

# Medical Drug Clinical Criteria

**Subject:** Dupixent (dupilumab)

**Document #:** CC-0029

**Publish Date:** 09/10/2025

**Status:** Revised

**Last Review Date:** 08/15/2025

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## Overview

This document addresses the use of Dupixent (dupilumab). Dupixent, an interleukin-4 (IL-4)/interleukin 13 (IL-13) inhibitor, is approved in individuals for the treatment of moderate to severe atopic dermatitis (AD) when disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. It is also approved for other dermatologic conditions including prurigo nodularis and bullous pemphigoid. Dupixent is approved as add-on maintenance therapy for Asthma, chronic obstructive pulmonary disease (COPD), and chronic rhinosinusitis with nasal polyposis (CRSwNP) that is inadequately controlled on prior therapy. It is additionally approved for chronic spontaneous urticaria and eosinophilic esophagitis.

### Atopic Dermatitis

Atopic dermatitis, the most common form of eczema, is frequently associated with a personal or family history of allergies, allergic rhinitis and asthma. AD typically follows a relapsing/chronic course but often resolves by adulthood. Symptoms can include erythema, edema, xerosis, excoriations, pruritus, oozing and crusting, or lichenification. The 2023 American Academy of Dermatology (AAD) guideline for the treatment of atopic dermatitis with topical therapies indicates that topical therapies are the mainstay of treatment based on their generally favorable safety and efficacy. In 2024, AAD published treatment guidelines for the treatment of AD with systemic therapies. The academy recommends the use of dupilumab, tralokinumab, baricitinib, abrocitinib, and upadacitinib. There are also recommendations for phototherapy, cyclosporine, methotrexate, azathioprine, and mycophenolate. Systemic corticosteroids are not recommended. In 2025, AAD published a focused update for the AD guidelines, recommending lebrikizumab for moderate to severe AD and nemolizumab with concomitant topical therapy for moderate to severe AD. The 2023 American Academy of Allergy, Asthma and Immunology/American College of Allergy, Asthma and Immunology Joint Task Force (AAAAI/ACAAI JTF) Atopic Dermatitis Guideline recommends dupilumab and tralokinumab in patients refractory, intolerant, or unable to use topical treatment. The addition of a JAK inhibitor is recommended for patients refractory, intolerant, or unable to use topical treatment and systemic treatment inclusive of a biologic.

### Prurigo Nodularis

Prurigo nodularis (PN) is a chronic skin disease characterized by severe itch and multiple nodular lesions that can cover large areas accessible to scratching. Other skin symptoms include pain, burning, and stinging. Prurigo nodularis is associated with the highest itch intensity scores among pruritic conditions, and itch is perceived as the most burdensome aspect of the disease by patients with prurigo nodularis. Because of the effect of prurigo nodularis on patients' daily life and sleep, patients with prurigo nodularis have higher rates of depression and anxiety than healthy controls. Key treatment goals in the management of prurigo nodularis are itch relief, lesion healing, reduction of sleep disturbance, and overall improvement in quality of life. Dupixent was the first biologic approved for PN and was studied in individuals that had at least 20 nodular lesions despite treatment with medium or higher topical corticosteroids (TCS). According to the International Forum for the Study of Itch guideline on chronic prurigo including prurigo nodularis, a step-wise approach to treatment is recommended with TCS and TCIs and initial therapy.

### Bullous Pemphigoid

Bullous Pemphigoid is an autoimmune blistering skin disease characterized by the formation of large, tense blisters filled with fluid. The condition primarily impacts older adults and typically appears as widespread, itchy, hive-like plaques and firm, subepithelial blisters. The European Academy of Dermatology and Venereology (EADV) guidelines support the use of superpotent topical corticosteroids with or without the use of oral corticosteroids (prednisone 0.5 mg/kg/day) for the treatment of patients with severe BP. Dupixent is the first FDA-approved biologic for the treatment of BP. According to the package insert, Dupixent should be initiated with a tapering course of oral corticosteroids, after which it can be continued as monotherapy.

### **Chronic Rhinosinusitis with Nasal Polypsis**

Dupixent is approved as add-on maintenance treatment for CRSwNP in adults 18 years and older who were previously inadequately controlled. Studies included adults with nasal polypsis currently using intranasal corticosteroids, and who were refractory to surgical intervention or treatment with systemic corticosteroids in the past 2 years, or who were otherwise ineligible/intolerant to systemic corticosteroids. Clinical diagnosis of CRSwNP should be confirmed with objective documentation on imaging or direct visualization, such as anterior rhinoscopy, nasal endoscopy, or computed tomography (CT) according to the American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAO-HNSF 2015). Guidance from AAO-HNSF in the 2015 Adult Sinusitis update also recommends topical nasal steroids for long term treatment of nasal polyps, and if no response is seen, then a trial of oral corticosteroids is reasonable. Practice guidelines developed in 2014 by a joint task force representing the American Academy of Allergy, Asthma, and Immunology (AAAAI), the American College of Allergy, Asthma, and Immunology (ACAAI), and the Joint Council of Allergy, Asthma and Immunology (JCAAI) also strongly recommend use of intranasal corticosteroids and oral steroids in the treatment of CRSwNP as it an inflammatory disease. Other adjunctive therapy, such as nasal saline irrigation, may be beneficial for symptoms in some cases.

### **Eosinophilic Esophagitis**

Dupixent is additionally approved for eosinophilic esophagitis (EoE). This condition can make swallowing food difficult or painful. It is diagnosed by elevated eosinophils in the esophagus. EoE affects approximately 160,000 people in the United States. Guidelines from the American Gastroenterological Association (AGA 2020), which predate approval of Dupixent, recommend off-label treatment with topical glucocorticoids, budesonide inhalation or fluticasone inhalation, swallowed by mouth rather than inhaled. Additional treatment options include proton pump inhibitors (PPIs) and dietary modifications. Guidelines from the American College of Gastroenterology (ACG 2025) suggest PPIs and recommend swallowed topical steroids (fluticasone propionate or budesonide). The ACG guidelines suggest Dupixent in individuals who are nonresponsive to PPI therapy.

### **Chronic Spontaneous Urticaria**

Dupixent has received an additional FDA approved indication for chronic spontaneous urticaria. Chronic spontaneous urticaria (CSU) is defined as itchy hives that last at least 6 weeks and have no apparent external trigger. In 2022, the Dermatology Section of the European Academy of Allergology and Clinical Immunology (EAACI), the Global Allergy and Asthma European Network (GA<sup>LEN</sup>) and its Urticaria and Angioedema Centers of Reference and Excellence (UCAREs and ACAREs), the European Dermatology Forum (EDF) and the Asia Pacific Association of Allergy, Asthma, and Clinical Immunology (APAAACI) released guidelines on the management of urticaria. The international association suggests second generation H<sub>1</sub> antihistamine as first-line treatment for all types of urticaria. Recommended second-line treatment for chronic urticaria is up dosing of an H<sub>1</sub> antihistamine up to four-fold the standard dose. Guidelines predate approval of Dupixent for CSU.

### **Chronic Obstructive Pulmonary Disease (COPD)**

Dupixent is approved by the FDA as add-on maintenance treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype. The efficacy of Dupixent was demonstrated in two phase 3, multicenter, randomized, double-blind, placebo-controlled trials individuals with COPD with an eosinophilic phenotype. Participants were required to have a post-bronchodilator FEV<sub>1</sub> 30–70% of predicted normal, FEV<sub>1</sub>/FVC less than 0.7, and minimum blood eosinophil count of 300 cells/ml. Participants had a history of two moderate or one severe COPD exacerbation(s) in the previous 12 months while receiving triple inhaled therapy for COPD. The 2025 Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines indicate that Dupixent should be considered as an add-on therapy for individuals currently treated with triple therapy (LAMA+LABA+ICS) with symptoms of chronic bronchitis and eosinophils ≥300cells/ml.

### **Asthma**

Dupixent is FDA approved to treat moderate-to-severe asthma in those 6 months of age and older with an eosinophilic phenotype or with oral corticosteroid dependent asthma. Dupixent was studied in individuals with moderate to severe asthma who were currently utilizing moderate to high dose inhaled corticosteroids (ICS) along with another controller medication and 2 or more exacerbations in the previous year (Castro 2018) or daily corticosteroids along with high dose ICS and another controller medication and 2 or more exacerbations in the previous year (Rabe 2018). In individuals using ICS plus another controller medication, Dupixent reduced exacerbations in individuals with baseline blood eosinophils ≥ 150 cells/µL (cells per microliter); however, exacerbation rates in individuals with eosinophil counts < 150 cells/µL were similar to placebo. In those using daily oral corticosteroids, Dupixent use achieved greater reductions in daily maintenance oral corticosteroid doses and had fewer exacerbations while maintaining asthma control compared to placebo. The 2022 Global Initiative for Asthma (GINA) issued guidelines for the diagnosis and treatment of difficult-to-treat and severe asthma noting in Step 6b that Dupixent may be an option in those with severe asthma despite high-dose inhaled corticosteroid, long-acting beta

adrenergic (ICS-LABA) with or without daily oral corticosteroids. The 2022 GINA does not suggest the use of Dupixent in individuals with current or historic blood eosinophil counts >1500 cells/microliter.

#### **Comparative doses for Inhaled Corticosteroids (ICS) (Adults and Adolescents) (Wenzel 2021)**

<b>Drug</b>	<b>Low Daily Dose</b>	<b>Medium Daily Dose</b>	<b>High Daily Dose</b>
<b>Becлометазоне</b> 40 or 80 mcg/actuation	80-160 mcg	>160-320 mcg	>320-640 mcg
<b>Будесониде</b> 90 or 180 mcg/actuation	180-360 mcg	>360-720 mcg	>720-1440 mcg
<b>Сиклесониде</b> 80 or 160 mcg/actuation	160 mcg	320 mcg	640 mcg
<b>Флунисолиде</b> 80 mcg/dose	176-220 mcg 100-250 mcg	>220-440 mcg >250-500 mcg	>440-1760 mcg >500-2000 mcg
<b>Флутicasоне пропионате</b> MDI: 44, 110 or 220 mcg/actuation DPI: 50, 100 or 250 mcg/dose	50 mcg	100 mcg	200 mcg
<b>Флутicasоне фуарате</b> 50, 100 or 200 mcg/dose	200 mcg 220 mcg	>200-400 mcg >220-440 mcg	>400-800 mcg >440-880 mcg
<b>Мометасоне</b> MDI: 50, 100 or 200 mcg/actuation DPI: 110 or 220 mcg/actuation	80-160 mcg	>160-320 mcg	>320-640 mcg

DPI = dry powder inhaler; MDI = metered-dose inhaler

#### **Clinical Criteria**

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

#### **Dupixent (Dupilumab)**

Initial requests for Dupixent (dupilumab) for the treatment of asthma may be approved if the following criteria are met:

- I. Individual is 6 years of age or older; **AND**
  - II. Individual has a diagnosis of moderate-to-severe asthma as demonstrated by the following (NHLBI 2020):
    - A. A pretreatment forced expiratory volume in 1 second (FEV<sub>1</sub>) less than or equal to ( $\leq$ ) 80% predicted; **AND**
    - B. FEV<sub>1</sub> reversibility of at least 12% and 200 milliliters (ml) after albuterol (salbutamol) administration; **AND**
  - III. One of the following:
    - A. Documentation is provided that individual has a blood eosinophil count (in the absence of other potential causes of eosinophilia, including hypereosinophilic syndromes, neoplastic disease, and known or suspected parasitic infection) greater than or equal to 150 cells/microliter [1 microliter ( $\mu$ L) is equal to 1 cubic millimeter ( $mm^3$ )] at initiation of therapy; **AND**
    - B. Documentation is provided that individual has had a 3 month trial and inadequate response or intolerance to combination controller therapy (high dose inhaled corticosteroids plus long acting beta<sub>2</sub>-agonists, leukotriene modifiers, theophylline or oral corticosteroids) (ERS/ATS 2013, GINA2022); **AND**
- OR**
- C. Individual has oral corticosteroid dependent asthma; **AND**
  - D. Documentation is provided that individual has had a 3 month trial and inadequate response or intolerance to high dose inhaled corticosteroid with daily oral glucocorticoids given in combination with a controller medication (either a long-acting beta2-agonist, **or** leukotriene receptor antagonist, **or** theophylline) (ERS/ATS 2013, GINA2022); **AND**
- IV. Individual has experienced two or more asthma exacerbations in the prior 12 months requiring use of a systemic corticosteroid **or** temporary increase in the individual's usual maintenance dosage of oral corticosteroids (Castro 2018, Rabe 2018).

Continuation of therapy with Dupixent (dupilumab) for asthma may be approved if the following criteria are met:

- I. Individual has experienced one or more of the following:
  - A. Decreased utilization of reliever medications; **OR**
  - B. Decreased frequency of exacerbations (defined as worsening of asthma that requires an increase in inhaled corticosteroid dose or treatment with systemic corticosteroids); **OR**
  - C. Increase in predicted FEV<sub>1</sub> from pretreatment baseline; **OR**
  - D. Reduction in reported asthma-related symptoms, such as, asthmatic symptoms upon awakening, coughing, fatigue, shortness of breath, sleep disturbance, or wheezing; **AND**
  - E. Individual continues to use Dupixent in combination with inhaled corticosteroid-based controller therapy.

Approval Duration for asthma

Initial Requests: 6 months

Continuation Requests: 12 months

Initial requests for Dupixent (dupilumab) for the treatment of Chronic Obstructive Pulmonary Disease (COPD) may be approved if the following criteria are met:

- I. Individual is 18 years of age or older; **AND**
- II. Individual has a diagnosis of chronic obstructive pulmonary disease (COPD) with an eosinophilic phenotype; **AND**
- III. Documentation is provided that individual has a blood eosinophil count of at least 300 per microliter (in the absence of other potential causes of eosinophilia, including hypereosinophilic syndromes, neoplastic disease, and known or suspected parasitic infection) (Bhatt 2023); **AND**
- IV. COPD diagnosis is demonstrated by post-bronchodilator FEV<sub>1</sub>/FVC <0.7 (Bhatt 2023); **AND**
- V. Individual has moderate to severe airflow obstruction demonstrated by post-bronchodilator FEV<sub>1</sub> 30-70% predicted normal value (Bhatt 2023); **AND**
- V. Individual meets one of the following (Bhatt 2023) (A or B):
  - A. At least one (1) hospitalization or more than 24 hours of medical observation related to COPD in the past twelve (12) months; **OR**
  - B. In the past twelve (12) months, at least two (2) moderate COPD exacerbations required systemic steroids for at least one (1) exacerbation with or without antibiotics; **AND**
- VI. Documentation is provided that individual meets one of the following (Bhatt 2023) (A or B):
  - A. Individual is on a stable dose of LAMA-LABA therapy including inhaled glucocorticoid; **OR**
  - B. Individual is unable to use an inhaled glucocorticoid due to a medical reason and is on a stable dose of LAMA-LABA therapy.

Continuation requests for Dupixent (dupilumab) for Chronic Obstructive Pulmonary Disease (COPD) may be if approved if the following criteria are met:

- I. Individual will continue to use Dupixent (dupilumab) in combination with LAMA/LABA therapy OR ICS/LAMA/LABA therapy; **AND**
- II. Treatment with Dupixent has resulted in clinical improvement in one or more of the following:
  - A. Decreased utilization of reliever medication; **OR**
  - B. Decreased frequency or severity of exacerbations; **OR**
  - C. Increase in percent predicted FEV<sub>1</sub> from pretreatment baseline; **OR**
  - D. Reduction in reported COPD-related symptoms, including shortness of breath, cough, fatigue or sleep disturbance.

Approval Duration for COPD

Initial Requests: 6 months

Continuation Requests: 12 months

Initial requests for Dupixent (dupilumab) for the treatment of atopic dermatitis may be approved if the following criteria are met:

- I. Individual is age 6 months or older; **AND**
- II. Individual has a diagnosis of moderate to severe atopic dermatitis; **AND**
- III. Documentation is provided that individual has tried one of the following and treatment failed to achieve and maintain remission of low or mild disease activity:
  - A. Topical calcineurin inhibitors  
**OR**
  - B. Eucrisa;  
**OR**

- C. Opzelura;
- OR**
- D. Zoryve 0.15% Cream;
- OR**
- E. Vtama Cream;
- OR**
- F. Phototherapy (UVB or PUVA);
- OR**
- G. Non-corticosteroid systemic immunosuppressants (such as cyclosporine, azathioprine, methotrexate, or mycophenolate mofetil);
- OR**
- H. Individual has contraindications to topical calcineurin inhibitors AND Eucrisa AND Opzelura AND Zoryve 0.15% Cream AND Vtama Cream AND Non-corticosteroid systemic immunosuppressants (such as cyclosporine, azathioprine, methotrexate, or mycophenolate mofetil) AND unable to use Phototherapy.

Continuation requests for Dupixent (dupilumab) for atopic dermatitis may be if approved if the following criterion is met:

- I. Treatment with Dupixent has resulted in significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to decrease in affected body surface area, pruritus, or severity of inflammation, and/or improved quality of life).

Initial requests for Dupixent (dupilumab) for the treatment of chronic rhinosinusitis with nasal polyposis (CRSwNP) may be approved if the following criteria are met:

- I. Individual is age 12 years and older; **AND**
- II. Documentation is provided that individual has a diagnosis of CRSwNP demonstrated on one of the following (AAO-HNSF 2015):
  - A. Anterior rhinoscopy; **OR**
  - B. Nasal endoscopy; **OR**
  - C. Computed tomography (CT);
- AND**
- III. Individual has had recent trial and inadequate response to maintenance intranasal corticosteroids (AAO-HNSF 2015);
- AND**
- IV. Individual has had a trial and inadequate response or intolerance to one of the following agents (A or B) or has contraindications to all of the following agents (both A and B) (Bachert 2019):
  - A. Systemic corticosteroids; **OR**
  - B. Sino-nasal surgery;
- AND**
- V. Individual is requesting Dupixent (dupilumab) as add-on therapy to maintenance intranasal corticosteroids.

Continuation requests for Dupixent (dupilumab) for chronic rhinosinusitis with nasal polyposis (CRSwNP) may be if approved if the following criterion is met:

- I. Treatment with Dupixent has resulted in clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to improvement in nasal polyp score or nasal congestion score); **AND**
- II. Individual continues to use Dupixent in combination with maintenance intranasal corticosteroids.

#### Approval Duration for CRSwNP

Initial Requests: 6 months

Continuation Requests: 12 months

Initial requests for Dupixent (dupilumab) for the treatment of eosinophilic esophagitis (EoE) may be approved if the following criteria are met:

- I. Individual is 1 year of age or older and weighs at least 15kg; **AND**
- II. Individual has a diagnosis of EoE; **AND**
- III. Documentation is provided that individual has 15 or more intraepithelial eosinophils per high-power field (eos/hpf) (Rothenberg 2023); **AND**

- IV. Documentation is provided that individual has symptoms of dysphagia (Rothenberg 2023); **AND**
- V. Individual has had a trial and inadequate response or intolerance to a course of proton pump inhibitors (PPIs) (AGA 2020, ACG 2025); **AND**
- VI. Individual has had a trial and inadequate response or intolerance to a course of glucocorticoids (including but not limited to fluticasone propionate metered dose inhaler swallowed instead of inhaled, or budesonide inhalation swallowed instead of inhaled) for the treatment of EoE (AGA 2020, ACG 2025).

Continuation requests for Dupixent (dupilumab) for EoE may be if approved if the following criteria is met:

- I. Treatment with Dupixent has resulted in clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to improvement in symptoms of dysphagia).

Initial requests for Dupixent (dupilumab) for the treatment of Prurigo Nodularis (PN) may be approved if the following criteria are met:

- I. Individual is 18 years of age or older; **AND**
- II. Individual has a diagnosis of PN; **AND**
- III. Individual has 20 or more PN lesions (Yosipovitch 2023); **AND**
- IV. Documentation is provided that individual has tried one of the following and treatment failed to achieve and maintain remission of low or mild disease activity:
  - A. Medium to super-potent topical corticosteroids (Yosipovitch 2023);  
**OR**
  - B. Topical calcineurin inhibitors (Ständer 2020).

Continuation requests for Dupixent (dupilumab) for PN may be if approved if the following criteria is met:

- I. Treatment with Dupixent has resulted in clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to improvement of symptoms such as decreased itching, or decreased number or thickness of PN lesions).

Initial requests for Dupixent (dupilumab) for the treatment of Bullous Pemphigoid (BP) may be approved if the following criteria are met:

- I. Individual is 18 years of age or older; **AND**
- II. Individual has a diagnosis of BP; **AND**
- III. Documentation is provided that individual has had a trial and inadequate response or intolerance to high-potency topical corticosteroids or systemic corticosteroids (Borradori 2022); **AND**
- IV. Dupixent is initiated with a tapering course of oral corticosteroids.

Continuation requests for Dupixent (dupilumab) for BP may be if approved if the following criteria is met:

- I. Treatment with Dupixent has resulted in clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to decreased itching or improvement of BP lesions).

Initial requests for Dupixent (dupilumab) for chronic spontaneous urticaria (CSU) may be approved if the following criteria are met:

- I. Individual is 12 years of age or older; **AND**
- II. Individual has a diagnosis of chronic spontaneous urticaria (CSU); **AND**
- III. Individual has had an inadequate response to a two-week trial of a second generation H1 antihistamine up dosed to a maximum of four times the approved dose (Zuberbier 2022).

Continuation requests for Dupixent (dupilumab) for chronic spontaneous urticaria (CSU) may be approved if the following criterion is met:

- I. Treatment with Dupixent has resulted in clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to itch severity and hive count); **AND**
- II. Individual continues to use Dupixent in combination with second generation H1 antihistamine therapy.

Approval Duration for CSU

Initial Requests: 6 months

Continuation Requests: 12 months

Dupixent (dupilumab) may not be approved for the following:

- I. In combination with oral or topical JAK inhibitors; **OR**
- II. In combination with other immunosuppressants (such as cyclosporine, azathioprine, mycophenolate mofetil, or methotrexate); **OR**
- III. In combination with ensifentrine, tralokinumab, reslizumab, benralizumab, lebrikizumab, nemolizumab-, mepolizumab, tezepelumab, or omalizumab; **OR**
- IV. Individual is requesting Dupixent for the treatment of asthma; **AND**
  - A. Individual has current blood eosinophils greater than 1500 cells/microliter [1 microliter ( $\mu$ L) is equal to 1 cubic millimeter ( $mm^3$ )] (GINA 2022); **AND**
  - B. Asthma related causes have been excluded (GINA 2022); **OR**
- V. Requests for Dupixent (dupilumab) may not be approved when the above criteria are not met and for all other indications.

## Quantity Limits

### Dupixent (dupilumab) Quantity Limits

Drug	Limit
Dupixent (dupilumab) 100mg/0.67 mL syringe	2 syringes per 28 days
Dupixent (dupilumab) 200 mg/1.14 mL pre-filled syringe/pen *	<ul style="list-style-type: none"><li>• 11 years old or younger: 1 syringe/pen every 28 days@^</li><li>• 12 years old or older: 2 syringes/pens every 28 days</li></ul>
Dupixent (dupilumab) 300 mg/2 mL pre-filled syringe, 300 mg/2 mL pre-filled pen*	<ul style="list-style-type: none"><li>• 11 years old or younger: 1 syringe/pen per 28 days%+</li><li>• 12 years old or older: 2 syringes/pens per 28 days#</li></ul>
Override Criteria	
*Initiation of therapy: May approve two additional 200 mg/1.14 mL prefilled syringe OR 300 mg/2 mL pre-filled syringes in the first month of therapy for initiation dose for the indication of atopic dermatitis if the individual is 6 years old or older OR asthma if the individual is 12 years old or older OR prurigo nodularis OR chronic spontaneous urticaria OR bullous pemphigoid.	
@For individuals weighing 30kg or more, may approve 2 syringes/pens per 28 days.	
% For individuals more than 30 kg, may approve 2 syringes/pens per 28 days.	
^ In the treatment of eosinophilic esophagitis: May approve 2 syringes/pens per 28 days.	
# In the treatment of eosinophilic esophagitis: May approve 4 syringes/pens per 28 days.	
+ In the treatment of eosinophilic esophagitis for individuals weighing 40 kg or more: May approve 4 syringes/pens per 28 days.	

## Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

### HCPCS

J3590	Unclassified biologics [when specified Dupixent (dupilumab)]
C9399	Unclassified drugs or biologicals [when specified as Dupixent (dupilumab)]

### ICD-10 Diagnosis

L12.0	Bullous pemphigoid
L20.0-L20.9	Atopic dermatitis
L28.1	Prurigo nodularis

L50.1	Idiopathic urticaria
L50.8	Other urticaria
L50.9	Urticaria, unspecified
J44.0-J44.9	Other chronic obstructive pulmonary disease
J45.40-J45.52	Moderate/severe persistent asthma
J45.901-J45.998	Other and unspecified asthma
J82.83	Eosinophilic asthma
J32.0-J32.9	Chronic sinusitis
J33.0-J33.9	Nasal Polyp
K20.0	Eosinophilic esophagitis

## Document History

Revised: 08/15/2025

Document History:

- 08/15/2025 – Annual Review: Add new indications for bullous pemphigoid (BP) and update quantity limit override for BP; add requirement for continued intranasal steroids in chronic rhinosinusitis with nasal polyposis continuation criteria; add approval duration of 6 months for chronic spontaneous urticaria indication; update eosinophilic esophagitis wording for prior therapy; update references throughout; wording and formatting updates. Administrative update to add documentation. Coding Reviewed: Added ICD-10-CM L12.0.
- 06/09/2025 – Select Review: update chronic obstructive pulmonary disease criteria. Coding Reviewed: No changes.
- 05/16/2025 – Select Review: add chronic spontaneous urticaria and quantity limits update. Coding Reviewed: Added ICD-10-CM L50.1, L50.8, L50.9.
- 02/21/2025 – Select Review: Add Vtama to atopic dermatitis criteria, add ensifentrine, Ebglyss, and Nemluvio to do not approve criteria, wording. Administrative update to add documentation. Coding Reviewed: Updated descriptions for HCPCS NOC J3590 and C9399. Added ICD-10-CM J32.0-J32.8 and updated description for J32.0-J32.9.
- 11/15/2024 – Select Review: add new indication for COPD. Coding Reviewed: No changes.
- 10/02/2024 – Select Review: update CRSwNP age. Coding Reviewed: No changes.
- 09/09/2024 – Select Review: update prurigo nodularis criteria to include systemic therapies, remove topical overrides from prurigo nodularis, wording and formatting. Coding Reviewed: No change.
- 08/16/2024 – Annual Review: wording and formatting, update requirements and quantity limit for eosinophilic esophagitis, add Zoryve 0.15% Cream, add approval lengths for asthma and chronic rhinosinusitis with nasal polyposis. Coding Reviewed: Add ICD-10-CM L28.1.
- 03/11/2024 – Select Review: No change. Coding Reviewed: No changes.
- 02/23/2024 – Select Review: update eosinophilic esophagitis age, update asthma continuation criteria, update quantity limits for eosinophilic esophagitis. Coding Reviewed: No changes.
- 08/18/2023 – Annual Review: No changes. Coding Reviewed: No changes. 12/12/2022 – Select Review: update language for CRSwNP, add prurigo nodularis criteria, update quantity limit, wording and formatting. Coding Reviewed: No changes.
- 08/19/2022 – Annual Review: Update atopic dermatitis, add eosinophilic esophagitis criteria, update do not approve criteria, update quantity limits. Coding Reviewed: Added ICD-10-CM K20.0. Added HCPCS C9399. Removed HCPCS J3490.
- 08/01/2022 – administrative update to add documentation.
- 02/25/2022 – Select Review: clarify systemic therapy in atopic dermatitis, update do not approve criteria, wording and formatting changes Coding Reviewed: No changes.
- 12/13/2021 – Select Review: Update age limit on asthma criteria, add new strength. Coding Reviewed: No changes.
- 08/20/2021-Annual Review: Add continuation criteria for nasal polyps and atopic dermatitis. Coding reviewed: No changes.
- 08/01/2021 – Administrative update to add documentation.
- 08/21/2020 – Annual Review: Update asthma criteria to remove medium dose inhaled corticosteroids from requirements per GINA guidance. Update atopic dermatitis criteria to require use of both topical steroids and topical calcineurin inhibitors, OR use of phototherapy or systemic treatment. Wording, formatting, and

- reference updates. Administrative update to add drug specific quantity limit. Coding reviewed: No changes. Effective 7/1/21 Added ICD-10-CM J82.83.
- 06/08/2020 – Select Review: Update criteria for atopic dermatitis to expand pediatric use per FDA label. Coding Reviewed: No changes
  - 08/16/2019 – Annual Review: Add new FDA indication for chronic rhinosinusitis with nasal polyposis. Update QL override criteria. Update atopic dermatitis criteria to remove requirement for diagnosis present for 3 years. Coding Reviewed: Added ICD-10 codes J32.9, J33.0-J33.9
  - 05/17/2019 – Selected Review: Update Dupixent PA to allow for age 12 and older for the diagnosis of atopic dermatitis. Coding Reviewed: No changes
  - 10/23/2018 – Selected Review: Updated to add criteria for new asthma indication; added ICD-10 codes for moderate persistent and severe persistent asthma. Updated diagnosis codes: J44.0-J44.9, J45.40-J45.52, J82 due to FDA approved indication for Asthma.
  - 08/17/2018 – Annual Review: First review of Dupixent; Annual review. No changes. Review preliminary criteria for Asthma indication. Added diagnoses codes J45.901-J45.998 for other and unspecified asthma.

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