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: 08/05/2020

OVERVIEW

Odactra is a house dust mite allergen extract sublingual tablet 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 18 to 65 years of age. Odactra is not indicated for the immediate relief of allergic symptoms.

Clinical Efficacy

In clinical trials involving adult patients (one pivotal study included a small number of pediatric patients), 52 weeks of therapy with Odactra resulted in a 17% to 18% improvement in patients' average Total Combined Rhinitis Score (TCRS) [a measurement of both rhinitis symptoms and relief medication use] compared with placebo.[2,3] In a 24-week environmental exposure chamber study, Odactra therapy resulted in a 48.6% improvement in the average total nasal symptom score (TNSS) compared with placebo.[4] There are limited data with Odactra in patients < 18 years of age as well; however, the safety and efficacy has not been established at this time.[5,6,13]

Guidelines

Several guidelines address allergic rhinitis with or without conjunctivitis, house dust mite allergy, and sublingual immunotherapy. In general, it is recommended that allergen immunotherapy should be considered for patients with allergic rhinitis or allergic asthma and an inadequate response to medical therapy who have evidence of specific IgE antibodies to clinically relevant allergens.[7,8,14] House dust mite sublingual allergen immunotherapy is recommended for long-term benefit in house dust mite-induced allergic rhinitis with or without conjunctivitis (in select guidelines).[9] There is more evidence supporting the use of subcutaneous immunotherapy and therefore, these agents are more widely recommended.[10] However, sublingual immunotherapy is noted to be safe and effective. Additionally, in patients with house-dust mite-driven allergic asthma, house dust mite sublingual immunotherapy tablets have demonstrated a robust effect on several critical asthma parameters (e.g., exacerbations, control, and safety) in adult patients.[11,12] Therefore, house dust mite sublingual immunotherapy is recommended as an add-on to standard asthma therapy in house dust mite-sensitized adults who continue to have asthma exacerbations despite standard therapy.

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 Indications

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 ≥ 18 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 IgE 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 (e.g., Allergy Shots) or Sublingual Allergen Immunotherapy (e.g., 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], 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

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