EMPLOYEE BENEFITS

Specialty Rx

What is Specialty Rx?

While there is no true consensus on the definition of “specialty” medications, pharmacy benefit managers (PBMs) typically will identify a medication as specialty if it has one or more of the following characteristics: treats a complex, chronic and/or rare condition; is high cost (often exceeding $10,000 per year); limits distribution through an exclusive channel; requires special storage, handling and/or administration; and/or requires ongoing monitoring due to safety or effectiveness concerns. Since the 1990s, the number of specialty drugs available on the market has increased exponentially and a corresponding increase has been seen in the cost of specialty medications, leading to an annual increase in overall pharmacy expenditures in the United States.

The Problem

Employers with self-funded health plans have seen a rise in pharmacy expense due to the increasing availability and costs of specialty medications. As a result, employers are seeking innovative approaches to curb specialty spend such as specialty carve-out, specialty coverage limits or international specialty medication insourcing. All of these approaches may incur unintended compliance, regulatory or other consequences.

The lack of standardized definitions for specialty medications creates a barrier for employers trying to make an informed decision on a specialty carve-out or coverage limits. Employers may not understand which drugs will be impacted by these plan decisions. Limiting or excluding coverage of these medications could produce a significant unintended therapeutic coverage gap for members. Additionally, creating a plan design that requires members to obtain specialty medications from international sources (e.g., pharmacy tourism) can create significant legal and compliance risks for the employer.

The Consequences

Compliance and Regulatory Consequences
There are multiple compliance concerns that should be evaluated when considering specialty medication carve-outs, limiting coverage and/or international medication insourcing.

The Affordable Care Act (ACA) requires non-grandfathered, fully insured health plans in the small-group market to cover essential health benefits (EHBs). While EHBs are defined at the state level, they generally include comprehensive prescription drug coverage with specific coverage requirements (e.g., coverage of
at least one drug in every category and class or matching the state benchmark plan). This coverage requirement limits the flexibility of employers to change drug formulary offerings.

Self-funded employers or fully insured employers with large and/or all grandfathered group health plans are not required to cover all EHBs, therefore legally allowing for a specialty medication carve-out. However, should any of these plans decide to cover prescription drugs, they are restricted from enforcing an annual or lifetime limit but may enforce an out-of-pocket limit to be reached before the plan pays at 100 percent.

All large employers (generally those with 50 or more full-time employees) must offer coverage that meets the minimum value (MV) standard (plan pays at least 60 percent of plan costs) or be exposed to ACA penalties. Carving out prescription drug coverage (or specialty medication carve-out) could expose the employer to ACA penalties due to not reaching the MV threshold. For this reason, thoughtful consideration is of utmost importance in making this decision. For example, the MV calculator provided by the Center for Medicare & Medicaid Services can be used to determine the value of the plan (MV Calculator) following a carve-out.

Additional considerations should be given when considering a carve-out. For example, removing coverage of certain medications or categories of medications could be seen as either a Health Insurance Portability and Accountability Act (HIPAA) and/or an Americans with Disabilities Act (ADA) violation. HIPAA prohibits health plans from discriminating against individuals based upon a health status-related factor. Therefore, excluding a particular category of prescription drugs (e.g., psoriasis medications) could be considered discriminatory. It is important to note that at the writing of this paper, there is no court precedent. An employer could be setting a precedent.

The practice of importing medications from other countries to leverage international cost savings is considered illegal by many regulatory bodies. The U.S. Food & Drug Administration (FDA) states that any drugs purchased for consumption in the U.S. must be approved by the FDA for both use and sale. The practice of promoting insourcing medications from other countries is considered illegal by all state boards of pharmacy (BOP). Many online pharmacies have had
If after discussing all the potential consequences of a specialty carve-out or coverage limitation the employer wishes to move forward, appropriate selection of the PBM is paramount.

PBM SELECTION

Potential Unintended Consequences
When it comes to a complete specialty Rx carve-out by the employer, there are other potential unintended consequences. The first consequence of a complete carve-out is decreasing the value of the plan to current and potential employees, which may lead to issues with future employee attraction and employee retention. Secondly, carving out or limiting coverage of specialty medications may lead to decreased medication adherence and/or untreated medical conditions due to introducing medication access barriers. In general, specialty medications treat complex diseases which require medication adherence and frequent clinical monitoring. These unintended consequences could increase overall plan spend as members increase health care utilization to address uncontrolled disease states. Having an uncontrolled disease state may also lead to decreased work productivity and/or increased absences, which may in turn increase employer costs.

Possible Solutions
If after discussing all the potential consequences of a specialty carve-out or coverage limitation the employer wishes to move forward, appropriate selection of the PBM is paramount. Some PBMs currently offer unique solutions, including specialty carve-out and variable copay programs.

Specialty Carve-Out
Select a PBM that can offer member advocate services. Many manufacturers of specialty medications provide product directly to members meeting specific requirements. PBMs leveraging these programs and providing member advocate services can help lessen the financial burdens discussed earlier.

These programs typically offer the following:

1. Specialty medications are excluded from the plan.
2. A member tries to fill an excluded Rx at the pharmacy. The PBM contacts the member and assigns a member advocate.
3. The member advocate reaches out to the manufacturer and assists the member with the process until the drug is received by the member.
4. If coverage is denied by the manufacturer, the PBM works with the employer to determine if a medical necessity appeal should be processed/approved.
Variable Copay Programs
Some PBMs offer variable copay programs. These leverage the manufacturer copay assistance programs to reduce plan spend, reduce member costs (usually) and ensure accurate member out-of-pocket reporting.

Variable copay programs typically offer the following:

1. Specialty medications with a manufacturer copay program are listed in a Tier 4 (with variable copay to match manufacturer program requirements).
2. A member tries to fill a Tier 4 medication at the pharmacy (rejects with prior authorization). The PBM contacts the member and assigns a member advocate.
3. While on the phone, the member advocate enrolls the member into a copay program and resubmits the claim with copay information.
4. Typically, plan cost is reduced by 50 percent and member cost is reduced $5-$10 per prescription.
5. The PBM reports to the employer the actual member out-of-pocket expense.
6. The PBM retains a portion of the plan savings.
7. If a member is not approved for copay assistance, the specialty drug is moved to Tier 3 for applicable member cost-share.

If considering one of these programs, careful vetting must be done to ensure the PBM has experience in handling these programs. Obtaining references from current employers is helpful to determine if this is working well and how impactful the plan design is for members. Finally, a well-defined appeal process should be developed to guide the employer on handling denials to ensure fidelity of the plan design and limit discrimination exposure.

Conclusion
Specialty Rx expense will continue to rise and, while many novel approaches are being discussed in the market, it is important to understand the potential risks of specialty carve-outs or coverage limits. At this time, Hylant does not encourage the use of international pharmacy programs to lower specialty Rx costs. If a carve-out is necessary and/or desired, we can work with a reputable PBM that understands all potential compliance and regulatory risks and unintended consequences to minimize the associated risk.

This paper was written in clinical consultation with a registered pharmacist who serves as our pharmacy director.