Solving the Specialty Drug Puzzle:

Definitions and Pricing Strategies

by | **Susan A. Hayes**

Specialty drugs are one of the fastest growing areas of health care costs. In the first of a two-part series, the author explains how specialty drugs are defined and priced.

As the new century dawned, few people were aware of specialty drugs. Very rare or potentially fatal diseases were treated with these drugs, but the term *specialty drugs* was not commonly used. In two decades, the specialty drug marketplace has grown substantially. Despite only 2% of the population using specialty medications, these drugs were projected to reach 50% of total health care payer drug costs by 2020 (Meyer, 2019). Well-known drugs like Humira® cost more than $40,000 a year. Humira was the top-selling drug in the United States in 2016, earning manufacturer AbbVie more than $13.6 billion in sales (Frellick, 2017). More expensive examples include a gene therapy named voretigene neparvovec-rzyl (Luxturna®)—approved for the treatment of inherited retinal disease—with a nearly $850,000 price tag for a one-time treatment.

The average annual cost for a single specialty medication was almost $79,000 in 2017, and specialty drug prices increased more than three times faster than general inflation in 2017 (7.0% vs. 2.1%).

What Is a Specialty Drug?

Brand and generic drugs are defined by the length of the patent protection given to the development of drugs. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act (referred to as the Hatch-Waxman Act) to establish a legal framework to restore some of the innovation incentives lost as a result of protracted Food and Drug Administration (FDA) drug-testing and approval procedures. Brand and generic drugs are now defined and reported by the industry pricing source, Medi-Span.[1] Unfortunately, there is no such third-party objective designation for specialty drugs, and every insurance company or pharmacy benefit manager (PBM) has one or many lists or definitions of specialty drugs.

Specialty drugs are often classified as high-cost, high-complexity and/or high-touch. The Centers for Medicare & Medicaid Services (CMS) defines specialty drugs as those costing more than $670 monthly (Twachtman, 2020). Other sources differentiate specialty drugs from traditional drugs as requiring intense clinical monitoring, frequent adjustments in dosage, and/or specialized training for handling and/or administration (Academy of Managed Care Pharmacists, 2020). Both definitions could apply to many drugs.

Perhaps the confusion lies in that *specialty drugs* is too broad a term. Specialty drugs should refer only to biologics and orphan drugs.

Many brand and generic drugs fit the description of "high-cost." For example, the costs of metformin 1000 mg-ER (a generic) and Trulicity® (a brand) each exceed $670 per month. So, cost should likely not be a specialty drug–defining term because it could also include brand and generic drugs. As another example, the imprisoned Martin Shkreli obtained the patent for Daraprim® (pyrimethamine), a drug approved in 1953, and increased the price from $13.30 to $750 per pill overnight in September 2015 (Kliff, 2015). A 70-year-old drug used to treat malaria would not be considered a specialty drug, but merely increasing its cost resulted in it qualifying as a specialty drug.

Biologics are a better fit in the category of specialty drugs. A *biologic* is manufactured in a living system such as a microorganism, or plant or animal cells. Most biologics are very large, complex molecules, and many are produced using recombinant DNA technology. Small manufacturing process differences can significantly affect the nature of the finished biologic and, most importantly, the way it functions in the body. To ensure that a manufacturing process remains the same over time, biologics manufacturers must tightly control the source and nature of starting materials and consistently employ hundreds of process controls that assure predictable manufacturing outcomes (Biotechnology Innovation Organization, 2020).

There are no biological drugs that can be categorized as generics. FDA has stated that it has not determined how interchangeability can be established for complex proteins.[2] Historically, FDA has permitted interchangeability only when two products are "therapeutic equivalents." Because of the complexity of biologics, the only way to establish whether there are differences that affect the safety and effectiveness of the follow-on product is to conduct clinical trials.

There are, however, *biosimilars,* which are similarly made biotechnical drugs. These "generic" versions of biologic drugs are still costly but on average cost 15% less than their biologic counterparts. FDA has approved 29 biosimilars, although very few are on the market.[3] The first biosimilar was a similarly made version of Neupogen® (filgrastim), approved in March 2015. FDA has approved five biosimilars for Humira; however, direct biosimilar competition for Humira is not expected until 2023 because of legal challenges by Humira's manufacturer. Johnson & Johnson's Remicade has two biosimilar competitors—Inflectra® and Renflexis®. Those biosimilars have managed to garner only a combined 12% market share (Sullivan, 2020).

The last category of specialty drugs is *orphan drugs,* developed by the pharmaceutical industry not for economic reasons but to respond to public health need. The Orphan Drug Act (ODA) provides for qualified sponsors of drugs or biological products that treat a rare disease or condition to receive various development incentives, including tax credits for qualified clinical testing.[4]

Some specialty drugs require a Risk Evaluation and Mitigation Strategy (REMS). A REMS is a drug safety program that the FDA can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks.[5] REMS are designed to reinforce medication use behaviors and actions that support the safe use of that medication. Attaching a REMS requirement for a drug does not make a drug a specialty drug—It just means that the dispensing pharmacy has more paperwork to complete.

Why Are Specialty Drugs So Expensive?

The simple answer is that the market allows them to be priced expensively. In the U.S. health care market, unlike many other countries, manufacturers set the price of their products instead of the government. Such economic and public health policy has resulted in unsustainable price tags.

Manufacturers argue that the costs are due to the high costs to research and bring a drug to market. Research and development costs are only about 17% of total spending in most large drug companies. However, research suggests that once a drug has been approved by FDA, there are minimal additional research and development costs (Blumberg, 2019). Experts suggest a price increase cap once a drug enters the market.

Another argument is that the cost of drugs is set at the cost of an avoided hospital stay. A $100,000 price tag for hepatitis C treatment certainly seems like a bargain compared with the $240,000 cost of hospital stay (Xu, Tong and Lieder, 2014). However, many would argue that prices are not set on cost avoidance in other industries. The cost of an airline ticket does not consider what it would cost someone to build their own plane, get a pilot license, buy airline fuel and coordinate the flight. Further, there are many very inexpensive drugs that keep patients from inpatient stays, such as the inexpensive generic lisinopril that keeps blood pressure low, avoiding heart attacks, at a cost of about $4 a month.

Seventy percent of specialty drugs are purchased by four companies: CVS/Caremark, Express Scripts, Walgreens and OptumRx (Fein, 2019a). These companies, three of which are PBMs, also resell specialty drugs to plan sponsors through specialty drug facilities that they own. Specialty dispensing concentrated to four purchasers is the result pushed to payers and manufacturers from the PBMs themselves to narrow specialty drug channels that the PBM owns and operates. Therefore, both the "buy price" and the "sell price" of 70% of specialty drugs are controlled by four companies, limiting price competition.

In their plan contracts, PBMs have a list of specialty drugs and base their prices on a discount off average wholesale price (AWP). There are three issues with this practice. First, the manufacturer can set the AWP at any price it wants to, regardless of the cost to the manufacturer, the cost of purchasing the drug through a retail pharmacy or how effective the drug is. Second, the list is already outdated on the day the contract is executed because new specialty drugs without contracted discounts continue to arrive on the market. The PBMs are free to price these

takeaways

- Specialty drugs were projected to reach nearly 50% of total health care payer drug costs in 2020 and the average annual cost for a single specialty medication was $79,000 in 2017.
- The definition of *specialty drugs* varies. The Centers for Medicare & Medicaid Services defines specialty drugs as those costing more than $670 monthly, while other sources define them as those requiring intense clinical monitoring, frequent adjustments in dosage and/or specialized training for handling and/or administration.
- Specialty drugs actually include three types of drugs: high-cost drugs, biologics and orphan drugs.
- In the U.S., unlike in many other countries, drug manufacturers set the price for their products instead of the government. Manufacturers attribute drug costs to the high costs to research and bring a drug to market.
- Other factors in the high cost of specialty drugs include limited competition—with dispensing limited to a handful of purchasers— and pharmacy benefit manager (PBM) contracting practices.

new drugs as they wish, using any corresponding discount. Lastly, plan sponsors cannot readily tell whether the "specialty" drugs on a PBM's list are really specialty drugs (i.e., biologics) or traditional brands or generics. A pharmacist must review the list to determine whether the drugs are biologics or simply brand or generic drugs, then must argue with the PBM, some of whom will not alter the list.

Taking a brand or generic drug and placing it on a list reduces the effectiveness of the aggregate financial performance guarantees that PBMs promise to their plan sponsor clients on the purchase of brand and generic drugs. The table illustrates how shifting the classification of generic drugs to specialty drugs can impact aggregate financial performance guarantees for plan sponsors. The left column shows five specialty drugs with 15% discounts and two generic drugs with 50% and 60% discounts. The aggregate discount is 15% for the specialty drugs and 55% for the generic drugs. But the PBM can improve its aggregate financial performance on specialty drugs by shifting the two generic drugs (through overly broad definitions) into the specialty category.

PBMs argue that by limiting distribution to their own facilities, greater discounts can be offered. However, a typical PBM specialty discount is around 16% off AWP, while retail brand discounts average 17% to 18%. Thus, it may be more advantageous to have specialty drugs filled in retail pharmacies instead of in "exclusive" PBM specialty pharmacies.

PBMs contend that retail pharmacists are not adept at filling prescriptions for these medications. However, there are no state or federal laws prohibiting retail pharmacies from filling specialty drug prescriptions and no requirement to be licensed to dispense specialty medications. Specialty patients are often the most valuable for retailers, so there is an economic incentive for them to treat these patients better than average. In addition, all pharmacists must pass the same board of pharmacy exam.

The PBMs' own reports confirm that specialty costs are increasing more than traditional drug costs. The Express Scripts *2018 Drug Trend Report* stated that spending on specialty drugs grew by 9.4%, while spending on traditional drugs dropped by 5.8% (Fein,

TABLE

Recategorizing Specialty and Generic Claims

By classifying generic drugs as specialty drugs, pharmacy benefit managers (PBMs) can improve their aggregate financial performance guarantees.

Claims for Specialty and Generic Drugs		The Same Claims Reconciled by Moving Two Generic Claims Into the Specialty Category	
	Average Wholesale Price (AWP) Discount		AWP Discount
Specialty Claim One	15%	Specialty Claim One	15%
Specialty Claim Two	15%	Specialty Claim Two	15%
Specialty Claim Three	15%	Specialty Claim Three	15%
Specialty Claim Four	15%	Specialty Claim Four	15%
Specialty Claim Five	15%	Specialty Claim Five	15%
Average Specialty Drug Discount	**15%**		
Generic Claim One	50%	Reclassified Generic Claim Six	50%
Generic Claim Two	60%	Reclassified Generic Claim Seven	60%
Average Generic Drug Discount	**55%**	**Average Specialty Drug Discount**	**26.42%**

2019). The 2020 version of the report shows similar findings: Spending on specialty drugs grew by 11.6%, while spending on traditional drugs dropped by 5.0% (Fein, 2020). In a 2019 interview, Kent Rogers, OptumRx senior vice president, chief pharmacy contracting and procurement officer stated, "Drug manufacturers are responsible for the high cost of prescription drugs. In particular, this is why specialty drug prices are spiraling out of control" (OptumRx website, 2020). The latest available trend insight report from OptumRx stated that standalone traditional drug costs rose 0.9%, while specialty drug spend rose 13.2% (*OptumRx 2016 RxTrend Insight Report,* 2016). The CVS/Caremark *2019 Drug Trend Report* stated that traditional cost rose 1.4%, while specialty spend rose 9.3% (CVS/Caremark *2019 Drug Trend Report,* 2020).

Measures could be taken to rein in the control of specialty prices by PBMs. PBMs could use the National Drug Acquisition Cost (NADAC) to set prices instead of basing the price on a discount off AWP.[6] NADAC prices are published by CMS and reflect the pharmacies' acquisition costs for prescriptions. As of August 2020, the NADAC price for Humira (based on a 40 mg/0.8 mL syringe dose) was $2,363.47. The AWP of the same drug was $3,334.18 and would cost $2,800.71 with a 16% discount. That means that the cost to dispense Humira in a PBM facility would be $437.24 more than in a retail pharmacy (plus a modest dispensing fee of perhaps $10) if the PBM reimbursed the pharmacy acquisition cost (i.e., NADAC price) plus a dispensing fee rather than using an AWP discounted methodology.

Other Cost Factors

Biosimilars are less expensive than the original biologics, but many that have received FDA approval are not available. Originator biologic manufacturers have employed delay tactics to impede patient utilization of approved biosimilars (Zhai, Zarpatawari, Kesselheim, 2019), using ongoing patient litigation as the primary impediment (Cottler, Whitehall, Siedor, 2019). For example, AbbVie's active ingredient patent on adalimumab expired in 2016, but it was granted patents protecting everything from the manufacturing process to new formulations of the drug. A 2018 report found that 89% of these patent applications were filed after adalimumab was on the market, and 49% were filed after the first patent expired in 2014. This strategy of creating a wall of patents to protect assets is known as developing a "patent thicket."

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The second reason that biosimilars have not come to market may be the relationship between PBMs and manufacturers. At least one biosimilar manufacturer has alleged that originator biologic manufacturers have negotiated formulary exclusivity, often without disclosure to payers. In a 2017 lawsuit, a manufacturer of biosimilar infliximab claimed that the originator manufacturer entered into contracts with commercial payers to exclude biosimilars from drug formularies or include "fail first" provisions, requiring patients to have failed on the original product before a biosimilar could be reimbursed (*Pfizer Inc. v. Johnson & Johnson,* 333 F Supp 3d 494 (ED Pa 2018)). Rebates featured prominently in this practice. The infliximab lawsuit charged that the originator manufacturer told insurers that if they did not grant exclusive use of its product, the manufacturer would withhold rebates on other products (Hummer, 2019). At least 70% of commercially insured patients in the U.S. are affected by these exclusionary contracts.

Another practice that affects pricing is the designation of specialty drugs as a limited distributed drug (LDD). A manufacturer will often designate certain pharmacies in a limited distribution network (LDN) that can dispense its medications based on product characteristics, patient education, market reach, and administration and dispensing characteristics (Toman, 2018). This strategy is purported to help ensure safe distribution of high-risk drugs. However, LDNs hamper provider access to pharmaceuticals and facilitate price gouging.

Conclusion

The PBM practice of requiring exclusivity appears to have had little effectiveness in driving down the costs of specialty drugs. In fact, costs increase without competition (Feld-

man, 2020), and PBM-owned specialty pharmacy discounts are lower than retail pharmacy discounts. PBMs that use NADAC-based pricing can be particularly cost-effective for specialty drugs. Retail pharmacists can be just as effective as PBM pharmacists to counsel patients and provide quality dispensing.

Endnotes

1. Medi-Span defines brand and generic drugs through the multisource codes, referred to as the MONY codes and the brand name codes of B, T and G.
2. See www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/default.html.
3. An updated list can be found at www.fda.gov/drugs/biosimilars/biosimilar-product-information.
4. A complete listing of orphan drugs can be found on the Food and Drug Administration website at www.accessdata.fda.gov/scripts/opdlisting/oopd/.
5. A complete list of REMS drugs can be found at https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm.
6. National Average Drug Acquisition Cost (NADAC) is published by CMS and reflects the pharmacies' acquisition costs for prescriptions, available at https://data.medicaid.gov/Drug-Pricing-and-Payment/NADAC-National-Average-Drug-Acquisition-Cost-/a4y5-998d.

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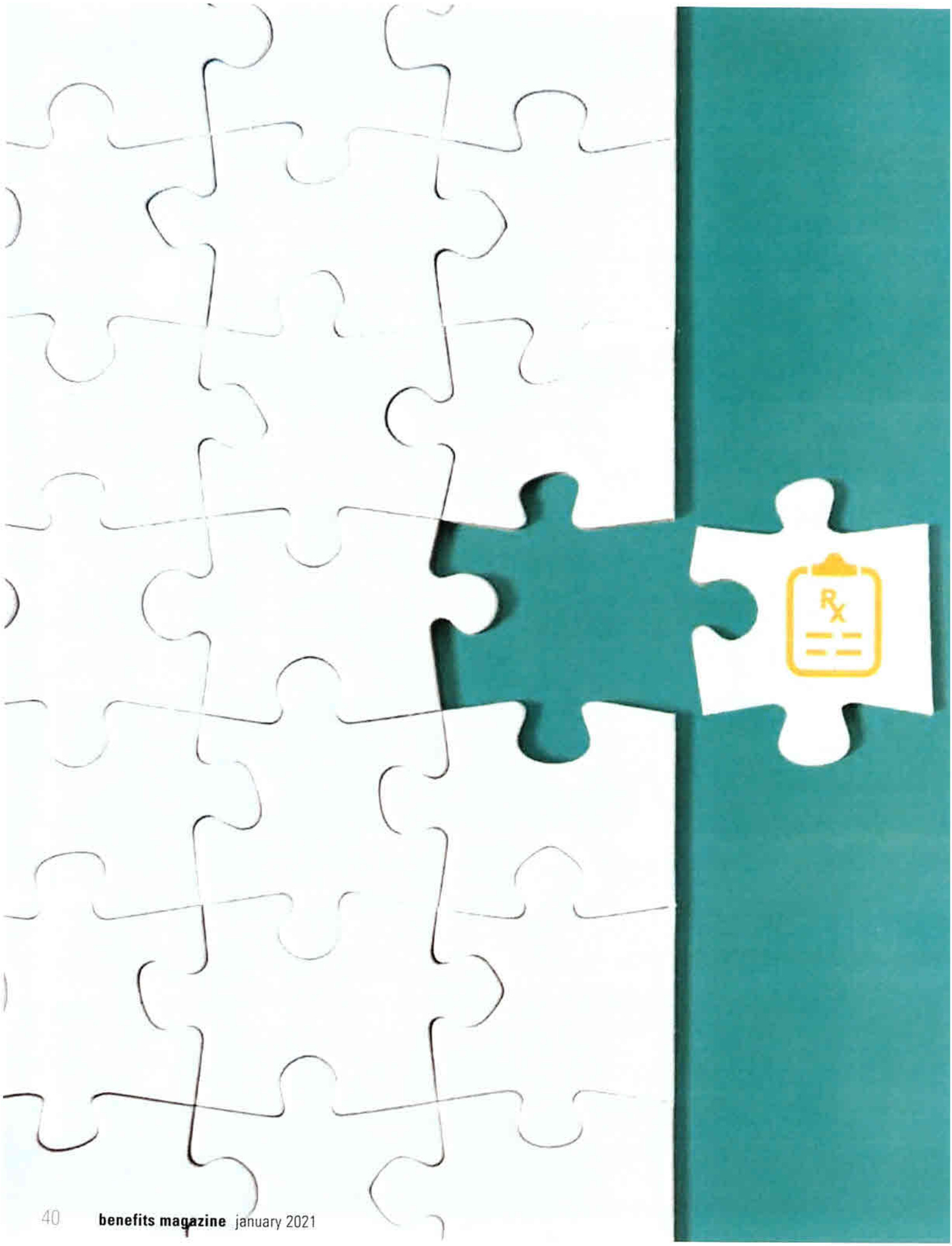
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Second in Two-Part Series

Solving the Specialty Drug Puzzle:

Employer and Plan Sponsor Strategies

by | **Susan A. Hayes**

Specialty drugs are one of the fastest growing areas of health care costs. In this second article of a two-part series, the author suggests strategies employers and plan sponsors can use to rein in drug costs.

There are many confusing issues regarding specialty drugs, such as what makes a drug a specialty drug. What is clear about specialty drugs is that pharmacy benefit manager (PBM) interests may not always align with employer interests: Some employers may rely heavily on their PBMs to set specialty drug policies, determine specialty drug lists and pass through discounts from manufacturers without independently verifying whether their own needs are best served in these arrangements.

Plans should recognize that PBM interests can diverge sharply from their own interests, such as a desire to limit the volume and price of specialty drugs. Because the specialty drug sector is complex and the vast majority of employers lack the in-house expertise to deal with PBMs on an equal footing, many employers likely would benefit from having independent experts assess their PBM contract terms and audit compliance with those terms.

Plans have been exploring a series of interventions to curtail the cost and utilization of specialty drugs, some with success, some with little success. The first article in this series discussed the definition and pricing of specialty drugs. This article focuses on employer and plan sponsor strategies to control use and pricing of specialty drugs. The table provides a checklist for plan sponsor specialty drug management.

Pricing

Although employers and plan sponsors have no control over how drug manufacturers set the prices for these drugs, they can employ a few strategies to reduce the amount their plans spend.

They can start by narrowly defining what qualifies as a specialty drug. Plans should define *specialty drugs* as biologics and orphan drugs. Lists of

TABLE

Specialty Drug Intervention Strategy Checklist

Pricing Strategies	Check the *specialty drug* definition. Is it overly broad or just focused on biologics and orphan drugs?
	Is there a list of specialty drugs that are out of date and includes brands and generics? If so, financial performance guarantees may be watered down.
	Are specialty drugs priced using National Drug Acquisition Cost (NADAC) or average wholesale price (AWP) pricing? AWP pricing will inflate costs when manufacturers increase prices.
	Is the pharmacy benefit manager (PBM) requiring exclusive use of its specialty facility rather than open competition? Competition and inclusion in retail networks will lower the cost of specialty drugs.
	Are coupons applied? This will lower costs but may increase use of specialty products since patients have no incentive to use lower cost first-level drugs.
	Does the PBM encourage use of foundation programs? These programs may violate antikickback laws and, like coupons, provide no incentive for lower cost agents.
Utilization Strategies	Are prior authorizations (PAs) for specialty drugs provided by an outside, unbiased third party, or is the PA process just a "speed bump"? Delays in therapy can hurt patient care, and if the PA is not a meaningful review, it may be of little use while potentially increasing costs.
	Does the plan have an ethics policy? Have employees signed a waiver understanding the side effects of specialty drugs? If not, the ethics of decision making are left to the PBM, which may or may not align with corporate goals for covering specialty drugs, and employees may not be aware of the harm that specialty drugs can cause.
	Does the PBM have a vigorous fraud, waste and abuse program aimed at specialty drugs? If not, the plan may be paying for drugs not picked up by patients or used by your members.

specialty drug *discounts* should be replaced with a list of actual prices that cannot be altered in a given contract year. If that is impractical, the guarantee for aggregate financial performance over the year should be specific and include only true specialty drugs. A list of these specialty drugs can be found on the Food and Drug Administration (FDA) website (i.e., the *Purple Book*), and orphan drugs can be found at www.accessdata.fda.gov/scripts/opdlisting/oopd/.

Plans also can insist that pricing is based on acquisition costs plus a dispensing fee. They could consider using the National Drug Acquisition Cost (NADAC) model mentioned in the first part of this series. This strategy eliminates the need to define brand, generic and specialty drugs into overall aggregate pricing buckets. A drug is simply priced at the NADAC price without averaging over many drugs.

Finally, open networks that promote competition among specialty vendors can reduce prices. PBM specialty drug facilities should compete with the remaining 65,000 pharmacies for dispensing purposes. Plan sponsors have the contractual right to select where members purchase specialty drugs. PBMs should negotiate the best price, regardless of where they are purchasing the drugs.

State health agencies, PBMs and health insurance providers would be in a better position to negotiate drug prices with drug makers if drug price transparency laws were passed.

Coupons and Copay Assistance Programs

Coupons have been used to reduce the price of specialty drugs. When using coupons, PBMs obtain manufacturer money to reduce the cost of a specialty drug—for example, $12,000 for a drug that costs $30,000 per year. The patient's copay is eliminated, and the cost to the plan sponsor is reduced to $18,000. Assuming that the plan sponsor had required the plan participant to pay a typical copay of $100 per month, or $1,200 annually, this arrangement results in a savings of $10,800 for the plan sponsor.

However, getting manufacturers to pay almost a third of the cost has consequences. Because many specialty medications have first-line brand or generic alternatives, using coupons to purchase specialty drugs when a brand or generic is available may increase overall pharmacy spend and reduce any opportunity for patients to try and fail these first-line alternatives, which often have fewer side effects and adverse risks.

According to the National Bureau of Economic Research, coupons increase the sales of brand-name drugs by 60% or more by reducing generic sales (Dafny, Ody & Schmitt, 2017). Bottom line, the very reason employers impose copays is to induce participants to think twice about pharmacy alternatives (generics before brands, brands before specialty drugs). Now, manufacturers and PBMs thwart the copay strategy. Plan sponsors should look for contracts with their PBMs that require the PBM to negotiate higher rebates from the manufacturers and pass back the savings to the plan that are roughly equal to the coupons while keeping in place incentives for patients to make better choices.

Another strategy that takes coupons to the next level is the use of funding by foundations to obtain financial assistance for the cost of specialty drugs. These programs require plans to completely carve out all specialty coverage from the PBM and contract with separate companies that specialize in searching for foundation payments. Then, these programs seek alternate funding programs, which are available nationwide, provided by foundations (primarily established by pharmaceutical companies). If the member does not qualify for foundation assistance, the claim reverts to the PBM coverage with the option of coupons, rebates and discounts.

Some brokers, third-party administrators (TPAs) and PBMs now accept commissions to engage in foundation programs. Many employers and plan sponsors may be unaware that their own TPA, consultant/broker or PBM is receiving a commission—Plan sponsors should be alert to the possibility that advisors may be swayed to encourage.

These foundation programs create concerns about violating federal antikickback rules if patients who receive the assistance are purchasing drugs that are manufactured by the fund's donors or if the funds limit their coverage to especially expensive or specialty drugs rather than supporting all FDA-approved treatments for a given disease. That can increase costs to the health system overall by steering patients away

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from lower cost therapies. Numerous suits, most notably one against Pfizer over the kidney cancer drug Sutent®, have resulted in severe fines.[1]

Employers using these foundation programs (such as Payer Matrix, Script-Sourcing and PBM-sponsored programs) should ask to see the contracts between foundation programs and the donor foundations. If these programs are solely covering a "list" of specialty products and not all products that indigent patients cannot afford, they may run afoul of antikickback laws.

Taking on Prior Authorizations

The most common method of determining medical necessity has been the prior authorization (PA) process. This is a process that directs the pharmacist who is processing a prescription to contact the prescribing physician, who must complete a form documenting medical necessity. That form is then sent to the PBM to authorize the drug.

It is important to have a rigorous review of a specialty drug. Cost is an obvious reason, but less obvious is the risk associated with a specialty drug. If a drug with fewer side effects can treat the patient, the patient should be directed to take that medication. Some side effects can be very severe or even fatal and include risks such as serious infections and cancer. However, this level of side effects may not be clear to patients *prior* to taking the drug. Those who do not investigate side effects may believe the drug is "safe" since the FDA approved it and may not read the patient insert information (i.e., the "Black Box" warnings) until after the drug has been prescribed and dispensed. Employers may want to implement a program whereby, once a drug is prior authorized, patients are sent a waiver requiring their signature warning them about the side effects specific to the drug they are prescribed. This waiver may reduce not only specialty drug use but also the risk of related side effects from those drugs.

While it is clearly important to have rigorous scrutiny over the administration of specialty drugs, the effectiveness of PA processes is unproven. As early as 2001, MacKinnon and Kumar wrote that "PA programs are common, their outcomes have not been adequately evaluated. Still, the scarcity of quality evaluations of the outcomes of PA programs should be of concern to patients, health care professionals, administrators, and others who work in managed care pharmacy since these programs are widely used. It is hard to be objective of our own sacred cows."

In addition, there is likely a conflict of interest in having a PBM perform the PA, leading to approval rates in the 90% range. First, the PBM profits in the cost of buying and selling the medication from its own pharmacy and results from PBMs requiring exclusivity of the owned specialty facility to dispense the drug. Secondly, PBMs garner rebates and other financial consideration for approving high-cost medication and nothing for not approving the medication. From a purely financial perspective, there is no reason to deny coverage.

Denying coverage also can result in time-consuming calls from patients, physicians and plans. The PA process, therefore, has merely become a "speed bump" for PBMs. Further, the PA process has been used to deny drugs that the PBM does not have rebate deals with while approving drugs that do have lucrative contracts (Georgetown University, Health Policy Institute, 2020).

Some plans have contracted with PA programs operated by pharmacy colleges and carved out the PA process from the PBM due to the conflict of interest. These programs use pharmacists and pharmacy students to develop PA criteria and to apply it to patients in need of a PA. These academically based programs achieve a much lower approval rate. Basically, the plan directs patients and physicians to contact the college instead of the PBM to seek PA

takeaways

- To reduce the prices they pay for specialty drugs, health plans should consider limiting what is defined as a specialty drug and insist that pricing from their pharmacy benefit managers (PBMs) be based on acquisition costs plus a dispensing fee rather than on discounts off average wholesale price.
- Plans also can control specialty drug use by eliminating the use of coupon programs. Plans should make sure that any foundation programs used to reduce the costs of specialty drugs do not violate antikickback laws.
- The prior authorization (PA) process has not been effective in limiting specialty drug use. Plans should consider contracting with an academically based pharmacy program to conduct PAs or potentially employ their own pharmacists to review patient histories and PAs, provide input on drug formulary development and manage PBM financial contract guarantees.
- Fraud, waste and abuse programs can help uncover savings.

review. However, many PBMs will either not allow PA to be carved out of the pharmacy benefit program or will adjust rebate guarantees or discounts if such a program is in place.

As specialty drugs grow more expensive and are more frequently prescribed, it may not be unrealistic for even the smallest of employer plans to contract with a physician or pharmacist full- or part-time to review patient histories and PAs, provide input on formulary development and manage PBM financial contract guarantees. Having the level of expertise to manage patients and determine the most appropriate therapy can only be done with personnel that have alignment with the plan—that is, their salaries are provided by the plan. Ideally, PBMs should be a utility to process claims, not provide clinical "advice." Physicians and pharmacists working in this area will need additional education in analytics, pharmacy benefit management and health care ethics to be effective.

A New Concept: Ethics Policies

Another area for in-house physicians, pharmacists and legal counsel to consider is ethics policies. Each plan manager should understand the ethics policies of the vendors contracted by the plan, including the PBM. When conducting a request for proposal for PBM services, the PBM should be questioned about its legal and ethics policies. Plans should research whether the PBM has been involved in litigation or subject to any settlements with government agencies.

Plans also should consider writing their own lists of ethical principles that will govern their decision making. A copy of the policy should be provided to drug plan benefit providers, and providers should be required to adhere to the policy.

Untapped Money: Fraud, Waste and Abuse

Fraud, waste and abuse (FWA) programs are of vast importance to managing specialty drug costs.

An example of how this may come into play is with patients who receive a devastating diagnosis like cancer, rheumatoid arthritis or HIV/AIDs. They may be immediately prescribed a drug, then the medication is quickly reviewed by the PA process, approved and sent to the plan for payment. In the meantime, the patient may not want to "jump" to a specialty drug immediately. That prescription may sit in a waiting bin in a pharmacy and never be picked up by the patient or reversed by the dispensing pharmacy. It is important, therefore, that every drug over a certain dollar limit is checked to ensure that it was paid for and picked up or received by the patient.

The author has experience with an FWA review that resulted in $5.9 million in recoveries for one PBM client. Of just the top 25 recovered claims, all were for specialty drugs, amounting to $656,219 in recoveries. In all of the cases, the provider (i.e., the specialty pharmacy at the PBM or independent specialty provider) could not substantiate the claim (i.e., it was a phantom claim) or that the patient had picked up the prescription. As U.S. Surgeon General C. Everett Koop famously stated, "Drugs don't work in patients who don't take them."

Conclusion

It is not impossible to manage specialty drug costs, but plans will need to realize that as costs increase, additional resources may be needed. These resources include objective consultants as well as medical and pharmacy personnel that are not in the business of dispensing medication or controlling formularies and rebates. Innovative PBMs that use alternative pricing sources such as NADAC also can drive costs down.

Federal legislation may provide the needed relief for employers in covering specialty drugs, and the court system may also be involved to determine the role of foundation programs. In the meantime, employers can best manage the cost and use of these drugs through thoughtful plan design that does not waive any incentive to use lower cost agents and aggressive structuring of the distribution channels and pricing associated with specialty drugs.

Endnote

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bio

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