



Decreasing Drug Costs for Patients with Rare Disease

July 12, 2024

Thank you!



Panelists

Decreasing Drug Costs for Patients with Rare Disease



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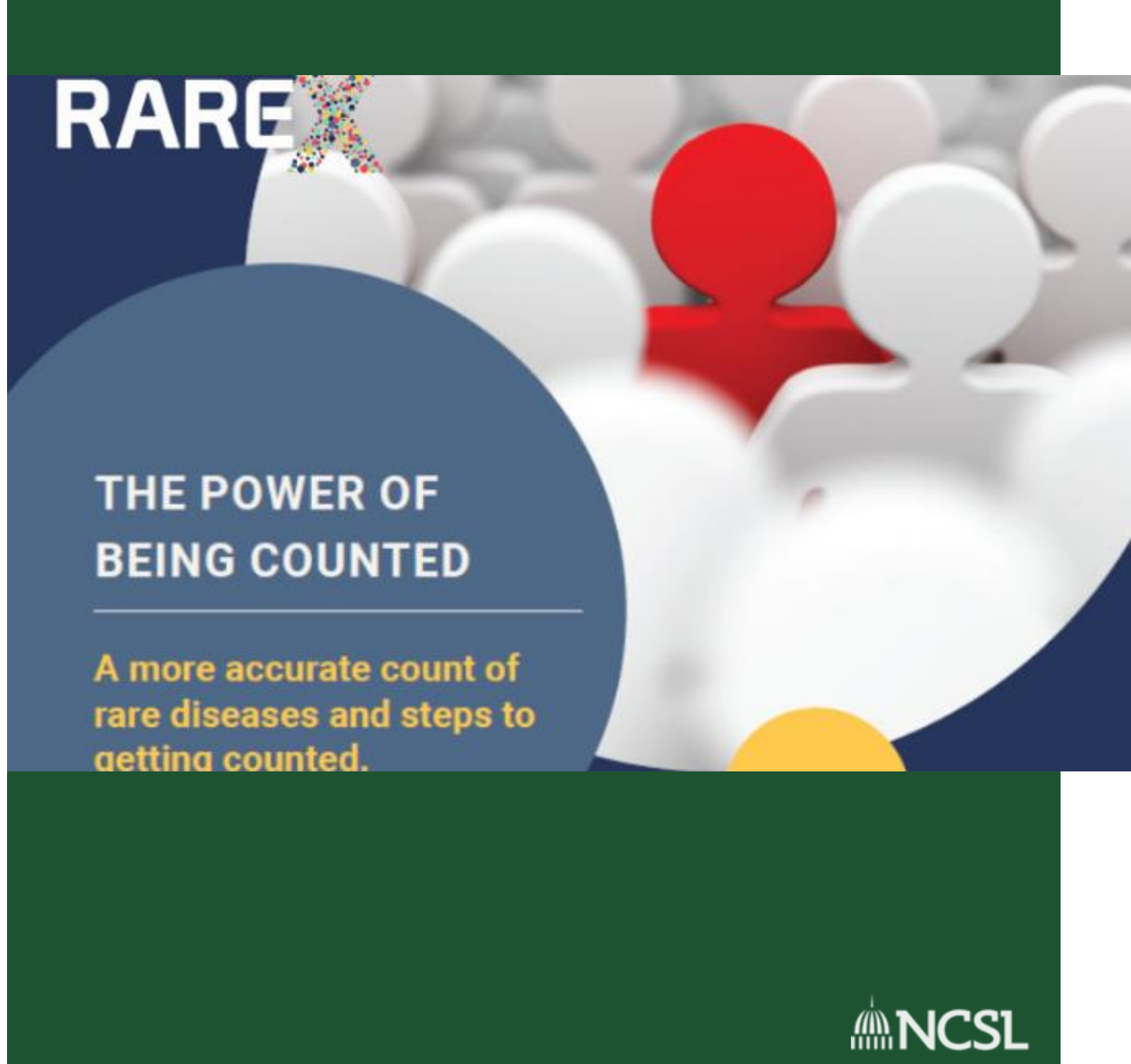


**Rep. Karen
Karls**

North Dakota

Facts About Rare Disease

- A rare disease is a disease or condition that affects fewer than 200,000 Americans.
- Rare X report, [The Power of Being Counted](#):
 - Collectively, 25-30 million Americans live with a rare disease.
 - Many—but not all—are genetic. Approximately two-thirds of Americans with rare disease are children.
 - There are as many as 10,867 rare diseases, including genetic and non-genetic diseases.
 - Less than 5% have an approved therapy.
- ICER, NORD, IQVIA other - \$32,000 average annual cost.
 - 39% of drugs with orphan indications - \$100,000.



Summary of Plan Sponsors' Tools for Accessing Manufacturer Patient Support Funds to Offset Drug Spending

COPAY ACCUMULATOR

- Exclude a manufacturer's copay support from patient's deductible
- Patient responsible for full value of deductible
- Plan can capture the value of two deductibles
- Typically offered directly by the plan's PBM

COPAY MAXIMIZER

- Patient's out-of-pocket obligation set to maximum value of copay support
- Patient incurs minimal out-of-pocket costs
- Plan can capture the value of a drug's copay offset program (less vendor fees)
- Typically offered by a third-party vendor partnered with the plan's PBM

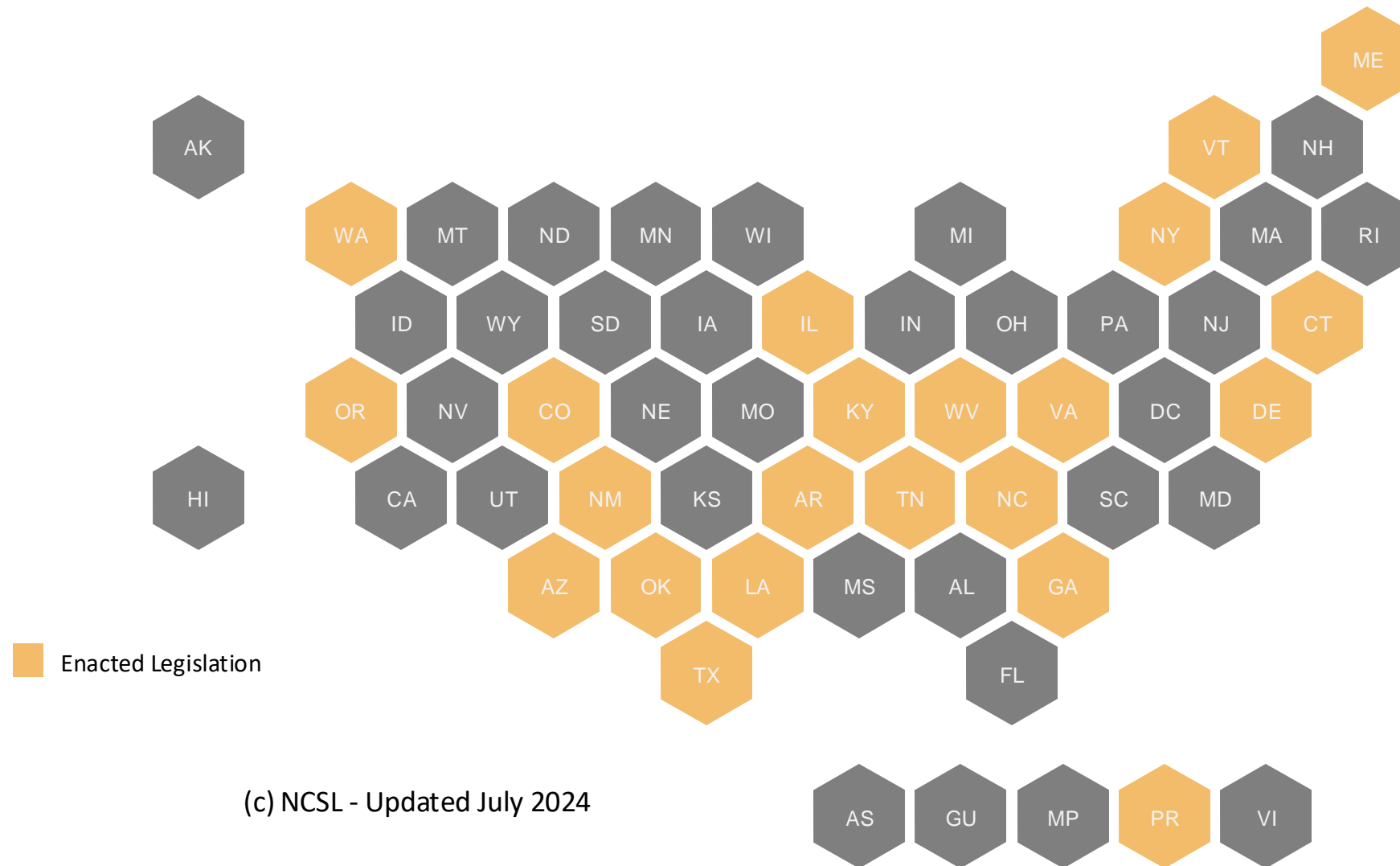
ALTERNATIVE FUNDING

- Coverage eliminated for selected specialty drugs. PAP pays for full drug cost.
- Patient incurs minimal out-of-pocket costs
- Plan can capture a drug's list price value (less vendor fees)
- Typically offered by a third-party vendor unaffiliated with the plan's PBM

PBM = pharmacy benefit manager

Source: Drug Channels Institute research. This chart appears as Exhibit 134 in *The 2024 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*.

Copayment Accumulator Programs: State Actions

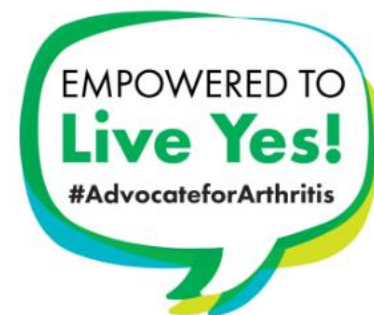




Arthritis Advocacy: Counting Copay Assistance

arthritis.org/advocacy

Arthritis Patient Perspective



About Arthritis

- Nearly 60 million adults are diagnosed with arthritis.
- Arthritis isn't a single disease; the term refers to joint pain or joint disease, and there are more than 100 types and affects people of all ages, races and sexes.
- Arthritis is the leading cause of disability in the U.S.

Utilizing Copay Assistance

- Arthritis patients who have used copay assistance as a payment are often unaware they are enrolled in a copay accumulator program until they go to the pharmacy counter and realize they must pay the full cost of their medication, which can lead them to abandon or delay their prescription.
- These programs can be called different names, are often marketed as a positive benefit, and are often disclosed many pages into plan materials, leading to a lack of awareness about them to patients.



Insurance Management

Benefits and Medication Checklist

Having access to your prescription medications is key to treating arthritis. This checklist will help you get started.

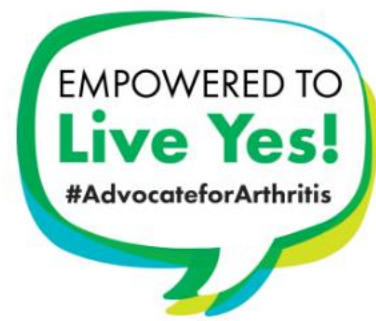


Insurance Management

Open Enrollment Checklist

Use this checklist to make sure you get the best plan for your healthcare needs.

The Arthritis Foundation created the [Your Coverage, Your Care Toolkit](#) to educate patients on their coverage, available at [arthritis.org](#)



Top Issue: Copay Accumulators

- Accumulators prevent any copay assistance that may be available for high-cost specialty drugs from counting towards a patient out-of-pocket costs, including your deductible or maximum out-of-pocket costs.
- If patients lose access to their copay assistance, they may experience an unnecessary increase in disease progression or life-threatening delays in their care and treatment, due to an inability to pay for their medication

95% of medicines

The overwhelming share of medicines subject to an accumulator program have no generic or biosimilar available, leaving patients without a less expensive alternative.

24% of patients

A 2017 survey found that when faced with a large, unexpected charge, 24% of respondents did not fill their prescription. Another 17% switched medicines, and 14% delayed picking up their prescription.

Reforming Cost Sharing to Count Copay Assistance

EMPOWERED TO
Live Yes!
#AdvocateforArthritis

State Model Legislation

- **Clarify the definition** of cost-sharing to ensure payments made “by or on behalf of” patients (a third party) count toward their deductible and/or out-of-pocket maximum

State Guidance

- **Nevada Division of Insurance issued guidance** stating all Nevada consumers enrolled in a Nevada marketplace plan will have their copay assistance counted towards their annual limits on cost-sharing in accordance with the 2020 NBPP.

Resources

- All Copays Count Coalition – AllCopaysCount.org
- The Aids Institute Reports – TheAidsInstitute.org
- Avalere State Copay Report
- Genentech Study on Health Inequity



Comparison of Marketplace Average Benchmark Premiums Between States With and Without Copay Accumulator Adjustment Bans

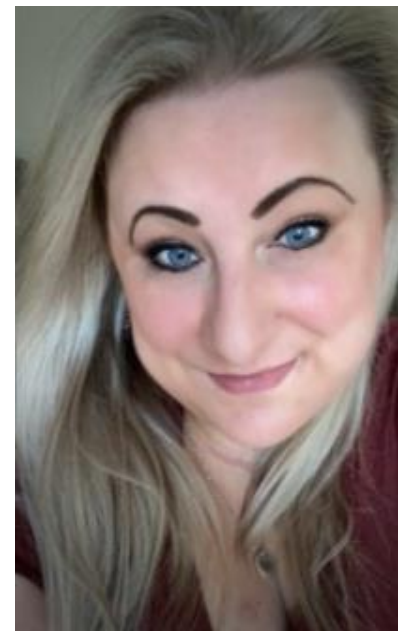
Between 2019 and 2022, 16 states enacted laws banning insurers and pharmacy benefit managers (PBMs) from diverting copay assistance funds intended to help patients living with serious, complex chronic illness afford the expensive medications on which they rely. Patients and providers first noticed this practice (called “copay accumulator adjustments”) in 2017.¹

The AIDS Institute analyzed annual premium changes in states with copay accumulator adjustment bans and those without. **We found no evidence that enacting a copay accumulator adjustment ban has a meaningful impact on average premiums.**



Thank You!

Questions?



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NCSL: Prescription Drug Prices

Sharon Lamberton, MS, RN, Deputy VP, State Policy, PhRMA

July 12, 2024

Medicines Are Transforming the Treatment of Many Rare Diseases

Collectively, rare diseases affect 30 million Americans. Treatments are available for only 5% of rare diseases, but recent advances are providing important new options to many patients for the first time.

Spinal Muscular Atrophy (SMA)⁸

SMA involves loss of motor neurons leading to progressive muscle weakness and wasting and, in severe cases, respiratory failure. The first gene therapy was approved in 2019 to treat children less than 2 years of age with the most common form of SMA and the leading genetic cause of infant mortality.

Acquired Thrombotic Thrombocytopenic Purpura (aTTP)⁹

aTTP is a life-threatening blood disorder affecting about 3 adults per million annually. The disease leads to disturbances in the nervous system and organs as a result of clots that form in the smallest of arteries. The first treatment for aTTP was approved in 2019.



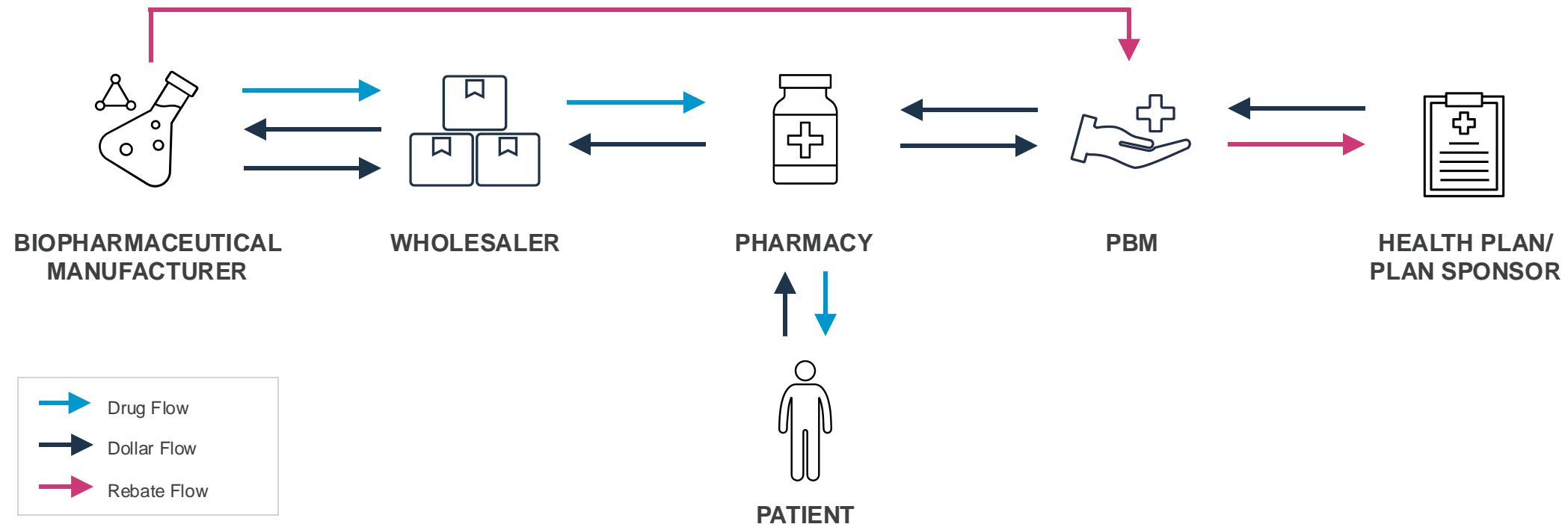
Tenosynovial Giant Cell Tumor¹⁰

This condition involves non-cancerous tumors around the joint areas which can cause painful damage to surrounding tissue and structures of the body. If left untreated, these tumors can lead to severe disability. The first treatment was approved in 2019 for patients who are not candidates for surgery.

Erythropoietic Protoporphyrria (EPP)¹¹

EPP is a disorder affecting about 4,000 US children and adults. The most common symptom is severe pain upon exposure to artificial and natural light which can lead to burns and ulcers on the skin. The first treatment to increase pain-free light exposure for EPP patients was approved in 2019.

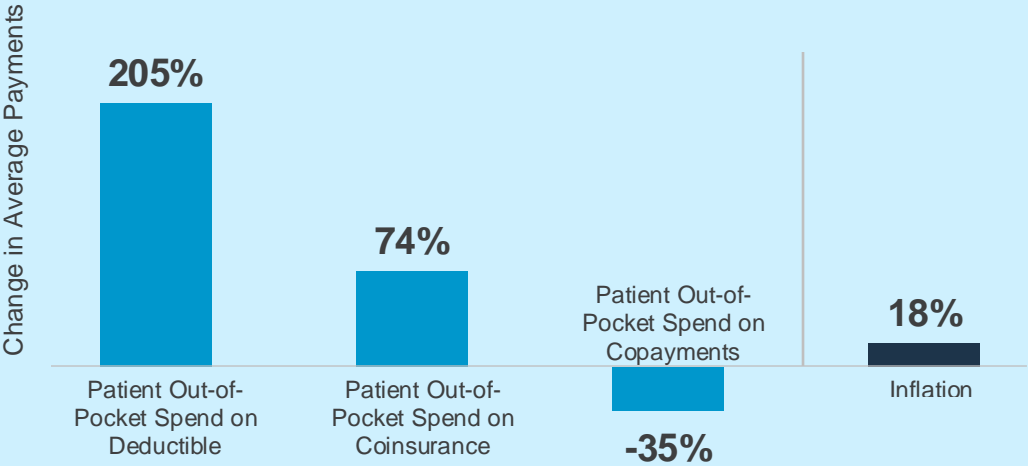
Many Stakeholders Have a Role in the Prescription Medicine Supply Chain



Patient Cost Sharing Is Increasingly Tied to List Prices through Coinsurance and Deductibles

Patient Spending Rises as Plans Use More Deductibles and Coinsurance

Change Among Large Employer Health Plans, 2007-2017

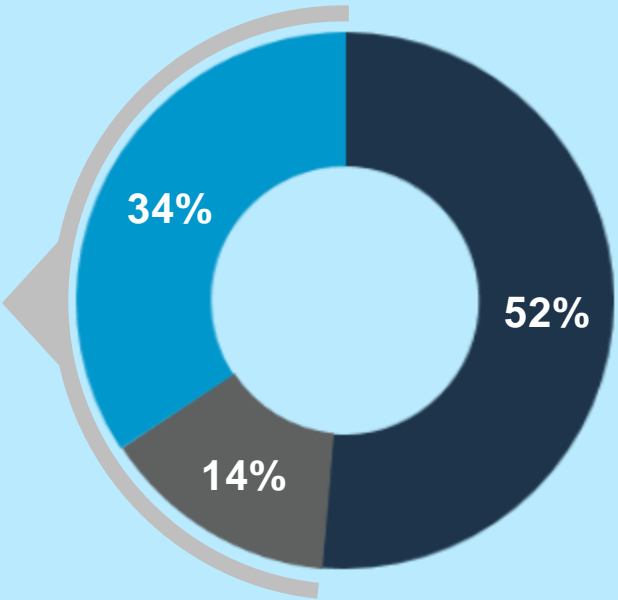


Source: Peterson Center on Healthcare and Kaiser Family Foundation. Tracking the rise in premium contributions and cost-sharing for families with large employer coverage. August 2019.

Nearly Half of Commercially Insured Patients' Cost Sharing For Brand Medicines Is Based on the Undiscounted List Price

49%
of patient cost sharing is based on list price

- Copay
- Deductible
- Coinsurance



Source: IQVIA Institute for Human Data Science. Medicine spending and affordability in the United States. August 2020.

PhRMA Created the Medicine Assistance Tool, or MAT, To Help Patients Navigate Medicine Affordability

MAT makes it easier for those struggling to afford their medicines to find and learn more about various programs that can make prescription medicines more affordable.

The Medicine Assistance Tool Includes:

A search engine to connect patients with

900+

assistance programs offered by biopharmaceutical companies, including some free or nearly free options



Resources to help patients navigate their insurance coverage

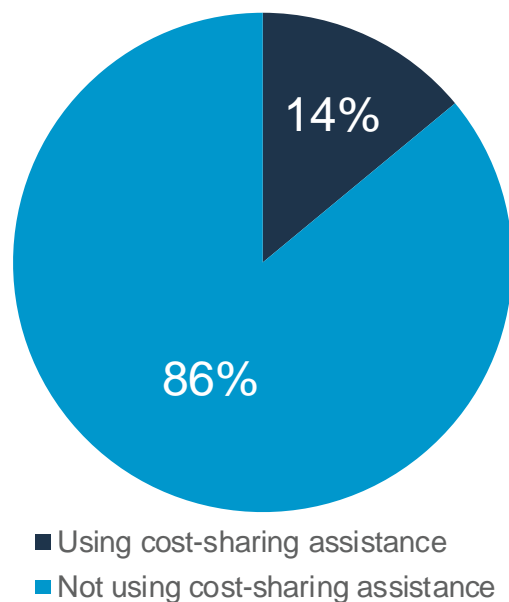


Links to biopharmaceutical company websites where information about the cost of a prescription medicine is available

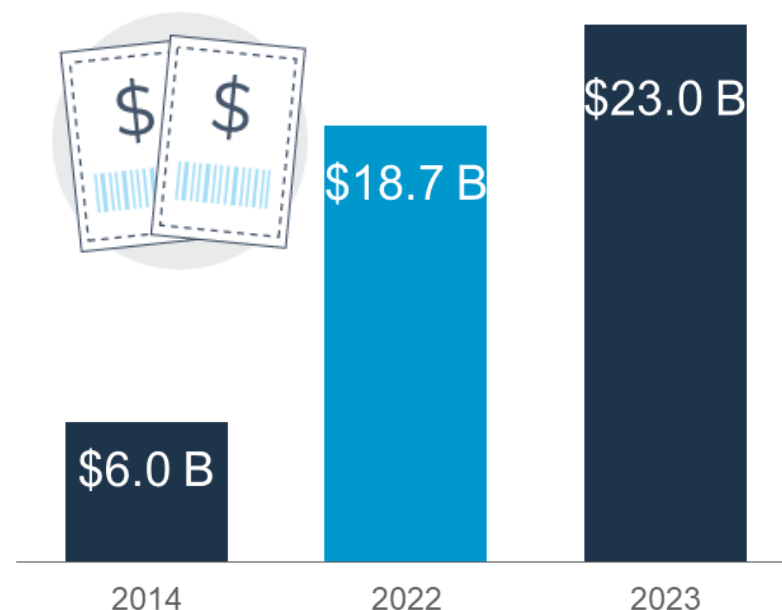
Manufacturer Cost-Sharing Assistance Is an Important Source of Financial Help for Commercially Insured Patients

Manufacturer cost-sharing assistance helps commercially insured patients who otherwise might struggle to afford their out-of-pocket costs.

Share of Commercially Insured Patients Using Manufacturer Cost-Sharing Assistance for Brand Medicines, 2020¹



Total Manufacturer Cost-Sharing Assistance Has Grown in Recent Years²⁻⁴



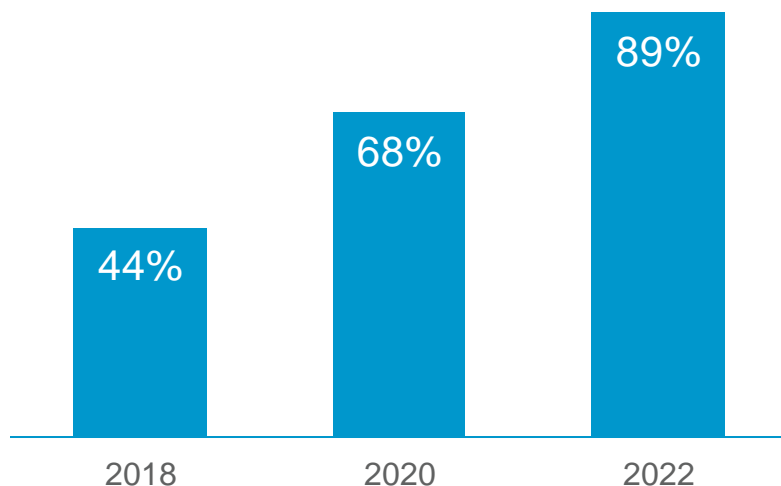
1. IQVIA. The use of medicines in the US. Spending and usage trends and outlooks to 2025. May 20, 2021. Accessed May 2022. <https://www.iqvia.com/insights/the-iqvia-institute/reports/the-use-of-medicines-in-the-us>
2. IQVIA. Medicine use and spending in the US. A review of 2018 and outlook to 2023. May 2019. Accessed April 2020. <https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-use-and-spending-in-the-us-a-review-of-2018-and-outlook-to-2023>
3. IQVIA. The use of medicines in the US. 2023. Usage and spending trends and outlooks to 2027. April 2023. Accessed May 2023. <https://www.iqvia.com/insights/the-iqvia-institute/reports/the-use-of-medicines-in-the-us-2023>
4. 1.IQVIA. The use of medicine in the US. 2024. Usage and spending trends and outlook to 2028. April 2024. Accessed June 2024. <https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/the-use-of-medicines-in-the-us-2024>

AAP Programs (Accumulator Adjustment Programs) Can Make It Harder for Patients to Afford Their Medicines

Accumulator adjustment programs (AAPs) exclude the value of manufacturer cost-sharing assistance from patients' deductibles and out-of-pocket maximums. This can result in increased patient costs and nonadherence.

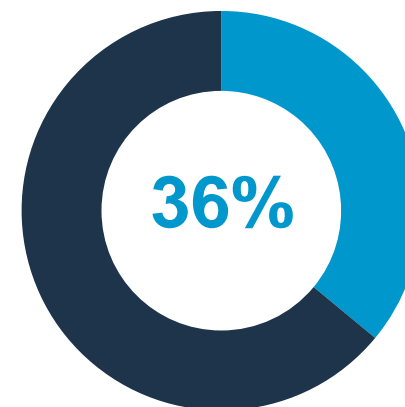
Patients are increasingly subjected to AAPs.

Share of Covered Lives at Risk of AAP Impact¹



Note: Percentages show commercial market lives covered by plans that have AAPs; not all health plans choose to opt into AAPs.

AAPs can result in unexpected patient costs.



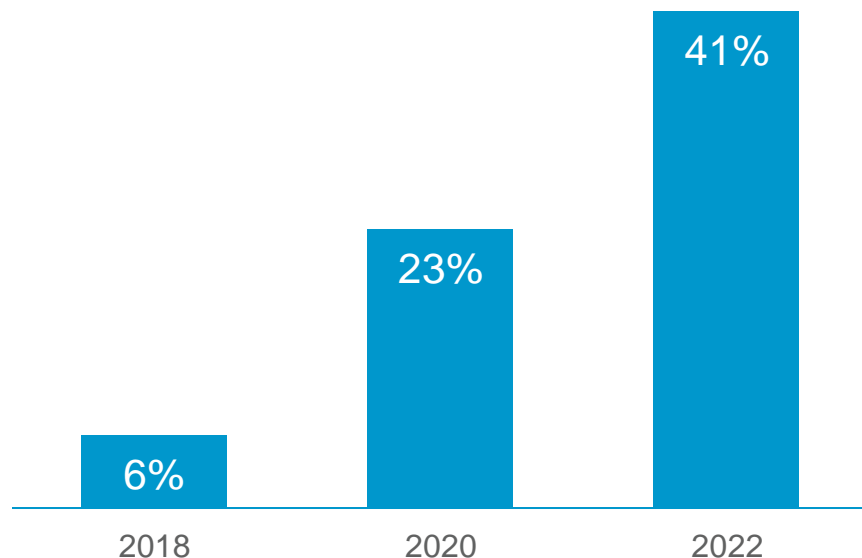
of patients discontinue therapy after facing a surprise cost of **\$1,500 or more** due to an AAP.²

1. Fein, A.J. Copay accumulator and maximizer update: adoption plateaus as insurers battle patients over copay support. Drug Channels. February 2023. Accessed May 2023. <https://www.drugchannels.net/2023/02/copay-accumulator-and-maximizer-update.html>
 2. IQVIA analysis for PhRMA. 2020.

Maximizers: Undermine the Intent of Manufacturer Assistance

Plans use maximizers to inflate patients' cost sharing for medicines to the **maximum** value of available manufacturer cost-sharing assistance, as much as thousands of dollars per prescription. Patients face **high** out-of-pocket costs unless they enroll in the maximizer program.

More health plans are subjecting patients to copay maximizers.¹



COPAY MAXIMIZER VENDORS

profit from cost-sharing assistance **intended for patients**. Some ask health plans to pay administrative fees of 25% or more of the total amount of cost-sharing assistance they divert through copay maximizer programs to these companies.²

1. Fein, A.J. Copay accumulator and maximizer update: adoption plateaus as insurers battle patients over copay support. Drug Channels. February 2023. Accessed May 2023. <https://www.drugchannels.net/2023/02/copay-accumulator-and-maximizer-update.html>
2. Fein A.J. The 2022 economic report on U.S. pharmacies and pharmacy benefit managers. Drug Channels Institute. March 2022.

Alternative Funding Programs

AFPs drive patients to charitable or manufacturer patient assistance funds meant for uninsured and financially disadvantaged patients

- Target specialty medicines
- Encourage health plans to remove coverage for specialty drugs on premise that manufacturer PAPs will pay for them
- Patient must enroll in the vendor's program or pay 100% of the cost of their medicines
- Once enrolled, vendor assists patient in applying for PAP
- If patient not eligible for PAP, they can appeal to have their medicine covered under the health plan

Decreasing Drug Costs for Patients with Rare Disease

Sean Dickson

Senior Vice President, Pharmaceutical Policy & Strategy

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Pharmacy Costs and Impacts

- Less than 2% of patients use specialty medications, but these medications are 51% of total pharmacy spending
- Out of 3,500 specialty drugs, 10 drugs account for 25% of pharmacy costs; 50 drugs account for 50% of costs
- For every dollar spent on health care, 22 cents goes to prescription drugs
- The system – patients, workers, employers, taxpayers, state governments – cannot afford higher drug costs



Health Insurance and Employment

- For most working Americans, health insurance is part of their compensation
- Changes in health care costs, including prescription drugs, impact hiring and payroll
- Spending has real impacts – for every 1% increase in health care prices:
 - Payroll and employment falls 0.4%
 - Per capita labor income decreases by 0.27%
 - Unemployment increases by 1%
 - Unemployment payments increase by 2.5%
 - Federal income tax receipts decrease by 0.4%
 - Deaths by suicide and overdose increase by 2.7%
- Unlike drug prices, **health insurance prices reflect actual input costs**, either through rate review or the direct costs paid by self-insured employers



What Are Copay Coupons?

Copay coupons are promotions that drug makers provide to specific patients for a short period of time.

These promotions are offered primarily for brand-name drugs that face competition from more affordable generic drugs.

These promotions are used as an **incentive for patients to use brand-name drugs** instead of less expensive generics.

Once the patient hits their maximum – and will not see the drug’s cost at the pharmacy counter – drug makers stop providing their promotions.

Copay coupons are **prohibited in federal health care programs** like Medicare and Medicaid. These programs consider copay coupons a **“kickback”** because they induce a patient to take a certain drug.

The Broader Financial Impact of Coupons

Repeated studies have shown coupons benefit drug manufacturers but have much larger, negative consequences to patients through the entire market.

- The [U.S. House Oversight Committee's report on drug pricing](#) found that drug companies use patient assistance programs as a sales tool – focusing on their rates of return, encouraging patients to stay on high-priced branded drugs after a generic is introduced, and subsidizing third-party foundations to drive sales and attract patients who otherwise might not have used the drug.

The Committee stressed that these programs **“do not provide sustainable support for patients and do not address the burden that the company’s pricing practices have placed on the U.S. health care system.”**

- The Committee’s [investigation](#) into one drugmaker found:
 - The manufacturer has raised the price of one drug used to treat leukemia and other rare forms of cancer and blood disorders 22 times since 2003 for a **cumulative price increase of 395%**.
 - After a generic alternative was introduced, enhanced patient assistance programs were a crucial piece of this manufacturer’s strategy to mitigate its loss of exclusivity by encouraging patients to stay on the branded drug.
 - The manufacturer’s internal strategy documents projected a **potential rate of return of \$8.90 for every \$1 spent** on their copay assistance program and noted **“because oncologic drugs are a necessity for patients, there is less sensitivity to price increases.”**

Accumulators Promote Greater Transparency – and Ultimately Lower Costs for Everyone

- Accumulators shift spending from the health insurance plan to the drug company for expensive drugs, reducing premiums without increasing patient out-of-pocket spending.
- Patients pay less at the pharmacy counter when a coupon is available and pay their standard cost-sharing after the coupon expires, never paying any more than the total out-of-pocket they selected for their health plan.
- Accumulators create up-front rebates for prescription drugs where the manufacturer is unwilling to negotiate a rebate with the health insurance plan.
- CMS allowed these programs because of the “market distortion effects related to direct drug manufacturer support amounts when consumers select a higher-cost brand name drug over an equally effective, medically appropriate generic drug.”
- **Brand drug companies still make more money with an accumulator than if the patient used a generic drug. Drug spending is still higher for everyone – just not as high as it would be without an accumulator.**
- **Banning accumulators raises costs for everyone:**
 - **Utah:** Accumulator ban would increase annual costs to the state employee plan by \$2.75 million per year (\$3.76 PMPM). The fiscal note highlights that **85% of that increase would directly benefit drug manufacturers but only 15% would benefit state employees.**
 - **North Dakota:** Accumulator ban would increase total expenses for the 2023-2025 state employee plan budget by **\$19.43 million.**
 - **California:** An accumulator ban would only impact 1.6% of prescription drugs sold in the state (CA law already bans many coupons) but it would increase insurance premiums in California by **\$81 million in the first year and \$164 million in the subsequent years** because of increased use of coupons and higher utilization of expensive medications.

Thank You

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Thank you!

NCSL Resources

- [State Policy Options and Pharmacy Benefit Managers \(PBMs\)](#)
- [Copayment Adjustment Programs](#)
- [Prescription Drug Legislation Database](#)
- [Prescription Drug Policy Resource Center](#)

Contact Information

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