years of age
    - Please approve or deny based on your professional clinical judgment

**Severe Eosinophilic Asthma: Reslizumab requests for members 12 to 17 years of age**

- Members 12 to 17 years of age
    - Please approve or deny based on your professional clinical judgment
- Two studies looked at the use reslizumab compared to placebo in individuals age 12 to 75 years old with poorly controlled asthma maintained on ICSs with a peripheral eosinophil count of ≥ 400 cells/µL. Castro et al showed a reduction in asthma exacerbation rates with reslizumab. Bjermer et al revealed improvements in time to first exacerbation, $FEV_1$, Asthma Control Questionnaire and quality-of-life scores for the reslizumab 3 mg/kg group compared to placebo.

**Other diagnoses/Off-label indications**

- Benralizumab, dupilumab, mepolizumab, omalizumab, and reslizumab are NOT indicated for the treatment of acute asthma exacerbations, acute bronchospasms or status asthmaticus since it has not been shown to alleviate asthma exacerbations acutely.
    - **Deny**
- Other off-label indications
    - Please approve or deny based on your professional clinical judgment

**Interpretation of peripheral absolute blood eosinophil levels**

- Absolute eosinophil count can be calculated with the following formula:
- Absolute eosinophil count (cells/µL) = white blood count x eosinophils/100
- If labwork is submitted that uses units other than the commonly reported cells/µL, a conversion can be done using this website: http://unitslab.com/node/77
    - e.g. 1.1 k/$mm^3$= 1,100 cells/ µL
- If an individual is noted to have been on systemic corticosteroids at the time of the blood draw for absolute blood eosinophil levels, this can be taken into account if the individual's absolute blood eosinophil levels do not reach our threshold for approval (≥ 150 cells/µL [for Nucala®, Dupixent® and Fasenra®], or ≥ 400 cells/µL [for Cinqair®]). This requirement can be bypassed.
    - Per Up-to-date: Administration of even low doses of glucocorticoids leads to dramatic reductions in circulating eosinophils.
- If an individual is currently taking one of the following agents: [Cinqair® (reslizumab), Dupixent® (dupilumab), Fasenra® (benralizumab), or Nucala® (mepolizumab)] for severe eosinophilic asthma but the prescriber subsequently wants to switch to another agent FDA-approved for eosinophilic asthma, we would not require another baseline absolute blood eosinophil level. As long as member meets other criteria, such as appropriate dosing and age, please issue approval for the new agent and end-date original PA.

**Table 1. Moderate to Severe Allergy-Related Asthma for Patients ≥ 12 Years of Age: Xolair® (omalizumab) administered every 2 to 4 weeks**

| Pre-treatment Serum IgE (IU/mL) | Body Weight (kg) | | | |
|---|---|---|---|---|
| | 30-60 | >60-70 | >70-90 | >90-150 |
| ≥ 30-100 | 150 mg | 150 mg | 150 mg | 300 mg |
| > 100-200 | 300 mg | 300 mg | 300 mg | 225 mg |
| > 200-300 | 300 mg | 225 mg | 225 mg | 300 mg |
| > 300-400 | 225 mg | 225 mg | 300 mg | |
| > 400-500 | 300 mg | 300 mg | 375 mg | |
| > 500-600 | 300 mg | 375 mg | DO NOT DOSE | |
| > 600-700 | 375 mg | | | |
| Every 2 weeks dosing | | | | |
| Every 4 weeks dosing | | | | |

**Table 2. Moderate to Severe Allergy-Related Asthma for Patients 6 to < 12 Years of Age: Xolair® (omalizumab) administered every 2 to 4 weeks***

| Pre-treatment Serum IgE (IU/mL) | Body Weight (kg) | | | | | | |
|---|---|---|---|---|---|---|---|
| | 20-25 | >25-30 | >30-40 | >40-50 | >50-60 | >60-70 | > 70-80 |
| ≥ 30-100 | 75 mg | 75 mg | 75 mg | 150 mg | 150 mg | 150 mg | 150 mg |
| > 100-200 | 150 mg | 150 mg | 150 mg | 300 mg | 300 mg | 300 mg | 300 mg |
| > 200-300 | 150 mg | 150 mg | 225 mg | 300 mg | 300 mg | 225 mg | 225 mg |
| > 300-400 | 225 mg | 225 mg | 300 mg | 225 mg | 225 mg | 225 mg | 300 mg |
| > 400-500 | 225 mg | 300 mg | 225 mg | 225 mg | 300 mg | 300 mg | 375 mg |
| > 500-600 | 300 mg | 300 mg | 225 mg | 300 mg | 300 mg | 375 mg | |
| > 600-700 | 300 mg | 225 mg | 225 mg | 300 mg | 375 mg | | |
| >700-800 | 225 mg | 225 mg | 300 mg | 375 mg | | | |
| >800-900 | 225 mg | 225 mg | 300 mg | 375 mg | | | |
| >900-1000 | 225 mg | 300 mg | 375 mg | | | | |
| >1000-1100 | 225 mg | 300 mg | 375 mg | | | | |
| >1100-1200 | 300 mg | 300 mg | | | | | |
| >1200-1300 | 300 mg | 375 mg | | | | | |
| Every 2 weeks dosing | | | | | | | |
| Every 4 weeks dosing | | | | | | | |
| Do Not Dose | | | | | | | |

*Additional dosing parameters are available for patients weighing >80 kg

**Table 3. Nasal Polyps for Adults: Xolair® (omalizumab) administered every 2 to 4 weeks**[1]

| Pre-treatment Serum IgE (IU/mL) | Body Weight (kg) | | | | | | |
|---|---|---|---|---|---|---|---|
| | >30-40 | >40-50 | >50-60 | >60-70 | >70-80 | >80-90 | > 90-125* |
| 30-100 | 75 mg | 150 mg | 150 mg | 150 mg | 150 mg | 150 mg | 300 mg |
| > 100-200 | 150 mg | 300 mg | 300 mg | 300 mg | 300 mg | 300 mg | 450 mg |

| Pre-treatment Serum IgE (IU/mL) | Body Weight (kg) | | | | | | |
|---|---|---|---|---|---|---|---|
| | >30-40 | >40-50 | >50-60 | >60-70 | >70-80 | >80-90 | > 90-125* |
| > 200-300 | 225 mg | 300 mg | 300 mg | 450 mg | 450 mg | 450 mg | 600 mg |
| > 300-400 | 300 mg | 450 mg | 450 mg | 450 mg | 600 mg | 600 mg | 450 mg |
| > 400-500 | 450 mg | 450 mg | 600 mg | 600 mg | 375 mg | 375 mg | 525 mg |
| > 500-600 | 450 mg | 600 mg | 600 mg | 375 mg | 450 mg | 450 mg | 600 mg |
| > 600-700 | 450 mg | 600 mg | 375 mg | 450mg | 450 mg | 525 mg | |
| >700-800 | 300 mg | 375 mg | 450 mg | 450 mg | 525 mg | 600 mg | |
| >800-900 | 300 mg | 375 mg | 450 mg | 525 mg | 600 mg | | |
| >900-1000 | 375 mg | 450 mg | 525 mg | 600 mg | | | |
| >1000-1100 | 375 mg | 450 mg | 600mg | | | | |
| >1100-1200 | 450 mg | 525 mg | 600 mg | | | | |
| >1200-1300 | 450 mg | 525 mg | | | | | |
| >1300-1500 | 525 mg | 600 mg | | | | | |
| Every 2 weeks dosing | | | | | | | |
| Every 4 weeks dosing | | | | | | | |
| Do Not Dose | | | | | | | |

*Refer to package insert for weight > 125 kg

**Point of Sale Criteria**

**Criteria:**

1. Claims for Cinqair® (reslizumab) (GSN: 075753) or Fasenra® (benralizumab) (GSN: 077921, 080268) will usually process and pay at the pharmacy without prior authorization if the member has a history of medical claims for severe eosinophilic asthma and paid claims for the requested agent for ≥84 in the last 120 days.
2. Claims for Nucala® (mepolizumab) (GSN: 075111, 079828, 079829) will usually process and pay at the pharmacy without prior authorization if the member has paid claims for Nucala® (mepolizumab) for ≥84 in the last 120 days and ONE of the following:
    a. A history of medical claims for severe eosinophilic asthma and quantity billed plus history is ≤1 vial/28 days, OR
    b. A history of medical claims for eosinophilic granulomatosis with polyangiitis (EGPA) and quantity billed plus history is ≤3 vials/28 days, OR
    c. A history of medical claims for hypereosinophilic syndrome (HES) and quantity billed plus history is ≤3 vials/28 days.
3. Claims for Xolair® (omalizumab) 150 mg vial and 75 mg syringe (GSN: 052758, 067907) will usually process and pay at the pharmacy without prior authorization if the member has a history of medical claims for moderate to severe allergy-related asthma and paid claims for Xolair® (omalizumab) for ≥84 in the last 120 days and quantity billed plus history is ≤ 6 units/28 days for 150 mg vial (052758), and ≤ 2 units/28 days for the 75 mg syringe (067907).
4. Claims for Dupixent® (dupilumab) (GSN: 077263, 079179, 081231) and Xolair (omalizumab) 150 mg syringe (067908) will usually reject at the pharmacy as requiring prior authorization.

**Applicable Coding:**

| Code | Medication |
|---|---|

| Code | Medication |
|---|---|
| J2786 | Cinqair (reslizumab) |
| J0517 | Fasenra (benralizumab) |
| J2182 | Nucala (mepolizumab) |
| J2357 | Xolair (omalizumab) |

## Clinical Background Information and References


1. Product Information. Xolair®, omalizumab. Genentech, Inc., South San Francisco, CA 07936-1080. 2014.
2. 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.
3. Product Information. Nucala®. GlaxoSmithKline. Research Triangle Park, NC. Dec 2017
4. Product Information. Cinqair®. Teva Frazer, PA. May 2016.
5. 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.


| 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 | | | |
|---|---|---|---|
| **Review Date** | **Summary of Revisions** | **Revision Effective Date** | **Approved by** |
| 12/1/2020 | 9.127 Asthma-Allergy Monoclonal Antibodies Policy retired. New policy created to align with MH Unified Formulary Policy | 1/1/2021 | P&T Committee |
| 2/4/2021 | Updated policy to match 1.22.21 state policy updates. Reflects new FDA-approved indication for Nucala for HES, criteria language changed for Nucala for EGPA and Dupixient for moderate to severe atopic dermatitis, provider specialties were added for Nucala (EGPA indication) criteria, point of sale criteria included | 2/4/2021 | P&T Committee |
| 2/26/2021 | Updated policy to reflect 2/12/21 FAQ | 2/26/2021 | P&T Committee |

| Policy Revisions History | | | |
|---|---|---|---|
| | changes | | |
| 3/3/2021 | Updated policy to reflect 2/28/21 changes from MH. Guideline updated to reflect new FDA-approved indication of nasal polyps for Xolair. Dupixent criteria included in the same row | 3/3/2021 | P&T Committee |
| 6/4/2021 | Updated policy to reflect 6/2 updates from the State: Guideline updated to allow providers to initiate therapy of Xolair with either the 150 mg or the 300 mg dose based upon clinical literature and outreach to multiple specialist prescribers. The appendix sections were also updated to remove verbiage for medical necessity of initiating dosing greater than 150 mg every 4 weeks. Additionally, verbiage changed in other criterias from weeks to days (e.g., every two weeks to every 14 days). Lastly, a note that medical necessity for Xolair 150 mg syringe instead of vial can now include information that member will be self-adminsitering Xolair was added. | 9/1/2021 | P&T Committee |

## 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.