New Hampshire Medicaid Fee-for-Service Program

Dupixent® (dupilumab) Criteria

Approval Date: January 26, 2023

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. Dupilumab is also indicated for the treatment of eosinophilic esophagitis and prurigo nodularis.

Medications

Brand Names	Generic Names	Dosage
Dupixent®	dupilumab	300 mg/2 mL, 200 mg/1.14 mL single-dose prefilled pen 300 mg/2 mL, 200 mg/1.14 mL, 100 mg/0.67 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**
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 months 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.

Criteria for Approval for Eosinophilic Esophagitis

1. Prescriber is a gastroenterologist, immunologist, or allergist (or one has been consulted)**; AND**
2. Patient is ≥ 12 years old and weighing ≥ 40 kg; **AND**
3. Diagnosis of eosinophilic esophagitis**.**

Length of Authorization

Length of Approval: Six months

Renewal: Twelve months

Criteria for Denial

Failure to meet criteria for approval.

Criteria for Renewal

Clinical improvement was seen.

Criteria for Approval for Prurigo Nodularis

1. Prescriber is a dermatologist, immunologist, or allergist (or one has been consulted); **AND**
2. Patient is ≥ 18years old; **AND**
3. Diagnosis of prurigo nodularis.

Length of Authorization

Length of Approval: Six months

Renewal: Twelve months

Criteria for Denial

Failure to meet criteria for approval.

Criteria for Renewal

Clinical improvement was seen.

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

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Commissioner Designee	Approval	02/24/2021
DUR Board	Revision	12/02/2021
Commissioner Designee	Approval	01/14/2022
DUR Board	Revision	12/13/2022
Commissioner Designee	Approval	01/26/2023