

Sublingual Immunotherapy as a Technique of Allergen Specific Therapy

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IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member.

The Medicare Advantage Medical Policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and the Centers of Medicare and Medicaid Services (CMS) policies, when available. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of CMS guidance for a requested service or procedure, the health plan may apply their Medical Policy Manual or MCG™ criteria, both of which are developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Medicare and EOCs exclude from coverage, among other things, services or procedures considered to be investigational, cosmetic, or not medically necessary, and in some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services.

DESCRIPTION

Allergen-specific immunotherapy involves administering allergen extracts. An initial induction or buildup phase progressively increases the allergen dose; this is followed by multiple years of maintenance injections at the highest dose. Allergen-specific immunotherapy has been used to treat a variety of conditions including insect allergy, allergic rhinitis, and asthma.

Subcutaneous injection of allergen-specific immunotherapy (SCIT) is the standard approach. However, due to the inconvenience of multiple injections, particularly in children, alternative delivery routes have been investigated and sublingual immunotherapy (SLIT) allergen extract tablets is the most prominent proposed treatment as a more convenient delivery route for treating a variety of allergic disorders. SLIT targets absorption to the sublingual and buccal mucosa. Allergen preparations used for SLIT are held under the tongue for one to several minutes and then swallowed or spit out.

MEDICARE ADVANTAGE POLICY CRITERIA

CMS Coverage Manuals*	None
National Coverage Determinations (NCDs)*	Antigens Prepared for Sublingual Administration (110.9)

POLICY GUIDELINES

REGULATORY STATUS

The FDA has approved several sublingual allergen extract tablets, which can be found at the following path: <http://www.fda.gov/BiologicsBloodVaccines/Allergenics/default.htm>. Enter the drug name in the search bar. Not all sublingual allergen extract tablets are FDA-approved. Note, the fact a service or procedure has been issued a CPT/HCPCS code or is FDA approved for a specific indication does not, in itself, make the procedure medically reasonable and necessary. Medicare contractors evaluate services, procedures, drugs or technology to determine if they may be considered Medicare covered services.

No liquid allergy extracts are currently approved by the FDA for use sublingually.

CROSS REFERENCES

None

REFERENCES

None

CODING

NOTE: There are no specific CPT or HCPCS codes for sublingually administered immunotherapy.

Codes	Number	Description
CPT	95199	Unlisted allergy/clinical immunologic service or procedure
HCPCS	None	

***IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.