

The Impact of Formulary Drug Exclusion Policies on Patients and Healthcare Costs

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Insurers are increasingly supplementing long-standing management approaches, such as tiered formularies, prior authorizations, and coverage restrictions, with formulary policies that exclude drugs deemed to offer questionable additional benefits over cheaper alternatives. Drug exclusion lists provide healthcare payers and pharmacy benefit managers (PBMs) greater negotiating power with product manufacturers and can be a potent tool in controlling drug spending.^{1,2}

The goal of a drug exclusion policy is to reduce costs by limiting patient access to an expensive drug for which there is a more cost-effective alternative. However, there is a risk in mandating that patients switch from their current treatment to an alternative drug, as it may affect adherence to therapy, disease control, and health outcomes. There is further concern that poor control of patients' conditions could lead to additional physician office visits and hospitalizations, and, ultimately, to an increase in overall healthcare costs.³⁻⁵

A better understanding of how drug exclusion policies impact patients and affect healthcare costs would aid in their implementation. The aim of this study was to identify and review empirical evaluations of drug exclusion policies and to examine how the policies have affected patients and affected healthcare costs.

METHODS

We performed a literature search to identify empirical studies that evaluated the impact of drug exclusion policies on affected patients (ie, patients who were required to change their medication as a result of the policy) and on healthcare costs. The search strategy is presented in [Table 1](#). We performed the literature search in September 2015 and included studies that examined the impact of the drug exclusion policy on affected patients. The studies excluded were those that evaluated physician- or patient-initiated medication changes (ie, medication changes not mandated by the insurer), as well as those that evaluated generic substitution or reference pricing policies.

Two researchers reviewed each abstract identified by the search strategy. We then evaluated each study that met our inclusion cri-

ABSTRACT

OBJECTIVES: In an attempt to increase the efficiency of their drug benefit policies, insurers are increasingly excluding drugs from their formularies that they deem to be of low value. Our objective was to identify and review empirical evaluations of drug exclusion policies and examine how they affected patients and healthcare costs.

STUDY DESIGN: Literature review.

METHODS: We performed a literature search to identify empirical studies that evaluated drug exclusion policies. We reviewed each study to determine how the policy impacted patients (ie, if disease control or frequency, or severity of symptoms, were affected) and if healthcare costs (eg, drug expenditures and costs associated with physician office visits, hospitalizations, laboratory tests) changed.

RESULTS: We included 26 studies pertaining to 27 drug exclusion policies. Twenty studies reported the impact of 21 drug exclusion policies on patients: 6 (28.6%) policies were reported to have had a positive impact, 6 (28.6%) to have had a negative impact, and 9 (42.8%) to not have impacted patients. Eighteen studies reported the impact of 19 drug exclusion policies on overall healthcare costs: 14 (73.7%) policies were reported to have reduced costs, 1 (5.3%) to have had a neutral impact on costs, and 4 (21.1%) to have increased costs.

CONCLUSIONS: Although there were important exceptions, most studies found that drug exclusion policies reduced costs and did not negatively impact patients.

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teria and extracted information as follows. First, we reported details of the change in treatment (ie, the drug that was excluded from the formulary and the drug to which patients were switched). Second, we recorded the reported impact that the drug exclusion policy had on patients. We considered a drug exclusion policy to have had a positive impact on patients if the patients' condition improved as a result. We considered a drug exclusion policy to have had a negative impact on patients if they were found to have experienced greater frequency or severity of symptoms, or if they experienced lapses in disease control (eg, if a patient's blood pressure increased following the exclusion of an antihypertensive drug from the formulary).

On occasion, studies reported that the drug exclusion policy's impact on study end points varied (ie, the policy had a positive or negative impact on some study end points but not others); in these instances, we reported the policy's net impact. For example, Parra et al⁶ reported the impact of a policy that led hypertensive patients to switch from amlodipine to an alternative calcium channel blocker and found a reduction in diastolic blood pressure ($P = .03$) and mean arterial pressure ($P = .03$), but no reduction in systolic blood pressure (P value reported as nonsignificant); accordingly, we determined the impact of the drug exclusion policy to be "positive." In another example, Condra et al⁷ reported the impact of a policy that led patients with gastroesophageal reflux disease (GERD) to switch from omeprazole to lansoprazole and found that patients reported an increase in treatment side effects ($P < .01$) but no difference in total reported symptom scores ($P = .28$); thus, we determined the impact of the drug exclusion policy to be "negative." No study in our sample reported that the drug exclusion policy positively impacted 1 or more end points while negatively impacting others.

Third, we reported how the drug exclusion policy affected healthcare costs. We considered all costs related to the drug exclusion policy, including drug expenditures, and costs related to physician office visits, hospitalizations, laboratory tests, and so on.

RESULTS

Our search strategy identified 3195 abstracts. Twenty-six studies met the study inclusion criteria. Of the 26 studies,^{3,5-29} 1 reported the impact of 2 separate drug exclusion policies, meaning that we included information pertaining to 27 drug exclusion policies in our study.⁸

Impact of Drug Exclusion Policies on Patients

Twenty studies reported the impact of 21 drug exclusion policies on patients. The studies reported the impact of the drug exclusion policies on a total of 44 study end points, of which 7 were positive, 8 were negative, and 29 were neutral. The net impact of the drug exclusion

TAKE-AWAY POINTS

Insurers are increasingly implementing policies that exclude drugs from their formularies that they deem to be of low value. We reviewed empirical evaluations of drug exclusion policies to examine the impact the policies had on patients and overall healthcare costs.

- ▶ Twenty-seven drug exclusion policies across 7 different conditions were included in our review.
- ▶ The majority of drug exclusion policies were reported to reduce costs and not negatively impact patients.
- ▶ However, roughly 20% of drug exclusion policies were found to increase costs, and roughly 25% of the policies were found to negatively impact patients (eg, patients' symptoms became more frequent or severe).

policies on patients varied. Six (28.6%) drug exclusion policies were reported to have a positive net impact on patients, 6 (28.6%) were reported to have a negative net impact on patients, and 9 (42.8%) were found to have a neutral net impact on patients (Table 2).

The 6 drug exclusion policies that were reported to have positively impacted patients were found to improve disease control: 3 studies found that policies for hypertension treatments reduced patients' blood pressure; 2 found that policies for hyperlipidemia treatments increased high-density lipoprotein cholesterol levels, while other lipid levels remained unchanged; and 1 found that a policy for glaucoma treatment reduced mean intraocular pressure (Table 2).

The drug exclusion policies that were reported to have negatively impacted patients did so in a variety of ways: 1 found that a policy for diabetes treatments negatively affected disease control by increasing glycated hemoglobin (A1C) levels, 1 reported that a policy for psychotropic disorder treatments increased the incidence of acute care events, 2 found that policies for GERD treatments increased the frequency and severity of symptoms, and 2 studies—1 examining a policy for GERD treatments and 1 examining a policy for hypertension treatments—found an increase in the frequency of side effects (Table 2).

Impact of Drug Exclusion Policies on Healthcare Costs

Eighteen studies reported the impact of 19 drug exclusion policies on healthcare costs: 14 (73.7%) drug exclusion policies were reported to have reduced overall healthcare costs, 1 (5.3%) was reported to

TABLE 1. Literature Search Strategy

We searched using the following search terms in the MEDLINE/PubMed database for English-language articles with no date restrictions:

{["Formulary exclusion"[tiab]] OR ["Formulary status change"] OR ["Formulary switch"[tiab]] OR ["Formulary change"[tiab]] OR ["Formulary conversion"[tiab]] OR ["Formulary management"[tiab]] OR ["Drug exclusion policy"] OR ["Formulary policy change"[tiab]] OR ["Not covered list"] OR ["Drug exclusion list"] OR ["Preferred drug list"[tiab]] OR ["Mandated drug switch"[tiab]] OR ["Mandatory drug switch"[tiab]] OR ["Medication conversion"[tiab]] OR ["Therapeutic substitution"[tiab]] OR ["Therapeutic interchange"[tiab]] OR ["Drug switching"[tiab]] OR ["Drug substitution"[tiab]] OR ["Insurance driven medication changes"] OR ["Insurance mediated medication changes"] OR ["Non-consented drug switch"] OR [{"Therapeutic substitution"[mh]} OR [{"Therapeutic interchange"[mh]} OR [{"Drug substitution"[mh]}]}

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TABLE 2. Studies Reporting Impact of Drug Exclusion Policies on Patients

Study	Country, Setting	Disease (drug switch)	Study Design	Number of Patients Affected by Policy	Direction of Study Outcome	Impact of the Drug Exclusion Policy on the Patients' Condition
Alexis G et al (1999) ⁹	USA, Massachusetts, Brockton/West Roxbury Veterans Administration Medical Center	Hypertension (nifedipine GITS → amlodipine)	Retrospective medical record analysis	72	Neutral	No change in BP control ($P = ns$).
Clay DR et al (2000) ¹⁰	USA, South Carolina, Charleston Naval Hospital	Hypertension (amlodipine → felodipine)	Retrospective medical record analysis	113	Negative	No change in BP control ($P = ns$); 27.4% of patients experienced treatment side effects, and 16.8% discontinued felodipine because of experienced side effects.
Gustin G et al (1996) ¹¹	USA, Connecticut, Newington Veteran's Administration Medical Center	Hypertension (nifedipine GITS → felodipine)	Prospective observational study	127	Positive	No change in systolic BP and heart rate (P not reported); diastolic BP reduced ($P < .05$). No differences in the incidence of side effects (P not reported).
Kinnon AL et al (1999) ^{12,a}	USA, South Carolina, William Jennings Bryan Dorn Veterans Affairs Medical Center	Hypertension (nifedipine ER → felodipine ER)	Retrospective medical record analysis	157	Neutral	No change in BP control (P not reported) and heart rate. No difference in the incidence of side effects (P not reported).
Krantz SR et al (1996) ^{13,a}	USA, Missouri, Kansas City Humana Health Care Plans	Hypertension (nifedipine GITS → felodipine ER)	Retrospective medical record analysis	246	Neutral	No change in BP control ($P = ns$). No difference in the frequency of reported adverse events ($P = ns$).
Parra D et al (2000) ^{5,a}	USA, Florida, West Palm Beach Department of Veterans Affairs Medical Center	Hypertension (amlodipine → alternative calcium channel blocker)	Retrospective medical record analysis	100	Positive	Reduction in diastolic BP ($P = .03$), systolic BP ($P = ns$), and mean arterial pressure ($P = .026$).
Usher-Smith J et al (2007) ^{8,a}	UK, primary care practice	Hypertension (losartan → candesartan)	Retrospective medical record analysis	108	Positive	Reduction in BP ($P = .006$).
Amidon PB et al (2000) ^{14,a}	USA, Maine, Togus Veterans Administration Hospital	GERD and related disorders (omeprazole → lansoprazole)	Retrospective medical record analysis	35	Negative	63% of patients failed to respond to lansoprazole (due to side effects or no response to treatment).
Condra LJ et al (1999) ^{7,a}	USA, San Diego Veterans Affairs Healthcare System	GERD and related disorders (omeprazole → lansoprazole)	Patient survey, mailed questionnaire	158	Negative	28% of patients reported an increase in treatment side effects ($P < .001$). There was no statistically significant difference in the median total reported symptom scores ($P = .28$).
Nelson WW et al (2000) ¹⁵	USA, Wisconsin, Unity Health Plans	GERD and related disorders (omeprazole → lansoprazole)	Patient survey, telephone interview	105	Negative	Symptom severity score increased ($P = .003$); 52% of patients experienced worsening heartburn symptoms.

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have had a neutral impact on overall healthcare costs, and 4 (21.1%) were reported to have increased overall healthcare costs (Table 3).

The drug exclusion policies that were found to increase overall healthcare costs typically did so because the reduction in drug expenditures was exceeded by the costs associated with increases in healthcare services elsewhere in the system (Table 3). In one ex-

ample, Alemayehu et al evaluated the impact of a large commercial payer excluding esomeprazole from its drug formulary, meaning that patients suffering from GERD were required to switch to a less expensive proton pump inhibitor (PPI).⁵ The study found that compared with the 6 months before implementation of the drug exclusion policy, there was a 4.2% increase in the number of inpatient

TABLE 2. Studies Reporting Impact of Drug Exclusion Policies on Patients (*continued*)

Study	Country, Setting	Disease (drug switch)	Study Design	Number of Patients Affected by Policy	Direction of Study Outcome	Impact of the Drug Exclusion Policy on the Patients' Condition
Schnee-weiss S et al (2006) ^{13,a}	Canada, British Columbia, provincial drug benefits program	GERD and related disorders (other PPIs → rabeprazole)	Time-trend analysis	38,426	Neutral	No increase in the monthly rate of hospitalization for gastrointestinal hemorrhage ($P = .35$) or major PUD complications ($P = .16$).
Fugit RV et al (2000) ^{16,a}	USA, New Mexico, Albuquerque Veterans Affairs Medical Center	Hyperlipidemia (simvastatin → lovastatin)	Prospective observational study	96	Neutral	No changes in lipid or liver function values ($P = \text{ns}$).
Longyhore DS et al (2009) ¹⁷	USA, Pennsylvania, St. Luke's Hospital and Health Network	Hyperlipidemia (atorvastatin → alternative statins as per the PDL)	Retrospective medical record analysis	71	Positive	No changes in LDL ($P = .417$), total cholesterol ($P = .885$), or triglycerides ($P = .637$). Increase in HDL levels ($P = .018$).
Patel RJ et al (1999) ^{18,a}	USA, California, Long Beach Veterans Affairs Medical Center	Hyperlipidemia (pravastatin → lovastatin)	Prospective observational study	170	Positive	No changes in LDL ($P = .431$), quality of life ^b (Mental Health Component Summary, $P = .913$; and Physical Component Summary, $P = .264$), and total symptom score ($P = .947$). Increase in HDL levels ($P = .004$).
Usher-Smith J et al (2007) ^{8,a}	UK, primary care practice	Hyperlipidemia (atorvastatin → simvastatin)	Retrospective medical record analysis	69	Neutral	No change in mean total serum cholesterol ($P = .66$).
Bryant GA et al (2013) ¹⁹	USA, Iowa Medicaid, academic medical center	Diabetes (insulin glargine → insulin detemir)	Retrospective medical record analysis	31 ^c	Neutral	No change in A1C in patients with type 1 ($P = .41$) or type 2 ($P = .57$) diabetes. ^c No changes in frequency of hypoglycemia.
Kabadi UM et al (2008) ²⁰	USA, Iowa Medicaid, academic medical center	Diabetes (insulin glargine → insulin detemir)	Retrospective medical record analysis	24	Negative	Increase in A1C ($P < .05$). No difference in frequency of hypoglycemic events ($P = \text{ns}$).
Nadel HL et al (1995) ^{21,a}	USA, New York, Bronx Municipal Hospital Center	Diabetes (glyburide → glipizide)	Retrospective medical record analysis	76	Neutral	No changes in glycemic control (P value not reported).
Law SK et al (2005) ²²	USA, California, HMO	Glaucoma (latanoprost → bimatoprost)	Retrospective medical record analysis	309	Positive	Reduction in mean intraocular pressure ($P = .005$).
McKinley SH et al (2009) ^{23,a}	USA, Texas, Houston Veterans Affairs Medical Center	Glaucoma (latanoprost → travoprost)	Retrospective medical record analysis	599	Neutral	No change in mean intraocular pressure ($P = .591$).
Robst JM et al (2010) ^{24,a}	USA, Florida, Medicaid pharmacy claims	Schizophrenia or schizoaffective, bipolar, or other psychotic disorders ^d (risperidone → alternative antipsychotics per the PDL)	Retrospective claims data analysis	247	Negative	Increase in the incidence of acute care events ($P = .02$), and increase in involuntary commitments ($P = .04$).

A1C indicates glycated hemoglobin; BP, blood pressure; ER, extended release; HDL-C, high-density lipoprotein cholesterol; HMO, health maintenance organization; GERD, gastroesophageal reflux disease; GITS, gastrointestinal therapeutic system; LDL-C, low-density lipoprotein cholesterol; ns, not significant; PDL, preferred drug list; PPI, proton pump inhibitor; PUD, peptic ulcer disease; UK, United Kingdom.

^aStudy that evaluated both clinical and economic outcomes of the drug switch.

^bMeasured with SF-36.

^cPatients with type 1 diabetes = 10; patients with type 2 diabetes = 21.

^dSixty-one percent had a diagnosis of schizophrenia.

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TABLE 3. Studies Reporting Impact of Drug Exclusion Policies on Healthcare Costs

Study	Country, Setting	Disease (drug switch)	Study Design	Number of Patients Affected by Policy	Direction of Study Outcome	Impact of the Drug Exclusion Policy on Economic Outcomes
Alemayehu B et al (2012) ⁵	USA, multi-state national HMO	GERD and related disorders (esomeprazole → alternative PPI per the PDL)	Retrospective claims data analysis	67,915	Negative	Increase in expenditures in the 6 months post esomeprazole exclusion for related medical services ($P < .05$) and PPI and non-PPI prescriptions ($P < .05$). Net increase in cost of \$273/patient.
Amidon PB et al (2000) ^{14,a}	USA, Maine, Togus Veterans Administration Hospital	GERD and related disorders (omeprazole → lansoprazole)	Retrospective medical record analysis	35	Negative	An increase in per-patient mean monthly medication costs of \$46.70 (63%).
Chase SL et al (1998) ²⁷	USA, Pennsylvania, Philadelphia academic medical center	GERD and related disorders (cimetidine and ranitidine → nizatidine)	Prospective observational study	131	Positive	Cost savings of over \$40,000 in the 4 months following policy implementation.
Condra LJ et al (1999) ^{7,a}	USA, California, San Diego Veterans Affairs Healthcare System	GERD and related disorders (omeprazole → lansoprazole)	Patient survey, mailed questionnaire	668	Positive	Estimated annual cost savings of \$29,251 in the 12 months following policy implementation.
Good CB et al (2000) ²⁸	USA, Pennsylvania, Veterans Affairs Pittsburgh Healthcare System	GERD and related disorders (nizatidine → cimetidine)	Retrospective claims data analysis	704	Positive	Fewer hospital admissions ($P < .001$). The number of GI-related hospital admissions did not differ ($P = ns$). Estimated monthly pharmaceutical savings of \$7260.
Schneweiss S et al (2006) ^{3,a}	Canada, British Columbia, provincial drug benefits program	GERD and related disorders (other PPIs → rabeprazole)	Time-trend analysis	38,426	Positive	Estimated 6-month cost-savings of more than C\$2.9 million.
Skinner BJ et al (2009) ²⁹	Canada, British Columbia, PharmaCare program	GERD and related disorders (other PPIs → rabeprazole)	Retrospective medical record analysis	253,449	Negative	Increase in PPI expenditures (C\$9.1 million, $P < .01$), physician services (C\$24.7 million, $P < .01$), and hospital services (C\$9.8 million [$P < .01$]) in the 3 years following policy implementation. Total increase of C\$43.51 million.
Kinnon AL et al (1999) ^{12,a}	USA, South Carolina, William Jennings Bryan Dorn Veterans Affairs Medical Center	Hypertension (nifedipine → felodipine)	Retrospective medical record analysis	157	Positive	Monthly cost savings of \$2085.
Krantz SR et al (1996) ^{13,a}	USA, Missouri, Kansas City Humana Health Care Plans	Hypertension (nifedipine GITS → felodipine)	Retrospective medical record analysis	246	Positive	Estimated 15% reduction in overall costs. Saved approximately \$150,000 per year.
Parra D et al (2000) ^{6,a}	USA, Florida, West Palm Beach Department of Veterans Affairs Medical Center	Hypertension (amlodipine → alternative calcium channel blocker)	Retrospective medical record analysis	100	Positive	Net annual cost savings of \$14,858 for each 100 patients converted from amlodipine to an alternative calcium channel blocker.

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TABLE 3. Studies Reporting Impact of Drug Exclusion Policies on Healthcare Costs (*continued*)

Study	Country, Setting	Disease (drug switch)	Study Design	Number of Patients Affected by Policy	Direction of Study Outcome	Impact of the Drug Exclusion Policy on Economic Outcomes
Usher-Smith J et al (2007) ^{8,a}	UK, primary care practice	Hypertension (losartan → candesartan)	Retrospective medical record analysis	108	Positive	Net annual cost savings of £13,374.
Fugit RV et al (2000) ^{16,a}	USA, New Mexico, Albuquerque Veterans Affairs Medical Center	Hyperlipidemia (simvastatin → lovastatin)	Prospective observational study	96	Negative	Net annual program cost of \$15,792. Reduction in drug expenditures (\$9915) offset by cost of clinical pharmacist (0.4 FTE; \$23,196.16) and laboratory monitoring (\$2511).
Meissner B et al (2006) ²⁵	USA, multi-state Medicaid MCO	Hyperlipidemia (atorvastatin → other statins)	Retrospective claims data analysis	3636	Positive	Net PMPY savings of \$82.40 (10.0%). Increased laboratory test costs (\$3.87, 31.5%) and increased medical office visits costs (\$6.41, 44.9%) were offset by the reduction in statin drug expenditures (\$92.68, 11.7%).
Patel RJ et al (1999) ^{18,a}	USA, California, Long Beach Veterans Affairs Medical Center	Hyperlipidemia (pravastatin → lovastatin)	Prospective observational study	170	Positive	Projected annual savings of \$210,816.
Usher-Smith J et al (2007) ^{8,a}	UK, primary care practice	Hyperlipidemia (atorvastatin → simvastatin)	Retrospective medical record analysis	69	Positive	Net annual cost-savings of £12,715.
Nadel HL et al (1995) ^{21,a}	USA, New York, Bronx Municipal Hospital Center	Diabetes (glyburide → glipizide)	Retrospective medical record analysis	76	Positive	54% reduction in costs of hypoglycemic agents in the first year following policy implementation; 51% reduction in costs in second year.
Benedetto SR et al (2000) ²⁶	USA, pharmacy claims data from 4 Northeast HMOs	Allergic rhinitis (loratadine → fexofenadine)	Retrospective claims data analysis	1217	Positive	Net cost savings of \$37,185.
McKinley SH et al (2009) ^{23,a}	USA, Texas, Houston, Veterans Affairs Medical Center	Glaucoma (latanoprost → travoprost)	Retrospective medical record analysis	599	Positive	Policy led to a 71% reduction in costs.
Robst JM et al (2010) ^{24,a}	USA, Florida, Medicaid pharmacy claims	Schizophrenia or schizoaffective, bipolar, or other psychotic disorders ^b (risperidone → alternative antipsychotics per the PDL)	Retrospective claims data analysis	247	Neutral	Reduction in pharmacy costs ($P = .46$) was offset by an increase in costs associated with acute care events ($P = .05$) and emergency visits ($P = .03$). No statistically significant change in costs ($P = .99$).

C\$ indicates Canadian dollars; FTE, full-time equivalent; GERD, gastroesophageal reflux disease; GI, gastrointestinal; GITS, gastrointestinal therapeutic system; HMO, health maintenance organization; MCO, managed care organization; ns, not significant; PDL, preferred drug list; PMPY, per member per year; PPI, proton pump inhibitor; UK, United Kingdom.

^aDrug switches that evaluated both clinical and economic outcomes.

^bSixty-one percent had a diagnosis of schizophrenia.

admissions and a 2.3% increase in the use of other services, including laboratory testing and ambulatory procedures in the following 6 months. The study also found that although switching to a cheaper PPI reduced 6-month prescription drug costs by \$177 per patient ($P < .01$), costs associated with other medical services increased by \$450 per patient ($P < .01$), resulting in a net increase of \$273 per patient.

In another study that examined a drug exclusion policy affecting patients with GERD, Skinner et al used a claims database to evaluate the impact of the PharmaCare program in British Columbia's policy that mandated that patients treated with a PPI switch from their current therapy to the least expensive PPI, which, at the time of the study, was rabeprazole.²⁹ The study found that because of greater

use of PPIs, PPI drug expenditures increased by 9.1 million Canadian dollars (C\$) ($P < .01$) following the drug exclusion policy. The study also found that the drug exclusion policy led to the cost of physician services increasing by C\$24.7 million ($P < .01$) and the cost of hospital services increasing by C\$9.8 million ($P < .01$).

Comparison of Studied Conditions

The included studies evaluated drug exclusion policies for 7 conditions. Five conditions were featured multiple times: GERD and related disorders (8 studies), hypertension (7), hyperlipidemia (5), diabetes (3), and glaucoma (2). Allergic rhinitis and psychotic disorders were featured in a single study.

Study findings varied among the 8 studies that evaluated drug exclusion policies for GERD treatments. Three of the 4 studies that reported the impact of the policy on patients found it to be negative, and 3 of the 7 studies that reported the impact of the policy on overall healthcare costs found that the reduction in drug expenditures was either offset or exceeded by costs incurred elsewhere in the health system.

Each of the 7 studies that evaluated drug exclusion policies for hypertension treatments reported the impact of the policy on patients, and only 1 found it to be negative; each of the 4 studies that reported the impact of the policy on overall healthcare costs reported that costs were reduced.

Each of the 4 studies that evaluated drug exclusion policies for hyperlipidemia treatments reported the impact of the drug exclusion policy on patients and found that patients were not adversely impacted; 1 of the 4 studies that reported the impact of the policy on overall healthcare costs reported that costs increased.

Each of the 3 studies that evaluated drug exclusion policies for diabetes treatments reported the impact of the drug exclusion policy on patients, and 1 found it to be negative; the 1 study that reported the impact of the policy on healthcare costs reported that costs were reduced.

Both of the studies that evaluated drug exclusion policies for glaucoma treatments reported the impact of the drug exclusion policy on patients and found that patients were not adversely impacted; the 1 study that reported the impact of the policy on overall healthcare costs reported that costs were reduced.

The study that evaluated a drug exclusion policy for psychotic disorders (ie, schizophrenia or schizoaffective, bipolar, or other psychotic disorders) reported a negative impact on patients, but that the policy had no impact on overall healthcare costs. The study that evaluated a drug exclusion policy for allergic rhinitis treatments did not report the impact of the drug exclusion policy on patients, but it did report that the policy reduced overall healthcare costs.

DISCUSSION

Insurers and PBMs are increasingly excluding drugs from their formularies that they deem to be of low value. Indicative of this trend,

in 2016, Express Scripts increased the number of drugs excluded from their preferred drugs list from 66 to 80, and CVS/Caremark increased the number of drugs excluded from their standard formulary from 95 to 124.^{1,2,30,31} Although much has been written about the proliferation of drug exclusion policies, little attention has been focused on their impact on patients.³²⁻³⁴ We identified and reviewed empirical evaluations of drug exclusion policies and examined their impact on patients and healthcare costs.

We found that roughly three-fourths of the included studies reported that the drug exclusion policies either positively impacted patients (ie, the patients' condition improved) or that patients' conditions were unaffected. In the one-fourth of studies that reported that drug exclusion policies negatively impacted patients, a number of factors may be at work. Although the excluded drug was often replaced with a drug in the same therapeutic class (eg, one PPI was replaced with another PPI), the drugs in the same class may not have identical safety, efficacy, or metabolic profiles, and some patients may respond differently to them.³⁵ In addition, drug exclusion policies may negatively impact patient adherence, which, in turn, can lead to compromised disease management.

We found that roughly four-fifths of the included studies reported that the drug exclusion policies reduced overall healthcare costs. In the remaining studies, savings from reductions in drug expenditures were offset or exceeded by costs incurred elsewhere in the healthcare system (eg, due to an increased rate of physician office visits or hospitalizations). Other reasons for increased overall costs may include the costs of implementing the drug exclusion policy, and the costs of additional office visits, medical authorizations, and phone calls that accompany the medication changes.

Looking Forward

Faced with the introduction of innovative technology and rising costs, insurers and PBMs will continue to search for ways to make their drug benefit designs more efficient. Payers may be prepared to accept some degree of disruption to patient care.³⁶ Removing drugs from formularies for which equally effective, but less expensive, alternatives are available is an attractive option. Our study suggests that, for the most part, these policies have been successful in reducing costs while minimizing the impact on patient care, although the exceptions provide room for caution. Decision makers should thus be mindful of the potential negative clinical and economic consequences of drug exclusion policies. Decision makers can help mitigate this risk by using formal cost-effectiveness analyses and budget impact models to account for all potential costs and benefits in their decisions.³⁷ Drug exclusion policies should be transparent, with the evidence that informed the policy clearly communicated to patients and physicians, and implemented with a goal of maximizing continuity of patient care.³⁸

Limitations

Our study has a number of limitations. The studies included in our review varied in their methodologies. Among the included studies were retrospective chart reviews,¹⁷ prospective cohort analyses,¹⁸ analyses of administrative claims data,²⁹ and patient surveys.¹⁵ Differences in the methods employed and the study end points prevented a formal synthesis of the included studies through meta-analysis. The included studies also varied in how study findings were reported. Not all studies reported the effect of the drug exclusion policy on both patients and healthcare costs. Further, some studies reported the costs incurred following the drug exclusion policy with greater granularity than others.

CONCLUSIONS

Insurers are increasingly using drug exclusion policies as a tool to help reduce the cost of their drug benefit. Our findings suggest that although there were important exceptions, a majority of policies have successfully reduced costs and have not negatively affected patients.

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