BlueCross BlueShield
Federal Employee Program

ODACTRA
(house dust mite allergen extract)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Odactra is a house dust mite (*Dermatophagoides farinae* and *Dermatophagoides pteronyssinus*) allergen extract formulated into a daily sublingual tablet used to treat house dust mite (HDM)-induced nasal inflammation (allergic rhinitis), with or without eye inflammation (conjunctivitis). These types of allergies can cause sneezing, runny or stuffy nose and watery eyes. Odactra exposes patients to house dust mite allergens, desensitizing the immune system in order to reduce the frequency and severity of nose and eye allergy symptoms. It is a once-daily tablet, taken year-round, that rapidly dissolves after it is placed under the tongue (1).

Regulatory Status

FDA-approved indication: Odactra is an allergen extract indicated as immunotherapy for the treatment of house dust mite (HDM)-induced allergic rhinitis, with or without conjunctivitis, confirmed by positive in vitro testing for IgE antibodies to *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites or by positive skin testing to licensed house dust mite allergen extracts. Odactra is approved for use in individuals 5 through 65 years of age (1).

Odactra has a boxed warning concerning systemic allergic reactions including anaphylaxis and laryngopharyngeal swelling which may be life threatening. The initial dose of Odactra 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 an auto-injectable epinephrine to patients receiving Odactra 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 Odactra (1).

Odactra 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) and a history of any severe systemic allergic reaction or severe local reaction after taking any sublingual allergen immunotherapy (1).

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

Concomitant dosing of Odactra 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 Odactra in patients younger than 5 years of age or older than 65 years of age have not been established (1).

Summary

Odactra is an allergen extract used to treat house dust mite (HDM)-induced allergic rhinitis, with or without conjunctivitis, confirmed by in vitro testing for IgE antibodies to *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites. The safety and effectiveness of Odactra 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 Odactra while maintaining optimal therapeutic outcomes.

References

1. Odactra [package insert]. Swindon, Wiltshire: Catalent Pharma Solutions Limited; February 2025.