Generic Name: Dupilumab

Therapeutic Class or Brand Name: Dupixent®

Applicable Drugs (if Therapeutic Class): N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 8/4/2017

Date Last Reviewed / Revised: 1/21/2025

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through IV are met)

I. Documented diagnosis of one of the following conditions A through E and must meet criteria under each applicable diagnosis:

A. Moderate-to-severe atopic dermatitis (AD)

1. Meets all specified criteria outlined in the Targeted Immune Modulator policy.

B. Moderate-to-severe asthma

1. Documentation of either a or b:
   a) Documentation that the member has oral corticosteroid-dependent asthma (eg, at least 5 mg oral prednisone or equivalent per day).
   b) Documented blood eosinophilia count of at least 150 cells/mcL at baseline.
2. Documentation that the patient has been on a minimum of a six-month trial of a high-dose inhaled corticosteroid (ICS) used in combination with a long-acting inhaled beta-2 agonist (LABA).
3. Documentation that the patient's asthma symptoms are poorly controlled despite therapy AND meets at least one of the following criteria i through v:
   a) Poor symptom control (eg, Asthma Control Questionnaire [ACQ] score consistently greater than 1.5 or Asthma Control Test [ACT] score consistently less than 20)
   b) Two or more asthma exacerbations requiring systemic corticosteroids within the past 12 months.
   c) One or more asthma exacerbations requiring emergency treatment (ie, hospitalization, mechanical ventilation, emergency room visit) within the past 12 months.
   d) Worsening asthma when oral corticosteroids are tapered.
   e) Baseline forced expiratory volume in one second (FEV1) <80% predicted.

4. Minimum age requirement: 6 years old.

C. Moderate-to-severe chronic obstructive pulmonary disease (COPD)
   1. Documentation of both a and b:
      a) Spirometry test confirming COPD diagnosis, meeting criteria i and ii:
         i. Post-bronchodilator FEV1/FVC less than 0.7.
         ii. Post-bronchodilator FEV1 30 to 70% predicted normal.
      b) Blood eosinophil count of at least 300 cells/microliter at baseline.
   2. Documentation of history of chronic bronchitis.
   3. Documentation that the patient has been on a minimum of a six-month trial on LAMA + LABA + ICS (long-acting muscarinic antagonist + long-acting beta agonist + inhaled corticosteroids) therapy OR LAMA + LABA therapy if ICS is contraindicated.
   4. Documentation of COPD exacerbation history in the past 12 months that meets criteria a OR b:
      a) Two or more COPD exacerbations requiring systemic corticosteroids and/or antibiotics.
         i. One of the exacerbations must require the use of systemic corticosteroids.
      b) One or more COPD exacerbations requiring emergency treatment (ie, hospitalization, mechanical ventilation, emergency room visit).
   5. Dupixent will be used in conjunction with LAMA + LABA + ICS or LAMA + LABA therapy as an add-on maintenance treatment.
   6. Minimum age requirement: 18 years old.

D. Chronic rhinosinusitis with nasal polyps (CRSwNP)
   1. Documentation the patient has had 2 the following signs/symptoms for 12 weeks or longer:
      a) Facial pain, pressure, or fullness
      b) Nasal blockage, obstruction, or congestion
      c) Purulent drainage
      d) Reduced or absent sense of smell
   2. Documentation nasal polyps are present by one of the following:
      a) Sinus CT
      b) Nasal endoscopy

c) Sinus MRI

3. Documentation that the patient's symptoms are inadequately controlled with a high-dose intranasal corticosteroid used for a minimum of 4 weeks.
4. Dupixent will be used in conjunction with a nasal corticosteroid as an add-on maintenance treatment.
5. Patient has received treatment with oral corticosteroids to reduce size of nasal polyps OR had a polypectomy.
6. Minimum age requirement: 12 years old.

E. Eosinophilic esophagitis

1. Documented eosinophilia count ≥15 eosinophils per high-power microscopy field (eos/hpf).
2. Eosinophilic esophagitis is confirmed by endoscopic appearance and/or symptoms (eg, dysphagia, food impaction, food refusal, abdominal pain, heartburn, regurgitation, chest pain, odynophagia).
3. Documentation of clinically significant treatment failure with an 8-week trial of inhaled corticosteroid (ie, budesonide, fluticasone) administered as a spray that is swallowed.
4. Documentation of clinically significant treatment failure with an 8-week trial of a proton pump inhibitor or evidence of contraindication.
5. Minimum age requirement: 1 year old, weighing at least 15 kg.

F. Prurigo nodularis (PN)

1. Meets all specified criteria outlined in the Targeted Immune Modulator policy.

II. Treatment must be prescribed by or in consultation with an allergist, ear, nose, and throat (ENT) specialist, gastroenterologist, immunologist, otolaryngologist, or pulmonologist.

III. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

IV. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- Treatment of acute bronchospasm or status asthmaticus.
- Treatment of other eosinophilic conditions.
- Concurrent use with other anti-asthma monoclonal antibodies (ie, Cinqair (reslizumab), Fasenra (benralizumab), Nucala (mepolizumab), Tezspire (tezepelumab), Xolair (omalizumab).

Other Criteria

- N/A

Quantity / Days Supply Restrictions

- Asthma:
    - Age ≥12 years: Two 200 mg syringes or pens for the first 14 days, then two 200 mg syringes or pens every 28 days thereafter OR two 300 mg syringes or pens for the first 14 days, then two 300 mg syringes or pens every 28 days thereafter.
    - Age ≥12 years with oral corticosteroid-dependent asthma or comorbid moderate to severe AD: Two 300 mg syringes or pens for the first 14 days, then two 300 mg syringes or pens every 28 days thereafter.
    - Adults with comorbid CRSwNP: Two 300 mg syringes or pens for the first 14 days, then two 300 mg syringes or pens every 28 days thereafter.
    - Age 6 to 11 years:
        - 15 kg to 30 kg: Two 100 mg syringes every 28 days or two 300 mg syringes or pens every 56 days.
        - ≥ 30 kg: Two 200 mg syringes or pens every 28 days.
    - Age 6 to 11 years with comorbid moderate-to-severe Atopic Dermatitis
        - 15 to < 30 kg: Two 300 mg syringes or pens for the first 28 days, then two 300 mg syringes or pens every 56 days thereafter.
        - 30 to < 60 kg: Two 200 mg syringes or pens for the first 14 days, then two 200 mg syringes or pens every 28 days thereafter.
        - ≥ 60 kg: Two 300 mg syringes or pens for the first 14 days, then two 300 mg syringes or pens every 28 days thereafter.
- Chronic obstructive pulmonary disease: Two 300 mg syringes or pens every 28 days.
- Chronic rhinosinusitis with nasal polyps: Two 300 mg syringes or pens every 28 days.
- Eosinophilic esophagitis: Four 300 mg syringes or pens every 28 days.

Approval Length

- **Authorization:** 6 months
- **Re-Authorization:** 12 months.
    - Eosinophilic esophagitis: an updated letter of medical necessity or progress notes showing sustained clinical benefits from the drug treatment, including a decrease in eosinophils per high-power microscopy field (eos/hpf) compared to baseline.
    - Chronic obstructive pulmonary disease: an updated letter of medical necessity or progress notes showing sustained clinical benefits from the drug treatment (ie, decreased use of beta agonists, decreased use of systemic corticosteroids, decreased

emergency department visits, decreased hospital admissions, and preservation of pulmonary function).

- All other diagnosis: An updated letter of medical necessity or progress notes showing that current medical necessity criteria are met and that the medication is effective.

APPENDIX

- N/A

REFERENCES

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4. Global Initiative for Chronic Obstructive Lung Disease. 2025 REPORT Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease. 2025. https://goldcopd.org/wp-content/uploads/2024/11/GOLD-2025-Report-v1.0-15Nov2024_WMV.pdf
5. Rank MA, Chu DK, Bognanni A, et al. The Joint Task Force on Practice Parameters GRADE guidelines for the medical management of chronic rhinosinusitis with nasal polyposis. *J Allergy Clin Immunol*. 2023;151(2):386-398. doi:10.1016/j.jaci.2022.10.026
6. Orlandi RR, Kingdom TT, Hwang PH, et al. International Consensus Statement on Allergy and Rhinology: Rhinosinusitis. *Int Forum Allergy Rhinol.* 2016;6:S22-S209
7. Hirano, I, Chan, ES, Rank, MA, et al. AGA Institute and Joint Task Force on Allergy-Immunology Practice Parameters clinical guidelines for the management of eosinophilic esophagitis. Gastroenterology. 2020;158(6):1776-1786. doi:10.1016/j.anai.2020.03.020