Geisinger

Geisinger Health Plan Policies and Procedure Manual

Policy: MP344

Section: Medical Policy

Subject: Sublingual Immunotherapy

I. Policy: Sublingual Immunotherapy

II. Purpose/Objective:

To provide a policy of coverage regarding Sublingual Immunotherapy

III. Responsibility:

A. Medical Directors
B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards of good medical treatment practiced by the general medical community.
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
(ii) The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
(iii) The service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.

DESCRIPTION: Sublingual immunotherapy (SLIT, SIT) has been studied as a treatment for allergic rhinitis, asthma and sensitivity to seasonal allergens (e.g., grass and pollen) and to other common allergens including, but not limited to dust mites, pet dander, molds and/or nuts. SLIT is administered via liquid or a tablet placed under the tongue, allowing the allergen to be absorbed by oral mucosa. SLIT is thought to desensitize the patient to the allergen, much the same as conventional allergy immunotherapy by injection. To date, the FDA has approved four sublingual allergen extract tablets (Grastek®, Oralair®, Ragwitk® and Odactra®) There are no FDA-approved sublingual liquid immunotherapy formulations currently.

CRITERIA FOR COVERAGE:
Food and Drug Administration (FDA) approved sublingual allergen extract tablets may be covered under the Pharmacy benefit when criteria outlined in the specific policies are met. Please see the following Pharmacy policies:

Commercial Business Segment:
340.0 Grastek
341.0 Oralair
442.0 Ragwitek
500.0 Odactra

Medicare Business Segment:
399.0D Grastek
400.0D Oralair
401.0D Ragwitek
653.0D Odactra

Medicaid Business Segment:
1267.0F Grastek
1268.0F Oralair
1269.0F Ragwitek
1433.0F Odactra

EXCLUSIONS:
Non-FDA approved sublingual tablet or liquid immunotherapy for the treatment of allergic rhinitis, asthma and sensitivity to seasonal allergens and to other common allergens is considered **experimental, investigational or unproven** and **NOT COVERED.**

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

Medicaid Business Segment:
Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

CODING ASSOCIATED WITH:
The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov ***or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.***

95165 Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy; single or multiple antigens (specify number of doses)
95199 Unlisted allergy/clinical immunologic service or procedure

LINE OF BUSINESS:

Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:

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Yang J, Zhang L, Zhao Z, et al. Sublingual immunotherapy for pediatric allergic conjunctivitis: a meta-analysis of randomizedcontrolled trials. Int Forum Allergy Rhinol. Nov 2018; 8(11): 1253-1259.

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Mahler V, Esch RE, Kleine-Tebbe J, et al. Understanding differences in allergen immunotherapy products and practices in North America and Europe. J Allergy Clin Immunol. 2019 Mar;143(3):813-828.

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This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 5/21

Revised:

Reviewed: 5/22

Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at https://www.geisinger.org/health-plan/providers/ghp-clinical-policies