Managing the Complexity of Specialty Pharmacy Benefits

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Defining specialty

Specialty drugs do not have a consensus definition across all stakeholders in the specialty space, but they can generally be thought of as high-cost medications used to treat complex conditions. Often, these medications are biologically developed from a living organism into products such as hormones, proteins and vaccines.

However, some specialty drugs are derived chemically, similar to traditional medications, but still fall under the specialty umbrella because of the condition they treat and/or because they require extensive patient education, monitoring and management. Special storage and handling requirements, in addition to site-of-care administration are also common traits of specialty medications.

Infused medications for conditions such as rheumatoid arthritis and cancer make up about one-third of specialty spend and are unique because the infusion can occur at different sites of care, leading to high variability in expenditures. These sites of care generally fall into three main buckets: (1) outpatient hospital setting, (2) physician's office, and (3) patient's home. Not only does the price of the medication significantly vary between these settings, but the cost of administration does as well.

Medical vs. pharmacy benefit

How and where the medication is administered has historically dictated what benefit would cover the cost of the specialty product. Specialty drugs billed under the pharmacy benefit are generally self-injectables or oral medications administered by the patient or caregiver and dispensed through a specialty or retail pharmacy.

Drugs billed under the medical benefit are typically administered by a health care professional through injection or infusion and given in the hospital, physician's office, clinic or the home. These medications are normally dispensed in bulk by specialty distributors, sent to physician offices and billed after administration, which makes tracking and management more difficult for plan sponsors.

Some medications can be billed under either benefit and moving them solely under the pharmacy benefit is one potential management strategy if your health plan is not actively managing utilization and reimbursement. This strategy can upset some providers because many are financially incentivized to favor medications that are administered onsite by a health care professional as opposed to self-injectables. This is especially true at hospitals and oncology offices where a significant portion of revenue is generated by infusion and support services.

Due to the high price tag surrounding these infusion services, manufacturers of newer oral medications have set the price of their tablets to match (and in some cases exceed) the price of the infused specialty medications.

A recent analysis by Milliman for CVS Health revealed that 53 percent of specialty drug costs were paid for under the medical benefit. This is consistent with other analyses conducted by large health plans. Thus, it is important to understand the billing process for specialty medications under each benefit and what determines a medication's benefit coverage.

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Pricing for specialty medications also varies between the pharmacy and medical benefit. Like most other medications, pricing under the pharmacy benefit typically involves a discount off a standard price like average wholesale price (AWP) plus a dispensing fee (in some cases this is waved) or administration fee. Most contracts also include rebates for specialty medications that help offset the high cost. Pricing under the pharmacy benefit is driven off the submitted National Drug Code (NDC). Under the medical benefit, providers are typically reimbursed on a percentage of charges methodology depending on the Health Care Procedure Coding System (HCPCS) code submitted.

Aggressive plans are moving to alternative reimbursement arrangements, such as a standard fee schedule or some type of cost-plus model. Rebates are typically not passed back to plan sponsors under the medical benefit.

Trends and implications

The growth of the specialty drug marketplace has been quite substantial over the last quarter century. Only 10 specialty medications were available in 1990, but more than 900 specialty drugs were in development in 2012. As new specialty medications reach the market, more patients will be eligible to utilize specialty medications for the first time. Another factor increasing utilization lies with the increased effectiveness and safety for some of these medications over their traditional counterparts to treat the complex conditions for which they were designed.

According to Prime Therapeutics, the average specialty drug costs 50 times more than the average traditional medication. Many factors are leading to the high price tag for specialty medications and driving the trend to where analysts predict that total specialty spend will make up half of total pharmacy spend by 2018, which currently is around 25-30 percent. Until more competition is created within drug classes, the ability of payers to exert downward pressure on prices will continue to be limited. Due to the lack of competition within therapeutic classes, the pricing power wielded by specialty manufacturers makes traditional tools of benefit design less effective (but not obsolete). It is worth noting that before an employer can effectively manage their specialty pharmacy benefit, the traditional drug side needs to have the proper strategies in place through benefit design (e.g. coinsurance, promote generics) and utilization management (e.g. step therapy, quantity limits).

Utilization and contract management strategies

By far the most commonly utilized way to manage specialty medications is to ensure appropriate utilization through prior authorization (PA). Specialty medications covered under the pharmacy benefit should typically be subjected to PA programs. Step therapy edits can be built into PA criteria for a few conditions, such as rheumatoid arthritis, that utilize specialty medications at later stages in the treatment algorithm and prefer traditional generic and brand medications first.

As mentioned earlier, PA programs on the medical side are much more difficult to perform due to the challenges of HCPCS coding, but are not impossible to implement depending on the medical carrier.

As for step therapy, this can be an effective method of preferring the best-in-class medication for the therapeutic category while allowing the plan sponsor to benefit from an increase in manufacturer rebates. Formulary exclusions are also prominent among the largest PBMs as mechanisms to drive better pricing.

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We strongly recommend 30-day supply quantity limits on most specialty medications for at least the first year of filling. If a member demonstrates consistent adherence for a chronic specialty medication over the course of the year, an authorization for a 90-day supply could be granted if the member requests this for convenience purposes and the plan's turnover rate is relatively low. Many specialty medications are associated with discontinuation of therapy due to unmanageable side effects, especially for cancer and multiple sclerosis medications, which can lead to waste and avoidable costs.

For traditional medications, plan sponsors generally expect their plan participants to share about one-fifth of the total drug cost. Considering that the average specialty medication is around $3,000 per 30-day prescription, many plan sponsors understand that the same level of member cost-sharing is unfeasible, so some have created a coinsurance specialty copay tier with a minimum and maximum dollar amount in order to increase patient cost share and highlight the significant expense of the medication to their members.

While these higher-tier plans have helped offset a small portion of the specialty cost, a reduction in utilization for specialty drugs is often observed as well. This can be seen as both good and bad. It is positive for the patients that were taking specialty medications before trying lower-cost traditional alternatives but could be negatively impacting adherence to therapies that have become the only option for some patients. These short-term savings on the pharmacy benefit can generate significant expense on the medical side due to complications of the untreated conditions, such as increased hospitalizations. A solid utilization management strategy and a separate but reasonable patient out-of-pocket tier are good first steps.

Finally, the importance of contracting and its ability to reduce price and increase rebates cannot be understated. As manufacturers continue to increase the price of their products each year, negotiated price protection after a certain percent increase can save the plan from experiencing double digit trends. Formulary exclusions are another effective means of cost mitigation and rebate enhancement now that some classes have multiple therapeutic options. Even with medication exclusions, patients still have access to at least one medication for their disease state, and if that medication is ineffective, the ability to receive excluded drugs through prior authorization is available.

Next steps

While not every strategy will work for every plan sponsor, sitting idle cannot be an option. Depending on the plan sponsor's appetite and ability to change plan design, multiple options exist to manage specialty pharmacy in the context of overall pharmacy and medical spend. *For more information, contact Employers Health clinical pharmacist Matt Harman at mharman@employershealthco.com.*

Important Questions for Employers to Consider

What medications are dispensed under the medical and pharmacy benefit plans? Where are the medications dispensed and administered?

What clinical management and formulary management programs are in place under the pharmacy and medical benefit plans? What have I implemented and what can I implement?

What are the costs associated with self-injectable medications and oral medications administered under the pharmacy plan versus the medical plan? Are there savings?

How does the health plan work with the pharmacy benefit manager to integrate data?

Are there differences between the participant's out-of-pocket costs depending on whether the drug is administered under the pharmacy plan or medical plan? Are adjustments warranted?

What does my contract say about pricing/reimbursement for specialty medications under both the medical and pharmacy plans?

Have I effectively managed my traditional drug spend? Are there opportunities (e.g. compound management, step therapy protocols) to reduce spend for traditional therapies in order to offset increasing costs for specialty medications?

Have I implemented formulary exclusion strategies offered by my PBM? Is there a reason not to do this? Does my stop-loss policy cover specialty medications administered under the pharmacy benefit?