Medica Coverage Policy

<table>
<thead>
<tr>
<th>Policy Name:</th>
<th>Cytotoxic Testing for Allergy Diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effective Date:</td>
<td>10/15/2018</td>
</tr>
</tbody>
</table>

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare and Minnesota Health Care Programs, this policy will apply unless those programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica coverage policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

Coverage Policy

Cytotoxic testing for allergy diagnosis is investigative and unproven and therefore **NOT COVERED**. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

**Note:** See also related Medica Coverage Policy: *Antigen Leukocyte Cellular Antibody Test (ALCAT Test®) for Food & Chemical Allergies.*

**Note:** This policy is no longer scheduled for routine review of the scientific literature.

Description

Cytotoxic allergy testing has been in existence since the 1950s. Test procedures are referred to by various names including, but not limited to, the leukocytotoxicity test, the leukocytic food allergy test, the cytotoxic leukocyte test, Bryan’s test, and (in the lay press) the cytotoxic test. The test is based on the leukocytic index principle, which purports that the phenomenon of leukocyte counts dropping during an adverse food reaction is an index of an underlying food allergy.

The test is performed following blood specimen collection. Following collection, the specimen is processed and the leukocytes are separated for testing. The leukocytes are re-suspended in fluid and applied to slides that have been previously coated with specific food allergens. The leukocyte activity following assumed ingestion of the food allergen is then examined microscopically for up to two hours and results are recorded. If leukocyte activity slows and if they lose their pseudopods, swell, and finally disintegrate, the test is interpreted as indicative of a food allergy. In 1985, the FDA reviewed the scientific evidence for cytotoxic testing for allergy diagnosis. The FDA determined cytotoxic tests to be unproven diagnostic procedures. Since that time, use of cytotoxic tests for allergy diagnosis has sharply declined.

**FDA Approval**

No cytotoxic allergy tests have been granted FDA approval.
**Prior Authorization**

Prior authorization is not applicable. Claims for this service are subject to retrospective review and denial of coverage, as investigative services are not eligible for reimbursement.

**Coding Considerations**

Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

**CPT Codes:**

86807 - Serum screening for cytotoxic percent reactive antibody (PRA); standard method

86808 - Serum screening for cytotoxic percent reactive antibody (PRA); without titration

**Original Effective Date:** 12/1/2003

**Re-Review Date(s):**

6/27/2006
6/12/2009
7/18/2012
7/15/2015
7/18/2018
2/10/2020 – administrative update; format