Pharmacy Medical Necessity Guidelines:
Allergy Immunotherapy

Effective: November 10, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

Sublingual immunotherapy medications contain small amounts of an allergen extract. Exposure to the allergen allows the immune system to become less sensitive to the allergen. The natural response to the allergen is decreased, resulting in reduction in allergy symptoms.

FDA-APPROVED INDICATIONS

Oralair is indicated as immunotherapy for patients 5 to 65 years of age for the treatment of pollen-induced allergic rhinitis (hay fever), with or without conjunctivitis (eye inflammation) confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for Sweet vernal, orchard, perennial rye, timothy, and Kentucky blue grass mixed pollens.

Odactra (house dust mite allergen extract) is indicated for immunotherapy for house dust mite induced allergic rhinitis, with or without conjunctivitis, confirmed by in vitro testing for IgE antibodies to Dermatophagoides farina or Dermatophagoides pteronyssinus house dust mites, or skin testing to licensed house dust mite allergen extracts. Odactra is approved for use in patients 5 through 65 years of age.

Palforzia (Peanut, *Arachis hypogaea*, allergen powder-dnfp) is an oral immunotherapy indicated for the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut. It is approved for use in patients with a confirmed diagnosis of peanut allergy. Palforzia is to be used in conjunction with a peanut-avoidant diet and not indicated for the emergency treatment of allergic reactions, including anaphylaxis. Initial dose escalation may be administered to patients 1 through 17 years of age, while up-dosing and maintenance may be continued in patients 1 year of age and older.

COVERAGE GUIDELINES

The plan may authorize coverage of a sublingual immunotherapy medications medication for Members when **ALL** of the following criteria are met:

Odactra

1. Documentation the Member is between the ages 5 and 65 years old

AND

2. Confirmation of one of the following:
   - In vitro testing for IgE antibodies to Dermatophagoides farina or Dermatophagoides pteronyssinus house dust mites
   - Skin testing to licensed house dust mite allergen extracts

AND

3. Documentation the medication is prescribed by, or is based on the recommendations and consult of, an allergist or immunologist

AND

4. Documentation the Member has tried and failed or had an insufficient response or intolerance to at least two generic oral antihistamines, nasal antihistamines, or nasal corticosteroids

Oralair

1. Documentation the Member is between the ages 5 and 65 years old

AND

2. Confirmation of a positive skin test or in vitro testing for pollen-specific IgE antibodies for any of the following allergens: sweet vernal, orchard, perennial rye, Timothy, or Kentucky Blue Grass within the past 2 years

AND

3. Documentation the medication is prescribed by, or is based on the recommendations and consult of, an allergist or immunologist

AND

4. Documentation the Member has tried and failed or had an insufficient response or intolerance to at least two generic oral antihistamines, nasal antihistamines, or nasal corticosteroids

Palforzia

Initial criteria:

1. Documentation the Member meets one of the following:
    a. The member is between 1 and 17 years of age for initial dose escalation

    OR

    b. The member is 1 year of age and older for up-dosing and maintenance

    AND

2. The member has a confirmed diagnosis of peanut allergy by both of the following:
    a. A documented history of allergic reaction to peanuts

    AND

    b. A positive in vitro test for peanut specific-IgE or skin test

    AND

3. Documentation the medication is prescribed by an allergist or immunologist

Reauthorization Criteria:

1. Documentation the Member meets one of the following:
    a. The member is 1 year of age and older for up-dosing and maintenance

    OR

    b. The member is 18 years of age or older and has been stable on maintenance dose of Palforzia

    AND

2. Documentation the medication is prescribed by, or is based on the recommendations and consult of, an allergist or immunologist

LIMITATIONS

Sublinual Immunotherapy Medications:

1. The length of approval will be for 2 years. Subsequent approval will require a new authorization.

Palforzia:

1. Initial authorizations will be approved for a duration of therapy of 2 years. Subsequent authorizations must meet reauthorization criteria and will be for a period of 2 years. Members stable on drug and new to plan must meet reauthorization criteria.

CODES

None

REFERENCES

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APPROVAL HISTORY

September 13, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. November 14, 2023: Effective December 1, 2023, updated age requirements for Odactra to reflect updated package labeling. Updated fax number for RxUM.
2. November 12, 2024: No changes
3. November 4, 2025: Effective December 1, 2025, updated age requirements for Odactra and Palforzia to reflect updated package labeling.
4. November 10, 2026: No changes.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services