Impact of Copays on Vulnerable Populations

Although prescription drug spending growth has slowed in recent years, increasing just 8.2% in 2004, double-digit increases over the past 10 years have led many private health insurance plans to substantially increase prescription drug cost sharing.[1] Between 2001 and 2005, mean copays for generic drugs increased 43%, from $7 to $10; copays for preferred brand-name drugs rose 69%, from $13 to $22, whereas those for nonpreferred branded drugs rose 106%, from $17 to $35. In 2005, 89% of employees with insurance had some cost-sharing formula for prescription drugs, with 74% in plans with 3- or 4-tiered benefits.[2]

As a result, the Center for Studying Health System Change reports that more Americans, particularly those with chronic conditions, are going without necessary prescription drugs because of cost issues.[3] Additionally, a Kaiser Family Foundation survey found that 37% of those without insurance reported that they did not fill a prescription because of cost compared with 13% of those with insurance.[4]

The rationale for increased cost sharing of drugs with patients is to deter the use of drug therapies that do little to improve health or to pay for the higher costs of drugs individuals choose to take.[5] This rests on the assumption that individuals have the capacity to pay for essential drugs; will make rational, informed choices; and will prudently evaluate long-term consequences versus short-term costs.[5] This is not always the case, particularly among vulnerable populations (eg, the economically challenged, ethnic minorities, and the uninsured).[5]

Impact of Copays on Vulnerable Populations

Data attesting to the impact that even a small increase in copays can have on vulnerable populations' abilities to fill prescription drugs are significant, and show that cost affects both utilization and patient health. For example, Goldman et al retrospectively reviewed pharmacy claims from 1997 to 2000 from 30 employers and 52 health plans, linking claims with health plan benefit designs. Researchers found that doubling copay amounts led to a reduction in the use of drugs in 8 therapeutic classes, with the largest decreases occurring in nonsteroidal anti-inflammatories (45%) and antihistamines (44%); decreases found for other drug classes included cholesterol-lowering medications (34%), antiulcerants (33%), asthma medications (32%), antihypertensives (26%), antidepressants (26%), and diabetes medications (25%).[6]

Although they found a reduction in drug use in patients with diagnosed chronic disorders, that reduction seemed to come at the expense of other medications. For example, overall use of antidepressants decreased 26%, but by only 8% among those diagnosed with depression. Yet, the use of all other medications among those with depression decreased 25%. One possible explanation, the authors note, is that these patients used cost savings from other prescriptions to offset higher copays for antidepressants. The study authors also found evidence of increased emergency department (ED) visits and longer inpatient stays for patients with diabetes, asthma, and gastric acid disorder with higher copays. Although the results from this study are valid, it is important to note that the study used predictive modeling to examine the impact of higher copays on medical service utilization. So these are modeled effects.[6]

Cost sharing has an effect on vulnerable populations, even in countries with national

health insurance. In 1996, the Canadian province of Quebec legislated prescription drug insurance for all residents, implementing a deductible and a 25% coinsurance charge for the poor and elderly who had been receiving free medications. At the time, these populations used at least twice as many essential drugs (those necessary to maintain or improve health) as less essential drugs.[7]

Once the poor and elderly had to pay a share of their drug costs, however, their total number of drugs used on a daily basis decreased by 9.14% and 15.94%, respectively, with similar reductions for essential drugs. At the same time, the rate of adverse events in the elderly who reduced essential drug use increased from 5.8 to 12.6 events per 10 000 person-months, a net increase of 6.8 adverse events. There was also a significant increase of 12.9 (from 14.7 to 27.6) in adverse events in those patients who received welfare. The rate of ED visits related to patient reduction of the use of essential drugs also increased by 14.2 events per 10 000 person-months in the elderly and by 54.2 among patients receiving welfare.[7]

In an observational study of an intervention group of 20 326 children and a comparison group of 15 776 children aged 18 years or younger with attention-deficit/hyperactivity disorder (ADHD), Huskamp et al found that implementing a 3-tier formulary led to a 17% reduction in the monthly probability of medication use and a 20% decrease in expected total medication expenditures. There was also substantial cost shifting of copays from the health plan to the families. Children in the intervention group who were previously taking medications were more likely to take a drug in a different tier after switching to the 3-tier formulary than the comparison group. Increased copays associated with switching to the 3-tier formulary in this example resulted in lower total ADHD medication spending, a significant decrease in the probability of using these medications, and increases in out-of-pocket costs for families of children with ADHD.[8]

Roblin et al compared 12-month data on 13 110 episodes of oral antidiabetic drug use for members of 5 managed care organizations that increased cost sharing with data on 13 110 such episodes from a comparison group that did not experience a cost increase. They found that members with more than a $10 cost-sharing increase filled 18.5% fewer oral hypoglycemic drug prescriptions (as measured by average daily dose of medication) 6 months after the copay increase.[9]

In another study evaluating the use of medication in patients with diabetes, Piette et al surveyed 875 adults taking oral hypoglycemic drugs about their decision to underuse their prescribed drugs due to financial issues. Nineteen percent of those surveyed reported a reduction in the use of all medications in the previous year due to cost issues, with 11% reducing their use of diabetes medications. Seven percent of those surveyed said they reduced their use of diabetes medications at least once per month; 28% said they had gone without food or other essentials to pay for medications; 14% said they increased credit card debt to pay for prescription drugs; and 10% borrowed money from family or friends. Few patients reported that their healthcare provider helped them address these cost issues.[10]

In a study from the Veterans Administration on patients with schizophrenia, even a modest increase in the copayment amount (from $2 to $7) decreased psychotropic medication use among minorities, who reduced the use of psychotropic medication by 14.5% to 26.8%, leading to increased hospitalization rates of 3.6% to 8.5%.[11] In contrast, white patients experienced little change in hospitalization despite a 12.5% reduction in prescription fills.

Impact of Copays on Vulnerable Medicaid Beneficiaries

With state Medicaid spending increasing more than 18% between 1997 and 2000, most states implemented a variety of policies to limit the use of expensive or risky medications. These include increased cost sharing for beneficiaries, preferred drug lists, prior authorization, "fail first" policies, and drug category reimbursement exclusions.[12]

The few available studies on the impact of these changes report that requiring prior authorization of an effective, high-cost drug with few alternatives nearly eliminates the use of that drug and most likely has a negative effect on appropriate care.[12] Other stud-

ies find that drug category exclusions can lead to substitution of both proved and unproved therapies without reducing overall medication use or spending.[12] Meanwhile, research finds that Medicaid beneficiaries residing in states that do not require copays fill 5 more prescriptions annually than those living in states that require copays, even though most Medicaid copays are very small ($0.50-$3.00). Overall, Medicaid copays reduce annual drug use by 15.5%.[13]

Impact of Adherence on Cost and Outcomes

Although a reduction in the use of prescription medications might initially seem a boon to healthcare plans struggling with increased costs, it may also represent patient nonadherence to treatment recommendations. This could have unintended consequences for employers and private and public health plans, because greater adherence to treatment recommendations in chronic illnesses is associated with lower nondrug medical costs.

In New Hampshire, when noninstitutionalized patients with schizophrenia who were covered by Medicaid were limited to 3 prescriptions per patient per month for 11 months in the early 1980s, rates of ED visits and community health center services significantly increased. Compared with New Jersey Medicaid medical claims for the same period (which had no restrictions), the New Hampshire group experienced significant savings in drug costs, but those savings were offset by increased medical costs. Overall, every $1 in drug cost savings resulted in $17 more medical expenses elsewhere, in addition to pain and suffering experienced by the individuals and their caregivers.[14]

Sokol et al examined 4 chronic conditions that are major drivers of health spending: diabetes, hypertension, hyperlipidemia, and congestive heart failure. They measured disease-related and all-cause medical costs, drug costs, and hospitalization risk, then modeled them at varying levels of medication adherence (ie, how well patients followed prescribed guidelines for taking their medicine).[15] They found high levels of medication adherence associated with lower disease-related medical costs for diabetes and hypercholesterolemia, with higher drug costs being offset by medical cost reductions. For diabetes, hypercholesterolemia, and hypertension, the greatest adherence to medication led to offset costs for all-cause medical costs. Hospitalization rates for all 4 conditions were significantly lower for patients with high medication adherence.[15]

Regarding mental health, Weiden and Olfson found that the cost of nonadherence to medication therapy in schizophrenia was about $705 million over 2 years.[16] Meanwhile, a review of 16 published studies on medication adherence by those with mental health disorders found that poor adherence or nonadherence to pharmaceutical therapy tends to lead to more frequent relapses, more intense symptoms, and longer inpatient stays, putting increasing clinical and economic burdens on the healthcare system and caregivers.[17]

Gilmer et al evaluated Medicaid eligibility and claims data from 1998 to 2000 for San Diego County, California. Using pharmacy records to assess adherence to treatment with antipsychotic medication, they found annual rates of psychiatric hospitalization to be 14% for those adherent with medication, compared with rates of 35% for those who were nonadherent. They also found lower rates of medical hospitalization of 7% and 13%, respectively, for adherent versus nonadherent patients.[18]

Finally, Rosen et al evaluated the effect of making angiotensin-converting enzyme (ACE) inhibitors available to Medicare beneficiaries with no copays, a plan similar to the value-based insurance proposal outlined in the employer perspective section elsewhere in this supplement. Other studies showed ACE inhibitors were significantly underused, with prescription copays being 1 barrier to their use. Rosen et al found first-dollar coverage of ACE inhibitors not only saved lives, but reduced Medicare costs about $1606 per beneficiary and increased quality-adjusted life-year by 0.23. Results were similar even when the model was adjusted to account for the coverage under the new Medicare drug benefit, Medicare Part D.[19]

Dual Eligibles and Mental Illness

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003

provided for a change in outpatient prescription drug benefit, known as Medicare Part D. Although the implementation of drug coverage under Medicare Part D in January 2006 may mean greater access to medication for many Medicare beneficiaries, it may have unintended consequences for the 6.1-million dual eligibles, individuals who are enrolled in both Medicare and Medicaid, who previously received drug coverage through state Medicaid programs. This vulnerable population is more than twice as likely to have fair or poor health as other Medicare beneficiaries (52% vs 24%, respectively).[20]

Consequences may be particularly severe for those with mental health conditions. Because Medicare has had a very limited mental health benefit, there is no parity between mental and physical health benefits. The current Medicare benefit allows 190 days of psychiatric inpatient care for mental disease during a patient's lifetime, and an outpatient coinsurance of 50%.[21]

Thus, Medicare pays for about 7% of mental health and substance abuse spending, compared with 17% of total healthcare spending. Overall, 3% of Medicare dollars are spent on mental health and substance abuse services compared with 4% of private insurance and 12% of Medicaid dollars.[21]

Yet, about 25% of elderly patients and 50% of disabled Medicare beneficiaries used 1 or more psychotropic drugs in 2002.[21] Beneficiaries with mental illness have increased overall drug costs, with dual eligibles costing an average of $1408 each for medications in 2002.[21] They also have increased drug costs overall because of the presence of comorbidities. Studies find increased rates of chronic diseases, such as hypertension, diabetes, congestive heart failure, and osteoarthritis, among those with depression, and at least 1 comorbidity among those with schizophrenia, including hypertension.[22,23]

Among the possible implications of Medicare Part D on this vulnerable population:

- The law excludes coverage for benzodiazepines, a drug important to dual eligibles.[24] Abrupt discontinuation of benzodiazepines may have an adverse effect, possibly leading to withdrawal reactions, seizures, and ED visits.[25]
- All noninstitutionalized beneficiaries must participate in some cost sharing; thus, some dual eligibles may find themselves paying more for medications than with Medicaid.[24] Cost sharing for dual eligibles is to be limited to nominal copays of $1 to $3 and can be waived. However, in patients who require multiple medications, the higher cost-sharing requirements of Medicare Part D can be a financial burden, thereby forcing these patients to be selective in which illnesses they treat.
- Although about 50% of the cost of antipsychotics and antidepressants has moved to Medicare Part D, the cost of most mental healthcare remains with Medicaid, adding to an already fragmented system, with as many as 5 payers for mental health services: local government, state government, Medicaid, Medicare, and Part D of Medicare.[26] Also, most Medicaid programs have elected to continue coverage for benzodiazepines, further fragmenting care.[21]
- Medicare Part D permits more access restrictions, allowing for pharmacy utilization management measures, such as prior authorization, step therapy, and quantity limits for psychotropic drugs to control drug expenditures and ensure appropriate use of medications.[21] Although the Centers for Medicare & Medicaid Services (CMS) has specifically asked that such restrictions not be placed on psychotropic drugs,[27] it is up to the individual prescription drug plan whether or not to implement them.
- The aggressive management of formularies permitted under the Medicare prescription drug law could, and probably will, restrict access to medications. The law also allows prescription drug plans to deny coverage for off-label uses of medications that are currently covered by Medicaid.[28]
- Dual eligibles who have been unresponsive to previously available medications could be affected by not having access to newly approved drugs, because plans are permitted substantial time before considering a new medication for its formulary.[28]
- If drugs are withheld because beneficiaries are unable to pay their copay, it could interrupt treatment regimens and increase adverse events.[28]

Conclusion

In conclusion, information based on health outcome studies,[29,30] Medicaid sector studies, CMS guidance regarding antipsychotic drug classes, and the effects of copays on vulnerable populations suggest that access without impediment by financial barriers is critically important for vulnerable, high-risk patient populations. Pursuing alternatives to restricting access can help achieve clinical and economic goals.[29,30]

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