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Lyme Disease Testing

I. Policy Description

Lyme disease is a common multisystem inflammatory disease caused by spirochetes of the family *Borreliaceae* transmitted through the bite of an infected tick of the genus *Ixodes.*[1] Lyme disease affects the skin in its early localized stage, and spreads to the joints, nervous system, and other organ systems in its later disseminated stages.[2]

II. Indications and/or Limitations of Coverage

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request. Specifications pertaining to Medicare and Medicaid can be found in the "Applicable State and Federal Regulations" section of this policy document.

1) For individuals with symptoms of Lyme disease and a history of travel to a region endemic for Lyme (with or without a history of a tick bite), serologic testing (2-tier testing strategy using a sensitive enzyme immunoassay (EIA) or immunofluorescence assay, followed by a western immunoblot assay or FDA-cleared second EIA assay) **MEETS COVERAGE CRITERIA**.

2) For individuals with a history of travel to a region endemic for Lyme, serologic testing (2-tier testing strategy using a sensitive enzyme immunoassay (EIA) or immunofluorescence assay, followed by a western immunoblot assay or FDA-cleared second EIA assay) **MEETS COVERAGE CRITERIA** in any of the following situations:

   a) For individuals with acute myocarditis/pericarditis of unknown cause.

   b) For individuals with meningitis, encephalitis, or myelitis.

   c) For individuals with painful radiculoneuritis.

   d) For individuals with mononeuropathy multiplex including confluent mononeuropathy multiplex.

   e) For individuals with acute cranial neuropathy.

3) Serologic testing **DOES NOT MEET COVERAGE CRITERIA** in any of the following situations:

   a) For individuals with an erythema migrans (EM) rash (patients with skin rashes consistent with EM who reside in or who have recently traveled to an endemic area should be treated for Lyme disease).

   b) To screen asymptomatic patients living in endemic areas.

   c) For individuals with non-specific symptoms only (e.g., fatigue, myalgias/arthralgias).

   d) For individuals with amyotrophic lateral sclerosis.

   e) For individuals with relapsing-remitting multiple sclerosis.

   f) For individuals with Parkinson's disease.

   g) For individuals with dementia or cognitive decline, or new-onset seizures.

   h) For individuals with psychiatric illness.

4) Detection of *Borrelia burgdorferi* by nucleic acid identification techniques (direct or amplified probe) **DOES NOT MEET COVERAGE CRITERIA**.

5) For individuals who have previously tested positive for Lyme disease, repeat serologic testing **DOES NOT MEET COVERAGE CRITERIA**.

The following does not meet coverage criteria due to a lack of available published scientific literature confirming that the test(s) is/are required and beneficial for the diagnosis and treatment of an individual's illness.

6) All other testing for *Borrelia burgdorferi* not described above **DOES NOT MEET COVERAGE CRITERIA**.

7) For the diagnosis of Lyme disease, testing of the individual tick **DOES NOT MEET COVERAGE CRITERIA.**

III. Applicable State and Federal Regulations

DISCLAIMER: If there is a conflict between this Policy and any relevant, applicable government policy for a particular member [e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs) for Medicare and/or state coverage for Medicaid], then the government policy will be used to make the determination. For the most up-to-date Medicare policies and coverage, please visit the Medicare search website:

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https://www.cms.gov/medicare-coverage-database/search.aspx. For the most up-to-date Medicaid policies and coverage, visit the applicable state Medicaid website.

Food and Drug Administration (FDA)

Many labs have developed specific tests that they must validate and perform in house. These laboratory-developed tests (LDTs) are regulated by the Centers for Medicare and Medicaid (CMS) as high-complexity tests under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). As an LDT, the U. S. Food and Drug Administration has not approved or cleared this test; however, FDA clearance or approval is not currently required for clinical use.

IV. Applicable CPT/HCPCS Procedure Codes

CPT	Code Description
86617	Antibody; Borrelia burgdorferi (Lyme disease) confirmatory test (eg, Western Blot or immunoblot)
86618	Antibody; Borrelia burgdorferi (Lyme disease)
87475	Infectious agent detection by nucleic acid (DNA or RNA); Borrelia burgdorferi, direct probe technique
87476	Infectious agent detection by nucleic acid (DNA or RNA); Borrelia burgdorferi, amplified probe technique
0041U	Borrelia burgdorferi, antibody detection of 5 recombinant protein groups, by immunoblot, IgM Proprietary test: Lyme ImmunoBlot IgM Lab/Manufacturer: IGeneX Inc
0042U	Borrelia burgdorferi, antibody detection of 12 recombinant protein groups, by immunoblot, IgG Proprietary test: Lyme ImmunoBlots IgG Lab/Manufacturer: IGeneX Inc
0316U	Borrelia burgdorferi (Lyme disease), OspA protein evaluation, urine Proprietary test: Lyme Borrelia Nanotrap® Urine Antigen Test Lab/Manufacturer: Galaxy Diagnostics Inc

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Procedure codes appearing in Medical Policy documents are included only as a general reference tool for each policy. They may not be all-inclusive.

V. Evidence-based Scientific References

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