Effective Date **7/1/2025**
Coverage Policy Number **IP0516**

Odactra

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Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for Odactra® (house dust mite [*Dermatophagoides farina* and *Dermatophagoides pteronyssinus*] allergen extract sublingual tablets).

Medical Necessity Criteria

Odactra (house dust mite [*Dermatophagoides farina* and *Dermatophagoides pteronyssinus*] allergen extract sublingual tablets) is considered medically necessary when the following are met:

1. **House Dust Mite-Induced Allergic Rhinitis. Individual meets ALL of the following criteria:**
   A. Age 5 years old or older
   B. Diagnosis confirmed by **ONE** of the following:
      a. Positive skin test response to house dust mite allergen extracts
      b. Positive *in vitro* test (i.e., a blood test for allergen-specific IgE antibodies) for house dust mite (HDM)
   C. Failure, contraindication, or intolerance to **BOTH** of the following:
      a. Intranasal corticosteroid therapy
      b. Either oral or intranasal antihistamine

   When criteria are met, a maximum of 1 tablet per day will be covered.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Reauthorization Criteria

Continuation of Odactra® (house dust mite [*Dermatophagoides farina* and *Dermatophagoides pteronyssinus*] allergen extract sublingual tablets) is considered medically necessary for house dust mite-induced allergic rhinitis when the above medical necessity criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration: up to 12 months
Reauthorization approval duration: up to 12 months

Conditions Not Covered

Any other use is considered experimental, investigational or unproven, including the following (this list may not be all inclusive):

1. **Concurrent Use of Odactra with Subcutaneous Allergen Immunotherapy or Sublingual Allergen Immunotherapy.**
   This includes allergy shots as well as Grastek (Timothy grass pollen allergen extract sublingual tablets), Oralair (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass mixed pollens allergen extract sublingual tablets), and Ragwitek (short ragweed pollen allergen extract sublingual tablets). The efficacy and safety of Odactra have not been evaluated in patients who are receiving concomitant allergen immunotherapy.[1]

Approved product labeling for Odactra states that concomitant dosing with other allergen immunotherapy may increase the risk of local or systemic adverse events to either subcutaneous or sublingual allergen immunotherapy.

Background

OVERVIEW
Odactra, a house dust mite allergen extract, is indicated as immunotherapy for **house dust mite-induced allergic rhinitis**, with or without conjunctivitis, confirmed by positive *in vitro* testing for immunoglobulin E (IgE) antibodies to house dust mites or skin testing to licensed house dust mite allergen extracts.[1] It is approved for use in patients 5 to 65 years of age. Odactra is not indicated for the immediate relief of allergic symptoms.

Clinical Efficacy
Pivotal trials of Odactra involved patients as young as 5 years of age with house dust mite-induced allergic rhinitis with or without conjunctivitis.[1-4] The house dust mite sensitivity was confirmed by a positive skin test response to *Dermatophagoides pteronyssinus* and/or *D. farina* and a specific IgE level of ≥ 0.7 kU/L against *D. pteronyssinus*, *D. farina* or both.

References

1. Odactra® allergen extract sublingual tablets [prescribing information]. Horsholm, Denmark: ALK-Abellò; February 2024.
2. Nolte H, Bernstein DI, Nelson HS, et al. Efficacy of house dust mite sublingual immunotherapy tablet in North American adolescents and adults in a randomized, placebo-controlled trial. *J Allergy Clin Immunol*. 2016;138(6):1631-1638.
3. Demoly P, Emminger W, Rehm D, et al. Effective treatment of house dust mite-induced allergic rhinitis with 2 doses of the SQ HDM SLIT-tablet: results from a randomized, double-blind, placebo-controlled phase III trial. *J Allergy Clin Immunol*. 2016;137(2):444-451.
4. Nolte H, Maloney J, Nelson HS. Onset and dose-related efficacy of house dust mite sublingual immunotherapy tablets in an environmental exposure chamber. *J Allergy Clin Immunol*. 2015;135(6):1494-1501.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	No criteria changes	1/1/2025
Early Annual Revision	**House Dust Mite-Induced Allergic Rhinitis.** Criteria were updated to require the patient to be ≥ 5 years of age. Previously, criteria required the patient be ≥ 12 years of age. Removed documentation from failure, contraindication or intolerance to covered alternatives criterion.	7/1/2025

The policy effective date is in force until updated or retired.