

<b>POLICY TITLE</b>	<b>INTRAVENOUS ANTIBIOTIC THERAPY FOR LYME DISEASE</b>
<b>POLICY NUMBER</b>	<b>MP-2.026</b>

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**I. POLICY**

Treatment of Lyme disease consists of oral antibiotics, except for the following indications:

**Neuroborreliosis**

A 2- to 4-week course of IV antibiotic therapy may be considered **medically necessary** in patients with neuroborreliosis with objective neurologic complications of documented Lyme disease (see the following for methods of documentation).

Objective neurologic findings include:

- Lymphocytic meningitis with documented cerebrospinal fluid (CSF) abnormalities.
- Cranial neuropathy, other than uncomplicated cranial nerve palsy, with documented CSF abnormalities
- Encephalitis or encephalomyelitis with documented CSF abnormalities
- Radiculopathy
- Polyneuropathy

Lyme disease may be documented either on the basis of serologic testing or by clinical findings of erythema migrans in early infection. Documentation of CSF abnormalities is required for suspected central nervous system (CNS) infection, as indicated above.

Serologic documentation of infection requires:

- Positive or indeterminate enzyme-linked immunosorbent assay (ELISA), AND
- Positive immunoblot blot by CDC criteria.
- Documented CSF abnormalities include ALL of the following:
  - Pleocytosis;
  - Evidence of intrathecal production of *Borrelia burgdorferi* antibodies in CSF; and
  - Increased protein levels.

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Polymerase chain reaction (PCR)-based direct detection of *B. burgdorferi* in CSF samples may be considered **medically necessary** and may replace serologic documentation of infection in patients with a short duration of neurologic symptoms (<14 days) during the window between exposure and production of detectable antibodies.

**Lyme Carditis**

A single 2- to 4-week course of IV antibiotics may be considered medically necessary in patients with Lyme carditis, as evidenced by positive serologic findings (defined above) and associated with high degree atrioventricular block or a PR interval more than 0.3 seconds. Documentation of Lyme carditis may include PCR-based direct detection of *B. burgdorferi* in the blood when results of serologic studies are equivocal.

**Lyme Arthritis**

A single 2- to 4-week course of IV antibiotic therapy may be considered medically necessary in the small subset of patients with well-documented Lyme arthritis who have such severe arthritis that it requires the rapid response associated with IV antibiotics. Documentation of Lyme arthritis may include PCR-based direct detection of *B. burgdorferi* in the synovial tissue or fluid when results of serologic studies are equivocal.

**Antibiotic Therapy**

Intravenous antibiotic therapy is considered **not medically necessary** in the following situations:

- Patients with symptoms consistent with chronic fatigue syndrome or fibromyalgia;
- Patients with seronegative Lyme disease in the absence of CSF antibodies;
- Initial therapy in patients with Lyme arthritis without coexisting neurologic symptoms;
- Cranial nerve palsy (e.g., Bell’s palsy) without clinical evidence of meningitis;
- Antibiotic-refractory Lyme arthritis (unresponsive to 2 courses of oral antibiotics or to 1 course of oral and 1 course of intravenous antibiotic therapy);
- Patients with vague systemic symptoms without supporting serologic or CSF studies;
- Patients with a positive ELISA test, unconfirmed by an immunoblot or Western blot test (see definition above);
- Patients with an isolated positive serologic test in the setting of multiple negative serologic studies;
- Patients with chronic (>6 months) subjective symptoms (“post-Lyme syndrome”) after receiving recommended treatment regimens for documented Lyme disease.

Repeat or prolonged courses (e.g., greater than 4 weeks) of IV antibiotic therapy are considered **not medically necessary**.

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**II. PRODUCT VARIATIONS**

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This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

**FEP PPO:** Refer to FEP Medical Policy Manual MP-10.05.13, IV Antibiotics for Lyme Disease. The FEP Medical Policy Manual can be found at: [www.fepblue.org](http://www.fepblue.org)

**III. DESCRIPTION/BACKGROUND**

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Lyme disease is a multisystem inflammatory disease caused by the spirochete *Borrelia burgdorferi* and transmitted by the bite of an infected ixodid tick endemic to Northeastern, North Central, and Pacific coastal regions of the U.S. The disease is characterized by stages, beginning with localized infection of the skin (erythema migrans), followed by dissemination to many sites. Manifestations of early disseminated disease may include lymphocytic meningitis, facial palsy, painful radiculoneuritis, atrioventricular nodal block, or migratory musculoskeletal pain. Months to years later, the disease may be manifested by intermittent oligoarthritis, particularly involving the knee joint, chronic encephalopathy, spinal pain, or distal paresthesias. While most manifestations of Lyme disease can be adequately treated with oral antibiotics, intravenous (IV) antibiotics are indicated in some patients with neurologic involvement or atrioventricular heart block. However, overdiagnosis and overtreatment of Lyme disease are common due to its nonspecific symptoms, a lack of standardization of serologic tests, and difficulties in interpreting serologic test results. In particular, patients with chronic fatigue syndrome or fibromyalgia are commonly misdiagnosed as possibly having Lyme disease and undergo inappropriate IV antibiotic therapy. The purpose of this policy is to provide diagnostic criteria for the appropriate use of IV antibiotic therapy. The following paragraphs describe the various manifestations of Lyme disease that may prompt therapy with IV antibiotics and the various laboratory tests that are used to support the diagnosis of Lyme disease.

**Neuroborreliosis**

Lymphocytic meningitis, characterized by head and neck pain, may occur during the acute disseminated stage of the disease. Analysis of the cerebrospinal fluid (CSF) is indispensable for the diagnosis of Lyme meningitis. If the patient has Lyme disease, the CSF will show a lymphocytic pleocytosis (lymphocyte count greater than normal) with increased levels of protein. Intrathecal production of antibodies directed at spirochetal antigens is typically present. A normal CSF analysis is strong evidence against Lyme meningitis. Treatment with a 2- to 4-week course of IV antibiotics, typically ceftriaxone or cefotaxime, is recommended.

Cranial neuritis, most frequently Bell’s palsy, may present early in the course of disseminated Lyme disease, occasionally prior to the development of antibodies, such that a Lyme disease etiology may be difficult to rule in or out. While Bell’s palsy typically resolves spontaneously with or without treatment with oral antibiotics, some physicians have recommended a lumbar puncture and a course of IV antibiotics if pleocytosis in the CSF is identified, primarily as a prophylactic measure to prevent further neurologic symptoms.

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A subacute encephalopathy may occur months to years after disease onset, characterized by subtle disturbances in memory, mood, sleep, or cognition accompanied by fatigue. These symptoms may occur in the absence of abnormalities in the electroencephalogram (EEG), magnetic resonance imaging (MRI), or CSF. In addition, the symptoms are nonspecific and overlap with fibromyalgia and chronic fatigue syndrome. Thus diagnosis of Lyme encephalopathy may be difficult and may be best diagnosed with a mental status exam or neuropsychological testing. However, treatment with IV antibiotics is generally not indicated unless CSF abnormalities are identified.

Much rarer, but of greater concern, is the development of encephalomyelitis, characterized by spastic paraparesis, ataxias, cognitive impairment, bladder dysfunction, and cranial neuropathy. CSF examination reveals a pleocytosis and an elevation in protein. Selective synthesis of anti-spirochetal antigens can also be identified. A course of IV antibiotics with 3 to 4 weeks of ceftriaxone is suggested when CSF abnormalities are identified.

A variety of peripheral nervous system manifestations of Lyme disease have also been identified. Symptoms of peripheral neuropathy include paresthesias, or radicular pain with only minimal sensory signs. Patients typically exhibit electromyographic (EMG) or nerve conduction velocity abnormalities. CSF abnormalities are usually seen only in those patients with a coexistent encephalopathy.

**Cardiac Manifestations of Lyme Disease**

Lyme carditis may appear during the early dissemination stage of the disease; symptoms include atrioventricular heart block, tachyarrhythmias, and myopericarditis. Antibiotics are typically given, although no evidence proves that this therapy hastens the resolution of symptoms. Both oral and IV regimens have been advocated. Intravenous regimens are typically used in patients with a high-degree atrioventricular block or a PR interval on the electrocardiogram of greater than 0.3 second. Patients with milder forms of carditis may be treated with oral antibiotics.

**Lyme Arthritis**

Lyme arthritis is a late manifestation of infection and is characterized by an elevated IgG response to *B. burgdorferi* and intermittent attacks of oligoarticular arthritis, primarily in the large joints such as the knee. Patients with Lyme arthritis may be successfully treated with a 30-day course of oral doxycycline or amoxicillin, but care must be taken to exclude simultaneous central nervous system (CNS) involvement, requiring IV antibiotic treatment. In the small subset of patients that do not respond to oral antibiotics, an additional 30-day course of oral or IV antibiotics may be recommended.

**Fibromyalgia and Chronic Fatigue Syndrome**

Fibromyalgia and chronic fatigue syndrome are the diseases most commonly confused with Lyme disease. Fibromyalgia is characterized by musculoskeletal complaints, multiple trigger points, difficulty in sleeping, generalized fatigue, headache, or neck pain. The joint pain associated with fibromyalgia is typically diffuse, in contrast to Lyme arthritis, which is characterized by marked joint swelling in one or a few joints at a time, with few systemic symptoms. Chronic fatigue syndrome is characterized by multiple subjective complaints, such as

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overwhelming fatigue, difficulty in concentration, and diffuse muscle and joint pain. In contrast to Lyme disease, both of the above conditions lack joint inflammation, have normal neurological test results, or have test results suggesting anxiety or depression. Neither fibromyalgia nor chronic fatigue syndrome has been shown to respond to antibiotic therapy.

**Treatment of Lyme Disease**

As previously noted, treatment with IV antibiotics may be indicated only in patients with symptoms and laboratory findings consistent with CNS or peripheral neurologic involvement and in a small subset of patients with heart block or documented Lyme arthritis who have not responded to oral antibiotics. Typical IV therapy consists of a 2- to 4-week course of ceftriaxone or cefotaxime or penicillin. No data suggest that prolonged or repeated courses of IV antibiotics are effective. Lack of effect should suggest an incorrect diagnosis or slow resolution of symptoms, which is commonly seen in Lyme disease. In addition, some symptoms may persist after treatment, such as Lyme arthritis; this phenomenon may be related to various self-sustaining inflammatory mechanisms rather than persistent infection.

**REGULATORY STATUS**

Clinical laboratories may develop and validate tests in-house and market them as a laboratory service; laboratory-developed tests (LDTs) must meet the general regulatory standards of the Clinical Laboratory Improvement Act (CLIA). Laboratory testing for Lyme disease is available under the auspices of CLIA. Laboratories that offer LDTs must be licensed by CLIA for high-complexity testing. As of 2014, there were at least 70 approved commercial laboratories that perform serologic testing for Lyme disease. To date, the U.S. Food and Drug Administration has chosen not to require any regulatory review of this test.

**IV. RATIONALE**

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**Summary of Evidence**

For individuals who are suspected of having Lyme disease who receive genotyping or phenotyping of *B. burgdorferi* subspecies or are tested for determination of CXCL13 levels or C6 peptide assay, the evidence is limited. Relevant outcomes are test accuracy, change in disease status, and morbid events. Polymerase-chain reaction (PCR) –based testing for *B. burgdorferi* genospecies is feasible. However, no evidence was identified that knowledge of the genotype or phenotype of *B. burgdorferi* could be used to improve patient management and outcomes. Additional research is also needed to determine diagnostic utility of CXCL13 and C6 peptide levels. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with confirmed Lyme disease who receive prolonged or repeated courses of antibiotic therapy, the evidence includes randomized controlled trials (RCTs). Relevant outcomes are symptoms, change in disease status, morbid events, and health status measures. Oral antibiotics usually are adequate for treatment of Lyme disease, though, in some persistent cases, a 2- to 4-week course of intravenous (IV) antibiotics may be appropriate. Evidence from

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RCTs has not shown a benefit to prolonged (>4 weeks) or repeat courses of oral or IV antibiotics. The evidence is sufficient to determine that the technology is unlikely to improve the net health outcome.

**V. DEFINITIONS**

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**ELISA TEST** refers to Enzyme-Linked Immunosorbent Assay (ELISA). This test is the initial serologic test for LD.

**LYMPHOCYTIC PLEOCYTOSIS IS** a lymphocyte count greater than normal.

**VI. BENEFIT VARIATIONS**

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The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital BlueCross for benefit information.

**VII. DISCLAIMER**

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*Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.*

**VIII. CODING INFORMATION**

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**Note:** This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

**Covered when medically necessary:**

CPT Codes ®							
99601	99602						

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HCPCS Code	Description
S5035	Home infusion therapy, routine service of infusion device (e.g. pump maintenance)
S9379	Home infusion therapy, infusion therapy, not otherwise classified; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem
S9494	Home infusion therapy, antibiotic, antiviral, or antifungal therapy; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem
S9497	Home infusion therapy, antibiotic, antiviral, or antifungal therapy; once every 3 hours; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem
S9500	Home infusion therapy, antibiotic, antiviral, or antifungal therapy; once every 24 hours; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem
S9501	Home infusion therapy, antibiotic, antiviral, or antifungal therapy; once every 12 hours; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem
S9502	Home infusion therapy, antibiotic, antiviral, or antifungal therapy; once every 8 hours, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem
S9503	Home infusion therapy, antibiotic, antiviral, or antifungal; once every 6 hours; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem
S9504	Home infusion therapy, antibiotic, antiviral, or antifungal; once every 4 hours; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem

ICD-10-CM Diagnosis Code	Description
A69.20	Lyme disease, unspecified
A69.21	Meningitis due to Lyme disease
A69.22	Other neurologic disorders in Lyme disease
A69.23	Arthritis due to Lyme disease
A69.29	Other conditions associated with Lyme disease

*Note: Refer to the Laboratory Service policies for testing related to Lyme disease.*

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**X. POLICY HISTORY**

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<b>MP 2.026</b>	<b>CAC 7/29/03</b>
	<b>CAC 6/28/05</b> Consensus
	<b>CAC 7/25/06</b>
	<b>CAC 9/25/07</b>
	<b>CAC 3/25/08</b>
	<b>CAC 3/31/09</b> Consensus
	<b>CAC 3/30/10</b> Consensus
	<b>CAC 4/26/11</b> Adopt BCBSA. Changed title. Minor changes in wording and description. Added a new policy statement indicating “Determination of levels of the B lymphocyte chemoattractant CXCL 13 for diagnosis or monitoring treatment is considered investigational.
	<b>CAC 6/26/12</b> Minor revision. Added to Section I. Policy statement VIII that other diagnostic testing is considered investigational, including but not limited to C6 peptide ELISA. FEP variation added.
	<b>7/18/13</b> Admin Code review complete
	<b>CAC 09/24/13</b> Consensus review. References updated; no changes to the policy statements. Rationale added.
	<b>CAC 7/22/14</b> Consensus review. No changes to the policy statements. References and rationale updated. Policy statements renumbered to put the “not medically necessary” situations into their own numbered section (IV) and change the numbers of the subsequent sections.
	<b>CAC 7/21/15</b> Consensus review. No change to policy statements. References and rationale updated. Coding reviewed.
	<b>CAC 7/26/16</b> Consensus review. No change to the policy statements. Rationale and references updated. Coding reviewed.
	<b>Admin Update 11/9/16</b> Variation Reformatting
	<b>CAC 11/28/17</b> Consensus. “Stand-alone” added to the statement on C6 peptide ELISA for clarification. Background, rationale and references updated. Coding reviewed. End dated code 87477 removed; effective 1/1/18
<b>Administrative Update 4/1/18:</b> 0041U thru 0044U added; effective 4/1/18	
<b>Admin Update 2/1/19</b> Policy updated to remove testing for Lyme Disease, testing will be managed by the new Laboratory Service policies to be effective 2/1/19. Title changed to Intravenous Antibiotic Therapy for Lyme Disease. Coding updated.	
<b>Admin Update 4/1/19</b> Fixed policy error where Carditis should have been listed as Arthritis. No statement changes.	

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