



Allergenic Extracts (Oral)

WA.PHAR.27 Allergenic Extracts (Oral)

Background:

Allergic reactions can widely vary from mild to life threatening. Mild symptoms include skin rash, hives, runny nose, itchy eyes, nausea, or stomach cramping. However, severe allergy symptoms are extreme and can include swelling that can spread to the throat and lungs, causing allergic asthma or a condition known as anaphylaxis. Allergen immunotherapy has traditionally been administered by subcutaneous injections; a new alternate approach is administering allergens orally, more specifically with a sublingual methodology often referred to as sublingual immunotherapy (SLIT), as treatment for allergic respiratory diseases.

Medical necessity

Drug	Medical Necessity
<ul style="list-style-type: none"> • GRASTEK (Timothy Grass Pollen Allergen Extract) • ORALAIR (Sweet Vernal/Orchard/Rye/Timothy/Kentucky Blue Grass Mixed Pollen Allergen Extract) • RAGWITEK (Short Ragweed Pollen Allergen Extract) • ODACTRA (Dermatophagoides farinae or Dermatophagoides pteronyssinus extract) 	<p>Grastek, Oralair, Ragwitek and Odactra may be considered medically necessary when used for the treatment of severe, seasonal or perennial IgE-dependent symptoms of allergic rhinoconjunctivitis or asthma after natural exposure to the allergen and both skin test and/or serologic evidence of IgE-mediated antibody to a potent extract of the allergen</p>

Clinical policy:

Drug	Clinical Criteria (Initial Approval)
<ul style="list-style-type: none"> • GRASTEK (Timothy Grass Pollen Allergen Extract) • ORALAIR (Sweet Vernal/Orchard/Rye/Timothy/Kentucky Blue Grass Mixed Pollen Allergen Extract) • RAGWITEK (Short Ragweed Pollen Allergen Extract) • ODACTRA (Dermatophagoides farinae or Dermatophagoides pteronyssinus extract) 	<p>Grastek, Oralair, Ragwitek and Odactra may be covered when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. Diagnosis of severe allergen-induced allergic rhinoconjunctivitis or asthma confirmed by a positive skin test or in vitro testing for allergen-specific IgE antibodies 2. History of failure (per prescriber assessment) to ONE preferred product for at least 30 days within TWO different classes, or contraindication or intolerance to ALL of the following classes: <ol style="list-style-type: none"> a. Intranasal corticosteroids (e.g. budesonide, fluticasone propionate, mometasone furoate) b. Oral non-sedating antihistamines (e.g. loratadine, cetirizine) c. Intranasal antihistamines (e.g. azelastine)

	<p>d. Leukotriene modifiers (e.g. montelukast)</p> <p>3. Not used in combination with similar immunotherapy</p> <p>4. Currently between the ages of</p> <ol style="list-style-type: none"> a. Grastek: 5 and 65 years of age b. Oralair: 10 and 65 years of age c. Ragwitek/Odactra: 18 and 65 years of age <p>5. Initially prescribed by or in consultation with a specialist in allergy or immunology</p> <p>Approve for 6 months</p> <p>Criteria (Reauthorization)</p> <p>Grastek, Oralair, Ragwitek and Odactra may be continued when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. All of the initial criteria are met 2. Documentation of positive clinical response to treatment <p>Approve for 12 months</p>
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Dosage and quantity limits

Drug Name	Dose and Quantity Limits
GRASTEK (Timothy Grass Pollen Allergen Extract)	1 tablet (2800 BAU) per day; #30 tablets per 30-day supply
ORALAIR (Sweet Vernal/Orchard/Rye/Timothy/Kentucky Blue Grass Mixed Pollen Allergen Extract)	1 tablet (300 IR) per day; #30 tablets per 30-day supply
RAGWITEK (Short Ragweed Pollen Allergen Extract)	1 tablet (Amb a 1-U) per day; #30 tablets per 30-day supply
ODACTRA (Dermatophagoides farinae or Dermatophagoides pteronyssinus extract)	1 tablet (12 SQ-HDM) per day; #30 tablets per 30-day supply

Coding:

HCPCS Code	Description
J30.1	Allergic rhinitis due to pollen
J45.50	Asthma with allergic rhinitis, severe persistent
J45.51	Acute exacerbation of severe persistent allergic asthma

Definitions

Term	Description
BAU (Bioequivalent Allergy Units)	A unit of immunogenicity based on quantitative skin testing, which uses standardized extracts of various allergens. BAUs replace, but are not equivalent, to allergy units, in which the value of the units was arbitrarily assigned.
IR (Index of Reactivity)	Measure the allergenicity of an allergen extract
Amb a 1-U (Amb a 1-unit)	Is an arbitrary unit for the measurement of Amb a 1, a 38 kD glycoprotein that is the major allergen in short ragweed pollen allergen extracts
SQ-HDM (Standardized quality – House dust mites)	SQ is a method of standardization of biological potency, major allergen content and complexity of the allergen extract. HDM is an abbreviation for house dust mite

References

1. Product Information: GRASTEK(R) sublingual oral tablets, timothy grass pollen allergen extract sublingual oral tablets. Merck & Co, Inc. (per FDA), Whitehouse Station, NJ, 2014.
2. Product Information: ORALAIR(R) sublingual tablets, sweet vernal, orchard, perennial rye, timothy, and Kentucky blue grass mixed pollens allergen extract sublingual tablets. GREER Laboratories, Inc. (per FDA), Lenoir, NC, 2014.
3. Product Information: RAGWITEK(R) sublingual tablets, short ragweed pollen allergen extract sublingual tablets. Merck Sharp & Dohme Corp. (per manufacturer), Whitehouse Station, NJ, 2016.
4. Product Information: ODACTRA(TM) sublingual tablets, house dust mite allergen extract sublingual tablets. Merck Sharp & Dohme Corp (per FDA), Whitehouse Station, NJ, 2017
5. Micromedex® 2.0, (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: <http://www.micromedexsolutions.com> (cited: 01/31/2018).
6. deShazo R, Kemp S. Pharmacotherapy in Allergic Rhinitis. In: Up to Date. Wolters Kluwer, Philadelphia (PA). 2014 [cited 2014 May]. Available from www.uptodate.com with subscription.
7. Creticos P. Sublingual Immunotherapy for Allergic Rhinitis. In: Up to Date. Wolters Kluwer, Philadelphia (PA). 2014 [cited 2014 May]. Available from www.uptodate.com with subscription.
8. The Diagnosis and management of rhinitis: An updated practice parameter. American Academy of Allergy, Asthma, and Immunology. 2008 [cited 2014 May]. Available from <http://www.aaaai.org/Aaaai/media/MediaLibrary/PDF%20Documents/Practice%20and%20Parameters/rhinitis2008-diagnosis-management.pdf>
9. Oralair: FDA Allergenic Products Advisory Committee Briefing Document: November 2013. Available at: <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/AllergenicProductsAdvisoryCommittee/ucm367268.htm>. Accessed July, 2014.