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Odactra (house dust mite allergen extract)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

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 persons 18 through 65 years of age.

Odactra is not indicated for the immediate relief of allergic symptoms.

POLICY

Criteria for Initial Approval

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed as immunotherapy for the treatment of house dust mite (HDM) induced allergic rhinitis

AND

- The diagnosis has been confirmed by in vitro testing for pollen-specific IgE antibodies for *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites, or skin testing to licensed house dust mite allergen extracts.

AND

- The patient does not have any of the following: severe, unstable or uncontrolled asthma, history of any severe systemic allergic reaction or any severe local reaction to sublingual allergen immunotherapy, history of eosinophilic esophagitis
AND
- The requested drug is being prescribed by or in consultation with an allergist/immunologist.

Approval will be for 12 months.

RATIONALE

These criteria meet the Medicare Part D definition of a medically accepted indication. This definition includes uses which are approved by the FDA or supported by a citation included, or approved for inclusion, in one of the Medicare approved compendia.

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines.

Allergic rhinitis affects 20 to 40 percent of the population in the United States annually.⁴ Effective management of allergic rhinitis may require combinations of aggressive avoidance measures (e.g., avoidance of rhinitis triggers, limiting outdoor exposure when high pollen counts are present), medications, management of coexisting conditions, and/or allergen immunotherapy. A wide range of oral and intranasal pharmacologic treatments exists consisting of antihistamines, decongestants, corticosteroids, cromolyn, anticholinergics, anti-leukotriene agents, and nasal saline.⁵

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Odactra may not be suitable for patients with certain medical conditions that may reduce the ability to survive a serious allergic reaction or increase the risk of adverse reactions after epinephrine administration. Examples of these medical conditions include but are not limited to: markedly compromised lung function (either chronic or acute), unstable angina, recent myocardial infarction, significant arrhythmia, and uncontrolled hypertension.

Odactra may not be suitable for patients who are taking medications that can potentiate or inhibit the effect of epinephrine. These medications include beta-adrenergic blockers, alpha-adrenergic blockers, ergot alkaloids, tricyclic antidepressants, levothyroxine sodium, monoamine oxidase inhibitors, the antihistamines chlorpheniramine and diphenhydramine, cardiac glycosides, and diuretics.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- N/A

REFERENCES

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- Agency for Healthcare Research and Quality. Allergen-Specific Immunotherapy for the Treatment of Allergic Rhinoconjunctivitis and/or Asthma: Comparative Effectiveness Review. U.S. Department of Health and Human Services; 2013. <http://www.effectivehealthcare.ahrq.gov/ehc/products/270/1427/Allergy-Asthma-Immunotherapy-130319.pdf>. Accessed March 2022.
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POLICY HISTORY

Policy #: 05.02.31

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