Allergy Testing & Treatment

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INSTRUCTIONS:

“Medical Policy assists in administering UCare benefits when making coverage determinations for members under our health benefit plans. When deciding coverage, all reviewers must first identify enrollee eligibility, federal and state legislation or regulatory guidance regarding benefit mandates, and the member specific Evidence of Coverage (EOC) document must be referenced prior to using the medical policies. In the event of a conflict, the enrollee’s specific benefit document and federal and state legislation and regulatory guidance supersede this Medical Policy. In the absence of benefit mandates or regulatory guidance that govern the service, procedure or treatment, or when the member’s EOC document is silent or not specific, medical policies help to clarify which healthcare services may or may not be covered. This Medical Policy is provided for informational purposes and does not constitute medical advice. In addition to medical policies, UCare also uses tools developed by third parties, such as the InterQual Guidelines®, to assist us in administering health benefits. The InterQual Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. Other Policies and Coverage Determination Guidelines may also apply. UCare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary and to provide benefits otherwise excluded by medical policies when necessitated by operational considerations.”
POLICY DESCRIPTION:

This policy describes the use of allergy testing and treatment for allergic or hypersensitivity disorders. Allergies may be manifested by generalized systemic reactions as well as localized reactions in any organ system of the body. The reactions may be acute, subacute or chronic. Reactions may also be immediate or delayed, and are caused by numerous offending agents, such as: pollen, molds, dust, mites, animal dander, stinging insect venoms, foods, or drugs.

Allergy Testing: Allergy testing focuses on determining what allergens cause a particular reaction, the degree of the reaction, and provides justification for treatment recommendations. There are two types of allergy testing, in vivo and in vitro.

- **In vivo testing**: Testing that is performed in/on the body. Examples are: skin testing (skin prick testing, skin scratch testing, intradermal testing, skin patch testing, and skin endpoint titration), bronchial provocation tests, and food challenges.

- **In vitro testing**: Testing that is performed outside the body in a laboratory situation. Examples are blood tests to detect specific IgE antibodies to a particular antigen (RAST and ELISA tests) and leukocyte histamine release test (LHRT), also referred to as basophil histamine release test.

Allergy Treatment: Once the agent is identified, treatment typically consists of avoidance of the offending agent, medication or immunotherapy.

- **Avoidance**: Avoidance of the allergen responsible for the symptoms is the most effective treatment for allergy. Avoidance is the only treatment available for food allergies.

- **Medication**: In cases in which the allergen cannot be avoided completely (for example, dust or pollens), a variety of different medications, including antihistamines can be used.

- **Immunotherapy**: Allergy immunotherapy is the process of administering progressively increasing doses of an allergen as treatment for a person who has demonstrated sensitivity through allergy testing. This therapy is also known as desensitization, hyposensitization, allergy injection therapy, allergy vaccine, and therapy allergy shots. The goal is to desensitize the body to the substance, and induce tolerance of the allergen. Although immunotherapy helps to decrease allergy symptoms for many people with allergic rhinitis, allergic asthma, conjunctivitis (eye allergy) and stinging insect allergy, the therapy requires several years of maintenance injections.

- **Sublingual immunotherapy (SLIT)**: SLIT has been investigated as an alternative route of immunotherapy administration. With this type of administration allergen preparations are held under the tongue for one to several minutes and then swallowed or spit out.

- **Rapid Desensitization (Rush Immunotherapy or Cluster Immunotherapy)**: This therapy is for patients with drug hypersensitivity. When drug hypersensitivity reactions occur, in most cases the suspected drug is avoided in the future. However, for certain patients the particular drug may be essential for optimal therapy. Under these circumstances, rapid drug desensitization may be performed, administering increasing doses of the medication concerned over a short period of time (hours to a few days), until the total cumulative therapeutic dose is achieved and tolerated. It is a high-risk procedure used only in patients in whom alternatives are less effective or not available after a positive risk/benefit analysis.
COVERAGE RATIONALE /CLINICAL CONSIDERATIONS:

Allergy testing and allergy immunotherapy are considered **MEDICALLY NECESSARY** for members with a clinical history of significant allergic symptoms when those symptoms not been adequately controlled through medication and allergen exposure reduction.

A. The following specific allergy test are considered **MEDICALLY NECESSARY** when performed by or under the direct supervision of a physician, in conjunction with a positive clinical history and physical examination, for the purpose of establishing a diagnosis of allergy disease:

**IN VIVO ALLERGY SKIN TESTING:**

1. Percutaneous (scratch, prick or puncture) testing is the usual preferred method for allergy testing, when IgE-mediated reactions occur to any of the following:
   - Foods; or
   - Hymenoptera (stinging insects); or
   - Inhalants (allergic rhinitis, allergic or chronic rhinosinusitis, allergic rhinoconjunctivitis, allergic conjunctivitis, cat allergy, evaluating and managing patients with asthma); or
   - Specific drugs (penicillins and macromolecular agents).

2. Intradermal (Intracutaneous) when IgE-mediated reactions occur to any of the following:
   - Foods; or
   - Hymenoptera venom allergy (stinging insects); or
   - Inhalants (allergic rhinitis, allergic or chronic rhinosinusitis, allergic rhinoconjunctivitis, allergic conjunctivitis, cat allergy, evaluating and managing patients with asthma); or
   - Specific drugs (penicillins and macromolecular agents).

3. Skin Endpoint Titration (SET) (also known as intradermal dilutional testing (IDT)) for determining the starting dose for immunotherapy for:
   - Members highly allergic to hymenoptera venom allergy (stinging insects); or
   - Members highly allergic to inhalants.

4. Skin Patch Testing for diagnosing contact allergic dermatitis.

5. Photo Patch Testing for diagnosing photo-allergy (e.g., photo-allergic contact dermatitis).

6. Bronchial Challenge Test for testing with methacholine, histamine or antigens in defining asthma or airway hyperactivity when either of the following conditions is met:
   - Bronchial challenge test is being used to identify new allergens for which skin or blood testing has not been validated; or
   - Skin testing is unreliable.

7. Exercise Challenge Testing for exercise-induced bronchospasm

8. Ingestion (Oral) Challenge Test for any of the following:
   - Food or other substances (i.e., metabisulfite); or
   - Drugs when all of the following are met:
     - History of allergy to a particular drug; and
There is no effective alternative drug; and
- Treatment with that drug class is essential.

**IN VITRO ALLERGY SKIN TESTING:**

In Vitro IgE Antibody Tests (RAST, MAST, FAST, ELISA, ImmunoCAP) may be considered medically necessary for the initial allergy screen in lieu of skin testing:
- Allergic broncho-pulmonary aspergillosis (ABPA) and certain parasitic diseases; or
- Food allergy; or
- Hymenoptera venom allergy (stinging insects); or
- Inhalant allergy; or
- Specific drugs.

**B. IMMUNOTHERAPY:** Immunotherapy is considered **MEDICALLY NECESSARY** in the management of patients with demonstrated hypersensitivity, when positive test results for specific IgE antibodies correlate with suspected triggers and patient exposure, and symptoms cannot be managed by medications or avoidance. Any of the following:

- Allergic asthma
- Allergic rhinitis/conjunctivitis due to:
  - Seasonal pollinosis caused by trees, grasses and weeds, and/or mold-induced rhinitis.
  - Perennials such as cat and dog dander, dust mite and cockroach
- Stinging insect hypersensitivity. Patient with:
  - Severe systemic anaphylactic reaction after an insect sting
  - Delayed systemic reactions with symptoms of anaphylaxis or serum sickness

Injections of airborne or insect venom allergens should be prepared for the patient individually.

**RAPID DESSENSITIZATION:** Rapid desensitization is considered **MEDICALLY NECESSARY** in cases of allergy to insulin, penicillin and horse serum, as well as sulfonamides, cephalosporins and other commonly used drugs (e.g. aspirin), when circumstances require the use of one of these substances. Desensitization may need to be repeated if future circumstances require an additional course of the offending allergen.

**Note:** Immunotherapy should not be given to patients with negative test results for specific IgE antibodies or those with positive test results for specific IgE antibodies that do not correlate with suspected triggers, clinical symptoms, or exposure.

**C. The following services are considered EXPERIMENTAL AND/OR INVESTIGATIONAL** for the diagnosis and treatment of allergies, due to inadequate clinical evidence of safety and/or efficacy in published, peer-reviewed medical literature.

**Allergy Testing:**

1. Cytotoxicity testing (Bryan's test)
2. Provocation testing and neutralization therapy for food allergy (intracutaneous, subcutaneous or sublingually). Also called Intracutaneous Progressive Dilution Food Test (IPDFT)
3. Antigen leukocyte cellular antibody test (ALCAT) for all indications including but not limited to testing for food allergies or intolerance (chemical sensitivities) and as a tool to establish elimination
4. Electrodermal testing or electro-acupuncture  
5. Applied kinesiology or muscle strength testing of allergies  
6. Reaginic pulse testing or pulse testing for allergies  
7. Total serum immunoglobulin G (IgG), immunoglobulin A (IgA) and immunoglobulin M (IgM)  
8. Testing of specific IgG antibody (e.g., by RAST or ELISA testing)  
9. Lymphocyte subset counts  
10. Lymphocyte function assay  
11. Cytokine and cytokine receptor assay  
12. Food immune complex assay (FICA)  
13. Leukocyte histamine release testing  
14. Conjunctival challenge test (ophthalmic mucous membrane test)  
15. Nasal challenge test  
16. Direct skin testing for bacterial antigens  
17. Body chemical analysis  

**Allergy Treatment:**  
18. Urine autoinjection (autogenous urine immunization, a substance from the urine is injected into the skin)  
19. Sublingual immunotherapy (SLIT)  
20. Repository emulsion therapy  
21. Low dose immunotherapy also known as the "Rinkel" technique  
22. Enzyme-Potentiated Desensitization  
23. Acupuncture for allergies  
24. Homeopathy for allergies  
25. Rhinophototherapy  
26. Environmental therapy, also known as idiopathic environmental intolerance or clinical ecology treatment  

**Clinical Considerations:**  
**ALLERGY TESTS:**  
- **Recommended Number of Tests:**  
  - The evaluation of inhalant allergy may require up to 70 percutaneous tests, followed by up to 40 intracutaneous tests (which are usually performed when percutaneous tests are negative). However, in most cases, fewer tests are required.  
  - It is inappropriate to use Skin Endpoint Titration (SET) in place of skin testing; however, when used to determine the starting dose for immunotherapy in highly allergic members, up to 14 titration tests may be necessary. An additional 40 antigens or 80 IDT injections may be medically necessary if any of the initial test results is positive.  
  - In vitro tests may be medically necessary for the initial allergy screen in lieu of skin testing. An initial allergy screen is 12 tests. Additional tests may be medically necessary if any of the initial
test results is positive. If all test results are negative, additional testing beyond the initial allergy screen of 12 tests/allergens is not considered medically necessary.

- A maximum of 50 patch tests per beneficiary per year is allowed without the submission of documentation with the claim to support medical necessity. Greater than 50 patch tests per patient per year requires the submission of documentation with the claim to support medical necessity.

- Contraindications
  - Skin tests are not feasible when there is extensive skin disease, when allergy treatments that would invalidate skin test results cannot be discontinued, or when the patient’s history suggests a high risk of anaphylaxis.
  - Compliance with quantitative skin testing is an issue in some patients, due to the multiple pricks that are necessary.
  - Physiological and perhaps psychological factors that affect skin test results can vary among patients, detracting from reliability.
  - Challenge tests have some of the same clinical contraindications as skin testing; can be traumatic for patients, especially children; and are hampered by the lack of standardized methodology.

IMMUNOTHERAPY: The physician prescribing immunotherapy should be trained and experienced in prescribing and administering immunotherapy. Patients receiving maintenance immunotherapy should have follow-up visits at least every 6 to 12 months.

- Recommended for Individuals With:
  - Allergic rhinitis/conjunctivitis or allergic asthma whose symptoms are not well controlled by medications, or avoidance measures, or require high medication doses, multiple medications, or both to maintain control of their allergic disease.
  - Adverse effects of medications or who wish to avoid or reduce the long-term use of medications.
  - Aeroallergen-induced atopic dermatitis.
  - Flying insect or imported fire ant hypersensitivity who are at risk for anaphylaxis should receive venom immunotherapy (VIT) or whole-body extract, respectively.
  - Allergic asthma unresponsive to allergen avoidance, even when symptomatic relief can be achieved with drug therapy. Treatment plans vary, but generally follow an initial dosing of short intervals (2 to 7 days) and should be increased 1.5 to 2 times with each injection if no reaction occurs.
  - Rapid desensitization is indicated in cases of allergy to insulin, penicillin and horse serum, as well as sulfonamides, cephalosporins and other commonly used drugs (e.g. aspirin). In patients with a positive history of reaction and with documented skin test reactivity, every effort should be made to avoid the use of these substances. When circumstances require the use of one of these substances, the patient will have to be desensitized. Full-dose therapy requires strict physician monitoring in a hospital intensive care setting with continuous monitoring of vital signs and cardio-respiratory status. Desensitization may need to be repeated if future circumstances require an additional course of the offending allergen.

- Contraindications:
Immunotherapy should not be given to patients with negative test results for specific IgE antibodies or those with positive test results for specific IgE antibodies that do not correlate with suspected triggers, clinical symptoms, or exposure.

- Allergen immunotherapy can be continued, but is usually not initiated, in the pregnant patient.
- Immunotherapy can be considered in patients with immunodeficiency and autoimmune disorders.

**Patient Population:**
In patients who otherwise have the indication for specific immunotherapy, there is no absolute upper age limit for initiation of immunotherapy. Both children and adults can receive allergy shots, although it is not typically recommended for children under age five. This is because of the difficulties younger children may have in cooperating with the program and in articulating any adverse symptoms they may be experiencing. When considering allergy shots for an older adult, medical conditions such as cardiac disease should be taken into consideration and discussed with your allergist/immunologist first.

**BACKGROUND:**
Allergies are a significant cause of chronic disease in the United States, with more than 50 million Americans affected. Allergies are the immune system’s response to an antigen, usually a protein. In some cases, small molecules, such as penicillin, that are incapable of stimulating an immune response on their own, can become allergenic if they bind to endogenous proteins like albumin, leading to formation of recognizable antigenic complex. These small molecules are called haptens. An allergic reaction is the result of 3 interacting factors:

- An allergen, e.g., pollen, mold, dust mites, certain foods, latex, and animal dander;
- Mast cells residing primarily in connective tissues of the skin, tongue, lungs, upper airways, and linings of the nose and intestinal tract; and
- Immunoglobulin E (IgE), an allergic antibody that coats mast cell surfaces.

The immune system controls how the body defends itself. For instance, if an individual has an allergy to pollen, their immune system identifies pollen as an invader or allergen. The immune system overreacts by producing antibodies called Immunoglobulin E (IgE). These antibodies travel to cells that release chemicals, causing an allergic reaction. These reactions can range from sneezing and sniffing to a life-threatening response called anaphylaxis. Allergy tests, combined with a physical examination and medical history, can give precise information about what an individual may be allergic to.

**Hypersensitivity:**
There are 4 classic mechanisms of hypersensitivity:

- **Type I** is a hypersensitivity reaction or immediate allergic reaction, cross-linking of 2 adjacent IgE molecules on a mast cell or basophil by a multivalent antigen;
- **Type II** or cytotoxic-mediated hypersensitivity reaction, is a reaction of immunoglobulin G (IgG) and immunoglobulin M (IgM) to cell surface antigens, resulting in complement activation and cytotoxicity;
- **Type III,** or cytotoxic hypersensitivity reaction, in which soluble antigen-antibody complexes activate the complement system; and,
- **Type IV,** or delayed-type hypersensitivity reaction, activates cell-mediated immune memory response.
IN VIVO ANTIGEN TESTING (skin tests):
Skin tests involve putting a small amount of a suspected allergen onto the skin.

- **Puncture, Scratch or Prick Skin Test:** The skin is pricked, punctured, or scratched so that the allergen goes under the top layer of skin. The test is performed on the back or forearm. The physician watches closely for swelling and redness and other signs of a reaction. Results are usually seen within 15-20 minutes. Several allergens can be tested at the same time.

- **Intradermal Test:** The intradermal skin test involves injecting a small amount of allergen into the dermis. Used for venom and penicillin allergy testing when skin testing is negative, but there is a high suspicion of an allergy.

- **Patch Test:** The patch skin test is a method to diagnose the cause of skin reactions that occur after the substance touches the skin. Twenty to thirty antigens are used in the usual routine screening panel of patch tests. Possible allergens are taped to the skin for 48 hours and the health care provider would look at the area in 72-96 hours.

- **Skin Endpoint Titration (SET):** A quantitative modification of intradermal testing to indentify the lowest dilution that products a positive skin reaction. SET involved two steps: (1) Wheals of identical size are made in the most superficial layers of the skin, with successive applications of dilutions of increasing strength. The point at which this occurs is called the “endpoint.” (2) Use the endpoint dilution as the starting dilution for immunotherapy treatment beginning with an injection of an allergen adjusted to the endpoint concentration. More than one allergen can be tested this way.

- **Photo Patch Test:** This test involves applying two identical sets of allergens to the back on day one. One of the sets is exposed to UVA light, and the sites are examined as usual. A positive photo-patch test is recorded when an allergic reaction appears only on the light exposed site. A photosensitivity reaction may be suspected if a rash appears on areas exposed to the sunlight.

- **Exercise Challenge Test:** Exercise challenge testing is an accepted method of diagnosing exercise induced bronchospasm in asthmatic and non-asthmatic patients.

- **Bronchial Challenge Test:** Bronchial challenge testing with methacholine, histamine, or allergens is a method of defining asthma or airway hyperactivity when skin testing results are not consistent with the patient's medical history. Results of these tests are ordinarily evaluated by objective measures of pulmonary function and occasionally by characterization of bronchoalveolar lavage samples. Recommended dosage is an incremental increase of pharmacologic dose until a response is produced.

- **Ingestion Challenge Test:** Ingestion (oral) challenge testing is a method of diagnosing allergies to food, drug or other substances (i.e., metabisulfite). Drug challenge testing should not be confused with cutaneous or sublingual provocation and neutralization therapy, which is a non-covered modality.

IN VITRO ANTIGEN TESTING (blood tests):
An allergy blood test is used if the patient is taking a medicine that can interfere with the skin testing and cannot be stopped for a few days, or if the patient suffers from a severe skin condition like eczemas or psoriasis. Blood tests are also used on babies and very young children. It takes many days to get the results of the test.

- **Specific IgE Testing** (Radioallergosorben Test RAST, Multiple Radioallergosorbent Tests MAST, Fluorescent Allergosorben Test FAST, Enzyme-linked Immunosorben Assay ELISA, and ImmunoCAP): These tests detect specific IgE antibodies in the blood serum.
ALLERGY TREATMENT:
The treatment of allergy is approached 3 ways:

- **Avoidance Therapy:** complete avoidance of the known allergen responsible for inducing the signs and symptoms of the allergy is the most effective treatment for any allergic condition and results in a cure.
- **Pharmacologic Therapy:** when avoidance of a specific allergen such as house dust, molds or pollens is impossible, pharmacologic therapy is used (e.g., antihistamines, adrenergic agonists, anticholinergics, beta-adrenergic agonists, corticosteroids, cromolyn sodium and methylxanthines). It has been advocated that the utilization of air cleaners, humidifiers, or dehumidifiers is helpful in reducing allergic irritant substances in the environment; however, research indicates that the use of these mechanical devices was ineffective in reducing clinical symptoms.
- **Allergen Immunotherapy:** Allergen immunotherapy (also known as desensitization, hyposensitization, allergy injection therapy, or "allergy shots"), is effective for treating allergic rhinitis, allergic asthma, and Hymenoptera sensitivity with the goal to reduce the patient's allergy sensitivity when exposed to the offending allergen in the future. Allergy shots work like a vaccine in that the body responds to injected amounts of a particular allergen, given gradually in increased doses, thus building up immunity and desensitization of the allergen. The documented allergy should correspond to the allergen planned for immunotherapy. A trial of systemic medications or avoidance of the allergens should be attempted. There are two phases of immunotherapy including:
  1. The build up phase which involves receiving injections of increased doses about 1-2 times per week and for 3-6 months.
  2. The maintenance phase which starts when an effective dose is reached. There are longer periods of time between the treatments, possibly 2 to 6 weeks ongoing for several years.

Two or more medications (antihistamines, steroids, bronchodilators, intranasal cromolyn, if not contraindicated, should have been prescribed during the past year or the patient should be currently receiving immunotherapy.

REGULATORY STATUS:

1. **U.S. FOOD AND DRUG ADMINISTRATION (FDA):**
The Center for Biologics Evaluation and Research (CBER) regulates allergenic products. Currently, there are 2 types of allergenic products licensed for use: allergen patch tests and allergenic extracts. Allergen patch tests are diagnostic skin tests used for determining the specific causes of contact dermatitis. Allergenic extracts are injectable products that are used for the diagnosis and treatment of allergic diseases. These extracts are used in performing diagnostic allergy skin tests; however, CBER does not license the techniques themselves. Allergenic extracts are manufactured in 2 forms: standardized and unstandardized (for which there are no U.S. reference standards). Prior to release, standardized allergenic extracts are compared with U.S. reference standards for potency. These reference standards are maintained by CBER and are distributed to manufacturers. As of 2007, there were 19 standardized allergenic extracts. The extracts for which there are no U.S. reference standards are called unstandardized extracts (FDA, 2007; FDA, 2009).

The Food and Drug Administration (FDA) determined that the intracutaneous technique should be used for assigning standardized unitage (i.e., bioequivalency allergy units [BAU]). Patients with allergic
rhinitis and/or asthma from tree and grass pollens in the spring, ragweed pollen in the fall and year-round dust-mite sensitivity who have had inadequate response to acceptable symptomatic medication and allergen avoidance are excellent candidates for immunotherapy.

2. CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS):

I. Allergy Testing

Allergy testing is covered when clinically significant symptoms exist and conservative therapy has failed. Allergy testing includes the performance, evaluation, and reading of cutaneous and mucous membrane testing. These are considered technical services.

A. Allergy sensitivity tests: These tests include the performance and evaluation of selective cutaneous and mucous membrane tests in correlation with history, physical examination, and other observations of the patient. The tests are performed to determine body sensitivity and reaction to the antigen for the purpose of diagnosing the presence of allergic reaction to antigenic stimuli. The number of tests performed should be judicious and dependent upon the history, physical finding and clinical judgment. All patients should not necessarily receive the same tests or the same number of sensitivity tests. Intradermal tests are injections of small amounts of antigen into the superficial layers of the skin.

B. Patch testing: Patch testing is the gold standard method of identifying the cause of allergic contact dermatitis, is indicated to evaluate a nonspecific dermatitis, allergic contact dermatitis, pruritus, and other dermatitis to determine the causative antigen. It is a diagnostic test reserved for patients with skin eruptions for which a contact allergy source is likely. Examples of contact allergens (antigens) include nickel, rubber additives, and topical antibiotics. These allergens are part of a useful, but limited series of 29 allergens. While this series of 29 allergens represents some of the most common contact allergies, there are a significant number of patients who suffer intractable contact dermatitis for which the 29 allergens are inadequate to diagnose their problem. A supplemental series of allergens in this case can enhance accurate diagnosis, patient education, and treatment. This supplemental series is particularly critical in the diagnosis of occupationally induced dermatitis.

C. Provocative tests: For which there is limited or no evidence of validity include the cytotoxic test, the provocation-neutralization procedure, electrodermal diagnosis, applied kinesiology, the "reaginic" pulse test, and chemical analysis of body tissues. Controlled studies for the cytotoxic and provocation-neutralization tests demonstrated that the results are not reproducible and do not correlate with clinical evidence of allergy. Electrodermal diagnosis and applied kinesiology have not been evaluated for efficacy. Similarly, the "reaginic" pulse test and chemical analysis of body tissues for various exogenous chemicals have not been substantiated as valid tests for allergy.

1. Organ challenge test materials may be applied to the mucosae of the conjunctivae, nares, GI tract, or bronchi. Considerable experience with these methods is required for proper interpretation and analysis.

2. All organ challenge tests should be preceded by a control test with diluent and, if possible, the
procedure should be performed on a double blind or at least single-blind basis.

3. Direct nasal mucus membrane challenge tests may be informative provided that the patient’s nasal mucosa does not manifest nonspecific irritative responses and the results can be interpreted by objective measurements.

Ophthalmic mucous membrane tests and direct nasal mucous membrane tests are approved if levels of allergic mediators (such as histamine and tryptase) are measured and a placebo control is performed. This is usually performed in allergy research laboratories. It is also approved in the office setting if the physician is there to observe objective measurement of reactions which might include redness of the eyes, tearing and sneezing.

4. Inhalation bronchial challenge tests are often used to evaluate new allergens and may be used to substantiate the role of allergens in patients with significant symptoms. Results of these tests are ordinarily evaluated by objective measures of pulmonary function and occasionally by characterization of bronchoalveolar lavage samples.

   a. Inhalation bronchial challenge tests should be performed as dose-response assays wherein provocation concentration thresholds can be determined on the basis of allergen concentration required to cause a significant decrease in measured pulmonary function.

   b. Inhalation bronchial challenge tests with occupational allergens need to be carefully controlled with respect to dose and duration of exposure. When industrial small molecular weight agents are assessed, tests should be performed under conditions of continuous monitoring of the specific chemical being assessed so as not to exceed the threshold limit level permitted in the workplace.

5. Challenge ingestion food testing is a safe and effective technique in the diagnosis of food allergies. This procedure is covered when it is used on an outpatient basis, if it is reasonable and necessary for the individual patient. CMS Pub. 100-03 Chapter 1, Part 2 Section 110.12

WPS Medicare will cover this test for the following indications:

- Food allergy, dermatitis
- Anaphylactic shock due to adverse food reaction
- Allergy to medicinal agents
- Allergy to foods

Challenge ingestion food testing has not been proven to be effective in the diagnosis of rheumatoid arthritis, depression, or respiratory disorders. Accordingly, its use in the diagnosis of these conditions is not reasonable and necessary within the meaning of section 1862(a)(1) of the Medicare law, and no program payment is made for this procedure when it is so used.

D. Standard skin testing: Is the preferred method when allergy testing is necessary. Each test should be billed as one unit of service per procedure code, not to exceed two strengths per each unique antigen. Histamine and saline controls are appropriate and can be billed as two antigens. The number of antigens should be individualized for each patient based on history and environmental exposure.

E. Specific IgE in Vitro Test (RAST, MAST, FAST): These tests detect antigen-specific IgE antibodies in the patient’s serum. They are useful when testing for inhalant allergens (pollens, molds, dust mites, animal danders), foods, insect stings, and other allergens such as drugs or latex, when direct skin testing is impossible due to extensive dermatitis, marked dermatographism, or in children younger
than four years of age.

In-vitro testing is not as sensitive as skin testing, but is covered when skin testing is not possible or would be unreliable as indicated below. When in-vitro testing is ordered or performed, the medical record must clearly document the indication. In-vitro testing is covered only as a substitute for skin testing. It is not covered when done in addition to a skin test for the same antigen, except in the case of suspected latex sensitivity, hymenoptera, or nut/peanut sensitivity where both the skin test and the in-vitro test may be performed. The number of tests done; choices of antigens, frequency of repetition and other coverage issues are the same as for skin testing. Control testing is essential for proper interpretation. It is rarely necessary to test for more than 50 allergies and, if food allergy is not suspected, fewer than 30 are usually sufficient. Testing must be based on a careful history/physical examination which suggests IgE-mediated disease. If testing is inconclusive, and contraindications for skin testing have been resolved, then skin testing may be done and is covered. The medical record must document this rationale. Twelve (12) allergens per panel are used but no more than 2 panels/beneficiary over a 12-month period are allowed. The medical necessity of more tests must be submitted with the claim.

1. In-vitro allergen specific IgE testing is limited to the following:
   a. Direct skin testing is not possible due to extensive dermatitis, dermographism, ichthyosis, generalized eczema or the necessary continued use of H-1 blockers (antihistamines), or in the rare patient with a persistent unexplained negative histamine control,
   b. Testing in patients who have been receiving long-acting antihistamines, tricyclic antidepressants, beta-blockers or medications that may put the patient at undue risk if they are discontinued,
   c. Testing of uncooperative patients with mental or physical impairments,
   d. The evaluation of cross-reactivity between insect venoms,
   e. As adjunctive laboratory tests for disease activity of allergic bronchopulmonary aspergillosis and certain parasitic diseases, and
   f. When clinical history suggests an unusually greater risk of anaphylaxis from skin testing than usual (e.g., when an unusual allergen is not available as a licensed skin test extract).

   Twelve (12) allergens per panel are used but no more than 2 panels/beneficiary over a 12-month period are allowed. The medical necessity of more tests must be submitted with the claim.

2. Total Serum IgE is covered for follow-up of bronchopulmonary aspergillosis and it may be necessary to diagnose atopy in small children. It is not appropriate in most general allergy testing. Instead, individual IgE tests are performed against a specific antigen.

3. Quantitative multi-allergen screen is a non-specific screen that does not identify a specific antigen. It is a screening tool and therefore not covered by Medicare.

**F. Intracutaneous testing, delayed reaction:** More than 6 tests, may be covered but requires additional justification and case-by-case review for the number of tests performed and the medical necessity except when the skin test is used for:

A collagen sensitivity test must be administered prior to collagen implant therapy (Injectable Bulking Agent Implantation for Urinary Incontinence, and it must be evaluated over a four-week period.

Coverage Issues Section 65-9
G. Intradermal Dilutional Testing (IDT) (also known as Skin Endpoint Titration [SET]): Intradermal dilutional testing is intradermal testing of sequential and incremental dilutions of a single antigen. The endpoint is determined by intradermal testing with the use of approximately 0.1-ml of generally serial five-fold dilution extract. It is the weakest dilution that produces a positive skin reaction and initiates progressive increase in the diameter of the wheals with each stronger dilution.

H. Patch Testing: Allergy patch testing is a covered procedure only when used to diagnose allergic contact dermatitis after the following exposures:

Dermatitis due to detergents, oils and greases, solvents, drugs and medicines in contact with skin, other chemical products, food in contact with skin, plants (except food), cosmetics, metals, other and unspecified.

- A maximum of 50 patch tests per beneficiary per year is allowed without the submission of documentation with the claim to support medical necessity.
- Greater than 50 patch tests per patient per year requires the submission of documentation with the claim to support medical necessity.

The following tests are considered not medically necessary:

- Provocative Testing
- Blood, Urine or Stool Micro-Nutrient Assessments
- Qualification of Nutritional Assessments
- IgG (ELISA) Tests
- Environmental Cultures and Chemicals
- Live Cell Analysis
- Passive Transfer
- Re buck Skin Window
- Leukocyte Histamine Release
- Metabolic Assessments
- General Immune System Assessments
- Secretory IgA (Saliva)
- Qualitative Multi-Allergen Screen
- Food Allergenic Extract Immunotherapy
- Cytotoxic Food Testing

II. Allergy Immunotherapy

Indications for immunotherapy are determined by diagnostic testing appropriate to the individual needs of each patient and his/her clinical history of allergic diseases. Allergen immunotherapy should be differentiated from the process of desensitization, which usually applies to the rapid progressive administration of an allergenic substance to render effector cells less reactive.

The technique of allergen immunotherapy should also be differentiated from unproven techniques such as sublingual treatment and neutralization-provocation therapy.

The major risk of allergen immunotherapy is anaphylaxis. Allergen immunotherapy should, therefore, be administered under the supervision of an appropriately trained physician who can recognize early
symptoms and signs of anaphylaxis and administer emergency medications where necessary. In addition, immunotherapy should be administered only in facilities equipped to treat anaphylaxis.

Indications for immunotherapy are determined by appropriate diagnostic procedures coordinated with clinical judgment and knowledge of the natural history of allergic diseases. Controlled studies have shown that allergen immunotherapy is effective for patients with allergic rhinitis or conjunctivitis, allergic asthma, and stinging insect hypersensitivity.

A. The necessity of allergen immunotherapy may also depend on the degree to which symptoms can be reduced by medications; the ability of the patient to tolerate possible side effects of the medication; the amount, type and cost of the medications required to control symptoms; and whether proper avoidance is possible.

B. Aeroallergen immunotherapy is indicated for patients with allergic rhinitis due to seasonal pollinosis caused by trees, grasses and weeds, and in the treatment of mold-induced rhinitis. It is also indicated for perennials such as cat and dog dander, dust mite and cockroach.

C. Venom immunotherapy is indicated for patients who have a severe systemic anaphylactic reaction after an insect sting and a positive skin test or other documented IgE sensitivity to specific insect venom. Patients with delayed systemic reactions with symptoms of anaphylaxis or serum sickness, and with a positive skin test or presence of venom specific IgE by in vitro testing are also recommended for treatment.

D. Rapid desensitization is indicated in cases of allergy to insulin, penicillin and horse serum, as well as sulfonamides, cephalosporins and other commonly used drugs (e.g. aspirin). In patients with a positive history of reaction and with documented skin test reactivity, every effort should be made to avoid the use of these substances. When circumstances require the use of one of these substances, the patient will have to be desensitized. Full-dose therapy requires strict physician monitoring in a hospital intensive care setting with continuous monitoring of vital signs and cardiorespiratory status. Desensitization may need to be repeated if future circumstances require an additional course of the offending allergen.

E. Standardized dust mite extracts appear effective for immunotherapy. Other environmental allergens (e.g., kapok, jute, feathers, and unstandardized house dust extracts) are of questionable value in immunotherapy, however, and generally should not be used.

F. Allergen-induced asthma is an indication for immunotherapy along the guidelines for allergic rhinitis when there is a poor response to environmental control or pharmacologic treatment. Allergen immunotherapy is divided into codes that describe the injection only and codes that describe the preparation of the antigen to be delivered for injection by a different physician.

G. Clinical studies to date do not support the use of allergen immunotherapy for food hypersensitivity, chronic urticaria, or angioedema. Therefore, allergen immunotherapy for patients with these conditions is not recommended.

H. The following services are considered investigational and are considered not medically necessary services.
   a. Desensitization with commercially available extracts of poison ivy, poison oak, or poison sumac
   b. Desensitization for hymenoptera sensitivity using whole body extracts, with the exception of fire ant extracts
   c. Desensitization with bacterial vaccine (BAC: bacterial, antigen complex, streptococcus vaccine, staphylo-streptococcus vaccine, serobacterin, staphylococcus phage lysate)
   d. Food allergenic extract immunotherapy
<table>
<thead>
<tr>
<th></th>
<th>Intracutaneous desensitization (Rinkel Injection Therapy, RIT)</th>
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<tbody>
<tr>
<td>f.</td>
<td>Intracutaneous titration</td>
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<td>g.</td>
<td>Neutralization therapy (intradermal and subcutaneous)</td>
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<tr>
<td>h.</td>
<td>Repository emulsion therapy</td>
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<tr>
<td>i.</td>
<td>Sublingual desensitization</td>
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<td>j.</td>
<td>Sublingual provocative therapy</td>
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<td>k.</td>
<td>Urine autoinjection (autogenous urine immunotherapy)</td>
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<tr>
<td>l.</td>
<td>Allergen immunotherapy for the management of skin and mucous membrane disease such as atopic dermatitis, urticaria, and Candida vulvovaginitis</td>
</tr>
<tr>
<td>m.</td>
<td>Intranasal immunotherapy</td>
</tr>
<tr>
<td>n.</td>
<td>Postmortem examination for IgE antibodies to identify allergens responsible for lethal anaphylaxis (post mortem work is not-covered by Medicare)</td>
</tr>
</tbody>
</table>

**I. Treatment Schedules**

The starting dose of an allergenic extract and the progression of the dose must be individualized for each patient. The standard schedule uses a weekly injection that begins with one to two treatments per week, with gradual tapering of the frequency of injections when maintenance levels are achieved.

**J. Length of Therapy**

The duration of all forms of immunotherapy must be individualized. A presumption of failure can be made when, after 12-24 months of therapy, a person does not experience a noticeable decrease of symptoms, an increase in tolerance to the offending allergen, and a reduction in medication usage.

For many patients, the recommended duration of allergen immunotherapy is 3 to 5 years. However, the duration of immunotherapy should be individualized on the basis of clinical response, disease severity, immunotherapy reaction history, and patient preference. Treatment will not be reimbursed after a 2-year period when there is no apparent clinical benefit.

**K.** Patients who are mentally or physically unable to communicate clearly with the allergist and those with a history of noncompliance are not good candidates for allergy immunotherapy.

**L.** Immunotherapy with whole-body extracts of biting insects or other arthropod is covered only for fire ant extracts.

**M.** Evaluation and management codes are separately reimbursable on the same day as allergen immunotherapy only when a significant, separately identifiable service is performed.

### 3. MINNESOTA DEPARTMENT OF HUMAN SERVICES (DHS):

**MHCP Provider Manual: Physician and Professional Services: Allergy Immunotherapy – Allergy Testing**

**Covered Services:**

- Professional services to prepare raw antigen to a refined state allergenic extract
- Professional services to administer the allergenic extract
- Providing the injectables allergenic extract
- Physician ordered allergen immunotherapy and services performed by the physician or qualified personnel under the direction of a physician
- Professional services to monitor recipient's injection sites and observe for anaphylactic reaction
- Allergy testing is covered when clinically significant symptoms exist and conservative therapy has failed
- Evaluation and Management services are eligible for separate payment on the same day as allergen immunotherapy only when a significant, separately identifiable service is performed

**Non-Covered/Investigational Services:**

The following **allergy testing procedures** are considered investigative, and therefore are not covered:

- Cytotoxic leukocyte testing (Brian's test)
- Leukocyte histamine release testing
- Provocation-neutralization testing (sublingual, subcutaneous, intradermal, or intracutaneous)
- Rebuck skin window test
- Passive transfer or P-K Test (Prausnitz-Kustner)
- Candidiasis hypersensitivity syndrome testing
- IgG level testing General volatile organic screening test (volatile aliphatic panel)
- ELISA/ACT immunotherapy (Serammune Physician Lab, Reston VA)
- Antigen Leukocyte Cellular Antibody Test (ALCAT)

The following **allergy treatments** are considered investigative and therefore not covered:

- Provocation-neutralization treatment (sublingual, subcutaneous, intradermal, or intracutaneous)
- Oral and sublingual immunotherapy (includes oral drops, solutions, oral capsules, and tablets)
- Rinkel immunotherapy
- Autologous urine immunizations
- Clinical ecology urine immunizations
- Candidiasis hypersensitivity syndrome treatment and related services
- IV vitamin C therapy
- Enzyme potentiated desensitization
- Rhinophototherapy
- Poison Ivy/Poison Oak extracts for immunotherapy
- T.O.E. (Trichophyton, Oidiomycetes, and Epidermophyton immunotherapy for chronic otitis media)

**CLINICAL EVIDENCE:**

**Summary**

In vivo allergy testing (e.g., skin test, organ challenge/provocation test) is the most commonly used and preferred method of allergy testing. In vivo allergy tests are designed to confirm hypersensitivity and identify the antigen(s) responsible for the allergic reaction. Although a majority of the studies reported positive outcomes with in vivo allergy testing, lack of blinding procedures for assessors, and lack of randomized studies decreased the quality of evidence. In addition, due to the financial relationship between the authors and the manufacturers of in vivo testing devices and allergen extracts, investigator-bias cannot be excluded.

In vitro allergy testing has been demonstrated to be an effective alternative for patients with suspected IgE-mediated food or inhalant allergies who cannot be tested using in vivo methods, or as an alternative to
skin testing for the evaluation of cross-reactivity between insect venoms. In addition, specific IgE immunoassays may be used as adjunctive testing for disease activity of allergic bronchopulmonary aspergillosis and certain parasitic diseases.

Sublingual Immunotherapy: Despite additional placebo-controlled studies evaluating sublingual immunotherapy (SLIT), questions remain about the optimal dosing, duration of treatment, and the use of multiple allergens. Moreover, there are few studies comparing sublingual immunotherapy to injection allergen-specific immunotherapy (SCIT). The limited comparative evidence suggests that the two methods of administration have similar efficacy, but firm conclusions cannot be drawn due to variability in study design and limited statistical power. The sample sizes in the comparative studies are also too small to draw conclusions about the relative safety of SLIT and SCIT. Because of the above limitations in the evidence and the absence of any FDA-approved allergy extracts for sublingual immunotherapy, this treatment is considered investigational.

### APPLICABLE CODES:

The Current Procedural Terminology (CPT®) codes and HCPCS codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other medical policies and coverage determination guidelines may apply.

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<td>Personal history of allergy to eggs</td>
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<td>V15.06</td>
<td>Allergy to insects and arachnids</td>
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### CPT® Code

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<td>Allergen specific IgE; quantitative or semiquantitative, each allergen</td>
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<td>Intracutaneous (intradermal) tests with allergenic extracts, immediate type reaction, including test interpretation and report, specify number of tests</td>
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<td>Professional services for allergen immunotherapy in prescribing physicians office or institution, including provision of allergenic extract; two stinging insect venoms</td>
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<td>95199</td>
<td>Unlisted allergy/clinical immunologic service or procedure</td>
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</table>
REFERENCES:


38. Cox L et al., eds.; Joint Task Force on Practice Parameters; American Academy of Allergy, Asthma and Immunology (AAAAI); American College of Allergy, Asthma and Immunology (AAAAI); Joint Council of Allergy, Asthma and Immunology (JCAAI). Allergen immunotherapy: a practice parameter second update [correction appears in J Allergy Clin Immunol. 2008;122(4):842]. J Allergy Clin Immunol. 2007;120(3 Suppl):S25-S85.


81. Nepper-Christensen S, Backer V, DuBuske L, Nolte H. In vitro diagnostic evaluation of patients with inhalant


91. Saini S. Chronic urticaria: Diagnosis, theories of pathogenesis, and natural history. September 2010. UpToDate: Waltham, MA.


**POLICY HISTORY:**

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<tr>
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<td>New Policy 2013M0036A reviewed by Interim Medical Policy Committee.</td>
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<tr>
<td>08/22/2013</td>
<td>Reviewed and approved by the Quality Improvement Advisory and Credentialing Council (QIACC).</td>
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<tr>
<td>11/15/2013</td>
<td>Published to UCare.org</td>
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<tr>
<td>07/01/2015</td>
<td>Policy Update:</td>
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<td>• Added applicable ICD-10 codes to the Coding Section. The list of codes may not be all-inclusive and does not denote coverage.</td>
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<td>• Policy identification number updated to 2015M0036A.</td>
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