BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:
Allergy Immunotherapy

Policy #: 081
Category: Medical

Latest Review Date: October 2016
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).*

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 ranges 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.

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 **RUSH immunotherapy** as a **covered** benefit.

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 (CPT **95199**)

- Urine auto injections (CPT **95199**)
- Repository emulsion therapy (CPT **95199**)

For Sublingual Immunotherapy (SLIT) please refer to NCD "Antigens Prepared for Sublingual Administration" (110.9).

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.

Effective for dates of service on or after August 1, 2014 and prior to December 3, 2016:
Blue Advantage will treat **allergy immunotherapy** as a **covered** benefit in patients with demonstrated hypersensitivity that cannot be managed by medications or avoidance.

Blue Advantage will treat **RUSH immunotherapy** as a **covered** benefit.

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 (CPT **95199**)
- Urine auto injections (CPT **95199**)
- Repository emulsion therapy (CPT **95199**)

For Sublingual Immunotherapy (SLIT) please refer to NCD "Antigens Prepared for Sublingual Administration" (110.9).

Policy Grade A
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.

Effective for dates of service on or after May 1, 2009 and prior to August 1, 2014:
Blue Advantage will treat **allergy immunotherapy** as a **covered** benefit in patients with demonstrated hypersensitivity that cannot be managed by medications or avoidance.

Blue Advantage will treat **RUSH immunotherapy** as a **covered** benefit.

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 (CPT **95199**)
- Urine auto injections (CPT **95199**)
- Repository emulsion therapy (CPT **95199**)

For Sublingual Immunotherapy (SLIT) please refer to NCD "Antigens Prepared for Sublingual Administration" (110.9).

Blue Advantage will treat **allergy immunotherapy** as a **non-covered** benefit and as **investigational** for the following therapies**:**

- Ophthalmic mucous membrane test
- Direct nasal mucous membrane test
- Provocative testing (e.g. Rinkel test)
- Cytotoxicity, Leukocytotoxic test (Bryan's test)

Policy Grade A
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 ~~physician~~ 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.

Key Points:

Each year more than 50 million Americans suffer from allergic diseases. Rhinitis sinusitis, dermatitis, asthma, food allergy and other allergic disorders negatively impact quality of life and escalate healthcare costs. According to the American Academy of Allergy, Asthma and Immunology, there are four general principles used for managing allergic diseases:

1. Avoidance or minimizing exposure to allergens and irritants through environmental control.
2. Using appropriate medication.
3. Evaluating for allergen immunotherapy.
4. Educating the patient and appropriate caregiver(s). There are no well-controlled studies that support the use of allergen immunotherapy for food hypersensitivity. There are also conflicting data on the effectiveness of allergen immunotherapy in the management of atopic dermatitis.

Some considerations, as recommended by the American Academy of Allergy, Asthma and Immunology, that should be given to the patient being evaluated for allergy immunotherapy include severity and duration of symptoms using subjective and objective measures (response to conventional medications, time lost from work or school, emergency department visits and healthcare provider office visits). Also included is the impact of symptoms on quality of life, such as sleep disturbance, interference with concentration/productivity at work and/or school. The responsiveness of symptoms to other forms of treatment is included such as allergen avoidance, medications, and unacceptable adverse effects of medications and presence of coexisting medical conditions.

Allergy immunotherapy is indicated in patients whose triggering allergens are not readily avoidable, the allergy is IgE-mediated as documented by skin testing or RAST, the symptoms are not easily controlled with medication, the symptoms encompass more than one season and the patients are likely to cooperate in the program. Allergy immunotherapy is defined as the repeated administration of specific allergens to patients with IgE-mediated conditions, for the purpose of providing protection against the allergic symptoms and inflammatory reactions associated with natural exposure to these allergens.

Controlled studies have shown that allergen immunotherapy is effective for: allergic rhinitis, allergic conjunctivitis, allergic asthma and stinging insect. Research has demonstrated that allergy immunotherapy induces a state of allergen-specific T-lymphocyte tolerance with a subsequent reduction in mediator release and tissue inflammation. When administered to appropriately selected patients, immunotherapy is effective in most cases. Immunotherapy should be considered in patients who do not respond to a combination of environmental control measures and medications; experience substantial side effects with medications; have symptoms for a significant portion of the year that require daily therapy; or prefer long-term modulation of their allergic symptoms. The immunotherapy extract should be based on a correlation between the presence of specific IgE antibodies (demonstrated by allergy skin testing or in vitro testing) and the patient's history.

Rush schedules for immunotherapy are associated with an increased risk of systemic reaction. Systemic reactions with rush immunotherapy have been reported up to 2 hours after the final injection. Patients must remain under physician supervision for a longer period, 2 to 3 hours, than the 30 minutes recommended for patients receiving conventional therapy. This is per the 2005 Joint Council of Allergy, Asthma and Immunology.

Aspirin Sensitivity and Aspirin Desensitization Treatment

In 1922, the term "aspirin triad" was used by Widel to describe patients with aspirin sensitivity, asthma, and nasal polyps. The term "aspirin-exacerbated respiratory disease" (AERD) describes an aggressive and continuous inflammatory disease of the airways, combined with exacerbation of asthma and rhinitis attacks, after ingestion of aspirin and most NSAIDs. This condition is referred to as aspirin-induced asthma (AIA), the aspirin triad, ASA sensitivity, or ASA-intolerant asthma. The incidence of aspirin sensitivity in asthmatic adults is 3% to 5%, but this percentage doubles or triples when adult asthmatic patients are prospectively challenged with aspirin. The diagnosis can be made by provocation tests using increasing doses of aspirin.

Macy, et al (2007), states "aspirin desensitization should be performed in a facility able to provide advanced cardiac care, ventilator support, and constant observation by qualified personnel. The supervising physician must be immediately available and should be present at the bedside at the time of the first challenge and through the first reaction. The first reaction is almost always the most severe and is unpredictable. If the first reaction could have been managed without physician intervention, then subsequent challenges may proceed without the supervising physician being physically present."

B-blocker use, recent myocardial infarction, any other underlying medical condition or drug treatment regimen that would make the management of severe asthma or anaphylactoid reaction difficult, severe asthma, and history of severe or life-threatening aspirin or NSAID reaction are all patient risk factors. Inpatient desensitization is recommended when a patient has any risk factor.

ASA desensitization refers to the process of inducing refractoriness to ASA or NSAIDs by the administration of incremental doses of oral or inhaled ASA until all reactions disappear. One protocol uses increasing doses of ASA in 5 days until the maximum dose of 650 mg is tolerated. Daily doses of ASA (325 to 650 mg twice daily) are given, and improvement in the underlying chronic respiratory symptoms can be seen during maintenance of the desensitized state. Cross-desensitization is also seen for other NSAIDs.

The oral ASA challenge protocol was developed at the Scripps Clinic. Patients begin ASA challenges with a 30 mg dose of ASA. Then, patients are advanced to 45-60 mg 3 hours later, then 60-100 mg 3 hours after that, depending on the prior history of ASA induced asthmatic reaction. If an ASA-induced respiratory reaction occurs, such as rhinitis, conjunctivitis, bronchospasm, laryngeal spasm, or systemic response, it is reversed with the appropriate treatment and subsequent ASA challenges are not done that day. The FEV_1 and a clinical evaluation is performed multiple times during this protocol to determine the reaction. A lower respiratory tract reaction is defined as a 15% decrease in the FEV_1 from the baseline FEV_1. If the patient tolerates ASA, 650 mg, without reaction and the patient is not taking more than 10

mg of prednisone/day or an antileukotriene drug, the challenge is negative and the patient does not have AERD.

There are several published reports in the literature on aspirin desensitization therapy in aspirin-sensitive patients. Some of these are summarized below.

Stevenson, et al (1996), reported on 65 aspirin-sensitive patients with asthma who underwent aspirin challenge, followed by aspirin desensitization and daily treatment with aspirin over 1 to 6 years (mean, 3.1 years). The results showed there were significant reductions in numbers of sinus infections per year (median, 6 to 2), hospitalizations for treatment of asthma per year (median, 0.2 to 0), improvement in olfaction (median, 0 to 2), and reduction in use of systemic corticosteroids (mean, 10.2 to 2.5 mg) with p values less than 0.0001. Numbers of sinus and polyp operations per year were significantly reduced (median, 0.2 to 0; p=0.004), and doses of nasal corticosteroids were significantly reduced (mean dose, 139 to 106 micrograms, p=0.01). Emergency department visits and use of inhaled corticosteroids were unchanged. Berges-Gimeno, et al (2003), reported on 172 patients with AERD were desensitized to and treated with aspirin. The results showed by the first 6 months of aspirin treatment, there were significant reductions in sinus infections and numbers of short courses of prednisone and improvements in sense of smell and general assessment of nasal-sinus and asthma symptoms. The results persisted for 1 to 5 years. Twenty-four patients (14%) discontinued treatment due to side effects. The improvement rate was 115 of 148 patients (78%). Of the 126 patients who completed a year or more of aspirin treatment, 110 (87%) experienced improvement.

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	; two 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	; two or more injections
95130	; single stinging insect venom
95131	; two stinging insect venoms
95132	; three stinging insect venoms
95133	; four stinging insect venoms
95134	; five 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	two stinging insect venoms
95147	three stinging insect venoms
95148	four stinging insect venoms
95149	five 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	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
Available for comment October 19 through December 2, 2016
Medical Policy Group, March 2017