

LYME DISEASE

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Overview

Lyme disease is a tickborne disease caused by *Borrelia burgdorferi*, a corkscrew-shaped bacterium (spirochete). The primary vector for Lyme disease in the northeastern U.S. is the deer tick (*Ixodes scapularis*). Deer ticks are generally found near the ground in brushy or wooded areas. They can be active year-round, as long as the temperature is above freezing. In the northeastern U.S., the most common reservoir for *B. burgdorferi* is the white-footed mouse (*Peromyscus leucopus*). In addition to Lyme disease, there are two other diseases found in Massachusetts that are known to be transmitted by the deer tick: babesiosis and human granulocytic ehrlichiosis (HGE). A deer tick may be co-infected with and capable of simultaneously spreading any one or all of these tickborne diseases.

Lyme disease is acquired through the bite of an infected tick. The tick must generally remain attached to the body for 24 to 48 hours before the transmission of *B. burgdorferi* is likely. Since deer tick bites are often painless and may occur on parts of the body that are difficult to observe, cases of diagnosed Lyme disease frequently have no known history of a tick bite. Symptoms of early localized Lyme disease, such as erythema migrans and/or flu-like symptoms (fever, muscle aches, headache, swollen lymph glands, fatigue, mild neck stiffness, and joint pain), usually develop between 7 to 10 days following an exposure, but the incubation period for early Lyme disease can range from 3 to 32 days. Lyme disease is not communicable from person to person.

Diagnosis

The diagnosis of early localized Lyme disease is a clinical diagnosis, not a laboratory diagnosis. In a patient with a compatible epidemiologic and clinical history, the preferred means of diagnosis of early localized Lyme disease is visual inspection of the distinctive skin lesion (erythema migrans). Performing a Lyme serology on a patient with clinically diagnosed early localized Lyme disease can lead to confusing and contradictory results. Patients should be treated on the basis of clinical findings.

The vast majority of untreated persons with normal immune systems with persistent *B. burgdorferi* infections will eventually develop a strong antibody response and a positive serologic response. IgG antibodies to *B. burgdorferi* are usually detectable 4 to 6 weeks after the initial infection.

In the absence of physician-diagnosed erythema migrans, the manifestations of early disseminated Lyme disease are too non-specific to warrant a purely clinical diagnosis and laboratory support for the diagnosis is required. Similarly, in the absence of



physician-diagnosed erythema migrans, late Lyme disease is diagnosed based on the presence of at least one late manifestation and laboratory confirmation of infection.¹ Untreated patients who remain seronegative, despite continuing symptoms for 6 to 8 weeks are unlikely to have Lyme disease and other potential diagnoses should be actively pursued.

Serum specimens should be tested according to the Centers for Disease Control and Prevention (CDC) recommendations. Initial testing of serum specimens is by enzyme immunoassay (EIA) or immunofluorescent assay (IFA). Confirmatory testing of specimens with positive or equivocal results from these tests should be performed with a standardized Western Blot procedure.² The Massachusetts Department of Public Health (MDPH) Viral Serology Laboratory performs confirmatory testing for Lyme disease by Western Blot assay on specimens with either a positive or equivocal result by EIA or IFA at no charge. For additional information on specimen submission, contact the MDPH Viral Serology Laboratory at (617) 983-6396.

Following successful treatment, the antibody pattern may continue to evolve for weeks as the immune system catches up with the recent infection. The Western Blot pattern may fail to develop completely, but it will remain positive for years. There is no serologic proof of cure available for Lyme disease. (Lyme titers and the Western blot will remain positive for years after treatment for Lyme disease. If the plan member's symptoms have resolved, there is no point in rechecking the titer. If symptoms remain after treatment, other diagnoses should be considered.)

Testing of ticks for tickborne infectious agents is not recommended.

Prophylaxis

No vaccine is currently available in the U.S. to prevent Lyme disease in humans. Avoidance of ticks and use of tick repellents can prevent the disease. Since transmission of *B. burgdorferi* is more likely with prolonged tick attachment, prompt removal of ticks can also prevent disease.

Antibiotic prophylaxis after a tick bite is controversial. Routine use of antibiotics is not recommended. The Infectious Diseases Society of America (IDSA) recommends a single dose of doxycycline to adults and children 8 years of age and older³ when all of the following circumstances exist:

¹ When serology is positive or equivocal and Western Blot pattern is not diagnostic by CDC criteria, then the test is likely to be false positive. For patients with symptoms in excess of 4 weeks to be considered seropositive, reactivity must be present of the Western Blot specifically.

² Although useful for documentation of *B. burgdorferi* infection in research studies, amplification of *B. burgdorferi* DNA by polymerase chain reaction or culture of specimens of skin or blood for *Borrelia* species is not recommended. (IDSA Guidelines, 2006)

³ The IDSA does not believe that amoxicillin should be substituted for doxycycline in persons for whom doxycycline is contraindicated because of the absence of data on an effective short-course regimen for prophylaxis, the likely need for a multiday regimen (and its associated adverse effects), the excellent efficacy of antibiotic treatment of Lyme disease if infection were

1. The attached tick can be reliably identified as an *I. scapularis* tick that is estimated to have been attached for ≥ 36 hours,
2. Prophylaxis can be started within 72 hours of the time the tick was removed,
3. Ecologic information indicates that the local rate of infection of these ticks with *B. burgdorferi* is $\geq 20\%$, and
4. Doxycycline is not contraindicated (doxycycline is contraindicated in pregnant women and children < 8 years old).

It is not known whether antibiotic prophylaxis after a tick bite will reduce the incidence of HGE or babesiosis.

Treatment

The treatment of early localized or early disseminated Lyme disease has been extensively studied in well-conducted randomized controlled trials. Several conclusions can be drawn from these trials:

- Oral antibiotic therapy (doxycycline, amoxicillin, and cefuroxime axetil) has been shown to be highly effective in the treatment of erythema migrans and generally prevents development of late sequelae.
- Doxycycline has the advantage of being effective for treatment of HGE (but not for babesiosis) which may occur simultaneously with early Lyme disease.
- Amoxicillin is as effective as doxycycline in the treatment of early Lyme disease and is preferred for pregnant women and children less than 8 years of age. Cefuroxime axetil is also as effective as doxycycline in the treatment of early Lyme disease, but much more expensive.
- Patients in whom bacterial cellulitis cannot be excluded should be treated with cefuroxime axetil (or amoxicillin/clavulanic acid) since these drugs are effective against Lyme disease as well as *Streptococcus pyogenes* and most community-acquired strains of *Staphylococcus aureus*.
- Approximately 10% of individuals have persistent symptoms despite receiving therapy that appears to be curative. These individuals appear to have not responded to antibiotic therapy as evidenced by the presence of objective clinical manifestations, however rarely is re-treatment required.
- In general, patients who are more systemically ill at the time of diagnosis take longer to have a complete response to therapy.

Macrolide antibiotics (such as erythromycin and azithromycin) have been systematically studied and are less effective than the above recommended antibiotics. Macrolides are not recommended as first-line therapy for early Lyme disease. When used, they should be reserved for patients who are intolerant of amoxicillin, doxycycline and cefuroxime axetil. Patients treated with macrolides should be closely observed to ensure resolution of the clinical manifestations.

to develop, and the extremely low risk that a person with a recognized bite will develop a serious complication of Lyme disease. (IDSA Guidelines, 2006)



Manifestations of acute peripheral nervous system involvement in early Lyme disease include radiculopathy, cranial neuropathy, and mononeuropathy multiplex (multifocal involvement of anatomically unrelated nerves). Central nervous system involvement includes lymphocytic meningitis and rarely, encephalomyelitis. In the U.S., cranial neuropathy is the most common manifestation of early neurologic Lyme disease. Seventh nerve palsy is the most common of the cranial neuropathies, and bilateral involvement may occur. In the absence of erythema migrans, neurologic manifestations are too nonspecific to warrant a purely clinical diagnosis; laboratory support for the diagnosis is required. The vast majority of patients with early neurologic Lyme disease are seropositive.

Patients with symptomatic cardiac involvement associated with early Lyme disease (Lyme carditis) usually present with the acute onset of varying degrees of intermittent atrioventricular heart block, sometimes in association with clinical evidence of myopericarditis. In the absence of concomitant erythema migrans, the clinical manifestations of Lyme carditis are too nonspecific to warrant a purely clinical diagnosis. Under these circumstances, support for the diagnosis requires laboratory support for the diagnosis. The vast majority of patients with cardiac manifestations of Lyme disease are seropositive at the time of presentation. Hospitalization and continuous monitoring are recommended for symptomatic patients (e.g., those with syncope, dyspnea, or chest pain). A temporary pacemaker may be required for patients with advanced heart block.

In the absence of effective treatment of early Lyme disease, late manifestations of Lyme disease may become apparent weeks to even years after the initial infection. People may experience arthritis, encephalopathy, encephalomyelitis, and peripheral neuropathy.

Lyme arthritis typically involves the knee(s), however other large joints or the temporomandibular joint may be involved. Large knee effusions that are out of proportion to the pain are typical. A Baker's cyst may develop and may rupture. Lyme arthritis is often intermittent in nature if untreated, with episodes of joint inflammation spontaneously resolving after a few weeks to a few months. Persistent swelling of a joint for 12 months or more would not be characteristic of Lyme arthritis. In the vast majority of patients, the clinical manifestations are too nonspecific to warrant a purely clinical diagnosis of Lyme arthritis. Confirmation of the diagnosis requires serologic testing. In a seropositive patient, a positive PCR test result on a synovial fluid specimen adds diagnostic certainty. Positive PCR results for a joint fluid specimen from a seronegative patient should be regarded with skepticism.

Late neurological Lyme disease may present as encephalomyelitis, peripheral neuropathy, or encephalopathy. Because most patients with Lyme disease are now diagnosed and treated early in the course of infection, these more indolent forms of neurologic Lyme disease are quite rare. Neurologic evaluation that may include lumbar puncture should be performed for patients in whom there is a clinical suspicion of encephalomyelitis.

Some treated patients whose objective manifestations of Lyme disease have resolved with antibiotic treatment report subjective symptoms such as fatigue, musculoskeletal pain or cognitive difficulties of varying intensity that may persist over prolonged periods. Considerable confusion and controversy exist over the frequency and cause of this process and even over its existence. To date, there is no convincing biologic evidence for the existence of a post-Lyme disease syndrome (sometimes known as “chronic Lyme disease”). Microbiologic evaluation of these patients has failed to find evidence of either persistent *B. burgdorferi* infection or of infection with another tickborne pathogen. A randomized controlled study compared 129 symptomatic patients (78 seropositive and 51 seronegative) with a history of Lyme disease who were given 1 month of intravenous ceftriaxone plus 2 additional months of oral doxycycline to placebo and found no clinical benefit of antibiotic therapy. (Klempner MS, 2001) Antibiotic therapy has not proved to be useful and is not recommended for patients with symptoms lasting 6 months or more (“chronic Lyme disease”) following completion of the recommended treatment regimen for Lyme disease.

Definitions

Early localized Lyme disease – Signs and symptoms during early localized illness usually occur within 3–32 days of exposure to infected ticks, and they tend to be nonspecific. Symptoms may include fever, muscle aches, headache, swollen lymph glands, fatigue, mild neck stiffness, and joint pain. A distinctive rash called erythema migrans occurs at the site of the tick bite in approximately 80% of cases, although when these painless lesions occur in a location hidden from view (e.g., armpit, back), they may not be seen by the patient. Erythema migrans frequently clears in the center, resulting in the classic “bull’s-eye” presentation, but this does not always occur. The rash may be reported as warm or itchy, but it is usually painless.

Early disseminated Lyme disease – Without appropriate antibiotic treatment, the spirochete may begin affecting multiple organ systems within 3 to 5 weeks after the tick bite. A patient with disseminated infection may have symptoms of fever and fatigue (often profound). There may be multiple erythema migrans lesions, diffuse redness of the skin, or hives. Muscle and joint aches are commonly reported. Swollen lymph glands, sore throat, non-productive cough, and conjunctivitis may also be noted. Neurologic symptoms may include headache, stiff neck (aseptic meningitis), Bell’s (facial) palsy, and pain or tingling sensations in the extremities, as well as impairments of mood, memory, or sleep patterns. Less commonly, people may experience cardiac symptoms such as atrioventricular block or inflammation of the heart or of the sac surrounding the heart.

Erythema migrans – Primary erythema migrans is a round or oval, expanding erythematous skin lesion that develops at the site of deposition of *B. burgdorferi* by an *I. scapularis* tick. These skin lesions typically become apparent approximately 7 to 14 days (range, 3 to 30) after the tick has detached or was removed and should be at least 5 cm in diameter for a secure diagnosis. Erythema migrans frequently clears in the center, resulting in the classic “bull’s-eye” presentation, but this does not always occur. When there is more than one erythema migrans lesion, the secondary lesions are



believed to arise by hematogenous dissemination from the site of primary infection. Erythema migrans lesions can vary in appearance.

Late Lyme disease – In the absence of effective treatment of early Lyme disease, late manifestations of Lyme disease may become apparent weeks to even years after the initial infection. People may experience arthritis, commonly involving the large joints, such as the knees or the shoulders. The joint swelling and pain may be recurrent. Lyme arthritis may be confused with other forms of arthritis, particularly if the tick bite was unrecognized and early symptoms were undiagnosed. People with late Lyme disease may also experience neurologic or heart complications. The symptoms of late Lyme disease can be debilitating and can persist for prolonged periods of time.

Post-Lyme disease syndrome – Currently, there is no well-accepted definition of post-Lyme disease syndrome, also known as “chronic Lyme disease”. Generally it is defined as the presence of any of the following symptoms: widespread musculoskeletal pain, cognitive complaints, radicular pain, paresthesias, or dysesthesias that interfere with the ability to function. The onset of these symptoms usually begins within 6 months after the initial diagnosis and treatment of *B. burgdorferi* infection and persists for at least 6 months. Individuals with chronic symptoms and no serologic evidence of *B. burgdorferi* infection usually are suffering from a condition other than Lyme disease.

Policy

Prior authorization by an FCHP Medical Director is required for IV antibiotic therapy for the treatment of Lyme disease beyond 28 days.

FCHP covers the antibiotic treatment regimens recommended by the Infectious Diseases Society of America (Wormser et al., 2006) for plan members diagnosed with Lyme disease as specified in the Overview section of this policy. Prolonged courses of antibiotics are associated with significant morbidity, do not improve outcome, and are not recommended.

For most IV antibiotic regimens, a single course of treatment is 14 days, however, for late neurologic Lyme disease the recommended IV antibiotic regimen is 14 to 28 days. Regardless of the clinical manifestation(s) of Lyme disease, complete response to treatment may be delayed beyond the treatment duration. Relapse may occur with any of these regimens and plan members with objective signs of relapse may be treated with a second 14 day course of treatment. For plan members diagnosed with late neurologic Lyme disease, FCHP may authorize a second 14 to 28 day course of IV antibiotic therapy (i.e., up to 56 days of IV antibiotic treatment) when relapse is shown by reliable objective measures.

Note: FCHP covers medications for the treatment of Lyme disease subject to the terms and conditions of the member’s benefit plan. Some medications for the treatment of Lyme disease are covered under the medical benefit and other medications are covered under the prescription drug benefit. Plan members who do not have a prescription drug benefit, do not have coverage for prescription drugs for the treatment of Lyme disease.

Infectious Diseases Society of America recommended antibiotic regimens for the treatment of Lyme disease:

1. Lyme disease prophylaxis –
A single dose of doxycycline may be offered to non-pregnant adults (200 mg) and children 8 years of age or older (4 mg/kg, up to a maximum dose of 200 mg) when all of the following criteria are met:
 - a. The attached tick can be reliably identified as an *I. scapularis* tick that is estimated to have been attached for ≥ 36 hours,
 - b. Prophylaxis can be started within 72 hours of the time the tick was removed,
 - c. Ecologic information indicates that the local rate of infection of these ticks with *B. burgdorferi* is $\geq 20\%$, and
 - d. Doxycycline is not contraindicated (doxycycline is contraindicated in pregnant women and children < 8 years old).

2. Early localized or early disseminated Lyme disease associated with erythema migrans in the absence of specific neurologic manifestations –
 - a. Adults with early localized or early disseminated Lyme disease should be treated with oral antibiotic therapy (doxycycline, amoxicillin, or cefuroxime axetil) for 14 days.
 - b. Children with early localized or early disseminated Lyme disease should be treated with oral antibiotic therapy (amoxicillin or cefuroxime axetil, or doxycycline if ≥ 8 years of age) for 14 days.

Cefuroxime axetil (or amoxicillin/clavulanic acid) is preferred for patients in whom bacterial cellulitis cannot be excluded should be treated with since these drugs are effective against Lyme disease as well as *Streptococcus pyogenese* and most community-acquired strains of *Staphylococcus aureus*.

Note: Macrolide antibiotics should only be used for patients who are intolerant of amoxicillin, doxycycline and cefuroxime axetil. Patients treated with macrolides should be closely observed to ensure resolution of the clinical manifestations.

3. Early Lyme disease and acute neurologic manifestations –
 - a. Patients with early Lyme disease and seventh cranial nerve palsy should be treated oral antibiotic therapy (doxycycline, amoxicillin, or cefuroxime axetil) for 14 days.⁴

⁴ Seventh cranial nerve palsy usually resolves with or without antibiotic treatment, however, one small (N=16) study (Kalish et al., 2001) showed that 14 of 16 patients who were not treated with antibiotics later developed Lyme arthritis. Therefore, all patients with cranial nerve palsy should be treated with oral antibiotics (doxycycline, amoxicillin, and cefuroxime axetil), not for the purpose of treating the paralysis which will usually resolve within a few weeks regardless of treatment, but rather to prevent later complications.

- b. Adults with early Lyme disease and radiculopathy or meningitis should be treated with ceftriaxone intravenously for 14 days. Cefotaxime or penicillin G administered intravenously are acceptable alternatives.
 - c. Children with early Lyme disease and radiculopathy or meningitis should be treated with ceftriaxone or cefotaxime intravenously for 14 days. Penicillin G administered intravenously is an acceptable alternative.
4. Early Lyme disease and acute cardiac manifestations –
Patients with early Lyme disease and atrioventricular heart block and/or myopericarditis should be treated with an oral antibiotic (doxycycline, amoxicillin, or cefuroxime axetil) for 14 days, or an intravenous antibiotic (such as ceftriaxone) for 14 days. Cefotaxime or penicillin G intravenously are acceptable alternatives. For patients who require hospitalization, an intravenous regimen is recommended for the start of therapy; an oral regimen may be substituted to complete a course of therapy for to treat ambulatory patients.
5. Late Lyme arthritis without clinical evidence of neurologic disease –
 - a. Adults with Lyme arthritis without clinical evidence of neurologic disease should be treated with oral antibiotics (doxycycline, amoxicillin, or cefuroxime axetil) for 28 days.
 - b. Children with Lyme arthritis without clinical evidence of neurologic disease should be treated with oral antibiotic therapy (amoxicillin or cefuroxime axetil, or doxycycline if ≥ 8 years of age) for 28 days.

Patients who have persistent or recurrent joint swelling after a recommended course of oral antibiotic therapy should be re-treated with another 28 day course of oral antibiotics (doxycycline, amoxicillin, or cefuroxime axetil) or with a 14 day course of intravenous ceftriaxone. A second 28 day course of oral antibiotic therapy is recommended for the patient whose arthritis has substantially 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 retreatment with antibiotics because of the anticipated slow resolution of inflammation after treatment. During this period NSAIDs may be used, but intraarticular injections of corticosteroids are not recommended

- b. Children with Lyme arthritis without clinical evidence of neurologic disease should be treated with oral antibiotic therapy (amoxicillin or cefuroxime axetil, or doxycycline if ≥ 8 years of age) for 28 days.
6. Late Lyme arthritis with objective evidence of neurologic disease –
 - a. Adults with Lyme arthritis plus objective evidence of neurologic disease should be treated with intravenous ceftriaxone for 14 days. Cefotaxime or penicillin G administered intravenously are acceptable alternatives.
 - b. Children with Lyme arthritis plus objective evidence of neurologic disease should be treated with intravenous ceftriaxone or cefotaxime for 14 days. Penicillin G administered intravenously is an acceptable alternative.

7. Late neurologic Lyme disease⁵ –
Patients with late neurologic Lyme disease affecting the central or peripheral nervous system should be treated with ceftriaxone intravenously for 14 to 28 days. Cefotaxime or penicillin G administered intravenously are acceptable alternatives. Response to treatment is usually slow and may be incomplete. Retreatment is not recommended unless relapse is shown by reliable objective measures.⁶ Response to treatment may be delayed for weeks or months after the cessation of antibiotics.
8. Patients with widespread musculoskeletal pain, cognitive complaints, radicular pain, paresthesias, or dyesthesias that interfere with the ability to function, with or without a history of Lyme disease and with or without evidence of Lyme disease are recognized not to benefit from antibiotic therapy beyond that needed after initial treatment for Lyme disease.

Exclusions

1. Tick identification or testing of ticks for infectious diseases.
2. Amplification of *B. burgdorferi* DNA by polymerase chain reaction (PCR) or culture of specimens for *Borrelia* species (with the exception of PCR of synovial fluid in a seropositive patient with Lyme arthritis).

Codes

ICD-9-CM Diagnosis code 088.81 Lyme disease (erythema chronicum migrans) should be the primary diagnosis code on claims for services related to the diagnosis and treatment of Lyme disease.

Codes	Number	Description
CPT	96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
	96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour
	96367	Intravenous infusion, for therapy, prophylaxis, or

⁵ The diagnosis of late neurologic Lyme disease is a clinical diagnosis that requires demonstration of CSF evidence supporting CSN infection with *B. burgdorferi*.

⁶ Diagnosis of neurologic Lyme disease requires objective evidence of nervous system involvement. Clinical manifestations vary widely, depending on the site and severity of involvement. Both the central and peripheral nervous systems may be involved. Cranial neuropathies, particularly Bell palsy (which may be bilateral), are common, occurring in 5% to 10% of untreated infected patients. The other very common -- and most frequently misdiagnosed -- problem is an inflammatory radiculopathy. In patients with this disorder, the pain, sensorimotor symptoms, and deficits can precisely mimic a mechanical radiculopathy, except that there is usually no antecedent injury and findings on imaging studies are usually unimpressive. Neurophysiologic testing of the peripheral nervous system, imaging of the neuraxis, and examination of the cerebrospinal fluid can all be informative. In evaluating response to treatment and relapse, consideration should be given to the fact that many neurologic illnesses improve over time, regardless of treatment.



		diagnosis (specify substance or drug); additional sequential infusion, up to 1 hour
	96368	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); concurrent infusion
HCPCS	J0696	Injection, ceftriaxone, per 250 mg
	J0698	Cefotaxime sodium, per g
	J2510	Injection, penicillin G procaine, aqueous, up to 600,000 units
	S9494	Home infusion therapy, antibiotic, antiviral, or antifungal therapy; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment, per diem
	S9497	Home infusion therapy, antibiotic, antiviral, or antifungal therapy; once every 3 hours
	S9500	Home infusion therapy, antibiotic, antiviral, or antifungal therapy; once every 24 hours
	S9501	Home infusion therapy, antibiotic, antiviral, or antifungal therapy; once every 12 hours
	S9502	Home infusion therapy, antibiotic, antiviral, or antifungal therapy; once every 8 hours
	S9503	Home infusion therapy, antibiotic, antiviral, or antifungal therapy; once every 6 hours
	S9504	Home infusion therapy, antibiotic, antiviral, or antifungal therapy; once every 4 hours

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Products to Which This Policy Applies

- ⊕ FCHP Direct & Select Care
- ⊕ Fallon Preferred Care
- ⊕ Major Medical
- ⊕ MassHealth
- ⊕ Companion Care
- ⊕ Commonwealth Care
- ⊕ Medicare Advantage
- ∅ Summit ElderCare® PACE (Note: With the exception of emergency care, all services for Summit ElderCare® PACE participants must be authorized and arranged by the Summit ElderCare (SE) Interdisciplinary Team (IDT) overseeing the care for that participant. The applicable team can be determined by the site code on the participant ID card. The site codes and corresponding telephone numbers are: SW1-SE East Mtn St. Worcester-508-852-2026, SW2-SE Grafton St. Worcester-508-373-7400, SC1-SE Charlton-508-434-3200, SL1-SE Leominster-978-401-3100.)

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IMPORTANT NOTE:

Not all services are covered for all products or employer groups. This medical policy expresses FCHP's determination of whether certain services or supplies are medically necessary, experimental or investigational or cosmetic. FCHP has reached these conclusions based upon the regulatory status of the technology and a review of clinical studies published in peer-reviewed medical literature. Even though this policy may indicate that a particular service or supply is considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. Members and their providers need to consult the Evidence of Coverage to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and the plan of benefits, the provisions of the benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Medicare and Medicaid members, this policy will apply unless Medicare and Medicaid policies extend coverage beyond this medical policy.