BlueCross BlueShield of Vermont
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Date: February 18, 2014

To: Vermont House Committee on Health Care

From: Robert Wheeler, M.D.
Vice President and Chief Medical Officer
Blue Cross and Blue Shield of Vermont

Re: Treatment of Lyme Disease

The Blue Cross Blue Shield Association Technology Evaluation Center regularly reviews scientific literature for emerging evidence that may affect medical policy and benefit coverage determinations. In January 2014, this center updated the literature review for treatment of Lyme disease. The resulting updated medical policy includes review of literature, review of guidelines of national specialty societies, and is produced after consultation with practicing specialists and academic centers. If a case involving treatment of Lyme disease requires medical review, BCBSVT would rely on this policy:

Policy

Treatment of Lyme disease consists of oral antibiotics, except for the following indications:

I. A 2- to 4-week course of IV antibiotic therapy may be considered **medically necessary** in patients with neuroborreliosis with objective neurologic complications of documented Lyme disease (see the following for methods of documentation). **Objective neurologic findings include:**

- Lymphocytic meningitis with documented cerebrospinal fluid (CSF) abnormalities
- Cranial neuropathy, other than uncomplicated cranial nerve palsy, with documented CSF abnormalities
- Encephalitis or encephalomyelitis with documented CSF abnormalities
- Radiculopathy
- Polyneuropathy

Lyme disease may be documented either on the basis of serologic testing or by clinical findings of erythema migrans in early infection. Documentation of CSF abnormalities is required for suspected CNS infection, as indicated above.

Serologic documentation of infection requires:

- Positive or indeterminate enzyme-linked immunosorbent assay (ELISA), AND
- Positive immunoblot blot by CDC criteria.

Documented CSF abnormalities include ALL of the following:

- Pleocytosis;
- Evidence of intrathecal production of *Borrelia burgdorferi* antibodies in CSF; and
- Increased protein levels.

Polymerase chain reaction (PCR)-based direct detection of *B burgdorferi* in CSF samples may be considered **medically necessary** and may replace serologic documentation of infection in patients with a short duration of neurologic symptoms (<14 days) during the window between exposure and production of detectable antibodies.

II. A single 2- to 4-week course of IV antibiotics may be considered **medically necessary** in patients with Lyme carditis, as evidenced by positive serologic findings (defined above) and associated with a high degree of atrioventricular block or a PR interval of greater than 0.3 second. Documentation of Lyme carditis may include PCR-based direct detection of *B burgdorferi* in the blood when results of serologic studies are equivocal.

III. A single 2- to 4-week course of IV antibiotic therapy may be considered **medically necessary** in the small subset of patients with well-documented Lyme arthritis who have such severe arthritis that it requires the rapid response associated with IV antibiotics. Documentation of Lyme arthritis may include PCR-based direct detection of *B burgdorferi* in the synovial tissue or fluid when results of serologic studies are equivocal.

Intravenous antibiotic therapy is considered **not medically necessary** in the following situations:

- Patients with symptoms consistent with chronic fatigue syndrome or fibromyalgia, in the absence of objective clinical or laboratory evidence for Lyme disease;
- Patients with seronegative Lyme disease in the absence of CSF antibodies;
- Initial therapy in patients with Lyme arthritis without coexisting neurologic symptoms;
- Cranial nerve palsy (e.g., Bell palsy) without clinical evidence of meningitis;

- Antibiotic-refractory Lyme arthritis (unresponsive to 2 courses of oral antibiotics or to 1 course of oral and 1 course of intravenous antibiotic therapy);

- Patients with vague systemic symptoms without supporting serologic or CSF studies;

- Patients with a positive ELISA test, unconfirmed by an immunoblot or Western blot test (see definition above);

- Patients with an isolated positive serologic test in the setting of multiple negative serologic studies;

- Patients with chronic (≥6 months) subjective symptoms ("post-Lyme syndrome") after receiving recommended treatment regimens for documented Lyme disease.

IV. Repeat or prolonged courses (e.g., >4 weeks) of IV antibiotic therapy are considered **not medically necessary**.

V. Repeat PCR-based direct detection of *B burgdorferi* is considered **investigational** in the following situations:

- as a justification for continuation of IV antibiotics beyond 1 month in patients with persistent symptoms

- as a technique to follow therapeutic response

VI. PCR-based direct detection of *B burgdorferi* in urine samples is considered **investigational** in all clinical situations.

VII. Genotyping or phenotyping of *B burgdorferi* is considered **investigational**.

VIII. Other diagnostic testing is considered **investigational** including but not limited to C6 peptide ELISA or determination of levels of the B lymphocyte chemoattractant CXCL13 for diagnosis or monitoring treatment.