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Understanding Your Members' Out-of-Pocket Costs for Treatment

An Overview of Pharmacy Benefit Programs

What Is the Current Climate Around Prescription Drug Use and Affordability?

According to a 2021 Kaiser Family Foundation health tracking poll of adults:[1]

62%

are currently taking **at least one prescription drug**

25%

currently take **four or more**

- **32%** of those taking four or more prescription drugs have **difficulty affording their prescriptions**

29%

report **not taking their medicines as prescribed** at some point in the past year **because of the cost** including:

- About **16%** who have **not filled a prescription**
- About **22%** who took an **over-the-counter (OTC) drug instead**
- More than **13%** who **cut pills in half or skipped a dose**

In a 2022 IQVIA National Prescription Audit (New to Brand, LAAD Sample claims data), patients starting new therapy abandoned 94M prescriptions at pharmacies in 2022, of which 42M were under $10. Among all new prescriptions, 43% of those costing $125 to $249.99 and 53% of those costing more than $250 were abandoned.[2]

According to a 2022 Kaiser Family Foundation survey, about half of adults (47%, n=2,375) reported difficulty affording their out-of-pocket (OOP) costs, and more than 4 in 10 adults (44%) reported worrying about affording their deductible.[3]

43% of people reported, in the past 12 months, they or another family member living in their household has put off or postponed getting health care they needed because of the cost.

What Is Value-Based Pharmacy Benefit Design and the Impact on Cost Benefits?

Value-Based Pharmacy Benefit Design

The value-based insurance design (VBID) model for pharmacy benefits can **promote access** to high-value specialty medications. Drug pricing within a value-based benefit design allows payment for drugs in **proportion with the benefits they provide** to patients over existing drug options. The price of a drug is tied to whether and to what extent **the drug helps patients more than current treatment options**. Value-based benefit design also works to ensure that **patient access to innovative drugs is included** when determining the appropriate price for a drug.[4]

Considerations

A number of approaches can be taken by payers and purchasers to apply VBID to pharmacy benefits:[5]

- Imposing **reduced OOP cost sharing** on high-value medications
- Reducing cost sharing **based on patient- or disease-specific characteristics**
- Patients whose formulary-approved therapies **do not work** could be subject to **lower cost sharing** if they choose nonformulary treatments as **alternatives**

In general, three-tier pharmacy drug plan solutions can allow for cost sharing for specialty drugs at levels no greater than cost sharing for nonspecialty, nonpreferred branded medications.[5]

The elimination of four- and five-tier pharmacy drug plans are now required in state-regulated plans in multiple states.[5]

Consider how value-based pharmacy benefit designs may impact your members' access to affordable medications. Be sure to evaluate all possible solutions and related considerations before choosing a pharmacy benefit plan design.

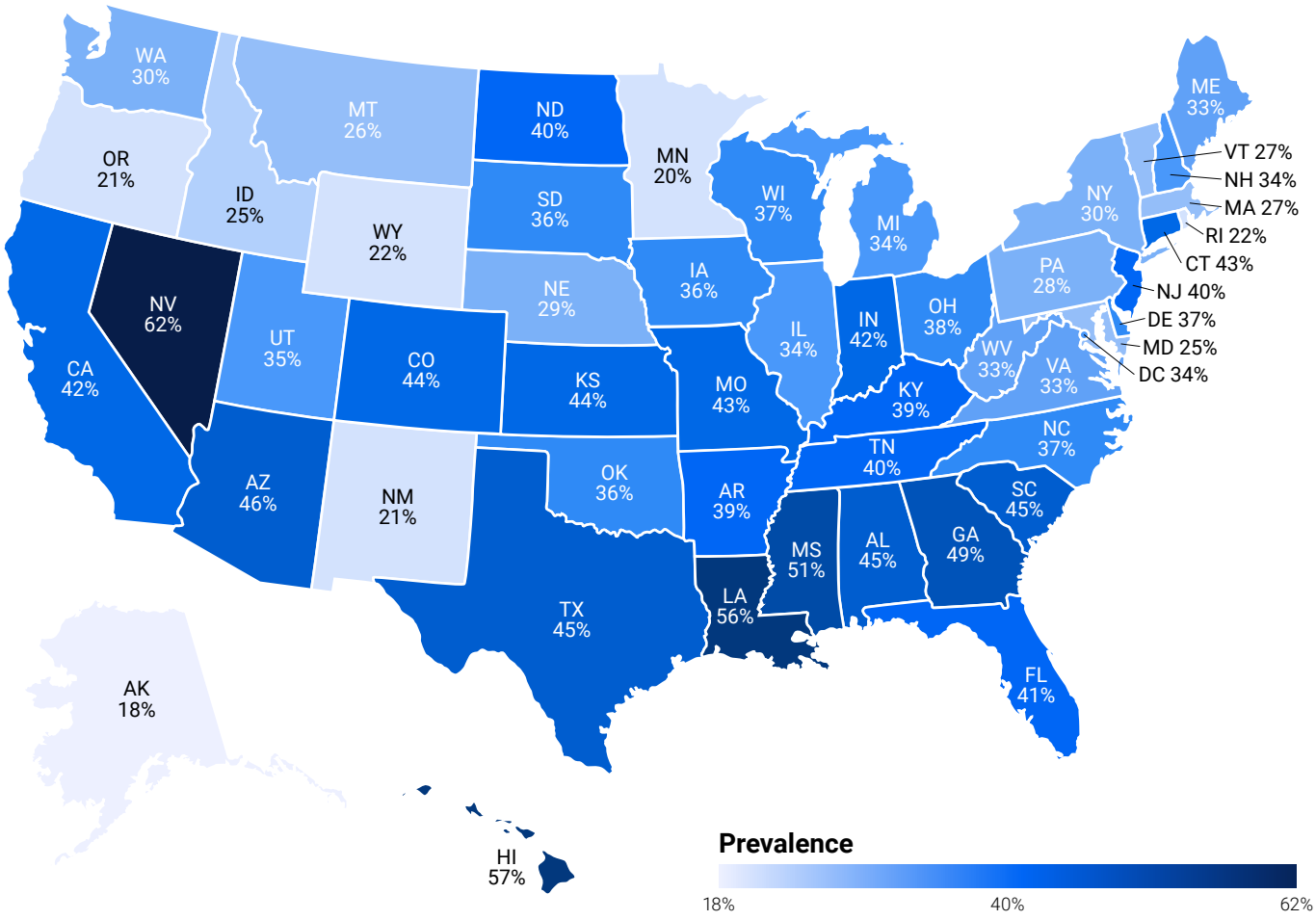
What Are Copay Cards?

- Copay card programs are offered by drug manufacturing companies to **lower OOP costs** for prescription drugs for eligible patients. The copay cards can enable patients to afford the medications preferred by them and their providers.[6]
- Patients with **commercial/private insurance** are eligible to enroll in a copay card program. Copay cards are usually **not need based**.[6]

Why Are Copay Cards Created?

Copay cards are created to **reduce the total OOP pharmacy expense** for the patient. When a copay card is used, the pharmacy benefit plan will then pay some of the cost and then the **manufacturer pays part or all of the member's copay** or coinsurance until maximum value of the copay card is reached.[7]

Prevalence of Copay Card Utilization by State in the Immunology Therapeutic Area, 2019–2021[8]



An assessment of copay card prevalence using IQVIA Longitudinal Access and Adjudication Data from January 1, 2019, to September 30, 2021 (N=4,073,599).

Many copay cards have an expiration date and a savings maximum. The maximum varies by medication and may be applied monthly or annually. There may also be restrictions on the maximum number of times the card can be used.[7]

What Is a Copay Accumulator Program?

Copay Accumulator

A pharmacy benefit program in which a manufacturer's copay assistance funds are **not counted** toward the member's deductible and OOP maximum.[9] Prescriptions are funded by the manufacturer's copay card/coupon **until the maximum value is reached**.[9] After that, OOP costs **start counting** toward a member's annual deductible and OOP maximum.[9]

Example of Member Cost Sharing With and Without an Accumulator Program

Without a copay accumulator

	Expenses covered by $4,000 copay card	Patient OOP	What insurer pays	Amount applied to $7,000 deductible
Jan	$1,000	$0	$0	$1,000
Feb	$1,000	$0	$0	$1,000
Mar	$1,000	$0	$0	$1,000
Apr	$1,000	$0	$0	$1,000
May	Value of copay card is met	$1,000	$0	$1,000
Jun		$1,000	$0	$1,000
Jul		$1,000	$0	$1,000
Aug		$50	$950	Deductible is met
Sep		$50	$950	
Oct		$50	$950	
Nov		$50	$950	
Dec		$50	$950	
Patient OOP: **$3,250**				

With a copay accumulator

	Expenses covered by $4,000 copay card	Patient OOP	What insurer pays	Amount applied to $7,000 deductible
Jan	$1,000	$0	$0	$0 ⚠
Feb	$1,000	$0	$0	$0 ⚠
Mar	$1,000	$0	$0	$0 ⚠
Apr	$1,000	$0	$0	$0 ⚠
May	Value of copay card is met	$1,000	$0	$1,000
Jun		$1,000	$0	$1,000
Jul		$1,000	$0	$1,000
Aug		$1,000	$0	$1,000
Sep		$1,000	$0	$1,000
Oct		$1,000	$0	$1,000
Nov		$1,000	$0	$1,000
Dec		$50	$950	Deductible is met
Patient OOP: **$7,050**				

⚠ Copy card amount not applied to $7,000 deductible.

Manufacturer's assistance (value of copay card) is not applied to the member deductible and OOP maximum.

Considerations

A copay accumulator program **may reduce the plan spend of benefit plan sponsors** but can increase member OOP expenses.

A **copay surprise** is when copay card payments aren't applied to a member's deductible, and when the copay card funding runs out, the **member is now responsible for the cost of medication until their deductible and/or OOP maximum is met**. Medication adherence may be compromised by these unexpected costs.[10]

As of January 2023, 16 states have banned copay accumulators: Arizona, Arkansas, Connecticut, Delaware, Georgia, Illinois, Kentucky, Louisiana, Maine, New York, North Carolina, Oklahoma, Tennessee, Virginia, Washington, and West Virginia, as well as Puerto Rico.[11]

In 2021, 80% of commercially insured beneficiaries were enrolled in plans with copay accumulators available in the plan design. However, only 43% of these beneficiaries are in plans that have proceeded with the implementation of copay accumulators.[9]

What Is a Copay Maximizer Program?

Copay Maximizer (e.g., Variable Copay Program)

A pharmacy benefit program that **excludes manufacturer cost-share assistance** for specialty/nonspecialty products from a member's OOP cost calculation AND **raises member cost share (copay or coinsurance)** on a drug-by-drug basis for specialty/nonspecialty products that have manufacturer copay support programs. The member's cost share is altered to take full advantage of the copay assistance program and ensure the annual limit on a copay assistance program is met; manufacturers' contributions do not count toward the member's OOP maximum, only contributions made by the member count toward the OOP maximum.[9]

Considerations

A copay maximizer program shares a **common goal:** maximize the value of copay assistance programs to reduce costs for benefit plan sponsors, members, and pharmacy benefit managers (PBMs).[9]

Maximizer programs can also generate fees **that can be 25% or more of the value** of a manufacturer's copay support program.[9] A large portion of the funds received from exclusive partners can be retained by PBMs.[9]

A drug manufacturer **may at any time** change their patient assistance program, leading to the ineligibility of members and/or **discontinuation** of maximizer programs that can result in a sudden **increase** in member cost-share responsibilities and may potentially impact medication adherence.

When health plans and PBMs adopt a third-party specialty medication program, patients enrolled are told they will have very low to no copayments for their impacted medications. Typically, if the patient does not want to enroll in the third-party specialty medication program, then the impacted medication would require a coinsurance, between 30% to 70% of the cost.[12]

Example of Member Cost Sharing for Specialty Drugs With and Without Enrollment in a Third-Party Copay Assistance Program Operating as a Maximizer

With Enrolling in a Third-Party Copay Assistance Program	
Specialty drug cost	$1,000 per month
Member copay artificially inflated by the plan	$1,005 per month
Member responsibility after enrolling in assistance program	**$5 per month**
Difference paid to the plan	$1,000

Without Enrolling in a Third-Party Copay Assistance Program	
Specialty drug cost	$1,000 per month
Coinsurance applied	30%
Member responsibility to pay coinsurance	**$300 per month**

Consideration

In comparing the monthly responsibility of $5 vs $300 per month in the example above, the third-party assistance programs places members in a position to enroll.

In 2021, 61% of commercially insured beneficiaries were enrolled in benefit plans that offer copay maximizer programs, with 45% of these beneficiaries in plans that have implemented copay maximizers.[9]

Pharmacy benefit design programs such as accumulators and maximizers have recently been the subject of litigation regarding their use or misuse.[13] As a result, these programs may be scrutinized to ensure improved access for underinsured members.

What Is an Alternative Funding Program?

Alternative Funding Program

A pharmacy benefit program in an employer-sponsored health plan that **partially or fully excludes coverage** for specialty drugs from its prescription drug benefit plan to reduce specialty pharmacy spend.[14]

Exclusion of coverage is achieved by **defining specialty medications as a nonessential** health benefit. Thus, members appear to be uninsured or underinsured.[15]

A pharmacy claim for a carved-out drug would **automatically be denied**.[14] The alternative funding vendor then can help the "uninsured" patient apply for needs-based programs to cover the cost of the prescription excluded by the plan.

Alternative funding programs may decrease the availability of funds to support individuals who are in financial need and can decrease the number of members who receive assistance.[15]

Considerations

Alternative funding programs can be **disruptive to members**.[14] **Onset of therapy may be delayed** since the process of applying for aid and waiting to see if funds are available takes time.[14]

If the member is not eligible for the alternative funding program, then the prescription will be sent back to the health plan for coverage and the drug will be covered like a regular pharmacy benefit, with appropriate patient cost sharing applied.[15]

Several funding programs, including needs-based programs, limit eligibility based on income.[14]

Funding through these alternative programs is **not guaranteed** and is subject to an annual cap.[7] Individual members may not qualify for assistance, eligibility **criteria may evolve** to render previously eligible members as ineligible, or funding may run out while treatment is ongoing.[14]

Alternative funding models may bring risks to patient access, with additional potential impacts on health equity and social determinants of health.[14]

According to a 2021 West Health and Gallup survey, an estimated 18 million Americans reported in June that they were unable to pay for at least one doctor-prescribed medication for their household during the prior 3 months.[16] Alternative funding vendors may contribute to misuse of patient assistance programs and compromise their future viability. In some cases, manufacturers have restricted the use of patient assistance funds when alternative funding programs have been established.

When a member appears to be uninsured or underinsured, alternative funding vendors can utilize needs-based pharmacy assistance from manufacturers or other charitable organizations to cover the cost of the drugs.[17]

What Is International Drug Sourcing?

International Drug Sourcing

International drug sourcing, or "pharmaceutical tourism," refers to **obtaining prescription medicines from countries outside the United States**.[18] With rising drug costs representing one of the most substantial costs to self-funded health plans, benefit plan sponsors are looking for **new and creative ways** to lower their pharmacy spend.

Currently, federal law prohibits the importation of drugs that have not been approved by the U.S. Food and Drug Administration (FDA), including foreign versions of FDA-approved drugs, to help ensure that the domestic drug supply is safe and effective.[15]

However, the FDA does allow for a personal use policy where an individual may be permitted to import an unapproved prescription drug for personal use if:[15]

- The product is not used to treat a serious condition, such as the use of an OTC; or the product is used to treat a serious condition; and
- The product is needed to treat the serious condition and the medication is not available in the United States
- There is no commercialization or promotion of the drug to U.S. residents
- The drug does not represent an unreasonable risk
- The individual importing the drug affirms in writing that the product is for personal use
- The quantity is not more than a 3-month supply; and either:
  1. The consumer provides contact information for the U.S. doctor providing treatment with the drug; or
  2. The consumer provides evidence that the product is for continuation of a treatment begun in a foreign country

As the FDA intended this policy to apply to importation by individuals, not large health plans attempting to lower their prescription drug costs, the importation of prescription drugs by alternative funding programs likely falls outside of what the FDA considers permissible conduct.[15]

Consideration

A drug sourced outside of the United States **does not** have to comply with the same safety, mislabeling, and adverse effects reporting requirements as drugs sourced within the country.[19]

On April 14, 2023, the FDA sent a response to Aimed Alliance's February 2023 letter regarding practices of importing prescription drugs that violate the FDA's policies and federal regulations:[19]

> **"FDA shares your concerns about risks posed by unapproved new drugs and misbranded drugs. Unapproved new drugs do not carry the same assurances of safety and effectiveness as FDA-approved drug products. Drugs that have circumvented regulatory safeguards may be contaminated, counterfeit, contain varying amounts of active ingredients, or contain different ingredients altogether."**
>
> **"We will continue to use our resources to find and take action against those companies that import or offer for import illegal products."**

Medicare Drug Price Reform Under the Inflation Reduction Act

A brief overview of Medicare's Drug Price Reform

The Inflation Reduction Act of 2022 (IRA) included 3 major Medicare reforms aimed at **lowering prescription drug costs**:[20]

- Medicare Part D **benefit redesign**, including a $2,000 annual limit on OOP costs
- **Mandatory rebates** penalizing drug manufacturers for raising prices faster than the rate of inflation
- **Price negotiation** for certain high-priced drugs

Starting in 2025, there will be a new Manufacturer Discount Program requiring **drug manufacturers to pay discounts** on certain brand-name drugs as well as biologics and biosimilars during both the **initial coverage phase** (10% discount) and the **catastrophic phase** (20% discount).[20]

Beginning in 2025, government responsibility in the catastrophic phase of Part D will decrease from **80% to 20%** for most brand-name drugs, biologics, and biosimilars and from **80% to 40%** for generics.[20]

Manufacturers who raise their drug prices faster than the rate of inflation will have to pay a rebate to Medicare.[20]

Medicare will announce the first 10 drugs selected for negotiation by September 1, 2023.[20] The law requires those 10 drugs to be taken from a list of the **highest-spending, brand-name Medicare Part D medications** that have been on the market for a certain period of time and do not have any generic or biosimilar competition.[20] New prices for these 10 selected drugs will be effective in 2026.[20]

Medicare will continue to **expand the program** by selecting 15 more Part D drugs for 2027, 15 more Part B or Part D drugs for 2028, and 20 more Part B/Part D drugs for each subsequent year.[20]

Plan sponsors must cover all selected drugs and make them available to all Medicare Part D plan sponsors at maximum fair price.

Considerations

According to Pharmaceutical Research and Manufacturers of America, the IRA may cause a **decline** in research and development (R&D) spending, **may reduce access** to medicines for Medicare Part B patients, and **lead to potentially fewer** Part D plan options.[21]

Clinical Organizations and Patient Advocacy Programs Speak Out on Benefit Designs That Limit Use of Third-Party Copay Assistance Programs

The American College of Rheumatology (ACR) position statement[22]

- The ACR **opposes insurance company rules** that prevent application of copay assistance funds toward member deductibles and OOP maximum limits.
- The ACR **encourages clear and transparent language** about insurance contracts that restrict patient benefits from copay assistance, in order to inform employers and patients that such programs increase OOP costs for patients.
- The ACR **encourages state and federal legislative protection** for including copay assistance as part of patient deductibles and OOP maximum payments.

American Society of Clinical Oncology (ASCO) position statement[23]

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 & 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 **CMS's Summary of Benefits and Coverage Instruction Guide**.

American Medical Association (AMA) position statement[24]

- To offer additional protections for patients with chronic conditions, the AMA urges CMS to **prohibit insurers' discriminatory copay accumulator policies**.
- Copay accumulator programs **prevent patient access** by denying financial relief from insurmountable cost-sharing obligations.
- These policies also **reduce the value of premiums** paid by patients with chronic conditions by allowing health plans to "double dip" and accept both the copay assistance obtained by the patient and the **additional cost sharing then paid by the patient** before the patient reaches their OOP limits.

National Alliance on Mental Illness (NAMI) position statement[25]

- The proposed rule **does not require** issuers and PBMs to count copay assistance for prescription drugs toward beneficiary deductibles and OOP maximum obligations.
- Without a requirement to count copay assistance toward deductible/OOP obligations, the OOP costs for patients can **significantly increase**.

Coalition of State Rheumatology Organizations (CSRO) position statement[26]

- CSRO supports legislation to **limit the use** of accumulator, maximizer, and alternative funding programs.
- Insurers have a responsibility to **clearly notify patients** of the existence of these programs in their insurance policy.
- CSRO is a member of the All Copays Count Coalition, which works to support state and federal legislation to **ban accumulator adjustment and other like programs**.

High-Deductible Health Plans May Present a Challenge for Members With Chronic Illness

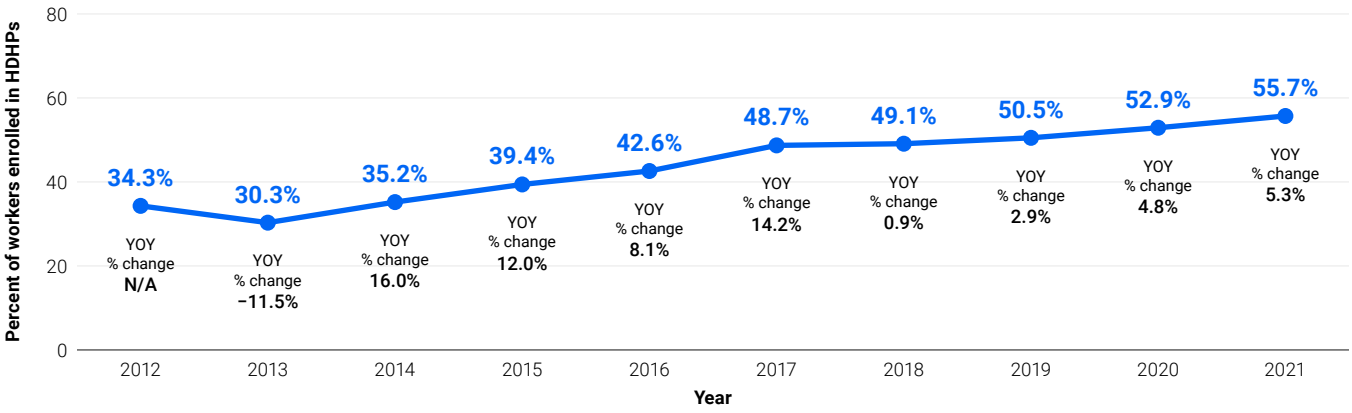
A 2008 phone and mail survey compared rates of delayed or forgone care due to cost in families with chronic conditions enrolled in HDHPs versus those in traditional plans. Adults with chronic conditions in HDHPs (n=205) reported a higher incidence vs those with traditional plans (n=365) for acute care visits (8.2% vs 3.8%, *P*=0.025), emergency department visits (5.3% vs 3.5%, *P*=0.303), chronic care visits (9.3% vs 2.7%, *P*=0.001), checkups (9.3% vs 3.3%, *P*=0.002), and tests (13.2% vs 1.4%, *P*<0.001).[27]

58% of large firms with 200 or more employees offered HDHPs according to the Kaiser Family Foundation's 2021 Employer Health Benefits Survey.[28]

- 22% of firms of all sizes offered HDHPs.[28]
- One in four covered employees in HDHPs have annual deductibles of $3,000 or more.[28]

According to a ValuePenguin analysis of State Health Compare tool data, **HDHPs have continued to grow** as the sole insurance option for more Americans aged 18 to 64 years, from **34.3%** in 2012 to **55.7%** in 2021.[29]

Rate of American Private-Sector Workers Enrolled in HDHPs[29]



Six in ten Americans live with at least one chronic disease.[30]

HDHPs may not be recommended for patients with chronic conditions as patients will need to pay the entire deductible before copays take effect.[29]

Some HDHPs have a combined medical and pharmacy deductible, making drug costs high, potentially impacting a member's ability to fill prescriptions until the deductible is met.

According to a 2021 Kaiser Family Foundation Health Tracking Poll, approximately 23% of adults say they or a family member in their household in the past year has avoided or postponed filling prescriptions due to cost.[3]

Considerations

According to the Internal Revenue Service, in 2023 an HDHP must have a deductible of at least $1,500 for individuals and $3,000 for families.[31]

HDHPs have higher deductibles than LDHPs, but they can be **more affordable** in terms of premiums. In general, HDHPs have lower monthly premiums than LDHPs.[32]

HDHP members take on a **greater financial risk if they incur major healthcare expenses**, which would result in higher OOP expenses.[33]

HDHP=high-deductible health plan; LDHP=low-deductible health plan; N/A=not applicable; YOY=year over year.

CASE STUDY

Impact of HDHP on Pharmacy Fill Rates[34]

Challenge

- Higher cost sharing appears to have caused patients with mental health disorders to **prioritize some services** over others.
- The prevalence of MDD, anxiety, and ADHD has been **increasing**. Between 2013 and 2019, the **percentage of the population increased** for individuals with MDD (4.1% to 5.3%), anxiety (4.8% to 8.1%), and ADHD (2.3% to 2.8%).

Intervention

The Employee Benefit Research Institute (EBRI) evaluated **the impact of HDHPs on healthcare utilization** among individuals with mental health disorders:

- EBRI conducted a search of medical claims related to 13 mental health conditions (anxiety, MDD, ADHDs, bipolar and manic disorders, post-traumatic stress disorder, phobias, autism, obsessive-compulsive disorder, eating disorders, schizophrenia, dissociative disorders, delusional disorders, and other behavioral/mental health disorders) and examined the **impact of switching from a PPO to an HDHP** on healthcare utilization and spend.
- Members who switched from a PPO to an HDHP were matched 1:1 with members who remained on a PPO using a propensity score model.
- Three cohorts were analyzed: individuals with anxiety (ages 18-64), MDD (ages 18-64), and ADHD (ages 5-24).
- **EBRI analyzed healthcare utilization and spend across several categories**, such as inpatient hospital days, emergency department visits, physician office visits, and prescription drug fills as well as total employer costs and total member costs.

Results

Members who switched to an HDHP were **less likely to utilize healthcare services**, including prescription fills, and increased their total healthcare spending compared to those who did not switch:

- Members who switched to an HDHP were less likely to fill a prescription for a sedative/benzodiazepine, hypnotic/anxiolytic, or antidepressant (depression −6%, −6%, −7%, $P<0.01$; anxiety −10%, −7%, −7%, $P<0.01$, respectively).
- Overall, members who switched to an HDHP filled fewer prescriptions per 100 plan members (depression −69, $P<0.01$; anxiety −48, $P<0.01$; ADHD −97, $P<0.01$) than those who did not switch.
- Members who switched to an HDHP had fewer primary care physician office visits per 100 plan members (depression −29, $P<0.01$; anxiety −37, $P<0.01$; ADHD −37, $P<0.01$).
- Yet, those who switched **spent more money on healthcare services** annually (depression $326, $P<0.01$; anxiety $321, $P<0.01$; ADHD $281, $P<0.01$).

Considerations

- Members with **chronic disease and who are enrolled in HDHPs** may be likely to go without care due to cost and/or face **financial burdens**, such as trouble paying bills, than families enrolled in traditional plans.[29]
- Enrollment in an HDHP combined with a savings account may lead to **increases in OOP spending**.[35]

Policymakers should consider allowing enhanced coverage for healthcare services for members with chronic health conditions.

Benefit plan sponsors should review their plan benefit designs to determine the potential impacts on OOP costs for their members.

ADHD=attention-deficit hyperactivity disorder; MDD=major depressive disorder; PPO=preferred provider organization.

What Next Steps Can I Take to Support My Members?

Review your current benefit plan designs to enhance value and address obstacles that may limit member access:

1. Make sure you are familiar with the current pharmacy benefit plan design and its impact on your population.
2. Based on your member's utilization, evaluate your existing benefit plan design and determine if changes are necessary to support adherence to treatment plans.
3. Partner with your benefit design vendors to develop a pharmacy plan that is affordable and comprehensive.

What should I do if I am a patient?[12]

- Know that you may be required to **pay more than you originally anticipated** to reach your deductible and annual OOP limit.
- Understand your plan materials in the event you experience **nonmedical switching**, a practice where you may essentially be notified that you have to be switched from your medications for financial reasons rather than medical.

What should I do if I am a provider?[12]

- Understand how these programs work, as patients are **more likely to contact your office** when they experience push-back from health plans or PBMs.
- Encourage patients to **review the terms and conditions** of the specialty medication program their health plan is partnering with.
- Encourage the patient or caregiver to **call the pharmacy benefit plan** to discuss any proposed switch and why the patient is entitled to their medication for the entirety of the plan year.

Taking these steps may help ensure members can access their treatment without being required to file any additional exception paperwork.

AbbVie's Employer Strategies Focus on Improving Workforce Health and Productivity by Addressing:

Disease State Awareness

Raising awareness of the burden and impact of disease

Access to Treatment

Establishing and expanding access to treatment

Engagement and Educational Support

Developing connections to promote engagement and educational support

For additional information and support, contact your AbbVie Account Executive.

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