

End of a long wait



The first generic disease-modifying medicine for MS is now available.

by Mary E. King, PhD

A long-awaited day arrived in June, when people with multiple sclerosis gained access to the first of what is hoped will be several generic medications for MS. Glatopa™, a generic form of glatiramer acetate injection that was initially available only under Teva's registered trademark Copaxone®, is now available from Sandoz, the generic pharmaceuticals division of Novartis.

"This is the first generic for any of the disease-modifying therapies for MS. That's a positive and exciting development," said Bruce Bebo, PhD, executive vice president, research, at the National MS Society. Like Copaxone, Glatopa is indicated for the treatment of people with relapsing forms of MS. Glatopa was approved by the U.S. Food and Drug Administration in the 20 mg/mL dose for daily injection, but not in the newer 40 mg/mL dose available for Copaxone. That higher dose, meant for injection three times a week, was developed later and is still under patent.

Generic versions of a medication can be marketed only after the patent on its equivalent brand-name medication expires—normally after 20 years, though patents may sometimes be extended. Pharmaceutical companies, however, may file for the patent long before clinical trials for FDA approval even begin, so once the FDA has approved a drug, a company will typically have seven to 12 years of market exclusivity. The generic form of glatiramer acetate injection, like all FDA-approved generics, is as safe and effective as the original medication. “Healthcare professionals and patients can be assured that FDA-approved generic drugs have met the same rigorous standards of quality as the brand-name drug,” said Dr. Janet Woodcock, director of the FDA’s Center for Drug Evaluation and Research, in an April 2015 FDA press release.

The generic pipeline

One reason it is taking so long for generic MS medications to reach the market is the degree of complexity involved. “If a medication is a simple small molecule produced in a chemical reaction, like baclofen, then it is pretty easy to make an exact copy, while others, like Copaxone, are more complicated and harder to copy,” Dr. Bebo explained. “These take longer to develop and to receive FDA approval.” He also clarified that interferons (for example, Avonex®) and alemtuzumab (Lemtrada®)—known as biologic medications because they are produced in living cells—are even more challenging to duplicate into a generic form, which may take even longer to reach patients.

The pricing difference

It’s no secret that MS medications are costly. “We’ve seen prices for MS medications go up and up without any stop,” Dr. Bebo said. Glatopa offers some price relief, with its wholesale list price about 15 to 18 percent less than branded Copaxone. Still, at an estimated wholesale cost of \$63,000 per year, it’s not cheap by anyone’s standards. “Even though people might be disappointed that the current pricing of Glatopa is not even lower, remember that this is the first time we’ve seen this type of generic medication for MS come on the market. I have tremendous hope that this is the start of a trend, and that with each additional generic disease-modifying medicine that becomes available, we will start to see improved pricing,” Dr. Bebo said.

Both the degree of complexity involved in developing a new medication and the cost of supporting it once it gets to market are just two of many factors involved in pricing a new drug. For example, Sandoz will offer financial assistance to qualified patients, as well as personalized injection training and 24-hour access to nurses for nonclinical questions, which add to the cost and differentiate Glatopa from generics used for many other conditions, Dr. Bebo pointed out. And, according to the FDA’s Center for Drug Evaluation and Research, which evaluated historical generic drug pricing in the U.S., “On average, the first generic competitor prices its product only slightly lower than the brand-name manufacturer.”

A hopeful future

“In the next few years, some of the disease-modifying medications for MS will lose their market exclusivity, so we are likely to see more MS generics in the near future,” Dr. Bebo

stated. “There is already another generic glatiramer acetate under review at the FDA, so there will be even more options for people living with MS soon.”

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