



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. BCBSOK may use reasonable discretion interpreting and applying this policy to services being delivered in a particular case. BCBSOK 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 Testing

Policy Number: CPCPLAB044

Version 1.0

Approval Date: April 12, 2023

Plan Effective Date: November 1, 2023

Description

BCBSOK 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. 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) **may be reimbursable**
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) **may be reimbursable** 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 **is not reimbursable** 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/arthritis)..
 - 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. 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. For individuals who have previously tested positive for Lyme disease, repeat serologic testing **is not reimbursable** in individuals.
6. All other testing for *Borrelia burgdorferi* not described above **is not reimbursable**.
7. For the diagnosis of Lyme disease, testing of the individual tick **is not reimbursable**

Procedure Codes

The following is not an all-encompassing code list. The inclusion of a code does not guarantee it is a covered service or eligible for reimbursement.

Codes
86617, 86618, 87475, 87476, 0041U, 0042U, 0316U

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*. <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. <https://doi.org/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. <https://www.cdc.gov/mmwr/preview/mmwrhtml/ss5710a1.htm>
- Barbour, A. (2022). Microbiology of Lyme disease - UpToDate. In J. Mitty & A. C. Steere (Eds.), *UpToDate*. <https://www.uptodate.com/contents/microbiology-of-lyme-disease>
- Bunikis, J., & Barbour, A. G. (2002). Laboratory testing for suspected Lyme disease. *Med Clin North Am*, 86(2), 311-340. <https://pubmed.ncbi.nlm.nih.gov/11982304/>
- CCDR. (2020). Modified two-tiered testing algorithm for Lyme disease serology: the Canadian context. *Can Commun Dis Rep*, 46(5), 125-131. <https://doi.org/10.14745/ccdr.v46i05a05>
- CDC. (2018, December 21, 2018). *Laboratory tests that are not recommended*. <https://www.cdc.gov/lyme/diagnosis/testing/labtest/otherlab/index.html>
- CDC. (2019). Updated CDC Recommendation for Serologic Diagnosis of Lyme Disease. 68(32). https://www.cdc.gov/mmwr/volumes/68/wr/mm6832a4.htm?s_cid=mm6832a4_w
- CDC. (2021a). *Diagnosis and Testing | Lyme Disease | CDC*. Retrieved 1/11/21 from <https://www.cdc.gov/lyme/diagnosis/testing/labtest/twostep/index.html>
- CDC. (2021b). How many people get Lyme disease? <https://www.cdc.gov/lyme/stats/humancases.html#:~:text=Lyme%20disease%20cases%20are%20concentrated,is%20shown%20by%20national%20surveillance.>
- Cook, M. J. (2015). Lyme borreliosis: a review of data on transmission time after tick attachment. *Int J Gen Med*, 8, 1-8. <https://doi.org/10.2147/ijgm.s73791>
- Davis, I. R. C., McNeil, S. A., Allen, W., MacKinnon-Cameron, D., Lindsay, L. R., Bernat, K., Dibernardo, A., LeBlanc, J. J., & 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. <https://doi.org/10.1128/jcm.01841-19>
- Halperin, J. J. (2015). Chronic Lyme disease: misconceptions and challenges for patient management. *Infect Drug Resist*, 8, 119-128. <https://doi.org/10.2147/idr.s66739>
- Hu, L. (2022). Diagnosis of Lyme disease - UpToDate. In J. Mitty (Ed.), *UpToDate*. <https://www.uptodate.com/contents/diagnosis-of-lyme-disease>
- Hyde, J. A. (2017). *Borrelia burgdorferi* Keeps Moving and Carries on: A Review of Borrelial Dissemination and Invasion. *Front Immunol*, 8. <https://doi.org/10.3389/fimmu.2017.00114>

Igenex. (2017a). *Development of a sensitive PCR-dot blot assay to supplement serological tests for diagnosing Lyme disease*. 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*. <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. <https://doi.org/10.3949/ccjm.86a.19029>

Joung, H. A., Ballard, Z. S., Wu, J., Tseng, D. K., Teshome, H., Zhang, L., Horn, E. J., Arnaboldi, P. M., Dattwyler, R. J., Garner, O. B., Di Carlo, D., & Ozcan, A. (2019). Point-of-Care Serodiagnostic Test for Early-Stage Lyme Disease Using a Multiplexed Paper-Based Immunoassay and Machine Learning. *ACS Nano*. <https://doi.org/10.1021/acsnano.9b08151>

Lantos, P. M., Rumbaugh, J., Bockenstedt, L. K., Falck-Ytter, Y. T., Agüero-Rosenfeld, M. E., Auwaerter, P. G., Baldwin, K., Bannuru, R. R., Belani, K. K., Bowie, W. R., Branda, J. A., Clifford, D. B., DiMario, F. J., Jr., Halperin, J. J., Krause, P. J., Lavergne, V., Liang, M. H., Meissner, H. C., Nigrovic, L. E., . . . Zemel, L. S. (2021). 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*. <https://doi.org/10.1093/cid/ciaa1215>

Margos, G., Marosevic, D., Cutler, S., Derdakova, M., Diuk-Wasser, M., Emler, S., Fish, D., Gray, J., Hunfeldt, K. P., Jaulhac, B., Kahl, O., Kovalev, S., Kraiczky, P., Lane, R. S., Lienhard, R., Lindgren, P. E., Ogden, N., Ornstein, K., Rupprecht, T., . . . Fingerle, V. (2017). There is inadequate evidence to support the division of the genus *Borrelia*. *Int J Syst Evol Microbiol*, 67(4), 1081-1084. <https://doi.org/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. <https://doi.org/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. <https://doi.org/10.15585/mmwr.mm6832a4>

Mead, P., & Schwartz, A. (2022). Epidemiology of Lyme disease In A. C. Steere & K. K. Hall (Eds.), *UpToDate*. <https://www.uptodate.com/contents/epidemiology-of-lyme-disease>

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

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

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*. <https://doi.org/10.1089/vbz.2019.2547>

Pritt, B. S., Mead, P. S., Johnson, D. K. H., Neitzel, D. F., Respicio-Kingry, L. B., Davis, J. P., Schiffman, E., Sloan, L. M., Schriefer, M. E., Replogle, A. J., Paskewitz, S. M., Ray, J. A., Bjork, J., Steward, C. R., Deedon, A., Lee, X., Kingry, L. C., Miller, T. K., Feist, M. A., . . . 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. [https://doi.org/10.1016/s1473-3099\(15\)00464-8](https://doi.org/10.1016/s1473-3099(15)00464-8)

Sabin, A. P., Scholze, B. P., Lovrich, S. D., & Callister, S. M. (2023). Clinical evaluation of a *Borrelia* modified two-tiered testing (MTTT) shows increased early sensitivity for *Borrelia burgdorferi* but not other endemic *Borrelia* species in a high incidence region for Lyme disease in Wisconsin. *Diagn Microbiol Infect Dis*, 105(1), 115837. <https://doi.org/10.1016/j.diagmicrobio.2022.115837>

Schriefer, M. E. (2015). Lyme Disease Diagnosis: Serology. *Clin Lab Med*, 35(4), 797-814. <https://doi.org/10.1016/j.cl.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*. <https://doi.org/10.1128/jcm.01655-19>

van Gorkom, T., Voet, W., Sankatsing, S. U. C., Nijhuis, C. D. M., Ter Haak, E., Kremer, K., & Thijsen, S. F. T. (2020). Prospective comparison of two enzyme-linked immunosorbent spot assays for the diagnosis of Lyme neuroborreliosis. *Clin Exp Immunol*, 199(3), 337-356. <https://doi.org/10.1111/cei.13393>

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. <https://doi.org/10.1371/journal.pone.0168613>

Weitzner, E., McKenna, D., Nowakowski, J., Scavarda, C., Dornbush, R., Bittker, S., Cooper, D., Nadelman, R. B., Visintainer, P., Schwartz, I., & 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. <https://doi.org/10.1093/cid/civ735>

Wormser, G. P., Schriefer, M., Aguero-Rosenfeld, M. E., Levin, A., Steere, A. C., Nadelman, R. B., Nowakowski, J., Marques, A., Johnson, B. J., & 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. <https://doi.org/10.1016/j.diagmicrobio.2012.09.003>

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

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8/15/2023	Document updated with literature review. Reimbursement information revised for clarity. References revised; some added, others removed.