

Asthma and Allergy Injectables
Cinqair (reslizumab)
Fasenra (benralizumab)
Nucala (mepolizumab)
Xolair (omalizumab)
Tezspire (tezepelumab-ekko)
Effective 06/01/2025

| | | | |
|-----------------------|--|---------------------|--|
| Plan | <input checked="" type="checkbox"/> MassHealth UPPL <input type="checkbox"/> Commercial/Exchange | Program Type | <input checked="" type="checkbox"/> Prior Authorization <input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy |
| Benefit | <input type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit | | |
| Specialty Limitations | N/A | | |
| Contact Information | Medical and Specialty Medications | | |
| | All Plans | Phone: 877-519-1908 | Fax: 855-540-3693 |
| Contact Information | Non-Specialty Medications | | |
| | All Plans | Phone: 800-711-4555 | Fax: 844-403-1029 |
| Notes | Fasenra, Nucala, Xolair, and Tezspire are also available on the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria. Additional agents from this class are available through the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria. | | |

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)
- Chronic rhinosinusitis with nasal polyps (CRSwNP)

Xolair is an anti-IgE antibody indicated for:

- Treatment of moderate to severe persistent allergic asthma
- Chronic Idiopathic Urticaria (CIU)
- Treatment of nasal polyps in adults

Tezspire is a thymic stromal lymphopoietin (TSLP) blocker monoclonal antibody IgG2λ indicated for:

- Add-on maintenance treatment of adult and pediatric patients 12 years of age and older with severe asthma

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members new to the plan 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 who meet all the following criteria and documentation has been provided:

Chronic Idiopathic Urticaria (CIU)

Xolair (omalizumab)

1. Diagnosis of chronic idiopathic urticaria
2. Prescriber is a specialist (i.e., allergist/immunologist or dermatologist) or consult notes from a specialist are provided
3. Member is ≥ 12 years of age
4. Paid claims or physician documented inadequate response (defined as ≥ 14 days of therapy) or adverse reaction to at least **TWO** different histamine₁ antihistamines, or contraindication to **ALL** histamine₁ antihistamines (See appendix for examples)
5. Paid claims or physician documented inadequate response (defined as ≥ 14 days of therapy), adverse reaction or contraindication to a histamine₁ antihistamine in combination with a histamine₂ antihistamine (See appendix for examples)
6. Appropriate dosing: 150 mg or 300 mg every 28 days. (See Appendix for dosing requests > 300 mg every 28 days)
7. 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)

Eosinophilic granulomatosis with polyangiitis (EGPA)

Nucala (mepolizumab)

1. Diagnosis of eosinophilic granulomatosis with polyangiitis
2. Member is ≥ 18 years of age
3. Prescriber is a specialist (i.e., allergist, cardiologist, hematologist, immunologist, pulmonologist, rheumatologist, etc.) or consult notes from a specialist are provided
4. Paid claims or physician documented inadequate response (defined as ≥ 30 days of therapy) or adverse reaction to **ONE** systemic glucocorticoid, or contraindication to **ALL** systemic glucocorticoids
5. **ONE** of the following:
 - a. Paid claims or physician documented inadequate response (defined as ≥ 30 days of therapy), adverse reaction to **ONE** of the following:
 - i. azathioprine
 - ii. methotrexate
 - b. Documented contraindication to **BOTH** of the following:
 - i. azathioprine
 - ii. methotrexate
6. Appropriate dosing (300 mg subcutaneously every 28 days)

Hypereosinophilic syndrome (HES)

Nucala (mepolizumab)

1. Diagnosis of hypereosinophilic syndrome
2. Documentation of diagnosis without an identifiable non-hematologic secondary cause
3. Prescriber is a specialist (i.e., allergist, cardiologist, GI, hematologist, immunologist, pulmonologist, etc) or consult notes from a specialist are provided
4. Member is ≥ 12 years of age
5. Paid claims or physician documented inadequate response (defined as ≥ 30 days of therapy) or adverse reaction to **ONE** systemic glucocorticoid, or contraindication to **ALL** systemic glucocorticoids



6. **ONE** of the following:
 - a. Paid claims or physician documented inadequate response (defined as ≥ 30 days of therapy) or adverse reaction to **ONE** of the following:
 - i. hydroxyurea
 - ii. methotrexate
 - iii. interferon alfa
 - b. Documented contraindication to **ALL** of the following:
 - i. hydroxyurea
 - ii. methotrexate
 - iii. interferon alfa
7. Appropriate dosing (300 mg subcutaneously every 28 days)

Moderate to Severe Allergy Related Asthma

Xolair (omalizumab)

1. Diagnosis of moderate to severe allergy-related asthma
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 (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) or consult notes from a specialist are provided
7. Appropriate dosing (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 (e.g., member will be self-administering)

Nasal Polyps

Nucala (mepolizumab)

Xolair (omalizumab)

1. Diagnosis of nasal polyps
2. Member is ≥ 18 years of age
3. Prescriber is a specialist (i.e., allergist, immunologist, otolaryngologist, pulmonologist) or consult notes from a specialist are provided
4. Paid claims or physician documented inadequate response or adverse reaction to **ONE** oral corticosteroid, or contraindication to **ALL** oral corticosteroids
5. Paid claims or physician documented inadequate response or adverse reaction to **ONE** intranasal corticosteroid, or contraindication to **ALL** intranasal corticosteroids
6. Appropriate dosing:
 - a. Nucala: 100 mg every 4 weeks
 - b. Xolair: based on weight and serum total IgE level: 75 to 600 mg every 14 to 28 days



7. 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)
8. Documentation that agent will be used as adjunctive therapy

Severe Eosinophilic Asthma

Cinqair (reslizumab)

Fasenra (benralizumab)

Nucala (mepolizumab)

1. Diagnosis of severe eosinophilic asthma
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 (Serevent)
 - c. Chronic oral corticosteroids (defined as ≥ 90 days of therapy within the last 120 days)
4. Physician attestation of evidence of an eosinophilic phenotype (i.e. peripheral blood eosinophil count ≥ 150 cells/ μ L [for Nucala and for Fasenra], or ≥ 400 cells/ μ L [for Cinqair], elevated sputum eosinophils or FeNO)
5. Prescriber is an asthma specialist (i.e., allergist, immunologist, pulmonologist) or consult notes from a specialist are provided
6. Dosing is appropriate:
 - a. Cinqair: 3 mg/kg intravenously every 4 weeks
 - b. Fasenra: 30 mg every 4 weeks for 3 doses, then 30 mg every 8 weeks
 - c. Nucala: 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

Severe Asthma

Tezspire (tezepelumab-ekko)

1. Diagnosis of severe asthma
2. Member is ≥ 12 years of age
3. Prescriber is an asthma specialist (i.e., allergist, immunologist, pulmonologist) or consult notes from a specialist are provided
4. Paid claims 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 (Serevent)
 - c. Chronic oral corticosteroids (defined as ≥ 90 days of therapy within the last 120 days)
5. Appropriate dosing

Continuation of Therapy

Reauthorization requires physician attestation 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 indications: 6 months



2. Reauthorizations will be granted for the following:
 - a. Chronic idiopathic urticaria: 4 months
 - b. All other diagnosis: 12 months

Appendix

Appendix A:

Examples of Traditional Therapies for CIU

H₁-Antihistamines (first generation):

Brompheniramine, carbinoxamine, chlorpheniramine, clemastine, cyproheptadine, diphenhydramine, hydroxyzine, promethazine, and doxepin

H₁-Antihistamines (second generation):

acrivastine/pseudoephedrine, cetirizine, desloratadine, fexofenadine, levocetirizine, loratadine

H₂-Antihistamines:

cimetidine, famotidine, nizatidine, ranitidine

Leukotriene Modifiers:

montelukast, zafirlukast, zileuton

Appendix B:

CIU: Omalizumab requests for > 300 mg every 4 Weeks

Requests for 450 mg every four weeks or 150 mg every two weeks can be approved for 3 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 3-month approval if provider submits request.

Recertification with either dosing will require documentation of positive response.

Appendix C:

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 | DO NOT DOSE |
| > 400-500 | 300 mg | 300 mg | 375 mg | |
| > 500-600 | 300 mg | 375 mg | | |
| > 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 weeks¹

| 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 |
| > 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 | 450 mg | 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 | 600 mg | | | | |
| >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

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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

03/16/2022 – Updated and Reviewed for March P&T; Guideline updated based on FDA-expanded indication for use of Nucala (mepolizumab) in CRSwNP. Decision made to follow same criteria as Dupixent and Xolair for this indication. However, it was also decided to remove requirement of a trial with a leukotriene antagonist (LTRA) given the updated black box warnings regarding potential for serious neuropsychiatric events that have been reported with the use of montelukast. In addition, current guidelines mention that there is a low quality of available evidence comparing montelukast with nasal corticosteroids and do not routinely recommend use unless there is an allergic component to the disease. Similar decision was also made for Xolair CIU criteria to remove the requirement of LTRA trial. Based on expanded indication for use of dupilumab as add-on maintenance treatment of patients aged 6 to 11 years with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral-corticosteroid dependent asthma, criteria was updated to include new age range and new dupilumab formulation 100 mg/0.67 mL syringe was added to the internal guideline. Doxepin was added to appendix section as suitable option for H1 antihistamine trial for CIU and appendix section was updated for moderate to severe allergy-related asthma for omalizumab requests for members < 6 years of age based on consensus guideline recommendations for alternative agents. Two new appendices (Dupilumab requests for once weekly treatment and Dupilumab requests attempting to bypass systemic immunomodulatory agent) were included. The appendix “Omalizumab requests for members with high (>700 IU/mL) IgE levels or weight (<30 kg or >150 kg)” was removed.

05/18/2022 – Reviewed and Updated for May P&T. Updated references. Matched MH UPPL. Guideline updated following NDR for Tezspire (tezepelumab-ekko). Dupixent is preferred drug. Requirement for systemic immunomodulatory agent removed from Dupixent in AD criteria; criteria for Dupixent in nasal polyps changed to just one requirement to oral corticosteroid, intranasal corticosteroid, prior nasal surgery, or contraindication to both OCS and INS. Dupixent initial approvals changed from 6 months to 1 year duration. Reference table updated to include Preferred Drug footnote. Added the appendix “CIU: Omalizumab requests for > 300 mg every 4 weeks.” The appendix “Moderate to Severe Atopic Dermatitis: Dupilumab requests attempting to bypass systemic immunomodulatory agent” was removed. Removed Foradil as a less costly alternative due to obsolete status. Effective 7/1/22.

11/16/2022 – Reviewed and updated for Nov P&T. Matched MH UPPL. Guideline update for expanded indications for Dupixent in children ≥ 6 months with moderate to severe atopic dermatitis as well as individuals ≥ 12 years of age with eosinophilic esophagitis. Effective 11/01/2022

3/15/23 – Reviewed and updated for Mar P&T. Admin update: Cinquair available through medical benefit. Effective 4/1/23.

05/10/23 – Reviewed and updated for P&T. Expanded indication for Dupixent in prurigo nodularis was added. Revision to Dupixent atopic dermatitis note section to allow for bypass of Eucrisa trial if disease is noted to be severe or if the affected area is noted to be too widespread. Included note that topical tacrolimus could be also bypassed if affected area noted to be too widespread. Added once-weekly dosing to Appendix. Effective 6/5/23.

07/12/23 – Reviewed and updated for P&T. Formatting changes made throughout policy. Brand preferred and mandatory generic language was added under Limitations. No clinical changes. Effective 7/31/23

05/15/25 – Reviewed and updated for P&T. Updated formatting and references. Dupixent removed from medical criteria as it is managed via pharmacy benefit only, available on MHD. Effective 6/1/25

