Pharmacy Benefits Management

Balancing Compassion & Compliance in Managing High-Cost Drug Claims

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The Challenge: Offering Cost Effective Life Changing Drug Therapies

Employers with self-funded benefit plans are performing an increasingly tenuous balancing act when it comes to unpredictable and budget-breaking specialty drug costs.

They want to meet the needs of plan members and their families whose lives may depend on one of the growing number of "miracle" drugs being developed. But when high cost drugs threaten the greater good (and solvency) of the plan and organization, who can blame them for asking: "Do we have to cover these drugs?" or "Can the same drug be accessed at a much lower cost through one of the mail-order importation firms?" or "Maybe we should pursue the Medical Tourism approach?"

These are fair reactions give the trends and the impact just one patient can have on a mid-size client's forecasted medical cost budget. Just last year, the $2.125 million price tag for one infusion of Zolgensma attracted as much attention as its status as a breakthrough gene therapy cure for children with spinal muscular atrophy, a rare and often deadly condition. Various other drug breakthroughs offer relief for serious conditions, but no cures, some costing $50,000 per month or more over a patient's lifetime.

There's no easy answer to a question that is sure to grow more pressing. But plan sponsors can help themselves by thoroughly exploring the options for relief from high-cost drug claims and understanding the risks of excluding these drugs from coverage.

TOP 5 DRUG CLAIM COSTS

*Estimated Cost Per Year

Zolgensma
$2,125,000
GENE THERAPY
Spinal Muscular Atrophy

FEIBA
$2,088,450
HEMATOLOGIC
Hemophilia

EXONDYS 51
$748,800
GENE THERAPY
Duchenne Muscular Dystrophy

NovoEight
$681,408
HEMATOLOGIC
Hemophilia

Soliris
$678,392
HEMATOLOGIC
Paroxysmal Nocturnal Hemoglobinuria (PNH) Therapy

The Options: Taking Control of Your Benefit Plan's Pharmacy Costs

THE GO-TO OPTION: YOUR TRADITIONAL PHARMACY BENEFIT MANAGER

Pharmacy Benefit Managers (PBM) and health plan players can significantly change drug therapy costs with their in-house programs. They also are often the best-case scenario for plans and their members. However, it may take a team effort by your employee benefits and pharmacy advisors to uncover and review the opportunities as the programs are new and not all account executives are educated. One solution is to coordinate access through the in-house specialty pharmacy to the pharmaceutical manufacturers' copay card or patient assistance programs that are designed to discount prices or offer free products to those who meet needs-based criteria.

THE BOLT-ON/INNOVATOR OPTION: INTERESTING, BUT BEWARE OF RISKS

If a solution isn't available within your PBM, the innovator option might be the next step. Innovators serve as intermediaries to the manufacturers' patient assistance programs, facilitating enrollment when a drug claim is denied or working to coordinate importation and medical tourism options. While they can provide a great, value-added service, their programs are inherently complex and place an administrative burden on participants and the plan. Plus, implementation is multi-stepped and complicated.

The top issues to consider are:

1. **Long-Term Viability of Set-Aside Funds**
   Funds set aside by pharmaceutical companies for patients with financial need are limited, and not uniformly offered. It's also a limited set of dollars with a specific intended use that's not sufficient to fund droves of commercially-insured patients. When these patients reach a critical mass, the funds in the drug company pools will be depleted.

2. **Overstated Savings Estimates**
   Some vendors will charge up to 25% shared savings, which can be a significant cost to the plan over time. They don't usually point out the other offsets. For example, larger, market-leading PBMs usually won't work with the innovators. If a PBM does, then its guarantees (like exclusive specialty network discounts and minimum rebates) can be forfeited — which reduces your savings. Another concern is that your stop loss coverage may not apply to prescription claims paid via an innovator, leaving you potentially liable for the full claim amount.

3. **Operational Risks**
   In most cases, these innovators are start-ups, subject to the small business growing pains caused by inconsistent volume and staffing. Customer and call center support have limited hours of operation, with inexperienced staff and often high staff turnover. These vendors also need robust and redundant systems and appropriate patient privacy protections; data security is a critical concern. Since self-funded employers already have a PBM carve-out, re-integrating an additional bolt-on can be clumsy at best, and in some cases impossible.

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THE OFFSHORE OPTION: LOOK OUT FOR LIMITATIONS

State-administered programs for wholesale prescription drug importation are starting to be passed and federal legislation has been proposed. However, today this approach still violates federal law. Although employers have found work-arounds in order to offer imported drugs, potential issues include supply, delivery, product integrity and overall clinical management issues. Others are testing medical tourism to carve-out high cost claimants from the U.S. specialty pharmacy to physicians and hospital-facilitated pharmacies in countries where drug costs are a small fraction of those in the U.S. Drawbacks include clinical management issues, patient perceptions over quality and safety, and drawbacks of the 90-day supply limit for travelers. Additionally, when a prescription is filled outside of the U.S., it is not captured within the patients' medical history, and claim financial adjudication is missing from U.S. carriers, TPAs, PBMs and stop-loss partners.

Compliance Implications of Drug Exclusions

If marketplace solutions don't suit your needs, a more consequential option is amend your plan to exclude a particular specialty drug, drug class, or all specialty drugs or impose limits on the use of some specialty drugs. In this instance, three compliance-related questions should be reviewed with your legal counsel:

1. **Is the drug included in the Affordable Care Act (ACA) preventive care list?** Under the ACA, if the U.S. Preventive Services Task Force, the Advisory Committee on Immunization Practices, and/or the Health Resources & Services Administration include a medication (among other items and services) on one of their preventative service lists, it must be covered by group health plans without cost sharing. Further, any limit placed by the plan on the drugs' use must be consistent with doctors' prescriptions for regular use.

2. **Does the proposed exclusion raise issues of discrimination by the plan?** As various discrimination provisions affect a blanket exclusion under a plan, employers should consider these issues before acting:

    - If the drug primarily treats a mental health or substance abuse condition, by limiting or excluding it, you may violate applicable Mental Health Parity and Addiction Equity Act rules.
    - If excluding the drug would unfairly target individuals with a specific disability, you could be open to lawsuits for violating the Americans with Disabilities Act.
    - Exclusions that target *particular* participants based on health factors, are prohibited by nondiscrimination rules under the Health Insurance Portability and Accountability Act (HIPAA). Excluding a drug for all individuals might generally be permissible, but an example in the HIPAA regulations suggests that doing so mid-year, after a claim has been filed, could violate these rules.

3. **Does the drug fall under an essential health benefit (EHB) that the plan covers?** Essential Health Benefits (EHBs) are 10 categories of services that individual and small group health insurance plans must cover under the ACA. Self-funded plans are not required to cover essential health benefits, but if they do, they cannot impose any lifetime or annual dollar limits on those benefits. EHBs are set by each state, vary significantly among them and aren't necessarily updated to reflect new drugs and therapies. Because making the EHB determination can be complicated, making it for potential drug exclusions should be done with the assistance of your legal counsel.

Other Factors and Risks to Consider

Even as you're evaluating vendors, crunching numbers and conferring with your advisors, other considerations need to be front and center in your specialty drug debate.

For one, there's the risk that excluding a drug from your plan will only shift the cost to the medical plan, long term. If possible, try to make similar exclusions on the medical plan as on the outpatient pharmacy plan. After all, if a drug is deemed medically necessary, the medical carrier may pay it even if the PBM denies the claim – and you'll often end up paying more for the same treatment under the medical plan. The exclusion also may force plan members to manage their condition other ways, like recurrent emergency room visits, countering the cost-savings you were looking to achieve.

Your decision also stands to have a profound impact on your corporate culture and brand. If yours is one that emphasizes the organization's "family" nature and cohesiveness, then it's contradictory to exclude a medication, however costly, that's critical to a family member's well-being. There's also the risk that a plan member, denied what can be a life-or-death treatment, will take it public. A number of Zolgensma treatment denials have been overturned after extensive media coverage[1]. And finally, aggrieved employees may also sue, which, no matter how strong your case, doesn't do much for your reputation internally or with the wider community.

As a society, we are struggling to find a solution for high cost medications. We are a long way from a solution that will address the needs of the average employer. In the meantime, employers must proceed carefully— working with benefit advisors who are experts in pharmacy and compliance — to find a short-term solution that will work for them.

[1] https://www.kare11.com/article/news/toddler-fights-for-access-to-worlds-most-expensive-drug/89-ad9adfb2-8c97-44a5-88a7-0237bffcd525

Strategic support that puts you in control

Is it time to evaluate your pharmacy program to fit with your organization, employee culture and budget? Your HUB advisor can support you with this or other solutions to help you better manage your employee benefits costs. Let's build a plan that meets your strategic goals, protects your employees and positions you for tomorrow's challenges.

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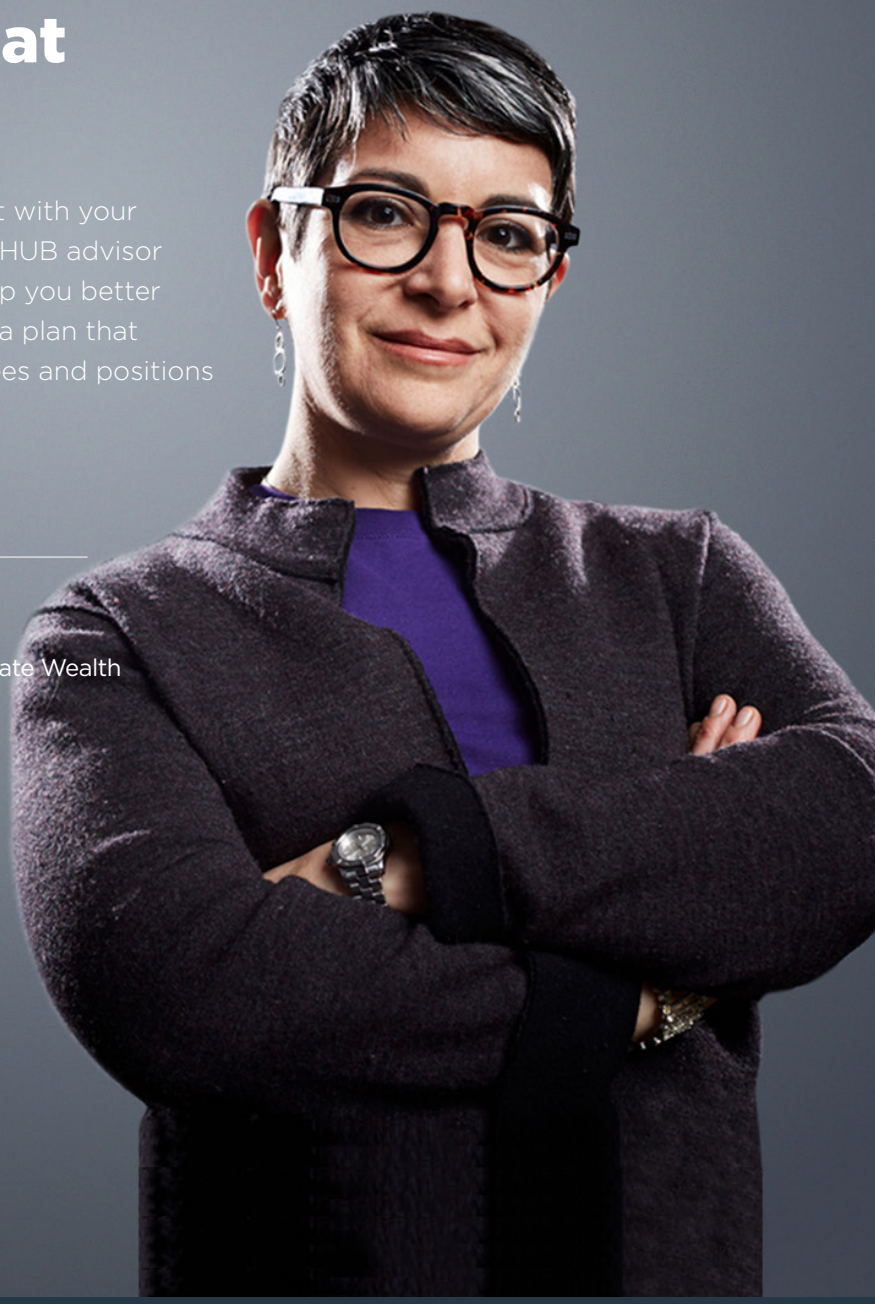

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