TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: Dupixent (dupilumab)

Effective: November 1, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	Rx	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

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 (dupilumab) 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 (dupilumab) can be used with or without topical corticosteroids.
- **Bullous pemphigoid**
  For the treatment of adult patients with bullous pemphigoid.
- **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
- **Chronic spontaneous urticaria**
  For the treatment of adult and pediatric patients aged 2 years and older with chronic spontaneous urticaria who remain symptomatic despite H1 antihistamine treatment. Dupixent (dupilumab) is not indicated for the treatment of other forms of urticaria.
- **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
- **Allergic Fungal Rhinosinusitis (AFRS)**
  For the treatment of adult and pediatric patients aged 6 years and older with allergic fungal rhinosinusitis who have a history of sino-nasal surgery

COVERAGE GUIDELINES

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

Allergic Fungal Rhinosinusitis

Initial Authorization Criteria

1. Documented diagnosis of allergic fungal rhinosinusitis as evidenced by fungal sensitization by serum-specific IgE or skin testing and characteristic findings on nasal endoscopy, sinus CT, and/or pathology

AND

2. Documentation that patient has persistent or recurrent disease following history of sino-nasal surgery

AND

3. Documentation of **one (1)** of the following:
   a. Inadequate response to intranasal or systemic corticosteroid therapy as part of postoperative management
   b. Contraindication to intranasal or systemic corticosteroid therapy

AND

4. Member is at least 6 years of age or older

AND

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

AND

6. The patient will not be concurrently treated with an alternative biologic for allergic fungal rhinosinusitis

Reauthorization Criteria

1. Documented diagnosis of allergic fungal rhinosinusitis

AND

2. Patient is at least 6 years of age or older

AND

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

AND

4. Documentation the Member has experienced a therapeutic response as defined by at least **one (1)** of the following:
    a. Decreased need for additional sinus surgery and/or systemic corticosteroid therapy
    b. Improvement in sinus opacification and/or nasal polyp size
    c. Improvement in allergic fungal rhinosinusitis symptoms (e.g., nasal congestion, sense of smell)

AND

5. The patient will not be concurrently treated with an alternative biologic for allergic fungal rhinosinusitis

Severe 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 month
    c. Current treatment with an alternative biologic indicated for moderate to severe allergic eosinophilic asthma

AND

2. Member is at least 6 years of age or older

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 or older

AND

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

AND

4. Documentation the Member has experienced a therapeutic response as defined by at least **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 or older

AND

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

AND

5. Documentation of **one (1)** of the following:
   a. Trial and failure of at least one medium to very high topical corticosteroid
   b. Contraindication to medium to very high topical corticosteroid

AND

6. Documentation of **one (1)** of the following:
   a. Trial and failure of at least one topical immunomodulator (e.g. tacrolimus, pimecrolimus)
   b. Contraindication to topical immunomodulators

Reauthorization Criteria

1. Documented diagnosis of moderate to severe atopic dermatitis

AND

2. Patient is at least 6 months of age or older

AND

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

AND

4. Documentation the Member 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

Bullous pemphigoid

Initial Authorization Criteria

1. Documented diagnosis of bullous pemphigoid as evidenced by findings from skin biopsy or immune serological tests

AND

2. Patient is at least 18 years of age or older

AND

3. Prescribed by or in consultation with a dermatologist

AND

4. Documentation of **one (1)** of the following:
   a. Dupixent will be used in combination with a tapering course of oral corticosteroids until disease control has occurred
   b. Contraindication to oral corticosteroids

AND

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

Reauthorization Criteria

1. Documented diagnosis of bullous pemphigoid as evidenced by findings from skin biopsy or immune serological tests

AND

2. Patient is at least 18 years of age or older

AND

3. Prescribed by or in consultation with a dermatologist

AND

4. Documentation the Member has experienced a therapeutic response as defined by **one (1)** of the following:
    a. Absence of new lesions or improvements in established lesions relative to pretreatment baseline
    b. Improvements in bullous pemphigoid symptoms such as itching
    c. Reduction in the use of rescue therapy

AND

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

Chronic obstructive pulmonary disease (COPD)

Initial Authorization Criteria

1. Documented diagnosis of chronic obstructive pulmonary disease

AND

2. Patient is at least 18 years of age or older

AND

3. Prescribed by or in consultation with a pulmonologist

AND

4. Documentation of presence of Type 2 inflammation evidence 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 or older

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

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 as evidenced by both of the following:
    a. Symptoms of chronic rhinosinusitis for at least 12 weeks (e.g., decreased sense of smell; facial pressure, pain, fullness; mucopurulent drainage, mucosal inflammation, nasal obstruction)
    b. Presence of nasal polyps

AND

2. Patient is at least 12 years of age or older

AND

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

AND

4. Documentation of **one (1)** of the following:
    a. Member is concurrently treated with 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 or older

AND

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

AND

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

AND

5. Documentation the Member 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

Chronic spontaneous urticaria

Initial Authorization Criteria

1. Documented diagnosis of chronic spontaneous urticaria defined by presence of the condition for at least six (6) weeks

AND

2. Patient is at least 2 years of age or older

AND

3. Prescriber by or in consultation with an allergist, dermatologist, or immunologist

AND

4. Documentation of **one (1)** of the following:
    a. Patient remains symptomatic despite treatment with a second-generation H1 antihistamine (e.g., cetirizine, fexofenadine, levocetirizine, loratadine)
    b. Contraindication to second-generation H1 antihistamines

Reauthorization Criteria

1. Documented diagnosis of chronic spontaneous urticaria

AND

2. Patient is at least 2 years of age or older

AND

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

AND

4. Documentation the patient has experienced a therapeutic response as defined by **one (1)** of the following:
    a. Reduced itching
    b. Reduction in the number and/or size of hives

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. Patient is at least 1 year of age or older

AND

3. Patient weighs at least 15 kg

AND

4. The prescribing physician is an allergist or gastroenterologist

AND

5. Documentation of poor control requiring additional treatment despite an 8-week trial of a proton pump inhibitor

Reauthorization Criteria

1. Documented diagnosis of eosinophilic esophagitis

AND

2. Patient is at least 1 year of age or older

AND

3. Patient weighs at least 15 kg

AND

4. The prescribing physician is an allergist 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 evidence by one (1) of the following:
    a. All of the following:
        i. Presence 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 or older

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 or older

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

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

CODES

None

REFERENCES

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2. Antiga E, Bech R, Maglie R, Genovese G, Borradori L, et al. S2k guidelines on the management of paraneoplastic pemphigus/paraneoplastic autoimmune multiorgan syndrome initiated by the European Academy of Dermatology and Venereology (EADV). J Eur Acad Dermatol Venereol. 2023 Jun. 37 (6):1118-1134.
3. Arkwright PD, Motala C, Subramanian H, et al. Atopic dermatitis working group of the Allergic Skin Diseases committee of the AAAI. Management of difficult-to-treat atopic dermatitis. J Allergy Clin Immunol Pract. 2013;1(2):142-51.
4. 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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7. Dawn MR Davis, et al. Guidelines of care for the management of atopic dermatitis in adults with phototherapy and systemic therapies. Journal of the American Academy of Dermatology. 2023 Nov;08(102):e1-e14.
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11. Elmariah S, et al. Practical approaches for diagnosis and management of prurigo nodularis: United States expert panel consensus. J Am Acad Dermatol. 2021;84:747-60.
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13. Stander S et al. IFSI-guideline on chronic prurigo including prurigo nodularis. Itch. 2020;5:e2.
14. Zuberbier T, Abdul Latiff AH, Abuzakouk M, et al. The international EAACI/GA²LEN/EuroGuiDerm/APAACI guideline for the definition, classification, diagnosis, and management of urticaria. Allergy. 2022 Mar. 77 (3):734-766.

APPROVAL HISTORY

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

- February 14, 2023: Added coverage criteria for the supplemental indication of prurigo nodularis (effective March 1, 2023).
- February 13, 2024: Updated age requirements for eosinophilic esophagitis based on updated FDA-approved labeling (eff 3/1/24).
- May 14, 2024: For chronic rhinosinusitis with nasal polyps removed documentation the patient remains symptomatic despite treatment with an intranasal corticosteroid or contraindication to

intranasal corticosteroids. Removed documentation of prior treatment with systemic corticosteroids, contraindication to systemic corticosteroids or previous nasal polyps (eff 6/1/2024).
- October 8, 2024: Updated age requirements for chronic rhinosinusitis with nasal polyps based on updated FDA-approved labeling (eff 11/1/24).
- December 10, 2024: Added coverage criteria for chronic obstructive pulmonary disorder (eff 2/1/25).
- December 9, 2025: Added coverage criteria for supplemental indication of bullous pemphigoid and chronic spontaneous urticaria (eff 2/1/26).
- October 13, 2026: For atopic dermatitis criteria, removed documentation of trial and failure or contraindication to crisaborole and trial and failure or contraindication to systemic immunosuppressive therapies (azathioprine, cyclosporine, methotrexate) for patients at least 18 years of age. For bullous pemphigoid criteria, removed documentation of trial and failure or contraindication with corticosteroid therapies and trial and failure and contraindication to systemic therapies (methotrexate, azathioprine, mycophenolate, tetracycline antibiotic). For chronic spontaneous urticaria, updated overview and criteria age requirement that patient is at least 2 years of age based on updated FDA-approved labeling. Added coverage criteria for the supplemental indication of allergic fungal rhinosinusitis (eff 11/1/26).

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.