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1.0 Description of the Procedure, Product, or Service

Management of the allergic recipient may include identifying the offending agent by means of allergy testing. The provider must take a thorough history before allergy tests are ordered. The medical record must document the medical necessity, based on the recipient's history, for each allergy test ordered.

Allergy testing can be broadly grouped into in vivo and in vitro methodologies:

- a. In vivo testing - includes allergy skin testing such as the scratch, puncture or prick test (epicutaneous), intradermal test (intracutaneous) and patch test.
- b. In vitro testing - includes various techniques to test the blood for the presence of specific IgE antibodies to a particular antigen.

Once the agent is identified, treatment is provided by avoidance, medication or immunotherapy (allergy shots). Allergic or hypersensitivity disorders may be manifested by generalized systemic reactions as well as by localized reactions in any organ system of the body. The reactions may be acute, subacute, or chronic, immediate or delayed, and may be caused by numerous offending agents: pollen, molds, dust mites, animal dander, stinging insect venoms, foods, drugs, etc..

2.0 Eligible Recipients

2.1 General Provisions

To be eligible, NCHC recipients must be enrolled on the date of service.

3.0 When the Procedure, Product, or Service Is Covered

3.1 General Criteria

NCHC covers procedures, products, and services related to this policy when they are medically necessary and

- a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the recipient's needs;
- b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available; **AND**
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

3.2 Specific Criteria

The following allergy testing modalities are considered eligible for coverage when medically necessary, and ordered by a physician:

- a. Direct Skin Testing (for immediate hypersensitivity)

1. Percutaneous or epicutaneous (scratch, prick, or puncture) - The number of tests required may vary widely depending on the recipient's age and the degree of hypersensitivity.
 2. Intradermal testing is considered to be a more sensitive, but less specific, testing method than percutaneous testing for the detection of IgE antibodies. The number of intradermal tests may also vary from recipient to recipient.
 3. The evaluation of inhalant allergy may require up to 70 prick/puncture tests followed by up to 40 intradermal tests, which are ordinarily performed when prick/puncture tests are negative. Under special circumstances and in certain geographic areas, a greater number of prick/puncture and/or intradermal tests may be appropriate. However, in many parts of the country and probably in most cases, fewer tests are required.
- b. Patch Testing (also called application testing) is indicated for evaluation of possible allergic contact dermatitis. A limited series of patch tests may be an appropriate initial step. Standard panels of allergens for patch testing are available from various commercial sources, the most commonly used being the T.R.U.E. TEST® by Allerderm. Each T.R.U.E. TEST® patch test unit includes 28 common allergens and a negative control. In addition to the standard series of 29 patch tests, six (6) additional allergens targeted at the recipient's most likely exposures may be performed initially. More comprehensive patch testing (greater than 35 patch tests) may be considered medically necessary when **BOTH** of the following criteria are met:
1. The recipient has persistent allergic contact dermatitis (ACD) after being previously evaluated and treated [including six (6) weeks of avoidance of any allergens that were positive on initial patch testing, and use of topical steroid products if appropriate]; **AND**
 2. The dermatitis interferes with the recipient's normal activities of daily living, such as occupational or work activities (use of hands), sleep patterns (due to itching), bathing or social interactions.
- c. Photo patch test: This test reflects contact photosensitization. A photosensitivity (sensitivity to sunlight) reaction may be suspected when a rash appears only in areas exposed to sunlight. The reaction may be caused by various drugs, substances applied to the skin (drugs or cosmetics), chemicals etc. Photo-patch testing 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 then examined as usual. A positive photo-patch test is recorded when an allergic reaction appears only on the light-exposed site.
- d. Specific IgE In Vitro Testing: Radioallergosorbent Test (RAST), Multiple Radioallergosorbent Tests (MAST), Fluorescent Allergosorbent Test (FAST), and Enzyme-linked Immunosorbent Assay (ELISA). These tests detect specific IgE antibodies in the recipients blood serum.
1. Specific IgE in vitro tests for inhalant allergens (pollens, molds, dust, mites, animal danders) and foods are considered eligible for coverage when medically necessary because the following criteria are met:

- (a) Direct skin testing is impossible due to an extensive dermatitis or marked dermagraphism;
 - (b) Direct skin testing is impossible such as in young children less than four years of age; or
 - (c) Direct skin testing results are not consistent with a history of anaphylactic or other severe reaction to an allergen and further treatment decisions would be impacted by confirmation of sensitivity;
 - (d) Inability to discontinue medications (e.g., antihistamines) that impair skin test sensitivity.
2. Specific IgE in vitro tests for insect sting and other allergens (for example, drugs) are considered eligible for coverage under the following circumstances:
- (a) Direct skin testing is impossible due to an extensive dermatitis or marked dermagraphism;
 - (b) Direct skin testing is impossible such as in young children less than four (4) years of age; or
 - (c) Direct skin testing results are not consistent with a history of anaphylactic or other severe reaction to an allergen and further treatment decisions would be impacted by confirmation of sensitivity; iv. Inability to discontinue medication (e.g., antihistamines) that impair skin test sensitivity.

Note: Specific IgE in vitro testing is considered medically necessary only after physician determination that one of the aforementioned conditions precludes the use of direct skin testing. Specific IgE in vitro testing should be judicious and include testing only for those allergens that could be reasonably suspected regardless of test kit packaging. Initial diagnostic screen is limited to 36 allergen specific antibodies. Additional testing beyond this number will require a review for medical necessity.

- e. Total Serum IgE Concentration - This testing modality is not indicated in all allergic recipients, but should be reserved for those recipients suspected of having allergic bronchopulmonary aspergillosis, immune deficiency disease (for example, Wiskott-Aldrich syndrome, hyper-IgE staphylococcal abscess syndrome), IgE myeloma or pemphigoid or for consideration of Xolair administration in recipients with moderate to severe asthma.
- f. Bronchial Challenge Testing - This procedure is performed with 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 difficult asthmatic recipient in whom routine skin testing is not sufficient to isolate the factors responsible for the asthma.
- g. Double-blind Food Challenge Testing - The recipient is required to eat the food to which sensitivity is suspected. The food is randomized by a noninterested party (i.e., dietitian) so that neither the recipient nor physician are aware of the specific food (blinded). The food may be lyophilized (freeze dried) and blended in liquid or placed in a capsule.

- h. Serial Dilution Endpoint Titration (SDET) - Also known as skin endpoint titration (SET), intradermal dilutional testing (IDT), serial endpoint titration, is a form of intradermal skin testing that uses increasing doses of antigen to determine the concentration at which the reaction changes from negative to positive (the "endpoint"). The test has been used to diagnosing allergic disorders, and is a potential alternative to other diagnostic tests such as skin prick testing or in vitro testing for this purpose. Also SET has been used to guide the initiation of immunotherapy, by using the endpoint dilution as the starting antigen dose.

4.0 When the Procedure, Product, or Service Is Not Covered

4.1 General Criteria

Procedures, products, and services related to this policy are not covered when

- a. the recipient does not meet the eligibility requirements listed in **Section 2.0**;
- b. the recipient does not meet the medical necessity criteria listed in **Section 3.0**;
- c. the procedure, product, or service unnecessarily duplicates another provider's procedure, product, or service; or
- d. the procedure, product, or service is experimental or investigational.

4.2 Specific Criteria

Allergy testing is not covered when:

- a. The medical criteria and guidelines in **Section 3.0** are not met.
- b. When it is considered investigational. The following allergy tests are considered investigational.

Test	Diagnosis	Reasons it is Considered Investigational
Nasal Challenge Test (Also called nasal mucous membrane test; nasal challenge /provocation test)	This test has been proposed as a tool in the diagnosis of allergic rhinitis. It is performed to duplicate the patient's main symptoms or signs by controlled exposure to a suspected antigen and is delivered by direct application to the nasal mucous membranes. Evaluation of the patient's response to the allergen is recorded.	This test is used in studies of allergic rhinitis, but its utility in clinical practice has not been established. The role of nasal challenge testing in the diagnosis and management of allergic diseases has not been established.
Leukocyte Histamine Release Test (LHRT)	Measures the amount of histamine released from the white blood cells in response to exposure to an allergen.	The published literature is not sufficient to permit conclusions on the diagnostic accuracy of LHRT.

Test	Diagnosis	Reasons it is Considered Investigational
Rebuck Skin Window Test	A test of the inflammatory process in which the skin is abraded and a cover slip is applied to the abraded area. The cover slips are removed and replaced at intervals and examined for the presence of cells involved in the immune response.	This test is not useful in documenting allergies since other immunodeficiencies can be found in patients with allergic conditions.
Passive Transfer of P-X (Prausnitz-Kustner Test)	Performed by injecting serum intradermally from a suspect allergic patient into a non-allergic patient and later challenging the injection site with antigens.	Danger of transferring infections. Considered obsolete. (It has been replaced by RAST.)
Cytotoxic Food Testing (Leukocytotoxic Test)	This test involves the response of specially collected white blood cells to the presence of food extracts to which the patient is allergic.	There is no proof that this is effective for foods or pollens. AAAAI*, NCHCT**
Provocation Neutralization Testing (sometimes referred to as the Rinkel Test)	This is a procedure that evolved from serial endpoint titration and has been proposed as a test for allergies to foods, inhalants and environmental chemicals. Patients are exposed to test doses of substances intradermally, subcutaneously or sublingually, with the goal of either producing or preventing symptoms.	It is an unproven test. AAAAI*, NCHCT**
Serum IgG levels, as part of allergy evaluation	This is a blood test for certain antibodies	Considered to be investigational due to incomplete and conflicting data. AAAAI*
Conjunctival Challenge Testing (ophthalmic mucous membrane test)	Allergenic extract is placed into the conjunctival sac of the eye, followed by observation for redness, itchiness, tearing of the eye, and other similar symptoms.	This test is qualitative, and not objectively interpreted.
Mediator Release Test (MRT)	The MRT has primarily been used to detect intolerance to foods and additives in patients with irritable bowel syndrome (IBS). It has also been promoted for use in patients with, but not limited to: chronic fatigue syndrome, migraine headaches, rheumatologic disorders, and dermatologic conditions. The results of the MRT have been used to design a patient-specific diet.	There are no studies of MRT reported in peer-reviewed published medical literature that demonstrate improvements in clinical outcomes by incorporating the MRT and associated dietary modifications into the clinical management of patients with these conditions.

*AAAAI = American Academy of Allergy, Asthma, and Immunology

**NCHCT = National Center for Health Care Technology

5.0 Requirements for and Limitations on Coverage

5.1 Prior Approval

Prior approval is not required for allergy testing.

5.2 Other

- a. Requirements of intradermal testing for delayed hypersensitivity of the tuberculin type should not usually exceed six (6) to eight (8) tests.
- b. The evaluation of inhalant allergy may require up to 70 prick/puncture tests followed by up to 40 intradermal tests, which are ordinarily performed when prick/puncture and/or intradermal tests are negative.
- c. Medical records may be requested for review in order to determine medical necessity testing that exceeds the policy limitations.
 1. Medical records will be requested for review of claims for greater than 35 patch tests.
 2. Specific IgE in vitro initial diagnostic screen is limited to 36 allergen specific antibodies. Additional testing beyond this number will require review for medical necessity.

6.0 Providers Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for procedures, products, and services related to this policy, providers shall

- a. meet NCHC qualifications for participation;
- b. be currently enrolled with NCHC; **AND**
- c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

7.0 Additional Requirements

7.1 Compliance

Providers must comply with all applicable federal, state, and local laws and regulations, including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements.

8.0 Policy Implementation/Revision Information

Original Effective Date: July 1, 2010

Revision Information:

Date	Section Revised	Change
July 1, 2010		Policy Conversion: Implementation of Session Law 2009-451, Section 10.32 "NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY."

Attachment A: Claims-Related Information

Reimbursement requires compliance with all NCHC guidelines.

A. Claim Type

Professional (CMS-1500/837P transaction)

Institutional (UB-04/837I transaction)

B. Diagnosis Codes

Providers must bill the ICD-9-CM diagnosis codes(s) to the highest level of specificity that supports medical necessity.

C. Procedure Code(s)

CPT Codes				
83516	83518	83519	83520	86003
86005	95004	95010	95015	95024
95027	95028	95044	95052	95056
95065	95070	95071	95075	

D. Modifiers

Providers are required to follow applicable modifier guidelines.

E. Billing Units

The appropriate procedure code(s) used determines the billing unit(s).

F. Place of Service

Outpatient Hospital and Office

G. Co-payments

Co-payment(s) may apply to covered prescription drugs and services.

H. Reimbursement

Providers must bill their usual and customary charges.