



## Effective Health Care Chronic Lyme Disease Nomination Summary Document

### Results of Topic Selection Process & Next Steps

- The topic of *Chronic Lyme Disease* is addressed by a small, but consistent, body of evidence that indicates that long-term antibiotic use is not beneficial and can result in harms. Given that these existing reports and guidelines address this nomination, no further activity will be undertaken on this topic.

National Institute of Allergy and Infectious Diseases. Chronic Lyme Disease. Last Updated: April 16, 2009.

<http://www.niaid.nih.gov/topics/lymedisease/understanding/pages/chronic.aspx>

Wormser GP, Dattwyler RJ, Shapiro ED, et al. The clinical assessment, treatment, and prevention of Lyme disease, human granulocytic anaplasmosis, and babesiosis: clinical practice guidelines by the Infectious Diseases Society of America. *Clinical Infectious Diseases: an official publication of the Infectious Diseases Society of America*. 2006 Nov 1;43(9):1089-134.

Lantos PM, Charini WA, Medoff G, et al. Final report of the Lyme disease review panel of the Infectious Diseases Society of America. *Clinical infectious diseases: an official publication of the Infectious Diseases Society of America*. 2010 Jul 1;51(1):1-5.

Halperin JJ, Shapiro ED, Logigian E, et al. Practice parameter: treatment of nervous system Lyme disease (an evidence-based review). Report of the Quality Standards Subcommittee of the American Academy of Neurology. *Neurology*. 2007 Jul 3;69:1-12.

Mygland A, Ljostad U, Fingerle V, Rupprecht T, Schmutzhard E, Steiner I, European Federation of Neurological Societies. EFNS guidelines on the diagnosis and management of European Lyme neuroborreliosis. *European Journal of Neurology*. 2010 Jan;17(1):8-16, e1-4.

### Topic Description

**Nominator(s):** *Individual*

**Nomination Summary:** The nominator asserts that there is skepticism regarding the existence of and current treatment guidelines for chronic Lyme disease. The nominator believes that an additional review might persuade guideline developers to recommend long-term treatment (beyond 2-4 weeks) with antibiotics.

**Staff-Generated PICO [or PICO from Nomination if supplied in nomination]**

**Population(s):** Patients diagnosed with chronic Lyme disease

**Intervention(s):** Long-term antibiotic treatment

**Comparator(s):** Placebo, antibiotic treatment beyond 2-4 weeks.

**Outcome(s):** Symptoms of chronic Lyme disease

**Key Questions from Nominator:** Are the currently employed treatments (long-term antibiotics, beyond 2-4 weeks) for chronic Lyme efficacious?

### Considerations

- The topic meets EHC Program appropriateness and importance criteria. (For more information, see [http://effectivehealthcare.ahrq.gov/index.cfm/submit-a-suggestion-for-research/how-are-research-topics-chosen/.](http://effectivehealthcare.ahrq.gov/index.cfm/submit-a-suggestion-for-research/how-are-research-topics-chosen/))
- Lyme disease is caused by the bacterium *Borrelia burgdorferi* and is transmitted to humans through tick bites. Symptoms include fever, headache, fatigue, and a characteristic skin rash called erythema migrans. Treatment involves a 2-4 week course of antibiotics.
- Subsets of patients treated for Lyme disease continue to have lingering symptoms of fatigue, pain, or joint and muscle aches. In some cases, the symptoms can persist for six months or longer. The presence of these symptoms after the treatment of Lyme disease is referred to as chronic Lyme disease, or post-Lyme disease syndrome. The exact cause of such symptoms is not yet known. Although most medical experts believe that the lingering symptoms are the result of residual damage to tissues and the immune system that occurred during the infection, some clinicians believe that the symptoms are caused by an ongoing low-grade infection. This has resulted in the clinical controversy regarding the value of antibiotic treatment for chronic Lyme disease after the administration of the recommended 2-4 week treatment regimens for acute Lyme disease.
- Existing evidence-based clinical practice guidelines that recommend antibiotic treatment with doxycycline or amoxicillin for 3-4 weeks total.

The Infectious Diseases Society of America (IDSA) states antibiotic therapy has not proven to be useful after initial treatment and is thus not recommended for patients with chronic subjective symptoms after administration of recommended treatment regimens for Lyme disease. This was most recently reviewed in 2010 as per an agreement between IDSA and the Connecticut Attorney General that required a new review panel to undertake a special review of the 2006 guidelines regarding chronic Lyme disease. The review panel concluded that the recommendations contained in the 2006 guidelines were medically and scientifically justified based on all of the available evidence and that no changes to the guidelines were necessary.

The American Academy of Neurology (AAN) determined that post-Lyme syndrome does not respond to prolonged courses of antibiotics and that such treatment can be associated with serious adverse events.

Based on its systematic literature review, the European Federation of Neurological Societies concluded that antibiotic therapy has no impact on chronic Lyme disease.

- Published clinical trials relevant to this topic also found that additional (i.e., beyond the 2-4 week recommended treatment period for Lyme disease) antibiotic therapy was not associated with an improvement in symptoms compared to a placebo.
- Given the consistency of findings from the clinical practice guidelines and the available evidence, no further activity will be undertaken on this topic.