Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member’s specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

BLUE CROSS®, BLUE SHIELD® and the Cross and Shield Symbols are registered service marks of the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield Plans. All other trademarks and service marks contained in this guideline are the property of their respective owners, which are not affiliated with BCBSAZ.

**Description:**

Odactra House Dust Mite (*Dermatophagoides farina & Dermatophagoides pteronyssinus*) allergen extract sublingual tablet is indicated in adults as immunotherapy for house dust mite (HDM)-induced allergic rhinitis, with or without conjunctivitis, confirmed by *in vitro* testing for immunoglobulin E (IgE) antibodies to *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* HDMs, or skin testing to licensed HDM allergen extracts. Odactra is not indicated for the immediate relief of allergic symptoms.

HDM allergies are a reaction to tiny bugs found in house dust on bedding, upholstered furniture, and carpeting. Individuals with HDM allergies experience a cough, runny nose, nasal itching, nasal congestion, sneezing, and itchy and watery eyes.

Allergen immunotherapy (AIT) for the treatment of allergic symptoms has traditionally been administered by subcutaneous injection therapy (SCIT) or as an aqueous or liquid extract of allergen, generally administered as
ODACTRA™ House Dust Mite (Dermatophagoides farina & Dermatophagoides pteronyssinus) allergen extract sublingual tablet (cont.)

drops, and held under the tongue for a specified period of time and then the residual is swallowed (SLIT-drop). A new alternative approach is administration of allergens using a dissolvable sublingual tablet (SLIT-tab).

SLIT-tab has a risk for anaphylaxis and they are not used in combination with other immunotherapy (other SLIT-tab, SLIT-drop, or SCIT) due to an increased risk for hypersensitivity reactions. Use of SLIT-tab in individuals with severe, unstable, or uncontrolled asthma is contraindicated.

The initial dose of SLIT-tab is given in the office setting, where the individual can be observed for 30 minutes after the first dose. Individuals require a prescription of epinephrine for home use for severe allergic reactions if they develop. SLIT-tab is not used to control acute symptoms or to provide immediate relief of symptoms. It should be noted that other long established therapeutic options mentioned below can be given at any time to control acute and chronic symptoms.

Six medication classes are available for use to treat allergic rhinitis: antihistamines (oral and intranasal), corticosteroids (oral and intranasal), leukotriene receptor antagonists (oral), sympathomimetic decongestants (oral and intranasal), chromolyn (intranasal), and the anticholinergic, ipratropium bromide (intranasal). Selection of any particular agent or combination of agents should be based on type of symptoms needed to control and other medical conditions of the individual.

Oral antihistamines may be less effective than other treatments for prominent congestion symptoms. For mild or intermittent symptoms, use of an oral or intranasal antihistamine may be considered first-line treatment. Due to less sedating effects, newer selective oral antihistamines are recommended over older nonselective antihistamines. Rhinorrhea may respond to intranasal ipratropium and rhinitis-only symptoms may be treated with intranasal rather than oral therapy. Intranasal corticosteroids may be effective for more severe or persistent symptoms.

Combination treatment may consist of oral antihistamine with intranasal corticosteroid, intranasal antihistamine and intranasal corticosteroid, and oral or intranasal antihistamine plus sympathomimetic. Combination therapy may be effective for symptoms nonresponsive to single medications.

Oral sympathomimetics may cause insomnia and their use may be limited in patients with certain comorbidities; intranasal sympathomimetics may cause rebound nasal congestion when used beyond 5 days. Oral leukotriene receptor antagonists may reduce asthma exacerbations in patients with comorbid asthma.

Odactra House Dust Mite allergen extract tablets contain house dust mite allergen extract from Dermatophagoides farinae and Dermatophagoides pteronyssinus. The precise mechanisms of action of allergen immunotherapy have not been fully established.

Definitions:

Drug related events:

Ineffective / failure
Use of a drug employing optimal doses (FDA-recommended doses) for optimal duration; where the condition being treated has not improved or worsened
A request for branded agent due to generic drug failure or ineffectiveness will be assessed for potential approval with documentation of use of optimal dose / duration of the generic product and meeting other criteria within the coverage guideline. When the drug in question is a combination product, there must be documentation of failure / ineffectiveness of concurrent use (each ingredient used at the same time) of individual generic components. When the drug in question is a low dose formulation, there must be documentation of failure / ineffectiveness of low dose generic formulation.

Adverse Drug Event: Allergic reaction / Hypersensitivity / Intolerance
Use of a drug produced a significant reaction where continued use of the drug places the individual at risk for either lack of improvement or worsening of the condition being treated or at risk for harm and the concern is documented in medical record. A significant adverse drug event is when an individual's outcome is death, life-threatening, hospitalization (initial or prolonged), disability resulting in a significant, persistent, or permanent change, impairment, damage or disruption in the individuals' body function/structure, physical activities or quality of life, or requires intervention to prevent permanent impairment or damage.

Allergic reaction / hypersensitivity – may or may not involve the active ingredient. When the active ingredient is involved, use of same or a chemically similar agent places the individual at risk for harm when the same or chemically similar agent is used. The subsequent reaction may be the same as the original reaction or a more exaggerated response may be seen, potentially placing the individual at even greater risk for harm.

If the reaction occurred from the active/main generic ingredient; request for branded agent with same active ingredient will not be considered unless it is proven (documented) that active ingredient did not cause reaction and the request meets other criteria within the coverage guideline

Intolerance – these events represent circumstance(s) where use of a drug produced a significant reaction and continued use may result in non-adherence to proposed therapy and this concern is documented in medical record

Contraindication
Use of a drug that is not recommended by the manufacturer or FDA labelling

Use of any drug in the face of a contraindication is outside of the FDA and manufacturer’s labelled recommendation and is considered investigational or experimental

Non-adherence
Individual does not follow prescribe regimen that places the individual at risk for lack of improvement or worsening of the condition being treated and this concern is documented in medical record

Precertification:
Precertification (Prior Authorization) is required for members with a Blue Cross Blue Shield of Arizona (BCBSAZ) pharmacy benefit for medication(s) or product(s) indicated in this guideline.
ODACTRA™ House Dust Mite (*Dermatophagoides farina* & *Dermatophagoides pteronyssinus*) allergen extract sublingual tablet (cont.)

This Pharmacy Coverage Guideline does not apply to FEP or other states’ Blues Plans.

Information about medications that require precertification is available at [www.azblue.com/pharmacy](http://www.azblue.com/pharmacy).

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

**Criteria:**

See “Resources” section for FDA-approved dosage.

- Precertification for Odactra House Dust Mite (*Dermatophagoides farina* & *Dermatophagoides pteronyssinus*) allergen extract requires completion of the specific request form in its entirety. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. Incomplete forms will be returned.

- **Initial therapy:** FDA-approved product labeling (indication, age, dosage, testing, contraindications, exclusions, etc.) of Odactra House Dust Mite (*Dermatophagoides farina* & *Dermatophagoides pteronyssinus*) allergen extract is considered medically necessary when ALL of the following criteria are met:

  1. Individual is 18 years of age or older

  2. Medical record documentation of a confirmed diagnosis of house dust mite-induced allergic rhinitis with or without conjunctivitis confirmed by in vitro testing for immunoglobulin E (IgE) antibodies to house dust mite-specific to *Dermatophagoides farina* or *Dermatophagoides pteronyssinus* house dust mites, or skin testing to a licensed house dust mite allergen extract

  3. Unable to use ALL of the following due to either they were not effective or not tolerated or are contraindicated:
     - At least ONE intranasal corticosteroid (over the counter or prescription only) for allergic rhinitis
     - At least ONE of the following other allergic rhinitis medication (over the counter or prescription only):
       - Oral or nasal antihistamine
       - Nasal anticholinergic
       - Oral leukotriene modifier
       - Nasal mast cell stabilizer
     - When applicable, for allergic rhinitis with conjunctivitis use of ONE ophthalmic anti-allergy medication (over the counter or prescription only)

  4. Absence of ALL of the following contraindications:
     - Severe, unstable or uncontrolled asthma
ODACTRA™ House Dust Mite (*Dermatophagoides farina & Dermatophagoides pteronyssinus*) allergen extract sublingual tablet (cont.)

- History of any severe systemic allergic reaction
- History of any severe local reaction to sublingual allergen immunotherapy
- History of eosinophilic esophagitis
- Hypersensitivity to any of the inactive ingredients contained in the product

5. Absence of **ALL** of the following exclusions:
   - Treatment of acute or immediate relief of allergy symptoms
   - Used with other allergen immunotherapy (SCIT, SLIT-drop, or other SLIT-tab)

- **Continuation of coverage (renewal request):** Odactra House Dust Mite (*Dermatophagoides farina & Dermatophagoides pteronyssinus*) allergen extract is considered medically necessary with documentation of **ALL** of the following:
  1. The individual has benefited from therapy but remains at high risk
  2. The condition has not progressed or worsened while on therapy
  3. Individual has not developed any contraindications or other exclusions to its continued use

- Odactra House Dust Mite (*Dermatophagoides farina & Dermatophagoides pteronyssinus*) allergen extract for all other indications not previously listed is considered experimental or investigational based upon:
  1. Lack of final approval from the Food and Drug Administration, and
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  3. Insufficient evidence to support improvement of the net health outcome, and
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  5. Insufficient evidence to support improvement outside the investigational setting.

**Resources:**


ODACTRA™ House Dust Mite (*Dermatophagoides farina & Dermatophagoides pteronyssinus*) allergen extract sublingual tablet (cont.)

FDA-approved indication and dosage:

<table>
<thead>
<tr>
<th>Indication</th>
<th>Recommended Dose</th>
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<tbody>
<tr>
<td>ODACTRA™ is an allergen extract indicated as immunotherapy for house dust mite (HDM)-induced allergic rhinitis, with or without conjunctivitis, confirmed by <em>in vitro</em> testing for IgE antibodies to <em>Dermatophagoides farinae</em> or <em>Dermatophagoides pteronyssinus</em> house dust mites, or skin testing to licensed house dust mite allergen extracts.</td>
<td>One ODACTRA tablet daily. For sublingual use only. Administer the first dose of ODACTRA in a healthcare setting under the supervision of a physician with experience in the diagnosis and treatment of allergic diseases. After receiving the first dose of ODACTRA, observe the patient for at least 30 minutes to monitor for signs or symptoms of a severe systemic or a severe local allergic reaction. If the patient tolerates the first dose, the patient may take subsequent doses at home. Data regarding the safety of restarting treatment after missing a dose of ODACTRA are limited. In the clinical studies, treatment interruptions for up to seven days were allowed. Prescribe auto-injectable epinephrine to patients prescribed ODACTRA and instruct patients in the proper use of emergency self-injection of epinephrine.</td>
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