Pharmacy Benefit News

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Specialty Spotlight

Drug Discontinuation Is Dependent on Follow Up

The Food and Drug Administration (FDA) recently published a review discussing follow up completeness for major oral antithrombotic trials, i.e., anti-clot drugs. The researchers compared what was expected for follow up with published rates. The published rates were consistently double digit percentages lower than the FDA's calculations. This indicated that the endpoint differences may not have been a result of drug effect, but of differential follow up. "The high rates of therapy discontinuation offer one explanation for why incomplete follow-up is common because these patients no longer need to return to the study sites to pick up drug supplies." The researchers conclude that reporting of follow-up data must be improved in order to give trial results proper validity.…"

JAMA Internal Medicine (01/11/16) Marciniak, Thomas A.; Cherepanov, Vasily; Golukhova, Elena; et al.

Commentary

The need for evidence that can be used in clinical practice is critical, especially in a world where payment is based on value. The FDA provided an assessment methodology for benchmarking trial results in this case. While studies like this do not indicate that clinical researchers have done anything wrong, the indication is that studies need to be validated. Essentially, the results of studies do not end with the publication, but with validation against methodological standards, re-evaluation of data by independent journal peer review, and possibly by re-running the studies with different populations of patients. Re-running studies is labor intensive and expensive, but analytics using the study data can simulate results for other populations. This should be considered for future validations of important findings.

Anthem Sues Express Scripts for $3B

Anthem CEO Joseph Swedish said Tuesday the insurer could save $3 billion annually on drug costs from a repricing provision in its current contract with Express Scripts. Anthem is working to renegotiate the contract this year to avoid overpaying for pharmaceuticals based on current market conditions. The insurer's 10-year contract with Express Scripts runs through 2019 but includes the repricing clause that became effective January 1, 2016. "This represents a substantial adjustment to drive lower care costs for our customers and improve our competitive position in the marketplace," Swedish said. Anthem conducted a market analysis to identify the potential savings, which would come primarily from lower generic drug pricing, Swedish said. "We have seen a substantial improvement in market pricing in just the last 12 months," he noted.

Reuters (01/13/16) Kelly, Susan; Humer, Caroline

Commentary

We don't know the specifics of this argument, but generally this disagreement brings up several general issues regardless of the specifics of this, or any, contract. Audits, reviews of contracts, and concurrent management reviews (Pro Pharma's Invoice Screens™) are all part of managing a medical and pharmacy benefit. At a time when specialty pharmaceuticals are raising trend to double digit rates, generic pricing is one area to anchor prices and counteract some percentage of brand driven price trend. The hope for biosimilars to perform this cost reduction is not timely, as multiple biosimilars will have to be approved in order to have any effect on specialty medications. In addition, based on the European experience, the price reductions of biosimilars may be closer to a discount of 15% than to 50%.

As a result, generic pricing based on Maximum Allowable Cost (MAC) prices are a legitimate target. It is unclear where Anthem has made their estimates, but re-formulating MAC lists to cover all generics, and price based on cost-plus provide significant opportunities over current methodologies. The management problem is to determine how much spread is introduced through PBM MAC pricing, what design parameters are necessary to formulate and manage the MAC going forward, and what basis (e.g., AWP, WAC, AMP, etc.) is to be used for price discounting. In the current environment of price trend, ignoring obvious management targets such as generic pricing is a major mistake.

FDA Wants Clinical Data To Make Biosimilars Substitutable?

A new report from the law firm Goodwin Proctor concludes that the FDA is "almost certain" to require clinical data in order for companies to demonstrate interchangeability between a biosimilar and its reference product. According to the report, the issue of how much data will be required will be a major factor in determining how quickly the U.S. biosimilars market will take off.

The report states: "comments made by FDA have indicated that this is a very real possibility," though the Biologics Price Competition and Innovation Act makes no mention of clinical studies for biosimilars. If clinical trials are required for a biosimilar to be considered interchangeable, that bar may essentially limit which biosimilars can be switched over from their reference products automatically. FDA is expected to issue its guidance on how industry should establish interchangeability sometime in 2016.

Regulatory Affairs Professionals Society (01/12/2016) Brennan, Zachary

Commentary:

There has been much discussion about what criteria will be used to get FDA approval for biosimilars. The core of the argument is that specialty manufacturers want the bar to be set high to protect their patents. On the other hand, biosimilar manufacturers want a lower bar so that they can capitalize on the revenue stream currently coming from their target branded specialty medication. This is reminiscent of the brand-generic battle, but in generics the ingredient is the same so there are no requirements for retesting patients as to how they will react. Hence, the potential for requiring clinical studies for biosimilars will place the biosimilar manufacturer on course to spend a great deal to demonstrate similar clinical benefits to the target specialty medication.

Of course, the generics market has long been populated by branded manufacturers who market both brand and generics of the same, or similar, drugs. The bottomline for patients and providers if clinical trials are required is that biosimilars will not have deep discounts to the target specialty medication and will still have high price tags. There is a corollary in the current market in that branded medications in the same therapeutic categories are offered as having similar benefits with marginal therapeutic differences. This may be the course of biosimilars where benefits are similar, risks are equal, and costs are 10-15% different. Then biosimilars will not provide huge price discounts, but rather slightly lower cost options. The Europeans have already witnessed this scenario.

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Maximum Allowable Cost [MAC]™

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Consulting Services Include Claims Management/Oversight and Management of Benefits, most specifically Client-Specific MAC List Development and Maintenance as follows:

Medicaid Compliance and/or CMS FUL Compliance
Flexible Pricing Determinants

- Lowest Cost
- Average of Lowest 3 Costs
- Average of all Generics
- Median of all Generics

Flexible Price Sources, including, CMS, MediSpan, First Data Bank, Redbook
Flexible Therapeutic Categories (Customizable)
Flexible Generic Availability

- Immediate availability
- Predetermined time gap from end of patent
- Minimum number of Generic Manufacturers
- Decision allowance for generic all, store brands, re-packagers, multisource, and/or branded generics

Flexible Code Basis, including GCN, GPI, and NDC

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are both Quality-Based and Cost-Conscious.

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