

**Asthma and Allergy Injectables**  
**Dupixent (dupilumab)**  
**Fasenra (benralizumab)**  
**Nucala (mepolizumab)**  
**Xolair (omalizumab)**  
**Effective 01/01/2026**

<b>Plan</b>	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit		
<b>Specialty Limitations</b>	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
<b>Contact Information</b>	<b>Medical Benefit</b> <b>Pharmacy Benefit</b>	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
<b>Exceptions</b>	N/A		

### Overview

**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 years 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 criteria have been met:

### 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 proteinase 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 beta<sub>2</sub>-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 beta<sub>2</sub>-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 proteinase 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  $\geq 12$  years of age
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  $\geq 30$  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  $\geq 1000$  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 beta<sub>2</sub>-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  $\geq$  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

##### Dupixent:

1. Atopic Dermatitis: 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. Asthma: 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. COPD: 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. Prurigo Nodularis: 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 polypos (CRSwNP): Authorization of 12 months may be granted for continuation of treatment of chronic rhinosinusitis with nasal polypos 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. Eosinophilic esophagitis: 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. CSU: 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. Bullous pemphigoid: 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. Asthma: 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 Fasentra 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 Fasentra as monotherapy.
2. Eosinophilic granulomatosis with polyangiitis: 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 Fasentra 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. Asthma: 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:
    - 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 Nucala as monotherapy.
2. Eosinophilic granulomatosis with polyangiitis: 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. HES: 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. COPD: 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. Asthma: 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. CSU: 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. **IgE-Mediated Food Allergy:** 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. **CRSwNP:** 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 for specific medications and diagnoses will be as follows:

##### 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 polyposis (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:

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 <sup>2</sup>
	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%
III. High potency (group 3)	Halobetasol propionate	Lotion	0.01%
	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%
IV. Medium potency (group 4)	Triamcinolone acetonide	Cream, Ointment	0.5%
	Betamethasone dipropionate	Spray	0.05%
	Clocortolone pivalate	Cream	0.1%
	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%
V. Lower-mid potency (group 5)		Aerosol Spray	0.2 mg per 2-second spray
	Betamethasone dipropionate	Lotion	0.05%
	Betamethasone valerate	Cream	0.1%



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

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## 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 ≥ 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



6/23/2023 – Reviewed and Updated for July P&T; added initial approval duration of 4 months for Dupixent prurigo nodularis under limitations. Effective 09/01/2023

11/15/2023 – Reviewed and Updated for Nov P&T; updated age requirement for reauthorization for Dupixent to 6 months of age. Effective 1/1/2024

12/13/2023 – Reviewed and Updated for Dec P&T; For all Drugs: removed “The member will not use requested medication concomitantly with other biologics indicated for asthma”. Dupixent for purigo nodularis: Removed pruritis lasting 6 weeks and history of signs of repeated itch scratch cycle. Dupixent and Nucala for CRSwNP: Removed disease involvement, including bilateral nasal endoscopy or rhinoscopy, removed nasal obstruction with rhinorrhea OR reduction or loss of smell. Xolair for Nasal polyps removed the requirement of a leukotriene inhibitor, only requires intranasal corticosteroid. Effective 1/1/24

08/14/2024 – Reviewed at updated for August P&T. Added initial and reauthorization criteria for Xolair for the treatment of IgE-mediated food allergy. Added Xolair auto-injector to the policy with quantity limitations. Updated approvable minimum age and weight for Dupixent for the treatment of eosinophilic esophagitis to one year and 15 kg, respectively, based on updated FDA-approved indication. Updated approvable age for Fasenra for the treatment of asthma to 6 years of age based on updated FDA-approved indication. Clarified step therapy language to indicate member must be new to the plan within the past 90 days. Effective 10/1/2024.

09/11/2024 – Reviewed and updated for September P&T. Updated atopic dermatitis criteria for Dupixent to remove lookback period of step through agents. Effective 10/1/2024.

12/11/2024 – Reviewed and updated for December P&T. Updated Dupixent criteria to include COPD. Updated Dupixent criteria for nasal polyps to decrease approvable age from 18 to 12 years old to align with updated FDA package labeling. Added EGPA criteria for Fasenra. Updated EGPA Nucala criteria to streamline relapsed/refractory disease requirement and included a requirement that the member is either on a corticosteroid or is unable to take a corticosteroid. Effective 4/1/2025.

01/08/2025 – Reviewed and updated for January P&T. Updated initial criteria for atopic dermatitis to include Eucrisa as a previous trial option and specified the needed length of trial for the topical agents and updated the reauthorization criteria to require documentation of clinical improvement. Updated severe asthma criteria for Nucala and Fasenra to remove allowance for approval if the member is dependent on systemic corticosteroids. Updated Nucala criteria for hypereosinophilic syndrome (HES) to allow for approval if the member has tried immunosuppressive agents or cytotoxic therapy and updated the required eosinophil count from 1500 to 1000. Updated policy to indicate that Xolair solution is no longer restricted to the medical benefit. Effective 4/1/2025.

02/12/2025 – Reviewed and updated for February P&T. Updated Dupixent criteria for CRSwNP to remove requirement that member has had a trial and failure with at least 2 months of treatment with an intranasal corticosteroid. Updated Dupixent criteria for asthma to remove stipulation for length of treatment with controllers. Effective 06/01/2025.

03/12/2025 – Reviewed and updated for March P&T. Updated Dupixent’s initial approval length for atopic dermatitis to 6 months - Effective 04/01/2025. Updated nasal polyps criteria for Xolair to remove previous treatment with an intranasal corticosteroid and updated language for concomitant use with another product during treatment. Effective 06/01/2025.

09/10/2025 – Reviewed and updated for September P&T. Added initial and reauthorization criteria for the following supplemental indications: CSU and bullous pemphigoid for Dupixent, and COPD for Nucala. Updated CSU criteria for Xolair to require previous up dosing with second generation antihistamine and concurrent use with a second generation H1 antihistamine. Effective 12/1/2025.

10/08/2025 – Reviewed and updated for October P&T. Effective 12/01/2025: Updated initial and reauthorization Nucala criteria for COPD and Dupixent criteria for bullous pemphigoid to require member is 18 years of age and older. Effective 01/01/2026: Updated policy to reflect that it will no longer apply to the medical benefit and removed Cinqair from the policy, as it will have its own separate policy.



