CHRONIC LYME DISEASE SUPPORT PROTOCOL

designs for health®

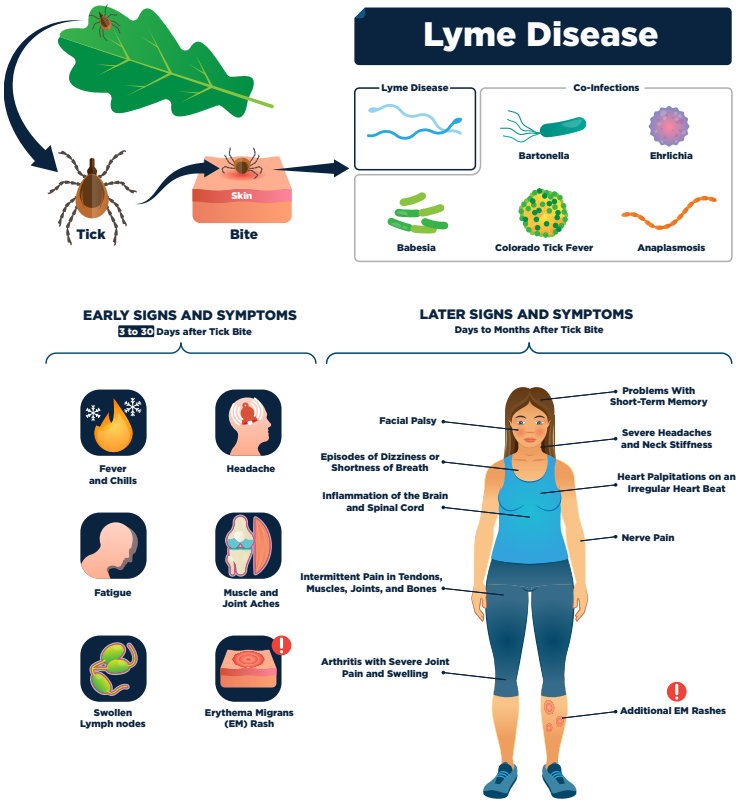
CLINICAL PROTOCOL TO ADDRESS IMMUNITY AND CO-INFECTION*

The Pathophysiology of Lyme Disease

A tick bite infection is the most common transmission of Lyme disease to humans (or Lyme borreliosis infections common to the U.S.), but not all tick species carry the disease. Tickborne diseases have similar signs and symptoms, and the geographic region of the tick species likely indicates the type of infection.[1] Although the incubation period varies, most infections are evidenced by a skin lesion within 3 to 30 days. This lesion is usually identifiable by a classic bull's eye–patterned rash occurring in approximately 70% to 80% of people, and was named the Southern Tick-Associated Rash Illness (STARI).[2] This rash occurs in the first of three infection stages (early localized, early disseminated, and late).[3]

Clinical presentations vary by stage and may include flu-like symptoms with fever and headaches, general malaise, rheumatological conditions such as myalgia and arthralgia, cardiac and neurological abnormalities, and lymphadenopathy. For some people, fatigue or brain fog may be their only symptoms. From a lifestyle perspective, this condition can be very debilitating and tick bite avoidance is the first defense. Naturally occurring cases are commonly estimated at 300,000 per year in the U.S., with additional tick-bite infectious reports now found to occur throughout the world.[4] However, some infections cannot be as easily traced to its origin, as the individual may be unaware they have been bitten.

This clinical protocol is designed to support the importance of early intervention and diagnosis, lifestyle modifications, and probiotic and herbal supplementation for patients presenting with Lyme disease.



Diagnostic Biomarkers/Clinical Indicators in Lyme Disease

- Two-tier serologic assay consisting of an enzyme-linked immunosorbent assay (ELISA) followed by an immunoblot[5,6]
- Early disease is indicated by the characteristic erythema migrans (EM) rash (however, an EM only presents in 60% to 80% of patients)[7]
- Late-stage infection can be characterized by persistent neurological signs and/or arthritis[8]
- Consider blood tests that include co-infections: Babesiosis, Bartonellosis, Ehrlichiosis, Powassan virus (POWV), Human granulocytic anaplasmosis (HGA), Epstein-Barr Virus (EBV), Cytomegalovirus (CMV)
- Monitor and examine blood sugar regulation. Hyperglycemia is known to impair neutrophil-mediated bacterial clearance of *Borrelia burgdorferi*[9]:
  - Fasting glucose
  - Hemoglobin A1C
  - Fasting insulin
  - C-peptide
  - Glucose tolerance test

Lifestyle Interventions

- Support stress management through lifestyle intervention and practices such as mindfulness-based stress reduction, meditation, and breath work
- Encourage patients to prioritize sleep for optimal energy and resolution of fatigue

Therapeutic Diet and Nutritional Considerations

- Recommend adoption of a low glycemic diet, high in dietary fiber, to help regulate blood sugar and prevent hyperglycemia
- Advise an increase in consumption of omega-3 fatty acids through intake of cold-water fish or dietary supplements such as OmegAvail TG1000 or SPM Supreme to address and support inflammatory pathways.* Inflammatory mediators are associated with pathophysiology of Lyme disease severity[10,11]

SUPPLEMENT PROTOCOL/REGIMEN

Primary Support:

Liposomal Cat's Claw Synergy	
Dose	2 pumps three times per day
Duration	3 months; reevaluate biomarkers, signs and symptoms
Formula Highlights	Liposomal Cat's Claw Synergy provides a unique blend of cat's claw, monolaurin, vitamin D and other ingredients formulated with liposomal technology. Liposomes are spheres made of phospholipids—the primary building blocks of cell membranes. Owing to this structure, liposomes bond easily with cell membranes to facilitate intracellular delivery of their nutrient cargo. Thanks to this enhanced delivery and absorption, nutrients delivered in liposomal form offer superior absorption and bioavailability. Each 1 mL serving (approx 2 pumps) of this formula provides a proprietary blend of ingredients including cat's claw, monolaurin, lemon balm extract, mint oil, vitamin D and other compounds

Silvercillin™ Liquid	
Dose	1 tablespoon twice per day
Duration	3 months; reevaluate biomarkers, signs and symptoms
Formula Highlights	Silvervillin is an effective preparation of pure silver complexed with purified water, which exhibits antimicrobial properties *in vitro.** Silvercillin™ uses Silver Sol Technology®, the term "sol" being a designation of a mineral permanently distributed into the structure of water. The silver becomes a part of that water molecule permanently so it will not fall out of the solution or suspension. Silvercillin™ contains 15 ppm of purified silver per serving. This is an incredibly powerful, non-toxic form of silver, with zero build-up in the body, so it does not cause argyria (blue man syndrome).*

Immunitone Plus™	
Dose	2-3 capsules three times per day
Duration	3 months; reevaluate biomarkers, signs and symptoms
Formula Highlights	Immunitone Plus™ is an herbal formula that is designed to support healthy immune system function.* It contains herbs that support normal natural killer (NK) cell activity and the balance of cytokines, which are the regulatory proteins released by immune cells as part of a normal immune system response.* The standardized herbs in this formula contain optimal and consistent amounts of the most active ingredients. Immunitone Plus™ is suitable for long-term use and for all age groups.

Allicillin™	
Dose	2-3 softgels three times per day
Duration	3 months; reevaluate biomarkers, signs and symptoms
Formula Highlights	Allicillin™ softgels contain Garlicillin™, a blend of garlic oil and parsley oil with specified levels of garlic sulfides and ajoene, the most bioactive compound formed from garlic. These softgels are enteric-coated to reduce the strong garlic odor and repeating that may occur from supplementing with garlic. The parsley oil further helps as a natural breath freshener.

References:

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2. Centers for Disease Control and Prevention. Ticks: symptoms of tickborne illness. https://www.cdc.gov/ticks/symptoms.html. Accessed: November 2, 2020.
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4. Steere AC, Strle F, Wormser GP, et al. Lyme borreliosis. Nat Rev Dis Primers 2016;2:16090. doi.org/10.1038/nrdp.2016.90
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7. Steere A. C. (1989). Lyme disease. N. Engl. J. Med. 321, 586–596. 10.1056/NEJM198908313210906
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9. Javid A, Zlotnikov N, Pětrošová H, et al. Hyperglycemia Impairs Neutrophil-Mediated Bacterial Clearance in Mice Infected with the Lyme Disease Pathogen. PLoS One. 2016;11(6):e0158019. Published 2016 Jun 24. doi:10.1371/journal.pone.0158019
10. Soloski MJ, Crowder LA, Lahey LJ, Wagner CA, Robinson WH, Aucott JN. Serum inflammatory mediators as markers of human Lyme disease activity. PLoS One. 2014;9(4):e93243. Published 2014 Apr 16. doi:10.1371/journal.pone.0093243
11. Ramesh G, Didier PJ, England JD, et al. Inflammation in the pathogenesis of lyme neuroborreliosis. Am J Pathol. 2015;185(5):1344-1360. doi:10.1016/j.ajpath.2015.01.024

Dosing recommendations are given for typical use based on an average 150 pound healthy adult. Health care practitioners are encouraged to use clinical judgement with case-specific dosing based on intended goals, subject body weight, medical history, and concomitant medication and supplement usage. Any product containing botanical substances has the potential for causing individual sensitivities, appropriate monitoring, including liver function tests (LFT) is recommended.

For considerations around herb/nutrient-drug interactions, please refer to reliable, evidence-based resources such as Natural Medicine Database or Stargrove, M. B., Treasure, J., & McKee, D. L. (2008). *Herb, nutrient, and drug interactions: Clinical implications and therapeutic strategies.* St. Louis, Mo: Mosby Elsevier.

***These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.**