Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: **Dupixent® (dupilumab)**

Effective: February 1, 2025

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Dupixent (dupilumab) is an interleukin-4 receptor alpha agonist indicated:

- **Asthma**
  As add-on maintenance treatment in patients with moderate-to-severe asthma aged 6 years and older with an eosinophilic phenotype or with oral corticosteroid dependent asthma. Dupixent is not indicated for the relief of acute bronchospasm or status asthmaticus.
- **Atopic dermatitis**
  For the treatment of patients aged 6 months and older with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Dupixent can be used with or without topical corticosteroids.
- **Chronic obstructive pulmonary disease (COPD)**
  As an add-on maintenance treatment of adult patients with inadequately controlled COPD and an eosinophilic phenotype. Limitations of use: Not for relief of acute bronchospasm.
- **Chronic rhinosinusitis with nasal polyps (CRSwNP)**
  As add-on maintenance treatment in adult and pediatric patients aged 12 years and older with inadequately controlled CRSwNP.
- **Eosinophilic Esophagitis**
  For the treatment of adult and pediatric patients aged 1 year and older, weighing at least 15 kg, with eosinophilic esophagitis
- **Prurigo Nodularis (PN)**
  For the treatment of adult patients with PN

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Dupixent for Members when **ALL** of the following criteria are met:

Asthma

Initial Authorization Criteria

1. Documented diagnosis of moderate to severe asthma of eosinophilic phenotype or with corticosteroid dependent asthma as determined by **one (1)** of the following:
   a. An eosinophilic phenotype confirmed by a blood eosinophil level of at least 150 cells/mcL within the past 12 months

b. Oral corticosteroid-dependent asthma defined as chronic corticosteroid use for at least 6 months
c. Current treatment with an alternative biologic indicated for moderate to severe allergic eosinophilic asthma

AND

2. Patient is at least 6 years of age

AND

3. Prescribed by or in consultation with an allergist, immunologist, or pulmonologist

AND

4. Documentation the patient is currently maintained on a maximally tolerated inhaled corticosteroid plus at least one other asthma maintenance medication (e.g., long-acting inhaled beta2-agonist, long-acting muscarinic antagonist, leukotriene receptor antagonist

AND

5. The patient will not be concurrently treated with an alternative biologic for asthma

Reauthorization Criteria

1. Documented diagnosis of **one (1)** of the following:
   a. Moderate to severe asthma of eosinophilic phenotype
   b. Corticosteroid dependent asthma

AND

2. Patient is at least 6 years of age

AND

3. Prescribed by or in consultation with an allergist, immunologist, or pulmonologist

AND

4. Documentation the patient has experienced a therapeutic response as defined by **one (1)** of the following:
   a. Increase in percent predicted Forced Expiratory Volume (FEV1) from pretreatment baseline
   b. Reduction in the dose of inhaled corticosteroids required to control asthma
   c. Reduction in asthma exacerbations (e.g., decreased frequency of use of unscheduled emergency department/urgent care visits)
   d. Reduction in asthma symptoms (e.g., chest tightness, coughing, shortness of breath, or nocturnal awakenings)
   e. Reduction in the use of oral corticosteroids to treat and/or prevent asthma exacerbations

AND

5. The patient will not be concurrently treated with an alternative biologic for asthma

Atopic Dermatitis

Initial Authorization Criteria

1. Documented diagnosis of moderate to severe atopic dermatitis

AND

2. Documentation the patient's condition meets **one (1)** of the following:
   a. Body Surface Area (BSA) of at least 10%
   b. Eczema Area and Severity Index EASI score of at least 16
   c. Investigator's Global Assessment/Physician Global Assessment (IGA/PGA) score of at least 3

AND

3. Patient is at least 6 months of age

AND

4. Prescribed by or in consultation with a dermatologist, allergist, or immunologist

AND

5. Documentation of **one (1)** of the following:
   a. Inadequate response or adverse reaction to one (1) of the following: a medium or high potency topical corticosteroid, a calcineurin inhibitor, or crisaborole
   b. Contraindication to all of the following: medium and high potency topical corticosteroids, topical calcineurin inhibitors, and crisaborole

Reauthorization Criteria

1. Documented diagnosis of moderate to severe atopic dermatitis

AND

2. Patient is at least 6 months of age

AND

3. Prescribed by or in consultation with a dermatologist, allergist, or immunologist

AND

4. Documentation the patient has experienced a therapeutic response as defined by one (1) of the following:
    a. Reduction in body surface area involvement relative to pretreatment baseline
    b. Improvement in atopic dermatitis symptoms as evidenced by marked improvements in symptoms such as pruritus, xerosis, crusting, or lichenification
    c. Reduction in the use of other topical or systemic therapies

Chronic Obstructive Pulmonary Disease (COPD)

Initial Authorization Criteria

1. Documented diagnosis of chronic obstructive pulmonary disease (COPD)

AND

2. Patient is at least 18 years of age

AND

3. Prescribed by or in consultation with a pulmonologist

AND

4. Documentation of presence of Type 2 inflammation evidenced by blood eosinophils greater than or equal to 300 cells per microliter at baseline

AND

5. Documentation of one (1) of the following:
    a. The patient is currently maintained on a maximally tolerated triple therapy regimen with an inhaled corticosteroid, a long-acting muscarinic antagonist, and a long-acting beta agonist
    b. The patient has a contraindication to inhaled corticosteroids AND currently maintained on a maximally tolerated regimen with a long-acting muscarinic antagonist and a long-acting beta agonist

AND

6. Documentation of a post-bronchodilator forced expiratory volume (FEV_1) / forced vital capacity (FVC) ratio less than 0.70 while on an optimized therapy

AND

7. Documentation of one (1) of the following within the previous 12 months:
    a. At least two (2) moderate exacerbations defined as treatment with either systemic corticosteroids and/or antibiotics
    b. At least one (1) severe exacerbation defined as requiring hospitalization or observation for over 24 hours in an emergency department or urgent care facility

Reauthorization Criteria

1. Documented diagnosis of chronic obstructive pulmonary disease (COPD)

AND

2. Patient is at least 18 years of age

AND

3. Prescribed by or in consultation with a pulmonologist

AND

4. Documentation of one (1) of the following:
    a. The patient is currently maintained on a maximally tolerated triple therapy regimen with an inhaled corticosteroid, a long-acting muscarinic antagonist, and a long-acting beta agonist
    b. The patient has a contraindication to inhaled corticosteroids AND currently maintained on a maximally tolerated regimen with a long-acting muscarinic antagonist and a long-acting beta agonist

AND

5. Documentation the patient has experienced a therapeutic response as defined by one (1) of the following:
    a. Improved lung function

b. A reduction in chronic obstructive pulmonary disease (COPD) exacerbations

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

Initial Authorization Criteria

1. Documented diagnosis of chronic rhinosinusitis with nasal polyps

AND

2. Patient is at least 12 years of age

AND

3. Prescribed by or in consultation with an allergist, immunologist, or otolaryngologist

AND

4. Documented of **one (1)** of the following:
   a. Patient is concurrently treatment intranasal corticosteroids
   b. Contraindication to intranasal corticosteroids

AND

5. The patient will not be concurrently treated with an alternative biologic for nasal polyps

Reauthorization Criteria

1. Documented diagnosis of chronic rhinosinusitis with nasal polyps

AND

2. Patient is at least 12 years of age

AND

3. Prescribed by or in consultation with an allergist, immunologist, or otolaryngologist

AND

4. Documented of **one (1)** of the following:
   a. Patient is concurrently treated with intranasal corticosteroids
   b. Contraindication to intranasal corticosteroids

AND

5. Document the patient has experienced a therapeutic response as defined by at least **one (1)** of the following:
   a. Adequate sinus ventilation and drainage
   b. Control of mucosal inflammation and edema
   c. Reduction in exacerbations

AND

6. The patient will not be concurrently treated with an alternative biologic for nasal polyps

Eosinophilic Esophagitis

Initial Authorization Criteria

1. Documented diagnosis of eosinophilic esophagitis as evidenced by both of the following:
   a. Chronic symptoms of esophageal dysfunction (e.g., dysphagia, food impaction, food refusal, abdominal pain, heartburn, regurgitation, chest pain, odynophagia)
   b. Findings from esophageal biopsies (e.g., eosinophil-predominant inflammation)

AND

2. The patient is at least 1 year of age

AND

3. The patient weighs at least 15 kg

AND

4. Prescribed by or in consultation with an allergist, immunologist, or gastroenterologist

AND

5. Documentation of poor control requiring additional treatment despite an 8-week trial of a proton pump inhibitor, unless intolerant or contraindicated

Reauthorization Criteria

1. Documented diagnosis of eosinophilic esophagitis

AND

2. The patient is at least 1 year of age

AND

3. The patient weighs at least 15 kg

AND

4. Prescribed by or in consultation with an allergist, immunologist, or gastroenterologist

AND

5. Documentation the patient has experienced a therapeutic response as defined by at least one (1) of the following:
    a. Decreased peak esophageal intraepithelial eosinophil count from baseline
    b. Improvement in symptoms of esophageal dysfunction (e.g., dysphagia, pain upon swallowing, food impaction)

Prurigo Nodularis

Initial Authorization Criteria

1. Documented diagnosis of prurigo nodularis as evidenced by one of the following:
    a. All of the following:
        i. Prescence of firm, nodular lesions
        ii. Pruritis lasting at least six weeks
        iii. History and/or signs of repeated scratching, picking, or rubbing
    b. Skin biopsy confirming prurigo nodularis

AND

2. The patient is at least 18 years of age

AND

3. Prescribed by or in consultation with a dermatologist, allergist or immunologist

AND

4. Documentation of poor control requiring additional treatment despite a trial of a medium to super high potency topical corticosteroid, unless intolerant or contraindicated

Reauthorization Criteria

1. Documented diagnosis of prurigo nodularis

AND

2. The patient is at least 18 years of age

AND

3. Prescribed by or in consultation with a dermatologist allergist or immunologist

AND

4. Documentation the patient has experienced a therapeutic response as defined by at least one (1) of the following:
    a. An improvement in symptoms of prurigo nodularis (e.g., itching)
    b. Clearing of prurigo nodularis lesions

Limitations

1. Documentation of a Member being a social drinker does not qualify as a medically acceptable contraindication or clinical inappropriateness to methotrexate therapy.
2. Initial approval of Dupixent will be authorized for six (6) months. Reauthorization of Dupixent will be provided in 12-month intervals.
3. Patients new to the plan stable on Dupixent should be reviewed against Reauthorization Criteria.

Codes

None

References

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3. Blauvelt A, Gooderham M, Foley P et al. Long-term management of moderate-to-severe atopic dermatitis (AD) with dupilumab and concomitant topical corticosteroids (TCS): a 1-year, randomized, placebo-controlled phase 3 trial (CHRONOS). Paper presented at the 2017 American Academy of Dermatology Annual meeting. Orlando, FL; 2017 March 4.
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9. Eichenfield LF, Tom WL, Berger TG, Krol A, Paller AS, Schwarzenberger K, et al. Guidelines of care for the management of atopic dermatitis: section 2. Management and treatment of atopic dermatitis with topical therapies. J Am Acad Dermatol. 2014 Jul;71(1):116-32.
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Approval And Revision History

September 13, 2022: Reviewed by the Pharmacy & Therapeutics Committee.

1. October 2022 e-vote: For eosinophilic esophagitis, updated to include in consultation with prescriber specialist, including immunologist. Updated language of PPI trial to include intolerance or contraindication.
2. February 14, 2023: Added coverage criteria for the supplemental indication of prurigo nodularis (effective March 1, 2023).
3. February 13, 2024: Updated age requirements for eosinophilic esophagitis based on updated FDA-approved labeling (eff 3/1/24).
4. May 14, 2024: For chronic rhinosinusitis with nasal polyps updated diagnosis requirements to a documented diagnosis of chronic rhinosinusitis with nasal polyps and removed documentation the patient remains symptomatic despite treatment with an intranasal corticosteroid or contraindication to intranasal corticosteroids (eff 6/1/2024).
5. October 8, 2024: Updated age requirements for chronic rhinosinusitis with nasal polyps based on updated FDA-approved labeling (eff 11/1/24).
6. December 10, 2024: Added coverage criteria for chronic obstructive pulmonary disorder (eff 2/1/25).

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a

guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.