

## **Clinical Policy: House Dust Mite Allergen Extract (Odactra)**

Reference Number: CP.PMN.111

Effective Date: 09.01.17

Last Review Date: 08.20

[Revision Log](#)

Line of Business: Commercial, HIM, Medicaid

**See [Important Reminder](#) at the end of this policy for important regulatory and legal information.**

### **Description**

House dust mite (*Dermatophagoides farinae* and *Dermatophagoides pteronyssinus*) allergen extract (Odactra<sup>™</sup>) is an allergen extract.

### **FDA Approved Indication(s)**

Odactra is 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.

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

### **Policy/Criteria**

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation<sup>®</sup> that Odactra is **medically necessary** when the following criteria are met:

#### **I. Initial Approval Criteria**

##### **A. Allergic Rhinitis (must meet all):**

1. Diagnosis of HDM-induced allergic rhinitis;
2. Prescribed by or in consultation with an allergist or immunologist;
3. Age  $\geq$  18 years and  $\leq$  65 years;
4. Confirmation of the presence of IgE antibodies to *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* HDM or skin testing to licensed HDM allergen extracts;
5. Failure of one intranasal corticosteroid, unless clinically significant adverse effects are experienced or all are contraindicated;
6. Failure of one oral antihistamine at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated;
7. Dose does not exceed one tablet per day.

##### **Approval duration:**

**Medicaid/HIM** – 12 months

**Commercial** – Length of Benefit

**B. Other diagnoses/indications**

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

**II. Continued Therapy**

**A. Allergic Rhinitis (must meet all):**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed one tablet per day.

**Approval duration:**

**Medicaid/HIM** – 12 months

**Commercial** – Length of Benefit

**B. Other diagnoses/indications (must meet 1 or 2):**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

**Approval duration: Duration of request or 12 months (whichever is less); or**

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

**III. Diagnoses/Indications for which coverage is NOT authorized:**

- A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid, or evidence of coverage documents.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

FDA: Food and Drug Administration

HDM: house dust mite

*Appendix B: Therapeutic Alternatives*

*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.*

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
OTC loratadine (Claritin <sup>®</sup> )	2 to 5 years: 5 mg PO QD ≥ 6 years: 10 mg PO QD	10 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
OTC loratadine-D (Claritin-D <sup>®</sup> 12 and 24 hour)	≥ 12 years: 1 tablet PO BID (12 hr) QD (24 hr)	10 mg/day
OTC cetirizine (Zyrtec <sup>®</sup> )	2 to 5 years: 2.5-5 mg PO QD ≥ 6 years: 10 mg PO QD	10 mg/day
OTC fexofenadine (Allegra Allergy <sup>®</sup> )	6-months to 2 years: 15 mg PO QD 2 to 11 years: 30 mg PO QD ≥ 12 years: 60 mg PO BID or 180 mg PO QD	180 mg/day
fluticasone propionate (Flonase <sup>®</sup> )	≥ 4 years: 1-2 sprays each nostril QD ≥ 12 years: 1-2 sprays each nostril QD	2 sprays each nostril/day
triamcinolone acetonide (Nasacort AQ <sup>®</sup> )	2-11 years: 1 spray each nostril QD ≥ 12 years: 1-2 sprays each nostril QD	2-11 years: 1 spray each nostril/day > 12 years: 2 sprays each nostril/day
mometasone furoate monohydrate (Nasonex <sup>®</sup> )	2-11 years: 1 spray each nostril QD ≥ 12 years: 2 sprays each nostril QD	2-11 years: 1 spray each nostril/day > 12 years: 2 sprays each nostril/day

*Therapeutic alternatives are listed as Brand name<sup>®</sup> (generic) when the drug is available by brand name only and generic (Brand name<sup>®</sup>) when the drug is available by both brand and generic.*

*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s): severe, unstable or uncontrolled asthma; history of eosinophilic esophagitis; history of any severe systemic allergic reaction or any severe local reaction to sublingual allergen immunotherapy; hypersensitivity to any of the inactive ingredients contained in this product
- Boxed warning(s): severe allergic reactions

**V. Dosage and Administration**

Indication	Dosing Regimen	Maximum Dose
HDM-induced allergic rhinitis	One tablet SL QD	1 tablet/day

**VI. Product Availability**

Tablet: 12 SQ-HDM

**VII. References**

1. Odactra Prescribing Information. Round Rock, TX: Alk, Inc.; April 2017. Available at: <http://www.odactra.com>. Accessed April 6, 2020.
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. The Journal of Allergy and Clinical Immunology 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. *The Journal of Allergy and Clinical Immunology* 2016; 137(2) 444-451.
4. Nolte H, Maloney J, Nelson HS, et al. Onset and dose-related efficacy of house dust mite sublingual immunotherapy tablets in an environmental exposure chamber. *The Journal of Allergy and Clinical Immunology* 2015; 135(6):1494-1501.
5. Seidman MD, Gurgel RK, Lin SY, et al. Clinical practice guideline: allergic rhinitis. *Otolaryngology – Head and Neck Surgery* 2015; 152(1S):S1-S43.
6. Wallace DV, Dykewicz MS, Oppenheimer J et al. Pharmacologic treatment of seasonal allergic rhinitis: synopsis of guidance from the 2017 Joint Task Force on Practice Parameters. *Ann Intern Med.* 2017 Dec 19;167(12):876-881. doi: 10.7326/M17-2203.
7. Brozek, JL, Bousquet J, Agache I et al. Allergic rhinitis and its impact on asthma (ARIA) guidelines-2016 revision. *J Allergy Clin Immunol.* 2017 Oct;140(4):950-958. doi: 10.1016/j.jaci.2017.03.050.
8. Greenhawt M, Oppenheimer J, Nelson M, et al. Sublingual immunotherapy: A focused allergen immunotherapy practice parameter update. *Ann Allergy Asthma Immunol.* 2017; 118: 276-282.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	03.17	08.17
3Q 2018 annual review: combined Medicaid and commercial (CP.CPA.315) polices; no significant changes from previously approved corporate policy; age added; Commercial: removed option of intranasal antihistamine or leukotriene modifier as a criteria trial; references reviewed and updated.	04.02.18	08.18
3Q 2019 annual review: no significant changes; corrected age restriction from < 65 years to ≤ 65 years per PI; references reviewed and updated.	04.22.19	08.19
3Q 2020 annual review: no significant changes; added HIM line of business; references reviewed and updated.	04.06.20	08.20

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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**Note:**

**For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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