Julie A. Griffith M.D
Neurology
5 Bon Air Rd, Building D, Suite 219, Larkspur, CA 94939
(415) 925-1616
Fax (415) 962 1303

Informed Consent for Treatment of Borreliosis 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 (LADS guidelines, as set forth below:

Table 4. of IDSA Treatment **guidelines**

Selected antimicrobials, drug regimens, or other modalities *not* 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, trimetho rim-sulfamethoxazole arnantadine ketolides, isoniazid, or fluconazole
Empirical antibabesiosis therapy in the absence of documentation of active babesiosis
Anti-Bartonella 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 entirety. 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 **weighting 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.

☐ Not to pursue antibiotic therapy

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

☐ I may obtain a copy of both the IDSA and ILADS guidelines by accessing footnoted sites.

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

List allergies:

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 a copy of complete IDSA and ILADS treatment guidelines used in diagnosis 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.

Some info is for adults
Some general concepts good
Allergic reaction

Julie A. Griffith, M.D., M.S.,
Neurology, Phone (415) 925-1616

Elaine 4159621303

TREATMENT OF LYME AND TICK BORNE DISEASES

Name: _____ Date: _____

Please read this document carefully especially the boxes marked,
Keep these instructions for future reference.

We have treated over 500 people for Lyme and tick borne diseases and this document is to help you understand the treatments and the possible side effects of the treatments and how to best avoid those side effects.

Treatment of Lyme involves the use of antibiotics, mostly antl-bacterials to kill Lyme bacteria (Borrelia burgdorferi), and coinfection bacteria: Ehrlichia bacteria. Bartonella bacteria (Bartonella hansalea). Sometimes we use anti-parasitics to kill a tick borne parasite that Causes Babesiosis (babesia microti or WA-1 babesia). Finally we may use an antifungal that kills yeasts or fungus if these become a problem.

All antibiotics can cause certain side effects:

ALL ANTIBIOTICS CAN DECREASE EFFECTIVENESS OF BIRTH CONTROL PILLS. USE CONDOMS OR OTHER BARRIER METHODS FOR CONTRACEPTION WHILE ON ANTIBIOTICS

☐ Antibiotics can promote the growth of fungus or yeast in the body by destroying your good bacteria in the intestinal tract. To control yeast growth and help replace the goad bacteria:

☐ NEVER STOP THIS, Take it 1-2 hours after or before antibiotics. If this is too complicated take it at the end of the meal.

☐ Probiotics

☐ Florastor or Sacharornyces 50 200 _____ times a week ← not if allergic to molds

☐ Caprillic acid as Capri Plus or Capryl 3 tablet with meal

☐ Eat fresh raw garlic as much as you are able. (cooked garlic)

Culterelle qhs
Claire Therbiotic
detox 1 support: qhs

☐ Modify your diet to have higher protein (fish, meat, eggs, soy) and lower carbs (pasta, bread, rice, grains) and more vegetables and less fruit. If you can eat dairy eat plain cultured yogurt Report yeast symptoms which include white or black tongue, yeast vaginitis, rectal itching etc

If stools become loose stick closely to a yeast *free*, high protein diet. If looseness persists or becomes worse stop antibiotics and call the office to be checked for Clostridia Difficile antigen

☐ **Antibiotics can bother your stomach/intestines and some can increase ulcer risk:**

Take your antibiotics with food.
Avoid mineral supplements and antacids within I hour of taking antibiotics,

If you experience burning in your stomach or gnawing hunger or nausea do the following:
- Take Pepto Bismol 2 wafers or 1 tablespoon 1 hour post antibiotic and before bed
- Take bismuth (prescription) 300mg 3-4 times a day
- Take Thome SF734 (this has bismuth, so don't take with bismuth) 2 3 times a day
- If this does not work take OTC pepcld 10mg 2 times a day and report at your next visit

If you experience nausea or lack of apetite on th,c antibiotics:
- Try the pepto blsmol as above
- Try ginger tea or ginger capsules from the health food store
- If this does not work take OTC pepcid 10mg 2 times a day and report at your next visit

If you experience bloating or excess g21
- Eat low carbohydrates and no refined sugar
- Follow advice for yeast above
- Call us for a Nystatin prescription

If you have diarrhea
- If only 1-2 loose or soft stools a day that are not voluminous this is ok
- If more than this then take pepto bismol 2 wafers 3 times a day
- If you still experience diarrhea start a BRAT diet (bananas, rice, apple sauce and toast)
- If this does not help stop all antibiotics and call the office to report symptoms.

If any of the above GI symptoms become severe in spite of following the advice, stop antibiotics and call us

TREATMENT OF LYME AND TICK BORNE DISEASES

Antibiotics can adversely affect your liver, kidneys, gall bladder or bone marrow

☐ Take Silymarin 1 tablet 3 times a day

☐ Take ALA (alpha lipoic acid) 100mg ☐ 1 time ☐ 2 times or ☐ 3 times a day

☐ Take vitamin C 1000mg ☐ 2000mg ☐ 1 time ☐ 2 times or ☐ 3 times a day

Avoid alcohol and acotaminophen while on antibiotics, Drink 8 glasses of water a day

Get monthly blood draws to check these CBC, Chemistry panel, amylase and UA

Killing Lyme bacteria with antibiotics can cause a die-off or Herehbeimer-Jarrisch (HJ) reaction, also called a flair. In. general this lasts for 3-7 days. If these symptoms are severe then stop antibiotics for 2-5 days until symptoms have resolved. This will not effect your overall treatment.

To treat these reactions if not severe enough to stop antibiotics Follow if reactions occur when

Try squeezing 1/3 lemon in water and drinking 3 times a day
Take vitamin C_____mg as Ascorbic acid 4 times a day or to bowel tolerance
Pick up sheet of how to take vitamin C to bowel tolerance
Sometime HJ reactions are caused by generation of free radicals when your immune system is activated. For this antioxidants help:
Take NAC 500mg 2_times a day. Take Fish Oil (Pharmaceutical Grade) Nordic Naturals high EFA 2 times a day
Take magnesium (from PCHF) 2, 3, 4 daily
Take Vitamin C as above and Juice Plus
Sometimes HJ reactions cause increase in pain in joints, head or anywhere else your Lyme bacteria is lurking:
Take ibuprofen up to 600mg 4 times a day for pain as long as it does not cause acid symptoms. If pain is too severe stop antibiotics for 3-5 days or until symptoms subside
In severe cases of Rheumatoid arthritis type picture or severe arthralgia we give celebrex or other prescriptions. Come in if this occurs
Sometimes the pain Is caused by Cytokine release by your immune system, there are alternative and pharmaceutical approaches to this problem

☐ Elavil 10mg 25mg at bedtime. Helps pain from nerve. Can cause a "hangover", which usually passes with continued use

Treatment Protocols

Tetracyclines

☐ Doxycycline ☐ 100mg, ☐ 200mg ☐ 300mg _____ times a day

☐ Minocycline ☐ 100mg ☐ 200mg ☐ 2 times a day

Take with food but not dairy and DO NOT LIE DOWN FOR 2 HOURS POST TAKING

Avoid the sun, wear sun block, hats and UV blocking clothing -- this is mandatory
Report any burning sensations Or severe red skin or rash
May cause loose stools and call office if loose stools persist greater than a week -- see loose bowel instructions above also if you get a bad sunburn feeling, tingling that is new or turn a bright red on any part of the skin, stop the drug until we talk. You can take benadryl 25mg 4 times a day for these symptoms.
Don't take Diflucan, Fluconzaole, or Sporonox with this drug

☐ Get monthly blood draws to check then CBC, Chemistry panel, amylase and UA

TREATMENT OF LYME AND TICK BORNE DISEASES - Pediatric Antibiotic Dosing

- Amoxicillin 50-100 mg/kg BID
- Bicillin 1.2 million units IM weekly over 7-8 y/o, up to twice weekly, depending on size of buttocks (limiting factor in using Bicillin is size of buttocks muscles). Use 3/4 inch needles
- Suprax (cefixime) 8-16 mg/kg/d in one or two doses, up to 400 mg daily
- Omnicef (celdinir) 125-250 mg BID up to 100 lbs
- Cedax (ceftibuten) under 8y/o 90 mg BID, over 8y/o up to 180 mg BID
- Ceftin (cefuroxime axetil) 125-250 mg BID up to 100 lbs

- Plaquenil (hydroxychloroquine) 100-200 rn- g BID-, especially if 31 or 39 KDa bands present as these often associated with high degree of autoimmunity. (I also use Plaquenil if a lot of joint pain is present due to its anti-inflammatory as well as anti-Borrelia effects)
- Mepron (atovaquone), use highest dose tolerated 1/2 to 1 tsp BID
- Minocin (minocycline) or doxycycline over 8y/o use 50-100 BID (I have pushed Minocin to 300 mg/day in 9-12y/o) Minocin can cause increased ICP and papilledema, especially in pen-pubescent girls)

- IV Primaxin (imipenem/cilastin) OK in kidS, crosses BBB better than PCN
- Cholestyramine resin dosing in under 100 lbs or under 12 y/o give 60 mg/kg per dose
- "Sleepers" to use in kids: Benadryl (diphenhydramine), chloral hydrate, Sonata (zaleplon) over 6 y/o, or benzodiazepines
- Safe in pregnancy: PCN, cephalopsorins, Zithromax, Mepron
- Not safe in pregnancy: quinolones, tetracyclyines, Flagyl Bactrim, Biaxin

- Zithromax (azithromycin)100 mg to 250 mg BID
- Biaxin (clarithromycin) 125-250 mg BID
  Careful: Biaxin can cause psychosis
- Tindamax (tinidazole) can be given as young as 1- 2 y/o at 125 mg BID, older 250 mg BID better tolerated 2 consecutive days per week
- Flagyl (metronidazole) 125 mg BID 1-3 y/o, older 250 mg BID
- Rifampin, ask pharmacist to make suspension 30 mg/ml. Dose at 10-20 mg/kg up to 600 mg daily
- Bactrim (trimethoprim/sulfamethoxazole) 10 mg/kg/d in two doses

- Ciprofloxacin 250- 500 mg BID. CiprofloxdarTaffelr tolerated as young as 12. (I have used it as young as 8 successfully) Can't use Levaquin (levofloxacin) or Avalox (moxifloxacin) in children as they have more tendon/muscle problems
- IV Rocephin (ceftriaxone) 100-200 mg/kg good average is 75 mg/kg up to 2 gm.QD
- IV Zithromax (azithromycin) in over 12 years
- IV doxycycline rarely used by Dr. Jones in kids
- IV Claforan (cefotaxime) 100 m/kg up to 2 gm dose BID (can decrease WBC and RBC, suppress bone marrow)

- For Ehrlichia: in kids under 8y/o use 1-4 wkS"df — doxycycline 1/2 tsp BID
- For Bartonella: in children under 8y/o use rifampin and Bactrim together for 1 wk to 3 months. Also use Bactrim and Zithromax or Rifampin and Zithromax (also for Mycoplasma fermentans
- For Borrelia: Zithromax and rifampin often good in combination, e.g. for 85 lb 10 y/o dose would be rifampin 150 mg BID and Zithromax 250 mg BID
- For Borrelia: Zithromax (intracellular) and cephalosporin or PCN (cell wall abx) in combination

- For autism symptoms: Flagyl and Zithro often good in combination
- For neurological tics: clonidine 0.1 mg QD
- With unrelenting HA and paresthesias think Babesia co-infection

- Dr. Jones has treated children anywhere from 3 months to 10 years of continuous antibiotics. He does not pulse treatment, only uses continuous antibiotic therapy. Duration of treatment is based on the child's symptoms. Continue antibiotics for a full 2 months after all symptoms have resolved, and until there is no recurrence of Lyme symptoms with concurrent infections, injury/trauma, surgery, emotional trauma or menses. Also treat until the child him/herself feels that the "Lyme bugs" are gone. Always ask the child what he/she thinks!

Pediatric

TREATMENT OF LYME AND TICK BORNE DISEASES

☐ 5-Nitroimidazoles

Anti Cyst or L form cyst drugs

☐Flaggyl 250mg, 500mg, 750mg _____ time(s) a day for _____ weeks. Pulse

☐Tindamax or tindazole 250, 500mg 3 times a day for _____weeks.

☐Pulse over cycle 1 week before and _____weeks during. ☐ Pulse every _____ weeks.

☐Plaquenil 200mg 2x a day

Avoid all alcohol whether wine, drinks or mouth wash, cough medicines etc.

If new numbness or tingling occur on these drugs please call us.

Plaquenil can cause problems with vision, report flashing light, yellowing vision. See an Opthamologist every 4 months while on this drug.

Take a B complex 2x a day while on these drugs, Source Naturals is available at the office.

☐ **Get monthly blood draws to check these : CBC, Chemistry panel, Amylase, and UA.**

☐ Rifampin

☐Rifampin 300mg,☐ 1 time a day ☐ 2 times a day. Take with food

It can turn your urine, tears (and contacts) orange.

Tell your PCP if you are on other medications as Rifampin interacts with several medications.

DO NOT TAKE WITH MEPRON

☐ **Get monthly blood draws to check these : CBC, Chemistry panel, Amylase, and UA.**

☐ Quinolones

☐ Levoquin 400mg, 500mg 1 time a day.

☐ Cipro 500mg☐ 2 times a day☐ 3 times a day. Avelox 400mg ☐ 1 time a day☐ 2 times a day.

If taking orally take these with food and lots of water (6-8 glasses of water a day)

If you are under 18 do not take these unless I have specifically instructed you to.

In rare cases tendon rupture is reported with these, if you have new tendon or joint problems stop the antibiotic and do not exercise until you have been told to at a visit.

Do not take dairy with this (ie: at least 2 hours away)

Avoid all caffeine

☐ **Get monthly blood draws to check these : CBC, Chemistry panel, Amylase, and UA.**

☐ Sulfa drugs

☐Septra (trimethoprim and sulfamethoxazole) DS 1 2x a day

☐Celebrex 200 ☐ 1 time a day☐ 2 times a day.

If you are allergic to sulfa do not take this.

Take with food

☐ **Get monthly blood draws to check these : CBC, Chemistry panel, Amylase, and UA.**

☐ Intramuscular (Shot)

☐ Bicillin ☐ 1.2 M units ☐ 2.4 M units ☐ 1 Time☐ 2 Times☐ 3Times per week.

☐ Take orally Probenecid 500mg a day with the bicillin shot

Use xylocaine topical ointment 5% on injection site one hour before.

Ice the site after injection massage the site to disperse the antibiotic.

You can also take a hot tub or heating pad to put on the site to help

OTC Tylenol or ibuprofen can help pain, take ½ hour before injection.

If you are giving yourself this injection make sure you have Epipen and Benadryl available.

Call if you develop hives or severe diarrhea or itching

☐ **Get monthly blood draws to check these : CBC, Chemistry panel, Amylase, and UA.**

Pediatric

TREATMENT OF LYME AND TICK BORNE DISEASES

Other Instructions: _____

I have read and understand these instructions. I will do my best to follow advice and will uphold my responsibilities for keeping my scheduled appointments. If I have symptoms that do not respond to these instructions, I will stop therapy as instructed above until the doctor and I discuss how to proceed.

_____ _____

(Name) (Date)