

Asthma and Allergy Injectables
Cinqair (reslizumab)
Dupixent (dupilumab)
Fasenra (benralizumab)
Nucala (mepolizumab)
Xolair (omalizumab)
Effective 12/01/2025

| Plan | ☐ MassHealth UPPL ⊠Commercial/Exchange | | Due awaye Tura | ☑ Prior Authorization |
|-------------|---|-----|-------------------|---|
| Benefit | □ Pharmacy Benefit □ Pharmacy Be | | Program Type | ☐ Quantity Limit☐ Step Therapy |
| | ☐ Medical Benefit | | | , |
| Specialty | These medications have been designated specialty and must be filled at a contracted | | | |
| Limitations | specialty pharmacy. | | | |
| | Medical and Specialty Medications | | | |
| Contact | All Plans | Pho | one: 877-519-1908 | Fax: 855-540-3693 |
| Information | Non-Specialty Medications | | | |
| | All Plans | Pho | ne: 800-711-4555 | Fax: 844-403-1029 |
| | Cinqair is only available through the Medical Benefit | | | |
| Exceptions | Dupixent and Xolair pen and autoinjector are only available through the Pharmacy Benefit | | | |

Overview

Cinqair is an interleukin-5 antagonist monoclonal antibody indicated for:

• As add-on maintenance treatment of severe asthma for members with an eosinophilic phenotype.

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

- As add-on maintenance treatment of adult and pediatric patients 6 years of age and older with severe asthma, and with an eosinophilic phenotype.
- Treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA)

Nucala is an interleukin-5 antagonist monoclonal antibody indicated for:

- Add-on maintenance treatment of adult and pediatric patients 6 yeas of age and older with severe asthma with an eosinophilic phenotype
- Treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA)
- Treatment of adult and pediatric patients 12 years of age and older with hypereosinophilic syndrome (HES) for greater than or equal to 6 months without an identifiable non
- Add-on maintenance treatment with adult patients aged 18 years and older with chronic rhinosinusitis with nasal polyps (CRSwNP)
- Add-on maintenance treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype

Dupixent is an interleukin-4 receptor alpha agonist indicated for:

- Adult and pediatric patients 6 months of age and older with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable
- Add-on maintenance treatment of adults with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype
- Add-on maintenance of adult and pediatric patients aged 12 years and older with inadequately controlled chronic rhinosinusitis with nasal polyps (CRSwNP)
- Add-on maintenance treatment of adult and pediatric patients 6 months of age and older with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma
- Treatment of adult and pediatric patients aged 1 year and older, weighing at least 15 kg, with eosinophilic esophagitis (EoE)
- Treatment of adult patients with prurigo nodularis
- Treatment of adult patients with bullous pemphigoid (BP)
- Treatment of adult and pediatric patients 12 years of age and older with chronic spontaneous urticaria (CSU) who remain symptomatic despite H1 anti-histamine treatment

Xolair is an anti-IgE antibody indicated for:

- Treatment of moderate to severe persistent allergic asthma in adults and pediatric patients 6 years of age and older with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that are inadequately controlled with inhaled corticosteroids.
- Chronic spontaneous urticaria (CSU) in adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment
- Chronic rhinosinusitis with nasal polyps (CRSwNP) in adult patients 18 years of age and older with inadequate response to nasal corticosteroids, as add-on maintenance therapy
- IgE-mediated food allergy in adult and pediatric patients aged 1 year and older for the reduction of
 allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one or
 more foods. Xolair should be used in conjunction with food allergen avoidance.

Coverage Guidelines

Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorization may be granted for members when all the following diagnosis-specific criteria have been met:

Cingair

Severe Asthma

- 1. Member has a diagnosis of severe asthma with an eosinophilic phenotype
- 2. Member is 18 years of age or older
- 3. Member is not an active smoker
- 4. Prescriber is an asthma specialist (i.e., allergist, immunologist, pulmonologist)
- 5. Documentation of an eosinophilic phenotype (i.e., peripheral blood eosinophil count ≥ 300 cells/μL, elevated sputum eosinophils)
- 6. Member is symptomatic despite receiving ONE of the following:
 - Combination inhaler containing an inhaled corticosteroid and a long-acting β-agonist
 - Combination of an inhaled corticosteroid and a long-acting β-agonist inhaler as separate agents
 - Chronic oral steroids



- 7. Prescriber confirms that Cingair will be administered only in a healthcare setting
- 8. The member has had an inadequate response, or intolerance to at least THREE (3) of the following preferred products:
 - Dupixent
 - Fasenra
 - Nucala
 - Xolair
- 9. Dose does not exceed 3mg/kg intravenously every four weeks
- 10. Cingair will be used as add-on maintenance treatment

Dupixent

Chronic Obstructive Pulmonary Disease

- 1. Diagnosis of chronic obstructive pulmonary disease (COPD)
- 2. Member is 18 years of age or older
- 3. Presence of Type 2 inflammation evidenced by blood eosinophils greater than or equal to 300 cells per microliter at baseline
- 4. Member is receiving ONE of the following therapies at maximally tolerated doses:
 - a. Triple therapy (i.e., an inhaled corticosteroid (ICS) (e.g., budesonide), a long-acting muscarinic antagonist (LAMA) [e.g., Spiriva (tiotropium), Incruse (umeclidinium)] and a long-acting beta agonist (LABA) (e.g., Serevent (salmeterol), arformoterol, formoterol)
 - b. If ICS are contraindicated, a LAMA and a LABA
- 5. Member has had one of the following within the past 12 months:
 - a. At least two exacerbations where systemic corticosteroids [intramuscular, intravenous, or oral (e.g., prednisone)] were required at least once
 - b. COPD-related hospitalization or emergency-medical visit

Moderate-to-severe atopic dermatitis

- 1. Member has a diagnosis of moderate to severe atopic dermatitis
- 2. Member is at least 6 months old
- 3. Affected body surface is greater than or equal to 10% body surface area OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
- 4. Member has had trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), intolerance, or contraindication to at least ONE of the following:
 - a. Medium or higher potency topical corticosteroid (see Appendix)
 - b. Pimecrolimus cream
 - c. Tacrolimus ointment
 - d. Eucrisa

Prurigo Nodularis

- 1. Member has a diagnosis of prurigo nodularis
- 2. Member is 18 years of age or older
- 3. Member must have a minimum of 20 nodular lesions
- 4. Member meets ONE of the following:
 - a. Inadequate response to ONE of the following:
 - i. Medium to super high potency topical steroid (see Appendix A)
 - ii. Topical calcineurin inhibitor
 - iii. Phototherapy (e.g., UVB, PUVA)
 - iv. Pharmacologic treatment with methotrexate or cyclosporine



- b. Intolerance or a clinical reason to avoid ANY of the following:
 - i. Medium to super high potency topical corticosteroid (see Appendix A) and topical calcineurin inhibitor
 - ii. Pharmacologic treatment with methotrexate and cyclosporine

Eosinophilic Esophagitis

- 1. Member has a diagnosis of eosinophilic esophagitis as evidenced by BOTH of the following:
 - a. Chronic symptoms of esophageal dysfunction (e.g., dysphagia, food impaction, food refusal, abdominal pain, heartburn, regurgitation, chest pain, odynophagia)
 - b. Findings from esophageal biopsies (e.g., eosinophil-predominant inflammation)
- 2. Member is at least 1 year of age and weighs at least 15kg
- 3. Member has had poor control requiring additional treatment despite a trial of a proton pump inhibitor (unless intolerant or contraindication)

Asthma

- 1. Member has a diagnosis of moderate to severe asthma
- 2. Member is at least 6 years old
- 3. Member meets ONE of the following criteria:
 - a. Member has inadequate asthma control (e.g. hospitalization or emergency medical care visit within the past year) despite current treatment with ALL of the following medications at optimized doses:
 - i. Inhaled corticosteroid
 - ii. Additional controller (long acting beta2-agonist, leukotriene modifier, or sustained-release theophylline)
 - iii. Oral glucocorticoids (at least 5 mg per day of prednisone/prednisolone or equivalent)
 - b. Member has a baseline blood eosinophil count of at least 150 cells per microliter and inadequate asthma control (e.g. hospitalization or emergency medical care visit within the past year) despite current treatment with BOTH of the following medications at optimized doses:
 - i. Inhaled corticosteroid
 - ii. Additional controller (long acting beta2-agonist, leukotriene modifier, or sustained-release theophylline)
- 4. Member will not use Dupixent as monotherapy

Chronic rhinosinusitis with nasal polyps (CRSwNP)

- 1. The member is at least 12 years old
- 2. Member has a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP)
- 3. Medication will be used in combination with another agent for CRSwNP (e.g., intranasal corticosteroid)
- 4. Prescribed by or in consultation with one of the following: Allergist/Immunologist, Otolaryngologist, Pulmonologist

Chronic spontaneous urticaria (CSU)

- 1. Diagnosis of chronic spontaneous urticaria
- 2. Member is 12 years of age or older
- 3. Both of the following:
 - a. Persistent symptoms (itching and hives) for at least 6 consecutive weeks despite concurrent use of [with] a second generation H1 antihistamine (e.g., cetirizine, fexofenadine), unless there is a contraindication or intolerance to H1 antihistamines
 - b. Minimum 2-week trial of up-dosing (e.g., up to 4x dose) of the second generation H1 antihistamine, unless there is a contraindication or intolerance to H1 antihistamines



4. Will be used concurrently with a second generation H1 antihistamine, unless there is a contraindication or intolerance to H1 antihistamines

Bullous Pemphigoid

- 1. Diagnosis of bullous pemphigoid
- 2. Member is 18 years of age or older
- 3. Member has had an inadequate response, adverse reaction, or contraindication to at least ONE of the following therapies:
 - a. Oral corticosteroid (e.g., prednisone)
 - b. High potency or super-high potency topical corticosteroid (see Appendix)
 - c. Tetracycline antibiotics (e.g., doxycycline)
- 4. Requested medication will be initiated in combination with a tapering course of oral corticosteroids, unless contraindicated

Fasenra

Eosinophilic granulomatosis with polyangiitis (EGPA)

- 1. Diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA)
- 2. Member is 18 years of age or older
- 3. Member has a history or the presence of an eosinophil count of greater than 1000 cells per microliter or a blood eosinophil level of greater than 10%.
- 4. Member has at least TWO of the following disease characteristics of EGPA:
 - a. Biopsy showing histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation
 - b. Neuropathy, mono or poly (motor deficit or nerve conduction abnormality)
 - c. Pulmonary infiltrates, non-fixed; sino-nasal abnormality
 - d. Cardiomyopathy (established by echocardiography or magnetic resonance imaging)
 - e. Glomerulonephritis (hematuria, red cell casts, proteinuria)
 - f. Alveolar hemorrhage (by bronchoalveolar lavage)
 - g. Palpable purpura
 - h. Anti-neutrophil cytoplasmic anti-body (ANCA) positive (Myeloperoxidase or proteinease 3)
- 5. Member meets ONE of the following:
 - a. Member is currently administering corticosteroid therapy (e.g., prednisolone, prednisone)
 - b. Member has a contraindication or intolerance to corticosteroid therapy
- 7. Member's disease has relapsed or is refractory to standard of care therapy (i.e., corticosteroid treatment with or without immunosuppressive therapy)

Severe Asthma

- 1. The member has a diagnosis of severe asthma
- 2. Member is 6 years of age or older
- 3. Member has a baseline blood eosinophil count of at least 150 cells per microliter
- 4. Member has inadequate asthma control (e.g., hospitalization or emergency medical care visit within the past year) despite current treatment with both of the following medications at optimized doses:
 - a. Inhaled corticosteroid
 - b. Additional controller (long-acting beta₂-agonist, leukotriene modifier, or sustained-release theophylline)
- 5. Member will not use Fasenra as monotherapy.



Nucala

Severe Asthma

- 1. Member has a diagnosis of severe asthma
- 2. Member is 6 years of age or older
- 3. Member has a baseline blood eosinophil count of at least 150 cells per microliter
- 4. Member has inadequate asthma control (e.g., hospitalization or emergency medical care visit within the past year) despite current treatment with both of the following medications at optimized doses:
 - a. Inhaled corticosteroid
 - b. Additional controller (long-acting beta₂-agonist, leukotriene modifier, or sustained-release theophylline)
- 5. Member will not use Nucala as monotherapy.

Chronic rhinosinusitis with nasal polyps (CRSwNP)

- 1. Member is 18 years of age or older
- 2. Member has a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP)
- 3. Medication will be used in combination with another agent for CRSwNP (e.g., intranasal corticosteroid)
- 4. Prescribed by or in consultation with one of the following: Allergist/Immunologist, Otolaryngologist, Pulmonologist

Eosinophilic granulomatosis with polyangiitis

- 1. Member has a diagnosis of eosinophilic granulomatosis with polyangiitis
- 2. Member is 18 years of age or older.
- 3. Member has a history or the presence of an eosinophil count greater than 1000 cells per microliter or a blood eosinophil level of greater than 10%.
- 4. Member has at least TWO of the following disease characteristics of EGPA:
 - a. Biopsy showing histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation
 - b. Neuropathy, mono or poly (motor deficit or nerve conduction abnormality)
 - c. Pulmonary infiltrates, non-fixed; sino-nasal abnormality
 - d. Cardiomyopathy (established by echocardiography or magnetic resonance imaging)
 - e. Glomerulonephritis (hematuria, red cell casts, proteinuria)
 - f. Alveolar hemorrhage (by bronchoalveolar lavage)
 - g. Palpable purpura
 - h. Anti-neutrophil cytoplasmic anti-body (ANCA) positive (Myeloperoxidase or proteinease 3)
- 5. Member meets ONE of the following:
 - a. Member is currently administering corticosteroid therapy (e.g., prednisolone, prednisone)
 - b. Member has a contraindication or intolerance to corticosteroid therapy
- 6. Member's disease has relapsed or is refractory to standard of care therapy (i.e., corticosteroid treatment with or without immunosuppressive therapy)

Hypereosinophilic syndrome (HES)

- 1. The member has a diagnosis of hypereosinophilic syndrome (HES)
- 2. The member is 12 years of age or older
- 3. The member has a diagnosis of HES without another identifiable non-blood related cause
- 4. The member has had at least 2 HES flares within the past 12 months
- 5. The member has had an inadequate response (defined as ≥ 30 days of therapy), adverse reaction or contraindication to one of the following:
 - a. Systemic steroid



- b. Immunosuppressive
- c. Cytotoxic therapy
- 6. The member has had an absolute eosinophil count ≥ 1000 cells per microliter for greater than six months
- 7. The prescriber is a specialist (i.e., allergist, cardiologist, hematologist, or immunologist)

Chronic obstructive pulmonary disease (COPD)

- 1. Diagnosis of chronic obstructive pulmonary disease (COPD)
- 2. Member is 18 years of age or older
- 3. Presence of Type 2 inflammation evidenced by one of the following:
 - a. Blood eosinophils greater than or equal to 150 cells per microliter at baseline
 - b. Blood eosinophils greater than or equal to 300 cells per microliter in the last 12 months
- 4. Member is receiving one of the following therapies at maximally tolerated doses:
 - a. Triple therapy (i.e., an inhaled corticosteroid (ICS) [e.g., budesonide], a long-acting muscarinic antagonist (LAMA) [e.g., tiotropium, umeclidinium] and a long-acting beta agonist (LABA) [e.g., salmeterol, arformoterol, formoterol]
 - b. If ICS are contraindicated, a LAMA and a LABA
- 5. Member has had one of the following within the past 12 months:
 - a. At least two exacerbations where systemic corticosteroids [intramuscular, intravenous, or oral (e.g., prednisone)] were required at least once
 - b. COPD-related hospitalization or emergency-medical visit

Xolair

Moderate to Severe Asthma

- 1. The member has a diagnosis of moderate to severe asthma
- 2. Member is 6 years of age or older.
- 3. Member has a positive skin test or in vitro reactivity to at least one perennial aeroallergen.
- 4. Member has a pre-treatment IgE level greater than or equal to 30 IU/mL.
- 5. Member has inadequate asthma control (e.g., hospitalization or emergency medical care visit within the past year) despite current treatment with both of the following medications at optimized doses:
 - a. Inhaled corticosteroid
 - b. Additional controller (long acting beta₂-agonist, leukotriene modifier, or sustained-release theophylline)
- 6. Member will not use Xolair as monotherapy.

Chronic spontaneous urticaria (CSU)

- 1. Diagnosis of chronic spontaneous urticaria
- 2. Member is 12 years of age or older
- 3. Both of the following:
 - a. Persistent symptoms (itching and hives) for at least 6 consecutive weeks despite concurrent use of a second generation H1 antihistamine (e.g., cetirizine, fexofenadine), unless there is a contraindication or intolerance to H1 antihistamines
 - b. Minimum 2-week trial of up-dosing (e.g., up to 4x dose) of the second generation H1 antihistamine, unless there is a contraindication or intolerance to H1 antihistamines
- 4. Requested medication will be used concurrently with a second generation H1 antihistamine, unless there is a contraindication or intolerance to H1 antihistamines



IgE-Mediated Food Allergy

- 1. Member has a diagnosis of IgE-mediated food allergy
- 2. Member is 1 year of age or older
- 3. Member has a serum IgE ≥ 30 IU
- 4. Requested medication is prescribed by or in consultation with an allergist or immunologist
- 5. Member will use Xolair in conjunction with allergen avoidance

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP):

- 1. Diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP)
- 2. Member is 18 years of age or older
- 3. The physician specialty is Allergist/Immunologist, Otolaryngologist, or Pulmonologist
- 4. Medication will be used in combination with another agent for nasal polyps (e.g. intranasal corticosteroid)

Continuation of Therapy

Cingair:

- 1. <u>Severe Asthma:</u> Authorization of 12 months may be granted for continuation of treatment of asthma in members 18 years of age or older when all of the following criteria are met:
 - a. Asthma control has improved on Cinqair treatment as demonstrated by at least one of the following:
 - i. A reduction in the frequency and/or severity of symptoms and exacerbation
 - ii. A reduction in the daily maintenance oral corticosteroid dose
 - b. Member will not use Cinqair as monotherapy

Dupixent:

- 1. <u>Atopic Dermatitis</u>: Reauthorizations may be granted for up to 12 months when documentation is submitted supporting clinical improvement in the member's condition as evidenced by low disease activity (e.g., clear or almost clear skin), or improvement in signs and symptoms of atopic dermatitis (e.g., redness, itching, oozing/crusting).
- 2. <u>Asthma</u>: Authorization of 12 months may be granted for continuation of treatment of asthma in members 6 years of age or older when all of the following criteria are met:
 - a. Asthma control has improved on Dupixent treatment as demonstrated by at least one of the following:
 - i. A reduction in the frequency and/or severity of symptoms and exacerbation
 - ii. A reduction in the daily maintenance oral corticosteroid dose
 - b. Member will not use Dupixent as monotherapy
- 3. <u>COPD</u>: Reauthorization may be granted for up to 12 months when the member meets all of the following criteria:
 - a. Member is 18 years of age or older
 - b. Member demonstrates positive clinical response to therapy;
 - c. Member continues to receive one of the following therapies:
 - i. Triple therapy (i.e., an inhaled corticosteroid [ICS], a long-acting muscarinic antagonist [LAMA] and a long-acting beta agonist [LABA])
 - ii. If ICS are contraindicated, a LAMA and a LABA
- 4. <u>Prurigo Nodularis:</u> Authorization of 12 months may be granted for members 18 years of age or older who are using Dupixent for prurigo nodularis when the member has achieved or maintained positive clinical response with Dupixent therapy as evidenced by one of the following:
 - 1. Low disease activity (i.e., clear or almost clear skin).



- 2. Reduction in pruritus intensity and improvement in extent and severity of nodular lesions.
- 5. Chronic rhinosinusitis with nasal polyps (CRSwNP): Authorization of 12 months may be granted for continuation of treatment of chronic rhinosinusitis with nasal polyps in members 12 years of age or older who achieve or maintain positive clinical response to Dupixent therapy as evidenced by improvement in signs and symptoms of CRSwNP (e.g., improvement in nasal congestion, nasal polyp size, loss of smell, anterior or posterior rhinorrhea, sinonasal inflammation, hyposmia and/or facial pressure or pain or reduction in corticosteroid use).
- 6. <u>Eosinophilic esophagitis:</u> Authorization of 12 months may be granted for continuation of treatment of eosinophilic esophagitis in members 1 years of age or older weighing at least 15kg when provider attests to improvement in symptoms of esophageal dysfunction (e.g., dysphagia, pain upon swallowing, food impact, etc.)
- 7. <u>CSU:</u> Authorization of 12 months may be granted for continuation of treatment of chronic spontaneous urticaria when all of the following criteria are met:
 - a. Member is 12 years of age or older.
 - b. Member has experienced one or both of the following:
 - i. Reduction in itching severity from baseline
 - ii. Reduction in number of hives from baseline
- 8. <u>Bullous pemphigoid:</u> Reauthorization may be granted for up to 12 months when the following criteria are met:
 - a. Member is 18 years of age and older
 - b. Member demonstrates a positive clinical response to therapy (e.g., reduction in blister formation, reduction in pruritus, increased rate of lesion healing)

Fasenra

- 1. <u>Asthma</u>: Authorization of 12 months may be granted for treatment of asthma when all of the following criteria are met:
 - a. Member is 6 years of age or older.
 - b. Asthma control has improved on Fasenra treatment as demonstrated by at least ONE of the following:
 - i. A reduction in the frequency and/or severity of symptoms and exacerbations
 - ii. A reduction in the daily maintenance oral corticosteroid dose
 - c. Member will not use Fasenra as monotherapy.
- 2. <u>Eosinophilic granulomatosis with polyangiitis</u>: Authorization of 12 months may be granted for continuation of treatment of eosinophilic granulomatosis with polyangiitis when all of the following criteria are met:
 - a. Member is 18 years of age or older.
 - b. Member has beneficial response to treatment with Fasenra as demonstrated by ONE of the following:
 - i. A reduction in the frequency of relapses
 - ii. A reduction in the daily oral corticosteroid dose
 - iii. No active vasculitis

Nucala

- 1. <u>Asthma</u>: Authorization of 12 months may be granted for continuation of treatment of asthma when ALL of the following criteria are met:
 - a. Member is 6 years of age or older.
 - b. Asthma control has improved on Nucala treatment as demonstrated by at least ONE of the following:



- A reduction in the frequency and/or severity of symptoms and exacerbations
- ii. A reduction in the daily maintenance oral corticosteroid dose
- c. Member will not use Nucala as monotherapy.
- 2. <u>Eosinophilic granulomatosis with polyangiitis</u>: Authorization of 12 months may be granted for continuation of treatment of eosinophilic granulomatosis with polyangiitis when all of the following criteria are met:
 - a. Member is 18 years of age or older.
 - b. Member has beneficial response to treatment with Nucala as demonstrated by ONE of the following:
 - i. A reduction in the frequency of relapses
 - ii. A reduction in the daily oral corticosteroid dose
 - iii. No active vasculitis
- 3. <u>HES</u>: Reauthorizations may be granted for up to 12 months when clinical documentation is submitted showing member has had a decrease in absolute eosinophils and improvement in condition
- 4. Chronic rhinosinusitis with nasal polyps (CRSwNP): Authorization of 12 months may be granted for continuation of treatment of chronic rhinosinusitis with nasal polyps in members 18 years of age or older who achieve or maintain positive clinical response to Nucala therapy as evidenced by improvement in signs and symptoms of CRSwNP (e.g., improvement in nasal congestion, nasal polyp size, loss of smell, anterior or posterior rhinorrhea, sinonasal inflammation, hyposmia and/or facial pressure or pain or reduction in corticosteroid use).
- 5. <u>COPD</u>: Reauthorization may be granted for up to 12 months when the member meets all of the following criteria:
 - a. Member is 18 years of age or older
 - b. Member demonstrates positive clinical response to therapy;
 - c. Member continues to receive one of the following therapies:
 - i. Triple therapy (i.e., an inhaled corticosteroid [ICS], a long-acting muscarinic antagonist [LAMA] and a long-acting beta agonist [LABA])
 - ii. If ICS are contraindicated, a LAMA and a LABA

Xolair

- 1. <u>Asthma</u>: Authorization of 12 months may be granted for continuation of treatment of asthma when ALL of the following criteria are met:
 - a. Member is 6 years of age or older.
 - b. Asthma control has improved on Xolair treatment as demonstrated by at least one of the following:
 - i. A reduction in the frequency and/or severity of symptoms and exacerbations
 - ii. A reduction in the daily maintenance oral corticosteroid dose
 - c. Member will not use Xolair as monotherapy.
- 2. <u>CSU:</u> Authorization of 12 months may be granted for continuation of treatment of chronic spontaneous urticaria when all of the following criteria are met:
 - a. Member is 12 years of age or older.
 - b. Member has experienced one or both of the following:
 - i. Reduction in itching severity from baseline
 - ii. Reduction in number of hives from baseline
- 3. <u>IgE-Mediated Food Allergy</u>: Authorization of 12 months may be granted for continuation of treatment for IgE-mediated food allergy when all of the following criteria are met:
 - a. Member is 1 year of age or older



- b. Member has had a positive response to treatment
- 4. <u>CRSwNP:</u> Authorization of 12 months may be granted for continuation of treatment for CRSwNP when all the following criteria are met:
 - a. Member is 18 years of age or older
 - b. Member has had a positive clinical response to therapy as evidenced by Improvement in signs and symptoms of CRSwNP (e.g., improvement in nasal congestion, nasal polyp size, loss of smell, anterior or posterior rhinorrhea, sinonasal inflammation, hyposmia and/or facial pressure or pain or reduction in corticosteroid use)

Limitations:

1. Initial approvals will be approved medication and diagnosis specific as follows:

Cinqair:

• Severe Asthma: 4 months

Dupixent:

- Prurigo nodularis: 4 months
- Asthma, Moderate to Severe Atopic Dermatitis, Chronic Rhinosinusitis with Nasal Polyps (CRSwNP), COPD, Chronic Spontaneous Urticaria, Bullous Pemphigoid, and eosinophilic esophagitis: 6 months

Fasenra:

- Asthma: 6 months
- Eosinophilic granulomatosis with polyangiitis: 12 months

Nucala:

- Asthma, chronic rhinosinusitis with nasal polyps (CRSwNP), COPD: 6 months
- Eosinophilic granulomatosis with polyangiitis: 12 months
- Hypereosinophilic syndrome: 4 months

Xolair:

Asthma, Chronic Spontaneous Urticaria, IgE-Mediated Food Allergy, CRSwNP: 6 months

2. The following quantity limits apply:

| The following quantity lithits apply. | | | | |
|---------------------------------------|-----------------------------|--|--|--|
| Drug Name | Quantity Limit | | | |
| Dupixent prefilled syringe | 2 syringes per 28 days | | | |
| Dupixent Pen-Injector | 2 pens per 28 days | | | |
| Fasenra Pen | 1 pen per 56 days | | | |
| Nucala autoinjector 100mg/ml | 3 autoinjectors per 28 days | | | |
| Nucala prefilled syringe 100mg/ml | 3 syringes per 28 days | | | |
| Nucala prefilled syringe 40 mg/mL | 1 syringe per 28 days | | | |
| Xolair prefilled syringe 75 mg/0.5 mL | 2 syringes per 28 days | | | |
| Xolair prefilled syringe 150mg/mL | 8 syringes per 28 days | | | |
| Xolair prefilled syringe 300 mg/2 mL | 4 syringes per 28 days | | | |
| Xolair autoinjector 75 mg/0.5 mL | 2 autoinjectors per 28 days | | | |
| Xolair autoinjector 150 mg/mL | 8 autoinjectors per 28 days | | | |
| Xolair autoinjector 300 mg/2mL | 4 autoinjectors per 28 days | | | |
| Xolair vial 150mg | 6 vials per 28 days | | | |

Appendix

Appendix A: Relative potency of select topical corticosteroid products



| Potency | Drug | Dosage form | Strength |
|---------------------------------|--------------------------------------|---|---------------------------------|
| I. Super-high potency (group 1) | Augmented betamethasone dipropionate | Ointment, Lotion, Gel | 0.05% |
| | Clobetasol propionate | Cream, Gel, Ointment, Solution, Cream (emollient), Lotion, Shampoo, Foam, Spray | 0.05% |
| | Fluocinonide | Cream | 0.1% |
| | Flurandrenolide | Tape | 4 mcg/cm ² |
| | Halobetasol propionate | Cream, Lotion, Ointment, Foam | 0.05% |
| II. High potency (group 2) | Amcinonide | Ointment | 0.1% |
| | Augmented betamethasone dipropionate | Cream | 0.05% |
| | Betamethasone dipropionate | Ointment | 0.05% |
| | Clobetasol propionate | Cream | 0.025% |
| | Desoximetasone | Cream, Ointment, Spray | 0.25% |
| | | Gel | 0.05% |
| | Diflorasone diacetate | Ointment, Cream (emollient) | 0.05% |
| | Fluocinonide | Cream, Ointment, Gel, Solution | 0.05% |
| | Halcinonide | Cream, Ointment | 0.1% |
| | Halobetasol propionate | Lotion | 0.01% |
| III. High potency (group 3) | Amcinonide | Cream, Lotion | 0.1% |
| | Betamethasone dipropionate | Cream, hydrophilic emollient | 0.05% |
| | Betamethasone valerate | Ointment | 0.1% |
| | | Foam | 0.12% |
| | Desoximetasone | Cream, Ointment | 0.05% |
| | Diflorasone diacetate | Cream | |
| | Fluocinonide | Cream, aqueous emollient | 0.05% |
| | Fluticasone propionate | Ointment | 0.005% |
| | Mometasone furoate | Ointment | 0.1% |
| | Triamcinolone acetonide | Cream, Ointment | 0.5% |
| | Betamethasone dipropionate | Spray | 0.05% |
| | Clocortolone pivalate | Cream | 0.1% |
| IV. Medium potency (group 4) | Fluocinolone acetonide | Ointment | 0.025% |
| | Flurandrenolide | Ointment | 0.05% |
| | Hydrocortisone valerate | Ointment | 0.2% |
| | Mometasone furoate | Cream, Lotion, Solution | 0.1% |
| | Triamcinolone acetonide | Cream | 0.1% |
| | | Ointment | 0.05% and 0.1% |
| | | Aerosol Spray | 0.2 mg per 2-second spray |
| | Betamethasone dipropionate | Lotion | 0.05% |
| V. Lower-mid potency (group | Betamethasone valerate | Cream | 0.1% |
| 5) | Desonide | Ointment, Gel | 0.05% |



| Potency | Drug | Dosage form | Strength |
|-----------------------------|-------------------------------------|--|----------|
| | Fluocinolone acetonide | Cream | 0.025% |
| | Flurandrenolide | Cream, Lotion | 0.05% |
| | Fluticasone propionate | Cream, Lotion | 0.05% |
| | Hydrocortisone butyrate | Cream, Lotion, Ointment, Solution | 0.1% |
| | Hydrocortisone probutate | Cream | 0.1% |
| | Hydrocortisone valerate | Cream | 0.2% |
| | Prednicarbate | Cream (emollient), Ointment | 0.1% |
| | Triamcinolone acetonide | Lotion | 0.1% |
| | | Ointment | 0.025% |
| | Alclometasone dipropionate | Cream, Ointment | 0.05% |
| | Betamethasone valerate | Lotion | 0.1% |
| VI. Low potency (group 6) | Desonide | Cream, Lotion, Foam | 0.05% |
| | Fluocinolone acetonide | Cream, Solution, Shampoo, Oil | 0.01% |
| | Triamcinolone acetonide | Cream, lotion | 0.025% |
| | Hydrocortisone (base, less than 2%) | Cream, Ointment, Solution | 2.5% |
| | | Lotion | 2% |
| VII. Least potent (group 7) | | Cream, Ointment, Gel, Lotion, Spray, Solution | 1% |
| | | Cream, Ointment | 0.5% |
| | Hydrocortisone acetate | Cream | 2.5% |
| | | Lotion | 2% |
| | | Cream | 1% |

References

- Bachert C, Han JK, Desrosiers M, et al. Efficacy and safety of dupilumab in patients with severe chronic rhinosinusitis with nasal polyps (LIBERTY NP SINUS-24 and LIBERTY NP SINUS-52): results from two multicentre, randomised, double-blind, placebo-controlled, parallel-group phase 3 trials. Lancet 2019; 394:1638
- 2. Bhatt SP, Rabe KF, Hanania NA, et al. Dupilumab for COPD with type 2 inflammation indicated by eosinophil counts. *NEJM*. 2023;389:205-214.
- 3. Cingair (reslizumab) [prescribing information]. West Chester, PA: Teva Respiratory, LLC; June 2020
- 4. Chong LY, Piromchai P, Sharp S, et al. Biologics for chronic rhinosinusitis. Cochrane Database Syst Rev 2020; 2:CD013513
- 5. Dupixent (dupilumab) [prescribing information]. Tarrytown, NY: Regeneron Pharmaceuticals; June 2025.
- 6. Emmi G, Bettiol A, Bajema IM, et al. Evidence-based guideline for the diagnosis and management of eosinophilic granulomatosis with polyangiitis. *Nat Rev Rheum*. 2023;19:378-393.
- 7. Fasenra (benralizumab) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; September 2024.
- 8. Gunsoy NB, Cockle SM, Yancey SW, et al. Evaluation of Potential Continuation Rules for Mepolizumab Treatment of Severe Eosinophilic Asthma. J Allergy Clin Immunol Pract 2018; 6:874
- 9. National Heart, Lung, and Blood Institute (NHLBI/NIH). Guidelines for the Diagnosis and Management of Asthma (EPR-3). URL: nhlbi.nih.gov/health-ro/guidelines/current/asthma guidelines. Available from internet. Accessed 2016 April 2018
- 10. Nucala (mepolizumab) [prescribing information]. Philadelphia, PA: GlaxoSmithKline; August 2025.



- 11. Paller AS, Siegfried EC, Thaçi D, et al. Efficacy and safety of dupilumab with concomitant topical corticosteroids in children 6 to 11 years old with severe atopic dermatitis: A randomized, double-blinded, placebo-controlled phase 3 trial. J Am Acad Dermatol 2020
- 12. Pham TH, Damera G, Newbold P, Ranade K. Reductions in eosinophil biomarkers by benralizumab in patients with asthma. Respir Med 2016; 111:21
- 13. Roufosse F, Kahn J-E, Rothenberg ME, Wardlaw AJ, Klion AD, Kirby SY, Gilson MJ, Bentley JH, Bradford ES, Yancey SW, Steinfeld J, Gleich GJ, Efficacy and safety of mepolizumab in hypereosinophilic syndrome: a Phase III, randomized, placebo-controlled trial, *Journal of Allergy and Clinical Immunology* (2020), doi: https://doi.org/10.1016/j.jaci.2020.08.037
- 14. Saini SS, Bindslev-Jensen C, Maurer M, et al. Efficacy and safety of omalizumab in patients with chronic idiopathic/spontaneous urticaria who remain symptomatic on H1 antihistamines: a randomized, placebocontrolled study. *Journal of Investigative Dermatology*. 2015;153:67-75.
- 15. Silverberg JI, Yosipovitch G, Simpson EL, et al. Dupilumab treatment results in early and sustained improvements in itch in adolescents and adults with moderate to severe atopic dermatitis: Analysis of the randomized phase 3 studies SOLO 1 and SOLO 2, AD ADOL, and CHRONOS. J Am Acad Dermatol 2020; 82:1328
- 16. Straesser MD, Oliver E, Palacios T, et al. Serum IgE as an immunological marker to predict response to omalizumab treatment in symptomatic chronic urticaria. J Allergy Clin Immunol Pract 2018; 6:1386
- 17. Tsurumaki H, Matsuyama T, Ezawa K, et al. Rapid Effect of Benralizumab for Hypereosinophilia in a Case of Severe Asthma with Eosinophilic Chronic Rhinosinusitis. Medicina (Kaunas) 2019; 55
- 18. van den Elzen MT, van Os-Medendorp H, van den Brink I, et al. Effectiveness and safety of antihistamines up to fourfold or higher in treatment of chronic spontaneous urticaria. Clin Transl Allergy 2017; 7:4
- 19. Wan KS. Efficacy of leukotriene receptor antagonist with an anti-H1 receptor antagonist for treatment of chronic idiopathic urticaria. J Dermatolog Treat 2009; 20:194
- 20. Wood RA. Togia A, Sicherer SH, et al. Omalizumab for the treatment of multiple food allergies. *NEJM*. 2024;390:889-899.
- 21. Xolair (omalizumab) [prescribing information]. San Francisco, CA: Genentech Inc; February 2024.
- 22. Zuberbier T, Aberer W, Asero R, et al. The EAACI/GA²LEN/EDF/WAO guideline for the definition, classification, diagnosis and management of urticaria. Allergy 2018; 73:1393

Review History

09/24/18 - Updated

11/20/19 – 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 \geq 6 years old for moderate to severe eosinophilic asthma (effective 6/1/20)

11/18/2020- Updated: changed criteria name to *Asthma & Allergy Injectables*, made one document for Cinqair, Dupixent, Fasenra, Nucala and Xolair criteria, added preferred trials for Cinqair, added new indication of HES for Nucala: Matching the CVS SGM criteria for Xolair, Nucala, Fasenra, and Dupixent. Effective 1/1/21.

09/22/2021 – Reviewed and Updated September P&T; added indication for nasal polyps for Xolair. Effective 01/01/2022

03/16/2022 – Reviewed and Updated for March P&T; updated age requirement from 12 years to 6 years for Dupixent for asthma per manufacture recommendations; added new indication and criteria for Nucala for nasal polyps; references updated; added appendix with high and very high corticosteroid list. Effective 05/01/2022 11/16/2022 – Reviewed and Updated for Nov P&T; updated age requirement for Dupixent from 12 years of age to 6 months for moderate to severe atopic dermatitis. Effective 02/01/2023.

01/11/2023 – Reviewed and updated for Jan P&T; Fasenra solution and Nucala solution available on pharmacy benefit. Added new indication of eosinophilic esophagitis and prurigo nodularis for Dupixent. Effective 4/1/23

