



Clinical Review Criteria Related to Treatment of Lyme Disease

I. Overview:

- A. Lyme Disease is a tick-borne, inflammatory disease that can infect multiple body systems. The disease usually occurs in stages and, typically, different clinical manifestations are noted in each stage.
 - 1. Early, localized disease occurs within a few days to one month after a tick bite, and is typically characterized by erythema migrans (bulls-eye rash), and/or nonspecific complaints resembling a viral syndrome.
 - 2. Early disseminated infection occurs days to 10 months after the tick bite, and may manifest as diseases involving multiple organs, with skin lesions, carditis, and neurologic involvement being most common.
 - 3. Late disseminated disease generally occurs months to years after the tick bite. Common manifestations include pain and swelling in one or more joints, neurologic symptoms, and cutaneous changes.

II. Criteria for Approval:

- A. Currently the Centers for Disease Control and Prevention (CDC) recommend a two-step method for initial testing and serologic diagnosis of Lyme Disease.
 - 1. Enzyme-Linked Immunosorbent Assay (ELISA) or Immunofluorescent Assay (IFA). When results of ELISA or IFA are negative, there is no need to test further.
 - 2. Western Immunoblot Test is used to confirm the serologic diagnosis of Lyme disease in patients with positive or indeterminate ELISA/IFA tests. If the Western Immunoblot is negative, it suggests that the ELISA or IFA was a false positive.
- B. MHI considers outpatient intravenous antibiotic therapy to be medically necessary in adult and pediatric members with the diagnosis of Lyme Disease only when it is based on the clinical presentation of signs and symptoms compatible with the disease and supported by a positive serologic and/or cerebrospinal fluid (CSF) titer as outlined above.
- C. Once a definitive diagnosis of Lyme Disease is established, MHI considers an initial course of up to 4 weeks of outpatient intravenous antibiotic therapy with ceftriaxone, cefotaxime, or penicillin G medically necessary when any of the following conditions is met:

1. Lyme arthritis which persists after failing to respond to a 4-week course of appropriate oral antibiotic therapy.
2. Moderate-to-severe cardiac involvement as evidenced by any of the following:
 - a. A first-degree heart block with P-R interval greater than 0.4 seconds
 - b. Congestive heart failure
 - c. Myopericarditis
 - d. Second-degree or higher AV block
3. Neurologic involvement of Lyme Disease (neuroborreliosis) as evidenced by any of the following:
 1. Encephalopathy/encephalomyelitis
 2. Meningitis confirmed by CSF analysis showing evidence of antibody production against *Borrelia burgdorferi* in the CSF
 3. Sensory/motor radiculoneuropathy or peripheral neuropathy
4. All cases of Lyme disease in pregnant women who exhibit symptoms and signs of any of the following:
 1. Stage II Lyme Disease with early dissemination documented by organ-specific manifestations of infection (arthritic, cardiac, or neurologic)
 2. Stage III late Lyme disease documented by findings of arthritis and/or neurologic complications, such as encephalomyelitis and subacute encephalitis

III. Required Documentation:

- A. Letter of medical necessity or office notes documenting clinical indications and oral antibiotic treatment failure if applicable
- B. Lab results of ELISA or IFA, confirmed with Western Blot, showing definitive diagnosis of Lyme Disease

IV. What is Not Covered:

- A. Use of intravenous imipenem-cilastin, ceftazidime, cefuroxime, vancomycin, bicillin, or ampicillin for the treatment of early or late disseminated stages of Lyme Disease
- B. Use of intravenous antibiotics beyond 4 weeks, as there is no evidence that such use is beneficial in the treatment of chronic or recurrent Lyme Disease. Available evidence suggests that prolonged or recurrent use of intravenous antibiotics does not improve treatment outcomes and is associated with an increased incidence of adverse event.
- C. Laboratory tests provided at IGeneX, Inc.
- D. Asymptomatic seropositivity

For asymptomatic seropositive patients who have not previously received antibiotic therapy for Lyme Disease, a single course of oral therapy for 28 days of doxycycline or amoxicillin. Some experts would not treat asymptomatic seropositive individuals with antibiotics given that the potential benefit of treatment in such patients has not been established definitively.

- E. Pregnant woman presenting with localized Lyme disease manifested as a single lesion of erythema migrans without any other symptoms suggestive of disseminated disease

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