New Hampshire Medicaid Fee-for-Service Program

Dupixent® (dupilumab) Criteria

Approval Date: January 14, 2022

Indications

Dupilumab is an interleukin-4 (IL-4) α-antagonist indicated as an add-on maintenance treatment in patients with moderate to severe asthma with an eosinophilic phenotype or with oral corticosteroid-dependent asthma, for the treatment of moderate-to-severe atopic dermatitis not adequately controlled with topical prescription therapies or when those therapies are inadvisable, and an add-on maintenance treatment for adults with inadequately controlled chronic rhinosinusitis with nasal polyposis.

Medications

Brand Names	Generic Names	Dosage
Dupixent®	dupilumab	300 mg/2 mL, 200 mg/1.14 mL, 100 mg/0.67 mL single-dose prefilled pen 300 mg/2 mL, 200 mg/1.14 mL single-dose prefilled syringe with needle shield

Criteria for Approval for Asthma

1. Prescriber is an allergist, immunologist, or pulmonologist (or one of these specialists has been consulted); **AND**
2. Patient is ≥ 6 years old; **AND**
3. Diagnosis of moderate or severe, persistent asthma; **AND**
4. Inadequately controlled asthma despite medium-to-high doses of corticosteroid (inhaled or oral) in combination with:
    a. Long-acting beta agonist; **OR**
    b. Leukotriene receptor agonist; **OR**
    c. Theophylline; **AND**
5. History of positive skin test or *in vitro* test to perennial aeroallergen or eosinophilic phenotype; **AND**

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6. Non-smoker status.

Length of Authorization

Initial six months, extended approval for 12 months if additional criteria are met.

Criteria for 12-Month Renewal

1. Approved for initial six-month trial; **AND**
2. Clinical improvement was seen.

Criteria for Denial

1. Above criteria are not met; **OR**
2. If being used for peanut allergy only; **OR**
3. Patient is an active smoker; **OR**
4. Failure to be compliant with current regimen as evidenced by review of claims history; **OR**
5. For asthma diagnosis only, no claims history of inhaled corticosteroid, long-acting beta agonist, leukotriene receptor, antagonists, or theophylline in the last 120 days for new prescriptions only.

Criteria for Approval for Atopic Dermatitis

1. Prescriber is a dermatologist, immunologist, or allergist (or one has been consulted); **AND**
2. FDA-approved indication and age:
   a. **Dupixent® (dupilumab):** Treatment of adults and children ≥ 6 years old with moderate to severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable; may be used with or without topical corticosteroids; **AND**
3. Patient has a defined failure, contraindication, or intolerance to a trial of topical corticosteroids. In general, a trial constitutes two weeks for high-potency topical corticosteroids (e.g., diflorasone diacetate) and four weeks for low-potency topical corticosteroids (e.g., hydrocortisone acetate); **AND**
4. Patient has a defined failure, contraindication, or intolerance to a trial of pimecrolimus **OR** a trial of tacrolimus. A trial constitutes at least one month of therapy; **AND**
5. Patient has a defined failure, contraindication, or intolerance to a trial of Eucrisa® (crisaborole). A trial constitutes at least one month of therapy; **AND**
6. Prescribed utilization is for short-term (up to six consecutive weeks at a time) therapy or for non-continuous intermittent therapy (up to one year in duration).

Length of Approval: Four months

Renewal: Six months

Criteria for Denial

1. Failure to meet criteria for approval; **OR**
2. Treatment of psoriasis; **OR**
3. Treatment of infected atopic dermatitis; **OR**
4. Treatment of Netherton's syndrome.

Criteria for Approval for Chronic Rhinosinusitis with Nasal Polyposis

1. Prescriber is an ear, nose, and throat (ENT) specialist (or one has been consulted)**; AND**
2. Patient is ≥ 18 years old; **AND**
3. Diagnosis of chronic rhinosinusitis with nasal polyposis**; AND**
4. Dupilumab will be used as an add-on maintenance treatment; **AND**
5. Patient has had prior sino-nasal surgery or treatment with, or who were ineligible to receive or were intolerant to, systemic corticosteroids within the past two years; **OR**
6. Patient's symptoms are not adequately controlled with intranasal steroids.

Length of Authorization

Length of Approval: Six months

Renewal: Twelve months

Criteria for Denial

1. Failure to meet criteria for approval; **OR**
2. Patients with chronic rhinosinusitis without nasal polyposis.

Criteria for Renewal

1. Clinical improvement was seen; **AND**
2. Dupilumab will be used as an add-on maintenance treatment.

References

Available upon request.

Revision History

Reviewed by	Reason for Review	Date Approved
DUR Board	New	06/30/2020
Commissioner Designee	Approval	08/7/2020
DUR Board	Revision	12/15/2020
Commissioner Designee	Approval	02/24/2021
DUR Board	Revision	12/02/2021
Commissioner Designee	Approval	01/14/2022