

Generic Drug Discount Programs: Are Prescriptions Being Submitted for Pharmacy Benefit Adjudication?

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ABSTRACT

BACKGROUND: In 2006, pharmacies began offering select generic prescription drugs at discount prices (e.g., \$4 for a 30-day supply) through nonmembership and membership programs. As part of the contract in membership generic drug discount programs, the member agrees to forgo submission of the claim to the insurance company. Claims not submitted for insurance adjudication may result in incomplete pharmacy benefit manager (PBM) and health plan data, which could negatively influence adherence reporting and clinical programs. To address potentially missing claims data, the Centers for Medicare & Medicaid Services (CMS) encourages Medicare Part D sponsors to incentivize network pharmacies to submit claims directly to the plan for drugs dispensed outside of a member's Part D benefit, unless a member refuses. The extent of PBM and health plan claims capture loss due to generic drug discount programs is unknown.

OBJECTIVE: To identify changes in levothyroxine utilizers' prescription claims capture rate following the advent of generic drug discount membership and nonmembership programs.

METHODS: This retrospective concurrent cohort study used claims data from 3.5 million commercially insured members enrolled in health plans located in the central and southern United States with Prime Therapeutics pharmacy benefit coverage. Members were required to be 18 years or older and younger than 60 years as of January 1, 2006, and continuously enrolled from January 1, 2006, through December 31, 2010. Members utilizing generic levothyroxine for at least 120 days during January 1, 2006, through June 30, 2006 (baseline period) from the same pharmacy group with supply on July 1, 2006, were placed into 1 of 3 pharmacy groups: (1) nonmembership (Walmart, Sam's Club, Target, Kroger, City Market, and King Soopers pharmacies), (2) membership (Walgreens, CVS, Albertsons, and Savon pharmacies), or (3) the reference group of all other pharmacies. The index date was defined as July 1, 2006. The levothyroxine claim providing supply on July 1, 2006, was the index claim. Members with a Kmart pharmacy index claim were excluded, since the Kmart membership drug discount program began prior to July 1, 2006. Levothyroxine claims capture nonpersistence, defined as the occurrence of a claim supply end date prior to a 180-day gap, was the primary outcome variable and was assessed from July 1, 2006, through June 30, 2010 (follow-up period). The odds of levothyroxine claims capture nonpersistence by pharmacy group were assessed using a logistic regression analysis adjusted for the following covariates: age, gender, median income in the ZIP code of residence (binomial for $\leq \$50,000$ vs. $> \$50,000$), switch to a brand levothyroxine product during the follow-up period, index levothyroxine claim supply of 90 days or more, and index levothyroxine claim member cost share per 30-day supply in tertiles ($\leq \$5.00$, $\$5.01$ - $\$7.99$, $\geq \$8.00$).

RESULTS: Of 2,632,855 eligible members aged 18 years or older, 13,427 met all study eligibility criteria. The baseline pharmacy groups were membership with 3,595 (26.8%), nonmembership with 1,919 (14.3%), and all other pharmacies with 7,913 (58.9%) members. The rates of levothyroxine claims capture persistency throughout the 4-year follow-up period were 85.4% for nonmembership ($P=0.593$ vs. all other pharmacies), 77.7% for the membership group ($P<0.001$ vs. all other pharmacies), and 85.9% for all other pharmacies. The Kaplan-Meier comparison of claims capture persistency found

nearly identical claims capture loss for the nonmembership compared with all other pharmacies group, and when compared in a multivariate logistic regression model, there was no difference in the odds of levothyroxine claims capture over 4 years follow-up (OR=1.01, 95% CI=0.88-1.16, $P=0.900$). The membership generic drug discount programs (Walgreens, CVS, Albertsons, and Savon pharmacies) had a statistically significant 61% higher odds (OR=1.61, 95% CI=1.45-1.79, $P<0.001$) of levothyroxine claims capture nonpersistence. The onset of the difference between the membership group and the all other pharmacies group was temporally associated with the launch of the membership programs. In comparison to index levothyroxine member cost of $\leq \$5.00$ per 30-day supply, higher cost shares were associated with higher levothyroxine claims capture nonpersistence ($\$5.01$ to $\$7.99$ OR 1.34, 95% CI 1.19-1.52 and $\geq \$8.00$ OR 1.60, 95% CI 1.40-1.82).

CONCLUSIONS: Among levothyroxine utilizers in 2006 (prior to the advent of drug discount programs), those with claims from a pharmacy that subsequently implemented a nonmembership generic drug discount program did not appear to have a different rate of levothyroxine claims capture than members from the reference group when followed through June 2010. Utilizers with claims from a pharmacy that subsequently implemented a membership program had a significantly lower levothyroxine claims capture rate. Increasing index levothyroxine member cost was associated with higher levothyroxine claims capture loss. Because the analysis could not directly measure claims capture loss associated with members who switched to a new pharmacy group without presenting their insurance information (e.g., membership discount programs), further research is needed to confirm these findings.

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What is already known about this subject

- Generic drug discount programs were first introduced in May 2006, when Kmart launched its \$15 for 90-day supply generic drug discount membership program. In September 2006, Walmart/Sam's Club (Walmart) launched its \$4 for a 30-day supply generic drug discount nonmembership program in Tampa Bay, Florida. Generic drug discount programs requiring an annual membership fee began with Walgreens in the fall of 2007.
- A 2011 survey of convenience samples of patients visiting a university-affiliated health system general medicine clinic found a significant increase in patient-reported use of generic drug discount programs from 2008 to 2010 (4.7% vs. 31.9%, respectively, $P<0.001$).
- Centers for Medicare & Medicaid Services released a memo in May 2012 encouraging Medicare Part D sponsors to incentivize network pharmacies to submit claims directly to the plan for drugs dispensed outside of a member's Part D benefit, unless a member refuses.
- A common concern is that an unknown proportion of \$4 generic drug claims are not submitted; therefore, pharmacy benefit manager (PBM) and health plan prescription information is incomplete.

What this study adds

- The onset of the claims capture nonpersistence divergence between the membership group and reference group was temporally associated with the membership programs' launch.
- As the index 2006 levothyroxine claim member cost increased from \leq \$5.00, to \$5.01-\$7.99, and to \geq \$8.00, there was an increased odds of levothyroxine claims capture persistency loss over a 4-year follow-up period.
- Although it is anticipated that individuals needing thyroid replacement therapy with history of levothyroxine use will require life-long therapy and thereby levothyroxine therapy persistency should be close to 100%, this study did not analyze thyroid replacement persistency. This study assessed the levothyroxine claims capture nonpersistence by pharmacy group. The nonmembership drug discount program pharmacies and the reference group (all other pharmacies) had an equivalent, approximately 15%, of nonpersistence claims capture rate and therefore were potentially unaffected by drug discount programs.
- The odds of claims capture nonpersistence was increased by 61% among members who in 2006 obtained their levothyroxine from pharmacies that subsequently launched a membership drug discount program.
- Health insurers and PBMs may want to initially focus their efforts on pharmacies with membership drug discount programs to obtain complete claims data.

Between 2001 and 2011, the average individual out-of-pocket (OOP) cost share for branded drugs increased by more than 80%, from \$16 to \$29.¹ Research has demonstrated that higher OOP cost share is negatively associated with medication adherence and is positively associated with prescription abandonment.²⁻⁵ The availability of generic drugs offer patients affordable alternatives, highlighted by the advent of generic drug discount programs, also known as \$4 generic drug programs.⁶⁻⁷ From a pharmacy benefit management (PBM) or data collection perspective, a major concern with generic drug discount programs is that pharmacy claims might not be submitted to the PBM company or health plan.^{6,8}

Pharmacy benefit managers and health plans are dependent on pharmacy claims as their primary data source in providing clinical programs such as retrospective drug utilization review (RDUR), medication therapy management (MTM), adherence, and utilization management (UM). An unknown proportion of generic drug claims associated with generic drug discount programs are not submitted because some pharmacies are not incentivized to submit if a patient pays cash and the total prescription cost is less than the copay, resulting in incomplete PBM and health plan prescription data.^{8,9} Patients may also choose not to present their prescription insurance cards or tell the pharmacy employee not to bill the transaction through their insurance.⁸ However, submitting the claims may be in a patient's best interests. Medicare Part D plan sponsors and

commercial insurers with Prime Therapeutics PBM coverage consider the \$4 price to be "usual and customary," superseding a plan's usual negotiated price for a drug.¹⁰ For example, if a patient whose plan applies the "usual and customary" rule to \$4 claims has a 25% coinsurance, the patient would have to pay only \$1 if the claim is submitted to the insurance.¹⁰

Generic drug discount programs were first introduced in May 2006, when Kmart launched its \$15 for 90-day supply generic drug discount membership program.¹¹ In September 2006, Walmart/Sam's Club (Walmart) launched its \$4 for a 30-day supply generic drug discount nonmembership program in Tampa Bay, Florida.¹² Subsequently, Target's nonmembership program launched in November 2006.^{13,14} Walgreens and CVS began offering generic drug discount programs that required an annual membership fee in fall 2007 and November 2008, respectively.^{15,16} Table 1 shows characteristics of some generic drug discount programs at large retailers.

Uninsured patients are more likely than those with insurance to use a generic drug discount program.^{13,17} However, according to company websites, membership programs include a stipulation that the program cannot be used in conjunction with other prescription drug insurance on the same transaction.¹⁸⁻²⁰ Since membership generic drug discount programs cannot be used in conjunction with an individual's pharmacy benefit insurance, the claims will not be submitted by the pharmacies.⁶ Nonmembership generic drug discount programs do not restrict use of the individual's insurance, allowing for submission and adjudication through the PBM. However, the prevalence of submission is unknown. A 2007 survey found that 47% of adults using generic drug discount programs have insurance coverage.²¹ Therefore, concern is warranted regarding incomplete claims data of insured patients.

The generic drug discount programs include over 400 drugs to treat common chronic conditions such as hypertension, hyperlipidemia, diabetes, and hypothyroidism.²²⁻²⁷ Five of the top 10 most prescribed drugs in the United States are included in the generic drug discount programs.²²⁻²⁸

Levothyroxine is the fourth most commonly prescribed drug in the United States and is included on all generic drug discount program lists.²²⁻²⁸ The American Association of Clinical Endocrinologists (AACE) state that "all physicians will treat clinical hypothyroidism with levothyroxine replacement therapy."²⁹ Levothyroxine is an appropriate drug to identify changes in PBM prescription claims capture rate because all strengths of levothyroxine (except 300 micrograms [mcg]) are included in the generic drug discount lists, and it is used to treat a chronic symptomatic disease.^{22-27,29} It is anticipated that individuals needing thyroid replacement therapy, with a history of levothyroxine use, will require life-long therapy, and thereby, an individual's levothyroxine therapy persistency should be close to 100%. Potential reasons for less than 100% levothyroxine persistency include a switch to a

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TABLE 1 Characteristics of Generic Drug Discount Programs Analyzed in This Study

Pharmacy	Generic Drug Discount Program Start Date	Drug Price ^a	Annual Membership Fee ^a
Nonmembership Programs			
Walmart/Sam's Club ^{12,22}	September 2006: 30-day supply only May 2008: 90-day supply added to program	\$4 for 30-day supply; \$10 for 90-day supply Men's health ^b : \$9 for 30-day supply Women's health ^c : \$9 for 30-day supply; \$24 for 90-day supply	None
Target ^{14,23}	November 2006	\$4 for 30-day supply; \$10 for 90-day supply Men's health ^b : \$9 for 30-day supply Women's health ^c : \$9 for 30-day supply; \$24 for 90-day supply	None
Kroger/City Market/ King Soopers ^{24,38}	Fall 2007: 30-day supply only May 2008: 90-day supply added to program	\$4 for 30-day supply; \$10 for 90-day supply Women's health ^d : \$9 for 30-day supply; \$24 for 90-day supply	None
Membership Programs			
Walgreens ^{15,25,35,39}	Fall 2007	30-day supply ^e : \$5 (tier 1), \$10 (tier 2), or \$15 (tier 3); 90-day supply ^e : \$10 (tier 1), \$20 (tier 2), or \$30 (tier 3) Lifestyle medications ^g	\$20 for individual; \$35 for family ^f
Albertsons/ Savon ^{18,26,36,40}	October 2008	\$4.99 for 30-day supply; \$10.99 for 90-day supply Women's health ^h : \$10.99 for 30-day supply	One-time cost of \$10 per family ^f
CVS ^{16,19,27}	November 2008	\$11.99 for 90-day supply ⁱ Women's health ^j : \$25.99 for 90-day supply	\$15 per person

^aAs of November 26, 2012.

^bFinasteride 5 mg.

^cAlendronate 35 mg and 70 mg, clomiphene 50 mg, Sprintec 28-Day, tamoxifen 10 and 20 mg, Tri-Sprintec 28-Day. Sprintec 28-Day and Tri-Sprintec 28-Day are for 30-day supplies only.

^dAlendronate 35 and 70 mg, clomiphene 50 mg, Sprintec 0.25/0.035, tamoxifen 10 and 20 mg, Trinessa 28.

^eAt the time of this study, drug price was \$9.99 for 30-day supply and \$12 for 90-day supply.

^fPersons receiving benefits from publicly funded health care programs such as Medicare and Medicaid are ineligible for membership.

^gBirth control ranging from \$12 to \$25.99 for 1-month supply; erectile dysfunction drugs ranging from \$28.99 to \$151.99 for 6 tablets; Latisse 0.03% for \$106.99; Propecia 1 mg (Pro Pak) for \$67.99.

^hClomiphene 50 mg, Mononessa 28, Previfem, Sprintec 28-Day, tamoxifen 10 and 20 mg, Trinessa, Tri-Previfem, Tri-Sprintec.

ⁱDoes not include 30-day supplies in the program.

^jSelect products: alendronate 35 and 70 mg, tamoxifen 10 and 20 mg, mg = milligram.

nonlevothyroxine thyroid replacement product; obtaining levothyroxine outside of the health plan insurance system, including a generic drug discount program that does not submit the claim; true nonpersistence; or having enough supply on hand due to dose adjustment to create the appearance of nonpersistence.

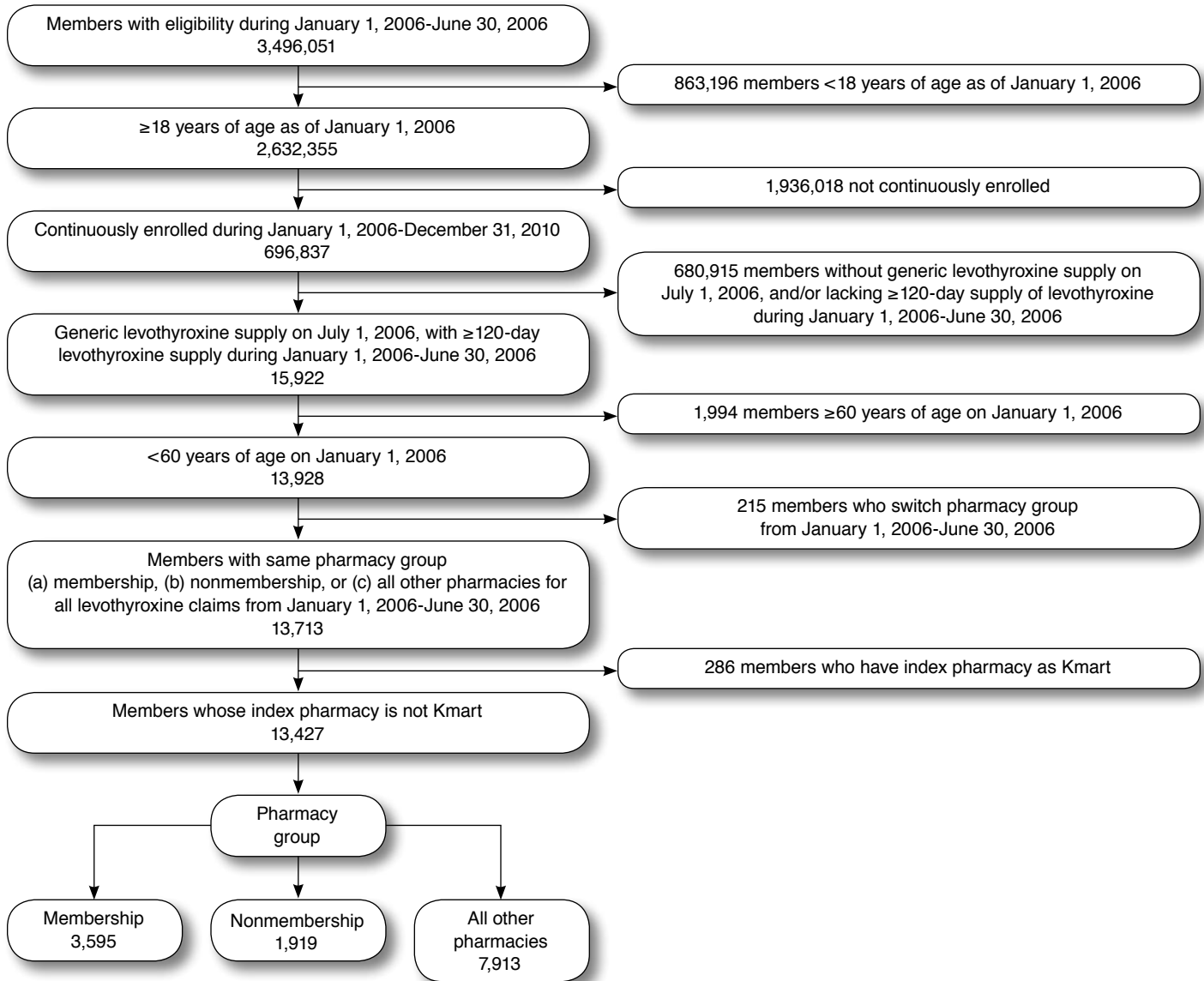
To our knowledge, this is one of the first studies to examine the impact of generic drug discount programs on pharmacy claims data. The objective of this study was to identify changes in levothyroxine utilizers' prescription claims capture rate following the advent of generic drug discount membership and nonmembership programs.

Methods

This retrospective concurrent cohort study utilized pharmacy claims data from 3.5 million commercially insured members enrolled in central and southern U.S. Blue Cross and Blue Shield plans with Prime Therapeutics pharmacy benefit coverage. To be eligible for analysis, members were required to

be 18 years or older and younger than 60 years as of January 1, 2006, and continuously enrolled from January 1, 2006, through December 31, 2010. Pharmacy claims were queried to identify members with a levothyroxine claim showing supply on July 1, 2006, and this claim was defined as the index claim. Levothyroxine claims were identified using the Medi-Span Generic Product Identifier (GPI; Wolters Kluwer Health, Indianapolis, IN) starting with 28100010. A member with an index claim indicating levothyroxine supply on July 1, 2006, was included if his or her levothyroxine claims during the baseline period (January 1, 2006, through June 30, 2006) met all of the following criteria: (a) cumulative days supply 120 days or more, (b) were from the same pharmacy group during the baseline period, and (c) the index claim was generic levothyroxine (levothyroxine, Levoxyl, Levothroid, Unithroid, Unithroid Direct). The member was assigned a pharmacy group using the pharmacy at which the index claim was filled. Pharmacies offering a membership or nonmembership generic drug discount program were identified from the listing

FIGURE 1 Analyzable Population Identification



provided by the National Conference of State Legislatures³⁰ and a review of our members' index levothyroxine claim pharmacies. Pharmacies that comprised 2% or more of index claims were identified and contacted to determine if they offered a nonmembership or membership generic drug discount program. The pharmacies with drug discount programs and 2% or more of index claims are shown in Table 1. Three pharmacy groups were then identified based on generic drug discount program category: (1) nonmembership (Walmart, Sam's Club, Target, Kroger, City Market, and King Soopers pharmacies), (2) membership (Walgreens, CVS, Alberstons, and Savon pharma-

cies), and the reference group (3) all other pharmacies. The all other pharmacies group comprised all pharmacies not previously defined.

Classification was based solely on the index pharmacy using an intention-to-treat approach. For example, a member whose index claim was filled at Walmart was assigned to the nonmembership pharmacy group. If a member used his or her prescription drug benefit at a pharmacy in an alternative pharmacy group during the follow-up period (July 1, 2006, through June 30, 2010), the member remained in his or her original pharmacy group.

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TABLE 2 Characteristics by Pharmacy Group

Characteristics	Membership Drug Discount Program (n = 3,595)	Nonmembership Drug Discount Program (n = 1,919)	All Other Pharmacies (n = 7,913)
Males % (n)	17.8 (638)	16.2 (311)	18.2 (1,444)
Age			
<41 % (n)	19.3 (695) ^a	22.9 (439) ^a	15.9 (1,255)
41 to 50 % (n)	35.4 (1,272)	38.4 (737)	37.4 (2,960)
≥51 % (n)	45.3 (1,628)	38.7 (743)	46.7 (3,698)
Residence ZIP code-derived median household income over \$50,000 % (n)	37.7 (1,354) ^a	32.5 (623) ^a	23.3 (1,843)
Follow-up period ^b switch to brand levothyroxine % (n)	19.7 (710) ^a	12.0 (231) ^a	9.7 (770)
Member cost share on index claim ^c			
≤\$5.00	23.7 (851) ^a	35.1 (673) ^a	38.2 (3,024)
\$5.01 to \$7.99	34.5 (1,240)	29.3 (563)	32.6 (2,580)
≥\$8.00	41.8 (1,504)	35.6 (683)	29.2 (2,309)
Extended supply ^d on index claim ^c % (n)	31.4 (1,130)	34.5 (662)	36.1 (2,853)

^aSignificant difference at $P < 0.05$ compared with the all other pharmacies group using Pearson chi-square for categorical variables and ANOVA for continuous variables.

^bJuly 1, 2006, through June 30, 2010.

^cIndex claim was the levothyroxine claim showing supply on July 1, 2006.

^dExtended supply was defined as 90-day supply or greater.

TABLE 3 Unadjusted Levothyroxine Claims Capture Persistency at 4 Years Follow-Up^a

Member Weighted Cost Share for Index Levothyroxine Claim ^b	Membership Drug Discount Program	Nonmembership ^c Drug Discount Program	All Other Pharmacies ^c	Difference Between Membership and All Other Pharmacies	Difference Between Nonmembership and All Other Pharmacies
≤\$5.00	81.4% (693 of 851)	89.6% (603 of 673)	87.8% (2,656 of 3,024)	-6.4%, $P < 0.001$	1.8%, $P = 0.1993$
\$5.01 to \$7.99	78.6% (975 of 1,240)	83.3% (469 of 563)	85.2% (2,197 of 2,580)	-6.6%, $P < 0.001$	-1.9%, $P = 0.2673$
≥\$8.00	74.9% (1,126 of 1,504)	83.0% (567 of 683)	84.2% (1,943 of 2,309)	-9.3%, $P < 0.001$	-1.2%, $P = 0.4793$

^aMeasured from July 1, 2006, through June 30, 2010.

^bIndex claim was the levothyroxine claim showing supply on July 1, 2006. Cost-sharing amounts are normalized to a 30-day supply and shown in tertile groups.

^cPharmacy used to fill the index levothyroxine claim. "Membership" pharmacies did not permit use of the drug benefit when filling prescriptions for discounted medications.

Covariates

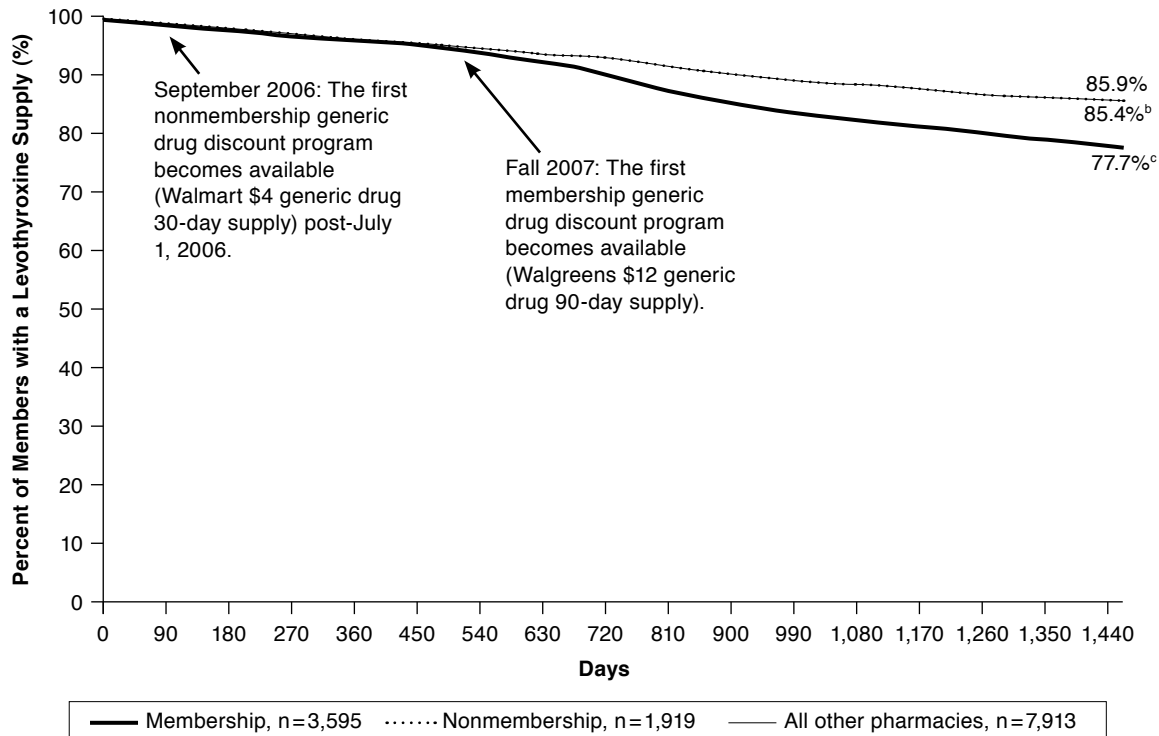
Age and gender as of January 1, 2006, were identified from eligibility files. The index levothyroxine claim day supply was used to categorize members as receiving an extended supply (90-day supply or greater, since some benefit designs allow a quantity of 102 for a 3-month supply). Income variable used the residence ZIP code median household income for the member from U.S. census data, and a dichotomous variable was created, \$0 to \$50,000 and greater than \$50,000. Income assignment at the ZIP code level was done because actual income data were unavailable. ZIP code was missing in 271 (2.02%) of 13,427 members; therefore, the ZIP code-derived median income was imputed using the Markov Chain Monte Carlo (MCMC) method.³¹ Levothyroxine member cost share was adjusted to 30-day supply by using the index pharmacy claim and categorized into tertiles ≤\$5.00, \$5.01 to \$7.99, and ≥\$8.00. A switch to a brand levothyroxine product (e.g., Synthroid) during the follow-up period was defined as having at least 1 brand levothyroxine claim using the Medi-Span multisource code indicator on the pharmacy claim.

Statistical Testing

Characteristics in the nonmembership and membership pharmacy groups were compared with those of the all other pharmacies group (reference group) using the Pearson chi-square test for categorical variables and the ANOVA for continuous variables. Levothyroxine claims capture nonpersistency, defined as the occurrence of a final claim supply end date prior to a 180-day gap, was the primary outcome variable and was assessed from July 1, 2006, through June 30, 2010, using the members' index levothyroxine claim and all levothyroxine claims thereafter through December 31, 2010.

Logistic regression was used to describe the association of levothyroxine claims capture nonpersistency with pharmacy groups, adjusted for switching to brand levothyroxine during the follow-up period, age, gender, income using ZIP code-level census data, levothyroxine extended supply on index claim, and index claim member cost share tertiles normalized to 30-day supply.

FIGURE 2 Levothyroxine Claims Capture Persistency^a by Pharmacy Group Among 13,427 Members with Supply on July 1, 2006, Followed for 4 Years



The nonmembership group and the all other pharmacies group lines overlap one another.

^aPersistency was defined as the last claim supply end date prior to a 180-day gap.

^bNonmembership group compared with all other pharmacies group, $P=0.593$.

^cMembership group compared with all other pharmacies group, $P<0.001$.

Results

Figure 1 shows the flow of members in the study. From the 3,496,051 million eligible members, 696,837 were 18 years and older with continuous enrollment from January 1, 2006, through December 31, 2010. The study sample consisted of 13,427 members who were between 18 and 60 years old, continuously enrolled from January 1, 2006, through December 31, 2010, with a supply of generic levothyroxine on July 1, 2006, and a cumulative levothyroxine days supply 120 days or more during the baseline period. Final pharmacy group distribution was drug discount membership 3,595 (26.8%) members, nonmembership 1,919 (14.3%) members, and all other pharmacies 7,913 (58.9%) members.

Significant differences in member characteristics within pharmacy groups existed, as shown in Tables 2 and 3. Compared with the all other pharmacies group, the drug discount program membership and nonmembership groups had a significantly larger proportion of members less than 41 years old, had a higher percentage of members with residence ZIP

code-derived median household income over \$50,000, higher percentage that switched to a brand levothyroxine product during the follow-up period, and lower proportion with a member cost share \$5.00 or less on the index levothyroxine claim.

As shown in Figure 2, levothyroxine claims capture persistency at the end of the 4-year follow-up period was as follows: 85.4% for the nonmembership group ($P=0.593$ vs. all other pharmacies), 77.7% for the membership group ($P<0.001$ vs. all other pharmacies), and 85.9% for the all other pharmacies group. The decrease in the membership group's levothyroxine claims capture persistency compared with the all other pharmacies group began soon after fall 2007, temporally associated with the Walgreens generic drug discount program and subsequent launch of other pharmacies' membership programs. Nonmembership generic drug discount programs claims capture persistency mirrored that of the all other pharmacies group with the lines in Figure 2 overlapping one another.

At baseline, the membership group had a significantly higher proportion (76.3%) of individuals with a more than

TABLE 4 Levothyroxine Claims Capture Nonpersistence^a Logistic Regression Model^b

	Odds Ratio (95% CI)	P Value
Pharmacy Group		
All other pharmacies	Reference	–
Membership drug discount program	1.61 (1.45-1.79)	<0.001
Nonmembership drug discount program	1.01 (0.88-1.16)	0.900
Age		
≥ 51	Reference	–
< 41	1.18 (1.04-1.34)	0.009
41 to 50	1.02 (0.92-1.13)	0.761
Male		
	1.08 (0.95-1.21)	0.234
Residence ZIP code-derived median household income (>\$50,000)		
	0.94 (0.84-1.04)	0.207
Follow-up period ^c switch to brand levothyroxine		
	1.35 (1.18-1.53)	<0.001
Member cost share on index claim ^c		
≤\$5.00	Reference	–
\$5.01 to \$7.99	1.34 (1.19-1.52)	<0.001
≥\$8.00	1.60 (1.40-1.82)	<0.001
Extended supply ^d on index claim ^c		
	1.21 (1.09-1.36)	<0.001

^aNonpersistence was defined as the last claim supply end date prior to a 180-day gap.

^bC-statistic = 0.594.

^cIndex claim was the levothyroxine claim showing supply on July 1, 2006.

^dExtended supply was defined as 90-day supply or greater.

CI = confidence interval.

\$5.00 cost share for their index levothyroxine claim than members in the all other pharmacies group (61.8%) or nonmembership group (64.9%). As shown in Table 3, unadjusted levothyroxine claims capture persistency at 4 years by pharmacy group decreased as member cost shares increased. In the nonmembership and membership groups, the decrease in claims capture persistency between the \$5.00 or less cost share and the \$8.00 or more cost share groups was 6.6 percentage points and 6.5 percentage points, respectively. The all other pharmacies group had a 3.6 percentage point decrease between the \$5.00 or less cost share and the \$8.00 or more cost share groups. The claims capture persistency differences between the membership group and the all other pharmacies group at each of the 3 cost shares was between 6.4 and 9.3 percentage points lower ($P < 0.001$), and there was no significant difference in claims persistency between the membership and all other pharmacies group at any cost share.

The logistic regression model adjusting for pharmacy group characteristics found that members in the nonmembership group had a nonsignificant odds for a difference in levothyroxine claims capture nonpersistence (odds ratio [OR] = 1.01, 95% confidence interval [CI] = 0.88-1.16, $P = 0.900$), while the membership group had a significantly higher odds (OR = 1.61, 95% CI = 1.45-1.79, $P < 0.001$), as shown in Table 4. Age less than 41 years ($P = 0.009$), member cost share on index levo-

thyroxine claim of more than \$5.00 ($P < 0.001$), switching to brand levothyroxine in the follow-up period ($P < 0.001$), and index levothyroxine claim with an extended supply ($P < 0.001$) were associated with a higher odds of levothyroxine claims capture loss. The extended supply association with higher odds of levothyroxine claims capture loss was no longer significant when analyzed independently. The loss of significance was due to a high colinearity between an index claim with an extended supply and a membership generic drug discount program pharmacy.

Discussion

This retrospective concurrent cohort study followed 13,427 members with levothyroxine utilization prior to the advent of generic drug discount programs for 4 subsequent years. For members with levothyroxine claims from a nonmembership generic drug discount program, the claims capture nonpersistence appeared nearly identical to the reference group. In contrast, members with levothyroxine claims from a membership generic drug discount program had a significant 8.2 percentage point higher claims capture nonpersistence and in a multivariate model had a 61% higher odds of having levothyroxine claims capture nonpersistence. The launch of membership drug discount programs appeared to be temporally associated with a higher levothyroxine claims capture nonpersistence when following levothyroxine utilizers prior to the drug discount program launch through the launch period, compared with the reference group. As the member cost of the index 2006 levothyroxine claim increased from \$5.00 or less, to \$5.01-\$7.99, and to \$8.00 or more, there was an increasing odds of levothyroxine claims capture persistency loss over a 4-year follow-up period. To ensure complete claims records, this study suggests that health insurers and PBMs may want to initially focus their efforts on pharmacies with membership drug discount programs.

The conventional wisdom espoused by health services researchers and health insurance consultants is that prescriptions dispensed via generic drug discount programs are potentially not submitted to health plans, PBMs, or Medicare Part D sponsors.^{6,9} In a recent Agency for Healthcare Research and Quality (AHRQ) report, “Using Health Information Technology to Determine Medication Adherence,” the authors state, “Many patients are paying cash/out-of-pocket for their prescriptions and therefore data [are] not captured in the insurer claim for generic prescriptions available at a low cost. For example, Walmart and Target pharmacies offer a \$4 prescription program. If patients fill their prescriptions via this program, a claim is never filed with the insurer and the insurer will never receive dispensing information for the related prescriptions to link with the prescription data.”⁹ The findings in this study from nonmembership (e.g., Walmart, Target) levothyroxine utilizers suggest claims capture nonpersistence is

impacting at most 1 in 6 members and was equivalent to the reference group. Levothyroxine prescription claims from the nonmembership generic drug discount program appeared to be submitted and visible to the PBM at the same rate as the reference group. AHRQ's concerns are well founded regarding membership drug discount programs for levothyroxine, with the validity appeared to be linked to the type (i.e., membership) of discount program rather than use of a drug discount program.

The value of having comprehensive pharmacy claims data is manifested in the adherence quality metrics set forth by the Pharmacy Quality Alliance (PQA) and adopted by the Centers for Medicare & Medicaid Services (CMS) as part of the CMS star ratings.^{32,33} As of 2012, the star rating scores will be used to determine bonus payments for Medicare Advantage plans. Plans must receive at least 3 of 5 stars to be eligible for bonus payments.³² In addition, Medicare Part D star ratings influence the plans' abilities to market their services. CMS star ratings include adherence measurements focusing on oral diabetes medications, angiotensin-converting enzyme inhibitors (ACEIs), angiotension II receptor blockers (ARBs), and statins.³³ Most of these drug classes are included in the generic drug discount lists.²²⁻²⁷ CMS recognizes the issue of missing claims data for drugs dispensed to members outside of their Medicare Part D benefits, such as \$4 generics and physician samples. In its May 11, 2012, memo, CMS states how vendors have been selling claims-level information from pharmacies to Medicare Part D sponsors.³⁴ The goal in achieving high star ratings has prompted Medicare plan sponsors to supplement their pharmacy claims data. Information from the vendors is used to compensate for missing claims in reporting prescription drug events (PDEs) and likely enhancing adherence rates. CMS has concerns regarding beneficiary privacy protections and data validation related to information provided by these vendors; therefore, CMS is "prohibit[ing] the reporting of any PDE data that has not been submitted directly by network pharmacies or beneficiaries."³⁴ To mitigate the issue of missing claims data from promotional programs (e.g., generic drug discount programs), CMS encourages Medicare Part D sponsors to incentivize network pharmacies to submit claims unless members refuse to have the claim submitted to their Part D benefit. To ensure complete claims capture rates, the findings from this study suggest Medicare Part D sponsors focus on working with the pharmacies that have membership generic drug discount programs. The exception is Walgreens and Albertsons because their membership program descriptions state that individuals receiving benefits from publicly funded health care programs such as Medicare and Medicaid are ineligible for membership.^{35,36}

In addition to adherence, clinical programs administered by PBMs or health plans can be affected by missing pharmacy claims data. For example, the clinical programs can identify members with a diagnosis for which guidelines recommend

pharmacotherapy and then assess the presence of pharmacotherapy in pharmacy claims to identify gaps in care. If claims are not submitted, some members may be misclassified as nonadherent, since the PBM or health plan have no record of the claims. These members could be inappropriately targeted, resulting in unnecessary member outreach that costs the health care system and potentially displeases members and providers by inaccurately identifying an adherent individual as nonadherent.

Although generic drug discount programs have been prevalent since 2008, uptake of the generic drug discount programs was gradual in the beginning. A 2011 study using survey data from a university-affiliated health system general medicine clinic found that only 4.7% of a convenience sample of patients used a generic drug discount program in 2008.¹⁷ However, there was a significant increase in the use of generic drug discount programs from 2008 to 2010 (4.7% vs. 31.9%, $P < 0.001$). Furthermore, a 2012 study using data from an integrated health system found that the monthly rate of prescriptions written to an out-of-plan pharmacy increased from 1.5% to 5.2%, and over 80% of these transferred prescriptions went to a pharmacy with a generic drug discount program.³⁷ A 2012 study on Medicare patients showed that only 16.3% of beneficiaries taking \$4 eligible drugs actually filled their prescriptions using the generic drug discount programs in 2007.¹³ Patients taking a greater number of prescription drugs were more likely to use a generic drug discount program (OR = 1.13, 95% CI = 1.01-1.27, $P = 0.036$).¹⁷ Increased utilization and expansion of the generic drug discount lists are likely to occur as major blockbuster drugs, such as atorvastatin (Lipitor) and clopidogrel (Plavix), become available as inexpensive generics.

The association between increasing member cost share and higher odds for levothyroxine claims capture persistency decline appeared to be driven by the membership group that had a significantly higher proportion (76.3%) of more than \$5.00 cost share members compared with the all other pharmacies group (61.8%), a 14.5% difference. Potentially, members with higher cost shares are more likely to sign up for the membership generic drug discount program; consequently, their levothyroxine claims are no longer submitted to the insurer as contractually required by the membership program. Members that switched to brand levothyroxine in the follow-up period had a 35% higher odds of levothyroxine claims capture non-persistency ($P < 0.05$). A potential explanation is that members switching to brand levothyroxine would be exposed to brand drug cost shares typically over \$20 and may subsequently have reverted back to generic levothyroxine and joined a membership generic drug discount program.

Limitations

The current study is not without limitations. First, generic levothyroxine is a relatively low cost drug. The total median

cost per 30-day supply was \$5.40, 25th percentile \$4.20, 75th percentile \$9.00; therefore, members may not be incentivized to use a generic drug discount program. This study does not generalize to more expensive generic drugs on the drug discount list. Second, this study was unable to measure claims capture nonpersistence attributable to individuals who switch pharmacies to fill their prescriptions using the drug discount program without presenting their insurance information. Third, members may have switched to a nonlevothyroxine alternative thyroid hormone replacement product (e.g., Liotrix), resulting in misclassifying members as no longer capturing their thyroid hormone replacements. The risk for this misclassification is believed to be equivalent for each pharmacy group and therefore unlikely to influence the study findings. Fourth, the 300 mcg strength of levothyroxine was not included in all generic discount drug programs. A total of 0.3% members had an index claim for levothyroxine 300 mcg; therefore, this limitation is unlikely to have influenced the result.

Fifth, membership generic drug discount programs are voluntary and have a required individual annual enrollment cost ranging from \$10 to \$20.^{19,35,36} The proportion of study individuals enrolled in the membership programs evaluated is unknown. If the generic program enrollment is low or nonexistent, then the claims capture rate persistency would be expected to be no different between the membership pharmacy groups and the all other pharmacies group. While the study results are most likely valid, since membership cannot be verified for the membership groups, caution should be warranted. Sixth, selection bias may be present, since members were continuously enrolled for 5 years and consequently may have a different socioeconomic background or behavior patterns. Seventh, data are limited to a commercial population in the central and southern United States with Prime Therapeutics pharmacy benefit coverage; therefore, findings may not be generalizable to Medicare/Medicaid populations or other geographic regions, including other countries in which not all strengths of levothyroxine are available generically, and some generic drug discount programs may not be captured. For example, Kmart's program is not captured, since its launch occurred before the index date; however, only 2.0% of index claims were from Kmart.

Variation in claims submissions among different stores of the same pharmacy chain may be present, since no consistent protocol for submission exists. Pharmacies not offering a generic drug discount program may price match, so individuals can obtain the same pricing for their prescriptions through these pharmacies without formally using a program. Additionally, adherence to thyroid replacement therapy is not included in the CMS patient safety star ratings, so the concern of Part D sponsors purchasing claims-level information to compensate for "missing claims" in reporting PDEs is minimal for this drug category.³²⁻³⁴

Eighth, whether claims capture persistency rates of other drugs included in the generic drug discount programs (e.g., antihypertensives, statins) is similar to levothyroxine is unknown. Finally, it is important to note that capture persistency is not equivalent to individual medication persistency. Although a pharmacy group may appear to have a higher claims capture nonpersistence rate, this may or may not equate to a lower individual medication use.

Conclusions

This study begins to quantify the influence of generic drug discount programs on health plan and PBM claims capture for nonmembership and membership programs. Nonmembership levothyroxine utilizers' claims capture nonpersistence was equivalent to the reference group, while the membership program appeared to have a significantly higher claims capture nonpersistence rate. In addition, higher member cost share appeared to be independently associated with higher claims capture loss. Health insurers and PBMs may want to initially focus their efforts to obtain complete claims data on pharmacies with membership drug discount programs. Further research is needed to confirm these findings and assess claims capture rates for additional drugs on the generic discount program lists.

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