Managing the Rx Pipeline: Specialty Prescription Drugs Require Attention

What Are Specialty Drugs?
In recent years, academic studies and news media have been filled with examples of annual double-digit percent increases in prescription drug spending. The driver for these projected and actual spending increases is mainly due to specialty drugs.

Specialty drugs, often referred to as “biologics” or “large molecule” by the healthcare industry, are classified as “specialty” when they have some or all of the following features:

- Manufacturing the drug is complex (e.g., genetically engineered categories).
- Drug requires special handling and administration (e.g., injectable or administered by a health care provider).
- The drug is needed by a relatively small percent of the population making the per-patient cost high.

Why Do They Matter?
Specialty drugs can be promising innovations that can collectively help millions of patients, but the prices set for these new drugs have created concern with respect to the cost of benefits and helping individuals manage their ongoing chronic health conditions.

The development of specialty drugs has become part of the core business model for the pharmaceutical industry. This trend is unlikely to subside—rather—it is expected to increase.

The expected increases in the number and utilization of specialty drugs make it imperative that benefit plan sponsors establish programs to manage specialty drugs—not only those already approved by the Food and Drug Administration (FDA), but also those in the pipeline.

Furthermore, the challenges inherent in bringing biosimilars (a drug nearly like a biologic) to market have limited the opportunities for price reductions in the specialty drug market.

Why Do Specialty Drugs Cost so Much?

A 2014 IMS Health* white paper cites some contributing factors:

- High R&D costs and an undefined regulatory pathway hamper the development of biosimilars
- Few close substitutes for specialty products
- Higher shipping and handling costs and more expensive site of care for specialty drugs

*IMS Health is an information and technology services company that serves the healthcare industry.

Biosimilars Are Not Generics
Over the last decade, over 100 biologics (specialty drugs) have entered the marketplace, but the regulatory pathway for biosimilars remains challenging.

To understand the complexities of biosimilar development, let’s step back and first define what constitutes a generic drug.
To begin, non-specialty drugs (which are small molecule, i.e., oral solids, versus specialty drugs which are large molecule) are developed using only chemical compositions. This scenario allows for “exact” duplication of the active ingredients.

After a patent on a non-specialty drug expires, exact duplication of a drug is possible without infringing on the innovator’s rights to produce and sell the drug exclusively (for all clinical indications that the FDA previously approved). Therefore, a generic drug manufacturer does not have to undertake research and development or an FDA approval process. It simply has to wait for a patent to expire. This enables generic drug manufacturers to provide price reductions of up to 60% compared to brand name non-specialty drugs.

**Insulin: The First Biologic**

- 1922: Successful test in a human
- 1923: Eli Lilly begins insulin production
- 1978: First genetically engineered insulin developed
- 2016: No biosimilar available in the U.S. to replace insulin

Next, let’s look at the research and development and FDA approval process for biologics and biosimilars. Biologics are developed using genetic and cellular material. Since the material for biologics are drawn from specific living organisms, there is no other “exact” material available. Consequently, the “exact duplication” scenario that exists in the non-specialty/generic drug market does not exist for biologics.

Now let’s turn our attention to biosimilars. Like a biologic, a biosimilar uses genetic or cellular material. While a biosimilar is nearly like a biologic, the material used will never be an “exact” duplicate of that used for the biologic.

This leads to the following issues:

- Brand name biologics strive to receive FDA approval for multiple clinical indications to protect and expand patent coverage. This strategy limits the ability of biosimilar producers to bring an alternative specialty drug to market, which is discussed in more detail below.

**The Race for Revenue**

Often a specialty drug is initially approved for a very specific clinical indication, which limits the pharmaceutical company’s revenue and profits.

Since specialty drugs serve small populations, one way for companies to expand a particular drug’s use is to obtain FDA approved indications that allow the drug to be prescribed to larger populations. Since this expansion strategy benefits brand name biologics by providing additional patent protections, it creates a very high barrier to entry for biosimilars.

The chart below provides examples of drug expansions.

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<thead>
<tr>
<th>Drug</th>
<th>First Approval</th>
<th>Expansions</th>
</tr>
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<tbody>
<tr>
<td>Keytruda®</td>
<td>Metastatic non-small lung cancer</td>
<td>First-line treatment for metastatic melanoma.</td>
</tr>
<tr>
<td>Humira®</td>
<td>Rheumatoid arthritis</td>
<td>Psoriatic arthritis, ankylosing spondylitis, juvenile idiopathic arthritis, Crohn’s disease, ulcerative colitis and chronic plaque psoriasis. As of 2015, the makers of Humira® are seeking another expansion for a rare skin disease.</td>
</tr>
<tr>
<td>Repatha® and Praluent®</td>
<td>Genetic disorder familial hypercholesterolemia</td>
<td>Expansion for use in patients with dangerously elevated cholesterol levels that do NOT have familial hypercholesterolemia being sought for both drugs.</td>
</tr>
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Although expansion strategies have extended the market share of biologics causing prices to remain high, recent progress in FDA reviews of biosimilars may change the competitive landscape in the biologic space.

For example, Zarzio® (filgrastim) which treats neutropenia (susceptibility to infection caused by chemotherapy) was the
first biosimilar to be approved in the U.S. Zarzio® competes with the brand name drug Neupogen®. More recently, the FDA has taken Remsima™ (infliximab) under consideration for approval. Remsima™ is an anti-inflammatory that is the biosimilar to Remicade®.

## The Plan Sponsor’s Dilemma

Can health plan sponsors control the cost of specialty drugs? The prices of specialty drugs are unlikely to decline rapidly based on the preceding discussion. However, plan sponsors can control spending on these drugs. The remainder of this article provides some best practices and strategies we have used to help plan sponsors manage the specialty drugs in their Rx programs.

## Finding the High Ground

From a clinical standpoint, the goal of prescription drug therapies is to provide “the right drug, to the right patient, at the right time.” From a cost perspective, a plan sponsor’s role is to manage “trend and spend” in a way that supports desired clinical outcomes and helps to maintain the sustainability of the plan.

It may be useful to note that since specialty drugs are sold at much higher prices compared to traditional prescription drugs, extensive cost sharing between the employer and participant is typically not viewed as an ideal way to control these costs. Extensive cost sharing results in a higher financial burden on plan participants. This creates the potential for adverse clinical outcomes that may result in higher spending on the medical side of the plan benefit as a result of complications due to non-adherence to prescribed therapies. Conversely, nominal cost sharing does little to reduce utilization. Instead, we have found that vendor management strategies produce better cost control results for plan sponsors when combined with the goal of optimizing therapeutic outcomes.

The practical question is: How can a plan sponsor find the high ground?

In the next section, we offer some best practices and vendor management strategies that can help you manage specialty drugs in ways that best serve plan participants, while preserving the financial stability of your health program.

## Best Practices to Integrate

The process of managing specialty drugs is multi-faceted and continuous. In working with our clients, we have found that implementing the practices below can help uncover and address key issues requiring attention in the management of specialty drugs.

### Monitor the specialty drug pipeline. Not all drugs will receive approval, but it is important to track their progress in order to take proactive steps in contracting and negotiating with your pharmacy benefit manager (PBM) before drugs are approved.

### Review the existing Pharmacy Benefit Management (PBM) contracts each year. Most PBM contracts provide plan sponsors with the ability to manage utilization. Hold your PBM accountable for what it agreed to do. In addition, your healthcare benefit consultant should be able to help you identify gaps and weaknesses in your current utilization management programs and better strategize your future PBM negotiations and procurements.

### Ongoing review and monitoring of PBMs’ precertification standards. PBM precertification criteria should optimize therapeutic outcomes while controlling spending. Since precertification criteria are intended to manage and control utilization patterns and spending for all drugs, evaluating your PBM in this regard is vital to the success of your health care program. The precertification criteria set by PBMs is especially relevant for specialty drug spending since the pipeline for these therapies continues to grow, both with respect to new drugs and approvals for multiple clinical indications. Plan sponsors can protect themselves from excessive spending due to misuse, waste, or fraud that may occur if a PBM has weak precertification standards. For example, plans should validate the efficacy of their PBM’s precertification criteria by comparing it to other PBMs and recommended guidelines, such as those issued by the American Heart Association or Academy of Cardiologists, etc.

### Determine if your PBM has programs that promote patient adherence. Non-compliance with prescription drug therapies can affect health care costs, and not just those associated with the Rx program. For example, better adherence to a traditional drug therapy could potentially limit the need for a specialty drug. If a specialty drug is the only option, PBMs can help facilitate better clinical outcomes by educating and training clinicians and patients on specialty drug use and adherence.
Opportunities to Manage the Pipeline

The chart below identifies some of the specific ways a plan sponsor’s health care consultant can help them manage the specialty drug pipeline. GRS has successfully used these methods with its clients.

<table>
<thead>
<tr>
<th>Methods</th>
<th>Initiatives</th>
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<tbody>
<tr>
<td>Managing Utilization</td>
<td>Key Areas: Specialty drug claims analysis, evaluating PBM precertification criteria, and tracking fulfillment of PBM performance guarantees, ongoing validation of the potential ROI for various new add-on programs.</td>
</tr>
<tr>
<td>PBM Contracts</td>
<td>Examine spend exposure using client-specific data, evaluate the plan sponsor’s ability to negotiate terms for drugs in the pipeline, and evaluate the sponsor’s PBM performance guarantees against the industry.</td>
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<tr>
<td>Procurement Disruption</td>
<td>As part of the PBM procurement process, inform the sponsor about possible patient care disruptions, changes in costs to participants, and help the sponsor manage the transition using targeted communication and education.</td>
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Key Takeaways

1) There are many specialty drugs within PBM formularies that require management.
   - Do you know where your financial exposure stands?
   - Are you actively engaged in holding your PBM accountable for performance guarantees, such as those tied to add-on programs for utilization or adherence (e.g., having your consultant validate ROI on an ongoing basis)?

2) Many new specialty drugs are in the FDA pipeline and others are in the research and development phases.
   - Are you proactively monitoring the pipeline to address PBM contracting terms for newly approved specialty drugs?

3) Patients requiring specialty drugs are often in catastrophic care categories.
   - Does your procurement strategy avoid patient care disruptions?
   - Have you implemented or considered a plan of action that avoids financial costs associated with procurement disruption?
   - Is your PBM coordinating with the medical administrator in providing clinical resources to help plan participants effectively manage their health conditions?

Conclusion

Managing specialty drugs and the associated PBM environment is often complex requiring the help of healthcare benefit consultants with sufficient expertise and analytic tools to help you address the scenarios above. Opening up a discussion about these issues is a great first step.
Spending on traditional drug therapies is expected to decline (primarily due to generic drugs) while specialty drugs are expected to increase rapidly.

An Express Scripts study indicates that specialty drugs comprise 1% of prescriptions, but 32% of total Rx costs.

The pharmacy or the medical benefit covers specialty drugs. Plan sponsors need to monitor both sides of the benefit.

Specialty drugs are often a catalyst for company mergers and acquisitions. Under this scenario, acquisition costs become part of the drug’s price.

Orphan drugs: The FDA classifies orphan drugs as those that serve less than 200,000 people in the U.S. Some in the industry define them as serving just up to a few thousand. Pricing for these specialty drugs is often based on the small market available—and is likely to be very high per patient.

Some non-orphan specialty drugs are being priced like orphan drugs. (e.g., Hepatitis C drugs).

In the future, the FDA pipeline is expected to have fewer non-specialty drugs so the cliff for generic drugs has largely been reached.
About the Authors

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About GRS Health and Welfare Consulting

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GRS’ clients are served by some of the most respected experts in the healthcare industry. We deliver unique, creative solutions that are designed for each client’s workforce goals, fiscal circumstances, and stakeholder expectations.

Our primary deliverable is always client satisfaction.

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