Coverage Summary

Allergy Testing and Allergy Immunotherapy

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<tbody>
<tr>
<td>Approved by:</td>
<td>UnitedHealthcare Medicare Benefit Interpretation Committee</td>
<td>Last Review Date: 03/21/2017</td>
</tr>
</tbody>
</table>

Related Medicare Advantage Policy Guidelines:
- Antigens Prepared for Sublingual Administration (NCD 110.9)
- Challenge Ingestion Food Testing (NCD 110.12)
- Cytotoxic Food Tests (NCD 110.13)
- Food Allergy Testing and Treatment (NCD 110.11)
- Intravenous Histamine Therapy (NCD 30.6)

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The benefit information in this Coverage Summary is based on existing national coverage policy, however, Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable.

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I. COVERAGE

Coverage Statement: Allergy testing and allergy immunotherapy (allergy therapy) are covered when Medicare coverage criteria are met.

Guidelines/Notes:
1. Allergy testing that **may be covered** include, but are not limited to:
   a. Complete blood count (CBC) with differential (e.g., eosinophil count, IgE level, smear of nasal secretions)
   b. Chest X-ray, when respiratory symptoms are present
   c. Skin testing
   d. Total gamma globulins
   e. Sputum exam
   f. Paranasal sinus X-ray

*See the Medicare Claims Processing Manual, Chapter 12, §200 - Allergy Testing and Immunotherapy.* (Accessed January 6, 2015)

Local Coverage Determinations (LCDs) exist and compliance with these policies is required.
g. Challenge ingestion food testing; see the NCD for Challenge Ingestion Food Testing (110.12) (Accessed January 9, 2017)

h. Radioallergosorbent Test (RAST) (CPT code 86003)
   - Medicare does not have a National Coverage Determination (NCD) for RAST.
   - Local Coverage Determinations (LCDs) which address IGE in Vitro Tests (e.g., RAST) exist and compliance with these LCDs is required where applicable. For state-specific LCDs, refer to the LCD Availability Grid (Attachment A).
   - For states with no LCDs, refer to the MCG™ Care Guidelines, 21st edition, 2017, Quantitative Allergen-Specific IgE Antibody Assays ACG: A-0149 (AC) for coverage guidelines. (IMPORTANT NOTE: After searching the Medicare Coverage Database, if no state LCD or Local Article is found, then use the above referenced policy.)
   - Committee approval date: March 21, 2017
   - Accessed July 5, 2017

2. Allergen immunotherapy to treat allergies is covered when:
   a. Patient is examined by a physician
   b. The physician who examines the patient, prepares the antigens and develops a plan of care and dosage regimen

   Note: Physician should instruct member on self-administration if member is capable of doing the injections. If a member lives too far from the allergist (rural area) the allergist may prepare the antigens and send the reasonable supply to another physician or qualified healthcare professional for administration.

   - Also see the Medicare Claims Processing Manual, Chapter 12, §200 - Allergy Testing and Immunotherapy. (Accessed January 9, 2017)

3. Reasonable Supply of Antigen

   Payment may be made for a reasonable supply of antigens that have been prepared for a particular patient if: (1) the antigens are prepared by a physician who is a doctor of medicine or osteopathy, and (2) the physician who prepared the antigens has examined the patient and has determined a plan of treatment and a dosage regimen.

   Antigens must be administered in accordance with the plan of treatment and by a doctor of medicine or osteopathy or by a properly instructed person (who could be the patient) under the supervision of the doctor. The associations of allergists that CMS consulted advised that a reasonable supply of antigens is considered to be not more than a 12-month supply of antigens that has been prepared for a particular patient at any one time. The purpose of the reasonable supply limitation is to assure that the antigens retain their potency and effectiveness over the period in which they are to be administered to the patient. (See §§20.2 and 50.2.)

4. The following are examples of tests/services that are not covered but are not limited to:
   a. Sublingual antigen; see the NCD for Antigens for Sublingual Administration (110.9) (Accessed January 9, 2017)
   b. Intravenous histamine administration; see the NCD for Intravenous Histamines (30.6) (Accessed December 17, 2015)
   c. Routine radioallergosorbent test (RAST) (see #1.h above)
   d. Cytotoxicity testing/Bryan’s test; see the NCD for Cytotoxic Food Test (110.13) (Accessed January 9, 2017)
   e. Urine autoinjection
   f. Skin titration/Rinkel method
   g. Provocative and neutralizing testing (subcutaneous) for food allergies; see the NCD for Food Allergy Testing and Treatment (110.11) (Accessed January 9, 2017)
   h. Sublingual provocative test; see the NCD for Food Allergy Testing and Treatment (110.11) (Accessed January 9, 2017)
   i. Serum allergy/histamine release tests

II. DEFINITIONS

III. REFERENCES

See above

IV. REVISION HISTORY

03/21/2017  Re-review with the following update:

01/17/2017  Annual review; no updates.

09/20/2016  Re-review with the following updates:
            • Guideline 1.h [Radioallergosorbent Test (RAST) (CPT code 86003)] -
              o For states with no LCDs replaced current default from the Wisconsin LCD for Allergy Testing and Allergy Immunotherapy (L34597)(retired) with the MCG™ Care Guidelines, 20th edition, 2016, Quantitative Allergen-Specific IgE Antibody Assays ACG: A-0149 (AC).
              o Moved the the following language:


                Local Coverage Determinations (LCDs) exist and compliance with these policies is required where applicable. See LCDs for (1) Allergen

- Guideline 2. Note section – Removed reference to the retired LCDs for Allergy Testing and Allergy.

- Guideline 3 (Reasonable Supply of Antigen) – Added the following verbiage explaining the definition Reasonable Supply of Antigen and appropriate reference link to the Medicare Benefit Policy Manual, Chapter 15, §50.4.4.1 Antigens:

  “Reasonable Supply of Antigen
  Payment may be made for a reasonable supply of antigens that have been prepared for a particular patient if: (1) the antigens are prepared by a physician who is a doctor of medicine or osteopathy, and (2) the physician who prepared the antigens has examined the patient and has determined a plan of treatment and a dosage regimen.

  Antigens must be administered in accordance with the plan of treatment and by a doctor of medicine or osteopathy or by a properly instructed person (who could be the patient) under the supervision of the doctor. The associations of allergists that CMS consulted advised that a reasonable supply of antigens is considered to be not more than a 12-month supply of antigens that has been prepared for a particular patient at any one time. The purpose of the reasonable supply limitation is to assure that the antigens retain their potency and effectiveness over the period in which they are to be administered to the patient. (See §§20.2 and 50.2.)”

- Definitions:
  Reasonable Supply of Antigen - Moved to section Guideline 3.

01/19/2016 Annual review with the following changes: Updated reference link(s) of the applicable LCDs to reflect the new condensed LCD link(s).

03/12/2015 Formatting change only.

02/15/2015 Annual review with following updates:
- Updated Guidelines #1.h Radioallergosorbent Test (RAST):
  - Removed coverage summary guideline; added reference link to the default Wisconsin LCD for Allergy testing and allergy immunotherapy (L30471).
  - Added language to indicate: Coverage guidelines of the available LCD align; there is uniformity. There is no applicable UnitedHealthcare Policy available at this time
- Definitions:
  - Dose- deleted, unable find CMS reference.
  - Reasonable supply of antigen - Updated definition and added applicable CMS reference.

02/18/2014 Annual review; no updates.

02/19/2013 Annual review; no updates.

02/27/2012 Annual review; no updates.
08/23/2011  Updated the LCD Availability Grid (Attachment A); deleted retired LCDs, Trailblazer L17419 and Palmetto L5625, L6955, L67882 and L17429.

02/21/2011  Annual review; Updated Guidelines #1.h - Radioallergosorbent Test (RAST) using the standard Coverage Summary language format and using L30471 guidelines for states with no LCDs.

V. ATTACHMENT(S)

<table>
<thead>
<tr>
<th>LCD ID</th>
<th>LCD Title</th>
<th>Contractor Type</th>
<th>Contractor</th>
<th>States</th>
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<td>L33261</td>
<td>Allergy Testing</td>
<td>A and B MAC</td>
<td>First Coast Service Options, Inc.</td>
<td>FL, PR, VI</td>
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<td>AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX</td>
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<td>CGS Administrators, LLC</td>
<td>KY, OH</td>
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End of Attachment A