MEDICAL MUTUAL®

Drug Policy

Policy:	**201704_MRx (01/23)**	**Initial Effective Date: 05/21/2017**
Code(s):	**HCPCS J3590, C9399**	**Annual Review Date: 11/21/2023**
SUBJECT:	**Dupixent® (dupilumab)**	**Last Revised Date: 11/21/2023**

☒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.

I. Length of Authorization

Coverage will be provided for 6 months and may be renewed (unless otherwise specified).

- Management of Immune Checkpoint Inhibitor-Related Toxicity may NOT be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Dupixent 300 mg prefilled single-use syringe and pen (2-pack): 1 kit every 14 days
- Dupixent 200 mg prefilled single-use syringe and pen (2-pack): 1 kit for initial loading dose, then 1 kit every 28 days
- Dupixent 100 mg single-use prefilled syringe (2-pack): 1 kit every 28 days

B. Max Units (per dose and over time) [HCPCS Unit]:

CRSwNP

- 300 mg every other week

Eosinophilic Esophagitis

- 300 mg every week

All Other Indications

- 600 mg initial loading dose, followed by 300 mg every other week

III. Initial Approval Criteria

Coverage is provided in the following conditions:

Universal Criteria [1]

- Will not be administered concurrently with live vaccines; **AND**
- Will not be used in combination with other anti-immunoglobulin E (IgE), anti-IL4, or anti-IL5 monoclonal antibody (e.g., omalizumab, mepolizumab, reslizumab, benralizumab, etc.); **AND**

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) † [1,15,16]

- Patient is at least 18 years of age; **AND**
- Patient has bilateral symptomatic sino-nasal polyposis with symptoms lasting at least 8 weeks; **AND**
- Patient has at least four (4) of the following indicators for biologic treatment *[Note: Patients with a history of sino-nasal surgery are only required to have at least three (3) of the indicators]*:
  - Patient has evidence of type 2 inflammation (i.e., biological biomarkers indicating immune dysregulation and epithelial barrier dysfunction)
  - Patient has required two or more short courses of systemic corticosteroids within the previous year
  - Disease significantly impairs the patient's quality of life
  - Patient has experienced significant loss of smell
  - Patient has a comorbid diagnosis of asthma; **AND**
- Patient does not have any of the following:
  - Antrochoanal polyps
  - Nasal septal deviation that would occlude at least one nostril
  - Disease with lack of signs of type 2 inflammation
  - Cystic fibrosis
  - Mucoceles; **AND**
- Other causes of nasal congestion/obstruction have been ruled out (e.g., acute sinusitis, nasal infection or upper respiratory infection, rhinitis medicamentosa, tumors, infections, granulomatosis, etc.); **AND**
- Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**
- Therapy will be used in combination with intranasal corticosteroids unless not able to tolerate or is contraindicated

Atopic Dermatitis (AD) † [1-8,11,12,16,17,22]

- Patient is at least 6 months of age; **AND**
- Patient has moderate-to-severe atopic dermatitis (AD) with at least 1 of the following:
  - Involvement of at least 10% of body surface area (BSA); **OR**
  - Eczema Area and Severity Index (EASI) score of 16 or greater; **OR**
  - Investigator's Global Assessment (IGA) score of 3 or more; **OR**
  - Scoring Atopic Dermatitis (SCORAD) score of 25 or more; **OR**
  - Incapacitation due to AD lesion location (i.e. head and neck, palms, soles or genitalia); **AND**
  - Two of the following 3 conditions must be met:
    - Patient did not respond adequately (or is not a candidate) to a 3-month minimum trial of topical agents [e.g., corticosteroids, calcineurin inhibitors (e.g., tacrolimus or pimecrolimus), crisaborole, etc.]; **OR**
    - Patient did not respond adequately (or is not a candidate) to a 3-month minimum trial of at least one (1) systemic agent (e.g., cyclosporine, azathioprine, methotrexate, mycophenolate mofetil, oral corticosteriods etc.); **OR**
    - Patient did not respond adequately (or is not a candidate******) to a 3-month minimum trial of phototherapy (e.g., Psoralens with UVA light (PUVA), UVB, etc.)

Asthma † [1,9,10,13,14,29]

- Patient is at least 6 years of age; **AND**
- Patient has moderate to severe***** disease; **AND**
  - Patient must have asthma with an eosinophilic phenotype and a baseline blood eosinophil count of ≥ 150 cells/mcL; **OR**
  - Patient has oral corticosteroid dependent asthma; **AND**
- Must be used for add-on maintenance treatment in patients regularly receiving BOTH of the following**:**
  - Medium to high-dose inhaled corticosteroids; **AND**
  - An additional controller medication (e.g., long-acting beta agonist, leukotriene receptor antagonist, etc.); **AND**
- Baseline measurement of at least one of the following for assessment of clinical status:
  - Use of systemic corticosteroids
  - Use of inhaled corticosteroids
  - Number of hospitalizations, ER visits, or unscheduled visits to healthcare provider due to condition

- Forced expiratory volume in 1 second (FEV_1); **AND**

- Will not be used for treatment of acute bronchospasm or status asthmaticus

Eosinophilic Esophagitis (EoE) † Φ [1,19-21]

- Patient is at least 12 years of age and weighs at least 40 kg; **AND**
- Patient has a documented diagnosis of EoE as evidenced by at least 15 intraepithelial eosinophils per high-power field (eos/hpf), or 60 eosinophils/mm^2 on endoscopic biopsy; **AND**
- Patient has a history of an average of at least two (2) episodes of dysphagia, with intake of solids, per week; **AND**
- Other causes of esophageal eosinophilia have been ruled out (i.e., active helicobacter pylori infection, hypereosinophilic syndrome and eosinophilic granulomatosis with polyangiitis, Crohn's disease, ulcerative colitis, celiac disease, achalasia, etc.)

Prurigo Nodularis (PN) † [1,26-28]

- Patient is at least 18 years of age; **AND**
- Patient has had a diagnosis of prurigo nodularis (PN) for at least (3) three-months; **AND**
- Patient's disease is not secondary to medications or medical conditions (i.e., neuropathy or psychiatric disease); **AND**
- Patient has an average worst itch score of at least 7 or greater on the Worst Itch Numeric Rating Scale (WI-NRS 0-10); **AND**
- Patient has at least 20 prurigo nodularis lesions, in total, on legs, arms and/or trunk; **AND**
- Patient did not respond adequately to a two-week trial of topical corticosteroids, unless not medically advisable

Management of Immune Checkpoint Inhibitor Related Toxicity ‡ [24,25]

- Patient has been receiving therapy with an immune checkpoint inhibitor (e.g. nivolumab, pembrolizumab, atezolizumab, avelumab, durvalumab, cemiplimab, ipilimumab, nivolumab/relatlimab-rmbw, etc.); **AND**
- Patient has refractory and severe (i.e., grade 3: intense or widespread, constant, limiting self-care activities of daily living or sleep) pruritus

**Examples of contraindications to phototherapy (PUVA or UVB) include the following: [11,12,23]
– Xeroderma pigmentosum – Pregnancy or lactation *(PUVA only)* – Lupus Erythematosus

– History of one of the following: 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 – Immunosuppression in an organ transplant patient*(UVB only)* – Photosensitizing medications *(PUVA only)* – Severe liver, renal, or cardiac disease *(PUVA only)* – Young age < 12 years old *(PUVA only)*

***Components of severity for classifying asthma as moderate may include any of the following (not all**
• Daily symptoms • Nighttime awakenings > 1x/week but not nightly • SABA use for symptom control occurs daily • Some limitation to normal activities • Lung function (percent predicted FEV_1) >60%, but <80% • Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to mild asthma
***Components of severity for classifying asthma as severe may include any of the following (not all inclusive):[9,13]**
• Symptoms throughout the day • Nighttime awakenings, often 7x/week • SABA use for symptom control occurs several times daily • Extremely limited in normal activities • Lung function (percent predicted FEV_1) <60% • Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to moderate asthma

† FDA Approved Indication(s); ‡ Compendia recommended indication(s); **Φ** Orphan Drug

IV. Renewal Criteria [1-5]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet universal and other indication-specific relevant criteria as identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: hypersensitivity reactions, conjunctivitis, keratitis, immunogenicity, arthralgia, parasitic (helminth) infection, eosinophilic conditions (e.g. vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy, especially upon reduction of oral corticosteroids). etc.; **AND**

Chronic Rhinosinusitis w/ Nasal Polyps [1,15]

- Disease response as indicated by improvement in signs and symptoms compared to baseline in one or more of the following: nasal/obstruction symptoms, improvement of sinus opacifications as assessed by CT-scans and/or an improvement on a disease activity scoring tool [e.g., nasal polyposis score (NPS), nasal congestion (NC) symptom severity score, sino-nasal outcome test-22 (SNOT-22), etc.]; **OR**
- Patient had an improvement in at least one (1) of the following response criteria:
    - Reduction in nasal polyp size
    - Reduction in need for systemic corticosteroids
    - Improvement in quality of life
    - Improvement in sense of smell
    - Reduction of impact of comorbidities

Atopic Dermatitis [1-8,11,12,16,17,22]

- Disease response as indicated by improvement in signs and symptoms compared to baseline in one or more of the following: pruritus, the amount of surface area involvement, EASI, IGA, and/or SCORAD

Asthma [1,9,10,13,14,29]

- Improvement in asthma symptoms or asthma exacerbations as evidenced by decrease in one or more of the following:
    - Use of systemic corticosteroids
    - Two-fold or greater decrease in inhaled corticosteroid use for at least 3 days
    - Hospitalizations
    - ER visits
    - Unscheduled visits to healthcare provider; **OR**
- Improvement from baseline in forced expiratory volume in 1 second (FEV_1)

Eosinophilic Esophagitis [1,19,20]

- Disease response as indicated by improvement in signs and symptoms compared to baseline in one or more of the following: dysphagia/swallowing pain, including chest pain, stomach pain, heartburn, regurgitation, and vomiting; **OR**
- Patient is in histologic remission defined as a peak esophageal intraepithelial eosinophil count of ≤6 eos/hpf

Prurigo Nodularis [1,26,27]

- Disease response as indicated by improvement (reduction) in signs and symptoms compared to baseline in one or more of the following: pruritus severity, number of lesions, and/or WI-NRS

Management of Immune Checkpoint Inhibitor-Related Toxicity [24,25]

- May not be renewed

V. Dosage/Administration [1,24,25]

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 • *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*:

Indication	Dose
	– Administer 200 mg subcutaneously every other week <u>Dosing in Asthma with co-morbid Atopic Dermatitis Pediatric Patients (6 to 11 years of age)</u> • *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	<u>Dosing in Eosinophilic Asthma in Adult and Pediatric Patients (12 years of age and older)</u> • 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 <u>Dosing in Oral Corticosteroid-Dependent Asthma OR Asthma with co-morbid Atopic Dermatitis in Adult and Pediatric Patients (12 years of age and older)</u> • Administer 600 mg (two 300 mg injections in different sites) subcutaneously initially, followed by 300 mg subcutaneously every other week
Adult Asthma with co-morbid Chronic Rhinosinusitis with Nasal Polyps	<u>Dosing in Adult Patients (18 years of age and older)</u> • Administer 600 mg (two 300 mg injections in different sites) subcutaneously initially, followed by 300 mg subcutaneously every other week

Indication	Dose
Chronic Rhinosinusitis with Nasal Polyps	Administer 300 mg subcutaneously every other week.
Eosinophilic Esophagitis	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.

VI. 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

VII. References

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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.