Pharmacy Benefit News

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Specialty Spotlight

Sandoz Biosimilar Takes Aim at Amgen's Pegfilgrastim

The Food and Drug Administration (FDA) has accepted Sandoz's submission for approval of a biosimilar version of pegfilgrastim (Neulasta—Amgen), which is used for the treatment of infections in cancer patients. Sandoz, a unit of Novartis, said it is seeking the same indication as pegfilgrastim. "Sandoz believes that the totality of evidence in its submission, including three pivotal clinical studies, will demonstrate that the proposed biosimilar is highly similar to the reference product," the company said this week. This is Sandoz's third biosimilar filing in the United States."

Reuters (11/18/15) Shields, Michael

Comment:
To address the issue of expensive specialty medications come biosimilars. The biosimilars are presumably less expensive than the pioneer product. However, even if the price of a biosimilar were 50% of the pioneer product, the price would often be beyond the affordability of the affected patient. This process is similar to the brand-generic war of the last two decades where the effectiveness and "goodness" of generics was constantly argued. As a result, we can expect that the price war will be supplemented with a war of whether biosimilars are just as "good" as the pioneer specialty medication they wish to supplant. The specialty argument is much more complicated due to the manufacture and pharmacology of these products so we can expect dueling verisons of the "truth". Watch for elements of truth dissolved in "good sounding" but irrelevant and disingenuous arguments.

Brand-Name Dugs Increase Cost but Not Patient Satisfaction

“ProPublica teamed up with the web site Iodine to measure the satisfaction associated with individual medications. The groups' conclusion is that when it comes to patient satisfaction, there is not much difference between brands and generics.

ProPublica compared the reviews of brands and generics in three drug categories: antipsychotic medications, antidepressants, and drugs that lower cholesterol. Iodine asks people if a drug is worth it, whether it is a hassle to take, and if it works well. For each category of drug, a generic scored best on each of the three questions. Joseph Ross, MD, an associate professor of medicine and a health policy researcher at Yale University School of Medicine, says he is not surprised that patient reviews of generic and brand-name medications are similar.

"Generic medications are manufactured to be equivalent in all ways (except appearances) to brand-name medications," Dr. Ross notes. "Unfortunately, many patients and physicians are convinced to spend more and use the brand-name medication by marketing initiatives, including advertisements on the television or drug coupons that promise similar out-of-pocket expenses for the higher-cost brand-name medications."

ProPublica (11/19/2015) Ornstein, Charles

Comment:
Expect a counter argument to this satisfaction survey. The most important issue to address is who was surveyed, what was the methodology, what were the biases, and what were the limitations? In an era of more data, it is important to determine if the data is relevant to the question being asked, and did the survey identify an association or actual causation.

Medicaid Denial for HCV Drugs Nearing 50% In Some States

“Medicaid programs in four states have rejected 46% of all recent claims for costly hepatitis C virus (HCV) drugs, according to data presented at the Liver Meeting 2015. Meanwhile, Medicare denies just 5% of claims for the drugs in Delaware, Maryland, New Jersey, and Pennsylvania, while commercial insurers deny 10%, said researchers from the University of Pennsylvania. To determine what factors are behind the denials, the researchers studied data from Burman's Specialty Pharmacy, focusing on direct-acting antiviral prescriptions written for patients with HCV genotype 1 2, or 3 infections from November 2014 through April 30, 2015.

The most common reasons cited for denying a claim were "incomplete data to determine medical need" and "lack of medical necessity." Data also revealed that patients without signs of cirrhosis were more likely to be denied, as were patients with prescriptions written between November 1, 2014 and January 31, 2015.”

Medscape (11/18/15) Harrison, Laird

Comment:
One would expect effective prior authorization programs to approved 10-20% of submissions rather than 80-90% approvals. If high percentages are approved, then why preform and pay for Prior Authorizations? The real problem here is that financial issues trump the applicability of patients and the expectation of benefit. What is really needed are studies that produce data that allow for sub-setting patients by age/gender, severity of disease, co-morbidities, and expectation probability of therapeutic benefit.

Clearly, other metrics may be necessary, but these metrics are a good starting place. The outcome may still not be generally affordable, but treating patients with a high probability of benefit will certainly be more cost-effective.

Data Analytics

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- Audit of Claims for Validity, Pricing, AWP, etc.
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- Financial Drivers of the Benefit
- Questionable/Abuse Audits
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- MMA Part D

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- Net Cost vs. Rebate Optimization Modeling
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- Drug Frequency Cost Audits
- Disease Frequency/Trends
- Technology Assessment/Impact

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