Navigating the Complexities *of Accessing Specialty Medicine*

The rapid pace of scientific advancement is transforming the pharmaceutical landscape, supporting the development of increasingly sophisticated medicines that benefit patients.

However, coverage barriers can delay or prevent patient access to these groundbreaking treatments.

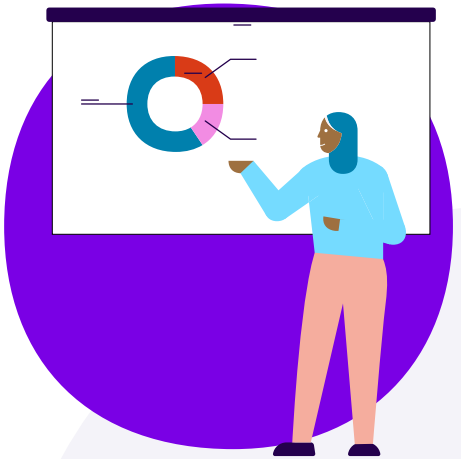
This issue is particularly pronounced for specialty medicines typically used to treat rare, complex, or chronic conditions. These medicines require additional patient education, ongoing monitoring, adherence support, and specialized handling, such as unique storage or shipment requirements. As a result, they require specific reimbursement and distribution processes.

Specialty pharmacies have emerged to address the challenge of delivering these complex medicines.

However, with significant consolidation among players in the drug delivery chain, specialty pharmacies are often owned by the same parent corporations as pharmacy benefit managers (PBMs).

These companies can steer patients toward their affiliated networks, creating a process fraught with misaligned incentives and conflicts of interest.

Despite the billions in rebates, discounts, and fees that manufacturers such as Sanofi pay to ensure patients can access their medicines, patients prescribed specialty medicines frequently encounter coverage restrictions enacted by these consolidated companies. These restrictions commonly involve step therapy, or prior authorization, which places barriers between patients and the treatments recommended by their physicians.



Too often, drug supply chain business tactics negatively impact patients.

Learn more about the relationship between list and net prices and factors that contribute to patient out-of-pocket costs.

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Out-of-pocket costs also create access challenges for patients. The federal government took steps to ease the prescription drug cost burden for seniors as part of the Inflation Reduction Act (IRA) of 2022, such as the Medicare Prescription Payment Plan and the Medicare Part D cap on out-of-pocket drug expenditures. However, these changes do not address barriers for patients with private health insurance.

All patients should be able to access their necessary medications without overly restrictive barriers to treatment. To do this, policies prioritizing oversight and accountability must be enacted. Sanofi advocates for measures that correct market distortions, such as:

- Preventing PBMs and other third-party entities from diverting manufacturer copay assistance meant to lower patient cost-sharing or denying coverage for medications.
- Enabling patients in federal health insurance programs to access manufacturer copay assistance when no generic or biosimilar alternatives are available.

A Closer Look at Copay Accumulators & Maximizers

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. Meanwhile, copay maximizers allow payors to exploit copay benefits and effectively reduce the manufacturer assistance available to commercial patients.

PBMs and insurers increasingly employ these tactics to divert funds from copay assistance programs, such as those provided by Sanofi, into their own revenue streams rather than applying them toward patients' deductibles or out-of-pocket maximums as intended. These strategies predominantly impact patients with private health insurance, highlighting a significant challenge in ensuring timely and affordable access to essential medications for patients.

The Impact and Limits of Medicare Changes

Two provisions of the IRA taking effect in 2025 will change how enrollees of Medicare Part D will pay for prescription drugs, with the potential to help those taking specialty medicines specifically.

The Medicare Prescription Payment Plan (M3P) allows patients to opt into a program to spread prescription costs into monthly payments without fees or interest. For instance, if a prescription costs $2,500 in January, the patient would pay $0 at the pharmacy and $167 monthly for 12 months.

Starting in 2025, out-of-pocket expenses in Medicare Part D will now be capped at $2,000 for each enrollee for all their medications covered by Medicare Part D. The limit can especially benefit Medicare patients who are prescribed specialty medicines.

While the Medicare Part D redesign can help with patient affordability, its impact is limited to Medicare patients.

Learn more about the ripple effects created by the IRA and what it means for patient access and affordability.

Learn more →

The Road *to Access*

Understanding Specialty Pharmacy Barriers

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

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
Physician provides more information and/or writes letter of appeal.

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

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