

THE CASE FOR A MEDICARE DRUG COVERAGE BENEFIT: A Critical Review of the Empirical Evidence

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■ **Abstract** The lack of an outpatient prescription drug benefit under Medicare has become a conspicuous omission in the face of accelerated growth in prescription drug expenditures and increased availability of highly effective medications. This article provides a critical review of the empirical evidence on the effect of drug coverage on the use of prescription drugs, health care outcomes, and health care costs among Medicare beneficiaries. The existing literature provides considerable evidence that drug coverage is associated with greater use of all drugs and clinically essential medications and that not all forms of coverage provide the same protection. Longitudinal evidence from elderly and disabled persons in Medicaid indicates that restricting coverage has serious adverse health outcomes for sick and low-income beneficiaries that actually lead to increased health care costs.

INTRODUCTION

Prescription drugs, when used appropriately, are effective in the treatment of many acute and chronic medical conditions. However, because Medicare does not include an outpatient prescription drug benefit, the prescription drug coverage market for Medicare beneficiaries is a patchwork of public and private policies with varying levels of coverage and eligibility requirements. Many near-poor and low-income beneficiaries (100%–200% of poverty) may be particularly vulnerable to underuse of essential drugs because they are simultaneously more likely to be sick, less likely to have employer-sponsored coverage, and not poor enough to qualify for Medicaid (37, 44). Even beneficiaries who have prescription drug coverage sometimes face high copayments and other limitations that restrict the appropriate use of prescription drugs (36, 41–43, 45).

Accelerated growth in prescription drug expenditures and increased availability of highly effective medications have led to renewed calls for a prescription drug benefit under Medicare. The ill-fated 1988 Medicare Catastrophic Coverage Act would have provided partial drug coverage to beneficiaries once they exceeded an annual deductible of \$600 (40). However, disagreements over who should pay, who would benefit, and how much the Medicare Catastrophic Coverage Act would cost resulted in its immediate repeal (48). Today, there is still much we do not understand about the relationships between drug coverage, drug use, health outcomes, and overall health care costs. However, the generally accepted hypothesis is that a Medicare drug coverage benefit will increase access to prescription drugs and thus improve health. The purpose of this article is to critically assess the existing literature on the effect of drug coverage on drug utilization, health outcomes, and health care costs in the Medicare population.

METHODS

We used Medline and a manual search of citations to identify studies of drug coverage and use in the Medicare population conducted between 1980 and 2000. Our Medline search terms included combinations of the following: Medicare; insurance; pharmaceutical services; prescription drug utilization; prescription drugs; physician practice patterns; elderly; disabled; and cost-sharing. We included all published literature and widely distributed unpublished reports of prescription drug coverage and prescription drug use in the elderly, disabled, and end stage renal disease patients. We did not include studies if they did not explicitly estimate the effect of coverage or insurance on drug use or if less than 40% of the sample was likely to be Medicare eligible.

We used previously employed criteria to assess the validity of study findings. Specifically, we considered the validity of the overall research design, the appropriateness of the study population, data quality and availability, the reliability of measures of utilization (3), and the adequacy of statistical analysis (46). Compared with randomized controlled trials, quasi-experimental designs are the second best option for estimating the effect of drug coverage on use and health. These studies can be further categorized into three groups: (a) well-controlled, (b) partially controlled, or (c) cross-sectional analytic studies. Well-controlled studies include time-series designs, which examine the effect of a change in coverage on simultaneous changes in utilization trends by examining utilization before, during, and after the change, preferably using a similar time series in a comparison group that did not change coverage. Partially controlled studies include repeated measures and pre/post designs with comparison groups. Cross-sectional analytic studies (i.e. one-shot surveys or studies using data collected only after a policy change) use multivariate analyses to estimate the association between drug coverage and the outcomes of interest at a given point in time, controlling for other factors. Valid causal inferences cannot be drawn from cross-sectional analytic studies, and all

nonrandomized studies are subject to potential selection bias (i.e. those with and without drug coverage have characteristics that make them noncomparable).

Predictably, the quality of these studies is limited by data quality and availability. Frequently, data on prior utilization are unavailable for those without coverage [e.g. previously uninsured individuals who enroll in a state pharmaceutical assistance program (PAP)]. Even with data on prior utilization, we cannot be sure whether differences in utilization after the coverage change are due to the presence of coverage itself or to other factors, such as deteriorating health or concurrent policy changes.

RESULTS

Overview of Reviewed Studies

We identified 35 published studies, one unpublished study, and one literature review on the relationships between drug coverage, drug use, and health outcomes among the elderly and disabled. Of the identified studies, 12 were descriptive (i.e. they provided cross tabulations of drug utilization statistics by drug coverage, income, race, health status, and various other characteristics). Although these descriptive presentations are useful for identifying patterns of use, they ignore the relationships between these various factors and can lead to spurious conclusions. Among the remaining 23 studies estimating the effect of insurance or coverage on use and health, we identified six that were well controlled and 17 cross-sectional studies. As we present the available evidence, we distinguish between studies using the various research designs and provide detail only for the most valid evidence on each topic.

Prescription Drug Consumption in the Medicare Population

Prescription drugs are currently the fastest growing component of national health expenditures (24). This increase in drug costs has been attributed to increases in the use of all prescription drugs, particularly newer and more expensive drugs (7, 24). One third of all prescription drug expenditures in the United States are attributable to people over age 65 (27).

In 1996, 86% of the noninstitutionalized Medicare beneficiaries used at least some prescription drugs during the year [see Health Care Financ. Admin. (13), Section 4: Table 4.17]. Average annual expenditures in 1995 were \$700, and the typical beneficiary filled more than 18 prescriptions; average out-of-pocket expenditures in that same year were \$303 (6). Out-of-pocket costs have risen dramatically during the past 30 years, as only 6.5% of Medicare beneficiaries in 1972 had out-of-pocket costs exceeding one half of their total drug expenditures (38). By 1999, average out-of-pocket expenditures had increased to about \$410 per year, or nearly half of average yearly drug expenditures (10).

In multivariate analyses, medication use among Medicare enrollees increases with income and age, and decreases with high functional and health status

(5, 17, 25, 37, 50). In addition, there is evidence that white beneficiaries are more likely to use prescription drugs than nonwhites and blacks, even when controlling for such factors as health status, income, and education (5, 8, 19). The reasons for these differences have yet to be elucidated. A few cross-sectional studies have found links between insurance status (independent of drug coverage) and drug use (25, 37, 58).

Drug Coverage in the Medicare Population

Medicare beneficiaries can obtain drug coverage through public or private sources. Public sources of drug coverage include Medicaid, the Veterans Administration, the Indian Health Service, PAPs, Medicare HMOs (Medicare + Choice), and local or community programs. Although states are not required to provide drug coverage as part of the standard Medicaid benefit package, 90% of the 6 million dually eligible Medicaid enrollees have drug coverage through this source (57). A small minority of Medicare beneficiaries is eligible to receive drug coverage through the Veterans Administration or the Indian Health Service.

The first state PAPs were introduced in the late 1970s (43). As of April 2000, there were 16 such programs in the United States (57), and 32 states had introduced pharmaceutical assistance legislation (12). State PAPs are generally targeted toward low-income people over age 65, and many include coverage for the young disabled. All the programs request some enrollee cost-sharing but generally provide first-dollar coverage (i.e. no deductible) (11).

Much attention has been given to the withdrawal of HMOs from Medicare + Choice plans. Most Medicare + Choice plans offer supplementary benefits, such as prescription drug coverage to beneficiaries generally without requiring additional premiums for basic packages of services (2). However, because of unanticipated increases in drug expenditures in recent years, these policies have grown more restrictive over time. For example, the percentage of plans with annual drug benefit limits of \$500 or less increased from 21% to 32% between 1999 and 2000 (14).

Former employers and Medigap are the two private sources of drug coverage available to Medicare beneficiaries. Medigap drug coverage is characterized by high copayments (50%), high deductibles (\$250), and benefit caps (\$1250 or \$3000 per year). In contrast, copayment amounts under Medicaid are generally \$1–\$2 per prescription because of federal regulation, although seven states impose caps on the number of reimbursable prescriptions (as few as three) per month. Employer-provided coverage for retirees, although varied, tends to be more generous than Medigap coverage (57).

Using the 1995 Medicare Current Beneficiary Survey (MCBS), Davis et al (6) estimated that 65% of Medicare beneficiaries have some coverage for outpatient prescription drug expenditures. Among those with coverage, 45% have employer-provided coverage, 14% Medigap coverage, 11% Medicare + Choice, 17% Medicaid, and 4% Veterans Administration, state PAP, or other publicly

provided coverage. Others have produced similar estimates of drug coverage using the MCBS (24a, 34, 57).

Unfortunately, Medicare enrollees with the greatest medical need for drug coverage—those with low incomes and fair-to-poor health—are not more likely to have it (1a). For example, although 65% of low-income beneficiaries (<\$10,000) have no drug coverage, less than 30% of high-income beneficiaries (>\$50,000) are lacking drug coverage (24a). In a multivariate study of the determinants of drug coverage in the Medicare population, Lillard et al (25) found that having employer insurance was the most significant predictor of coverage.

These estimates of current levels of drug coverage paint a misleadingly positive picture because they include many who are uncovered for part of the year: almost 19% of beneficiaries. Only 6%–7% of Medicaid enrollees reported being without coverage for part of the year compared with 30% of recipients of Medicare fee-for-service only. Furthermore, those in fair-to-poor health were slightly more likely to have coverage for only part of the year (53). Unfortunately, the duration and frequency of gaps in coverage are unknown. In a retrospective cohort study of four managed care organizations, Rector (35) found that beneficiaries were more likely to switch insurance providers once they exceeded their drug benefit spending limits and that switchers were more likely to be sick. Therefore, many of those who report being without coverage for part of the year may actually be those most in need of full year coverage (32).

The Effect of Coverage on Medication Use

Studies of the effect of coverage on use are generally restricted to cross-sectional analyses. However, there have been a few well-controlled studies of the effects of monthly caps on the number of prescriptions or dollar reimbursements for the elderly and disabled in Medicaid that increase our understanding of the effects of drug coverage on drug utilization. Using time-series research designs, Soumerai et al (41, 42, 45) examined the effect of limiting reimbursable prescriptions in New Hampshire to three prescriptions per month (the cap was replaced with a \$1 copayment 1 year later) on the use of essential drugs by elderly and disabled Medicaid recipients. In one study, the authors used interrupted time series to examine changes in prescription drug use for a group of Medicaid enrollees with a sizable proportion of elderly (46% were receiving old age assistance and 47% had a physical or mental disability). The authors found an immediate and sustained reduction in the number of prescriptions used (46% decrease) among multiple drug recipients during the period of the cap. Both essential (e.g. insulin and cardiac drugs) and nonessential use were affected, and the reduction in prescriptions was not offset by increases in the number of tablets per prescription (41).

In another study, the authors studied the use of essential cardiac drugs, chronic obstructive pulmonary disease (COPD) and asthma medications, insulin, anticonvulsants, and anticoagulants by elderly Medicaid residents in New Hampshire

and New Jersey (the comparison state) before, during, and after the period of the prescription drug cap. Although use of these essential medications was relatively stable and similar in both groups before the cap, the chronically ill elderly in New Hampshire experienced a sudden, sustained 35% ($p < 0.001$) decrease in the use of these essential medications during the period the cap was in effect. This drop was even more pronounced among patients using three or more classes of drugs. Medication use returned to near-baseline levels after the cap was replaced by the \$1 copayment (45).

A subsequent study by Soumerai et al (42) examined the effect of the New Hampshire cap on Medicaid enrollees with schizophrenia, a condition for which appropriate use of psychoactive medication has decreased the need for institutionalization (15, 18). The use of antipsychotics, sedative hypnotic agents, antidepressants, and lithium all dropped significantly during the period the cap was in place. Among regular users of antipsychotic drugs, use decreased 21.2% ($p < 0.001$) during the period of the cap (42).

Four studies examined the effect of copayments on use (16, 30, 36, 54). In a longitudinal interrupted time-series analysis of Medicaid claims by predominantly elderly residents from South Carolina and Tennessee, Nelson et al (30) found a drop in the use of prescription drugs after South Carolina implemented a 50¢ copayment per prescription (from 24.8 to 23 claims per eligible recipient per year), demonstrating the sensitivity of low-income elderly to even modest out-of-pocket payments. In subsequent analyses, the authors found the use of essential drugs, such as cardiac medicines, were also affected by the copayment (36).

In addition to these well-controlled studies, we identified cross-sectional studies that examine the association between drug coverage and drug use in a national sample of Medicare beneficiaries (1, 5, 25, 27, 37), which provide weaker evidence on the effect of drug coverage. Two of the five (1, 5) examined the use of clinically essential drugs, which is a proxy for the appropriateness of use; they also used the most comprehensive source of data available on beneficiary drug use and coverage, the MCBS. We present these results first.

Using the 1995 MCBS, Blustein (5) estimated the association between coverage and the use of antihypertensives¹ by Medicare beneficiaries with hypertension. Not having drug coverage of any kind was associated with an increase in odds of not purchasing any antihypertensive medication (adjusted odds ratio = 1.4, $p = 0.002$). Furthermore, those with drug coverage purchased more tablets than those without coverage, controlling for other factors such as income, education, and health status (460 tablets vs 423 tablets, $p = 0.02$).

In another analysis of hypertensive patients, we found that the association between coverage and use was much weaker for those with Medigap insurance, which is consistent with the high levels of cost-sharing and limited coverage associated with this type of coverage (1, 6, 27, 57). Specifically, we found that beneficiaries

¹Use of these drugs substantially reduces the risk of stroke, myocardial infarction, and death (29).

with state drug coverage had considerably higher total drug utilization compared with those with Medicare fee-for-service only, controlling for socio-demographic and health differences (\$302 vs \$191, $p < 0.05$). Beneficiaries with employer-provided drug coverage had estimated antihypertensive drug utilization of \$280 ($p < 0.01$) compared with \$225 for those with private insurance without drug coverage and \$251 ($p < 0.10$) for those with Medigap drug coverage (1).

Based on data from the 1990 Panel Survey of Income Dynamics, Rogowski et al (37) found that drug coverage provided by private insurance plans was associated with a significant increase in the probability of using any drugs (odds ratio = 1.44; $p < 0.05$). Both private drug coverage and Medicaid were significantly associated with lower out-of-pocket expenditures (private insurance, $p < 0.01$; Medicaid, $p < 0.05$). In a later study, Lillard et al (25) found that compared with people who have Medicare fee-for-service only, those who have private drug coverage had four times the odds of using prescription drugs (adjusted odds ratio = 4.4, $p < 0.05$). However, both studies used eligibility as a proxy for Medicaid enrollment and therefore could not provide reliable estimates of the effect of actual Medicaid coverage on drug use. Using the National Medical Expenditure Survey (NMES) (1987), Long (27) found that beneficiaries with Medigap drug coverage spent up to 26% more out-of-pocket than those with more generous forms of coverage.

In addition to these national studies, there have been several state- and community-level studies of the association between coverage and use (8, 21, 28, 49, 51, 52). The majority of these studies found positive associations between drug coverage and use (8, 49, 51, 52). Of the two dissenting studies, one examined drug use for a group of patients who were newly discharged from a hospital (21) and the other examined the use of benzodiazepine in a clinic setting (28).

Linking Coverage to Health Outcomes

Policy makers are often concerned about the effects of prescription drug coverage and medications on health status and health care costs. In the New Hampshire drug cap studies, Soumerai et al (45) were able to observe a dramatic increase in nursing home admissions for chronically ill elderly persons affected by the cap. In fact, elderly Medicaid enrollees in New Hampshire were almost twice as likely to be admitted to nursing homes during the period of the cap as those in New Jersey (risk ratio = 1.8; 95% confidence interval, 1.2–2.6). In addition, there was a slight trend toward higher rates of hospitalization in the New Hampshire cohort during the period of the cap, but this difference was not statistically significant (RR = 1.2; 95% confidence interval, 0.8–1.6) (45).

The authors found similar results for schizophrenic patients and their use of clinic emergency mental health services and partial hospitalization during the time of the cap. Use of one community mental health center increased 57% during the period of the cap ($p < 0.001$) and decreased to near pre-cap levels after the cap was repealed. At the same community mental health center, use of emergency services increased from no visits to an average of 0.03 services per

patient per month during the cap, then returned to no visits over the study period (42). Evidence from state programs and Medicare HMOs of the effect of drug coverage or copayments on health is unconvincing because of research design limitations (16, 26, 49, 54).

The Effect of Coverage on Health Care Costs

Evidence from the literature suggests that drug coverage increases drug costs (1, 5, 8, 25, 27, 37). Coverage can distort use by protecting beneficiaries from the true marginal cost of medications (59). To balance risk protection against inappropriate use, payers impose various forms of cost-sharing on their enrollees, including copayments and caps on expenditures or the number of drugs used.

The inherent hazard demonstrated by all well-controlled studies is that cost-sharing reduces the use of essential as well as less essential drugs (23, 36, 41, 42, 45). For example, facing a copayment, a patient might prioritize medications for symptom relief (e.g. analgesics) over those used for management of chronic conditions and associated with long-term survival (e.g. antihypertensives) (9, 36). Therefore, limiting coverage can have adverse consequences for health that increase overall health system costs. For example, although Medicaid drug expenditures decreased by about \$5 per person per month among chronically mentally ill in New Hampshire during the period of the drug caps, overall expenditures increased by about \$139 per month (42). Thus, the increase in overall expenditures due to increased use of mental health services exceeded the savings in drug expenditures by a factor of more than 17. Given that many drugs are cost-effective and actually save money when used appropriately (31), increasing access to effective medications can prevent future health care expenditures.

Factors Mediating the Effects of Drug Coverage

The above studies provide strong evidence that drug coverage increases access to prescription drugs and that restricting coverage can lead to decreased use of essential medications and poor health outcomes. However, regardless of their coverage status, patients cannot obtain prescription drugs without the consent of a physician, who may face pressure from patients, plans, payers, and the pharmaceutical industry to prescribe specific drug therapies (22). Furthermore, coverage cannot ensure compliance or the appropriate use of medications, both of which are of particular concern in the elderly (20, 33). Underuse is a conspicuous problem for beneficiaries with asymptomatic chronic illnesses like hypertension (39).

Despite widespread concerns about rationing mechanisms employed in managed care organizations to reduce the use or costs of specific drugs, implicit rationing occurs daily through price. This implicit rationing is compounded by the fact that beneficiaries with drug coverage face lower prices than those without coverage because of volume discounts negotiated with drug manufacturers (4). The Congressional Budget Office (56) estimated that the best price discount for single-source drugs averaged 19%; 9% had discounts of 50% off the wholesale

price. There is evidence that Medicare beneficiaries with employer coverage or state pharmaceutical assistance pay less out-of-pocket per tablet for essential drugs than those without drug coverage (1, 5).

CONCLUSIONS

The strongest evidence from the literature indicates that there is considerable unmet need in the Medicare population for a prescription drug benefit. Evidence from national data sources, the private sector, and state-based programs show that Medicare beneficiaries need and use a disproportionately higher amount of prescription drugs. This medication use is positively associated with higher rates of chronic disease (47), indicating that much of this use is necessary rather than discretionary. Furthermore, although most beneficiaries have some drug coverage, there is considerable variation in the generosity and duration of that coverage, even among public programs. Low-income beneficiaries have the greatest need for prescription drugs but are least likely to have drug coverage. Many policies impose dollar limits on expenditures and therefore do not provide any protection for the elderly and disabled against catastrophic drug costs.

The existing literature provides considerable evidence that drug coverage is associated with greater use of all drugs and clinically essential medications. However, whenever researchers were able to distinguish between different types of coverage or levels of generosity within coverage types, they found that not all coverage provided the same protection. Private Medigap coverage was associated with lower drug use, including use of clinically essential medications, and higher out-of-pocket costs compared with Medicaid, employer, and state drug coverage programs. Although evidence of the link between coverage, health outcomes, and care costs was sparse, the longitudinal analyses in elderly Medicaid populations found that limiting the number of reimbursable prescriptions per month had serious adverse health outcomes for sick and low-income beneficiaries. In some cases, the adverse events caused by the drug cap were irreversible (i.e. nursing home admissions).

DISCUSSION

More well-controlled studies of the effect of drug coverage on use and health outcomes in the Medicare population are needed. There is a particular need for longitudinal analyses of the effect of policy changes on the use of essential medicines and health outcomes. Many studies presented in this review were cross-sectional and therefore could not control for prior drug utilization, which is important for determining causal relationships. In addition, those with and without drug coverage may be dissimilar in ways that make comparisons difficult. Common statistical methods used to account for the influence of covariates may be inadequate. More

in-depth investigations of the link between socio-demographic characteristics and drug use and coverage could further assist policy makers in identifying vulnerable populations and in defining and targeting interventions.

Despite the varying quality of the empirical evidence, the vast majority of the studies provide strong evidence in support of additional coverage for Medicare beneficiaries. The United States is the only industrialized country that does not provide coverage for prescription drugs for the elderly. Given the importance of these therapies for increasing numbers of Medicare beneficiaries with chronic illnesses, the absence of a drug benefit under Medicare has become a conspicuous failure in national health policy, resulting in substantial preventable illness among the most vulnerable elderly. The preponderance of the evidence suggests not only that many Medicare enrollees benefit from drug coverage, but also that failure to provide access to essential drugs may have adverse health and economic consequences for sick and low-income patients.

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