Pharmacy Medical Necessity Guidelines: Dupixent® (dupilumab)

Effective: January 1, 2021

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:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:

RXUM: 617.673.0988

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:

- **Atopic dermatitis**
  For the treatment of patients aged 6 years 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.
- **Chronic rhinosinusitis with nasal polyps (CRSwNP)**
  As add-on maintenance treatment in adult patients with inadequately controlled CRSwNP
- **Moderate-to-severe asthma**
  As add-on maintenance treatment in patients with moderate-to-severe asthma aged 12 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.

COVERAGE GUIDELINES

The plan may authorize coverage of Dupixent (dupilumab) for Members, when all of the following criteria are met:

Atopic Dermatitis

1. Documented diagnosis of moderate to severe atopic dermatitis

AND

2. The Member is at least 6 years of age

AND

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

AND

4. Documentation of **one (1)** of the following:
   a. Inadequate response or adverse event to **one (1)** superpotent or potent topical corticosteroid
   b. Contraindication to **all** superpotent or potent topical corticosteroids

AND

5. Documentation of **one (1)** of the following:
   a. Inadequate response or adverse reaction to topical tacrolimus or Eucrisa
   b. Contraindication to topical tacrolimus and Eucrisa

AND

6. Documentation of **one (1)** of the following:
   a. Inadequate response or adverse event to **one (1)** systemic immunomodulatory agent (e.g., azathioprine, cyclosporine, methotrexate, mycophenolate mofetil, mycophenolic acid)
   b. Contraindication to **all** systemic immunosuppressive therapies

Chronic rhinosinusitis with nasal polyps (CRSwNP)

1. Documented diagnosis of chronic rhinosinusitis with polyps

AND

2. Member is at least 18 years of age

AND

3. The prescribing physician is a specialist (e.g., allergist, immunologist, pulmonologist)

AND

4. Documented inadequate response, adverse reaction or contraindication to **one (1)** oral corticosteroid

AND

5. Documented inadequate response, adverse reaction or contraindication to **one (1)** intranasal corticosteroid

AND

6. Documented inadequate response, adverse reaction, or contraindication to **one (1)** leukotriene antagonist

Asthma

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

AND

2. Member is at least 12 years of age

AND

3. Prescribing physician is an asthma specialist (e.g., allergist, immunologist, pulmonologist)

AND

4. Documentation the Member is symptomatic despite receiving **one (1)** of the following:
    a. Combination inhaler
    b. Combination of an inhaled corticosteroid and long-acting beta agonist inhaler
    c. Chronic oral corticosteroids (defined as ≥90 days of therapy within the last 120 days)

AND

5. Documentation of **one (1)** of the following:
    a. Evidence of an eosinophilic phenotype (i.e., peripheral blood eosinophil count ≥150 cells/µL, elevated sputum eosinophils or FeNO)
    b. Member is receiving chronic oral corticosteroids (defined as ≥90 days of therapy within the last 120 days)
    c. Member has documented concomitant diagnosis of atopic dermatitis or chronic rhinosinusitis with nasal polyps and either moderate-to-severe eosinophilic asthma or oral corticosteroid-dependent asthma

LIMITATIONS

- Coverage of Dupixent (dupilumab) prefilled syringe is limited as follows:
    a) 300 mg/2 mL: 2 per 28 days, following a loading dose of 600 mg (two 300 mg injections)
    b) 200 mg/2mL: 2 per 28 days, following a loading dose of 400 mg (two 200 mg injections)

CODES

None

REFERENCES

1. 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.
2. 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.
3. Castro M, Corren J, Pavord ID, et al. Dupilumab efficacy and safety in moderate-to-severe uncontrolled asthma. N Engl J Med. 2018 Jun 28;378(26):2486-96.
4. Dupixent (dupilumab) [prescribing information]. Bridgewater, NJ: Sanofi-aventis U.S. LLC; 2020 May.

5. Eichenfield LF, Tom WL, Chamlin SL, Feldman SR, Hanifin JM, Simpson EL, et al. Guidelines of care for the management of atopic dermatitis: section 1. Diagnosis and assessment of atopic dermatitis. J Am Acad Dermatol. 2014 Feb;70(2):338-51.
6. 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.
7. Rabe KF, Nair P, Brusselle G, et al. Efficacy and safety of dupilumab in glucocorticoid-dependent severe asthma. N Engl J Med. 2018 Jun 28;378(26):2475-85.

APPROVAL HISTORY

November 24, 2020: Reviewed by Pharmacy & Therapeutics Committee for an effective date of January 1, 2021 for implementation of MassHealth ACPP/MCO Partial Unified Formulary. Coverage criteria update and reauthorization criteria removed.

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.