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:	08/28/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

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

1. Diagnosis of house dust mite (HDM)-induced allergic rhinitis;
2. Confirmation of the presence of IgE antibodies to Dermatophagoides farinae or Dermatophagoides pteronyssinus HDM or skin testing to licensed HDM allergen extracts;
3. Trial and failure of one intranasal corticosteroid, unless contraindicated or clinically significant adverse effects are experienced;
4. Trial and failure of one oral antihistamine unless contraindicated or clinically significant adverse effects are experienced.

Approval Duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

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

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. 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. Available at: https://pubmed.ncbi.nlm.nih.gov/27521719/. Accessed August 28, 2024.
2. 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. Available at: https://pubmed.ncbi.nlm.nih.gov/26292778/. Accessed August 28, 2024.
3. 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 e6. Available at: https://pubmed.ncbi.nlm.nih.gov/25636947/. Accessed August 28, 2024.
4. 125395. Clinical practice guideline: allergic rhinitis. American Academy of Otolaryngology-Head and

Neck Surgery (AAO-HNS). Available at: https://www.entnet.org/quality-practice/quality-products/clinical-practice-guidelines/allergic-rhinitis/. Accessed August 28, 2024.

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. References were updated.	07/02/2020	09/14/2020
Policy was reviewed: 1. Continued Therapy Approval Criteria II.A.1 was updated to include "Diagnosis of HDM-induced allergic rhinitis…". 2. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance…". 3. References were reviewed and updated.	06/24/2021	09/14/2021
Policy was reviewed: 1. Continued Therapy Approval Criteria II.A.2 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 2. References were reviewed and updated.	03/28/2022	07/18/2022
Policy was reviewed: 1. Initial Approval Criteria, I.A.3: Updated age criteria from Age ≥ 18 years and ≤ 65 years to Age ≥ 12 years and ≤ 65 years. 2. References were reviewed and updated.	04/24/2023	07/13/2023
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed age restrictions. 2. Removed prescriber restrictions. 3. Removed dose restrictions. 5. Updated Continued therapy approval	08/28/2024	09/13/2024

with auto-approval based on lookback functionality within the past 120 days. 6. Removed reauthorization requirement for positive response to therapy. 6. Updated approval duration verbiage. 7. References were reviewed and updated.		