BlueCross BlueShield Federal Employee Program

DUPIXENT (dupilumab)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Dupixent (dupilumab) is a human monoclonal IgG4 antibody that inhibits interleukin-4 (IL-4) and interleukin-13 (IL-13) signaling by specifically binding to the interleukin-4 receptor alpha (IL-4Rα) subunit shared by the IL-4 and IL-13 receptor complexes. This blocks the IL-4 and IL-13 cytokine-induced inflammatory responses, including the release of proinflammatory cytokines, chemokines, nitric oxide, and IgE; however, the mechanism of action for Dupixent has not been definitively established (1).

Regulatory Status

FDA-approved indications: Dupixent is an interleukin-4 receptor alpha antagonist indicated: (1)

1. Atopic Dermatitis
    a. For the treatment of adult and pediatric patients aged 6 months and older with moderate-to-severe atopic dermatitis (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.
2. Asthma
    a. 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.
        i. Limitations of Use: Not for the relief of acute bronchospasm or status asthmaticus.
3. Chronic Rhinosinusitis with Nasal Polyps
    a. 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).
4. Eosinophilic Esophagitis
    a. For the treatment of adult and pediatric patients aged 1 year and older, weighing at least 15 kg, with eosinophilic esophagitis (EoE).
5. Prurigo Nodularis
    a. For the treatment of adult patients with prurigo nodularis (PN).
6. Chronic Obstructive Pulmonary Disease (COPD)

a. As an add-on maintenance treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype.
    i. Limitations of Use: Not for the relief of acute bronchospasm.

7. Chronic Spontaneous Urticaria (CSU)
    a. 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.
        i. Limitations of Use: Not indicated for other forms of urticaria.

Dupixent has warnings for hypersensitivity reactions, conjunctivitis and keratitis, and parasitic infections. Patients should be monitored and Dupixent treatment should be discontinued if appropriate (1).

Patients should not discontinue systemic, topical, or inhaled corticosteroids abruptly upon initiation of Dupixent therapy. Steroids should be reduced gradually, if appropriate (1).

FEP adherence is defined as ≥50% utilization within the last 180 days.

Dupixent is approved to treat both asthma and COPD. Patients with features of both these conditions should follow treatment for asthma, per the Global Initiative for Asthma (GINA) report (2).

The safety and effectiveness of Dupixent in pediatric patients less than 6 months of age with atopic dermatitis have not been established. The safety and effectiveness of Dupixent in pediatric patients less than 6 years of age with asthma have not been established. The safety and effectiveness of Dupixent in pediatric patients less than 1 year of age with eosinophilic esophagitis have not been established. The safety and effectiveness of Dupixent in pediatric patients less than 12 years of age with CRSwNP and CSU have not been established. The safety and effectiveness of Dupixent in pediatric patients less than 18 years of age with PN and COPD have not been established (1).

Summary

Dupixent (dupilumab) is an interleukin-4 receptor alpha antagonist indicated for the treatment of atopic dermatitis (AD), asthma, eosinophilic esophagitis (EoE), chronic rhinosinusitis with nasal

polyps (CRSwNP), prurigo nodularis (PN), chronic obstructive pulmonary disease (COPD), and chronic spontaneous urticaria (CSU). Dupixent has warnings for hypersensitivity reactions, conjunctivitis and keratitis, and parasitic infections. Patients should be monitored and Dupixent treatment should be discontinued if appropriate. The safety and effectiveness of Dupixent in pediatric patients less than 6 months of age with atopic dermatitis have not been established. The safety and effectiveness of Dupixent in pediatric patients less than 6 years of age with asthma have not been established. The safety and effectiveness of Dupixent in pediatric patients less than 1 year of age with eosinophilic esophagitis have not been established. The safety and effectiveness of Dupixent in pediatric patients less than 12 years of age with CRSwNP and CSU have not been established. The safety and effectiveness of Dupixent in pediatric patients less than 18 years of age with PN and COPD have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Dupixent while maintaining optimal therapeutic outcomes.

References

1. Dupixent [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals Inc.; April 2025.
2. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2024. Available from www.ginasthma.org.