White paper

A balancing act: Managing specialty medications and mitigating spending

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Introduction

As the healthcare system continues to evolve, the rising cost of pharmaceuticals raises concerns for many employers as to how to effectively manage conditions while monitoring costs. According to a study by Express Scripts, in 2014 there was an increase of more than 13% in pharmaceutical spending, which represents the largest jump since 2003. While there are many marketplace and legislative factors that contribute to this trend, the role of specialty medication presents an area of unique concern. To illustrate this, one specialty medication — Humira, commonly used to treat autoimmune inflammatory disorders — had an average wholesale price increase of 64% over 4 years. While comprising only 1% of prescriptions in the U.S., specialty medications contributed to more than 31% of the total pharmacy costs.

Definition of specialty medication

As specialty medications continue to be a primary research and development focus for the pharmaceutical industry, employers in the U.S. are trying to create strategies to contain costs and utilization, while enhancing clinical outcomes. Unfortunately, no universally recognized definition has been established for specialty, or biologic, medications.

Typical specialty medications:

- Treat complex, chronic, and rare conditions that are challenging to manage
- May include blood derivatives or bioengineered proteins
- Are administered via injection or infusion, and, rarely, orally
- Often require special handling and storage, including refrigeration or radiation shielding
- Require monitoring for efficacy, safety, and an ideal clinical response
- May be genetically engineered
- Have a high cost, generally exceeding $600 monthly

Scope, cost, and impact

In 2016, pharmacy costs are projected to constitute 29% of total healthcare costs. According to our 2017 healthcare claim trend forecast, pharmacy costs will continue to grow at a rate between 8.9% and 16.5% in 2016, and 10.7% to 17.2% in 2017. Specialty drugs are expected to trend on average between 20.9% and 21.6% during this time. As stated above, specialty medications are typically used with limited patient populations. However, in 2015, specialty medications alirocumab and evolocumab — PCSK9 inhibitors — were approved for the treatment of hyperlipidemia to improve blood cholesterol levels. As specialty medication use expands to treat more common chronic conditions and prevent potentially serious events (cardiovascular events, in the case of PCSK9 inhibitors), the cost to employer groups compounds. Conservative estimates predict that if 5% of the 27% of U.S. adults with hyperlipidemia were prescribed these new drugs, the annual insurance premium for all members would increase by $124.

To control costs associated with specialty medications, employer pharmacy and medical plan management strategies have included altering benefit plan design, coordinating care, distributing through specialty pharmacy providers, increasing price transparency, participating in accountable care organizations (ACOs), and managing the population’s health risk. For each of these interventions, there are potential challenges and benefits.

Among the 2015 PBMI Specialty Drug Benefit Report respondents who cover at least one specialty drug under their medical benefit, 72% use prior authorization, 61% use care management, 54% use preferred products or a formulary, 51% use step therapy and days’ supply limits, and 35% limit first fills to a one to two week supply. These strategies are used much more often with larger employers. However, opportunities exist for medical
management of specialty drugs, especially with small and midsize employers.

- **Benefit design modifications**: These strategies include requiring prior authorization based on therapeutic need and clinical data (to prevent overutilization), quantity limits (to prevent waste), step therapy (to be cost effective), and cost tiers with variable copayments and coinsurance (to increase member contribution). Unfortunately, some of these interventions increase the financial burden for the patient. Innovative contracting can help minimize the risk to employers by providing reimbursement for treatments that exceed certain limits. It can also help to limit costs while instilling confidence in payers to invest in an efficacious treatment program. Substitutions using “biosimilars” (chemically similar products, which may produce the same clinical results for less cost) may also offer savings over time. However, due to variances in price differences and laws regarding substitutions, total savings can be difficult to predict. Additionally, regulatory pathways and production costs may quickly erode the savings passed on to buyers. The first biosimilar on the market, released in 2015 by Novartis, offered savings of around 15%. Another cost associated with specialty drugs is in the administration of the drugs. Outpatient hospital settings, while necessary for some drugs, are the most costly. When medically appropriate, benefit design changes and voluntary patient transition to home or medical office settings can save up to 87% of administration fees.

- **Coordination of care and medication therapy management**: In this approach, a team of clinical specialists and pharmacists collaborate to help patients understand their courses of treatment, to promote adherence, to monitor treatment plans, and to decrease costs for administration of specialty drugs. Newer models allow for virtual counseling, which lets patients interact with a pharmacist from the privacy of their homes. In a study of patients with multiple sclerosis (MS) using a specialty pharmacy management service, therapy adherence rates rose by 82%, resulting in fewer MS-related emergency room visits and lower medical costs versus the nonparticipating group. Higher consumption of therapies in compliance with coordination of care might cause an initial uptick of pharmacy costs, but savings associated with better outcomes should outweigh these costs.

- **Specialty pharmacy providers**: These organizations are able to negotiate contract pricing and reimbursement with pharmaceutical companies and provide internal controls for evaluating treatment plans and clinical needs. New reports suggest the need for more transparency on pricing because of potential conflicts of interest with specialty pharmacy services. Since these providers profit from dispensing drugs, it would be potentially advantageous to have an objective third party confirm their recommendations. Pharmacy and therapeutics (P&T) committees exist within many payers to evaluate the most cost-effective drugs and restrict availability; however, their methods are not readily disclosed and have been found in some cases to be “subjective, unsystematic, and incomplete.” Independent data mining can prove valuable in providing objective data to measure the effectiveness of therapies in relation to costs and in identifying potential upcoming specialty pharmacy utilization by analyzing conditions within a population. Data platforms can also assist in accurately tracking costs; about half of specialty drugs are funded through the pharmacy benefit, and the other half as a medical benefit, leading to challenges in integrated medical management.

- **Transparency and regulation**: In 2015, the American Medical Association (AMA), proposed a ban on direct-to-consumer pharmaceutical advertising to reduce marketing costs built into drug prices and encourage transparency. The AMA has also proposed becoming more involved with supporting federal regulations that discourage anticompetitive tactics by pharmaceutical companies, including patent reform and monitoring mergers and acquisitions. Employer groups, such as the Minnesota Health Action Group, propose to unite purchasers in a combined effort to force pharmaceutical
companies to provide transparency on their pricing, require pharmacy benefit managers (PBMs) to use a more objective approach for step therapy and prior authorizations, and eliminate incentives for providers to administer more expensive drugs.13

- **ACOs:** Accountable care organizations, created as part of healthcare reform, strive to create value-based pricing by improving the quality and efficiency of care and analyzing patient outcomes from both a clinical and financial perspective.1 The use of evidence-based medicine, where verifiable outcomes need to be present to justify higher priced interventions, has also grown in popularity as a cost-control mechanism.2

- **Population health management:** While most specialty medications are indicated for relatively rare diseases, the introduction of specialty medications for more common conditions such as hyperlipidemia, combined with the rising costs for non-specialty diabetes treatments, creates an opportunity to combat rising pharmaceutical costs with effective health and wellness interventions. According to a 2014 Drug Trend Report by Express Scripts, diabetes drugs were the most expensive in traditional therapy class (per member per year).1 With a less than 50% generic utilization rate,1 branded diabetes drugs that are expensive can quickly increase costs over a large patient base. Patients with diabetes who are not fully compliant with their medication (38.9% do not adhere), can necessitate the need for more aggressive and potentially more expensive therapies. Based on a study by the American Diabetes Association, in a typical pool of 1,000 employees, if 25% of prediabetic employees were to successfully avoid developing diabetes, the result would be $724,506 saved annually in healthcare costs and improved productivity.14

### Conclusion

Cost containment for both specialty and non-specialty drugs is a complicated problem that requires a multifaceted approach. Strategies to minimize financial risk must consider physician recommendations, evidence-based recommendations, and patient outcomes. Controlling access, minimizing waste, and coordinating care can help mitigate costs for current patients. Meanwhile, strategies to seek price transparency, analyze data, and minimize overall pharmacy cost through health initiatives can yield long-term cost savings.

**How can we help?**

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2. Rocky Mountain Health Plans Uniform Pharmacy Prior Authorization Request Form.
6. IMS Institute for Healthcare Informatics.
12. American Medical Association. AMA Calls for Ban on Direct to Consumer Advertising of Prescription Drugs and Medical Devices.
13. Pare, Carolyn. Specialty Pharmacy Pricing: Will the Buck Ever Stop?

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