

Utilization Management and Clinical Medical Policy

Policy Name: Dupilumab (Dupixent®)	Policy Number: MP-RX-FP-23-23	Scope: <input checked="" type="checkbox"/> MMM MA <input checked="" type="checkbox"/> MMM MultiHealth	Origination Date: 11/30/2023 Last Review Date: 05/06/2026	Effective Date: 05/06/2026 Frequently Revision: Annual
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Service Category:

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| <input type="checkbox"/> Anesthesia | <input type="checkbox"/> Medicine Services and Procedures |
| <input type="checkbox"/> Surgery | <input type="checkbox"/> Evaluation and Management Services |
| <input type="checkbox"/> Radiology Procedures | <input type="checkbox"/> DME/Prosthetics or Supplies |
| <input type="checkbox"/> Pathology and Laboratory Procedures | <input checked="" type="checkbox"/> Other: Part B Drugs |

Service Description:

This document addresses the use of Dupilumab (Dupixent®), a drug approved by the Food and Drug Administration (FDA) for the treatment of individuals 6 years and older 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; as add-on maintenance treatment of adult and pediatric individuals aged 6 years and older with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid-dependent asthma; as add-on maintenance treatment in adult and pediatric individuals aged 12 years and older with inadequately controlled chronic rhinosinusitis with nasal polyps (CRSwNP); for the treatment of adult and pediatric individuals aged 1 year and older, weighing at least 15 kg, with eosinophilic esophagitis (EoE); for the treatment of adult individuals with prurigo nodularis (PN); as add-on maintenance treatment of adult individuals with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype; for the treatment of adult and pediatric individuals aged 12 years and older with chronic spontaneous urticaria (CSU) who remain symptomatic despite H1 antihistamine treatment; for the treatment of adult individuals with bullous pemphigoid (BP); and for the treatment of adult and pediatric individuals aged 6 years and older with allergic fungal rhinosinusitis (AFRS) who have a history of sino-nasal surgery.

Background Information:

Dupixent is an interleukin-4 receptor alpha antagonist that inhibits IL-4 and IL-13 signaling. The dose of Dupixent for AD in adults is an initial dose of 600 mg (two 300 mg injections) followed by 300 mg given every other week. In pediatric individuals with AD, dosing is age- and weight-based. The dose of Dupixent for asthma in adult and pediatric individuals 12 years of age and older is an initial dose of 400 mg or 600 mg followed by 200 mg or 300 mg every other week; in pediatric individuals 6 to 11 years of age, dosing is weight-based. The recommended dose for CRSwNP is 300 mg every other week. The recommended dose for EoE is weight-based in adult and pediatric individuals aged 1 year and older weighing at least 15 kg. The recommended dose for PN is an initial dose of 600 mg followed by 300 mg every other week. The recommended dose for COPD is 300 mg every other week. The recommended dose for CSU in adults is an initial dose of 600 mg followed by 300 mg every other week, and in pediatric individuals 12 to 17 years of age dosing is weight-based. The recommended dose for BP is an initial dose of 600 mg followed by 300 mg every other week, used in combination with a tapering course of oral corticosteroids. The recommended dose for AFRS in adults is 300 mg every other week, and in pediatric individuals 6 to 17 years of age dosing is weight-based.

Per the American Academy of Dermatology (AAD) AD, the most common form of eczema, affects approximately 2% to 3% of adults and 25% of children. AD 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

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crusting, or lichenification. While there is no accepted standardized method of classifying disease severity, categorization is usually based upon objective disease features, extent of skin involvement and possibly subjective disease features. Due to the impaired skin integrity, affected individuals are more susceptible to skin infections. Current AAD guidance includes updated topical, systemic, and pediatric recommendations for AD.

In 2023 and 2025, the American Academy of Dermatology (AAD) published updated guidelines for the treatment of atopic dermatitis with topical and systemic therapies, including focused updates. The guidelines state that topical therapies remain the mainstay of treatment for many individuals with AD. Topical calcineurin inhibitors (TCIs), topical corticosteroids (TCS), crisaborole (Eucrisa), topical PDE-4 inhibitors, and topical JAK inhibitors are currently supported as acceptable treatments for AD. In 2024, AAD published treatment guidelines for the treatment of AD with systemic therapies. AAD systemic therapy guidance strongly recommends dupilumab and other selected biologic and JAK inhibitor options for appropriate individuals and recommends against systemic corticosteroids.

Dupilumab is FDA approved to treat moderate-to-severe asthma in those 6 years of age and older with an eosinophilic phenotype or with oral corticosteroid dependent asthma. Dupilumab 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, Dupilumab reduced exacerbations in individuals with baseline blood eosinophils ≥ 150 cells/ μ L (cells per microliter); however, exacerbation rates in individuals with eosinophil counts < 150 cells/ μ L were similar to placebo. In those using daily oral corticosteroids, Dupilumab use achieved greater reductions in daily maintenance oral corticosteroid doses and had fewer exacerbations while maintaining asthma control compared to placebo. The 2025 Global Initiative for Asthma (GINA) includes dupilumab as an add-on option for severe eosinophilic asthma or asthma with Type 2 airway inflammation, and for patients requiring maintenance oral corticosteroids. GINA continues to note that dupilumab is not advised for patients with current or past blood eosinophils ≥ 1500 cells/microliter.

Dupilumab is approved as add-on maintenance treatment for CRSwNP in adult and pediatric patients aged 12 years and older who were previously inadequately controlled. Studies included adults with nasal polyposis 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 is an inflammatory disease. Other adjunctive therapy, such as nasal saline irrigation, may be beneficial for symptoms in some cases.

On May 20, 2022, Dupilumab received an additional FDA approval for eosinophilic esophagitis (EoE) and the current label now includes adult and pediatric patients aged 1 year and older, weighing at least 15 kg. This

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condition can make swallowing food difficult or painful. It is diagnosed by elevated eosinophils in the esophagus. Current gastroenterology guidance recognizes dupilumab as an option for patients who are treatment-resistant to initial therapies and for those with multiple atopic conditions. Additional treatment approaches include dietary therapy, proton pump inhibitors, swallowed topical steroids, and dilation when appropriate.

Dupixent was approved in 2023 as an add-on maintenance treatment for adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) who have an eosinophilic phenotype. IL-4 and IL-13 are implicated in the inflammatory pathways associated with COPD, particularly in patients with eosinophilic inflammation. Clinical trials for Dupixent in COPD demonstrated significant reductions in exacerbation rates and improvements in lung function among patients with elevated blood eosinophil counts. Participants in these trials were already on background standard therapy: high-dose inhaled corticosteroids (ICS) combined with long-acting beta2-agonists (LABAs), or triple therapy with ICS, LABAs, and long-acting muscarinic antagonists (LAMAs), indicating that Dupixent is most effective as an add-on treatment rather than a replacement therapy. Current GOLD 2026 materials include dupilumab as an add-on option for selected patients with eosinophilic COPD who continue to experience exacerbations despite optimized inhaled therapy. The labeled dose for COPD is 300 mg every 2 weeks.

Dupixent is also FDA approved for the treatment of adult patients with prurigo nodularis (PN). PN is a chronic inflammatory skin disease characterized by intensely pruritic nodules and significant burden on quality of life. In clinical trials, Dupixent demonstrated improvement in itch and skin lesions compared with placebo.

Dupixent is also FDA approved for the treatment of adult and pediatric patients aged 12 years and older with chronic spontaneous urticaria (CSU) who remain symptomatic despite H1 antihistamine treatment. It is not indicated for other forms of urticaria.

Dupixent is FDA approved for the treatment of adult patients with bullous pemphigoid (BP). Per the prescribing information, therapy is used in combination with a tapering course of oral corticosteroids.

Dupixent is FDA approved for the treatment of adult and pediatric patients aged 6 years and older with allergic fungal rhinosinusitis (AFRS) who have a history of sino-nasal surgery. According to the prescribing information, adverse reactions for AFRS are similar to those reported for CRSwNP.

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

Drug	Low Daily Dose	Medium Daily Dose	High Daily Dose
Beclomethasone 40 or 80 mcg/actuation	80-160 mcg	>160-320 mcg	>320-640 mcg
Budesonide 90 or 180 mcg/actuation	180-360 mcg	>360-720 mcg	>720-1440 mcg
Ciclesonide 80 or 160 mcg/actuation	160 mcg	320 mcg	640 mcg
Flunisolide 80 mcg/dose	176-220 mcg 100-250 mcg	>220-440 mcg >250-500 mcg	>440-1760 mcg >500-2000 mcg
Fluticasone propionate MDI: 44, 110 or 220 mcg/actuation DPI: 50, 100 or 250 mcg/dose	50 mcg	100 mcg	200 mcg
Fluticasone furoate 50, 100 or 200 mcg/dose	200 mcg 220 mcg	>200-400 mcg >220-440 mcg	>400-800 mcg >440-880 mcg
Mometasone 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

Approved Indications

Dupilixent is indicated for the treatment of:

- A. Adult and pediatric patients aged 6 months and older with moderate-to-severe AD whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.
- B. As an add-on maintenance treatment of adult and pediatric patients aged 6 years and older with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma.
- C. As an add-on maintenance treatment in adult and pediatric patients aged 12 years and older with inadequately controlled chronic rhinosinusitis with nasal polyps (CRSwNP).
- D. Adult and pediatric patients aged 1 year and older, weighing at least 15 kg, with eosinophilic esophagitis (EoE).
- E. Adult patients with prurigo nodularis (PN).
- F. As an add-on maintenance treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype.
- G. Adult and pediatric patients aged 12 years and older with chronic spontaneous urticaria (CSU) who remain symptomatic despite H1 antihistamine treatment.
- H. Adult patients with bullous pemphigoid (BP).
- I. Adult and pediatric patients aged 6 years and older with allergic fungal rhinosinusitis (AFRS) who have a history of sino-nasal surgery.

Other Uses

- A. None.

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Medical Necessity Guidelines:

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.

Dupilumab (Dupixent®)

I. Asthma

A. Criteria for Initial Approval

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 (FEV1) less than or equal to (\leq) 80% predicted; **AND**
 - B. FEV₁ 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 (μ 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 beta₂ –agonists, leukotriene modifiers, theophylline or oral corticosteroids) (ERS/ATS 2013, GINA2020);

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, GINA2020); **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).

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B. Criteria for Continuation Therapy

Continuation of therapy with Dupixent (dupilumab) for asthma after 12 months 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 FEV₁ 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.

C. Authorization Duration

- i. Initial Request: 6 months
- ii. Continuation Requests: 12 months

II. Atopic Dermatitis

A. Criteria for Initial approval

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%;

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OR

E. Phototherapy (UVB or PUVA);

OR

F. Non-corticosteroid systemic immunosuppressants (such as cyclosporine, azathioprine, methotrexate, or mycophenolate mofetil);

OR

G. Individual has contraindications to topical calcineurin inhibitors AND Non-corticosteroid systemic immunosuppressants (such as cyclosporine, azathioprine, methotrexate, or mycophenolate mofetil) AND unable to use Phototherapy.

B. Criteria for Continuation Therapy

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).

C. Authorization Duration

- i. Initial Request: 6 months
- ii. Continuation Requests: 12 months

III. Chronic Rhinosinusitis with nasal polyposis (CRSwNP)

A. Criteria for Initial Approval

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 confirmed by 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**

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- 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):

A. Systemic corticosteroids;

OR

B. Sino-nasal surgery; **AND**

- v. Individual is requesting Dupixent (dupilumab) as add-on therapy to maintenance intranasal corticosteroids.

B. Criteria for Continuation Therapy

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

- i. Treatment with Dupixent has resulted in confirmed 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).

C. Authorization Duration

- i. Initial Requests: 6 months
- ii. Continuation Requests: 12 months

IV. Eosinophilic Esophagitis (EoE)

A. Criteria for Initial Approval

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) (NCT03633617); **AND**
- iv. Documentation is provided that individual has symptoms of dysphagia; **AND**
- v. Individual has tried a course of proton pump inhibitors (PPIs) (Hirano,2020);

OR

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- vi. Individual has tried 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 (Hirano, 2020).

B. Criteria for Continuation Therapy

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

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

C. Authorization Duration

- i. Initial Request: 6 months
- ii. Continuation Requests: 12 months

V. Prurigo Nodularis (PN)

A. Criteria for Initial Approval

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

- i. Individual has a diagnosis of PN; **AND**
- ii. Individual has 20 or more PN lesions (NCT04202679); **AND**
- iii. 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 (NCT04202679);
 - OR**
 - B. Topical calcineurin inhibitors.

B. Criteria for Continuation Therapy

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

- i. Treatment with Dupixent has resulted in confirmed 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).

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C. Authorization Duration

- i. Initial Request: 6 months
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VI. Chronic Obstructive Pulmonary Disease (COPD)

A. Criteria for Initial Approval

Initial requests for Dupixent (dupilumab) for the treatment of adult patients with 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 FEV1/FVC <0.7 (Bhatt 2023, GOLD 2024); **AND**
- v. Individual has moderate to severe airflow obstruction demonstrated by post-bronchodilator FEV1 30-70% predicted normal value (Bhatt 2023); **AND**
- vi. Individual meets one of the following (Bhatt 2023) (A or B):
 - 1. At least one (1) hospitalization or more than 24 hours of medical observation related to COPD in the past twelve (12) months; **OR**
 - 2. In the past twelve (12) months, at least two (2) moderate COPD exacerbations and required systemic steroids for at least one (1) exacerbation with or without antibiotics; **AND**
- vii. Documentation is provided that individual meets one of the following (Bhatt 2023) (A or B):
 - 1. Individual is on a stable dose of LAMA-LABA therapy including inhaled glucocorticoid; **OR**
 - 2. Individual is unable to use an inhaled glucocorticoid due to a medical reason and is on a stable dose of LAMA-LABA therapy.

B. Criteria for Continuation Therapy

Continuation of therapy with Dupixent (dupilumab) for COPD after 12 months may be approved if the following criteria are met:

- i. Individual has experienced one or more of the following:
 - A. Decreased utilization of rescue inhaler or reliever medications;

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OR

B. Decreased frequency of COPD exacerbations (defined as worsening of COPD symptoms that requires an increase in maintenance inhaled corticosteroid dose or treatment with systemic corticosteroids);

OR

C. Increase in post-bronchodilator FEV₁ from pretreatment baseline;

OR

D. Reduction in reported COPD-related symptoms, such as, breathlessness, coughing, fatigue, exercise intolerance, sleep disturbance, or wheezing; **AND**

E. Individual continues to use Dupixent as an add-on to their current COPD maintenance therapy, including at least one of the following:

a. Inhaled corticosteroids (ICS);

OR

b. Long-acting beta2-agonists (LABA);

OR

c. Long-acting muscarinic antagonists (LAMA)

C. Authorization Duration

- i. Initial Request: 6 months
- ii. Continuation Requests: 12 months

VII. Chronic Spontaneous Urticaria (CSU)

A. Criteria for Initial Approval

Initial requests for Dupixent (dupilumab) for the treatment of adult patients with chronic spontaneous urticaria 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).

B. Criteria for Continuation Therapy

Continuation of therapy with Dupixent (dupilumab) for chronic spontaneous urticaria after 12 months may be approved if the following criteria are 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**

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- ii. Individual continues to use Dupixent in combination with second generation H1 antihistamine therapy

C. Authorization Duration

- i. Initial Request: 6 months
- ii. Continuation Requests: 12 months

VIII. Bullous Pemphigoid

A. Criteria for Initial Approval

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

- i. Individual has a diagnosis of Bullous Pemphigoid; **AND**
- ii. Individual is 18 years of age or older; **AND**
- iii. Documentation is provided that individual has had a trial and inadequate response or intolerance to highpotency topical corticosteroids or systemic corticosteroids (Borradori 2022); **AND**
- iv. Dupixent is initiated with a tapering course of oral corticosteroids.

B. Criteria for Continuation Therapy

Continuation of therapy with Dupixent (dupilumab) for Bullous Pemphigoid after 12 months may be approved if the following criteria are 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).

D. Authorization Duration

- i. Initial Request: 6 months
- ii. Continuation Requests: 12 months

IX. Allergic Fungal Rhinosinusitis

A. Criteria for Initial Approval

Initial requests for Dupixent (dupilumab) for the treatment of adult patients with Allergic Fungal Rhinosinusitis 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 allergic fungal rhinosinusitis (AFRS); **AND**
- iii. Documentation is provided that the individual has a history of sino-nasal surgery; **AND**
- iv. Individual has inadequately controlled disease.

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B. Criteria for Continuation Therapy

Continuation of therapy with Dupixent (dupilumab) for Allergic Fungal Rhinosinusitis after 12 months may be approved if the following criteria are 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 obstruction, nasal discharge, sense of smell, facial pressure, or endoscopic findings).

C. Authorization Duration

- i. Initial Request: 6 months
- ii. Continuation Requests: 12 months

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

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

- i. In combination with oral or topical JAK inhibitors;
OR
- ii. In combination with biologic immunomodulators;
OR
- iii. In combination with other immunosuppressants (such as cyclosporine, azathioprine, mycophenolate mofetil, or methotrexate);
OR
- iv. In combination with ensifentrine, depemokimab, tralokinumab, reslizumab, benralizumab, lebrikizumab, nemolizumab-, mepolizumab, tezepelumab, or omalizumab;
OR
- v. Individual is requesting Dupixent for the treatment of asthma; **AND**
 - a. Individual has current blood eosinophils greater than 1500 cells/microliter [1 microliter (µL) is equal to 1 cubic millimeter(mm³)] (GINA 2022); **AND**
 - b. Asthma related causes have been excluded (GINA 2022);
OR
- vi. For the treatment of acute bronchospasm or status asthmaticus (Label);
OR
- vii. Requests for Dupixent (dupilumab) may not be approved when the above criteria are not met and for all other indications.

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Limits or Restrictions:

A. Therapeutic Alternatives

The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.

- i. N/A

B. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

Drug	Limit
Dupilumab (dupilumab) 200 mg/1.14 mL pre-filled syringe/pen *	<ul style="list-style-type: none"> • 11 years old or younger: 1 syringe/pen every 28 days^{@^} • 12 years old or older: 2 syringes/pens every 28 days
Dupilumab (dupilumab) 300 mg/2 mL pre-filled syringe, 300 mg/2 mL pre-filled pen*	<ul style="list-style-type: none"> • 11 years old or younger: 1 syringe/pen per 28 days^{#+} • 12 years old or older: 2 syringes/pens per 28 days[#]

Exceptions

* 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.

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Codes Information:

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

ICD-10 Diagnostic Codes:

Codes	Description
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

HCPCS Codes:

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

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Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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Policy History:

Type of Review	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Focus Review	Updated Service Description, Background Information, Approved Indications, and Clinical Criteria to incorporate new FDA-labeled indications for chronic spontaneous urticaria (CSU), bullous pemphigoid (BP), and allergic fungal rhinosinusitis (AFRS), and to align existing language with the current Dupixent prescribing information. Updated dosing/quantity table. Coding reviewed and updated to add ICD-10-CM codes L12.0, L50.1, L50.8, and L50.9, and to expand sinusitis coding to J32.0-J32.9. Updated references. Administrative update to incorporate new template.	5/1/2026	05/06/2026
Annual Review	Updated COPD clinical criteria aligned with GOLD 2024. Add chronic spontaneous urticaria and quantity limits update. Add clinical criteria for Bullous Pemphigoid.	9/5/2025	9/16/2025
Annual Review	<ul style="list-style-type: none"> - Added COPD criteria and update conditions not covered to include acute bronchospasm and status asthmaticus. - Update CRSwNP age. - Update prurigo nodularis criteria to include systemic therapies, remove topical overrides from prurigo nodularis, wording and formatting. - 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. - Update eosinophilic esophagitis age, update asthma continuation criteria, update quantity limits for eosinophilic esophagitis. Coding Reviewed: No changes. 	11/18/2024	12/17/2024
Policy Inception	Elevance Health’s Medical Policy adoption.	N/A	11/30/2023