Medica Coverage Policy

Policy Name: Compounded Sublingual, Oral, or Intranasal Allergenic Extracts for Allergy Diagnosis and/or Immunotherapy

Current Policy Effective Date: 2/1/2024

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Please refer to the member's plan document for specific coverage information. If there is a difference between this general information and the member's plan document, the member's plan document will be used to determine coverage. With respect to Medicare, Medicaid and MinnesotaCare members, this policy will apply unless these programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica coverage policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

Coverage Policy

Compounded sublingual, oral or intranasal allergenic extracts for allergy diagnosis and/or immunotherapy are investigative and therefore NOT COVERED. This does not apply to FDA approved sublingual allergy extract tablets. For a list of COVERED FDA-approved sublingual immunotherapies through the pharmacy benefit, refer to the Medica Preferred Drug List L: https://www.medica.com/providers/pharmacy

Description

Allergen therapy is the repeated administration of specific allergens to patients with IgE-mediated conditions for the purpose of providing protection against allergenic symptoms and inflammatory reactions associated with natural exposure to these allergens. Specific allergens are also sometimes administered for diagnostic purposes. Traditionally, allergen immunotherapy is administered as a subcutaneous injection. Several less invasive methods are under investigation including sublingual, oral, and intranasal routes of administration.

In sublingual allergy treatment, also called sublingual immunotherapy (SLIT), involves the administration of a diluted dose of an allergen in the form of a liquid or a tablet under the tongue, which allows the allergen to contact the oral mucosa. There are several different methods of allergen delivery described in the literature including low dose sublingual swallow and high dose sublingual swallow. In some studies the allergen is expectorated instead of swallowed. Low dose therapy uses an extremely diluted amount of allergen as compared to standard subcutaneous allergy injections, while high dose therapy uses doses five to 300 times (or more) higher than standard allergy injections. The therapy protocol begins with a build-up period where the amount and concentration of allergen is gradually increased each day until a daily maintenance dose is reached, generally 25 to 30 days. The maintenance dose is continued on a regular basis until the allergy season ends or longer.

For over a century, allergen immunotherapy has been administered subcutaneously (commonly known as allergy shots), and in recent years the administration of these allergen serums via sublingual drops has grown in popularity. Compounded sublingual drops are not FDA-approved and are thus considered investigative and are NOT COVERED. The FDA has approved four sublingual tablet formulations (Oralair®, Ragwitek®, Grastek® and Odactra®), each of which is commercially available and should be processed through the member's pharmacy benefit.

FDA Approval
Compounded sublingual immunotherapy is a procedure and therefore, is not subject to regulation by the FDA. The allergen products used for this procedure would be subject to FDA approval by the Center for Biologics Evaluation and Research (CBER).

FDA Approved Products
Oralair, Ragwitek, Grastek and Odactra are oral tablets which have been FDA approved for use in sublingual immunotherapy. These oral products have been approved for dissolution under the tongue.

Oralair is a 5-Grass Pollen Allergy Extract Sublingual tablet containing Sweet Vernal, Orchard, Perennial Rye, Timothy and Kentucky Blue Grass for the treatment of grass pollen-induced allergic rhinitis with or without conjunctivitis confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for any of the five grass species contained in Oralair, in people ages 5 through 65 years.

Ragwitek is an immunotherapy for the treatment of short ragweed pollen-induced allergic rhinitis with or without conjunctivitis confirmed by a positive skin prick test or in vitro testing for pollen-specific IgE antibodies for short ragweed pollen in adults 5 years through 65 years of age.

Grastek is an immunotherapy for the treatment of grass pollen-induced allergic rhinitis with or without conjunctivitis confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for Timothy grass or cross-reactive grass pollens, in people ages 5 through 65 years.

Odactra is an immunotherapy for the treatment of 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 in people ages 12 through 65 years of age.

Prior Authorization
Prior authorization is not applicable. Claims for this service are subject to retrospective review and denial of coverage, as investigative services are not eligible for reimbursement.

Coding Considerations
Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

CPT Codes:

CPT Code: 91599 - Unlisted allergy/clinical immunologic service or procedure.

Original Effective Date:	7/1/2002
Re-Review Date(s):	8/28/2007
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