Employee Benefit News
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Biosimilars: What employers need to know

Earlier this month, Novartis' Zarxio was the first biosimilar product approved in the United States, ushering in a new era for the drug industry, consumers and third parties who manage medical and drug benefits. The introduction of cheaper alternatives to relatively complex biologic drugs has created confusion over the U.S. Food and Drug Administration's approval process and specialty-related product availability to be used or marketed.

Seen as a potentially less expensive alternative to Amgen's Neupogen®, which boosts white blood cells to reduce infections in cancer patients, Zarxio is a "biosimilar." Biosimilars are versions of biologics that are sufficiently similar to the more costly biologic drug, but not an identical match, as in the case of generics. Biosimilars are regarded as not having meaningful clinical differences with the brand-name biologic drugs they resemble.

This is the first real effort to support plan sponsors in their cost management efforts to save on branded biologic drugs to treat cancer and other ailments. The potential value of unit cost savings for Zarxio represents an estimated 10% to 20%, but the savings will likely not impact the overall cost trend for treating the condition. In foreign countries where biosimilars are already sold, they are often priced 20% to 30% below the original brand version. It is hoped that at a minimum, reduced costs for biosimilars should be about the same in the U.S.

Also see: Specialty drugs present challenges, opportunities for plan sponsors

The FDA's approval for marketing Zarxio does not mean it can automatically be used in place of the brand drug, as is the case with traditional generic drugs. This is significant, as one important plan sponsor issue that still remains unresolved by the FDA is interchangeability. Will it be safe as well as legal for pharmacists to dispense a sufficiently similar biosimilar instead of the brand-name product? Amgen recently told The Wall Street Journal that it "supports a science-based, patient-centric, regulatory framework for all biosimilars that will be approved in the U.S."

Reflecting on the importance the FDA is placing on this initial step, the approval does not guarantee product availability if a patent or other legal barriers remain in place to prevent a copy of the original drug product. The FDA often follows the recommendations of its advisory panels, but it is not required to do

For plan sponsors, this situation is not ideal and continues to cause mportant to benefit coverage sought by members as patients for these new biol . In addition, pricing has not been determined but is unlikely to rein in rising spec ar spending on medical or pharmacy benefits in the U.S.

Also see: Employee satisfaction with pharmacy benefits hinges on flexibility

So what's an employer to do?

1. Have a conversation with your pharmacy benefit management organization and/or health plan regarding their coverage approach or policy related to biosimilars. If you have questions about how biosimilars are different, ask them.

2. Review your vendor contract and coverage of specialty drugs to determine the impact on current or future plan costs to your organization.

3. Review your own plans' drug use patterns and if this type of approval would make a cost savings difference to your members.

4. Determine if this will make any difference on annual cost trend for the plan versus just the unit cost of a particular drug for an individual medical condition like cancer-related anemia.

5. Continue to advocate for full cost transparency on all specialty drug products by your vendors.

This is a lot for employers to stay on top of as regulations are changing and news drugs are approved.

Cheryl Larson is vice president, Midwest Business Group on Health, and Randy Vogenberg is principal, The Institute for Integrated Healthcare. The MBGH offers free tools and resources to help plan sponsors stay current on issues related to specialty pharmacy drugs, benefit design and contracting strategies at www.specialtyrxtoolkit.com.