



Specialty Drugs: Four Options for Managing Costs

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With specialty drug costs growing at a double-digit pace and new drugs entering the market, plan sponsors struggle to keep up. The author describes challenges plan sponsors face with some particular high-cost drugs and offers four cost-control strategies.

Prescription drug plan sponsors have seen alarming growth in the cost of prescription drugs, driven by inflation, new medications coming to the market (including traditional and specialty drugs), and even alleged price gouging by some pharmaceutical manufacturers.

Plan members have been historically shielded from pharma price increases but, with the uptake in the use of high-deductible health plans, members now have an insider's view of what has been occurring for years. This article will focus on the price increases that have occurred for specialty medications and will offer strategies for containing some of those costs.

Since their debut, specialty medications have provided more advanced treatment and, in some cases, even cures of certain diseases. For example, they have established that cancer can be targeted with safer, more effective therapies than traditional chemotherapy. At the same time, they have provided the pharmaceutical industry with a unique way to generate significant revenue. The number of specialty medica-

tions approved by the U.S. Food and Drug Administration (FDA) has grown from just ten in 1990 to more than 400 today,¹ and the trend is expected to continue. In 2015, CVS Caremark estimated that 42% of medications in the pharmaceutical late-stage pipeline were for specialty medications. There are nearly 700 medications in development today, with 300 of those medications defined as specialty.

The definition of *specialty medication* varies throughout the United States, but generally they are expensive medications that may or may not be bioengineered for the management of chronic, sometimes rare conditions. These medications can be injectable or delivered orally and treat conditions ranging from a common diagnosis of gout to exceptionally rare diseases such as Duchenne muscular dystrophy. Specialty drugs can be administered at a physician's office or hospital or purchased at a pharmacy through a drug plan. They may require special handling or administration or have some additional dispensing or monitoring requirements.

This growth in specialty medications, though exciting to the general population, might terrify benefits managers who know these therapies do not come cheap. The average annual cost of a specialty medication in 2015 was more than \$50,000, and the cost of specialty medications increased again in 2016 by 13%.² The double-digit increase experienced in 2016 isn't unique, as specialty medications have averaged 10-20% annual price increases since the early 2000s. The annual cost increase of Humira®, a drug that treats rheumatoid arthritis, has nearly quadrupled since 2003 to reach \$53,280 in 2016.³ Specialty medications are driving 30% of pharmacy costs despite only being used by 1-2% of the population.

Unfortunately, the tools plan sponsors have historically used to manage the costs of medications do not meet the need for complete management of specialty drugs. Despite quantity limits, narrow pharmacy networks and prior authorizations, 1% of the population is

widely expected to consume 50% of the pharmacy benefit by the end of 2018. Specialty drug management requires unique solutions to offset these costs. The question becomes: What can plans do to effectively manage specialty costs while providing access to them?

Option 1: Exclude Medications, and Don't Forget Traditional Medications

In some cases, plan sponsors may have limited options in select classes of high-cost specialty drugs. For example, plan sponsors don't have the option of removing Tecfidera®, a recently approved drug for multiple sclerosis, from the formulary because of the efficacy associated with this medication. The drug's active ingredient is dimethyl fumarate, which can be purchased for \$59.30 for 100 grams, according to Sigma-Aldrich. That would equate to roughly 30 cents per day of bulk ingredient costs. Meanwhile, the current average wholesale price of Tecfidera is \$272 per day.

In other cases, there may be opportunities to remove specialty medications. A newly approved steroid, Rayos®, was studied in only rheumatoid arthritis, but FDA approved it for all of the indications another steroid, generic prednisone, is approved for. Rayos costs between \$1,000 and \$3,000 per month, while the cost of generic prednisone is \$10 per month. This is an enormous cost difference despite the two steroids having the same active ingredient and working similarly in clinical trials.^{4, 5} For the cost of one month of Rayos, a plan could treat 100+ patients with a treatment that offers similar value.

Plan sponsors should be prudent with the resources that are available. Some exceptionally expensive specialty medications have viable, lower cost treatment alternatives available (e.g., Hetlioz®, Emflaza™, Orenitram®).^{6, 7, 8, 9} These products, which treat conditions such as non-24-hour sleep-wake disorder, Duchenne muscular dystrophy and pulmonary hypertension, respectively, can range in cost from roughly \$80,000 to \$115,000 per patient annually, depending on the drug. Alternative drugs for these conditions range from over-the-counter medications that may cost \$10 for 100 tablets up to \$65,000 annually. These specialty drugs may never show up on a plan's top-25 list or be indicated within the participant population but, if a plan can avoid paying for one of these drugs for just one patient while providing an equally effective, low-cost alternative drug therapy, it could save the plan \$100,000 on that one patient.

Another great example of a disease state that has specialty medication

takeaways

- The increase in the number of specialty drugs in the United States is a major factor in the growth of prescription drug costs for plan sponsors.
- The average annual cost of a specialty medication in 2015 was more than \$50,000, and the cost of specialty medications increased again in 2016 by 13%.
- Excluding coverage of some specialty drugs, particularly those that may not be more effective than less costly traditional drugs, is one option for controlling costs.
- Plan sponsors also should review how medical benefits and drug benefits are coordinated and where medications are administered to control costs.
- Plan sponsors may be able to access savings through copayment assistance programs offered by drug manufacturers.
- Biosimilars also offer potential for cost savings, but the three biosimilars currently on the market have had limited uptake thus far.

treatment and that offers an opportunity for cost savings without sacrificing therapeutic outcomes is hepatitis C. In the span of ten years, treatments for hepatitis C improved from curing only one-third of patients with 48 weeks of therapy to curing 95% of patients with 12 weeks of therapy. Multiple treatment options are available, with varying treatment durations and costs ranging from \$54,600 to \$94,500 per 12 weeks of therapy. Zepatier®, which is the least costly of hepatitis C regimens, offers advantages over more expensive regimens. In fact, an analysis published in the *Journal of Managed Care & Specialty Pharmacy* indicates that Zepatier is the most cost-effective therapy for the management of hepatitis C.¹⁰ Some pharmacy benefit managers (PBMs) have taken steps to reduce or exclude the use of the more expensive hepatitis C specialty drug treatments and are using Zepatier to treat more patients and at a lower cost.

To obtain savings from products that provide equal therapeutic outcome results and where one medication is substantially cheaper than the other, a plan sponsor should exclude the more expensive product from coverage. Plan sponsors need to evaluate administrators and benefit plans that offer these options to ensure they are getting the best value for their plan dollars.

Specialty medications are indicated in a small percentage of the population, but the principles presented for controlling specialty costs by identifying and limiting use to lower cost products with effective therapeutic outcomes extend into the traditional drug space as well. Duexis® is a traditional medication that combines ibuprofen 800 mg with an over-the-counter acid suppressor. The manufacturer has reduced the number of tablets a patient takes per day into a convenient single tablet at a cost of \$30 (average wholesale price) per tablet, or about \$900 per month, while the separate comparable drugs cost \$1.33 per tablet, or \$20 to \$40 per month. Manufacturers are constantly combining therapies, changing dosage strengths or changing how the medication is released and increasing overall costs by slipping through the cracks of management solutions. Plan sponsors should look for administrative partners that are proactive in identifying these medications as they come to market and blocking them in order to substitute the use of lower cost alternatives.

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Option 2: Control Site of Service

Site of service is a broad term used to describe how and where health care services are adjudicated. It's a relatively simple idea: If two medications are equal (both in safety and efficacy), it would seem that a patient should pay the same amount regardless of where the medication is administered, whether it's in a hospital, at a pharmacy or at a physician's office. But costs can vary by site of service. Vaccines provide one example. Medical benefits typically cover flu shots, and the fee comes in two parts: (1) the cost of the injection and (2) the administration of the vaccine. A typical cost is \$40 to \$45 per vaccine. However, the same flu shot administered at a local pharmacy may cost \$15 to \$25 under the pharmacy benefit.

Contracts with physicians to administer a medication may be substantially lower than the cost of the same medicine administered at a hospital. Hospitals typically receive the highest reimbursement for medications administered. An analysis presented in *Specialty Pharmacy Times* showed a common medication administered under the medical benefit, immunoglobulins, varied by as much as 87% when it was administered at home compared with a hospital.¹¹ Remicade® is another commonly administered hospital product that in some cases can be administered through home health care and adjudicated at a decreased cost under the pharmacy benefit; however, the population that receives home administration must be carefully selected because of a risk of severe infusion reactions.

Decreasing specialty drug costs isn't limited to the pharmacy benefit, and it is important to understand where health care dollars are being spent. Plan sponsors can design benefits that place incentives or restrictions to promote the safest and most cost-effective site of service. Plans should work

with their health care partners to identify how they and their members can save money through site-of-care initiatives. These initiatives could be as simple as waiving copayments for patients who receive the medication through a home health vendor or requiring physicians to use the PBM to acquire the therapy instead of the physician's office acquiring it.

In addition to managing the site of service, medication management styles also may differ between the medical and pharmacy benefits. For example, Stelara®, a recently approved drug for managing Crohn's disease, is a self-administered injection with the exception of the first dose, which is given intravenously. This first dose is likely to be administered under the medical benefit, while all subsequent administrations are given by the patient at home. The drug might be available under the medical benefit but not under the pharmacy benefit. If the health plan doesn't have the same utilization management strategies and pharmacy benefits, such as prior authorization, a plan paying for the drug under its medical benefit may be on the hook for \$100,000 when the patient may have responded to an increased dose of a current medication or by switching to a cheaper alternative.

Similar to this is the varying approval criteria for Synagis®. Synagis is FDA-approved to help reduce serious infections in patients at high risk for respiratory syncytial virus. The indication provides a blanket statement for appropriate use, while American Academy of Pediatrics guidelines for the use of Synagis provide evidence it may only work in a very defined subgroup of high-risk patients.¹² Plan sponsors should ensure criteria alignment on both the medical and pharmacy benefit to improve the appropriate use of health care dollars in an evidence-based fashion. In the case of Synagis, if coverage is denied under the pharmacy benefit, the physician might submit under the medical benefit instead, which may have differing criteria and possibly be approved.

Option 3: Copayment Assistance

As patient copays for drugs increase, manufacturers want to ensure patients have access to therapy and will help offset the copayment through free-to-enroll copayment assistance programs (CAPs) or patient assistance programs (PAPs). These programs vary in amount, the minimum patient co-

payment required and duration, but they all share the idea of encouraging use of the medication by decreasing member costs.

Insulin is a great example of these programs. Lantus® is a long-acting insulin indicated in patients with diabetes. If a plan has a flat copayment of \$25 per month, the manufacturer is willing to help patients afford their medications by reducing their out-of-pocket costs to just \$10 per month for 12 months. In a similar scenario, a patient who has a flat copayment of \$50 per month may receive assistance from a manufacturer that still brings the copayment down to \$10 per month for 12 months. This means whether the member's copayment is \$25 or \$50 per month, his or her out-of-pocket costs will be reduced to just \$10.

Plan sponsors should work with their insurance and PBM partners to provide plan design recommendations to take advantage of such programs and reduce costs. Further, patients benefit from PAPs because they gain access to case management support offered through these programs.

Option 4: Biosimilars: The Potential

Biosimilars offer another potential solution for specialty drug cost management. Biosimilars are similar to generics but are substituted for specialty drugs. They are not identical to the original biologic drug and, unlike generics, it is unlikely that a biosimilar will appear on any \$4 per month list.

Once a specialty drug loses its patent, competing manufacturers can create their own versions of the innovator's product. However, it's not always easy to bring a biosimilar to market. Even when the patent on the innovator drug runs out, the patent for the development process often extends past the patent of the molecule itself. The original manufacturer may pursue patent litigation against a biosimilar manufacturer, delaying the release of the biosimilar drug.

Only three biosimilars—Zarxio®, Basaglar® and Inflectra®—are on the market at the time of this writing. All three products cost about 15% less than the innovator product. These drugs have had very little uptake, linked to physician comfort, formulary status, reimbursement rates and pharmacist ability to interchange products. Physicians may not be comfortable with switching patients to a biosimilar, since

it is considered *similar* to the innovative product but not bio-equivalent. These drugs may have limited clinical evidence supporting switching patients who may be at risk for worsening severe disease states. Data is becoming increasingly available, and physicians may increase their use.

Conclusion

Specialty medications continue to be a roller coaster of innovation—with highs of altering disease function and lows of providing little value for the provided cost. Because of the perceived and realized value of specialty medications, manufacturers will continue to search for products that provide a significant return on investment. Ultimately, this will lead to additional cures and improving the length and quality of life, but benefit coordinators still must ask these questions: At what cost? And how can plans find ways to continue to afford specialty medications? 📍

Endnotes

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