# Medical Coverage Policies

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# Cytotoxic Leukocyte Testing

EFFECTIVE DATE	02/19/2008	LAST UPDATED	02/17/2009

#### **Description:**

The cytotoxic leukocyte test (also known as Bryan's Test, leukocytotoxicity test, leukocytic food allergy test, cytotoxic test, metabolic intolerance test, or sensitivity testing) involves adding a food allergen to a blood sample. The sample is then examined under a microscope at various intervals to verify if the white blood cells (leukocytes) have changed shape or were destroyed. The theory is that any change in the blood cells is a sign of allergy to the particular food.

Cytotoxic leukocyte testing has not been approved by the Food and Drug Administration. There is insufficient evidence in the published, peer-reviewed, scientific literature to support the use of cytotoxic leukocyte testing in the diagnosis and treatment of allergies.

### Medical Criteria:

Cytotoxic leukocyte testing is considered **not medically necessary** as there is insufficient evidence in published, peer-reviewed literature to support its use.

#### **Policy:**

Cytotoxic leukocyte testing is considered **not medically necessary** as there is insufficient evidence in published, peer-reviewed literature to support its use.

#### Coverage:

Benefits may vary between groups/contracts. Please refer to the appropriate member certificate, subscriber agreements, or BlueCHiP for RIte Care contract for applicable "Not Medically Necessary Services."

#### Codes:

There is no specific CPT code regarding cytotoxic leukocyte testing.

#### Also Known As:

Bryan's Test Leukocytotoxicity test Leukocytic food allergy test Cytotoxic test Metabolic intolerance test Sensitivity testing

#### **Related Topics:**

Not applicable.

## Published:

Policy Update, May 2007 Provider Update, April 2008 Provider Update, June 2009

#### **References:**

American Academy of Allergy: Position Statement 8, Controversial Techniques; Journal of Allergy and Clinical Immunology 67:333-338, 1980. Reaffirmed in 1984.

Cytotoxic testing for allergic diseases. FDA Compliance Policy Guide 7124.27, 3/19/85, Updated in 1995. Retrieved 1/11/2008 from:http://www.fda.gov/ora/compliance\_ref/cpg/cpgdev/cpg370-100.html.

Centers for Medicare and Medicaid Services, Medicare Coverage Database. NCD for CYTOTOXIC Food Tests (110.13) Retrieved 1/20/09 from: <u>http://www.cms.hhs.gov/mcd/viewncd.asp?</u> ncd\_id=110.13&ncd\_version=1&basket=ncd%3A110%2E13%3A1%3ACytotoxic+Food+Tests.

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