

Informed Consent for Treatment of Persistent Lyme Disease

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.

Your Diagnosis. The diagnosis of Lyme disease is primarily a clinical determination made by your doctor based on your exposure to ticks, your report of symptoms, and your doctor's observation of signs of the disease, with diagnostic test playing a supportive role.

Doctors differ in how they diagnose Lyme disease.

- Some physicians rely on surveillance case criteria of the Center for Disease Control (CDC) for clinical diagnosis, even though the CDC cautions against this approach and states that Lyme disease is a clinical diagnosis which should be made by a qualified physician. If the CDC case definition is followed strictly as a means to make a diagnosis of Lyme disease, physicians may fail to diagnose some patients who actually have Lyme disease. For these patients, treatment will either not occur or may be delayed.
- Other physicians use different criteria for diagnosing Lyme disease, relying heavily on exposure, case history, symptoms, and response to past or current therapies. These physicians use laboratory tests to supplement the clinical diagnosis, bearing in mind that some patients who have Lyme disease are seronegative (test negative on test) and placing a heavier weight on individual antibody bands as opposed to the CDC surveillance band criteria for tests. These physicians believe it is better to err on the side of treatment because of the potentially serious consequences of failing to treat active Lyme disease. This approach to your chronic illness may result in a tendency to over-diagnose and over-treat Lyme disease.

Your doctor also may need to rule out other possible causes of your symptoms, such as arthritis, lupus, syphilis, Reiter's syndrome, Multiple Sclerosis (MS), Chronic Fatigue Syndrome (CFS), and Fibromyalgia Syndrome (FMS).

Your Treatment Choices. The medical community is divided regarding the best approach for treating persistent Lyme disease. At this time the majority of physicians follow the treatment guidelines of the Infectious Disease Society of America, which recommends short-term treatment only and view the long-term effects of Lyme disease as an autoimmune process or permanent damage that is unaffected by antibiotics. Others believe that persistent symptoms reflect an on-going infection that is difficult to eradicate, and therefore requires long-term treatment with intravenous, intramuscular, or oral antibiotics, frequently in high and/or combination doses.

Your treatment options include:

1. Not pursuing antibiotic treatment and, if appropriate, seeking symptomatic relief for your continuing symptoms;
2. Treating your illness with antibiotics until clinical resolution of your symptoms, regardless of duration of treatment; or
3. Treating your illness with antibiotics for thirty days only.

If you elect to pursue antibiotic treatment, you will be treated with antibiotics selected to address the Lyme bacteria as well as any other tick-borne co-infections you may have, such as Ehrlichiosis, Babesiosis, or Bartonellosis. Your doctor will sometimes recommend IV medication when there is neurological involvement, carditis, complicated Lyme arthritis, or inadequate response to oral medications. Sometimes treatment consists of IV antibiotic treatment followed by oral antibiotics. Other classes of drugs may be needed to treat non-bacterial tick-borne diseases such as babesiosis.

Potential Benefits of Treatment. Antibiotic treatment may result in improvement in your clinical condition. Some clinical studies support longer term treatment approaches, while others do not. Although the experience at the Jemsek Specialty Clinic is that most patients improve with continued treatment, not all patients improve with treatment.

Patient response varies widely:

- Some patients experience substantial improvement of their symptoms and do not require further treatment,
- Some patients feel worse initially during treatment before improving,
- Some patients improve with antibiotic treatment but relapse when treatment stopped, and
- Some patients do not respond to antibiotic treatment. Sometimes persistent symptoms represent permanent changes to a patient's body, in which case further antibiotic treatments may be of no further benefit. Other times the illness progresses but, for unknown reasons, does not respond to additional treatment.

Risks of treatment. There are potential risks involved in using any treatment. Some of the problems with antibiotics can include allergic reactions, which may manifest as rashes, swelling, and difficulty with breathing. These problems may require medications to reverse the allergic reaction and may require emergency treatments. Other potential complications include stomach and bowel upset, abdominal pain, diarrhea, or bowel irritation, which may require interruption of the antibiotic and prescribing other medications to manage digestive upset. It is also possible that secondary infections such as yeast infection of the skin, mouth, intestinal, and genital tracts may occur in some people, causing discomfort and the need for corrective therapies. Although unlikely, it is possible that other problems such as adverse effects on liver, kidney, gallbladder, or other organs may occur.

Factors to consider in your decision. No one knows the optimal treatment of symptoms that persist after being 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 additional therapy. By taking antibiotics for longer periods of time, you place yourself at greater risk that a potentially serious infection will progress. Antibiotics are the only form of treatment shown to be effective for treating 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 from your body. Other forms of treatment designed to strengthen your immune system also may be important. Some forms of treatment are only intended to make you more comfortable by relieving your symptoms and do not address any underlying infections. If you are unsure of your diagnosis or treatment plan, be sure to discuss this with your doctor and remember that you have the right to obtain a second opinion.

Your decision about continued treatment may depend on a number of factors and importance of these factors to you. Some of these factors are listed below:

- The severity of your illness and degree to which it impairs your quality of life
- Whether you have co-infections which can complicate treatment
- Your ability to tolerate antibiotic treatment and the risk of major and minor side effects associated with the treatment
- Whether you have been responsive to antibiotics in the past
- Whether you relapse or your illness progresses when you stop taking antibiotics
- Your willingness to accept the risk that, left untreated, a bacterial infection potentially may get worse

For example, if your illness is severe significantly affects the quality of your life, and you have been responsive to antibiotic treatment in the past, you may wish to continue your treatment. However, if you are willing to accept the risk that the infection may progress or if you are not responsive to antibiotics, you may wish to terminate treatment. Be sure to ask your doctor if you need any more information to make this decision.

Based on this information, I have decided: (CHECK ONE)

- To treat my Lyme disease with antibiotics until my clinical symptoms resolve.
- Only to treat my Lyme disease with antibiotics for thirty days, even if I still have symptoms.
- Not to pursue antibiotic therapy.

I am allergic to the medication listed below:

Signature: _____

Date: _____

Print Name: _____

Witness: _____

Date: _____