PRIOR AUTHORIZATION POLICY

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

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INSTRUCTIONS FOR USE

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CIGNA NATIONAL FORMULARY COVERAGE:

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.
- **Bullous pemphigoid,** for the treatment of patients ≥ 18 years of age.
- **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.

- **Chronic rhinosinusitis with nasal polyposis (CRSwNP)** [i.e., nasal polyps], as an add-on maintenance treatment in patients ≥ 12 years of age with inadequately controlled disease.
- **Chronic spontaneous urticaria**, in patients ≥ 12 years of age who remain symptomatic despite H_1 antihistamine treatment.
  Limitation of Use: Dupixent is not indicated for the treatment of other forms of urticaria.
- **Eosinophilic esophagitis**, in patients ≥ 1 year of age who weigh ≥ 15 kg.
- **Prurigo nodularis**, for the treatment of patients ≥ 18 years of age.

Clinical Efficacy

Asthma

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]

Atopic Dermatitis

In atopic dermatitis, the majority of studies evaluated the efficacy of Dupixent at 16 weeks.[1,6-10] There are data with Dupixent in patients ≥ 6 months of age. Additionally, one study evaluated Dupixent in patients ≥ 12 years of age with atopic dermatitis with moderate to severe hand and/or foot involvement.[1,44]

Bullous Pemphigoid

One pivotal study, evaluated Dupixent for the treatment of adults with moderate-to-severe bullous pemphigoid.[41,42]

Chronic Obstructive Pulmonary Disease

Two pivotal studies evaluated Dupixent in adults with COPD.[11,12] To be eligible for enrollment, patients had a blood eosinophil level ≥ 300 cells per microliter. Patients were required to have been receiving background triple inhaler therapy (i.e., an inhaled corticosteroid [ICS] with a long-acting muscarinic antagonist [LAMA] and a long-acting beta2-agonist [LABA]) or LAMA/LABA combination therapy if the patient had an ICS contraindication, for at least 3 months prior to randomization. Patients also had experienced at least two moderate COPD exacerbations (e.g., resulted in systemic corticosteroid treatment) or one severe COPD exacerbation (e.g., resulted in hospitalization for≥ 24 hours) the year prior to screening. Overall, at least one of the patient's exacerbations had to have occurred while they were receiving ICS/LAMA/LABA therapy (or a LAMA/LABA if the patient had an ICS contraindication). Patients were randomized to receive either Dupixent or placebo in addition to background maintenance therapy (i.e., ICS/LAMA/LABA triple therapy or LAMA/LABA therapy if the patient had an ICS contraindication) for 52 weeks. While lung function parameters were improved as early as Week 12 (3 months), the other major efficacy endpoints were evaluated at Week 52 (e.g., exacerbations, dyspnea scores).

Chronic Rhinosinusitis with Nasal Polyps

The pivotal studies involving patients with CRSwNP evaluated the primary efficacy endpoints following 24 weeks of treatment.[1,13-15] Patients continued treatment with intranasal corticosteroids throughout the studies.

Chronic Spontaneous Urticaria

The pivotal studies of Dupixent in patients with chronic spontaneous urticaria involved patients who were symptomatic despite H_1 antihistamine treatment at approved or higher doses.[16,38] In both studies, patients were required to have experienced itch and hives for >

6 consecutive weeks, despite treatment with an H_1 antihistamine up to 4 times a standard dose. The primary efficacy endpoints were evaluated following 24 weeks of treatment.

Eosinophilic Esophagitis
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.[17] 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.[1,18] Endoscopic biopsy evidence of eosinophilic infiltration despite treatment with a proton pump inhibitor was again required for study enrollment.

Prurigo Nodularis
Two pivotal studies, PRIME and PRIME2, evaluated Dupixent's efficacy in the treatment of prurigo nodularis.[19] 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 (2025) proposes a stepwise approach to asthma treatment.[20] Dupixent is listed as an option for add-on therapy in patients ≥ 6 years of age with severe eosinophilic/Type 2 asthma or who require treatment with a maintenance oral corticosteroid. Severe asthma is defined as asthma that is uncontrolled despite adherence to optimized high-dose ICS/LABA therapy or that worsens when high-dose treatment is decreased. 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 inhaled corticosteroid (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.[21,22] 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: forced expiratory volume in 1 second (FEV_1) < 80% predicted after appropriate bronchodilator withholding.

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.[23,24] 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).

Bullous Pemphigoid Guidelines
Guidelines for the management of bullous pemphigoid from the European Academy of Dermatology and Venereology (EADV) [2022] have not been updated since the approval of Dupixent for this indication.[43] However, Dupixent is a recommended treatment option.

Chronic Obstructive Pulmonary Disease Guidelines
The Global Initiative for Chronic Obstructive Lung Disease (GOLD) Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease (2025) recommends triple inhaled therapy with an ICS/LAMA/LABA combination in patients with a history of exacerbations and elevated eosinophils.[25] However, guidelines note that ICS therapy increases the risk of pneumonia in patients with COPD, particularly those with severe disease. Dupixent is a recommended treatment option in patients who continue to have symptoms despite ICS/LAMA/LABA therapy and have eosinophils ≥ 300 cells/microliter and symptoms of chronic bronchitis.
Chronic Rhinosinusitis with Nasal Polyps Guidelines
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.[26] 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.[27-30] 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.[27,28,30]

Chronic Spontaneous Urticaria Guidelines
Guidelines for the definition, classification, diagnosis, and management of urticaria have been published by the European Academy of Allergy and Clinical Immunology/Global Allergy

and Asthma European Network/European Dermatology Forum/Asia Pacific Association of Allergy, Asthma and Clinical Immunology (2022).[31] The American Academy of Dermatology was involved in the development of these guidelines and endorses their recommendations. Chronic spontaneous urticaria is defined as the appearance of wheals, angioedema, or both for > 6 weeks due to known or unknown causes. Signs and symptoms may be present daily/almost daily or have an intermittent recurrent course. Second generation H_1-antihistamines taken regularly are the recommended first-line treatment for all types of urticaria following elimination of possible underlying causes. If standard doses do not eliminate urticaria signs and symptoms, the dose of the antihistamine should be increased up to 4-fold. Guidelines have not been updated since the approval of Dupixent. Short courses of rescue systemic corticosteroids are recommended for treatment of patients with acute exacerbations of chronic urticaria. However, guidelines recommend against the long-term use of systemic steroids.

Eosinophilic Esophagitis Guidelines
Guidelines for the diagnosis and management of EoE from the American College of Gastroenterology (2025) confirm that the diagnosis of EoE should be based on the presence esophageal dysfunction symptoms and ≥ 15 eosinophils per high-power field on esophageal biopsy.[32] Treatment with a proton pump inhibitor is recommended. Dupixent is a recommended treatment for patients who are ≥ 1 year of age who are nonresponsive to proton pump inhibitor therapy. A food elimination diet is recommended. However, it is noted that patient preferences should be taken into account and that any decisions regarding diet should be agreed upon between the patient and the provider.

Prurigo Nodularis Guidelines
A United States Expert Panel Consensus provides a practical approach for the diagnosis and management of prurigo nodularis (2021).[33] The primary findings in patients with prurigo nodularis are the presence of firm, nodular lesions; pruritus lasting at least 6 weeks; and history 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.

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is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indications

1. **Asthma.** Approve for the duration noted if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, iv, and v):
     - **i.** Patient is ≥ 6 years of age; AND
     - **ii.** Patient meets ONE of the following (a or b):
       - **a)** Patient meets ONE of the following (1 or 2):
         - **(1)** Patient has a blood eosinophil level ≥ 150 cells per microliter within the previous 6 weeks; OR
         - **(2)** Patient had a blood eosinophil level ≥ 150 cells per microliter prior to treatment with Dupixent or another monoclonal antibody therapy that may alter blood eosinophil levels; OR
           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).
       - **b)** According to the prescriber, the patient has oral (systemic) corticosteroid-dependent asthma (e.g., the patient has received ≥ 5 mg oral prednisone or equivalent per day for ≥ 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$_2$-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.
     - **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, 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 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_1) < 80% predicted; OR
       - **d)** Patient has an FEV_1/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; OR

B) Patient is Currently Receiving Dupixent. Approve for 1 year if the patient meets ALL of 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 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 (A or B):

A) Initial Therapy. Approve for 4 months if the patient meets ALL of the following (i, ii, iii, and iv):
- **i.** Patient is ≥ 6 months of age; AND
- **ii.** Patient meets ONE of the following (a or b):
  - **a)** Patient has atopic dermatitis involvement estimated to be ≥ 10% of the body surface area; OR
  - **b)** Patient meets BOTH of the following (1 and 2):
    - **1)** Patient has moderate to severe hand and/or foot atopic dermatitis; AND
    - **2)** Patient is ≥ 12 years of age; AND
- **iii.** 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)** According to the prescriber, inadequate efficacy was demonstrated with this topical corticosteroid therapy; AND
- **iv.** The medication is prescribed by or in consultation with an allergist, immunologist, or dermatologist; OR

B) Patient is Currently Receiving Dupixent. Approve for 1 year if the patient meets BOTH of 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 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. Bullous Pemphigoid. Approve for the duration noted if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i and ii):
- **i.** Patient is ≥ 18 years of age; AND
- **ii.** The medication is prescribed by or in consultation with a dermatologist; OR

B) Patient is Currently Receiving Dupixent. Approve for 1 year if the patient meets BOTH of 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 criterion 3A (Bullous Pemphigoid, Initial Therapy).
- **ii.** Patient has experienced a beneficial clinical response, defined by ONE of the following (a, b, c, d, or e):
  - **a)** Decreased area of skin involvement; OR
  - **b)** Decreased lesions, including blisters or erosions (bullae); OR
  - **c)** Decreased urticaria, OR
  - **d)** Decreased erythema; OR
  - **e)** Reduced or no need for systemic or topical corticosteroid therapy.

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

A) Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, iv, and v):
- **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.** Patient meets ONE of the following (a or b):
  - **a)** Patient experienced two or more COPD exacerbations requiring treatment with a systemic corticosteroid with or without an antibiotic in the previous 12 months; OR

b) 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.

v. The medication is prescribed by or in consultation with an allergist, immunologist, or pulmonologist; OR

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 criterion 3A (Chronic Obstructive Pulmonary Disease, Initial Therapy).

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.

5. Chronic Rhinosinusitis with Nasal Polyps. Approve for the duration noted if the patient meets ONE of 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 ≥ 12 years of age; AND

ii. Patient has chronic rhinosinusitis with nasal polyps 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 4 weeks 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); OR

B) Patient is Currently Receiving Dupixent. Approve for 1 year if the patient meets ALL of 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 criterion 4A (Chronic Rhinosinusitis with 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.

6. Chronic Spontaneous Urticaria (Chronic Idiopathic Urticaria). Approve Dupixent for the duration noted if the patient meets ONE of the following (A or B):

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

i. Patient is ≥ 12 years of age; AND

ii. Patient has/had urticaria for > 6 weeks (prior to treatment with Dupixent), with symptoms present > 3 days per week despite daily non-sedating H_1 antihistamine therapy with doses that have been titrated up to a maximum of four times the standard FDA-approved dose; AND
Note: Examples of non-sedating H_1 antihistamine therapy are cetirizine, desloratadine, fexofenadine, levocetirizine, and loratadine.

iii. The medication is prescribed by or in consultation with an allergist, immunologist, or dermatologist; OR

B) Patient is Currently Receiving Dupixent. Approve Dupixent for 1 year if the patient meets BOTH 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 (Chronic Spontaneous Urticaria [Chronic Idiopathic Urticaria], Initial Therapy).

ii. Patient has experienced a beneficial clinical response, defined by ONE of the following (a, b, or c):

a) Decreased itch severity; OR

b) Decreased number of hives; OR

c) Decreased size of hives

7. Eosinophilic Esophagitis. Approve for the duration noted if the patient meets ONE of 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, vi and vii):

i. Patient is ≥ 1 year of age; AND

ii. Patient weighs ≥ 15 kg; AND

iii. Patient has a diagnosis of eosinophilic esophagitis as confirmed by an endoscopic biopsy demonstrating ≥ 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; OR

B) Patient is Currently Receiving Dupixent. Approve for 1 year if the patient meets BOTH of 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 criterion 6A (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.

8. Prurigo Nodularis. Approve for the duration noted if the patient meets ONE of 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 has ≥ 20 identifiable nodular lesions in total on both arms, and/or both legs, and/or trunk; AND
- **iii.** Patient has experienced pruritus for ≥ 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)** According to the prescriber, the patient has a secondary cause of prurigo nodularis that has been identified and adequately managed; AND
- **v.** 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)** According to the prescriber, inadequate efficacy was demonstrated with this topical corticosteroid therapy; AND
- **vi.** The medication is prescribed by or in consultation with an allergist, immunologist, or dermatologist; OR

B) Patient is Currently Receiving Dupixent. Approve for 1 year if the patient meets BOTH of 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 criterion 6A (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 COVERED

- **Dupixent® (dupilumab subcutaneous injection – Regeneron/Sanofi-Aventis)**

is(are) considered not medically necessary for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as newly published data are available):

1. **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), Ebglyss® (lebrikizumab-lbkz subcutaneous injection), Fasenra® (benralizumab subcutaneous injection), Nemluvio® (nemolizumab-ilto subcutaneous injection), Nucala® (mepolizumab subcutaneous injection), Tezspire® (tezepelumab-ekko subcutaneous injection), or Xolair® (omalizumab subcutaneous injection).

2. **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.[34-37]
   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).

3. **Peanut Allergy.** Dupixent is not indicated for the management of patients with peanut allergy.[1] One phase II, single-arm, open-label study evaluated Dupixent in children and adolescents with peanut allergy (n = 24).[39] Following 24 weeks of therapy, Dupixent monotherapy did not improve desensitization to peanut exposure after food challenge. Only 2 patients (8.3%) were able to achieve the primary endpoint of passing the 24-week double-blind placebo-controlled food challenge (DBPCFC) [≥ 444 mg {cumulative} of peanut protein]. Another 8 patients (33.3%) experienced a grade 2 allergic reaction at the 24-week DBPCFC and 10 patients (41.7%) used epinephrine rescue medication. An additional study (n = 128) evaluated whether Dupixent enhances the efficacy and safety of an oral immunotherapy product, Palforzia® (peanut [*Arachis hypogaea*] allergen powder-dnfp for oral administration), in patients 6 to ≤ 17 years of age with peanut allergy.[40] Patients received either Dupixent + Palforzia or placebo + Palforzia during a 28- to 40-week up-dosing period. Then, patients in the Dupixent + Palforzia group were re-randomized to receive Dupixent + Palforzia or placebo + Palforzia during a 24-week maintenance period. Following the up-dosing period, Dupixent + Palforzia resulted in a modest increase in efficacy vs. placebo + Palforzia (20.2% increase in the number of patients who passed a DBPCFC [2,044 mg peanut protein {cumulative}] with Dupixent + Palforzia vs. placebo + Palforzia). Similarly, during the maintenance period, Dupixent + Palforzia increased the number of patients who passed the DBPCFC (2,044 mg peanut protein [cumulative]) vs. placebo + Palforzia (16.6% treatment difference). However, Dupixent was not found to provide protection against Palforiza-related anaphylaxis, which occurred in 5.1% of patients receiving Dupixent + Palforzia and 4.0% of patients receiving placebo + Palforzia. Additional studies are needed to establish the efficacy of Dupixent for peanut allergy.

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HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Conditions Not Covered :** Criteria were updated to clarify that use of Dupixent with another monoclonal antibody therapy is specific to Cinqair, Fasenra, Nucala, Tezspire, Xolair, and Adbry.	03/22/2023
Selected Revision	**Conditions Not Covered :** Criteria were added for "Concurrent Use of Dupixent with Janus Kinase Inhibitors (JAKis) [oral or topical]".	05/10/2023
Selected Revision	**Chronic Rhinosinusitis with Nasal Polyps:** 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.	02/14/2024

HISTORY (CONTINUED)

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Asthma:** Removed leukotriene receptor antagonists as an example of additional asthma controller or asthma maintenance medications.	04/19/2024
Selected Revision	**Chronic Rhinosinusitis with Nasal Polyps:** The age of approval was changed from ≥ 18 years of age to ≥ 12 years of age. **Asthma:** Eosinophil level requirements were clarified to require a level ≥ 150 cells/microliter either within the previous 6 weeks OR prior to treatment with a monoclonal antibody that may alter eosinophil levels. Previously, criteria required a level ≥ 150 cells/microliter either within the previous 6 weeks OR within 6 weeks prior to treatment with a monoclonal antibody that may lower eosinophil levels. Throughout the policy, Ebglyss (lebrikizumab-lbkz subcutaneous injection) and Nemluvio (nemolizumab-ilto subcutaneous injection) were added to notes as examples of monoclonal antibody therapies.	09/25/2024
Selected Revision	**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 Covered , 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.	10/09/2024

Annual Revision	**Chronic Spontaneous Urticaria (Chronic Idiopathic Urticaria):** This condition and criteria for approval were added to the policy. New approval criteria for this indication were added that include an age requirement, a duration of symptom requirement, a trial of H_1 antihistamine therapy, and specialist involvement. **Conditions Not Covered** **, Peanut Allergy:** Peanut allergy was added to the "Conditions Not Covered".	04/23/2025
Selected Revision	**Chronic Obstructive Pulmonary Disease:** Criteria requiring the patient to have signs and symptoms of chronic bronchitis were removed. Exacerbation criteria were simplified to require the patient to have experienced two or more COPD exacerbations requiring treatment with a systemic corticosteroid with or without an antibiotic in the previous 12 months or one or more COPD exacerbations requiring a hospitalization in the previous 12 months. Previously, these criteria required that the patient experienced two or more COPD exacerbations requiring treatment with a systemic corticosteroid and/or an antibiotic in the previous 12 months and one or more of these exacerbations required treatment with a systemic steroid and one or more of these exacerbations occurred while the patient was receiving combination inhaled therapy. Previous criteria also required that one or more COPD exacerbations requiring a hospitalization in the previous 12 months had occurred while the patient was receiving combination inhaled therapy.	06/04/2025
Selected Revision	**Atopic Dermatitis:** Criteria were updated to require that the patient either has atopic dermatitis involvement estimated to be ≥ 10% of the body surface area OR the patient is ≥ 12 years of age and has moderate to severe hand and/or foot atopic dermatitis. Previously, criteria required that the patient have atopic dermatitis involvement estimated to be ≥ 10% of the body surface area. **Bullous Pemphigoid:** This condition and criteria for approval were added to the policy.	07/02/2025