Attention Turns to Specialty Pharmacy

Specialty biotech drugs represent 1-2% of prescriptions yet 35% or more of overall pharmacy costs—and are projected to reach 50% of costs over the next three years. In the United States, the cost of these drugs is multiples more than in other countries, and their use presents global competitiveness and philosophical challenges for plan sponsors. This article examines specialty drug trends, discusses balancing access to them versus their impact and reviews the current state of specialty drug management. It provides plan sponsors with key considerations for the future. While specialty biotech management will remain an area of focus affecting benefits budgets for years to come, options are available to help manage their impact and improve outcomes.

by David Dross | Mercer

hey are nothing less than therapeutic breakthroughs: specialty biotech medications that treat chronic conditions like hepatitis C, multiple sclerosis and a growing roster of other diseases. While they have vastly better cure rates and milder side effects than previous therapies, their costs are extremely high at \$80,000 or more per treatment regimen, which is unsustainable for nearly all employers. In the United States, the cost of these drugs is multiples more than in other countries, and their use presents global competitiveness and philosophical challenges for plan sponsors.

Costs and Trends

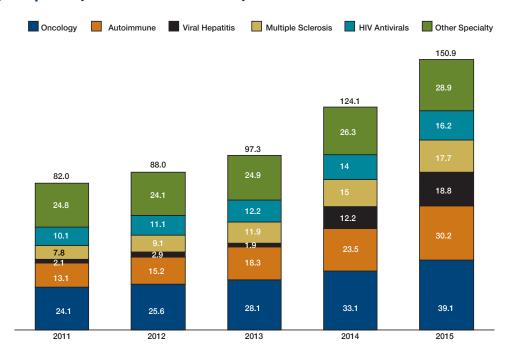
Specialty biotech drugs represent 1-2% of prescriptions (and the same percentage of members to whom they are prescribed), yet they represent 35% or more of overall pharmacy costs. Spending on specialty medications has nearly doubled since 2011 (Figure). They likely will reach 50% of pharmacy costs in the next three years, according

to Medicines Use and Spending in the U.S.-A Review of 2015 and Outlook to 2020 from IMS Institute for Healthcare Informatics.¹

- In the period from 2011-2015, specialty medications represented 70% of the increased costs in U.S. pharmacy spending, despite being under 2% of prescriptions.
- The pipeline for these medications is robust, with 40-50 new drug introductions anticipated annually for each of the next five years.
- Specialty medication is trending highest in costs among all health-related benefits—approaching 20% increases annually in some industries.
- Some pharmaceutical companies may offer a rebate to help defray the costs of medication. However, this rebate is not paid until six to nine months after the prescription is dispensed, and it is paid to the plan sponsor, not the member.

FIGURE

Spending on Specialty Medications Has Nearly Doubled Since 2011 (in billions of dollars)



Source: IMS Health, National Sales Perspectives, January 2016.

Balancing Access and Impact

If plan sponsors restrict use of specialty drugs, patients who would benefit are denied access to life-enhancing drugs. However, if they are dispensed without restriction, they could affect budgets, possibly requiring plan design reductions that affect all plan members. In addition, their use increases overall plan costs and may affect overall business results.

Simply stated, specialty biotech medications represent the best and worst of the U.S. medical system—outstanding innovation and clinical impact but at costs that complicate their use.

Current State of Management

Management of specialty drugs is highly fractured. Several issues contribute to this.

• Specialty medications are not managed in one place or plan. In most cases, about half of specialty drug spending is through the medical plan and half through the pharmacy plan.

- Because specialty is split among plans, employers may not know their total spending because they do not receive consolidated reporting.
- Utilization management criteria often vary between the pharmacy and medical plans, resulting in patients on the same medication having a different experience (and level of benefit) depending on where they access the medication.
- The site of care is also highly variable, ranging from a doctor's office to an infusion center to an outpatient hospital. Because most specialty medications are infused, the costs of administration can be a major contributor to overall cost. However, there is little to no therapeutic difference by site of care for most therapies. (Certain rare conditions may require a certain site, but they are very uncommon.)

Health plans and pharmacy benefit managers (PBMs) have clinical and structural approaches to manage specialty spending. However, each provider receives revenue when these medications are dispensed. Some industry observers

International Society of Certified Employee Benefit Specialists

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and plan sponsors feel this dynamic results in misaligned incentives, with the entities charged with managing utilization also benefiting from it.

In addition, some medications are purchased and dispensed by the treating physician. In this scenario, the physician has an incentive to use a higher cost medication because compensation is higher for costlier medications. Some industry analysts estimate that certain medical specialist practices get 25% or more of their revenue from drug dispensing and administration.

Many plan sponsors are concerned about the current state of specialty management, but some believe they have few options because the three biggest PBMs—CVS Health, Express Scripts and Optum—have a combined 70% market share. However, some health plans (and a few large plan sponsors) have taken a different approach. Many regional health plans that do not own their own PBM contract with a firm like one of the big three PBMs to handle nonspecialty pharmacy and hire a separate entity—a specialty pharmacy—to handle management of this unique space. While the reasons for this may vary, some of the common advantages of a specialty pharmacy are:

- Operational flexibility to adjust to the health plan needs
- Singular focus
- Established track record of management across both medical and pharmacy plans
- A continuum of management options ranging from "behind-the-scenes" rebate management to full carveout of all functions related to specialty management.

Key Considerations for the Future

Specialty pharmacy management is changing because of market need driven by plan sponsors of all types. Many of them are requesting new approaches. The nature of the requests varies, but three points are common:

 Transparency: Many plan sponsors are requesting more visibility into the procurement of specialty medications. While they recognize the high costs of these medications, there is a strong desire to ensure that the medications are being sourced in the most efficient manner.

- Financial structure: Increasingly, plan sponsors are concerned that the fastest-growing pricing improvement lever is pharma-funded rebates. There are several concerns regarding this development:
 - Rebate payments lag the dispensing of the prescription by up to nine months. In addition, rebate payments usually are made in bulk for utilization during a particular time frame. So it is nearly impossible for a plan sponsor to determine the final net price, since the sponsor cannot match the claims unit cost when dispensed and the rebate associated with it.
 - Rebate payments are made to the plan sponsor, not the member. Rebates have helped keep pharmacy trend in single digits, but gross trend is still in double digits, and the gap between gross and net trend has grown in recent years. Many plan sponsors have moved to consumer-directed plans, with coinsurance-based plan designs resulting in the member seeing the higher unit cost, not the higher rebate. Some PBMs may offer a "point-of-sale" rebate, but in many cases the payout is much lower, since the PBM has not been paid the rebate at the time the drug is dispensed.
 - Recent price increases in a variety of areas (not just specialty drugs) have raised concerns about the structure and costs of the U.S. drug distribution system. Some pharma companies assert that up to half of the end price of certain drugs is due to the channels of distribution, including drug retailers, wholesalers, PBMs and carriers. Some of the concern is about the role of rebates in overall pricing. In essence, some observers indicate that prices are increasing to fund the bigger rebates required by the distribution system. As noted, while these payments may help reduce net trend, gross trend is still high and directly affects members who are on coinsurance-based plan designs.
- Some plan sponsors are concerned about the selection of preferred products on pharmacy administrators' preferred drug lists—commonly referred to as formularies. In the past, nonpreferred drugs were

available at a higher member cost share. Increasingly, the drugs that are not preferred are excluded. Since some drugs may have some advantage over others in their drug class, many plan sponsors still want to maintain that choice. In many cases, the pharmacy administrators do not release their clinical selection criteria, which causes some plan sponsor concern regarding the selection process.

Point of View

Specialty pharmacy is one of the major concerns voiced by today's plan sponsors. Given this, every employer may want to consider taking two steps regarding specialty management, regardless of current plan structure:

- 1. **Specialty diagnostic:** Each plan sponsor should complete a diagnostic across the medical and pharmacy plans to determine their current state and identify changes to improve management through existing providers. After completing these analyses in the past, Mercer has found the following:
 - Significant disparities in effectiveness in managing site-of-care administration, with the pharmacy plan typically doing a better job
 - Significant "misses" on in-force clinical programs on both the PBM and medical carrier sides. In some cases, clinical programs and protocols were not followed, resulting in wastage, missed diagnoses and lack of documentation of required testing.
 - Large disparities in the efficacy of sourcing are often identified. The same drug can have a 20%+ difference in price between the medical plan and pharmacy plans. However, actual results will vary by drug class/disease state and by provider, so there is no common rule of thumb regarding this issue.

At the conclusion of the diagnostic, the plan sponsor can make an informed decision on the revisions of its plan structure to optimize pharmacy management with current providers. Savings typically are in the 5-10% range. However, these savings occur in the short term, and the plan sponsor should revisit its structure at least semiannually because vendor capabilities change over time. In addition, if the plan sponsor

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changes medical or pharmacy providers, the plan structure should be revisited based on the capabilities of the new provider.

2. **Specialty provider review:** A diagnostic can lead to better results without changing providers. However, in some cases the diagnostic may identify that one or more of the current providers are not able to achieve best-in-class results. If so, the plan sponsor has the options of accepting below-market results, working with the current provider to achieve better results over some defined time frame or seeking other providers. Specialty pharmacies can help address this possible need. However, since they are addressing only 1-2% of the patients, the core PBM and the 98% of the population not on specialty drugs do not see any changes, so this option does not have the same level of disruption as changing the core PBM. Plan sponsors need to review their current contracts to determine if there are any restrictions to adopting this approach. In addition, since there are different providers with varying strengths, care should be used in selecting a partner.

Specialty biotech management will remain an area of focus for years to come. While it will continue to affect benefits budgets, the good news is that there are options to help manage their impact and improve outcomes.

Endnote

1. Murray Aitken. *Medicines Use and Spending in the U.S.-A Review of 2015 and Outlook to 2020*, IMS Institute for Healthcare Informatics, Parsippany, New Jersey, April 2016, available at https://morningconsult.com/wp-content/uploads/2016/04/IMS-Institute-US-Drug-Spending-2015.pdf.