

## 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**

Dupixent is indicated for the treatment of adult and pediatric patients aged 2 years and older with chronic spontaneous urticaria who remain symptomatic despite H<sub>1</sub> antihistamine treatment.

#### **Bullous Pemphigoid**

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

#### **Allergic Fungal Rhinosinusitis**

Dupixent is indicated for the treatment of adult and pediatric patients aged 6 years and older with allergic fungal rhinosinusitis who have a history of sino-nasal surgery.

## Coverage Guidelines

### Atopic Dermatitis

The individual must meet all 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  $\geq 10\%$  of the body surface area; OR
  - Has moderate to severe hand and/or foot atopic dermatitis and 12 years of age or older.

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  $\geq 150$  cells per microliter within the previous 6 weeks; OR
  - Had a blood eosinophil level  $\geq 150$  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  $\geq 5$  mg oral prednisone or equivalent per day for  $\geq 6$  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*);

Dupixent® (dupilumab)

- 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<sub>1</sub>) < 80% predicted; OR
  - Has an FEV<sub>1</sub>/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  $\geq 300$  cells per microliter within the previous 6 weeks; OR
  - Had a blood eosinophil level  $\geq 300$  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<sub>2</sub>-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 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 had the diagnosis of chronic rhinosinusitis with nasal polyps for at least 6 months;
- Has experienced two or more of the following symptoms for at least 8 weeks: 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 within the previous year (*note: one course of a systemic corticosteroid is  $\geq 3$  consecutive days of treatment or one long-acting injectable dose*); 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  $\geq 15$  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 the following criteria for initial authorization:

- Is 18 years of age or older;
- Has  $\geq 20$  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 for at least 14 consecutive days but had an inadequate efficacy;
- 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**

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

- Is 2 years of age or older;
- Has or had urticaria for at least 6 weeks (prior to receiving Dupixent);
- Has tried high-dose oral second-generation H<sub>1</sub> antihistamine therapy (e.g., cetirizine, desloratadine, fexofenadine, levocetirizine, and loratadine);
- 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:
  - Decreased itch severity; OR
  - Decreased number of hives; OR
  - Decreased size of hives.

### **Bullous Pemphigoid**

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

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

The individual must meet both of the following 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.

## Allergic Fungal Rhinosinusitis

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

- Is 6 years of age or older;
- Has immunoglobulin E (IgE)-mediated inflammatory response to fungal hyphae as evidenced by specific IgE serology or skin test;
- Has presence of nasal polyps as evidenced by direct examination, endoscopy, or sinus computed tomography (CT) scan;
- Has presence of signs characteristic of allergic fungal rhinosinusitis on CT scan (e.g., hyperdensities, bony demineralization, or bone erosion of sinus);
- Has had at least one prior sino-nasal surgery;
- Dupixent is prescribed by or in consultation with an allergist, immunologist, otolaryngologist (ear, nose, and throat [ENT] physician specialist), rhinologist, pulmonologist, or infectious disease specialist.

The individual must meet both of the following 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 responded to Dupixent therapy (e.g., reduced nasal polyp size, improved nasal congestion, reduced sinus opacification, decreased sinonasal symptoms, improved sense of smell, reduced use of systemic corticosteroids).

**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 2 weeks.

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

| <b>Body Weight</b>    | <b>Initial and Subsequent Dosage</b> |
|-----------------------|--------------------------------------|
| 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:*

| <b>Body Weight</b>    | <b>Initial Loading Dose</b> | <b>Subsequent Dosage</b> |
|-----------------------|-----------------------------|--------------------------|
| 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:*

| <b>Initial Loading Dose</b>                                                                                                                                                                              | <b>Subsequent Dosage</b> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
| 400 mg                                                                                                                                                                                                   | 200 mg every 2 weeks     |
| OR                                                                                                                                                                                                       |                          |
| 600 mg                                                                                                                                                                                                   | 300 mg every 2 weeks     |
| <b>Dosage for patients with oral corticosteroid-dependent asthma or with co-morbid moderate to severe atopic dermatitis, chronic rhinosinusitis with nasal polyps, or allergic fungal rhinosinusitis</b> |                          |
| 600 mg                                                                                                                                                                                                   | 300 mg every 2 weeks     |

*Dosage in Pediatric Patients 6 to 11 Years of Age:*

| <b>Body Weight</b>    | <b>Recommended Dosage</b> <i>(no initial loading dose is recommended)</i> |
|-----------------------|---------------------------------------------------------------------------|
| 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 2 weeks.

## **Eosinophilic Esophagitis**

| <b>Body Weight</b>    | <b>Recommended Dosage</b> |
|-----------------------|---------------------------|
| 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 2 weeks.

## **Chronic Obstructive Pulmonary Disease**

The recommended dosage is 300 mg given every 2 weeks.

### Chronic Spontaneous Urticaria

#### *Dosage in Adults:*

The recommended dosage is an initial dose of 600 mg, followed by 300 mg given every 2 weeks.

#### *Dosage in Pediatric Patients 2 years to 5 years of age:*

| Body Weight           | Recommended 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 |

### Bullous Pemphigoid

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

### Allergic Fungal Rhinosinusitis

#### *Dosage in Adults:*

The recommended dosage is 300 mg given every 2 weeks.

#### *Dosage in Pediatric Patients 6 years to 17 years of age:*

| Body Weight           | Recommended Dosage   |
|-----------------------|----------------------|
| 15 to less than 30 kg | 300 mg every 4 weeks |
| 30 to less than 60 kg | 200 mg every 2 weeks |
| 60 kg or more         | 300 mg every 2 weeks |

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