



If a conflict arises between a Clinical Payment and Coding Policy (“CPCP”) and any plan document under which a member is entitled to Covered Services, the plan document will govern. If a conflict arises between a CPCP and any provider contract pursuant to which a provider participates in and/or provides Covered Services to eligible member(s) and/or plans, the provider contract will govern. “Plan documents” include, but are not limited to, Certificates of Health Care Benefits, benefit booklets, Summary Plan Descriptions, and other coverage documents. BCBSNM may use reasonable discretion interpreting and applying this policy to services being delivered in a particular case. BCBSNM has full and final discretionary authority for their interpretation and application to the extent provided under any applicable plan documents.

Providers are responsible for submission of accurate documentation of services performed. Providers are expected to submit claims for services rendered using valid code combinations from Health Insurance Portability and Accountability Act (“HIPAA”) approved code sets. Claims should be coded appropriately according to industry standard coding guidelines including, but not limited to: Uniform Billing (“UB”) Editor, American Medical Association (“AMA”), Current Procedural Terminology (“CPT®”), CPT® Assistant, Healthcare Common Procedure Coding System (“HCPCS”), ICD-10 CM and PCS, National Drug Codes (“NDC”), Diagnosis Related Group (“DRG”) guidelines, Centers for Medicare and Medicaid Services (“CMS”) National Correct Coding Initiative (“NCCI”) Policy Manual, CCI table edits and other CMS guidelines.

Claims are subject to the code edit protocols for services/procedures billed. Claim submissions are subject to claim review including but not limited to, any terms of benefit coverage, provider contract language, medical policies, clinical payment and coding policies as well as coding software logic. Upon request, the provider is urged to submit any additional documentation.

## Lyme Disease

**Policy Number: CPCPLAB044**

**Version 1.0**

**Enterprise Medical Policy Committee Approval Date: 1/25/2022**

**Plan Effective Date: May 1, 2022**

## Description

BCBSNM has implemented certain lab management reimbursement criteria. Not all requirements apply to each product. Providers are urged to review Plan documents for eligible coverage for services rendered.

## Reimbursement Information:

1. 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) for all patients with a history of travel to a Lyme region (with or without a history of a tick bite) with compatible symptoms of Lyme disease **may be reimbursable**

2. 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) **may be reimbursable** for individuals with a history of travel to a Lyme region presenting with any of the following disorders:
  - a. Acute myocarditis/pericarditis of unknown cause
  - b. Meningitis, encephalitis, or myelitis
  - c. Painful radiculoneuritis
  - d. Mononeuropathy multiplex including confluent mononeuropathy multiplex
  - e. Acute cranial neuropathy
3. Serologic testing **is not reimbursable** in the following situations:
  - a. In patients with an erythema migrans (EM) rash. Patients with skin rashes consistent with EM who reside in or have recently traveled to an endemic area should be treated for Lyme disease.
  - b. For screening of asymptomatic patients living in endemic areas.
  - c. For patients with non-specific symptoms only (e.g., fatigue, myalgias/artralgias). The use of serologic testing in populations with a low pre-test probability of Lyme disease results in a greater likelihood of false positive test results than true positive test results.
  - d. In patients with amyotrophic lateral sclerosis
  - e. In patients with relapsing-remitting multiple sclerosis
  - f. In patients with Parkinson's disease
  - g. In patients with dementia or cognitive decline, or new-onset seizures
  - h. In patients with psychiatric illness
4. Polymerase chain reaction (PCR)-based direct detection of *B. burgdorferi* in CSF samples **may be reimbursable** and may replace serologic documentation of infection in patients with a short duration of neurologic symptoms (<14 days) during the window between exposure and production of detectable antibodies.
5. Repeat serologic testing **is not reimbursable** in individuals who have tested positive previously since positive results may not distinguish between past and possible current infection(s).
6. Repeat PCR-based direct detection of *Borrelia burgdorferi* **is not reimbursable** in the following situations:
  - a. As a justification for continuation of IV antibiotics beyond one month in patients with persistent symptoms.
  - b. As a technique to follow a therapeutic response.
  - c. Via urine sample.
7. Other testing for *Borrelia burgdorferi* **is not reimbursable**, including but not limited to:
  - a. Genotyping and phenotyping
  - b. Determination of levels of the B lymphocyte chemoattractant CXCL<sub>13</sub>
  - c. Urine assays, including urinary-based antigen capture assays
  - d. Panel immunoblot testing, such as Lyme ImmunoBlot IgM, Lyme ImmunoBlot IgG, and Lyme Dot Blot
8. Testing of the individual tick **is not reimbursable** for the diagnosis of Lyme disease.

## Procedure Codes

| Codes                                    |
|--|
| 86617, 86618, 87475, 87476, 0041U, 0042U |

## References:

AAP. (2018). Lyme Disease. In D. Kimberlin, M. Brady, M. Jackson, & S. Long (Eds.), *Red Book: 2018 Report of the Committee on Infectious Diseases* (pp. 515-523): American Academy of Pediatrics.

ACR. (2013). ACRheum - Testing for Lyme disease | Choosing Wisely. Retrieved from <http://www.choosingwisely.org/clinician-lists/american-college-rheumatology-testing-for-lyme-disease/>. <http://www.choosingwisely.org/clinician-lists/american-college-rheumatology-testing-for-lyme-disease/>

Adeolu, M., & Gupta, R. S. (2014). A phylogenomic and molecular marker based proposal for the division of the genus *Borrelia* into two genera: the emended genus *Borrelia* containing only the members of the relapsing fever *Borrelia*, and the genus *Borrelia* gen. nov. containing the members of the Lyme disease *Borrelia* (*Borrelia burgdorferi* sensu lato complex). *Antonie Van Leeuwenhoek*, *105*(6), 1049-1072. doi:10.1007/s10482-014-0164-x

Bacon, R. M., Kugeler, K. J., & Mead, P. S. (2008). Surveillance for Lyme disease--United States, 1992-2006. *MMWR Surveill Summ*, *57*(10), 1-9. Retrieved from <https://www.cdc.gov/mmwr/preview/mmwrhtml/ss5710a1.htm>

Barbour, A. (2019). Microbiology of Lyme disease - UpToDate. In J. Mitty (Ed.), *UpToDate*. Retrieved from [https://www.uptodate.com/contents/microbiology-of-lyme-disease?source=see\\_link](https://www.uptodate.com/contents/microbiology-of-lyme-disease?source=see_link)

Beard, C. B. (2018). Epidemiology of Lyme disease - UpToDate. In J. Mitty (Ed.), *UpToDate*. Retrieved from [https://www.uptodate.com/contents/epidemiology-of-lyme-disease?source=see\\_link](https://www.uptodate.com/contents/epidemiology-of-lyme-disease?source=see_link)

Bunikis, J., & Barbour, A. G. (2002). Laboratory testing for suspected Lyme disease. *Med Clin North Am*, *86*(2), 311-340. Retrieved from <http://dx.doi.org/>

Cameron, D. J., Johnson, L. B., & Maloney, E. L. (2014). Evidence assessments and guideline recommendations in Lyme disease: the clinical management of known tick bites, erythema migrans rashes and persistent disease. *Expert Rev Anti Infect Ther*, *12*(9), 1103-1135. doi:10.1586/14787210.2014.940900

CCDR. (2020). Modified two-tiered testing algorithm for Lyme disease serology: the Canadian context. *Can Commun Dis Rep*, *46*(5), 125-131. doi:10.14745/ccdr.v46i05a05

CDC. (2017, 2017-08-07T05:14:10Z). Diagnosis and Testing | Lyme Disease | CDC. Retrieved from <https://www.cdc.gov/lyme/diagnosis/testing/labtest/twostep/index.html>

CDC. (2018a). How many people get Lyme disease? Retrieved from <https://www.cdc.gov/lyme/stats/humancases.html#:~:text=Lyme%20disease%20cases%20are%20concentrated,is%20shown%20by%20national%20surveillance>.

CDC. (2018b). Laboratory tests that are not recommended. Retrieved from <https://www.cdc.gov/lyme/diagnosis/testing/labtest/otherlab/index.html>

CDC. (2018c). *Lyme disease data tables | Lyme Disease | CDC*. Retrieved from <https://www.cdc.gov/lyme/datasurveillance/recent-surveillance-data.html>

CDC. (2019a). Diagnosis and Testing | Lyme Disease | CDC. Retrieved from <https://www.cdc.gov/lyme/diagnosis/testing/labtest/twostep/index.html>

CDC. (2019b). Updated CDC Recommendation for Serologic Diagnosis of Lyme Disease. *68*(32). Retrieved from [https://www.cdc.gov/mmwr/volumes/68/wr/mm6832a4.htm?s\\_cid=mm6832a4\\_w](https://www.cdc.gov/mmwr/volumes/68/wr/mm6832a4.htm?s_cid=mm6832a4_w)

Cook, M. J. (2015). Lyme borreliosis: a review of data on transmission time after tick attachment. *Int J Gen Med*, *8*, 1-8. doi:10.2147/ijgm.s73791

Davis, I. R. C., McNeil, S. A., Allen, W., MacKinnon-Cameron, D., Lindsay, L. R., Bernat, K., . . . Hatchette, T. F. (2020). Performance of a Modified Two-Tiered Testing Enzyme Immunoassay Algorithm for Serologic Diagnosis of Lyme Disease in Nova Scotia. *Journal of Clinical Microbiology*, *58*(7), e01841-01819. doi:10.1128/jcm.01841-19

Halperin, J. J. (2015). Chronic Lyme disease: misconceptions and challenges for patient management. *Infect Drug Resist*, *8*, 119-128. doi:10.2147/idr.s66739

Hu, L. (2018). Diagnosis of Lyme disease - UpToDate. In J. Mitty (Ed.), *UpToDate*. Retrieved from [https://www.uptodate.com/contents/diagnosis-of-lyme-disease?search=lyme%20disease&source=search\\_result&selectedTitle=3~150&usage\\_type=default&display\\_rank=3](https://www.uptodate.com/contents/diagnosis-of-lyme-disease?search=lyme%20disease&source=search_result&selectedTitle=3~150&usage_type=default&display_rank=3)

Hu, L. (2019). Diagnosis of Lyme disease - UpToDate. In J. Mitty (Ed.), *UpToDate*. Retrieved from [https://www.uptodate.com/contents/diagnosis-of-lyme-disease?search=lyme%20disease&source=search\\_result&selectedTitle=3~150&usage\\_type=default&display\\_rank=3](https://www.uptodate.com/contents/diagnosis-of-lyme-disease?search=lyme%20disease&source=search_result&selectedTitle=3~150&usage_type=default&display_rank=3)

Hyde, J. A. (2017). *Borrelia burgdorferi* Keeps Moving and Carries on: A Review of Borrelial Dissemination and Invasion. *Front Immunol*, *8*. doi:10.3389/fimmu.2017.00114

IDEG. (2020). Guidance for Primary Care and Emergency Medicine Providers in the Management of Lyme Disease in Nova Scotia. Retrieved from [https://novascotia.ca/dhw/cdpc/documents/statement\\_for\\_managing\\_ld.pdf](https://novascotia.ca/dhw/cdpc/documents/statement_for_managing_ld.pdf)

Igenex. (2017a). Development of a sensitive PCR-dot blot assay to supplement serological tests for diagnosing Lyme disease. Retrieved from [https://igenex.com/wp-content/uploads/Publication\\_Development\\_of\\_a\\_Sensitive\\_PCR-dot\\_Blot\\_Assay\\_to\\_Supplement\\_Serological\\_Tests\\_for\\_Diagnosing\\_Lyme\\_Disease.png.pdf](https://igenex.com/wp-content/uploads/Publication_Development_of_a_Sensitive_PCR-dot_Blot_Assay_to_Supplement_Serological_Tests_for_Diagnosing_Lyme_Disease.png.pdf)

Igenex. (2017b). Lyme ImmunoBlot. Retrieved from <https://igenex.com/wp-content/uploads/LymeImmunoBlot-DataSheet.pdf>

John, T. M., & Taege, A. J. (2019). Appropriate laboratory testing in Lyme disease. *Cleve Clin J Med*, 86(11), 751-759. doi:10.3949/ccjm.86a.19029

Joung, H. A., Ballard, Z. S., Wu, J., Tseng, D. K., Teshome, H., Zhang, L., . . . Ozcan, A. (2019). Point-of-Care Serodiagnostic Test for Early-Stage Lyme Disease Using a Multiplexed Paper-Based Immunoassay and Machine Learning. *ACS Nano*. doi:10.1021/acsnano.9b08151

Lantos, P. M., Rumbaugh, J., Bockenstedt, L. K., Falck-Ytter, Y. T., Aguero-Rosenfeld, M. E., Auwaerter, P. G., . . . Zemel, L. S. (2020). 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*. doi:10.1093/cid/ciaa1215

Margos, G., Marosevic, D., Cutler, S., Derdakova, M., Diuk-Wasser, M., Emler, S., . . . Fingerle, V. (2017). There is inadequate evidence to support the division of the genus *Borrelia*. *Int J Syst Evol Microbiol*, 67(4), 1081-1084. doi:10.1099/ijsem.0.001717

Marques, A. R. (2015). Laboratory diagnosis of Lyme disease: advances and challenges. *Infect Dis Clin North Am*, 29(2), 295-307. doi:10.1016/j.idc.2015.02.005

Mead, P., Petersen, J., & Hinckley, A. (2019). Updated CDC Recommendation for Serologic Diagnosis of Lyme Disease. *MMWR Morb Mortal Wkly Rep*, 68(32), 703. doi:10.15585/mmwr.mm6832a4

NICE. (2018). Lyme disease. Retrieved from <https://www.nice.org.uk/guidance/ng95/chapter/Recommendations>

NICE. (2019). National Institute for Health and Care Excellence (NICE): Quality standard on Lyme disease. Retrieved from <https://www.nice.org.uk/guidance/qs186/chapter/Quality-statements>

NICE. (2020). Diagnosing Lyme disease. Retrieved from file:///C:/Users/AHCS8330/Downloads/lyme-disease-diagnosing-lyme-disease.pdf

Nigrovic, L. E., Lewander, D. P., Balamuth, F., Neville, D. N., Levas, M. N., Bennett, J. E., & Garro, A. (2019). The Lyme Disease Polymerase Chain Reaction Test Has Low Sensitivity. *Vector Borne Zoonotic Dis*. doi:10.1089/vbz.2019.2547

Onyett, H. (2020). Lyme disease in Canada: Focus on children. Retrieved from <https://www.cps.ca/en/documents/position/lyme-disease-children>

PHAC. (2020). For health professionals: Lyme disease. Retrieved from <https://www.canada.ca/en/public-health/services/diseases/lyme-disease/health-professionals-lyme-disease.html#a3>

Pritt, B. S., Mead, P. S., Johnson, D. K. H., Neitzel, D. F., Respicio-Kingry, L. B., Davis, J. P., . . . Petersen, J. M. (2016). Identification of a novel pathogenic *Borrelia* species causing Lyme borreliosis with unusually high spirochaetaemia: a descriptive study. *Lancet Infect Dis*, 16(5), 556-564. doi:10.1016/s1473-3099(15)00464-8

Schriefer, M. E. (2015). Lyme Disease Diagnosis: Serology. *Clin Lab Med*, 35(4), 797-814. doi:10.1016/j.cll.2015.08.001

Shakir, S. M., Mansfield, C. R., Hays, E. D., Couturier, M. R., & Hillyard, D. R. (2019). Evaluation of a Novel High-Definition PCR Multiplex Assay for the Simultaneous Detection of Tick-Borne Pathogens in Human Clinical Specimens. *J Clin Microbiol*. doi:10.1128/jcm.01655-19

Waddell, L. A., Greig, J., Mascarenhas, M., Harding, S., Lindsay, R., & Ogden, N. (2016). The Accuracy of Diagnostic Tests for Lyme Disease in Humans, A Systematic Review and Meta-Analysis of North American Research. *PLoS One*, 11(12), e0168613. doi:10.1371/journal.pone.0168613

Weitzner, E., McKenna, D., Nowakowski, J., Scavarda, C., Dornbush, R., Bittker, S., . . . Wormser, G. P. (2015). Long-term Assessment of Post-Treatment Symptoms in Patients With Culture-Confirmed Early Lyme Disease. *Clin Infect Dis*, 61(12), 1800-1806. doi:10.1093/cid/civ735

Wormser, G. P., Schriefer, M., Aguero-Rosenfeld, M. E., Levin, A., Steere, A. C., Nadelman, R. B., . . . Dumler, J. S. (2013). Single-tier testing with the C6 peptide ELISA kit compared with two-tier testing for Lyme disease. *Diagn Microbiol Infect Dis*, 75(1), 9-15. doi:10.1016/j.diagmicrobio.2012.09.003

ZEUS\_Scientific. (2019). ZEUS Borrelia MTTT™: A paradigm shift in testing for Lyme disease. Retrieved from <https://www.zeusscientific.com/what-is-mttt>

### Policy Update History:

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| 5/1/2022 | New policy |
|----------|------------|