Pharmacy Medical Necessity Guidelines: Allergy Immunotherapy

Effective: May 18, 2020

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:

Commercial Products

☒ Tufts Health Plan Commercial products – large group plans
☒ Tufts Health Plan Commercial products – small group and individual plans
☒ Tufts Health Freedom Plan products – large group plans
☒ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:

RXUM: 617.673.0988

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

Grastek, Oralair, and Ragwitek are indicated as immunotherapy 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 the following:

- Oralair: sweet vernal, orchard, perennial rye, Timothy, and Kentucky blue grass mixed pollens
- Grastek: Timothy grass pollen
- Ragwitek: short ragweed pollen

Oralair and Grastek are approved for children and adults. Oralair is approved for 10 to 65 years of age and Grastek for 5 to 65 years of age. Ragwitek is approved only in adults 18 through 65 years of age.

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 adults 18 through 65 years of age.

Palfozia (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.

COVERAGE GUIDELINES

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

Grastek

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 the following allergen: Timothy grass pollen 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

Odactra

1. Documentation the Member is between the ages 18 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 10 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

Ragwitek

1. Documentation the Member is between the ages 18 and 65 years old

AND

2. Confirmation of a positive skin test or in vitro testing for pollen-specific IgE antibodies for the following allergen: short ragweed pollen 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

<u>Palfozia</u>

The plan may authorize coverage of a **Palforzia** for Members when **all** of the following criteria are met:

Initial criteria:

1. Documentation the Member meets one of the following:
    a. The member is between 4 and 17 years of age for initial dose escalation

    OR

    b. The member is 4 years 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 4 years 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.
2. The following quantity limitations apply:

Grastek	30 sublingual tablets per 30 days
Odactra	30 sublingual tablets per 30 days
Oralair	30 sublingual tablets per 30 days
Ragwitek	30 sublingual tablets per 30 days

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

1. Blaiss M, Maloney J, Nolte H et al. Efficacy and safety of timothy grass allergy immunotherapy tablets in North American children and adolescents. *J Allergy Clin Immunol*. 2011;127(1):64-71.
2. Cox LS, Casale TB, Nayak AS, et al. Clinical efficacy of 300IR 5-grass pollen sublingual tablet in a US study: the importance of allergen-specific serum IgE. *J Allergy Clin Immunol*. 2012;130:1327-34 e1.
3. Cox L, Esch RE, Corbett M, et al. Allergen immunotherapy practice in the United States: guidelines, measures, and outcomes. *Ann Allergy Asthma Immunol*. 2011;107(4):289-99.
4. Creticos P, Maloney J, Bernstein D, et al. Randomized controlled trial of a ragweed allergy immunotherapy tablet in North American and European adults. *J Allergy Clin Immunol*. 2013;131(5):1342-49.
5. Didier A, Malling HJ, Worm M, et al. Optimal dose, efficacy, and safety of once-daily sublingual immunotherapy with a 5-grass pollen tablet for seasonal allergic rhinitis. *J Allergy Clin Immunol*. 2007; 120:1338-45.
6. Didier A, Worm M, Horak F, et al. Sustained 3-year efficacy of pre- and coseasonal 5-grass-pollen sublingual immunotherapy tablets in patients with grass pollen-induced rhinoconjunctivitis. *J Allergy Clin Immunol*. 2011; 128:559-66.
7. Food and Drug Administration. Grastek FDA Advisory Committee briefing document. URL: www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/AllergenicProductsAdvisoryCommittee/UCM378092.pdf. Available from Internet. Accessed 2016 June 22.
8. Food and Drug Administration. Ragwitek FDA Advisory Committee briefing document. URL: www.fda.gov/downloads/advisorycommittees/committeesmeetingmaterials/bloodvaccinesandotherbiologics/allergenicproductsadvisorycommittee/ucm382841.pdf. Available from Internet. Accessed 2016 June 22.
9. Grastek (Timothy grass pollen allergen extract)[package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; April 2017.
10. Hadley JA, Derebery MJ, Marple BF. Comorbidities and allergic rhinitis: not just a runny nose. *J Fam Pract*. 2012 Feb; 61(2 Suppl):S11-5.

11. Horak F, Zieglmayer P, Zieglmayer R, et al. Early onset of action of a 5- grass-pollen 300-IR sublingual immunotherapy tablet evaluated in an allergen challenge chamber. *J Allergy Clin Immunol*. 2009; 124:471-7, 7 e1.
12. Maloney J, Bernstein D, Nelson, H et al. Efficacy and safety of grass sublingual immunotherapy tablet, MK-7243: a large randomized controlled trial. Ann Allergy Asthma Immunol. 2014; 112(2):146-153.
13. Nolte H, Hebert J, Berman G, H et al. Randomized controlled trial of ragweed allergy immunotherapy tablet efficacy and safety in North American adults. *Ann Allergy Asthma Immunol*. 2013;110:450-6.
14. Odactra prescribing information. Whitehouse Station, NJ: Merck & Co., Inc.; 2018 April.
15. Oralair (sweet vernal, orchard, perennial rye, timothy, and Kentucky blue grass mixed pollens) [package insert]. Lenoir, NC: GREER Laboratories, Inc.; 2014.
16. Palfozia prescribing information. Brisbane, CA: Aimmue Therapeutics, Inc.; January 2020.
17. Ragwitek (short ragweed pollen allergen extract) [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; Mar 2017.
18. The American Academy of Asthma Allergy and Immunology. SLIT treatment (allergy tablets) for allergic rhinitis nothing to sneeze about. URL: https://www.aaaai.org/conditions-and-treatments/library/allergy-library/sublingual-immunotherapy-for-allergic-rhinitis. Accessed 2016 June 22.
19. Wahn U, Tabar A, Kuna P, et al. Efficacy and safety of 5-grass-pollen sublingual immunotherapy tablets in pediatric allergic rhinoconjunctivitis. *J Allergy Clin Immunol*. 2009;123:160-6 e3.

APPROVAL HISTORY

July 8, 2015: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- July 14, 2015: No changes
- January 1, 2016: Administrative change to rebranded template applicable to Tufts Health Direct.
- July 12, 2016: No changes. Effective July 12, 2016 Medical Necessity Guideline applies to Tufts Health Together.
- April 11, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether.
- July 11, 2017: No changes.
- April 10, 2018: Added criteria for Odactra. Effective 10/1/18, criteria for Oralair, Grastek, and Ragwitek were updated to require trial and failure of two *generic* oral antihistamines, nasal antihistamines, or nasal corticosteroids.
- November 12, 2019: Administrative updates, name of allergen Kentucky Blue Grass was updated as listed on the package insert.
- May 12, 2020: Updated name of MNG from Sublingual Allergy Immunotherapy to Allergy Immunotherapy and added initial and reauthorization coverage criteria for Palforzia.

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