



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 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.

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 (30) days, even if I still have symptoms.
<input type="checkbox"/>	Not to pursue antibiotic therapy
<input type="checkbox"/>	To treat my lyme disease with antibiotics for several months, and then re-evaluate. I may decide to continue antibiotic or discontinue with the possibility of utilizing other alternative treatments. I accept that this may lead to treatment failure and that this is my choice and not a consequence of poor medical practice on the part of my doctor.

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

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-
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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: _____

Handout adapted from Lymedesease.org 2021

Lyme Disease Symptoms:

The symptoms of Lyme disease are extraordinarily extensive. While you are highly unlikely to experience all, or even most, it is important to know what might be associated with this multi-symptom disease so that you can seek appropriate medical help promptly.

The tick bite

If you get a rash it may be:

Raised, hot to the touch, itchy, crusty or oozy

Circular, spreading out, oval, triangular or long thick line.

Disappear and return at the site of the bite or on other parts of your body

(Note: you may never see a tick or you may never get the rash. Generally the rash is larger than a fifty cent piece.)

Head, Face, Neck:

• Headaches • Facial paralysis (“Bell’s palsy”) • Tingling sensations • Stiff neck • Sore throat, swollen glands • Heightened allergic sensitivities • Twitching of facial/other muscles • Jaw pain/stiffness (“TMJ”) • Change in smell or taste

Digestive/Excretory System:

• Upset stomach (nausea, vomiting) • Abdominal pain • Irritable bladder • Unexplained weight loss or gain • Loss of appetite, anorexia

Respiratory/Circulatory Systems:

• Difficulty breathing, air hunger • Night sweats or unexplained chills • Heart palpitations • Diminished exercise tolerance • Heart block, murmur • Chest pain or rib soreness

Psychiatric Symptoms:

• Mood swings, irritability, agitation • Depression and anxiety • Malaise • Aggressive behavior / impulsiveness • Suicidal thoughts (rare cases of suicide) • Overemotional reactions, crying easily • Disturbed sleep: too much, too little, difficulty falling or staying asleep • Feeling as though you are losing your mind • Obsessive-compulsive behavior

Cognitive Symptoms:

• Forgetfulness, memory loss • Attention problems, distractibility • Confusion, difficulty thinking • Difficulty with concentration, reading, spelling • Disorientation: getting lost in familiar areas

Reproduction and Sexuality

Females:

• Unexplained menstrual pain, irregularity • Reproduction problems, such as miscarriage, stillbirth, premature birth, neonatal • Extreme PMS symptoms • Pelvic pain

Males:

• Testicular or pelvic pain

Eye, Vision:

• Double or blurry vision • Sensitivity to light • Eye pain • Floaters

Ears/Hearing:

• Decreased hearing • Ringing or buzzing in ears • Sound sensitivity • Pain in ears

Musculoskeletal System:

• Joint pain, swelling, or stiffness • Shifting joint pains • Muscle pain or cramps • Poor muscle coordination, loss of reflexes • Loss of muscle tone, muscle weakness

Neurologic System:

• Numbness in body, tingling, pinpricks • Burning /stabbing sensations in the body • Burning sensations in feet • Weakness or paralysis of limbs • Tremors or unexplained shaking • Seizures, stroke • Poor balance, difficulty walking • Increased motion sickness, wooziness • Lightheadedness, dizziness • Encephalitis (inflammation of the brain) • Meningitis (inflammation of the protective membrane around the brain) • Encephalomyelitis (inflammation of the brain and spinal cord) • Difficulty with multitasking • Difficulty with organization and planning • Word finding problems • Slowed speed of processing

Skin Problems:

• Erythema Migrans (rash) • Benign nodules • ACA degenerative chronic atrophy of skin

General Well-being:

• Decreased interest in play (children) • Extreme fatigue • Unexplained fevers (high or low grade) • Flu-like symptoms (early in the illness) • Symptoms seem to change or come and go

Other Organ Problems:

• Dysfunction of the thyroid (under or over active) • Bladder & kidney problems (including bed wetting, urgency/frequency to urinate) • Newly developed beef or meat allergy (usually from LoneStar ticks)