

**American Society of Clinical Oncology Position Statement: Copay Accumulators and Copay Maximizers****Approved by the ASCO Board of Directors January 21, 2021****Background**

Rising health care costs are a persistent concern among patients, policymakers, providers, and payers. While costs are rising in many parts of the system it is the amount that patients bear out-of-pocket that is often the most concerning to them. Over the last decade, patients have faced increasing out-of-pocket costs as a result of rising deductibles and shifts in employer-based coverage. According to a report by the Kaiser Family Foundation, annual deductibles have increased 25% over the past five years.<sup>1</sup> As deductibles increase and become more common, the share of people with over \$2,000 in annual out-of-pocket spending has increased from 4% to 12% in the last 15 years.<sup>2</sup>

Rising out-of-pocket costs have raised concerns about care affordability and access, especially when they are connected to the cost of prescription drugs. Manufacturer copay assistance programs are typically created by drug manufacturers to directly support patient use of their drug products. Assistance usually comes in the form of a drug coupon or card, which a patient then brings to their pharmacy to obtain a discount on their cost-sharing. Oncology practice staff often spend a significant amount of time locating copay assistance for patients. In choosing health plans, patients increasingly consider cost-related factors more important than benefit design compared to previous years.<sup>3</sup>

As the leading professional organization for physicians and oncology professionals caring for people with cancer, ASCO is deeply concerned about the effect rising out-of-pocket cost has on individuals affected by cancer. The purpose of this ASCO Position Statement is to provide a summary of issues our members have raised about steps pharmacy benefit managers (PBMs) and insurers are taking to inhibit the kind of copay assistance programs commonly offered by manufacturers. Specifically, this statement aims to highlight the impact of copay accumulator adjustment and copay maximizer programs on patient costs in benefit design and outline ASCO's opposition to these harmful programs.

**Copay Accumulator Adjustment Program Design**

PBMs and insurers impose a variety of administrative rules, known collectively as utilization management, to limit or deny coverage for selected treatments. In 2018, ASCO highlighted an emerging utilization management approach being imposed on benefit design, known as "copay accumulator adjustment programs".<sup>4</sup> Copay accumulator adjustment programs prevent funds provided by manufacturer copay assistance programs from applying toward a patient's annual

out-of-pocket maximum or deductible. Only after the value of the coupon is exhausted can patient out-of-pocket costs begin counting toward an annual deductible and out-of-pocket maximum. As a result, insurers and PBMs are receiving the full amount of the manufacturer copay assistance program's value in addition to the patient's copay. This means that patients will experience increased out of pocket costs and delays in reaching their required deductibles.

Such utilization management tactics negate the intended benefit of patient assistance programs—and remove a safety net for patients who need specialty medications but cannot afford them. This could lead to poorer health outcomes and potentially higher costs to the health care system. Additionally, copay accumulator adjustment programs are often implemented without consumer notice or education, meaning the patient typically discovers one has been added to their plan after they incur an exorbitant cost-share, often in the middle of their plan year.

ASCO members have reported increasing concerns about the impact of copay accumulator adjustment programs, which prevent patients most in need from leveraging the full value of available assistance. Rising costs have led some practices to hire full time financial navigators to help patients in need, only to see that assistance negated by copay accumulator policies. One private payer recently attempted, and later withdrew, a suggested policy that would require providers to report on patients' receipt of such financial assistance.<sup>5,6</sup> ASCO has long opposed such unnecessary administrative burdens on providers.<sup>7</sup>

These programs have the potential to harm patients by discouraging the appropriate utilization of specialty therapies and reducing adherence to recommended treatment. A recent study found that health savings account patients under an accumulator adjustment program for autoimmune drugs had significantly lower monthly prescription fill rates, higher risk of discontinuation, and lower proportion of days covered compared to patients enrolled in preferred provider organization plans. This suggests that copay accumulator programs have the potential to negatively affect specialty drug use.<sup>8</sup> Specific to cancer, another study found that higher prescription copayments were associated with both non-persistence and non-adherence to prescribed treatment, particularly among older women.<sup>9</sup>

### **Copay Maximizers**

Similar to copay accumulator adjustment programs is the copay maximizer. In these programs, the manufacturer copay assistance maximum is applied evenly throughout the benefit year but still does not count toward the patient's deductible and out-of-pocket maximum. Copay maximizers appear as a more patient-friendly alternative by shielding patients from significant out-of-pocket costs. However, they encourage plans to use manufacturer copay assistance as a strategy to allow payers – not patients – to reap the benefits of manufacturer copay assistance programs. Patients are required to sign up to this program separately and, if a patient does not sign up, they may face significant out-of-pocket costs that exceed their plan's out-of-pocket

maximums as well as the maximums established by the Patient Protection and Affordable Care Act. PBMs and insurers that operate maximizers keep up to 25% of the value of the manufacturer's patient support funds.<sup>10</sup> In this way, copay maximizers may not have the same immediately visible negative impact on patients but still serve to keep their out-of-pocket costs higher.

### **Federal and State Action**

In its 2020 Notice of Benefit and Payment Parameters (NBPP) final rule, the U.S. Department of Health and Human Services introduced limits to copay accumulator adjustment programs in the individual and group insurance markets as well as large employer health insurance plans. Under the 2020 regulation, issuers could, but were not required to, exclude the value of pharmaceutical manufacturer assistance from counting towards the annual limit on cost-sharing for brand-name prescription drugs that have a generic equivalent.<sup>11</sup> However, the 2021 final NBPP rule revokes those previous protections, allowing health plans to implement copay accumulator adjustment programs.<sup>12</sup>

Several states have acted through legislation to protect their residents from copay accumulator programs. To date, five states have passed laws to ban or restrict the use of copay accumulators in individual and small group health care plans, however, states do not have the authority to ban copay accumulators in self-insured plans.

### **Conclusion**

Patients are bearing a rising share of health care costs. The escalating costs of cancer treatments coupled with high patient out-of-pocket expenses contribute to treatment-related financial harm, known as financial toxicity.<sup>13</sup> It is clear these programs have begun to proliferate in the private sector and are also slowly making their way into public payer programs. They are of particular concern for patients with cancer who need to access many expensive specialty drugs. Due to PBMs and insurers rapidly deploying copay accumulator adjustment programs in their health plans, it has become an exigent need for ASCO to develop a position statement on the issue.

In light of all these increased concerns and the expected rise in patient out-of-pocket costs, ASCO, in the interest of supporting high-value, high-quality care, supports policies that promote equitable, timely, and affordable access to necessary treatment for all patients with cancer. Further, insurance plans should provide patients transparent and easy to understand information about plan policy regarding copays—and should provide such information at the time of enrollment. Patients should be informed of any changes in such policies prior to implementation. **ASCO strongly opposes the use of copay accumulator adjustment and copay maximizer programs for patients with cancer and makes the following recommendations:**

- **The Centers for Medicare and Medicaid Services (CMS) should prohibit the use of copay accumulator adjustments and copay maximizers in the programs it administers and regulates.**
- **To further protect patients, federal and state governments should pass legislation that prohibit the use of copay accumulator adjustment and copay maximizer programs.**
- **Commercial insurers and PBMs should immediately discontinue the use of copay accumulator adjustment and copay maximizer programs.**
- **At a minimum, while copay accumulator adjustment programs remain in place, public and commercial insurers and PBMs should ensure transparency by clearly describing its design for beneficiaries, as required by the Centers for Medicare and Medicaid Services Summary of Benefits and Coverage Instruction Guide.**

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<sup>1</sup> Kaiser Family Foundation. 2020 Employer Health Benefits Survey. October 8, 2020.

<https://www.kff.org/health-costs/report/2020-employer-health-benefits-survey/>

<sup>2</sup> Peterson-KFF Health System Tracker. What do we know about people with high out-of-pocket health spending? September 29, 2020.

<https://www.healthsystemtracker.org/chart-collection/know-people-high-pocket-spending/#item-high-oop-average-out-of-pocket-spending-by-service-area-among-nonelderly-people-with-large-employer-coverage-who-have-out-of-spending-2000-vs-all-nonelderly-enrollees-2017>

<sup>3</sup> Kaiser Family Foundation. Kaiser Family Foundation/LA Times Survey Of Adults With Employer-Sponsored Insurance. May 2, 2019. <https://www.kff.org/report-section/kaiser-family-foundation-la-times-survey-of-adults-with-employer-sponsored-insurance-section-4-health-insurance-decision-making-and-trade-offs/>

<sup>4</sup> American Society of Clinical Oncology. American Society of Clinical Oncology Position Statement: Pharmacy Benefit Managers and Their Impact on Cancer Care. [https://www.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/ASCO-Position-Statement-PBMs-Aug-2018.pdf?et\\_cid=40510620&et\\_rid=1760459169&linkid=the+statement](https://www.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/ASCO-Position-Statement-PBMs-Aug-2018.pdf?et_cid=40510620&et_rid=1760459169&linkid=the+statement)

<sup>5</sup>

<https://www.uhcprovider.com/content/dam/provider/docs/public/policies/protocols/Accumulator-Adjustment-Medical-Benefit-Program-Protocol.pdf>

<sup>6</sup> <https://www.uhcprovider.com/en/resource-library/news/featured-news/accumulator-adjustment.html>

<sup>7</sup> American Society of Clinical Oncology. American Association of Clinical Oncology Policy Statement On the Impact of Utilization Management Policies for Cancer Drug Therapies.

<https://www.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2017-ASCO-Utilization-Management-Statement.pdf>

<sup>8</sup> 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 Jul;25(7):335-340. PMID: 31318506.

<sup>9</sup> Neugut AI, Subar M, Wilde ET, et al. Association between prescription co-payment amount and compliance with adjuvant hormonal therapy in women with early-stage breast cancer. *J Clin Oncol*. 2011;29(18):2534-2542. doi:10.1200/JCO.2010.33.3179

<sup>10</sup> Drug Channels. Copay Accumulator and Maximizer Update: Adoption Accelerating As Pushback Grows. November 17, 2020. <https://www.drugchannels.net/2020/11/copay-accumulator-and-maximizer-update.html>

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<sup>11</sup> Department of Health and Human Services. Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020. <https://www.govinfo.gov/content/pkg/FR-2019-04-25/pdf/2019-08017.pdf>

<sup>12</sup> Department of Health and Human Services. Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2021; Notice Requirement for Non-Federal Governmental Plans. <https://s3.amazonaws.com/public-inspection.federalregister.gov/2020-10045.pdf>

<sup>13</sup> <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/financial-toxicity>