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Copay accumulators and the impact on patients

Assessing the proliferation of copay accumulators hindering patient access through an opaque benefit design

Copay accumulators threaten patient access

In recent years, commercial health plans and their pharmacy benefit managers (PBMs) have launched copay accumulator adjustment programs (AAPs), insurance designs that exclude the value of manufacturer-sponsored copay assistance from a patient's accrual of out-of-pocket (OOP) expenses toward OOP limits throughout a plan benefit year. The restriction on copay assistance may have an adverse impact on patients' adherence to prescribed therapy regimens and therefore may affect patient health and overall healthcare costs. While large, self-funded, employer-sponsored plans have led the charge in saturating the commercial market with these designs, recent federal regulation has given way to even more plans adopting AAPs and threatened the beneficial impact of copay assistance to patients on a long-term basis. This issue brief explores the breadth of AAPs in the commercial market, assesses the impact on patients, and reviews the AAP policy landscape.

Figure 1. Explaining copay accumulator adjustment programs

Copay assistance: traditional scenario	
Monthly fill for branded medication	
Patient OOP spending	$5
Copay assistance amount	$995
Insurance amount	$4,000
Total amount applied to patient OOP calculation	**$1,000**
Patient amount remaining to exhaust OOP maximum of $6,000	**$5,000**
The patient OOP spending and copay assistance amounts all apply to OOP accrual calculation, helping patients reach their OOP maximum more quickly.	

Copay accumulator adjustment programs	
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Patient OOP spending	$5
Copay assistance amount	$995
Insurance amount	$4,000
Total amount applied to patient OOP calculation	**$5**
Patient amount remaining to exhaust OOP maximum of $6,000	**$5,995**
Only the amount of the patient's OOP cost applies to the OOP accrual calculation, hindering patients from exhausting their OOP maximum.	

Patients' OOP costs continue to increase

Over the past decade, commercial health insurers have designed benefits that result in patients absorbing a greater portion of their OOP healthcare costs for brand medicines, pushing some into precarious financial and/or health circumstances.[1] Patient OOP costs for many brand medicines, particularly for specialty therapies, are increasingly high and burdensome. In 2020, large employer plans generally required that patients pay a percentage of the drug price (coinsurance) for specialty drugs, averaging a 26% coinsurance rate.[2] Since coinsurance is typically based on the list price of a drug, the patient's OOP cost set by the health plan can raise significant affordability concerns. For example, coinsurance set at 26% of $500 ($130) or $10,000 ($2,600) likely exceeds the financial means of many patients.

Deductibles are another contributor to high—and higher—OOP costs. The share of covered workers in plans with an annual deductible has increased significantly over time, from 70% in 2010 to 83% in 2020. The average deductible amounts for covered workers have also increased over the same period, from $917 in 2010 to $1,644 in 2020.[3] Satisfying the deductible before health insurance even begins to cover any of a patients' healthcare costs can also represent a daunting hurdle.

To help minimize this financial burden for affected patients, pharmaceutical manufacturers offer copay assistance programs to support qualifying commercially insured enrollees.[a] This copay assistance has generally been included in the accrual calculation of a patient's OOP costs, which is important for patients to progress through the insurance benefit, including meeting deductibles and annual OOP maximum requirements. Manufacturer copay assistance programs typically cap the amount provided to the patient; once the cap is reached, the patient pays any additional OOP costs.

Copay accumulator adjustment programs have skyrocketed in prevalence over the past 3 years

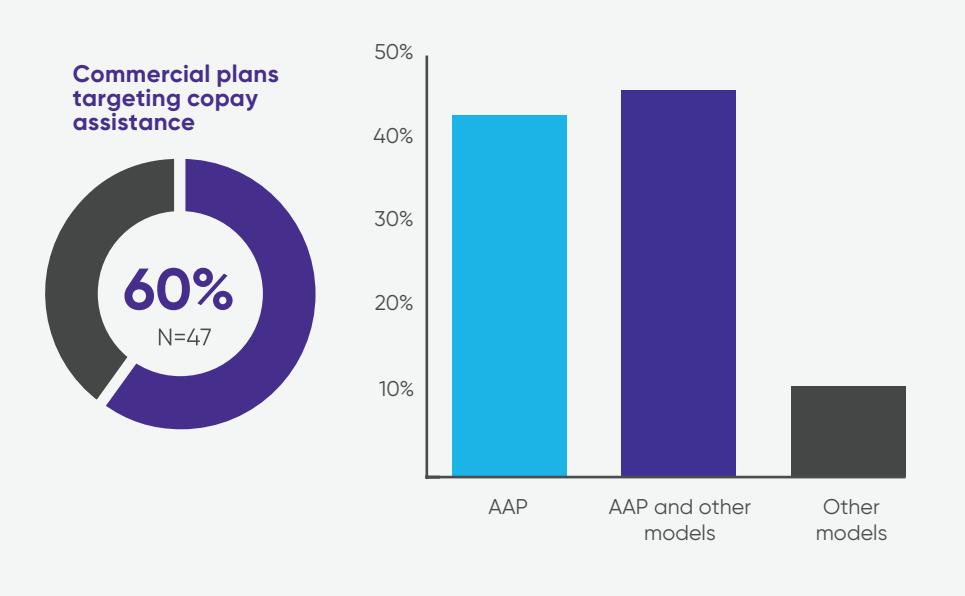
In recent years, commercial health insurers have explored methods to limit how copay assistance can be used. To date, the most frequently used model for limiting the usefulness of copay assistance is an AAP. Under an AAP, the insurer and/or PBM does not count manufacturer copay assistance toward the patient's OOP cost-accrual calculation. Commercial insurers' use of AAPs has been increasing since 2018.[4] In 2020, a majority of surveyed payers from Xcenda's Managed Care Network (60%) limited copay assistance, and of those insurers doing so, nearly 90% utilized some variation of the AAP model.[5]

Large employers are driving the uptake of AAPs. Of the commercial insurers surveyed by Xcenda in 2020 (roughly 50), over 60% consistently reported that both self-funded and fully insured employer plan customers were adopting AAPs to save on pharmaceutical spending, potentially failing to grasp the impact on their employees who are prescribed specialty medications.[5] The use of AAPs in the small business and individual markets may also be on the rise,[2] especially given federal policy facilitating greater use of these models.

As the breadth and scope of AAPs have expanded since 2018, so have the number of commercial enrollees affected by the models. Extrapolating results from a 2020 survey of 16 health plans consisting of different payer types (national plans, regional plans, integrated delivery networks, and PBMs), Guidehouse Primary Research Analysis's survey results imply that potentially 131 million Americans are insured by entities that are using AAPs.[6]

Employers are often the final decision makers on whether to utilize a plan or PBM's AAP or not. While these programs have been a popular tool for employers, a survey by MME Advisors found that some employers are increasingly aware of the possible negative impacts of AAPs and are pushing back against plans' use of them.[7]

Figure 2. Current tactics to restrict how copay assistance is applied to a patient's cost-sharing responsibility by surveyed plans

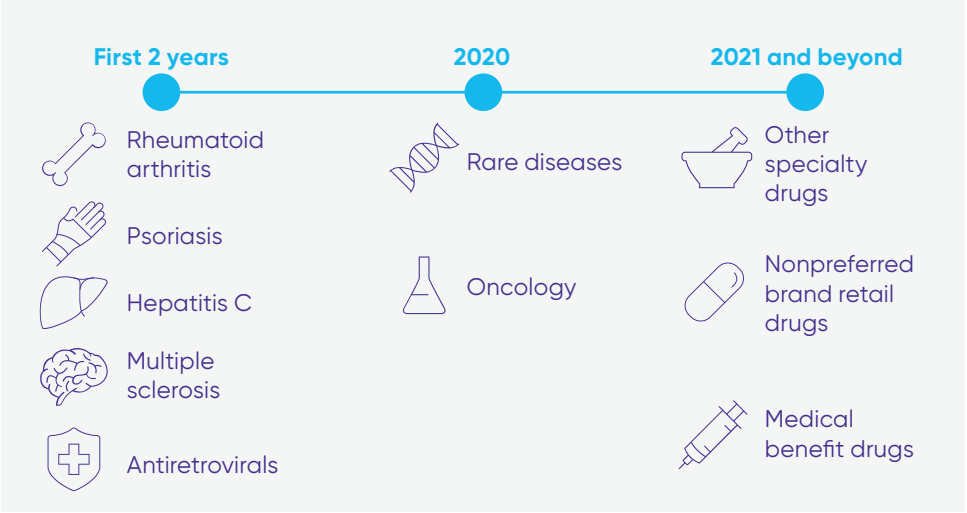


Source: Xcenda Managed Care Network Survey. February 2020[5]

[a] For uninsured patients, pharmaceutical manufacturers provide other types of assistance, including programs that provide free or low-cost prescription drugs.

While AAPs were initially applied to products in select therapeutic areas, commercial payers are now applying them to most specialty drugs. Xcenda's survey of health plans has revealed that payers initially applied AAPs to products treating rheumatoid arthritis, hepatitis C, multiple sclerosis, and psoriasis, but, in 2020, insurers broadened their focus to include oncology and rare diseases. In future years, they intend to apply them to nearly all specialty drugs and even nonpreferred branded retail drugs.[2] Furthermore, commercial payers may even expand the reach of AAPs to medical benefit drugs. One the largest national insurance companies, UnitedHealthcare, planned to apply AAPs to specialty medications under the medical benefit,[8] but the insurer declined to move forward based on the outcry from network providers.[9]

Figure 3. Current and potential therapeutic categories targeted by plans to hinder the usefulness of manufacturer copay programs



Source: Xcenda Managed Care Network Survey. February 2020[5]

AAPs adversely affect patient access

AAPs represent a considerable threat to patient access, given the adverse effect on adherence to a prescribed therapy and lack of transparency about their use, which may catch unaware patients by surprise.

Most concerningly, patients may exhaust the manufacturer copay assistance for the year well in advance of hitting their plan's deductible or OOP maximum because the assistance was not being counted toward it. As a result, patients may face major financial challenges paying for their prescriptions once their copay assistance is exhausted. As most patients are unaware that their health plan may be using an AAP, having to cover the deductible or other large OOP costs in the middle of the year—when they assumed the assistance was satisfying these OOP requirements—can be a huge financial shock.

A recent analysis by the consulting firm IQVIA studied the impact of AAPs by reviewing 3 programs and how patients responded once their copay assistance was exhausted.[10] The analysis found that from 2018 to 2020, 25% to 36% of patients discontinued treatment when they faced an unexpectedly high OOP cost of $1,500 or more in the middle of the plan year due to an AAP.

Additionally, evidence suggests that this nonadherence caused by AAPs can worsen patients' physical and financial health.[11,12] When patient OOP cost-sharing starts to exceed $25, adherence can start dropping off by 10%.[13] A previous analysis found that most patients who abandon their prescriptions do not fill any other prescription within 3 months, suggesting that they are not using a lower-cost medicine but are instead failing to continue the treatment prescribed by their physician.[8] Considering that 44% of Americans would have trouble paying an unexpected $400 emergency expense, the implications of AAPs on medication adherence are significant.[14]

Medication nonadherence has dramatically negative effects on health and associated high costs—all of which are avoidable. A literature review funded by the federal government reported that the lack of adherence is estimated to cause approximately 125,000 deaths in the US, at least 10% of hospitalizations, and a substantial increase in morbidity and mortality.[15] Nonadherence has been estimated to cost the US healthcare system between $100 billion and $289 billion annually.

Compounding the nonadherence threat, the use of AAPs is shrouded in a lack of transparency, and patients are generally unaware of their use. Patient awareness and understanding of AAPs is opaque for a number of reasons, as commercial insurers utilize widely varying terminology for the programs, offer program details in buried sections of plan materials, and fail to generally disclose if AAPs are being used across all drug classes or selectively with only some medications.[16,17]

There is hope on the horizon about payers' opaque usage of AAPs. Transparency rules for health plans issued by the Departments of Health and Human Services (HHS), Labor, and Treasury in October 2020 include a provision that effectively requires health plans and PBMs to disclose to their enrollees that they are using AAPs.[18] While promising, it should be noted that this provision does not solve the problem. For example, health plans may not fully comply with their transparency requirements or may intentionally make it difficult to find the disclosure. Additionally, finding out whether or not a plan uses an AAP merely informs patients; it does not eliminate their usage.

Recent federal regulations are further facilitating copay accumulator adjustment programs

While employer-sponsored health plans have driven the AAP trend, recent regulatory action has opened the door even further. The federal government completely reversed its policy toward AAPs for non-grandfathered individual and group health plans (including self-insured plans). In rulemaking for the 2020 plan year, the federal government permitted plans to use AAPs only for brand drugs that had medically appropriate generic equivalents available. For 2021, however, the federal government shifted gears and allowed plans to use AAPs at their discretion, regardless of whether a generic equivalent is available.

Potentially even more damaging, the Centers for Medicare & Medicaid Services finalized a rule requiring manufacturers to "ensure" that copay assistance is provided entirely to patients in order to be excluded from Medicaid best-price calculations. This rule is scheduled to go into effect January 1, 2023.[19] However, manufacturers cannot control when plans subject a patient's medication to an AAP. The policy could have a downstream negative impact on patients if manufacturers have to reduce the generosity or availability of assistance offered.

Despite federal regulatory activity eroding patient access, some states have taken action against AAPs in state-regulated markets. To date, 10 states have successfully passed legislation that limits or outright bans AAPs—Virginia, West Virginia, Illinois, Arizona, Georgia, Kentucky, Oklahoma, Arkansas, Tennessee, and Connecticut—thus helping protect patients from surprise OOP costs.[20] While certainly a victory for patient access, these laws have limited scope, as self-funded employer plans are regulated under the Employee Retirement Income Security Act (ERISA), thereby exempting them from state insurance laws.

Looking to the future of copay accumulator adjustment programs

HHS, Congress, and state legislatures that have not already passed AAP bans should consider examining the negative impacts the programs have on patient affordability. Patients almost universally support such bans. A National Hemophilia Foundation survey of 1,000 registered voters fielded in October 2020 found that 86% of participants felt the government should require copay assistance to be applied to a patient's OOP cost-sharing requirements.[21]

Patients are not the only stakeholders opposed to AAPs. Healthcare providers have great concern about the impact of AAPs on patient adherence and health, as well as the increased administrative burden on their staff.[22–24]

Ensuring an appropriate balance of cost-sharing between insurers and patients is critical in the commercial market. Collectively, we must ensure that patients are able to afford their OOP costs for medications to maintain adherence to prescribed therapies. As AAPs generally exacerbate nonadherence, policymakers should explore appropriate laws and regulations focused on maintaining patient access and overall adherence.

Note: This publication was originally commissioned by the Pharmaceutical Research and Manufacturers of America (PhRMA).

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