PRIOR AUTHORIZATION POLICY

POLICY: Allergen Immunotherapy – Odactra Prior Authorization Policy
- Odactra® (house dust mite [*Dermatophagoides farina* and *Dermatophagoides pteronyssinus*] allergen extract sublingual tablets – Merck)

REVIEW DATE: 08/31/2022; selected revision 02/01/2023

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 *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 12 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 12 years of age with house dust mite-induced allergic rhinitis with or without conjunctivitis.[2-4] The house dust mite sensitivity was confirmed by a positive skin test response to *D. pteronyssinus* and/or *D. farina* and a specific IgE level of ≥ 0.7 kU/L against *D. pteronyssinus*, *D. farina* or both.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Odactra. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Odactra is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **House Dust Mite-Induced Allergic Rhinitis.** Approve for 1 year if the patient meets ALL of the following criteria (A and B):
   - **A)** Patient is ≥ 12 years of age; AND
   - **B)** The diagnosis of house dust mite-induced allergic rhinitis is confirmed by meeting ONE of the following conditions (i or ii):
     - **i.** Patient has a positive skin test response to house dust mite allergen extracts; OR
     - **ii.** Patient has a positive *in vitro* test (i.e., a blood test for allergen-specific immunoglobulin E antibodies) for house dust mite.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Odactra is not recommended in the following situations:

1. **Concurrent Use of Odactra with Subcutaneous Allergen Immunotherapy or Sublingual Allergen Immunotherapy.** Note: 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 the subcutaneous or sublingual allergen immunotherapy.

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Odactra® allergen extract sublingual tablets [prescribing information]. Whitehouse Station, NJ: Merck; January 2023.
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.