

Generic Name: Dupilumab

Therapeutic Class or Brand Name: Dupixent

Applicable Drugs (if Therapeutic Class): N/A

GPI Code: 9027302000

Preferred: N/A

Non-preferred: N/A

Date of Origin: 8/4/2017

Date Last Reviewed / Revised: 11/18/2020

PRIOR AUTHORIZATION CRITERIA

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

- I. Documented diagnosis of one of the following conditions A through D and must meet criteria under each applicable diagnosis:
 - A. Moderate-to-severe atopic dermatitis and the following criteria 1 through 5 are met:
 1. Documented trial and failure of, intolerance, or contraindication to two high to very high potency topical corticosteroids (i.e. betamethasone dipropionate augmented cream or ointment 0.05%, triamcinolone acetonide cream or ointment 0.5%, etc.).
 2. Documented trial and failure of, intolerance, or contraindication to one topical calcineurin inhibitor (i.e. tacrolimus, etc.).
 3. Documented trial and failure of, intolerance, or contraindication to one systemic immunosuppressive drug (i.e. cyclosporine, azathioprine, and methotrexate).
 4. Documentation that the patient has Body Surface Area (BSA) involvement of at least 10% OR that the atopic dermatitis is impairing the patient's activities of daily living (ADLs).
 5. Minimum age requirement: 6 years old
 - B. Moderate-to-severe asthma dependent on corticosteroid treatment and following criteria 1 through 4 are met:
 1. Documentation of oral corticosteroid treatment (at least prednisone 5 mg daily or equivalent).
 2. Documentation that environmental factors and comorbid conditions that worsen patient's asthma symptoms are being identified and resolved.
 3. Documentation that patient has been on a minimum of a six-month trial of a high-dose inhaled corticosteroid used in combination with a long-acting inhaled beta-2 agonist AND both criteria a and b are met:

- a. Documentation that patient is adherent to therapy as evidenced by pharmacy claims review (patient must have MPR greater than or equal to 80% over the previous 180 days).
 - b. Documentation that patient's asthma symptoms are poorly controlled despite therapy.
4. Minimum age requirement: 12 years old
- C. Eosinophilic asthma and the following criteria 1 through 3 are met:
1. Documented blood eosinophilia count at least 150 cells/mcl in the previous 6 weeks.
 2. Documentation that environmental factors and comorbid conditions that worsen patient's asthma symptoms are being identified and resolved.
 3. Documentation that patient has been on a minimum of a six-month trial of a high-dose inhaled corticosteroid used in combination with a long-acting inhaled beta-2 agonist AND both criteria a and b are met:
 - a. Documentation that patient is adherent to therapy as evidenced by pharmacy claims review (patient must have MPR greater than or equal to 80% over the previous 180 days).
 - b. Documentation that patient's asthma symptoms are poorly controlled despite therapy.
- D. Chronic rhinosinusitis with nasal polyps (CRSwNP) and the following criteria 1 through 5 are met:
1. Documentation of 2 or more of the following signs or symptoms:
 - a. Decreased sense of smell.
 - b. Nasal obstruction.
 - c. Mucopurulent discharge from anterior and posterior sinuses.
 - d. Facial Pressure and pain or fullness
 2. Patient has been on a nasal corticosteroid for minimum of 12 weeks.
 3. Dupixent will be used in conjunction with a nasal corticosteroid as an add-on maintenance treatment.
 4. Patient has received treatment with oral corticosteroids to reduce size of nasal polyps OR had a polypectomy.
 5. Minimum age requirement: 18 years old

- II. Prescribing physician must be a dermatologist, allergist, or immunologist.

EXCLUSION CRITERIA

- Concurrent use with other anti-asthma monoclonal antibodies (i.e. Cinqair® (reslizumab), Nucala® (mepolizumab), Xolair® (omalizumab), Fasenra® (Benralizumab)).
- Treatment of other eosinophilic conditions.
- Treatment of acute bronchospasm or status asthmaticus.

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- 4 syringes in the first 28 days, then 2 syringes every 28 days thereafter.

APPROVAL LENGTH

- **Authorization:** 6 months.
- **Re-Authorization:** 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

1. <https://www.aad.org/practicecenter/quality/clinical-guidelines/atopic-dermatitis>.
2. https://www.regeneron.com/sites/default/files/Dupixent_FPI.pdf.
3. Medi-Span.
4. https://www.nhlbi.nih.gov/sites/default/files/media/docs/asthgdl_n_1.pdf
5. Castro M, Corren J, Pavord ID, et al. Dupilumab efficacy and safety in moderate-to-severe uncontrolled asthma. N Engl J Med 2018;378:2486-96. (QUEST)
6. Rabe K, Nair P, Brusselle G, et al. Efficacy and safety of dupilumab in glucocorticoid-dependent severe asthma. N Engl J Med 2018;378:2475-85. (VENTURE)