Pharmacy Utilization and the Medicare Modernization Act

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To control expenditures and use medications appropriately, the Medicare drug coverage program has established pharmacy utilization management (PUM) measures. This article assesses the effects of these strategies on the care of seniors. The literature suggests that although caps on drug benefits lower pharmaceutical costs, they may also increase the use of other health care services and hurt health outcomes. Our review raises concerns regarding the potential unintended effects of the Medicare drug program's PUM policies for beneficiaries. Therefore, the economic and clinical impact of PUM measures on seniors should be studied further to help policymakers design better drug benefit plans.

Key Words: Pharmacy utilization management, seniors, cost-sharing mechanisms, administrative restriction tools.

PHARMACY UTILIZATION MANAGEMENT (PUM) measures are used extensively in health care delivery systems throughout the industrialized world (Bloor and Freemantle 1996; Bloor, Maynard, and Freemantle 1996; Freemantle and Bloor 1996). The most widely used strategies are policies that require financial contributions from patients (e.g., copayments, coinsurance, deductibles, and drug benefit caps) and policies that restrict the number and particular kinds of medications prescribed (e.g., formularies and

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prior authorization) (Soumerai et al. 1993; Thomas et al. 2002). The intentions and benefits for such policies are to control expenditures on drugs and to improve their efficiency by reducing inappropriate prescriptions, overutilization, and iatrogenic risks (Levy 1992; Soumerai et al. 1993). PUM initiatives may also, however, limit patients' access to needed medications and promote the use of medications that are less effective or more likely to cause adverse events. From an economic perspective, therefore, the short-term drug cost savings realized from PUM measures may be offset by long-term increases in overall health care utilization (Soumerai et al. 1993). Furthermore, the unintended effects of PUM programs may be magnified in a sensitive, vulnerable patient population such as seniors, many of whom have few financial resources but many medical needs.

Access to appropriate pharmaceutical treatment for seniors has become a major health policy issue in the United States (Iglehart 2001). In fact, persons aged 65 and older represent about 13 percent of the population but consume approximately 30 percent of all prescription medications (AARP 1999; Arnett et al. 1990). On average, a person in this group receives 20 prescriptions per year (Poisal and Murray 2001), which can be a severe financial burden.

In 1998, seniors spent an average of \$537 (representing 3.55% of family income) on out-of-pocket prescription drugs, much more than the out-of-pocket average of \$192 (representing 1.25% of family income) for working-age adults (Xu 2003). The disproportionate financial burden of prescription drugs for seniors versus nonseniors was found across all family income levels. The continued aging of the population, the expanded numbers and types of available medications, and the rise in the cost of drugs are intertwining factors that will certainly exacerbate the problem of access to medications for seniors (Elwood 2000; Soumerai and Ross-Degnan 1999).

In the past, Medicare has not provided comprehensive prescription drug coverage for its 40 million enrollees, although it has covered some medications prescribed for outpatients, such as those to prevent oral cancer and immunosuppressive agents (Beers, Baran, and Frenia 2000; Iglehart 2001; Soumerai and Ross-Degnan 1999). In general, seniors have had to pay for their prescriptions out of their own pockets or obtain medication coverage through private sources (e.g., employer-sponsored plans and self-insurance), Medicaid, or state pharmaceutical

assistance programs. Unfortunately, the number of employers offering health benefits to Medicare-eligible retirees has fallen significantly, from 40 percent in 1993 to 24 percent in 2000 (Mercer Human Resources Consulting 2003), and in 1998 an estimated 10 million Medicare beneficiaries had no drug coverage at all (Poisal and Murray 2001).

The Medicare Prescription Drug, Improvement, and Modernization Act (MMA), signed into law on December 8, 2003, adds a prescription drug benefit to Medicare health benefits (Oliver, Lee, and Lipton 2004). The new benefit represents the most significant change since the program's inception and will certainly help many beneficiaries lacking insurance or having insufficient coverage of prescription drugs. The cost of the Medicare drug program is estimated to be \$400 billion over the next decade, and cost-containment mechanisms—including caps, copayments, and formularies—have been put in place to control expenditures and encourage the appropriate use of medications. Although health economists and policy experts acknowledge the great importance of the Medicare drug program, these cost-containment measures may make it difficult for beneficiaries, especially those with low incomes, to obtain all their needed medications (Commonwealth Fund 2003; Moon 2004).

Over the last 20 years, a growing body of empirical research has examined the impact of PUM on several sample populations, and a number of review articles have summarized the evidence (Lexchin 2002; Lexchin and Grootendorst 2004; MacKinnon and Kumar 2001; Olson 2003; Soumerai et al. 1993). Many of these studies, however, looked at insured working-age adults and so may not be generalizable to seniors. All other things being equal, though, individuals' decisions to purchase health care services are influenced by their ability to pay for them (Broyles et al. 2000; Stuart and Grana 1998). Moreover, because the cost of pharmaceuticals is usually only a small proportion of their incomes (Xu 2003), working-age individuals may be less sensitive than seniors are to variations in drug use and costs caused by PUM policies.

Our article reviews the published literature evaluating the impact of PUM activities that are included—or may be used—in the Medicare drug benefit plan for the care of seniors. We focus on research studies that used specific method designs and concentrated on seniors. We then summarize the principal findings and make recommendations regarding the Medicare drug coverage program.

Methods

We conducted a comprehensive evaluation of the peer-reviewed literature assessing the impact on seniors of specific PUM measures pertinent to the Medicare medication program. We limited our search to English-language publications indexed in Medline or CINAHL (Cumulative Index to Nursing & Allied Health Literature) between January 1995 and May 2003. The search was confined to the following types of PUM (Soumerai et al. 1993): (1) cost-sharing mechanisms such as copayments, coinsurance, deductibles, and benefit caps; and (2) administrative mechanisms such as prior authorization and formularies. We excluded reference pricing—reimbursement ceilings set by governments or other third-party payers for interchangeable drugs within a specific class—from our search for two important reasons. First, reference pricing is not mentioned in the MMA. Second, the MMA provisions prohibit the government from negotiating drug prices directly (Oliver, Lee, and Lipton 2004). As a result, reference-pricing programs appear highly unlikely to be implemented without legislative amendments to the MMA.

Because PUM activities do not use the same terms, we had to conduct our search using variations of the following terms: pharmaceutical, drug, medication, utilization, control, measure, measurement, cost, benefit, cap, prescription, limit, payment, copayment, coinsurance, deductible, cost sharing, formulary, tier, authorization, substitution, generic, reimbursement, cost containment, policy, Medicaid, and Medicare. We obtained all the relevant articles meeting our search criteria regarding target PUM measures.

Next, we singled out those articles describing the effects of selected PUM measures and conducted a snowball search using the references listed in these articles, choosing those published from 1983 onward. We included studies conducted both in and outside the United States that specifically addressed the effects of target PUM strategies.

Using Soumerai and colleagues' (1993) evaluation framework, we included those articles in our review that met all of the following criteria:

1. *Measured outcomes.* The studies had to assess the effect of PUM measures on one or more of the following processes or outcomes: prescription drug utilization and/or expenditures; effects on other health services such as hospital admissions and office visits;

underuse of effective medications; clinical outcomes; adverse events; and impact on the subject's behavior, such as voluntary disenrollment.

2. *Senior population.* We selected those articles whose study population covered only persons who were 60 years or older or who had a mean age of 60 years or older, and whose results for seniors could be distinguished from those of younger subjects.
3. *Research design.* We included both randomized studies and quasi-experiments. Although quasi-experimental designs do not have the same level of scientific rigor, they sometimes reveal causal relationships. Some of these quasi-experimental studies were well controlled, but others were not. We discussed those limitations in our review, but we did not discuss nonexperimental designs (such as cross-sectional studies) because they cannot answer cause-and-effect questions (Shadish, Cook, and Campbell 2002).

Results

Eighteen articles met our selection criteria. Of these, five investigated the effects of drug benefit caps; seven, copayments, coinsurance, and deductibles; one, prior authorization; and five, formularies. The rest of our article describes and analyzes the major findings for each PUM policy we examined and discusses their implications for seniors.

Cost-Sharing Mechanisms

Drug Benefit Cap. Capping the number or total value of prescriptions reimbursed is a popular strategy in the United States (Soumerai et al. 1993). The policies of most Medicaid programs limit prescription benefits in regard to both charges to patients and monthly coverage limitations (Cromwell et al. 1999; Fortess et al. 2001; Soumerai et al. 1993). Financial limits on the available annual coverage also are common in Medicare's managed care plans (Andrade and Gurwitz 2002). Many people are concerned, however, that lower caps may put poor and chronically ill seniors at a greater risk of unintended, adverse consequences. For instance, Cox and colleagues (2001) found that Medicare beneficiaries who were fearful of reaching their drug benefit cap reported taking fewer medications than prescribed, discontinuing taking

prescribed medications, or borrowing money for prescriptions. A recent study of Medicare+Choice plans offering different financial drug coverage found that 22 percent, 14 percent, and 4 percent of Medicare patients exceeded their prescription benefit caps of \$750, \$1,000, and \$2,000, respectively, per year, significantly increasing their out-of-pocket costs and potentially reducing their medication compliance (Tseng *et al.* 2003).

Various studies have investigated the effects of drug benefit cap policies on seniors (Table 1). In sum, the literature agrees that cap policies reduce pharmaceutical costs but also suggests that these measures increase the use of other health care services and may hurt clinical outcomes.

In two separate studies (Cox, Motheral, and Fairman 2000; Rector 2000) analyzing prescription and eligibility data of beneficiaries in a range of Medicare managed care plans with different types of drug benefit caps, the researchers found that drug benefit cap measures were associated with a significant increase in the risk of patients' disenrolling from their health plan, potentially leading to the discontinuation of care. But these studies' conclusions were limited by their using only post-test data (Soumerai *et al.* 1993). In addition, Cox, Motheral, and Fairman did not describe in detail the sample populations and the analysis design.

Three studies investigated New Hampshire's Medicaid drug benefit cap and its associated potential impact on patients' health. The policy's initial prescription cap of three per patient per month was replaced by a \$1 per prescription copayment. In the first study, Soumerai and colleagues (1987) found that although caps on prescriptions saved quite a bit of money, they also reduced the number of prescriptions, with a substantial decline in "essential" medications such as insulin (28%) and thiazides (28%). People who took many drugs, mainly seniors, were most affected by the policy. Replacing the cap with a copayment then returned the number of prescriptions to approximately the pre-cap level. However, the estimated Medicaid savings obtained by using the copayment strategy were similar to the savings gained by using the drug benefit cap policy.

In a further evaluation of a cohort of seniors, the authors (Soumerai *et al.* 1991) observed that the prescription cap was also associated with a significant growth in rates of admission to nursing homes, which subsided when the cap was discontinued and replaced by a copayment. Therefore, it was not clear whether the Medicaid drug benefit cap policy had saved money overall, since the observed reduction in pharmaceutical expenditures was offset by the increased number of nursing home

TABLE 1
Summary of Reviewed Studies of Drug Benefit Cap

Authors	Setting	Study Design	Study Sample	Outcomes Measures	Results
Cox, Motheral, and Fairman 2000	3 HMOs with different drug benefit caps ranging from \$600 to \$1,500.	Post-test design, no comparison group. Administrative data, Jan. 1997 to Dec. 1998.	Medicare beneficiaries.	Voluntary disenrollment.	The risk of disenrollment was associated with exhaustion of prescription coverage, older age, and greater disease burden.
Fortess et al. 2001	New Hampshire.	Pre-test/post-test design, no comparison group. Policy change date: Sept. 1981; study period: 12 months before and 6 months after policy change.	343 Medicaid users of essential medications aged ≥ 60 years enrolled for ≥ 10 months before and ≥ 4 months after policy change period.	Prescription drug utilization, presence of comorbidities, hospitalizations, and outpatient services.	Because of the policy, consumption of essential medications (i.e., anti-anginals, diuretics, antiarrhythmics, bronchodilators, inhaled steroids, insulin, oral hypoglycemics, anticoagulants, and anticonvulsants) fell 34%. Patients with mental illnesses and chronic pain were affected the most. Bigger reductions in use of essential medications were associated with greater use of precap medications, longer hospitalizations, and greater use of outpatient services.
Rector 2000	4 health plans with different drug benefit caps varying from \$300 to \$1,000.	Post-test design, no comparison group administrative database, 1998.	61,412 Medicare enrollees aged ≥ 65 years.	Voluntary disenrollment.	The probability of exhausting drug benefits varied from 17% to 25% across the four health plans. Disenrollment of Medicare beneficiaries from health plans was associated with caps on drug benefits.

TABLE 1—*Continued*

Authors	Setting	Study Design	Study Sample	Outcomes Measures	Results
Soumerai <i>et al.</i> 1987	2 states: New Hampshire (before, during, and after introduction of cap) and New Jersey (no cap).	Pre-test/post-test time-series design with comparison group. Policy change in NH: cap benefits Sept. 1981, then copayment Aug. 1982; study period: 20 months before and 11 months during cap benefits, 17 months after copayment introduced.	10,734 Medicaid subjects in NH, including 860 recipients of multiple drugs (48% of total aged ≥ 60 years; mean age: 56). 74,027 subjects in NJ (comparison group).	Prescription drug utilization and associated costs.	After the cap, prescriptions fell 30%. Seniors and disabled subjects and recipients of multiple drugs were most affected. After copayment replacement, drug use rose to approximately 10% below precap level. Cap policy and subsequent copayment replacement led to a comparable estimated savings of \$0.4 million to \$0.8 million annually.
Soumerai <i>et al.</i> 1991	2 states: New Hampshire (before, during, and after introduction of cap) and New Jersey (no cap).	Pre-test/post-test time-series design with comparison group. Policy change in NH: cap benefits Sept. 1981, then copayment Aug. 1982; study period: 14 months before and 11 months during cap benefits, 11 months after copayment introduced.	411 Medicaid subjects in NH and 1,375 subjects in NJ (comparison group) aged ≥ 60 years.	Prescription drug utilization, hospitalizations, and nursing home admissions.	After the cap, prescriptions fell 35%. No significantly increased risk of hospitalization but significantly increased risk of institutionalization in nursing home. After copayment, medication use returned to baseline, and the excess risk of nursing home admission ceased.

admissions. More important, the growth in seniors' nursing home admissions suggests that the decrease in medication use may have worsened their preexisting medical conditions.

Finally, Fortess and colleagues (2001) analyzed a sample of senior beneficiaries to find out which patients were most affected by the drug benefit limits and found that persons with multiple chronic diseases—especially those with mental health issues (anxiety/sleep and psychosis/bipolar disorders) and chronic pain—were more apt to cut back their use of “essential” medications, thereby potentially aggravating their health status. But the study's generalizability was limited by its small sample population, by the absence of a comparison group, and by the short follow-up observation period after the policy's implementation, which may have reduced the likelihood of capturing the true long-term effects on patients' drug use and providers' prescribing behaviors in the new context (Soumerai et al.1993).

Copayments, Coinsurance, and Deductibles. The three main forms of cost-sharing mechanisms are copayments, coinsurance, and deductibles (Levy 1992). A *copayment* is a fixed dollar payment made by the patient when purchasing a pharmaceutical product. *Coinsurance* is a percentage payment made by a patient and is generally between 10 and 20 percent of the prescription cost. A *deductible* is a fixed dollar amount that a patient must pay before he or she can be reimbursed. The increasing popularity of these mechanisms has raised questions about whether these cost-sharing strategies affect prescription drug utilization and, consequently, patients' health status. A recent analysis of data from the 1992 Medicare Current Beneficiaries Survey (Stuart and Zacker 1999) found that Medicaid beneficiaries in those states with a cost-sharing policy reported filling fewer prescriptions than did their counterparts in states without cost-sharing mechanisms. Of particular concern, patients with a poor self-reported health status took fewer drugs.

Studies that targeted seniors showed conflicting results and thus were inconclusive in regard to the effects of such PUM measures (Table 2). There is some evidence, though, that cost-sharing policies do influence drug utilization. In a controlled study, Nelson, Reeder, and Dickson (1984) found that a South Carolina Medicaid small copayment program (\$0.50 per prescription) was able to reduce drug consumption and expenditures. In a subsequent analysis, Reeder and Nelson (1985) found that copayments for prescription services appeared to influence utilization to varying degrees, depending on therapeutic category. Overall,

TABLE 2
Summary of the Reviewed Studies on Copayments, Coinsurance, and Deductibles

Authors	Setting	Study Design	Study Sample	Outcomes Measures	Results
Blais et al. 2001	Quebec (Canada).	Pre-test/post-test time-series design, no comparison group. Policy change date: Aug. 1996; study period: 4 years before and 13 months after policy change.	4 random samples of community-dwelling seniors aged ≥ 65 years who were users of one of the selected classes of medications as follows: 54,771 users of nitrates; 133,146 users of antihypertensive agents; 45,534 users of anticoagulants; and 26,165 users of benzodiazepines.	Prescription drug utilization.	Copayment policy did not significantly reduce the consumption of any of the four classes of medications.
Johnson et al. 1997a	2 Medicare HMOs in Kaiser Permanente Northwest with 2 different cost-sharing policies.	Pre-test/post-test design with comparison group. Cost-sharing policies changed over five-year period studied: In one HMO the copayment rose from \$1 to \$3 and then to \$5 per prescription, while in the other HMO the copayment rose from 50% to 70%, and the ceiling payment per dispensing rose from \$25 to \$30 (Jan. 1987 to Dec. 1991).	Sample size ranged from 6,704 to 7,962 over 4 two-year analysis periods. Subjects' ages were ≥ 65 years.	Prescription drug utilization and health status (measured via an indirect method).	Modest increases in cost sharing did not affect prescription drug utilization, but larger increases appeared to have greater influence on drug use. Measures of health status did not change because of modest cost sharing. The effect on health status of larger increases in cost sharing was unclear.

Johnson et al. 1997b	See Johnson et al. 1997a.	See Johnson et al. 1997a.	See Johnson et al. 1997a.	Prescription drug utilization and associated costs, office visits, hospitalizations, and other medical care services utilization and their associated costs.	No relationship between increased copayments and medical utilization and expenses.
Nelson, Reeder, and Dickson 1984	2 states: South Carolina (before and after introduction of copayment) and Tennessee (no copayment).	Pre-test/post-test time-series design with comparison group. Medicaid claims from a stratified sample of 18 counties. Policy change date: Jan. 1977; study period: 1 year before and 3 years after policy change.	17,811 Medicaid subjects in SC, 65% aged ≥ 60 years; 27,841 subjects in TN, 58% aged ≥ 60 years.	Prescription drug utilization and associated costs.	After the copayment introduction, prescriptions fell 11%. Small copayment was a successful mechanism to control cost and reduce pharmaceutical utilization.
Pilote et al. 2002	Quebec (Canada).	Pre-test/post-test design, no comparison group. Policy change date: Aug. 1996.	22,066 community-dwelling subjects aged ≥ 65 years who experienced acute myocardial infarction between Jan. 1994 and Dec. 1998.	Prescription drug utilization of selected cardiac medication, health services utilizations, and mortality.	Increases in out-of-pocket copayment did not change prescribing patterns and care related to acute myocardial infarction in seniors. The rates of readmission and number of visits to individual physicians and emergency departments remained unchanged. Mortality rate was unchanged before and after policy implementation.

TABLE 2—Continued

Authors	Setting	Study Design	Study Sample	Outcomes Measures	Results
Reeder and Nelson 1985	South Carolina before and after introduction of copayment.	Pre-test/post-test time-series design, no comparison group. Medicaid claims from a stratified sample of 9 counties. Policy change date: Jan. 1977; study period: 1 year before and 3 years after policy change.	17,811 Medicaid subjects in SC, 65% aged ≥60 years.	Prescription drug utilization of 10 selected therapeutic categories (adrenergics, analgesics, antihistamines, anti-infectives, cardiovasculars, cholinergics, diuretics, gastrointestinal, psychotherapeutics, sedatives/hypnotics) and associated costs.	Copayment for prescription services appeared to influence utilization to varying degrees depending on therapeutic category. Drug use in cardiovascular, cholinergic, diuretic, and psychotherapeutic categories decreased significantly.
Tamblyn et al. 2001	Quebec (Canada).	Pre-test/post-test time-series design, no comparison group. Policy change date: Aug. 1996; study period: 3 years before and 17 months after policy change.	93,950 community-dwelling subjects aged ≥65 years and 55,333 adult welfare recipients.	Prescription drug utilization, emergency department visits, and serious adverse events (defined as acute care hospitalization, long-term care admission, or death).	After cost-sharing implementation, use of essential drugs fell 9% in seniors and 14% in welfare recipients; use of less essential drugs fell 15% and 22%, respectively. Rates of adverse events and ED visits increased substantially in both populations. Rates of adverse events increased substantially in both populations.

there was a short-term decrease in expenditures in all ten of the investigated therapeutic groups except analgesic and sedative/hypnotic. The authors postulated that an observed reduction in cardiovascular and diuretic drugs, often prescribed for life-threatening chronic conditions, could exacerbate patients' health status, although they had not studied this effect (Soumerai et al. 1993).

Other studies reported results showing a small change in the consumption of pharmaceutical products as a consequence of implementing a cost-sharing program. In 1997, Johnson and colleagues published two studies of higher prescription drug copayments in two Medicare HMOs. In the first study (Johnson et al. 1997b), the authors examined the impact on both "essential" medications (including antihypertensive, cardiac agents, antidiabetics, and thyroid preparations) and "discretionary" medications (such as cough and cold preparations) and found that small changes in copayments did not have a substantial effect on the use of prescription medications and the associated costs of drugs used for both self-limiting (discretionary drugs) and progressive chronic conditions (essential drugs). Larger changes in copayments, though, were associated with a decrease in the use of essential medications and so could have worsened the patients' health status, although the study's health status measure was not validated. In another analysis, the authors (Johnson et al. 1997a) reported that small increases in copayments lowered the annual per capita use of prescription medications and costs but were not associated with the greater use of other medical services. They did not report the effect of larger copayments.

Three studies analyzed the effects of a 1996 cost-sharing drug insurance plan for senior residents of the Canadian province of Quebec (Blais et al. 2001; Pilote et al. 2002; Tamblyn et al. 2001). Before the plan was implemented, elderly persons paid C\$2 per prescription (up to a maximum of C\$100 per year) for medications on the Quebec drug formulary. Beginning in August 1996, seniors were responsible for a 25 percent coinsurance fee for prescription drugs up to an annual maximum contribution (i.e., C\$200, C\$500, or C\$750) based on their income. The studies show conflicting results, possibly because of the differences in sample populations and outcomes investigated. In addition, as the authors acknowledged, their conclusions may have been weakened by the absence of a control group. Because these studies were conducted in Canada, their results should be extended cautiously to U.S. seniors, given the two countries' social, economic, and political differences.

Both Blais and colleagues (2001) and Pilote and colleagues (2002) found that Quebec's cost-sharing policy did not significantly affect seniors' utilization of the studied drugs (antihypertensives, anticoagulants, nitrates, and benzodiazepines; and cardiac prescriptions following myocardial infarction, respectively). In addition, Pilote and colleagues (2002) indicated that the change in drug policy did not affect the rate of readmission, number of visits to individual physicians and emergency departments, and mortality. But Tamblyn and colleagues (2001) reached different conclusions. They found that the senior population's consumption of "essential" medications (e.g., anticoagulants, antidepressants, insulin) and "less essential" medications (e.g., benzodiazepines) dropped by 9.1 percent and 15.1 percent, respectively. The number of adverse events and emergency department visits also rose substantially, especially for those individuals who had reduced their use of essential medications.

Administrative Restriction Tools

Prior Authorization. Under prior authorization programs, coverage for a particular drug or therapeutic class requires approval from the pharmacy benefit manager or insurer before the drug can be dispensed, in order to guarantee reimbursement (Olson 2003; Soumerai et al. 1993). The purpose of this policy is to improve the quality of patient care by encouraging the appropriate utilization of medications while simultaneously containing their costs (MacKinnon and Kumar 2001; Smalley et al. 1995). Prior authorization programs are typically aimed at new, costly medications or potentially unnecessary and dangerous medications and promote the use of existing, less expensive, or safer alternatives (Table 3) (Soumerai et al. 1993).

Medicaid programs and commercial plans in the United States are turning more and more to these programs to control costs and manage patients' access to pharmaceuticals. Under the provisions of the Omnibus Budget Reconciliation Act of 1990 and its revisions in 1993, Medicaid programs cannot implement any policies that limit coverage of a medication. But the act does allow the states to manage drug utilization and expenditures through prior approval. As of 2001, 45 states had implemented prior authorization procedures for certain medications as part of their Medicaid drug utilization review programs (National Pharmaceutical Council 2001). In the same year, 74 percent of employers also reported using these strategies to manage pharmacy benefits (*Takeda Report* 2002).

TABLE 3
Summary of Reviewed Studies of Prior Authorization

Authors	Setting	Study Design	Study Sample	Outcomes Measures	Results
Smalley et al. 1995	Tennessee.	Pre-test/post-test time-series design, no comparison group. Policy change date: Oct. 1989; study period: 1 year before and 2 years after policy change.	All Medicaid enrollees (ranged from 495,821 at the base-line year to 547,403 at the second year). Subgroup analysis performed by age and other demographic characteristics (18% aged ≥ 65 years).	Prescribing drug utilization of nongeneric and generic NSAIDs, prescribing drug utilization of other analgesic or anti-inflammatory drugs, outpatient services, and hospitalizations for management of pain or inflammation.	Annual expenditures for NSAIDs per person-year of enrollment decreased by 53% after policy implementation (approximately \$13 million estimated savings over 2 years). This change was most pronounced among those over 65 years old. No variations for expenditures for other anti-inflammatory medications, and for outpatient and inpatient services.

Prior authorization initiatives have been criticized for focusing on cost containment rather than quality of care (Kaiser Commission 2003). One reason for concern is that restricting specific drug categories may lead to less access to essential medications, thereby exposing patients to less effective drug substitutions and possibly increasing the use of other medical services (Smalley et al. 1995).

Regrettably, published data on the impact of prior authorization programs on seniors are almost nonexistent. Researchers (Smalley et al. 1995) observed that after Tennessee's Medicaid prior authorization program was implemented, a shift from nongeneric nonsteroidal anti-inflammatory drugs (NSAIDs) to generic NSAIDs lowered the expenditures for NSAIDs as a class. The decrease in expenditures was more pronounced among the elderly. Overall, the expenditures for other analgesic and anti-inflammatory medications, or for outpatient and inpatient services (hospitalizations and emergency department visits), did not seem to rise. Because the costs were restricted to Medicaid expenditures, these results should be generalized only cautiously to seniors, for whom the primary insurer is Medicare. In addition, because the authors were not able to measure changes in levels of pain or inflammation, it is not known whether the reduced use of NSAIDs hurt seniors' health status.

Formulary. The most common tool used to manage prescription drug costs and utilization is the formulary. A *formulary* is a list of either the only drugs reimbursed by an insurance plan or the products that the health plan would prefer physicians to choose when prescribing (Sica 2001). A formulary is intended to improve drug therapy and outcomes in patients by persuading physicians to choose the most efficient and cost-effective drugs (Rucker 1999; Rucker and Schiff 1990). One recent national survey revealed that in 2001, 83 percent of employers had implemented a formulary to manage prescription drug benefits (*Takeda Report* 2002).

There are three types of formularies: open, closed, and "incented" (Penna 2000; *Takeda Report* 2002). An *open* formulary, the least restrictive, covers all drugs, even those that are not listed. A *closed* formulary, the most restrictive, does not cover unlisted drugs and holds the patient responsible for the full cost of an unlisted drug. Open and closed formularies are currently being replaced by *incented* formularies, hybrid cost-containment strategies combining the properties of an administrative tool (formulary) with the characteristics of a cost-sharing mechanism (copayment). Using different cost-sharing levels to encourage patients to

use generic or preferred drugs, an incented formulary typically includes a three-tier copayment system in which the copayment for each tier rises. In general, generic drugs are in the first tier; preferred brand-name drugs are in the second tier; and nonpreferred brand-name drugs are in the third tier. A few plans now have a fourth tier composed of lifestyle or other expensive drugs that often are not covered but that members can buy for a discounted price negotiated by the plan.

The studies discussed next and summarized in Table 4 describe the impact on seniors of the strategies used in managing formularies.

Closed Formulary. The only published information about the potential impact of formulary restrictions on seniors is in a study conducted by Horn, Sharkey, and Phillips-Harris (1998). The results of a comparative analysis of older versus younger patients in six HMOs with different levels of formulary restriction (Horn, Sharkey, and Gassaway 1996) indicated that formulary control/restrictions were associated overall with a greater number of prescriptions, higher drug costs, and more office visits and hospitalizations. This association was significantly greater for seniors after controlling for severity of illness and other variables.

This study was extensively criticized for major shortcomings in its design and methodology (Curtiss 1996; Ross-Degnan and Soumerai 1996). It used a post-test, nonequivalent group design, the weakest research design for inferring causative effects, and failed to control for preexisting variability among the HMOs on the basis of patterns of care, member characteristics, and administrative strategies for physicians and other providers, all factors that might have substantially influenced health care consumption and costs. Finally, the criteria for selecting patients were not adequately described.

Therapeutic Substitution. Therapeutic substitution is a tool used to reduce costs within a formulary design. According to the 2002 *Takeda Prescription Drug Survey Report*, 56 percent of the 461 large employers surveyed said that therapeutic substitution programs were part of their drug management benefit plans. Therapeutic substitution refers to switching a patient from a more expensive to a less expensive drug in the same therapeutic class (Good et al. 2000). The assumption is that the drugs are equivalent in therapeutic value and that the only effect of the switch is the lower cost. But because the new drug is a different chemical entity, adverse drug reactions, compromised quality of care, and higher overall treatment costs are potential risks. In addition, therapeutic substitution appears to be unpopular with patients. In a survey study, Condra and

TABLE 4
Summary of Reviewed Studies of Formularies

Authors	Setting	Study Design	Study Sample	Outcomes Measures	Results
Gustin et al. 1996	Veterans Administration Medical Center (Connecticut).	Pre-test/post-test design, no comparison group; cross-sectional patient survey policy change: early 1994; study period: March 1994 to Sept. 1994.	127 hypertensive subjects switched from nifedipine to felodipine; mean age: 70 years.	Blood pressure and adverse events reported by providers and patients.	Mandatory switching of stable calcium channel blocker therapy did not result in any significant changes in short-term blood pressure control or increased number of adverse events.
Horn, Sharkey, and Phillips- Harris 1998	3 for-profit and 3 not-for-profit HMOs in 6 different states with different formulary restrictions.	Post-test design, with comparison group; study period: Jan. 1992 to Dec. 1992.	12,997 subjects admitted at each site with specific diseases (asthma, otitis media, arthritis, epigastric pain or ulcers, hypertension); nonsenior and senior populations computed separately: 2,306 (18%) aged ≥65 years.	Prescription drug utilization and associated costs, office visits, and hospitalizations.	Significant associations between formulary limitations and resource utilizations. These associations were significantly greater for seniors after controlling for severity of illness and other individual characteristics.

Milligan et al. 2002	HMO in St. Louis, Mo.	Pre-test/post-test design, no comparison group. Policy change date: Jan. 2000; study period: 8 months before and 10 months after policy change.	182 subjects who elected to switch from Coumadin to generic warfarin; mean age: 75 years.	International normalized ratio and thrombotic and hemorrhagic events.	Substitution of generic warfarin for Coumadin did not cause significant clinical variation or increase number of adverse events.
Taylor et al. 2001	Walter Reed Army Medical Center, Washington, D.C.	Post-test design, no comparison group; cross-sectional patient survey. Policy change date: Aug. 1999; study period: Jan. 2000 to April 2000.	980 subjects switched to cerivastatin or simvastatin; mean age: 68 years.	LDL level, adverse events reported by patients, and drug costs.	Overall costs were reduced by \$115/patient treatment-year. Statin formulary interchange program improved lipid control without increasing number of adverse events.
Witt et al. 2003	Kaiser Permanente Colorado Region HMO.	Pre-test/post-test design, no comparison group. Policy change date: 1998.	2,299 subjects who had received uninterrupted oral anticoagulation therapy during 90 days before and 90 days after switch to generic warfarin; mean age: 69 years.	International normalized ratio, thrombotic and hemorrhagic events, and costs.	The conversion program was associated with an estimated cost savings of \$32/patient-years. Patients were successfully switched to generic warfarin with similar clinical results and without significant difference in number of adverse events.

colleagues (1999) found that most patients who were switched from omeprazole to lansoprazole after a formulary conversion in the Veterans Affairs Healthcare System not only reported more side effects but also were willing to pay an additional fee for their previous drug.

Two studies looked at the effect of therapeutic substitution strategies on seniors. When studying patients in one Veterans Administration medical center, Gustin and colleagues (1996) found that the mandatory switching of stable calcium channel blocker therapies did not significantly change short-term blood pressure control or increase the number of adverse events. The study's generalizability was limited by the small, mostly male sample (127 patients, 95% male) and by the absence of a control group. Taylor and colleagues (2001) found that a statin formulary interchange program at Walter Reed Army Medical Center reduced costs while maintaining lipid-lowering efficacy at an acceptable risk level of adverse drug reactions. No control group was used, however. Although both studies had methodological limitations, they provided evidence that therapeutic substitution lowers costs and does not cause adverse events.

Generic Substitution. Generic substitution has been described as one of the most effective strategies for containing drug benefit costs and is widely employed in formulary policies (*Takeda Report* 2002). Although generic drugs are chemically identical to their brand-name counterparts, they are typically less expensive than brand-name drugs. Incentives to use generics are offered to both consumers and pharmacists. Patients often are responsible for a greater copayment if they choose a brand-name drug when a generic drug is available, and pharmacists are paid higher fees for dispensing generic drugs.

The literature offers only little evidence regarding the effects of generic substitution initiatives. Although generics are extensively used, some concerns about the therapeutic interchangeability and bioequivalence of these products have not been resolved, especially for certain drugs with narrow therapeutic indexes, such as digoxin, levothyroxine, and warfarin (Henderson and Esham 2001; Murphy 1999). The potential effects of generic medications should be considered in regard to seniors, who might be most affected by lapses in effectiveness or increases in rates of adverse events.

Two studies examined the disputed reintroduction in 1997 of generic warfarin products. Both supported the claim that generic substitution does not compromise therapeutic efficacy. In an older HMO patient

population, a study by Milligan and colleagues (2002) found that the substitution of generic warfarin for Coumadin did not cause significant clinical variations or increase the number of adverse events. Similarly, Witt and colleagues (2003) found that older patients in an HMO were successfully switched from brand-name to generic warfarin, saving a lot of money without worsening their clinical status. But again, the absence of an adequate comparison group limited the generalizability of the two studies.

Incented Formulary. The use of an incented formulary has recently gained popularity in formulary designs. In 2001, 54 percent of employers using a formulary to manage drug benefits reported having an incented formulary (*Takeda Report* 2002). The few studies examining the impact of an incented formulary on drug use, costs, and health outcomes found that it lowered overall drug expenditures considerably (Huskamp et al. 2003; Rector et al. 2003) without significantly increasing the use of other medical resources (Joyce et al. 2002; Motheral and Fairman 2001; Nair et al. 2003). But these studies' samples were of younger populations, and so their results cannot be generalized to seniors.

Limitations

We were unable to employ statistical methods of aggregating study results, like those used in meta-analysis, since the studies on this topic are a heterogeneous mix of study samples, outcome measures, and drugs/drug classes. As a narrative type, therefore, our review is intrinsically limited (Shadish, Cook, and Campbell 2002). Our analysis was based on the published literature, which represents only a part of the research on pharmacy utilization management. It is likely that managed care and pharmacy benefit management organizations have conducted numerous evaluations of PUM measures that have not been published. In some cases, inadequate research design, such as the absence of a comparison group and the analysis of post-test data only, may limit the generalizability of a study's conclusions. Inconsistencies in the description of study samples as well as differences in outcomes make the evidence suggested by the studies we selected difficult to compare. For example, much of the research came from low-income populations that are inherently more subject to financial constraints and so may not be generalizable to the entire Medicare population. However, the most important concerns about the impact of PUM measures included in the Medicare

Prescription Drug, Improvement, and Modernization Act pertain to the effects on Medicare beneficiaries with low incomes. In addition, most of the studies focused on the economic impact of PUM measures, but often considered only the impact on pharmaceutical expenditures, rather than the offsetting impact on total health care costs. Assessments of clinical and humanistic outcomes also were essentially neglected. Finally, because of these studies' retrospective nature, little information is available about changes in out-of-pocket expenses associated with policy changes and the economic implications for seniors.

Discussion

Overall, our review showed that the impacts of PUM strategies on seniors' health have not been adequately evaluated. The small number of studies and inconsistencies in their methodologies make it difficult to draw valid conclusions. Because the cost-containment policies of the MMA affect a large—and often more vulnerable—segment of the population, we need more research to expand our knowledge of the consequences of PUM mechanisms on the care of older individuals. Nevertheless, our analysis of the published data provides important insights. The following section describes the PUM measures included in the Medicare drug benefit program and discusses their potential effects based on our review.

Cost-Containment Measures in the Medicare Prescription Drug Benefit

Caps, copayments, coinsurance, and deductibles, as well as formularies and prior approval, are PUM measures included in the Medicare drug benefit. The Medicare law provisions require enrollees to contribute a monthly premium of about \$35 (AARP 2003; Oliver, Lee, and Lipton 2004). After they have paid a deductible of \$250, Medicare will pay 75 percent of drug costs up to a cap of \$2,250. Once the cap is reached, enrollees will be responsible for all drug costs up to \$5,100, after which Medicare will cover 95 percent of their drug expenses. The law provides subsidies for low-income beneficiaries. Caps and deductibles are eliminated for seniors with incomes under 150 percent of the federal poverty level, and specific cost-sharing rules are substituted, based on the beneficiary's income level (e.g., a flat copayment of \$1 to \$3 per prescription drug for those with incomes below 100 percent of the poverty line).

Although the Medicare drug benefit program permits prescription drug plans to use a formulary to monitor medication usage, the language of the law is vague and the type of formulary format is not specified. The MMA states only that a formulary should include at least two drugs in each therapeutic category and class, as well as meet certain other standards (U.S. Pharmacopeia 2004). The law directs the U.S. Pharmacopeia to draw up a model list of drug categories and classes. This model, however, is still being developed. The characterization of drug categories and classes is crucial, because it will significantly affect the number and types of medications available to physicians for treating a medical condition. It will also influence off-label drug uses, which are permitted by law for medications with a labeled use providing for its coverage within a formulary. Finally, because the law allows physicians to override formularies if they determine that alternative drugs not on the formulary are medically necessary, prior authorization programs are likely to be used, but they are not described specifically.

Implications for the New Medicare Law

Crucial questions surround the Medicare drug benefit provisions. Are the MMA's cost-containment strategies the most appropriate to monitor drug usage while preserving access to essential medications? Can these measures help control health care expenses without hurting health status? Are these initiatives able to improve the quality of care provided? Although the existing evidence does not answer these questions definitively, it suggests that the Medicare drug program's PUM policies may have adverse, unintended effects on beneficiaries. Moreover, the different types of PUM measures will affect all seniors, and the combined effects could be greater than the effect of each measure alone.

Of greater concern is the fact that the plan relies heavily on the intricate design of the drug benefit caps. The literature suggests that using caps cuts the cost of medications but may also have deleterious effects, including less use of essential medications, disenrollment from health plans, and a greater risk of hospitalization or admittance to nursing home facilities. For persons who will not benefit from subsidies, the drug benefit cap of \$2,250 plus the deductible and copayments might be a significant barrier. With an estimate of \$3,160 as the average annual drug expenditure per Medicare beneficiary in 2006 (Kaiser Family Foundation 2003), the proportion of seniors at risk of reaching their

benefit limit could be high. One could extrapolate from our findings that reaching the benefit limit may discourage persons from adhering to their medication regimens and even discontinue their therapy and increase their use of other health care services.

Regarding the other MMA cost-sharing mechanisms (copayment, coinsurance, and deductible), the evidence is mixed, particularly as it pertains to potential negative effects on seniors' health. The research suggests that copayments and deductibles may lower drug expenditures, although the extent of this reduction depends on both the cost-sharing amount and the therapeutic category of the drug. In addition, the lower cost may be offset by greater utilization of other health care services. The question remains whether modest cost sharing would limit the access of low-income Medicare beneficiaries, especially seniors with multiple health care needs, to needed medications. There is some evidence that for low-income populations, even small copayments may lead them to reduce their use of effective medications (Reeder and Nelson 1985).

A lack of evidence limits our ability to assess the implications of the MMA's administrative control tools for seniors and to evaluate the relative effectiveness of one strategy over another. The available data on formularies are insufficient for drawing conclusions, but specific types of formulary instruments, such as substitution programs, appear to cut drug costs without hurting health status. Nevertheless, formularies should avoid excessive restrictions in order to minimize the risk of patients' discontinuing treatment or adverse drug effects.

Although the limited evidence regarding prior authorization programs indicates that they decrease the utilization of targeted drugs without increasing that of alternatives, such programs carry substantial administrative costs. Because measures to control the prescription of drugs not on the formulary will be part of the Medicare drug program, we recommend that prior approval programs be enacted in a way that ensures the quality of care and makes appropriate medications available to seniors without unnecessary delay.

We encourage policymakers and administrators to consider the findings of our research before implementing the Medicare drug benefits. More important, we urge them to supply financial resources to examine the short- and long-term impacts of PUM policies on beneficiaries (e.g., monitoring the effects of the program on the consumption and costs of medications, as well as on the use of and spending in other health care areas).

Conclusion

A variety of PUM measures, including cost-sharing mechanisms and administrative restriction tools, are key components of the upcoming Medicare drug benefit to control pharmaceutical utilization and costs. Although the current literature does not contain adequate information about the impact of PUM on seniors, it suggests that the Medicare drug benefit's use of caps may be harmful and may undermine the legislation's purported intention of improving access to needed drugs for seniors. Seniors with chronic conditions requiring extensive pharmaceutical management may be prevented from obtaining drug benefits at the time of greatest need, resulting in gaps in access and compliance, increased utilization (and cost to Medicare), and less desirable health outcomes.

PUM measures are undeniably needed to prevent the inappropriate use of medications and to avoid jeopardizing the financial health of public insurance. Proposals and policies can be made only in accordance with evidence from a rigorous evaluation of the consequences of these mechanisms. Our review demonstrates conclusively that more resources must be dedicated to studying the scope and magnitude of the economic and clinical impacts of PUM measures on the care of seniors.

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