

** IMMUNOTHERAPY AND TESTING **

Protocol: MSC032  
Effective Date: December 1, 2018

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** INSTRUCTIONS FOR USE **

This protocol provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee's document (e.g., Certificate of Coverage (COC) or Evidence of Coverage (EOC)) may differ greatly. In the event of a conflict, the enrollee's specific benefit document supersedes this protocol. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this Protocol. Other Protocols, Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Protocols, Policies and Guidelines as necessary. This protocol is provided for informational purposes. It does not constitute medical advice. This policy does not govern Medicare Group Retiree members.

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** COMMERCIAL & MEDICAID COVERAGE RATIONALE **

** MCG Care Guidelines 22nd Edition: Percutaneous and Intracutaneous Allergy Testing (A-0148) **

** Clinical Indications for Procedure **

Percutaneous or intracutaneous (intradermal) skin testing may be indicated for ALL of the following:

- High clinical suspicion of appropriate condition, as indicated by 1 or more of the following:
  - Allergic bronchopulmonary aspergillosis, as indicated by ALL of the following:
    - Asthma or cystic fibrosis with unexplained clinical deterioration
    - Laboratory or radiology test results suggestive of diagnosis (e.g., total IgE greater than 1000 International Units per milliliter (IU/mL) (1000 kIU/L), central bronchiectasis, pulmonary infiltrates
  - Allergic rhinitis or conjunctivitis and ALL of the following:
    - Clinically complex allergic rhinitis, as indicated by 1 or more of the following:
      - Asthma exacerbations associated with allergic rhinitis

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Immunotherapy and Testing
▪ History of 2 or more seasons of allergy symptoms
▪ Perennial allergy symptoms

▪ Inadequate response to standard medical management interventions, including ALL of the following:
  ▪ Avoidance of exposure to allergen triggers
  ▪ Nasal antihistamine, nasal cromolyn, or nasal ipratropium
  ▪ Nasal corticosteroids
  ▪ Oral antihistamines and decongestants
  ▪ Use of HEPA filter for dust mites, mold or animal dander allergies, or use of integrated pest management for cockroach trigger

▪ Strong correlation between symptoms and suspected allergic triggers to 1 or more of the following:
  ▪ Animal allergens
  ▪ Cockroaches
  ▪ Dust mites
  ▪ Grasses
  ▪ Molds
  ▪ Pollens
  ▪ Trees

  ▪ Asthma and all of the following:
  ▪ Inadequate response to standard medical management interventions, including ALL of the following:
    ▪ Avoidance of exposure to allergen triggers and irritants (eg, tobacco smoke)
    ▪ Controller medication (eg, inhaled corticosteroids, leukotrienes, long-acting beta-agonist with corticosteroid, tiotropium)
    ▪ Rescue medication (eg, inhaled bronchodilators)
    ▪ Use of HEPA filter for dust mites, mold, or animal dander allergies, or use of integrated pest management for cockroach trigger
  ▪ Strong correlation between symptoms and suspected allergic triggers to 1 or more of the following:
    ▪ Animal allergens
    ▪ Cockroaches
    ▪ Dust mites
    ▪ Grasses
    ▪ Molds
    ▪ Pollens
    ▪ Trees

  ▪ Beta-lactam antibiotic (eg, penicillin, amoxicillin, cephalosporin) hypersensitivity and 1 or more of the following:
    ▪ Anaphylaxis during general anesthesia, when penicillin administered during procedure
    ▪ Patient history of immediate or non-immediate reaction to a beta-lactam antibiotic, and 1 or more of the following:
      ▪ Patient is likely to need beta-lactam antibiotics frequently in the future (eg, immune deficiency, cystic fibrosis, bronchiectasis).
      ▪ Treatment with a beta-lactam antibiotic cannot be avoided.

  ▪ Food allergy or hypersensitivity and 1 or more of the following:
• IgE-mediated food allergy, suspected, and ALL of the following:
  ▪ Strong correlation between food exposure and signs or symptoms consistent with IgE-mediated food allergy, as indicated by 1 or more of the following:
    - Abdominal pain
    - Acute wheezing
    - Anaphylaxis
    - Angioedema
    - Atopic dermatitis (eczema)
    - Diarrhea
    - Eosinophilic esophagitis
    - Oral pruritus
    - Rhinoconjunctivitis
    - Syncope
    - Urticaria
  ▪ Patient is not pregnant
• Oral food challenge planned, and sensitivity results from percutaneous allergy testing are required to plan appropriate and safe testing.
  o Stinging insect hypersensitivity, and strong correlation between insect sting and symptoms consistent with IgE-mediated allergy, as indicated by 1 or more of the following:
    ▪ Age 16 years or older, and systemic reaction limited to cutaneous signs and symptoms (eg, urticaria, pruritus, flush)
    ▪ Patient with systemic reaction to sting that included respiratory symptoms, cardiovascular symptoms, or both
• Patient not receiving medication or treatment known to inhibit allergy skin testing (eg, imipramine, oral antihistamine, phenothiazine, topical corticosteroid, UV light treatment).

Alternatives to Procedures
Alternatives include:
• For allergic rhinitis and conjunctivitis:
  o Blood testing for allergens for patients unable to discontinue treatment. Refer to Quantitative Allergen-Specific IgE Antibody Assays further information.
  o Medical management:
    ▪ Avoidance of exposure to allergen triggers
    ▪ Nasal corticosteroids
    ▪ Nasal cromolyn
    ▪ Oral antihistamines and decongestants
    ▪ Use of HEPA filter for mold or animal dander allergies
• For asthma:
  o Blood testing for allergens for patients unable to discontinue treatment. Refer to Quantitative Allergen-Specific IgE Antibody AssaysAC for further information.
  o Medical management:
    ▪ Avoidance of exposure to allergen triggers
    ▪ Cromolyn
    ▪ Inhaled beta-adrenergic agonist
    ▪ Inhaled or oral corticosteroids
    ▪ Leukotriene receptor antagonists
- Omalizumab
- Theophylline
- Use of HEPA filter for mold or animal dander allergies

  - For food allergy:
    - Elimination diets
    - Oral food challenge
  - For stinging insect allergy: blood testing for allergens. Refer to Quantitative Allergen-Specific IgE Antibody Assays

**Criteria**

For allergic bronchopulmonary aspergillosis, evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. A national asthma guideline notes that allergic bronchopulmonary aspergillosis may complicate asthma and cystic fibrosis, and skin testing or quantitative Aspergillus-specific IgE should be considered when asthma is severe and refractory, is associated with infiltrates on chest x-ray, or requires ongoing oral corticosteroids. A specialty society guideline recommends that adults with non-cystic fibrosis bronchiectasis should be evaluated for allergic bronchopulmonary aspergillosis. A prospective cohort study of 372 patients with asthma and suspected allergic bronchopulmonary aspergillosis found that skin testing had diagnostic sensitivity of 95% and specificity of 80%, while Aspergillus-specific IgE levels had sensitivity of 100% and specificity of 69%.

For allergic rhinitis or conjunctivitis, evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. A review article notes that a diagnosis of allergic rhinitis may be made clinically; however, diagnostic testing for allergic rhinitis may be helpful after lack of response to allergen avoidance measures and pharmacologic treatments. A review article reports that skin tests are considered appropriate for patients with a history suggesting allergic rhinitis. Skin prick tests have high specificity and sensitivity for inhalant allergens; however, intracutaneous skin tests are not useful for inhalant allergens. A specialty society guideline recommends skin testing for allergic rhinitis when empiric treatment is unsuccessful, when the diagnosis is unclear, or when identification of a specific antigen will change treatment. A specialty society guideline on testing for allergies in children recommends testing for seasonal allergic rhinitis and conjunctivitis allergens if treatment resistance occurs; however, testing is recommended for all patients suspected of having perennial rhinitis or conjunctivitis in order to identify the causal allergens.

For asthma, evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. A national practice guideline on asthma recommends assessment of the contribution from indoor allergens for patients with persistent asthma by performance of skin testing; medical history can identify seasonal allergen sensitivity, with diagnostic testing reserved for select cases in which the results may help with asthma education.

For beta-lactam antibiotic hypersensitivity, evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. Skin testing is highly accurate for the diagnosis of penicillin allergy, although skin reactivity may decrease over time after a reaction. When results of skin testing are negative, penicillin
can be administered with an approximate 6% risk of immediate reaction, similar to the incidence in the general population. Penicillin has a 3% cross-reactivity rate with cephalosporins and less than 2% cross-reactivity rate with aminopenicillins (eg, amoxicillin, ampicillin).

For food allergy or hypersensitivity, evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. Intracutaneous (intradermal) skin tests for food allergies are not recommended because of the risk of systemic reactions, including anaphylaxis, and because they are overly sensitive (increasing the rate of false-positive results). A systematic review found that while skin prick (percutaneous) testing, food challenges, and serum food-specific IgE all have a role in the diagnosis of common food allergies, no one test can be recommended over the others. Some experts consider oral food challenges, especially double-blind placebo-controlled food challenges, to be the gold standard for the diagnosis of food allergies, but they are time-consuming, expensive, and carry the risk of severe anaphylactic reactions.) A positive skin prick test has a positive predictive value of food allergy of only 50% or less, but a negative skin test virtually rules out an IgE-mediated mechanism, with a negative predictive value greater than or equal to 90%. A study of cow's milk protein allergy in children found that a positive response to skin tests containing extracts of 3 main milk proteins, as opposed to wheal diameter, has greater specificity and may be a useful way of avoiding oral food challenges. In another study of skin prick testing for cow's milk protein allergy in children, 100% of patients did not react to a food challenge if the wheal diameter was less than 7 mm, and 90% did not react if the wheal diameter was less than 12 mm. In a study of peanut allergy in children, skin tests were predictive of oral food challenges among those sensitized if they had low peanut-specific IgE (less than 10 kUA/L), had not reacted to peanuts within the last 2 years, and had never required epinephrine for anaphylaxis to peanuts. A systematic review of several food allergens found that the predictive value of wheal diameter for the avoidance of oral food challenge varied between studies and that wheal diameter thresholds also varied between infants and older children. Structural problems with these studies included variation in participant age, test allergens, and food challenge protocol. A study of 5276 infants reported that skin prick testing for peanut, egg, baked egg, and sesame had sensitivity of 54%, 46%, 0%, and 48%, respectively, and specificity of 98%, 93%, 99%, and 99%, respectively, as compared with oral food challenge. A systematic review and meta-analysis of 24 studies (with a total of 2831 subjects) that evaluated the diagnostic performance of skin prick and allergen-specific IgE testing in suspected food allergy to cow's milk, egg, soy, peanut or tree nut, and/or wheat as compared with food challenge concluded that both test methods tended to be more sensitive than specific, and performance characteristics varied with the food tested. The authors noted that a lack of high-quality studies limited interpretation of the evidence base.

For stinging insect hypersensitivity, evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. Skin prick testing can be used as a primary approach to stinging insect (Hymenoptera) venom. A case report and literature review notes that patients who experience systemic reaction after Hymenoptera sting are appropriate for skin testing; a positive test result indicates candidacy for immunotherapy. False-negative test results may occur in the first few weeks after the reaction, in which case retesting in 6 weeks would be appropriate.
Inconclusive or Non-Supportive Evidence
For inhaled allergens, evidence demonstrates a lack of net benefit; additional research is recommended. A specialty society guideline states that intracutaneous (intradermal) skin testing is not useful for the diagnosis of allergy due to inhaled allergens.

** End of MCG A-0148 Guideline**

Note: Testing and immunotherapy must be provided by a board certified allergist and immunologist.

MCG Care Guidelines 22nd Edition: Immunotherapy, Subcutaneous (A-0429)

Clinical Indications for Procedure
Subcutaneous immunotherapy may be indicated for 1 or more of the following:

- Allergic rhinitis or conjunctivitis and ALL of the following:
  - Age 5 years or older:
  - Initial or subsequent course of treatment, as indicated by 1 or more of the following:
    - Initial course of treatment, as indicated by ALL of the following:
      - Clinically complex allergic rhinitis, as indicated by 1 or more of the following:
        - Asthma exacerbations associated with allergic rhinitis
        - History of 2 or more seasons of allergy symptoms
        - Perennial allergy symptoms
      - Inadequate response to standard medical management interventions, including ALL of the following:
        - Avoidance of exposure to allergen triggers
        - Nasal antihistamine, nasal cromolyn, or nasal ipratropium
        - Nasal corticosteroids
        - Oral antihistamines and decongestants
        - Use of HEPA filter for dust mites, mold, or animal dander allergies, or use of integrated pest management for cockroach trigger
      - Patient not pregnant at time of initiation of immunotherapy
    - Positive skin test or quantitative allergen-specific IgE antibody assay to agents suspected as allergic triggers
    - Strong correlation between symptoms and suspected allergic triggers to 1 or more of the following:
      - Animal allergens
      - Cockroaches
      - Dust mites
      - Grasses
      - Mold
      - Pollens
      - Trees
    - Subsequent course of treatment indicated if there has been favorable response to prior administration, as indicated by 1 or more of the following:
      - Decrease in amount of medication required to control symptoms
      - Improvement in clinical symptom scores
Immunotherapy and Testing

- No concomitant administration of beta-blockers
- No current significant cardiovascular disease (e.g., recent myocardial infarction, unstable angina, significant arrhythmia) or compromised pulmonary function (e.g., asthma exacerbation or poorly controlled chronic obstructive pulmonary disease)

- Asthma and all of the following:
  - Age 5 years or older
  - Initial or subsequent course of treatment, as indicated by 1 or more of the following:
    - Initial course of treatment, as indicated by all of the following:
      - FEV1 70% or more of predicted
      - Inadequate response to standard medical management interventions, including all of the following:
        - Avoidance of exposure to allergen triggers and irritants (e.g., tobacco smoke)
        - Controller medication (e.g., inhaled corticosteroids, leukotrienes, long-acting beta-agonist with corticosteroid, tiotropium)
        - Rescue medication (e.g., inhaled bronchodilators)
        - Use of HEPA filter for dust mites, mold, or animal dander allergies, or use of integrated pest management for cockroach trigger
      - Patient not pregnant at time of initiation of immunotherapy
      - Positive skin test or quantitative allergen-specific IgE antibody assay to agents suspected as allergic trigger
      - Strong correlation between symptoms and suspected allergic triggers to 1 or more of the following:
        - Animal allergens
        - Cockroaches
        - Dust mites
        - Grasses
        - Pollens
        - Trees
    - Subsequent course of treatment is indicated if there has been favorable response to prior administration, as indicated by 1 or more of the following:
      - Decrease in amount of medication required to control symptoms and maintain peak flow rates or other measures of pulmonary function
      - Improvement in clinical symptom scores
- No concomitant administration of beta-blockers
- No current significant cardiovascular disease (e.g., recent myocardial infarction, unstable angina, significant arrhythmia) or compromised pulmonary function (e.g., asthma exacerbation or poorly controlled chronic obstructive pulmonary disease)

- Stinging insect hypersensitivity and all of the following:
  - Age 5 years or older
  - Initial or subsequent course of treatment, as indicated by 1 or more of the following:
    - Initial course of treatment, as indicated by all of the following:
      - Appropriate diagnostic test results, as indicated by 1 or more of the following:
        - Positive skin test
- Positive venom-specific IgE antibody assay
  ▫ Patient not pregnant at time of initiation of immunotherapy
  ▫ Systemic reaction to sting, as indicated by 1 or more of the following:
  - Patient older than 16 years and systemic reaction limited to cutaneous signs and symptoms (e.g., urticaria, pruritus, flush)
  - Patient with systemic reaction to sting that included respiratory symptoms, cardiovascular symptoms, or both
  ▪ Subsequent course of treatment is indicated if there has been favorable response to prior administration.
  o No concomitant administration of angiotensin-converting enzyme inhibitors
  o No current clinically significant cardiovascular disease (e.g., recent myocardial infarction, unstable angina, significant arrhythmia) or compromised pulmonary function (e.g., asthma exacerbation or poorly controlled chronic obstructive pulmonary disease

Criteria
For allergic rhinitis or conjunctivitis, evidence demonstrates at least moderate certainty of at least moderate net benefit. (RG A1) A systematic review evaluating subcutaneous immunotherapy identified 49 randomized controlled trials addressing rhinitis/rhinoconjunctivitis (with and without concomitant asthma) and found high-grade evidence that immunotherapy reduces rhinitis/rhinoconjunctivitis symptoms and moderate evidence that it decreases rhinitis/rhinoconjunctivitis medication usage.

For asthma, evidence demonstrates at least moderate certainty of at least moderate net benefit. A systematic review of subcutaneous immunotherapy identified 38 randomized controlled trials addressing asthma (with and without concomitant rhinitis/rhinoconjunctivitis) and found high-grade evidence that immunotherapy reduces asthma symptoms and medication use. A review article noted that severe or poorly controlled asthma is considered a contraindication for subcutaneous immunotherapy.

For stinging insect hypersensitivity, evidence demonstrates at least moderate certainty of at least moderate net benefit. Venom immunotherapy is strongly recommended for patients who have had systemic reactions to Hymenoptera stings, especially when associated with respiratory or cardiovascular symptoms, accompanied by positive skin tests or evidence of specific IgE antibodies. A patient 16 years or younger who presents only with systemic cutaneous reactions to Hymenoptera or imported fire ants usually does not require immunotherapy. Some patients who have negative venom skin test results and negative venom-specific IgE test results are reported to have had subsequent systemic reactions to stinging insects. There are insufficient studies on the efficacy of immunotherapy in these patients to make conclusive recommendations. Approximately 5% to 10% of patients with negative venom skin test results with a history of systemic reactions have a positive venom-specific serum IgE test result. Regarding a subsequent course of venom immunotherapy treatment, long-term follow-up studies suggest that a 5-year course might be sufficient for most allergic individuals. However, treatment may be appropriately continued indefinitely in patients with a history of extreme or near-fatal anaphylaxis to a sting, or with honeybee allergy. A systematic review of randomized controlled trials concluded that venom immunotherapy is effective for the prevention of additional allergic reactions due to insect stings, with a small but significant risk of adverse systemic reaction. A retrospective cohort study of 1532 patients who underwent sting challenge to evaluate the effectiveness of venom immunotherapy reported that predictors of treatment failure included allergy to honeybee
venom, use of ACE inhibitor medication during sting challenge, high risk for systemic mastocytosis, and systemic allergic reactions during the buildup or maintenance phase of immunotherapy; chances of failure decreased with longer duration of immunotherapy.

**Inconclusive or Non-Supportive Evidence**

For atopic dermatitis, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. A systematic review and meta-analysis evaluating the efficacy of specific allergen immunotherapy for atopic eczema that identified 6 randomized controlled trials of subcutaneous immunotherapy concluded that immunotherapy could not be recommended for the treatment of atopic eczema due to the low quality of evidence; the authors recommended future large blinded randomized controlled trials to clarify the role of allergen immunotherapy for this disorder. Although some studies indicate that immunotherapy can be effective for atopic dermatitis (eczema) when this condition is associated with aeroallergen sensitivity, the studies involve a small number of patients. A specialty society guideline recommends against the use of subcutaneous immunotherapy to treat atopic dermatitis.

For chronic urticaria or angioedema, evidence demonstrates a lack of net benefit; additional research is recommended. Clinical studies do not support the use of allergen immunotherapy for chronic urticaria or angioedema.

For food allergy or hypersensitivity, evidence demonstrates a lack of net benefit; additional research is recommended. Clinical studies do not support the use of allergen immunotherapy for food hypersensitivity. The primary treatments for food allergy include an avoidance diet as well as education about emergency measures to be taken in case of accidental food allergen ingestion. Subcutaneous immunotherapy is contraindicated for food allergy due to the risk of anaphylaxis.

For latex allergy, evidence demonstrates a lack of net benefit; additional research is recommended. A review article identified only 3 randomized trials (64 patients) studying the use of subcutaneous immunotherapy for latex allergy, of which only one trial demonstrated improvement in symptoms; however, patients in all 3 trials experienced systemic reactions, with an incidence ranging from 47% to 82%. The authors noted that published guidelines do not support the use of subcutaneous immunotherapy for latex allergy.

**End of MCG A-0429 Guideline**

**Note:** Testing and immunotherapy must be provided by a board certified allergist and immunologist.

**BACKGROUND**

Skin testing is used to identify allergens suspected to have triggered an allergic reaction. In the percutaneous (prick-puncture, skin prick) tests, the antigen is applied on the skin and introduced into the epidermis using various devices. In the intracutaneous (intradermal) tests, the antigen is injected into the dermal layer using a hypodermic syringe and needle. Allergic reactions are assessed by the size of the wheal produced. The results are used to guide subcutaneous immunotherapy, as well as the management of food allergies and drug hypersensitivities.
The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Coverage Determination Guidelines may apply.

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<td>95004</td>
<td>Percutaneous tests (scratch, puncture, prick) with allergenic extracts, immediate type reaction, including test interpretation and report, specify number of tests</td>
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<td>95017</td>
<td>Allergy testing, any combination of percutaneous (scratch, puncture, prick) and intracutaneous (intradermal), sequential and incremental, with venoms, immediate type reaction, including test interpretation and report, specify number of tests</td>
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<td>95018</td>
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<td>95027</td>
<td>Intracutaneous (intradermal) tests, sequential and incremental, with allergenic extracts for airborne allergens, immediate type reaction, including test interpretation and report, specify number of tests</td>
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<td>95028</td>
<td>Intracutaneous (intradermal) tests with allergenic extracts, delayed type reaction, including reading, specify number of tests</td>
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REFERENCES


Scadding GK. Optimal management of allergic rhinitis. Archives of Disease in Childhood 2015;100(6):576-582. DOI: 10.1136/archdischild-2014-306300.


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The foregoing Health Plan of Nevada/Sierra Health & Life Healthcare Operations protocol has been adopted from an existing UnitedHealthcare coverage determination guideline that was researched, developed and approved by the UnitedHealthcare Coverage Determination Committee.