MVP Health Care Medical Policy

Medicare Part B: Lyme Disease/IV Antibiotic Treatment

Type of Policy: **Medical Therapy**
Prior Approval Date: **NA**
Approval Date: **12/01/2024**
Effective Date: **02/01/2025**
Related Policies: **N/A**

Codes Requiring Prior Authorization when used for the treatment of Lyme Disease (covered under the medical benefit)

J0696 (ceftriaxone, per 250mg)

J0698 (cefotaxime, per gram)
J2540 (penicillin G potassium, up to 600,000 units)

Refer to the Medicare Part D formulary for drugs that may be covered under the Part D benefit.

Refer to the MVP website for the Medicare Part B policies for coverage criteria of drugs covered under the medical benefit.

Please refer to relevant CMS LCDs/NCDs/Policy Articles for most up to date Medicare Part B guidance if available.

Overview

Lyme disease is a multisystem illness due to infection with the tick-borne spirochete, Borrelia burgdorferi. Lyme disease can occur in 3 stages: an early localized stage, a disseminated stage, and a late stage. The early localized stage is generally characterized by the bull's eye rash, which forms at the site of the tick bite. The disseminated stage

typically occurs in the first few weeks to 6 months after infection. Lyme disease that is untreated and progressed for more than 6 months is late-stage disease. Late-stage Lyme disease may manifest as encephalitis, encephalomyelitis, arthritis, neuropathies and cerebral arteritis. Oral antibiotic therapy (ex. doxycycline, amoxicillin or cefuroxime axetil) is the standard of care for members in early localized and early disseminated stages without neurologic or cardiac symptoms, and therapy is recommended for 14 to 21 days. Intravenous antibiotics are indicated for treatment of late-stage disease or for disseminated disease with neurologic or cardiac involvement, and therapy is recommended for 14 to 28 days.

Currently there is a two-step process for testing blood for Lyme disease bacteria. The common first step is ELISA (enzyme-linked immunosorbent assay) which can detect IgM antibodies to Borrelia burgdorferi. If the ELISA result is negative, an alternative diagnosis should be considered, or if the member has signs and symptoms consistent with Lyme disease for < 30 days, consider retesting after 4-6 weeks of initial symptoms. As of August 2019, the CDC has updated their guidelines for diagnosis. If the ELISA result is positive or indeterminate, perform the Western Blot or a second FDA cleared enzyme immunoassay. Clearance by FDA indicates "that test performance has been evaluated and is substantially equivalent to or better than a legally marketed predicate test". Results are considered positive only if both the ELISA and the Western Blot or second enzyme immunoassay are positive[8,10].

Indications/Criteria and Documentation Requirements

MVP will provide coverage for the use of intravenous antibiotics for Lyme disease, when all the following criteria are met:

A. Current lab results indicating a positive (or equivocal) enzyme immunoassay (e.g. ELISA)

B. Current lab results indicating a positive w striped type western immune blot test **OR** a second positive enzyme immunoassay which includes:

- For Western Immunoblot test:
  - For signs or symptoms >30 days an IgG immunoblot that includes:
  - IgG immunoblot must have at least five of the following 10 bands present:
    - 18 kDa
    - 21 kDa (OspC)*

- 28 kDa
- 30 kDa
- 39 kDa (BmpA)
- 41 kDa (Fla)
- 45 kDa
- 58 kDa (not GroEL)
- 66 kDa
- 93 kDa

- For signs or symptoms ≤ 30 days, the above criteria for an IgG Western Blot must be met **AND** an IgM western immunoblot must have at least two of the following bands present:
  - 24 kDa (OspC)*
  - 39 kDa (BmpA)
  - 41 kDa (Fla)

C. Contraindication or intolerance to all appropriate first-line oral antibiotic therapy at recommended maximum dosages except for the following:
   - Neurologic early Lyme Disease
   - Lyme-Disease Related parenchymal involvement of the brain or spinal cord
   - Refer to the IDSA guidelines Clinical Practice Guidelines by the Infectious Diseases Society of America (IDSA), American Academy of Neurology (AAN), and American College of Rheumatology (ACR): 2020 Guidelines for the Prevention, Diagnosis and Treatment of Lyme Disease | Clinical Infectious Diseases | Oxford Academic

D. Documentation includes signs or symptoms of early disseminated Lyme disease or late Lyme disease with one of the following:
   1. Neurologic early Lyme Disease: Neurologic disease manifested by meningitis, cranial neuropathy, radiculoneuropthy or with other peripheral nervous system manifestations with clinical and laboratory evidence (e.g. lymphocytic cerebrospinal fluid pleocytosis, CSF elevation)
   2. Lyme-Disease Related parenchymal involvement of the brain or spinal cord: evident by MRI imaging or focal findings on neurologic examination
   3. Carditis (early Lyme disease)

- Examples: Atrioventricular (AV) heart block and/or myopericarditis associated with early Lyme disease.

4. Lyme arthritis with persistent joint swelling with no or minimal response to an initial course of oral antibiotic treatment
    - Documentation of serum antibody testing OR
    - For seropositive members , PCR applied to synovial fluid or tissue
5. Late neurologic disease affecting the central or peripheral nervous system. (Retreatment is not recommended unless relapse is shown by reliable objective measures.) Retreatment is not recommended and the prospective, controlled clinical trials have demonstrated little benefit from prolonged antibiotic therapy. Due to a lack of efficacy supported in peer reviewed literature, long term (>28 days) antibiotic therapy is not considered medically necessary.

E. Chart notes from appropriate specialists (e.g. rheumatologist, cardiologist, neurologist), in the absence of neurologic or cardiac manifestations, that have ruled out underlying conditions that may have the similar symptoms as Lyme disease.

F. Treatment with IV antibiotics is supported by medical guidelines or peer reviewed literature and meets MVP Clinical Coverage Criteria for medical necessity.

Medicaid Variation: Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self-administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf

Exclusions

- Additional or prolonged courses of antibiotic therapy have not been demonstrated to benefit individuals and may expose them to significant risk from adverse effects of the medications.
- Indication, age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Intravenous antibiotic therapy in excess of 28 days.
- Members with a positive ELISA test but unconfirmed by striped type immunoblot tests approved by the FDA and currently recommended by CDC

- Treatment of post-Lyme disease or post-Lyme disease syndrome (symptomatic therapy is recommended)
- Additional therapy after recommended treatment for members with persistent or recurring nonspecific symptoms (i.e. fatigue, pain or cognitive impairment) who lack objective evidence of reinfection or treatment failure
- Prophylaxis of Lyme disease in the absence of clinical symptoms.
- Treatment with IV antibiotics for non-specific symptoms (fatigue, headache, etc.)

References

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2. Medline Plus. A service of U.S. National Library of Medicine, National Institutes of Health. Lyme disease. August 2011. Available: www.nlm.nih.gov/medlineplus/ency/article/001319.htm.
3. Centers for Disease Control and Prevention (CDC). Lyme disease, diagnosis and treatment, laboratory testing, understanding the immunoblot test. Available: www.cdc.gov
4. Halperin, J.J. et.al. Report of the Quality Standards Subcommittee of the American Academy of Neurology. "Practice Parameter: Treatment of Nervous System Lyme Disease (an evidence-based review). http://www.neurology.org/content/69/1/91.short
5. Mead P, Petersen J, Hinckley A. Updated CDC Recommendation for Serologic Diagnosis of Lyme Disease. Morbidity and Mortality Weekly Report; 2019 Aug; 68(32). https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6832a4-H.pdf
6. Lantos PM, Rumbaugh J, Bockenstedt LK, et al. Clinical Practice Guidelines by the Infectious Diseases Society of America, American Academy of Neurology, and American College of Rheumatology: 2020 Guidelines for the Prevention, Diagnosis, and Treatment of Lyme Disease. Neurology. 2021 Feb 9;96(6):262-273. doi: 10.1212/WNL.0000000000011151. Epub 2020 Nov 30. Erratum in: Neurology. 2021 Feb 9;96(6):296. PMID: 33257476.
7. Treatment of Lyme Disease. Centers for Disease Control and Prevention (CDC). Updated March 1, 2022. Available at: Treatment of Lyme Disease | Lyme Disease | CDC.
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