

## **Subject: Lyme/Tick-Borne Diseases: Use of Parenteral Antibiotics**

### **Authorization:**

Prior authorization is required for ALL parenteral antibiotic treatment of Lyme and Tick-Borne Diseases provided in outpatient, office, or home settings.

- Medical record documentation including history of ALL prior treatment for Tick-Borne Disease(s), and results of any relevant diagnostic testing must be submitted.

### **Policy and Coverage Criteria:**

#### **Lyme Disease**

Harvard Pilgrim Health Care (HPHC) considers parenteral antibiotics therapy (e.g. ceftriaxone, cefotaxime, clindamycin, erythromycin or penicillin) for treatment of Lyme Disease as reasonable and medically necessary for up to 30 consecutive days when it is ordered by a licensed physician and documentation confirms ALL the following:

1. Diagnosis is confirmed by positive Lyme-specific Immunoglobulin G (IgG) Western blot on two tier testing, and clearly documented in the medical record; AND
2. Member meets the indications for any of the following conditions:
  - Lyme Meningitis when medical record documentation confirms ALL the following:
    - Clinical features of meningitis (e.g., acute headache, photosensitivity, nuchal rigidity, fever); AND
    - Positive Lyme specific IgM Western blot on two tier testing, with or without IgG positivity; AND
    - Other causes of meningitis have been evaluated and determined to be less likely; AND
    - Cerebrospinal fluid (CSF) findings (if appropriate) of elevated protein, lymphocytosis/monocytosis, and normal glucose; AND
    - Requirement for CSF findings may be waived if spinal tap is contraindicated or refused by the member.
  - Lyme Cranial Neuritis when medical record documentation confirms ALL the following:
    - Unilateral or bilateral cranial nerve symptoms with cranial nerve seven (CN VII) palsy; AND
    - Other causes of cranial nerve palsy have been evaluated and determined to be less likely; AND
    - CSF findings (if appropriate) of elevated protein, lymphocytosis/monocytosis, and normal glucose;
      - Requirement for CSF findings may be waived if spinal tap is contraindicated or refused by the member;
  - Lyme Radiculoneuritis, or Mononeuritis Multiplex when medical record documentation confirms ALL the following:
    - Clinical exam and/or electromyogram/nerve conduction studies (EMG/NCS) documents findings of ANY of the following:

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- Singular or multiple root involvement with motor, sensory, and reflex changes in a physiologic pattern; OR
  - Axonal changes on EMG/NCS; OR
  - Findings of mononeuritis multiplex on EMG/NCS (consistent with clinical history and exam)
- Other causes of radiculoneuritis or mononeuritis multiplex have been evaluated and are less likely; AND
- CSF findings (if appropriate) of elevated protein, lymphocytosis/monocytosis, normal glucose.
  - Requirement for CSF findings may be waived if spinal tap is contraindicated or refused by the member.
- Lyme Carditis when medical record documentation confirms ANY of the following:
  - 1<sup>st</sup> degree AV block with PR interval >0.3 sec; OR
  - 2<sup>nd</sup> or 3<sup>rd</sup> degree block (usually managed in a monitored setting).
- Lyme Arthritis when medical record documentation confirms ALL of the following:
  - Intermittent or persistent arthritis with BOTH:
    - Effusion of the knee or other large joints or clinical involvement of the temporomandibular joint; AND
    - History of abrupt onset of attacks that required joint aspiration
  - Joint fluid with inflammatory characteristics (i.e. polymorphonuclear predominance  $\geq$  2K cells); AND
  - If no neurologic involvement, completion of at least one 28-day courses of oral antibiotics, and incomplete patient response.
- Lyme Encephalopathy when medical record documentation confirms ALL the following:
  - Evidence of cognitive impairment (documented by a neurologist, and results of neuropsychiatric testing); AND
  - Other causes of encephalopathy have been evaluated and determined to be less likely; AND
  - CSF findings (if appropriate) of intrathecal antibody index positivity and/or elevated protein with or without a CSF pleocytosis.
    - Requirement for CSF findings may be waived if spinal tap is contraindicated or refused by the member
- Lyme Encephalomyelitis (European-borrelia strains) when medical record documentation confirms ALL the following:
  - Presence of focal neurologic manifestations and cognitive impairment documented by objective testing and detailed mental status exam; AND
  - MRI demonstrates focal areas of inflammation with increased T2 and FLAIR signal, or enhancement with gadolinium; AND
  - Other causes of encephalomyelitis have been evaluated and determined to be less likely; AND
  - CSF findings (if appropriate) of elevated protein, lymphocytosis/monocytosis, and normal glucose.
    - Requirement for CSF findings may be waived if spinal tap is contraindicated or refused by the member
- Lyme Peripheral Neuropathy when other causes have been evaluated and determined less likely and medical record documentation confirms ANY of the following:
  - Symmetric distal paresthesias (i.e., burning, tingling, numbness), multimodal sensory loss (e.g., pinprick, vibration), and mild or absent weakness/hyporeflexia; OR

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- EMG/NCS documentation of patchy axonal polyneuropathy or confluent mononeuritis multiplex
  - Note: Results of Lumbar Puncture may be required (if clinically indicated) to exclude central inflammatory conditions in complex cases. Requirement may be waived if spinal tap is contraindicated or refused by member.

**For members enrolled in Connecticut-based plans, HPHC covers extended antibiotic treatment ordered by physicians board-certified in Infectious Disease, Neurology, or Rheumatology.**

**For members enrolled in Massachusetts-based plans, HPHC covers extended antibiotic treatment if determined to be medically necessary and ordered by licensed physicians after making a thorough evaluation of the individual's symptoms, diagnostic test results or response to treatment; and provided further, that clinical diagnosis is based on knowledge obtained through medical history and physical examination only or in conjunction with testing that provides supportive data for such clinical diagnosis. In addition, HPHC covers experimental drugs for long-term antibiotic treatment of Lyme disease if the Food and Drug Administration (FDA) has approved it for any other indication.**

### **Human Granulocytic Anaplasmosis (HGA)**

Harvard Pilgrim Health Care (HPHC) considers parenteral doxycycline as reasonable and medically necessary for up to 14 days when documentation confirms ALL of the following:

1. Member has acute onset of systemic viral-like illness (e.g., fever, myalgia, headache), often in association with thrombocytopenia, leucopenia and /or elevated liver enzymes; AND
2. The member cannot tolerate an oral antibiotic.

### **Babesiosis**

Harvard Pilgrim Health Care (HPHC) considers parenteral clindamycin as reasonable and medically necessary for up to 10 days when member has acute onset of systemic viral-like illness (e.g. fever, myalgia, headache) and documentation confirms EITHER of the following:

1. Member has positive parasitemia on blood smear, OR
2. Member has positive PCR amplification of babesial DNA.

Note: Requests for parenteral antibiotics for treatment of other Tick-Borne Diseases (including *B. miyamotoi* and Tularemia) are reviewed on a case by case basis. Treatment may be approved when medical record documentation (including evidence of clinical manifestations, and results of appropriate diagnostic testing, when available) confirms the diagnosis, and medical necessity of the proposed treatment plan.

### **Exclusions:**

Harvard Pilgrim Health Care (HPHC) considers parenteral antibiotics for treatment of Lyme or other Tick-Borne Diseases as not medically necessary when above criteria are not met. In addition, HPHC does not cover:

- Parenteral antibiotics (i.e. Imipenem-Cilastatin, Ceftazidime, Cefuroxime, Vancomycin, Bicillin, Ampicillin, Azithromycin) for the treatment of early or late disseminated stages of Lyme disease
- Doses of antimicrobials far in excess of approved doses or multiple, repeated courses of antimicrobials for the same episode of Lyme disease or a duration of antimicrobial therapy prolonged far in excess of approved regimens
- Combination antimicrobial therapy for Lyme disease
- Less than daily use of covered parenteral antibiotics
- Parenteral antibiotics for treatment of nonspecific, noninflammatory musculoskeletal complaints/arthalgias or for fatigue

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- Diagnoses of infection based on diagnostic tests that have not been scientifically validated. (Such use is not clinically indicated)
- Treatment of Lyme Borrelia infection when diagnosis is based on invalidated tests including (but not limited to):
  - Antigen urine assay
  - Culture, immunofluorescence staining, or cell sorting of cell wall-deficient or cystic forms of *B. burgdorferi*
  - IgM or IgG tests without a previous ELISA/EIA/IFA
  - Lymphocyte transformation tests
  - Measurements of antibodies in joint fluid (synovial fluid) Polymerase chain reaction (PCR) testing of either serum or urine
  - Positive Western blot in the absence of a positive or equivocal other antibody test (i.e., not using two tier testing)
  - Quantitative CD57 lymphocyte assays
  - "Reverse Western blots"
  - Western blot positivity that does not meet CDC criteria

### Guidelines:

IgG is considered positive only when 5/10 of the following kDa bands are seen: 18, 23, 28, 30, 39, 41, 45, 58, 66, 93. IgM is considered positive only when the IgM is performed within 4 weeks of illness onset, and when 2/3 of the following bands are seen: 23, 39, 41.

For the small proportion of patients who have negative or indeterminate IgM positivity, repeat testing should be performed 2-4 weeks later if suspicion remains high. In those cases, authorization for treatment with parenteral antibiotics will not be delayed pending repeat test results.

### Coding:

**Codes are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. The list may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible.**

#### For Lyme Diagnosis only:

HCPCS Codes	Description
J0120	Injection, tetracycline, up to 250 mg
J0558	Injection, penicillin G benzathine and penicillin G procaine, 100,000 units
J0561	Injection, penicillin G benzathine, 100,000 units
J0696	Injection, ceftriaxone sodium, per 250 mg
J0697	Injection, sterile cefuroxime sodium, per 750 mg
J0698	Injection, cefotaxime sodium, per g
J1364	Injection, erythromycin lactobionate, per 500 mg
J2510	Injection, penicillin G procaine, aqueous, up to 600,000 units
J2540	Injection, penicillin G potassium, up to 600,000 units
S0077	Injection, clindamycin phosphate, 300 mg

### Billing Guidelines:

Member's medical records must document that services are medically necessary for the care provided. Harvard Pilgrim Health Care maintains the right to audit the services provided to our members, regardless of the

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participation status of the provider. All documentation must be available to HPHC upon request. Failure to produce the requested information may result in denial or retraction of payment.

## References:

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## Summary of Changes:

Date	Changes
<b>11/17</b>	Policy coverage criteria refined, references updated
<b>8/16</b>	Add language to ensure compliance with new MA mandate.
<b>6/16</b>	Added language specific to CT mandated coverage
<b>12/15</b>	Clarify policy is applicable to parenteral (IV, IM) meds. Update coding profile.

**Approved by Medical Review Committee: 12/19/17**

**Reviewed/Revised: 5/07, 6/08, 5/09, 4/10, 5/11, 5/12, 9/13, 10/14; 12/15; 6/16; 8/16; 11/17**

**Initiated: 12/06**

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