



MEDICAL COVERAGE GUIDELINES  
SECTION: MEDICINE

ORIGINAL EFFECTIVE DATE: 06/26/13  
LAST REVIEW DATE: 06/24/14  
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## LEUKOCYTE HISTAMINE RELEASE TEST

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Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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### Description:

The leukocyte histamine release test (LHRT) is designed to provide an in vitro correlate to an in vivo allergic response (i.e., skin prick testing). An allergen is added to the peripheral blood leukocytes of the individual being tested and the in vitro release of the allergen is measured. Histamine is normally released as a consequence of the interaction of allergen with cell-bound IgE antibodies. In contrast, the RAST test (radioallergosorbent test) attempts to correlate the presence of allergy to serum levels of antigen-specific IgE as an index of allergic reactivity. Initially, measurements of histamine release required isolation of leukocytes from whole blood followed by the isolation of the released histamine; the laboratory techniques were difficult and time consuming and thus LHRT was primarily used as a research tool only. Recently, a special type of glass fiber has been developed that binds histamine with high affinity and selectivity. These glass fibers can be used as a "solid phase" to absorb the histamine that is released directly into the blood.



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## LEUKOCYTE HISTAMINE RELEASE TEST (cont.)

### Criteria:

- The leukocyte histamine release test (LHRT) as a technique for the diagnosis and management of allergic disorders is considered ***experimental or investigational*** based upon:
  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational setting.

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### Resources:

Resources prior to 06/26/13 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

1. 2.04.42 BCBS Association Medical Policy Reference Manual. Leukocyte Histamine Release Test. Re-issue date 12/03/2009, issue date 06/27/2005.