



Tiers of Pain

Is Your Medication Safe from Specialty-Tier Pricing?

BY ANDREA KING COLLIER

Dominick Spatafora, of Scottsdale, AZ, has lived with a rare neurologic disorder called multifocal motor neuropathy since 2005. “My medications cost about \$40,000 to \$50,000 per year, but they keep me out of a wheelchair and leading a productive life,” says Spatafora, who is president of the Neuropathy Action Foundation (neuropathyaction.org). The intravenous immunoglobulin (IVIG) that he takes not only keeps him alive but also enables him to make a living—and thereby keep his insurance. Luckily, Spatafora says, he has “good insurance,” which keeps his out-of-pocket costs affordable. But millions of Americans like him face the possibility that their medications—including drugs used to treat neurologic disorders such as multifocal motor neuropathy and multiple sclerosis (MS)—may soon be out of reach.

In recent years, Medicare and many private insurers have severely cut the rate of reimbursement for “infused biologics” such as IVIG, which is derived from blood plasma and replaces missing antibodies in people with multifocal motor neuropathy. (An infused drug is one that is given intravenously. A biologic drug is produced in plant or animal cells, which can be sensitive to changes in the drug manufacturing process. Many experts feel that generic versions of biologics are not as reliable as generic versions of non-biologic drugs.)

Many Medicare Part D plans and private insurers have moved these medications to specialty-tier status. Instead of paying a fixed co-pay amount, people with these plans pay co-insurance, which is somewhere between 25 percent and 33 percent of the cost of the medication each month. This can mean additional hundreds or even thousands of dollars per month.



THE LEGAL BATTLE

In 2010, the State of New York became the first to pass legislation prohibiting insurers from creating specialty tiers of reimbursement and cost-sharing. Earlier this year, advocates from three groups—the Northern California Chapter of the National Multiple Sclerosis Society, the San Francisco Medical Society, and the Alliance for Plasma Therapies—supported a bill that would protect patients from insurer-escalated costs on these drugs.

Similar bills to protect patients are being proposed in Arizona, Florida, Hawaii, Minnesota, Ohio, and Nebraska. If passed, these bills would put a cap on the amount of co-pays and limit the amount of out-of-pocket expenditures for high-cost medications. The California legislation would also prevent private insurers from creating specialty tiers through co-insurance. Michelle Vogel, the executive director of the Alliance for BioTherapeutics and one of the country’s more vocal advocates for protective legislation, says that this will prevent insurers from establishing co-pays that exceed 500 percent of the lowest co-

pay cost on the insurance plan.

“Legislation is really the only thing that can stop insurers from raising the costs to consumers,” Vogel says. Currently, neither private insurers nor Medicare Part D plans are required to grant exceptions for high-cost, vital medications that they decide to place in the specialty-tier category—even if there is no lower-cost alternative. For the majority of infused biologics, Vogel says, there are no generics that can be effectively substituted.

MEDICATION OR RENT?

The problem of specialty-tier co-insurance for patients with chronic conditions that must be managed by infused medica-

tions is on the rise. In 2009 alone, half of all Part D enrollees who were in plans that had a specialty tier were subject to the 33 percent co-insurance for their IV medications. Vogel predicts that as both private and Medicare insurers look to reduce reimbursement costs, patients will see more of their medications become a part of the specialty-tier formularies of plans around the country.

Specialty tiers of reimbursement have a major impact on people living with neurologic disorders. They also affect people living with chronic conditions such as HIV, hemophilia, breast and colorectal cancers, and leukemia, to name a few. Many of the medications used to treat these diseases are expensive to produce and cannot be safely replaced by generic or lower-cost drugs.

Vogel suggests that these medications have not changed during the past 20 years in any way that might warrant changes in reimbursement. Instead, she believes that specialty tiers are a way for insurers to redistribute costs at the expense of the patient. “Specialty tiers really

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—DOMINICK SPATAFORA

undermine the whole purpose of health insurance, which was to spread and share health care costs,” she says.

In 2010, The National Multiple Sclerosis Society reviewed the impact that specialty tiers would have on people who rely on medications such as infused biologics. The organization concluded that in these tough economic times, specialty tiers may force people to make a choice between taking life-saving medications and buying food or paying rent. People with MS may be hit especially hard: Of the 12 most common drugs to go into specialty-tier reimbursement pricing, four are prescribed to manage MS.

Jeanna Thornton, 54, of Jackson, MS, has lived with MS for the past six years, but it has only been over the last three that she has been on an infusion treatment called natalizumab (Tysabri). “It isn’t a cure, and it hasn’t given me back what I had, but it definitely has kept me from losing ground,” Thornton says of the once-a-month IV treatment she receives in an outpatient medical center. She says she feels fortunate that her insurance provider has not changed her medication to specialty-tier status. The real cost of a medication such as natalizumab can be \$30,000 to \$40,000 a year or more, according to the National Multiple Sclerosis Society.

What’s more, “Patients are often on an IV medication to manage their MS in addition to several other expensive meds to help manage their symptoms,” says Anthony Reder, M.D., a neurologist at the University of Chicago and a member of the American Academy of Neurology (AAN). According to Dr. Reder, the infused medications used to help patients manage MS—when taken early and on a consistent basis—can slow the progression of MS and keep patients active longer. “They can also lessen the severity of flare-ups,” Dr. Reder says. But many patients are considering stopping their

medications because they can no longer afford them, he says.

The American Association of Retired Persons (AARP) reports that over 20 million Americans belong to an insurance plan that already has specialty-tier medications in their formulary. And in testimony from John Dicken of the U.S. Government Accountability Office (GAO) before the U.S. Senate Special Committee on Aging last year, it was reported that specialty-tier costs accounted for \$5.6 billion of the total \$54 billion in prescription drug spending in Medicare Part D in 2007. According to the GAO, more than half of the beneficiaries who are taking at least one specialty-tier medication reached the catastrophic coverage threshold, which was \$6,152.75 in 2009. After a patient reaches this threshold, Medicare pays 80 percent of the cost of medication (versus 100 percent before the threshold is reached).

Tina Tockarszewsky, the president and CEO of the Neuropathy Association (neuropathy.org) believes that specialty-tier pricing deserves more attention in the medical and patient-advocacy communities. The Neuropathy Association is working to shape policy on these co-insurance and co-pays. “Patients shouldn’t fear for their lives or their livelihoods because a life-sustaining treatment is being taken away,” Tockarszewsky says.

A CALL TO ACTION

Many patient advocates are fighting to ban insurers from being able to switch patients from a fixed co-pay to a shared cost co-insurance at any point during the year.

Dominick Spatafora, for one, worries about this type of “bait-and-switch” loophole in insurance coverage. “When

you enroll and are new to a plan, you may be able to get the medications you need and afford it,” he says. “But after you get in, they can move you to a co-insurance, which means that instead of paying a set amount, you end up paying thousands.”

Specialty-tier reimbursement seems to be one of the gray areas in the Patient Protection and Affordable Care Act. “For all the good that the Act did, it didn’t address the cost of things,” Spatafora says. There is currently no Federal provision that prevents health plans from doubling or tripling the costs passed on to patients, according to Spatafora. “Health care plans will now try to target the sickest of the sick with these IV medications—at costs they cannot charge for pills.”

So what should you do if you find yourself taking a medication that gets moved to the specialty tier? Vogel says that there will be some tough choices ahead for those facing this new level of out-of-pocket cost. “There is no appeal process. These rules are written into the policies and agreements, so we need to change the policies,” Vogel says. She suggests contacting a patient-advocacy organization in your area to help join the fight. The AAN supports state efforts that make sure people with neurologic conditions have access to medications at prices that do not cause them to pick between drugs and other vital necessities. The AAN also urges its member neurologists to speak out on behalf of their patients who lack access to needed medications.

Vogel predicts that many people who rely on infused biologics will end up needing more expensive specialized care in hospitals.

Spatafora agrees, and says that nobody should assume their specialized medicines will always be affordable to them. “I will be on my drugs for the rest of my life, and I’m afraid that one day I’ll get a letter saying they’ve been moved to a specialty tier.” NN