

Clinical Policy Title:	house dust mite allergen extract
Policy Number:	RxA.424
Drug(s) Applied:	Odactra®
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2020
Line of Business Policy Applies to:	All lines of business

Background

House dust mite (*Dermatophagoides farinae* and *Dermatophagoides pteronyssinus*) allergen extract (Odactra®) is an allergen extract.

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.

Limitation of use:

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

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
house dust mite allergen extract (Odactra®)	HDM-induced allergic rhinitis	One tablet SL QD	1 tablet/day

Dosage Forms

- Tablet: 12 SQ-HDM

Clinical Policy

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

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 ≥ 18 years and ≤ 65 years;
4. Confirmation of the presence of IgE antibodies to *Dermatophagoides farinae* or

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

- Dermatophagoides pteronyssinus* HDM or skin testing to licensed HDM allergen extracts;
5. Failure of one intranasal corticosteroid, unless all are contraindicated or clinically significant adverse effects are experienced;
 6. Failure of one oral antihistamine at up to maximally indicated doses, unless all are contraindicated or clinically significant adverse effects are experienced;
 7. Dose does not exceed one tablet per day.

Approval Duration

Commercial: 12 months

Medicaid: 12 months

II. Continued Therapy Approval

A. Allergic Rhinitis (must meet all):

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
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

Commercial: 12 months

Medicaid: 12 months

III. Appendices

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
loratadine (Claritin®)	2 to 5 years: 5 mg PO QD ≥ 6 years: 10 mg PO QD	10 mg/day
loratadine-D (Claritin-D® 12 and 24 hour)	≥ 12 years: 1 tablet PO BID QD	10 mg/day
cetirizine (Zyrtec®)	2 to 5 years: 2.5-5 mg PO QD ≥ 6 years: 10 mg PO QD	10 mg/day
fexofenadine (Allegra Allergy®)	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®)	≥ 4 years: 1-2 sprays each nostril QD ≥ 12 years: 1-2 sprays each nostril QD	2 sprays each nostril/day
triamcinolone acetonide (Nasacort Allergy 24HR®)	2-11 years: 1 spray each nostril QD ≥ 12 years: 1-2 sprays each nostril QD	2-5 years: 1 spray each nostril/day > 6 years: 2 sprays each nostril/day
mometasone furoate monohydrate (Nasonex®)	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® (generic) when the drug is available by brand name only and generic (Brand name®) 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

APPENDIX D: General Information

None

References

1. Odactra Prescribing Information. Round Rock, TX: Alk, Inc.; April 2017. Available at: <http://www.odactra.com> zAccessed July 02, 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. Accessed July 02, 2020.
3. Demoly P, Emminger W, Rehm D, Backer V, Tommerup L, Kleine-tebbe J. 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.e8. Accessed July 02, 2020.
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5. Seidman MD, Gurgel RK, Lin SY, et al. Clinical practice guideline: Allergic rhinitis. Otolaryngology – Head and Neck Surgery 2015; 152(1Suppl):S1-43. Accessed July 02, 2020.
6. Wallace DV, Dykewicz MS, Oppenheimer J, Portnoy JM, Lang DM. 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. Accessed July 02,2020.

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. Accessed July 02, 2020.
8. House dust mite allergen extract, Lexi-Drug. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Accessed with subscription at: <http://online.lexi.com>. Accessed July 02, 2020.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Policy title table was updated 2. Clinical policy was updated: updated verbiage in Continued Therapy Approval to “Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy” and updated approval duration 3. Removed OTC labelling for Therapeutic Alternatives 4. Appendix: D was updated 5. References were updated	07/02/2020	09/14/2020