Commercial PA Criteria

Effective: November 7th, 2018

Prior Authorization: Dupixent® (dupilumab injection)

Products Affected: Dupixent (dupilumab injection) prefilled syringe and pen-injector

Covered 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.
2. **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.
3. **Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP)** [i.e., nasal polyps], as an add-on maintenance treatment in adults with inadequately controlled disease.
4. **Eosinophilic Esophagitis** in patients ≥ 1 year of age who weigh ≥ 15 kg.
5. **Prurigo Nodularis** in patients ≥ 18 years of age.
6. **Chronic obstructive pulmonary disease (COPD)**, as add-on maintenance treatment in patients ≥ 18 years of age with inadequately controlled disease and an eosinophilic phenotype.
   Limitation of Use: Dupixent is not indicated for the relief of acute bronchospasm.

Exclusion Criteria:

1. Relief of acute bronchospasm or status asthmaticus
2. Concurrent Use of Dupixent with another Monoclonal Antibody Therapy
3. Concurrent Use of Dupixent with Janus Kinase (JAK) Inhibitors (oral or topical). Use of JAK inhibitors are not recommended for use in combination with other JAK inhibitors, biologic immunomodulators (e.g., Dupixent), or with other immunosuppressants.
   Note: Examples of JAK inhibitors are Cibinqo® (abrocitinib tablets), Leqselvi™ (deuruxolitinib tablets), Rinvoq®/Rinvoq® LQ (upadacitinib extended-release tablets and oral solution), and Opzelura™ (ruxolitinib cream).

Required Medical Information:

1. Diagnosis
2. Previous therapies tried with dates of treatment
3. Percentage of body surface area (BSA) affected
4. Physician chart notes

Age Restrictions:

1. Asthma: Patient must be 6 years of age and older
2. Atopic dermatitis: Patient must be 6 months and older.
3. Chronic Obstructive Pulmonary Disease: Patient must be 18 years of age and older.
4. Chronic Rhinosinusitis with Nasal Polyps: Patient must be 18 years of age and older
5. Eosinophilic Esophagitis: Patient must be 1 years and older
6. Prurigo Nodularis: Patient must be 18 years of age and older

Prescriber Restrictions: Dupixent must be prescribed in consultation with an allergist, immunologist, dermatologist, gastroenterologist, pulmonologist, or otolaryngologist

Coverage Duration:
Initial*:* 4months - 12 months (see specific criteria)
Continuation: 1 year

Other Criteria:

1. **Asthma.** Approve for the duration noted if the patient meets the following
   A. Initial Therapy. Approve for 6 months if patient meets the following (I, ii, iii **AND** iv):
      i. Patient meets one of the following criteria; (a **OR** b)
         a. 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).
         b. 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**
      ii. 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$_2$-agonists, inhaled long-acting muscarinic antagonists, leukotriene receptor antagonists, anti-interleukin-5 therapies (e.g., Cinqair, Fasenra, Nucala), and theophylline. Use of a combination inhaler containing both an inhaled corticosteroid and a long-acting beta$_2$-agonist would fulfil the requirement for both criteria i and ii.
      iii. Patient has asthma that is uncontrolled or was uncontrolled at baseline as defined by **ONE** of the following (i, ii, iii, iv, or v):
      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.
         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 hospitalization or an emergency department visit in the previous year; **OR**
         c. Patient has a forced expiratory volume in 1 second (FEV_1) < 80% predicted; **OR**
         d. Patient has an FEV_1/forced vital capacity (FVC) < 0.80; **AND**
         e. Patient has asthma that worsens upon tapering of oral corticosteroid therapy
   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 Initial Therapy criterion

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 or emergency department visits due to asthma; decreased requirement for oral corticosteroid therapy.

2. Atopic Dermatitis. Approve for the duration noted if the patient meets the following (A or B)

A. Initial Therapy. Approve for 4 months if the patient meets the following (i, **AND** ii):

i. Patient has atopic dermatitis involvement estimated to be ≥ 10% of the body surface area according to the prescriber; **AND**

ii. Patient meets ALL of the following (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

B. Patient is Currently Receiving Dupixent. Approve for 1 year if the patient meets the following (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 Initial Therapy criterion

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. Chronic Obstructive Pulmonary Disease (COPD). Approve for the duration noted if the patient meets the following (A **or** B):

A. Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, iv, v, **and** vi):

i. Patient is ≥ 18 years of age; **AND**

ii. Patient meets ONE of the following (a **or** b):

a. Patient has a blood eosinophil level ≥ 300 cells per microliter within the previous 6 weeks; **OR**

b. Patient 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; **AND**
Note: Examples of monoclonal antibody therapies that may alter blood eosinophil levels include Dupixent, Adbry (tralokinumab-ldrm subcutaneous injection), Cinqair (reslizumab intravenous infusion), Ebglyss (lebrikizumab-lbkz subcutaneous injection); Fasenra (benralizumab subcutaneous injection), Nemluvio (nemolizumab-ilto subcutaneous injection); Nucala (mepolizumab subcutaneous injection), Tezspire (tezepelumab subcutaneous injection), and Xolair (omalizumab subcutaneous injection).

iii. Patient meets ONE of the following (a **or** b):
   a. Patient has received at least 3 consecutive months of combination therapy with ALL of the following (1, 2, **and** 3):
      (1) Inhaled long-acting beta$_2$-agonist (LABA); **AND**
      (2) Inhaled long-acting muscarinic antagonist (LAMA); **AND**
      (3) Inhaled corticosteroid (ICS); **OR**
      Note: Use of single-entity inhalers or a combination inhaler containing multiple agents from the medication classes listed would fulfill the requirement.
   b. Patient meets BOTH of the following (1 **and** 2):
      (1) Patient has received at least 3 consecutive months of combination therapy with an inhaled LABA and an inhaled LAMA; **AND**
      Note: Use of single-entity inhalers or a combination inhaler containing multiple agents from the medication classes listed would fulfill the requirement.
      (2) According to the prescriber, the patient has a contraindication to the use of an inhaled corticosteroid; **AND**

iv. According to the prescriber, the patient has had signs or symptoms of chronic bronchitis (e.g., chronic productive cough) for ≥ 3 months in the previous 12 months; **AND**

v. Patient meets ONE of the following (a **or** b):
   a. Patient meets ALL of the following (1, 2, **AND** 3):
      (1) Patient experienced two or more COPD exacerbations requiring treatment with a systemic corticosteroid and/or an antibiotic in the previous 12 months; **AND**
      (2) One or more of these COPD exacerbations required treatment with a systemic corticosteroid; **AND**
      (3) One or more of these COPD exacerbations occurred while the patient was receiving combination therapy with an ICS, LAMA, and LABA or with a LAMA and LABA, if the patient has a contraindication to an ICS; **OR**
   b. Patient meets ALL of the following (1 **and** 2):
      (1) Patient experienced one or more COPD exacerbation(s) requiring a hospitalization in the previous 12 months; **AND**
      Note: A hospitalization includes a hospital admission or an emergency medical care visit with observation lasting > 24 hours.
      (2) One or more of these COPD exacerbations occurred while the patient was receiving combination therapy with an ICS, LAMA, and LABA or with a LAMA and LABA, if the patient has a contraindication to an ICS; **AND**

vi. 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 (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 Initial Therapy criterion

ii. Patient continues to receive combination therapy with an inhaled LABA and LAMA; **AND**
Note: Use of single-entity inhalers or a combination inhaler containing multiple agents from the medication classes listed would fulfill the requirement.

iii. Patient has experienced a beneficial clinical response, defined by ONE of the following (a, b, c, d, **OR** e):
   a. Reduced COPD symptoms; **OR**
   b. Reduced COPD exacerbations; **OR**
   c. Reduced COPD-related hospitalizations; **OR**
   d. Reduced emergency department or urgent care visits; **OR**
   e. Improved lung function parameters.

4. Chronic Rhinosinusitis with Nasal Polyps. Approve for the duration noted if the patient meets the following;

A. Initial Therapy. Approve for 6 months if the patient meets the following (i, ii, iii **AND** iv):
   i. Patient has chronic rhinosinusitis with nasal polyps as evidenced by direct examination, endoscopy, or sinus computed tomography **(**CT) scan; **AND**
   ii. 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**
   iii. Patient meets BOTH of the following (a **AND** b):
      a. Patient has received at least 4 weeks of therapy with an intranasal corticosteroid; **AND**
      b. Patient will continue to receive therapy with an intranasal corticosteroid concomitantly with Dupixent; **AND**
   iv. 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.

B. Patient is Currently Receiving Dupixent. Approve for 1 year if the patient meets the following (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 Initial therapy criterion.
   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. Eosinophilic Esophagitis. Approve for the duration noted if the patient meets the following;

A. Initial Therapy. Approve for 6 months if the patient meets the following (i, ii, iii, iv, v, vi **AND** vii):
   i. Patient weighs ≥ 15 kg; **AND**
   ii. Patient has a diagnosis of eosinophilic esophagitis as confirmed by an endoscopic biopsy demonstrating ≥ 15 intraepithelial eosinophils per high-power field; **AND**
   iii. 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.
   iv. Patient has received at least 8 weeks of therapy with a proton pump inhibitor; **AND**
   v. 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.

B. Patient is Currently Receiving Dupixent. Approve for 1 year if the patient meets the following (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 Initial Therapy criterion
   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.

6. Prurigo Nodularis. Approve for the duration noted if the patient meets the following;
A. Initial Therapy. Approve for 6 months if the patient meets the following (i, ii, iii, iv, v, **AND** vi):
   i. Patient has ≥ 20 identifiable nodular lesions in total on both arms, and/or both legs, and/or trunk; **AND**
   ii. Patient has experienced pruritus for ≥ 6 weeks; **AND**
   iii. 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**
   iv. Patient meets ALL of the following (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
B. Patient is Currently Receiving Dupixent. Approve for 1 year if the patient meets the following (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 Initial Therapy criterion
   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.

References:

1. Dupixent® subcutaneous injection [prescribing information]. Tarrytown, NY: Regeneron/Sanofi-Aventis; September 2024.
2. Product Information: DUPIXENT® subcutaneous injection, dupilumab subcutaneous injection. Regeneron Pharmaceuticals Inc (per FDA), Tarrytown, NY, 2022.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	Updated Policy, new template, new indication	All	11/7/18

2	Policy Revision	Updated Age range to match FDA Label	All	3/15/19
3	Policy Update	Added new indication CRSwNP to match FDA Label	Covered Uses, Age Restrictions, Prescriber Restrictions, Other Criteria	6/28/2019
4	Policy update	Atopic dermatitis age updated to 6 years of age or older Removed exclusion criteria:1. Dupixent has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval in the following circumstances. 2. Pediatric patients, and 3. Not for use in combination with other biologics	Age restrictions Exclusion Criteria	6/10/2020
5	Policy update	Asthma- changed the age to 6 years and older Atopic Dermatitis- topical corticosteroid application changed from 30 days to 28 days, Asthma- Initiation criteria, Nasal Polyps- initiation criteria	Other Criteria, Age Restrictions	12/8/2021
6	Policy Update	Covered Uses: added eosinophilic esophagitis, Exclusion Criteria: removed Treatment naïve patients; Age Restrictions: added eosinophilic esophagitis 12 years or older; Prescriber Restrictions: added gastroenterologist; Other Criteria: added eosinophilic esophagitis	Covered Uses, Exclusion Criteria, Age Restrictions, Prescriber Restrictions, Other Criteria	7/13/2022
7	Policy Update	Atopic Dermatitis – updated to 6 months or older	Age restrictions	8/1/2022
8	Policy Update	Exclusion Criteria to include Concurrent use with another Monoclonal Antibody Therapy.	Exclusion Criteria	12/2022
9	Policy Update	Addition of Prurigo Nodularis to covered uses Addition of Concurrent use with JAK inhibitor for exclusion criteria Approval condition updated from “Nasal Polyps” to “Chronic Rhinosinusitis with Nasal Polyps”. Duration of the intranasal corticosteroid requirement was changed from 3 months to 4 weeks. Eosinophilic Esophagitis The age of approval was reduced from ≥ 12 years of age to ≥ 1 year of age. Additionally, the weight requirement was reduced from ≥ 40 kg to ≥ 15 kg.	Covered uses Exclusion Criteria Criteria	2/2024
10	Policy Update	Removed leukotriene receptor antagonists as an example of additional asthma controller or asthma maintenance medications.	Other Criteria	7/2024

11	Policy Update	Chronic Obstructive Pulmonary Disease: This condition and criteria for approval were added to the policy. New approval criteria for this indication were added that include an age requirement, an eosinophil requirement, a trial of inhaled therapies, a history of chronic bronchitis signs or symptoms, a history of COPD exacerbations, and specialist involvement. Conditions not Recommended for Approval, Concurrent Use of Dupixent with Janus Kinase (JAK) Inhibitors (oral or topical): Leqselvi™ (deuruxolitinib tablets) and Rinvoq® LQ (upadacitinib oral solution) were added as examples of JAK inhibitors.	Covered Uses, Exclusion Criteria, Age Restrictions, Other Criteria	12/2024