Dupixent® (dupilumab)

When requesting Dupixent® (dupilumab), the individual requiring treatment must be diagnosed with one of the following FDA-approved indications and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indications

Atopic Dermatitis
Dupixent is indicated for the treatment of adult and pediatric patients aged 6 months and older with moderate to severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.

Asthma
Dupixent is indicated 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.

Chronic Rhinosinusitis with Nasal Polyps
Dupixent is indicated as an add-on maintenance treatment in adult and pediatric patients aged 12 years and older with inadequately controlled chronic rhinosinusitis with nasal polyps.

Eosinophilic Esophagitis
Dupixent is indicated for the treatment of adult and pediatric patients aged 1 year and older, weighing at least 15 kg, with eosinophilic esophagitis.

Prurigo Nodularis
Dupixent is indicated for the treatment of adult patients with prurigo nodularis.

Chronic Obstructive Pulmonary Disease
Dupixent is indicated as an add-on maintenance treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease and an eosinophilic phenotype.

Chronic Spontaneous Urticaria (Chronic Idiopathic Urticaria)
Dupixent is indicated for the treatment in patients 12 years and older who remain symptomatic despite H_1 antihistamine treatment.

Bullous Pemphigoid
Dupixent is indicated for the treatment of adult patients with bullous pemphigoid.

Coverage Guidelines

Atopic Dermatitis

The individual must meet all of the following criteria for initial authorization:

- Is 6 months of age or older;
- Has tried at least one medium-, medium-high, high-, and/or super-high potency prescription topical corticosteroid for at least 28 consecutive days but had an inadequate response;
- Dupixent is prescribed by or in consultation with an allergist, immunologist, or dermatologist;
- Meets one of the following:
    - Has atopic dermatitis involvement estimated to be ≥ 10% of the body surface area; OR
    - Has moderate to severe hand and/or foot atopic dermatitis and is ≥ 12 years of age.

The individual must meet both of the following criteria for re-authorization:

- Has already received at least 4 months of Dupixent therapy *(NOTE: Patients who have received < 4 months of therapy or those who are restarting therapy with Dupixent should be considered under initial criteria)*;
- Has responded to Dupixent therapy (e.g., marked improvements in erythema, induration/papulation/edema; reduced pruritus; decreased requirement for other topical or systemic therapies; reduced body surface area affected with atopic dermatitis).

Asthma

The individual must meet all of the following criteria for initial authorization:

- Is 6 years of age or older;
- Meets one of the following:
    - Has a blood eosinophil level ≥ 150 cells per microliter within the previous 6 weeks; OR
    - Had a blood eosinophil level ≥ 150 cells per microliter prior to treatment with Dupixent or another monoclonal antibody therapy that may alter blood eosinophil levels;
    - Has oral corticosteroid-dependent asthma (e.g., has received ≥ 5 mg oral prednisone or equivalent per day for ≥ 6 months);
- Has received at least 3 consecutive months of combination therapy with an inhaled corticosteroid AND at least one additional asthma controller or asthma maintenance medication *(note: use of a combination inhaler containing both an inhaled corticosteroid and additional asthma controller/maintenance medication(s) would fulfill the requirements)*;
- Has asthma that is uncontrolled or was uncontrolled at baseline as defined by one of the following (i.e., prior to receiving Dupixent or another monoclonal antibody therapy for asthma):
    - Has experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year; OR

    - Has experienced one or more asthma exacerbation(s) requiring a hospitalization, an emergency department visit, or an urgent care visit in the previous year; OR
    - Has a forced expiratory volume in 1 second (FEV_1) < 80% predicted; OR
    - Has an FEV_1/forced vital capacity (FVC) < 0.80; OR
    - Has asthma that worsens upon tapering of oral corticosteroid therapy;
- Dupixent is prescribed by or in consultation with an allergist, immunologist, or pulmonologist.

The individual must meet all of the following criteria for re-authorization:

- Has already received at least 6 months of Dupixent therapy *(NOTE: Patients who have received < 6 months of therapy or those who are restarting therapy with Dupixent should be considered under initial criteria)*;
- Continues to receive therapy with one inhaled corticosteroid or one inhaled corticosteroid-containing combination inhaler;
- Has responded to Dupixent therapy (e.g., decreased asthma exacerbations; decreased asthma symptoms; decreased hospitalizations, emergency department visits, or urgent care visits due to asthma; decreased requirement for oral corticosteroid therapy).

Chronic Obstructive Pulmonary Disease (COPD)

The individual must meet all of the following criteria for initial authorization:

- Is 18 years of age or older;
- Meets one of the following:
    - Has a blood eosinophil level ≥ 300 cells per microliter within the previous 6 weeks; OR
    - Had a blood eosinophil level ≥ 300 cells per microliter prior to treatment with Dupixent or another monoclonal antibody therapy that may alter blood eosinophil levels;
- Meets one of the following *(note: use of single-entity inhalers or a combination inhaler containing multiple agents from the medication classes listed would fulfill the requirement)*:
    - Has received at least 3 consecutive months of combination therapy with all of the following: inhaled long-acting $beta_2$-agonist (LABA), inhaled long-acting muscarinic antagonist (LAMA), and inhaled corticosteroid (ICS); OR
    - Has received at least 3 consecutive months of combination therapy with an inhaled LABA and an inhaled LAMA and has a contraindication to the use of an inhaled corticosteroid;
- Meets one of the following:
    - Has experienced two or more COPD exacerbations requiring treatment with a systemic corticosteroid with or without an antibiotic in the previous 12 months; OR
    - Has experienced one or more COPD exacerbation(s) requiring a hospitalization in the previous 12 months (note: a hospitalization includes a hospital admission or an emergency medical care visit with observation lasting more than 24 hours);

- Dupixent is prescribed by or in consultation with an allergist, immunologist, or pulmonologist.

The individual must meet all of the following criteria for re-authorization:

- Has already received at least 6 months of Dupixent therapy *(NOTE: Patients who have received < 6 months of therapy or those who are restarting therapy with Dupixent should be considered under initial criteria)*;
- Continues to receive combination therapy with an inhaled LABA and LAMA;
- Has experienced a beneficial clinical response defined by one of the following:
    - Reduced COPD symptoms; OR
    - Reduced COPD exacerbations; OR
    - Reduced COPD-related hospitalizations; OR
    - Reduced emergency department or urgent care visit; OR
    - Improved lung function parameters.

Chronic Rhinosinusitis with Nasal Polyps

The individual must meet all of the following criteria for initial authorization:

- Is 12 years of age or older;
- Has chronic rhinosinusitis with nasal polyps as evidenced by direct examination, endoscopy, or sinus computed tomography (CT) scan;
- Has experienced two or more of the following symptoms for at least 6 months: nasal congestion, nasal obstruction, nasal discharge, and/or reduction or loss of smell;
- Has received at least 4 weeks of therapy with an intranasal corticosteroid and will continue to receive an intranasal corticosteroid concomitantly with Dupixent;
- Meets one of the following:
    - Has received at least one course of treatment with a systemic corticosteroid for 5 days or more within the previous 2 years; OR
    - Has a contraindication to systemic corticosteroid therapy; OR
    - Has had prior surgery for nasal polyps;
- Dupixent is prescribed by or in consultation with an allergist, immunologist, or an otolaryngologist (ear, nose, and throat [ENT] physician specialist).

The individual must meet all of the following criteria for re-authorization:

- Has already received at least 6 months of Dupixent therapy *(NOTE: Patients who have received < 6 months of therapy or those who are restarting therapy with Dupixent should be considered under initial criteria)*;
- Continues to receive therapy with an intranasal corticosteroid;
- Has responded to Dupixent therapy (e.g., reduced nasal polyp size, improved nasal congestion, reduced sinus opacification, decreased sinonasal symptoms, improved sense of smell).

Eosinophilic Esophagitis

The individual must meet all of the following criteria for initial authorization:

- Is 1 year of age or older;
- Weighs 15 kg or more;
- Has a diagnosis of eosinophilic esophagitis confirmed by an endoscopic biopsy demonstrating ≥ 15 intraepithelial eosinophils per high-power field;
- Does not have a secondary cause of eosinophilic esophagitis (e.g., hypereosinophilic syndrome, eosinophilic granulomatosis with polyangiitis, and food allergy);
- Has received at least 8 weeks of therapy with a proton pump inhibitor;
- Meets one of the following:
    - Has tried dietary modifications to treat/manage eosinophilic esophagitis; OR
    - Is not an appropriate candidate for dietary modifications;
- Dupixent is prescribed by or in consultation with an allergist or gastroenterologist.

The individual must meet both of the following criteria for re-authorization:

- Has already received at least 6 months of Dupixent therapy *(NOTE: Patients who have received < 6 months of therapy or those who are restarting therapy with Dupixent should be considered under initial criteria)*;
- Has experienced a beneficial clinical response, defined by one of the following:
    - Reduced intraepithelial eosinophil count; OR
    - Decreased dysphagia/pain upon swallowing; OR
    - Reduced frequency or severity of food impaction.

Prurigo Nodularis

The individual must meet all of the following criteria for initial authorization:

- Is 18 years of age or older;
- Has ≥ 20 identifiable nodular lesions in total on both arms, and/or both legs, and/or trunk;
- Has experienced pruritus for at least 6 weeks;
- Meets one of the following:
    - The condition is not medication-induced or secondary to a non-dermatologic condition such as neuropathy or a psychiatric disease; OR
    - Has a secondary cause of prurigo nodularis that has been identified and adequately managed;
- Has tried at least one high- or super-high potency prescription topical corticosteroid and was applied daily for at least 14 consecutive days but had an inadequate efficacy with this topical corticosteroid therapy;
- Dupixent is prescribed by or in consultation with an allergist, immunologist, or dermatologist.

The individual must meet both of the following criteria for re-authorization:

- Has already received at least 6 months of Dupixent therapy *(NOTE: Patients who have received < 6 months of therapy or those who are restarting therapy with Dupixent should be considered under initial criteria)*;

- Has experienced a beneficial clinical response, defined by one of the following:
    - Reduced nodular lesion count; OR
    - Decreased pruritus; OR
    - Reduced nodular lesion size.

Chronic Spontaneous Urticaria (Chronic Idiopathic Urticaria)

The individual must meet all the following criteria for initial authorization:

- Is 12 years of age or older;
- Has or had urticaria for > 6 weeks (prior to receiving Dupixent), with symptoms present > 3 days per week despite daily non-sedating H1 antihistamine therapy with doses that have been titrated up to a maximum of four times the standard FDA-approved dose;
  Note: Examples of non-sedating H1 antihistamines are cetirizine, desloratadine, fexofenadine, levocetirizine, and loratadine).
- Prescribed by or in consultation with an allergist, immunologist, or dermatologist

The individual must meet both of the following criteria for re-authorization:

- Has already received at least 6 months of Dupixent therapy *(NOTE: Patients who have received < 6 months of therapy or those who are restarting therapy with Dupixent should be considered under initial criteria)*;
- Has experienced a beneficial clinical response, defined by one of the following:
    - Decreased itch severity; OR
    - Decreased number of hives; OR
    - Decreased size of hives.

Bullous Pemphigoid

The individual must meet both criteria for initial authorization:

- Is 18 years of age or older;
- Prescribed by or in consultation with a dermatologist.

The individual must meet both criteria for re-authorization:

- Has received at least 6 months of Dupixent therapy *(NOTE: Patients who have received < 6 months of therapy or those who are restarting therapy with Dupixent should be considered under initial criteria)*;
- Has experienced a beneficial clinical response, defined by one of the following:
    - Decreased area of skin involvement; OR
    - Decreased lesions, including blisters or erosions (bullae); OR
    - Decreased urticaria; OR
    - Decreased erythema; OR
    - Reduced or no need for systemic or topical corticosteroid therapy.

Approval duration (initial): 4 months (atopic dermatitis); 6 months (all other indications)
Approval duration (renewal): 12 months

Dosing Recommendations

Dupixent is administered by subcutaneous injection.

Atopic Dermatitis

Dosage in Adults:
The recommended dosage is an initial dose of 600 mg, followed by 300 mg given every other week.

Dosage in Pediatric Patients 6 Months to 5 Years of Age:

Body Weight	Initial and Subsequent Dosage
5 to less than 15 kg	200 mg every 4 weeks
15 to less than 30 kg	300 mg every 4 weeks

Dosage in Pediatric Patients 6 Years to 17 Years of Age:

Body Weight	Initial Loading Dose	Subsequent Dosage
15 to less than 30 kg	600 mg	300 mg every 4 weeks
30 to less than 60 kg	400 mg	200 mg every 2 weeks
60 kg or more	600 mg	300 mg every 2 weeks

Asthma

Dosage in Adult and Pediatric Patients 12 Years and Older:

Initial Loading Dose	Subsequent Dosage
400 mg	200 mg every 2 weeks
OR	
600 mg	300 mg every 2 weeks
Dosage for patients with oral corticosteroid-dependent asthma or with co-morbid moderate to severe atopic dermatitis or adults with co-morbid chronic rhinosinusitis with nasal polyps	
600 mg	300 mg every 2 weeks

Dosage in Pediatric Patients 6 to 11 Years of Age:

Body Weight	Initial Dose and Subsequent Dosage
15 to less than 30 kg	300 mg every 4 weeks
30 kg or more	200 mg every 2 weeks

Chronic Rhinosinusitis with Nasal Polyps

The recommended dosage is 300 mg given every other week.

Eosinophilic Esophagitis

Body Weight	Recommended Dosage
15 to less than 30 kg	200 mg every 2 weeks
30 to less than 40 kg	300 mg every 2 weeks
40 kg or more	300 mg every week

Prurigo Nodularis

The recommended dosage is an initial dose of 600 mg, followed by 300 mg given every other week.

Chronic Obstructive Pulmonary Disease

The recommended dosage is 300 mg given every other week.

Chronic Spontaneous Urticaria

Dosage in Adults

The recommended dosage is an initial dose of 600 mg, followed by 300 mg given every other week.

Dosage in Pediatric Patients 12 to 17 Years of Age

Body Weight	Initial Loading Dose	Subsequent Dosage
30 to less than 60 kg	400 mg	200 mg every 2 weeks
60 kg or more	600 mg	300 mg every 2 weeks

Bullous Pemphigoid

The recommended dosage is an initial dose of 600 mg (two 300 mg injections), followed by 300 mg given every other week.
Use Dupixent in combination with a tapering course of oral corticosteroids. Once disease control has occurred, gradually taper corticosteroids after which continue Dupixent as monotherapy. In case of relapse, corticosteroids may be added if medically advisable.

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