

## Medical Necessity Guidelines: Lyme Disease: Antibiotic Coverage

Effective: October 21, 2020

<b>Prior Authorization Required</b> If <u>REQUIRED</u> , submit supporting clinical documentation pertinent to service request.	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
<p><b>Applies to:</b></p> <p><b>COMMERCIAL Products</b></p> <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Tufts Health Plan Commercial products; Fax: 617.972.9409</li> <li><input checked="" type="checkbox"/> Tufts Health Freedom Plan products; Fax: 617.972.9409</li> <li>• CareLink<sup>SM</sup> – Refer to <a href="#">CareLink Procedures, Services and Items Requiring Prior Authorization</a></li> </ul> <p><b>TUFTS HEALTH PUBLIC PLANS Products</b></p> <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 888.415.9055</li> <li><input type="checkbox"/> Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax: 888.415.9055</li> <li><input type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax: 857.304.6404</li> <li><input type="checkbox"/> Tufts Health Unify* – OneCare Plan (a dual-eligible product); Fax: 857.304.6304</li> </ul> <p>*The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists.</p> <p><b>SENIOR Products</b></p> <ul style="list-style-type: none"> <li>• Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product) – Refer to the <a href="#">Tufts Health Plan SCO Prior Authorization List</a></li> <li>• Tufts Medicare Preferred HMO, (a Medicare Advantage product) – Refer to the <a href="#">Tufts Medicare Preferred HMO Prior Authorization and Inpatient Notification List</a></li> </ul>	

### OVERVIEW

**Lyme disease** is a multisystem inflammatory, tick-transmitted infection caused by the spirochete bacterium *Borrelia burgdorferi*. The bacterium is carried and transmitted by deer ticks (*Ixodes scapularis*). In most cases, Lyme disease is first characterized by the appearance of a red skin lesion (erythema chronicum migrans), which begins as a small elevated round spot (papule) that expands to at least five centimeters in diameter. Symptoms may then progress to include low-grade fever, chills, muscle aches (myalgia), headaches, a general feeling of weakness and fatigue (malaise), and/or pain and stiffness of the large joints (infectious arthritis), especially in the knees. Such symptoms may tend to occur in recurrent cycles. In severe cases, heart muscle (myocardial) and/or neurological abnormalities may occur.

**Chronic Lyme disease** is a generally unrecognized diagnosis that encompasses “a broad array of illnesses or symptom complexes for which there is no reproducible or convincing scientific evidence of any relationship to *B. burgdorferi* infection.” There is no reliable scientific evidence that “chronic” Lyme disease is caused by a persistent infection. It is distinct from post-treatment Lyme disease syndrome, a set of lingering symptoms which may persist after successful treatment of infection with Lyme spirochetes.

Rhode Island has had a mandate regarding the treatment of Lyme disease since 2013, [Rhode Island General Law § 27-20-48](#), under which coverage must be provided for diagnostic testing and long-term antibiotic treatment of Lyme disease. In August 2016, the Massachusetts Legislature passed M.G.L Ch. 175, 47HH: An Act relative to long-term antibiotic therapy for the treatment of Lyme disease, which became [Chapter 183 of the Acts of 2016](#). This bill also mandates certain types of coverage for long-term antibiotic therapy for the treatment of Lyme disease. New Hampshire implemented a mandate in 2011 relative to the use of long-term antibiotics for the treatment of Lyme disease, [New Hampshire Chapter 157 HB 295](#). This guideline will provide guidance to Tufts Health Plan and its’ providers regarding how Tufts Health Plan will (or may) review claims submitted for long-term antibiotic treatment for Lyme disease. Note that **prior authorization is not required** for initiation or continuation of any antibiotic treatment for Lyme disease.

## CLINICAL COVERAGE CRITERIA

**PRIOR AUTHORIZATION IS NOT REQUIRED:** Providers will not routinely be required to submit documentation to Tufts Health Plan prior to providing services. However, documentation may be requested at any time to confirm that the services provided meet current standards referenced below:

**ALL** the following are required for any proposed treatment regime:

1. Member must have (or have had) proven Lyme disease. "Proven Lyme disease" can be shown by the clinical diagnosis of a patient by a licensed physician, in conjunction with diagnostic testing that provides supportive data for such clinical diagnosis. Diagnostic testing supporting a clinical diagnosis of Lyme disease is **one** of the following (documentation must be provided by an independent, state credentialed diagnostic lab):
  - a. Serologic findings by Enzyme-Linked Immunosorbent Assay (ELISA) for *B. burgdorferi* antibodies and immunoblot (i.e., Western blot)

**OR**

  - b. Polymerase Chain Reaction (PCR) based direct detection in cerebral spinal fluid (CSF), synovial tissue or synovial fluid.
2. A licensed physician may prescribe, administer or dispense long-term (up to 6 months) antibiotic therapy for a therapeutic purpose to eliminate infection or to control a patient's symptoms upon making a clinical diagnosis that the patient has Lyme disease or displays symptoms consistent with a clinical diagnosis of Lyme disease, if such clinical diagnosis and treatment are documented in the patient's medical record by the prescribing licensed physician. For Tufts Health Plan Freedom products, long-term antibiotic therapy for Lyme disease is not limited to 6 months.<sup>4,5</sup>
3. Coverage of antibiotics for the treatment of Lyme disease must be expected, based on medical literature, to be effective in the treatment of Lyme disease; any antibiotic used to treat Lyme must have supporting literature showing that it is effective in vitro or in vivo against *Zorrelia burgdorferi*). The antibiotics currently known to be effective in the treatment of Lyme disease, and which will be reimbursable are limited to:
  - a. First line agents: doxycycline, amoxicillin, and cefuroxime axetil
  - b. Second line agents: azithromycin, clarithromycin, erythromycin

**NOTE:** Antibiotics for the treatment of Lyme disease other than those listed above as first and second line agents may be covered provided such drug is recognized for treatment of Lyme disease in one of the standard reference compendia, or in the medical literature. To receive reimbursement, prescribers must submit clinical documentation supporting the drug's effectiveness in treating Lyme disease, including the applicable literature if appropriate. Payment for Lyme disease antibiotic treatment will not be denied solely because such treatment may be characterized as unproven, experimental, or investigational.

4. Long-term antibiotics, under this guideline must be prescribed by a licensed physician, not a Registered Nurse Practitioner or a Physician Assistant, as required under applicable law.
5. Coverage of the treatment of "co-infections" with long-term antibiotics or other treatments not currently supported by the mainstream medical literature will not be covered. Usual standards of medical practice will be used to evaluate the treatment of co-infections and will require demonstrated proof that the member has the infection in question, as documented by appropriate laboratory testing; documentation must be provided by an independent, state credentialed lab. Treatment courses limited to time periods and agents known to be effective based on the usual treatment standards and the current medical literature.

## LIMITATIONS

- At present, most other tests are not sufficient to prove that a member has, or has had, Lyme disease. These tests include but are not limited to the following:
  - PCR-based direct detection of *B. burgdorferi* in urine samples
  - Genotyping or phenotyping of *B. burgdorferi*
  - Determination of levels of the B lymphocyte chemoattractant CXCL13 for diagnosis or monitoring treatment

- Capture assays for antigens in urine
  - Culture, immunofluorescence staining, or cell sorting of cell wall-deficient or cystic forms of *B. burgdorferi*
  - Lymphocyte transformation tests
  - Quantitative CD57 lymphocyte assays
  - "Reverse Western blots"
  - Measurements of antibodies in joint fluid (synovial fluid)
  - IgM or IgG tests without a previous ELISA/EIA/IFA
- Repeat PCR-based direct detection of *B. burgdorferi* is generally considered not medically necessary

## CODES

**Table 1: ICD-10 Codes**

ICD-10 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

## REFERENCES

1. Commonwealth of Massachusetts. An Act Relative to Long-term Antibiotic Therapy for the Treatment of Lyme Disease. Chapter 183 Acts of 2016. <https://malegislature.gov/Laws/SessionLaws/Acts/2016/Chapter183>.
2. Rhode Island General Law (RIGL). 27-20-48 Mandatory coverage for certain Lyme disease treatments. <http://webserver.rilin.state.ri.us/Statutes/TITLE27/27-20/27-20-48.HTM>.
3. Commonwealth of Massachusetts. XVI Chapter 112 Section 12DD. <https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXVI/Chapter112/Section12DD>.
4. New Hampshire House Bill HB 1287-FN. An act relative to the duration of antibiotic therapy for tick-borne illness. March 11, 2020. <https://bills.nhliberty.org/bills/2020/HB1287>.
5. New Hampshire Lyme disease law, An Act relative to the use of long-term antibiotics for the treatment of Lyme disease. Chapter 157, HB 295. June 9, 2011.
6. Centers for Disease Control and Prevention. Lyme disease: Diagnosis and testing. August 2019. <http://www.cdc.gov>. Accessed September 4, 2020.

## APPROVAL HISTORY

October 11, 2017: Reviewed by the Integrated Medical Policy Advisory Committee (IMPAC) for an effective date of October 11, 2017

Subsequent endorsement date(s) and changes made:

- October 10, 2018: Reviewed by IMPAC, renewed without changes
- October, 2018: Template and disclaimer updated
- July 1, 2019: Applicability to Tufts Health Direct indicated
- October 16, 2019: Reviewed by IMPAC, renewed without changes
- October 21, 2020: Reviewed by IMPAC. Applicability to Tufts Health Plan Freedom products indicated; added long-term antibiotic therapy for Lyme disease is not limited to 6 months
- October 26, 2020: Fax number for Unify updated

## BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Medical Necessity Guidelines are developed to determine coverage for benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.

[Provider Services](#)