# Dupixent (dupilumab)

| Override(s) | Approval Duration |
|---|---|
| Prior Authorization<br>Quantity Limit | Asthma:<br>Initial: 6 months<br>Continuation: 1 year<br><br>Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP):<br>Initial: 6 months<br>Continuation: 1 year<br><br>Chronic Obstructive Pulmonary Disease (COPD)<br>Initial: 6 months<br>Continuation: 12 months<br><br>All other diagnoses:<br>1 year |

| Medications | Quantity Limit |
|---|---|
| Dupixent (dupilumab) 100 mg/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/2mL 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# |

*Initiation of therapy: May approve two additional 200 mg/1.14 mL OR 300 mg/2 mL pre-filled syringes/pens 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.

@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.

## APPROVAL CRITERIA

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

I. Individual is 6 years of age or older; **AND**
II. Individual has a diagnosis of moderate-to-severe asthma as demonstrated by the following (NHLBI 2020):
    A. A pretreatment forced expiratory volume in 1 second ($FEV_1$) less than or equal to (≤) 80% predicted; **AND**
    B. $FEV_1$ 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 ($mm^3$)] at initiation of therapy; **AND**
    B. Documentation is provided that individual has had a 3 month trial and inadequate response or intolerance to combination controller therapy (high dose inhaled corticosteroids plus long acting $beta_2$ –agonists, leukotriene modifiers, theophylline or oral corticosteroids) (ERS/ATS 2013, GINA 2022);

    **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 $beta_2$-agonist, **or** leukotriene receptor antagonist, **or** theophylline) (ERS/ATS 2013, GINA 2022);

**AND**
IV. Individual has experienced two or more asthma exacerbations in the prior 12 months requiring use of a systemic corticosteroid **or** temporary increase in the individual's usual maintenance dosage of oral corticosteroids (Castro 2018, Rabe 2018).

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

I. Individual has experienced one or more of the following:

A. Decreased utilization of reliever medications; **OR**
B. Decreased frequency of exacerbations (defined as worsening of asthma that requires an increase in inhaled corticosteroid dose or treatment with systemic corticosteroids); **OR**
C. Increase in predicted $FEV_1$ 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.

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

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

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

I. Individual will continue to use Dupixent (dupilumab) in combination with LAMA/LABA therapy OR ICS/LAMA/LABA therapy ; **AND**
II. Treatment with Dupixent has resulted in clinical improvement in one or more of the following:

A. Decreased utilization of reliever medication; **OR**
B. Decreased frequency or severity of exacerbations; **OR**
C. Increase in percent predicted FEV1 from pretreatment baseline; **OR**
D. Reduction in reported COPD-related symptoms, including shortness of breath, cough, fatigue or sleep disturbance.

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

I. Individual is 6 months or older; **AND**
II. Individual has a diagnosis of moderate to severe atopic dermatitis; **AND**
III. Documentation is provided that individual has tried one of the following, and treatment failed to achieve and maintain remission of low or mild disease activity:
    A. Topical calcineurin inhibitors;
    **OR**
    B. Eucrisa;
    **OR**
    C. Opzelura;
    **OR**
    D. Zoryve 0.15% Cream;
    **OR**
    E. Vtama Cream;
    **OR**
    F. Phototherapy (UVB or PUVA);
    **OR**
    G. Non-corticosteroid systemic immunosuppressants (such as cyclosporine, azathioprine, methotrexate, or mycophenolate mofetil);
    **OR**
    H. Individual has contraindications to topical calcineurin inhibitors **AND** Eucrisa **AND** Opzelura **AND** Zoryve 0.15% Cream **AND** Vtama cream **AND** Non-corticosteroid systemic immunosuppressants (such as cyclosporine, azathioprine, methotrexate, or mycophenolate mofetil) **AND** unable to use Phototherapy.

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

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

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

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

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

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

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 15 kg; **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 (NCT03633617); **AND**
V. Individual has tried a course of proton pump inhibitors (PPIs) (Hirano,2020); **AND**
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)

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 is 18 years of age or older; **AND**
II. Individual has a diagnosis of PN; **AND**
III. Individual has 20 or more PN lesions (NCT04202679); **AND**
IV. Documentation is provided that individual has tried one of the following and treatment failed to achieve and maintain remission of low or mild disease activity:
    A. Medium to super-potent topical corticosteroids (NCT04202679);
    **OR**
    B. Topical calcineurin inhibitors.

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

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

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

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

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

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

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

I. In combination with oral or topical JAK inhibitors; **OR**
II. In combination with other immunosuppressants (such as cyclosporine, azathioprine, mycophenolate mofetil, or methotrexate); **OR**
III. In combination with ensifentrine, tralokinumab, reslizumab, benralizumab, lebrikizumab-ibkz, nemolizumab-ilto, mepolizumab, tezepelumab, or omalizumab; **OR**
IV. Individual is requesting Dupixent for the treatment of asthma; **AND**
    A. Individual has current blood eosinophils greater than 1500 cells/microliter [1 microliter (µL) is equal to 1 cubic millimeter (mm3)] (GINA 2022); **AND**
    B. Asthma related causes have been excluded (GINA 2022);

**OR**

V. Requests for Dupixent (dupilumab) may not be approved when the above criteria are not met and for all other indications.

**Key References**:


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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.