Lyme Disease Payment Policies Under Fire

Insurers say there's a limit to how far they'll go for Lyme disease patients

Vocal consumer groups, physicians, and home infusion therapy providers have called on insurance companies to modify their restrictive payment policies for intravenous antibiotic therapy for Lyme disease. The debate over what is acceptable medical treatment is heating up as a growing number of Americans contract Lyme disease.

Since 1981, more than 40,000 Lyme disease cases have been reported in the United States, says the federal Centers for Disease Control. In 1991, more than 9,300 cases of Lyme disease were reported in 46 states, a 17.64 percent increase from the year before, CDC says.

Costly to Treat

Lack of reliable diagnostic tests often leads to late treatment of Lyme disease and can result in high medical costs. The disease begins with a rash and flu-like symptoms. But if it's not treated promptly—by oral or I.V. antibiotic therapy—Lyme disease can lead to chronic problems including heart irregularities, arthritis, and neurologic damage.

When I.V. antibiotic therapy is administered in the patient's home, usual costs can reach $3,000 a week—approximately half the cost of hospital-based treatment. Oral antibiotics cost from $50 to about $200 a week.

The average cost in lost income and medical bills for an individual diagnosed with Lyme disease could reach more than $61,500, a recent study cosponsored by the Lyme Disease Foundation and the Society of Actuaries concludes. If treatment is delayed for more than 12 months after the disease is contracted, however, average costs could soar to $91,500, the study says.

Short-Term vs. Long-Term Treatment

There is a bitter controversy in the medical community as to what level and how long I.V. antibiotic therapy should be ordered to treat Lyme disease, says Ann Ebert, president of Victims Against Insurance Company Exploitation, a consumer advocacy group opposing insurance company attempts to cut benefits for chronically ill patients.

Some insurance companies, including Blue Cross and Blue Shield of New Jersey, Prudential Insurance Co. of America, and Aetna, are now adopting payment policies that Lyme disease is effectively treatable with only 28 days of oral or I.V. antibiotic therapy, says Ebert.

"Twenty-eight days is grossly inadequate for treating Lyme disease," she says, noting that oral or I.V. antibiotic treatment may be needed beyond the 28-day period to wipe out the spirochete organism that causes Lyme disease.

In a May 1992 position statement, Blue Cross and Blue Shield of New Jersey states that, while it considers I.V. antibiotics and other therapy for late-stage manifestations of Lyme disease to be appropriate, after 28 days, the therapy is considered "investigational" and not eligible for continued coverage unless medical necessity—as determined by BCBS—is demonstrated.

"Neither the National Institutes of Health nor the CDC has issued any rigid guidelines for treating Lyme disease," according to New Jersey internist John Bleiweiss, M.D., a vocal critic of insurance company payment policies for the disease. "Insurance carriers have adopted a standard of care that is inconsistent with the available research data."

Bleiweiss charges that one major New Jersey-based insurance company could not provide him with one article that examined the effectiveness of only 28 days of antibiotic I.V. therapy—nor could the company cite a study that evaluated the efficacy of longer therapy.

Physicians must base their judgment on what is best for the patient," he says.

Pure Economics

Pentech Infusions, a Pennsylvania-based home infusion company, has also come up against private insurers on Lyme disease therapy reimbursement. "Some insurance companies might pay for oral antibiotics even after 28 days of I.V. antibiotic therapy," says Jerry Francesco, president of Pentech.

"The policy comes down to pure economics," Francesco says. "They are clearly trying to save money. But is the disease cured or not?"

Better research could finally solve this payment policy dispute, says David Dennis, coordinator of the CDC's Lyme disease program.

"I have never seen a study that looks at long-term versus short-term Lyme disease treatment," Dennis says. "That is the problem. We don't have published data to evaluate the effectiveness of extended treatments."

Herbert P. Weiss is a Gaithersburg, Maryland-based writer specializing in health care and aging topics.

(**Self-Referrals**, *continued from page 2)*

confining hospital setting, and would prevent them from continuing their work and home activities. Slow continuous infusion of chemotherapy tends to be easier on the patient than single injections of large doses, which have worse side effects.

"When we prohibited self-referrals for clinical laboratory services in 1989, we provided an exception for referral by pathologists because, after all, laboratory services are integrally related to a pathologist's medical practice. Similarly, the drug therapies administered through these portable infusion pumps are not only an integral part of the medical oncologist's practice, for all intents and purposes, they constitute the practice itself. Treating cancer through drug therapies is what a medical oncologist does."

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When Payers Won't Pay

When a private insurer denies a legitimate claim, legal action may be the only hope, says one expert

Getting correctly coded claims out the door is a tough job, but keeping insurance companies from delaying or denying payment is just as challenging. Home infusion providers must be prepared to present their case to the payer's appeal process to reduce the possibility of costly litigation.

Private insurers have increasingly developed guidelines to monitor medical claims, and during this review process payment can be delayed or denied for several reasons. First, the medical treatment may not be covered by the patient's insurance policy. Second, the treatment may be regarded as experimental or not medically necessary. Finally, the payer may not consider the charge to be usual and customary for the treatment.

Home infusion providers can take steps in advance to reduce the probability of claim denial, says Abraham Wax of the Manhattan, New York law firm of Moldover, Hertz, Cooper, & Gidaly, who has handled more than 100 claims against insurance companies. "Insurance carriers fail to pay up to 30 percent of all claims submitted by home infusion providers," Wax notes.

Verify, Verify, Verify

"The first step is to verify the terms of the policy as to the coverage and the coverage limitations," Wax says. "Insurance companies never give this type of information in writing, so it becomes important for you to document your conversation," he says.

If the home care provider hasn't correctly verified the policy, it is going to lose in the appeals process, Wax warns. "In many cases, you can't verify the patient's coverage until you talk to a case manager."

Once a claim has been denied, your first step should be to monitor the explanation of benefits to determine if any coding or documentation errors have occurred (see box). This will help you clear up any discrepancies.

Appealing the Denial

Before considering litigation, take your case through the insurance company's appeal process.

Many home infusion providers include clinical documentation when the claim is initially submitted. Wax recommends that providers also resubmit the complete documentation during the appeal process. "Don't rely on the insurance company to have this documentation if your claim is denied and you appeal the decision," he advises. "They often claim that they never received it."

When compiling supporting clinical documentation for your appeal, don't forget to include the nurses' notes, Wax tells us. "The notes record the progress of the patient and frequently show that the treatment was necessary."

In addition, "send the doctor's certificate of medical necessity and the plan of treatment," Wax recommends. "Many providers often don't include these documents in the appeals process."

Always demand a copy of the consultant's report—a formal or informal medical opinion solicited by the insurance company—especially if it's being used to deny your claim, Wax recommends. "The insurance company should not conduct the appeal if they are going to use documents that you don't know about, but they do," he says.

When appealing a denial on the usual and customary charge, document if the payer previously paid the same amount for the same service, Wax says. If you can't find supporting documentation, provide the rates of your competitors.

When All Else Fails

If the payer's decision is upheld in appeal, "institute suit immediately," Wax advises.

Once a lawsuit is initiated, the insurer has only 20 to 30 days to answer the complaint, and will often assign a paralegal (or a paramedical) to research the case. "At this stage, in my experience, if it should get paid, it will get paid," he says. Unfortunately, however, this often doesn't happen until a lawsuit has already begun.

By Herbert P. Weiss, a Gaithersburg, Maryland-based writer specializing in health care and aging topics. Weiss is the managing editor of Brown University Long-Term Care News.

Spotting Coding and Documentation Errors

The following tips on monitoring the explanation of medical benefits (EOMB) can provide valuable information on a third-party payer's reimbursement policy and can help you to flag coding errors.

- Locate the amount of payment on the EOMB. Does the third-party payer consistently pay the same amount for the same services? If not, contact the payer to clear up the discrepancy.
- Identify procedures that have been down-coded. Provide the third-party payer with documentation that justifies the use of the original procedure codes.
- Determine if the claim was processed completely. Be sure that the third-party payer did not mistakenly "drop" a code. If it did, resubmit the claim immediately.
- If payment for service is denied because medical necessity is not justified, reexamine the diagnoses listed on the claim. If they are incorrect or incomplete, make corrections and resubmit the claim with all necessary documentation.

Source: *St. Anthony' CPT Coding for Physician Reimbursement*, August 1989, p.4. Reprinted with permission of St. Anthony's Publishing, Inc.

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INFUSION

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KNOWING THE FEDERAL ANTIKICKBACK RULE

Your best intentions may not be enough

Home infusion providers gained a greater insight into the intricacies of the federal statutes relating to Medicare and Medicaid fraud and abuse during an NHIA Third Annual Conference workshop, "Legal Issues in Home Infusion Therapy." The Third Annual Conference was held April 27-30 at Nashville's Opryland Hotel.

While the federal antikickback statute is in itself not news, making sure your home infusion therapy operations are in full compliance is of ever-increasing importance, speaker Elizabeth Carder, Esq., of the Washington, DC-based law firm of Reed, Smith, Shaw, and McClay told providers. Despite your best intentions, lack of knowledge about the statute can financially hurt your company, as noncompliance might result in hefty fines and exclusion from the Medicare and Medicaid programs, Carder explained.

Under the felony statute, providers convicted of soliciting or paying a kickback can be fined $25,000 and face five years imprisonment and exclusion from the programs. Bear in mind that the definition of "kickback" is quite broad. "If there is something of value that is being given it can be considered a kickback even though it is not cold, hard cash," she cautioned.

If the Department of Health and Human Services Inspector General's Office (OIG) concludes that a provider has been paying or receiving kickbacks, a review will take place before an HHS administrative panel. "Forget a trial by jury or the legal protection of 'beyond a reasonable doubt,'" Carder added.

As the old saying goes, ignorance is no excuse. Health care providers found to have filed claims for services that they knew *or should have known* were not provided can be excluded from Medicare and Medicaid by HHS's civil exclusion authority, even if they choose to settle the case by paying a civil money penalty, Carder warned.

CASE STUDIES

Carder noted that the OIG offers little guidance to providers about what it considers improper behavior. Therefore, "it becomes necessary to glean information from enforcement activities," she said.

During her session, Carder highlighted the following cases to give providers a better understanding of what type of activities the OIG has investigated. While the examples do not relate specifically to home I.V. providers, there are lessons to be learned from these precedents:

Elizabeth Carder, Esq.

- **Frequent prescriber program.** A pharmaceutical manufacturer offered physicians a starter bottle of a new drug and prescription pads. After prescribing the medication and completing a simple patient profile, the physician accumulated points that could be used for free airline tickets and medical textbooks. The Massachusetts Medicaid fraud control unit charged the manufacturer with providing points to induce physicians to prescribe the drug. The company settled with the state for $195,000; the company later paid an $830,000 fine assessed by the OIG.
- **Blood Glucose Monitor Rebates.** Under a special rebate program, a manufacturer offered a $25 rebate to individuals purchasing monitors from pharmacists, but the rebate was not reflected in the claim submitted to Medicare. An OIG review concluded that the patient rather than the Medicare program benefited from the rebate program. The manufacturer agreed to restructure the program to give the rebate to the pharmacist who then reported it on the claim.
- **Therapeutic Switch Payments.** A manufacturer proposed to pay a $35 fee to pharmacists for every patient switched to its antihypertensive drug from a competing product. Because of complaints from the competitor, the program was later changed to pay pharmacists for

(Continued on page 2)

(**Antikickback Rule**, *continued from page 1)*

"cognitive and counseling services." Eleven state attorneys general questioned the practice under the federal statute and state consumer protection statutes, alleging that deceptive advertising occurred when the pharmacists influenced patients to switch drugs without telling them they were paid to do so. The manufacturer paid a $605,000 fine; the OIG is still investigating this case.

Protecting Yourself

Providers can protect themselves against fraud and abuse charges by documenting everything. "Keep all your old newsletters that provide tips on billing," Carder suggested, because they might be needed down the line to negate criminal intent.

Watch out, too, for lavish entertaining that might be perceived as inducements for referrals. For example, said Carder, it's a red flag to the OIG when a company holds meetings of its medical board at four-star hotels. Meals at these events should always be modest, she added.

In a 1991 report on pharmaceutical industry promotional practices, the OIG charged that physician prescribing practices are unduly influenced by payments and gifts, including drug studies, speaking engagements, and program attendance, according to Carder. Based on this report, the least questionable gifts are those that assist physicians in their offices. "The OIG viewed pencils or pens worth less than $100 as least questionable gifts," she explained.

It is crucial for home infusion providers to thoroughly understand and comply with the fraud and abuse statute. Regardless of whether comprehensive national health care reform legislation passes, the statute will probably be expanded this year to cover all third-payer payers, Carder predicts.

By Herbert Weiss, N.H.A., a Providence, Rhode Island-based freelance writer covering health care and aging issues.

Exceptions to the Antikickback Statute

Carder identified five statutory exceptions to federal fraud and abuse laws

- **Drug discounts.** Pharmaceutical companies may, in some situations, offer discount pricing on pharmaceuticals.
- **Employer payments to employees.** Sales commissions by an employer to an employee are exempt.
- **Group purchasing.** Pharmacies are allowed to participate in group purchasing arrangements.
- **Waiver of certain coinsurance.** Hospitals might choose to waive a patient's Part A coinsurance; however, Part B coinsurance may not be waived.
- **Safe harbors.** If a company follows specific business practices, called "safe harbors," while entering into a business arrangement, it will be protected from prosecution and civil penalties of the antikickback statute.

DMERC Warns of 'Serious Billing Problems'

Although claims processing is generally speeding up at the four Medicare Part B DME regional carriers, "serious billing errors" are still occurring on many parenteral and enteral nutrition claims. Many of these errors stem from following billing protocols from the previous PEN carriers.

Watch out for the following, advises Region D electronic claims specialist Cara Shockley:

- All measures of days or units for PEN claims should be stated without decimal points. For example, billing for 30 or 31 days of service, this should be stated as 30 or 31—not 30.0 or 31.0. When a decimal point is used, the DMERC system is interpreting this as 300 or 310 days.
- Don't list the grams of amino acids on the HCFA 1500. Instead, use the appropriate HCPCS code.

"These billing errors could result in an overpayment," says Shockley. "If you have received an overpayment, it should be refunded to the DMERC immediately, regardless of the therapy or dates of service. While we recognize that these billing errors have been unintentional, continuation of these practices will constitute fraud and abuse."

Other Billing Issues

The Region D DMERC has also provided the following updated billing information:

- **Catheter Supplies.** Supplies for catheter maintenance must be bundled under the code K0110. This code includes such items as dressings, tape, topical antibiotics and antiseptics, needles, syringes, and flush solutions. One unit of service is allowed for each week of covered therapy and up to four weeks of maintenance between therapy when the patient is on an intermittent drug administration protocol.
- **Noncovered items.** Remember that disposable infusion pumps (infusers) are noncovered items. Infusion therapy administered by push or gravity is also not covered. It is not necessary to submit a claim for noncovered items, but should you wish to do so for denial, or at the beneficiary's request, the modifier ZY should be used to indicate that the claim is for a noncovered item, and the claim should note that a disposable pump or that the drugs and supplies were used without a pump. In this case, any supplies billed for should be billed under the code A9270, and drugs should be coded using the appropriate J code or (if there's no code) code A9270.
- **Physician Office Claims.** Do not submit claims to the DMERC for drugs administered in a physician's office. If an external infusion pump is filled in the physician's office and worn home by the patient for at least overnight, use place of service 12 or 33 (as appropriate) for all charges submitted for the drugs, supplies, and pump.

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