BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Allergy Immunotherapy

Policy #: 081
Latest Review Date: January 2025
Category: Medicine

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 and after May 16, 2024:

Allergy Immunotherapy

Blue Advantage will treat **allergy immunotherapy** as a **covered benefit** for individuals 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 **non-covered benefits**:

- Provocative and neutralization therapy for food allergies, using oral, intradermal and subcutaneous routes.
- Urine auto-injections.
- Repository emulsion therapy.
- Tolerance Induction Program™ (TIP).

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 the member's formulary and benefit plan design.

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

Aspirin Desensitization

Blue Advantage will treat **aspirin (ASA) desensitization** as a **covered benefit** for individuals with aspirin-exacerbated respiratory disease (AERD) when one of the following criteria is 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.

Effective for dates of service prior to May 16, 2024

Allergy Immunotherapy

Blue Advantage will treat **allergy immunotherapy** as a **covered benefit** for individuals 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 **non-covered benefits**:

- 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 non-covered under the medical benefit.

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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 (e.g., desensitization, allergy injection therapy, or "allergy shots"), is an effective treatment for allergic rhinitis, allergic asthma, atopic dermatitis and Hymenoptera sensitivity. Immunotherapy is indicated in individuals whose triggering allergens have been determined by appropriate skin or in vitro testing. The goal is to reduce the allergy individual's sensitivity when exposed to the offending allergen in the future. Treatment begins with low doses to prevent severe reactions. Gradually the doses are increased and are given once or twice a week until the body becomes tolerant of the allergen. After the maintenance dose is achieved, the interval between injections may range between 2 and 6 weeks. Immunotherapy may be administered continuously for several years.

Rush desensitization 95180 (also known as rush, cluster or acute desensitization) is a treatment that includes a fast increase in concentration and allergen extract doses. It was started to reduce hospital visits, and the required hospital stay. This treatment delivers doses varying between 15 to 60 minutes over 1-3 days until the target therapeutic dose is achieved. Extremely sensitive individuals may experience various degrees of systemic reaction during this procedure. Therefore, physicians who use this method frequently pre-medicate individuals with both antihistamines and corticosteroids to minimize the risk of a systemic reaction. These forms of immunotherapy allow for faster advancement to maintenance.

The major risk factor of allergy immunotherapy is anaphylaxis. Immunotherapy should be administered under the supervision of an appropriately trained physician who can recognize early signs and symptoms of anaphylaxis and administer emergency medications if needed.

Provocative and Neutralization Therapy

This procedure is purported to diagnose allergy to foods, chemicals, inhalant allergens, and endogenous hormones. Varying concentrations of test extracts of these substances are given to the patient by intracutaneous or subcutaneous injection or sublingually. The individual records all subjective sensations for 10 minutes afterward, and any reported sensation is taken as a positive test result for allergy. In the event of a positive test result, other doses of the same substance are given until the sensation has disappeared, at which point the action is said to be “neutralized.” Some proponents recommend measuring increase in the size of the injected wheal in the intracutaneous provocation procedure, but the primary indication of a positive result is the provocation and neutralization of symptoms.

Oral Immunotherapy (OIT) is an allergen-specific approach to the treatment of food allergy. Providers prescribe and supervise a regimen of allergenic food, gradually increasing the dosage each day. This type of therapy will desensitize the food to the point where accidental ingestion of the allergenic food in a social setting would not cause anaphylaxis, and possibly intentionally eaten food can be added safely to a regular diet.

KEY POINTS:

The most recent literature review for this policy was performed January 8, 2025.

Summary of Evidence
For provocative and neutralization therapy for food allergies, urine auto-injections, and repository emulsion therapy, the evidence includes studies, and randomized controlled trials. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Oral immunotherapy for food is a major focus of investigation in the treatment of food allergy. However, studies have yet to demonstrate the ability to cure food allergy (and induce true tolerance). Furthermore, allergic reactions to OIT are common and occur at higher rates in patients on OIT than those avoiding the food. Many unanswered questions remain, and additional long-term follow-up data are needed to help determine in which individuals the benefits may outweigh the risks. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

American Academy of Allergy, Asthma & Immunology and the American College of Allergy, Asthma, & Immunology formed the Allergy Immunology Joint Task Force

Allergen Immunotherapy: A Practice Parameter 2012
Allergen immunotherapy is appropriate in patients who:

Have symptoms of allergic rhinitis or allergic asthma with natural exposure to allergens and who demonstrate specific IgE antibodies (by skin tests or in vitro tests) to relevant antigens, and symptoms not controlled adequately by pharmacotherapy and avoidance measures, or a need to avoid adverse effects of pharmacotherapy or a wish to reduce long-term use of pharmacotherapy. have a history of systemic reaction to Hymenoptera venom and specific IgE antibodies (by skin tests or in vitro tests) to venom.

Allergen immunotherapy should be administered in a setting where procedures that can reduce the risk of anaphylaxis are in place and where the prompt recognition and treatment of anaphylaxis is assured. Patients should remain in the physician's office at least 20-30 minutes after an injection.

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, Tolerance Induction Program, TIP, food allergy, oral immunotherapy, OIT, autogenous urine therapy

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 dose 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
Available for comment March 17-April 30, 2009
Medical Policy Group, April 2010
Medical Policy Group, March 2011
Medical Policy Group, March 2012
Medical Policy Group, December 2012
Medical Policy Group, November 2013
Medical Policy Group, August 2014
Available for comment July 29 through September 11, 2014
Medical Policy Group, June 2015

Medical Policy Group. October 2016
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Medical Policy Group, March 2017
Medical Policy Group, October 2020
Medical Policy Group, November 2020
Medical Policy Group, January 2022
Medical Policy Group, January 2023
UM Committee, December 2023: Policy approved by UM Committee for use for Blue Advantage business.
Medical Policy Group, February 2024: Reviewed by consensus. No new published peer-reviewed literature is available that would alter the coverage statement in this policy update.
Medical Policy Group, March 2024: Available for comment April 5, 2024, through May 15, 2024. Policy statement updated to include oral provocative and neutralization therapy and tolerance induction program for food allergies as non-covered benefits.
UM Committee, April 2024: Policy annual review updates approved by UM Committee
Medial Policy Group, January 2025
UM Committee, January 2025: Annual review of policy approved by UM Committee for use for Blue Advantage business.
