



HM TREND WATCH:

THE RISING COSTS OF SPECIALTY PHARMACEUTICALS

HM INSURANCE
GROUP

EXECUTIVE SUMMARY

Specialty drugs play a significant role in the rising cost of claims. And while a small number of the population use these drugs, their costs contribute to a substantial percentage of overall health coverage expenses. **The key points covered in this paper are below:**

- In 2012, specialty drug spending was approximately \$87 billion, and it could exceed \$400 billion by 2020.¹
- There may be as many as 5,000 specialty drugs in the development pipeline, which is significantly higher than the 300 defined as specialty in 2012.²
- The long exclusivity period for specialty drugs means more than a decade before cheaper generic alternatives can be introduced.³
- Costs differ significantly for the same drug administered in different settings.
- The specialty drug trend's forecasted spending is expected to be 16 percent year-over-year for 2014-2016.⁴
- Designating specialty pharmacy vendors as preferred providers can help to contain costs due to their expertise in cost-saving processes and protocols.
- Many employers are concerned about the expense of specialty drugs and are focusing on prior authorization as the top strategy for managing the costs.²
- Several actions can be taken to reduce costs associated with specialty drugs: carving out the pharmacy benefit, requiring preauthorization, limiting specialty drug dispensing, implementing four-tier drug plans and contracting with a well-vetted specialty pharmacy vendor.
- Plan sponsors, administrators, brokers and Stop Loss carriers must maintain excellent communication so that situations are continuously monitored for savings opportunities.

The following information explains these key points in greater detail to provide brokers, TPAs and employer groups valuable information about the specialty pharmacy trend and its impact on the insurance industry, including those who self-fund with Stop Loss protection.

As with any benefits decisions, groups should refer to their benefits consultants regarding benefit plan design and modifications.

THE DEFINITION OF SPECIALTY DRUGS

Specialty pharmaceuticals are developed to help a small number of people who are suffering from chronic and/or rare disabilities and/or life-threatening diseases like cancer, multiple sclerosis, HIV/AIDS, hepatitis C, rheumatoid arthritis, Crohn's disease and growth hormone disorders. While a standard industry definition does not exist, a general description includes the cost threshold used by Medicare Part D for pharmaceuticals that considers the negotiated monthly allowed price to be \$600 or more,² with the following additional characteristics:

- Costs exceeding \$10,000 per month with some more than \$110,000 annually, depending on duration of treatment⁵
- Complex regimens for treatment, including ongoing clinical assessment and patient education/monitoring that adds to medical costs⁶
- Limited or exclusive product availability and distribution⁶
- Special handling and delivery requirements for temperature-controlled monitoring⁶
- Risk Evaluation Mitigation Strategy (REMS), which is defined by the FDA as a program to manage a known or potential serious risk associated with a drug or biologic product. REMS programs can include: a medication guide, a communication plan, elements to assure safe use, an implementation system, restricted distribution and a timetable for assessment⁸

THE GROWTH OF SPECIALTY DRUGS AND THEIR COSTS

The growth in pharmaceutical costs is driving overall medical spending upward, with specialty drugs playing the most significant role in this pharmaceutical spending growth. With some drugs costing patients more than \$110,000 annually, groups, producers, carriers and providers must keep an eye on this escalating situation and develop feasible solutions to help control costs in a very challenging health care environment.

Specialty pharmaceuticals (also known as biologics) are developed for a small segment of the population suffering from rare, life-threatening or disabling diseases.⁵ Development of these drugs has grown from 10 drugs in 1990 to more than 300 in 2012.⁶ Experts estimate that there may be as many as 5,400 specialty drugs in the development pipeline, and while estimates do vary, it is clear that the pipeline is long and growing.²

In 2012, the specialty drug spend was **approximately \$87 billion**, and that number **could exceed \$400 billion by 2020**.¹ This is a *361 percent growth* in just eight years.

But why are the costs so high? Several factors come into play. These drugs are complex and costly to manufacture. In addition, brand name specialty drugs have a 12-year exclusivity period once the drug has been approved by the FDA, compared to a five-year exclusivity period for traditional brand drugs.³ The lack of generic substitutes for this long period of time makes it a great challenge for payors to implement traditionally effective cost containment practices.

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THE GROWTH OF SPECIALTY DRUGS AND THEIR COSTS

Another factor thwarting cost containment efforts is when specialty pharmacy medications are billed to the health plan's medical benefits rather than the pharmacy benefit. Costs differ significantly for the same drug administered in different settings. For example, when administered in a hospital, there are facilities fees added to the cost, driving up the overall spend for the treatment.

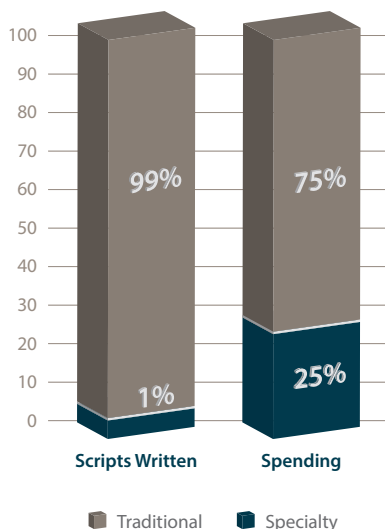
The specialty drug spend is expected to grow 16 percent year-over-year for 2014-2016. Leading the way are drugs used to treat Hepatitis C and respiratory conditions, which often mean prolonged use since many are life-long, chronic conditions.⁴

The overall cost of specialty drugs has been a top concern of employers who are working to contain their medical spending. The practice of prior authorization under both medical and pharmacy benefits has been and remains the leading strategy for 90 percent of employers and their partners working to manage specialty costs.²

THE ACCELERATED DEVELOPMENT OF SPECIALTY PHARMACEUTICALS

In 1990, there were just 10 specialty drugs on the market. In 2012, more than 300 medications met the defining criteria of a specialty drug.² And while industry experts predict varying numbers of specialty drugs in the development pipeline – exceeding 5,000 in some sources – they all agree that growth will be significant.²

Prescriptions Written & Spending by Type of Drug, 2012



In fact, Express Scripts is forecasting a 40 percent growth in the development of specialty pharmaceuticals for 2014 – growth that the company anticipates will rise to 67 percent by 2015. This growth was exhibited by recent developments, such as in 2012 when the FDA approved 39 new drugs, with 25 considered specialty drugs.

And while specialty drugs only made up about one percent of all prescriptions written, they accounted for **25 percent of prescription spending** in 2012.⁹

Nearly half of the new specialty drugs were for cancer treatment.⁷ The Pharmacy Benefit Management Institute's (PBMI) 2014 report estimated that nearly 70 percent of its estimated 5,400 specialty medications are "first in class," meaning different from any drugs already approved.²

THE INFLUENCE OF SPECIALTY DRUGS ON THE PHARMACY BENEFIT

In 2012, specialty drug spending was approximately \$87 billion (about 25 percent of total drug spending) and could exceed \$400 billion by 2020.¹ In 2013, specialty drugs for rheumatoid arthritis, multiple sclerosis and cancer accounted for more than 60 percent of the total pharmacy spend for specialty medications billed through a pharmacy benefit.⁴

Cancer-related medications are particularly costly, accounting for **\$27.9 billion in total spending in 2013**. The average costs for branded cancer drugs were \$10,000 per month that year, compared to \$5,000 just ten years prior.¹⁰

THE LOCATION FACTOR

Costs can differ for the same drug when administered in different settings. Often, specialty pharmacy medications are billed to the health plan's medical benefits, rather than the pharmacy benefit, when they are administered in a hospital instead of at an outpatient facility or in-home.

If a specialty drug is administered by a provider, it is billed under the medical benefit. Any self-administered specialty drugs are covered under the pharmacy benefit. Most administration of cancer drugs is handled by a physician or clinician in a doctor's office, at a hospital facility or in an infusion center. In fact, 80 percent of cancer drug spending is billed through the medical benefits of the patient.¹¹

When drug administration is moved from the hospital to an outpatient location or home, **savings can range from 20 to 60 percent per infusion**, a potentially significant cost savings lever.

Some providers use a "buy-and-bill" process, which means that the provider purchases the drug and then bills the payor for reimbursement at a marked-up rate. It is estimated that about 75 percent of infused drugs are administered by providers and billed under the medical benefit.¹² Many employers are moving specialty drugs from the medical benefit to the pharmacy benefit to eliminate the large "buy-and-bill" mark-ups that take place in this scenario.

To help control and reduce costs, the practices of "white bagging" and "brown bagging" have come into play. When white bagging, specialty medications are purchased for each patient at lower costs through a specialty pharmacy and then shipped to the provider for administration. With brown bagging, drugs are purchased through a specialty pharmacy and shipped directly to the patient, who personally transports the drug to the provider for administration.¹² Both are attractive alternates to the "buy and bill" model for provider drug reimbursements.

THE COST CONTAINMENT CONUNDRUM

Because specialty drugs have no substitutes, they have a long exclusivity period before generics can be introduced. This makes it quite difficult to contain costs. Specialty drugs also require intensive education, ongoing monitoring and significant assistance in managing the medication by highly skilled staff. Complicating matters, patients often are required to cost-share on these medications. If the cost is too great, many can no longer adhere to the specialty drug program, and that can lead to expensive medical complications.³

Shifting specialty drugs into a separate specialty pharmacy benefit results in the same price paid for the drug, no matter where the drug is dispensed or administered. There also would be patient cost-sharing, standard utilization review policies and procedures, coordinated clinical care management activities and real-time integration of medical and pharmacy data, all practices that help to lower costs through proper oversight.³

Unfortunately, the J Code of the Healthcare Common Procedure Coding System (HCPCS) and National Drug Code (NDC) are incompatible, making it a significant challenge to put a universal practice into place. It currently is not known if efforts are being made to address the incompatibility.

THE APPROACH TO COST CONTAINMENT WITH PREFERRED SPECIALTY PHARMACY VENDORS

One cost containment practice that is available is for payors to designate certain specialty pharmacies as preferred providers, which can help reduce drug costs. Specialty pharmacies differ from traditional pharmacies. They are certified to dispense specialty drugs and offer services that extend beyond those typically offered at traditional pharmacies. In addition to the distribution of specialty drugs, specialty pharmacies also use high-touch, patient-centered management practices to facilitate patient access and proper adherence to the expensive treatments.

High-quality specialty pharmacies should have a number of important processes and protocols in place:

- Access to the drug manufacturers of limited distribution drugs
- Patient counseling and education that help to enforce compliance with drug use
- 24/7 customer service access to clinical pharmacists
- Knowledge of financial support programs for those balancing the high out-of-pocket costs of specialty drugs
- URAC and PCAB (Pharmacy Compounding Accreditation Board) accreditation
- An internal quality assurance department/program
- Waste management initiatives that set limits on quantities for dispensing and eliminate auto-refills
- Extensive data management and reporting capabilities
- Cost containment practices that include prior authorization and formulary management
- Customer satisfaction support services including a call center, prior authorization services, capability to bill an insured's medical benefit as well as the pharmacy benefit, legal and regulatory compliance, regional account management, a marketing department and formulary management services¹³

When evaluating a specialty pharmacy, these capabilities, certifications and accreditations help to ensure cost containment and quality expectations will be met.

WHAT GROUPS CAN DO

There are several actions that can be taken to help manage the costs associated with specialty drug benefits.

- 1. Carve out the pharmacy benefit** – Because costs differ based on self-administration versus provider-administered drugs, using the medical coverage rather than the pharmacy benefit can actually add costs and not improve the quality of care received by the insured. Moving as many pharmaceutical purchases as possible to the pharmacy benefit can help to reduce costs.³
- 2. Require a pre-authorization** – In fact, in 2013, 90 percent of employers reported using prior authorization under the pharmacy benefit, which remained the top strategy for employers seeking to manage specialty drug costs.²
- 3. Limit specialty drug dispensing** – Employers can choose to limit dispensing to a 30-day supply, which can reduce costs and the potential for waste if a patient cannot tolerate the medication. Reports indicate that 65 percent of employers kept refills at a 30-day supply in 2013, which is up from 57 percent in 2011.²
- 4. Implement four-tier drug plans** – These typically involve an increase in co-pays for the high cost drugs. Approximately 28 percent of employers use these plans, which had an average co-pay of \$100 in 2013.²
- 5. Contract with the well-vetted specialty pharmacy vendor** – These providers have capabilities, certifications and accreditations that help to ensure quality cost containment expectations will be met.

THE ROLE OF THE STOP LOSS CARRIER

Costs of specialty pharmaceuticals can play a significant role in claims exceeding deductible levels for self-insured groups. Stop Loss carriers know that to best manage these costs before they create a Stop Loss claim, they must maintain excellent communication with those administering the underlying plans. Open dialogue and continuous monitoring can lead to savings opportunities.

Results can vary from administrator to administrator depending on that party's relationship with its pharmacy vendors. Factors include: willingness to potentially carve out a specialty pharmacy program, commitment to implementing preauthorization plans prior to scripts being filled or the ability create step programs that require standard drug use before a specialty drug can be attempted.

Most agree that each of these approaches can help to cut costs, but none have become a standard procedure that is implemented regularly. And while everyone recognizes that specialty pharmacy costs are growing and creating significant spending issues for everyone involved, currently not much is being done to address the overall trend in a meaningful way.

ABOUT HM INSURANCE GROUP

Headquartered in Pittsburgh, HM Insurance Group (HM) is a recognized leader in Employer Stop Loss insurance. For more than 30 years, HM has helped thousands of self-funded companies protect their financial assets from the loss associated with unexpected large or catastrophic medical claims. As a direct writer with in-house decision-making responsibilities, HM tailors innovative plans to satisfy each group's level of risk tolerance and delivers smarter solutions, better performance and unparalleled support.

Through its insurance companies, all rated A- (Excellent) by A.M. Best Company, HM Insurance Group holds insurance licenses in 50 states and the District of Columbia. The company maintains 23 regional sales offices across the country. For more information about HM Insurance Group, visit www.hmig.com.

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