



The Commonwealth of Massachusetts

HEALTH POLICY COMMISSION

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To: External Review Agencies under Contract with the Health Policy Commission Pursuant to M.G.L. c. 176O, § 14
From: Nancy K. Ryan, Director, Office of Patient Protection
Re: External Review for Denials of Coverage for Lyme Disease Treatment
Date: January 24, 2019

External Review for Denials of Coverage for Lyme Disease Treatment

Required Benefits for Coverage of Lyme Disease Treatment

Massachusetts law requires coverage of long-term antibiotic therapy for patients with Lyme disease when determined to be medically necessary and ordered by a licensed physician after making a thorough evaluation of the patient's symptoms, diagnostic test results or response to treatment. An experimental drug shall be covered as a long-term antibiotic therapy if it is approved for an indication by the United States Food and Drug Administration; provided, however, that a drug, including an experimental drug, shall be covered for an off-label use in the treatment of Lyme disease if the drug has been approved by the United States Food and Drug Administration.

MGL c. 175, § 47HH, MGL c. 176A, § 8JJ, MGL c. 176B, § 4JJ, MGL c. 176G, §4BB

Definition of Lyme Disease

Massachusetts law defines "Lyme disease" as "the clinical diagnosis of a patient by a physician licensed ... of the presence of signs or symptoms compatible with acute infection with *Borrelia burgdorferi*; late stage, persistent or chronic infection with *Borrelia burgdorferi*; complications related to such infection; or with such other strains of *Borrelia* that become identified or recognized by the National Centers for Disease Control and Prevention as a cause of Lyme disease; provided, however, that "Lyme disease" shall also include an infection that meets the surveillance criteria set forth by the National Centers for Disease Control and Prevention and a clinical diagnosis of Lyme disease that does not meet the National Centers for Disease Control and Prevention surveillance criteria but presents other acute and chronic signs or symptoms of Lyme disease as determined by the treating physician; and provided further, that clinical diagnosis shall be based on knowledge obtained through medical history and physical examination only or in conjunction with testing that provides supportive data for such clinical diagnosis."

M.G.L. c. 112, § 12DD.

Definition of Long-term Antibiotic Therapy

Massachusetts law defines “Long-term antibiotic therapy” as “the administration of oral, intramuscular or intravenous antibiotics singly or in combination, for periods of time in excess of 4 weeks.”

M.G.L. c. 112, § 12DD.

Eligibility for External Review

Health insurance carrier denials of coverage for long-term antibiotic therapy for Lyme disease are eligible for external review when the carrier issues a final adverse determination based on the Massachusetts definition of medical necessity, internal health plan criteria and guidelines which are used to assess medical necessity, or the contention that a treatment is experimental or investigational. The external review will be based upon medical necessity, as defined in Massachusetts law:

Medical Necessity or Medically Necessary means health care services that are consistent with generally accepted principles of professional medical practice as determined by whether the service:

- (1) is the most appropriate available supply or level of service for the insured in question considering potential benefits and harms to the individual;
- (2) is known to be effective, based on scientific evidence, professional standards and expert opinion, in improving health outcomes; or
- (3) for services and interventions not in widespread use, is based on scientific evidence.

See M.G.L. c. 176O, § 1; 958 CMR 128.020; 211 CMR 52.03.

If you have questions about external reviews and Lyme disease treatment, please contact Nancy K. Ryan, Director of the Office of Patient Protection, at Nancy.K.Ryan@mass.gov or 617-274-1844.