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SYMPTOM OR SIGN	CURRENT SEVERITY				CURRENT FREQUENCY				
	NONE	MILD	MODERATE	SEVERE	NA	NEVER	OCCASIONAL	OFTEN	CONSTANT
Hearing: buzzing, ringing, decreased hearing									
Increased motion sickness, vertigo, spinning									
Off balance, "tippy" feeling									
Lightheadedness, wooziness, unavoidable need to sit or lie									
Tingling, numbness, burning or stabbing sensations, shooting pains, skin hypersensitivity									
Facial paralysis-Bell's Palsy									
Dental pain									
Neck creaks and cracks, stiffness, neck pain									
Fatigue, tired, poor stamina									
Insomnia, fractionated sleep, early awakening									
Excessive night time sleep									
Napping during the day									
Unexplained weight gain									
Unexplained weight loss									
Unexplained hair loss									
Pain in genital area									
Unexplained menstrual irregularity									
Unexplained milk production; breast pain									
Irritable bladder or bladder dysfunction									
Erectile dysfunction									
Loss of libido									
Queasy stomach or nausea									
Heartburn, stomach pain									
Constipation									
Diarhea									
Low abdominal pain, cramps									
Heart murmur or valve prolapse?									
Heart palpitations or skips									
"Heart block" on EKG									
Chest wall pain or ribs sore									
Head congestion									
Breathlessness, "air hunger", unexplained chronic cough									
Night sweats									
Exaggerated symptoms or worse hangover from alcohol									
Symptom flares every 4 wks									
Degree of disability									

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.

My Diagnosis. The diagnosis of Lyme disease is primarily a clinical determination made by my doctor based on my exposure to ticks, my report of symptoms, and my 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 itself cautions against this approach. These physicians may 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. Since no treatment is risk-free, use of broader clinical criteria to diagnose disease could in some cases expose patients to increased treatment complications. This approach may result in a tendency to over-diagnose and over-treat Lyme disease.

My Treatment Choices. 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 and view the long-term effects of Lyme disease as an autoimmune process or permanent damage that is unaffected by antibiotics.[1] 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).[2] Table 4 of the new IDSA guidelines strongly recommend against many of the common treatment approaches used by physicians who follow the ILADS guidelines, as set forth below:

Table 4. of IDSA Treatment guidelines
Selected antimicrobials, drug regimens, or other modalities <u>not</u> recommended for the treatment of Lyme disease.
Doses of antimicrobials far in excess of those provided in tables 2 and 3
Multiple, repeated courses of antimicrobials for the same episode of Lyme disease or a duration of antimicrobial therapy prolonged far in excess of that shown in table 3
Combination antimicrobial therapy
Pulsed-dosing (i.e., antibiotic therapy on some days but not on other days)
First-generation cephalosporins, benzathine penicillin G, fluoroquinolones, carbapenems, vancomycin, metronidazole, tinidazole, trimethoprim-sulfamethoxazole, amantadine, ketolides, isoniazid, or fluconazole

Empirical antibabesiosis therapy in the absence of documentation of active babesiosis
Anti- <i>Bartonella</i> therapies
Hyperbaric oxygen therapy
Fever therapy (with or without malaria induction)
Intravenous immunoglobulin
Ozone
Cholestyramine
Intravenous hydrogen peroxide
Vitamins or nutritional managements
Magnesium or bismuth injections

Potential Benefits of Treatment. Some clinical studies support longer term treatment approaches, while others do not. The experience in this office is that although most patients improve with continued treatment, some do not.

Risks of treatment. 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 difficulty with breathing, (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.

Factors to consider in my 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, I place myself at greater risk of developing side effects. By stopping antibiotic treatment, I place myself at 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 from my body. Other forms of treatment designed to strengthen my immune system also may be important. Some forms of treatment are only intended to make me more comfortable by relieving my symptoms and do not address any underlying infection.

My decision about continued treatment may depend on a number of factors and the importance of these factors to me. Some of these factors include (a) the severity of my illness and degree to which it impairs my quality of life, (b) whether I have co-infections, which can complicate treatment, (c) my ability to tolerate antibiotic treatment and the risk of major and minor side effects associated with the treatment, (d) whether I have been responsive to antibiotics in the past, (e) whether I relapse or my illness progresses when I stop taking antibiotics, and (f) my willingness to accept the risk that, left untreated, a bacterial infection potentially may get worse.

For example, if my illness is severe, significantly affects the quality of my life, and I have been responsive to antibiotic treatment in the past, I may wish to continue my treatment. However, if I am

willing to accept the risk that the infection may progress or if I am not responsive to antibiotics, I may wish to terminate treatment. I will ask my doctor if I need any more information to make this decision and am aware that I have the right to obtain a second opinion at any time if I think this would be helpful.

I realize that the choice of treatment approach to use in treating my condition is mine to make in consultation with my physician. After weighing the risks and benefits of the two treatment approaches, I have decided: (CHECK ONE)

- To treat my Lyme disease through a treatment approach that relies heavily on clinical judgment and may use 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.
- Only to treat my Lyme disease with antibiotics for thirty days, even if I still have symptoms.
- Not to pursue antibiotic therapy
- I may obtain a copy of both the IDSA and ILADS guidelines by specifically requesting a copy from my physician to aid my decision. I choose not to obtain a copy at this time.

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

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: _____

Witness: _____

For more information on the treatment approaches used in diagnosing and treating Lyme disease, see:

1. Wormser GP, RJ Dattwyler, ED Shapiro, AJ Halperin, AC Steere, MS Klempner, PJ Krause, JS Bakken, F Strle, G Stanek, L Bockenstedt, D Fish, JS Dumler, and RB Nadelman. The clinical assessment, treatment, and prevention of Lyme disease, Human Granulocytic Anaplasmosis, and Babesiosis: Clinical practice guidelines by the Infectious Diseases Society of America. Clin Infect Dis. 2006; 41(1 November): 1089. Available at www.journals.uchicago.edu/CID/journal/issues/v43n9/40897/40897.web.pdf
2. The International Lyme and Associated Diseases Society. ILADS Evidence-based guidelines for the management of Lyme disease. Expert Rev. Anti-infect. Ther. 2004; 2(1): S1-S13. Available at www.ilads.org.
3. The National Guidelines Clearinghouse (www.guideline.gov); enter Lyme in the search box.

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 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 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.

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: _____

Witness: _____