# Navigating the Complexities *of Accessing Specialty Medicines*

Scientific advances are driving development of increasingly sophisticated medicines, yet coverage barriers continue to delay—or even prevent—patient access. Coverage barriers and system-level pressure—consolidation, variation in insurance, and increased cost shifting in benefit design—complicate timely access to medicines, particularly **specialty medicines** used to treat rare, complex, or chronic conditions.

### *What Makes Specialty Medicines Different*

Because specialty medicines are highly complex and often require special handling, they are not available at a traditional retail pharmacy counter. Instead, they must be dispensed through specialty pharmacies, adding another layer of administrative, clinical, and logistical coordination to the patient access journey.

**Specialty Medicines**

Unlike traditional medications, these therapies require:

- Additional patient education
- Special handling, including refrigeration and careful preparation
- Ongoing clinical monitoring and support
- Distribution through specialty pharmacies

**Specialty Pharmacies**

- Provide expertise in complex medication management
- Offer high-touch clinical support 24/7
- Support benefits verification and prior authorization requirements
- Coordinate specialized dispensing and distribution

## *The Specialty Pharmacy Monopoly: The Human Cost of Consolidation*

Over the past decade, vertical integration has fundamentally reshaped how specialty medicines reach patients.

**Market concentration is *accelerating***

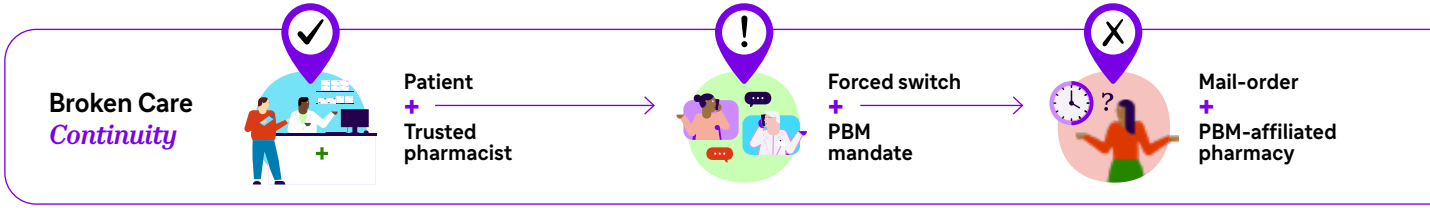
The three largest PBMs—CVS Caremark, Express Scripts and OptumRx—now own specialty pharmacies controlling *68%* of all specialty drug revenue, up from 54% in 2016.

**Independent pharmacies are *shrinking***

The share of independent specialty pharmacies has declined from 59% in 2015 to 29% in 2024.

As this consolidation accelerates, business incentives along the drug-delivery chain increasingly work against patients' interests. PBMs and their affiliated specialty pharmacies can *steer patients* toward their networks, meaning the same entity that decides whether to approve access to a therapy may also profit when the patient fills it at their pharmacy.

**The result is deeply personal:** patients are routinely forced to switch from their trusted pharmacists, who know their histories and understand the nuances of their conditions, to pharmacies in mandated PBM-affiliated networks and mail-order channels, which now dispense over 60% of specialty drugs. Patients experience an average of 3-week treatment gaps due to mandatory switching.




**PBMs can also require physician-administered drugs to:**

- Ship from their own specialty pharmacy to a physician's office (i.e., **white bagging**) rather than the physician's office purchasing the medicine directly from a wholesaler.
- Be directly delivered to a patient (i.e., **brown bagging**), leaving the patient to coordinate between their PBM and physician's office.

***These practices steer specialty drugs to PBM-owned specialty pharmacy channels, which can delay care and cause a higher administrative burden for providers and patients.***

# Insurance Barriers: *A Tale of Two Americas*

## Medicare Reforms Show What's Possible...

The implementation of Medicare Part D reforms in 2025 offers compelling evidence that patient-focused policy solutions work. Under a new $2,100 annual cap on out-of-pocket costs for medicines, seniors finally have predictable, manageable prescription drug costs for which they can budget.

**The results speak for themselves:** Medicare patients saw a *25%* increase in specialty drug utilization in the first quarter of 2025 compared to 2024, before the reforms took effect.

The Medicare Prescription Payment Plan allows beneficiaries to spread their out-of-pocket costs throughout the year with zero interest, eliminating the shock of thousand-dollar pharmacy bills. While Medicare Part D plans must offer this option to Medicare patients, minimal enrollment demonstrates a widespread lack of patient awareness, only *0.53% of Medicare patients* have filled a prescription under the Medicare Prescription Payment Plan option.

## ...But Commercial Insurance Challenges Persist

While progress has been made for Medicare patients, Americans with employer-sponsored or private insurance face mounting barriers. Unlike Medicare, commercial plans have:

- **No out-of-pocket caps** for specialty medicines
- **No payment spreading options** to manage cost shocks

*84%* of commercial payors **use copay accumulators** that prevent manufacturer cost-sharing assistance from counting towards patient deductibles and other cost-sharing obligations.

## *A Closer Look at Programs Prohibiting Patients from Receiving the Value of Manufacturer Assistance*

One of the most widespread access challenges faced by patients is the use of copay accumulator and maximizer programs. **When manufacturer assistance doesn't count toward deductibles, patients face devastating mid-year costs they cannot afford.**

**Copay Accumulators:** Prevent contributions from a manufacturer's copay assistance program from being applied toward a commercial patient's deductible or cost-sharing obligations, leading to financial harm for patients.

**Copay Maximizers:** Allow payors to exploit manufacturer's copay assistance programs and effectively reduce the manufacturer assistance available to commercially insured patients.

Despite having insurance, patients with serious and rare conditions often face significant cost-sharing requirements for their specialty medicines. Manufacturers' assistance programs are designed to bridge this gap, yet accumulator and maximizer programs block this from counting toward patient deductibles, cost-sharing obligations, and maximum out-of-pocket costs.

This impact is severe—over *60%* of commercial patients abandon treatment entirely when a drug costs over $250 and assistance runs out, and *20-30%* of patients attempt dangerous medication rationing.

# Excluding Certain Specialty Drugs and *Shifting Coverage to Other Pathways*

> *When insurance plans use accumulator programs to pocket assistance meant for specialty patients, they're forcing the sickest and most vulnerable to choose between their life-saving treatments and their financial survival. For a child with a rare disease or a young adult with multiple sclerosis, interrupting treatment doesn't just mean managing symptoms—it can mean irreversible progression and lost futures."*
>
> **Adam Gluck**
> *Head, U.S. & Specialty Care Corporate Affairs, Sanofi*

**Commercial health plans are increasingly excluding certain specialty drugs from their formularies and routing patients to alternative, often unauthorized access pathways.**

These **alternative funding programs (AFPs)** are operated by third-party vendors and route certain patients—who have had their specialty medicine excluded from their formulary—to either manufacturer patient assistance programs (PAPs) or unauthorized international sources. PAPs established by manufacturers are not intended for those with health insurance coverage but exist so uninsured or financially vulnerable patients can get access to drugs.

Excluding certain specialty drugs simply due of the existence of PAPs undermines patients' timely access to medically necessary treatment. AFPs replace a patient's own covered benefits with a patchwork of programs that delay access—putting patients' health and the continuity of their care at risk.

## *Policy Reform Needed to Protect Patient Access to Specialty Medications*

While we support state efforts to ban copay accumulators and maximizers, the patchwork of state protections leaves millions of Americans vulnerable and doesn't account for patients who get their insurance through the federal government.

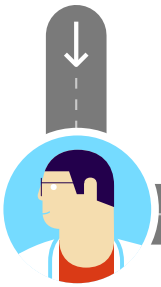
**We call on federal policymakers to help protect patient access to specialty medications by implementing policies that address the following areas:**

- Ensuring manufacturer assistance counts toward all privately insured patient deductible and cost-sharing obligations so that patients can get to their maximum out-of-pocket costs.
- Prohibiting alternative funding programs that shift coverage onto a patchwork of charity care and sometimes unauthorized international sources.
- Preserving patient choice of specialty pharmacies and limiting practices that delay or fragment the delivery of care.

# The Road *to Access*

**The journey to access specialty medicines is far from straightforward, as insurer-mandated utilization management tactics and specialized handling protocols mean patients often struggle with timely access and affordability.**

**Patient receives new Rx from physician**



**Benefits Verification**
Physician offices check and confirm a patient's insurance policy details including what medications are covered.

**Prior Authorization**
Physician offices send information to the insurance company's PBM to authorize medications or treatments. This process can delay access by 15-30 days, impacting patient care.

**Coverage Approved**

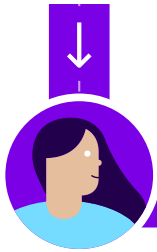
Patients must pay out-of-pocket before receiving medication, with costs varying by coverage plan.

**For new therapies**, manufacturers may provide free medicines during formulary decision-making. Medicare patients can now spread costs over the year.

**High-deductible plans** or insurance that excludes manufacturer assistance from deductibles can increase costs.

**Medication dispensed**
Specialty pharmacy sends medicine to patient and provides education as needed.

**Specialty pharmacy delivers medicine to provider (white bagging) or patient (brown bagging).**



**Patient starts treatment**

**Patients may need to switch therapies annually due to changes in coverage plans and formularies, even if they are accustomed to a specific treatment.**

**Coverage Denied**
The patient does not meet the coverage policy.

**Coverage Approved After Review**


If denied, patients and physicians revisit treatment plan and patients may not end up on the therapy originally prescribed.

**Appeal Process Starts**
Steps vary depending on insurance plan

**PBM conducts internal review of appeal**
A coverage decision is made.

**State regulator conducts an external review.** A coverage decision is made.