BlueCross BlueShield Federal Employee Program

ORALAIR

(Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens Allergen Extract)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Oralair is an allergen extract consisting of 5 species of grass, formulated into a daily sublingual tablet used to treat grass pollen-induced hay fever / allergies that can cause sneezing, runny or stuffy nose and watery eyes. Oralair contains a mixture of freeze-dried extracts from the pollens of five grasses, including Kentucky Blue Grass, Orchard, Perennial Rye, Sweet Vernal and Timothy (1).

Regulatory Status

FDA-approved indication: Oralair is an allergen extract indicated as immunotherapy for the treatment of grass pollen-induced allergic rhinitis with or without conjunctivitis confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for any of the five grass species contained in this product (1).

Oralair has a boxed warning concerning systemic allergic reactions including anaphylaxis and laryngopharyngeal swelling which may be life threatening. The initial dose of Oralair must be administered in a healthcare setting under the supervision of a physician and they must be monitored for at least 30 minutes to watch for signs and symptoms of life-threatening systemic or local allergic reaction. If the patient tolerates the first dose, subsequent doses may be taken at home. The prescriber should prescribe and an auto-injectable epinephrine to patients receiving Oralair with instruction on how to recognize the signs and symptoms of a severe allergic reaction and in the proper use of emergency auto-injectable epinephrine. Instruct patients to seek immediate medical care upon use of auto-injectable epinephrine and to stop treatment with Oralair (1).

Oralair is contraindicated in patients with severe, unstable or uncontrolled asthma (rescue inhaler use greater than 2 days or more per week; significantly impaired activity levels due to troublesome symptoms), a history of any severe systemic allergic reaction or severe local reaction after taking any sublingual allergen immunotherapy (1).

Oralair has a boxed warning that therapy might not be suitable for patients with certain underlying

medical conditions that may reduce their ability to survive a serious allergic reaction, or who may be unresponsive to epinephrine or inhaled bronchodilators, such as patients on beta-blockers (1).

Sublingual tablet immunotherapy is associated with eosinophilic esophagitis. Oralair is contraindicated in patients with eosinophilic esophagitis (1).

Concomitant dosing of Oralair with other allergen immunotherapy may increase the likelihood of local or systemic adverse reactions to either subcutaneous or sublingual allergen immunotherapy (1).

The safety and effectiveness of Oralair in patients younger than 10 years of age or older than 65 years of age have not been established (1).

Summary

Oralair is an allergen extract used to treat allergic rhinitis (hay fever) with or without conjunctivitis (eye inflammation) confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for any of the five grass species contained in this product. The safety and effectiveness of Oralair in patients younger than 5 years of age or older than 65 years of age have not been established (1).

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

References

1. Oralair [package insert]. Antony, France: Stallergenes S.A., Inc.; November 2018