Odactra

Description

Odactra (house dust mite allergen extract)

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). This type of allergies can cause sneezing, runny or stuffy nose and watery eyes. Odactra exposes patients to house dust mite allergens, gradually training the immune system in order to reduce the frequency and severity of nasal 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 in vitro testing for IgE antibodies to Dermatophagoides farinae or Dermatophagoides pteronyssinus house dust mites, or skin testing to licensed house dust mite allergen extracts (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 and 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), a history of any severe systemic allergic reaction or severe local reaction after taking any sublingual allergen immunotherapy (1).

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 18 years of age or older than 65 years of age have not been established (1).

Related policies
Grastek, Oralair, Ragwitek

Policy
This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Odactra may be considered medically necessary in patients 18 through 65 years of age for the treatment of house dust mite (HDM)-induced allergic rhinitis and if the conditions indicated below are met.

Odactra may be considered investigational inpatients under 18 years of age or older than 65 years of age or patients and for all other indications.

Prior-Approval Requirements
Age 18 through 65 years of age
Diagnosis

Patient must have the following:

House dust mite (HDM)-induced allergic rhinitis

AND ALL of the following:

a. Confirmation with either a positive skin test or in vitro testing for pollen-specific for IgE antibodies to *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites

b. Physician has adequate training and experience in the treatment of allergic diseases

c. Patient has shown unacceptable response to at least one oral or intranasal steroid and at least one oral antihistamine

d. Absence of severe, unstable or uncontrolled asthma (rescue inhaler use greater than 2 days or more per week; significantly impaired activity levels due to troublesome symptoms)

e. Absence of eosinophilic esophagitis

f. Auto-injectable epinephrine has been prescribed and the patient instructed in its use

g. Will NOT be used with other allergen immunotherapies

h. NO history of severe local reaction to sublingual allergen immunotherapy

Prior – Approval *Renewal* Requirements

Age

18 through 65 years of age

Diagnosis

Patient must have following:

House dust mite (HDM)-induced allergic rhinitis

AND ALL of the following:

a. Absence of severe, unstable or uncontrolled asthma (rescue inhaler use greater than 2 days or more per week; significantly impaired activity levels due to troublesome symptoms)

b. Absence of eosinophilic esophagitis
c. Will **NOT** be used with other allergen immunotherapies

### Policy Guidelines

**Pre - PA Allowance**

None

**Prior - Approval Limits**

- **Quantity**: 90 tablets per 90 days
- **Duration**: 12 months

**Prior – Approval ** *Renewal* Limits

Same as above

### Rationale

**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 18 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**


### Policy History

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December 2019  Annual review

**Keywords**

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective on January 1, 2020.