Commercial/Healthcare Exchange PA Criteria

Effective: November 7th, 2018

Prior Authorization: Dupixent® (dupilumab injection)

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

Covered Uses:

1. Atopic Dermatitis
2. Asthma
3. Chronic Rhinosinusitis with Nasal Polyposis
4. Eosinophilic Esophagitis

Exclusion Criteria:

1. Relief of acute bronchospasm or status asthmaticus
2. Concurrent use with another monoclonal antibody therapy

Required Medical Information:

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

Age Restrictions:

1. Atopic dermatitis: Patient must be 6 months and older.
2. Asthma: Patient must be 6 years of age and older
3. CRSwNP: Patient must be 18 years of age and older
4. Eosinophilic Esophagitis: Patient must be 12 years and older

Prescriber Restrictions: Dupixent must be prescribed in consultation with an Allergist, Immunologist, Dermatologist, Gastroenterologist, Pulmonologist, or Otolaryngologist

Coverage Duration: 12 months

Other Criteria:

I. Initial Criteria

1. **Asthma**. Approve if (A, B, C, and D):

A. Patient meets **ONE** of the following criteria (i or ii):

i. Patient has a blood eosinophil level ≥ 150 cells per microliter within the previous 6 weeks or within 6 weeks prior to treatment with any anti-interleukin therapy or Xolair; **OR**

Note: Examples of anti-interleukin therapies include Dupixent, Nucala (mepolizumab subcutaneous injection), Cinqair (reslizumab intravenous injection), and Fasenra (benralizumab subcutaneous injection).

ii. 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**

B. Patient has received at least 3 consecutive months of combination therapy with **BOTH** of the following (i and ii):

i. An inhaled corticosteroid; **AND**

ii. 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.

C. 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 any Dupixent or other anti-interleukin- 5 therapies (i.e., Cinqair, Fasenra, or Nucala).

i. Patient experienced **TWO** or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year; **OR**

ii. Patient experienced one or more asthma exacerbation(s) requiring hospitalization or an emergency department visit in the previous year; **OR**

iii. Patient has a forced expiratory volume in 1 second (FEV_1) < 80% predicted; **OR**

iv. Patient has an FEV_1/forced vital capacity (FVC) < 0.80; **OR**

v. Patient has asthma that worsens upon tapering of oral corticosteroid therapy; **AND**

D. The medication is prescribed by or in consultation with an allergist, immunologist, or pulmonologist.

II. Continuation Criteria

2. Patient is Currently Receiving Dupixent. Approve for 1 year if the patient meets the following criteria (A, B, and C):

A. 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).

B. Patient continues to receive therapy with one inhaled corticosteroid or one inhaled corticosteroid-containing combination inhaler; **AND**

C. 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.

III. Initial Criteria

3. **Atopic Dermatitis.** Approve if the patient meets the following criteria (A **and** B):

A. Patient meets **ONE** of the following (i **or** ii):

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

ii. Patient has atopic dermatitis involvement estimated to be **< 10% of the body** surface area according to the prescriber and meets **ALL** of the following criteria (a, b, c, **AND** d):
a. Patient has atopic dermatitis affecting ONLY the following areas: face, eyes/eyelids, skin folds, and/or genitalia; **AND**
b. Patient has tried tacrolimus ointment; **AND**
c. Tacrolimus ointment was applied daily for at least 28 consecutive days; **AND**
d. Inadequate efficacy was demonstrated with tacrolimus ointment, according to the prescriber; **AND**

B. The medication is prescribed by or in consultation with an allergist, immunologist, or dermatologist.

IV. Continuation Criteria

4. Patient is Currently Receiving Dupixent. Approve if the patient meets the following criteria (A **and** B):
A. 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).

B. 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.

V. Initial Criteria

5. **Nasal Polyps.** Approve if the patient meets the following criteria (A, B, C, D, **and** E):
A. Patient has chronic rhinosinusitis with nasal polyposis as evidenced by direct examination, endoscopy, or sinus computed **tomography (**CT) scan; **AND**
B. 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**
C. Patient meets BOTH of the following (i **and** ii):
i. Patient has received at least 3 months of therapy with an intranasal corticosteroid; **AND**
ii. Patient will continue to receive therapy with an intranasal corticosteroid concomitantly with Dupixent; **AND**
D. Patient meets ONE of the following (i, ii, **or** iii):
i. Patient has received at least one course of treatment with a systemic corticosteroid for 5 days or more within the previous 2 years; **OR**
ii. Patient has a contraindication to systemic corticosteroid therapy; **OR**
iii. Patient has had prior surgery for nasal polyps; **AND**
E. The medication is prescribed by or in consultation with an allergist, immunologist, or an otolaryngologist (ear, nose, and throat [ENT] physician specialist).

VI. Continuation Criteria

6. Patient is Currently Receiving Dupixent. Approve if the patient meets the following criteria (A, B, **and** C):

A. 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]).

B. Patient continues to receive therapy with an intranasal corticosteroid; **AND**

C. 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.

7. **Eosinophilic Esophagitis**

A. Initiation- (Approve if i, ii, iii, iv, and v)

i. Patient must weigh at least 40kg; **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. Continuation - 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 Initial 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.

References:

1. Dupixent [prescribing information]. Bridgewater, NJ: Sanofi Aventis; July 2017.

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
8	Policy Update	Exclusion Criteria to include Concurrent use with another Monoclonal Antibody Therapy.	Exclusion Criteria	12/2022
7	Policy Update	Atopic Dermatitis – updated to 6 months or older	Age restrictions	8/1/2022
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
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

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
3	Policy Update	Added new indication CRSwNP to match FDA Label	Covered Uses, Age Restrictions, Prescriber Restrictions, Other Criteria	6/28/2019
2	Policy Revision	Updated Age range to match FDA Label	All	3/15/19
1	New Policy	Updated Policy, new template, new indication	All	11/7/18