AdvancedHealth
Bridging the Future of Healthcare

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Phone: 541-269-7400 Fax: 541-269-7147

Dupilumab – Dupixent® Drug Use Criteria

Created: 8/1/2025
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Includes:
Dupixent® (Dupilumab)

GUIDELINE FOR USE:

Initial Request: Complete all criteria below for the relevant indication.

Atopic Dermatitis (AD)

1. Does the member have a diagnosis of severe atopic dermatitis? (functional impairment as indicated by Dermatology Life Quality Index (DLQI) ≥ 11 or Children's Dermatology Life Quality Index (CDLQI) ≥ 13 (or severe score on another validated tool) AND one or more of the following:
    - At least 10% body surface area involved, or
    - Hand, foot, face, or mucous membrane involvement

    a. If yes, go to 2
    b. If no, deny as not meeting criteria

2. Is **Dupixent®** (Dupilumab) prescribed by or in consultation with dermatologist/allergist/immunologist

    a. If yes, go to 3
    b. If no, deny as not meeting criteria. Please refer member to a specialist (dermatologist/allergist/immunologist) for further evaluation.

3. Has the member had a documented trial with medium-high potency topical corticosteroid for 4 or more weeks IN COMBINATION WITH a topical calcineurin inhibitor (document name, dose, duration, outcome)?

    a. If yes, go to 4
    b. If no, deny as not meeting criteria.

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4. Has the member had a documented trial with a topical PDE-4 inhibitor (e.g., crisaborole) for at least 4 weeks?

    a. If yes, go to 6
    b. If no, deny as not meeting criteria. Step therapy trial for at least 4 weeks with a PDE-4 inhibitor is required.

5. Has the member had a documented trial for at least 8 weeks with an oral systemic agent (e.g., methotrexate, cyclosporine)?

    a. If yes, go to 7
    b. If no, deny as not meeting criteria. Trial for at least 8 weeks with an oral systemic agent (e.g., methotrexate or cyclosporine) is required.

6. Is the requested dose within FDA-approved guidelines for the indicated diagnosis?

    a. If yes, approve for up to 6 months.
    b. If no, deny as not meeting criteria. Off-label use is not a covered benefit of OHP

Asthma (Eosinophilic Phenotype or Oral Corticosteroid Dependent, age ≥6 years)

1. Does the member have a documented diagnosis of moderate-to-severe asthma with eosinophilic phenotype or is oral corticosteroid-dependent?

    a. If yes, go to 2
    b. If no, deny as not meeting criteria.

2. Is the member age ≥6 years?

    a. If yes, go to 3
    b. If no, deny as not meeting criteria. Treatment with Dupixent for this indication is FDA-approved for patients 6 years of age or greater. Off-label use is not a covered benefit of OHA.

3. Is the prescriber a pulmonologist or an allergist who specializes in management of severe asthma?
    a. If yes, go to 4
    b. If no, deny as not meeting criteria. Please refer member to a pulmonologist for further evaluation.

4. Has the member experienced one of the following:
    - at least 4 asthma exacerbations requiring systemic corticosteroids in the previous 12 months OR
    - taking continuous oral corticosteroids at least the equivalent of prednisolone 5 mg per day for the previous 6 months OR

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- at least 1 hospitalization or ≥ 2 emergency department (ED) visits in the past 12 months while receiving a maximally-dosed inhaled corticosteroid AND 2 additional controller drugs (i.e., long-acting inhaled beta agonist, montelukast, zafirlukast, tiotropium)?

a. If yes, go to 5 (Note: Document number asthma exacerbations over the previous 12 months or oral corticosteroid dose over the previous 6 months or number of hospitalizations or ED visits in the past 12 months. This is the baseline value to compare to in renewal criteria.
b. If no, deny as not meeting criteria

5. Has the member been adherent to current asthma therapy in the past 12 months?

a. If yes, go to 6
b. If no, deny as not meeting criteria

6. If the request for asthma with an eosinophilic phenotype, has documentation been provided supporting one of the following biomarkers:

- severe eosinophilic asthma, confirmed by blood eosinophil count ≥150 cells/µL OR
- fractional exhaled nitric oxide (FeNO) ≥25 ppb in the past 12 months?

a. If yes, approve for up to 12 months based on FDA-approved dosing for this indication
b. If no, deny as not meeting criteria

Eosinophilic Esophagitis (EoE, age ≥1 year, weight ≥15 kg)

1. Does the member have diagnosis of EoE confirmed by endoscopic biopsy?

a. If yes, go to 2
b. If no, deny as not meeting criteria

2. Is the prescriber a gastroenterologist or allergist?

a. If yes, go to 3
b. If no, deny as not meeting criteria

3. Has the member completed a documented trial of high-dose proton pump inhibitors for ≥ 8 weeks with inadequate response?

a. If yes, go to 4
b. If no, deny as not meeting criteria

4. Has the member completed a documented trial of corticosteroid therapy with local administration of fluticasone multi-use inhaler for ≥ 8 weeks (use nasal inhaler and swallow contents of the spray)?

a. If yes, go to 5

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b. If no, deny as not meeting criteria

5. Is there member experiencing documented ≥2 dysphagia episodes per week despite treatment?

    a. If yes, go to 6
    b. If no, deny as not meeting criteria

6. Is the requested dose within FDA-approved guidelines?
    a. If yes, approve for up to 6 months
    b. If no, deny as not meeting criteria

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP, age ≥12 years)

1. Does the member have a confirmed diagnosis of chronic rhinosinusitis with nasal polyps?

    a. If yes, go to 2
    b. If no, deny as not meeting criteria

2. Is the prescriber an otolaryngologist, or allergist who specializes in treatment of chronic rhinosinusitis with nasal polyps?

    a. If yes, go to 3
    b. If no, deny as not meeting criteria

3. Has the member failed medical therapy with intranasal corticosteroids (2 or more courses administered for 12 to 26 weeks each)?

    a. If yes, go to 4
    b. If no, deny as not meeting criteria

4. Is the requested dose within FDA-approved guidelines?

    a. If yes, approve for up to 6 months
    b. If no, deny as not meeting criteria

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Renewal Criteria:

1. Has the member demonstrated continued clinical improvement as indicated below for the applicable diagnosis?

Atopic Dermatitis	• at least a 50% reduction in the Eczema Area and Severity Index score (EASI 50) from when treatment started OR • at least a 4-point reduction in the Dermatology Life Quality Index (DLQI) from when treatment started OR • at least a 2-point improvement on the Investigators Global Assessment (IGA) score?
Asthma (Eosinophilic or Oral Corticosteroid-Dependent)	• currently taking an inhaled corticosteroid and 2 additional controller drugs (i.e., long-acting inhaled beta agonist, montelukast, zafirlukast, tiotropium) AND • number of emergency department (ED) visits or hospitalizations in the last 12 months been reduced from baseline OR • reduced systemic corticosteroid dose by ≥50% compared to baseline?
Eosinophilic Esophagitis	• patient's symptoms improved with therapy
Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP)	• patient's symptoms improved with therapy

   a. If yes, go to 2
   b. If no deny as not meeting criteria. Clinical response does not support continued use of the requested medication.

2. Is the request for renewal submitted by a specialist after member re-evaluation since the previous renewal period?

   a. If yes, approve for up to 12 months
   b. If no, deny as not meeting criteria

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Rationale: Ensure prescribing of Dupilumab – Dupixent® is consistent with FDA-approved indications, national clinical practice guidelines, and evidence-based standards while promoting stepwise optimization of cost-effective therapies before initiating high-cost biologics. Supports appropriate specialist involvement and confirms clinical necessity through documented treatment history/response. Implementing clear, standardized criteria helps improve patient outcomes, ensure safety, and maintain responsible stewardship of healthcare resources.

Mechanism of Action: Dupixent (dupilumab) is a monoclonal antibody that inhibits interleukin-4 and interleukin-13 signaling by binding to the IL-4Rα subunit, thereby reducing type 2 (Th2) inflammation.

References:

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5. Regeneron Pharmaceuticals. Dupixent HCP Dosing & PA Resources. Accessed August 7, 2025. https://www.dupixenthcp.com
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