



BlueCross BlueShield
of Alabama

Name of Blue Advantage Policy:
Allergy Immunotherapy

Policy #: 081
Category: Medical

Latest Review Date: November 2020
Policy Grade: D

BACKGROUND:

Blue Advantage medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
 - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
 - *Furnished in a setting appropriate to the patient's medical needs and condition;*
 - *Ordered and furnished by qualified personnel;*
 - *One that meets, but does not exceed, the patient's medical need; and*
 - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill **Original Medicare for covered services that are related to **clinical trials** that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Effective for dates of service on or after December 3, 2016:

Allergy Immunotherapy

Blue Advantage will treat **allergy immunotherapy** as a **covered** benefit in patients with demonstrated hypersensitivity that cannot be managed by medications or avoidance when delivered based on ALL of the following guidelines:

- Maximum of 180 units for the first year of therapy during escalation, **and**
- Maximum of 120 units for yearly maintenance therapy thereafter, **and**
- Per unit reimbursement for allergy immunotherapy is based on the **number of dosages** prepared and intended for administration.

Blue Advantage will treat the following treatments for allergies as a **non-covered** benefit and as **investigational**:

- Provocative and neutralization therapy for food allergies, using intradermal and subcutaneous routes
- Urine auto-injections
- Repository emulsion therapy

As of August 1, 2014, Sublingual Immunotherapy (SLIT), including FDA approved tablets (Oralair®, Grastek® and Ragwitek™), is considered a prescription benefit and coverage is dependent on member's formulary and benefit plan design.

Non-FDA approved SLIT therapy which is typically prepared and billed by an allergist is considered a non-covered under the medical benefit.

Aspirin Desensitization

Blue Advantage will treat **aspirin (ASA) desensitization** as a **covered** benefit in patients with aspirin-exacerbated respiratory disease (AERD) when **one** of the following criteria are met:

- Asthma or rhinosinusitis which is suboptimally controlled with inhaled corticosteroids and leukotriene-modifying drugs; **OR**
- Individuals who have required multiple polypectomies for nasal polyp control; **OR**
- Individuals who require anti-platelet therapy with cyclo-oxygenase-Y inhibitors.

The testing **must** be done in a hospital or physician's office with direct supervision by an eligible provider. The desensitization procedure should be followed by daily aspirin therapy.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

Allergy immunotherapy involves regular injections of offending allergens in the form of antigen extract over a period of time, with the goal of reducing symptoms. In conventional schedules a single dose increase is given on each visit, and the visit frequency can vary from 1 to 3 times a week. The duration of this phase depends on the frequency of the injections but generally range from 3 to 6 months. After a maintenance antigen dose is achieved, the interval between injections may range from 2 to 6 weeks. Immunotherapy may continue for several years. The incremental increases of the allergen cause the immune system to become less sensitive to the substance as immunity to the antigen develops. Any allergen immunotherapy requires an appropriate allergy evaluation. The response is antigen-specific and depends on proper identification and selection of requisite allergens based on the patient's history and diagnostic test results.

The Joint Council of Allergy, Asthma and Immunology state that rush immunotherapy and cluster immunotherapy are forms of allergen immunotherapy in which incremental doses of allergen are administered at varying intervals, until the optimal effective dose is achieved. Cluster immunotherapy is an accelerated build-up schedule that entails administering several injections at increasing doses (generally 2-3 per visit) sequentially in a single day of treatment on non-consecutive days. The maintenance dose is generally achieved more rapidly than with a conventional (single injection per visit) build-up schedule (generally within 4-8 weeks). Rush immunotherapy delivers doses varying between 15 to 60 minutes over 1-3 days until the target therapeutic dose is achieved. Very sensitive patients may experience various degrees of systemic reaction during this procedure. Therefore, physicians who use this method frequently pre-medicate patients with both antihistamine and corticosteroids to minimize the risk of systemic reaction. These forms of immunotherapy allow for faster advancement to maintenance.

KEY POINTS:

This evidence review was created with a search of the PubMed database through November 30, 2020.

Practice Guidelines and Position Statements:

In 2013, the American Academy of Allergy, Asthma and Immunology and the European Academy of Allergy and Clinical Immunology published a consensus report on allergy immunotherapy. The report summarized the literature and current practices in the U.S. and Europe; it did not include clinical recommendations. The authors concluded, "AIT (allergy immunotherapy) is effective in reducing symptoms of allergic asthma and rhinitis, as well as venom-induced anaphylaxis. In addition, AIT modifies the underlying course of disease. However, AIT remains a niche treatment secondary to symptomatic drugs because of its cost, long duration of treatment and concerns regarding safety and effectiveness..."

In 2011, a joint task force of the American Academy of Allergy, Asthma and Immunology, the American College of Allergy, Asthma and Immunology, and the Joint Council of Allergy, Asthma and Immunology issued updated practice parameters for allergen immunotherapy. The document stated that RCTs of SLIT for individuals with allergic rhinitis and asthma have

demonstrated significant improvement in symptoms. The authors note that there are no FDA approved extract formulations for a non-injection route of immunotherapy.

U.S Preventive Services Task Force Recommendations

Not applicable.

KEY WORDS:

Allergy immunotherapy, IgE antibodies, allergen, antigen, immunotherapy, Rush immunotherapy, Rush schedules, sublingual immunotherapy, SLIT, acetylsalicylic acid (ASA), aspirin, asthma, desensitization, aspirin desensitization treatment, asthma-exacerbated respiratory disease (AERD), Allervision, cluster immunotherapy

APPROVED BY GOVERNING BODIES:

Not applicable.

BENEFIT APPLICATION:

Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT codes:

95115	Professional services for allergen immunotherapy, not including provision of allergenic extracts; single injection
95117	Professional services for allergen immunotherapy not including provision of allergenic extracts; 2 or more injections
95120	Professional services for allergen immunotherapy in the office of the prescribing physician or other qualified health care professional, including provision of allergenic extract; single injection
95125	Professional services for allergen immunotherapy in the office or institution of the prescribing physician or other qualified health care professional, including provision of allergenic extract; 2 or more injections
95130	Professional services for allergen immunotherapy in the office or institution of the prescribing physician or other qualified health care professional, including provision of allergenic extract; single stinging insect venom

95131	Professional services for allergen immunotherapy in the office or institution of the prescribing physician or other qualified health care professional, including provision of allergenic extract; 2 stinging insect venoms
95132	Professional services for allergen immunotherapy in the office or institution of the prescribing physician or other qualified health care professional, including provision of allergenic extract; 3 stinging insect venoms
95133	Professional services for allergen immunotherapy in the office or institution of the prescribing physician or other qualified health care professional, including provision of allergenic extract; 4 stinging insect venoms
95134	Professional services for allergen immunotherapy in the office or institution of the prescribing physician or other qualified health care professional, including provision of allergenic extract; 5 stinging insect venoms
95144	Professional services for the supervision of preparation of antigens for allergen immunotherapy, single does vials (specify number of vials)
95145	Professional services for the supervision and provision of antigens for allergen immunotherapy (specify the number of doses); single stinging insect venom
95146	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); 2 single stinging insect venoms
95147	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); 3 single stinging insect venoms
95148	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); 4 single stinging insect venoms
95149	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); 5 single stinging insect venoms
95165	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy; single or multiple antigens (specify number of doses)
95170	Professional services for the supervision of preparation and provision of antigens for allergen

	immunotherapy; whole body extract of biting insect or other arthropod (specify number of doses)
95180	Rapid desensitization procedure, each hour (e.g., insulin, penicillin, equine serum)
95199	Unlisted allergy/clinical immunologic service or procedure

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POLICY HISTORY:

Adopted for Blue Advantage, March 2009
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 Medical Policy Group, April 2010
 Medical Policy Group, March 2011
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 Medical Policy Group. October 2016

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Medical Policy Group, March 2017
Medical Policy Group, October 2020
Medical Policy Group, November 2020

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.