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M E D I C A T I O N M A N A G E M E N T

# MS Drug Going Generic Without Making Waves

**Generics for other diseases have upended formularies, but the effect of generic Copaxone may be limited.**

Thomas Reinke



The multiple sclerosis medications, a specialty class of therapy that costs \$5,000 to \$6,000 a month, is about to get its first generic. In April the FDA approved a knockoff of the class-leading, disease-modifying agent Copaxone, which has annual sales of more than \$3 billion.

When generic versions of such class leaders as Lipitor and Nexium came out, they turned formulary design on its head and put a real dent in drug expenditures. But that won't happen in MS. The factors that allowed generics to completely dominate branded drugs in other classes simply don't exist in MS.

Moreover, experts say that while health plans and PBMs will need to

figure out how generic Copaxone fits in, they should also focus on broader issues in MS therapy.

## Limited impact

MS is an autoimmune disease that attacks the myelin sheaths of the nerves of the central nervous system. Between 250,000 and 400,000 Americans have the disease, which is the leading cause of permanent

The generic name for Copaxone is glatiramer acetate. It is a synthetic protein that is antigenically similar to myelin basic protein, a component of the myelin sheath that protects nerves. Copaxone works by blocking T cells that damage myelin. How it does so is uncertain.

One reason generic Copaxone will have a limited impact is the lack of branded me-too agents for MS, all with the same mechanism of action. When a generic comes along for a disease with lots of branded copycat drugs, it has ample opportunity to knock out some of those copycats. Copaxone doesn't have copycats, so the pickings won't be so easy for generic Copaxone.

Another factor is the lack of strong treatment guidelines for MS that would give a particular drug—or drugs sharing the same mechanism of action—a dominant position in the armamentarium. As a result, clinicians take many different approaches to treating MS, and some of those approaches don't include Copaxone—or, presumably, the newly available generic, explains Atheer Kaddis, PharmD, a senior vice president at Diplomat Pharmacy, a specialty pharmacy in Flint, Mich.

New formulary designs may be developed because of generic Copaxone, says Atheer Kaddis, PharmD, of Diplomat Pharmacy.

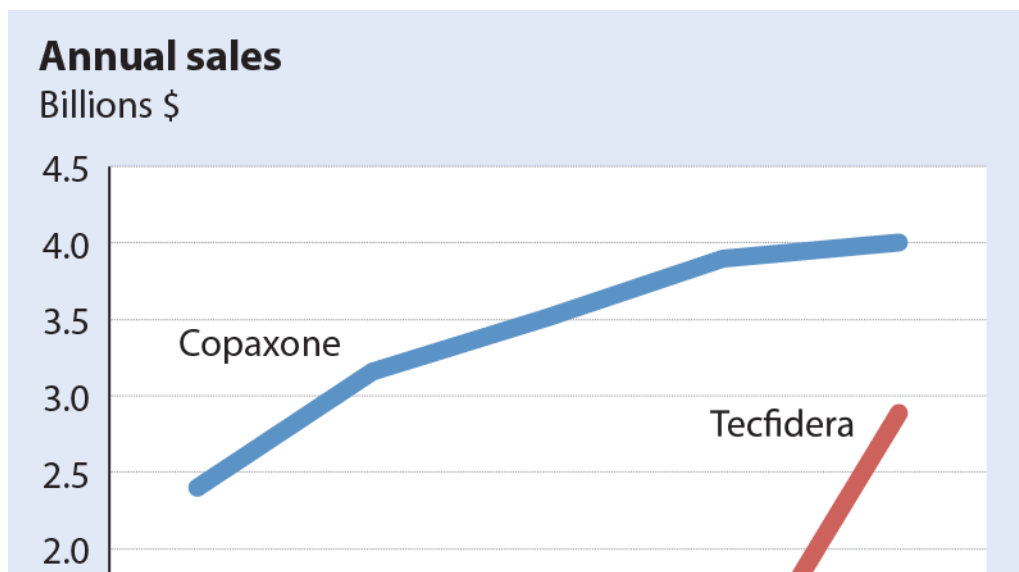


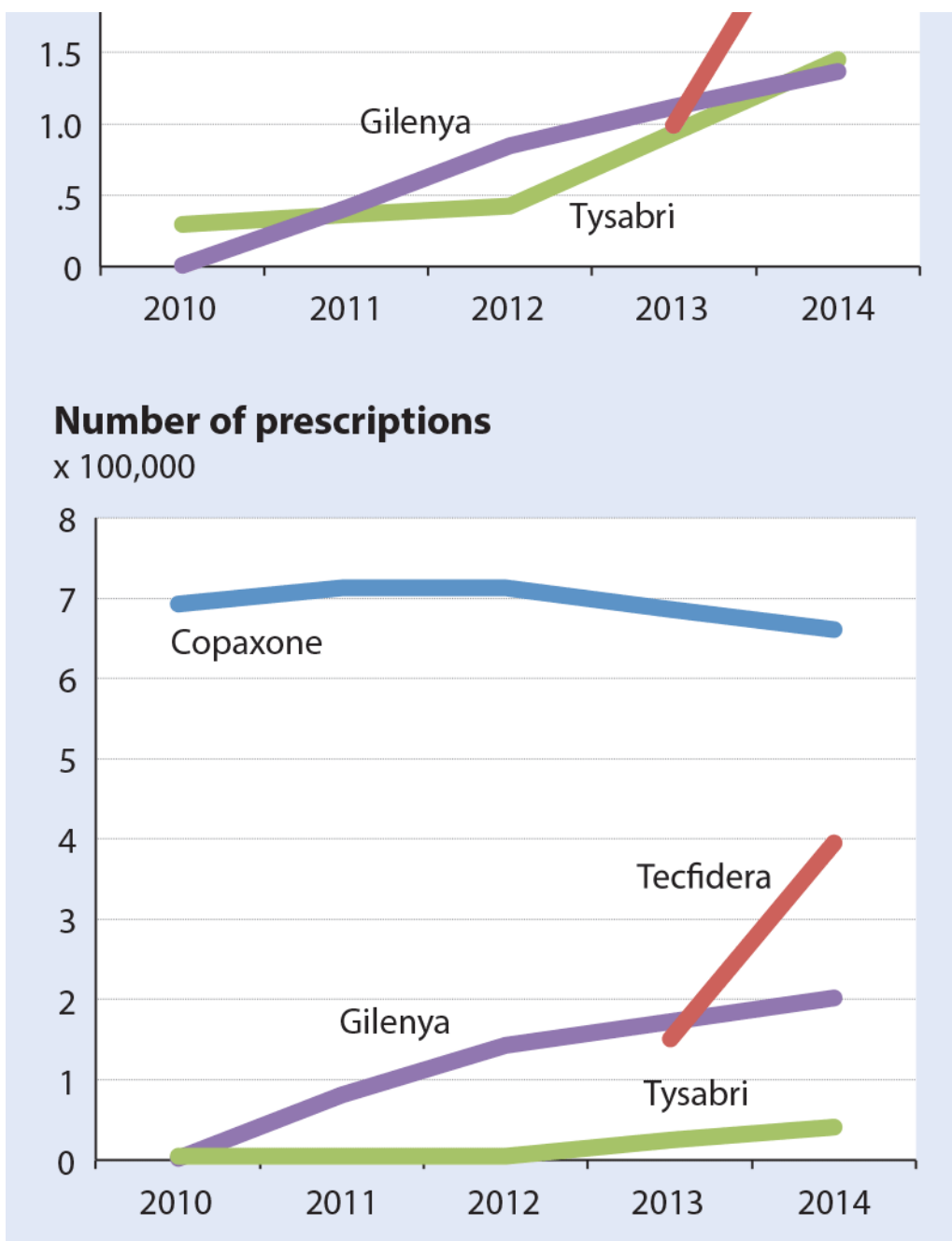
The new generic kid on the block, from Sandoz, also faces some stiff competition. Teva saw the patent expiration coming, so it rolled out a patented 40-mg version that reduces the frequency of injections from daily to three times per week. The FDA approved Teva's formulation in March 2014. Since then, the company has shifted more than 60% of its volume to the three-days-a-week version, according to Kaddis.

### A market for generic Copaxone

The formularies for MS agents often include Copaxone as a preferred agent, so now it is a question of whether the generic version will get listed instead.

## Annual sales and total prescriptions for leading MS drugs





Source: IMS National Sales Perspectives

Currently, in highly managed formularies there is usually a preferred interferon, Copaxone, one or more of newer oral agents, and natalizumab (Tysabri), a monoclonal antibody with a unique mechanism of action, according to Kaddis. For less-managed formularies, there may be two interferons, perhaps two orals, Copaxone,

and natalizumab.

Rebates are offered by pharmaceutical manufacturers for the brand-name MS therapies, Kaddis explains. The rebates are typically market-share based so additional rebates are offered if greater market share is driven toward formulary preferred therapies.

Kaddis expects there to be a solid market for generic Copaxone. An increasing number of physicians are taking on risk by participating in ACOs and other value-based care. In some of those arrangements pharmacy costs are measured, and physicians are rewarded for reducing them. Even if 60% of Copaxone sales have moved to the new three-days-a-week formulation, 40% of the volume is still open to the generic. That can result in a considerable cost savings, notes Kaddis.

Moreover, new formulary designs may be developed because of generic Copaxone, says Kaddis: “There’s the potential for health plans to implement step therapy or to provide incentives such as a fixed copay in place of a percentage coinsurance.”

### **High hopes for monoclonal antibodies**

Generic Copaxone is entering the market as treatment of MS is changing and is more likely to involve fairly aggressive treatment with the goal of preventing relapse and slowing long-term disease progression. Kaddis says part-and-parcel of a more aggressive approach to treatment is greater attention to the diagnosis of the disease and recognition of clinically isolated syndrome (CIS), the appearance of single or multiple neurologic symptoms such as an attack of optic neuritis or weakness on one side. If CIS is confirmed through MRI or other means, doctors nowadays may prescribe MS drugs to head off a full-blown exacerbation of the disease.

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