# Medical Policy

**Healthcare Services Department**

| Policy Name | Policy Number | Scope |
|---|---|---|
| Dupilumab (Dupixent) | MP-RX-FP-23-23 | ☒ MMM MA ☐ MMM Multihealth |

**Service Category**

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Part B Drug

## Service Description

This document addresses the use of Dupilumab (Dupixent) , a drug approved by the Food and Drug Administration (FDA) for the treatment of n 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 18 years and older who were previously inadequately controlled.

**Background Information**

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.

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

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relapsing/chronic course 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.

Guidelines from the AAD regarding the treatment of AD recommend non-pharmacologic therapy, pharmacologic therapy and phototherapy (AAD 2014). Non-pharmacologic therapy includes use of moisturizers (I, A) and use of wet wrap therapy with or without a topical corticosteroid for those with moderate to severe AD during flares (II, B). First line topical pharmacologic therapy are topical corticosteroids (I, A). Labeled dosage guidance from high dose topical steroids recommend limiting consecutive use to 2 weeks (Ultravate 2020, Diprolene 2019). Topical calcineurin inhibitors are recommended for use on actively affected areas as a steroid sparing agent (I, A). Labeled dosage guidance for Elidel and Protopic recommend re-evaluation if signs and symptoms persist beyond 6 weeks of use (Elidel 2017, Protopic 2019). Phototherapy is recommended as a second line treatment, after failure of first-line treatment (topical therapy) (II, B). In addition, phototherapy can be used as maintenance therapy in those with chronic disease. Systemic immunomodulatory agents (such as cyclosporine, azathioprine, methotrexate) are indicted when individuals have disease symptoms not controlled by optimized topical regimens and/or phototherapy (I, II, B).

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.

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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 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 an inflammatory disease. Other adjunctive therapy, such as nasal saline irrigation, may be beneficial for symptoms in some cases.

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.

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

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

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

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## 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 |
| 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.*

### *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 (FEV1) less than or equal to (≤) 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 (µL) is equal to 1 cubic millimeter (mm3)] 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).

**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 rescue 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.

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**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. Individual meets one of the following (A or B):

A. Failure of topical pharmacological therapy as indicated by both (1 and 2) of the following:

1. Daily treatment of topical corticosteroids of medium to higher potency for at least fourteen (14) days has failed to achieve and maintain remission of low or mild disease activity state; **OR**

B. Topical corticosteroids are not indicated due to severe hypersensitivity reactions or concomitant clinical situations, including but not limited to (AAD 2014):

i. Individual has lesions located in sensitive areas (including, but not limited to, face, anogenital area or skin folds); **OR**

ii. Individual has steroid-induced atrophy; **OR**

iii. History of long-term or uninterrupted topical steroid use;**AND**

2. Documentation is provided that daily treatment of topical calcineurin inhibitors for six (6) weeks has failed to achieve and maintain remission of low or mild disease activity state; **OR**

A. Documentation is provided that topical calcineurin inhibitors (TCI) are not indicated due to severe hypersensitivity reactions or concomitant clinical situations, including but not limited to:

i. History of or active malignant or pre-malignant skin conditions; OR

ii. Individual has Netherton's Syndrome or other skin diseases that can increase the risk of systemic absorption of TCI; **OR**

iii. Individual is considered to be immunocompromised, including those on systemic immunosuppressive medications on an ongoing basis; **OR**

iv. Individual is less than 2 years old;**OR**

B. One of the following:

1. Documentation is provided that phototherapy (UVB or PUVA) has failed to achieve and maintain remission of low or mild disease activity state or is contraindicated; **OR**

2. Documentation is provide that non-corticosteroid systemic immunosuppressants (such as cyclosporine, azathioprine, methotrexate, or mycophenolate mofetil) have failed to achieve and maintain remission of low or mild disease activity state or is contraindicated.

**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).

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**Initial requests for Dupixent (dupilumab) for the treatment of chronic rhinosinusitis with nasal polyposis (CRSwNP) may be approved ifthe following criteria are met:**
I. Individual is age 18 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**
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.

**Continuation requests for Dupixent (dupilumab) for 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).

**Initial requests for Dupixent (dupilumab) for the treatment of eosinophilic esophagitis (EoE) may be approved if the following criteria are met**:
I. Individual is 12 years of age or older and weighs at least 40kg; **AND**
II. Documentation is provided that individual has a diagnosis of EoE confirmed by the following (NCT03633617):
A. 15 or more intraepithelial eosinophils per high-power field (eos/hpf); **AND**
B. Symptoms of dysphagia; **AND**
III. Individual has tried a course of proton pump inhibitors (PPIs) (Hirano,2020); **OR**
IV. 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).

**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).

**Initial requests for Dupixent (dupilumab) for the treatment of 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**

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III. Individual meets one of the following (A or B):

A. Individual has tried at least a two (2) week course of medium to super-potent topical corticosteroids or such topical corticosteroids are not appropriate for the individual (NCT04202679);

1. Topical corticosteroids are not indicated due to severe hypersensitivity reactions or concomitant clinical situations, including but not limited to (NCT04202679): **OR**

a. Individual has lesions located in sensitive areas (including, but not limited to, face, anogenital area or skin folds); **OR**

b. Individual has steroid-induced atrophy; **OR**

c. History of long-term or uninterrupted topical steroid use; **OR**

B. Individual has tried a course of topical calcineurin inhibitors for two (2) weeks has failed to achieve and maintain remission of low or mild disease activity state or topical calcineurin inhibitors are not appropriate for the individual (NCT04202679);**OR**

1. Topical calcineurin inhibitors (TCI) are not indicated due to severe hypersensitivity reactions or concomitant clinical situations, including but not limited to:

a. History of or active malignant or pre-malignant skin conditions; **OR**

b. Individual has Netherton's Syndrome or other skin diseases that can increase the risk of systemic absorption of TCI; **OR**

c. Individual is considered to be immunocompromised, including those on systemic immunosuppressive medications on an ongoing basis.

**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).

**Dupixent (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 Cinqair, Tezspire, Fasenra, Nucala or Xolair; **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. 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. 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 |
|---|---|
| Dupixent (dupilumab) 100mg/0.67 mL syringe | 2 syringes per 28 days[@] |
| Dupixent (dupilumab) 200 mg/1.14 mL pre-filled syringe/pen * | • 11 years old or younger: 1 syringe/pen every 28 days[@]<br>• 12 years old or older: 2 syringes/pens every 28 days |
| Dupixent (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[%]<br>• 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.<br><br>@For individuals weighing 30kg or more, may approve 2 syringes/pens per 28 days<br>% For individuals more than 30 kg, may approve 2 syringes/pens per 28 days<br># In the treatment of eosinophilic esophagitis: May approve 4 syringes/pens per 28 days | |

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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 | MPCC Approval Date |
|---|---|---|---|
| Policy Inception | Elevance Health's Medical Policy adoption. | N/A | 11/30/2023 |

Revised: 08/18/2023