

## PRIOR AUTHORIZATION POLICY

**POLICY:** Immunologicals – Dupixent Prior Authorization Policy

- Dupixent® (dupilumab subcutaneous injection – Regeneron/sanofi-aventis)

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### OVERVIEW

Dupixent, an interleukin-4 receptor alpha antagonist, is indicated for the following uses:<sup>1</sup>

- **Asthma**, as an add-on maintenance treatment in patients  $\geq 6$  years of age with moderate-to-severe disease with an eosinophilic phenotype or with oral corticosteroid-dependent asthma.  
Limitation of Use: Dupixent is not indicated for the relief of acute bronchospasm or status asthmaticus.
- **Atopic dermatitis**, for the treatment of patients  $\geq 6$  months of age with moderate-to-severe disease not adequately controlled with topical prescription therapies or when those therapies are not advisable.
- **Chronic rhinosinusitis with nasal polyposis (CRSwNP)** [i.e., nasal polyps], as an add-on maintenance treatment in adults with inadequately controlled disease.
- **Eosinophilic esophagitis**, in patients  $\geq 12$  years of age who weigh  $\geq 40$  kg.
- **Prurigo nodularis**, in patients  $\geq 18$  years of age.

### Clinical Efficacy

Timing of efficacy assessments varied by indication across the numerous pivotal studies in which Dupixent demonstrated benefit. In the asthma trials, efficacy with Dupixent was assessed as early as 24 weeks.<sup>2,3</sup> In atopic dermatitis, the majority of studies evaluated the efficacy of Dupixent at 16 weeks.<sup>1,4,5,27,28</sup> The pivotal studies involving patients with CRSwNP evaluated the primary efficacy endpoints following 24 weeks of treatment. Patients continued treatment with intranasal corticosteroids throughout the studies.<sup>1,6-8</sup>

In Dupixent's eosinophilic esophagitis pivotal study, patients were required to have disease confirmed by baseline endoscopic biopsies with a demonstration of eosinophilic infiltration on central reading (peak cell count  $\geq 15$  eosinophils per high-powered field) that was unresponsive to an 8 week course of treatment with a high-dose proton pump inhibitor.<sup>25,26</sup> In total, 74.1% of patients had also previously received swallowed topical corticosteroids to treat their eosinophilic esophagitis. Patients with other causes of eosinophilic esophagitis, such as hypereosinophilic syndrome and eosinophilic granulomatosis with polyangiitis, were excluded from the study. In the first portion of this study, efficacy, as measured by objective assessments (e.g., intraepithelial eosinophil count) and subjective assessments (e.g., dysphagia symptoms) was evaluated after 24 weeks (6 months) of Dupixent therapy.

Two pivotal studies, PRIME and PRIME2, evaluated Dupixent's efficacy in the treatment of prurigo nodularis.<sup>29,30</sup> To enroll, patients were required to have  $\geq 20$  identifiable nodular lesions in total on both legs, and/or both arms, and/or trunk and to have failed a 2-week trial of a topical corticosteroid. Patients with prurigo nodularis secondary to medications or a medical condition such as neuropathy or psychiatric disease were excluded from the studies. The primary endpoint was evaluated at Week 24 in PRIME and initially at Week 12 and again at Week 24 in PRIME2.

## **Guidelines**

### *Asthma Guidelines*

The Global Initiative for Asthma Global Strategy for Asthma Management and Prevention (2022) proposes a stepwise approach to asthma treatment.<sup>9</sup> The majority of patients can be managed with an inhaled corticosteroid (ICS) with or without a long-acting beta<sub>2</sub>-agonist and/or an additional controller. Dupixent is listed as an option for add-on therapy in patients ≥ 6 years of age with severe eosinophilic/Type 2 asthma or for patients ≥ 12 years of age who require treatment with a maintenance oral corticosteroid. Higher blood eosinophil levels and higher fractional concentration of exhaled nitric oxide may predict a good asthma response to Dupixent.

According to the European Respiratory Society/American Thoracic Society guidelines (2014; updated in 2020), severe asthma is defined as asthma which requires treatment with a high-dose ICS in addition to a second controller medication (and/or systemic corticosteroids) to prevent it from becoming uncontrolled, or asthma which remains uncontrolled despite this therapy.<sup>10,11</sup> Uncontrolled asthma is defined as asthma that worsens upon tapering of high-dose ICS or systemic corticosteroids or asthma that meets one of the following four criteria:

- 1) Poor symptom control: Asthma Control Questionnaire consistently ≥ 1.5 or Asthma Control Test < 20; OR
- 2) Frequent severe exacerbations: two or more bursts of systemic corticosteroids in the previous year; OR
- 3) Serious exacerbations: at least one hospitalization, intensive care unit stay, or mechanical ventilation in the previous year; OR
- 4) Airflow limitation: FEV<sub>1</sub> < 80% predicted after appropriate bronchodilator withholding.

### *Atopic Dermatitis Guidelines*

European consensus guidelines for the treatment of atopic dermatitis (2018) recommend Dupixent as a disease-modifying drug for patients with moderate-to-severe atopic dermatitis, in whom topical treatment does not produce a sufficient response and other systemic treatment is not advisable.<sup>12</sup> These guidelines note that daily emollients should be used with Dupixent and it may be combined with other topical anti-inflammatory medications as needed. US guidelines do not address Dupixent.<sup>13-15</sup> However, they reinforce that most patients with atopic dermatitis can achieve disease control with non-pharmacologic interventions (e.g., emollients), standard topical anti-inflammatory therapies (e.g., topical corticosteroids, topical calcineurin inhibitors), and elimination of exacerbating factors.

### *Eosinophilic Esophagitis Guidelines*

Guidelines for the management of eosinophilic esophagitis from the American Gastroenterological Association and the Joint Task Force on Allergy-Immunology Practice Parameters (2020) have not been updated since the FDA approval of Dupixent for this indication.<sup>24</sup> In patients with symptomatic disease, use of a proton pump inhibitor is recommended over no treatment, as is treatment with topical corticosteroids. Guidelines recommend diet modifications, such as an elemental diet (amino-acid based formulas) or an elimination diet, over no treatment. However, it is noted that patients who put a higher value on avoiding the challenges of adherence to these diets and the prolonged process of dietary reintroduction may reasonably decline this treatment option.

### *Nasal Polyp Guidelines*

A 2014 Practice Parameter on the Diagnosis and Management of Rhinosinusitis, a 2020 Practice Parameter for the Management of Rhinitis from the Joint Task Force for Practice Parameters (JTFPP), and a 2015 Clinical Practice Guideline update on Adult Sinusitis from the American Academy of Otolaryngology (AAO) make similar recommendations regarding the diagnosis and management of CRSwNP.<sup>16-20</sup> The presence of two or more signs and symptoms of chronic rhinosinusitis (e.g., rhinorrhea, postnasal drainage, anosmia, nasal congestion, facial pain, headache, fever, cough, and purulent discharge) that persist for an extended period of time makes the diagnosis chronic rhinosinusitis likely. However, this requires confirmation of sinonasal inflammation, which can either be done via direct visualization or computed tomography (CT) scan. Nasal corticosteroids are recommended for the management of CRSwNP, as they decrease nasal polyp size, prevent regrowth of nasal polyps following surgical removal, and improve nasal symptoms. Short courses of oral corticosteroids are also recommended. Endoscopic surgical intervention may be considered as an adjunct to medical therapy in patients with chronic rhinosinusitis that is not responsive or is poorly responsive to medical therapy. Dupixent is listed as a treatment option in the JTFPP practice parameter, but with no specific recommendations for use. The AAO guidelines do not address Dupixent.

The European Forum for Research and Education in Allergy expert board on uncontrolled severe CRSwNP and biologics (2021) recommends that these agents, including Dupixent, only be used for severe uncontrolled CRSwNP when Type 2 inflammation is present.<sup>21</sup> Severe CRSwNP is defined as bilateral CRSwNP with a nasal polyp score  $\geq 4$  and persistent symptoms (e.g., loss of smell/taste, nasal obstruction, secretion or postnasal drip, facial pain or pressure) with the need for add-on treatment to supplement intranasal corticosteroids. Severe CRSwNP is considered to be uncontrolled if the patient has received continuous treatment with an intranasal corticosteroid and has needed at least one course of systemic corticosteroids in the previous 2 years (or has a medical contraindication or intolerance) and/or has a previous sinonasal surgery.

### *Prurigo Nodularis Guidelines*

A United States Expert Panel Consensus provides a practical approach for the diagnosis and management of prurigo nodularis (2021).<sup>31</sup> The primary findings in patients with prurigo nodularis are the presence of firm, nodular lesions; pruritus lasting at least 6 weeks; and or signs, or both, of repeated scratching, picking, or rubbing. Goals of treatment are to reduce pruritus, interrupt the itch-scratch cycle, and completely heal prurigo nodularis lesions.

## **POLICY STATEMENT**

Prior Authorization is recommended for prescription benefit coverage of Dupixent. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Dupixent as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Dupixent to be prescribed by or in consultation with a physician who specializes in the condition being treated.

**Automation:** None.

## **RECOMMENDED AUTHORIZATION CRITERIA**

Coverage of Dupixent is recommended in those who meet one of the following criteria:

### FDA-Approved Indications

- 1. Asthma.** Approve for the duration noted if the patient meets one of the following conditions (A or B):
  - A) Initial Therapy.** Approve for 6 months if the patient meets the following criteria (i, ii, iii, iv, and v):
    - i.** Patient is  $\geq 6$  years of age; AND
    - ii.** Patient meets ONE of the following criteria (a or b):
      - a)** Patient has a blood eosinophil level  $\geq 150$  cells per microliter within the previous 6 weeks or within 6 weeks prior to treatment with Dupixent or another monoclonal antibody therapy that may lower blood eosinophil levels; OR  
Note: Examples of monoclonal antibody therapies that may lower blood eosinophil levels include Dupixent, Adbry (tralokinumab-ldrm subcutaneous injection), Cinqair (reslizumab intravenous injection), Fasentra (benralizumab subcutaneous injection), Nucala (mepolizumab subcutaneous injection), Tezspire (tezepelumab subcutaneous injection), and Xolair (omalizumab subcutaneous injection).
      - b)** Patient has oral (systemic) corticosteroid-dependent asthma according to the prescriber (e.g., the patient has received  $\geq 5$  mg oral prednisone or equivalent per day for  $\geq 6$  months); AND
    - iii.** Patient has received at least 3 consecutive months of combination therapy with BOTH of the following (a and b):
      - a)** An inhaled corticosteroid; AND
      - b)** At least one additional asthma controller or asthma maintenance medication; AND  
Note: Examples of additional asthma controller or asthma maintenance medications are inhaled long-acting beta<sub>2</sub>-agonists, inhaled long-acting muscarinic antagonists, leukotriene receptor antagonists, and monoclonal antibody therapies for asthma (e.g., Cinqair, Fasentra, Nucala, Tezspire, and Xolair). Use of a combination inhaler containing both an inhaled corticosteroid and additional asthma controller/maintenance medication(s) would fulfil the requirement for both criteria a and b.
    - iv.** Patient has asthma that is uncontrolled or was uncontrolled at baseline as defined by ONE of the following (a, b, c, d, or e):  
Note: “Baseline” is defined as prior to receiving Dupixent or another monoclonal antibody therapy for asthma. Examples of monoclonal antibody therapies for asthma include Dupixent, Cinqair, Fasentra, Nucala, Tezspire, and Xolair.
      - a)** Patient experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year; OR
      - b)** Patient experienced one or more asthma exacerbation(s) requiring a hospitalization, an emergency department visit, or an urgent care visit in the previous year; OR
      - c)** Patient has a forced expiratory volume in 1 second (FEV<sub>1</sub>)  $< 80\%$  predicted; OR
      - d)** Patient has an FEV<sub>1</sub>/forced vital capacity (FVC)  $< 0.80$ ; OR
      - e)** Patient has asthma that worsens upon tapering of oral (systemic) corticosteroid therapy; AND
    - v.** The medication is prescribed by or in consultation with an allergist, immunologist, or pulmonologist.
  - B) Patient is Currently Receiving Dupixent.** Approve for 1 year if the patient meets the following criteria (i, ii, and iii):
    - i.** Patient has already received at least 6 months of therapy with Dupixent; AND  
Note: A patient who has received  $< 6$  months of therapy or who is restarting therapy with Dupixent should be considered under criterion 1A (Asthma, Initial Therapy).
    - ii.** Patient continues to receive therapy with one inhaled corticosteroid or one inhaled corticosteroid-containing combination inhaler; AND
    - iii.** Patient has responded to therapy as determined by the prescriber.

Note: Examples of a response to Dupixent therapy are decreased asthma exacerbations; decreased asthma symptoms; decreased hospitalizations, emergency department visits, or urgent care visits due to asthma; decreased requirement for oral corticosteroid therapy.

**2. Atopic Dermatitis.** Approve for the duration noted if the patient meets one of the following conditions (A or B):

- A) Initial Therapy.** Approve for 4 months if the patient meets the following criteria (i, ii, iii, and iv):
- i.** Patient is  $\geq$  6 months of age; AND
  - ii.** Patient has atopic dermatitis involvement estimated to be  $\geq$  10% of the body surface area according to the prescriber; AND
  - iii.** Patient meets ALL of the following criteria (a, b, and c):
    - a)** Patient has tried at least one medium-, medium-high, high-, and/or super-high-potency prescription topical corticosteroid; AND
    - b)** This topical corticosteroid was applied daily for at least 28 consecutive days; AND
    - c)** Inadequate efficacy was demonstrated with this topical corticosteroid therapy, according to the prescriber; AND
  - iv.** The medication is prescribed by or in consultation with an allergist, immunologist, or dermatologist.
- B) Patient is Currently Receiving Dupixent.** Approve for 1 year if the patient meets the following criteria (i and ii):
- i.** Patient has already received at least 4 months of therapy with Dupixent; AND  
Note: A patient who has received < 4 months of therapy or who is restarting therapy with Dupixent should be considered under criterion 2A (Atopic Dermatitis, Initial Therapy).
  - ii.** Patient has responded to therapy as determined by the prescriber.  
Note: Examples of a response to Dupixent therapy are marked improvements in erythema, induration/papulation/edema, excoriations, and lichenification; reduced pruritus; decreased requirement for other topical or systemic therapies; reduced body surface area affected with atopic dermatitis; or other responses observed.

**3. Eosinophilic Esophagitis.** Approve for the duration noted if the patient meets one of the following conditions (A or B):

- A) Initial Therapy.** Approve for 6 months if the patient meets the following criteria (i, ii, iii, iv, v, vi and vii):
- i.** Patient is  $\geq$  12 years of age; AND
  - ii.** Patient weighs  $\geq$  40 kg; AND
  - iii.** Patient has a diagnosis of eosinophilic esophagitis as confirmed by an endoscopic biopsy demonstrating  $\geq$  15 intraepithelial eosinophils per high-power field; AND
  - iv.** Patient does not have a secondary cause of eosinophilic esophagitis; AND  
Note: Examples of secondary causes of eosinophilic esophagitis are hypereosinophilic syndrome, eosinophilic granulomatosis with polyangiitis, and food allergy.
  - v.** Patient has received at least 8 weeks of therapy with a proton pump inhibitor; AND
  - vi.** Patient meets ONE of the following (a or b):
    - a)** Patient has tried dietary modifications to treat/manage eosinophilic esophagitis; OR
    - b)** The provider has determined that the patient is not an appropriate candidate for dietary modifications; AND  
Note: Examples of dietary modifications to treat eosinophilic esophagitis include an elemental diet or an elimination diet.
  - vii.** The medication is prescribed by or in consultation with an allergist or gastroenterologist.
- B) Patient is Currently Receiving Dupixent.** Approve for 1 year if the patient meets the following criteria (i and ii):

- i. Patient has already received at least 6 months of therapy with Dupixent; AND  
Note: A patient who has received < 6 months of therapy or who is restarting therapy with Dupixent should be considered under criterion 3A (Eosinophilic Esophagitis, Initial Therapy).
  - ii. Patient has experienced a beneficial clinical response, defined by ONE of the following (a, b, or c):
    - a) Reduced intraepithelial eosinophil count; OR
    - b) Decreased dysphagia/pain upon swallowing; OR
    - c) Reduced frequency/severity of food impaction.
4. **Nasal Polyps.** Approve for the duration noted if the patient meets one of the following conditions (A or B):
- A) Initial Therapy. Approve for 6 months if the patient meets the following criteria (i, ii, iii, iv, v, and vi):
- i. Patient is  $\geq 18$  years of age; AND
  - ii. Patient has chronic rhinosinusitis with nasal polyposis as evidenced by direct examination, endoscopy, or sinus computed tomography (CT) scan; AND
  - iii. Patient has experienced two or more of the following symptoms for at least 6 months: nasal congestion, nasal obstruction, nasal discharge, and/or reduction/loss of smell; AND
  - iv. Patient meets BOTH of the following (a and b):
    - a) Patient has received at least 3 months of therapy with an intranasal corticosteroid; AND
    - b) Patient will continue to receive therapy with an intranasal corticosteroid concomitantly with Dupixent; AND
  - v. Patient meets ONE of the following (a, b, or c):
    - a) Patient has received at least one course of treatment with a systemic corticosteroid for 5 days or more within the previous 2 years; OR
    - b) Patient has a contraindication to systemic corticosteroid therapy; OR
    - c) Patient has had prior surgery for nasal polyps; AND
  - vi. The medication is prescribed by or in consultation with an allergist, immunologist, or an otolaryngologist (ear, nose, and throat [ENT] physician specialist).
- B) Patient is Currently Receiving Dupixent. Approve for 1 year if the patient meets the following criteria (i, ii, and iii):
- i. Patient has already received at least 6 months of therapy with Dupixent; AND  
Note: A patient who has received < 6 months of therapy or who is restarting therapy with Dupixent should be considered under criterion 3A (Nasal Polyps, Initial Therapy).
  - ii. Patient continues to receive therapy with an intranasal corticosteroid; AND
  - iii. Patient has responded to therapy as determined by the prescriber.  
Note: Examples of a response to Dupixent therapy are reduced nasal polyp size, improved nasal congestion, reduced sinus opacification, decreased sinonasal symptoms, improved sense of smell.

- 5. Prurigo Nodularis.** Approve for the duration noted if the patient meets one of the following conditions (A or B):
- A) Initial Therapy.** Approve for 6 months if the patient meets the following criteria (i, ii, iii, iv, v, and vi):
- i.** Patient is  $\geq$  18 years of age; AND
  - ii.** Patient has  $\geq$  20 identifiable nodular lesions in total on both arms, and/or both legs, and/or trunk; AND
  - iii.** Patient has experienced pruritus for  $\geq$  6 weeks; AND
  - iv.** Patient meets ONE of the following (a or b):
    - a)** Patient’s prurigo nodularis is NOT medication-induced or secondary to a non-dermatologic condition such as neuropathy or a psychiatric disease; OR
    - b)** The patient has a secondary cause of prurigo nodularis that has been identified and adequately managed, according to the prescriber; AND
  - v.** Patient meets ALL of the following criteria (a, b, and c):
    - a)** Patient has tried at least one high- or super-high-potency prescription topical corticosteroid; AND
    - b)** This topical corticosteroid was applied daily for at least 14 consecutive days; AND
    - c)** Inadequate efficacy was demonstrated with this topical corticosteroid therapy, according to the prescriber; AND
  - vi.** The medication is prescribed by or in consultation with an allergist, immunologist, or dermatologist.
- B) Patient is Currently Receiving Dupixent.** Approve for 1 year if the patient meets the following criteria (i and ii):
- i.** Patient has already received at least 6 months of therapy with Dupixent; AND  
Note: A patient who has received < 6 months of therapy or who is restarting therapy with Dupixent should be considered under criterion 5A (Prurigo Nodularis, Initial Therapy).
  - ii.** Patient has experienced a beneficial clinical response, defined by ONE of the following (a, b, or c):
    - a)** Reduced nodular lesion count; OR
    - b)** Decreased pruritus; OR
    - c)** Reduced nodular lesion size.

#### CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Dupixent is not recommended in the following situations:

- 1. Concurrent use with another Monoclonal Antibody Therapy.** The efficacy and safety of Dupixent in combination with other monoclonal antibody therapies (e.g., Adbry, Cinqair, Fasenna, Nucala, Tezspire, Xolair) have not been established.
- 2.** Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

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