

STATE OF WEST VIRGINIA DEPARTMENT OF HUMAN SERVICES BUREAU FOR MEDICAL SERVICES

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Office of Pharmacy Services
Prior Authorization Criteria
DUPIXENT® (dupilumab)
Effective 11/19/2025

Prior Authorization Request Form

DUPIXENT is an interleukin-4 receptor alpha antagonist indicated:

- for the treatment of adult and pediatric patients aged 6 months and older with moderate-to-severe AD 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.
- as an add-on maintenance treatment of adult and pediatric patients aged 6 years and older with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma. Limitations of Use: Not for the relief of acute bronchospasm or status asthmaticus.
- as an add-on maintenance treatment in adult and pediatric patients aged 12 years and older with inadequately controlled chronic rhinosinusitis with nasal polyps (CRSwNP).
- for the treatment of adult and pediatric patients aged 1 year and older, weighing at least 15 kg, with eosinophilic esophagitis (EoE).
- for the treatment of adult patients with prurigo nodularis (PN).
- as an add-on maintenance treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype. Limitations of Use: Not for the relief of acute bronchospasm.
- for the treatment of adult and pediatric patients aged 12 years and older with chronic spontaneous urticaria (CSU) who remain symptomatic despite H1 antihistamine treatment. Limitations of Use: Not indicated for other forms of urticaria.
- for the treatment of adult patients with bullous pemphigoid (BP).

Atopic Dermatitis- Criteria for approval:

- 1. Must be prescribed by a M.D./D.O. or a specialty trained prescriber with a clinical specialty certification/degree in allergy, immunology, or dermatology; **AND**
- Documented diagnosis of moderate to severe Atopic Dermatitis (AD). Documentation must include the affected body surface area (BSA), areas of involvement and severity of symptoms;
 AND
- 3. The patient must be within the age range as recommended by the Food and Drug Administration (FDA) label and indication; **AND**



- 4. Affected body surface area is greater than or equal to 10%; AND
- 5. Patient has failed to find relief of symptoms after a minimum of 30-day trials of two agents from the following list in the last 12 months:
 - a. Medium to High potency topical corticosteroid*
 - b. Elidel
 - c. Eucrisa
 - d. Tacrolimus

*Trial of medium to high potency topical steroid is required unless the affected area involves sensitive areas such as the face, skin folds or genitals. However, a trial of two other agents among the list above, are still required prior to Dupixent approval.

Initial approval of Dupixent for atopic dermatitis will be for 90 days. Additional therapy shall be approvable with documentation of satisfactory patient response (including current affected BSA and severity of symptoms).

Asthma- Criteria for approval:

- 1. Must be prescribed by a M.D./D.O. or a specialty trained prescriber with a clinical specialty certification/degree in allergy, immunology, or pulmonology; **AND**
- The patient must be within the age range as recommended by the FDA label and indication; AND
- 3. Patient must have documented adherence to a therapeutic regimen consisting of a LABA + high dose ICS therapy in the last 90 days; **AND**
- 4. Documentation must be supplied indicating one of the following:
 - a. A positive sputum test for eosinophilic phenotype asthma with sputum eosinophil level ≥ 3% OR
 - b. Asthma with eosinophilic phenotype with blood eosinophil count greater than or equal to 150 cells/mcL within the past 6 weeks or blood eosinophil count greater than or equal to 300 cells/mcL in the past 12 months; **OR**
 - c. Claims data that reflect a <u>continual</u> reliance on oral corticosteroid therapy in the last 90 days.

Initial approval of Dupixent for asthma will be for 90 days. Additional therapy shall be approvable with documentation of satisfactory patient response and compliance on inhaled therapy.

Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP)- Criteria for approval:

- 1. Must be prescribed by a M.D./D.O. or a specialty trained prescriber with a clinical specialty certification/degree in allergy or otolaryngology; **AND**
- 2. Member must have a diagnosis of CRSwNP which has been inadequately controlled after at least 3-months of therapy with any intranasal steroid; **AND**
- 3. The patient must be within the approved age range according to the FDA label and indication; **AND**
- 4. Dupixent is only approvable as add-on therapy for CRSwNP.

Continuation of coverage requires documentation of reduction/elimination of nasal polyps AND patient adherence to therapy (including the original agent Dupixent was supplementing).

Eosinophilic Esophagitis- Criteria for approval:

- 1. Must be prescribed by a M.D./D.O. or a specialty trained prescriber with a clinical specialty certification/degree in allergy, immunology, pulmonology, or gastroenterology; **AND**
- 2. The patient must be within the age range as recommended by the FDA label and indication; AND
- 3. The patient has an eosinophilic count ≥15 eosinophils per high-power microscopy field (eos/hpf); **AND**
- 4. The patient has symptoms of dysphagia or prior history of esophageal dilation; AND
- 5. The patient has had a 90-day trial resulting in an inadequate response to topical/systemic glucocorticoids, unless contraindicated.

Initial approval of Dupixent for Eosinophilic Esophagitis will be for 90 days. Additional therapy shall be approvable with documentation showing that the member has achieved a significant reduction in dysphagia symptoms since treatment initiation.

For the indication of Prurigo Nodularis, prior authorization requests may be approved if the following criteria are met:

- 1. Must be prescribed by a M.D./D.O. or a specialty trained prescriber with a clinical specialty certification/degree in dermatology, allergy, or immunology; **AND**
- 2. The patient must be within the age range as recommended by the FDA label and indication; AND
- 3. Patient has a Worst Itch Numeric Rating Scale (WI-NRS) score of ≥7 on a scale of 0 to 10; AND
- 4. The patient has at least 20 nodular lesions; AND
- 5. The patient has had a trial resulting in an inadequate response/treatment failure to a super potent topical corticosteroid or an intralesional corticosteroid, unless contraindicated.

Initial approval of Dupixent for Prurigo Nodularis will be for 90 days. Additional therapy shall be approvable with documentation of satisfactory patient response and compliance on therapy.

COPD with an eosinophilic phenotype- Criteria for approval:

- 1. Must be prescribed by a M.D./D.O. or a specialty trained prescriber with a clinical specialty certification/degree in pulmonology, allergy, or immunology; **AND**
- 2. The patient must be within the age range as recommended by the FDA label and indication; AND
- 3. The patient must have an eosinophilic count of ≥ 300 cells per mcL within 12 months prior to initiation of therapy; **AND**
- 4. The patient has a history of uncontrolled disease, as indicated by ≥ 2 moderate* or ≥ 1 severe exacerbation* within the past 12 months; **AND**
- 5. The patient has been on standard of care triple therapy with at least one (1) inhaled long-acting anticholinergic (LAMA), at least one (1) inhaled long-acting beta-agonist (LABA), AND one (1) inhaled corticosteroid (ICS) for at least 3 months prior to request, and at a stable dose for at least 1 month prior. *LAMA-LABA is allowed if ICS is contraindicated.

^{*}Moderate exacerbations are defined as exacerbations that resulted in treatment with a systemic corticosteroid, an antibiotic agent, or both. Severe exacerbations are defined as exacerbations that

led to hospitalization or an emergency medical care visit. At least one of the moderate exacerbations was to have resulted in the use of systemic corticosteroid, and at least one exacerbation had to have occurred while the patient was receiving inhaled corticosteroid plus LAMA–LABA (or LAMA–LABA alone if inhaled corticosteroid was contraindicated).

Initial approval of Dupixent for COPD will be for 90 days. Additional therapy shall be approvable with documentation of satisfactory patient response and compliance on therapy.

All other indications require case-by-case by review by the medical director.