

# The Office of Dr. Mischa Grieder, N.D.

at

San Francisco Preventive Medical Group

## 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 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 (30) 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 Erlichiosis, 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.

# The Office of Dr. Mischa Grieder, N.D.

at

San Francisco Preventive Medical Group

**Potential Benefits of treatment.** Antibiotic treatment may result in improvement of 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 infections 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 a 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 an 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.

# The Office of Dr. Mischa Grieder, N.D.

at

## San Francisco Preventive Medical Group

- 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 that 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 (30) days, even if I still have symptoms.
- Not to pursue antibiotic therapy.

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

---

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

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

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

# The Office of Dr. Mischa Grieder, N.D.

at

San Francisco Preventive Medical Group

## IV Treatment Consent Form

In certain situations, IV medications are preferred or may be used to supplement oral medications. IV treatment is sometimes recommended when there is neurological involvement, carditis, complicated Lyme arthritis, or inadequate response to oral medications. Because the GI system is bypassed, 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 a PICC line in your vein to allow easier IV treatment. PICC lines may result in local infection (a less than 1% risk), or if unchecked, systemic infection. If signs of skin inflammation occur, the line may need to be removed. PICC lines rarely (less than 1% risk) may break off when they are being removed and may then require removal by a radiologist. One study suggests that the risks associated with IV antibiotics are estimated at 1 in 1,000 for major side effects and 3 in 100 for minor side effects. [1] However, other studies suggest that the risk of blood clots from a PICC line ranges from 3-10% [11] If a clot forms, the PICC line may be removed and you may be hospitalized for the initiation of anti-coagulation therapy. The risk of clot development is decreased 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 (the most commonly used IV antibiotic) 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 actigal with the ceftriaxone. Other antibiotics commonly used to treat Lyme disease are not known to have gallbladder side effects. Monitoring your blood may help detect the development of any liver or gallbladder problems.

---

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

---

**I am aware of the additional risks involved in IV treatment and consent to the use of IV treatment.**

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

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

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

# The Office of Dr. Mischa Grieder, N.D.

at

San Francisco Preventive Medical Group

## Attachment A. Lyme Disease Treatment Studies

No clinical studies have determined the optimal antibiotics or the optimal duration of treatment. Controlled clinical studies have been limited and conflicting, although two out of the three studies showed improvement on retreatment. Non-controlled studies also indicate that most patients improve with continued treatment. The controlled and non-controlled studies are described below.

### Controlled studies of Persistent Lyme Disease

Study	Treatment	Results	Comments
Krupp (2003)[2]	4 weeks of IV ceftriaxone	64% showed improvement on fatigue. No improvement on cognition.	Cognition finding was criticized because subjects were not selected based on cognitive impairment. Hence, improvement on this scale would not be expected since no initial impairment was demonstrated.
Klempner (2001) [3]	4 weeks IV ceftriaxone, then 2 months of oral Doxycycline.	No improvement on SF-36	Study was criticized because subjects were not selected based on fatigue. Improvement on this scale would not be expected since no initial impairment was demonstrated. ILADS has issued a position paper outlining in detail substantial criticisms of the study. [4]
Fallon (2004)[5]	10 weeks of IV ceftriaxone	Cognitive improvement	Preliminary results as date are still being analyzed and official study is being written.

Despite the current focus on controlled studies, some researchers note that there is a high correlation between controlled and observational studies and that they "usually produce the same results".[5] In addition, non-controlled studies often provide more clinically-relevant treatment information because they deal with the diversity of patients seen in practice and allow for more flexibility in terms of treatment approach.

### Non-Controlled Studies Supporting Longer Treatment Approaches or Retreatment

Study	Comments
Oksi (1999)[6]	9 of 13 patients (69%) with disseminated Lyme Disease who were initially treated for 3 months with oral or IV antibiotics but subsequently relapsed had good response to retreatment with IV ceftriaxone for 4-6 weeks " <u>[T]reatment...with appropriate antibiotics for even more than 3 months may not always eradicate the spirochete and long term antibiotics may be necessary.</u> "
Donta (1997)[7]	277 patients with chronic Lyme treated for <u>between 1 and 11 months</u> : 20% were cured, 70% improved and 10% had treatment failure.
Oksi (1998)[8]	<u>30 patients with disseminated Lyme treated for 100 days. 90% with good or excellent responses: "prolonged courses of antibiotics may be beneficial in this setting".</u>
Whalberg (1994)[9]	Success rates for 100 patients with late Lyme disease: 31% (4 of 13) with 14 days of ceftriaxone; 89% (50 of 56) with ceftriaxone, then 100 days of amoxicillin and probenecid; and 83% (19 of 23) with ceftriaxone, then 100 days of cephadroxil.
Fallon (1999)[10]	18 patients retreated either with intravenous, intramuscular or oral antibiotics scored better on overall and individual measures of cognition. Those retreated with intravenous therapy showed greatest improvement.

The studies described above are necessarily limited to the choice of antibiotics tested and the duration that the antibiotics were given in the study. They do not tell us what would happen if patients were treated with different antibiotics or for longer periods of time.

# The Office of Dr. Mischa Grieder, N.D.

at

San Francisco Preventive Medical Group

## References

1. Maes, E., P. Lecomte, and N. Ray, *A cost-of-illness study of Lyme disease in the United States*. Clin Ther, 1998. 20(5): p. 993-1008; discussion 992.
2. Krupp, L.B., et al., *Cognitive functioning in late Lyme borreliosis*. Arch Neurol, 1991. 48(11): p. 1125-9.
3. Klemmner, M.S., et al., *Two controlled trials of antibiotic treatment in patients with persistent symptoms and a history of Lyme disease*. N Engl J Med, 2001, 345(2): p. 85-92.
4. The International Lyme and Associated Diseases Society (ILADS), *Evaluation of antibiotic treatment in patients with persistent symptoms of Lyme disease*. April 2003. <http://www.ilads.org/position2.html>.
5. Fallon, B.A., *Laboratory findings in chronic Lyme disease and results of the controlled treatment study*. In *Lyme & Other Tick-Borne Diseases: Technology Leading the Way Conference*. 2004, Rye Town, NY.
6. Oksi, J., et al., *Borrelia burgdorferi detected by culture and PCR in clinical relapse of disseminated Lyme borreliosis*. Ann Med, 1999. 31(3): p. 225-32.
7. Donta, S.T., *Tetracycline therapy for chronic Lyme disease*. Clin Infect Dis, 1997. 25 Suppl 1: p. S52-6.
8. Oksi, J., Nikoskelainen, and M.K. Viljanen, *Comparison of oral cefixime and intravenous ceftriaxone followed by oral amoxicillin in disseminated Lyme borreliosis*. Eur J Clin Microbiol Infect Dis, 1998. 17(10): p. 715-9.
9. Wahlberg, P., et al., *Treatment of late Lyme borreliosis*. J Infect, 1994. 29(3): p. 255-61.
10. Fallon, B.A., *Repeated antibiotic treatment in chronic Lyme disease*. J Spirochet Tick Borne Dis, 1999. 6(Fall/Winter): p. 94-101
11. Wickham, R., S. Purl, and D. Welker, *Long Term Central Venous Catheters: Issues for Care*. Seminars in Oncology Nursing, 1996. 9(2(May)): p. 133-47