BlueCross BlueShield of North Carolina

Corporate Medical Policy

Intravenous Antibiotic Therapy for Lyme Disease

File Name: intravenous_antibiotic_therapy_for_lyme_disease
Policy Number: DRU4129
Origination: 3/2006
Last Review: 3/2008
Next Review: 3/2010

Description of Procedure or Service

Lyme disease (LD) is a multisystem inflammatory disease caused by the **spirochete** *Borrelia burgdorferi* and transmitted by the bite of an infected ixodid tick endemic to Northeastern, North Central, and Pacific coastal regions of the United States. The disease is characterized by stages, beginning with localized infection of the skin (erythema migrans), followed by dissemination to many sites. Manifestations of early **disseminated** disease may include **lymphocytic meningitis**, facial **palsy**, painful **radiculoneuritis**, atrioventricular nodal block, or migratory musculoskeletal pain. Months to years later, the disease may be manifested by intermittent **oligoarthritis**, particularly involving the knee joint, chronic **encephalopathy**, spinal pain, or distal **paresthesias**. While most manifestations of LD can be adequately treated with oral antibiotics, intravenous (IV) antibiotics are indicated in some patients with neurologic involvement or **atrioventricular heart block**. However, overdiagnosis and overtreatment of LD is common due to its nonspecific symptoms, a lack of standardization of serologic tests, and difficulties in interpreting serologic test results. In particular, patients with chronic fatigue syndrome or fibromyalgia are commonly misdiagnosed as possibly having LD and undergo inappropriate IV antibiotic therapy. The purpose of this policy is to provide diagnostic criteria for the appropriate use of IV antibiotic therapy. The following paragraphs describe the various manifestations of LD that may prompt therapy with IV antibiotics and the various laboratory tests that are used to support the diagnosis of LD.

Neurologic Manifestations of Lyme Disease (Neuroborreliosis)

Lymphocytic meningitis, characterized by head and neck pain, may occur during the acute **disseminated** stage of the disease. Analysis of the cerebrospinal fluid (CSF) is indispensable for the diagnosis of Lyme **meningitis**. If the patient has LD, the CSF will show a **lymphocytic pleocytosis** (presence of too many cells) with increased levels of protein. **Intrathecal** production of antibodies directed at spirochetal **antigen**s is typically present. A normal CSF analysis is strong evidence against Lyme **meningitis**. Treatment with a 2- to 4-week course of IV antibiotics, typically ceftriaxone or cefotaxime, is recommended.

Cranial **neuritis**, most frequently **Bell's palsy**, may present early in the course of **disseminated** LD, occasionally prior to the development of antibodies, such that an LD etiology may be difficult to rule in or out. While **Bell's palsy** typically resolves spontaneously with or without treatment with oral antibiotics, some physicians have recommended a lumbar puncture and a course of IV antibiotics if **pleocytosis** in the CSF is identified, primarily as a **prophylactic** measure to prevent further neurologic symptoms.

A subacute **encephalopathy** may occur months to years after disease onset, characterized by subtle disturbances in memory, mood, sleep, or **cognition** accompanied by fatigue. These symptoms may occur in the absence of abnormalities in the electroencephalogram (EEG), magnetic resonance imaging (MRI), or CSF. In addition, the symptoms are nonspecific and overlap with fibromyalgia and chronic fatigue syndrome. Thus diagnosis of Lyme **encephalopathy** may be difficult and may be best diagnosed with a mental status exam or neuropsychological testing. However, treatment with IV antibiotics is generally not indicated unless CSF abnormalities are identified.

Much rarer, but of greater concern, is the development of encephalomyelitis, characterized by spastic **paraparesis**, **ataxia**s, cognitive impairment, bladder dysfunction, and cranial neuropathy. CSF examination reveals a **pleocytosis** and an elevation in protein. Selective synthesis of anti-spirochetal **antigen**s can also be identified. A course of IV antibiotics with 3 to 4 weeks of ceftriaxone is suggested when CSF abnormalities are identified.

A variety of peripheral nervous system manifestations of LD have also been identified. Symptoms of peripheral neuropathy include **paresthesias**, or radicular pain with only minimal sensory signs. Patients typically exhibit electromyographic (EMG) or nerve conduction velocity abnormalities. CSF abnormalities are usually seen only in those patients with a coexistent **encephalopathy**.

Cardiac Manifestations of Lyme Disease

Lyme carditis may appear during the early dissemination stage of the disease; symptoms include **atrioventricular heart block**, **tachyarrhythmias**, and **myopericarditis**. Antibiotics are typically given, although no evidence proves that this therapy hastens the resolution of symptoms. Both oral and IV regimens have been advocated. Intravenous regimens are typically used in patients with a high degree atrioventricular block or a PR interval on the electrocardiogram (EKG) of greater than 0.3 second. Patients with milder forms of carditis may be treated with oral antibiotics.

Lyme Arthritis

Lyme arthritis is a late manifestation of infection and is characterized by an elevated **IgG** response to *B. burgdorferi* and intermittent attacks of oligoarticular arthritis, primarily in the large joints such as the knee. Patients with Lyme arthritis may be successfully treated with a 30-day course of oral doxycycline or amoxicillin, but care must be taken to exclude simultaneous central nervous system (CNS) involvement, requiring IV antibiotic treatment. In the small subset of patients that do not respond to oral antibiotics, an additional 30-day course of oral or IV antibiotics may be recommended.

Fibromyalgia and Chronic Fatigue Syndrome

Fibromyalgia and chronic fatigue syndrome are the diseases most commonly confused with LD. Fibromyalgia is characterized by musculoskeletal complaints, multiple trigger points, difficulty in sleeping, generalized fatigue, headache, or neck pain. The joint pain associated with fibromyalgia is typically diffuse, in contrast to Lyme arthritis, which is characterized by marked joint swelling in one or a few joints at a time, with few systemic symptoms. Chronic fatigue syndrome is characterized by multiple subjective complaints, such as overwhelming fatigue, difficulty in concentration, and diffuse muscle and joint pain. In contrast to LD, both of the above conditions lack joint inflammation, have normal neurological test results, or have test results suggesting anxiety or depression. Neither fibromyalgia nor chronic fatigue syndrome has been shown to respond to antibiotic therapy.

Serologic Tests

The **antibody** response to infection with *B. burgdorferi* follows a typical pattern. During the first few weeks after the initial onset of infection, there is no **antibody** production. The specific **IgM** response peaks between the third and sixth week. The specific **IgG** response develops only after months and includes antibodies to a variety of spirochetal **antigen**s. **IgG** antibodies produced in response to LD may persist for months or years. Thus detection of **IgG** antibodies only indicates exposure, either past or present. In LD endemic areas, underlying asymptomatic seropositivity may range up to 5%–10%. Thus, as with any laboratory test, interpretation of serologic tests requires close correlation with the patients' signs and symptoms. For example, patients with vague symptoms of LD, chronic fatigue syndrome, or fibromyalgia may undergo multiple serologic tests over many weeks to months in an effort to establish the diagnosis of LD. Inevitably, in this setting of repeat testing, one enzyme-linked immunosorbent assay (ELISA) or test, whether **IgG** or **IgM**, will be reported as positive. These results most likely represent false positive test results in the patient who has had long-standing symptoms and previously negative test results.

Currently, the Centers for Disease Control and Prevention (CDC) recommend a 2-step method for the serologic diagnosis of LD:

1. Enzyme-Linked Immunosorbent Assay (ELISA)

This test is the initial serologic test for LD. For **IgG** determinations, a titer of ≥ 800 is considered positive; a titer between 1:200 and 1:400 is considered indeterminate, and a titer of ≤ 100 is considered negative. For **IgM** determinations, a titer of ≥ 200 is considered positive, a titer of 1:100 is considered indeterminate, and a titer of ≤ 100 is considered negative. A positive or indeterminate ELISA test result alone is inadequate serologic evidence of LD. All of these tests must be confirmed with an immunoblot test. In addition, as with any laboratory test, results must be correlated with the clinical picture.

2. Immunoblot or Western Blot

This test is used to confirm the serologic diagnosis of LD in those cases in which the ELISA test result is either interpreted as positive or indeterminate. In contrast to the ELISA test, the immunoblot investigates the specific **antibody** response to the different **antigen**s of *B. burgdorferi*. Typically, some 18 **antigen**s are tested. The test result is considered positive if 2 of the 8 most common **IgM** **antibody** bands to spirochetal **antigen**s are present, or 5 of the 10 most frequent **IgG** **antibody** bands are present.

Other tests include:

Polymerase Chain Reaction (PCR)

In contrast to the above 2 serologic tests, which only indirectly assess prior or present exposure to *B. burgdorferi*, PCR directly tests for the presence of the **spirochete**. Because PCR technology involves amplification of DNA from a portion of *B. burgdorferi*, there is a high risk of exogenous contamination, resulting in false positive results. In addition, the test cannot distinguish between live **spirochete**s or fragments of dead ones. The PCR technique has been used in both tissue samples, and samples of synovial fluid, CSF, and urine. The PCR technique has also been used as the first step in the ultimate genotypic analysis of *B. burgdorferi*. PCR-based genotyping analysis has suggested that different species of *B. burgdorferi* may preferentially cause distinct clinical manifestations of Lyme disease.

T-Cell Proliferative Assay

A small number of patients may develop attenuated, late manifestations of LD, characterized by joint pain or mild joint swelling, following inadequate antibiotic treatment during the first several weeks of the disease. These patients may be seronegative and diagnosed as having seronegative LD. However, a cellular immune response may be detected using a T-cell proliferative assay. But it should be noted that “seronegative” LD is a rarity, and these patients with mild joint symptoms do not require treatment with IV antibiotics. In addition, a small proportion of patients with objective CNS findings consistent with LD will have evidence of **antibody** production in the CSF, although serology studies are negative. These patients may be treated with IV antibiotics; however, the decision for such treatment is based on the positive CSF.

Evaluation of the Cerebrospinal Fluid (CSF)

Aside from the standard evaluation of CSF for **pleocytosis**, protein levels, and glucose levels, various tests are available to determine whether anti-*B. burgdorferi* antibodies are being selectively produced within the central nervous system. Techniques include a variety of immunoassays, including capture assays and ELISA test. Regardless of the technique used, it is imperative to simultaneously test the serum and CSF to determine whether the antibodies are actually being selectively produced in the CNS, as opposed to leaking across the blood-brain barrier. The PCR techniques can also be used to detect the spirochete in the CSF.

Treatment of Lyme Disease

As noted above, treatment with IV antibiotics is generally indicated only in patients with symptoms and laboratory findings consistent with CNS or peripheral neurologic involvement, and in a small subset of patients with heart block or documented Lyme arthritis who have not responded to oral antibiotics. Typical IV therapy consists of a 2- to 4-week course of ceftriaxone or cefotaxime, both third-generation cephalosporins, or penicillin or chloramphenicol. No data suggest that prolonged or repeated courses of IV antibiotics are effec-

tive. Lack of effect should suggest an incorrect diagnosis or slow resolution of symptoms, which is commonly seen in LD. In addition, some symptoms may persist after treatment, such as Lyme arthritis; this phenomenon may be related to various self-sustaining inflammatory mechanisms rather than persistent infection.

Policy

BCBSNC will provide coverage for intravenous antibiotic therapy for Lyme Disease when it is determined to be medically necessary and when medical criteria and guidelines shown below are met.

Benefits Application

Please refer to Certificate for availability of benefits. This policy relates only to the services or supplies described herein. Benefits may vary according to benefit design, therefore certificate language should be reviewed before applying the terms of the policy.

When Intravenous Antibiotic Therapy for Lyme Disease is covered

Note: The clinical indications and discussion of Intravenous Antibiotic Therapy for Lyme Disease is complex and technical. If you have any questions concerning this treatment, please talk with your physician.

Treatment of Lyme Disease consists of oral antibiotics, except for the following indications (A, B or C):

A. 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 LD (see below for methods of documentation).

Objective neurologic findings include:

1. **Lymphocytic meningitis** associated with CSF abnormalities
2. Cranial neuropathy, other than uncomplicated cranial nerve palsy, with documented CSF abnormalities
3. Encephalitis or encephalomyelitis associated with CSF abnormalities
4. Radiculopathy
5. Polyneuropathy

Lyme disease may be documented either on the basis of **serologic testing** or examination of the **CSF**.

- Positive **serologic** diagnosis is defined as **BOTH** criteria a. and b. below:

a. Positive or indeterminate ELISA test, as characterized by:

i. **IgG** showing a titer > 800 (positive) or a titer between 1:200 and 1:400 (indeterminate); **OR**;

ii. **IgM** ELISA test showing a titer of > 200 (positive) or 1:100 (indeterminate).

AND

b. Positive immunoblot or Western blot, as characterized by:

i. 2 of the 8 most common **IgM antibody** bands to spirochetal **antigen**s are present; **OR**;

ii. 5 of the 10 most frequent **IgG antibody** bands are present.

Note: All positive or indeterminate ELISA tests must be confirmed with immunoblot.

- Positive **CSF** findings include **ALL** of the following:

  a. **Pleocytosis**;

  b. Evidence of **intrathecal** production of *B. burgdorferi* antibodies in CSF; **and**

  c. Increased protein levels.

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

B. A 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.

C. A 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 requires either unequivocal serologic studies, or when serologic studies are equivocal, PCR-based direct detection of B. burgdorferi in the synovial fluid.

- Patients who have persistent or recurrent joint swelling after a recommended course of oral antibiotic therapy should be re-treated with another 4-week course of oral antibiotics or with a 2-4 week course of intravenous ceftriaxone. A second 4-week course of oral antibiotic therapy is recommended for the patient whose arthritis has substantively improved but has not yet completely resolved, reserving intravenous antibiotic therapy for those patients whose arthritis failed to improve at all or worsened. Clinicians should consider waiting several months before initiating re-treatment with antimicrobial agents because of the anticipated slow resolution of inflammation after treatment.

When Intravenous Antibiotic Therapy for Lyme Disease is not covered

A. Intravenous antibiotic therapy for LD is considered not medically necessary in the following situations:

1. Patients with symptoms consistent with chronic fatigue syndrome or fibromyalgia;
2. Patients with seronegative LD in the absence of CSF antibodies;
3. Initial therapy in patients with Lyme arthritis without coexisting neurologic symptoms;
4. Cranial nerve palsy (e.g. **Bell's palsy**) without clinical evidence of meningitis;
5. Antibiotic-refractory Lyme arthritis (unresponsive to 2 courses of oral antibiotics or to 1 course of oral and 1 course of intravenous antibiotic therapy);
6. Patients with vague systemic symptoms without supporting serologic or CSF studies;
7. Patients with a positive ELISA test, unconfirmed by an immunoblot or Western blot test (see definition above);
8. Patients with an isolated positive serologic test in the setting of multiple negative serologic studies.

B. Repeat or prolonged courses (greater than 4 weeks) of antibiotic therapy are considered not medically necessary.

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

1. as a justification for continuation of IV antibiotics beyond 1 month in patients with persistent symptoms
2. as a technique to follow therapeutic response

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

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

Policy Guidelines

Three different CPT codes describe direct detection of *B. burgdorferi*: direct probe (87475), amplified probe technique (87476), and quantification (87477). When these codes were introduced in 1998, for the sake of consistency, the same grouping of 3 codes was used for a wide variety of different organisms. However, only the amplified probe technique (87476) is used clinically for the detection of *B. burgdorferi*. The direct probe technique (87475) is not clinically useful due to the small numbers of organisms present. The quantification technique (87477) has no clinical role at this time since treatment decisions are not based on the quantification of organisms present. Therefore, codes 87475 and 87477 would be considered investigational.

Published literature suggests that IV antibiotic therapy should be limited to those patients with objective and laboratory evidence of neuroborreliosis, those patients with carditis and heart block, and in those with well-documented severe Lyme arthritis that requires prompt relief of symptoms. No evidence supports prolonged (greater than 1 month) or repeated courses of IV antibiotic therapy.

Practice guidelines regarding the treatment of Lyme disease have been issued by the Infectious Diseases Society of America. These guidelines included the following recommendations for IV antibiotics. Note that none of the recommendations suggest longer than a 1-month course of IV antibiotics:

- **Meningitis** or radiculopathy; 14–28 days
- 3rd degree heart block; 14–21 days
- Recurrent arthritis after oral regimen; 14–28 days
- CNS or peripheral nervous system disease; 14–28 days

In addition, these guidelines recommend symptomatic treatment for symptoms that persist after appropriate antibiotic therapy. For example, patients with persistent arthritis may be treated with anti-inflammatory agents or arthroscopic synovectomy.

The Quality Standards Subcommittee of the American Academy of Neurology published evidenced-based practice parameters for the treatment of nervous system Lyme disease (Halperin, et al., 2007). The recommendations state:

- prolonged courses of antibiotics do not improve the outcome of post-Lyme syndrome, are potentially associated with adverse events, and are therefore not recommended,
- Recommended duration of both oral and parenteral regimens is 14 days, although it is noted that published studies have used courses ranging from 10 to 28 days without significantly different outcomes.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: 90774,86617,87475, 87476, 87477

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Policy Key Words

Key Words: Lyme disease, tick bite, ticks, deer tick, red rash, Borreliosis, DRU4129

Medical Term Definitions

Ataxia
failure of muscular coordination; irregularity of muscular action.

Antibody
a protein that is produced by the immune system against a specific antigen.

Antigen
any substance that the body regards as foreign or potentially dangerous. The body produces antibodies against this substance. Antigens may be soluble substances such as toxins and foreign protein or particulate such as bacteria and tissue cells.

Atrioventricular heart block
impairment of conduction of cardiac impulses from the atria to the ventricles, usually due to a block in the atrioventricular junctional tissue (atrioventricular node, bundle of His, or bundle branches). It is generally subclassified as first, second, or third degree atrioventricular block.

Bell's palsy
unilateral facial paralysis of sudden onset, due to lesion of the facial nerve and resulting in characteristic distortion of the face.

Cognition
that operation of the mind by which one becomes aware of objects of thought or perception; it includes all aspects of perceiving, thinking, and remembering.

Disseminated
scattered; distributed over a considerable area.

Encephalopathy
any degenerative disease of the brain.

IgG
immunoglobulin G.

IgM
immunoglobulin M

Intrathecal
into the subarachnoid space of the spinal column.

Lymphocytic
pertaining to, characterized by, or of the nature of lymphocytes.

Meningitis
inflammation of the meninges, usually by either a bacterium (bacterial m.) or a virus (viral m.).

Myopericarditis
inflammation of the muscular wall of the heart and of the enveloping pericardium.

Neuritis
inflammation of a nerve, with pain and tenderness, anesthesia and paresthesias, paralysis, wasting, and disappearance of the reflexes. See also neuropathy.

Oligoarthritis
arthritis of a small number of joints.

Palsy
complete or partial muscle paralysis, often accompanied by loss of sensation and uncontrollable body movements or tremors.

Paraparesis
a partial paralysis of the lower extremities.

Paresthesia
an abnormal touch sensation, such as burning, prickling, or formication, often in the absence of an external stimulus.

Pleocytosis
presence of a greater than normal number of cells in the cerebrospinal fluid.

Prophylactic
preventive measures taken before any disease is present.

Radiculoneuritis
acute idiopathic polyneuritis.

Spirochete
a spiral bacterium.

Tachyarrhythmia
rapid irregular heart beat.

Scientific Background and Reference Sources

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Policy Implementation/Update Information

3/2/06 Notification of new policy. Treatment of Lyme Disease consists of oral antibiotics, except for the following indications: A 2-to 4-week course of IV antibiotic therapy may be considered medically necessary (1) in patients with neuroborreliosis with objective neurologic complications of documented Lyme Disease. Objective neurologic findings include lymphocytic meningitis associated with CSF abnormalities, Bell's palsy or other cranial neuropathy associated with CSF abnormalities, encephalitis or encephalomyelitis associated with CSF abnormalities, radiculopathy, polyneuropathy; (2) in patients with Lyme carditis as evidenced by positive serologic findings and associated with a high degree of atrioventricular block or a PR interval of greater than 0.3 second; (3) 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.

Lyme Disease may be documented either on the basis of serologic testing or examination of the CSF. Positive serologic diagnosis is defined as both (1) positive or indeterminate ELISA test as characterized by IgG showing a titer >800 (positive) or a titer between 1:200 and 1:400 (indeterminate) or IgM ELISA test showing a titer of >200 (positive) or 1:100 (indeterminate) and (2) positive immunoblot or Western blot as characterized by (1) 2 of the 8 most common IgM antibody bands to spirochetal antigens are present or 5 of the 10 most frequent IgG antibody bands are present. All positive or indeterminate ELISA tests must be confirmed with immunoblot. Positive CSF findings include all of the following: pleocytosis; evidence of intrathecal production of *B.burgdorferi* antibodies in CSF; and increased protein levels.

IV antibiotic therapy for Lyme Disease is considered <u>not medically necessary</u> in the following situations: patients with symptoms consistent with chronic fatigue syndrome or fibromyalgia; patients with seronegative Lyme disease in the absence of CSF antibodies; initial therapy in patients with Lyme arthritis without coexisting neurologic symptoms; 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; patients with an isolated positive serologic test in the setting of

multiple negative serologic studies; repeat or prolonged courses (greater than 4 weeks) of antibiotic therapy.

The following are considered investigational: Repeat PCR-based direct detection of *B. burgdorferi* as a justification for continuation of IV antibiotics beyond 1 month in patients with persistent symptoms or as a technique to follow therapeutic response; PCR-based direct detection of *B. burgdorferi* in urine samples; genotyping or phenotyping of *B. burgdorferi;* CPT codes 87475 and 87477.

Notification given 3/2/06. Effective date 5/8/06.

5/5/08 Item A.2 in the When Covered section revised to read, "Cranial neuropathy, other than uncomplicated cranial nerve palsy, with documented CSF abnormalities." Revised the last sentence in Item C. to read, "Documentation of Lyme arthritis requires either unequivocal serologic studies, or when serologic studies are equivocal, PCR-based direct detection of B. burgdorferi in the synovial fluid." Also added bullet to Item C. with the following statement: "Patients who have persistent or recurrent joint swelling after a recommended course of oral antibiotic therapy should be re-treated with another 4-week course of oral antibiotics or with a 2-4 week course of intravenous ceftriaxone. A second 4-week course of oral antibiotic therapy is recommended for the patient whose arthritis has substantively improved but has not yet completely resolved, reserving intravenous antibiotic therapy for those patients whose arthritis failed to improve at all or worsened. Clinicians should consider waiting several months before initiating re-treatment with antimicrobial agents because of the anticipated slow resolution of inflammation after treatment." The following statements added to the Not Covered section: "Cranial nerve palsy (e.g. Bell's palsy) without clinical evidence of meningitis" and "Antibiotic-refractory Lyme arthritis (unresponsive to 2 courses of oral antibiotics or to 1 course of oral and 1 course of intravenous antibiotic therapy)." Statement from the American Academy of Neurology added to Policy Guidelines section. References updated. Specialty Matched Consultant Advisory Panel review 3/31/08. Notification given 5/5/08. Effective date 8/11/08.