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

Initial Therapy

1. Documented diagnosis of moderate to severe atopic dermatitis

AND

2. The Member is at least 6 years of age

AND

3. The prescribing physician is a dermatologist, allergist, or immunologist

AND

4. Documentation of involvement of at least 10% of body surface area

AND

5. Documented contraindication to or failure of or intolerance to one medium to very high topical corticosteroid (e.g., betamethasone valerate 0.1% cream or ointment, betamethasone dipropionate augmented 0.05% ointment)
   Note: failure is defined as refractory disease despite daily treatment with at least 4 weeks of each

AND

6. Documented contraindication to or failure of or intolerance to a calcineurin inhibitors (e.g., tacrolimus)
   Note: failure is defined as refractory disease despite daily treatment with at least 4 weeks of each

AND

7. Documented contraindication to or failure of or intolerance to Eucrisa (crisabrole)

Note: failure is defined as refractory disease despite daily treatment with at least 4 weeks of each

AND

8. Documentation of one of the following:
    a. Trial and failure with or intolerance to at least one of the following systemic immunosuppressive therapies: azathioprine, cyclosporine, or methotrexate
    b. Contraindication to all of the following systemic immunosuppressive therapies: azathioprine, cyclosporine, and methotrexate

Note: Failure of most recent prerequisite therapy must be within the previous three months.

Reauthorization Criteria

1. Documented diagnosis of moderate to severe atopic dermatitis

AND

2. The Member is at least 6 years of age

AND

3. The prescribing physician is a dermatologist, allergist, or immunologist

AND

4. Documentation the Member has experienced a therapeutic response as defined by one 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 rhinosinusitis with nasal polyps (CRSwNP)

Initial Therapy

1. Documented diagnosis of chronic rhinosinusitis defined by at least 12 weeks of:
    a. Mucosal inflammation AND
    b. At least 2 of the following:
        i. Decreased sense of smell
        ii. Facial pressure, pain, fullness
        iii. Mucopurulent drainage
        iv. Nasal obstruction

AND

2. Documentation of nasal polyps

AND

3. Member is at least 18 years of age

AND

4. The prescribing physician is an allergist, immunologist, or otolaryngologist

AND

5. Documentation of poor control requiring additional treatment despite an adherent ≥3 month trial of an intranasal corticosteroid in combination with a leukotriene modifier

AND

6. Documentation the Member is concurrently treated with intranasal corticosteroids

Reauthorization Criteria

1. Documented diagnosis of chronic rhinosinusitis with nasal polyps

AND

2. Member is at least 18 years of age

AND

3. The prescribing physician is an allergist, immunologist, or otolaryngologist

AND

4. Documentation the Member continues to receive an intranasal corticosteroid

AND

5. Documentation the Member has experienced a therapeutic response as defined by one of the following:
    a. Adequate sinus ventilation and drainage
    b. Control of mucosal inflammation and edema
    c. Reduction in exacerbations

Severe Asthma

Initial Therapy

1. Documentation of one of the following:
    a. Oral corticosteroid dependent asthma defined as regular use of oral steroid use for ≥6 months in preceding 12 months
    b. Pre-treatment serum eosinophil count of at least 300 cells/mcL

AND

2. Member is at least 12 years of age

AND

3. Prescribed by or in consultation with an asthma specialist (e.g., allergist, immunologist, pulmonologist)

AND

4. Documentation the underlying conditions or triggers of asthma or pulmonary disease are being maximally managed

AND

5. Documentation of poor asthma control or recurrent exacerbations requiring additional treatment despite an adherent trial of at least 3 months duration of a medium to high-dose inhaled corticosteroid in combination with a long-acting inhaled beta-2 agonist (LABA), leukotriene modifier, or theophylline or the Member is intolerant or has a contraindication to all of these medications

    Note: Poor asthma control may include but is not limited to clinical documentation of limitation in activities of daily living, nighttime awakening, or dyspnea

    Note: Recurrent exacerbation is defined as 2 or more acute exacerbations in a 12-month period

    Note: Additional medical treatment may include any of the following: Treatment with oral corticosteroids, emergency department visits, hospitalizations, or frequency office visits

<u>Reauthorization Criteria</u>

1. Documentation of one of the following:
    a. Oral corticosteroid dependent asthma
    b. Eosinophilic asthma

AND

2. Member is at least 12 years of age

AND

3. Prescribed by or in consultation with an asthma specialist (e.g., allergist, immunologist, pulmonologist)

AND

4. Documentation the Member has experienced a therapeutic response as defined by at least one 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

APPENDIX

NHBLI Estimated Comparative Daily Dosages for Inhaled Corticosteroids in Adults

Drug	Medium Daily Dose	High Daily Dose (Adult ≥ 12 years old)
Beclomethasone HFA 40 or 80 mcg/puff	>160 to 320 mcg	>320 mcg
Budesonide DPI 90 or 180 mcg/inhalation	>360 to 720 mcg	>720 mcg
Ciclesonide HFA 80 or 160 mcg/puff	>160 to 320 mcg	>320 mcg
Flunisolide HFA 80 mcg/puff	>320 to 640 mcg	>640 mcg
Fluticasone propionate HFA 44, 110, 220 mcg/puff	>220 to 440 mcg	>440 mcg
Fluticasone propionate DPI 50, 100, 250 mcg/inhalation	>250 to 500 mcg	>500 mcg

Drug	Medium Daily Dose	High Daily Dose (Adult ≥ 12 years old)
55, 113, 232 mcg/inhalation		
Fluticasone furoate DPI 50, 100, 200 mcg/inhalation	100 mcg	200 mcg
Mometasone DPI 110, 220 mcg/actuation	>220 to 440 mcg	>440 mcg
Mometasone HFA 100, 200 mcg/actuation	>200 to 400 mcg	>400 mcg

DPI: dry powder inhaler, HFA: hydrofluoroalkan

LIMITATIONS

- For the treatment of asthma, coverage will not be authorized if the Member is also receiving another biologic medication for the treatment of asthma (e.g., Cinqair, Fasenra, Nucala, Xolair).
- Documentation of a Member being a social drinker does not qualify as a medically acceptable contraindication or clinical inappropriateness to methotrexate therapy.
- For the treatment of atopic dermatitis, initial coverage of Dupixent (dupilumab) will be authorized for 4 months. Reauthorization of Dupixent (dupilumab) for atopic dermatitis will be provided in 12-month intervals.
- For the treatment of chronic rhinosinusitis with nasal polyps, initial coverage of Dupixent (dupilumab) will be authorized for 6 months. Reauthorization of Dupixent (dupilumab) for chronic rhinosinusitis with nasal polyps will be provided for 12-month intervals.
- For the treatment of asthma, initial approval by the plan will be limited to 6 months. Reauthorization of Dupixent (dupilumab) for severe asthma will be provided in 12-month intervals.
- Members new to the plan stable on Dupixent (dupilumab) should be reviewed against Reauthorization Criteria for all indications.
- 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

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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

July 11, 2017: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. September 18, 2018: No changes
2. November 13, 2018: Added coverage criteria for eosinophilic asthma and oral corticosteroid dependent asthma.

3. March 12, 2019: Effective July 1, 2019, for atopic dermatitis updated the prerequisite requirements to require documented contraindication to all and failure of at least one of the following systemic immunosuppressive therapies: azathioprine, cyclosporine, methotrexate.
4. April 9, 2019: For atopic dermatitis, updated the Member age requirement to at least 12 years of age based on package labeling. For eosinophilic asthma, removed the requirement that pre-treatment serum eosinophil count is measured within 6 weeks prior to initiation of treatment.
5. May 7, 2019: Clarified July 1, 2019 effective date atopic dermatitis prerequisite requirements to require documented contraindication to all or failure of at least one of the following systemic immunosuppressive therapies: azathioprine, cyclosporine, methotrexate.
6. August 13, 2019: Added criteria for the expanded indication of add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyps.
7. April 14, 2020: Effective July 1, 2020, modified reauthorization criteria for all indications and consolidated coverage criteria for eosinophilic asthma and oral corticosteroid dependent asthma and updated wording to "Prescribed by or in consultation with an asthma specialist." Consolidated the coverage criteria for asthma to eliminate separate requirements for documentation of poor asthma control or recurrent exacerbations and prerequisite therapies and removed requirement for documentation the Member is receiving other treatments for asthma. Added the following Limitations "Members new to the plan stable on Dupixent (dupilumab) should be reviewed against Reauthorization criteria for all indications" and "Documentation of a Member being a social drinker does not qualify as a medically acceptable contraindication or clinical inappropriateness to methotrexate therapy." Updated a Limitation to the following: "For the treatment of asthma, coverage will not be authorized if the Member is also receiving another biologic medication for the treatment of asthma (e.g., Cinqair, Fasenra, Nucala, Xolair)."
8. July 14, 2020: Updated age requirements for atopic dermatitis based on FDA approved labeling.
9. December 8, 2020: Effective January 1, 2021, Tufts Health Together removed from the Medical Necessity Guideline.

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.