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Section:	Prescription Drugs	**Effective Date:**	January 1, 2024
Subsection:	Biologicals	**Original Policy Date:**	March 24, 2017
Subject:	Odactra	**Page:**	1 of 5

Last Review Date: December 8, 2023

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). 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 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. Odactra is approved for use in persons 12 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).

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 12 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** if the conditions indicated below are met.

Odactra may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 12 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 12 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 12 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; January 2023.

Policy History

Date	Action
March 2017	Addition to PA
June 2017	Annual review
November 2018	Annual review and reference update
December 2019	Annual review
December 2020	Annual review and reference update
September 2021	Annual review

September 2022	Annual review
June 2023	Per PI update, revised age requirement from 18 through 65 to 12 through 65 years of age
September 2023	Annual review
December 2023	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 8, 2023 and is effective on January 1, 2024.