ALLERGEN EXTRACT-HOUSE DUST MITE

Generic	Brand	HICL	GCN	Exception/Other
HOUSE DUST MITE	ODACTRA		42527	ROUTE = SUBLINGUAL

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of house dust mite (HDM)-induced allergic rhinitis with or without conjunctivitis and meet **ALL** of the following criteria?
   - Diagnosis is 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
   - Patient is between 18 and 65 years old
   - The medication is prescribed by or in consultation with an allergist, immunologist, or other physician experienced in the diagnosis and treatment of allergic diseases
   - The patient has persistent symptoms of allergic rhinitis (persistent symptoms are defined as symptoms presenting at least 4 days a week or for at least 4 weeks)
   - The patient has moderate to severe symptoms of allergic rhinitis (moderate-to-severe symptoms include one or more of the following: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)
   - The patient has a current claim or prescription for auto-injectable epinephrine within the past 365 days

   If yes, **approve for 12 months by GPID with a quantity limit of #1 tablet (12 SQ-HDM) per day.**
   APPROVAL TEXT: Renewal requires an improvement in signs and symptoms of allergic rhinitis from baseline.

   If no, do not approve.
   DENIAL TEXT: The guideline named **ALLERGEN EXTRACT-HOUSE DUST MITE (Odactra)** requires a diagnosis of house dust mite (HDM)-induced allergic rhinitis with or without conjunctivitis. The following criteria must also be met:
   - Diagnosis is 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
   - Patient is between 18 and 65 years old
   - The medication is prescribed by or in consultation with an allergist, immunologist, or other physician experienced in the diagnosis and treatment of allergic diseases
   - The patient has persistent symptoms of allergic rhinitis (persistent symptoms are defined as symptoms presenting at least 4 days a week or for at least 4 weeks)

   (Initial denial text continued on next page)

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ALLERGEN EXTRACT-HOUSE DUST MITE

INITIAL CRITERIA (CONTINUED)

- The patient has moderate to severe symptoms of allergic rhinitis (moderate-to-severe symptoms include one or more of the following: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)
- The patient has a current claim or prescription for auto-injectable epinephrine within the past 365 days

RENEWAL CRITERIA

1. Has the patient experienced an improvement in signs and symptoms of allergic rhinitis from baseline?

   If yes, **approve for 12 months by GPID with a quantity limit of #1 tablet (12 SQ-HDM) per day.**
   If no, do not approve.
   DENIAL TEXT: The guideline named **ALLERGEN EXTRACT-HOUSE DUST MITE (Odactra)** requires that the patient has experienced an improvement in signs and symptoms of allergic rhinitis from baseline for renewal.

RATIONALE
Promote clinically appropriate utilization of Odactra based on its FDA approved indications.

FDA APPROVED INDICATION
Odactra is an allergen extract indicated as immunotherapy for 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 adults 18 through 65 years of age.

DOSAGE AND ADMINISTRATION
One tablet (12 SQ-HDM) 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.

REFERENCES
- Odactra [Prescribing Information]. Merck, Sharp & Dohme Corp. Whitehouse Station, NJ. March 2017.

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Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/18

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Client Approval: 02/18

P&T Approval: 01/18