

## Highlights of the new restrictive IDSA treatment guidelines with commentary

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“Clinical findings are sufficient for the diagnosis of erythema migrans [rash], but clinical findings alone are not sufficient for diagnosis of extracutaneous manifestations of Lyme disease or for diagnosis of HGA or babesiosis. . . .“Erythema migrans is the only manifestation of Lyme disease in the United States that is sufficiently distinctive to allow clinical diagnosis in the absence of laboratory confirmation.”

*Comment: The guidelines now entirely preclude the exercise of clinical discretion in diagnosis of Lyme disease. (The sole exception is the diagnosis of the rash.) It is known by CDC surveillance criteria that at least 31% of CDC surveillance cases do not have a rash.[1] This means that these patients cannot be diagnosed without positive lab tests. Yet it is also known that patients with probable or possible Lyme test positive only 26-69% of the time.[2] Physician diagnosed cases, which include the use of clinical discretion, exceed CDC surveillance cases 30 fold.[3] Exclusion of clinical discretion ensures that countless patients with Lyme disease will go undiagnosed and untreated. Many diseases, like MS for example, lack gold standard testing and must rely on clinical discretion.*

“Because of a lack of biologic plausibility, lack of efficacy, absence of supporting data, or the potential for harm to the patient, the following are *not* recommended for treatment of patients with any manifestation of Lyme disease: first-generation cephalosporins, fluoroquinolones, carbapenems, vancomycin, metronidazole, tinidazole, amantadine, ketolides, isoniazid, trimethoprim-sulfamethoxazole, fluconazole, benzathine penicillin G, combinations of antimicrobials, pulsed-dosing (i.e., dosing on some days but not others), long-term antibiotic therapy, anti-*Bartonella* therapies, hyperbaric oxygen, ozone, fever therapy, intravenous immunoglobulin, cholestyramine, intravenous hydrogen peroxide, specific nutritional supplements, and others (see table 4) (E-III).

*Comment: Note again, the evidentiary rating E-III (strong recommendation based on little evidence) It is not common to see extensive lists of prohibited practices in treatment guidelines. Here, the list appears to be directly targeted at the treatment practices of physicians following the ILADS treatment guidelines. This means that insurers may deny coverage of the prohibited practices, hospitals may use this list to deny or revoke hospital privileges, and medical boards may use this list to pursue unprofessional conduct actions.*

“There is no well-accepted definition of post-Lyme disease syndrome. This has contributed to confusion and controversy and to a lack of firm data on its incidence, prevalence, and pathogenesis. In an attempt to provide a framework for future research on this subject and to reduce diagnostic ambiguity in study populations, a definition for post-Lyme disease syndrome is proposed in these guidelines. Whatever definition is eventually adopted, having once had objective evidence of *B. burgdorferi* infection must be a condition sine qua non. Furthermore, when laboratory testing is done to support the original diagnosis of Lyme disease, it is essential that it be performed by well-qualified and reputable laboratories that use recommended and appropriately validated testing methods and interpretive criteria. Unvalidated test methods (such as urine antigen tests or blood microscopy for *Borrelia* species) should not be used. There is no convincing biologic evidence for the existence of symptomatic chronic *B. burgdorferi* infection among patients after receipt of recommended treatment regimens for Lyme disease. Antibiotic therapy has not proven to be useful and is not recommended for patients with chronic (6 months) subjective symptoms after recommended treatment regimens for Lyme disease (E-I).”

*Comment: Here is another attempt to narrow the definition of the disease for “future research and to reduce diagnostic ambiguity in study populations .The emphasis is again on “objective evidence” and the E-I evidence rating for the recommendation that antibiotic treatment is ineffective is the highest rated evidence, but is based on only one of the three treatment studies funded by the NIH—a treatment study authored by one of the panel members to the exclusion of the other two studies, which yielded conflicting results*

1. Centers for Disease Control and Prevention. Lyme Disease -- United States, 1991-1992. MMWR. 1993; 42(18): 345.

2. Coulter P, C Lema, D Flayhart, A Linhardt, J Aucott, P Auwaerter, and J Dumler. Two-year evaluation of *Borrelia burgdorferi* culture and supplemental tests for definitive diagnosis of Lyme disease. J. Clin. Microbiology. 2005; 43(10): 5080-84.

3. Boltri JM, RB Hash, and RL Vogel. Patterns of Lyme disease diagnosis and treatment by family physicians in a southeastern state. J Community Health. 2002; 27(6): 395-402.