Pharmacy Cost Trends and System Impacts: Specialty Drugs

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This is the third installment of the Pharmacy Cost Trends and System Impacts fact sheet series. Previous fact sheets have explored pharmaceutical cost trends and the role of drug supply and pharmacy payments. This fact sheet focuses on specialty drugs, conditions requiring specialty drugs, and factors influencing costs.

INTRODUCTION

While there are varying definitions of specialty drugs, they are often defined as drugs that treat complex conditions, require a high-level of clinical monitoring, are biologics (many of which are complex mixtures that are not easily identified or characterized), or are orphan drugs used to treat rare diseases and disorders.[1] An estimated 85 percent of payers also use cost as a determining factor in classifying a therapy as a specialty drug.[2]

Figure 1: Conditions Often Requiring Specialty Drug Treatment

- Human immunodeficiency virus (HIV) / acquired immune deficiency syndrome (AIDS)
- Hepatitis C
- Cancers
- Psoriasis
- Inflammatory bowel disease (IBD)
- Rheumatoid arthritis (RA)
- Other chronic diseases, including diabetes management (insulin therapies)

Specialty drugs often provide life-saving treatments for individuals diagnosed with certain conditions (see Figure 1). For example, the average wholesale cost of Enbrel®, a biologic drug that modifies the immune system and is used to treat rheumatoid arthritis (RA), exceeds $4,000 for a 30-day supply.[3] The high cost creates access barriers for many patients, which can result in irreversible physical damage and additional costs stemming from the untreated disease. Untreated RA can lead to chronic pain and disability, causing joint damage in 80 to 85 percent of patients within the first two years of diagnosis.[4] Complications can lead to hospitalization and potential long-term care needs.[3]

While specialty drugs may offer new and advanced options for treating chronic or complex diseases, the associated cost has become a controversial issue, as specialty drugs represent one of the fastest-growing areas of overall healthcare spending. A 2011 study estimated that specialty drug spending represented 25 percent of overall prescription drug spending for people who are privately insured and under age 65. The same study also estimated that specialty drug spending would account for approximately 50 percent of total pharmaceutical spending by 2018.[5]

Utilization for traditional drugs grew slightly from 2014 to 2015 but total growth slowed likely due to cost-control measures and generic equivalent usage (see Table 1). Specialty drug utilization, however, jumped nearly seven percent, increasing total spending in this category by almost 18 percent.[6]

Table 1: Drug Spending in 2015 for Private Payers (Compared to 2014)

	PMPY	Utilization	Unit Cost	Total
Traditional	$708.09	1.9%	-2.1%	-0.1%
Specialty	352.66	6.8%	11.0%	17.8%
Total	$1,060.75	2.0%	3.2%	5.2%

Factors Influencing Specialty Drug Costs

- **Manufacturing Costs**—Drug manufacturers often cite the high cost of pharmaceutical production, particularly biologics, as a major driver of costs. However, a lack of transparency into drug manufacturing practices makes it difficult to measure its overall impact.[1]
- **Distribution and Storage Costs**—Many specialty drugs require additional handling considerations, including specialized shipping materials and refrigeration needs.[7]
- **Pharmaceutical Competition and Patient Choice**—Several specialty drugs have no generic alternative or therapeutic equivalent, allowing manufacturers to charge higher prices for these therapies.[4] Some large

pharmacy benefit managers (PBMs) have their own specialty pharmacies and restrict patient access to only those pharmacies.

There are many concerns regarding high-price justifications for specialty drugs, with additional scrutiny placed on drug manufacturers. As generic drugs continue to saturate the U.S. market—they represent 86 percent of prescriptions filled in 2014 compared to 40 percent in 1995—some have suggested that manufacturers are leveraging high prices for specialty drugs to make up for generic drug losses,[8] although generics are increasing in price as well.

Impact of Specialty Drug Costs

The high cost of specialty drugs has negative impacts on both payers and consumers. As specialty drug utilization rates have increased, payers have struggled to cover alternative treatment courses for their beneficiaries. Payers also face limited ability to negotiate with pharmacy benefit managers (PBMs) as many classes of specialty drugs lack therapeutic equivalents to drive down costs. Within Arkansas, the State and Public School Employee Health Plan administered by the state's Employee Benefits Division (EBD) has experienced significant increases in specialty drug spending, despite a lower increase in utilization than trends in other private health plans (see Figure 2).[9]

Figure 2: Specialty Drug Statistics EBD

- Specialty drugs accounted for 0.6% of all plan prescriptions, but **34.9% of the total plan paid** for pharmacy costs in 2015
- Average cost per specialty prescription was **$2,733.96** in 2015 (up 14.1% from 2014)
- Highest cost specialty drugs included medications used to treat: **chronic inflammatory disease, hepatitis C, multiple sclerosis, cancers, and HIV**

Within state Medicaid programs, access to expensive specialty drugs used to treat hepatitis C has been debated with respect to the point at which such therapy should be a covered service. Medicaid and Medicare are required to cover medically necessary treatments, but there has been disagreement over whether high cost drugs such as Harvoni® and Sovaldi® should be covered for individuals who are affected by liver disease but do not yet manifest advanced stages. Medicaid programs in states such as Massachusetts and Florida have decided to expand access to these drugs to those who have not yet developed serious complications from the disease, while most others require progression of disease.[10]

Cost-Reduction Strategies

The primary strategy used by payers to curtail utilization is through cost-sharing requirements passed onto beneficiaries, including the use of co-payments and co-insurance.[5] Payers utilize the following to manage specialty drug costs:

- **Formularies**—Many health plans place specialty drugs in higher-tiered categories, known as specialty tiers, which shift additional out-of-pocket expenses to beneficiaries;
- **Prior Authorization**—Often used in conjunction with higher-tiering strategies, prior authorization requires that an individual's provider submit documentation to demonstrate the medical necessity of high-cost specialty drugs;
- **Step Therapy**—For conditions that have multiple therapies available, health plans will often require that lower-cost therapies be utilized as a first course of action before covering higher-cost specialty treatments.[2]

Consumer Protections

The Affordable Care Act (ACA) established out-of-pocket limits for qualified health plans and further limited cost-sharing exposure for lower-income individuals and families purchasing coverage through the Health Insurance Marketplace. However, specialty drugs are still cost prohibitive for many consumers and may lead to reduced treatment adherence or prescription abandonment, i.e., the patient never picks up the prescription from the pharmacy. At least seven states have implemented measures to reduce out-of-pocket payments for specialty drugs, such as capping on out-of-pocket payments for a specialty prescription per month (Delaware, Louisiana, Maine, Maryland, Montana, New York, and Vermont).[11] The Affordable Care Act (ACA) also added

protection from out-of-pocket spending for Medicare beneficiaries, but high out-of-pocket costs for specialty drugs remain problematic.[12]

For some consumers, prescription assistance programs (PAPs) can provide assistance in the procurement of high-cost drugs. However, many of these programs are only eligible for those with very low incomes, leaving out consumers that fall just above the threshold to qualify. Additionally, federal anti-kickback laws prevent Medicare beneficiaries from participating in these programs, although Medicare beneficiaries represent approximately one-third of overall prescription drug spending.[13]

Drug coupons including monthly savings cards and maximum copay cards offered by drug manufacturers are another mechanism to lower out-of-pocket expenses for consumers.[14] While drug coupons may reduce direct consumer costs at point of drug purchase, payers absorb the remaining costs and are faced with limited ability to control utilization through cost-sharing. In the long-term, this can result in cost-shifting for all consumers through premium increases.

CONCLUSION

Some specialty drugs offer good value for both patients and payers. However, as payers are left with fewer options to manage the cost of specialty drugs, additional transparency of cost trends and clinical efficacy is needed to develop comprehensive solutions. Additionally, greater competition is needed among specialty pharmacies to ensure greater pricing transparency and competition. The next fact sheet in this series will further explore options for payers through plan management strategies.

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