

Protocol for dupilumab (Dupixent)

DURB Approval Date	4/2019, 7/2020, 7/2021, 1/2023, 7/2024; 10/2025
Commissioners Approval Date	10/2019, 5/2021, 5/2022, 2/2024, 1/2025; 2/2026

Protocol applies to FDA approved biosimilars and related indications and dosages**Addendum:**

The protocol has been updated to include chronic obstructive pulmonary disease, chronic spontaneous urticaria and bullous pemphigoid. The criteria for use of Dupixent in asthma was updated to ensure patients are utilizing at least 3 months of conventional asthma treatment and continue to present with symptomatic asthma. Nasal irrigation was added to the criteria for Chronic Rhinosinusitis with Nasal Polyposis. Eosinophilic Esophagitis criteria updated to include a trial of a high dose proton pump inhibitor and a swallowed topical corticosteroid. References are updated.

Background:

Dupilumab (Dupixent®) is an interleukin-4 receptor alpha antagonist that is indicated for the treatment of atopic dermatitis, asthma, eosinophilic esophagitis, prurigo nodularis, chronic rhinosinusitis with nasal polyposis, chronic obstructive pulmonary disease, chronic spontaneous urticaria and bullous pemphigoid.

Criteria for approval:

1. Patient is of the FDA-labeled or compendial approved age
2. Medication is not concomitantly used with another biologic immunomodulator or JAK inhibitor for the same diagnosis
3. Medication is prescribed by or in consultation with a specialist in the appropriate field
4. Patient does not have any contraindications to therapy
5. Patient's current weight is provided for indications utilizing weight-based dosing
6. The medication requested is prescribed in accordance with a Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with a medically-appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence

Atopic Dermatitis (all of the following)

- a. Patient has a diagnosis of moderate to severe atopic dermatitis
- b. Patient has a minimum of 10% body surface area involvement OR has clinically difficult to treat areas (e.g., face, neck, genital) that interfere with quality of life
- c. Patient has tried and failed or has contraindications for ALL of the following:
 - i. One medium to very high potency topical prescription corticosteroid for a trial of ≥ 2 weeks
 - ii. One topical calcineurin inhibitor (e.g., Elidel, Protopic) for a trial of ≥ 4 weeks
- d. Topical emollients are concomitantly used in problem areas (e.g., face, neck, genitals) to help prevent flares

Asthma (all of the following)

- a. The patient has moderate to severe asthma and meets ONE of the following (i. or ii.):
 - i. Patient has an eosinophilic phenotype and blood eosinophil counts ≥ 150 cells/microliter on current laboratory assessment
 - ii. Patient has oral corticosteroid-dependent asthma and is adherent to an oral corticosteroid regimen
- b. The patient is has been treated with ONE of the following maximally tolerated conventional

regimens for at least the past 3 months

- i. Patients 12 years of age and older must receive ONE of the following:
 - a. An inhaled corticosteroid (ICS) plus formoterol (or another long-acting beta agonist (LABA) with an as-needed short-acting beta agonist (SABA)) plus long-acting muscarinic antagonist (LAMA)
 - b. ICS plus LABA plus leukotriene receptor antagonist (LTRA)
 - c. ICS plus LABA plus theophylline
- ii. Patients 6 to 11 years of age must receive an ICS plus formoterol (or another LABA with an as needed SABA) or ICS plus LABA plus LTRA or ICS plus LABA plus tiotropium
- c. The patient is continuing to utilize maximally tolerated conventional asthma treatment with requested medication
- d. The patient has experienced ONE of the following events despite regular use of conventional therapies within the past 12 months (must meet i. ii. or iii.)
 - i. Two or more exacerbations requiring systemic corticosteroids (steroid bursts)
 - ii. At least one asthma exacerbation requiring hospitalization or emergency medical care visits
 - iii. Poor symptom control defined by ONE of the following:
 1. Frequent asthma symptoms
 2. Frequent rescue medication use
 3. Limited activity due to asthma
 4. Night waking due to asthma

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) (ALL of the following)

- a. Patient has a confirmed diagnosis of CRSwNP
- b. The patient meets at least ONE of the following:
 - i. The patient had an inadequate response to oral systemic corticosteroids or has an intolerance or contraindication to all oral systemic corticosteroids
 - ii. The patient is not a candidate for sinonasal surgery or nasal laser therapy
 - iii. The patient had an inadequate response to sinonasal surgery or nasal laser therapy
- c. The patient had an inadequate response to a 3-month trial of at least one intranasal corticosteroid (INCS) and an 8-week trial of nasal saline irrigation or has an intolerance or contraindication to all intranasal corticosteroids and nasal saline irrigation
- d. The patient has ongoing symptoms of nasal congestion, blockage, or obstruction with moderate to severe symptom severity along with another CRSwNP related symptom
- e. Medication is being used as add-on therapy for CRSwNP, unless all other therapies are contraindicated

Eosinophilic Esophagitis (ALL of the following)

- a. Patient has a diagnosis of eosinophilic esophagitis (EoE) and has an eosinophil count of ≥ 15 intraepithelial eosinophils per high power field on esophageal biopsy
- b. Patient has signs or symptoms of esophageal dysfunction
- c. Patient had an inadequate response to at least an 8-week trial of a swallowed topical steroid (e.g. budesonide respules) and/or a high dose proton pump inhibitor or has an intolerance or contraindication to corticosteroids and proton pump inhibitors

Prurigo Nodularis (ALL of the following)

- a. Patient has a diagnosis of prurigo nodularis (PN)
- b. Patient has widespread or recalcitrant ≥ 20 nodular lesions
- c. Patient has a Worst Itch Numeric Rating Scale (WI-NRS) score ≥ 7 on a scale of 0 to 10

- d. Patient had an inadequate response to at least one previous PN treatment
- e. Patient has an intolerance or contraindication to all other PN treatments

Chronic Obstructive Pulmonary Disease (must meet ALL of the following):

- a. Patient has a confirmed diagnosis of chronic obstructive pulmonary disease (COPD)
- b. Patient has confirmed eosinophilic phenotype as shown by an eosinophilic count ≥ 300 cell/ μ L despite trial of conventional therapy
- c. Medication is used as an add-on maintenance treatment to conventional therapy that includes a LABA plus LAMA with or without an inhaled corticosteroid trial and has continued to experience ≥ 2 moderate exacerbations or ≥ 1 exacerbation leading to hospitalization

Chronic Spontaneous Urticaria (must meet ALL of the following):

- a. Patient has a confirmed diagnosis of chronic spontaneous urticaria
- b. Unless patient has an intolerance or contraindication must try BOTH of the following:
 - i. Two different second-generation H1-antihistamine at maximally tolerated dose
 - ii. One second-generation H1-antihistamine together with a LTRA

Bullous Pemphigoid (must meet ALL of the following):

- a. Patient has a confirmed diagnosis of bullous pemphigoid
- b. Unless there is an intolerance or contraindication patient has tried a high-dose glucocorticoid plus at least one of the following:
 - i. High potency topical corticosteroid
 - ii. Antibiotic
 - iii. Immunosuppressant

Continuation of therapy:

- 1. Documentation of a positive clinical response
- 2. Medication is not used concomitantly with another biologic with the same indication
- 3. The patient is continuing to utilize maximally tolerated conventional asthma treatment with requested medication, where indicated

Approval Duration:

- Initial approval: atopic dermatitis - 4 months; COPD - 12 months; all others - 6 months
- Renewal approval: 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:

- 1. Dupixent® (package insert). Regeneron Pharmaceuticals, Inc. Tarrytown, NY. June 2025.
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