COVERAGE:

The following Allergy Testing modalities are considered medically necessary when ordered by a physician. In each instance documentation will be required for additional consideration if testing exceeds the number of allergen tests listed. These modalities are:

1. Direct Skin Testing

   - Percutaneous (scratch, prick, or puncture) - placing a drop of allergen(s) on the skin making a needle scratch, prick, or puncture through the drop(s) and into the underlying epidermis. The number of tests required may vary widely dependent on the patient's age and degree of hypersensitivity. Rarely are more than 40 percutaneous tests required.

   - Intracutaneous (intradermal) - injection of a small amount of one or more allergic substances (within a solution) between the epidermal and dermal layers of the skin. Intradermal testing is considered to be more sensitive but less specific than percutaneous testing for the detection of IgE antibodies. The number of intracutaneous tests may also vary from patient to patient. Rarely are more than 20 intracutaneous tests required. Intradermal testing from delayed hypersensitivity of the tuberculin type should not exceed six to eight tests.

2. Patch (Application) Testing - suspected allergen(s) are applied to the patient's back under dressings and allowed to remain in contact with the skin for 48 hours. The area is then examined for evidence of delayed hypersensitivity reactions. Patch testing with 20 to 30 allergens using a screening patch test will detect as many as 70% of all cases of allergies causing contact dermatitis.

3. Photo Patch Test - reflects contact photosensitization. The suspected sensitizer is applied to a patch of skin and left on for 48 hours. If no reaction occurs, the area is exposed to a dose of ultraviolet light sufficient to produce inflammatory redness of the skin. If the test is positive, a more severe reaction develops at the patch site than on the surrounding skin.

4. Specific IgE in vitro testing - detects antigen-specific IgE antibodies in the patient's serum. This testing is considered equivalent to percutaneous skin testing for inhalant allergens (pollens, molds, dust, mites, and animal danders), foods, and other allergens. Testing for drug and insect sting sensitivity should only be done by intradermal testing. Serum allergy testing is an
essential alternative in patients in whom skin testing is contraindicated or unacceptable. This includes, but is not limited to those in whom:

- Direct skin testing is impossible due to extensive dermatitis or marked dermatographism,
- Direct skin testing is impossible as the patient may be unable to cooperate or stop using antihistamines,
- Direct skin testing is impossible in children less than four years of age,
- Direct skin testing has not been conclusive, and further diagnostic testing is necessary, or
- Direct skin testing has been refused by the patient.

These serum allergy tests include:
- Radioallergosorbent Test (RAST),
- Multiple Radioallergosorbent Test (MAST),
- Fluorescent Allergosorbent Test (FAST), and
- Enzyme-linked Immunosorbent Assay (ELISA which is similar to RAST).

5. Total Serum IgE Concentration - not indicated in most allergic patients, but may be indicated for those patients suspected of having allergic bronchopulmonary aspergillosis, immune deficiency disease characterized by increased IgE levels (such as Wiskott-Aldrich syndrome, hyper-IgE staphylococcal abscess syndrome), IgE myeloma, or pemphigoid.

6. Bronchial Challenge Test - aeroallergens or other chemical substances such as histamine, methacholine, and volatile chemicals encountered at home, school, or work. Such testing is generally reserved for the patient with hyper-responsive airways, such as the difficult asthmatic patient in whom routine skin testing is not sufficient to isolate the factors responsible for the asthma. If dust, ragweed, or other common allergens are the suspected cause of the problem, this test is not medically necessary, since skin tests can be used in these situations.

7. Double Blind Food Challenge Test - ingesting of food to which sensitivity is suspected. Both the patient and the physician are "blinded." This is usually done at home, but in some instances of extreme suspected hypersensitivity, it may be performed in the office setting.
The following Allergy Testing modalities are considered investigational:

- Provocative tests for food or food additive allergies - intradermal injection or sublingual (under the tongue) placement of dilute extracts of the suspected substance, followed by observation of the patient's response or reaction. A symptomatic response indicates an allergy to that food and the reaction can be neutralized by application of a similar extract of a greater dilution;

- Provocative tests of chemical substances (also known as Neutralization Testing) - intradermal titration and sublingual provocative neutralization for phenol, synthetic ethanol, formaldehyde, serotonin, histamine, Fluogen, and mixed respiratory viruses;

- Serial dilution end point titration (SDET or Rinkel/Rinkle method) - intradermal testing with series of increasing levels of allergen solutions to determine starting dose and therapeutic dose of immunotherapy. Generally used for quantifying patient sensitivity to ragweed pollen;

- Nasal challenge test - precise measurements of changes in nasal resistance, commonly known as the "sniff test." A visual assessment is done of the mucosal swelling and rhinorrhea following the inhalation of a small amount of dry pollen;

- Conjunctival challenge test (ophthalmic mucous membrane test) - placement of an allergenic extract into the conjunctival sac of the eye, followed by observation for redness, itching, tearing, and other similar symptoms. This is a qualitative test;

- Cytotoxic food tests (Bryan's Test) - involves the response of specially collected white blood cells to the presence of food extracts that the patient is allergic to;

- Leukocyte histamine release test (LHRT) - washed leukocytes from the patient are challenged by suspected allergens, followed by observation and measurement of released histamines;

- Rebuck skin window test - study of inflammatory cellular skin pattern or reaction, to an allergen, following a needle-prick or venipuncture;

- Passive transfer or P-X (Prausnitz-Kustner) test - considered obsolete and has been replaced by RAST; and,
• Antigen leukocyte cellular antibody test (ALCAT) – determines hematological changes to specific food substances by measuring non-IgE medicated reactions in whole blood.

Allergy testing, regardless of type is considered not medically necessary, when used to screen individuals who have not been shown by history and/or examination to have probable allergic hypersensitivity refractory to avoidance and/or pharmacologic treatment.

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Allergy Immunotherapy in patients with demonstrated hypersensitivity that cannot be managed by medications and avoidance are considered medically necessary. Suspensions for injection of airborne or insect venom allergens should be prepared for the patient individually and under physician supervision

Special Consideration of RUSH IMMUNOTHERAPY:

RUSH Immunotherapy for the rapid desensitization of biologicals/medications (such as insulin) and/or toxoids/vaccines (such as tetanus toxoid), to avoid an anaphylactic reaction, are medically necessary as a special consideration when timing and urgent treatment are necessary. An example of RUSH Immunotherapy is when penicillin desensitization is used as an emergent need to prepare an allergic patient for treatment of bacterial endocarditis. Hospitalization would be required for the one to three day treatment course.

The following Allergy Immunotherapy modalities for the treatment of food, molds, chemicals, pollens, and other allergies, are considered investigational:

• Provocative and neutralization therapy, using intradermal and subcutaneous routes - injections of antigen of sufficient quantity are administered to elicit symptoms, followed immediately by an injection of a weaker or stronger dilution of the same antigen to relieve the provoked symptoms;

• Sublingual - oral application of natural or enzymatically altered antigens;

• RUSH immunotherapy - hyper-accelerated rate of allergen injections or sublingual application with simultaneous antihistamine protection following an anaphylactic reaction. Hospitalization would be required for the one to three day treatment course. In some
situations, treatment is done in the office setting in less than 8 (eight) hours;

• Topical - localized application of an allergen directly to the organ creating the allergy response, such as the nose for allergic rhinitis;

• Urine auto-injections (autogenous urine immunization) - freshly collected urine, having been sterilized and filtrated, injected to the donating patient;

• Repository emulsion therapy - solutions of vegetable and mineral oils containing additional allergens, to produce slow releases of the allergens at the injection site; and,

• Serial dilution endpoint titration (SDET) therapy (Rinkel/Rinkle Method) - intradermal injections consisting of a series of increasing levels of allergen solutions used to determine the starting dose and therapeutic dose of immunotherapy.

As a method of avoidance therapy, allergen-proof supplies, such as mattresses, mattress casings, pillows, pillow casings, et cetera, are not medically necessary, as they are considered personal convenience items and not medical in nature.

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Special Comment on Clinical Ecology Services: Clinical Ecology Services are not included in this policy. These services sometimes are being billed as allergy services and are considered investigational. Refer to the Clinical Ecology policy - MED206.003.

DESCRIPTION:

**Allergy Management** includes assessment and testing followed by treatment.

An allergy is an abnormal reaction to an ordinarily harmless substance called an allergen. When an allergen (such as pollen) is absorbed into the body of an allergic person, that person's immune system views the allergen as an invader and a chain reaction is initiated. White blood cells of the immune system produce IgE antibodies. These antibodies attach themselves to special mast cells causing a release of potent chemicals such as histamine. These chemicals cause generalized symptoms as well as localized reactions in any organ system of the body. The reactions may be acute, subacute, chronic,
immediate or delayed, and may be caused by numerous offending agents, such as pollen, molds, dust, mites, animal dander, stinging insect venoms, foods, and drugs.

**Allergy Testing:** The optimum management of the allergic patient should include -
- a careful history and physical examination and
- confirmation of the cause of the allergic reaction obtained from some of the testing methods.

**Allergy Therapy:** Once the offending agent is identified, treatment is managed by avoidance, medication, or immunotherapy.

1. Avoidance is the preferred treatment to eliminate the allergen, requiring a change of diet, occupation, or residence; discontinuance of a drug; or removal of a household pet. However, complete avoidance is impossible.

2. Medication may provide symptomatic relief for the patient but it does not address the cause of the problem. Medications may include steroids, antihistamines, or decongestants.

3. Immunity has been defined as freedom from or protection against certain diseases. Immunotherapy, desensitization, or "allergy shots," are recommended for patients with moderate to severe symptoms throughout most of the year who do not respond adequately to medications, and whose symptoms are triggered by an allergen that is not easily avoided (such as pollens or house dust mites). Immunotherapy involves the repeated injections of allergenic extracts (tiny amounts of allergen) that are given over a period of three to five years. By gradually increasing the amount of extract, tolerance to the offending allergen will increase, and the patient's symptoms will be relieved. Gradual injections may begin once or twice weekly over a period of months. After the maintenance dose is achieved, the interval between injections may range between two and six weeks. Immunotherapy may be administered continuously for several years.

Drug, pollen, or venom RUSH Immunotherapy is done if sensitivity has been established by history, anaphylactic shock, positive challenge testing, and/or positive skin testing. In cases where drug administration for treatment is essential and no alternative exists, rapid desensitization is done by increasing dosages of allergen through intravenous access. The doses are increased over a two day period. In most situations, the patient is hospitalized to provide oxygen, epinephrine, and resuscitation equipment to promptly treat the patient for any life-threatening reaction.
RATIONAL:

Specific tests are used to confirm sensitivity to a particular allergen or allergens. For this purpose, skin tests are the most convenient. They should be selected and based on the information provided by the patient's history.

Typically, it has been common practice to do prick skin testing first. This is usually sufficient for detecting sensitivity to most allergens. More sensitive intradermal testing can be used to test suspected inhaled allergens that have previously produced negative or equivocal prick tests. For foods, prick tests alone are diagnostic. Food intradermal tests are likely to produce positive reactions of no clinical significance, as determined by double-blind oral symptom provoking challenge tests. On the other hand, insect sting and drug testing are accurate only when performed by intradermal testing.

The American Academy of Allergy, Asthma, and Immunology has concluded that serum IgE testing (such as RAST) is comparable in sensitivity to prick or puncture tests. Intradermal testing is more sensitive and is required for the definitive evaluation of insect sting and drug allergies and in some cases, of aeroallergen disease in which patients are minimally sensitive or where available extracts are of suboptimal potency for skin testing.

There has been no evidence to support the use of those tests or therapies listed within this policy as investigational. Among those listed are cutaneous or sublingual provocation testing/treatment, neutralization testing or treatment, or leukocytotoxic testing in allergy diagnosis and management.

In spite of all the recent advances in allergy and immunology, there are still only three basic methods of treating allergies.

Avoidance/Environmental controls are the most important component of therapy. In many cases, if a patient can eliminate their exposure to an allergen their symptoms will decrease markedly and there is no need for further forms of treatment.

The second mode of therapy is medication. Medication is also an important form of therapy and in some patients such as asthmatics it is essential. In recent years, newer and better medications make complete control of the allergic patient possible. In most situations medication relieves or alleviates the symptoms but does not address
the cause. In many patients medication and avoidance are enough to relieve the patient adequately so that no further treatment is necessary.

Currently, immunotherapy is used to treat patients who are sensitive to inhaled allergens, such as pollens, molds, dander, and house dust. Studies have also found immunotherapy to be extremely effective in many cases of stinging insect allergy as well. Immunotherapy for food allergies is not recommended because of the chance of a severe allergic reaction to the injection and because avoidance can often be achieved. Immunotherapy is not a cure.

PRICING:

For RAST, FAST, and ELISA Allergy Testing; use 86003.

For MAST; use 86005.

Double Blind Food Challenge Test may be performed in the office setting. This is considered to be part of the office visit as this testing is usually done at home.

REFERENCES:


"In Vitro Allergy Tests for Specific IgE." BCBSA TEC Evaluation (1990 May): 56-84.


"Joint Task Force on Practice Parameters for Immunology." The Joint Council of Allergy, Asthma, and Immunology (1999 November 22) (Web site): http://www.jcaai.org/Param/Shots.HTM.


DISCLAIMER:

State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, takes precedence over Medical Policy and must be considered first in determining coverage. The member’s contract benefits in effect on the date that services are rendered must be used. Any benefits are subject to the payment of premiums for the date on which services are rendered. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically. HMO Blue Texas physicians who are contracted/affiliated with a capitated IPA/medical group must contact the IPA/medical group for information regarding HMO claims/reimbursement information and other general polices and procedures.