



MEDICAL COVERAGE GUIDELINES  
SECTION: LABORATORY

ORIGINAL EFFECTIVE DATE: 04/03/18  
LAST REVIEW DATE: 03/05/19  
LAST CRITERIA REVISION DATE:  
ARCHIVE DATE:

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## LYME DISEASE AND TICK-BORNE RELAPSING FEVER (TBRF) IMMUNOBLOT TESTING

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Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

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.

This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

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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## **LYME DISEASE AND TICK-BORNE RELAPSING FEVER (TBRF) IMMUNOBLOT TESTING (cont.)**

### **Description:**

Tick-borne relapsing fever (TBRF) is a bacterial infection characterized by recurring episodes of fever, headache, muscle and joint aches and nausea. It is caused by certain species of *Borrelia* spirochetes.

Lyme disease is a multisystem inflammatory disease caused by the spirochete *Borrelia burgdorferi* and transmitted by the bite of an infected *Ixodes scapularis* (northeastern U.S.) or *Ixodes pacificus* (Pacific coast, most common in Northern California) tick.

Generally, Lyme disease is diagnosed by a two-tiered testing approach involving an enzyme-linked immunosorbent assay (ELISA) followed by a Western blot test. Validated and FDA-approved EIA (enzyme immunoassay) tests include ELISA and ELFA (enzyme-linked fluorescent immunoassay). Lyme disease testing measures an individual's immune response to the bacteria that cause Lyme disease.

The immunoblot is a laboratory test that has been investigated to detect antibodies to antigens of the *Borrelia burgdorferi* bacteria. Immunoblot tests for Lyme disease testing can detect two different classes of antibodies: IgM and IgG.

IGeneX Inc. developed specific testing for Lyme disease and TBRF. Tests include:

- Lyme ImmunoBlot IgG
- Lyme ImmunoBlot IgM
- TBRF ImmunoBlot IgG
- TBRF ImmunoBlot IgM

The Lyme ImmunoBlot IgG, and TBRF ImmunoBlot IgG are qualitative and immunoassay tests. The indicators of exposure are Lyme ImmunoBlot IgM for *Borrelia burgdorferi* and the TBRF ImmunoBlot IgM for TBRF *Borrelia*. These tests have not been FDA approved.

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### **Criteria:**

- ImmunoBlot tests for the evaluation and monitoring of Lyme disease and TBRF are considered ***experimental or investigational*** based upon:
  1. Lack of final approval from the Food and Drug Administration, and
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  3. Insufficient evidence to support improvement of the net health outcome, and
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.



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## **LYME DISEASE AND TICK-BORNE RELAPSING FEVER (TBRF) IMMUNOBLOT TESTING (cont.)**

### **Resources:**

**Literature reviewed 04/03/18. We do not include marketing materials, poster boards and non-published literature in our review.**

1. Centers for Disease Control and Prevention. Understanding Lyme Disease and Tick-borne Relapsing Fever (TBRF) Accessed 03/15/2018.
2. IGeneX. Borrelia Diagnostic Tests. Accessed 03/15/2018.
3. LymeDisease.org. IGeneX introduces new tests for Lyme disease and tick-borne relapsing fever. 10/16/2017.
4. UpToDate.com. Diagnosis of Lyme disease. 05/09/2017.



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## LYME DISEASE AND TICK-BORNE RELAPSING FEVER (TBRF) IMMUNOBLOT TESTING (cont.)

### Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, [crc@azblue.com](mailto:crc@azblue.com). You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>

### Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe'é atah nilinígíí Blue Cross Blue Shield of Arizona haada yit'éego bina'idíílkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yina'idíílkidgo beehaz'ánii hólo díí t'áa hazaadk'ehjí háká a'doowołgo bee haz'ą doo baqah ilinígóó. Ata' halne'ígíí kojí' bich'í' hodíilnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.

