Design, Implementation, and First-Year Outcomes of a Value-Based Drug Formulary

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ABSTRACT

BACKGROUND: Value-based insurance design attempts to align drug copayment tier with value rather than cost. Previous implementations of value-based insurance design have lowered copayments for drugs indicated for select “high value” conditions and have found modest improvements in medication adherence. However, these implementations have generally not resulted in cost savings to the health plan, suggesting a need for increased copayments for “low value” drugs. Further, previous implementations have assigned equal copayment reductions to all drugs within a therapeutic area without assessing the value of individual drugs. Aligning the individual drug’s copayment to its specific value may yield greater clinical and economic benefits. In 2010, Premera Blue Cross, a large not-for-profit health plan in the Pacific Northwest, implemented a value-based drug formulary (VBF) that explicitly uses cost-effectiveness analyses after safety and efficacy reviews to estimate the value of each individual drug. Concurrently, Premera increased copayments for existing tiers.

OBJECTIVE: To describe and evaluate the design, implementation, and first-year outcomes of the VBF.

METHODS: We compared observed pharmacy cost per member per month in the year following the VBF implementation with 2 comparator groups: (1) observed pharmacy costs in the year prior to implementation, and (2) expected costs if no changes were made to the pharmacy benefits. Expected costs were generated by applying autoregressive integrated moving averages to pharmacy costs over the previous 36 months. We used an interrupted time series analysis to assess drug use and adherence among individuals with diabetes, hypertension, or dyslipidemia compared with a group of members in plans that did not implement a VBF.

RESULTS: Pharmacy costs decreased by 3% compared with the 12 months prior and 11% compared with expected costs. There was no significant decline in medication use or adherence to treatments for patients with diabetes, hypertension, or dyslipidemia.

CONCLUSIONS: The VBF and copayment changes enabled pharmacy plan cost savings without negatively affecting utilization in key disease states.

J Manag Care Spec Pharm. 2015;21(4):269-75

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What this study adds

- Cost-effectiveness analysis can be implemented in a U.S. managed care context to inform formulary positioning.
- One year after implementation, pharmacy plan costs decreased by \$7.82 per member per month due to copayment increases.
- There was no significant decline in medication use or adherence to treatments for patients with diabetes, hypertension, or dyslipidemia.

In the past decade, rising health care costs and a weak economy have led employer-based health plans to increase member cost sharing and reduce health care benefits.¹ Cost-sharing measures, such as deductibles and copayments, may slow the short-term growth of health plan drug expenditures. However, indiscriminately increasing cost sharing, without considering the value provided by individual pharmaceutical agents, may have long-term unintended consequences.²⁻⁶

By contrast, a value-based insurance design approach to structuring pharmacy benefits results in formulary positioning that reflects explicit value rather than cost.² Recently, authors investigating value-based plans found that reducing or eliminating copayments for high-value maintenance medications to treat chronic conditions (e.g., asthma, congestive heart failure, diabetes, hyperlipidemia, and hypertension) improved medication adherence by 1.5% to 9.4%.⁷⁻¹² Although promising, these plans have limitations. First, lowering copayments for high-value drugs without increasing copayments for low-value drugs may be unsustainable, since this may not necessarily result in cost savings to the employer.¹³⁻¹⁵ Evidence suggests that consumers may be willing to accept higher copayment for low-value drugs, if this maintains the affordability of their coverage.¹⁶ In addition, previous value-based insurance schemes assigned equal copayment reductions to all drugs within a therapeutic area, without assessing the value of each individual agent. Aligning each individual drug’s copayment to its specific value may yield greater clinical and economic benefits.

The purpose of this research was to describe and evaluate first-year outcomes of a novel value-based drug formulary (VBF) benefit for employees of Premera Blue Cross (PBC). Specifically, we describe (a) development and implementation of the novel drug formulary, (b) formulary structure before and

What is already known about this subject

- Patient cost sharing has increased over the past decade.
- Value-based insurance design attempts to provide clinical nuance to cost sharing by aligning drug copayment tier with value.
- Previous implementations have shown modest improvements in medication adherence but has not generally been cost saving for health plans.

TABLE 1 Premera's Pharmacy Copayment Structures Before and After Implementation

Tier	Before VBF (\$)	VBF (\$)
Preventive	Not applicable	0
Tier 1	10	20
Tier 2	30	40
Tier 3	50	65
Tier 4	Not applicable	100

Note: Amounts shown are the retail copayments per 30-day supply of medication. Mail order copayments are 2.5 times this amount per 90 days.

VBF = value-based formulary.

TABLE 2 Value-Based Formulary Tier Placement and Incremental Cost-Effectiveness Thresholds

Tier	Typical Case ICER Threshold	Special Case ICER Threshold
Tier 1	Cost saving or < \$10,000/QALY	Cost saving or < \$50,000/QALY
Tier 2	\$10,000-< \$50,000/QALY	\$50,000-\$150,000/QALY
Tier 3	\$50,000-\$150,000/QALY	> \$150,000/QALY
Tier 4	> \$150,000/QALY or insufficient evidence to determine ICER	Insufficient evidence to determine ICER

Note: Premera's VBF defines value in terms of the ICER. These ratios are used to assign drugs to 1 of 4 copayment tiers for typical and special cases.

ICER = incremental cost-effectiveness ratio; QALY = quality-adjusted life-year; VBF = value-based formulary.

after implementation, (c) outcomes of the VBF based on cost and utilization metrics along with findings from several focus group sessions, and (d) the implications and next steps for PBC.

Methods

The Premera Blue Cross Value-Based Formulary

Design. In 2009, we proposed the development of a VBF designed to meet the needs of large employers struggling to balance premium cost with affordability of high value medications. A series of meetings were held throughout 2009 with stakeholders from the University of Washington, the pharmacy benefit manager (Medco Health Solutions, Franklin Lakes, NJ), and medical group partners, along with internal PBC stakeholders from multiple departments (e.g., actuary, communications, medical services, pharmacy, product strategy and development, and legislative/regulatory affairs). Initially, these meetings focused on gauging stakeholder interest while assessing feasibility. Following approval by PBC leadership, we began developing the design and organizational processes for the VBF.

We assessed value primarily using cost-effectiveness analysis (CEA), which compares the relative value of one therapy with a reference standard therapy using an incremental cost-effectiveness ratio (ICER). When comparing 2 drugs, the ICER quantifies the incremental cost required to obtain an additional unit of health outcome (e.g., quality-adjusted life-year).¹⁷ Although there is still considerable debate among researchers regarding CEA methods, it has been adopted by health care payers internationally as a key method for economic analyses.¹⁸⁻²³ Moreover, because CEA has been widely used, data are available for many common drugs.

We designed the VBF as a 4-tier formulary system, with an additional "preventive drug" tier (Table 1). Drugs in the preventive tier are not subject to member cost sharing. Drugs were assigned to subsequent tiers based upon their ICERs, with higher value (lower ICER) drugs placed in lower tiers and, therefore, subject to lower copayments. To set ICER thresholds, we reviewed the literature on thresholds used by

decision makers globally and multi-tier member cost-sharing arrangements prevalent among U.S. commercial insurance plans.²⁴⁻²⁹ Recognizing the limitations of CEA, we designed the threshold ranges to allow for the consideration of other factors such as bioethical issues and societal values. We also created an additional set of higher ICER thresholds for drugs used for rare medical conditions that lacked effective treatment options. Such drugs with established clinically meaningful benefits were assigned to this special case tier structure (Table 2).

Formulary Design. Formulary decisions for the VBF involved 2 separate processes and committees. The first step was an evaluation of the clinical safety and effectiveness of a drug. The second step involved the value assessment and copayment tier. These 2 steps are described more completely in the following paragraphs.

Clinical safety and effectiveness assessment. The decision to include a drug on the standard Premera formulary is based on a formal assessment of its safety and effectiveness by the Pharmacy and Therapeutics (P&T) committee, which consists entirely of external experts. A detailed description of Premera's P&T process has been published elsewhere.³⁰ The P&T committee considers evidence synthesized from published medical literature, assessments by domestic and international technology assessment organizations, and drug manufacturers submissions in accordance with the requirements of the Academy of Managed Care Pharmacy (AMCP) Format for Formulary Submissions.³¹ The P&T committee then votes on whether to include the drug in the standard Premera formularies. Cost is considered when 2 or more alternative therapies are judged to have comparable net clinical benefit. The P&T process does not include formal cost-effectiveness evaluations.

Value assessment. Results of the P&T review are forwarded to the Value Assessment Committee (VAC). This committee reviews the P&T findings and then assigns drugs to VBF tiers, based upon the evidence of comparative drug value. The VAC is composed of 4 economists, 2 practicing clinicians, 1 ethicist

and a member of the public. Such membership diversity promotes the consideration of various aspects of value during the decision-making process. The economists evaluate the validity and uncertainty of ICER estimates. The clinicians ensure that VAC decisions are clinically reasonable and reflect best practices. The ethicist and public member contribute important ethical and social value perspectives. All voting members of the P&T committee and VAC must be free from conflicts of interest regarding the drug under assessment.

Premiera pharmacists review available ICER estimates, which come from a variety of sources, including (a) economic models provided by the manufacturer, (b) published economic studies, (c) data from the Tufts CEA registry, (d) Cochrane reviews, and (e) reviews by technology assessment organizations, including but not limited to the National Institute for Health and Care Excellence and the Canadian Agency for Drugs and Technologies in Health.³²⁻³⁵ If the evidence is not sufficiently transparent and/or is not translatable to Premiera clinical practice, Premiera conducts its own economic analyses in accordance with recommendations for good modeling practices.³⁶

Several factors influence drug value, including the net clinical benefit, cost-effectiveness, societal values and preferences, and budget impact. Net clinical benefit encompasses the safety, efficacy, and real-world effectiveness of a drug. When considering cost-effectiveness, Premiera prefers models that conform to the AMCP modeling guidelines.³¹ Societal values and preferences, such as ethical issues, disease rarity, unmet clinical needs, and regulatory requirements, influence the value of drugs, but they are often not reflected in the ICER.

Developing the Initial Formulary. From September 2009 to April 2010, Premiera pharmacists produced value assessment summaries for drugs in each of the 25 highest volume drug classes used by Premiera members in the previous year. These classes represent approximately three-fourths of the total drug utilization within the plan. Over this same period, the VAC met regularly to determine the value and corresponding formulary placement of these drugs. Other existing drugs were assigned to a tier based on their placement in Premiera's standard 4-tier formulary.

In traditional formularies, drugs with lower copayments tend to have low acquisition costs. However, since value is defined based on a ratio of costs to benefits, it is possible for high-cost drugs to achieve a lower tier status if the benefits outweigh the costs. We illustrate this here by describing how biologic agents used to treat rheumatoid arthritis (RA) were assigned to tiers in the VBF. In 2010, RA drugs accounted for approximately 4.5% of total drug costs. To manage utilization, other 4-tier Premiera formularies moved these drugs into the highest tier, usually with 20% coinsurance. However, biologics, such as TNF-alpha inhibitors, are considerably more efficacious

TABLE 3 Member Characteristics

Characteristic	Year Prior to VBF	Year After VBF
Members	6,190	5,837
Rx users	4,446	4,196
Male (%)	43	44
Age, years (%)		
< 19	28	27
20-39	30	31
40-64	37	37
≥ 65	5	5
Prescriptions per member	16	18
Days of therapy per member	473	518

Rx = drug; VBF = value-based formulary.

than methotrexate alone in managing early aggressive and long-standing RA. This efficacy was reflected in the base case ICER estimates, which ranged from \$52,000 to \$95,000 when comparing methotrexate plus adalimumab, etanercept, or infliximab with methotrexate alone. The committee also believed that RA therapies had additional societal value because of the substantial disability that can occur when patients are not initiated on disease-modifying biologics as a first-line therapy.³⁷ Consequently, biologic treatments for RA were placed in tier 2, despite their high acquisition cost and budget impact.

Pilot Implementation: First-Year Outcomes

In July 2010, PBC was the first employer to implement a VBF for its employees and dependents enrolled in the standard preferred provider organization (Premiera Associates Plan). The characteristics of the enrolled members are displayed in Table 3. The enrolled members moved from a 3-tier formulary to the VBF with 4 tiers plus the preventive drug tier. Simultaneously, copayments were increased by the plan sponsor in an attempt to mitigate rising pharmacy costs. The VBF is intended to offset the impact of these increases on members taking high-value medications for chronic diseases. PBC reported performance metrics during the first year of VBF implementation. Metrics included (a) prescription drug cost per member per month (PMPM) for the plan and members, (b) drug utilization, and (c) medication adherence.

First-Year Evaluation Methods

Plan Medication Savings. Premiera took 2 approaches to analyzing changes in pharmacy costs. First, PBC actuaries compared the first year PMPM with the previous 12 months. Then a counterfactual approach was used, where plan savings were estimated by projecting the hypothetical PMPM, assuming no changes were made to the pharmacy benefits, and comparing this with the observed PMPM during the first year. To estimate the hypothetical PMPM, autoregressive integrated moving average techniques were applied to 36 months of

TABLE 4 Change in Distribution of Formulary Placement Before and After VBF Implementation

	Month Before VBF	Month After VBF	Change
Preventive	Not applicable	2,567 (39.9%)	2,567 (39.9%)
Tier 1	2,571 (40.2%)	900 (14.0%)	-1,671 (-26.2%)
Tier 2	1,037 (16.2%)	2,319 (36.0%)	1,282 (19.8%)
Tier 3	2,609 (40.8%)	477 (7.4%)	-2,132 (-33.4%)
Tier 4	Not applicable	171 (2.7%)	171 (2.7%)

VBF = value-based formulary.

historic PMPMs, while adjusting for Premera's book of business pharmacy trend. Using the resulting model, monthly PMPM values were estimated for the first year (July 2010–June 2011). Monthly savings were calculated as the difference between the estimated and observed PMPM. Finally, monthly results were weighted by the number of member months to create an annual savings estimate. The counterfactual approach was also used to estimate the impact of the VBF on member cost share within cohorts of patients with select chronic diseases (i.e., diabetes, hypertension, and dyslipidemia). These cohorts were classified by Symmetry Episode Treatment Groups, an episode grouper based on medical and pharmacy claims.

Drug Use and Adherence. Within the 3 chronic disease cohorts, the impact of the VBF on the use of, and adherence to, key drug therapies was measured using interrupted time series analyses. Monthly measurements of use and adherence were created for each drug therapy measured for each cohort. Within a given 90-day period, cohort members were considered to have “used” a drug of interest if they filled it 1 or more times. Adherence was measured based on the proportion of days covered (days' supply dispensed in a 90-day period divided by 90) and was only measured in those members who had a dispensing event during the period. Further, for cohort members newly using a medication of interest (no fills for the medication in the 270 days prior to the end of the month of interest), their measurement period was reduced from 90 days to only consider the earliest dispensing date forward. The percentage of use and average adherence rate were calculated for each therapy.

A comparison group was formed using members from 3 employer groups enrolled in Premera disease and case management programs that increased pharmacy copayments in July 2010 without using the VBF. Comparison group members were analyzed as previously described, and a series of monthly ratios of the VBF members to the comparison group members were calculated. These ratios served as the dependent variable, Y_t , in the models. The regression equations used for testing differences for each cohort and drug therapy had this general form:

$$Y_t = \beta_0 + \beta_1 \times \text{time}_t + \beta_2 \times \text{intervention}_t + \beta_3 \times \text{time after intervention}_t + e_t$$

FIGURE 1 Projected and Actual Costs Per Member Per Month

Note: The vertical reference line marks the VBF implementation date. PMPM = per member per month; VBF = value-based formulary.

Coefficients are as follows: β_0 estimates the baseline ratio in September 2007; β_1 estimates trend prior to July 2010, where *time* is the number of months at time *t* from September 2007; β_2 estimates the change postintervention, where *intervention* is an indicator variable with value “0” (prior to July 2010) or “1” (beginning July 2010); β_3 estimates the additional trend in the ratio postimplementation of VBF where *time after intervention* is the number of months after introduction of VBF. The term e_t includes random error and autocorrelation. For each model, the null hypothesis was no change in use (or adherence) after implementation.

Results

Table 4 shows that implementation of the VBF resulted in large changes in the proportion of unique drugs (as defined by active ingredient, strength, and dosage form) falling into each tier. For example, the preventive tier did not exist prior to VBF implementation, but after VBF implementation, this tier comprised 39.9% of drugs. Tiers 1, 2, 3, and 4 included 40.2%, 16.2%, 40.8%, and 0% of drugs, respectively, prior to VBF implementation (June 2010) and 14%, 36%, 7.4%, and 2.7% of drugs, respectively, after implementation (July 2010).

The plan's pharmacy payments were reduced by 3%, or \$6.87 PMPM, during the first year, compared with the previous 12 months (Figure 1). The trend was stratified into 3 components: underlying trend (8%), increases in the member copayment (-15%), and increased utilization induced by the

TABLE 5 Impact of Value-Based Benefits on Use of and Adherence to Drugs in 3 Disease Cohorts

Parameter	Coefficient (SE)		P Value
Use of antidiabetic medications in the diabetic cohort			
Level	0.024	(0.022)	0.270
Trend	-0.00003	(0.004)	0.994
Adherence to antidiabetic medications in the diabetic cohort			
Level	0.047	(0.036)	0.197
Trend	-0.006	(0.005)	0.253
Use of antihypertensive medications in the hypertension cohort			
Level	-0.003	(0.003)	0.757
Trend	0.004	(0.001)	0.003
Adherence to antihypertensive medications in the hypertension cohort			
Level	-0.003	(0.011)	0.798
Trend	0.006	(0.001)	<0.001
Use of lipid-lowering medications in the hyperlipidemia cohort			
Level	0.028	(0.023)	0.218
Trend	-0.005	(0.003)	0.129
Adherence to lipid-lowering medications in the hyperlipidemia cohort			
Level	0.002	(0.019)	0.895
Trend	-0.003	(0.002)	0.284

Note: Level compares the change in use and adherence measures over a 1-year period before and after VBF implementation. Trend assesses the additional change in use and adherence measures over a 1-year period after VBF implementation. SE=standard error; VBF=value-based formulary.

VBF and preventive drug tier (6%; these numbers do not add exactly due to rounding and because they are actually successive multipliers). The counterfactual approach found that the plan's pharmacy payments were reduced by 11%, or \$7.82 PMPM, compared with the estimated payments if no changes were made to the drug benefit.

Cost Impact to Members with Chronic Disease

Within the plan membership, cohorts with diabetes (n=264), hypertension (n=703), and dyslipidemia (n=644) were identified through historic medical and pharmacy claims data. While the overall average member cost share was projected to increase 12% without the benefit changes, the observed increase was 5% for the diabetes cohort, 8% for the hypertension cohort, and 2% for the dyslipidemia cohort.

Drug Use and Adherence

Results from the interrupted time series regression models are displayed in Table 5. Within the hypertension cohort, use of blood pressure-lowering medications increased relative to the comparison group postimplementation (coefficient was positive and statistically significant). Likewise, adherence to blood pressure-lowering medications by the same cohort of members also increased relative to the comparison group. Considered collectively and across the 6 models, the results generally appear to support the notion that the VBF coupled

with targeted copay relief had a protective effect on both use and adherence among cohort members. We draw this conclusion in part because the measures did not decline significantly after the introduction of a higher member cost-share structure.

Discussion

The PBC VBF uses CEA to determine formulary tier placement in the United States. It was designed to meet the needs of large employers, struggling to balance rising premium costs with affordability of high-value medications. Internal analyses suggest pharmacy benefit savings for PBC over the first year. Furthermore, in the context of overall copayment increases, member cost sharing increased less for members with diabetes, hypertension, or dyslipidemia than was projected, without negatively impacting adherence. This suggests that the VBF, and particularly the preventive drug tier, may incentivize greater adherence by reducing the cost shift for members in these cohorts.

Health technology assessment organizations outside the United States often use a single cost-effectiveness threshold to make coverage and reimbursement decisions. The tiered approach has the advantage of being less restrictive, while still promoting the use of higher-value products. Much thought went into assigning copayment amounts to each VBF tier, with the intent of using these to communicate to the members the value of each medication. Despite this, focus group members were generally unaware or lacked understanding regarding the VBF. However, when the concept was explained, they reacted positively. We believe that a VBF will be well received in settings where a trust relationship exists between employer and associates, such that most associates believe that the employer cares about their health and is acting in their best interest. When implementing a VBF, sharing the rationale behind it with the employees can enhance this relationship.

Limitations

A major obstacle to supporting the VBF is timely access to high quality economic evidence from pharmaceutical manufacturers. Pharmaceutical manufacturers regularly produce these analyses for submission to health care payers outside the United States. We remain concerned by the frequency with which our requests for economic data were either denied or ignored. Manufacturers often believe that they are legally prohibited from providing economic information. Premera's VAC uses the AMCP Format for Formulary Submissions, which explicitly requests a full range of economic evidence. Such requests, when initiated by the technology evaluator, are considered to be an unsolicited request to the manufacturer and are permissible by the U.S. Food and Drug Administration.³¹ Moreover, Section 114 of the Food and Drug Administration Modernization Act provides explicit protection to the manufacturer when providing economic information to formulary committees.³⁸ Under the

act, economic information will not be cited as false or misleading when the economic information directly relates to an approved indication and is based upon “competent and reliable scientific evidence.” Our response to this is to develop internal capacity and expertise to estimate incremental cost-effectiveness without having to rely on manufacturer submissions.

This evaluation has limitations that constrain the generalizability of the findings. The small size and limited duration of the evaluation may lead to uncertain conclusions about the long-term impact of a VBF. We were unable to assess health outcomes. Subsequent analyses should utilize longer study durations and more robust statistical controls. Furthermore, although this study suggests pharmacy cost savings, the impact on member and overall health plan costs remains unclear.

Conclusions

This study suggests that it is possible to implement a VBF in a U.S. employer-based health plan. Premara's formulary achieved cost savings for the pharmacy plan without negatively affecting utilization in several key disease states.

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DISCLOSURES

No external or internal funds were used to support this research. Yeung was funded through the University of Washington NIH/CTSA TL1 Scholars program. Sullivan, Burke, Garrison, and Veenstra are paid members of the Premara Blue Cross Value-Assessment Committee. Burke receives grant funding from the National Institutes of Health for pharmacogenetic research. Veenstra is a consultant for Genetech, Jazz Pharmaceuticals, National Pharmaceutical Council, and Abbott Dx.

Study concept and design were contributed by Sullivan, Yeung, Garrison, and Watkins, assisted by the other authors. Data were collected by Sullivan, Yeung, and Wong, assisted by the other authors, and analyzed by Sullivan, Murphy, and Veenstra, with assistance from the other authors. The manuscript was written primarily by Sullivan, Yeung, and Vogeler, with assistance from the other authors, and revised by Sullivan, Yeung, and Ramsey, assisted by the other authors.

ACKNOWLEDGMENTS

The authors acknowledge advice and contributions of Michael Drummond, DPhil; Sanchita Roy Choudhury, PhD; Stephanie Yamamoto, PharmD; Yeni Son, FSA, MAAA; Rick McGee, MD; and Pamela Wells, FSA, MAAA. The authors thank Joanna Sanderson for editorial support.

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