ORIGINAL RESEARCH

A 30-Month Evaluation of the Effects on the Cost and Utilization of Proton Pump Inhibitors From Adding Omeprazole OTC to Drug Benefit Coverage in a State Employee Health Plan

DONNA S. WEST, RPh, PhD; JILL T. JOHNSON, PharmD, BCPS; and SONG HEE HONG, PhD

ABSTRACT

OBJECTIVE: On March 1, 2004, the state employee health plan began covering omeprazole OTC (over the counter) at a $5 copayment. Reimbursement to pharmacy providers for omeprazole OTC increased by $10.50 per claim, from $2.50 to a $13 dispensing fee. Initially, neither generic omeprazole prescription (Rx) nor brand omeprazole Rx was covered because omeprazole OTC was available in the same strength as the Rx products at a lower cost, but an omeprazole OTC shortage necessitated coverage of generic omeprazole Rx at a $10 copay. The objective of this study was to evaluate the long-term financial impact of a drug benefit policy change on a mid-size state employee health plan and its beneficiaries associated with the addition to coverage of omeprazole OTC.

METHODS: The pharmacy claims database for the employee benefits division (EBD) was used to examine utilization and cost data for beneficiaries who received proton pump inhibitors (PPIs). Pharmacy claims for the 30-month period for dates of service from December 1, 2002, through May 31, 2005, were extracted from the database, yielding a preperiod of 15 months and a postpolicy change period of 15 months.

RESULTS: In the 15-month postperiod, the number of PPI claims per member per month (PMPM) decreased by 3.9%, but the days of PPI therapy PMPM increased from 1.71 to 1.82 (6.4%). Price as measured by the allowed charge per day of drug therapy decreased from $4.25 to $2.74 (35.6%) despite an increase of $1.89 (76%) in the average dispensing paid per PPI claim to pharmacies, from $2.49 to $4.38. The average beneficiary copayment decreased by $0.50 (2.0%) per PPI claim, from $25.06 in the preperiod to $24.56 per claim in the postperiod. Therefore, the net heath plan cost for PPIs decreased by $2.20 PMPM (37.6%) during the 15-month postperiod, from $5.84 to $3.64 PMPM, producing savings of $4,207,350, or annualized savings of $3,365,880, in this employee benefit plan of 127,495 members.

CONCLUSION: A change in policy to include coverage of omeprazole OTC and an increase in pharmacy reimbursement for omeprazole OTC resulted in 38% net savings to a state employee health plan. The large difference in drug acquisition cost between omeprazole OTC and the other Rx-only PPIs made it possible to implement a program intervention that provided financial benefit to pharmacists, beneficiaries, and the drug plan sponsor despite a 6% increase in PPI utilization.

KEYWORDS: Proton pump inhibitors, OTC medications, Rx copayments, Rx utilization

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In recent years, there has been an increase in the number of products switched from prescription (Rx)-only to over-the-counter (OTC) status, increasing the potential for coverage of OTC products in Rx drug benefits.[1-3] Specifically, the availability of omeprazole (Prilosec) OTC in the same strength as omeprazole Rx, presents a potential opportunity for health plans to cover an OTC product. As a class, proton pump inhibitor (PPI) products ranked second in overall retail sales, at $11.9 billion in 2002 and nearly $12.8 billion in 2003.[4,5] The patent on omeprazole Rx expired in October 2001, but litigation kept generic omeprazole off the market until December 2002,[2] and the price of generic omeprazole Rx has not been significantly less than brand-name omeprazole Rx.

The U.S. Food and Drug Administration (FDA) announced on October 31, 2003, that it had approved omeprazole OTC for sale in the popular 20 mg strength, and by July 2004, omeprazole could be purchased for $0.63 per tablet for a 42-day supply, less than 20% of the price of the alternative PPIs.[6] Thus, health plans have considered covering the less-expensive omeprazole OTC with the opportunity to treat 5 patients with omeprazole OTC for the same cost as treating 1 patient with an alternative brand PPI.

We initially reported on the Arkansas State Employee Benefits Division's (EBD, Little Rock) decision to cover omeprazole OTC beginning in March 2004.[7] The EBD covered approximately 129,500 members with Rx benefits and had an annual drug budget of $74.6 million in 2003. PPIs represented 12% ($8.9 million) of the pharmaceutical costs for the EBD in 2003.

Using clinical evidence from systematic literature reviews,[8-10] the Drug Utilization Evaluation (DUE) Committee for the EBD concluded that all PPIs were therapeutically equivalent in efficacy and safety. Based on cost considerations, the DUE Committee recommended making omeprazole OTC the preferred drug among PPIs. The EBD was paying, on average, more than $90 per prescription PPI (e.g., average brand omeprazole Rx cost to the EBD was $123.40 and average generic omeprazole Rx cost was $91.71 in February 2004). Because the average wholesale price (AWP) was significantly lower for omeprazole OTC, it was estimated that the OTC product would save more than $40 per claim. The EBD administrator adopted the benefit change to cover omeprazole OTC, effective March 1, 2004.

Based on the results of the first 2 months of omeprazole OTC coverage, we projected that the EBD would save approxi-

TABLE 1 Benefit Design and Pharmacy Reimbursement Changes for PPIs

	Prepolicy (Prior to March 1, 2004)	OTC Coverage Policy (Effective March 1, 2004)	OTC Coverage Policy With Modification (Effective June 1, 2004)
Copayment:			
Omeprazole OTC	Not covered by plan	$5 (new OTC tier)	$5 (new OTC tier)
Generic omeprazole Rx	$10	10 mg capsule only—$25*	$10
Brand omeprazole Rx	$25	Not covered*	Not covered
Rabeprazole	$25	$50*	$50
Esomeprazole	$25	$50*	$50
Lansoprazole	$50	$50*	$50
Pantoprazole	$50	$50*	$50
Dispensing fee:			
OTC	Not covered	$13	$13
Rx	$2.50	$2.50	$2.50
Drug cost reimbursement:			
OTC	Not covered	AWP-13%	AWP-13%
Generic omeprazole Rx	AWP-13%	AWP-13% (10 mg capsule only)	AWP-13% until October 1, 2004, then MAC +$2.50†
Brand omeprazole Rx	AWP-13%	AWP-13%	AWP-13%
Days-supply limit‡:			
OTC	Not covered	42-day supply	42-day supply
Rx	30-day supply	30-day supply	30-day supply

**These coverage and copayment changes became effective on March 15, 2004.*
† As of October 1, 2004, the lesser of AWP-13% or MAC ($1.49 per capsule).
‡ Days-supply limit; there is not a quantity (units) limit on any PPI claim.[7]
This table is adapted from Harris BN et al. J Manag Care Pharm. 2004[7]; Johnson JT, West DS, Drug Benefit Trends. 2005.[11]
AWP=average wholesale price; MAC=maximum allowable cost; OTC=over the counter; PPI=proton pump inhibitor; Rx=prescription.

mately $3,978,240 annually for an average eligible membership of 127,500.[7] This initial projection was based on the original benefit design that included OTC coverage but not coverage of generic omeprazole Rx. However, because of the shortage of omeprazole OTC, the benefit design was later modified, effective October 1, 2004, to include coverage of both omeprazole OTC and generic omeprazole Rx.

Methods

The purpose of this study was to evaluate the longer-term financial impact of the Arkansas State EBD policy change on the health plan and its beneficiaries by examining the utilization and cost of PPIs during the 15 months prior to and 15 months following implementation of omeprazole OTC coverage on March 1, 2004.

The Pharmacy Benefit Design for PPIs

Prior to omeprazole OTC coverage in March 2004, generic omeprazole Rx was covered in the first tier with a $10 copayment; rabeprazole, esomeprazole, and brand omeprazole Rx were covered in the second tier with a $25 copayment; and lansoprazole and pantoprazole were covered in the third tier with a $50 copayment (Table 1). EBD reimbursement to pharmacies was based upon a product (ingredient) cost rate of AWP minus 13% plus a $2.50 dispensing fee for single-source brand PPI drugs and generic omeprazole Rx.

The DUE Committee for the EBD not only recommended making omeprazole OTC the preferred drug but also changed the beneficiary copayment and pharmacy reimbursement structure to encourage use of omeprazole OTC. The EBD administrator adopted these policy recommendations, as outlined in Table 1. The OTC-tier copayment and reimbursement structure changes became effective March 1, 2004. To allow time for the benefit change to be communicated to all stakeholders, the copayment changes for the Rx PPI drugs were implemented 2 weeks later, on March 15, 2004. As noted in Table 1, coverage of generic omeprazole Rx was discontinued initially, except that a $25 copayment was permitted for the 10 mg (capsule) strength. Neither generic omeprazole Rx nor brand omeprazole Rx was covered because omeprazole OTC was available in the same strength as the Rx products, at a significantly lower cost.

The benefit was designed with the intent to provide a beneficiary incentive to switch from Rx-only PPIs to omeprazole OTC and to facilitate pharmacy participation. The financial incentive for the beneficiary was significant. Not only did the new omeprazole OTC have a $5 copay per Rx but it also provided longer days of therapy per Rxs (i.e., 42- vs. 30-days supply). A 42-day supply of omeprazole was provided because of the OTC product packaging. Since only 9 omeprazole OTC claims (of 42 units each) would be necessary per PPI-utilizing member per year, there was an expected reduction of 3 PPI

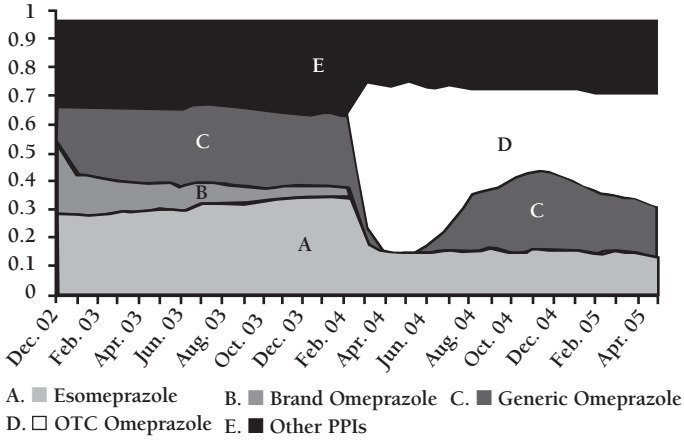
claims per year per beneficiary switched from an Rx PPI to omeprazole OTC. To encourage pharmacists to facilitate the switch from an Rx PPI to omeprazole OTC, a $13 dispensing fee per claim for omeprazole OTC was implemented. The purpose of this larger dispensing fee was to ensure that switching beneficiaries from an Rx to OTC product would be at least revenue-neutral and perhaps revenue-favorable for the pharmacy provider.[7] With the $13 dispensing fee, the dollar gross margin for omeprazole OTC would be similar to the other PPIs. The higher dispensing fee was also perceived as helping to compensate pharmacists for the extra work in switching patients, which involved calling prescribers to obtain an Rx for omeprazole OTC but thereby avoided the need for a physician office visit.

Within 2 months of implementation of the policy changes, there was a shortage of omeprazole OTC. Reacting to the marketplace and considering product availability, the EBD modified the PPI benefit design. Effective June 1, 2004, generic omeprazole Rx was covered at a $10 copay for a 30-day supply, and pharmacies were reimbursed AWP-13% + $2.50 for generic omeprazole Rx. On October 1, 2004, the EBD changed its pharmacy benefit manager (PBM), and the reimbursement structure for generic omeprazole Rx changed to the lesser of AWP-13% + $2.50 or maximum allowable cost (MAC) + $2.50. The MAC price was set at $1.49 per capsule.

There was originally an appeals process for physicians on behalf of a plan beneficiary to request a brand Rx PPI at a lower copayment ($25). Receipt of an Rx PPI at a lower copayment required verification of the diagnosis of Zollinger-Ellison (ZE) syndrome or other hypersecretory condition. The physician had to inform the EBD of the patient's condition and request approval for the higher-cost PPI at a lower copayment. Although omeprazole is effective and approved by the FDA for ZE syndrome and other hypersecretory conditions, there were insufficient data to directly compare the effectiveness of omeprazole to the other PPIs so these diagnoses were originally established as sufficient criteria for a successful appeal. Although several appeals were submitted, none met the criteria and were therefore denied.[7] At this time, a diagnosis of ZE or other hypersecretory condition is no longer accepted as the basis for appeal since all PPI drugs are still available to each member, at a higher copay.

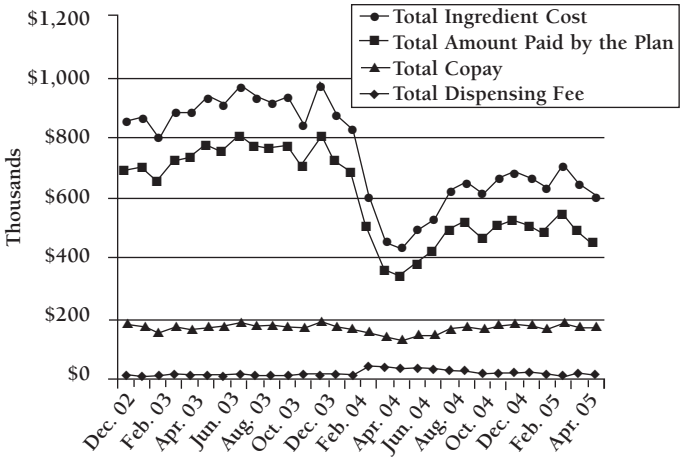
The Rx claims database for the EBD was used to examine utilization and cost data for beneficiaries who received Rxs for PPIs. Summary data included the number of Rxs for each PPI, total ingredient cost, total dispensing fee, total allowed charge, total copayment, and total amount paid by the EBD (net EBD cost). Data for claims with dates of service from December 1, 2002, to May 31, 2005, were extracted from the database, reflecting the 15 months prior to policy implementation and the 15 months following policy implementation. March 1, 2004, was considered the start date of OTC coverage, although the entire benefit change was phased in over a 2-week period, as previously mentioned. These data were assessed to determine market share changes after policy implementation and the resulting shifts in ingredient costs, dispensing fees, amount paid by the plan, and amount paid by the beneficiary (copayment). Prescriptions per member per month (PMPM), days of therapy PMPM (days PMPM), charge PMPM, charge per prescription,

FIGURE 1 Rx Share Trend of PPI Drugs by Drug Type Before and After Coverage of Omeprazole OTC



OTC=over the counter; PPI=proton pump inhibitor; Rx=prescription.

FIGURE 2 Monthly Trend in Total Costs of All PPI Claims Before and After Coverage of Omeprazole OTC



Note: Omeprazole OTC coverage was implemented March 1, 2004, and then modified on June 1, 2004 (generic omeprazole Rx was changed to a $10 copayment to account for the product supply shortage of omeprazole OTC). OTC=over the counter; PPI=proton pump inhibitor.

TABLE 2 Cost and Utilization of PPI Drugs in 3-Month Periods Before and After Coverage of Omeprazole OTC*

3-Month Periods	Member-Months	Rxs	Days Supply	Days/Rx	Ingredient Cost ($)†	Dispensing Fee ($)‡	Allowed Charge ($)§	Copayment ($)	Net EBD Cost ($)‖
Preperiod									
Dec. 02-Feb. 03	385,824	20,267	611,166	30.2	2,523,198	46,817	2,570,015	523,682	2,048,571
Mar. 03-May 03	377,196	21,537	650,250	30.2	2,702,482	51,462	2,753,944	532,433	2,223,882
Jun. 03-Aug. 03	367,427	22,219	671,186	30.2	2,810,632	54,802	2,865,434	545,813	2,322,108
Sep. 03-Nov. 03	373,686	21,254	642,783	30.2	2,703,263	53,596	2,756,859	527,503	2,231,766
Dec. 03-Feb. 04	383,556	21,471	650,256	30.3	2,690,087	59,120	2,749,207	546,164	2,205,483
Preperiod total	1,887,689	106,748	3,225,641	30.2	13,429,662	265,797	13,695,459	2,675,595	11,031,810
Postperiod									
Mar. 04-May 04	387,615	20,424	706,356	34.6	1,508,718	130,278	1,638,996	444,615	1,196,575
Jun. 04-Aug. 04	376,318	19,743	667,830	33.8	1,658,204	114,400	1,772,604	480,918	1,293,880
Sep. 04-Nov. 04	378,583	20,871	684,402	32.8	1,936,187	82,277	2,018,464	532,149	1,487,231
Dec. 04-Feb. 05	384,706	21,425	706,233	33.0	1,992,011	67,707	2,059,718	548,118	1,511,798
Mar. 05-May 05	385,210	21,444	714,218	33.5	1,965,334	60,424	2,025,758	546,339	1,479,644
Postperiod total	1,912,432	103,907	3,479,039	33.5	9,060,454	455,086	9,515,540	2,552,139	6,969,128
Change	24,743	-2,841	253,398	3.3	-4,369,208	189,289	-4,179,919	-123,456	-4,062,682
% change	1.3%	-2.7%	7.9%	10.9%	-32.5%	71.2%	-30.5%	-4.6%	-36.8%

** P values could not be calculated for these summary data for the population of all EBD beneficiaries.*
† Drug ingredient cost reimbursement to pharmacies is average wholesale price-13%.
‡ Dispensing fee may be greater than set reimbursement rate of $2.50 because of generic incentive programs that pay a higher dispensing fee in this state employee health plan.
§ Allowed charge is the sum of the pharmacy professional fee plus the drug ingredient cost.
‖ Net EBD costs are slightly higher than the allowed charge minus copayment because the net EBD cost includes the administrative fee paid to the pharmacy benefits manager for processing the pharmacy claims.
EBD=employee benefits division; OTC=over the counter; PPI=proton pump inhibitor; Rx=prescription.

charge per day, copay per prescription, net PMPM, and net cost per days of therapy were then calculated. Frequencies and derived measures are reported.

Results

Within a month of the policy decision, omeprazole OTC accounted for more than 55% of all PPI pharmacy claims, eliminating almost all of the omeprazole Rx claims (Figure 1). Further, the implementation of the omeprazole OTC coverage cut the Rx market share of esomeprazole in half and even replaced one third of all other brand Rx PPI claims. As a result, the initial financial impact of the policy change amounted to the savings of $40.86 per PPI claim or $270,440 per month.[7]

However, the initial savings of that magnitude were undercut by the shortage of omeprazole OTC immediately following the OTC coverage decision. The EBD put generic omeprazole Rx into the first tier of copayment in a prompt response to the OTC shortage. The preferential treatment of generic omeprazole Rx allowed the generic to recover most of its share lost to omeprazole OTC while compromising the potential for omeprazole OTC to save the plan money. By November 2004, the market share of generic omeprazole Rx had increased to approximately 28% from 0% in April 2004. On the other hand, the share for omeprazole OTC was more than 50% in April 2004 but decreased to about 28% in November 2004. As the shortage eased, omeprazole OTC gradually regained some of its lost share, to about 41% of the Rx share of PPIs by the end of the 15-month follow-up period (Figure 1).

The share that omeprazole OTC captured of the PPI market was translated into dollar savings (Figure 2). The amount paid by the plan showed a sharp drop in the first month of the OTC coverage benefit. The plan paid about $700,000 per month for all PPI claims before the implementation but paid less than $400,000 immediately following the implementation. Although the paid amounts increased to about $500,000 per month during the OTC shortage, they gradually began to decrease as the shortage eased around November 2004. Savings were realized without shifting costs to providers or beneficiaries. Following the OTC coverage decision, the fees for pharmacist dispensing had increased, and the out-of-pocket costs for beneficiaries had decreased. However, the trend of paid amounts by the EBD showed a direct relationship to total ingredient costs; total ingredient costs and paid amounts moved together throughout the study period.

TABLE 3 Cost and Utilization Measures for PPI Drugs in 3-Month Periods

Derived Measures	Rxs PMPM	Days PMPM	Charge PMPM ($)	Charge/ Rx ($)	Charge/ Day ($)	Copay/ Rx ($)	Net/Rx ($)	Net/Day ($)	Net PMPM ($)
Preperiod									
Dec. 02-Feb. 03	0.053	1.584	6.66	126.81	4.21	25.84	101.08	3.35	5.31
Mar. 03-May 03	0.057	1.724	7.30	127.87	4.24	24.72	103.26	3.42	5.90
Jun. 03-Aug. 03	0.060	1.827	7.80	128.96	4.27	24.57	104.51	3.46	6.32
Sep. 03-Nov. 03	0.057	1.720	7.38	129.71	4.29	24.82	105.00	3.47	5.97
Dec. 03-Feb. 04	0.056	1.695	7.17	128.04	4.23	25.44	102.72	3.39	5.75
Preperiod average	0.057	1.709	7.26	128.30	4.25	25.06	103.34	3.42	5.84
Postperiod									
Mar. 04-May 04	0.053	1.822	4.23	80.25	2.32	21.77	58.59	1.69	3.09
Jun. 04-Aug. 04	0.052	1.775	4.71	89.78	2.65	24.36	65.54	1.94	3.44
Sep.04-Nov. 04	0.055	1.808	5.33	96.71	2.95	25.50	71.26	2.17	3.93
Dec. 04-Feb. 05	0.056	1.836	5.35	96.14	2.92	25.58	70.56	2.14	3.93
Mar. 05-May 05	0.056	1.854	5.26	94.47	2.84	25.48	69.00	2.07	3.84
Postperiod average	0.054	1.819	4.98	91.58	2.74	24.56	67.07	2.00	3.64
Change	-0.002	0.110	-2.28	-36.72	-1.51	-0.50	-36.27	-1.42	-2.20
% change	-3.9%	6.5%	-31.4%	-28.6%	-35.6%	-2.0%	-35.1%	-41.4%	-37.6%

Rx=prescription; PMPM=per member per month; PPI=proton pump inhibitor.

The number of PPI claims for the 15 months following policy implementation decreased by 2,841 (2.7%) over the prior 15-month period (Table 2). The number of claims likely decreased because of the omeprazole OTC commercial packaging, which allowed the beneficiary to receive a 42-day supply, thereby reducing the number of prescriptions needed per utilizing member per year. In fact, the average days of therapy per prescription increased by 10.9% (from an average of 30.2 days per PPI claim in the preperiod to 33.5 days per PPI claims in the postperiod). Utilization of PPIs adjusted for membership changes decreased by 3.9%, from 0.057 Rxs PMPM to 0.054 but increased by 6.5% in days of PPI therapy PMPM, from 1.71 in the preperiod to 1.82 in the postperiod (Table 3).

Price, as measured by the average allowed charge (drug cost plus pharmacy dispense fee) per PPI claim, dropped by 28.6% ($36.72), from $128.30 in the 15-month preperiod to $91.58 in the 15-month postperiod. Adjusted for change in days supply, the price per PPI day of therapy dropped by 35.6% ($1.51), from $4.25 in the preperiod to $2.74 in the postperiod. After consideration of the average $0.50 (2.0%) decrease in member cost-share per PPI claim (from $25.06 to $24.56), the net plan cost per day of PPI drug therapy dropped by 41.4% ($1.42 per day) to $2.00 in the postperiod. Adjusted for membership, the net plan cost PMPM decreased by $2.20 (37.6%) to $3.64 PMPM in the postperiod compared with $5.84 in the preperiod (Table 3). Therefore, during this 15-month period of omeprazole OTC coverage, net EBD costs for PPIs decreased by 37.6%, or $4,207,350, for the 1,912,432 member-months of eligibility (Table 2) in the postperiod. Annualized savings for an average of 127,495 eligible members were $3,365,880 in 2004-2005 dollars, unadjusted for inflation.

While the average copayment for all PPI pharmacy claims dropped by only 2.0% ($0.50), the member copayment for a claim for omeprazole OTC was 90% less compared with the copayment amount for the 4 single-source brand PPIs and 50% less than the copayment for generic omeprazole Rx. Drug plan members did not realize all of this potential in lower out-of-pocket costs since omeprazole OTC ultimately accounted for only about 41% of all PPI claims by the end of the 15-month postperiod (Figure 1), resulting in a small increase in the average member cost-share for all PPI claims, from 19.5% ($25.06/$128.30) in the preperiod to 26.8% ($24.56/$91.58) in the postperiod (derived from data presented in Table 2).

The average pharmacy dispensing fee for PPI drugs increased by $1.89 (76%) per claim to $4.38 in the 15-month postperiod compared with $2.49 in the 15-month preperiod (derived from data presented in Table 2).

Discussion

During the first 15 months of omeprazole OTC coverage in the period ended May 31, 2005, this state employee health plan of 127,495 members saved $4,207,350 on spending for PPI drugs, or annualized savings in 2004-2005 dollars of $3,365,880, which would be larger by 5% or more after adjustment for price

inflation in PPI drugs during this time period. Actual net plan cost savings were $4,062,682 prior to adjustment for changes in membership.

Initial savings for this employee health plan were projected to be $2.56 PMPM based upon the experience in the first 2 months of the benefit change, which included an Rx share of 55% for omeprazole OTC.[7] Actual savings after 15 months of follow-up were lowered by 14% to $2.20 PMPM, attributable almost entirely to the supply shortage of omeprazole OTC (Figure 1). The final Rx share for omeprazole OTC in the last 3-month period of this study was 39.6%.

The present study not only extended the follow-up period to 15 months from 2 months but it also increased the preperiod from 2 months to 15 months. Based upon this expanded analysis, the initial price savings on all PPI charges declined from $1.82 (43.7%) per day in the earlier analysis to $1.51 (35.6%) per day savings in the present analysis. The lower price savings on all PPI claims, before copayment but including pharmacy dispensing fees, were offset somewhat in the present analysis by a smaller increase in PPI utilization. In the 2-month analysis, PPI utilization in days of therapy PMPM was estimated to have increased by 17.2%, from 1.63 in the preperiod to 1.91 in the postperiod. The extended analysis over 30 months showed a smaller increase in days of PPI therapy, 6.5% higher in the 15-month postperiod, 1.82 days PMPM versus 1.71 days PMPM in the 15-month preperiod. This is an anticipated outcome given the larger 42-days supply for omeprazole OTC packaging.

One can only speculate about the financial impact on this state employee health plan absent the supply shortage of omeprazole OTC. It seems that the initial 55% share of all PPI claims would have been maintained and perhaps increased to 60% or more. Nevertheless, this multifaceted change in drug benefit policy to include a financial incentive for members and a financial incentive for pharmacists produced 38% net costs savings on expenditures for all PPI drugs. Certainly, net plan savings would have been larger, as much as 80%, had coverage been eliminated for all PPI alternatives to omeprazole OTC. Due to the supply shortage of omeprazole OTC that occurred almost immediately after the benefit policy change in March 2004, a closed formulary approach would have necessitated coverage of a PPI alternative to omeprazole OTC at least in nonpreferred status, to maintain continuity of care.

This analysis focused on the financial effects, including utilization changes in the PPI class of drugs. The somewhat surprising market share resilience of the nonformulary PPIs with an average copayment of $50 per claim for the 4 brand-only PPIs (esomeprazole, lansoprazole, pantoprazole, and rabeprazole) is no doubt attributable to several factors, including direct-to-consumer advertising and drug manufacturer promotion of PPIs to physicians. There were also anecdotal stories of beneficiaries who did not like receiving a box of omeprazole OTC in a package where each tablet had to be punched out, some opting instead for generic omeprazole capsules over omeprazole OTC tablets. Another obvious explanation is that education of plan beneficiaries and their prescribers was less than optimally successful. Future studies should identify factors associated with these prescribing trends.

The opportunity for additional cost savings from the more than 60% Rx share of PPIs that is not yet dispensed as omeprazole OTC has caused the EBD to consider other plan design changes. In August 2005, the EBD adopted an additional policy for the PPI drug class whereby the plan will pay up to $0.90 per capsule for any brand or generic Rx PPI. For 1 capsule a day (a 31-day supply), the plan reimbursement will therefore be no more than $27.90 for any PPI claim, and the plan beneficiary is responsible for the difference between the MAC of $0.90 per unit (capsule or tablet) reimbursement and the allowed pharmacy charge. It will be interesting to observe if this policy change impacts market share of brand Rx PPIs. Coverage of omeprazole OTC coverage continues as does the $13 dispensing fee for pharmacy providers for each omeprazole OTC claim. From this multifaceted intervention, it is difficult to determine the relative influence of copayment incentives for beneficiaries versus favorable pharmacy reimbursement in the shift to omeprazole OTC and the significant drug cost savings for the state employee health plan.

When reviewing the data from this 15-month postperiod, the cost of generic omeprazole Rx has gradually decreased (the net EBD cost for generic omeprazole Rx claim in February 2004 was $91.71 and in June 2005 was $58.15). As the generic omeprazole price decreases, it is important for the EBD to continually assess the marketplace and evaluate the benefit plan design. There will likely be a time in the future when generic omeprazole Rx will be priced comparably with the OTC product. In June 2005, the average cost to the EBD after subtraction of member cost-share was $0.87 per day for omeprazole OTC ($32.32 for an average supply of 37 days) compared with $1.82 per day for generic omeprazole Rx ($58.15 for an average supply of 30 days), $3.18 per day for esomeprazole ($95.51 for an average supply of 30 days), or $3.26 per day for lansoprazole ($97.94 for an average supply of 30 days). These average costs per day of PPI therapy and per pharmacy claim reflect the reason for continuation of omeprazole OTC coverage since significant cost savings can be realized as market share is shifted to the OTC product.

It might be argued that the $13 dispensing fee is no longer necessary, nearly 2 years after adoption of this financial incentive for pharmacies to dispense the preferred, OTC product. However, the EBD continues to support pharmacist involvement in dispensing the preferred, much-lower-cost OTC product by maintenance of the $13-per-claim dispensing fee, judged to make the pharmacy dollar revenue nearly the same for dispensing omeprazole OTC and the PPI alternatives. The EBD also intends to continue to engage pharmacists in other pharmacy benefit

interventions in the future and maintains this visible financial support, in part, as a matter of good will. To some observers, the dispensing fee differential of $10.50 ($13.00 vs. $2.50) for each omeprazole claim may seem large, but in fact, it is less than 15% of the average net cost differential between brand PPIs and omeprazole OTC.

The success of this multifaceted intervention in pharmacy benefits management begs the obvious question of what similar opportunities exist for other drugs classes with OTC equivalents. For the low-sedating antihistamines (LSAs), also known as second generation antihistamines, one study suggested that a substantial decrease in utilization and cost occurred even for plan sponsors who did not cover loratadine OTC when it became available.[12] The health plans that did not cover loratadine OTC experienced cost savings, in part, by shifting costs to the beneficiaries to pay for the OTC drug out of pocket. Meissner et al. found that the use of LSAs, and the therapeutic alternative nasal steroids, was resilient to a $10 (47%) increase in member cost-share.[13] Utilization of LSAs and nasal steroids increased by 8.9%, but net health plan costs decreased for allergic rhinitis drugs, all drugs used by allergic rhinitis patients, and all drugs used by continuously enrolled health plan members. Further studies of the utilization and cost effects of benefit design changes to encourage the use of drugs for treatment of allergic rhinitis are warranted.

The statin drugs may be another target of Rx-to-OTC switching in the future. The first OTC statin was introduced to the market in the United Kingdom in August 2004 as Zocor Heart-Pro.[14] While not yet available in the United States, Richards, Blumenfield, and Lyon found generally favorable opinions among pharmacy and medical officers in managed care organizations (MCOs) and PBMs regarding the possible introduction of lovastatin OTC to the U.S. market.[15] However, there was a curious lack of PBM support, and only small MCO support, for changing the formulary status of other statins if coverage was expanded to an OTC statin.[16] The findings of this study suggest that a multifaceted intervention with substantial member financial incentive is necessary to attain maximum value from the availability of an OTC therapeutic alternative.

The drug benefit plan design adopted by the EBD and implemented in March 2004 reduced costs for both the plan and for beneficiaries. If the EBD had not covered the OTC product and kept the original benefit design for PPIs, it is likely that the shift to the OTC product would have been gradual, if it occurred at all. By covering the OTC product, in a multifaceted intervention, the EBD received the immediate financial benefit of beneficiaries switching to a less-expensive product. Cost savings would have been larger absent the product shortage of omeprazole OTC and under larger financial incentives for plan beneficiaries to use the preferred (OTC) drug. The adoption of the therapeutic MAC for PPI drugs, effective for the EBD and Arkansas state employees and their beneficiaries in August 2005, was intended to realize more of the cost-savings opportunity that exists in this class of drugs from the use of omeprazole OTC as a therapeutic alternative to other PPIs.

When drug products are determined to be therapeutically equivalent based on clinical evidence, strategies to reduce costs should be considered when there is a low-cost therapeutic alternative in the class. Once a preferred drug product is selected, the Rx benefit should be designed to encourage use of the preferred drug(s). In the present study, this meant encouraging beneficiaries to switch to the preferred drug and modifying pharmacy reimbursement to facilitate use of the preferred drug. Community pharmacists are in a position to identify beneficiaries eligible for switching and to communicate with beneficiaries and physicians about cost-effective options within a particular benefit plan.

Limitations

This was a cost-outcome analysis and did not consider clinical or service outcomes (e.g., either beneficiary or pharmacist satisfaction with the program) other than the overall 2% average decrease in member cost-share for all PPI drugs. This study did not measure the incidence or costs of medical visits, which would presumably decrease with increasing use of the OTC drug. Additionally, the study did not include assessment of the administrative costs associated with implementing the policy.

Conclusion

This multifaceted strategy of extending coverage to omeprazole OTC saved the drug benefit plan sponsor 38% in the net cost of all PPI drugs after 15 months despite an interruption in the supply of the preferred OTC drug and the consequent need to cover generic omeprazole at a $10 copayment. The significant cost savings were achieved with near-maximum choice of PPIs for drug plan members and no copayment increase for 2 of the 4 brand-only PPIs. The net savings were $2.20 PMPM after consideration of lower average member cost-share and higher average pharmacy dispensing fee reimbursement, yielding total savings of $4,207,350 over the first 15 months of coverage of omeprazole OTC. Annualized savings for this state health plan of approximately 127,500 members was $3,365,880.

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