

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Dupixent under the patient's prescription drug benefit.

Description:

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

- Add-on maintenance treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype.
- Treatment of patients aged 6 months and older with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Dupixent can be used with or without topical corticosteroids - Review under Dupixent State C21976-A Aetna NJ Medicaid
- Add-on maintenance treatment in patients aged 6 years and older with moderate-tosevere asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma - Review under Dupixent State C21976-A Aetna NJ Medicaid
- Add-on maintenance treatment in patients aged 12 years and older with inadequately controlled chronic rhinosinusitis with nasal polyps (CRSwNP) - Review under Dupixent State C21976-A Aetna NJ Medicaid
- Treatment of adult and pediatric patients aged 1 year and older, weighing at least 15 kg, with eosinophilic esophagitis (EoE) Review under Dupixent State C21976-A
 Aetna NJ Medicaid
- Treatment of adult patients with prurigo nodularis (PN) Review under Dupixent State C21976-A Aetna NJ Medicaid

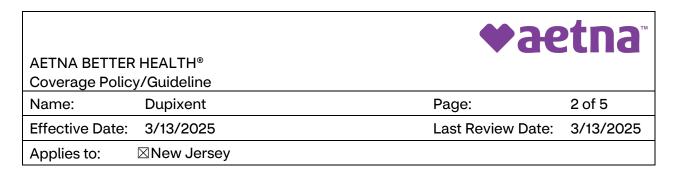
Limitations of Use

Not indicated for the relief of acute bronchospasm or status asthmaticus.

Compendial Uses

• Immune checkpoint inhibitor-related toxicities

All other indications are considered experimental/investigational and not medically necessary.



Applicable Drug List:

Dupixent

Policy/Guideline:

Documentation:

Submission of the following information is necessary to initiate the prior authorization review:

Chronic obstructive pulmonary disease (COPD)

<u>Initial requests:</u>

- Chart notes or medical record documentation demonstrating clinical signs and/or symptoms of COPD.
- Chart notes, medical record documentation, or claims history of prerequisite therapies including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
- Chart notes or medical record documentation showing absolute blood eosinophil count prior to initiating therapy with the requested medication.
- Chart notes or medical record documentation of moderate or severe exacerbations within the last year.

Continuation requests:

Chart notes or medical record documentation supporting positive clinical response.

Prescriber Specialties:

This medication must be prescribed by or in consultation with ONE of the following:

• Chronic obstructive pulmonary disease: pulmonologist or allergist/immunologist

Coverage Criteria:

Chronic obstructive pulmonary disease (COPD)

Authorization of 12 months may be granted for treatment of COPD in members 18 years of age or older when ALL the following criteria are met:

- Diagnosis has been confirmed by spirometry showing forced expiratory volume in one second (FEV₁)/forced vital capacity (FVC) less than 0.7 post-bronchodilation.
- Member demonstrates classic signs or symptoms of COPD (e.g., dyspnea, wheezing, chest tightness, fatigue, activity limitation, cough with or without sputum production, chronic bronchitis).
- Member has an absolute blood eosinophil count of at least 300 cells per microliter prior to initiating therapy with the requested medication.
- Member has inadequately controlled COPD as demonstrated by experiencing EITHER of the following in the last year:
 - At least two moderate exacerbations resulting in treatment with systemic glucocorticoids, antibiotics, or both.

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- One or more severe exacerbation(s) requiring hospitalization or an emergency medical care visit.
- Member meets EITHER of the following:
 - Member is currently receiving maintenance inhaled triple therapy (i.e., inhaled corticosteroid [ICS], long-acting muscarinic antagonist [LAMA], and longacting beta₂-agonist [LABA]).
 - Member is currently receiving a LAMA and LABA and has a contraindication to ICS.
- Member will continue to use maintenance COPD treatments (e.g., ICS with LAMA and LABA, LAMA and LABA) in combination with the requested medication.

Continuation of Therapy:

Chronic obstructive pulmonary disease (COPD)

Authorization of 12 months may be granted for continuation of treatment of COPD in members 18 years of age or older when BOTH the following criteria are met:

- Member has achieved or maintained a positive clinical response as evidenced by improvement in signs and symptoms of COPD (e.g., decrease in exacerbations, improvement in pre-bronchodilator FEV₁) or stabilization of disease.
- Member will continue to use maintenance COPD treatments (e.g., ICS with LAMA and LABA, LAMA and LABA) in combination with the requested medication.

Other

Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

Note: If the member is a current smoker or vaper, they should be counseled on the harmful effects of smoking and vaping on pulmonary conditions and available smoking and vaping cessation options.

Approval Duration and Quantity Restrictions:

Approval:

• Initial and Renewal: 12 months

Quantity Level Limit:

Dupixent 200 mg / 1.14 mL pre-filled syringe / pen:	2 syringes/pens per 28 days	
Dupixent 300 mg / 2 mL prefilled syringe/pen:	4 syringes/pens per 28 days	
Dupixent 100 mg / 0.67 mL prefilled syringe:	2 syringes per 28 days	

NOTE: Quantity approved with requests will be based upon FDA-approved dosage.

References:

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