Asthma and Allergy Injectables

Cinqair (reslizumab)
Dupixent (dupilumab)
Fasenra (benralizumab)
Nucala (mepolizumab)
Xolair (omalizumab)

Effective January 1, 2021

Plan
☐ MassHealth
☒ MassHealth (PUF)
☐ Commercial/Exchange

 Benefit
☒ Pharmacy Benefit
☐ Medical Benefit (NLX)

Program Type
☒ Prior Authorization
☐ Quantity Limit
☐ Step Therapy

Specialty Limitations
This medication has been designated specialty and must be filled at a contracted specialty pharmacy when obtained through the pharmacy benefit.

Contact Information

Specialty Medications
All Plans
Phone: 866-814-5506
Fax: 866-249-6155

Non-Specialty Medications
MassHealth
Phone: 877-433-7643
Fax: 866-255-7569

Commercial
Phone: 800-294-5979
Fax: 888-836-0730

Exchange
Phone: 855-582-2022
Fax: 855-245-2134

Medical Specialty Medications (NLX)
All Plans
Phone: 844-345-2803
Fax: 844-851-0882

Exceptions
Cinqair is available on the Medical Benefit only

Overview

Cinqair and Fasenra are interleukin-5 antagonist monoclonal antibodies indicated for:
- Add-on maintenance treatment of severe asthma for members with an eosinophilic phenotype.

Nucala is an interleukin-5 antagonist monoclonal antibody indicated for:
- Treatment of severe asthma with an eosinophilic phenotype
- Eosinophilic granulomatosis with polyangiitis
- Hypereosinophilic syndrome (HES)

Dupixent is an interleukin-4 receptor alpha agonist indicated for:
- Atopic Dermatitis
- Chronis rhinosinusitis with nasal polyps
- Moderate to severe asthma with an eosinophilic phenotype

Xolair is an anti-IgE antibody indicated for:
- Treatment of moderate to severe persistent allergic asthma
- Chronic Idiopathic Urticaria (CIU)
Coverage Guidelines
Authorization may be reviewed on a case by case basis for members new to AllWays Health Partners who are currently receiving treatment and stable with the requested medication, excluding when the product is obtained as samples or via manufacturer’s patient assistance program
OR
Authorization may be granted for members with severe asthma who meet all the following criteria and documentation has been provided:

**Chronic Idiopathic Urticaria**
**Xolair** (omalizumab)
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. Member is ≥ 12 years of age
3. Paid claims or physician documented inadequate response (defined as ≥14 days of therapy), adverse reaction or contraindication to at least **TWO** different histamine\_1 antihistamines (See appendix for examples)
4. Paid claims or physician documented 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)
5. Paid claims or physician documented 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)
6. For initial requests, starting dose of ≤150 mg every four weeks or clinical rationale for using a starting dose >150 mg every four weeks (see Appendix for dosing requests > 150 mg for the initial request)
7. **ONE** of the following:
   a. Prescriber is an allergist/immunologist or dermatologist
   b. Prescriber provides consultation notes from an allergist/immunologist or dermatologist regarding the diagnosis and treatment recommendations
8. If request is for the 150 mg syringe, medical necessity for the 150 mg syringe instead of the 150 mg vial

**Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP)**
**Dupixent** (dupilumab)
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. Member is ≥ 18 years of age
3. Prescriber is a specialist (i.e., allergist, immunologist, pulmonologist)
4. Paid claims or physician documented inadequate response, adverse reaction or contraindication to **ONE** oral corticosteroid
5. Paid claims or physician documented inadequate response, adverse reaction or contraindication to **ONE** intranasal corticosteroid
6. Paid claims or physician documented inadequate response, adverse reaction or contraindication to **ONE** leukotriene antagonist
7. Dosing is appropriate (300 mg subcutaneously every 2 weeks)
8. Documentation that dupilumab will be used as adjunctive therapy

**Eosinophilic granulomatosis with polyangiitis (EGPA)**

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Nucala (mepolizumab)
Prescriber provides documentation of ALL of the following:
1. Appropriate diagnosis
2. Member is ≥ 18 years of age
3. Paid claims or physician documented inadequate response (defined as ≥ 30 days of therapy), adverse reaction or contraindication to ONE systemic glucocorticoid
4. Paid claims or physician documented inadequate response (defined as ≥ 30 days of therapy), adverse reaction or contraindication to ONE of the following:
   a. azathioprine
   b. methotrexate
5. Prescriber is a specialist (i.e., allergist, immunologist, pulmonologist, rheumatologist)
6. Dosing is appropriate (300 mg subcutaneously every 28 days)

Moderate to Severe Allergy Related Asthma
Xolair (omalizumab)
Prescriber provides documentation of ALL of the following:
1. Appropriate diagnosis
2. Member is ≥ 6 years of age
3. Paid claim or physician documentation that the member is symptomatic despite receiving ONE of the following:
   a. Combination inhaler (Advair®, Breo®, Dulera®, fluticasone/salmeterol [Airduo®], or Symbicort®)
   b. Combination of an inhaled corticosteroid (Alvesco®, ArmonAir®, Arnuity®, Asmanex®, Flovent®, Pulmicort® or Qvar®) AND a long-acting β-agonist inhaler (Foradil® or Serevent®)
   c. Chronic oral corticosteroids (defined as ≥ 90 days of therapy within the last 120 days)
4. Baseline serum IgE between 30 IU/mL to 700 IU/mL **see Appendix for higher IgE levels**
5. Physician documentation of evidence of specific allergic sensitivity (i.e. positive skin test or blood test [radioallergosorbent test or RAST] for IgE)
6. Prescriber is an asthma specialist (i.e., allergist, immunologist, pulmonologist)
7. Dosing is appropriate (Dosing range is 75 to 375 mg subcutaneously every two to four weeks [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])
8. If request is for the 150 mg syringe, medical necessity for the 150 mg syringe instead of the 150 mg vial

Moderate to severe atopic dermatitis
Dupixent (dupilumab)
Prescriber provides documentation of ALL of the following:
1. Appropriate diagnosis
2. Member is ≥6 years of age
3. Prescriber is an allergist/immunologist or dermatologist, or provides consultation notes from an allergist/immunologist or dermatologist
4. ONE of the following:
   a. Paid claim or physician documented inadequate response or adverse reaction to ONE superpotent or potent topical corticosteroid
   b. Contraindication to ALL superpotent or potent topical corticosteroids*
5. ONE of the following:

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AllWays Health Partners includes AllWays Health Partners, Inc. and AllWays Health Partners Insurance Company
a. Paid claim or physician documented inadequate response or adverse reaction to topical tacrolimus or Eucrisa® (crisaborole)
b. Contraindication to topical tacrolimus and Eucrisa® (crisaborole)

6. **ONE** of the following:
   a. Paid claim or physician documented inadequate response or adverse reaction to **ONE** systemic immunomodulatory agent† (e.g. azathioprine, cyclosporine, methotrexate, mycophenolate mofetil, mycophenolic acid)
b. Contraindication to **ALL** systemic immunomodulatory agents

7. Appropriate dosing

**Moderate-severe eosinophilic asthma or oral corticosteroid-dependent asthma**

**Dupixent®** (dupilumab)

Prescriber provides documentation of **ALL** of the following:

1. Appropriate diagnosis
2. Member is ≥ 12 years of age
3. Paid claims or physician documentation member is symptomatic despite receiving **ONE** of the following:
   a. Combination inhaler (Advair®, Breo®, Dulera®, fluticasone/salmeterol [Airduo®], or Symbicort®)
   b. Combination of an inhaled corticosteroid (Alvesco®, ArmonAir®, Arnuity®, Asmanex®, Flovent®, Pulmicort® or Qvar®) AND a long-acting β-agonist inhaler (Foradil® or Serevent®)*
   c. Chronic oral corticosteroids (defined as ≥ 90 days of therapy within the last 120 days)

4. **ONE** of the following:
   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)
   b. Member is receiving chronic oral corticosteroids (defined as ≥ 90 days of therapy within the last 120 days)
   c. Member has documented concomitant diagnosis of atopic dermatitis or CRSwNP and either moderate-to-severe eosinophilic asthma or OCS-dependent asthma

5. Prescriber is an asthma specialist (i.e., allergist, immunologist, pulmonologist)
6. Dosing is appropriate

**Severe Eosinophilic Asthma**

**Cinqair** (reslizumab),

**Fasenra** (benralizumab)

**Nucala** (mepolizumab)

Prescriber provides documentation of **ALL** of the following:

1. Appropriate diagnosis
2. Member is ≥ 6 years of age (for Nucala®), ≥ 12 years of age (for Fasenra®) or ≥ 18 years of age (for Cinqair®)
3. Paid claim or physician documentation the member is symptomatic despite receiving **ONE** of the following:
   a. Combination inhaler (Advair®, Breo®, Dulera®, fluticasone/salmeterol [Airduo®], or Symbicort®)
b. Combination of an inhaled corticosteroid (Alvesco®, ArmonAir®, Arnuity®, Asmanex®, Flovent®, Pulmicort® or Qvar®) AND a long-acting β-agonist inhaler (Foradil® or Serevent®)
c. Chronic oral corticosteroids (defined as ≥ 90 days of therapy within the last 120 days)

4. Physician documentation of 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)

5. Prescriber is an asthma specialist (i.e., allergist, immunologist, pulmonologist)

6. Dosing is appropriate (3 mg/kg intravenously every four weeks [for Cinqair®], 30 mg every 4 weeks for 3 doses, then 30 mg every 8 weeks [for Fasenra®], or 100 mg subcutaneously every four weeks in those ≥ 12 years of age and 40 mg subcutaneously every four weeks in those 6 to 11 years of age [for Nucala®])

**Continuation of Therapy**
Reauthorization requires physician documentation of continuation of therapy and positive response to therapy.

**Limitations**
1. Initial approvals will be granted for the following:
   a. Chronic idiopathic urticaria: 4 months
   b. All other diagnosis: 6 months
2. Reauthorizations will be granted for the following:
   a. Chronic idiopathic urticaria: 4 months
   b. All other diagnosis: 12 months

**Appendix A**
**Examples of Traditional Therapies for CIU**

**H₁-Antihistamines (first generation):**
Brompheniramine, carboxamine, chlorpheniramine, clemastine, cyproheptadine, diphenhydramine, hydroxyzine, promethazine

**H₁-Antihistamines (second generation):**
acrivastine/pseudoephedrine, cetirizine, desloratadine, fexofenadine, levocetirizine, loratadine

**H₂-Antihistamines:**
cimetidine, famotidine, nizatidine, ranitidine

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

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

<table>
<thead>
<tr>
<th>Pre-treatment Serum IgE (IU/mL)</th>
<th>30-60</th>
<th>&gt;60-70</th>
<th>&gt;70-90</th>
<th>&gt;90-150</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥ 30-100</td>
<td>150 mg</td>
<td>150 mg</td>
<td>150 mg</td>
<td>300 mg</td>
</tr>
<tr>
<td>&gt; 100-200</td>
<td>300 mg</td>
<td>300 mg</td>
<td>300 mg</td>
<td>225 mg</td>
</tr>
</tbody>
</table>
### Table 2. Moderate to Severe Allergy-Related Asthma for Patients 6 to < 12 Years of Age: Xolair® (omalizumab) administered every 2 to 4 weeks*

<table>
<thead>
<tr>
<th>Pre-treatment Serum IgE (IU/mL)</th>
<th>20-25</th>
<th>&gt;25-30</th>
<th>&gt;30-40</th>
<th>&gt;40-50</th>
<th>&gt;50-60</th>
<th>&gt;60-70</th>
<th>&gt;70-80</th>
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</thead>
<tbody>
<tr>
<td>≥ 30-100</td>
<td>75 mg</td>
<td>75 mg</td>
<td>75 mg</td>
<td>150 mg</td>
<td>150 mg</td>
<td>150 mg</td>
<td>150 mg</td>
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<tr>
<td>&gt; 100-200</td>
<td>150 mg</td>
<td>150 mg</td>
<td>150 mg</td>
<td>300 mg</td>
<td>300 mg</td>
<td>300 mg</td>
<td>300 mg</td>
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<tr>
<td>&gt; 200-300</td>
<td>150 mg</td>
<td>150 mg</td>
<td>225 mg</td>
<td>300 mg</td>
<td>300 mg</td>
<td>225 mg</td>
<td>225 mg</td>
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<td>&gt; 300-400</td>
<td>225 mg</td>
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<td>&gt; 400-500</td>
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<td>300 mg</td>
<td>375 mg</td>
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<td>&gt; 500-600</td>
<td>300 mg</td>
<td>300 mg</td>
<td>225 mg</td>
<td>300 mg</td>
<td>300 mg</td>
<td>300 mg</td>
<td>375 mg</td>
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<tr>
<td>&gt; 600-700</td>
<td>300 mg</td>
<td>225 mg</td>
<td>225 mg</td>
<td>300 mg</td>
<td>300 mg</td>
<td>375 mg</td>
<td>375 mg</td>
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<tr>
<td>&gt; 700-800</td>
<td>225 mg</td>
<td>225 mg</td>
<td>300 mg</td>
<td>375 mg</td>
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<td>375 mg</td>
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<tr>
<td>&gt; 800-900</td>
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<td>&gt; 900-1000</td>
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<td>300 mg</td>
<td>375 mg</td>
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<td>375 mg</td>
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<td>&gt; 1000-1100</td>
<td>225 mg</td>
<td>300 mg</td>
<td>375 mg</td>
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<td>375 mg</td>
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<tr>
<td>&gt; 1100-1200</td>
<td>300 mg</td>
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<td>375 mg</td>
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<td>375 mg</td>
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<tr>
<td>&gt; 1200-1300</td>
<td>300 mg</td>
<td>375 mg</td>
<td>375 mg</td>
<td>375 mg</td>
<td>375 mg</td>
<td>375 mg</td>
<td>375 mg</td>
</tr>
</tbody>
</table>

Every 2 weeks dosing

Do Not Dose

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

**References**


7. Talmadge EK. Treatment and prognosis of eosinophilic granulomatosis with polyangiitis (ChurgStrauss). In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on December 26, 2017).


**Review History**

09/24/2018 – Updated

11/20/2019 – Updated to require only failure of separate ICS inhaler w/ LABA or combination product and removed requirement of DX based on diagnostic criteria

03/18/2020 – Reviewed and Updated P&T Mtg; age updated ≥ 6 years old for moderate to severe eosinophilic asthma (effective 6/1/20)

11/05/2020- Updated; Effective 1/1/21 Updated to be in compliance with the Masshealth partial unified formulary requirements

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