MEDICAL MUTUAL®

Drug Policy

Policy:	**201704_MRx (01/23)**	**Initial Effective Date: 05/21/2017**
Code(s):	**HCPCS J3590, C9399**	**Annual Review Date: 04/17/2025**
SUBJECT:	**Dupixent® (dupilumab)**	**Last Revised Date: 04/17/2025**

☒Subject to Site of Care

Prior approval is required for some or all procedure codes listed in this Corporate Drug Policy.

Initial and renewal requests for the medication(s) listed in this policy are subject to site of care management. When billed under the medical benefit, administration of the medication will be restricted to a non-hospital facility-based location (i.e., home infusion provider, provider's office, free-standing ambulatory infusion center) unless the member meets the site of care exception criteria. To view the exception criteria and a list of medications subject to site of care management please click here.

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 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.
- **Eosinophilic esophagitis**, in patients ≥ 1 year of age who weigh ≥ 15 kg.
- **Prurigo nodularis**, in patients ≥ 18 years of age.

POLICY STATEMENT

This policy involves the use of Dupixent. Prior authorization is recommended for pharmacy benefit coverage of Dupixent. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

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 be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

Automation: None.

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

FDA-Approved Indications

1. **Asthma.** Approve for the duration noted if the patient meets ONE of the following (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.

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. According to the prescriber, the patient has atopic dermatitis involvement estimated to be ≥ 10% of the body surface area; AND

iii. Patient meets **two of the following three** conditions:

a) Patient did not respond adequately to (or is not a candidate for) a 3-month minimum trial of topical agents [e.g., corticosteroids, calcineurin inhibitors (e.g., tacrolimus or pimecrolimus), crisaborole, etc.]; OR

b) Patient did not respond adequately to (or is not a candidate for) a 3-month minimum trial of at least one (1) systemic agent (e.g., cyclosporine, azathioprine, methotrexate, mycophenolate mofetil, oral corticosteriods etc.); OR

c) Patient did not respond adequately to (or is not a candidate for) a 3-month minimum trial of phototherapy (e.g., Psoralens with UVA light (PUVA), UVB, etc.); AND
Note: Examples of contraindications to phototherapy (PUVA or UVB) include the following: Xeroderma pigmentosa; pregnancy or lactation (PUVA only); lupus erythematosus; immunosuppression in an organ transplant patient (UVB only); photosensitizing medications (PUVA only); severe liver, renal, or cardiac disease; age less than 12 years old (PUVA only); and history of photosensitivity diseases (e.g., chronic actinic dermatitis, solar urticaria), melanoma, non-melanoma skin cancer, extensive solar damage (PUVA only), or treatment with arsenic or ionizing radiation.

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

B) Patient is Currently Receiving Dupixent. Approve for 1 year if the patient meets 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. 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, 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 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.

4. 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 12 weeks: 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).

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.

5. 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, b, or c):
  - **a)** Patient has received at least 8 weeks of therapy of a topical (esophageal) corticosteroid; OR
    Note: Topical (esophageal) corticosteroids include fluticasone propionate metered dose inhaler swallowed instead of inhaled, budesonide inhalation swallowed instead of inhaled.
  - **b)** Patient has adrenal insufficiency; OR
  - **c)** Patient has a history of oral candidiasis; AND
- **vii.** 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.
- **viii.** The medication is prescribed by or in consultation with an allergist or gastroenterologist.

B) Patient is Currently Receiving Dupixent. Approve for 1 year if the patient meets 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 5A (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.

6. 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 ≥ 3 months; 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 two of the following three conditions:
  - **a)** Patient did not respond adequately to (or is not a candidate for) a 3-month minimum trial of topical agents [e.g., corticosteroids, calcineurin inhibitors (e.g., tacrolimus or pimecrolimus), crisaborole, etc.]; OR
  - **b)** Patient did not respond adequately to (or is not a candidate for) a 3-month minimum trial of at least one (1) systemic agent (e.g., cyclosporine, azathioprine, methotrexate, mycophenolate mofetil, oral corticosteriods etc.); OR
  - **c)** Patient did not respond adequately to (or is not a candidate for) a 3-month minimum trial of phototherapy (e.g., Psoralens with UVA light (PUVA), UVB, etc.); AND
    Note: Examples of contraindications to phototherapy (PUVA or UVB) include the following: Xeroderma pigmentosa; pregnancy or lactation (PUVA only); lupus erythematosus; immunosuppression in an organ transplant patient (UVB only); photosensitizing medications (PUVA only); severe liver, renal, or cardiac disease; age less than 12 years old (PUVA only); and history of photosensitivity diseases (e.g., chronic actinic dermatitis, solar urticaria), melanoma, non-melanoma skin cancer, extensive solar damage (PUVA only), or treatment with arsenic or ionizing radiation.
- **vi.** The medication is prescribed by or in consultation with an allergist, immunologist, or dermatologist.

B) Patient is Currently Receiving Dupixent. Approve for 1 year if the patient meets 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.

Uses with Supportive Evidence

7. **Management of Immune Checkpoint Inhibitor Related Toxicity.** Approve for 6 months if the patient meets both of the following (A or B):
   - **C)** Patient has been receiving therapy with an immune checkpoint inhibitor (e.g. nivolumab, pembrolizumab, atezolizumab, avelumab, durvalumab, cemiplimab, ipilimumab, nivolumab/relatlimab-rmbw, etc.); AND
   - **D)** Patient has refractory and severe (i.e., grade 3: intense or widespread, constant, limiting self-care activities of daily living or sleep) pruritus.

CONDITIONS NOT RECOMMENDED FOR APPROVAL
Coverage of Dupixent is not recommended in the following situations:

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), Teszpire® (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.[29-31,35]
   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. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Dosage/Administration

Indication	Dose
Atopic Dermatitis	**Dosing in Pediatric Patients:** Patients 6 months to 5 years of age: • *Body weight 5 to < 15 kg:* Administer 200 mg (one 200 mg injection) subcutaneously every 4 weeks • *Body weight 15 to < 30 kg*: Administer 300 mg (one 300 mg injection) subcutaneously every 4 weeks ***Note:** No initial loading dose is recommended for patients 6 months to 5 years of age* Patients 6 to 17 years of age • *Body weight 15 to < 30 kg:* Administer 600 mg (two 300 mg injections in different sites) subcutaneously initially, followed by 300 mg subcutaneously every 4 weeks

Indication	Dose
	• *Body weight 30 to < 60 kg*: Administer 400 mg (two 200 mg injections in different sites) subcutaneously initially, followed by 200 mg subcutaneously every other week • *Body weight ≥ 60 kg*: Administer 600 mg (two 300 mg injections in different sites) subcutaneously initially, followed by 300 mg subcutaneously every other week **Dosing in Adult Patients** Administer 600 mg (two 300 mg injections in different sites) subcutaneously initially, followed by 300 mg subcutaneously every other week
Pediatric Asthma (Eosinophilic) OR Asthma with co-morbid Atopic Dermatitis	Dosing in Pediatric Patients (patients 6 to 11 years of age) • *Body weight 15 to < 30 kg* – Administer 100 mg subcutaneously every other week OR 300 mg subcutaneously every 4 weeks • *Body weight ≥ 30 kg*: – Administer 200 mg subcutaneously every other week Dosing in Asthma with co-morbid Atopic Dermatitis Pediatric Patients (6 to 11 years of age) • *Body weight 15 to < 30 kg* – Administer 600 mg (two 300 mg injections in different sites) subcutaneously initially, followed by 300 mg subcutaneously every 4 weeks • *Body weight 30 to < 60 kg*: – Administer 400 mg (two 200 mg injections in different sites) subcutaneously initially, followed by 200 mg subcutaneously every other week • *Body weight ≥ 60 kg*: – Administer 600 mg (two 300 mg injections in different sites) subcutaneously initially, followed by 300 mg subcutaneously every other week
Adult and Pediatric Asthma (Eosinophilic) OR Oral Corticosteroid-Dependent Asthma OR Asthma with co-morbid Atopic Dermatitis	Dosing in Eosinophilic Asthma in Adult and Pediatric Patients (12 years of age and older) • Administer 400 mg (two 200 mg injections in different sites) subcutaneously initially, followed by 200 mg subcutaneously every other week; **OR** • Administer 600 mg (two 300 mg injections in different sites) subcutaneously initially, followed by 300 mg subcutaneously every other week Dosing in Oral Corticosteroid-Dependent Asthma OR Asthma with co-morbid Atopic Dermatitis in Adult and Pediatric Patients (12 years of age and older)

Indication	Dose
	• Administer 600 mg (two 300 mg injections in different sites) subcutaneously initially, followed by 300 mg subcutaneously every other week
Chronic Rhinosinusitis with Nasal Polyps	Administer 300 mg subcutaneously every other week.
Eosinophilic Esophagitis	Recommended dosing in Adults and Pediatric patients 1 year and older, weighing at least 15kg: • *Body weight 15 to < 30 kg:* Administer 200 mg subcutaneously every other week • *Body weight 30 to < 40 kg*: Administer 300 mg subcutaneously every other week • *Body weight > 40 kg:* Administer 300 mg subcutaneously every week
Prurigo Nodularis	Administer 600 mg (two 300 mg injections in different sites) subcutaneously initially, followed by 300 mg subcutaneously every other week
Management of Immune Checkpoint Inhibitor-Related Toxicity	Administer 600 mg (two 300 mg injections in different sites) subcutaneously initially, followed by 300 mg subcutaneously every other week **Must ONLY be administered by a health care provider.
Dupixent is administered by subcutaneous injection and is intended for use under the guidance of a healthcare provider. Provide proper training to patients and/or caregivers on the preparation and administration of Dupixent prior to use according to the "Instructions for Use". – The pre-filled pen is for use in adult and pediatric patients aged 2 years and older. – The pre-filled syringe is for use in adult and pediatric patients aged 6 months and older. – A caregiver or patient 12 years of age and older may inject Dupixent using the pre-filled syringe or pre-filled pen. – In pediatric patients 12 to 17 years of age, administer under the supervision of an adult. – In pediatric patients 6 months to less than 12 years of age, administer by a caregiver.	

Billing Code/Availability Information

HCPCS Code:

- J3590 – Unclassified biologic
- C9399 – Unclassified drugs or biologicals (*Hospital Outpatient Use ONLY*)

NDC(s):

- Dupixent 300 mg/2 mL single-dose pre-filled syringe with needle shield (2-pack): 00024-5914-xx

- Dupixent 200 mg/1.14 mL single-dose pre-filled syringe with needle shield (2-pack): 00024-5918-xx
- Dupixent 100 mg/0.67 mL single-dose pre-filled syringe with needle shield (2-pack): 00024-5911-xx
- Dupixent 300 mg/2 mL single-dose pre-filled Pen (2-pack): 00024-5915-xx
- Dupixent 200 mg/1.14 mL single-dose pre-filled Pen (2-pack): 00024-5919-xx

References

1. Dupixent® subcutaneous injection [prescribing information]. Tarrytown, NY: Regeneron/sanofi-aventis; September 2024.
2. Castro M, Corren J, Pavord ID, et al. Dupilumab efficacy and safety in moderate-to-severe uncontrolled asthma. *N Engl J Med*. 2018;378(26);2486-2496.
3. Wenzel S, Castro M, Corren J, et al. Dupilumab efficacy and safety in adults with uncontrolled persistent asthma despite use of medium-to-high-dose inhaled corticosteroids plus a long-acting β2 agonist: a randomised double-blind placebo-controlled pivotal phase 2b dose-ranging trial. *Lancet*. 2016;388(10039):31-44.
4. Rabe KF, Nair P, Brusselle G, et al. Efficacy and safety of dupilumab in glucocorticoid-dependent severe asthma. *N Engl J Med*. 2018;378(26):2475-2485.
5. Bacharier LB, Maspero JF, Katelaris CH, et al. Dupilumab in children with uncontrolled moderate-to-severe asthma. *N Engl J Med*. 2021;385(24):2230-2240.
6. Simpson EL, Bieber T, Guttman-Yassky E, et al. Two phase 3 trials of dupilumab versus placebo in atopic dermatitis. *N Engl J Med*. 2016;375(24):2335-2348.
7. Blauvelt A, de Bruin-Weller M, Gooderham M, et al. Long-term management of moderate-to-severe atopic dermatitis with dupilumab and concomitant topical corticosteroids (LIBERTY AD CHRONOS): a 1-year, randomised, double-blinded, placebo-controlled, phase 3 trial. *Lancet*. 2017;389:2287-2303.
8. Simpson EL, Paller AS, Siegfried EC, et al. Efficacy and safety of dupilumab in adolescents with uncontrolled moderate to severe atopic dermatitis: a phase 3 randomized clinical trial. *JAMA Dermatol*. 2020;156(1):44-56.
9. Paller AS, Siegfried EC, Thaci D, et al. Efficacy and safety of dupilumab with concomitant topical corticosteroids in children 6 to 11 years old with severe atopic dermatitis: a randomized, double-blinded, placebo-controlled phase 3 trial. *J Am Acad Dermatol*. 2020;83(5):1282-1293.
10. Paller AS, Simpson EL, Siegfried EC, et al. Dupilumab in children aged 6 months to younger than 6 years with uncontrolled atopic dermatitis: a randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet*. 2022;400:908-919.
11. Bachert C, Han JK, Desrosiers M, et al. Efficacy and safety of dupilumab in patients with severe chronic rhinosinusitis with nasal polyps (LIBERTY NP SINUS-24 and LIBERTY NP SINUS-52): results from two multicenter, randomized, double-blind, placebo-controlled, parallel-group phase3 trials. *Lancet*. 2019;394(10209):1638-1650.
12. Bachert C, Mannent L, Naclerio RM, et al. Effect of subcutaneous dupilumab on nasal polyp burden in patients with chronic sinusitis and nasal polyposis: a randomized clinical trial. *JAMA*. 2016;315(5):469-479.
13. Jonstam K, Swanson BN, Mannent L, et al. Dupilumab reduces local type 2 pro-inflammatory biomarkers in chronic rhinosinusitis with nasal polyposis. *Allergy*. 2019;74(4):743-752.
14. Dellon ES, Rothenberg ME, Collins MH, et al. Dupilumab in adults with adolescents with eosinophilic esophagitis. *N Engl J Med*. 2022;387(25):2317-2330.
15. Yosipovich G, Mollanazar N, Stander S, et al. Dupilumab significantly improves itch and skin lesions in patients with prurigo nodularis: results from a 2nd Phase III trial (LIBERTY-PN PRIME) [presentation]. Presented at: the European Academy of Dermatology and Venereology; Milan, Italy; September 7-10, 2022.
16. Yosipovich G, Mollanazar N, Stander S, et al. Dupilumab significantly improves itch and skin lesions in patients with prurigo nodularis: results from a Phase III trial (LIBERTY-PN PRIME 2) [presentation]. Presented at: the 2022 Annual Meeting of the American Academy of Dermatology; Boston, MA; March 25-29, 2022.
17. Global Initiative for Asthma. Global strategy for asthma management and prevention. Updated 2022. Available at: http://www.ginasthma.org. Accessed on April 10, 2024.
18. Chung KF, Wenzel SE, Brozek JL, et al. International ERS/ATS guidelines on definition, evaluation and treatment of severe asthma. *Eur Respir J*. 2014;43:343-373.

19. Holguin F, Cardet JC, Chung KF, *et al*. Management of severe asthma: a European Respiratory Society/American Thoracic Society Guideline. *Eur Respir J*. 2020;55:1900588.
20. Davis DMR, Drucker AM, Alikhan A, et al. Guidelines of care for the management of atopic dermatitis in adults with phototherapy and systemic therapies. *J Am Acad Dermatol*. 2024;90(2):e43-e56.
21. Sidbury R, Alikhan A, Cohen DE, et al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies. *J Am Acad Dermatol*. 2023;89(e1-e20).
22. Rank MA, Chu DK, Bognanni A, et al. Joint Task Force on Practice Parameters GRADE guidelines for the medical management of chronic rhinosinusitis with nasal polyposis. *J Allergy Clin Immunol*. 2023;151(2):386-398.
23. Peters AT, Spector S, Hsu J, et al. Diagnosis and management of rhinosinusitis: a practice parameter update. *Ann Allergy Asthma Immunol.* 2014:347-385.
24. Dykewicz MS, Wallace DV, Baroody F, et al. Treatment of seasonal allergic rhinitis: an evidenced-based focused 2017 guideline update. *Ann Allergy Asthma Immunol.* 2017;119(6):489-511.
25. Rosenfeld RM, Piccirillo JF, Chandrasekhar SS, et al. Clinical practice guideline (update): adult sinusitis. *Otolaryngol Head Neck Surg*. 2015;152(2S):S1-S39.
26. Joint Task Force on Practice Parameters: American Academy of Allergy, Asthma and Immunology and the American College of Allergy, Asthma and Immunology. Rhinitis 2020: a practice parameter update. *J Allergy Clin Immunol.* 2020;146:721-767.
27. Hirano I, Chan ES, Rank MA, et al. AGA Institute and Joint Task Force on Allergy-Immunology Practice Parameters Clinical Guidelines for the Management of Eosinophilic Esophagitis. *Gastroenterology*. 2020;158(6):1776-1786.
28. Elmariah S, Kim B, Berger T, et al. Practical approaches for diagnosis and management of prurigo nodularis: United States expert panel consensus. *J Am Acad Dermatol*. 2021;84(3):747-760.
29. Cibinqo® tablets [prescribing information]. New York, NY: Pfizer; February 2023.
30. Rinvoq® extended-release tablets/Rinvoq® LQ oral solution [prescribing information]. North Chicago, IL: AbbVie; April 2024.
31. Opzelura® cream [prescribing information]. Wilmington, DE: Incyte; January 2023.
32. Bhatt SP, Rabe KF, Hanania NA, et al. Dupilumab for COPD with type 2 inflammation indicated by eosinophil counts. *N Engl J Med*. 2023;289(3):205-214.
33. Bhatt SP, Rabe KF, Hanania NA, et al. Dupilumab for COPD with blood eosinophil evidence of type 2 inflammation. *N Engl J Med*. 2024;390(24):2274-2283.
34. Global Initiative for Chronic Obstructive Lung Disease. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease. National Institutes of Health, National Heart, Lung, and Blood Institute; 2024. Available at: https://goldcopd.org/gold-reports/. Accessed on September 30, 2024.
35. Leqselvi™ tablets [prescribing information]. Whippany, NJ: Sun/Halo; July 2024.

Documentation Requirements:
The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

FOR MEDICAL BENEFIT COVERAGE REQUESTS:
Prior approval is required for HCPCS Codes J3590 and C9399

†When *unclassified biologics* (J3590) or *unclassified drugs or biologicals* (C9399) is determined to be Dupixent

Edits and Denials:

Prior approval: Prior approval is required for Dupilumab **(HCPCS Codes J3590, C9399)**. Requests for prior approval will be authorized by a nurse reviewer if submitted documentation meets criteria outlined within the Corporate Medical Policy.

Requests for prior approval will be forwarded to a qualified physician reviewer if submitted documentation does not meet criteria outlined within Corporate Medical Policy.

TOPPS: Claims received with **HCPCS Codes J3590, C9399** will pend with **Remark Code M3M or M4M** and will be adjudicated in accordance with the Corporate Medical Policy.

Liability: A participating provider will be required to write off charges denied as not medically necessary.