

## A Benefit-Based Copay for Prescription Drugs: Patient Contribution Based on Total Benefits, Not Drug Acquisition Cost

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Several managerial mechanisms have been used by managed care organizations to affect prescription drug utilization and related expenditures. Some efforts have focused on monitoring clinical conditions, drug use, and compliance, whereas other efforts have focused on consumer cost sharing and changing product-mix. Efforts focusing on improving quality of care by identifying untreated patients or by enhancing compliance can lead to appropriately increased drug costs, although perhaps with reduced overall medical expenditures. In contrast, the mechanisms implemented to constrain drug costs raise concerns regarding missed opportunities to enhance clinical outcomes, and the possibility of higher medical expenditures.

Cost sharing plays a critical role in defining the pharmaceutical benefit. To balance the demands for access to pharmaceuticals with pressures to constrain costs, levels of cost sharing must be set in a manner that achieves appropriate clinical and financial outcomes. Modern multitier systems often base patient contributions on drug acquisition cost, and often do not consider medical necessity as a coverage criterion. Using an alternative approach, the benefit-based copay, patient contributions are based on the potential for clinical benefit, taking into consideration the patient's clinical condition. For any given drug, patients with a high potential benefit would have lower copays than patients with a low potential benefit. Implementation of such a system would provide a financial incentive for individuals to prioritize their out-of-pocket drug expenditures based on the value of their medications, not their price.

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**P**rescription drug coverage is a critical agenda item on the healthcare policy landscape. Increasing utilization of available drugs, coupled with the sustained development and marketing of innovative products, is largely responsible for double-digit inflation in this sector.<sup>1-4</sup> As a result, man-

aged care organizations (MCOs) find themselves caught between enrollees and clinicians demanding access to approved therapies and employers insisting that cost growth be constrained. Thus, many employers and MCOs are actively evaluating benefit design changes in an attempt to simultaneously maintain enrollee satisfaction and stem rising drug costs.

Several managerial mechanisms have been used by MCOs to directly or indirectly affect prescription drug utilization and related expenditures.<sup>5</sup> These mechanisms affect some combination of patient and physician incentives, as well as prices. Although approaches toward utilization management vary widely, one trait they have in common is that they do not recognize the heterogeneity in potential benefit among patients.

Each mechanism has demonstrated some success in reducing costs. For example, closed or highly restrictive formularies have been associated with lower costs and smaller increases in drug utilization and expenditures.<sup>6</sup> Mechanisms to influence physicians' prescribing patterns through financial incentives have also been shown to have some limited effects on drug utilization.<sup>7</sup> In each case, it remains

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unclear whether the success in reducing costs will ever extend to success in reducing the rate of cost growth over time.<sup>8</sup> It also remains to be seen if overall medical expenditures will be affected by restraint on pharmaceutical spending.

Consumer cost sharing has been a long-standing component of pharmaceutical cost containment. Published MCO data clearly demonstrate that higher copays are associated with lower utilization and lower prescription drug costs.<sup>9,10</sup> However, the \$1, \$3, or \$5 copayments evaluated in many of these studies are inadequate to provide the level of financial offsets necessary today. Estimates of the price elasticity of demand for prescription drugs range from 0.1 to 0.2, meaning that cost sharing does matter, but that a doubling of a copayment may yield only a 10% to 20% decrease in the quantity of prescriptions purchased.<sup>10</sup> Therefore, copayments of \$10 and \$15 are now the norm, with some plans charging \$25 or more in some cases.<sup>5</sup> In certain instances, increases in copayments have restricted access to medications, causing undesired effects, particularly among poor and elderly populations.<sup>11-13</sup> Despite these concerns, further copay increases are expected, given the marginal successes of other mechanisms to curtail drug expenditures.

Managed care organizations are implementing multitiered cost-sharing arrangements to balance the demands for increased access to pharmaceuticals with pressures to constrain costs.<sup>14,15</sup> Managed care organizations want to allow consumers to express their preferences for selected products by their willingness to pay, while ensuring that no prescription goes unfilled because a patient cannot afford the copay. A recent survey demonstrated that financial incentives for patients would increase their likelihood to use generic drugs, even for those individuals who perceived generic agents as riskier than branded products.<sup>16</sup>

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... PATIENT COST SHARING: CONCEPTUAL  
FRAMEWORK ...

Multitiered copays and reference-pricing schemes allow MCOs to define a "basic" level of coverage, with low cost sharing for certain agents and coverage of other products at higher copayments. This basic level of coverage fulfills the risk-sharing mission of insurance, but higher copays allow consumers access to preferred products at additional cost. The differences between various multitier and reference-pricing systems are in the defining of the

number and breadth of tiers and the magnitude of the incremental cost sharing in successively higher tiers. These systems differ from formulary-only systems in that some coverage is provided for all products, albeit at potentially high levels of cost sharing for nonpreferred drugs. In certain situations, multitier systems require that patients weigh the differences in copayments with the differences in the perceived benefit of the alternative treatment options.

Is it appropriate to place the burden of weighing the incremental benefits and costs of alternative medications on the patient?<sup>9</sup> In select instances, such as the choice of products for cosmetic purposes (eg, hair growth), consumers might be able to make informed cost/benefit decisions. However, for most common medical conditions (eg, hypertension, cholesterol lowering), the decisions are complex and the responsibility for decision making might best involve the clinician or the provider of the prescription drug benefit.

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... THE BENEFIT-BASED COPAY ...

Creativity is called for in the design of cost-sharing schemes that effectively constrain costs, but also ensure that individuals who need prescription drugs have affordable access to them.<sup>17</sup> To meet this aim, we suggest a new concept, called the "benefit-based copay" (BBC). The BBC builds on the fundamental concept of all drug benefit plans in its desire to provide basic pharmaceutical coverage. What distinguishes the BBC from existing systems is its determination of patient copays based on medical need and costs, as best determined from the available medical and economic evidence. In the BBC, a patient's copay is based on the expected clinical benefit from the prescribed drug(s). The BBC allows the copay to vary by the evidence-based benefit of the medication for the individual patient. The key to implementing the BBC is that MCOs and their clinicians accept the responsibility for decision making on the benefits and costs of prescription drugs and create clearly defined systems for their determination.

Specifically, the starting point for establishing BBC copays are estimates of the benefit a patient would receive from a specific drug as determined from the available scientific evidence, relative to the total cost of treatment. Lower copays are established for patients who present with clinical attributes similar to individuals for whom a drug has been proved to be beneficial in clinical studies (eg, statin

therapy for a patient with a history of 2 myocardial infarctions and an abnormal low-density lipoprotein level [LDL > 160 mg/dL]). Higher copays are charged to patients who are less likely to benefit clinically (eg, statin therapy for a individual with 1 coronary artery disease risk factor and a borderline normal cholesterol [LDL = 130 mg/dL]). The full benefit/cost analysis (preferably from a societal perspective) is used to determine the copay.

The concept of determining copays based on measures other than prescription drug prices has received wide support.<sup>18</sup> On one extreme, copayments might need to be set unreasonably high to discourage unnecessary services. On the other extreme, some authors have suggested that copayments might be negative (ie, paying patients to fill prescriptions) in the case of certain patients and certain medications.<sup>19</sup> One key to determining patient-specific copays is the perspective taken by the designer of the prescription drug benefit. We might envision an ideal system in which a societal perspective is adopted uniformly by insurers. However, individual third-party payers may also use a balance of patient and clinician perspectives to balance their needs for ties to customers and provider networks. Moreover, some have observed that MCOs' development of formularies or preferred lists of medications need to account for socioeconomic considerations, and not just drug price.<sup>20,21</sup> Once implemented, the BBC could be used to help low-income patients most in need of access through lower financial barriers. Again, the perspective of the designer, be it society or patient focused, becomes critical in decisions involving socioeconomic considerations.

**Derivation**

The BBC approach can be used by an MCO to determine the enrollee contribution, while simultaneously tracking the health plan's expenditure for a specific prescription drug. In addition, the BBC can be used in a dynamic format that allows for enrollee contributions to change, as the overall use (or price) of the drug changes. Thus, when certain target expenditures are met, a different set of copays can be put in place after utilization data are examined.

For example, assume there are 2 patient groups (high benefit [H] and low benefit [L]) and 2 drugs (old product [O] and new product [N]) are available for a specific indication. Individuals are assigned to H or L based on clinical indication(s) and the proven relative effectiveness of drugs O and N for that indication. The relative likelihood of benefits, relative to costs, determines the copay for each drug (eg, C<sup>H,N</sup> is

the copay [C] for high-benefit patients [H] for drug N). The copay for any drug is always lower for the high-benefit than low-benefit patients (C<sup>H,N</sup> < C<sup>L,N</sup>). Therefore, the average patient contribution and purchaser cost can be calculated using Equations 1a and 1b and be easily compared to current contributions under a standard multitiered plan:

Equation 1a: patient contribution =  $\theta^H[\varphi^{H,N} C^{H,N} + \varphi^{H,O} C^{H,O}] + \theta^L[\varphi^{L,N} C^{L,N} + \varphi^{L,O} C^{L,O}]$ ,

Equation 1b: purchaser cost =  $\theta^H[\varphi^{H,N} P^N + \varphi^{H,O} P^O] + \theta^L[\varphi^{L,N} P^N + \varphi^{L,O} P^O]$

1a) Copay	Average copay under the BBC, per prescription filled
1b) Cost	Average purchaser cost under the BBC, per prescription filled
$\theta^H$	Percent of total population in high-benefit group [H] ( $\theta^H + \theta^L = 1$ )
$\theta^L$	Percent of total population in low-benefit group [L]
$\varphi^{H,N}$	Percent of patients in high-benefit group who choose the new medication [N]
$\varphi^{L,N}$	Percent of patients in low-benefit group who choose the new medication
$\varphi^{H,O}$	Percent of patients in high-benefit group who choose the old medication [O]
$\varphi^{L,O}$	Percent of patients in low-benefit group who choose the old medication
P <sup>N</sup>	Purchase price of new medication, per prescription (excluding copay)
P <sup>O</sup>	Purchaser price of old medication (excluding copay)
C <sup>H,N</sup>	Copay under BBC for the new medication for high-benefit patients
C <sup>H,O</sup>	Copay under BBC for the old medication for high-benefit patients
C <sup>L,N</sup>	Copay under BBC for the new medication for low-benefit patients
C <sup>L,O</sup>	Copay under BBC for the old medication for low-benefit patients

Given the number of variables in the above equations that the MCO controls, there are numerous ways in which a health plan can use the BBC system to meet specific managerial objectives. For example, a payer can select the copay parameters such that total expenditures on a drug would be equal under the BBC and a standard multitiered system, while enhancing compliance and clinical outcomes. In set-

ting the 4 copay amounts (C), it is important to recognize that the relative number of patients choosing a drug within each patient group (captured by the percentages –  $\varphi$ ) will depend on the copays selected.

**Motivation**

We offer several motivations for the BBC approach. The first is derived from the basic economic motivation for copayments. Economic theory views consumer cost sharing as a mechanism to reduce the moral hazard (ie, overconsumption) that occurs when insurance lowers the price of care paid by patients. Yet, high copays transfer risk to the consumer. Optimal copays balance the tendency for overconsumption with the spreading of risk among consumers.<sup>22</sup> In situations in which spending is not responsive to prices (inelastic demand), copays should be low because there is little overconsumption to discourage (eg, antiemetic agents for patients undergoing chemotherapy). In situations in which spending is responsive to prices (elastic demand), economic theory argues that copays should be higher. Although we know something about demand elasticities for prescription drugs as a whole, and for certain classes of drugs for certain populations, much more research in this area will be required.<sup>10,12,13</sup>

Reference-pricing systems implicitly consider responsiveness to price, by assuming that spending on the reference product is not discretionary. Optimal cost sharing in reference-pricing systems would likely be somewhat below the full incremental price because of consumers' aversion to risk.<sup>23</sup> Other multitiered systems also incorporate elasticity of demand. A low copay charged for the bottom tier (as opposed to no cost sharing) can be viewed as an attempt to discourage overconsumption in those situations in which no consumption is a possibility.

The distinction between BBC and reference pricing is that reference-pricing systems do not recognize that the elasticity of demand for a drug is often related to the clinical benefits obtainable by that agent. In one situation a drug may be life saving and in others that same drug may be used for less clinically important reasons (eg,  $\beta$  blockers to reduce mortality from congestive heart failure or to reduce performance anxiety). The BBC system links the copayment amount to the estimated benefit for the patient in each situation. Patients most likely to benefit are assumed to be relatively unresponsive to prices (if fully informed) and in the BBC system are charged a lower copay than patients less likely to benefit from the same drug. This higher copay is an

attempt to offset the potential for insurance-induced overconsumption in the low-benefit group. The specific elasticity estimates have not been prepared with the BBC in mind, but calculation of such estimates is a manageable exercise.

A second motivation for a BBC system centers on imperfect information. Some evidence has suggested that patients may not always have complete information regarding the benefits of their prescribed agents and, as a result, consumption may not be optimal. For example, individuals who may benefit substantially from cholesterol-lowering agents may not perceive that benefit while they are asymptomatic. Thus, at any given price, they may be less (or more) likely to buy and consume pharmaceuticals than if they were fully informed. Copays in the BBC system could be set to reward "appropriate" consumption/compliance and discourage inappropriate use. We acknowledge that copays are not the only factor, and certainly not the most important factor in compliance. To some extent, however, copayments do influence the patient's decision on prescription drug spending.

The third justification of the BBC relies on arguments of equitable access to pharmaceuticals. Multitiered copay systems may be particularly taxing on low-income consumers. The elderly and the poor may be at risk for adverse health status changes if copays become burdensome.<sup>12</sup> Socioeconomic status is an important predictor of health status and medical care utilization. The importance of issues surrounding the ability to pay for needed prescription medications was highlighted during the past presidential campaign. The lower copay for "high-benefit" patients in the BBC system reduces the financial burden for patients who would most benefit from the medication. Persons with lower levels of disposable income would particularly welcome lower out-of-pocket expenditures. Again, the perspective of the end user of the BBC is important. Equity considerations will enter into the BBC only to the extent that the perspective of the designer includes equity considerations and the designer is willing and able to define parameters of benefit that are differential by socioeconomic status.

**Example—Cholesterol Reduction**

The rigorous level of evidence required to implement the BBC does not allow its use in all clinical areas. However, we believe this approach can be used confidently in several important clinical areas. One clinical situation in which data are available to pilot the BBC approach is cholesterol reduction.

Substantial research has resulted in guidelines for targeting cholesterol levels and for testing and initiation of therapy. Guidelines for target cholesterol levels in both the United States and Europe are based on patient-specific, clinical values.<sup>24,25</sup> These guidelines also specifically address cost considerations. Among the guidelines for testing and initiation of therapy are the Sheffield tables, which specify age, gender, hypertension, smoking, diabetes, and left ventricular hypertrophy factors along with total cholesterol levels.<sup>26</sup> The recommendations in these tables are based on the value of primary prevention of persons whose risk for coronary death exceeds 1.5% per year and are updated for patients whose risk for coronary events exceeds 3% per year. These tables are based on expected levels of LDL cholesterol level reduction with the initiation of statins and costs per life-year saved. Models and analyses based on trials have further refined guidelines to account for the range of available therapies.<sup>27,28</sup> Clinicians and patients alike could easily understand a copay system for statins that is based on well-defined factors that identify both the increased risk of the underlying medical condition (coronary artery disease) and the benefits of therapy (through lowering of the serum cholesterol).

Thus, relating to the first motivation for a BBC—balancing risk and moral hazard—guidelines for statin therapy take into consideration the clinical benefits of therapy and the economic benefits in terms of reduced future treatment costs, as well as the present costs of testing and drug therapy. By establishing lower copays based on patient characteristics (eg, prior infarction) for products that effectively reduce the probability of an adverse event, we hypothesize that a greater percentage of patients will comply with recommended therapy after previously established financial barriers are reduced.

Regarding imperfect information, statin therapy is a clear example of an area in need of attention. In every setting investigated, statins are underused according to guidelines, and inconsistency exists regarding which patients are targeted to receive, and comply with, prescribed therapy.<sup>29-32</sup> Further, patients are likely unaware of clinical and economic differences among medications in this class—information that could be used in the design of the BBC.<sup>31</sup> Through lower copays, the BBC would expand the appropriate use of these life-saving drugs.

Pertaining to equitable access, it is widely recognized that substantial disparities exist in the health-care system in the United States.<sup>33</sup> Differences exist for a number of services, including drug coverage,

and disparities are associated with a number of sociodemographic factors, including age.<sup>34-36</sup> The BBC would reduce these disparities where they matter most: where potential for clinical benefit is greatest.

### Implementation

The primary drawback of the BBC system is its implementation—a common problem encountered in benefit redesign.<sup>37</sup> Several conditions must be met for such a system to be feasible. First, the BBC is possible only if patients can be easily characterized by potential benefit from a specific agent. Outcomes research data and other clinical studies are increasingly being performed that explicitly provide this information. Emerging data suggest that BBCs can be determined for “safer” or “better” products such as cyclo-oxygenase 2 (COX-2)-specific nonsteroidal anti-inflammatory drugs, proton pump inhibitors, or selective antibiotics. Some MCOs are now demanding such data be presented before authorizing payment of a drug.<sup>38</sup> Other MCOs and provider organizations are putting such a system in place for reasons that extend beyond just managing the pharmacy benefit.<sup>39,40</sup>

Substantial time and effort will need to be devoted to eliciting the appropriate perspective (societal or other), criteria (target spending levels, equity concerns), and observable factors to be used to determine important clinical and economic parameters necessary to set the precise copay amount. In the case of cholesterol reduction, there is a good match of perspectives (as presented by National Cholesterol Education Program guidelines), criteria that were followed (cost per life-years saved), and observable factors (total cholesterol, LDL-C, age, other comorbidities). Treatment guidelines and protocols exist for many other common conditions such as diabetes mellitus and osteoporosis.

Second, patients and clinicians must be willing and able to use the system. There are some areas in which appropriate use of prescription drugs depends on factors that are either not observed or are easily manipulated by patients or physicians anxious to obtain pharmaceuticals at lower costs. It has been found that some physicians act as economic agents on behalf of their patients, in addition to their role as medical agents.<sup>41</sup> Such behavior could undermine any system of benefit coverage. Provider or patient backlash against systems that are too complex or deemed unfair can also have negative consequences.<sup>42</sup> Employers expect MCOs to contain costs, but providers and patients will not select plans that

do not meet their needs. Although we would advocate a societal perspective, to maximize efficiency of the healthcare system as a whole, BBC designers with a third-party perspective (the likely party) may also need to consider patient and clinician views.

Closely related to the issue of acceptance of the BBC is how it fits with other cost-sharing and utilization management systems. In an ideal setting, separate BBCs would exist for physician services, hospital services, ancillary services, and prescription drugs. To the extent that systems conflict, the BBC might be less effective. For instance, if access to physician office visits is restricted by high visit copayments, there may be little effect of a low BBC for an essential, preventive care medication.

A third potential drawback is concern over the number of copay levels or frequently changing copays. This problem is not unique to BBCs; in many multitiered systems the patient and the physician are frequently unaware of the exact copay until the patient reaches the pharmacy. Because the BBC will require clinical information to determine the copay, information systems must be able to calculate the copay before the patient leaves the clinical encounter. This timely information should eliminate the unwanted situation in which a patient is unable to pay for a prescription that has been filled. While an idealized system might have copays varying by small amounts changing over a course of treatment, practicality may dictate that copays be rounded to the nearest dollar, that they be consistent within an episode of care, and that calculated "optimal" amounts not exceed the market price of the prescription.

In summary, several managerial tools have been developed to ensure appropriate uses of medications and to curtail the rapid growth of pharmaceutical expenditures. To this end, efforts that have focused on identifying untreated patients or enhancing compliance rates have led to increased drug costs. In contrast, mechanisms implemented to constrain prescribing patterns have led to concerns that patients cannot fill their necessary prescription(s) because of an inability to pay the out-of-pocket component. Despite these concerns, enrollee cost sharing must undoubtedly play a critical role in defining future drug benefit, if prescription plans are to remain a viable part of the healthcare benefit.

By linking the patient contribution to the estimated evidence-based clinical and economic benefit at a patient-specific level, a greater proportion of the population most likely to benefit from taking a medication will be able to do so. Though unproven,

the BBC is a concept that stands on science and equity, and its objective to ensure that effective drugs get into the hands of patients who truly need them is consistent with the basic goals of healthcare delivery.

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