PRIOR AUTHORIZATION POLICY

POLICY: Immunologicals – Dupixent Prior Authorization Policy
- Dupixent® (dupilumab subcutaneous injection – Regeneron/sanofi-aventis)

REVIEW DATE: 04/19/2024

OVERVIEW

Dupixent, an interleukin-4 receptor alpha antagonist, is indicated for the following uses:[1]
Asthma, as an add-on maintenance treatment in patients ≥ 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 ≥ 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 ≥ 1 year of age who weigh ≥ 15 kg.
Prurigo nodularis, in patients ≥ 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.2-5 In atopic dermatitis, the majority of studies evaluated the efficacy of Dupixent at 16 weeks.1,6-10 The pivotal studies involving patients with CRSwNP evaluated the primary efficacy endpoints following 24 weeks of treatment.1,11-13 Patients continued treatment with intranasal corticosteroids throughout the studies.

In Dupixent's eosinophilic esophagitis pivotal study, patients ≥ 12 years of age were required to have disease confirmed by baseline endoscopic biopsies with a demonstration of eosinophilic infiltration on central reading (peak cell count ≥ 15 eosinophils per high-powered field) that was unresponsive to an 8 week course of treatment with a high-dose proton pump inhibitor.14 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. A very similarly designed pivotal study evaluated the efficacy of Dupixent for the treatment of eosinophilic esophagitis in patients 1 to 11 years of age.1 Endoscopic biopsy evidence of eosinophilic infiltration despite treatment with a proton pump inhibitor was again required for study enrollment.

Two pivotal studies, PRIME and PRIME2, evaluated Dupixent's efficacy in the treatment of prurigo nodularis.15,16 To enroll, patients were required to have ≥ 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 (2023) proposes a stepwise approach to asthma treatment.17 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.18,19 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:
Poor symptom control: Asthma Control Questionnaire consistently ≥ 1.5 or Asthma Control Test < 20; OR
Frequent severe exacerbations: two or more bursts of systemic corticosteroids in the previous year; OR
Serious exacerbations: at least one hospitalization, intensive care unit stay, or mechanical ventilation in the previous year; OR
Airflow limitation: FEV1 < 80% predicted after appropriate bronchodilator witholding.

Atopic Dermatitis Guidelines
Guidelines for the care and management of atopic dermatitis (with topical therapies in adults [2022], with phototherapy and systemic agents [2023]) have been updated to address Dupixent.20,21 The guidelines note that despite the availability of newer, systemic therapies (e.g., Dupixent), topical agents remain the mainstay of treatment due to their proven track record and favorable safety profiles. Several topical agents are recommended, with topical corticosteroids commonly used first-line for mild to severe atopic dermatitis in all skin regions. If topical therapy and basic management (e.g., moisturizers, bathing modifications) have been optimized and the patient has not achieved adequate control, consider an alternative diagnosis or systemic therapy. In this setting, use of Dupixent is recommended in patients with moderate to severe disease (strong recommendation).

Chronic Rhinosinusitis with Nasal Polyps Guidelines
The The Joint Task Force on Practice Parameters (JTFPP) published a focused guideline update for the medical management of CRSwNP (2023), which updated recommendations regarding intranasal corticosteroids and biologic therapies.22 Intranasal corticosteroids are recommended for the treatment of CRSwNP. Use of biologics (e.g., Dupixent) is also recommended. However, in patients who derived a sufficient benefit from other therapies such as intranasal corticosteroids, surgery, or aspirin therapy after desensitization, biologics may not be preferred. Conversely, biologics may be preferred over other medical treatment options in patients who continue to have a high burden of disease despite receiving at least 4 weeks of treatment with an intranasal corticosteroid.

The diagnosis of CRSwNP was not addressed in this focused guideline update, but previous guidelines have noted that 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.23-26 However, this requires confirmation of sinonasal inflammation, which can either be done via direct visualization or computed tomography (CT) scan. Oral corticosteroids and surgical intervention were not specifically addressed in this update, but prior guidelines recommend short courses of oral corticosteroid as needed and consideration of surgical removal as an adjunct to medical therapy in patients with CRSwNP that is not responsive or is poorly responsive to medical therapy.23,24,26

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.27 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.

Prurigo Nodularis Guidelines
A United States Expert Panel Consensus provides a practical approach for the diagnosis and management of prurigo nodularis (2021).28 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

Asthma. Approve for the duration noted if the patient meets one of the following (A or B):
Initial Therapy. Approve for 6 months if the patient meets the following (i, ii, iii, iv, and v):
Patient is ≥ 6 years of age; AND
Patient meets ONE of the following (a or b):
Patient has a blood eosinophil level ≥ 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 infusion), Fasenra (benralizumab subcutaneous injection), Nucala (mepolizumab subcutaneous injection), Tezspire (tezepelumab subcutaneous injection), and Xolair (omalizumab subcutaneous injection).
Patient has oral (systemic) corticosteroid-dependent asthma according to the prescriber (e.g., the patient has received ≥ 5 mg oral prednisone or equivalent per day for ≥ 6 months); AND
Patient has received at least 3 consecutive months of combination therapy with BOTH of the following (a and b):
An inhaled corticosteroid; AND
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 beta2-agonists, inhaled long-acting muscarinic antagonists, and monoclonal antibody therapies for asthma (e.g., Cinqair, Fasenra, Nucala, Tezspire, and Xolair). Use of a combination inhaler containing both an inhaled corticosteroid and additional asthma controller/maintenance medication(s) would fulfill the requirement for both criteria a and b.
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, Fasenra, Nucala, Tezspire, and Xolair.
Patient experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year; OR
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
Patient has a forced expiratory volume in 1 second (FEV1) < 80% predicted; OR
Patient has an FEV1/forced vital capacity (FVC) < 0.80; OR
Patient has asthma that worsens upon tapering of oral (systemic) corticosteroid therapy; AND
The medication is prescribed by or in consultation with an allergist, immunologist, or pulmonologist.
Patient is Currently Receiving Dupixent. Approve for 1 year if the patient meets the following (i, ii, and iii):
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).
Patient continues to receive therapy with one inhaled corticosteroid or one inhaled corticosteroid-containing combination inhaler; AND
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.

Atopic Dermatitis. Approve for the duration noted if the patient meets one of the following (A or B):
Initial Therapy. Approve for 4 months if the patient meets the following (i, ii, iii, and iv):
Patient is ≥ 6 months of age; AND
Patient has atopic dermatitis involvement estimated to be ≥ 10% of the body surface area according to the prescriber; AND
Patient meets ALL of the following (a, b, and c):
Patient has tried at least one medium-, medium-high, high-, and/or super-high-potency prescription topical corticosteroid; AND
This topical corticosteroid was applied daily for at least 28 consecutive days; AND
Inadequate efficacy was demonstrated with this topical corticosteroid therapy, according to the prescriber; AND
The medication is prescribed by or in consultation with an allergist, immunologist, or dermatologist.
Patient is Currently Receiving Dupixent. Approve for 1 year if the patient meets the following (i and ii):
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).
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.

Chronic Rhinosinusitis with Nasal Polyps. Approve for the duration noted if the patient meets one of the following (A or B):
Initial Therapy. Approve for 6 months if the patient meets the following (i, ii, iii, iv, v, and vi):
Patient is ≥ 18 years of age; AND
Patient has chronic rhinosinusitis with nasal polyps as evidenced by direct examination, endoscopy, or sinus computed tomography (CT) scan; AND
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
Patient meets BOTH of the following (a and b):
Patient has received at least 4 weeks of therapy with an intranasal corticosteroid; AND
Patient will continue to receive therapy with an intranasal corticosteroid concomitantly with Dupixent; AND
Patient meets ONE of the following (a, b, or c):
Patient has received at least one course of treatment with a systemic corticosteroid for 5 days or more within the previous 2 years; OR
Patient has a contraindication to systemic corticosteroid therapy; OR
Patient has had prior surgery for nasal polyps; AND
The medication is prescribed by or in consultation with an allergist, immunologist, or an otolaryngologist (ear, nose, and throat [ENT] physician specialist).
Patient is Currently Receiving Dupixent. Approve for 1 year if the patient meets the following (i, ii, and iii):
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).
Patient continues to receive therapy with an intranasal corticosteroid; AND
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.

Eosinophilic Esophagitis. Approve for the duration noted if the patient meets one of the following (A or B):
Initial Therapy. Approve for 6 months if the patient meets the following (i, ii, iii, iv, v, vi and vii):
Patient is ≥ 1 year of age; AND
Patient weighs ≥ 15 kg; AND
Patient has a diagnosis of eosinophilic esophagitis as confirmed by an endoscopic biopsy demonstrating ≥ 15 intraepithelial eosinophils per high-power field; AND
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.

Patient has received at least 8 weeks of therapy with a proton pump inhibitor; AND
Patient meets ONE of the following (a or b):
Patient has tried dietary modifications to treat/manage eosinophilic esophagitis; OR
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.
The medication is prescribed by or in consultation with an allergist or gastroenterologist.
Patient is Currently Receiving Dupixent. Approve for 1 year if the patient meets the following (i and ii):
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).
Patient has experienced a beneficial clinical response, defined by ONE of the following (a, b, or c):
Reduced intraepithelial eosinophil count; OR
Decreased dysphagia/pain upon swallowing; OR
Reduced frequency/severity of food impaction.

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

Conditions Not Recommended for Approval
Coverage of Dupixent is not recommended in the following situations:

Concurrent Use of Dupixent with another Monoclonal Antibody Therapy. The efficacy and safety of Dupixent in combination with other monoclonal antibody therapies have not been established.
Note: Monoclonal antibody therapies are Adbry® (tralokinumab-ldrm subcutaneous injection), Cinqair® (reslizumab intravenous injection), Fasenra® (benralizumab subcutaneous injection), Nucala® (mepolizumab subcutaneous injection), Teszpire® (tezepelumab-ekko subcutaneous injection), or Xolair® (omalizumab subcutaneous injection).

Concurrent Use of Dupixent with Janus Kinase (JAK) Inhibitors (oral or topical). Use of JAK inhibitors is not recommended for use in combination with other JAK inhibitors, biologic immunomodulators (e.g., Dupixent), or with other immunosuppressants.29-31
Note: Examples of JAK inhibitors are Cibinqo® (abrocitinib tablets), Rinvoq® (upadacitinib tablets), and Opzelura™ (ruxolitinib cream).

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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