Alternate Financial Incentives in Multi-tiered Formulary Systems to Improve Accountability for Outcomes

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ABSTRACT

BACKGROUND: Drug manufacturer rebates paid to health plans and pharmacy benefit management companies have come under increased public scrutiny. Over the past several years, numerous articles have appeared in the literature encouraging a shift to a more quality-based decision-making process for health plan drug formularies.

OBJECTIVE: To propose a new basis for formulary placement decisions that would include consideration of health-plan-specific measures (clinical outcomes, total cost, adherence, and appropriateness of care) and align incentives for health plans, physicians, pharmacists, and pharmaceutical companies to promote high-quality care.

SUMMARY: The proposed approach builds on key components of the Academy of Managed Care Pharmacy’s Framework for Drug Therapy Management in the 21st Century and the Academy of Managed Care Pharmacy’s Format for Formulary Submission, including a focus on patient outcomes and evidence-based decision making. The proposed approach would lessen the influence of drug manufacturer rebates on formulary placement by shifting the focus to appropriateness of care, clinical outcomes, patient adherence, and total cost of care. Pharmaceutical manufacturers would benefit from the focus on adherence to drug therapy and total cost of care. Health plans and pharmacy benefit management companies would gain in that they may be able to reduce efforts in drug utilization review as pharmaceutical manufacturers are given incentives to market their drugs more appropriately. Physicians and pharmacists would benefit because the rebate money would be used to provide quality-based financial incentives related to adherence and appropriate use of drugs.

CONCLUSION: The implementation of this approach would be difficult and require cooperation from employers, pharmacists, pharmaceutical manufacturers, health plans, and pharmacy benefit management companies. Aspects of this approach could be incorporated into existing pharmacy benefit management processes to encourage the delivery of high-quality health care.

KEYWORDS: Financial incentives, Drug formulary, Outcomes assessment

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T he practice of providing drug manufacturer rebates to health plans and pharmacy benefit management companies (PBMs) has recently come under greater public scrutiny.1-3 In April 2003, the Office of Inspector General (OIG), U.S. Department of Health and Human Services, issued a compliance program guidance for pharmaceutical manufacturers, which states (in part):

In particular, manufacturers should ask the following questions, among others, about any problematic arrangements or practices they identify: Does the arrangement or practice have a potential to interfere with, or skew, clinical decision-making? Does it have a potential to undermine the clinical integrity of the formulary process? If the arrangement or practice involves providing information to decision-makers, prescribers, or patients, is the information complete, accurate, and not misleading?1-3

Though not prohibited, discounts to purchasers, including rebates, need to be carefully reviewed to ensure they do not violate these OIG guidelines. The current process in drug formulary development and management tends to focus more on net drug cost than total (medical and pharmaceutical) costs and is therefore influenced significantly by the amount of drug rebates. This may be particularly true for PBMs that benefit financially from rebate revenues but do not share the risk for medical expenditures.3 The focus on drug rebates may lead to consequences that include inappropriate use and overuse of certain medications. Health plans respond to perceived misuse with drug utilization management strategies and interventions that may increase administration costs to the system.

The proposed (alternate) approach would realign incentives for pharmaceutical manufacturers, health plans, pharmacists, and physicians in an effort to improve the quality of care and clinical outcomes. This approach draws on suggestions from Pharmacy’s Framework for Drug Therapy Management in the 21st Century1 and the Academy of Managed Care Pharmacy’s Format for Formulary Submissions. Pharmacy’s Framework for Drug Therapy Management encourages a focus on patients and their clinical, service, and cost outcomes, while the Format for Formulary Submissions calls for comprehensive evaluation of documents that could be used in evidence-based decision making. Emphasis on outcomes and evidence-based decision making are key components of the approach proposed here, the specific goals of which include

1. lessening the influence of proposed rebates on formulary placement by shifting the focus to appropriateness of care,
clinical outcomes, patient adherence, and total cost of care; 2. encouraging health plans and PBMs to develop effective quality improvement programs, including incentive programs; 3. rewarding physicians and pharmacists for “best practices,” including improvements in patient adherence and appropriate use of drugs; and 4. encouraging pharmaceutical manufacturers to promote their drugs appropriately.

This approach is based on the assumption that total cost of care will be reduced through the encouragement of the appropriate use of the most cost-effective pharmaceuticals.

**Current System**

Current procedures for managing formularies vary considerably based on market conditions and organizational structure. In general, for 2 drugs that are considered to be equally safe and efficacious, the dollar amount of proposed rebates may be the factor that determines level of formulary placement (Figure 1). Regardless of whether a pharmaceutical attains preferred status on a formulary, it may be promoted in the community by pharmaceutical sales representatives. Because these representatives are often given volume-based financial incentives, their promotion of the pharmaceutical may result in overuse or inappropriate use. This may lead to suboptimal clinical outcomes and unnecessary inflation of pharmaceutical costs. Managed care organizations respond to this cost inflation with mechanisms that attempt to control costs while maintaining high-quality care, including prior authorization, counter-detailing, and differential copayment levels.6-11

**Proposed System**

Our proposed approach focuses on encouraging best practices for health plans, PBMs, physicians, pharmacists, and pharmaceutical manufacturers within a formulary management system, particularly one tied to tier-copay benefit designs (Figure 2). Multi-tiered copayments in prescription drug benefits have increased in number over the past several years as managed care organizations have struggled to meet patient preferences for open formularies (choice) while containing costs.12 A survey of 700 large employers found that 60% were using a multi-tiered copayment structure in drug benefit design in 2002, up from 48% in 2001.13 Moving to a multi-tiered copayment structure results in cost savings to health plans and employers by encouraging members to shift to lower-cost generic and brand-drug alternatives, increasing member copayments for their more costly drug choices, decreasing drug usage, and increasing rebates to health plans from pharmaceutical manufacturers.

Our proposed approach involves changing the basis for formulary placement in a multi-tiered system. Rather than basing decisions for drugs with similar safety and efficacy on net drug price, the proposed approach would expand the focus to include appropriateness of care, clinical effectiveness, total cost of care, and patient adherence. Net drug price would be one component of total cost of care.

**Appropriate Use of Pharmaceuticals**

Many of the newer pharmaceuticals have been proven to be cost effective for specific types of patients. Health plans have implemented preauthorization requirements to encourage appropriate use of many brand-name drugs and step-therapy protocols that specify first-line use of generic alternatives. Under the proposed system, fewer preauthorization requirements would be needed as pharmaceutical manufacturers would become more accountable for appropriate drug use. The drug makers would receive reports on the appropriate use of their drugs, relative to
competitors, and formulary placement would depend, in part, on the level of appropriate use.

Health plans and PBMs are already actively involved in developing prior-authorization requirements or system edits to encourage appropriate use of pharmaceuticals, particularly high-cost ones. Moreover, in the Pharmacy's Framework for Drug Therapy Management's self-assessment tool, pharmacists are encouraged to consider whether the patient has been effectively assessed and accurately diagnosed and whether appropriate drug therapy has been selected (Core Focus Area #3). Under the proposed approach, health plans would work with pharmacists and physicians to derive guidelines for appropriate use, based on evidence from the literature and/or analysis of claims data. The pharmacist's self-assessment grid could be modified to include a component indicating whether the use of the drug was appropriate based on these guidelines. Once the criteria are approved, pharmaceutical manufacturers could be given a profile of the use of their drug compared to others in the same therapeutic category.

For example, Table 1 summarizes the appropriate usage of COX-2 inhibitors for 2 brand drugs according to appropriateness criteria developed by a health plan. Concomitant use was defined as use of another drug within 60 days of the COX-2 inhibitor. History of comorbidities was defined as having at least one ICD-9 code for a given condition within 1 year prior to the COX-2 inhibitor prescription. The following ICD-9 codes were used in the analyses: rheumatoid arthritis 714.0-714.3x; osteoarthritis 715.xx; chronic spondylitis 721.xx; systemic lupus erythematosus 710.0; gastroduodenal ulcer 531.x, 532.x; GI bleed 578.x.

| TABLE 1 | Number of Patients Who Met the Criteria for Appropriate COX-2 Usage* |
|---------|------------------|-------------------|------------------|
|         | Total A          | Drug A            | Drug B           |
| N       | %                | N                | %                | P Value  |
| 1. Age >60 | 6,583 (40.2% 4,330 (44.7% 2,253 (33.6% <0.0001 |
| 2. Medically significant chronic disease (osteoarthritis, rheumatoid arthritis, chronic spondylitis, systemic lupus erythematosus) | 5,423 (33.1%) 3,454 (35.7%) 1,969 (29.3% <0.0001 |
| 3. History of gastroduodenal ulcer or GI bleed | 976 (6.0%) 600 (6.2%) 376 (5.6%) 0.1131 |
| 4. Patient is on concomitant glucocorticoid or anticoagulant therapy | 1,359 (8.3%) 866 (9.0%) 493 (7.3%) 0.0003 |
| 5. Patient is on concomitant misoprostol, proton-pump inhibitor, histamine antagonist, or misoprostol-diclofenac combination | 1,859 (11.3%) 1,161 (12.0%) 698 (10.4%) 0.0016 |
| 6. Patient is on chronic high-dose NSAID therapy | 74 (0.4%) 42 (0.43%) 32 (0.48%) 0.6867 |

*The sample population for this illustration was composed of patients in possession of a COX-2 inhibitor on March 31, 2002. Concomitant use was defined as use of another drug within 60 days of the COX-2 inhibitor. History of comorbidities was defined as having at least one ICD-9 code for a given condition within 1 year prior to the COX-2 inhibitor prescription. The following ICD-9 codes were used in the analyses: rheumatoid arthritis 714.0-714.3x; osteoarthritis 715.xx; chronic spondylitis 721.xx; systemic lupus erythematosus 710.0; gastroduodenal ulcer 531.x, 532.x; GI bleed 578.x.
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If a health plan or PBM wanted to go a step further, they could also ask physicians to rate the appropriateness of a manufacturer’s drug detailing in their community. Researchers in Canada developed the Assessment Instrument for Drug Detailing (AIDD) that asks physicians to score the quality of drug detailing provided by pharmaceutical sales representatives.15 Mean scores for each major pharmaceutical manufacturer could be calculated and used to support formulary decisions.

Although health plans might prefer to influence participating physicians without interference from drug sales representatives, the reality is that these representatives spend a considerable amount of time educating physicians about their products. The proposed approach would encourage pharmaceutical manufacturers to work with health plans and PBMs to develop appropriateness criteria and to reward sales representatives for promoting appropriate use. Giving preferred formulary placement to products that are marketed appropriately, through detailing and advertisement, would ultimately lead to more cost-effective care. Ideally, this would encourage sales representatives to make longer, more meaningful calls on physicians that would allow them to discuss appropriateness.

With the pharmaceutical manufacturers given incentives to improve appropriateness, health plans may need fewer preauthorization requirements. For instance, a health plan might agree to remove preauthorization requirements if a drug were to reach a certain level of appropriate use (e.g., 90%). In addition, a specific physician might not need to seek preauthorization when he or she reaches a certain threshold for appropriate usage. Appropriate-use criteria would be reviewed regularly to ensure continued cost-effective care.

Patient Adherence

Randomized controlled trials generally follow a strict protocol and have regular monitoring to insure high patient adherence. Part of the reason that efficacy demonstrated in clinical trials is not always evident in the community is that patients outside of clinical trials are much less likely to adhere to drug treatment plans.16 Under the proposed system, health plan or PBM staff would analyze retrospective claims data to assess differences in adherence between all drugs for a specific condition. These analyses would be based on possession ratios calculated from pharmacy claims. For instance, for each drug, one could compare the percentage of patients who had the drug in their possession at least 80% of the time. Adherence would not be examined for drugs taken as needed.

Clinical Effectiveness of Care

Under the proposed system, health plans or PBMs in partnership with health plans, would analyze retrospective claims data to determine which drugs demonstrated the best patient outcomes, including fewer side effects (e.g., bleeding) and adverse events (e.g., acute myocardial infarction). When available, health-related quality of life, attainment of goal lab values, and work days lost would also be examined.

There are several reasons why these outcomes analyses might be worth the effort. As stated above, efficacy data from clinical trials often do not mirror real-world experience, partly because adherence rates tend to be lower outside of clinical trials. Second, a health plan’s membership may differ from the clinical trial population in terms of age, severity of disease, ethnicity, or other important characteristics. Prior evidence suggests that drug efficacy differs with respect to patient characteristics.17

Analysis of health plan data would reveal information on outcomes for the specific population that would be affected by any decisions. While this type of drug-specific outcomes analysis would only be possible for high-volume drugs, the analyses might be modified to look at outcomes by therapeutic class for other drugs with less volume. This review of health-plan-specific effectiveness data, in conjunction with evidence from the literature, would provide decision makers with a more comprehensive view of the potential impact of formulary decisions.

Total Cost of Care

Evidence from the literature clearly suggests that many drug therapies improve the health of patients, thereby decreasing hospital admissions and increasing productivity.18 When drug formulary placement decisions are made, however, medical service offsets are often not considered. Rather, the net drug cost, calculated from the price and potential rebates, is often the only cost figure taken into account. Under the proposed model, cost analyses would focus on total costs of care, including pharmaceutical, inpatient, outpatient, and physician fees. The goal of the proposed approach would not be to reduce drug expenditures but to increase expenditures on the most cost-effective medications, reduce expenditures on inappropriately used medications, and reduce medical costs through improved outcomes.

Rebates Replaced With Quality-Improvement Incentives

Rebates currently average between 2% and 20% of the drug’s wholesale price and are given to health plans by drug manufacturers based on market share and other factors. Under the proposed system, rebates from pharmaceutical companies would be replaced by payments tied to specific programs that promote high-quality care, including disease management and quality-based financial incentive programs for physicians and pharmacists. Use of incentives to promote quality in health maintenance organizations and preferred provider organization health plans has become increasingly common. In September 2002, the Centers for Medicare and Medicaid Services announced a demonstration project that would reward physicians in group practices for improvements in the quality of care they provide to Medicare enrollees.19 The “bonus” money would be derived from savings achieved through improvements in patient management. The concept of pharmacy incentives is a natural extension of the use of incentives for physicians.20,21 These incentive programs could include bonuses for improving patient adherence.
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and appropriate use of medications. When generic drugs are used instead of brand-name drugs, money could still be allocated to quality incentive programs by health plans by using a portion of the savings from switching to generic drugs. As an example, a pharmaceutical company provided disease management and health literacy services to Florida Medicaid enrollees in lieu of rebate payments. Results from the first year of performance are pending, but preliminary data suggest that the program may be associated with reduced hospital admissions.

Underlying Assumptions

There are several assumptions that would need to be true for this approach to be effective. First, we assume that the measurement of clinical outcomes and appropriateness can be done accurately and effectively. This focus on outcomes will work best for high-use drugs. For drugs with low utilization or rare outcomes, a single health plan’s data would be unlikely to provide evidence of significant differences among treatment alternatives. However, groups of health plans, such as members of the Blue Cross and Blue Shield Association, could pool data to examine outcomes. Second, the quality of the outcomes analyses would depend on the quality of the data employed. Health plans would need to invest in data infrastructure prior to implementing this approach and would often need to collaborate with a PBM company to measure outcomes. Once algorithms were defined, the level of resources needed may diminish.

Discussion and Limitations

Over the past several years, numerous articles have appeared in the literature encouraging movement toward a more quality-based decision-making process for pharmaceutical formulas. Under the proposed approach, decisions regarding formulary placement would be based on evidence from the literature as well as health-plan-specific measures including appropriateness, adherence, clinical outcomes, and total cost. Incentives for health plans, physicians, pharmacies, and pharmaceutical manufacturers would be realigned to promote the delivery of high-quality care. Health plans would benefit from the improvement in the health of their members. They would also receive support for quality-improvement programs that have demonstrated positive outcomes, and they may be able to reduce the cost of their drug utilization review as pharmaceutical manufacturers are given incentives to market their drugs more appropriately. Pharmacists and physicians would be rewarded for increases in patient adherence to drug therapy and appropriate use of specific pharmaceuticals. Pharmaceutical manufacturers would see the rebate money being used to increase patient adherence. Drugmakers with relatively more effective products would also benefit from the focus on total cost rather than net drug price.

Health plans could also use the results to inform employers and members of the cost-effectiveness of pharmaceuticals. Employers are increasingly requesting this type of information as they make decisions regarding coverage options for their employees.

One limitation would be lack of plan-specific outcomes for new drugs. The FDA approved an average of 38 new drugs per year during the 1990s. Because health-plan specific outcomes data would not be available for new pharmaceuticals, formulary decisions would need to be based on available evidence from trials and published studies.

Another limitation would be the lack of sufficient data, in terms of scope and timeliness, to compare specific drugs. With regard to scope, systems that do not have integrated medical and pharmaceutical data would have difficulty linking drugs with total cost of care or outcomes of care. This is a significant limitation but not an insurmountable one. It is possible to develop partnerships between health plans and PBMs that would facilitate the sharing of these data. In addition, although outcomes data might be limited, aggregation of data may sometimes be acceptable, such as comparing drug therapy outcomes at the therapeutic-class level rather than the trade-name level. PBMs may also combine data from several health plans to draw general conclusions on effectiveness. Moreover, while timeliness of data is an important issue, we believe that new technologies have permitted prompt processing of claims, spurred further by scrutiny from the National Committee for Quality Assurance.

This manuscript is largely hypothetical and does not address some of the unresolved issues in formulary placement. For example, should the market share of a drug affect formulary placement? While community physicians and members might prefer that the health plan offer preferred status to a drug they use most often, a purely evidence-based approach would not give preference to drugs with higher market share. Another question that remains is: Should a health plan attempt to strike business partnerships with all drug manufacturers by allowing each to have a “preferred” drug in at least one therapeutic class? By embracing all drug manufacturers in some fashion, a health plan might avoid encouraging one pharmaceutical manufacturer to initiate an aggressive marketing campaign to offset formulary decisions. While these issues are not addressed in this approach, they would need to be considered when making formulary decisions.

Conclusion

The proposed approach would retain a multi-tier copayment system but would base drug formulary position on health-plan-specific data concerning appropriateness, patient adherence, clinical outcomes, and total cost of care as well as evidence from the literature. Implementation of this approach would be difficult and require cooperation among employers, pharmaceutical manufacturers, pharmacies, physicians, and health plans. However, aspects of this approach have already been incorporated in pharmacy benefit management processes and quality-of-care initiatives across the country. For example, in 1998, Regence BlueShield of Seattle adopted formulary submission guidelines that focused on demonstrating the outcomes and
value of pharmaceuticals.30 These guidelines have become a model for health plans across the country. Moreover, researchers at the Department of Veteran’s Affairs Medical Center in Durham developed and validated a Medication Appropriateness Index for use in research, quality improvement initiatives, and clinical care.31 By integrating aspects of initiatives like these that have been successfully implemented across the country, the proposed approach seeks to encourage health plans, PBMs, physicians, pharmaceutical manufacturers, and pharmacists to help bridge the “quality chasm” documented in the Institutes of Medicine report.32

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REFERENCES