## **EWAITING ROOM**

THIS WAY IN

## The Cost of MS Drugs

BY TOM VALEO

lthough current therapies cure multiple sclerosis (MS), drug companies have made inroads in developing treatments that control symptoms, to some degree, by reducing immune system attacks on the fatty white myelin that insulates nerve cells. Without drug therapy, those attacks—which produce numbness, weakness, vertigo, vision problems, and an array of other symptomstend to increase in frequency and severity, often causing permanent disability. (A disability is a physical or mental impairment that has a substantial and long-term adverse effect on someone's ability to carry out normal day-to-day activities. In the case of MS, disability often means needing a wheelchair and help with bathing and other routine tasks.)

Someone with relapsing-remitting MS may experience infrequent attacks. But if the disease progresses to secondaryprogressive MS, that person will experience more frequent episodes of illness. Two other types of MS-primary-progressive and progressive-relapsing—are characterized by a steady progression of symptoms and disability from the beginning of the disease with few periods of remission.

Drugs for MS are given in an effort to increase the periods of good health between attacks and to postpone or even prevent disability. Unfortunately, many people in the U.S. who need these drugs cannot afford them.

"Recently, I saw a woman who had failed to respond adequately to both interferon and glatiramer acetate and had been placed on fingolimod," says Bruce A. Cohen, M.D., professor of neurology and director of the Multiple Sclerosis Program at Northwestern University's Feinberg School of Medicine in Chicago, IL, and Fellow of the American Academy of Neurology (AAN). "The company she worked for changed insurance companies, and her co-pay went to \$1,000 per month. Even with the drug company's assistance plan, it still would have been \$800 per month, and she couldn't stay on the drug."

Studies have shown that fingolimod cuts MS relapses by more than half, apparently by curbing the ability of white blood cells to launch an attack against myelin. Approved by the US Food & Drug Administration in 2010, fingolimod was found to be an effective and convenient addition to the arsenal of drugs designed to control MS, but the cost—approximately \$4,000 a month in the U.S.—has curtailed its use.

> A recent study published in the AAN's medical journal Neurology concluded that A CONTRACTOR OF THE PARTY OF TH the cost of MS drugs in the U.S. lowers their cost-effectiveness scores significantly in this country. That doesn't mean they're not effective or

that they shouldn't

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-IOHN CORBOY, M.D.

be used by people who need them, the authors stress. In fact, evidence continues to mount that treating MS early and consistently is the best way to increase the symptom-free periods between relapses and reduce long-term disability.

"I just don't believe these medications need to be so costly, and I would like to see our research influence both private enter-

prise and public discourse on this issue," says Robert G. Holloway, M.D., M.P.H., one of the authors of the study and an AAN Fellow.

The study followed more than 910 MS patients for 10 years and determined cost-effectiveness using a complex formula that included not just the price of treatments but also hospitalization, time off from work, and other costs of the illness. Lowering the price of MS drugs in the U.S. to levels in other countries would improve cost-effectiveness markedly, the study concluded.

But prices in general for MS drugs have almost doubled since 2008, according to John Corboy, M.D., a neurologist at the University of Colorado School of Medicine and a Fellow of the AAN, who recently gathered current costs while preparing a talk on the discontinuation of disease-modifying therapies in MS.

"The cost of these medications in the U.S. is astounding," Dr. Corboy says. He attributes this, in part, to the fact that Medicare is prohibited from negotiating prices with the drug companies as other nations do.

However, the Veterans Administration, along with the Department of Defense, the Public Health Service, and the Coast Guard, may negotiate, and they receive dramatic discounts. "For them, glatiramer acetate and the interferons cost about \$14,000 as opposed to \$41,000 per year," Dr. Corboy says.

"In addition, the costs are dramatically lower in Canada and Europe, so that, in a perverse sense, private insurers in the U.S.—and the patients who pay the premiums—subsidize those with federal insurance or who live in other countries. Although a wide variation in the cost of these medications exists, even at the lower costs these are still very expensive drugs," Dr. Corboy adds.

In Dr. Corboy's opinion, the MS drug market "is like reverse capitalism. In other businesses, when competition goes up, prices usually go down, but it's the opposite with drugs. When a new drug comes on the market and threatens to reduce the market share of other companies, those companies just raise their prices to protect their overall income from the drug."

However, some neurologists have criticized the study published in *Neurology*.

"Ten years is not a long time in MS," Dr. Cohen says. "This is a disease that often spans 25 to 30 years. Also, the investigators point out that they looked at a limited number of people with advanced disease, which is important because several studies (not restricted to ones sponsored by drug companies)

demonstrate the increased cost of MS in relation to increased severity. If early treatment delays the onset of progressive disease, then the savings may be seen over a longer interval."

Several drug companies offer financial assistance to MS patients who cannot afford the drugs they need. A spokeperson for Bayer Healthcare tells *Neurology Now*, "Access to potentially life-saving products is important for the more than 49.5 million uninsured people in the United States. In this time of need, Bayer has various programs that can assist qualified patients with access to therapy."

Even with financial assistance, some MS patients cannot afford the medications they need. Dr. Cohen's patient, for example, had to stop fingolimod because she could not afford the \$800 co-pay

made possible by the drug company's financial assistance and has had to consider other options.

"We're looking at another drug made by a company that also offers an assistance program," Dr. Cohen says. "If that doesn't work, then I probably will have to look at off-label options, or perhaps she could enroll in a clinical trial, although then she might end up on a placebo."

The National MS Society helps direct patients in need of financial assistance to appropriate drug company programs, but not everyone qualifies, according to Nicholas Larocca, vice president of Health Care Delivery and Policy Research. "The programs are certainly a good thing, and they help many people," Larocca says, "but they don't always cover all out-of-pocket costs, and some people simply don't meet the requirements. It's frustrating for doctors and for patients, but we're looking to the future. There are a large number of medications in the pipeline, and that's a good thing."

New drugs coming to market offer hope for MS patients, in part because they allow doctors to utilize combination therapy, customizing drug regimens for each patient in an effort to maximize effectiveness and minimize side-effects.

But this opportunity also might make the high prices an even greater obstacle to treatment, according to Timothy Vollmer, M.D., professor of neurology at the University of Colorado School of Medicine and AAN Fellow.

"I think combination therapy is the future of MS treatment, but it could cost \$100,000 per patient per year," he says, "and that could seriously limit our ability to use these drugs."



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