PREVENTION, EVALUATION, AND TREATMENT OF LYME DISEASE (BORRELIA BURGDORFERI)
MED207.104

COVERAGE:

1. Prevention of Lyme Disease (LD) by aid of vaccine.

Administration of the LD vaccine MAY BE ELIGIBLE FOR COVERAGE if the patient is between 15 to 70 years of age and lives or works in a grassy or wooded area where ticks harboring the bacterium Borrelia burgdorferi are present.

NOTE: The FDA has not approved the LD vaccine for use in children less than 15 years of age.


When sufficient documentation (see notes below) to support the medical necessity is provided, Diagnostic Testing for LD MAY BE ELIGIBLE FOR COVERAGE. The Centers for Disease Control (CDC) recommends a two step method for serologic (antibody-antigen testing) diagnosis of LD. They are:

A. Enzyme-Linked Immunosorbent Assay (ELISA) – the initial serologic test for LD. Immunoglobulin IgG and IgM antibodies are tested for the level of response to antigens and exposure.

   • The IgG determinations, a titer of equal to or greater than 800, is considered positive, a titer between 1:200 and 1:400 is considered indeterminate, and a titer equal to or lesser than 100 is considered negative.

   • The IgM determinations, a titer equal to or greater than 200 is considered positive, a titer of 1:100 is considered indeterminate, and a titer equal to or lesser than 100 is considered negative.

   • A positive or indeterminate ELISA test result alone is inadequate serologic evidence of LD.

All of these tests must be confirmed with an immunoblot test;

B. Immunoblot or Western Blot – the confirmation serologic test for LD. In contrast to the ELISA test, the immunoblot investigates the specific antibody response to the different antigens of Borrelia burgdorferi. Typically, some 18 antigens are tested. To confirm the Diagnosis of LD two of the 8 most common IgM antibody bands to spirochetal antigens should be present and five of the 10 most frequent IgG antibody bands should be present. The Center for Disease Control (CDC) has recommended a two step testing (ELISA and Western Blot) process.

Other tests include:
• Polymerase Chain Reaction (PCR) - directly tests for the presence of the Borrelia burgdorferi spirochete and

• T-Cell Proliferative Assay - tests the cellular immune response of those patients who exhibit late manifestations of LD, following possible inadequate antibiotic treatment, and who may have negative serologic tests.

**NOTE:** Documentation must include a History and Physical and/or Consultation that indicates the classical symptoms of LD, such as;

• history of an early skin lesion with or without neurologic, cardiac, and/or joint abnormalities and
• arthritis, primarily of the large joints.

**NOTE:** Documentation must include the Serologic Test results that indicate the confirmation of LD, in addition to the classical symptoms (listed above).

**NOTE:** ALL POSITIVE OR INDETERMINATE ELISA TESTS MUST BE CONFIRMED WITH IMMUNOBLOT.

Diagnostic Testing for Lyme Disease (LD) IS NOT ELIGIBLE FOR COVERAGE when vague or nonspecific symptoms (for example, fatigue, myalgia, arthralgia, headache) are present.

### 3. Treatment for Lyme Disease (LD).

When sufficient documentation to support the medical necessity is provided, Treatment for Lyme Disease (LD) MAY BE ELIGIBLE FOR COVERAGE. The treatment includes use of oral and/or intravenous antibiotics.

**NOTE:** Treatment failures have occurred with all the regimens listed above, and continued or retreatment may be necessary. Prolonged courses (greater than four weeks) of intravenous antibiotic therapy ARE NOT ELIGIBLE FOR COVERAGE as there is no evidence of improved outcomes beyond this time.

Treatment of LD IS NOT ELIGIBLE FOR COVERAGE (as the risks of treatment with antibiotics outweighs the benefits and costs) when the following situations exist:

• vague or nonspecific symptoms (for example, fatigue, myalgia, arthralgia, headache) or symptoms consistent with chronic fatigue syndrome or fibromyalgia are present;

• serologic test results indicate seronegative LD in the absence of cerebrospinal fluid antibodies;

• initial treatment of Lyme arthritis without the presence of coexisting neurologic symptoms;

• vague systemic symptoms without supporting serologic or cerebrospinal fluid studies;
• positive ELISA test, unconfirmed by an immunoblot or Western blot test;

• an isolated positive serologic test in the setting of multiple negative serologic studies;

DESCRIPTION:

Lyme Disease (LD) is a tick transmitted, multisystem inflammatory disorder caused by the spirochetal bacterium, Borrelia burgdorferi. It is a multistage disease beginning with an early skin lesion, known as erythema chronicum migrans (ECM), that may be followed up months to years later by neurologic, cardiac, and/or joint abnormalities.

The most common symptoms accompanying ECM (or preceding it by a few days) suggest a summer flu-like syndrome, including symptoms of malaise and fatigue, chills and fever, headache, stiff neck and muscle, and joint achiness. The symptoms are characteristically intermittent and changing, but malaise and fatigue may linger for weeks. Within weeks or months, neurologic and/or myocardial abnormalities occur. Arthritis occurs in about half of the patients with ECM but may not appear until two years or long after the initial exposure.

Although all stages of LD may respond to antibiotics, early-stage treatment is generally the most successful. The type of antibiotic is based upon the stage of the disease. The stages are:

a. EARLY: demonstrated by a history of a recent tick bite and/or early skin lesion appearance with or without flu-like symptoms. A possible course of treatment would be an oral antibiotic, such as tetracycline, doxycycline, amoxicillin, or erythromycin, for as long as 10 to 21 days;

b. SECOND: demonstrated by an additional history of neurologic and cardiac abnormalities and a skin condition known as lymphadenosis benigna cutis. A possible course of treatment would be an intravenous administration of an antibiotic, such as ceftriaxone, penicillin, or chloramphenicol, for as long as 14 days OR an oral administration of doxycycline for as long as 30 days;

c. CHRONIC: demonstrated by an additional history of joint abnormalities, particularly of the knees. A possible course of treatment would be an intravenous administration of an antibiotic, such as ceftriaxone, penicillin, or chloramphenicol, for as long as 14 days OR an oral administration of an antibiotic, such as doxycycline or amoxicillin and probenecid, for as long as 30 days.

Prevention of LD may be accomplished by avoiding grassy or wooded areas where infected ticks are present and/or wearing protective clothing, using tick repellent, and removing attached ticks. Protection against LD by use of vaccine has recently been approved by the FDA. The vaccine is divided into three doses given over the span of 12 months. However, it is not known how long protection against LD lasts after vaccination.

RATIONALE:
While most manifestations of LD can be adequately treated with oral antibiotics, intravenous antibiotics are indicated in some patients with neurologic or cardiac involvement. However, over-diagnosis and over-treatment of LD is common due to its nonspecific symptoms, lack of standardized testing and difficulties in interpreting the testing. Intravenous antibiotic therapy in patients with presumed LD may be inappropriately recommended in the following situations:

- an incorrect diagnosis and

- when oral antibiotics are adequate.

Published literature suggests that intravenous antibiotic therapy should be limited to those patients with objective and laboratory evidence of Lyme neurologic and cardiac abnormalities, and in those with well-documented severe Lyme arthritis that require prompt relief of symptoms. There is no evidence to support prolonged (greater than one month) courses of intravenous antibiotic therapy.

DISCLAIMER:

State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, takes precedence over Medical Policy and must be considered first in determining coverage. The member’s contract benefits in effect on the date that services are rendered must be used. Any benefits are subject to the payment of premiums for the date on which services are rendered. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

HMO Blue Texas physicians who are contracted/affiliated with a capitated IPA/medical group must contact the IPA/medical group for information regarding HMO claims/reimbursement information and other general polices and procedures.

---

Blue Cross and Blue Shield of Texas, a Division of Health Care Service Corporation, a Mutual Legal Reserve Company*
Southwest Texas HMO, Inc.* d/b/a HMO Blue® Texas
* Independent Licensees of the Blue Cross and Blue Shield Association

Posted Jan. 7, 2003