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:	09/14/2021
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	12 SQ-HDM ( )sub lingually once daily	12 SQ-HDM()/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. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

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 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. Maximum dose does not exceed 12 SQ-HDM per day.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy Approval

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

1. Diagnosis of HDM-induced allergic rhinitis;
2. Member is currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
3. Member is responding positively to therapy;
4. If request is for a dose increase, new dose does not exceed 12 SQ-HDM 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
IgE: Immunoglobulin E

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
loratadine (Claritin®)	2 to 5 years: 5 mg orally once daily ≥ 6 years: 10 mg orally once daily	10 mg/day
loratadine-D (Claritin-D® 12 and 24 hour)	≥ 12 years: 5 mg orally twice daily and 10 mg once daily respectively	10 mg/day
cetirizine (Zyrtec®)	2 to 5 years: 2.5-5 mg orally once daily ≥ 6 years: 10 mg orally once daily	10 mg/day
fexofenadine (Allegra Allergy®)	6-months to 2 years: 15 mg orally once daily; 2 to 11 years: 30 mg orally once daily; ≥ 12 years: 60 mg orally twice daily or 180 mg orally once daily	180 mg/day
fluticasone propionate (Flonase®)	≥ 4-11 years: 100 mcg/day;	≥ 4-11 years: 200 mcg/day;

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	≥ 12 years: 200 mcg/day;	≥ 12 years: 200 mcg/day;
triamcinolone acetonide (Nasacort Allergy 24HR®)	2-11 years: 110 mcg once daily; ≥ 12 years: 220 mcg once daily	2-11 years: 110 mcg once daily ≥ 12 years: 220 mcg once daily
mometasone furoate monohydrate (Nasonex®)	2-11 years: 100 mcg (administer as 1 spray into each nostril, each spray containing 50 mcg of mometasone furoate) once daily; ≥ 12 years: 200 mcg (administer as 2 sprays into each nostril, each spray containing 50 mcg of mometasone furoate) once daily	2-11 years: 100 mcg/day intranasally > 12 years: 200 mcg/day intranasally

Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand, Brand name® when the drug is available by brand only and generic name when the drug is available by generic only.

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):
  - Odactra™ can cause life-threatening allergic reactions such as anaphylaxis and severe laryngopharyngeal restriction;
  - Do not administer Odactra™ to patients with severe, unstable or uncontrolled asthma;
  - Observe patients in the office for at least 30 minutes following the initial dose;
  - Prescribe auto-injectable epinephrine, instruct and train patients on its appropriate use, and instruct patients to seek immediate medical care upon its use;
  - Odactra™ may not be suitable for patients with certain underlying medical conditions that may reduce their ability to survive a serious allergic reaction;
  - Odactra™ may not be suitable for patients who may be unresponsive to epinephrine or inhaled bronchodilators, such as those taking beta-blockers.

APPENDIX D: General Information

- Diagnosis of HDM-induced allergic rhinitis; Inform patients of the signs and symptoms of serious allergic reactions and instruct them to seek immediate medical care and discontinue therapy should any of these occur.
- In case of oral inflammation or wounds, stop treatment with Odactra™ to allow complete healing of the oral cavity.

References

1. Odactra™ Prescribing Information. Round Rock, TX: Alk, Inc.; March 2020.Available at: https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=71ca220d-78d5-47d4-be84-8d6e844b24b3&type=display. Accessed June 24, 2021.
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Review/Revision History	Review/Revision 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
Policy was reviewed: 1) Statement about provider sample ''The provision of provider samples does not guarantee coverage…" was added to	06/24/2021	09/14/2021

Clinical Policy. 2) Continued Therapy Approval Criteria II.A.1 was updated to include “Diagnosis of HDM-induced allergic rhinitis…”. 3) Continued Therapy Approval CrtieriaII.A.1 was rephrased to “Member is currently receiving medication that has been authorized by RxAdvance…”. 4) Appendix A was updated to include abbreviation “IgE: Immunoglobulin E.” 5) Therapeutic Alternatives verbiage was rephrased to "Below are suggested therapeutic alternatives based on clinical guidance..". 6) Statement about drug listing format in Appendix B is rephrased to "Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand; Brand name® when the drug is available by brand only and generic name when the drug is available by generic only". 7) Appendix D was updated to include “Diagnosis of HDM-induced allergic rhinitis; Inform patients…” and “In case of oral inflammation or wounds, stop treatment with Odactra…”. 8) References were reviewed and updated.		