

# Specialty Drugs: Ensuring payment accuracy beyond prior authorizations

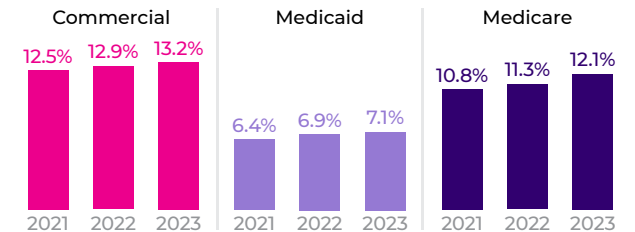
By Jonathan Starr, PharmD, Senior Consultant and Matthew Herbein, Director, Audit Operations

Specialty drugs comprise a complex, high-stakes area of claim processing for health plans. These medications are often injectable drugs administered by a provider and are used to treat chronic, complex diseases such as cancer, cystic fibrosis, HIV, atopic dermatitis, and autoimmune disorders. Specialty drugs are notoriously expensive, with U.S. prescription dispensing revenues from specialty pharmaceuticals estimated at \$243 billion in 2023, according to Drug Channels Institute.

While health plans have to keep up with rising costs of specialty drugs, they also must keep an eye on new drugs being approved every month. In 2023, the FDA approved a total of 55 new drugs—and the overwhelming majority of those medications qualify as specialty drugs.

Since specialty drugs are inherently complex, it follows that billing and payment for their corresponding claims are complex as well. These drugs are managed by two separate member benefits—medical benefits and pharmacy benefits—and both medical drug spend and utilization is rising. Medical drug spend as a share of total ambulatory medical spend has been gradually increasing and is now up to 13%, according to data across Cotiviti’s Payment Policy Management clients. There is also a higher percentage of spend in the outpatient setting (52%) than other ambulatory services (36%). But the strongest utilization increases are within commercial and Medicaid plans (Figure 1).

Medical Drugs Contribution to Ambulatory Medical Spend



Medical Drugs Utilization Growth | 2021-2023

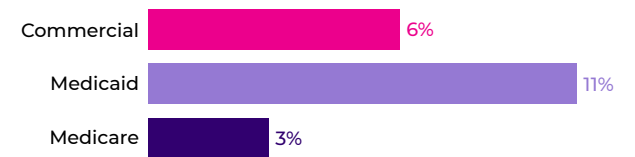


Figure 1. 2021-2023 medical drug spend and utilization growth.

Because of the cost and complexity surrounding specialty drugs, providers and plans must pay close attention to every detail to ensure the patient is receiving proper treatment and that the claim is billed correctly.

Prior authorization is one common method used by plans and pharmacy benefit managers (PBMs) to prospectively limit excessive costs and inefficient utilization of expensive specialty drugs. Medications that pass through the prior authorization process must meet certain pre-determined criteria in order to be approved for payment. Some plans and PBMs may apply certain approval limitations based on criteria such as dose, diagnosis, and frequency. **However, once a medication is approved, many prior authorization systems do little to monitor these details in an ongoing fashion.** Relying solely on prior authorizations to deliver prospective payment integrity can leave room for significant financial losses.

The complex and expensive nature of specialty drugs also makes this an area ripe for fraud, waste, and abuse (FWA) by potential “bad actors”—providers, pharmacies, or members—and prior authorizations do very little to identify or prevent aberrant patterns.

In this white paper, we walk through frequent challenges to proper billing and propose several payment integrity best practices to consider in the prevention and recovery of billing errors and FWA.

## Specialty drugs and prior authorization

As noted, many plans rely solely on prior authorization to enforce prospective payment integrity for specialty drugs. PBMs may have additional restrictions (e.g., refill-too-soon, quantity limits) in place for pharmacy claims, but that is not always the case with specialty drug claims billed through the medical benefit.

Whether a drug requires prior authorization depends on several factors such as patient safety, patient outcomes, and cost. Once a drug is submitted for prior authorization review, it is scrutinized for various criteria, which may include:

- Diagnosis
- Patient age, weight, or BSA
- Dose and quantity
- Prior and/or concurrent therapy
- Laboratory values
- Procedure results

Once approved, however, these criteria may not be monitored until the prior authorization is up for renewal—often one year later. This is a circumstance where being overly reliant on prior authorizations can create problems. Specialty drugs that have been approved are still subject to coding errors, waste, drug interactions, and other potential problems.

But at least prior authorizations help mitigate increasing prescription drug costs, right? Possibly not.

Despite their purpose of generating savings, prior authorizations place significant administrative burden on plans, providers, and pharmacies as well as causing non-adherence for patients, leading to additional healthcare costs. In fact, one survey from the American Medical Association found that 86% of physicians reported that the requirements for prior authorization increased the overall utilization of healthcare resources, creating unnecessary waste instead of cost-savings.

## Common concerns

Relying too much on prior authorizations can mean that valuable data slips through the cracks. And the complexity behind specialty drug claims means that nuances can often be lost in any automation that is not designed to catch common errors. Let’s explore a few examples:

## Inaccurate coding

Medical claims for specialty drugs are subject to various mistakes. The claims are submitted after the drug has been administered to the patient, so unfortunately, no correction can be made to that end. However, monitoring for various types of errors can ensure the claim is coded and paid accurately.

Cotiviti's payment policy research team has observed the following claim details to contain the most inaccuracies:

- Diagnosis codes
- Maximum daily dose
- National Drug Codes (NDC)
- Drug wastage
- Route of administration

As mentioned before, prior authorization programs may initially check the appropriateness and accuracy of these details when reviewing a request for approval. However, many systems stop there. Following approval of a drug, future claims for that medication might be submitted (and paid) with inappropriate diagnosis codes, excessive doses and drug wastage, incorrect NDC numbers, or improper route of administration codes.

For instance, let's consider a claim example for the drug Bevacizumab, a common

# Relying solely on prior authorizations to deliver prospective payment integrity can leave room for significant financial losses.

antineoplastic medication used to treat multiple types of cancer. We'll assume the drug has been pre-authorized for up to 200 units per dose for a patient with colorectal cancer. The provider administers an appropriate, weight-based dose of 120 units and, based on the vial size of 100 units, there are 80 unused units remaining. These remaining units may be subsequently billed as drug wastage, using modifier (JW). However, a clerical error is made, and the provider bills for 120 units of wastage in addition to the 120 units administered to the patient. Both lines are then paid in full for \$12,000 each, causing an overpayment

of \$4,000. Unless the plan has a system monitoring for errors such as this one, significant overpayments will regularly occur.

## Duplicate billing

Duplicate billing occurs when a claim is billed for a drug by multiple providers despite only one of them actually supplying the medication. For example, a patient might pick up a prescription for leuprolide (a drug to treat endometriosis and other health conditions) from the pharmacy on Tuesday, and then take the prescription to a clinic on Thursday for administration. The provider at the clinic should only bill for the administration of the medication, but inadvertently bills for the cost of the drug (\$1,500) as well. Since providers do often order and supply the medication, it is easy to lose track of where the medication was sourced. Therefore, unless there are tools in place to detect these errors, plans can quickly lose thousands of dollars.

These errors are increasingly prevalent as "white-bagging" and "brown-bagging" continue to become more common. White-bagging and brown-bagging both refer to the process of a medication being dispensed by a specialty pharmacy and then delivered to a provider for administration. The only difference between the two is whether the

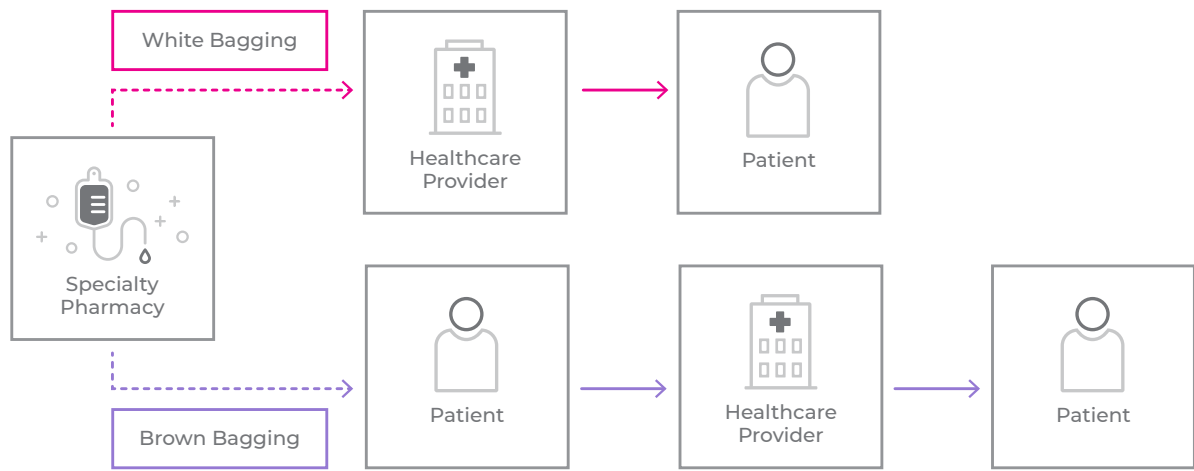


Figure 2. Specialty drug distribution process.

pharmacy delivers the medication directly to the provider or whether the patient acts as intermediary (Figure 2).

Despite sounding like a basic concept, catching duplicate billing can be quite difficult. Not only does the frequency of administration vary widely between drugs, but days or weeks can sometimes pass between a pharmacy dispensing the drug and the patient actually receiving it. To add more complexity, specialty pharmacies have the capability to bill either medical or pharmacy benefits, depending on each health plan's preference. This means that duplicate billing needs to be monitored in two ways: between multiple medical providers and across medical and pharmacy claims.

### Specialty drugs in FWA

The expensive nature of specialty drugs makes them ideal targets for FWA in both medical and pharmacy claims. Here are some real-life examples discovered by Cotiviti's FWA investigators:

1. **Excessive use of brand-name drugs when generics (or biosimilars) are available.** A prescriber insisted on patients using brand-name Harvoni despite a generic being available. Four patients received multiple fills of Harvoni, totaling over \$431,000 while the generic would have totaled \$154,000—a potential savings of \$277,000.

2. **Missing indication.** A family medicine physician prescribed Nuedexta to four elderly patients which led to 57 fills, totaling \$22,000. Nuedexta is only approved to treat pseudobulbar affect (PBA), and studies have shown no benefits in other conditions such as dementia or Parkinson's disease. In this case, none of the patients were diagnosed with PBA.
3. **Refilling discontinued medication.** A pharmacy allowed two different patients to refill anti-HIV medications that they were no longer supposed to be taking. One patient had recently switched providers, and his new provider switched him from Atripla to Odefsey. The second patient's provider switched him from Truvada to Descovy, but the Truvada still had active refills. Together, the unnecessary fills cost the plan over \$4,000.
4. **Improper prescribing and over-subscribing.** The demand for Ozempic and similar semaglutide drugs has rocketed in recent years as a weight loss solution, and this high demand and higher costs have created a litany of issues. Some patients have turned to compounding pharmacies to obtain these prescriptions, despite reported risks that some compounded semaglutides have caused adverse effects. The FDA also warns that poor compounding practices may

result in quality problems, such as the compounding pharmacy failing to mix the medications with the proper levels of ingredients or failing to include the active ingredient in the medication. As such, semaglutide drugs from compounding pharmacies may not work as promised and should be researched with scrutiny.

Other FWA trends involving specialty drugs include billing without dispensing, unsolicited auto-refills, prescription renewals without prescriber approval, and prescribing outside a provider's scope of practice. None of these is unique to specialty drugs alone, but as illustrated above, focusing on specialty drugs is especially productive in identifying savings opportunities.

### Improved payment integrity for specialty drug claims

Adding a multifaceted and integrated payment integrity approach on top of a plan's prior authorization process can prevent and solve many instances of specialty drug errors, waste, abuse, and even fraud. Integrated payment integrity comes into play after a prior authorization has already been granted, and while it doesn't replace the need for prior authorization, the right approach creates an added layer of verification to ensure that the claim is as accurate as possible and that it

isn't part of a larger FWA scheme or pattern. Whether it's a matter of reviewing a claim prepayment, catching an error post-payment, or even identifying fraudulent or wasteful patterns, having a robust set of solutions is essential.

## Having a robust set of payment integrity solutions is essential.

Here are the key attributes of a successful specialty drug payment integrity program:

- **Dedicate a team to drug-specific payment integrity solutions.** Do not short-change the solution by lumping it in with other, broad-sweeping tools that only look at the "big picture." A pharmacist is an obvious must-have, but a well-rounded team that also includes pharmacy technicians, nurses, physicians, and data analysts is ideal to provide a complete perspective on specialty drugs billed to the medical and pharmacy benefits. Experienced personnel can sift through thousands of lines of data and pull out the "needle in a haystack" that doesn't look right.

- **Focus on the details.** Drug claims contain countless details from NDC to quantity to diagnosis and so much more. Each detail has value but also presents an opportunity for errors—and corrections.
- **Approach from multiple angles and points of view.** Prepay solutions can prevent errors and waste while maintaining good provider relationships. Since specialty drugs can be billed under both the medical and the pharmacy benefit, prepay solutions can enable the ability to cross-reference claims and aid pharmacy claims history with medical claim review to avoid duplicates. A postpay safety net solution is also necessary for scenarios that require additional verification/confirmation. When searching for FWA activity, many analysts only monitor the prescriber, whereas aberrant behavior often exists.
- **Create a closed loop system.** Connecting prepay, postpay, and FWA programs and teams creates a process that covers all areas. For example, connecting postpay claim review results to your FWA pattern detection analytics can reduce duplication of effort and speed up the final conclusion, as well as feed other initiatives like machine-learning driven insights and accuracy.

## Proven results with Cotiviti

Cotiviti's integrated Payment Accuracy suite unlocks incremental value for health plan clients by offering solutions that work together to review 100% of your claims across all major claim types at the right intervention point for the claim scenario. Our proven technology; rules, policies, and concepts; and experienced and well-rounded staff enable the following solutions, which are used by dozens of health plan clients to catch and correct the specialty drug errors, fraud, waste, and abuse.

### Payment Policy Management: Drugs and Biologicals

Cotiviti's prepay claim review solution includes a team of experienced pharmacy and medical professionals specifically dedicated to prospective payment accuracy of specialty drugs (Drugs and Biologicals) on professional and outpatient claims. With the ability to execute a cross-claim approach and comprehensive edit recommendations across both pharmacy and medical claims, plans have the potential for saving substantially. In fact, in 2023, Cotiviti clients saved over \$381 million by applying our Drugs and Biologicals policies, which represented an average 9.6% of all policy savings among all Payment Policy Management clients.

## Data Mining

Cotiviti's postpay solutions leverage both medical and pharmacy claims data to identify and recover high-value claim overpayments of all types, including those from specialty drug duplicate billing and other areas of waste or error. We helped clients recover \$145 million in 2023 from inappropriate specialty drug spend.

### Pharmacy FWA Solutions

Our FWA solution applies drug-specific FWA logic that identifies suspicious claims and trends among patients, pharmacies, and providers. Detailed, actionable referrals are delivered to clients who can collect on past payments as well as put standards in place to prevent future aberrant behavior. Our FWA solutions and SIU team identified \$14.9 billion in suspect claims in 2023 looking across our entire hosted set of active medical and dental clients, nearly half of which were in areas of pharmacy and specialty pharmacy categories.

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**Learn more about Cotiviti's Payment Accuracy Solutions and find a fit that works for your plan's specialty drug claims and more.**

Discover more in Payment Accuracy

## About the authors



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Jonathan directs a team of pharmacy specialists in developing new content related to pharmacy claims. He also supports Cotiviti's vast library of Drugs and Biological payment policies and aids in presenting these policies to clients.



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