

## Informed Consent for Treatment of Persistent Lyme Disease

Patient-centered care focuses on shared medical decision-making that takes into account the individual circumstances and values of the patient. It is particularly important when the evidence base is uncertain. Patient involvement is also critical to make the “right choice” when different combinations of treatment options, uncertain outcomes and implicit trade-offs exist. Under shared decision-making, clinicians are viewed as the experts in the evidence and patients are the experts in what matters most to them.

There is considerable uncertainty regarding the diagnosis and treatment of Lyme disease. No single diagnostic and treatment program for Lyme disease is universally successful or accepted. Medical opinion is divided, and two schools of thought regarding diagnosis and treatment exist. Each of the two schools of thought is described in peer-reviewed, evidence-based treatment guidelines. Until we know more, patients must weigh the risks and benefits of treatment in consultation with their doctor.

**Diagnosis.** The diagnosis of Lyme disease is primarily a clinical determination made by the doctor based on your exposure to ticks and your signs and symptoms of the disease, with diagnostic tests playing a supportive role. Doctors differ in how they diagnose Lyme disease.

- Some physicians rely on the narrow surveillance case criteria of the CDC for clinical diagnosis even though the CDC itself cautions against this approach. These physicians may fail to diagnose some patients who actually have Lyme disease. These patients are likely to develop a more complicated and difficult-to-treat illness.
- Other physicians use broader clinical criteria for diagnosing Lyme disease. These physicians believe it is better to err on the side of treatment because of the serious consequences of failing to treat active Lyme disease. These physicians sometimes use the antibiotic responsiveness of the patient to assist in their diagnosis. Since no treatment is risk-free, use of broader clinical criteria to diagnose disease could in some cases expose patients to treatment side-effects and complications. This approach may result in a tendency to over-diagnose and over-treat Lyme disease.

**Treatment Options.** The medical community is divided regarding the best approach for treating persistent Lyme disease. At this time, many physicians follow the treatment guidelines of the Infectious Diseases Society of America (IDSA) that recommend short-term treatment only. They view the long-term effects of Lyme disease as an autoimmune process or permanent damage that is unaffected by antibiotics. Other physicians believe that the infection persists, is difficult to eradicate, and therefore requires long-term treatment with intravenous, intramuscular, or oral antibiotics, frequently in high and/or combination doses. These physicians follow the guidelines promulgated by the International Lyme and Associated Diseases Society (ILADS).

The guidelines of the IDSA strongly recommend against many of the common treatment approaches used by physicians who follow the ILADS guidelines, including larger doses of antibiotics, combination antibiotic therapy, repeated therapy, and pulsed-dosing (antibiotics used on some days, but not others).

**Potential Benefits of Treatment.** Very few clinical trials on the treatment of persistent Lyme disease have been conducted, the sample size have been small, and the results have conflicted. Some clinical studies support longer term treatment approaches, while others do not. In addition, patients vary in their clinical manifestations, the presence of co-infections, and their response to treatment.

**Deciding Whether to Treat.** There are potential risks involved in using any treatment, just as there are in foregoing treatment entirely. Some of the problems with antibiotics may include (a) allergic reactions, which may manifest as rashes, swelling, and breathing difficulty; (b) stomach or bowel upset; or (c) yeast infections. Severe allergic reactions may require emergency treatments, while other problems may require suspension of treatment or adjustment of medication. Other problems such as

adverse effects on liver, kidneys, gallbladder, or other organs may occur. Patients who elect not to treat run the risk of permitting an infectious process to progress.

**Factors to consider in your decision.** No one knows the optimal treatment of symptoms that persist after a patient is diagnosed with Lyme disease and treated with a simple short course of antibiotic therapy. The appropriate treatment may be supportive therapy without the administration of any additional antibiotics. Or, the appropriate treatment might be additional antibiotic therapy. If additional antibiotic therapy is warranted, no one knows for certain exactly how long to give the additional therapy.

By taking antibiotics for longer periods of time, patients incur a greater risk of developing side effects. By stopping antibiotic treatment, patients incur a greater risk that a potentially serious infection will progress. Antibiotics are the only form of treatment shown to be effective for Lyme disease, but not all patients respond to antibiotic therapy. There is no currently available diagnostic test that can demonstrate the eradication of the Lyme bacteria in a patient. Other forms of treatment designed to strengthen the immune system also may be important. Some forms of treatment are only intended to make patients more comfortable by relieving symptoms and do not address any underlying infection.

The decision about continued treatment may depend on a number of factors and the importance of these factors to the individual patient, including (a) the severity of illness and degree to which it impairs quality of life, (b) whether co-infections are present, (c) a patient's ability to tolerate antibiotic treatment and the risk of major and minor side effects associated with the treatment, (d) whether the patient has been responsive to antibiotics in the past, (e) whether the patient's illness relapses or progresses when antibiotics are stopped, (f) the patient's willingness to accept the risk that, left untreated, a bacterial infection potentially may get worse, and (g) the costs associated with treatment.

For example, patients with severe illness that significantly affects quality of life who have been responsive to antibiotic treatment in the past, may wish to continue treatment. Patients who have been unresponsive to previous treatment, have less severe illness, or who are reluctant to take antibiotics may wish to terminate treatment. You can ask your doctor if you need any more information to make this decision and have the right to obtain a second opinion at any time if you think this would be helpful.

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**Antibiotics: I realize that the choice of treatment approach to use in treating my condition is will be a shared decision between me and my physician. After weighing the risks and benefits of the two treatment approaches, I have decided: (CHECK ONE)**

<input type="checkbox"/>	To treat my Lyme disease through a treatment approach that relies heavily on clinical judgment and may recommend using antibiotics until my clinical symptoms resolve. I recognize that this treatment approach does not conform to IDSA guidelines and that insurance companies may not cover the cost of some or all of my treatment. I understand that I may stop treatment at any time.
<input type="checkbox"/>	Only to treat my Lyme disease with antibiotics for thirty days, even if I still have symptoms.
<input type="checkbox"/>	Not to pursue antibiotic therapy

**To my knowledge, I am not allergic to any medications except those listed below:**

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I understand the benefits and risks of the proposed course of treatment, and of the alternatives to it, including the risks and benefits of foregoing treatment altogether. My questions have all been answered in terms I understand. All blanks on this document have been filled in as of the time of my signature.

**Signature:** \_\_\_\_\_

**Date:** \_\_\_\_\_

**Print Name:** \_\_\_\_\_

## **Intravenous Treatment Consent Form**

In certain situations, intravenous (IV) medications are preferred or may be used to supplement oral medications. IV treatment is sometimes recommended when there is neurological involvement, heart problems, severe joint inflammation, or inadequate response to oral medications. Because the GI system is bypassed, IV dosing greatly increases the probability of adequate medication blood levels and reduces gastrointestinal symptoms. IV antibiotics also may penetrate the blood brain barrier more effectively.

There are additional risks associated with IV treatment. IV treatment usually involves the installation of an intravenous line in my vein to allow easier IV treatment. PICC lines may result in local infection, or if unchecked, systemic infection. If signs of skin inflammation occur, the line may need to be removed. Rarely, PICC lines break off when they are being removed and may then require surgical removal. There is also a chance that, upon insertion, a nerve near the vein could be damaged. There is a risk of blood clots from PICC line insertion. If a clot forms, the PICC line may be removed and I may be hospitalized for the initiation of anti-coagulation therapy. The risk of clot development is decreased, although not eliminated, by flushing the PICC line twice daily with saline and heparin and by avoiding vigorous repetitive motion activity of the arm in which the PICC line is placed. The overall risk of significant adverse events for IV depends on the duration of treatment and is 1.8% per 1,000 days on an IV.

The major side effects of ceftriaxone, an intravenous antibiotic often used for treating persistent Lyme disease, include rash (in about 1.7% of all cases), diarrhea (2.7%), changes in liver function (approximately 3%) and gallstones (less than 1%). Ceftriaxone is related to penicillin, and a small percentage of patients with penicillin allergies will have allergic reactions to ceftriaxone (5-8%). Some patients when treated with ceftriaxone develop pain that seems like gallbladder disease. This usually goes away after the medication is stopped. However, some patients using ceftriaxone have had to have their gallbladders removed. Some doctors believe that this risk can be reduced by taking a medication called Actigall with the ceftriaxone. Other antibiotics commonly used to treat Lyme disease are not known to have gallbladder side effects. Monitoring my blood may help detect the development of any liver or gallbladder problems but does not guarantee that gallbladder or liver problems will not ensue.

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**My questions have all been answered in terms I understand. I am aware of the risks in foregoing IV treatment as well as the potential side effects if I undergo this treatment, and I consent to the use of IV treatment.**

**Signature:** \_\_\_\_\_

**Date:** \_\_\_\_\_

**Print Name:** \_\_\_\_\_