Mass General Brigham
Health Plan

Asthma and Allergy Injectables
Cinqair (reslizumab)
Exdensur (depemokimab)
Fasenra (benralizumab)
Nucala (mepolizumab)
Xolair (omalizumab)
Tezspire (tezepelumab-ekko)
Effective 01/04/2027

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 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 is a interleukin-5 antagonist monoclonal antibody indicated for:

- Add-on maintenance treatment of severe asthma for members with an eosinophilic phenotype.

Fasenra is a interleukin-5 antagonist monoclonal antibody indicated for:

- Add-on maintenance treatment of severe asthma for members with an eosinophilic phenotype.
- Hypereosinophilic syndrome (HES)

Exdensur is an IL-5 antagonist (humanized IgG1 kappa monoclonal antibody) indicated for:

- treatment of severe eosinophilic asthma that has an extended dosing duration of every six months

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)
- Chronis 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

- Add-on maintenance treatment of inadequately controlled chronic rhinosinusitis with nasal polyps (CRSwNP) in adult and pediatric patients ≥12 years of age

Coverage Guidelines
If member is new to the plan (as evidenced by coverage effective date of less than or equal to 90 days), submission of medical records documenting that the member is currently receiving treatment with the requested drug, excluding when the product is obtained as samples or via manufacturer's patient assistance programs
OR
Authorization may be granted when all of the following criteria are met:

Xolair (omalizumab)
Chronic Spontaneous Urticaria (CSU)
1. Diagnosis of chronic spontaneous 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. Inadequate response (defined as ≥14 days of therapy) or adverse reaction to at least **ONE** different histamine$_1$ antihistamines, or contraindication to **ALL** second generation histamine$_1$ antihistamines (See appendix for examples)
5. **ONE** of the following:
    a. Inadequate response (defined as ≥14 days of therapy) or adverse reaction to **ONE** of the following:
        i. Increased dose of a second generation histamine$_1$ antihistamine (up to four times the standard dose)
        ii. Second generation histamine$_1$ antihistamine in combination with a histamine$_2$ antihistamine
        iii. Second generation histamine$_1$ antihistamine in combination with a leukotriene receptor antagonist
        iv. Second generation histamine$_1$ antihistamine in combination with a first-generation histamine$_1$ antihistamine at bedtime
    b. **BOTH** of the following:
        i. Contraindication to **ALL** of the following:
            1. histamine$_2$ antihistamines
            2. first-generation histamine$_1$ antihistamines
            3. leukotriene receptor antagonists
        ii. Clinical rationale why the dose of a second generation histamine$_1$ antihistamine cannot be increased to up to four times the standard dose (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 or 300 mg syringe or auto-injection, medical necessity for the requested formulation instead of the vial (e.g., member will be self-administering)

IgE-Mediated Food Allergy
1. Diagnosis of IgE-Mediated Food Allergy
2. Prescriber is an allergist or immunologist or consultation notes from an allergist or immunologist are provided
3. Member is ≥ 1 year of age

4. Baseline serum IgE between 30 IU/mL to 1,850 IU/mL
5. Evidence of specific allergic sensitivity (i.e. positive skin test or blood test [radioallergosorbent test or RAST] for IgE)
6. Appropriate dosing (Dosing range is 75 to 600 mg subcutaneously every 14 to 28 days)
7. For the 150 mg or 300 mg syringe or auto-injection, medical necessity for the requested formulation instead of the vial (e.g., member will be self-administering)

Moderate to Severe Allergy Related Asthma

1. Diagnosis of moderate to severe allergy-related asthma
2. Member is ≥ 6 years of age
3. Member is symptomatic despite receiving **ONE** of the following:
    a. Combination inhaler (fluticasone/salmeterol inhalation [Advair], fluticasone/vilanterol [Breo], Dulera, fluticasone/salmeterol, budesonide/formoterol [Symbicort], fluticasone/umeclidinium/vilanterol [Trelegy] or budesonide/glycopyrrolate/formoterol [Breztri])
    b. Combination of an inhaled corticosteroid (Alvesco, Arnuity, Asmanex, beclomethasone HFA, fluticasone propionate, Pulmicort or Qvar) **AND** a long-acting β-agonist inhaler (arformoterol, formoterol, Serevent, or Striverdi [olodaterol])
    c. Combination of fluticasone/vilanterol and Incruse (umeclidinium), fluticasone furoate inhalation powder and umeclidinium/vilanterol or Bevespi (glycopyrrolate/formoterol) and Pulmicort (budesonide inhalation powder)
    d. Chronic oral corticosteroids (defined as ≥ 90 days of therapy within the last 120 days)
4. Baseline serum IgE between 30 IU/mL to 1,300 IU/mL ***see Appendix for higher IgE levels***
5. 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 or 300 mg syringe or auto-injection, medical necessity for the requested formulation instead of the vial (e.g., member will be self-administering)

Chronic Rhinosinusitis with Nasal Polyps

1. Diagnosis of c*hronic Rhinosinusitis with* 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. **ONE** of the following:
    a. Inadequate response or adverse reaction to **ONE** or contraindication to **BOTH** of the following:
        i. oral corticosteroid
        ii. intranasal corticosteroid
    b. History of prior nasal surgery
5. Baseline serum IgE between 30 IU/mL to 1,500 IU/mL
6. Appropriate dosing: 75 to 600 mg every 14 to 28 days (based on weight and serum total IgE level)
7. If request is for Xolair 150 mg or 300 mg syringe or auto-injection, medical necessity for the requested formulation instead of the vial (e.g., member will be self-administering)
8. Documentation that agent will be used as adjunctive therapy

Systemic Mastocytosis (Off-Label)

1. Diagnosis of systemic mastocytosis
2. Prescriber is a specialist or consult notes from a specialist are provided (e.g., hematologist, oncologist, allergist, immunologist)
3. Inadequate response, adverse reaction, or contraindication to **ALL** of the following:
    a. Corticosteroids
    b. Histamine1 antihistamine
    c. Histamine2 antihistamine
4. Appropriate dosing (150 to 300 mg subcutaneously every 28 days)
5. For the 150 mg or 300 mg syringe or auto-injection, medical necessity for the requested formulation instead of the vial (e.g., member will be self-administering)

Nucala (mepolizumab)

Chronic Obstructive Pulmonary Disease (COPD)

1. Diagnosis of moderate to severe COPD
2. Prescriber is a specialist (i.e., pulmonologist, allergist, or immunologist) or consult notes from a specialist are provided
3. Appropriate dosing
4. **ONE** of the following:
    a. **BOTH** of the following:
        i. Inadequate response (defined as ≥ 90 days of therapy) or adverse reaction to **ONE** of the following or any combination of separate inhalers equivalent to **ONE** of the following
            1. Anoro (umeclidinium/vilanterol)
            2. Bevespi (glycopyrrolate/formoterol)
            3. Duaklir (aclidinium/formoterol)
            4. Stiolto (tiotropium/olodaterol)
        ii. Contraindication to the use of an inhaled corticosteroid (e.g., history of pneumonia)
    b. Inadequate response (defined as ≥ 90 days of therapy within a 120- day time period) or adverse reaction to **ONE** or any combination of separate inhalers equivalent to **ONE** of the following or contraindication to **BOTH** of the following:
        i. Breztri (budesonide/glycopyrrolate/formoterol)
        ii. Trelegy (fluticasone furoate/umeclidinium/vilanterol)
5. Evidence of an eosinophilic phenotype [i.e. peripheral blood eosinophil count ≥ 150 cells/µL]
6. Requested agent will be used as adjunctive therapy with either dual or triple inhaled therapy

Eosinophilic granulomatosis with polyangiitis (EGPA)

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. Inadequate response (defined as ≥ 30 days of therapy) or adverse reaction to **ONE** systemic glucocorticoid, or contraindication to **ALL** systemic glucocorticoids

5. Appropriate dosing (300 mg subcutaneously every 28 days)

Hypereosinophilic syndrome (HES)

1. Diagnosis of hypereosinophilic syndrome

2. Documentation of diagnosis without an identifiable non-hematologic secondary cause of HES (e.g., drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy)
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. Baselines blood eosinophil level of ≥ 1,000 cells/µL (prior to use of any monoclonal antibody therapy)
6. Member is not FIP1L1-PDGFRα kinase-positive
7. Inadequate response (defined as ≥ 30 days of therapy) or adverse reaction to **ONE** systemic glucocorticoid, or contraindication to **ALL** systemic glucocorticoids
8. Inadequate response (defined as ≥ 30 days of therapy) or adverse reaction to **ONE** or contraindication to BOTH of the following:
    a. hydroxyurea
    b. peginterferon alfa
9. Inadequate response, adverse reaction or contraindication to Fasenra (benralizumab)
10. Appropriate dosing (300 mg subcutaneously every 28 days)

Chronic Rhinosinusitis with Nasal Polyps

1. Diagnosis of chronic rhinosinusitis with 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. **ONE** of the following:
    a. Inadequate response (defined as ≥ 90 days of therapy) or adverse reaction to **ONE** or contraindication to **BOTH** of the following:
        i. oral corticosteroid
        ii. intranasal corticosteroid
    b. History of prior nasal surgery
5. Appropriate dosing: 100 mg every 4 weeks
6. Documentation that agent will be used as adjunctive therapy

Severe Eosinophilic Asthma

1. Diagnosis of severe eosinophilic asthma
2. Member is ≥ 6 years of age
3. Member is symptomatic despite receiving **ONE** of the following:
    a. Combination inhaler (fluticasone/salmeterol inhalation [Advair], fluticasone/vilanterol [Breo], Dulera, fluticasone/salmeterol , budesonide/formoterol [Symbicort] or fluticasone/umeclidinium/vilanterol [Trelegy] or budesonide/glycopyrrolate/formoterol [Breztri])
    b. Combination of an inhaled corticosteroid (Alvesco, , Arnuity, Asmanex, beclomethasone HFA, fluticasone propionate, Pulmicort or Qvar) **AND** a long-acting β-agonist inhaler (arformoterol, formoterol, Serevent [salmeterol] or Striverdi [olodaterol])
    c. Combination of fluticasone/vilanterol and Incruse (umeclidinium} or fluticasone furoate inhalation powder and umeclidinium/vilanterol or Bevespi (glycopyrrolate/formoterol) and Pulmicort (budesonide inhalation powder)
    d. Chronic oral corticosteroids (defined as ≥ 90 days of therapy within the last 120 days)
4. Evidence of an eosinophilic phenotype (i.e. peripheral blood eosinophil count ≥ 150 cells/µL, 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. For members ≥ 12 years of age, 100 mg subcutaneously every 28 days
    b. For members 6 to 11 years of age, 40 mg subcutaneously every 28 days

Cinqair (reslizumab)

Severe Eosinophilic Asthma

1. Diagnosis of severe eosinophilic asthma
2. Member is ≥ 18 years of age
3. Member is symptomatic despite receiving **ONE** of the following:
    a. Combination inhaler (, fluticasone/vilanterol [Breo], Dulera, fluticasone/salmeterol inhalation [Advair], fluticasone/salmeterol, budesonide/formoterol [Symbicort] or fluticasone/umeclidinium/vilanterol [Trelegy] or budesonide/glycopyrrolate/formoterol [Breztri])
    b. Combination of an inhaled corticosteroid (Alvesco, , Arnuity, Asmanex, beclomethasone HFA, fluticasone propionate, Pulmicort or Qvar) **AND** a long-acting β-agonist inhaler (arformoterol, formoterol, Serevent [salmeterol] or Striverdi [olodaterol])
    c. Combination of fluticasone/vilanterol and Incruse (umeclidinium} or fluticasone furoate inhalation powder and umeclidinium/vilanterol or Bevespi (glycopyrrolate/formoterol) and Pulmicort (budesonide inhalation powder)
    d. Chronic oral corticosteroids (defined as ≥ 90 days of therapy within the last 120 days)
4. Evidence of an eosinophilic phenotype (i.e. peripheral blood eosinophil count ≥ 400 cells/µL, 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: 3 mg/kg intravenously every 4 weeks

Fasenra (benralizumab)

Eosinophilic granulomatosis with polyangiitis (EGPA)

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. Inadequate response (defined as ≥ 30 days of therapy) or adverse reaction to **ONE** systemic glucocorticoid, or contraindication to **ALL** systemic glucocorticoids
5. Appropriate dosing (30 mg subcutaneously every 28 days)

Severe Eosinophilic Asthma

1. Diagnosis of severe eosinophilic asthma
2. Member is ≥ 6 years of age
3. Member is symptomatic despite receiving **ONE** of the following:
    a. Combination inhaler (fluticasone/salmeterol inhalation [Advair], fluticasone/vilanterol [Breo], Dulera, fluticasone/salmeterol , budesonide/formoterol [Symbicort] or fluticasone/umeclidinium/vilanterol [Trelegy] or budesonide/glycopyrrolate/formoterol [Breztri])

b. Combination of an inhaled corticosteroid (Alvesco, Arnuity, Asmanex, beclomethasone HFA, fluticasone propionate, Pulmicort or Qvar) **AND** a long-acting β-agonist inhaler (arformoterol, formoterol, Serevent [salmeterol] or Striverdi [olodaterol])
c. Combination of fluticasone/vilanterol and Incruse (umeclidinium} or fluticasone furoate inhalation powder and umeclidinium/vilanterol or Bevespi (glycopyrrolate/formoterol) and Pulmicort (budesonide inhalation powder)
d. Chronic oral corticosteroids (defined as ≥ 90 days of therapy within the last 120 days)

4. Evidence of an eosinophilic phenotype (i.e. peripheral blood eosinophil count ≥ 150 cells/µL, 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. For members ≥ 12 years of age and members 6 to 11 years of age weighing ≥ 35 kg, 30 mg every 28 days for 3 doses, then 30 mg every 56 days
    b. For members 6 to 11 years of age weighing < 35 kg, 10 mg every 28 days for 3 doses, then 10 mg every 56 days

Hypereosinophilic syndrome (HES)

1. Diagnosis of hypereosinophilic syndrome
2. Documentation of diagnosis without an identifiable non-hematologic secondary cause of HES (e.g., drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy)
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. Baseline blood eosinophil level of ≥ 1,000 cells/µL (prior to use of any monoclonal antibody therapy)
6. Member is not FIP1L1-PDGFRα kinase-positive
7. Inadequate response (defined as ≥ 30 days of therapy) or adverse reaction to **ONE** systemic glucocorticoid, or contraindication to **ALL** systemic glucocorticoids
8. Inadequate response (defined as ≥ 30 days of therapy) or adverse reaction to **ONE** or contraindication to **BOTH** of the following:
    a. hydroxyurea
    b. peginterferon alfa
9. Appropriate dosing

Tezspire (tezepelumab-ekko)

Severe Asthma

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. Member is symptomatic despite receiving **ONE** of the following:
    a. Combination inhaler (, fluticasone/vilanterol [Breo], Dulera, fluticasone/salmeterol inhalation [Advair], budesonide/formoterol [Symbicort] or fluticasone/umeclidinium/vilanterol [Trelegy] or budesonide/glycopyrrolate/formoterol [Breztri])
    b. Combination of an inhaled corticosteroid (Alvesco, , Arnuity, Asmanex, , beclomethasone HFA, fluticasone propionate, Pulmicort or Qvar) **AND** a long-acting β-agonist inhaler (arformoterol, formoterol, Serevent [salmeterol] or Striverdi [olodaterol])

c. Combination of fluticasone/vilanterol and Incruse (umeclidinium} or fluticasone furoate inhalation powder and umeclidinium/vilanterol or Bevespi (glycopyrrolate/formoterol) and Pulmicort (budesonide inhalation powder)
d. Chronic oral corticosteroids (defined as ≥ 90 days of therapy within the last 120 days)

5. Appropriate dosing
6. **ONE** of the following:
    a. **BOTH** of the following:
        i. Member has evidence of eosinophilic phenotype (i.e. peripheral blood eosinophil count ≥ 150 cells/µL, elevated sputum eosinophils or FeNO)
        ii. Inadequate response, adverse reaction or contraindication to **BOTH** of the following
            1. Dupixent (dupilumab)
            2. Fasenra (benralizumab)
    b. Member does not have eosinophilic phenotype

Chronic Rhinosinusitis with Nasal Polyps

1. Diagnosis of chronic rhinosinusitis with nasal polyps
2. Prescriber is a specialist (i.e., allergist, immunologist, otolaryngologist pulmonologist) or consult notes from a specialist are provided
3. Member is ≥ 12 years of age
4. **ONE** of the following:
    a. Inadequate response (defined as ≥ 90 days of therapy) or adverse reaction to **ONE** or contraindication to **BOTH** of the following:
        i. intranasal corticosteroid
        ii. oral corticosteroid
    b. History of prior nasal surgery
5. Inadequate response, adverse reaction, or contraindication to Dupixent
6. Inadequate response, adverse reaction, or contraindication to Nucala
7. Appropriate dosing: 210 mg every 4 weeks
8. Requested agent will be used as adjunctive therapy

Exdensur (depemokimab)

Severe Eosinophilic Asthma

1. Diagnosis of severe eosinophilic asthma
2. Prescriber is an asthma specialist (i.e., allergist, immunologist, pulmonologist) or consult notes from a specialist are provided
3. Member is ≥ 12 years of age
4. Member is symptomatic despite receiving **ONE** of the following:
    a. Combination inhaler (fluticasone/ salmeterol inhalation [Advair], fluticasone/vilanterol [Breo], Dulera, fluticasone/salmeterol , budesonide/formoterol [Symbicort] or fluticasone/umeclidinium/vilanterol [Trelegy] or budesonide/glycopyrrolate/formoterol [Breztri])
    b. Combination of an inhaled corticosteroid (Alvesco, Arnuity, Asmanex, beclomethasone HFA, fluticasone propionate, Pulmicort or Qvar) AND a long-acting β-agonist inhaler (arformoterol, formoterol, Serevent [salmeterol] or Striverdi [olodaterol])
    c. Combination of fluticasone/vilanterol and Incruse (umeclidinium} or fluticasone furoate inhalation powder and umeclidinium/vilanterol or Bevespi (glycopyrrolate/formoterol) and Pulmicort (budesonide inhalation powder)
    d. Chronic oral corticosteroids (defined as ≥ 90 days of therapy within the last 120 days)

5. Evidence of an eosinophilic phenotype (i.e. peripheral blood eosinophil count ≥ 150 cells/µL, elevated sputum eosinophils or FeNO)
6. Appropriate dosing: 100 mg subcutaneously every six months
7. Inadequate response, adverse reaction or inadequate response to **TWO** of the following or contraindication to **ALL** of the following:
    a. Dupixent (dupilumab)
    b. Fasenra (benralizumab)
    c. Nucala (mepolizumab)

Continuation of Therapy
Resubmission by prescriber will infer a positive response to therapy.

Limitations
1. Initial approvals will be granted for the following:
    a. Xolair CIU/CSU and systemic mastocytosis: 4 months
    b. Fasenra and Nucala: 12 months
    c. All others: 6 months
2. Reauthorizations will be granted for 12 months

Appendix
Appendix A:

Examples of Traditional Therapies for CIU

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

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

H_2-Antihistamines:
cimetidine, famotidine, nizatidine, ranitidine

Leukotriene Modifiers:
montelukast, zafirlukast, zileuton

Appendix B:

CSU/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 every two weeks. The response to these trials should be evident after three doses.

- Requests for gradual dose escalations by an additional 150 mg per dose every four weeks to a maximum 600 mg may be approved for **four months**.

Requests for gradual increases in frequency (e.g., from 300 mg every four weeks to 300 mg every two or three weeks) may be approved for **four months** if the provider documents an inadequate response to every four-week regimen.

Recertification with either dosing will require documentation of positive response.

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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: Cinqair 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 MHDL. Effective 6/1/25
07/09/25 – Reviewed and updated for P&T. Aligning with MH criteria. Nucala for EGPA – removed trial/failure requirement of azathioprine and methotrexate. And added step-through with Fasenra. Added EGPA criteria for Fasenra and IgE-mediated food allergy for Xolair. Fasenra received expanded age indication to now include ≥ 6 years of age. Added Systemic Mastocytosis to Xolair. Effective 7/1/25
9/10/25 – Reviewed and updated for P&T. Xolair criteria for CIU was updated to CSU and step-through criteria was further elaborated. Nucala was updated to include COPD indication following an expanded indication update. Effective 10/1/25
6/10/26 – Reviewed and updated for P&T. Removed Appendix C of dosing table for Xolair. Updated Appendix B. Exdensur 100 mg/mL injection added to the medical benefit only with PA. A step-through trial with Dupixent and Fasenra will be required. Expanded labeling of CRwNP for Tezspire was added. A step-through trial with Dupixent and Nucala will be required. Tezspire criteria for severe asthma updated to include requirement for documentation of whether member has an eosinophilic phenotype and if so, trials with preferred agents Dupixent and Fasenra will be required. Nucala criteria for CRwNP was updated to require a step-through trial with Dupixent. Nucala criteria for severe eosinophilic asthma was updated to require a step-through trial with Dupixent and Fasenra. The initial approval duration for Fasenra was updated from 6 to 12 months.
And the reauthorization approval duration was updated to 12 months. Added stability info to Limitations. Effective 7/1/26
09/10/26 – Reviewed and updated for P&T. Fasenra was updated to include HES indication. Nucala criteria for EGPA was updated to require a step-through trial with Fasenra. Nucala criteria for HES was updated to include requirement for documentation of whether member has an adequate parameter of baseline blood eosinophilic level and to ensure the member is not FIP1L1-PDGFRα kinase-positive. Nucala criteria for HES was updated to require a step-through trial with Fasenra. Inadequate response was defined as ≥ 90 days of therapy was specified for chronic rhinosinusitis with nasal polyps. Effective 10/1/26
11/4/26 – Reviewed and updated for P&T. Nucala became preferred product - Removed step requirement of Dupixent and Fasenra from Nucala's indication of severe eosinophilic asthma. Removed step requirement of Fasenra from Nucala's indication of EGPA. Removed step requirement of Dupixent from Nucala's indication of COPD. Updated all asthma indications to remove AirDuo and ArmonAir and to include beclomethasone HFA, fluticasone propionate, Breztri and the separate components of Bevespi and Pulmicort as options for inhaled trial. Updated baseline serum IgE max from 1700 to 1,300 IU/mL for Xolair's indication of moderate to severe allergy related asthma. Added a baseline serum IgE to Xolair's indication of chronic rhinosinusitis with nasal polyps. Added Nucala as a step-requirement for Exdensur's indication of severe eosinophilic asthma. Updated formatting and references. Effective 1/4/2027