Prescription Drug Cost Sharing

Associations With Medication and Medical Utilization and Spending and Health

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Context Prescription drugs are instrumental to managing and preventing chronic disease. Recent changes in US prescription drug cost sharing could affect access to them.

Objective To synthesize published evidence on the associations among cost-sharing features of prescription drug benefits and use of prescription drugs, use of nonpharmaceutical services, and health outcomes.

Data Sources We searched PubMed for studies published in English between 1985 and 2006.

Study Selection and Data Extraction Among 923 articles found in the search, we identified 132 articles examining the associations between prescription drug plan cost-containment measures, including co-payments, tiering, or coinsurance (n=65), pharmacy benefit caps or monthly prescription limits (n=11), formulary restrictions (n=41), and reference pricing (n=16), and salient outcomes, including pharmacy utilization and spending, medical care utilization and spending, and health outcomes.

Results Increased cost sharing is associated with lower rates of drug treatment, worse adherence among existing users, and more frequent discontinuation of therapy. For each 10% increase in cost sharing, prescription drug spending decreases by 2% to 6%, depending on class of drug and condition of the patient. The reduction in use associated with a benefit cap, which limits either the coverage amount or the number of covered prescriptions, is consistent with other cost-sharing features. For some chronic conditions, higher cost sharing is associated with increased use of medical services, at least for patients with congestive heart failure, lipid disorders, diabetes, and schizophrenia. While low-income groups may be more sensitive to increased cost sharing, there is little evidence to support this contention.

Conclusions Pharmacy benefit design represents an important public health tool for improving patient treatment and adherence. While increased cost sharing is highly correlated with reductions in pharmacy use, the long-term consequences of benefit changes on health are still uncertain.

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MEDICAL PRACTICE IN THE United States has changed dramatically in the last several decades, including an increase in use of prescription drugs. More and better-quality drugs are available to prevent and manage chronic illness, and these drugs reduce mortality, forestall complications, and make patients more productive.[1] Thus, access to outpatient drugs is now a cornerstone of an efficient health care system.

But with recent increases in pharmacy spending, pharmacy benefit managers and health plans have adopted benefit changes designed to reduce pharmaceutical use or steer patients to less-expensive alternatives. The rapid proliferation of mail-order pharmacies, mandatory generic substitution, coinsurance plans, and multitiered formularies has transformed the benefit landscape. In this review, we analyze how the salient cost-sharing features of prescription drug benefits may affect access to prescription drugs and synthesize what is known about how these features may affect medical spending and health outcomes.

Most beneficiaries are now covered by incentive-based formularies in which drugs are assigned to one of several tiers based on their cost to the health plan, the number of close substitutes, and other factors.[2] For example, generics, preferred brands, and nonpreferred brands might have co-payments of $5, $15, and $35, respectively. In contrast, plans may require beneficiaries to pay coinsurance—ie, a percentage of the total cost of the dispensed prescription. The purpose of tiered co-payments and coinsurance is to give beneficiaries an incentive to use generic or low-cost brand-name medications and to encourage manufacturers to offer price discounts in exchange for inclusion of their brand-name products in a preferred tier. By 2005, most workers with employer-sponsored coverage (74%) were enrolled in plans with 3 or more tiers, nearly 3 times the rate in 2000 (27%).[3]

Some plans also impose benefit caps that limit either the coverage amount or the number of covered prescriptions. For example, the standard Medicare Part D benefit offers beneficiaries coverage of up to $2400 in spending in 2007, at which point coverage stops until beneficiaries reach a catastrophic cap

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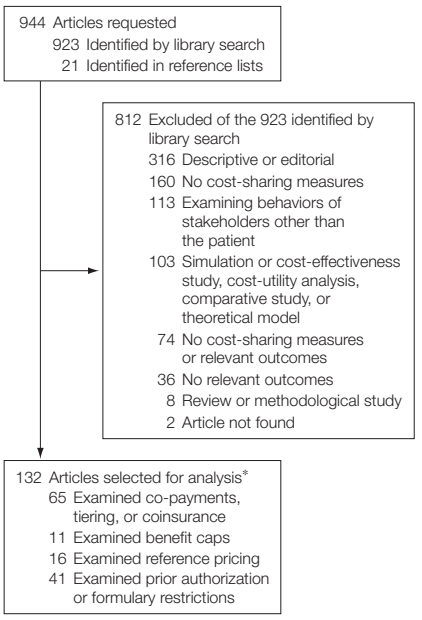
Figure. Study Design



*One article examines the effects of both co-payments and benefit caps.

($5451). Once the catastrophic cap is reached, coverage resumes with minimal cost sharing. Prior to the introduction of Part D, benefit caps—without this catastrophic limit—were a standard feature of Medicare + Choice plans (now known as Medicare Advantage) and some retiree plans. As of 2002, 94% of Medicare + Choice plans that covered branded drugs had an annual dollar cap ranging from $750 to $2000 per year.[4] Analogous policies used by state Medicaid programs place limits on the number of prescriptions dispensed per patient per month. Because benefit caps represent an extreme version of cost sharing—patients who reach them must pay all additional pharmacy costs out of pocket—and their central role in Part D, we include them in our review.

Additional cost-saving measures include prior authorization (requiring permission before certain drugs can be dispensed), step therapy (requiring use of lower-cost medications before providing coverage for more expensive alternatives), closed formularies, mandatory generic substitution, and reference pricing (a cap on the amount a plan will pay for a prescription within a specific therapeutic class). There is a growing literature on each of these cost-containment measures.

METHODS

We conducted electronic searches of PubMed for studies published in English between 1985 and 2006. The primary search was based on combinations of 2 sets of key words. The first set included various terms for drug cost sharing: *cost-sharing*, *incentive-based*, *copay*, *coinsurance*, *tiered benefit*, *benefit cap*, *patient charge/fee*, *user charge/fee*, *prescription charge/fee*, *step therapy*, *reference pricing*, *prior authorization*, *formulary*, *formulary restriction*, *formulary limit*, *closed formulary*, *open formulary*, and *generic only*. The second set included *drug spending*, *drug cost*, *prescription drug*, *medication*, and *pharmacy benefit*. Articles that contained at least 1 term were included. We performed another search specifically for Medicaid-related drug cost sharing measures by combining one of the terms *access restriction*, *drug/prescription/reimbursement limit*, or *preferred drug list* with *Medicaid* and with one of the terms *spending*, *use*, or *cost*. We excluded issue briefs, comments, letters, editorials, essays, articles without author names, and reviews. This process yielded 923 studies. We then screened these studies based on titles, abstracts, and, in a few cases, the full text, as described in the FIGURE.

A study was included in this review if (1) the article was published in a peer-reviewed journal; (2) it examined the effects of cost sharing (co-payments, tiers, coinsurance, reference pricing, formulary restrictions, or benefit caps) on at least 1 of the relevant outcomes (prescription drug utilization or spending, medical utilization or spending, or health outcomes); and (3) it analyzed primary or secondary data (to exclude simulations).

Among the 923 studies, 111 met these criteria. An additional 21 studies were added based on reference lists, resulting in 132 studies for final analysis. Sixty-five studies examined co-payments, tiers, or coinsurance[5-69]; 11 examined benefit caps[4,43,70-78]; 41 examined formulary restrictions[79-119]; and 16 examined reference pricing.[120-135] (One study examined both co-payments and benefit caps.[43])

Because the majority of these studies analyzed observational data, understanding how the associations between cost sharing and the outcomes of interest were measured is important. We classified study designs as follows:

- (Aggregated) time series: analyzed changes over time in data aggregated at the geographic or plan level, with the data spanning a period when benefits changed
- Cross-sectional: analyzed individual-level data at a single time point for multiple benefit designs—for example, across health plans
- Repeated cross-sectional: analyzed cross-sectional data from multiple time periods
- Longitudinal: analyzed individual-level data with repeated observations for the same beneficiaries over time
- Before-and-after: compared outcomes at 2 points in time, before and after a benefit change
- Randomized trial

The literature on cost sharing is much more diffuse than many medical interventions, which benefit from clear delineation of primary and secondary clinical end points. For example, some articles examine pharmaceutical spending, while others observe utilization. And, among the latter, utilization is measured in at least 5 different ways: medication possession ratio, proportion of days covered, cumulative multiple-refill gap, number of prescriptions, and aggregate days supplied. This problem is further exacerbated by the wide range of "treatments"—eg, adding a second or third tier, raising co-payments, requiring coinsurance—and treated populations with very different diseases. The result is tremendous heterogeneity in benefit changes, the way results are re-