RATIONALE FOR INCLUSION IN PA PROGRAM

**Background**

Dupixent is a medication used for the treatment of atopic dermatitis (eczema). Atopic dermatitis, a chronic inflammatory skin disease, is often referred to as “eczema,” which is a general term for several types of inflammation of the skin. In atopic dermatitis, the skin develops red, scaly and crusted bumps, which are extremely itchy. Scratching leads to swelling, cracking, “weeping” clear fluid, and finally, coarsening and thickening of the skin. Dupixent is an antibody that binds to a protein that causes inflammation. By binding to this protein, Dupixent is able to inhibit the inflammatory response that plays a role in the development of atopic dermatitis (1-6).

Dupixent is a human monoclonal IgG4 antibody that inhibits interleukin-4 (IL-4) and interleukin-13 (IL-13) signaling by specifically binding to the IL-4Ra 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 Dupixent action in asthma has not been definitively established (1).

**Regulatory Status**

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

1. For the treatment of adult patients 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.

2. As an add-on maintenance treatment in patients with moderate-to-severe asthma aged 12 years and older with an eosinophilic phenotype or with oral corticosteroid dependent asthma.

Limitations of use: Not for the relief of acute bronchospasm or status asthmaticus (1).

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).

The safety and effectiveness of Dupixent in pediatric patients <18 years of age with atopic dermatitis have not been established. Safety and effectiveness of Dupixent in pediatric patients <12 years of age with asthma have not been established (1).

Summary
Dupixent is a medication used for treatment of atopic dermatitis (eczema) and asthma. Dupixent is an antibody that binds to a protein that causes inflammation. By binding to this protein, Dupixent is able to inhibit the inflammatory responses that play a role in the development of atopic dermatitis and asthma. The safety and effectiveness of Dupixent in pediatric patients <18 years of age with atopic dermatitis have not been established. Safety and effectiveness of Dupixent in pediatric patients <12 years of age with asthma 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