

Five-Year Examination of Utilization and Drug Cost Outcomes Associated with Benefit Design Changes Including Reference Pricing for Proton Pump Inhibitors in a State Employee Health Plan

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ABSTRACT

BACKGROUND: The Arkansas State Employee Benefits Division (EBD) is a self-insured program comprising public school and other state employees, their spouses, and dependents. Previous research published in *JMCP* (2006) showed drug cost savings of \$2.20 per member per month (PMPM; 37.6%) or annualized savings of \$3.4 million associated with a benefit design change and coverage of the proton pump inhibitor (PPI) omeprazole over-the-counter (OTC) beginning in March 2004. On May 1, 2005, brand esomeprazole was excluded from coverage, with current users grandfathered for 4 months until September 2005. Reference pricing for PPIs, including esomeprazole but excluding generic omeprazole, was implemented on September 1, 2005, and the beneficiary cost share for all PPIs except generic omeprazole was determined from comparison of the PPI actual price to the \$0.90 omeprazole OTC reference price per unit.

OBJECTIVE: To examine PPI utilization and drug costs before and after (a) excluding esomeprazole from coverage (with grandfathering current users) and (b) implementing a therapeutic maximum allowable cost (TMAC), or reference-pricing benefit design, for the PPI class in a large state employee health plan with fairly stable enrollment of approximately 127,500 members in 2005 through 2008 and approximately 128,000 members in 2009 Q1.

METHODS: The pharmacy claims database for the EBD was used to examine utilization and cost data for PPIs in a longitudinal analysis for the 61-month period from March 1, 2004, through March 31, 2009. Pharmacy claims data were compared for the period 14 months prior to esomeprazole exclusion (preperiod), 4 months during the esomeprazole exclusion (postperiod 1), and the ensuing 43 months of PPI reference pricing (postperiod 2). PPI cost and utilization data for the intervention group of approximately 127,500 beneficiaries were compared with a group of 122 self-insured employers with a total of nearly 1 million beneficiaries whose pharmacy benefits did not include reference pricing for PPIs.

RESULTS: Despite 79% of existing esomeprazole users being grandfathered during the 4-month esomeprazole-exclusion period (postperiod 1), the share of omeprazole OTC claims increased from 35.2% to 42.5% (+7.3 percentage points) of all PPI claims, and esomeprazole claims decreased from 16.7% to 12.0% (-4.7 percentage points), with little change in the use of other PPIs. The average allowed charge (price) per day of PPI drug therapy decreased in postperiod 1 by 8.9% from \$2.81 to \$2.56, while utilization increased by 2.2% from 1.83 days PMPM to 1.87 days PMPM; the net plan cost PMPM decreased by \$0.40 PMPM from \$3.78 to \$3.38 (-10.6%), representing a reduction in spending of \$35,664 per month while the average member copayment per claim was essentially unchanged. In the 43 months of reference pricing in postperiod 2, PPI utilization was essentially unchanged at 1.82 days PMPM compared with the preperiod (1.83 days PMPM) and 2.7% lower than the esomeprazole-exclusion period (1.87 days PMPM); however, price (charge per day) decreased by 38.4% during refer-

ence pricing to \$1.73 from \$2.81 in the preperiod and by 32.4% compared with \$2.56 in the esomeprazole-exclusion period, despite an increase in the average pharmacy dispensing fee to \$5.21 per PPI claim. Net plan cost decreased by \$1.87 PMPM (49.5%) to \$1.91 PMPM during reference pricing compared with the preperiod (\$3.78 PMPM) and by \$1.47 PMPM (43.5%) compared with the esomeprazole-exclusion period 1 (\$3.38 PMPM). Beneficiary costs (copayment per claim) for PPIs decreased to \$1.24 PMPM (\$23.27 per claim) compared with the preperiod (\$1.37 PMPM, \$24.95 per claim) and compared with the esomeprazole-exclusion period (\$1.40 PMPM, \$25.06 per claim). The reductions in net plan costs represented lower plan spending for the 43 months of reference pricing (postperiod 2) of approximately \$9.4 million or an average of approximately \$219,500 per month compared with the preperiod or \$7.9 million (approximately \$183,900 per month) compared with the esomeprazole-exclusion period. Compared with a group of self-insured health plans without pharmacy benefit reference pricing of PPIs, the cost savings over the 43-month period from September 1, 2005, through March 31, 2009, were approximately \$7.2 million or \$1.31 PMPM.

CONCLUSIONS: For this state employee health plan, the policy change that excluded esomeprazole from coverage but grandfathered current users was associated with a relatively small reduction in PMPM spending on PPIs compared with the subsequent policy change that applied reference pricing to the PPI class based on the price (drug cost plus dispensing fee) for omeprazole OTC. Over 43 months of reference pricing, net plan costs fell dramatically by 49.5% PMPM compared with the preperiod or decreased by 43.5% compared with the esomeprazole-exclusion period. While utilization was essentially unchanged compared with the 18 months before reference pricing, the average pharmacy dispensing fee per PPI claim increased, and beneficiary costs PMPM decreased.

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What is already known about this subject

- A longitudinal analysis of 15 months pre-intervention and 15 months post-intervention for the Arkansas State Employee Benefits Division (EBD) found that the addition of omeprazole OTC to coverage and adjustment of the community pharmacy dispensing fee to account for fewer prescriptions filled (with a 42-day vs. 30-day supply) were associated with a decrease of \$4,207,350 in proton pump inhibitor (PPI) drug cost or \$3,365,880 over 12 months (\$2.20 PMPM).

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What is already known about this subject (*continued*)

- A therapeutic maximum allowable cost (TMAC) intervention in 2006 in 1 small U.S. employer that imposed a defined benefit amount of \$0.67 per day (\$20 per month) for heartburn drugs including PPIs was associated with an 81% reduction in net health plan cost per day for heartburn drug therapy (from \$3.33 to \$0.62), 92% reduction in PMPM heartburn drug cost (from \$4.59 to \$0.39), and 18% reduction in total PMPM drug benefit cost (from \$29.30 to \$23.91).
- A change in formulary status to tier 3 (nonpreferred) for esomeprazole in the Veterans Affairs formulary and a modest financial incentive of as little as \$13 copayment for a 90-day mail-order supply, and \$0 copayment at military pharmacies if esomeprazole was obtained via prior authorization (PA), was associated with 15.0% of esomeprazole users switching to other prescription PPIs, 73.3% of esomeprazole users continuing the use of esomeprazole, 0.6% of users switching to a non-PPI prescription, and 11.1% stopping all prescription acid-reducing medications.

What this study adds

- In the pre/post comparison, excluding esomeprazole from coverage was associated with a net plan cost decrease of 7.7% for PPIs (from \$465,746 to \$430,082 per month) or an average cost savings of \$35,664 per month. Although not analyzed specifically, grandfathering exempted 79% of esomeprazole users and appeared to have limited the potential savings from this intervention.
- In the pre/post comparison, reference pricing was associated with an immediate and sustained reduction in the net EBD cost from an average \$3.78 PMPM in the 14-month preperiod to \$1.91 PMPM during the 43-month postperiod, savings of \$1.87 PMPM (49.5%) in the pre/post comparison or drug cost savings of approximately \$1.31 PMPM (\$7.2 million over 43 months) versus projected costs without reference pricing in a comparison group.
- Compared with a group of health plans that did not implement PPI reference pricing, this health plan experienced a decrease in PMPM cost after subtraction of member cost share that was approximately 50% (\$1.67) in the first 4 months but declined over the 43-month follow-up period to about \$0.63 PMPM during the first 3 months of 2009.
- The average member cost share per PPI claim was essentially unchanged in the esomeprazole-exclusion period compared with the preperiod (\$25.06 vs. \$24.95, respectively) and 6.7% less in the 43-month reference-pricing period (\$23.27); PPI utilization was 1.83 days PMPM in the preperiod and 1.82 days PMPM in the 43-month reference-pricing period.

Previously, we reported the cost and utilization of proton pump inhibitors (PPIs) associated with the decision by the Arkansas State Employee Benefits Division (EBD; Little Rock) to cover omeprazole over-the-counter (OTC) beginning in March 2004.^{1,2} Because the PPIs constituted a substantial portion of the pharmacy benefit spending, 12% (\$8.9 million) of the total drug budget of \$74.6 million in 2003 for approximately 127,500 beneficiaries, the PPI class was targeted for a possible cost savings measure to be implemented if the necessary access to needed therapies could be maintained.¹

Based on cost considerations, the Drug Utilization and Evaluation Committee (DUEC) 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 (Prilosec OTC), there was a large cost savings opportunity. Analysis of 15 months of coverage of omeprazole OTC in this drug benefit plan showed \$4.2 million in cost savings for the drug plan sponsor or approximately \$2.20 PMPM.¹

The specific pharmacy benefit design change that produced the PPI cost savings was implemented in March 2004, when coverage was extended for a 42-day supply of omeprazole OTC 20 mg tablets at a \$5 copayment and a \$13 dispensing fee for pharmacists.¹⁻³ With the enhanced dispensing fee for community pharmacists, the market share moved quickly from prescription PPIs to omeprazole OTC. Over the first year of coverage of omeprazole OTC, its share of total PPI claims rose from 0% to 35% in the first 4 months of 2005, compared with 22% share for generic omeprazole claims. Because brand PPIs still accounted for 43% of PPI claims, there was additional cost savings opportunity if more members switched to either omeprazole OTC or generic omeprazole.

EBD is a self-insured plan that comprises Arkansas state employees and public school employees. In 2005, EBD covered approximately 127,500 beneficiaries of whom approximately 78,000 (61%) were employees, yielding a beneficiary-to-employee ratio of approximately 1.63. In 2007, EBD had an annual drug budget of \$98.3 million in pharmacy and third-party administrative costs. EBD employs a pharmacy benefits management (PBM) company to administer the prescription drug benefit, including adjudicating claims, providing drug coverage strategies and consultative support regarding benefit design, reporting, and rebate support. The pharmacy benefit plan has a 3-tier copayment structure with the following copayments for up to a 31-day supply: \$10 for generic, \$30 for preferred brand, and \$60 for nonpreferred brand.

EBD strives to keep pharmacy costs controlled while maintaining access to medications for its membership. To achieve

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TABLE 1 Description of Pharmacy Benefit Interventions for PPIs

	Preperiod OTC Coverage Policy (beginning March 15, 2004)	Postperiod 1 Exclusion of Esomeprazole (May 1, 2005, to August 31, 2005)	Postperiod 2 Reference Pricing (September 1, 2005, to March 31, 2009)
Copayment			
Omeprazole OTC	\$5 OTC tier	\$5 OTC tier	\$5 OTC tier
Generic omeprazole	\$10	\$10	\$10
Brand omeprazole	Not covered	Not covered	RP = max. \$0.90 per unit
Rabeprazole	\$50	\$50	RP = max. \$0.90 per unit
Esomeprazole	\$50	Not covered	RP = max. \$0.90 per unit
Lansoprazole	\$50	\$50	RP = max. \$0.90 per unit
Pantoprazole	\$50	\$50	RP = max. \$0.90 per unit
Generic pantoprazole	Not available	Not available	RP = max. \$0.90 per unit
Dispensing fee per claim			
Omeprazole OTC	\$13	\$13	\$13
All other PPIs	\$2.50	\$2.50	\$2.50
Drug cost reimbursement			
Omeprazole OTC	AWP-13%	AWP-13%	AWP-13%
Generic omeprazole	AWP-13% until October 1, 2004, then MAC	AWP-13% until October 1, 2004, then MAC	AWP-13% until October 1, 2004, then MAC
Brand omeprazole	AWP-13%	AWP-13%	AWP-13%
Rabeprazole	AWP-13%	AWP-13%	AWP-13%
Esomeprazole	AWP-13%	AWP-13%	AWP-13%
Lansoprazole	AWP-13%	AWP-13%	AWP-13%
Pantoprazole	AWP-13%	AWP-13%	AWP-13%
Days-supply limit^a			
Omeprazole OTC	42-day supply	42-day supply	42-day supply
All other PPIs	31-day supply	31-day supply	31-day supply

^aDays-supply limit; there is not a quantity (units) limit on any PPI claim.

AWP = average wholesale price; MAC = maximum allowable cost; OTC = over-the-counter; PPI = proton pump inhibitor; RP = reference price.

this goal, the DUEC meets quarterly to discuss and vote on various clinical and formulary issues. The DUEC decisions are then confirmed, changed, or denied by the State and Public School Life and Health Insurance Board. Any approved changes generally take effect at the beginning of the following calendar quarter, depending on the need for member-specific communication. The DUEC is composed of 3 pharmacists, 4 physicians, 1 registered nurse, 1 state employee, and 1 public school employee.

The purpose of this study was 2-fold: to examine PPI utilization and drug costs before and after (a) excluding esomeprazole from coverage (with grandfathering current users) and (b) implementing a therapeutic maximum allowable cost (TMAC), or reference-pricing benefit design, for the PPI class in a large state employee health plan of approximately 127,500 members in 2005, which rose slightly to almost 130,000 members in 2008 and the first quarter of 2009.

Description of the Pharmacy Benefit and Interventions

The PPI interventions for EBD began with a literature search that revealed 3 systematic reviews that found the 5 available PPIs to be similar in tolerability, safety, and efficacy when dosed equipotently for use in the treatment of gastroesophageal reflux disease (GERD), the treatment and prevention of peptic ulcer disease, and for eradicating *Helicobacter pylori* infection.⁴⁻⁷

The literature review showed that the PPIs are a particularly well-tolerated class of drugs. Using this evidence, the DUEC concluded that all PPIs were therapeutically equivalent in efficacy and safety. From an evidence-based perspective, any PPI would be clinically acceptable as the preferred drug. Thus, the EBD considered PPI drug cost in making coverage decisions for PPIs in the pharmacy benefit.

The benefit design structure for PPIs at the beginning of the present study remained as it existed at the end of the previous evaluation that included omeprazole OTC coverage with \$5 member copayment and \$13 pharmacy dispensing fee; generic omeprazole with a \$10 copayment; and brand esomeprazole (Nexium), rabeprazole (Aciphex), pantoprazole (Protonix), and lansoprazole (Prevacid) with nonpreferred \$50 copayment per prescription.¹⁻³ The first intervention for the present study began on May 1, 2005, when brand esomeprazole was excluded from coverage, and current users were grandfathered until September 1, 2005 (Table 1). Drugs excluded from plan coverage were eligible for the PBM contractual discount (AWP minus 13% plus \$2.50 dispensing fee), and the member was responsible for 100% of the allowed charge for esomeprazole unless grandfathered due to prior use.

The second intervention began on September 1, 2005, when reference pricing was adopted for the entire PPI class, including coverage for esomeprazole. The reference-pricing strategy

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TABLE 2 Summary of Cost and Utilization of PPI Drugs Before and After Implementation of Reference Pricing

Evaluated Months ^a	Member Months	Claims	Days Supply	Days Per Claim	Ingredient Cost (\$) ^b	Dispensing Fee (\$) ^c	Allowed Charge (\$) ^d	Copayment (\$)	Net EBD Cost (\$) ^e
Preperiod—coverage of omeprazole OTC^f									
Totals	1,784,319	96,851	3,245,531		8,457,304	432,373	8,889,677	2,374,730	6,520,449
Average per month	127,451	6,918	231,824	33.51	604,093	30,884	634,977	169,624	465,746
Postperiod 1—exclusion of esomeprazole from coverage									
Totals	508,565	28,288	951,665		2,328,213	100,723	2,428,936	708,608	1,720,328
Average per month	127,141	7,072	237,916	33.64	582,053	25,181	607,234	177,152	430,082
Change	-310	154	6,093	0.13	-22,040	-5,703	-27,743	7,528	-35,664
% change	-0.2%	2.2%	2.6%	0.4%	-3.6%	-18.5%	-4.4%	4.44%	-7.7%
Postperiod 2—reference pricing									
Totals	5,489,404	293,536	10,028,631		15,813,967	1,530,515	17,344,482	6,757,383	10,587,099
Average per month	127,661	6,826	233,224	34.16	367,767	35,593	403,360	157,148	246,212
Change from preperiod	209	-92	1,400	0.65	-236,326	4,710	-231,617	-12,475	-219,534
% change from preperiod	0.2%	-1.3%	0.60%	1.9%	-39.1%	15.3%	-36.5%	-7.4%	-47.1%
Change from postperiod 1	519	-246	-4,692	0.3	-214,287	10,413	-203,874	-20,004	-183,870
% change from postperiod 1	0.4%	-3.5%	-2.0%	1.6%	-36.8%	41.4%	-33.6%	-11.3%	-42.8%

^aBecause of the timing of interventions, not all time periods are the same.

^bAllowed drug ingredient cost reimbursement to pharmacies is average wholesale price minus 13%.

^cDispensing fee may be greater than \$2.50 because of generic incentive programs that pay a higher dispensing fee. The dispensing fee for omeprazole OTC is \$13.00. The average pharmacy dispensing fee was \$4.46 in the preperiod, \$3.56 in postperiod 1, and \$5.21 in postperiod 2.

^dAllowed charge is the sum of the dispensing fee plus the drug ingredient cost.

^eNet EBD costs are slightly higher than the allowed charge minus copayment because the net cost includes the administrative fee paid to the pharmacy benefits manager for processing the pharmacy claims.

^fCoverage of omeprazole OTC was continuous throughout the study period, through March 31, 2009.

EBD = Arkansas Employee Benefits Division; OTC = over-the-counter; PPI = proton pump inhibitor.

provided coverage of any drug in the PPI class at the price per unit for the least expensive drug. The reference price was calculated from the cost for 42 brand omeprazole OTC tablets, using the 14-count packages, and a pharmacy dispensing fee of \$13 to compensate for 3 fewer fills per year. This price minus the \$5 copayment divided by 42 units determined the maximum plan paid amount of \$0.90 per unit. If the patient preferred a PPI other than omeprazole OTC, the patient was responsible for the cost above the plan cost of \$0.90 per unit.

Generic prescription omeprazole was not reference priced and remained available at the \$10 generic-tier copayment throughout the study period (Table 1). Generic omeprazole was excluded from reference pricing because the plan wanted to ensure members would have access to a less costly PPI, and there was a shortage of omeprazole OTC during 2004. Later, generic omeprazole was excluded from reference pricing because the market price for generic omeprazole was expected to fall substantially. However, by 2007 the price per unit for generic omeprazole was not considerably different from the allowed cost per unit established by the reference price.

The pharmacy benefit design for all covered drugs included copayment tiers \$10/\$25/\$50 per prescription. PPIs were the only therapeutic category for which there was a \$5 copayment option (for omeprazole OTC). The \$5 PPI option began in March 2004 and remained unchanged throughout the

61-month evaluation period. Beginning in 2007 Q1, copayments for all non-PPI drug categories increased to \$10/\$30/\$60 and remained constant through the end of the evaluation period (March 2009). Members receiving omeprazole OTC paid a \$5 copayment. Although the increase in copayments for tier 2 and tier 3 non-PPI drugs may have affected some beneficiaries' abilities to afford other medications, the effect on the ability to afford PPIs was not explored.

The EBD health plan offers a mail-order pharmacy option, but it is used by a small proportion (approximately 0.1%) of the members. Thirty-day and 90-day fills are available to members by mail order or a community pharmacy.

Methods

PPI claims were extracted from the EBD pharmacy claims database using Medi-Span (Wolters Kluwer Health, Indianapolis, IN) Generic Product Identifier (GPI) codes beginning with 4,927 for claims with dates of service from March 1, 2004, through March 31, 2009. This time period encompasses the 14 months prior to implementation of the 2 policy changes (preperiod), 4 months of the esomeprazole exclusion from coverage intervention (postperiod 1), and 43 months following the reference-pricing intervention (postperiod 2). Member-months and the PPI cost and utilization data were aggregated by calendar periods to permit pre/post analyses of changes in PPI market

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TABLE 3 Derived Measures for Cost and Utilization of PPI Drugs Before and After Implementation of Reference Pricing

Derived Measures for Evaluation Periods ^a	Claims PMPM	Days PMPM	Allowed Charge PMPM (\$)	Allowed Charge Per Claim (\$)	Allowed Charge Per Day (\$)	Copayment Per Claim (\$)	Net Per Claim (\$) ^b	Net Per Day (\$)	Net PMPM (\$)
Preperiod—coverage of omeprazole OTC^c									
Mar–May 04	0.053	1.82	4.23	80.25	2.32	21.77	58.59	1.69	3.09
Jun–Aug 04	0.052	1.77	4.71	89.78	2.65	24.36	65.54	1.94	3.44
Sept–Nov 04	0.055	1.81	5.33	96.71	2.95	25.50	71.26	2.17	3.93
Dec 04–Feb 05	0.057	1.88	5.57	97.01	2.96	25.82	71.22	2.17	4.09
Mar–Apr 05	0.056	1.87	5.45	97.30	2.91	25.64	71.65	2.14	4.01
Preperiod average	0.055	1.83	5.15	93.71	2.81	24.95	67.77	2.06	3.78
Postperiod 1—exclusion of esomeprazole from coverage									
May–Jun 05	0.055	1.84	4.82	87.76	2.62	25.66	62.10	1.86	3.41
Jul–Aug 05	0.056	1.91	4.73	84.00	2.48	24.45	59.55	1.76	3.36
Postperiod 1 average	0.056	1.87	4.78	85.90	2.56	25.06	60.84	1.81	3.38
Change from preperiod	0.001	0.04	-0.38	-7.80	-0.26	0.11	-6.93	-0.25	-0.40
% change from preperiod	1.3%	2.2%	-7.3%	-8.3%	-8.9%	0.4%	-10.2%	-12.3%	-10.6%
Postperiod 2—reference pricing									
Sep–Dec 05	0.051	1.71	2.92	56.52	1.71	24.74	32.40	0.97	1.66
Jan–Mar 06	0.047	1.65	2.80	59.38	1.68	24.64	34.74	0.99	1.64
Apr–Jun 06	0.049	1.70	2.83	58.30	1.67	23.16	35.14	1.01	1.71
Jul–Sep 06	0.050	1.74	2.92	58.38	1.70	22.72	35.66	1.03	1.78
Oct–Dec 06	0.051	1.74	3.00	59.32	1.73	23.31	36.01	1.05	1.82
Jan–Mar 07	0.051	1.76	3.06	59.55	1.74	23.42	36.12	1.05	1.85
Apr–Jun 07	0.053	1.81	3.16	59.34	1.76	23.05	36.29	1.06	1.93
Jul–Sep 07	0.054	1.85	3.29	60.36	1.77	23.16	37.19	1.10	2.02
Oct–Dec 07	0.055	1.86	3.26	59.33	1.75	22.61	36.73	1.08	2.02
Jan–Mar 08	0.055	1.85	3.27	59.42	1.77	22.61	36.82	1.09	2.03
Apr–Jun 08	0.057	1.91	3.38	59.49	1.75	22.18	37.31	1.11	2.12
Jul–Sep 08	0.058	1.99	3.43	58.69	1.72	22.21	36.48	1.07	2.13
Oct–Dec 08	0.059	2.02	3.47	59.01	1.73	22.16	36.85	1.07	2.17
Jan–Mar 09	0.059	2.01	3.50	59.81	1.74	22.43	37.38	1.09	2.19
Postperiod 2 average	0.053	1.82	3.15	59.02	1.73	23.27	35.76	1.05	1.91
Change from preperiod	-0.002	-0.009	-2.00	-34.69	-1.08	-1.68	-32.01	-1.01	-1.87
% change from preperiod	-3.6%	-0.5%	-38.8%	-37.0%	-38.4%	-6.7%	-47.2%	-49.0%	-49.5%
Change from postperiod 1	-0.002	-0.049	-1.62	-26.88	-0.83	-1.80	-25.08	-0.76	-1.47
% change from postperiod 1	-4.0%	-2.7%	-34.0%	-31.3%	-32.4%	-7.2%	-41.2%	-42.1%	-43.5%

^aBecause of the timing of the interventions, the time periods do not all have the same number of months.

^bAverages were used to report the numbers and may not be exactly equal to the results from calculation using the raw numbers.

^cCoverage of omeprazole OTC was continuous throughout the study period, through March 31, 2009.

OTC = over-the-counter; PMPM = per member per month; PPI = proton pump inhibitor.

share, beneficiary cost (copayment), ingredient cost, dispensing fees, allowed charge (ingredient cost plus dispensing fee), and net plan (EBD) cost after subtraction of beneficiary cost share. Derived measures included utilization and cost per claim, per day of therapy, and per member per month (PMPM).

Due to the differences in the number of months in pre/post periods, monthly averages were also calculated for the 3 principal time periods (14 months for the preperiod, 4 months for postperiod 1, and 43 months for postperiod 2). The PPI cost and utilization data were also aggregated by calendar quarter to permit long-term trend analysis. A comparison group was created by the EBD's PBM from 122 self-insured employer health

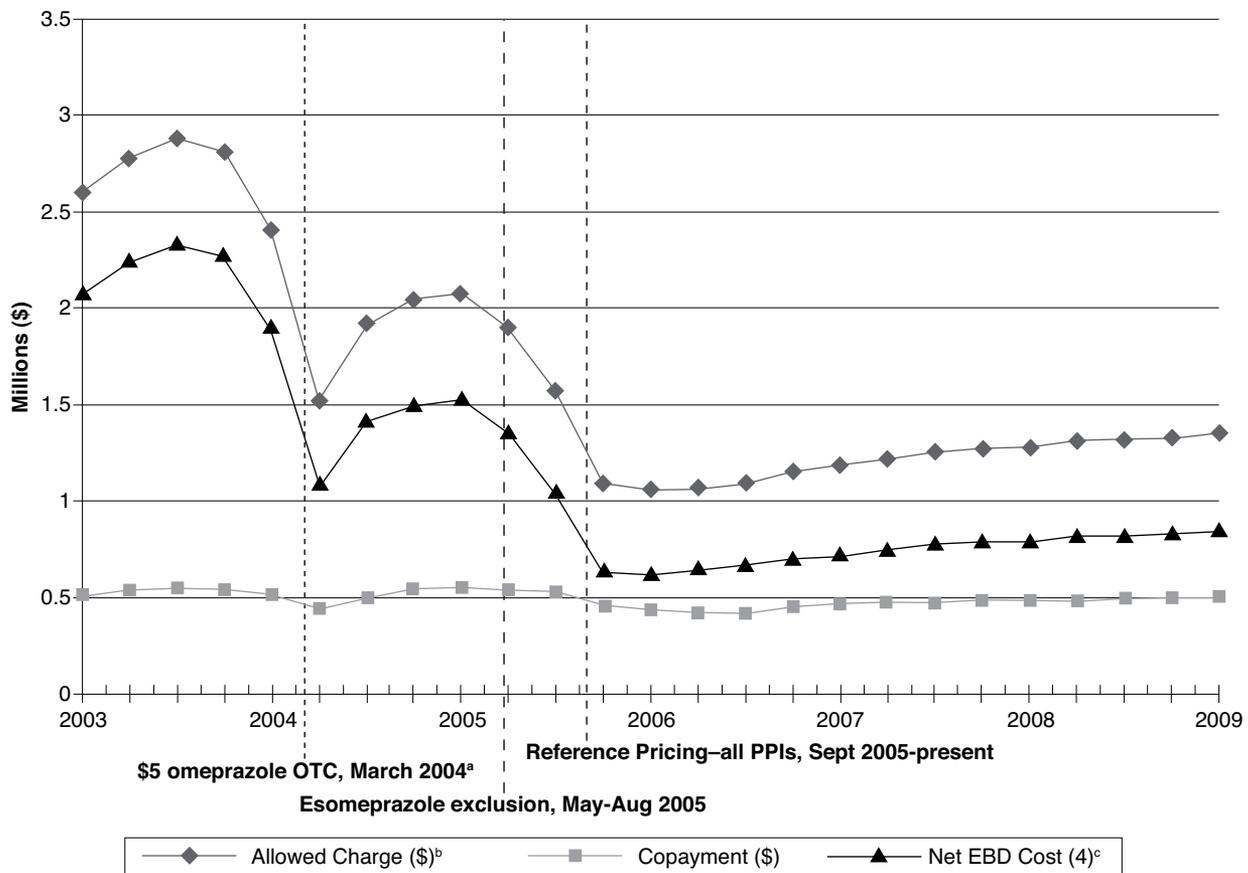
plans and 50 union trust funds. These individual health plans had the ability to implement plan-specific pharmacy benefit designs but none implemented PPI reference pricing during the study period. The health plans in this comparison group were managed by the PBM for the entire study period, and the average eligible membership was 984,731.

Results

The member-month counts and PPI utilization and cost data are aggregated by calendar period in Table 2, and the derived measures per claim, per day, and PMPM are shown in Table 3. Cost and utilization trend data by calendar quarter are shown

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FIGURE 1 Cost Trend for All PPI Claims Before and After Implementation of Reference Pricing



^aThe downward trend that started prior to 2004 Q1 included data from implementation of the \$5 omeprazole OTC when the 47% of the PPI claim share shifted to omeprazole OTC.

^bAllowed charge is the sum of the dispensing fee plus the ingredient cost.

^cNet EBD costs are slightly higher than the allowed charge minus copayment because the net cost includes the administrative fee paid to the pharmacy benefits manager for processing the pharmacy claims.

EBD = Arkansas Employee Benefits Division; OTC = over-the-counter; PPI = proton pump inhibitor; Q = quarter.

in figures 1 and 2. PPI market shares by prescription claims are shown in Figure 3 for time periods associated with the PPI benefit design changes. Cost and utilization data for EBD versus the comparison group are shown in tables 4 and 5 and in Figure 4. All cost data are unadjusted for inflation.

The 14-Month Preperiod

During the 14 months of the preperiod, the average member enrollment was 127,451 per month (Table 2). The total number of prescriptions was 96,851, or an average of 6,918 per month. The average net cost per claim was \$67.77 (Table 3). The average allowed charge per day was \$2.81, and the net plan (EBD) cost per day was \$2.06. The net plan (EBD) cost PMPM was \$3.78. Utilization, measured by the number of claims PMPM, was 0.055 or 1.83 days PMPM. The average copayment per claim

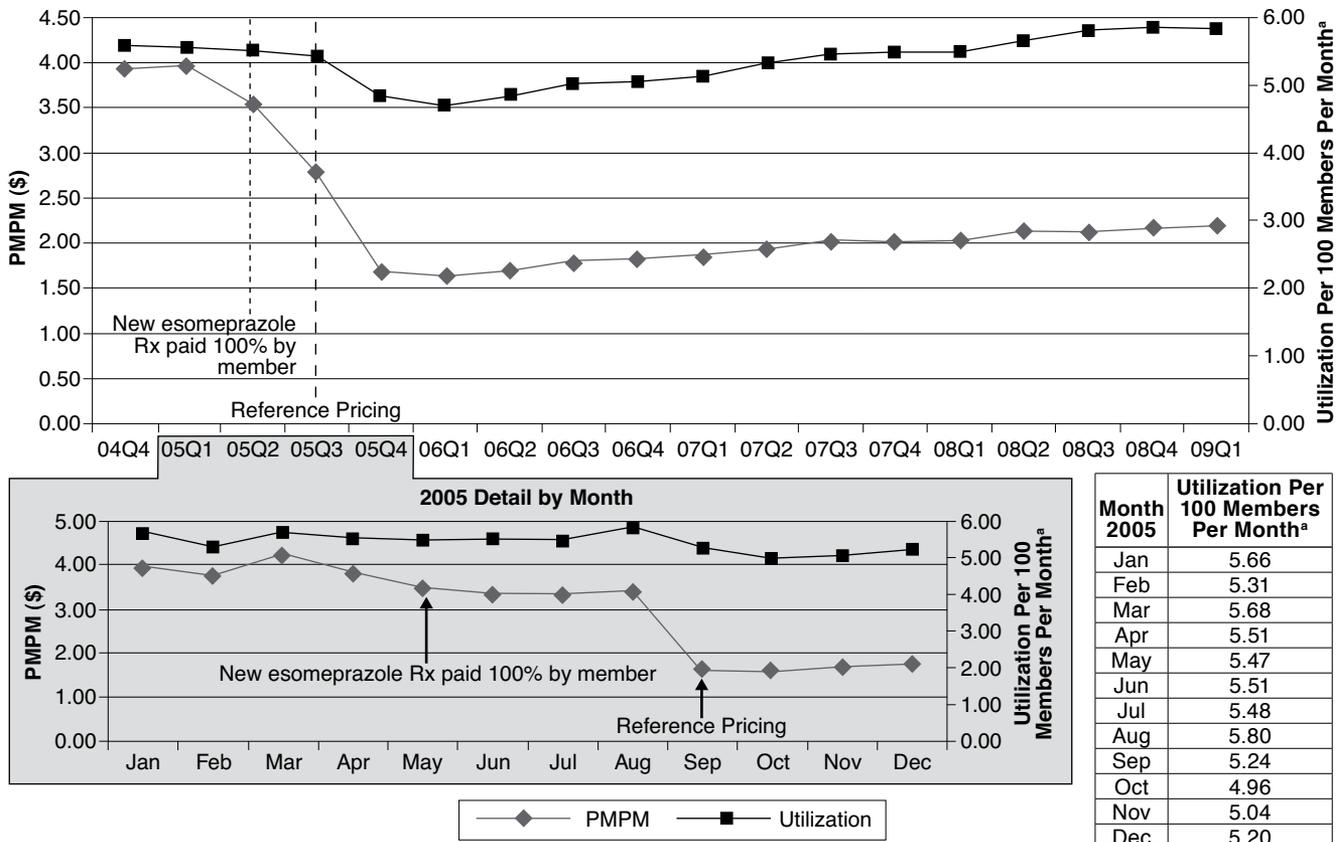
was \$24.95 (or \$1.33 PMPM, data not shown). Omeprazole OTC accounted for 35.2% of the PPI pharmacy claims in the 4 months immediately before the first intervention (January-April 2005; Figure 3).

The 4-Month Postperiod 1—Esomeprazole Exclusion

Of the total of 1,448 members who received esomeprazole during the exclusion period, 1,145 (79%) were continuing users and were grandfathered; 303 (21%) were not grandfathered and paid 100% of the cost. During the 4-month esomeprazole-exclusion period (postperiod 1), the omeprazole OTC market share as measured by the number of claims increased from 35.2% to 42.5% (+7.3 percentage points; Figure 3). Esomeprazole market share in claims decreased from 16.7% to 12.0% (-4.7 percentage points) with little change in the other

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FIGURE 2 PPI Quarterly PMPM Utilization and Drug Cost Trend (inset – 2005 detail)



^aUtilization is shown as PPI claims per 100 members per month.

EBD = Arkansas Employee Benefits Division; PMPM = per member per month; PPI = proton pump inhibitor; Q = quarter; Rx = pharmacy claim.

PPI drugs. The average allowed charge (price) per day of PPI drug therapy in postperiod 1 decreased by 8.9% to \$2.56 from \$2.81 in the preperiod (Table 3). The average enrollment per month decreased 0.2%, to 127,141 (Table 2). PPI utilization adjusted for enrollment increased by 2.2% from 1.83 days PMPM to 1.87 days PMPM (Table 3). The net cost decreased by 10.2% per PPI claim or 12.3% per day, and the net cost PMPM decreased by 10.6% (Table 3). Net cost per month unadjusted for membership was 7.7% lower in postperiod 1 compared with the preperiod (\$430,082 vs. \$465,746, respectively), or an average reduction in net plan cost of \$35,664 per month (Table 2). The average member copayment per claim was essentially unchanged at \$25.06 compared with \$24.95 in the preperiod (Table 3).

The 43-Month Postperiod 2—Reference Pricing for PPIs

Based on analysis of days PMPM, there appeared to be a small decrease in PPI utilization in the initial months of reference pricing in the last 4 months of 2005 and into 2006 (Table 2

and Figure 2). Assessed by the less precise measure of claims in August 2005 before reference pricing began, PPI utilization was 5.80 claims per 100 members per month (Figure 2 inset shows monthly utilization). After 2 months of reference pricing, PPI utilization fell to the low point of 4.96 claims per 100 members per month. However, by December 31, 2005, utilization rebounded and gradually increased so that by the end of the evaluation period in 2009 Q1 (Figure 2), utilization had increased to 5.86 claims per 100 members per month. Compared with the preperiod average of 0.055 claims PMPM, utilization decreased 3.6% to an average of 0.053 claims PMPM for the entire postperiod 2. By the more precise measure of days PMPM, PPI utilization was unchanged at an average 1.82 in postperiod 2 during reference pricing, compared with 1.83 days PMPM in the preperiod (Table 3). The average copayment per claim decreased by 6.7% from \$24.95 in the preperiod to \$23.27 during the 43 months of reference pricing.

During the first 4 months of reference pricing, omeprazole OTC accounted for 77.1% of all PPI pharmacy claims, up from

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FIGURE 3 PPI Prescription Share^a for January 2005 Through 2009 Q1

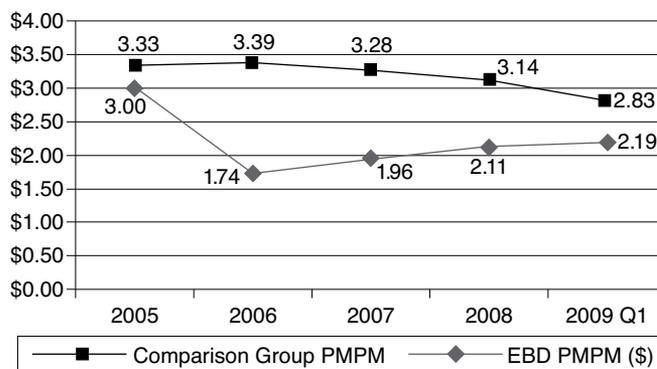
Drug Name	Rx Share %
January - April 2005 (prior to omeprazole exclusion)	
omeprazole OTC	35.2
generic omeprazole	21.7
esomeprazole	16.7
lansoprazole	11.7
pantoprazole	7.8
rabeprazole	6.2
May - August 2005 (esomeprazole exclusion)	
omeprazole OTC	42.5
generic omeprazole	18.5
esomeprazole	12.0
lansoprazole	12.0
pantoprazole	7.9
rabeprazole	6.3
September - December 2005 (first 4 months of reference pricing)	
omeprazole OTC	77.1
generic omeprazole	3.5
esomeprazole	6.4
lansoprazole	5.0
pantoprazole	4.8
rabeprazole	2.4
2009 Q1^b (last 3 months of reference pricing)	
omeprazole OTC	53.7
generic omeprazole	32.1
esomeprazole	5.4
lansoprazole	3.0
generic pantoprazole	4.0
rabeprazole	0.9

^aShare calculated by the number of claims.

^bLansoprazole includes 0.8% solutab share; omeprazole-sodium bicarbonate had 0.5% Rx share and brand pantoprazole had 0.2% Rx share. OTC = over-the-counter; PPI = proton pump inhibitor; Q = quarter; Rx = pharmacy claim.

42.5% in the preceding 4 months during the esomeprazole-exclusion period (Figure 3). The generic omeprazole market share in claims decreased from 18.5% to 3.5% over that time. Esomeprazole accounted for 16.7% of claims in the 14 months prior to its exclusion period, 12.0% of claims during the exclusion period, 6.4% and 5.4% of PPI claims in the first 4 months and last 3 months of reference pricing, respectively. Most of the other PPIs accounted for lower market share during reference pricing compared with postperiod 1. At the end

FIGURE 4 Net Plan Cost PMPM for All PPIs^a



^aPlan paid cost is the allowed charge (drug cost plus dispense fee) minus the member cost share. The \$3.00 net plan cost for EBD in calendar year 2005 includes 4 months in the preperiod (omeprazole OTC coverage, January-April), 4 months (May-August) of esomeprazole exclusion, and 4 months of referencing pricing (September-December).

EBD = Arkansas Employee Benefits Division; OTC = over-the-counter; PMPM = per member per month; PPI = proton pump inhibitor; Q = quarter.

TABLE 4 EBD and Comparison Group Average Charge Per Claim, Utilization, and Cost Share for PPIs^a

Year	Arkansas Employee Benefits Division			Comparison Group		
	Average Allowed Charge Per Claim	Claims Per 100 Members Per Month	Member Cost Share %	Average Allowed Charge Per Claim	Claims Per 100 Members Per Month	Member Cost Share %
2005	\$81.64	5.3	31.2	\$153.80	2.6	15.7
2006	\$58.85	4.9	39.8	\$158.49	2.5	16.0
2007	\$59.65	5.3	38.7	\$158.22	2.5	15.8
2008	\$59.15	5.7	37.7	\$152.38	2.4	14.3
2009 Q1	\$59.81	5.9	37.5	\$149.61	2.2	14.3

^aThe utilization rate (claims per 100 members per month) for the comparison group was approximately half that of EBD. Conversely, the average claim cost for the comparison group was roughly twice that of EBD. The comparison group includes drug plans such as unions that have high mail service utilization and therefore higher cost per claim compared with EBD in which mail service was used by approximately 0.1% of members. Because days-supply data were not available for the comparison group, it was not possible to calculate charge per day for the comparison group.

EBD = Arkansas Employee Benefits Division; PPI = proton pump inhibitor; Q = quarter.

of the evaluation period in 2009 Q1, omeprazole OTC market share had decreased to 53.7% and generic omeprazole market share had increased to 32.1%, for a combined 85.8% share of all PPI claims. The average enrollment was 127,661 during 43 months of reference pricing, a slight increase of 0.2% compared with the preperiod (Table 2). The average number of PPI claims decreased by 1.3% during reference pricing compared

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TABLE 5 PPI Cost Savings Estimates Based on PMPM Net Cost for EBD and Comparison Group

Time Period	EBD Member Months	EBD PMPM	Comparison Group PMPM ^{a,b,c}	PMPM Cost Ratio ^d	Actual EBD Net Plan Cost	Projected Net Plan Cost ^e	Cost Savings	Cost Savings PMPM
Jan-Apr 2005	513,826	\$3.93	\$3.33	0.85	\$2,019,211	\$1,716,329	-\$302,882	-\$0.59
May-Aug 2005	508,565	\$3.38	\$3.33	0.99	\$1,720,328	\$1,703,125	-\$17,203	-\$0.03
Sept-Dec 2005	501,529	\$1.66	\$3.33	2.01	\$830,412	\$1,669,128	\$838,716	\$1.67
2006	1,514,661	\$1.74	\$3.39	1.95	\$2,633,356	\$5,135,044	\$2,501,688	\$1.65
2007	1,542,348	\$1.96	\$3.28	1.67	\$3,017,292	\$5,038,878	\$2,021,586	\$1.31
2008	1,545,183	\$2.11	\$3.14	1.49	\$3,261,579	\$4,859,753	\$1,598,174	\$1.03
2009 Q1	385,683	\$2.19	\$2.83	1.29	\$844,370	\$1,089,237	\$244,867	\$0.63
Total ^f	5,489,404				\$10,587,009	\$17,792,040	\$7,205,031	\$1.31

^aComparison group represents an average eligible membership of 984,731 lives during the study period for a mix of self-insured employer groups and union trust funds. These employer groups were with the PBM during the entire study period and had the ability to adopt employer-specific pharmacy benefit designs but did not implement PPI reference pricing during this evaluation period.

^bComparison group PMPM cost was calculated by dividing the plan paid amount by the plan's eligibility by 12 (months).

^cComparison group PMPM cost breakdowns for 2005 corresponding to EBD were not available so the 2005 aggregate was used.

^dCost ratio is derived from the comparison group PMPM cost divided by the EBD (intervention group) PMPM cost.

^eProjected EBD total allowed charge was derived from the product of the actual EBD total allowed charge multiplied by the cost ratio.

^fThe total for the 43-month reference pricing period from September 1, 2005, through March 31, 2009 (i.e., reference pricing was not in effect from January 2005 through August 2005, so the first 2 rows of this table are therefore not included in the cost savings calculation).

EBD=Arkansas Employee Benefits Division; PBM=pharmacy benefit management company; PMPM=per member per month; PPI=proton pump inhibitor; Q=quarter.

with the preperiod, but utilization adjusted for enrollment was unchanged at 1.82 days PMPM compared with 1.83 days PMPM during the 14-month preperiod (Table 3). The net cost per claim decreased by \$32.01 (47.2%) from an average of \$67.77 in the preperiod to \$35.76 in postperiod 2.

Price, as measured by the average allowed charge (drug cost plus pharmacy dispensing fee) per PPI claim, dropped by 37.0% (\$34.69), from an average \$93.71 during the preperiod to \$59.02 in the 43-month reference-pricing period. Adjusted for days supply per claim, the price per PPI day of therapy dropped accordingly by 38.4% (\$1.08), from \$2.81 in the preperiod to \$1.73 in 43 months of reference pricing. After consideration of the average decrease of \$1.68 per PPI claim in member cost share (copayment), the net plan cost per day of PPI drug therapy dropped by \$1.01 (49.0%), from \$2.06 to \$1.05 during 43 months of reference pricing. Adjusted for membership, the net plan cost PMPM decreased by \$1.87 (49.5%) from \$3.78 in the 14-month preperiod to \$1.91 PMPM during 43 months of reference pricing (Table 3). The reductions in PMPM costs represented lower plan spending for the 43 months of reference pricing of approximately \$9.4 million or an average of \$219,534 per month compared with the preperiod, or \$7.9 million (\$183,870 per month) compared with the esomeprazole-exclusion period (preperiod 1).

Comparison Group

The key measures of PMPM cost, average charge per claim, utilization rate, and cost share were compared with comparison data obtained from the same PBM in an attempt to better isolate the effects on PPI cost and utilization of the 2 plan

design changes. The comparison data were composed of a mix of 122 self-insured employer groups and 50 union trust funds that used the PBM during the entire study period. Although these 122 pharmacy benefit plans had the flexibility to implement pharmacy benefit design changes, none adopted reference pricing of PPIs during the period of the present study. Specific information was unavailable regarding the mail-order options in the 122 plans in the comparison group, but the cost and utilization data suggest common use of mail service and/or quantities greater than 30-day supply for PPI claims (Table 4). Days supply was not provided for the comparison group, preventing calculation of the average days supply per PPI claim to contrast with the approximate average 34 days supply for the EBD group (Table 2). However, the data in Table 4 show an average allowed charge per claim for the comparison group that was nearly twice that for the EBD group in calendar year 2005, and utilization in PPI claims per 100 members per month was about one-half that of the EBD group. The combination of utilization and price (i.e., allowed charge per claim) was \$288.37 per 100 member-months for EBD in calendar year 2006 versus \$396.23 for the comparison group (Table 4), but the gap narrowed to only an approximate 8% advantage for EBD in calendar year 2008 (\$337.16 vs. \$365.71).

EBD Versus Comparison Group

Net plan cost was nearly identical for EBD (\$3.38) and the comparison group during the esomeprazole-exclusion period, but the EBD costs for the calendar year were composed of \$3.93 PMPM during the first 4 months of 2005, \$3.38 during 4 months of esomeprazole exclusion, and \$1.66 during

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reference pricing in the last 4 months of the year (Table 5). The cost difference between the 2 groups was large during the first full year of reference pricing: \$1.74 PMPM in the EBD group versus \$3.39 in the comparison group, a PMPM cost ratio of 1.95 with estimated cost savings of approximately \$2.5 million in calendar year 2006.

Using this method of comparing net plan cost PMPM for EBD and the comparison group, the estimated cost savings declined to an estimated \$2.0 million in calendar year 2007, \$1.6 million in calendar year 2008, and approximately \$245,000 in 2009 Q1 (Table 5). Total estimated PPI drug cost savings for EBD were \$7,205,031 over the 43 months of reference pricing from September 1, 2005, through March 31, 2009, or an average \$1.31 PMPM.

Discussion

Many different strategies exist to control costs of pharmacy benefits. An evaluation of a small U.S. employer described a 92% reduction in PMPM cost for heartburn drugs when a TMAC strategy was applied to all agents used to treat heartburn.⁸ Although cost reduction for the TMAC intervention was dramatic, a drop in utilization of more than 50% factored significantly in the cost reduction for the plan sponsor. In another study, a Canadian TMAC intervention for PPIs was associated with an 11.7% reduction in average cost per day and an 11.9% decrease in utilization for PPI users in an employer-based plan, but this intervention did not include an OTC product.⁹ Both of these interventions were associated with reduced plan costs, but the evaluations showed decreases in utilization by the members or increased member cost share.

The present study of this large state-employee health plan describes the relatively unsuccessful attempt at cost savings with the exclusion of a single product, esomeprazole, followed by successful reference pricing of the entire class. The reference-pricing strategy was associated with no reduction in PPI utilization, a small but favorable 6.7% reduction in the average member copayment per PPI claim, and a large effect on the average PPI price associated with an increase in the share of PPIs attributable to generic omeprazole and omeprazole OTC from approximately 61% in the 4 months immediately preceding reference pricing (i.e., the esomeprazole-exclusion period) to 86% in 2009 Q1. In the pre/post comparison, net plan cost savings PMPM were approximately 50% for reference pricing compared with the 14-month period before the 2 benefit design changes or 44% for comparison of 43 months of reference pricing versus the 4-month period of esomeprazole exclusion that immediately preceded reference pricing.

Utilization, as measured by claims PMPM, decreased to a low point of 0.047 in 2006 Q1 but rebounded quickly and steadily increased to 0.059 claims PMPM in 2009 Q1, which exceeded the utilization of 0.055 claims PMPM in the 14-month baseline period. The initial decrease was not unexpected because some

member disruption was anticipated with the 2 benefit design changes as members transitioned to alternate therapies or forewent filling a prescription in anticipation of increased out-of-pocket expense for high-cost brand PPIs. However, overall PPI utilization was not adversely affected by reference pricing. Our finding of no effect of reference pricing on PPI utilization may contrast with the TMAC studies because our follow-up period was much longer.^{8,9}

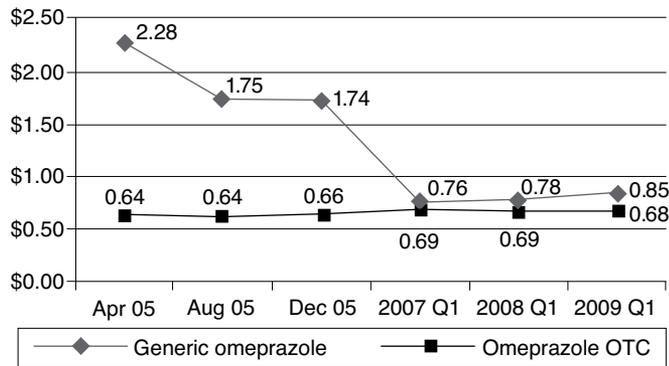
Redistribution of plan cost onto members via higher copayments was avoided in this intervention as evidenced by a 6.7% decrease in average copayment per claim from \$24.95 for the preperiod to \$23.27 during 43 months of reference pricing. The average copayment per claim was essentially unchanged during the esomeprazole-exclusion period compared with the preperiod and decreased by approximately 7% during reference pricing compared with the 4-month period of esomeprazole exclusion. Beginning January 1, 2007, the EBD plan increased copayments from \$5/\$10/\$25/\$50 to \$5/\$10/\$30/\$60 per prescription; for omeprazole OTC; and for tier 1, 2, and 3 drugs, respectively. The reference-pricing strategy effectively capped what the plan would pay for any PPI prescription with the exception of generic omeprazole and was not based on the copayment tier placement. The plan's increase in copayments for all nonreference-priced drugs in tiers 2 or 3 did not directly affect costs for this class of drugs because the copayment for omeprazole OTC and generic omeprazole remained the same; members who received omeprazole OTC or generic omeprazole continued to pay \$5 or \$10 copayments, respectively. Members who received any other PPI continued to pay a copayment calculated by the difference in the price of the PPI compared with the reference price as measured by the price per unit instead of a dollar copayment. It is unknown to what degree the increase in the dollar copayments for tier 2 and tier 3 drugs affected the utilization of PPIs, but overall utilization of PPIs did not change over the 61 months in the present study, and average member cost share as a percentage of the allowed charge per claim declined slightly in 2007 through 2009 Q1 compared with 2006.

The short-lived esomeprazole-exclusion period (postperiod 1) was associated with a small change in the combined omeprazole OTC and generic omeprazole share from approximately 57% in the preceding 14-month period to approximately 61%. Although the precise effect of grandfathering current esomeprazole users could not be determined, a total of 1,448 utilizing members continued esomeprazole, 1,145 (79%) were grandfathered, and 303 (21%) were not grandfathered and paid 100% of the cost. Other branded PPI market shares remained essentially unchanged during esomeprazole exclusion. In the pre/post comparison, net plan costs decreased by -10.6% from \$3.78 PMPM to \$3.38 PMPM, and the allowed charge decreased by -7.3% from \$5.15 PMPM to \$4.78 PMPM.

Reference pricing, by contrast, was associated with a quick

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FIGURE 5 EBD Net Cost Per Unit: Omeprazole OTC and Generic Omeprazole^a



^aThe average EBD (plan) paid cost is calculated from allowed charge (ingredient cost plus dispensing fee) minus member copayment.
EBD=Arkansas Employee Benefits Division; OTC=over-the-counter; Q=quarter.

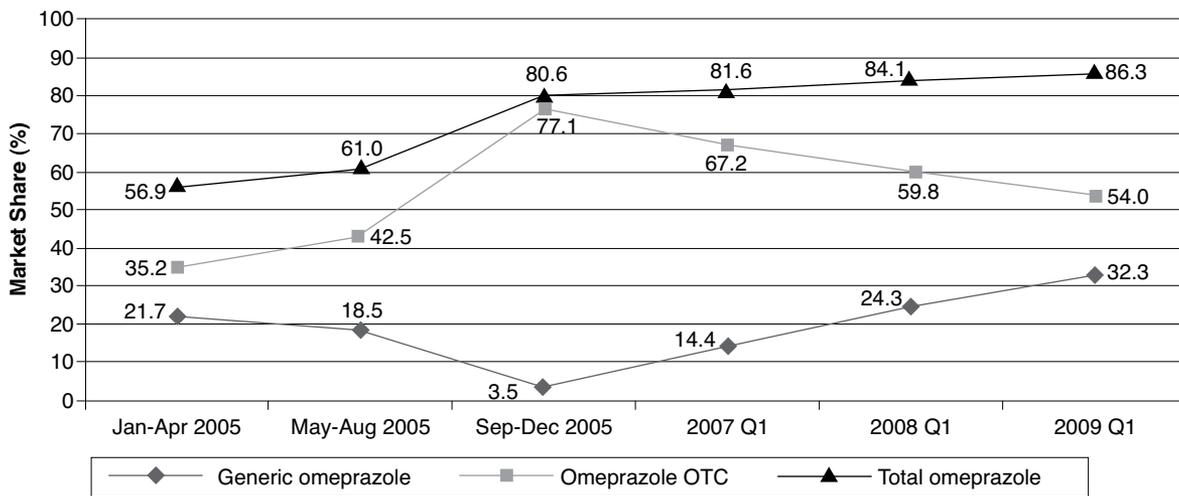
and dramatic change in PPI market shares (Figure 3). Upon the implementation of reference pricing, all brand products were limited to the maximum plan paid price per unit of \$0.90. During the first 4 months of reference pricing, the omeprazole OTC market share increased from 42.5% to 77.1%, and the combined share of omeprazole OTC and generic omeprazole was over 80%. In the pre/post comparison, net plan costs decreased by almost 50% during 43 months of reference pricing, associated with an increase in the proportion of generic omeprazole and omeprazole OTC to approximately 86% of all

PPI claims.

The combined market share of OTC and generic omeprazole of 86% of all PPI claims was associated with an average charge of \$3.50 PMPM in 2009 Q1. Directly comparable national data are not available, but one source reported PPI spending of \$45.76 per member per year (PMPY) in 2009 or \$3.81 PMPM including a 40% PPI market share.¹⁰ How these national data compare with EBD net plan cost of \$2.19 PMPM in 2009 Q1 is not known. PPI net price and net cost per day are unfortunately not available from national data sources. The ratios of generic omeprazole and omeprazole OTC in the EBD plan in the most recent period (2009 Q1) were 32.1% and 53.7%, respectively. Some of the generic omeprazole utilization with a \$10 copayment per claim versus \$5 copayment for omeprazole OTC may be explained by the small difference in the copayment amounts because generic omeprazole was not subject to reference pricing. Some of generic omeprazole utilization might also be explained by some patients using a higher dose of 1 generic omeprazole 40 mg tablet rather than two 20 mg tablets of omeprazole OTC. A small amount of generic omeprazole versus omeprazole OTC use might be explained by new members or new PPI users who may not be fully aware of the benefit design features and therapeutic alternatives. The influence of patient or prescriber perception of lower efficacy with OTC products is also unknown.

Savings in this pharmacy benefit plan could have been larger if generic omeprazole had been subject to reference pricing (Figure 5). In the first 4 months of reference pricing, generic omeprazole accounted for 3.5% of all PPI claims, but the proportion increased to 32.1% in the last 3 months of the

FIGURE 6 Omeprazole OTC Versus Generic Omeprazole Rx Share^a



^aMarket share represents the percentage of claims within the PPI class.
OTC=over-the-counter; PPI=proton pump inhibitor; Q=quarter; Rx=pharmacy claim.

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study period in 2009 Q1 (Figure 6). By 2009 Q1, the unit cost of omeprazole OTC averaged \$0.68 while generic prescription omeprazole had edged back up to an average cost of \$0.85 per unit. Excluding generic omeprazole from reference pricing was important during 2005 when there were shortages of omeprazole OTC, but this decision might have been revisited in subsequent periods when the supply of omeprazole OTC stabilized and the acquisition price of generic omeprazole changed. Generic pantoprazole also became available during the study period, and because its cost exceeded the PPI reference price, the cost was capped by the reference price. Cost savings from new generic PPIs are automatic because all PPIs are subject to the reference price. Accordingly, the initially higher costs of single-source generic products are also not paid by the plan sponsor because all products are capped at the reference price.

Limitations

This study assessed drug cost and utilization outcomes and did not consider other clinical or service outcomes. Second, the study did not account for administrative costs associated with implementing the policy, although the increase in dispensing fees to \$13 per omeprazole OTC claim for pharmacy dispensing costs was included in the evaluation. Third, the absence of actual claims data for the comparison group precluded a more definitive difference-in-difference analysis. We also could not determine the mix of benefit designs in the comparison group other than the absence of reference pricing for PPIs, and we were not able to compare the 2 groups by demographic characteristics.

Conclusions

Whereas previous studies of managed care interventions have achieved savings by excluding coverage of nonpreferred PPIs or applied a type of reference pricing to PPIs (e.g., TMAC), the reported savings were associated with increased member cost share and reduction in PPI utilization. The present study shows that PPI drug cost savings for the plan sponsor were attained with rapid and sustained reduction in plan cost as well as reduction in the average price per day of PPI therapy, both with negligible effects on utilization and member cost share. The present study found reductions in PMPM costs representing reduced plan spending of approximately \$9.4 million over 43 months of reference pricing compared with the preperiod. When compared with a group of health plans not utilizing PPI reference pricing, the net plan (EBD) estimated PPI cost savings were \$7.2 million over 43 months or an average of \$1.31 PMPM. These savings were associated with essentially unchanged PPI utilization in days of therapy PMPM, a 6.7% reduction in member copayment per PPI claim, and an increase in the average pharmacy dispensing fee per PPI claim. Cost savings may have been larger if the exclusion of generic

omeprazole from reference pricing had been rescinded and the reference price per unit had been reset to adjust for changes in the PPI market over time.

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Johnson and Neill designed the study, collected and interpreted the data, and wrote the manuscript, with the assistance of Davis. Johnson revised the manuscript with the assistance of Neill and Davis.

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