Addendum to the Protocol for dupilumab (Dupixent®)

Approved July 2024

Addendum:
Addition of all FDA-labeled indications for dupilumab (Dupixent)

Background:
Dupilumab (Dupixent®) is an interleukin-4 receptor alpha antagonist that is indicated for the treatment of atopic dermatitis, asthma, eosinophilic esophagitis, prurigo nodularis, and chronic rhinosinusitis with nasal polyposis.

Criteria for approval:

1. Medication dosage is appropriate for the patient's indication and age
2. Medication will not be used concomitantly with another biologic immunomodulator or JAK inhibitor
3. Medication is prescribed by or in consultation with a specialist in the appropriate field
4. Medication 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, Lexi-Drugs, national guidelines, or other peer-reviewed evidence

5. **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
    e. Success of treatment will be assessed regularly

6. **Asthma** (all of the following)
    a. Patient has moderate to severe asthma with ONE of the following:
        i. Patient has an eosinophilic phenotype and has blood eosinophil counts ≥150 cells/microliter OR
        ii. Patient has oral corticosteroid-dependent asthma and has been on and adherent to an oral corticosteroid regimen
    b. ONE of the following:
        i. Patient has been on and is currently being treated with maximally tolerated conventional therapies
            1. An inhaled corticosteroid regimen in the past 12 months; **AND**
            2. A regimen containing either a long-acting beta agonist, long-acting muscarinic antagonist, leukotriene receptor antagonist, theophylline, or zileuton for the last 6 months
        ii. Patient has documented intolerance, contraindication, or hypersensitivity to all the therapies outlined in 6.b.i

c. The patient has had either of the following events despite regular use of conventional therapies (above):
   i. Two or more exacerbations requiring systemic corticosteroids (steroid bursts) within the past 12 months OR
   ii. At least one asthma exacerbation requiring hospitalization, intubation/mechanical ventilation OR
   iii. Multiple emergency department visits within the past 12 months for asthma exacerbations

7. **Chronic Rhinosinusitis with Nasal Polyposis (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 sinonasal surgery
      ii. The patient is not a candidate for sinonasal surgery
      iii. The patient had an inadequate response to oral systemic corticosteroids or has intolerance, contraindication, or hypersensitivity to all oral systemic corticosteroids.
   c. The patient had an inadequate response to a 3-month trial of at least one intranasal corticosteroid (INCS) or has intolerance, contraindication, or hypersensitivity to all intranasal corticosteroids
   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

8. **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 light microscopy following a treatment course of a proton pump inhibitor (PPI)
   b. Patient has regurgitation, dysphagia, or food impaction
   c. Patient has had an inadequate response to at least a 90-day trial of one appropriate corticosteroid
   d. Patient has an intolerance, hypersensitivity or contraindication to the therapies listed in 8.c.

9. **Prurigo Nodularis** (all of the following)
   a. Patient has a diagnosis of prurigo nodularis (PN)
   b. Patient has ≥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 has had an inadequate response to one previous PN treatment,
   e. Patient has an intolerance, hypersensitivity, or contraindication to all other PN treatments

Continuation of therapy:

1. Documentation of a positive clinical response
2. Medication is not used concomitantly with another biologic with the same indication

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:

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4. Sidbury R, Davis DM et al. Guidelines of care for the management of atopic dermatitis. J Am Acad Dermatol, July 2014 Volume 71, Issue 1, Pages 116–132
5. Global Initiative for Asthma (GINA). Global Strategy For Asthma Management and Prevention, Global Initiative for Asthma (GINA) 2022. Available at www.ginasthma.org
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8. Gonsalves NP, Aceves SS, Diagnosis and Treatment of Eosinophilic Esophagitis. J Allergy Clin Immunol. 2020 January ; 145(1): 1–7. doi:10.1016/j.jaci.2019.11.011.
9. Yosipovitch, G., Mollanazar, N., Ständer, S. et al. Dupilumab in patients with prurigo nodularis: two randomized, double-blind, placebo-controlled phase 3 trials. Nat Med 29, 1180–1190 (2023). https://doi.org/10.1038/s41591-023-02320-9