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Impact of Prior Authorization on the Use and Costs of Lipid-Lowering Medications Among Michigan and Indiana Dual Enrollees in Medicaid and Medicare: Results of a Longitudinal, Population-Based Study

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Abstract

Background—Some Medicaid programs have adopted prior-authorization (PA) policies that require prescribers to request approval from Medicaid before prescribing drugs not included on a preferred drug list.

Objective—This study examined the association between PA policies for lipid-lowering agents in Michigan and Indiana and the use and cost of this drug class among dual enrollees in Medicare and Medicaid.

Methods—Michigan and Indiana claims data from the Centers for Medicare and Medicaid Services were assessed. Michigan Medicaid instituted a PA requirement for several lipid-lowering medications in March 2002; Indiana implemented a PA policy for drugs in this class in September 2002. Although the PA policies affected some statins, they predominantly targeted second-line treatments, including bile acid sequestrants, fibrates, and niacins. Individuals aged 18 years who were continuously dually enrolled in both Medicare and Medicaid from July 2000 through September 2003 were included in this longitudinal, population-based study, which included a 20-month observation period before the implementation of PA in Michigan and a 12-month follow-up period after the Indiana PA policy was initiated. Interrupted time series analysis was used to examine changes in prescription rates and pharmacy costs for lipid-lowering drugs before and after policy implementation.

Results—A total of 38,684 dual enrollees in Michigan and 29,463 in Indiana were included. Slightly more than half of the cohort were female (Michigan, 53.3% [20,614/38,684]; Indiana, 56.3% [16,595/29,463]); nearly half were aged 45 to 64 years (Michigan, 43.7% [16,921/38,684];

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Indiana, 45.2% [13,321/29,463]). Most subjects were white (Michigan, 77.4% [29,957/ 38,684]; Indiana: 84.9% [25,022/29,463]). The PA policy was associated with an immediate 58% reduction in prescriptions for nonpreferred medications in Michigan and a corresponding increase in prescriptions for preferred agents. However, the PA policy had no apparent effect in Indiana, where there had been little use of non-preferred medications before the policy was implemented (3.3%). The policies were associated with an immediate reduction of \$24,548 in prescription expenditures in Michigan and an immediate reduction of \$16,070 in Indiana.

Conclusions—The PA policy was associated with substantially lower use of nonpreferred lipid-lowering drugs in Michigan, offset by increases in the use of preferred medications, but there was less change in Indiana. Data limitations did not permit the evaluation of the impact of policy-induced switching on clinical outcomes such as cholesterol levels. The monetary benefit of PA policies for lipid-lowering agents should be weighed against administrative costs and the burden on patients and health care providers.

Keywords

drug expenditure; drug utilization; lipid-lowering drugs; Medicaid; prior authorization; statins

INTRODUCTION

Hyperlipidemia (total cholesterol ≥ 240 mg/dL) is a common condition with an estimated prevalence of 16% in the year 2006 among the US adult population.¹ It is an important, modifiable risk factor in the development and progression of coronary heart disease, a leading cause of morbidity and mortality.² The estimated direct and indirect cost of coronary heart disease was \$165 billion in the United States in 2009.¹ Lipid-lowering medications are effective for reducing the risks of coronary events and cardiovascular mortality among patients with elevated risk of coronary heart disease.^{2–4}

Cardiovascular medication, including lipid-lowering drugs, is the most commonly prescribed drug class in the United States, accounting for 18% of all prescriptions in the year 2003 in Medicaid.⁵ Consequently, they have also been the target of cost-containment strategies such as prior authorization (PA). PA policies require prescribers to request approval from Medicaid before prescribing drugs not included on a preferred drug list.⁶ A step-therapy requirement of a trial of a preferred drug before authorization for a non-preferred agent is often coupled with PA policies. However, the clinical and economic consequences of these policies for cardiovascular medications are largely unknown.

In March 2002, the Michigan Medicaid program instituted a PA requirement for several lipid-lowering medications. Indiana Medicaid implemented a PA policy affecting drugs of this class in September 2002. Within the therapeutic class of lipid-lowering medications, statins (3-hydroxy-3-methylglutaryl-coenzyme A reductase inhibitors) are the first-line therapy for management of dyslipidemia and, therefore, are the most commonly used drugs.^{7, 8} Both the Michigan and Indiana PA policies predominantly targeted second-line treatments, including bile acid sequestrants, fibrates, and niacin products (Table). The policies did affect 2 statins in Michigan and 1 in Indiana, but several other preferred statins were available. The aim of this study was to examine the association between PA policies for lipid-lowering agents and the use and costs of this drug class among dual enrollees in Medicare and Medicaid. Because the PA policies for lipid-lowering medications in both Michigan and Indiana made alternative within-class drugs available, the authors of the present study anticipated that the policies would be associated with reductions in the use of nonpreferred agents, corresponding increases in preferred agents, and detectable drug cost savings.

METHODS

Data Sources and Study Population

This retrospective cohort analysis used Michigan and Indiana claims data that were purchased from the Centers for Medicare and Medicaid Services. This data use was reviewed by the institutional review board at the Harvard Pilgrim Health Care Institute (Boston, Massachusetts) and found to be exempt from continuing review. We used an analytic cohort that included all individuals aged ≥ 18 years who were continuously enrolled in both Medicare and Medicaid (ie, individuals with simultaneous eligibility and enrollment in both programs).⁹ Dual enrollees are a particularly vulnerable subset of the Medicaid population because of high rates of disability and chronic illness that necessitate frequent use of costly prescription drugs.^{9, 10} As in our previous studies,^{9, 10} we excluded the few dual enrollees with any Medicare or Medicaid managed-care enrollment because the data capture used in this study might not have represented the complete claims history of such patients. The study period of July 2000 through September 2003 included a 20-month observation period before implementation of the PA policy in Michigan and a 12-month follow-up period after the Indiana PA policy was initiated; this provided sufficient data points for interrupted time series analysis.¹¹

We analyzed the use of lipid-lowering drugs, including statins, niacin, fibrates (eg, gemfibrozil), and bile acid sequestrants (eg, cholestyramine). The table shows the list of drugs included in this study and their PA status in Michigan and Indiana.

Outcome Measures

We used a previously validated claim-based outcome measure—the number of prescriptions per 1000 enrollees per month—in a time series model predicting changes in the level and trend in rates of medication use before and after the policy.^{9, 12} We calculated the number of prescriptions per 1000 enrollees per month for total lipid-lowering agents, as well as for preferred and nonpreferred drugs separately. Furthermore, we assessed changes in costs by calculating the total pharmacy reimbursement for lipid-lowering medications per 1000 enrollees per month. All costs were converted to year 2003 US \$ using the Consumer Price Index.¹³

Statistical Analysis

We used an interrupted time series design,¹¹ a quasi-experimental method, to examine the impact of PA on all outcomes in Michigan and Indiana. This analytical method estimated post-policy-implementation changes in both the level and trend (ie, slope) of each outcome, adjusting for the existing level and trend before implementation of the policies. This method can provide strong evidence of causal effects because it takes into consideration the question of whether an intervention causes abrupt and measurable interruptions in the preexisting trend.^{11, 14} Because the Michigan and Indiana PA policies were initiated 6 months apart, they were treated as 2 distinct interventions in separate models. To allow direct comparison between the states, we analyzed all outcomes as rates. We controlled for autocorrelation by including any significant autoregressive parameters up to 12 months.¹¹ We conducted all statistical analyses using SAS software version 9.1.3 (SAS Institute, Cary, North Carolina), using the AUTOREG procedure.

RESULTS

There were 38,684 dual enrollees in Michigan and 29,463 in Indiana who met our study inclusion criteria. Slightly more than half of our cohort were female (Michigan, 53.3% [20,614/38,684]; Indiana, 56.3% [16,595/29,463]); nearly half were aged 45 to 64 years

(Michigan, 43.7% [16,921/38,684]; Indiana, 45.2% [13,321/29,463]); and the subjects were predominantly white (Michigan, 77.4% [29,957/38,684]; Indiana, 84.9% [25,022/29,463]).⁹

Pre-Policy-Implementation Use

There were some major differences in the PA status of lipid-lowering drugs between the states (Table). Most notably, simvastatin, a statin used commonly in both states, was targeted by the PA policy in Michigan but not in Indiana.

In the pre-policy-implementation period in Michigan, the drugs subsequently subjected to the PA policy represented 23.7% (24,606/103,615) of prescriptions and 30.6% (2,208,195/7,207,249) of pharmacy costs for all lipid-lowering agents. Simvastatin alone accounted for 17.1% (17,756/103,615) of the prescriptions and 24.1% (1,734,180/7,207,249) of the costs.

By contrast, in the pre-policy-implementation period in Indiana, the agents later affected by the PA only accounted for 3.3% (2446/73,400) of prescriptions and 3.6% (207,307/5,795,566) of the reimbursements for lipid-lowering drugs. Simvastatin was commonly used in this state (19.9% [14,628/73,400] of prescriptions and 28.0% [1,621,492/5,795,566] of costs) but, as noted previously, it was unaffected by Indiana's PA requirement.

Overall Medication Use

The trend in use of lipid-lowering drugs increased over the study period in both states, before and after their respective policies were implemented (Figure 1). In both states, the time series models did not detect significant changes in the utilization level of lipid-lowering drugs (Michigan estimate, -2.76 [95% CI, -8.16 to 2.64]; Indiana estimate, -0.82 [95% CI, -4.84 to 3.21]). There were no significant changes in the trend in either state (Michigan estimate, -0.23 [95% CI, -0.62 to 0.16]; Indiana estimate, 0.02 [95% CI, -0.43 to 0.46]).

Use of Preferred and Nonpreferred Agents

In Michigan, the PA policy was associated with a sudden, dramatic switch in use from nonpreferred to preferred agents (Figure 2A). Our time series model indicated that the prescription rate for nonpreferred drugs dropped by 28.96 prescriptions per 1000 enrollees (95% CI, -32.96 to -24.95; $P < 0.001$) when first implemented, representing an immediate reduction of 58%. There was also a slight decrease of 0.33 in the trend (95% CI, -0.69 to 0.02), but it was not statistically significant. The reduction in the prescription rate was offset by an almost identical increase of 27.79 prescriptions per 1000 enrollees in the use of preferred drugs (95% CI, 23.55 to 32.03; $P < 0.001$), with a slight decrease of 0.32 in subsequent trend (95% CI, -0.69 to 0.04) that was not statistically significant. The observed switch was predominantly driven by a shift from simvastatin, a nonpreferred agent (estimate of level change, -15.86 [95% CI, -20.88 to -10.85]; $P < 0.001$) to atorvastatin, a preferred agent (estimate of level change, 12.48 [95% CI, 8.11 to 16.85]; $P < 0.001$).

In Indiana, there was no immediate reduction in the prescription rate for nonpreferred agents after the policy implementation (Figure 2B). However, the PA policy was associated with a significant decrease of 0.20 in the trend (95% CI, -0.29 to -0.12; $P < 0.001$). For preferred agents, there were no significant changes in either the level (estimate, -1.91 [95% CI, -6.23 to 2.40]) or the trend (estimate, -0.03 [95% CI, -0.51 to 0.45]).

Pharmacy Costs

Figure 3 shows the reimbursement costs per 1000 enrollees per month in both states. In Michigan, the switch in use from nonpreferred to preferred drugs was associated with an

immediate reduction in costs of \$634.57 per 1000 enrollees (95% CI, -1265.41 to -3.72; $P < 0.05$) in the first month after the policy was enacted. There was a slight reduction of \$28.43 per 1000 enrollees per month in the subsequent trend (95% CI, -57.61 to 0.75), but it was not statistically significant. In Indiana, there was an immediate reduction of \$545.44 per 1000 enrollees when the policy was first implemented (95% CI, -832.76 to -258.12; $P < 0.01$), but no significant change in trend (estimate, -18.96 [95% CI, -56.91 to 18.99]). Overall, these estimates represented an immediate pharmacy savings of \$24,548 in Michigan after policy implementation and an immediate cost reduction of \$16,070 in Indiana.

DISCUSSION

This study contributes to the increasing body of empirical evidence that the impact of PA policies differs depending on the targeted medication class, the medical condition for which medications are prescribed, and the affected patient population.

With respect to medications for symptomatic conditions, such as NSAIDs, cyclooxygenase-2 inhibitors, and proton pump inhibitors, PA policies have been found to produce substantial reductions in use and costs of medications.^{15–17} By contrast, little pharmacy cost savings but considerable unintended reductions in medication use were associated with PA policies for psychotropic drugs.^{10, 14, 18–20} The results of the present study, as well as those of a previous study of a PA policy for antihypertensive medications,⁹ suggest that when the policy allows a choice of several drugs that are deemed clinically interchangeable, the total use of medications within a therapeutic class does not decrease dramatically when some drugs in the class are subject to PA.

All of these observations suggest that PA policies can be a powerful tool for changing medication use. Carefully designed, these policies can encourage the use of certain drugs with minimal unintended reductions in the overall use of essential medications. However, the consequences of forcing patients to switch medications as a result of PA policy remain unclear. Other drug policies have been shown to negatively affect statin adherence in patients without preexisting cardiovascular disease.²¹ Furthermore, other observational studies suggest that switching statins may be associated with undesirable outcomes. For example, switching to another statin within the first year of therapy among new users was associated with reductions of 19% and 21% in compliance and persistence, respectively.²² Similarly, switching from atorvastatin to simvastatin in the UK primary care setting was associated with increased treatment discontinuation.²³ Finally, a US study using nationwide pharmacy claims data reported a lower therapeutic dose in 38% of those who switched between atorvastatin and simvastatin.²⁴ Physicians should consider and prescribe doses that are therapeutically equivalent when switching statins, monitor cholesterol levels in the early stages after switching medications, and titrate statin doses as necessary to achieve adequate control of cholesterol.

There are several limitations of this study. First, our analysis was based on claims data, so the impact of the policy on important clinical outcomes such as cholesterol levels could not be assessed. Second, additional rebates negotiated between state Medicaid programs and manufacturers in exchange for preferred drug status were not included in the cost-savings estimates because the details of such rebates are kept confidential. However, some of these cost savings would likely be offset by the unmeasured administrative costs for operating the PA policy.²⁰ To account for inflation, we used the Consumer Price Index in this analysis, which has several measurement limitations.²⁵ However, our estimates of the impact of PA policies would not be affected unless the Consumer Price Index changed dramatically at the same time that the policies were introduced. Finally, it has been noted that PA policies represent an administrative burden to patients and prescribers; there are considerable costs to

physicians for complying with these requirements.^{6, 26–28} These costs and the administrative burden should be weighed carefully against the benefit of pharmacy cost savings to determine whether PA policies are cost-effective overall.

CONCLUSIONS

Empirical evidence of the effects of PA policies on medication use and costs is mixed. The PA policy for lipid-lowering medications was associated with substantially reduced use of nonpreferred drugs in Michigan, offset by corresponding increases in the use of preferred medications, but there was less change in Indiana. Our findings suggest that when therapeutic alternatives within a given drug class are available, PA policies can reduce drug costs by shifting use from nonpreferred to preferred medications. However, data limitations did not permit the evaluation of the impact of policy-induced switching on clinical outcomes such as cholesterol levels. The monetary benefit of PA policies should be weighed against their administrative costs and the burden they place on patients and health care providers.

Further research is needed to determine whether drug switches related to these PA policies affected medication adherence or health outcomes, particularly among patients who were already established on therapy with a nonpreferred agent.

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This study was conceived and designed by Drs. Lu, Law, Soumerai, Ross-Degnan, and Adams. Drs. Lu and Law analyzed the data. Drs. Lu, Law, Soumerai, Zhang, Ross-Degnan, and Adams interpreted the data. Drs. Lu, Law, and Adams drafted the manuscript, and Drs. Lu, Law, Soumerai, Zhang, Ross-Degnan, and Adams and Ms. Graves and Mr. LeCates provided critical revision. Drs. Lu and Law and Ms. Graves and Mr. LeCates provided administrative support. Drs. Soumerai, Ross-Degnan, and Adams provided study supervision.

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Figure 1.

Number of prescriptions for lipid-lowering medicines per 1000 people continuously enrolled in Medicare and Medicaid in Michigan ($n = 38,684$) and Indiana ($n = 29,463$) from July 2000 through September 2003. Prior-authorization policies for these drugs were implemented in March 2002 in Michigan and September 2002 in Indiana.

Figure 2.

Number of prescriptions for preferred and nonpreferred lipid-lowering medications per 1000 people continuously enrolled in Medicare and Medicaid in (A) Michigan ($n = 38,684$) and (B) Indiana ($n = 29,463$) from July 2000 through September 2003. Prior-authorization policies for these drugs were implemented in March 2002 in Michigan and September 2002 in Indiana.

Figure 3.

Reimbursements for lipid-lowering medications per 1000 people continuously enrolled in Medicare and Medicaid in Michigan ($n = 38,684$) and Indiana ($n = 29,463$) from July 2000 through September 2003. Prior-authorization policies for these drugs were implemented in March 2002 in Michigan and September 2002 in Indiana.

Table

Baseline utilization of lipid-lowering drugs among patients dually enrolled in Medicare and Medicaid in Michigan (n = 38,684) and Indiana (n=29,463), based on a review of Medicare claims data from the period before prior authorization policies for these drugs were implemented in March and September 2002, respectively.*

Drug	Brand Name (Manufacturer)	Prior Authorization Status		Prescriptions, No. (% of Total)		Pharmacy Costs, US \$ (% of Total) [†]	
		Michigan	Indiana	Michigan	Indiana	Michigan	Indiana
Statins							
Atorvastatin	Lipitor® (Pfizer Inc, New York, New York)	–	–	49,949 (48.2)	34,738 (47.3)	3,530,929 (49.0)	2,728,581 (47.1)
Simvastatin	Zocor® (Merck & Co, Inc, Whitehouse Station, New Jersey)	Required	–	17,756 (17.1)	14,628 (19.9)	1,734,180 (24.1)	1,621,492 (28.0)
Pravastatin	Pravachol® (Bristol-Myers Squibb, Princeton, New Jersey)	–	–	12,056 (11.6)	6548 (8.9)	968,310 (13.4)	582,828 (10.1)
Fluvastatin	Lescol® (Novartis, Basel, Switzerland)	–	–	4190 (4.0)	2082 (2.8)	175,301 (2.4)	94,122 (1.6)
	Lescol XL® (Novartis, Basel, Switzerland)	–	–	327 (0.3)	177 (0.2)	16,726 (0.2)	10,081 (0.2)
Lovastatin	Mevacor® (Merck & Co, Inc)	Required	Required	2543 (2.5)	1460 (2.0)	218,567 (3.0)	137,322 (2.4)
	Generic lovastatin	–	–	130 (0.1)	72 (0.1)	8697 (0.1)	6835 (0.1)
Cerivastatin	Baycol® (Bayer AG, Leverkusen, Germany) [‡]	–	–	2548 (2.5)	1545 (2.1)	117,392 (1.6)	73,807 (1.3)
Niacin	Niacor® (Upsher-Smith Laboratories, Minneapolis, Minnesota)	–	Required	7 (0.0)	0	25 (0.0)	0
	Generic niacin, Slo-Niacin® (Upsher-Smith Laboratories), generic niacin TD, Niaspan® (Abbott Laboratories, North Chicago, Illinois), Niadelay® (Rising Pharmaceuticals Inc, Allendale, New Jersey)	–	–	1322 (1.3)	1410 (1.9)	39,719 (0.6)	43,900 (0.8)
Niacin/lovastatin	Advicor® (Abbott Laboratories)	Required	–	0	1 (0.0)	–	41 (0.0)
Fibrates							
Fenofibrate	Tricor® (Abbott Laboratories)	Required	–	3887 (3.8)	3272 (4.5)	218,914 (3.0)	207,227 (3.6)
Gemfibrozil	Generic gemfibrozil	–	–	7287 (7.0)	5578 (7.6)	88,043 (1.2)	178,106 (3.1)
	Lopid® (Pfizer Inc)	Required	Required	1 (0.0)	25 (0.0)	15 (0.0)	2408 (0.0)
Clofibrate	Atromid-S® (Wyeth-Ayerst Laboratories Inc, Philadelphia, Pennsylvania [now part of Pfizer Inc])	–	–	2 (0.0)	0	38 (0.0)	–
Bile acid sequestrants							
Colestevlam	Welchol® (Daichi Sankyo, Tokyo, Japan)	Required	Required	227 (0.2)	276 (0.4)	24,656 (0.3)	30,172 (0.5)
Cholestyramine/sucrose	Generic cholestyramine/sucrose	–	–	540 (0.5)	578 (0.8)	26,341 (0.4)	25,633 (0.4)
	Questran® (Bristol-Mvers Squibb)	Required	Required	47 (0.1)	97 (0.1)	2557 (0.0)	9646 (0.2)

Drug	Brand Name (Manufacturer)	Prior Authorization Status		Prescriptions, No. (% of Total)			Pharmacy Costs, US \$ (% of Total) [†]		
		Michigan	Indiana	Michigan	Indiana	Indiana	Michigan	Indiana	Indiana
Cholestyramine/aspartame	Locholest [®] (Warner Chilcott Laboratories, Rockaway, New Jersey)	Required	–	12 (0.0)	3 (0.0)		354 (0.0)	174 (0.0)	
	Cholestyramine Light [®] (Epic Pharma LLC, Laurelton, New York)	–	–	324 (0.3)	318 (0.4)		15,319 (0.2)	15,264 (0.3)	
	Questran Light [®] (Bristol-Myers Squibb)	Required	Required	41 (0.0)	58 (0.1)		4225 (0.1)	7095 (0.1)	
	Prevalite [®] (Upsder-Smith Laboratories)	Required	Required	90 (0.1)	71 (0.1)		4613 (0.1)	3732 (0.1)	
Colestipol	Locholest Light [®] (Warner Chilcott Laboratories)	Required	–	2 (0.0)	4 (0.0)		114 (0.0)	168 (0.0)	
	Colestid [®] (Pfizer Inc)	–	Required	327 (0.3)	459 (0.6)		12,214 (0.2)	16,932 (0.3)	
All lipid-lowering drugs				103,615	73,400		7,207,249	5,795,566	

* Utilization in the period before policy implementation (July 2000 through February 2002).

[†] Adjusted to year 2003 US \$ using the Consumer Price Index.¹³

[‡] Withdrawn from US market in August 2001.