

Policy Name Dupilumab (Dupixent®)	Policy Number MP-RX-FP-23-23	Scope <input checked="" type="checkbox"/> MMM MA <input type="checkbox"/> MMM Multihealth
Service Category <input type="checkbox"/> Anesthesia <input type="checkbox"/> Surgery <input type="checkbox"/> Radiology Procedures <input type="checkbox"/> Pathology and Laboratory Procedures <input type="checkbox"/> Medicine Services and Procedures <input type="checkbox"/> Evaluation and Management Services <input type="checkbox"/> DME/Prosthetics or Supplies <input checked="" type="checkbox"/> Part B Drug		
Service Description <p>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, moderate to severe asthma in individuals 6 years and older with an eosinophilic phenotype or with oral corticosteroid dependent asthma, add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP), moderate-to-severe asthma in those 6 months of age and older with an eosinophilic phenotype or with oral corticosteroid dependent asthma and add-on maintenance treatment for CRSwNP in adults and patients 12 years and older who were previously inadequately controlled.</p> <p>Background Information</p> <p>This document addresses the use of Dupixent (dupilumab). Dupixent, an interleukin-4 (IL-4)/interleukin 13 (IL-13) inhibitor, is approved in 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. It is also approved for treatment of moderate to severe asthma in individuals 6 years and older with an eosinophilic phenotype or with oral corticosteroid dependent asthma. IL-4 and IL-13 are thought to be major drivers in atopic dermatitis and asthma. Additionally, Dupixent is approved for add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP). The dose of Dupixent for AD is an initial dose of 600 mg (two 300 mg injections) followed by 300 mg given every other week. The dose of Dupixent for asthma is an initial dose of 400 mg or 600 mg followed by 200 mg or 300 mg every other week. The recommended dose for CRSwNP is 300mg every other week.</p> <p>Per the American Academy of Dermatology (AAD 2014) 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</p>		

Policy Name	Policy Number	Scope
Dupilumab (Dupixent®)	MP-RX-FP-23-23	<input checked="" type="checkbox"/> MMM MA <input type="checkbox"/> MMM Multihealth

but often resolves by adulthood. Symptoms can include erythema, edema, xerosis, excoriations, pruritus, oozing and 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.

In 2023, the American Academy of Dermatology (AAD) published updated guidelines for the treatment of atopic dermatitis with topical therapies. The guidelines state that “Despite advances in systemic therapy for AD, topical therapies remain the mainstay of treatment due to their proven track record and generally favorable safety profile.” Topical calcineurin inhibitors (TCIs), topical corticosteroids (TCS), crisaborole (Eucrisa), and ruxolitinib (Opzelura) are currently supported as acceptable treatments for AD. In 2024, AAD published treatment guidelines for the treatment of AD with systemic therapies. The academy recommended the use of dupilumab (Dupixent), tralokinumab (Adbry), baricitinib (Olumiant), abrocitinib (Cibinqo), and upadacitinib (Rinvoq). There are also recommendations for phototherapy, cyclosporine, methotrexate, azathioprine, and mycophenolate. Systemic corticosteroids are not recommended.

Dupilumab 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. 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 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 Dupilumab 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 Dupilumab in individuals with current or historic blood eosinophil counts >1500 cells/microliter.

Dupilumab is approved as add-on maintenance treatment for CRSwNP in adults 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

Policy Name	Policy Number	Scope
Dupilumab (Dupixent®)	MP-RX-FP-23-23	<input checked="" type="checkbox"/> MMM MA <input type="checkbox"/> MMM Multihealth
<p>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.</p> <p>On May 20, 2022, Dupixent received an additional FDA approval for eosinophilic esophagitis (EoE) for individuals at least 12 years of age and weighing 40kg or more. 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. Current guidelines from the American Gastroenterological Association (AGA 2020) recommends off-label treatment with topical glucocorticoids, budesonide inhalation or fluticasone inhalation, swallowed by mouth rather than inhaled. Additional treatment options include proton pump inhibitors and dietary modifications.</p> <p>Dupixent was approved in 2023 as an add-on maintenance therapy for adult patients with chronic obstructive pulmonary disease (COPD) who have an eosinophilic phenotype and whose disease is inadequately controlled on standard therapies. 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 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. Dupixent was associated with decreased exacerbations, particularly in patients with blood eosinophils ≥ 300 cells/μL. Current COPD guidelines from the Global Initiative for Chronic Obstructive Lung Disease (GOLD) do not include Dupixent in their primary treatment recommendations but acknowledge the potential benefit of biologics like Dupixent for patients with eosinophilic inflammation who remain symptomatic despite optimized COPD therapy. The dose of Dupixent for COPD is typically an initial 400 mg or 600 mg, followed by 200 mg or 300 mg every other week, tailored to the individual patient’s needs.</p>		

Policy Name	Policy Number	Scope
Dupilumab (Dupixent®)	MP-RX-FP-23-23	<input checked="" type="checkbox"/> MMM MA <input type="checkbox"/> MMM Multihealth

Comparative doses for Inhaled Corticosteroids (ICS) (Adults and Adolescents) (Wenzel 2019)

Drug	Low Daily Dose	Medium Daily Dose	High Daily Dose
Beclomethasone 40 or 80 mcg/actuation	80-160 mcg	>160-320 mcg	>320 mcg
Budesonide 90 or 180 mcg/actuation	180-360 mcg	>360-720 mcg	>720 mcg
Ciclesonide 80 or 160 mcg/actuation	80-160 mcg	>160-320 mcg	>320 mcg
Flunisolide 80 mcg/dose	320 mcg	>320-640 mcg	Insufficient data
Fluticasone propionate MDI: 44, 110 or 220 mcg/actuation DPI: 50, 100 or 250 mcg/dose	88-220 mcg 100-250 mcg	>220-440 mcg >250-500 mcg	>440 mcg >500 mcg
Fluticasone furoate 50, 100 or 200 mcg/dose	50 mcg	100 mcg	200 mcg
Mometasone MDI: 50, 100 or 200 mcg/actuation DPI: 110 or 220 mcg/actuation	100-200 mcg 110-220 mcg	>200-400 mcg >220-440 mcg	>400 mcg >440 mcg

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

Approved Indications

Dupixent is indicated for the treatment of:

- 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.
- 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.
- 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).
- adult and pediatric patients aged 1 year and older, weighing at least 15 kg, with eosinophilic esophagitis (EoE).
- adult patients with prurigo nodularis (PN).
- as an add-on maintenance treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype.

Other Uses

N/A

Applicable Codes

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.

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

ICD-10	Description
L20.0-L20.9	Atopic dermatitis
L28.1	Prurigo nodularis
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
J32.9	Chronic sinusitis, unspecified
J33.0-J33.9	Nasal Polyp
K20.0	Eosinophilic esophagitis

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.

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

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).

Policy Name	Policy Number	Scope
Dupilumab (Dupixent®)	MP-RX-FP-23-23	<input checked="" type="checkbox"/> MMM MA <input type="checkbox"/> MMM Multihealth

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% cream;
 - OR**
 - E. Phototherapy (UVB or PUVA);
 - OR**

Policy Name	Policy Number	Scope
Dupilumab (Dupixent®)	MP-RX-FP-23-23	<input checked="" type="checkbox"/> MMM MA <input type="checkbox"/> MMM Multihealth
<p>F. Non-corticosteroid systemic immunosuppressants (such as cyclosporine, azathioprine, methotrexate, or mycophenolate mofetil);</p> <p>OR</p> <p>G. Individual has contraindications to topical calcineurin inhibitors AND Eucrisa AND Opzelura AND Zoryve 0.15% Cream AND Non-corticosteroid systemic immunosuppressants (such as cyclosporine, azathioprine, methotrexate, or mycophenolate mofetil) AND unable to use Phototherapy.</p> <p>B. Criteria for Continuation Therapy Continuation requests for Dupixent (dupilumab) for atopic dermatitis may be if approved if the following criterion is met:</p> <p>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).</p> <p>C. Authorization Duration</p> <p>i. Initial Request: 6 months</p> <p>ii. Continuation Requests: 12 months</p>		
<p>III. Chronic Rhinosinusitis with nasal polyposis (CRSwNP)</p>		
<p>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:</p> <p>i. Individual is age 12 years and older; AND</p> <p>ii. Documentation is provided that individual has a diagnosis of CRSwNP confirmed by one of the following (AAO-HNSF 2015):</p> <p>A. Anterior rhinoscopy;</p> <p>OR</p> <p>B. Nasal endoscopy;</p> <p>OR</p> <p>C. Computed tomography (CT); AND</p> <p>iii. Individual has had recent trial and inadequate response to maintenance intranasal corticosteroids (AAO-HNSF 2015); AND</p> <p>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):</p> <p>A. Systemic corticosteroids;</p> <p>OR</p>		

Policy Name	Policy Number	Scope
Dupilumab (Dupixent®)	MP-RX-FP-23-23	<input checked="" type="checkbox"/> MMM MA <input type="checkbox"/> MMM Multihealth
<p>B. Sino-nasal surgery; AND</p> <p>v. Individual is requesting Dupixent (dupilumab) as add-on therapy to maintenance intranasal corticosteroids.</p> <p>B. Criteria for Continuation Therapy</p> <p>Continuation requests for Dupixent (dupilumab) for chronic rhinosinusitis with nasal polyps may be if approved if the following criterion is met:</p> <p>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).</p> <p>C. Authorization Duration</p> <p>i. Initial Requests: 6 months</p> <p>ii. Continuation Requests: 12 months</p> <p>IV. Eosinophilic Esophagitis (EoE)</p> <p>A. Criteria for Initial Approval</p> <p>Initial requests for Dupixent (dupilumab) for the treatment of eosinophilic esophagitis (EoE) may be approved if the following criteria are met:</p> <p>i. Individual is 1 year of age or older and weighs at least 15kg ; AND</p> <p>ii. Individual has a diagnosis of EoE; AND</p> <p>iii. Documentation is provided that individual has 15 or more intraepithelial eosinophils per high-power field (eos/hpf) (NCT03633617); AND</p> <p>iv. Documentation is provided that individual has symptoms of dysphagia; AND</p> <p>v. Individual has tried a course of proton pump inhibitors (PPIs) (Hirano,2020);</p> <p>OR</p> <p>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).</p> <p>B. Criteria for Continuation Therapy</p> <p>Continuation requests for Dupixent (dupilumab) for EoE may be if approved if the following criteria is met:</p> <p>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).</p>		

Policy Name	Policy Number	Scope
Dupilumab (Dupixent®)	MP-RX-FP-23-23	<input checked="" type="checkbox"/> MMM MA <input type="checkbox"/> MMM Multihealth

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).

C. Authorization Duration

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

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**

Policy Name	Policy Number	Scope
Dupilumab (Dupixent®)	MP-RX-FP-23-23	<input checked="" type="checkbox"/> MMM MA <input type="checkbox"/> MMM Multihealth
<ul style="list-style-type: none"> ii. Individual has a diagnosis of COPD; AND iii. Individual has a documented diagnosis of COPD with an eosinophilic phenotype, as confirmed by: <ul style="list-style-type: none"> A. A history of chronic airflow limitation with post-bronchodilator FEV₁/FVC ratio < 0.7; OR B. Documented presence of eosinophilic inflammation (e.g., elevated blood eosinophil count > 300 cells/μL in the absence of other causes of eosinophilia); AND iv. Individual has a history of moderate to severe COPD, characterized by: <ul style="list-style-type: none"> A. Frequent exacerbations requiring systemic corticosteroids (2 or more exacerbations in the previous 12 months); OR B. A history of hospitalization due to COPD exacerbation in the previous year. v. Individual has tried one of the following and treatment failed to achieve or maintain disease control: <ul style="list-style-type: none"> A. High-dose inhaled corticosteroids combined with long-acting beta2-agonists (LABAs); OR B. Triple therapy with inhaled corticosteroids, long-acting beta2-agonists (LABAs), and long-acting muscarinic antagonists (LAMAs); AND vi. Dupixent is being requested as an add-on therapy to the patient's current maintenance COPD treatment regimen (e.g., inhaled corticosteroids, LABA, or LAMA). 		
<p>B. Criteria for Continuation Therapy</p>		
<p>Continuation of therapy with Dupixent (dupilumab) for COPD after 12 months may be approved if the following criteria are met:</p>		
<ul style="list-style-type: none"> i. Individual has experienced one or more of the following: <ul style="list-style-type: none"> A. Decreased utilization of rescue inhaler or reliever medications; 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: <ul style="list-style-type: none"> a. Inhaled corticosteroids (ICS); OR b. Long-acting beta2-agonists (LABA); OR 		

Policy Name	Policy Number	Scope
Dupilumab (Dupixent®)	MP-RX-FP-23-23	<input checked="" type="checkbox"/> MMM MA <input type="checkbox"/> MMM Multihealth
c. Long-acting muscarinic antagonists (LAMA)		
C. Authorization Duration		
<ul style="list-style-type: none"> i. Initial Request: 6 months ii. Continuation Requests: 12 months 		
Conditions Not Covered		
Dupixent (dupilumab) may not be approved for the following:		
<ul style="list-style-type: none"> 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 Adbry, Cinqair, Fasentra, Nemluvio, Nucala, Tezspire, or Xolair; OR v. Individual is requesting Dupixent for the treatment of asthma; AND <ul style="list-style-type: none"> 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. 		

Policy Name	Policy Number	Scope
Dupilumab (Dupixent®)	MP-RX-FP-23-23	<input checked="" type="checkbox"/> MMM MA <input type="checkbox"/> MMM Multihealth

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) 100mg/0.67 mL syringe	• 2 syringes per 28 days
Dupilumab (dupilumab) 200 mg/1.14 mL pre-filled syringe/pen *	• 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*	• 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.

@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.

Reference Information

1. Bhatt, Surya P et al. "Dupilumab for COPD with Type 2 Inflammation Indicated by Eosinophil Counts." *The New England journal of medicine* vol. 389,3 (2023): 205-214. doi:10.1056/NEJMoa2303951.
2. Bhatt, Surya P et al. "Dupilumab for COPD with Blood Eosinophil Evidence of Type 2 Inflammation." *The New England journal of medicine* vol. 390,24 (2024): 2274-2283. doi:10.1056/NEJMoa2401304.
3. Blauvelt A, de Bruin-Weller M, Gooderham M, et al. Long-term management of moderate-to-severe atopic dermatitis with dupilumab and concomitant topical corticosteroids (LIBERTY AD CHRONOS): a 1-year, randomised, double-blinded, placebocontrolled, phase 3 trial. *Lancet*. 2017; 389(10086):2287-2303.
4. Castro M, Corren J, Pavord J, et al. Dupilumab efficacy and safety in moderate to severe asthma. *New Engl J Med*. 2018; 378: 2486-96.
5. Chung KF, Wenzel SE, Brozek JL, et al. International European Respiratory Society/American Thoracic Society guidelines on definition, evaluation and treatment of severe asthma. *Eur Respir J*. 2014; 43(2):343-373.
6. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
7. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: June 22, 2022.
8. Davis DMR, Drucker AM, Alikhan A, et al. Guidelines of care for the management of atopic dermatitis in adults with phototherapy and systemic therapies. *J Am Acad Dermatol*. 2024;90(2):e43-e56. doi:10.1016/j.jaad.2023.08.102
9. Diprolene (betamethasone dipropionate lotion). 1983. Revised 5/2019. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. Available at file:///C:/Users/AF38863/Downloads/20190514_db069ce-f93e-4f67-bcb2-dfbb932a1f15.pdf. Accessed July 12, 2021.
10. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
11. Eichenfield L. Guidelines of care for the management of atopic dermatitis: section 2. Management and treatment of atopic dermatitis with topical therapies. *Journal of the American Academy of Dermatology*. 2014-01;71:116.
12. Elidel (pimecrolimus cream). 2001. Revised 12/2017. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. Available at file:///C:/Users/AF38863/Downloads/20191218_e4027e5a-0f9b-4070-b196-f60172f45c4c.pdf. Accessed July 12, 2021.
13. Elmariah, Sarina et al. "Practical approaches for diagnosis and management of prurigo nodularis: United States expert panel consensus." *Journal of the American Academy of Dermatology* vol. 84,3 (2021): 747-760. doi:10.1016/j.jaad.2020.07.025
14. Cloutier MM, Baptist AP, Blake KV, et al; Expert Panel Working Group of the National Heart, Lung, and Blood Institute administered and coordinated National Asthma Education and Prevention Program Coordinating Committee; 2020 focused updates to the asthma management guidelines: a report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group [published correction appears in *J Allergy Clin Immunol*. 2021;147(4):1528–1530]. *J Allergy Clin Immunol*. 2020;146(6):1217-1270. Available from: <https://www.nhlbi.nih.gov/health-topics/asthmamanagement-guidelines-2020-updates>. Accessed June 22, 2022.

Policy Name	Policy Number	Scope
Dupilumab (Dupixent®)	MP-RX-FP-23-23	<input checked="" type="checkbox"/> MMM MA <input type="checkbox"/> MMM Multihealth
<p>15. Global Initiative for Asthma. Global strategy for asthma management and prevention, 2024. Updated May 2024. Available at: https://ginasthma.org/wp-content/uploads/2024/05/GINA-2024-Strategy-Report-24_05_22_WMS.pdf</p> <p>16. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.</p> <p>17. Reddel HK, Bacharier LB, Bateman ED, et al. Global Initiative for Asthma Strategy 2022: Global Strategy for Asthma Management and Prevention. Available from: https://ginasthma.org/wp-content/uploads/2022/05/GINA-Main-Report-2022-FINAL-22-05-03-WMS.pdf. Accessed June 22, 2022</p> <p>18. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.</p> <p>19. Hirano I, Chan ES, Rank MA, et al. AGA institute and the joint task force on allergy-immunology practice parameters clinical guidelines for the management of eosinophilic esophagitis. <i>Ann Allergy Asthma Immunol.</i> 2020;124(5):416-423. doi:10.1016/j.anai.2020.03.020. Accessed on: June 22, 2022</p> <p>20. Rabe KF, Nair P, Brusselle G, et al. Efficacy and safety of dupilumab in glucocorticoid-dependent severe asthma. <i>New Engl J Med.</i> 2018; 378:2475-85.</p> <p>21. Peters AT, Spector S, Hsu J, et al. Diagnosis and management of rhinosinusitis: a practice parameter update. <i>American College of Allergy, Asthma & Immunology.</i> 2014;113:347-385. Accessed July 12, 2021.</p> <p>22. Protopic (tacrolimus ointment). 2000. Revised 4/2019. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. Available at file:///C:/Users/AF38863/Downloads/20190501_51218de3-dabc-4972-9c5b-750c8b1d8083.pdf Accessed July 12, 2021.</p> <p>23. Rosenfeld RM, Piccirillo JF, Chandrasekhar SS, et.al. American Academy of Otolaryngology-Head and Neck Surgery Clinical Practice Guideline (Update): Adult Sinusitis. <i>Otolaryngology-Head and Neck Surgery.</i> 2015;152(2S)S1-S39. Accessed July 12, 2021.</p> <p>24. Ständer, Sonja et al. (2020). IFSI-guideline on chronic prurigo including prurigo nodularis. <i>Itch.</i> 5. e42-e42.</p> <p>25. 10.1097/itx.0000000000000042. Stevens WW, Schleimer RP, Kern RC. Chronic Rhinosinusitis with Nasal Polyps. <i>J Allergy Clin Immunol Pract.</i> 2016;4(4):565-572. doi:10.1016/j.jaip.2016.04.012. Accessed June 22, 2022.</p> <p>26. Study of Dupilumab for the Treatment of Patients With Prurigo Nodularis, Inadequately Controlled on Topical Prescription Therapies or When Those Therapies are Not Advisable (PRIME2). <i>ClinicalTrials.gov</i> identifier: NCT04202679. Updated September 28, 2022. Accessed October 7, 2022. https://clinicaltrials.gov/ct2/show/NCT04202679</p> <p>27. Study of Dupilumab for the Treatment of Patients With Prurigo Nodularis, Inadequately Controlled on Topical Prescription Therapies or When Those Therapies are Not Advisable (LIBERTY-PN PRIME). <i>ClinicalTrials.gov</i> identifier: NCT04183335. Updated September 28, 2022. Accessed October 7, 2022. https://clinicaltrials.gov/ct2/show/record/NCT04183335</p> <p>28. Ultravate (halobetasol propionate lotion). 1990. Revised 5/2020. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. Available at file:///C:/Users/AF38863/Downloads/20200509_0d563d44-17fd-4976-9f2cf1d509f29587.pdf. Accessed July 12, 2021.</p> <p>29. Wenzel S. Treatment of severe asthma in adolescents and adults. Last updated June 11, 2020. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: July 12, 2021.</p>		

Medical Policy

Healthcare Services Department

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Dupilumab (Dupixent®)	MP-RX-FP-23-23	<input checked="" type="checkbox"/> MMM MA <input type="checkbox"/> MMM Multihealth

30. Wenzel S, Castro M, Corren J, et al. Dupilumab efficacy and safety in adults with uncontrolled persistent asthma despite use of medium to high dose inhaled corticosteroids plus a long-acting Beta-2 agonist: a randomized double-blind, placebo-controlled pivotal phase 2b dose-ranging trial. Lancet. 2016; 388:31-44.

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

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Policy History

Revision Type	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Choose an item.			
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

Revised: 09/27/2024.