

Navigating Copay Adjustment Programs in Specialty Pharmacy

Published on behalf of the ASHP Section of Specialty Pharmacy Practitioners (SSPP)

Advisory Group on Business Development

Date of Publication: June 2024

Contributing Authors:

Farah Barada, PharmD, MBA, DPLA
Pharmacy Director, Ambulatory Pharmacy
Clinical Services & Specialty Pharmacy
Northwestern Memorial Hospital
Chicago, IL

Angelica Berni, PharmD, MS, BCPS, CPh
Director, Specialty Pharmacy & Clinical
Ambulatory Pharmacy Services
Baptist Health South Florida
Miami Lakes, FL

Sarah Fillman, PharmD, BCPS, BCOP Specialty Program Manager – Oncology Ambulatory and Specialty Pharmacy Reading Hospital Reading, PA

Samuel Casey Yokum, PharmD
Director, Specialty Pharmacy
WVU Medicine
Morgantown, WV

Table of Contents

Introduction	3
Copay Adjustment Program Definitions	3
Accumulators	3
Maximizers	3
Impact on Patient Care and Pharmacy Operations	4
Legislative Review	5
Advocacy Resources	7
Patient Navigation	7
Step 1: Identifying the program	7
Step 2: Educating your patient	8
Step 3: Locating alternatives	8
Key Takeaways	8
References	ç



Introduction

Many patients rely on copay cards from manufacturers to help pay for prescriptions, especially for specialty and brand name medications which often result in higher out of pocket expenses. Historically, copay card savings were applied to the patient's out of pocket expense and/or deductible to help the patient save money on their prescription and benefit plan responsibilities. In some cases, this added up to thousands of dollars in savings.

However, in 2018, many Pharmacy Benefit Managers (PBMs) and insurance plans began utilizing copay adjustment programs known as "copay accumulators" and "copay maximizers" as forms of utilization management. These programs are designed to effectively negate the savings that patients were receiving from copay card programs, often leaving them responsible for high deductibles and high prescription costs. Many PBMs assert that copay cards drive utilization of high cost medications and in essence circumvent the formulary structure.

This resource guide was developed to provide a framework for navigating the complex nature of copay adjustment programs. Pharmacy staff and leadership must be able to define and identify these programs, evaluate their potential impact on pharmacy services and patient access, understand evolving legislation on their utilization, and be prepared to assist patients in navigating through enrollments and alternative financial assistance strategies.

Copay Adjustment Program Definitions

Accumulators

As defined by the American Society of Clinical Oncology, a **copay accumulator** is a "feature or program within an insurance plan whereby a manufacturer's payments do not count toward the patient's deductible and/or out of pocket maximum".² The manufacturer copay card funds prescriptions until the maximum value on the coupon card is reached. Once reached, the patient will pay full cost for the prescription, and only then will these payments begin counting toward their annual deductible and out of pocket maximum.

Maximizers

Similarly, a **copay maximizer** does not count toward the patient's deductible and out of pocket maximum however, the maximum value of the manufacturer's coupon card is applied evenly throughout the benefit year.² While this particular medication may remain affordable, patients will experience higher out of pocket costs than they may have paid in prior benefit years.

In the absence of a copay adjustment program, when a patient utilizes a copay card or coupon, the portion paid by the manufacturer would contribute to the patient's out of pocket maximum and/or deductible for their prescription benefit.

Example of a copay adjustment program:

- A patient is enrolled in an insurance plan with a \$5,000 deductible.
- The patient is prescribed a specialty medication and has a copay card available up to \$4,000 for the year.
 - No Copay Adjustment Program: The \$4,000 coupon will count toward the
 patient's annual \$5,000 deductible: \$5,000 \$4,000= \$1,000. The patient is
 responsible only for the remaining \$1,000 before reaching the deductible.



With Copay Adjustment Program: The \$4,000 coupon will not count toward the
patient's deductible: \$5,000 - \$0 = \$5,000. The patient must pay the full \$5,000 of
their cost sharing requirement before the plan benefit kicks in and they receive
any coverage.

Impact on Patient Care and Pharmacy Operations

Copay adjustment programs can have a significant impact on both patient care and pharmacy operations in several ways:





At time of publication of this resource, it is estimated that 83% of enrollees are in plans that have implemented copay accumulator programs and 73% are in plans that have implemented copay maximizer programs, yet patients are often unaware of the existence of these programs until they experience a negative outcome or high out of pocket expense.³ The inability to afford medication-related out of pocket (OOP) expenses can impact health outcomes, having been linked to depression and an increase in mortality associated with decreased medication adherence.⁴⁻⁵ Cavalier and colleagues conducted an exploratory focus group study to capture patient perceptions of copay cards and copay adjustment programs. Participants expressed concern that copay adjustment programs could raise their OOP costs considerably, and if copay cards were not able to be utilized as originally intended, many of them envisioned having to switch medications, not fill their prescription, or stretch the medication they have left.⁶

Furthermore, a retrospective cohort analysis assessed the impact of copay accumulator adjustment program (CAAP) on usage patterns of autoimmune specialty drugs. A total of 603 patients were included and outcomes were assessed before and after implementation of the CAAP. Monthly fills per person decreased rapidly, risk of treatment discontinuation was significantly higher, and proportion of days covered was significantly lower after implementation. This can be especially problematic to lower-income patients and those enrolled in high-deductible health plans. These programs have a clear impact on patient outcomes and further complicate pharmacy operations.

Most specialty pharmacies complete a benefits investigation for their patients to determine insurance coverage and identify alternative payment assistance options, such as copay cards or patient assistance programs. As patients are suddenly burdened by the high cost of a medication after a copay card is exhausted, the usual pharmacy operations are paused to assess and resolve the patients' concerns. As a result, repeated benefit investigations may be necessary to understand the copay changes and communicate them to patients. Patients may need to pursue alternative financial assistance options, or the specialty pharmacy may require additional communication with providers if the medication is no longer affordable. In most situations, the pharmacy may be unable to continue dispensing the medication, impacting pharmacy operations at the benefit investigation, clinical assessment, and dispensing level. Unfortunately, copay adjustment programs could prevent specialty pharmacies from providing optimal care and connecting chronically ill patients with lifesaving medications, simply due to cost.

Copay adjustment programs add layers of complexity and responsibility to pharmacy operations. Balancing these impacts is essential for the effective delivery of healthcare services. Additionally, they present challenges that can negatively impact patient care, leading to a complex interplay of benefits and drawbacks within the healthcare system.

Legal and Regulatory Review

The Department of Health and Human Services (HHS), publishes the notice of benefit and payment parameters (NBPP), which is a set of rules and guidelines for health insurers and health plans.⁸

- The NBPP required insurers to count copay assistance towards a patient's annual deductible and total out-of-pocket cost.
- 2021 HHS introduced a rule allowing health plans to use copay accumulators. The new rule negated the 2020 regulation that had allowed copay assistance to contribute toward annual deductibles and out of pocket maximums.



2023 On September 29th, 2023, in the HIV and Hepatitis Policy Institute et al v. HHS, the court system agreed with advocacy groups, by overturning the 2021 rule and mandating that health plans include copay assistance and patient cost sharing.⁹ This essentially banned the use of copay accumulators by health insurers and plans. Unfortunately, this ruling has not been strictly enforced by the federal government.

In addition, the ruling does not apply to branded medications that have a generic equivalent. By choosing one of these brand medications, a patient's copay assistance may not count towards the deductible and annual limit. However, if they had attempted the generic and it was ineffective, then copay assistance for the brand name medication should count. Fortunately, copay accumulators are not allowed for brand only medications, or for biologics or biosimilars.

2024 HHS released the 2025 NBPP and failed to include support for enforcement of the original 2020 NBPP provision requiring copay assistance to be counted towards patient cost-sharing. ¹⁰

Individuals are more likely to feel the effects of copay accumulators with self-insured or employer-sponsored health plans, specifically those registered in a high-deductible plan. ¹¹ Regulations on acceptable use of copay maximizers and accumulators vary by state, with legislation currently enacted or introduced in over half of the country.

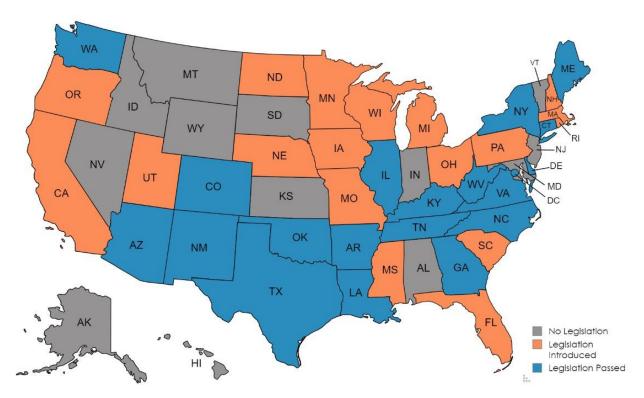


Figure 1. Legislative action by state, as of April 2024.¹⁰

The following resources can assist patients and advocates for those affected by copay accumulator programs.



Advocacy Resources

- All Copays Count Coalition: Learn more about the impact of copay adjustment programs and the regulatory actions that can be taken at state and federal levels. https://allcopayscount.org/
- Coverage Rights: Determine patient rights and actions that can be taken when insurers are improperly delaying or denying coverage, state by state. http://coveragerights.org/
- Arthritis Foundation: Read about the impact of copay adjustment programs and visit the action center to advocate for various federal and state initiatives to combat these programs. https://www.arthritis.org/advocate/issue-briefs/accumulator-adjustment-programs
- Crohn's & Colitis Foundation: Review their resource page for updates on 2024 copay accumulator & maximizer programs. Resources include information for both patients and employers to advocate for the Help Ensure Lower Patient (HELP) Copays Act and to initiate conversations with pharmacy benefit managers not abiding by the HIV + Hepatitis Policy Institute, et al. v HHS decision. https://www.crohnscolitisfoundation.org/patientsandcaregivers/managing-the-cost-of-ibd/copay-accumulator-maximizer-programs
- PAN Foundation Action Center: Submit a letter to your senators requesting their support of the Help Ensure Lower Patient (HELP) Copays Act (S. 1375) to prohibit the use of copay accumulator programs. https://www.votervoice.net/PANFoundation/campaigns/111284/respond
- National Hemophilia Foundation: Submit a letter to your representatives requesting their support of the Help Ensure Lower Patient (HELP) Copays Act (H.R. 5801) to prohibit the use of copay accumulator programs. https://p2a.co/SuYalE6

Patient Navigation

Patients are often unaware if a copay accumulator or maximizer is included in their pharmacy benefit design. Employers may indicate in their benefits packages if they have contracted with a third-party savings company for specialty medications, but the purpose of these programs may not be apparent to patients. In most cases, the pharmacy processing the payment claims may be the first to become aware of the patient's status in one of these programs. Here is how you, as a specialty pharmacy representative, can help your patients:

Step 1: Identifying the program

Your patient may be enrolled in an accumulator or maximizer if you notice any of the following:

- Very high copay that does not decrease after the first few refills, or a very high copay that occurs after the first few fills
- Copays exceeding the patient's deductible (if known)
- Message on the processed claim stating the patient must enroll in a third-party savings or coupon card program (may even provide a phone number or website for enrollment)
- Copay card maximum is met very early in the benefit year



Step 2: Educating your patient

Discuss the concept of a maximizer or accumulator with your patient at a level that they can understand. Some patients may be able to reach out directly to their benefits administrators and inquire about enrollment in these programs, while others may have a hard time grasping the overall concept. You may consider reaching out to a family member or other advocate to provide further clarification. Programs may go by a variety of names other than "maximizer" or "accumulator".

Alternative terminology may include 12

- Out-of-Pocket Protection Program
- True Accumulation
- Coupon Adjustment: Benefit Plan Protection Program
- Variable Copayment
- Out-of-Pocket Maximum Calculation Process
- Primary Coupon Adjustment

Step 3: Locating alternatives

Once you've identified that a copay adjustment program may be in place, investigate the further assistance by contacting:

- The number of a third-party savings program, which may be indicated on the processed claim for enrollment in the required program.
- The insurance provider or PBM to confirm if they are enrolled in a copay adjustment program and inquire if any additional benefits are available after the copay card maximum is met.
- Their employer's human resources department or benefits team to inquire if they have a maximizer or accumulator and if any additional benefits are available after the copay card maximum is met.
- The medication manufacturer to inquire if they are eligible for a copay card maximum extension or another patient assistance program.

Failing these options, additional alternatives may include:

- Foundations (not always available for commercially insured patients)
- Patient assistance ("free drug") programs
- Internal financial assistance programs, grants, or foundations
- Alternative treatment options

Key Takeaways

Ensuring medication affordability is an essential role of the specialty pharmacy to ensure positive patient outcomes. Copay adjustment programs have created new challenges by increasing out of pocket expenses for unexpecting patients. This has further led to medication non-adherence, treatment discontinuation, and frustration for patients, providers, and pharmacies alike. As a result, new legislative efforts are being assessed and implemented in many states keep ensure affordability and access to these essential medications. Enforcement of these laws has been inconsistent, and the rules vary by state. Patient and pharmacy education on copay adjustment programs and navigation strategies is crucial to assisting patients through their specialty medication financial journey.



References

- Patient Access Network Foundation. Ban copay accumulator, maximizer, and alternative funding programs. https://www.panfoundation.org/our-positions/ban-copay-accumulator-maximizer-alternative-funding-programs/ (accessed 2024 Mar 12).
- American Society of Clinical Oncology. Copay accumulators and copay maximizers policy brief. https://society.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2021-AccumulatorsPolicyBrief.pdf (accessed 2024 Apr 30).
- Avalere. Copay accumulator and maximizers: evolving policy landscape (2021).
 https://avalere.com/insights/copay-accumulator-and-maximizers-evolving-policy-landscape (accessed 2024 Mar 12).
- Smalley KB, Warren JC, Barefoot KN. Connection between depression and inability to fill
 prescriptions in rural FQHC patients with chronic disease. *Rural Ment Health*. 2016;
 40(2):113-123.
- Chandra A, Flack E, Obermeyer Z. The health costs of cost sharing. National Bureau of Economic Research; 2021.
 https://www.nber.org/system/files/working-papers/w28439/w28439.pdf (accessed 2024 Apr 30).
- 6. Cavalier D, Doherty B, Geonnotti G, et al. Patient perceptions of copay card utilization and policies. *J Mark Access Health Policy*. 2023; 11(1):2254586.
- 7. Sherman BW, Epstein AJ, Meissner B, Mittal M. Impact of a co-pay accumulator adjustment program on specialty drug adherence. *Am J Manag Care*. 2019; 25(7):335-340.
- Centers for Medicare & Medicaid Services. Patient protection and Affordable Care Act; HHS
 notice of benefit and payment parameters for 2021; notice requirement for non-federal
 governmental plans (May 2020).
 - https://www.federalregister.gov/documents/2020/05/14/2020-10045/patient-protection-and-



- <u>affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2021</u> (accessed 2024 Apr 22).
- United States District Court for the District of Columbia. HIV and Hepatitis Policy Institute et al., v. United States Department of Health and Human Services et al. (September 2023).
 https://www.govinfo.gov/content/pkg/USCOURTS-dcd-1 22-cv-02604/pdf/USCOURTS-dcd-1 22-cv-02604/pdf/USCOURTS-dcd-1 22-cv-02604-0.pdf (accessed 2024 Apr 30).
- 10. All Copays Count Coalition. Patient and provider groups again disappointed by 2025 notice of benefit and payment parameters final rule. 2024. https://allcopayscount.org/wp-content/uploads/2024/04/ACCC-Press-Release-April-5-2024.pdf (accessed 2024 Apr 30)
- 11. Arthritis Foundation. Accumulator adjustment programs.
 https://www.arthritis.org/advocate/issue-briefs/accumulator-adjustment-programs (accessed 2024 Apr 22).
- 12. CancerCare. What are copay accumulator adjustor programs?

 https://www.cancercare.org/publications/459-

 what are copay accumulator adjustor programs (accessed 2024 Apr 22).

