RESEARCH ARTICLE

Sensitivity of Medication Use to Formulary Controls in Medicare Beneficiaries: A Review of the Literature

Rahul Shenolikar, PhD; Amanda Schofield Bruno, PhD, MPH; Michael Eaddy, PharmD, PhD; Christopher Cantrell, PhD

Background: Several studies have examined the impact of formulary management strategies on medication use in the elderly, but little has been done to synthesize the findings to determine whether the results show consistent trends.

Objective: To summarize the effects of formulary controls (i.e., tiered copays, step edits, prior authorization, and generic substitution) on medication use in the Medicare population to inform future Medicare Part D and other coverage decisions.

Methods: This systematic review included research articles (found via PubMed, Google Scholar, and specific scientific journals) that evaluated the impact of drug coverage or cost-sharing on medication use in elderly (aged ≥65 years) Medicare beneficiaries. The impact of drug coverage was assessed by comparing patients with some drug coverage to those with no drug coverage or by comparing varying levels of drug coverage (e.g., full coverage vs $1000 coverage or capped benefits vs noncapped benefits). Articles that were published before 1995, were not original empirical research, were published in languages other than English, or focused on populations other than Medicare beneficiaries were excluded. All studies selected were classified as positive, negative, or neutral based on the significance of the relationship (P < .05 or as otherwise specified) between the formulary control mechanism and the medication use, and on the direction of that relationship.

Results: Included were a total of 47 research articles (published between 1995 and 2009) that evaluated the impact of drug coverage or cost-sharing on medication use in Medicare beneficiaries. Overall, 24 studies examined the impact of the level of drug coverage on medication use; of these, 96% (N = 23) supported the association between better drug coverage (i.e., branded and generic vs generic-only coverage, capped benefit vs noncapped benefit, supplemental drug insurance vs no supplemental drug insurance) or having some drug coverage and enhanced medication use. Furthermore, 84% (N = 16) of the 19 studies that examined the effect of cost-sharing on medication use demonstrated that decreased cost-sharing was significantly associated with improved medication use.

Conclusion: Current evidence from the literature suggests that restricting drug coverage or increasing out-of-pocket expenses for Medicare beneficiaries may lead to decreased medication use in the elderly, with all its potential implications.

Patient access to healthcare resources is an important topic of healthcare discussion, research, and reform in the United States. Access issues are usually framed in the context of patients having health insurance, as the quality of health insurance facilitates patient access to necessary medical and pharmaceutical therapies. Although patient access to medications is essential, formulary management strategies may introduce barriers aimed at restricting utilization, including curbing patient demand by increasing the cost borne by the patient or providing incentives to select lower-cost alternatives. Examples of these strategies include tiered copays, coinsurance, and benefit caps.
The advent of Medicare Part D in 2006 made the federal government the single largest payer of medications in the country, providing coverage to Medicare beneficiaries and the disabled. Although Part D is sponsored by the Centers for Medicare & Medicaid Services (CMS), it is administered by health plans that have the ability to implement restrictions on medication use in the form of drug benefit. Evidence generated from previous studies demonstrate that formulary controls can impact patients’ medication-taking behavior and, ultimately, patient outcomes. However, conclusions drawn from these studies were largely based on populations that included nonelderly, commercial, or non-US populations. Elderly people could behave differently from younger people in response to formulary controls, given their increased likelihood of comorbidities and greater need for medications to maintain good health.

No study to date has collated existing data to assess the consistency in the findings regarding the impact of formulary controls on medication use—defined in this current study as adherence, change in days supply, medication fills, and number of tablets—in the elderly. Synthesizing evidence from previous studies involving elderly populations may help in assisting Medicare and other health plan benefit design guidelines in the future.

Therefore, the objective of this study was to summarize the effects of formulary controls on the US elderly (ie, Medicare) population based on previously published studies to generate evidence using earlier research that could be used to make future coverage decisions. Formulary controls included all formulary strategies that use mechanisms such as formulary restrictions and benefit design, including tiered copayments, step edits, prior authorization, and generic substitution.

Methods

Study Selection

First, a list of search terms was applied to a database of the medical sciences (PubMed, published by the National Library of Medicine), the search engine Google Scholar, and specific scientific journals. Second, articles from certain journals, such as Health Affairs, Medical Care, the American Journal of Geriatric Pharmacotherapy, and the Journal of the American Geriatrics Society, were individually searched. These journals were selected because of their wide readership and focus on healthcare policy studies and research related to clinical care, and because of recent developments in drug therapy in the elderly.

The list of search terms used in step 1 was designed to address the impact of formulary controls on patient medication use. Formulary controls included in this study encompassed all formulary strategies that use formulary restrictions and benefit design mechanisms, as noted above (ie, tiered copayments, step edits, prior authorization, and generic substitution). Some of these strategies are intended to curb patient demand for drug therapies, by increasing the cost borne by the patient or by providing incentives to select lower-cost alternatives.

The set of search terms, therefore, included: Medicare, elderly, older, compliance, adherence, persistence, outcomes, adverse event, utilization, resource use, prescription drug expenditures, cost, cost share, copayment, out of pocket, coinsurance, deductible, pharmacy coverage, step therapy, benefit change, cap, premium, insurance coverage, insurance type, tiered benefit design, formulary, consumer-driven health plans, prescription drugs, generic drug use, branded drugs, access, capitated, fee for service, and retrospective analysis.

More than 500 research articles were obtained that pertained to these search terms. To make the articles applicable to this literature review, certain exclusion criteria were applied (Figure 1). Articles were excluded if they were published before 1995, were not original empirical research, were published in languages other
than English, or focused on populations other than Medicare enrollees. These exclusion criteria were used after a review of the title and content of the abstracts. A full article review was conducted in cases where the title and abstract review were inconclusive. There was no restriction on study design.

The third component of the search strategy included an examination of the list of references from all studies selected in steps 1 and 2 to determine whether the studies met the selection criteria.

**Study Variables**

Formulary controls are tools used by payers to restrict the number of medications covered for each patient. Operational definitions of formulary controls evaluated in this study were based on the definitions in the studies that met the selection criteria. Included studies examined a variety of formulary controls—except step therapy and prior authorization—and were classified according to whether the specific control affected either (1) the level of drug coverage or (2) medication cost-sharing (Table 1). The classification of studies into these 2 categories allowed for the assessment of the impact of drug coverage on medication use by comparing, for example, patients with some drug coverage with those with no drug coverage, or by comparing different levels of drug coverage (eg, branded and generic vs generic-only coverage).

The impact of cost-sharing, however, was examined by comparing differences in patient copayment or the coinsurance amount for medications. Medication use—
Figure 2 Positive Study Classification, Based on Relationships of Interest

<table>
<thead>
<tr>
<th>Better drug coverage or lower medication cost-sharing</th>
<th>Enhanced medication use</th>
</tr>
</thead>
</table>

aDrug coverage or lower cost-sharing associated with significantly improved medication use was considered a positive relationship, whereas reduced drug coverage or increased cost-sharing associated with significantly reduced medication use was considered a negative relationship. Relationships that were not significant were considered neutral.

bFor example, branded and generic versus generic-only coverage, capped benefit versus noncapped benefit, supplemental drug insurance versus no supplemental drug insurance.

Table 2 Studies with Positive Status: Impact of Coverage Type on Medication Use in the Medicare Population

<table>
<thead>
<tr>
<th>Impact on medication use</th>
<th>Positive status studies, N (%)</th>
<th>Total studies, N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Impact of drug coverage</td>
<td>23 (96)</td>
<td>24</td>
</tr>
<tr>
<td>Impact of medication cost-sharing</td>
<td>16 (84)</td>
<td>19</td>
</tr>
<tr>
<td>Total</td>
<td>39 (91)</td>
<td>43</td>
</tr>
</tbody>
</table>

aExcluding descriptive studies.

bThe “positive” and “negative” categories are not mutually exclusive. A study could be included in multiple categories if it examined more than 1 relationship of interest or if it was classified as a positive and a negative study.

the outcome variable included in the study—was also defined according to the definitions used in the included studies (Table 1), and together these variables were used to represent the variable medication use.

Study Classification into Positive, Negative, or Neutral Categories

This literature review included 2 types of studies:
1. Studies that examined the relationship between cost-sharing/level of drug coverage and medication use, using hypothesis testing
2. Descriptive studies. (Some descriptive studies were not categorized and are described separately in the Results section.)

All other studies were classified as positive, negative, or neutral based on the following 2 criteria. First, we determined whether the relationship between the impact of the level of drug coverage or medication cost-sharing on medication use was statistically significant. Second, if the relationship was significant, we determined the direction of relationship, that is, whether it was positive or negative based on a predetermined definition of positive relationship, as illustrated in Figure 2. For example, better drug coverage (eg, branded and generic vs generic-only coverage, capped benefit vs noncapped benefit, supplemental drug insurance vs no supplemental drug insurance) or lower cost-sharing associated with significantly improved medication use was considered a positive relationship, whereas reduced drug coverage or increased cost-sharing associated with significantly reduced medication use was considered a negative relationship. Relationships that were not significant were considered neutral.

In addition, the following decision rule was applied to research articles that examined multiple disease states, outcome measures, therapies, or periods of study. Studies with positive and neutral relationships between the impact of drug coverage level or medication cost-sharing on medication use were classified as positive; studies with negative and neutral relationships were classified as negative; and those with positive and negative relationships were classified as both positive and negative. Studies that assessed the impact of cost-sharing as well as drug coverage were counted as 2 different studies in the results of this systematic review.

Results

A total of 47 research articles met the selection criteria and were included in this systematic review (see Appendix at www.AHDBonline.com/node/868).1-51 Of these studies, 13% (N = 6) were descriptive.46-51 Overall, in the 15-year (1995-2009) time frame, 24 studies examined the impact of level of drug coverage on medication use,5-28 and 19 studies examined the impact of cost-sharing on medication use.52-45 The majority of these studies were cross-sectional and used the Medicare Current Beneficiary Survey (MCBS, a predesigned survey) or medical and/or pharmacy claims as a data source and were not specific to a particular disease state. Studies that were specific, however, focused on a single disease or on multiple diseases (including cardiovascular conditions, diabetes, arthritis, lung disease, and depression). The studies by Bluestein21 and by Steinman22 were counted twice, because they assessed the level of drug coverage as well as the impact of cost-sharing on medication use.

Of the 24 studies that examined the impact of drug coverage,27 96% (N = 23) were positive, indicating that better coverage was associated with increased use of medications (Table 2). Similarly, of the 19 studies that examined the effect of cost-sharing on medication use,
84% (N = 16) were positive, demonstrating that decreased cost-sharing improved medication use.8,22,29-42

Findings from Descriptive Studies

All 6 of the descriptive studies were published before the launch of Medicare Part D.46-51 Their findings are described separately, because those studies did not include hypothesis testing to examine the relationship between formulary control and medication use. They simply described the variation in medication use for different levels of cost-sharing or drug coverage.

The study by Davis and colleagues that used the 1995 MCBS showed that elderly persons with drug coverage averaged 20.3 prescriptions annually, whereas those with no drug coverage averaged 5 (25%) fewer prescriptions annually.46 In addition, patients with dual eligibility for Medicare and Medicaid used about twice as many (102% more) prescriptions, on average, as those in fee-for-service plans with no supplemental insurance (25.6 vs 12.7 prescriptions annually, respectively).46

The US Department of Health and Human Services reported similar findings using 1996 MCBS data,48 and another study examining 2 years of data (1995 and 1996) reported that in 1996, on average, Medicare beneficiaries without drug coverage used 5 (24%) fewer prescriptions than those with drug coverage (16.01 vs 21.14 prescriptions, respectively).49

This finding was supported by a follow-up study using 1998 data that showed even greater differences in medication utilization between Medicare beneficiaries with and without drug coverage.49 Those with drug coverage used almost 8 (46%) more prescriptions annually than those without coverage (24.35 vs 16.65 prescriptions, respectively).49

Another study supporting the relationship between drug coverage and medication use based on the 1996 MCBS data reported that Medicare beneficiaries who were always covered during the year filled 22.4 prescriptions compared with 16.7 prescriptions filled by those with no coverage, a 34% difference; beneficiaries with only partial-year coverage fell in between, filling only 21.8 prescriptions for the year.50

The final descriptive study, which examined 4 years (1996-1999) of MCBS data, revealed little difference between Medicare beneficiaries with and without drug coverage in acquiring prescribed medications.51 Less than 3.5% of beneficiaries in each group (those with and without coverage) reported that they did not acquire a prescribed medicine.51

Selected Study Findings

Impact of drug coverage or cost-sharing on medication use. Irrespective of formulary control, the majority of the studies included in our analysis supported the hypothesis that more restrictive drug coverage is associated with decreased medication use. From a more granular perspective, studies that empirically examined the relationship between the level of coverage or cost-sharing and medication use showed that implementing 2 cost-sharing options (ie, full prescription drug coverage vs $1000 maximum annual coverage) increased the overall rates of discontinuation over time.

A study that investigated the use of lipid-lowering agents demonstrated that among elderly patients who were initially prescribed a statin, the 12-month discontinuation rates were 33% for those with full drug benefit coverage and 50% for those with $1000 maximum annual coverage. After 21 months, these rates increased to 60% and 86%, respectively (P = .023).5 In another study, an effective price decrease of 10% for prescription drugs was estimated to increase utilization by 5.4% (P < .05).5

In addition, a separate study showed that the odds of failing to purchase any antihypertensive medications were 40% greater (odds ratio [OR], 1.4; P = .002) for those lacking drug coverage compared with those with drug coverage.8 In the same study, drug coverage significantly increased the number of tablets purchased during the year (from 423 tablets to 460, adjusted for other covariates; P = .02).8 In another study, the risk for delay in filling medications was significantly lower (OR, 0.33; P < .001) among those who had drug coverage compared with those who lacked drug coverage.14

However, in a sample of 310 community-dwelling elderly, those who reported having some drug coverage did not report increased daily use of medications, regardless of their out-of-pocket amount.12 Respondents with Medicaid coverage were 17.24 times more likely (90% confidence interval [CI], 1.24–239) to report using at least 1 medication, and those with a service benefit (2.49; 90% CI, 0.53-11.6) or indemnity coverage (OR, 2.67; 90% CI, 0.58-12.5) were more than twice as likely as those who were uninsured to report using a prescription drug; however, these effects were not significant.12 These neutral findings could have been the result of the small sample size, and warrant additional investigation.

Managed care Medicare beneficiaries who reached their prescription drug capped amount were more likely to engage in behavior to decrease out-of-pocket expenses, including taking fewer medications than prescribed (OR, 2.83; 95% CI, 1.55-5.20) and discontinuing medication use (OR, 3.36; 95% CI, 1.63-6.94).12

A 2004 survey of Medicare+Choice beneficiaries revealed that a higher proportion of patients exceeding their coverage cap reported using fewer prescribed med-
ications than the controls (18% vs 10%, respectively; \(P < .001\)), but similar proportions reported stopping their medications completely (8% for both; \(P = .86\)), and those with chronic conditions such as asthma, hyperlipidemia, and hypertension were most responsive to benefit caps.\textsuperscript{27}

These results suggest that formulary controls should perhaps be targeted to avoid affecting the elderly at greatest risk for adverse health outcomes. In addition, 2 studies addressed drug benefit generosity. One study showed that Medicare beneficiaries with the most generous drug coverage (defined as the percentage of annual drug expenditures paid by insurance) were twice as likely (OR, 2.22; 95% CI, 1.80-2.75) to receive cyclooxygenase-2 inhibitors as those with no third-party coverage.\textsuperscript{11}

Evidence suggests that formulary management controls designed to direct patients toward lower-cost therapies or reduce their overall medication use have unintended consequences, often resulting in the underuse or discontinued use of medications.

Another study showed that no drug coverage (no retiree drug benefits or no spending covered by an employer) was associated with lower odds of using essential cardiovascular medications, such as statins (OR, 0.34; 95% CI, 0.21-0.56) for coronary artery disease (CAD) or hyperlipidemia, or angiotensin-converting enzyme (ACE) inhibitors or angiotensin-receptor blockers (OR, 0.35; 95% CI, 0.23-0.55) for congestive heart failure CAD.\textsuperscript{14} Those with no drug coverage (Medicare fee-for-service only and Medigap without drug coverage) were less likely to receive statins than those with some form of drug coverage (OR, 0.16; 95% CI, 0.05-0.49).\textsuperscript{11}

Although certain drug classes were affected more than others, elderly patients who chose 3-tier drug coverage (25% were members of a staff model health maintenance organization with a generic-only benefit (lowest level of coverage) were more likely (OR, 1.70; 95% CI, 1.25-2.31) to report taking less than the prescribed dose and discontinuing regular medications more frequently (OR, 1.77; 95% CI, 1.27-2.47) than those with 1- or 2-tier coverage.\textsuperscript{19}

### Discussion

This study intended to summarize published evidence in an effort to inform policies related to medication use, medication access, and drug benefits in Medicare plans. Based on the available research previously published, this review suggests that more restrictive drug coverage—or formulary strategies that are intended to curb patient demand for drug therapies by increasing the cost borne by the patient or by providing incentives to select lower-cost alternatives—in the elderly leads to decreased utilization of drug therapies.

Since 1995, 4 studies reported nonsignificant, neutral relationships. Two of these studies had a relatively low sample size (300-800 patients), and therefore, merit consideration in light of other studies conducted in larger Medicare populations.\textsuperscript{26,31} One of the benefits of implementing formulary controls is that they can be used as a cost-control mechanism to limit or reduce prescription spending. However, these benefits could be short-term. There is little evidence documenting their long-term impact on healthcare costs and patient quality of care.\textsuperscript{12,33}

Furthermore, even though such strategies help control prescription drug spending, they can have limitations. Evidence suggests that formulary management controls designed to direct patients toward lower-cost therapies or reduce their overall medication use have unintended consequences, often resulting in the underuse or discontinued use of medications.\textsuperscript{12,31}

The evidence is constant in commercial and in privately insured populations as well. In a study of privately insured individuals aged 18 to 64 years, Goldman and colleagues showed that doubling the patient copayment was associated with a significant reduction in the use of anti-ulcer drugs (33% reduction), anti-asthmatic agents (32%), antidepressants (26%), antihypertensives (26%), antihyperlipidemic drugs (34%), antidiabetic drugs (25%), anti-inflammatory drugs (45%), and antihistamines (44%).\textsuperscript{34}

Although price sensitivity is greatest in therapies used to treat the symptoms of disease, there is a fair degree of price elasticity in patient demand for essential therapies that are taken regularly for the treatment of chronic...
and/or serious illnesses.\textsuperscript{54,56} One study compared employer-sponsored health plans in which one plan simultaneously switched from a 1-tier to a 3-tier formulary and increased all enrollee copayments for medications. The second employer switched from a 2-tier to a 3-tier formulary, changing only the copayments for tier-3 drugs. Enrollees covered by the employer who implemented more dramatic changes experienced slower growth in the probability of the use of a drug than the comparison group.\textsuperscript{35}

Research shows that reduced medication use can lead to worse health outcomes. Inconsistent use of beta-blockers after a myocardial infarction has been associated with increased rates of mortality,\textsuperscript{57,58} suboptimal use of antidepressants has been related to decreased productivity\textsuperscript{19} and quality of life,\textsuperscript{60} and intermittent use of inhaled corticosteroids in patients with asthma has been linked to exacerbations requiring visits to the emergency department and hospital admission.\textsuperscript{61}

Although these types of unintended effects are undesirable, they support increased efforts by health policy-makers to design formulary controls that aim to improve appropriate use of medications to reduce disease burden and improve the overall health of patient populations.

For this reason, it could be argued that formulary controls should be implemented only after considering the potential unintended consequences, such as discontinuation of needed medications, that could further lead to poor health outcomes and inefficient use of medical resources. Broad population-based controls aimed directly at reducing the total pharmacy budget may therefore be less beneficial than more customized approaches that encourage value-based spending.

As formulary controls are becoming more complex, with 86% of Medicare Part D plans utilizing 4- or 5-tier structures,\textsuperscript{42} consideration of the unintended consequences of restricted coverage in this population will continue to be important. Since the inception of Part D, elderly beneficiaries have faced less restrictive coverage with more drug options on formulary; however, there is evidence that beneficiaries are not reevaluating available coverage options to best meet their needs.\textsuperscript{33}

In addition, drug prices are often not transparent to patients, who can in some cases pay the full price of brand-name medications under reference-based pricing schedules.\textsuperscript{63} Furthermore, although subsidies are provided to help low-income elderly patients pay for their drug coverage, the most optimal plan is not always selected, because the set of alternatives is difficult to navigate.\textsuperscript{44}

To compound matters, coverage completion and beneficiary selection of a “best plan” is compromised by the highly variable mix of drug therapies needed by patients over time.\textsuperscript{46} A recent survey conducted by the AARP showed that nearly 17% of all elderly respondents believed they would be unable to afford their medications in the coming year.\textsuperscript{66}

Finally, the recent rise in pharmaceutical drug spending\textsuperscript{67} and health reform efforts to support the implementation of more comparative effectiveness studies will ensure that increased attention will be paid to the contribution of high-cost drug therapies to healthcare budgets. Payers, in turn, will face greater pressure to implement management strategies that reduce drug costs and drug demand while still providing access to valuable treatments.

Since the inception of Part D, elderly beneficiaries have faced less restrictive coverage with more drug options on formulary; however, there is evidence that beneficiaries are not reevaluating available coverage options to best meet their needs.

The results of this study may therefore inform payer and other stakeholder decisions that affect treatment access in the elderly through the promotion of customized, value-based approaches to curbing drug and overall medical spending.

Limitations
This study has several limitations. First, the selection criteria might have excluded some studies with useful results. For example, studies that defined older patients as those aged ≥50 years were excluded, because not all patients in these studies were Medicare enrollees. In addition, Canadian studies conducted in a population aged ≥65 years were excluded, because this review was focused on the US Medicare population.

Second, the internal validity of included studies might have been affected by study design or other components of the methodology, such as the lack of standardized measures to assess patterns of medication use or the use of patient-reported measures of medication use. Very few studies used widely accepted and validated measures, such as the Medication Possession Ratio and Proportion of Days Covered measure, that use patients’ pharmacy claims, partly because these data were unavailable to the researchers.

This literature review evaluated studies that were conducted after, as well as before, the implementation of Medicare Part D. The reason for evaluating these studies together was that there were few published studies conducted after the implementation of Part D. To gain future insights, other researchers should investigate studies conducted only after the implementation of Part D.
Finally, the measurement of long-term outcomes is inadequate, because of the lack of large databases with clinical and/or economic information for elderly patients. The number of total studies included was low despite the minimally restrictive selection criteria. This low number could be the result of limited access to appropriate data sources, creating a need for greater efforts to be made to release this information to organizations and individuals conducting health services research.

Conclusion

As additional studies become available, results should continue to be synthesized for policy recommendations. CMS has issued a final ruling that permits the use of claims data collected from Medicare Part D beneficiaries for research by external researchers, including other federal agencies such as the US Food and Drug Administration and the Agency for Healthcare Research and Quality, as well as reputable academic centers and think-tank organizations. The release of these data may allow the study of the benefits and risks of different formulary controls, which would, in turn, inform benefit design and the differential impact of certain management strategies on patient subgroups, such as those with specific chronic conditions.

With such increased research and an active political environment determined to maximize value in the US healthcare system, the results presented here suggest that medication use among the elderly, along with clinical outcomes and economic efficiency, can potentially be improved through carefully crafted policies and drug coverage decisions that account for unintended consequences.

Acknowledgment

GlaxoSmithKline provided funding for this study; it had no influence over the content.

Author Disclosure Statement

Dr Shenolikar and Dr Cantrell are employees of and own shares of GlaxoSmithKline. Dr Schofield Bruno and Dr Eaddy are Consultants for GlaxoSmithKline.

References


We Need More Research on True Value-Based Benefit Design that Will Improve Outcomes and Control Costs

M EDICAL/P HARM ACY D IRECT OR S: Managing the Medicare drug benefit is one of the most challenging aspects of a Pharmacy and Therapeutics (P&T) committee’s duties. One of the major charges of a P&T committee is to provide plan members a wide range of drugs for a broad number of clinical indications. This must be done in the context of the overall pharmacy benefit cost. Keeping the benefit plan affordable, while providing adequate coverage for a broad range of medications, is not an easy task. To do this, we must balance not only the cost of the drugs but also the expected utilization, and one of the drivers of that utilization is plan member cost-sharing.

Dr Shenolikar and his colleagues have performed a systematic review of the literature for their study. They analyzed the 47 articles that evaluated the impact of drug coverage or cost-sharing on medication use in the Medicare population in the past 15 years (1995-2009). Their conclusion is not surprising to those involved in evidence-based pharmacotherapy and long-term mortality after acute myocardial infarction, JAMA. 2007;297:177-186.
suggests that restricting drug coverage or increasing out-of-pocket expenses for Medicare beneficiaries may lead to decreased medication use in the elderly, with all its potential implications.”

This is an issue that regularly comes up in benefit design discussions, and the P&T committee members are aware that increasing plan member cost may lead to a reduction in the use of essential medications, as well as medications that may not be essential or may even be inappropriate. It is the latter—nonessential and inappropriate medication use—that formularies and benefit designs are intended to address.

We all share the authors’ goal to create benefit designs and formularies that provide access to needed medications, while avoiding the cost associated with inappropriate or more costly medications that have clinically appropriate, lower-cost alternatives.

However, there is no easy solution to this cost versus benefit problem. Although it is tempting to lower member cost-sharing to improve the uptake and use of essential medications, experience tells us that when that is done, the utilization of essential as well as nonessential medications increases. That becomes important, because the result of increased utilization is increased cost to the plan.

We also know that as plan costs increase, the affordability of the plan drops, and some plan members are forced to drop drug coverage or choose less costly alternative plans that are even more restrictive. This may ultimately create the unintended consequence of more individuals having no, or only minimal, coverage because of their inability to afford the plan costs.

POLICYMAKERS/RESEARCHERS: I therefore agree with the authors’ conclusion that more research is needed to better understand the best ways to create affordable drug coverage plans. Such research must address how to motivate Medicare beneficiaries and their prescribers to make clinically and cost-effective medication choices, how to create benefit designs that facilitate these choices, and how benefit design and member cost-sharing impact clinical outcomes.

Our work is just starting in this area, and if we are to develop true value-based benefit designs that simultaneously improve outcomes and control cost, we will need much more research to help drive those decisions.

Gary M. Owens, MD
President, Gary Owens Associates
Philadelphia, PA