

## Specialty Drugs: Definitions, Pricing and Plan Management Techniques

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## **Introduction**

As the new century dawned, few people were aware of specialty drugs. Very rare or potentially fatal diseases were treated with specialty drugs, such as HIV/AIDs and Multiple Sclerosis but the term “specialty drugs” was not a commonly used term. In just more than two decades, the specialty drug marketplace has grown substantially. In 1990, there were 10 specialty drugs on the market, whereas in 2012 there were nearly 300 agents that met the definition of a specialty drug. Even more astounding is that approximately 40% of current agents in the pharmaceutical pipeline are likely to be considered specialty agents when they are released to the market (American Journal of Managed Care, 2013).

According to Drug Bank.com, there are 2,166 biotech drugs as compared to 11,414 small molecule drugs. Despite only 2% of the population using specialty medications, it is estimated that these drugs now represent nearly 50% of payer costs (Meyer, 2019). Currently, well known drugs like Humira cost over \$40,000 a year. Humira was the top-selling drug in the United States in 2016, earning manufacturer AbbVie more than \$13.6 billion in sales (Frellick, 2017). Tezacaftor/ivacaftor and ivacaftor (Symdeko), which was FDA-approved in 2018 for the treatment of cystic fibrosis, launched with an annual price tag of approximately \$290,000. A gene therapy named voretigene neparvovecrzyl (Luxturna) was approved for the treatment of an inherited retinal disease with a price tag of nearly \$850,000.

The average annual cost for a single specialty medication used on a chronic basis was almost \$79,000 in 2017. Specialty drug prices increased more than three times faster than general inflation in 2017 (7.0 percent v. 2.1 percent). In 2017, retail prices for 97 widely used specialty prescription drugs increased by 7.0 percent. This average annual increase was lower

than the specialty drug price increases observed during the prior decade (i.e., 2008 to 2017), which ranged from 7.1 percent to 9.7 percent (AARP, 2019).

Approximately half of all specialty drugs are considered self-administered and are covered under the pharmacy benefit program and managed by Pharmacy Benefit Managers (PBMs). The other half are office administered drugs, which are infused or administered in physician offices or infusion clinics (or some home infusion) or administered in a hospital as an inpatient. These drugs are paid under a medical benefit. This paper mainly focuses on drugs used on an outpatient basis and purchased by the patient through a PBM administered program, as opposed to drugs purchased by health care providers, and administered to patients.

With no end in sight, plans will struggle to cover the cost of specialty drugs in 2020 and the years to come. This paper will focus on the most significant challenges facing health care payers with respect to specialty pharmacy management, the solutions payers are implementing, and the potential implications for key stakeholders, including patients, providers, and payers. Specifically, the following questions are explored:

- What is a specialty drug?
- How are specialty drugs priced?
- What are the strategies to control specialty costs?
- What can employers do outside of plan management?

### **One: What is a Specialty Drug: I'll Know It When I See It**

Brand and generic drugs are defined by the length of the patent protection given to the development of drugs. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act (referred to as the Hatch-Waxman Act) to establish a legal framework to restore

some of the innovation incentives lost as a result of protracted Food and Drug Administration (FDA) drug testing and approval procedures, and provide an abbreviated approval pathway for generic drugs, including a framework for determining whether a generic version of an FDA-approved drug may be commercialized prior to the expiration of the patents covering that drug. As a result, brand and generic drugs are defined and then reported by the industry pricing source MediSpan.<sup>1</sup>

Unfortunately, there is no such third-party objective coding of specialty drugs. Therefore, every insurance company, managed health plan or Pharmacy Benefit Manager has one or many lists or definitions of a “specialty” drug. The following is an attempt to break down the various definitions of specialty drugs and to provide a clearer understanding of the term “specialty drug.”

Specialty drugs or specialty pharmaceuticals are a recent designation of pharmaceuticals that are classified as high-cost, high complexity and/or high touch. CMS simply defines specialty drugs as those costing more than \$670 a month (Twachtman, 2020). The Academy of Managed Care Pharmacists differentiate specialty drugs from traditional drugs in that these drugs typically require intense clinical monitoring to manage severe side effects, frequent adjustments in dosage, and/or specialized training for handling and/or administration. Specialty pharmaceuticals are often large, injectable, protein-based molecules, produced through a biotechnology process, but they may also be small molecules produced through traditional pharmaceutical manufacturing methods (Academy of Managed Care Pharmacists, 2020). Both

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<sup>1</sup> MediSpan defines Brand and Generic drugs through the Multi-Source codes, referred to as the MONY codes and the Brand Name Codes of B, T and G.

the CMS and the AMCP definitions could apply to just about any type of drug and are therefore, not of assistance to patients or plans.

Perhaps the confusion lies in that “specialty drugs” is too broad of a term. Specialty drugs can be broken into three groups: high cost drugs, biologics and orphan drugs.

#### High Cost Drugs are Not Specialty Drugs

High cost drugs can be, according to CMS, any drug over \$670 a month. As mentioned, this is a problematic definition. Many brand and even generic drugs fall into this category. Common small molecule drugs like metformin 1000mg-ER (a generic) and Trulicity (a brand) routinely cost over \$670 a month. So, this is not an appropriate definition in terms of managing “specialty drugs” as it is far too inclusive of routinely made small molecule drugs. Further, simply because a drug is “high cost” does not mean the drug requires any special handling or patient care. The currently imprisoned Martin Shkreli obtained the patent for Daraprim (pyrimethamine), a drug approved by the FDA in 1953. On September 17, 2015, the price of a dose of the drug in the U.S. market increased by a factor of 56 (from \$13.30 to \$750 per pill) overnight (Kliff, 2015). In no way would a 70-year-old drug used to treat malaria be considered a specialty drug. So merely by increasing the cost of a very old and generic drug, this drug could fall into the definition of more than \$670 a month.

#### In the Thicket of Biologics

Biologics are often what is truly referred to as a specialty drug. A biologic is manufactured in a living system such as a microorganism, or plant or animal cells. Most biologics are very large, complex molecules or mixtures of molecules. Many biologics are produced using recombinant DNA technology. A Brand or Generic drug is typically

manufactured through chemical synthesis, which means that it is made by combining specific chemical ingredients in an ordered process and have well-defined chemical structures, and a finished drug can usually be analyzed to determine all its various components. By contrast it is difficult, and sometimes impossible, to characterize a complex biologic by testing methods available in the laboratory, and some of the components of a finished biologic may be unknown. The living systems used to produce biologics can be sensitive to very minor changes in the manufacturing process. Small process differences can significantly affect the nature of the finished biologic and, most importantly, the way it functions in the body. To ensure that a manufacturing process remains the same over time, biologics manufacturers must tightly control the source and nature of starting materials, and consistently employ hundreds of process controls that assure predictable manufacturing outcomes (Biotechnology Innovation Organization, 2020).

A specialty drug must follow the same rules as brand and generic drugs to qualify as a generic product. To be approved as a generic, a drug must have the same active ingredient, strength, dosage form, and route of administration as the reference drug, and it must also be "bioequivalent." This means that generic drugs are the same chemically as their innovator counterparts and that they act the same way in the body. The bioequivalence of the generic drug is demonstrated through relatively simple analyses such as blood level testing, without the need for human clinical trials. In approving a generic drug under 505(j) of the FDCA, FDA determines that the generic is "therapeutically equivalent" to the innovator drug and is interchangeable with it.

The FDA has stated that it has not determined how interchangeability can be established for complex proteins.<sup>2</sup> Historically, the FDA has permitted interchangeability only when two products are "therapeutic equivalents." However, when the follow-on manufacturer establishes a new manufacturing process, beginning with new starting materials, it will produce a product that is different from and not therapeutically equivalent with that of the innovator. Because of the complexity of biologics, the only way to establish whether there are differences that affect the safety and effectiveness of the follow-on product is to conduct clinical trials.

Therefore, there are no biological drugs that can be categorized as "generics." A similarly made biotechnical drug is called a "bio-similar." There are currently 29 biosimilars approved by the FDA although very few are on the market.<sup>3</sup> The first biosimilar was a similarly made version of Neupogen (filgrastim) approved in March 2015. For instance, there have been five biosimilar approvals for Abbvie's Humira, but none of those are on the market in the US. According to Abbvie, direct biosimilar competition for Humira in the US is not expected until 2023. Johnson & Johnson's Remicade has two biosimilar competitors – Inflectra and Renflexis. However, those biosimilars have only managed to garner a combined 12% market share (Sullivan, 2020).

If there are biologics that are available in the U.S., approved by the FDA, why are they not available? If there is competition for these products, wouldn't prices be lower? Manufacturers of the originator biologic products have employed several tactics to delay market entry of already approved biosimilars and impede patient utilization even after a biosimilar

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<sup>2</sup><http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/default.html>

<sup>3</sup> An updated list can be found at <https://www.fda.gov/drugs/biosimilars/biosimilar-product-information>



successfully launches (Zhai, Zarpawari, Kesselheim, 2019). The primary reasons for delayed market entry include ongoing patent litigation or agreements to defer entry because of settling a patent dispute (Cottler, Whitehill, Siedor, 2019). Although AbbVie's active ingredient patent on adalimumab expired in 2016, it was granted a series of patents protecting everything from the manufacturing process to new formulations of the drug. One 2018 report found that 89% of these patent applications were filed after adalimumab was on the market, and 49% were filed after the first patent expired in 2014. This strategy of creating a wall of patents to protect assets is known as developing a "patent thicket."

The second reason that biosimilars have not come to market is the cozy PBM/manufacturer relationship. Originator manufacturers have employed a strategy to limit biosimilar uptake by negotiating formulary exclusivity, without disclosure to payers. In a 2017 lawsuit, for example, a biosimilar infliximab manufacturer alleged that the originator manufacturer entered into contracts with commercial payers to exclude biosimilars from drug formularies or include "fail first" provisions, which would require a patient to have failed on the original product before a biosimilar could be reimbursed (*Pfizer Inc v Johnson & Johnson*, 333 F Supp 3d 494 (ED Pa 2018)). Rebate schemes have featured prominently in this practice. The infliximab lawsuit charged that the originator manufacturer told insurers that if they did not grant exclusive use of its product, the manufacturer would withhold rebates on other products (Hummer, 2019). At least 70% of commercially insured patients in the United States are affected by these exclusionary contracts.

### Orphan Drugs Find a Home

The last category of specialty drugs is orphan drugs, developed by the pharmaceutical industry not for economic reasons, but which respond to public health need. The Orphan Drug Act (ODA) provides for granting special status to a drug or biological product (“drug”) to treat a rare disease or condition upon request of a sponsor. This status is referred to as orphan designation (or sometimes “orphan status”). For a drug to qualify for orphan designation both the drug and the disease or condition must meet certain criteria specified in the ODA and FDA’s implementing regulations at 21 CFR Part 316. Orphan designation qualifies the sponsor of the drug for various development incentives of the ODA, including tax credits for qualified clinical testing (FDA website, 2020). Penicillamine, a small molecule drug (not a biotechnically developed drug) was developed to treat Wilson's disease, a rare hereditary disease that can lead to a fatal accumulation of copper in the body. This drug was later found to be effective in treating arthritis. Bischofine tetrathiomolybdate is currently under investigation as a therapy against Wilson's disease (Taylor, Cumming and Corenblum, 1981). Valeant, the disgraced manufacturer involved in several suits regarding price gouging, raised the cost of the medication from about \$500 to \$24,000 per month in 2016 (Petersen, 2019). A list of Orphan Drugs can be found on the FDA’s website.

### Strategies to Limit Distribution by the FDA and Manufacturers

Some specialty drugs require Risk Evaluation and Mitigations Strategies (REMS). A Risk Evaluation and Mitigation Strategy (REMS) is a drug safety program that the U.S. Food and Drug Administration (FDA) can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks. REMS are designed to reinforce

medication use behaviors and actions that support the safe use of that medication. REMS are implemented when the advantages of the drug outweigh the potential risks associated with the drug. For example, a drug may induce sleepiness in patients up to three hours after injection. Therefore, a REMS might be that the patient must remain in a health care facility for three hours after injection to avoid an adverse event. Not all specialty drugs have REMS but some do and there are even REMS associated with brand and generic drugs. A complete list of REMS drugs can be found at <https://www.accessdata.fda.gov/scripts/cder/remis/index.cfm>.

Another way to limit the distribution of specialty drugs is to designate a drug as a Limited Distributed Drug (LDD). Manufacturers will often limit the number of specialty pharmacies that can dispense its medications. Pharmaceutical manufacturers will determine this distribution strategy based on product characteristics, patient education, market reach, and administration and dispensing characteristics (Toman, 2018). A limited distribution network (LDN) restricts the distribution channel for a pharmaceutical drug to one or a very small number of distributors. This strategy may allow for more effective allocation of drugs in shortage and is purported to help ensure the safe distribution of high-risk drugs to small patient populations. However, in recent years, some drug companies, including Turing Pharmaceuticals, have used LDNs to prevent generic and biosimilar companies from accessing samples of drug products necessary to perform testing required by the FDA for generic and biosimilar drug applications. LDNs also hamper provider access to pharmaceuticals and facilitate price gouging.

Some drug companies point to the FDA Risk Evaluation and Mitigation Strategies (REMS) as their primary rationale for creating an LDN. However, this ignores the facts that LDNs are not required as part of REMS and that many of the drugs with LDNs are not considered a great enough safety risk by the FDA to warrant REMS. However, with LDNs, not

only is the manufacturer setting the price, now there is only one pharmacy selling the drug. This monopolist method of manufacturer and distribution reduces any attempt at price negotiation.

In summary, “specialty” drugs definitions are all over the board and overly broad. The term “biologic” or bio-technically developed drug is the true “specialty” drug as these drugs are made in a different manner than small molecule drugs and have a significantly different path to “generic” (i.e. biosimilar) manufacturing. Any other drug categorized as a specialty drug is merely thrown into the mix for purely financial reasons or to confuse plans and patients.

### **Two: How Specialty Drugs are Priced: That’s Some Price Tag**

Clearly, the major issue around “specialty drugs” is the price tag. If a plan has a member with a rare disease, the plan would without doubt want the member treated and back to work. However, the cost of these drugs must be now weighed against the benefit for one member versus the viability of the plan for many members, an ethical policy setting exercise that plans are reluctant to address.

Why are these drugs so expensive? The simple answer is that the market allows them to be priced expensively. In the U.S. health care market, unlike many other countries, manufacturers set the price of their products instead of the government. Such economic and public health policy has resulted in price tags that are unsustainable.

Manufacturers argue that the costs are due to the high costs to research drugs and bring a drug to market. However, a study conducted by manufacturer insiders does not support such pricing policies. In a study funded by The Tufts Center for the Study of Drug development (CSDD), which itself is funded in part by unrestricted grants from pharmaceutical and biotechnology firms, as well as companies that provide related services (e.g., contract research,

consulting, and technology firms) to the research-based industry, it was found that the cost to bring a drug to market averaged \$2.9 billion (DeMasi, Grabowski & Hansen, 2016). However, as stated above, the revenue generated by a drug like Humira is over \$13 billion in a single year. Then why isn't the cost of Humira declining instead of increasing?

Research and development costs are only about 17% of total spending in most large drug companies. Once a drug has been approved by the FDA, there are minimal additional research and development costs so drug companies cannot justify price increases by claiming research and development costs (Blumberg, 2019). Experts suggest a price increase cap once a drug enters the market.

Another argument is that the cost of drugs is set at the cost of an avoided hospital stay. A \$100,000 price tag for Hep C treatment certainly seems like a bargain compared to the range of 2011 costs associated with just Hep C of \$53,626 (Xu, Tong and Lieder, 2014) or the cost of a Hep C patient with Hep C and a liver transplant which would incur costs of \$239,999. However, prices are not set on cost avoidance in other industries. The cost of an airline ticket does not take into account what it would cost someone to build their own plane, get a pilot license, buy airline fuel and coordinate the flight on their own. Further, there are many very inexpensive drugs that also keep patients from inpatient stays. A relatively inexpensive generic such as lisinopril keeps blood pressure low and avoids heart attacks and costs about \$4 a month.

It would stand for reason that the largest purchasers of specialty drugs would drive down the costs of these drugs. The four largest purchasers of specialty drugs are CVS/Caremark, Express Scripts, Walgreens and Optum (Fein, 2019a). These purchasers *should* drive down the cost of acquiring specialty drugs, but these PBMs (with the exception of Walgreens) also resell specialty drugs through their own facilities to corporate sponsored plans. The concentration of

specialty dispensing revenues from a limited four purchasers (who combined purchase 70% of all specialty drugs) results largely from strategies pushed to payers and manufacturers from the PBMs themselves to narrow specialty drug channels. Manufacturers continue to limit and manage the specialty pharmacies eligible to dispense these expensive medications through LDNs. PBMs typically further limit the number of specialty pharmacies selected by the manufacturer by requiring patients to use the specialty pharmacy that the plan or PBM owns and operates. Said concisely, 70% of specialty drugs are purchased and dispensed by four pharmacies that control both the “buy price” and the “sell price” further reducing any competition in the market for these drugs. This oligarchical arrangement does not encourage price competition.

In summary, the cost of specialty drugs is set by the manufacturer without regard for the cost to develop the drug, manufacturer the drug, the drug’s safety profile or the drug’s effectiveness compared to like agents and distributed exclusively by four pharmacies, three of which are PBMs that also control the price to plans.

#### Specialty Drugs: The Gift that Keeps Giving to PBMs

As the top purchasers of specialty drugs, PBMs would be in a perfect position to lower the cost, improve quality, lower risks and manage use. However, the systems around management of specialty drugs have done just the opposite: keep cost high, reduce price competition, encourage inappropriate use and reduce the quality of care. Each of these market and contracting strategies are described below.

### Out of Date Lists

PBMs price specialty drugs as a discount off Average Wholesale Price. Typically, there is no dispensing fee because the “professional fee” is absorbed by the spread between buying the drug and selling the drug to payers. For the last decade or so, PBM/Plan contracts refer to a list of drugs that are “specialty drugs” and each drug is listed with a corresponding discount off AWP. There are three issues with this practice. First, as stated, since the manufacturer sets AWP, the “discount off” has no bearing on the cost to the manufacturer, the effectiveness of the drug or the cost to purchase the drug which continues to inflate at the whim of the manufacturer. Second, the list is out of date on the day the contract is executed because new specialty drugs come on the market with “no price” and therefore the PBM can price these new drugs with *any* corresponding discount. Lastly, plan sponsors cannot readily tell if the list of “specialty” drugs are really specialty drugs (i.e. biologics) or traditional brands or generics. A pharmacist must review the list to determine if the drugs on the list are “specialty” or simply brand or generic drugs, then must argue with the PBM, some of whom will not alter the list. Taking a brand or generic drug and placing it on such a list reduces the effectiveness of the aggregate financial performance guarantees of brand and generic drugs. Oftentimes, Limited Distribution Drugs are removed altogether from any pricing guarantee and plans must pay whatever the PBM charges, with little or no correlation to what the PBM “bought” the drug for from the LDD pharmacy. Table One illustrates how shifting drugs from one category to another can impact aggregate financial performance guarantees. In the left column, there are five specialty drugs with 15% discounts and two generic drugs with 50% and 60% discounts off AWP. If priced separately, the specialty drug category achieves a 15% discount and the two generic drugs achieve a 55%

discount. But if the two generic drugs are moved into the specialty category (through overly broad definitions), the PBM achieves a 26.4% discount.

*Table 1 - Recategorizing Specialty and Generic Claims*

Seven Claims Adjudicated at.....		The Same Seven Claims Reconciled by moving two generic claims into the specialty category	
	AWP Discount		
Specialty Claim One	15%	Specialty Claim One	15%
Specialty Claim Two	15%	Specialty Claim Two	15%
Specialty Claim Three	15%	Specialty Claim Three	15%
Specialty Claim Four	15%	Specialty Claim Four	15%
Specialty Claim Five	15%	Specialty Claim Five	15%
<b>Average</b>	<b>15%</b>		
Generic Claim One	50%	Generic Claim Six	50%
Generic Claim Two	60%	Generic Claim Seven	60%
<b>Average</b>	<b>55%</b>	<b>Average</b>	<b>26.42%</b>

Next, the definition of a specialty drug in most PBM contracts encompass all of the specialty drugs discussed above: high cost, biologics, orphan drugs and LDD drugs. However, this definition is misleading. PCMA, the trade group for PBMs and manufacturers, defines specialty drugs as a drug that possesses any number of these common attributes (PCMA, 2020):

- Prescribed for a person with a complex or chronic medical condition, defined as a physical, behavioral, or developmental condition that may have no known cure, is progressive, and/or is debilitating or fatal if left untreated or under-treated.
- Treats rare or orphan disease indications.



- Requires additional patient education, adherence, and support beyond traditional dispensing activities.
- Is an oral, injectable, inhalable, or infusible drug product.
- Has a high monthly cost.
- Has unique storage or shipment requirements, such as refrigeration; and
- Is not stocked at a majority of retail pharmacies.

A better definition would be as follows and plans should attempt to adopt a definition that restricts “specialty” drugs as biologics and orphan drugs.:

Biological and biosimilar products include a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins.

Biologics can be composed of sugars, proteins, or nucleic acids or complex combinations of these substances, or may be living entities such as cells and tissues. Biologics are isolated from a variety of natural sources—human, animal, or microorganism. There are no small cell Specialty Products. There are no Generic or Multi-source Specialty drugs.

#### Limiting Distribution Channels Increases Costs

PBMs argue that by limiting distribution to its own facility, costs can be better regulated, achieve greater compliance and offer greater discounts. However, with no competition, these facilities are not price competitive. Many of the PBM contracts offer lackluster pricing for specialty drugs, with discounts around 16% off AWP (as of August 2020). Retail brand discounts average 17% to 18%. Given this, it would be more advantageous to have specialty

drugs filled in retail pharmacies rather than “exclusive” PBM specialty pharmacies. PBMs contend that retail pharmacists are not adept at filling prescriptions for these medications, although there are no state or federal laws prohibiting retail pharmacies from filling specialty drugs. Retail pharmacies can also purchase LDDs as easily as PBMs and sell LDD drugs in the same way PBM pharmacies can do so. And there is no requirement that pharmacists have to be separately licensed to dispense specialty medications, and a rather insulting implication that a retail pharmacist does not have knowledge that a PBM pharmacist would also have about specialty drugs; all pharmacists in a state have to pass the same Board of Pharmacy exam.

The PBMs’ own reports confirm that specialty costs are increasing more than traditional spend, questioning why plans would entrust specialty spend *exclusively* to “managers” that admit openly that “specialty costs are spiraling out of control.” Express Scripts’ 2018 Drug Trend Report stated that spending on specialty drugs grew by 9.4%, while spending on traditional drugs dropped by -5.8% (Fein, 2019b). The 2020 Express Scripts’ Drug Spend Report shows similar findings: Spending on specialty drugs grew by 11.6%, while spending on traditional drugs dropped by -5.0% (Fein, 2020). In a 2019 interview, Kent Rogers, OptumRx SVP, Chief Pharmacy Contracting and Procurement Officer stated, “drug manufacturers are responsible for the high cost of prescription drugs. In particular, this is why specialty drug prices are spiraling out of control (OptumRx website, 2020).” In the last available OptumRx 2016 RxTrend Insights stated that stand-alone traditional drug spend rose 0.9% while specialty drug spend rose 13.2% (OptumRx 2016 RxTrend Insight Report, 2016). CVS/Caremark’s 2019 Drug Trend Report stated that traditional spend rose 1.4% while specialty spend rose 9.3% (CVS/Caremark Drug Trend Report, 2020).

Measures could be taken to rein in the control of specialty **prices** by PBMs. Take the example of Humira. If PBMs were interested in lowering the cost of specialty drugs, PBMs would not price on a discount off AWP but would price on NADAC pricing<sup>4</sup>. As of August 2020, the NADAC price for HUMIRA 40 MG/0.8 ML SYRINGE was \$2,363.47 (Data.Medicaid.Gov page, NADAC price for Humira, accessed August 2020). The AWP of the same drug was \$3,334.18 and with a 16% discount would cost \$2,800.71. That means that the cost to dispense Humira in a PBM facility would be \$437.24 more than in a retail pharmacy (plus a modest dispensing fee of perhaps \$10) if the PBM reimbursed the pharmacy acquisition cost (i.e. NADAC price) plus a dispensing fee rather than an AWP discounted methodology.

In summary, PBMs requiring exclusivity to use just the owned specialty facility does nothing to drive down the costs of specialty drugs. In fact, costs increase without competition (Feldman, 2020). This is especially true because specialty discounts are not as great as retail discounts. PBMs that use NADAC based pricing can be particularly cost effective for specialty drugs. Retail pharmacists are just as effective as PBM pharmacists to counsel patients and provide quality dispensing. Specialty patients are often the most valuable patients for retailers and therefore, retailers have an economic incentive to treat these patients better than average. It is the mandate of the PBM, not retailers, to carve specialty products away from retail pharmacies.

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<sup>4</sup> NADAC or National Average Drug Acquisition Cost is published by CMS and reflects the pharmacies' acquisition costs for prescriptions.

### **Three: How Employers Can Manage Specialty Drugs: The Heavy Lift**

What is clear about specialty drugs is that PBMs' interests may not align with employers' interests: some employers may be relying heavily on their PBMs to set specialty drug policies, determine specialty drug lists, and pass through discounts from manufacturers, without independently verifying whether their own needs are best served in these arrangements. Plans (employers) need to recognize that PBMs' interests can diverge sharply from their own interests, as PBMs don't have the same incentives as plans to limit the volume and the prices of drugs. Because the specialty drug sector is complex and the vast majority of employers lack the in-house expertise to deal with PBMs on an equal footing, many employers likely would benefit from having independent experts assess their PBM contract terms and audit compliance with those terms.

Stop-loss carriers are becoming increasingly concerned about high cost specialty claims. In a recent report by Sun Life, a major stop loss carrier, 86% of employers have a stop loss claim in any given year. The report further states that "it is a critical consideration for self-funded employers that want to limit the risk associated with their medical and pharmacy plan to create a self-funding strategy that works for their business. Ensure your drug formulary supports selecting the most reasonable cost drug in each category. Investigate how the PBM approaches management of high-dollar medications and mitigating financial risk (Sun Life, 2020)."

Consider the following situation. Henkle of America, Inc., a leading household goods manufacturer, sued its stop loss vendor, Reliastar and the PBM, Express Scripts, for not paying stop loss insurance on a \$47 million claim (Henkel of America, Inc. v. Reliastar Life Insurance Co. et. al). Reliastar refused to pay stop loss insurance because, it alleges that Express Scripts

(ESI) abused its discretion or otherwise violated its duties to the Henkel Plan, specifically whether ESI's dual role as a plan administrator, with a financial interest in the outcome of the participants' claims, created a conflict of interest giving rise or contributing to an abuse of discretion. ESI claims that the physicians who signed the Prior Authorization documentation were not truthful about the patients' conditions. However, Reliastar's audit found a lack of medical necessity for the prescriptions ordered by the physicians, based on insufficient testing to confirm the diagnoses in question, and the audit, which relied on an interpretation of Aetna's clinical policy for the condition at issue, found that the amount of and manner in which the drugs were prescribed rendered their use experimental and investigational. Therefore, this case involves a situation where ESI may have taken a shortcut in only reviewing the "check the box" form signed by the physicians and not asking for the underlying testing and documentation which would have made coverage for the \$47 million worth of medication non-compensable.

Given the current environment rife with conflicts of interest, with manufacturers managing the price of the AWP of specialty drugs, and PBMs managing (and increasing) the access to specialty drugs, are there alternatives for plans? Plans have been exploring a series of interventions to curtail the cost and utilization of specialty drugs, some with success, some with little success. Below are interventions currently available in the market, broken down between "price" strategies and "utilization" strategies. Table 2 is a checklist of the intervention strategies discussed below.

Table 2 - Employer Checklist for Specialty Drug Management

<b><u>Specialty Drug Intervention Strategy Checklist</u></b>	
<b>Pricing Strategies</b>	Check the “specialty” drug definition...is it overly broad or just focused on biologics and orphan drugs?
	Is there a list of specialty drugs that are out of date and include brands and generics? If so, financial performance guarantees are water down.
	Are specialty drugs priced on NADAC or AWP pricing? AWP pricing will inflate costs when manufacturers increase prices.
	Is the PBM requiring exclusive use of the PBM’s specialty facility rather than open competition? Competition and inclusion in retail networks will lower the cost of specialty drugs.
	Are coupons applied? This will lower costs but increase use of specialty products as patients have no incentive to use lower cost first level drugs.
	Does your PBM encourage Foundation programs? These programs may violate Anti-Kickback laws and, like coupons, provide no incentive for lower cost agents.
	Are the “right drugs” covered in the medical and pharmacy plan? Leaving drugs in the medical plan that can be purchased by patients in a pharmacy can increase costs.
<b>Utilization Strategies</b>	Are specialty drugs Prior Authorized by an outside, unbiased third party or just a “speed bump?” Delays in therapy can hurt patient care and if not a meaningful review, are useless and can increase costs.
	Does your plan have an ethics policy? In full disclosure, have employees signed a waiver understanding the side effects of specialty drugs? If not, the ethics of decision making are left to the PBM which may or may not align with your corporate goals for covering specialty drugs and employees may not be aware of the harm that specialty drugs can cause.
	Does your PBM have a vigorous FWA program aimed at specialty drugs? If not, your plan may be paying for drugs not picked up by patients or used by your members.

### Pricing Solutions: Show me the Money

Clearly from the above discussion, there are opportunities for pricing concessions. There is a plethora of proposals at the national level to lower prescription drug costs. However, the focus of the next section of this paper outlines what plans (employers) can do now regardless of the political and national public health policy efforts to lower cost.

The first step is to understand how specialty drugs are defined and priced in the PBM contract. Abstract definitions that allow small molecule brand and generics drugs into the biologic and orphan drug area weaken financial performance guarantees in PBM contracts. Plans should address “specialty drugs” as biologics and orphan drugs (BOD) not overarching

definitions that allow PBMs to play games around the price of these drugs. Lists of specialty drug discounts that are quickly out of date should be replaced with an overall aggregate discount guarantees for biologics and orphan drugs. Table 1 illustrates the overachievement of financial performance guarantees from redefining and recategorization of brand or generic drugs as specialty drugs with lower discounts as the performance guarantee.

Next, pricing should be based on acquisition costs pricing plus a dispensing fee, like the NADAC model pricing. NADAC pricing deflates, while AWP inflates (Medicare.gov. 2020). NADAC pricing will prevent upticks in random increases by manufacturers in specialty drug pricing. NADAC pricing also eliminates the need to define brand, generic and specialty drugs into overall aggregate pricing “buckets,” as well as the need to create a confusing and out of date list. A drug is simply priced at the NADAC price without averaging over many drugs, some of which can be higher or lower than the benchmark, as with AWP pricing. Note that in compiling NADAC pricing, CMS excludes specialty pharmacies. It is not clear why specialty pharmacies are excluded from CMS’ survey which compiles NADAC pricing (mail order facilities are also excluded) although experts surmised that CMS considers these pharmacies as “closed door” (not accessible by everyone) and that acquisition pricing would be distorted by what PBM owned facilities could negotiate or report as “acquisition” pricing (Hill & Metro, 2011).

Finally, open networks that promote competition among specialty vendors can reduce prices. PBM “specialty” drug facilities should compete with the remaining 65,000 pharmacies for dispensing purposes. While it is unrealistic to “bid” or compete on a given patient’s drug by all pharmacies in a network, large chains that offer specialty pricing are often less expensive than PBM facility pricing.

Greater competition in pricing would allow lower costs. In one such example, Grennan and Swanson (2016) examined the impact of greater price information transparency in the market for medical devices. They found that prices that different hospitals paid for the same medical devices varied considerably. However, when hospitals gained access to a benchmarking database of prices paid by peer hospitals, they were able to negotiate lower prices. Through a similar mechanism, drug transparency laws will improve the bargaining ability that state health agencies, pharmacy benefit managers, and health insurance providers have when negotiating drug prices with drug makers and will consequently lead to lower prices.

### Cutting Coupons

In recent years, coupons have been used to reduce the price of specialty drugs. Coupons work by PBMs obtaining manufacturer money for a given drug, say \$12,000 for the cost of a \$30,000 a year drug. Then the copay for that drug is raised to \$12,000 so that the patient obligation is eliminated, and the employer saves what would be the difference between a typical copay (such as \$100 copay per month or \$1,200). The cost of the drug then drops from \$30,000 less the \$12,000 plus the typical copay, or a savings of \$10,800.

However, getting manufacturers to pay almost a third of the cost has consequences. Because many specialty medications have first line brand or generic alternatives, using coupons to purchase specialty drugs when a brand or generic is available may increase overall pharmacy spend and reduce any opportunity for patients to try and fail these first line alternatives, often with less side effects and adverse risks of specialty medication. According to the National Bureau of Economic Research, coupons increase the sales of brand name drugs by 60 percent or more by reducing generic sales (Dfney, Ody & Schmitt, 2017). For this reason, coupons tend to



benefit drug manufacturers but can increase cost to employers by increasing specialty use. Take careful consideration about the amount a PBM will save you when making the decision to partner for pharmacy services.

Additional academic research found that copay coupons tend to benefit drug manufacturers with large profit margins relative to other manufacturers, while generally, but not always, benefiting patients; insurer costs tend to increase with coupons from high-price drug manufacturers and decrease with coupons from low-price manufacturers (King, Chao, Deunyas, 2019). Coupons coupled with direct to consumer advertising had an even more powerful increase in engagement. Consumers exposed to prescription drug advertising with a coupon had significantly more favorable ad and brand-related attitudes, and intention to inquire about the drug to their doctors (Bhutada, Cook, Perri, 2009). Bottom line, the very reason employers impose copays is to induce participants to think twice about pharmacy alternatives (generics before brands, brands before specialty drugs). Now, manufacturers and PBMs thwart the copay strategy, resulting in patients having no reason to think about less costly alternatives. PBMs would be of better service to employers if higher rebates were negotiated and passed back to the employer roughly equal to the coupons and then keeping some incentive for patients to make better choices.

### Rocky Foundations

Another strategy that takes coupons to the next level is the use of Foundation money to source specialty drugs. These programs require plans to completely carve out all specialty coverage. Then, these programs seek alternate funding programs which are available nationwide, provided by private foundations (primarily established by pharmaceutical

companies), public charities, state, county, and municipal programs, and state specialty access programs. Upon identifying potential alternate funding, the program coordinates with those enrollees to provide necessary information to the alternate funding program. If a patient is not eligible for alternate funding identified by the program, the program will automatically submit the program enrollee's diverted claim back to the PBM for processing.

These "Foundation" programs are rocky at best. Sham Foundation programs cannot induce patients to "purchase" prescription drugs as this would be a violation of the Anti-Kickback rules, specifically, Section 1128B (b) of the Social Security Act and the False Claims Act. Of particular concern is disease-specific funds for patients affected by specific conditions, which should not be so narrowly defined that they result in "funding exclusively or primarily" products manufactured by the fund's donors, and funds that limit their coverage to especially expensive or specialty drugs, rather than supporting all FDA-approved treatments for a given disease, which can increase costs to the health system overall by steering patients away from lower-cost therapies. Numerous suits, most notably one against Pfizer over the kidney cancer drug Sutent, have resulted in severe fines.<sup>5</sup>

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<sup>5</sup> Department of Justice, "Drug Maker United Therapeutics Agrees to Pay \$210 Million to Resolve False Claims Act Liability for Paying Kickbacks," December 20, 2017, <https://www.justice.gov/opa/pr/drug-maker-unitedtherapeutics-agrees-pay-210-million-resolve-false-claims-act-liability>; Department of Justice, "Drug Maker Pfizer Agrees to Pay \$23.85 Million to Resolve False Claims Act Liability for Paying Kickbacks," May 24, 2018, <https://www.justice.gov/opa/pr/drug-maker-pfizer-agrees-pay-2385-million-resolve-false-claims-act-liability-paying-kickbacks>; Department of Justice, "Drug Maker Actelion Agrees to Pay \$360 Million to Resolve False Claims Act Liability for Paying Kickbacks," December 6, 2018, <https://www.justice.gov/opa/pr/drug-makeractelion-agrees-pay-360-million-resolve-false-claims-act-liability-paying>; Department of Justice, "Three Pharmaceutical Companies Agree to Pay a Total of Over \$122 Million to Resolve Allegations That They Paid Kickbacks Through Co-Pay Assistance Foundations," April 4, 2019, <https://www.justice.gov/opa/pr/threepharmaceutical-companies-agree-pay-total-over-122-million-resolve-allegations-they-paid>; Department of Justice, "Two Pharmaceutical Companies Agree to Pay a Total of Nearly \$125 Million to Resolve Allegations That They Paid Kickbacks Through Copay Assistance Foundations," April 25, 2019, <https://www.justice.gov/opa/pr/twopharmaceutical-companies-agree-pay-total-nearly-125-million-resolve-allegations-they-paid> 5 Department of Justice, "Drug Maker United Therapeutics Agrees to Pay \$210 Million to Resolve False Claims Act Liability for Paying Kickbacks," December 20, 2017, <https://www.justice.gov/opa/pr/drug-maker-unitedtherapeutics-agrees-pay-210-million-resolve-false-claims-act-liability>; Department of Justice, "Drug Maker Actelion Agrees to Pay \$360 Million to

Foundation programs will have to assure employers that the donors do not support just products owned by the drug company Foundation as the Office of the Inspector General for HHS has determined that doing so would violate the Anti-Kickback laws. Therefore, employers using these programs should ask Foundation programs (such as Payer Matrix and ScriptSourcing and PBM sponsored programs) to see the contracts between Foundation programs and the donor Foundations. If these programs are solely covering a “list” of specialty products and not all products that indigent patients cannot afford, the program may run afoul of the Anti-Kickback laws.

Further problematic is the term “indigent.” If patients could afford the cost of medication, say a typical copay of \$100 a month, but cannot afford the cost of a \$100,000 a year medication, *but for* the fact that the plan had determined not to cover these medication, are these patients really indigent? DHS OIG released new guidance on Patient Assistance Programs<sup>6</sup> in 2014 but this guidance *assumes* the patient cannot afford the medication and the medication is not covered under a benefit program. Creating a “des faits faux” situation of indigence is certainly bound to be tried in courts in the near future. Patients *could* afford specialty medication with a \$100 copay, but plans have been coaxed into not covering specialty medications, *forcing indigence*, then providing Foundation programs to cover these medications, which seems like a disingenuous effort at best, and a fraudulent situation at worst. Also

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Resolve False Claims Act Liability for Paying Kickbacks," December 6, 2018, <https://www.justice.gov/opalpr/drug-maker-actelion-agrees-pay-360-million-resolve-false-claims-act-liability> 6 Settlement Agreement between U.S. Department of Justice on behalf of HHS-OIG and United Therapeutics Corporation, pg. 2, December 19, 2017, <https://www.justice.gov/usao-ma/press-release/file/1019336/download> 7 Department of Health and Human Services Office of the Inspector General letter to James C. Stansel re: Drug Companies that Provide Free Drugs to Federal Health Care Program Beneficiaries Impacting by Caring Voice Coalition, Inc.'s Decision Not to Provide Patient Assistance in 2018, January 4, 2018, <https://oig.hhs.gov/compliance/alerts/guidance/stansel-letter.pdf>

<sup>6</sup> <https://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/independent-charity-bulletin.pdf>

problematic is that much of the HHS and OIG rules apply to Medicare and Medicaid benefits but not benefit programs under ERISA. Therefore, these Foundation plans have operated with little or no scrutiny for commercial (employer) plans.

Most of these programs charge upwards of 30% of discounted AWP as fees. The concept is that the plan would have paid close to 80% of the discounted costs and are now saving “so much money” by implementing these programs. The discounted cost refers to the discount off AWP that the plan’s PBM would have charged. So, a \$100,000 a year drug with a 15% discount off AWP would “cost” the plan \$85,000 and the “Foundation” program would then charge 30% or \$25,500. But the math really does not work. In addition to the discount, the plan may also have received coupons and rebates (which are no longer applicable). An average specialty rebate can be as much as \$1,500 a month or \$18,000 a year. Coupons can run as much as \$30,000 a year. So, the plan “cost” is not \$85,000 but \$37,000 (\$85,000 minus the \$18,000 in rebates and \$30,000 in coupons). So, the plan, under the Foundation program is charged \$25,000 and under the PBM combination of discount, rebates and coupons would be charged \$37,000. While this still represents a \$12,000 saving, it is not the savings amounts that are touted by these Foundation program.

A last point concerning Foundation programs. Brokers, Third Party Administrators and PBMs now accept commission to engage these programs over employer plans. Much of these commission-based programs are held in secret with employers not knowing that their own TPA, consultant/broker or PBM is receiving a commission. If these programs are considered a breach of Anti-Kickback laws, brokers, TPAs and PBMs may be caught up in recommending programs that are with “rocky” foundation and as a result get fined in addition to the manufacturers funding these programs.

### Out of Site

While this paper has focused on outpatient drugs, as mentioned in the introduction, half of the costs of specialty drugs are covered under the medical plan (Freeman, 2017). Strategies for managing specialty drugs in the medical plan are not discussed herein. However, there are drugs processed in the medical plan that would be more cost effective if covered in the pharmacy plan. While this increases prescription drug costs, it decreases the overall costs of drugs paid for by employers.

The first step is to review the drugs processed in the medical plan. Most drug claims are processed by a J-Code number. Drugs covered under the medical benefit are billed directly to the plan, usually via a CMS 1500 or UB-04 claim form. These claims typically do not undergo the same real-time processing as do pharmacy claims, they can be obscured by “bundle billing” (where multiple services are reimbursed under one code), and they are often billed to a payer after the procedure or infusion has occurred. These claims usually are not consolidated with a patient's pharmacy claims; therefore, they often limit a plan's visibility into cost and utilization trends. In addition, depending on the site of administration, and often on the specialty of the physician administering the drug, the cost for a drug covered by the medical benefit can vary widely.

The result is that specialty drugs that are covered under the medical benefit have significant variance in cost, tend to be more difficult to analyze, and do not have the same degree of structured clinical and utilization management programs as their pharmacy-adjudicated counterparts. These dynamics present challenges to the effective management of specialty pharmaceuticals in the medical benefit (Einodshofer and Duren, 2012).

Nonetheless, in a recent review of J-Codes paid by a client under its medical plan, Pharmacy Investigators and Consultants found that many of the drugs could have been obtained at a retail, mail order or specialty pharmacy under the pharmacy benefit at a considerable cost reduction than what was paid by the medical carrier. Table 2 illustrates a sample of claims paid under the medical plan that could have been paid under the pharmacy plan at a substantially reduced cost.

*Table 3 - Outpatient Medication Paid in the Medical Plan*

Label Name	Claims Amount
BOTOX INJ 100UNIT	\$8,578.00
MIRCERA INJ 100MCG	\$1,350.95
XGEVA INJ	\$84,363.46
MEDROXYPR AC INJ 150MG/ML	\$547.20
LIDOCAINE GEL 2% JELLY	\$276.00
NASAL DECONG SPR 0.05%	\$8.00
ONDANSETRON TAB 4MG ODT	\$47.51
TESTOSTERONE POW	\$154.00

### Utilization Strategies: Determining Medical Necessity

All the above strategies discussed ways to lower the **price** of specialty medication. But, a question remains, does the patient need the specialty medication currently in the patient's disease state? The most common method of determining medical necessity has been the Prior Authorization process. This is a process that stops the claim at the pharmacy and directs the pharmacist to contact the prescribing physician who must complete a form documenting medical necessity. Most of the time, patients are left out of the loop and wonder what is keeping the pharmacist from filling and dispensing the medication. It is important to have a rigorous review of a specialty drug. The obvious reason is the cost. But less obvious is the risk associated with a specialty drug. If a drug with less side effects can treat the patient, the patient should be directed

to take that medication. According to the Black Box<sup>7</sup> warning for Humira, the most utilized biologic in the U.S., side effects for the drug include:

“SERIOUS INFECTIONS: • Increased risk of serious infections leading to hospitalization or death, including tuberculosis (TB), bacterial sepsis, invasive fungal infections (such as histoplasmosis), and infections due to other opportunistic pathogens. • Discontinue HUMIRA if a patient develops a serious infection or sepsis during treatment. • Perform test for latent TB; if positive, start treatment for TB prior to starting HUMIRA. • Monitor all patients for active TB during treatment, even if initial latent TB test is negative. MALIGNANCY: • Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers including HUMIRA. • Post-marketing cases of hepatosplenic T-cell lymphoma (HSTCL), a rare type of T-cell lymphoma, have occurred in adolescent and young adults with inflammatory bowel disease treated with TNF blockers including HUMIRA (Humira webpage, 2020).”

This level of side effects may not be clear to patients PRIOR to taking the drug. Those that do not investigate side effects prior to taking a drug may believe that since the FDA approved the drug, it is “safe.” That is not necessarily true which is why REMS requirements are placed on the drug. It is only after the drug has been prescribed and dispensed that a patient may read the patient insert information (i.e. the “Black Box” warnings). Employers may want to implement a program whereby, once a drug is Prior Authorized, patients are sent a waiver,

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<sup>7</sup> A black box warning is the FDA's most stringent warning for drugs and medical devices on the market. Black box warnings, or boxed warnings, alert the public and health care providers to serious side effects, such as injury or death.

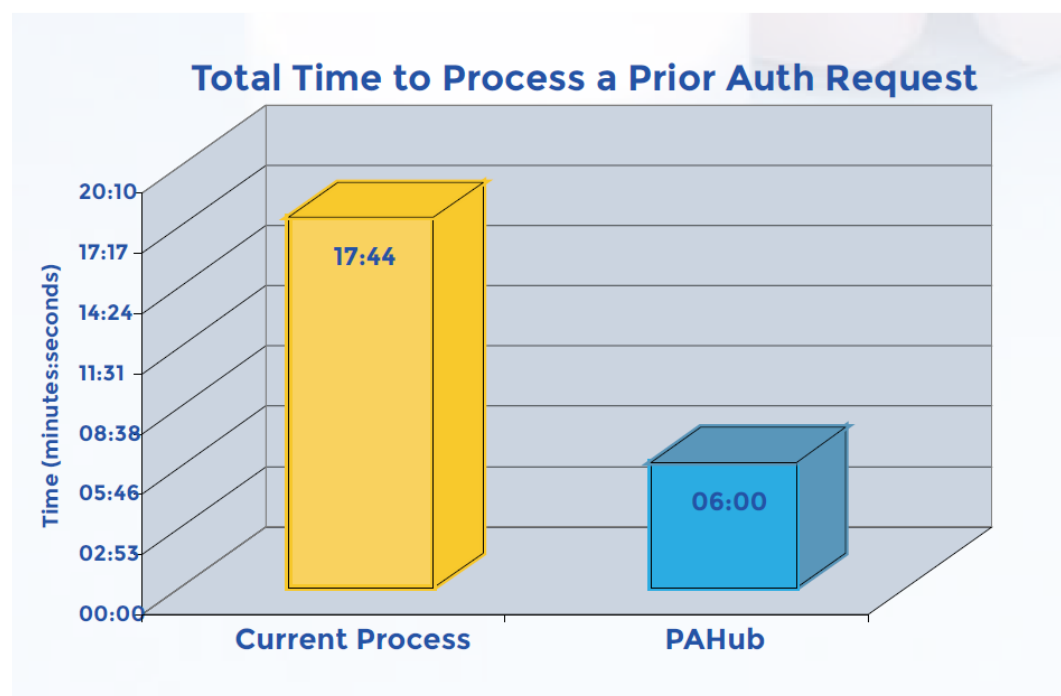
requiring their signature, which warns the patient about the side effects specific to the drug they are prescribed. This waiver may not only reduce specialty drug use, but may also reduced related side effects.

While it is clearly important to have rigorous scrutiny over the administration of specialty drugs, the actual Prior Authorization (PA) processes are unproven. As early as 2001, MacKinnon and Kumar wrote that “PA programs are common, their outcomes have not been adequately evaluated. PA is not alone, however; evaluation of administrative policies and programs in health care and in pharmacy benefit management today is rarely adequate. Still, the scarcity of quality evaluations of the outcomes of PA programs should be of concern to patients, health care professionals, administrators, and others who work in managed care pharmacy since these programs are widely used. It is hard to be objective of our own sacred cows.” Since 2001, the only major change is that now all PBMs use this program to evaluate the effectiveness of specialty drugs but there is still a lack of evidence that these programs are effective. From the provider perspective, the workflow referred to as the “medication PA process” is more accurately characterized as a hodgepodge of uncompensated tasks that provide little if any benefit to patients and may result in harm to some patients. Providers have consistently expressed the need to eliminate or at least modernize PA. The dearth of observational, qualitative literature substantiating provider PA “pain points” has contributed to the improvement lag (Bhattacharjee, Murcko, Fair, & Warholak, 2019). The AMA states that on average, a medical practice will complete 29.1 PA requests per physician per week that take 14.6 hours to process. About half of the requests are for medical services, while the other half are for prescriptions (Robeznieks, 2018).



Most PBMs use a product called PA Hub offered by Agadia. In a case study posted on Agadia's web page touting the benefits of its PA Hub program, Agadia states that the average time it takes to process a PA by PA Hub is 6 minutes versus 17 minutes and 44 seconds.

Table 4 - Time to Process a PA by PA Hub<sup>8</sup>



It is hard to imagine how a person can review a complex history of a patient needing a specialty drug in 17 minutes, let alone six minutes. One can imagine, however, that the PA

<sup>8</sup> Table retrieved from Agadia website.

process can be achieved in 6 minutes if, as Shabbir Ahmed, Chief Commercial Officer, CareMetx (2020), states, specialty drugs have a 98% approval rate.

On one hand, physicians complain about the overwhelming paperwork and time it takes for PA approvals and PBMs tout how quickly the process moves along. Until there can be an empirical study of the PA process without the “politics” surrounding the issue, the effectiveness of the PA process will continue to be questioned.

One thing is certain about the PA process. There is a conflict of interest in having a PBM perform the PA, which is what is leading to approval rates in the 90% range. First, the PBM profits in the cost of buying and selling the medication from its own pharmacy and this is the case of PBMs requiring exclusivity of the owned specialty facility to dispense the drug. Secondly, PBMs garner rebates and other financial consideration for approving high cost medication and nothing for not approving the medication. From a purely financial perspective, there is no reason to deny coverage. Denying coverage can also result in time consuming calls from patients, physicians, and plans. The PA process, therefore, has merely become a “speed bump” for PBMs to go through the charade of pretending to manage the benefit to its plan clients, given 90% plus approval rates, while winking and nodding that it can be done in six minutes to the PBMs’ drug manufacturer clients. Further, the PA process is used to deny drugs that the PBM does not have rebates deals with, while approving drugs that do have lucrative contracts (Georgetown, 2020).

#### Taking on Prior Authorizations: Is there a Doctor in the House?

Some plans have contracted with College of Pharmacy based Prior Authorization programs and carved out the PA process from the PBM due to the conflict of interest exposed

above. These programs use pharmacists and pharmacy students to develop Prior Authorization criteria and to apply the criteria to patients in need of a Prior Authorization. These academically based programs achieve a much lower PA approval rate. Basically, the plan directs patients and physicians to contact the Medical College, versus the PBM, to seek PA review. Not surprisingly, many PBMs will either not allow the Prior Authorization to be carved out of the pharmacy benefit program or will adjust rebate guarantees or discounts if such a program is in place. RxResults, a company that is owned by the University of Arkansas Medical School, touts that it saved \$82.5 million in the last five years through its evidence based Prior Authorization program. RxResults also offers a formulary based on evidence-based research on high performing and less costly medication within a therapeutic category.

As specialty drugs grow more expensive and more frequent, it may not be unrealistic for even the smallest of employer plan to contract with a physician or pharmacist full or part time to review patient histories, perform PA reviews, provide input on formulary development and manage PBM financial contract guarantees. Having the level of expertise to manage patients and determine most appropriate therapy can only be done with personnel that have alignment with the plan, that is, his or her salaries are provided by the plan. PBMs should really be seen as a utility to process claims, contract with pharmacies and provide rebate money. PBMs should not be relied upon for expertise in managing the prescription drug program. Physicians and pharmacists working in this area will need additional education in analytics, pharmacy benefit management and health care ethics to be effective.

A New Concept: Ethics Policies for Employer Plans and Providers

Another area for in-house physicians, pharmacists, and legal counsel to consider is ethic policies. Each plan manager should understand the ethic policies of the vendors contracted by the plan, including the PBM. Does the PBM have extensive litigation brought against it for law violations, such as the Anti-Kickback law, Health Care Fraud, Misbranding or more typical white-collar crimes such as “Pump and Dump” Stock deals or “Channel Stuffing?”<sup>9</sup> Has research been done to see if the PBM or its parent companies on any type of Corporate Compliance Agreements issued by a state or Federal agency. For example, CVS Corporation, the parent company of CVS/Caremark agreed to pay \$3.5 million to resolve allegations that 50 of its stores violated the Controlled Substances Act by filling forged prescriptions for controlled substances – mostly addictive painkillers – more than 500 times between 2011 and 2014. In addition, CVS entered into a three-year compliance agreement with the Drug Enforcement Administration (DEA) that requires CVS to maintain and enhance programs it has developed in recent years for detecting and preventing diversion of controlled substances (DOJ webpage, 2020). Corporate Compliance Agreements, somewhat like probation arrangements for Corporations, allow the Department of Justice to approve programs, policies, and procedures within an accused company to mitigate damages brought on by the wrongdoings. Many Corporate Compliance Officers have dual reporting to both an outside independent reviewer and the company to ensure ethics policies are abided by for a period of “probation.” When conducting a Request for Proposal for PBM services, the PBM should be questioned about its legal and ethic policies to ensure, as

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<sup>9</sup> Pump and dump schemes are the fraudulent practice of encouraging investors to buy shares in a company to inflate the price artificially, and then selling one's own shares while the price is high. Channel stuffing is a deceptive business practice used by a company to inflate its sales and earnings figures by deliberately sending retailers along its distribution channel more products than they are able to sell to the public. Channel stuffing typically would take place just before quarter-end or year-end so that management, fearful of bad consequences to their compensation, can "make their numbers."

fiduciaries, the plan is satisfied that the company is working for the plan, not other stakeholders such as drug manufacturers and has not been involved in many legal disputes with other clients or involved in illegal activity.

Further, plans should consider writing out a list of ethic principles that should govern the plan's decision making. While such action has been politicized in recent years, the practice of each employer setting ethics policies should not be considered a political, but a very necessary step of operating the plan. The ethic policy should clearly state the overarching values of the plan (i.e. to keep members well and healthy and able to function at work). In applied ethics, there are three main ways of thinking about ethic policy: virtue ethics ("I am good therefore I make good decisions"), deontological ethics ("Rules are followed regardless of the consequences") and consequentialists ethics ("What matters is the outcome, not the rules imposed.") (Ashcroft, Dawson, Draper and McMillan, 2007, p. 12-17). These basic ways of looking at decision making should be explored by senior management as to how they apply to the culture of the company and its shareholders and employees. The four basic tenants of health care ethics: autonomy, nonmaleficence, beneficence and justice, should be incorporated into the day to day decision making of the plan and answer these questions:

- How should the formulary be developed for specialty drugs?
- How should prior authorizations be made and by whom?
- What drug therapy provides the best outcome and the lowest cost?
- How should plan assets be distributed (in the form of cost share between the plan and members) and who should make these decisions?

A copy of the ethics policy should be provided to all providers of the PBM benefit plan and providers should be required to adhere to the plan's ethics policies.

#### Untapped Money: Fraud, Waste and Abuse programs

One area yet to be mentioned is fraud, waste and abuse (FWA). PBMs have not been vigilant in monitoring fraud, waste or abuse in plans. These programs are expensive and are typically reserved for the largest PBMs clients, clients that demand FWA programs or Medicaid and Medicare programs. FWA programs have not been widely adopted for commercial employer plans because plans have not required these programs. Many employers believe that “their employees” could not possibly be committing fraud and for the most part, employers are correct in this assumption. True fraud typically happens between pharmacists and physicians who stand the most to gain financially by submitting claims that are not legitimately written to cure a patient's illness, but to have PBMs send these fraudsters money for prescriptions that were never written.

However, there is a reason PBMs do not operate rigorous FWA programs. Most traditional PBMs make money on the “spread” – that is, PBMs reimburse pharmacists less than what is charged the plan for the same transaction and keep the difference. In FWA programs, recoveries are made on fraudulently submitted claims, **but** reducing or eliminating these claims **also** reduces the spread that is pocketed by PBMs. Rigorous FWA programs would reduce a PBMs' reported revenue by 10%, a disaster for shareholders.

Nonetheless, FWA monitoring is of vast importance to managing specialty drugs. First, patients who are given a devastating diagnosis like cancer, rheumatoid arthritis or HIV/AIDs may be immediately prescribed a drug, the medication is quickly reviewed by the Prior

Authorization process and the medication has been adjudicated (and send to the plan for payment). In the meantime, the patient may not want to “jump” to a specialty drug immediately. That specialty claim may sit in a waiting bin in a pharmacy and never be picked up the patient or reversed by the dispensing pharmacy. It is important, therefore, that every drug over a certain dollar limit is checked to ensure that it actually was paid for and picked up or received by the patient.

Last year, Pharmacy Investigators and Consultants audited 51,500 claims for a PBM client which resulted in \$5.9 million in recoveries. Of just the top 25 recovered claims, all were for specialty drugs, amounting to \$656,219 in recoveries. All of these 25 prescriptions involved the provider (i.e. specialty pharmacy at the PBM or independent specialty provider) not being able to substantiate the claim (i.e. it was a phantom claim) or that the patient had picked up the prescription. For that reason, FWA programs are critical in ensuring proper management of prescription drugs. As US Surgeon General C. Everett Coop famously stated, “Drugs don't work in patients who don't take them.” Specialty drugs are an expensive example of when patients do not get the drug because they have chosen not to receive them yet plans pay for these medications unwittingly.

## **Conclusions**

It is not impossible to manage specialty drugs. But plans will need to realize as costs increase that additional resources may be needed. These resources include objective consultants and medical and pharmacy personnel that are not in the business of dispensing medication or controlling formularies and rebates. Innovative PBMs that use alternative pricing sources such as NADAC will drive costs down as much as possible.

National legislation, which was not a topic of this paper, may provide the needed relief of employers in covering biologics and orphan drugs, which are the true specialty drugs. The courts system may also be involved to determine the role of Foundation programs. In the meantime, employers can best manage the cost and use of these drugs, through thoughtful plan design that does not waive any incentive to use lower costs agents and aggressive structuring of the distribution channels and pricing associated with specialty drugs.



## **References**

- AARP Public Policy Institute (2019). Trends in Retail Prices of Specialty Prescription Drugs Widely Used by Older Americans: 2017 Year-End Update. Retrieved from <https://www.aarp.org/content/dam/aarp/ppi/2019/06/trends-in-retail-prices-of-specialty-prescription-drugs-year-end-update.doi.10.26419-2Fppi.00073.001.pdf>
- Academy of Managed Care Pharmacy (2020). Specialty Pharmaceuticals. Retrieved from <https://www.amcp.org/about/managed-care-pharmacy-101/concepts-managed-care-pharmacy/specialty-pharmaceuticals>
- Ahmed, S. (2020). Rethinking the Prior Authorization Process. *Pharmacy Times*. February 2018. Retrieved from <https://www.pharmacytimes.com/publications/specialty-pharmacy-times/2020/February2020/rethinking-the-prior-authorization-process>
- American Journal of Managed Care (2013). The Growing Cost of Specialty Pharmacy-Is it Sustainable? February 18, 2013. Retrieved from <https://www.ajmc.com/view/the-growing-cost-of-specialty-pharmacyis-it-sustainable>
- Ashcroft, R., Dawson, A., Draper, H., & McMillan, J. (2007). Principles of Health Care Ethics. Second Edition, John Wiley & Sons., Chichester, U.K.
- Bhattacharjee, S., Murcko, A. C., Fair, M. K., & Warholak, T. L. (2019). Medication prior authorization from the providers perspective: a prospective observational study. *Research in Social and Administrative Pharmacy*, 15(9), 1138-1144.
- Bhutada, N., Cook, C. & Perri, M. (2009). Consumers Responses to Coupons in Direct-to-Consumer Advertising of Prescription Drugs, *Health Marketing Quarterly*, 26:4, 333-346
- Biotechnology Innovation Organization (2020). How do Drugs and Biologics Differ? Retrieved from <https://archive.bio.org/articles/how-do-drugs-and-biologics-differ>

- Blumberg, Y. (2019). Here's why many prescription drugs in the US cost so much—and it's not innovation or improvement. CNBC: Money. Retrieved from <https://www.cnbc.com/2019/01/10/why-prescription-drugs-in-the-us-cost-so-much.html>
- Bunis, D. (2019). AARP Report: Specialty Drug Prices Soar to Nearly \$79,000 a Year. AARP. Retrieved from <https://www.aarp.org/politics-society/advocacy/info-2019/specialty-drug-prices-rise.html>
- Henkel of America, Inc. v. Reliastar Life Insurance Co. et. al. *Henkel of Am., Inc. v. Reliastar Life Ins. Co.*, 3: 18 CV 965 (JAM), (D. Conn. Dec. 6, 2019). Retrieved from <https://casetext.com/case/henkel-of-am-inc-v-reliastar-life-ins-co>
- Cottler M, Whitehill J, Siedor A. (2019). The 2018 biosimilar litigation landscape: a primer. *BioPharma Dive*. December 14, 2017. <https://www.biopharmadive.com/news/the-2018-biosimilar-litigationlandscape-a-primer/512982/>.
- Dafny, L., Ody, C. & Schmitt, M. (2017). When Discounts Raise Costs: The Effect of Copay Coupons on Generic Utilization. *American Economic Journal: Economic Policy*, 9(2): 91–123
- Department of Justice Webpage (2016). CVS to Pay \$3.5 Million to Resolve Allegations that Pharmacists Filled Fake Prescriptions. Retrieved from <https://www.justice.gov/usao-ma/pr/cvs-pay-35-million-resolve-allegations-pharmacists-filled-fake-prescriptions>
- DiMasi, J., Grabowski, H., Hansen, R. (2016). Innovation in the pharmaceutical industry: New estimates of R&D costs. *Journal of Health Economics* 47 (2016) 20–33
- Drug Bank (2020). Drug Statistics. Retrieved from <https://www.drugbank.ca/stats>.

- Einodshofer, M., Duren, L., (2012). Cost Management through Care Management, Part 2: The Importance of Managing Specialty Drug Utilization in the Medical Benefit. Retrieved from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4031694/#R2>
- Fein, A. (2019a). The Top 15 Specialty Pharmacies of 2018: PBMs Keep Winning. Drug Channels. Retrieved from <https://www.drugchannels.net/2019/04/the-top-15-specialty-pharmacies-of-2018.html>
- Fein, A. (2019b). Express Scripts Confirms It (Again): Minimal Growth in Drug Spending and Prescription Costs. Drug Channels. Retrieved from <https://www.drugchannels.net/2019/02/express-scripts-confirms-it-again.html>
- Feldman, R. (2020). Perverse incentives: Why everyone prefers high drug prices except for those who pay the bills? *Harvard Journal on Legislation*, 57(2), 303-376.
- Freeman, G. (2017). Specialty Drugs Paid Under Medical Benefits Thwart Cost Control Measures. *American Health Drug Benefits*. 2012 Sep-Oct; 5(6): 359–364. Retrieved from <https://www.healthleadersmedia.com/finance/specialty-drugs-paid-under-medical-benefit-thwart-cost-control-measures>
- Frellick, M. (2017). Humira Again Top-Selling Drug In U.S. WebMd. Retrieved from <https://www.webmd.com/drug-medication/news/20171003/humira-again-top-selling-drug-in-us>
- Grennan, Matthew, and Ashley Swanson. 2016. “Transparency and Negotiated Prices: The Value of Information in Hospital-Supplier Bargaining.” National Bureau of Economic Research (NBER) Working Paper 22039.
- Hill, R., Metro, J., Gormanly, V. & Smith, R. (2011). CMS discusses details of new "National Average Drug Acquisition Cost" survey. Retrieved from

<https://www.lexology.com/library/detail.aspx?g=6f5e6d91-366e-4f5e-a5d0-5ba698e70f68>

Humer C., (2019). Pfizer files suit against J & J over Remicade contracts. Reuters. September 20, 2017. <https://www.reuters.com/article/us-pfizer-trial-johnsonjohnson/pfizer-files-suit-against-jj-over-remicade-contracts-idUSKCN1BV1S8>.

Humira webpage. (2020). Full Prescribing Information. Retrieved from <https://www.rxabbvie.com/pdf/humira.pdf>

King, G., Chao, X., Duenyas, I. (2019). Who Benefits When Prescription Drug Manufacturers Offer Copay Coupons? *Home Management Science*, Vol. 65, No. 8

Kliff, S. (2015). Martin Shkreli Raised His Drug Price 5,500 Percent Because, in America, He Can. Vox Explainers. Retrieved from <https://www.vox.com/2015/9/22/9366721/daraprim-price-shkreli-turing>

Lotvin, A. (2020). CVS Health 2019 Drug Trend Report. Retrieved from <https://payorsolutions.cvshealth.com/insights/2019-drug-trend-report>

MacKinnon, N., Kumar, R. (2001). Prior Authorization Programs: A Critical Review of the Literature. *Journal of Managed Care Pharmacy*, Vol. 7, No. 4

Medicaid. Gov Website. (2020). Methodology for Calculating the National Average Drug Acquisition Cost (NADAC) for Medicaid Covered Outpatient Drugs, NADAC Methodology. Retrieved from <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/ful-nadac-downloads/nadacmethodology.pdf>

Meyer, Lauren (2019). Something Has to Give: Balancing Specialty Drug Cost With Value. *Pharmacy Times*. Retrieved from <https://www.pharmacytimes.com/news/something-has-to-give-balancing-specialty-drug-cost-with-value>

- Park, E. (2018). Trump Administration Encourages States to Seek Waivers to Opt Out of Medicaid Drug Rebate Program. Georgetown University, Health Policy Institute. Retrieved from <https://ccf.georgetown.edu/2018/07/16/trump-administration-encourages-states-to-seek-waivers-to-opt-out-of-medicaid-drug-rebate-program/>
- Petersen, Melody. "How 4 drug companies rapidly raised prices on life-saving drugs". Los Angeles Times. Retrieved from <https://www.latimes.com/business/la-fi-senate-drug-price-study-20161221-story.html>
- PCMA Website. (2020). What is a Specialty Drug? Retrieved from <https://www.pcmanet.org/pcma-cardstack/what-is-a-specialty-drug/>
- Robeznieks, A. (2018). Prior authorization is a major practice burden. How do you compare? American Medical Association. Retrieved from <https://www.ama-assn.org/practice-management/sustainability/prior-authorization-major-practice-burden-how-do-you-compare>
- Rogers, K. (2020). Who is Lowering Drug Costs? Optum Webpage. Retrieved from <https://www.optum.com/business/resources/library/lowering-drug-costs.html>
- Stern, D & Reissman, D. (2006). Specialty Pharmacy Cost Management Strategies of Private Health Care Payers. Journal of Managed Care Pharmacy JMCP November/December 2006 Vol. 12, No. 9.
- Sullivan, T. (2020). High Expectations For New Biosimilars About to Hit Market. *Policy & Medicine*. Retrieved from <https://www.policymed.com/2020/02/high-expectations-for-new-biosimilars-about-to-hit-market.html>
- Sun Life (2020). 2020 Sun Life Stop Loss Research Report: High-cost claims and injectable drug trends analysis. Retrieved from

<https://www.sunlife.com/us/News+and+insights/Insights/2020+Sun+Life+Stop-Loss+research+report>

Taylor, P., Cumming, T., Corenblum, B. (1981). Successful treatment of D-penicillamine-induced breast gigantism with danazol. *British Medical Journal*. 282 (6261): 362–3.

Toman, A., (2018). The Ins and Outs of Limited Distribution Specialty Drugs. *Pharmacy Times*. Retrieved from <https://www.pharmacytimes.com/news/the-ins-and-outs-of-limited-distribution-specialty-drugs>

Twachtman, G. (2020). CMS proposes second specialty tier for Medicare drugs. *Internal Medicine News*. Retrieved from <https://www.mdedge.com/internalmedicine/article/216931/business-medicine/cms-proposes-second-specialty-tier-medicare-drugs>

Xu, F., Tong, X., Leidner, A. (2014). Hospitalizations and Costs Associated With Hepatitis C And Advanced Liver Disease Continue To Increase. *Health Affairs*. 33:10. Specialty Pharmaceutical Spending & Policy. Retrieved from [https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2014.0096#:~:text=Hospitalization%20rates%20for%20hepatitis%20C,portal%20hypertension%20\(62%20percent\)](https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2014.0096#:~:text=Hospitalization%20rates%20for%20hepatitis%20C,portal%20hypertension%20(62%20percent)).

Zhai, M., Sarpatwari, A., Kesselheim, A. (2019). Why Are Biosimilars Not Living up to Their Promise in the US? *AMA Journal of Ethics*® August 2019, Volume 21, Number 8: E668-678 Policy Forum