

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 standards of care 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 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 cautions against this approach. These physicians will fail to diagnose some patients who actually have Lyme disease. For these patients, treatment will either not occur or will be delayed.
- 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 a patient to assist in their diagnosis.

Your doctor also may need to rule out other possible causes of your symptoms, such as arthritis, lupus, syphilis, Reiter's syndrome, MS, CFS, and FMS. If you are unclear of your diagnosis, be sure to discuss this with your doctor.

Your Treatment Choices. The medical community is divided regarding the best approach for treating persistent Lyme disease. Some physicians think that the long-term effects of Lyme disease are caused by damage to the immune system and are therefore unaffected by antibiotics. Others 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.

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 medications 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. Although there is substantial evidence that most patients improve with continued treatment, not all patients improve with treatment (See Attachment A).

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 is 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 the 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, kidneys or other organs may occur. For oral antibiotics, it is estimated that the risk of major side effects is 1 in 10,000 (very small) and the risk of minor side effects is 4 in 100 (slightly greater).[1]

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 the additional therapy. By taking antibiotics for longer periods of time, you place yourself at greater risk of developing the side effects. By stopping antibiotic treatment, 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 infection.

Your decision about continued treatment may depend on a number of factors and the 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.

Not to pursue antibiotic therapy

Only to treat my Lyme disease with antibiotics for thirty days, even if I still have symptoms.

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 physician

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

Signature: _____

Date: _____

Print Name: _____

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 touch, itchy, crusty, or oozy
- Circular, spreading out, oval, triangular, or long-thin 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 get a rash and still be infected with Lyme disease

Head, Face, Neck

- Headache, mild or severe
- Facial paralysis (Bell's palsy)
- Tingling of nose, cheek, or face
- Twitching of facial or other muscles (motor tics)
- Jaw pain or stiffness (TMJ like problems)
- Neck is stiff, painful, creaks or cracks
- Sore Throat, swollen glands
- Hoarseness or vocal cord problems
- Sinusitis or increase in allergy symptoms
- Difficulty chewing, swallowing, speaking
- Change in smell, taste
- Unexplained hair loss

Eyes/Vision

- Double or blurry vision
- Wandering or lazy eye
- Drooping eyelid
- Vision changes incl. blindness, retinal damage, optic atrophy
- Red eyes
- Conjunctivitis or "pinkeye"
- Floaters or spots appearing in the line of sight
- Pain or inflammation of eyes, or swelling around eyes
- Oversensitivity to light
- Decreased perception of light or color
- Flashing lights

Ears/Hearing

- Decreased hearing in one or both ears
- Pain in ears
- Ringing or buzzing in one or both ears
- Sound sensitivity

Digestive and Excretory Systems

- Diarrhea or constipation
- Upset stomach (nausea, vomiting, pain)
- Irritable bladder (trouble starting, stopping)
- Unexplained weight gain or loss
- Loss of appetite, anorexia

Musculoskeletal System

- Joint pain, swelling, or stiffness
- Stiff neck
- Shifting joint pains
- Muscle pain or cramps
- Burning in feet
- Shin splints
- Drooping shoulders
- Loss of reflexes
- Poor muscle coordination
- Loss of muscle tone, muscle weakness

Respiratory and Circulatory Systems

- Shortness of breath, cough
- Difficulty breathing or pneumonia
- Chest pain or rib soreness
- Night sweats or unexplained chills
- Heart palpitations, extra beats or pulse skips
- Heart blockage, heart murmur, valve prolapse
- Heart attack
- Swelling or enlargement of heart
- Diminished exercise tolerance

Neurologic System

- Burning or stabbing sensations in the body
- Weakness or paralysis of limbs
- Tremors or unexplained shaking
- Seizures
- White matter lesions
- Pressure in head
- Numbness in body, tingling, pinpricks
- Poor balance, dizziness, difficulty walking
- Increased motion sickness, wooziness
- Lightheadedness, fainting
- Stroke
- Meningitis
- Encephalopathy (dysfunction of the brain)
- Encephalomyelitis (inflammation of the brain & spinal cord)

Psychological Well-being

- Mood swings, irritability, or extreme agitation
- Depression and anxiety
- Personality changes
- Depersonalization
- Malaise
- Suicidal thoughts (rare cases of suicide)
- Anxiety/panic attacks
- Aggressive behavior or impulse violence
- Obsessive-compulsive behavior
- Bipolar disorder/manic episodes
- Schizophrenic-like states
- Dementia
- Eating disorders
- Increased suspiciousness, paranoia/hallucinations
- Disorientation (getting or feeling lost)
- Feeling as if you are losing your mind
- Overemotional reactions, crying easily
- Disturbed sleep: difficulty falling or staying asleep, too much, too little or early awakening

Mental Capability

- Forgetfulness, memory loss (short or long term)
- Poor school or work performance
- Attention deficit problems, distractibility
- Confusion, difficulty in thinking
- Difficulty with concentration, reading, or spelling
- Disorientation: getting lost or going to the wrong place
- Difficulty with speech (slowed, slurred or stammering)
- Dyslexia-type reversals, Difficulty with writing
- Word retrieval problems (can't remember words/stop mid-sentence)
- Forgetting how to perform simple task
- Problems with numbers

Reproduction and Sexuality

Loss of sex drive

Sexual dysfunction

Females only:

Unexplained menstrual pain, irregularity

Unexplained breast pain, discharge

Endometriosis

Reproduction problems: miscarriage, stillbirth,
premature birth, neonatal death (rare),

congenital Lyme disease (passes from mother to fetus)

Males only: Testicular or pelvic pain

General Well-being

Decreased interest in play (kids)

Unexplained weight gain, loss

Extreme fatigue, tiredness, exhaustion, poor stamina

Swollen glands

Unexplained fevers (high or low grade), sweats, chills, flushing

Continual infections (sinus, kidney, eye, ear, etc.)

Symptoms seem to change, come and go

Pain migrates (moves) to different body parts

Early on, experience a "flu-like" illness, possibly not feeling well since

Exaggerated symptoms or worse hangover from alcohol

Skin Problems

Acrodermatitis Chronica Atrophicans (ACA)-degenerative and chronic skin
condition that leads to atrophy of the skin

Benign tumor-like nodules

Other Organ Problems

Liver infections/abnormalities

Enlarged or tender spleen

Underactive thyroid glands

Bladder & kidney problems (including bed wetting)

SOME OF THE 200 OTHER DISEASES LYME SYMPTOMS MAY MIMIC INCLUDE:

Multiple Sclerosis

Fibromyalgia

Chronic Fatigue Syndrome

Infectious Mononucleosis

Systemic Lupus

Attention Deficit Disorder

Alzheimer's

Guillain-Barre Syndrome

Lou Gehrig's Disease (ALS)

Rheumatoid Arthritis

The above information was compiled from the following sources:

Lyme@Primer by the Lyme Disease Association, Inc.

Coping with Lyme Disease by Denise Lang with Joseph Territo, M.D.

Everything You Need To Know About Lyme Disease by Karen Vanderhoof-Forschner

The New Lyme Disease by Joseph J. Burrascano, Jr. M.D., October 1998

www.lyme.org, The Lyme Disease Foundation

GLDTF Lyme Disease Forum information from June 16, 1998

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