At a Glance

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Review of Outcomes Associated With Formulary Restrictions: Focus on Step Therapy

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As healthcare spending continues to rise, more employers, managed care organizations, and pharmacy benefit managers are implementing novel pharmacy benefit designs and formulary management policies to control drug spending.[1] Some common pharmacy management policies include multitier designs, preferred drug lists (PDLs), drug benefit caps, prior authorization (PA), and step-therapy programs (also known as step edits). This review will primarily address step edits, but to fully understand the impact of step edits, a review of linked formulary management policies is necessary.

A multitier formulary is a pharmacy-management policy designed to increase consumer cost sharing for nonpreferred medications and provide financial incentives for health plan members to accept medications on lower tiers. Plans are increasingly moving from 2-tier to 3-tier (and in some cases 4-tier) designs in an effort to control utilization and reduce costs.[2]

Similar to a multitier formulary, a PDL is a pharmacy-management policy that encourages the prescribing of less expensive alternatives in a therapeutic class before more expensive alternatives are used.[3] A PDL provides the opportunity to control inappropriate use of high-cost or potentially harmful drugs with the intent of minimizing harm and maximizing savings. Another pharmacy-management technique is to cap drug benefits, requiring patients to pay the full price for drugs after their spending exceeds the cap amount. It is hoped the cap will encourage diligent use of drug therapy. A more restrictive technique is to require a PA or approval from a plan sponsor before a prescription claim is paid. Approval of the claim is generally based on the presence of a particular risk factor, condition, prior treatment failure, adverse event, or special consideration (eg, participation in a wellness program) where the plan has determined the drug to be medically necessary.[4] Prior authorization is designed to encourage judicious use of costly, new, and/or potentially toxic drugs.

Step therapy is a broad term that often encompasses 1 or more components of the policies described above. Step

ABSTRACT

Objective: To evaluate the effect on outcomes of formulary restrictions with a focus on step-therapy programs.

Study Design: Literature review.

Methods: A literature search was conducted on PubMed and MEDLINE for primary articles published between January 2003 and April 2007.

Results: A total of 15 articles related to step therapy or similar restrictions were identified. Studies that included a cost analysis all reported lower drug costs, but few reported on total costs. Several studies reported significant numbers of patients going without or underutilizing medication following a plan restriction. Two studies found that removing restrictions improved clinical status and decreased total healthcare expenditures.

Conclusion: Although formulary restrictions are intended to reduce costs while maintaining or improving quality, few comprehensive studies support these claims. Further research is needed to quantify the effect of formulary restrictions such as step therapy.

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therapy usually requires the use of lower-cost (first-line) drugs before "stepping up" to more expensive (second-line) medications.[4] A trial of a first-line medication is required before a second- or third-line medication is reimbursed by the pharmacy benefit manager or health plan. Typically, when step edits are administered at the point of service (ie, retail pharmacy), members with a history of using the restricted medication are not affected by the step edit and are, in essence, "grandfathered" into the program. In order for a second-line medication to be covered for a first-time prescription, proof of first-line medication use or proof of medical necessity through a PA is required. A common example of step therapy in the antihypertensive class is the required use of generic angiotensin-converting enzyme inhibitors before branded angiotensin receptor blockers (ARBs) will be covered.

Use of step edits by health plans and pharmacy benefit managers is increasing as more branded products lose patent protection and managed care organizations continue to focus on managing pharmacy per-member per-month (PMPM) costs. For example, the number of members served by Express Scripts (St. Louis, MO), whose pharmacy benefit includes a step edit, grew from less than 1 million in 2002 to more than 14 million in 2006.[4] During that time, the average number of step edits (modules) per program increased from 2.5 to 8.4.

Whereas these programs are increasingly common, little information regarding their effect (aside from their effect on pharmacy costs) has been published. Therefore, this review sought to identify studies that assessed the effect of formulary-management techniques, with a focus on step edits, and to highlight their findings.

METHODS

A literature search was conducted on PubMed and MEDLINE for primary articles published between January 2003 and April 2007, limited to English text only. Key words searched included (generic) step edits, step therapy, formulary restrictions (control, tiers, cost), drug coverage restrictions, prior authorization, managed care pharmacy, drug utilization, and tiered therapy. The search produced a limited number of studies that evaluated step-therapy programs specifically; therefore, the search was broadened to include other formulary controls with similar restrictions to step edits. All published articles were assessed for relevance to this review.

RESULTS

A total of 15 published studies were identified as being related to step therapy or other formulary restrictions (**Table**).[3,5-18] Of the 15 studies, 3 assessed only the drug component of healthcare costs, and 12 considered other outcomes such as adherence, clinical status, satisfaction, and healthcare utilization. Only 5 of the 15 studies assessed step edits specifically. We discuss these 15 articles in 2 subsections: (1) financial effects and (2) utilization and clinical outcomes. Studies that assessed multiple outcomes are included in both subsections.

PRACTICAL IMPLICATIONS

A literature search for primary articles published between January 2003 and April 2007 resulted in 15 articles related to step therapy or similar restrictions.

- Studies that included a cost analysis all reported lower drug costs, but few reported on total costs.
- Several studies reported significant numbers of patients going without or underutilizing medication following a plan restriction.

Financial Effects

Payer Drug Savings. Formulary restrictions are implemented with the intent to minimize drug costs while maintaining therapeutic equivalence. Disease states have been studied for which multiple therapeutically equivalent agents and/or generic equivalents are available. For example, Dunn et al[5] assessed antidepressant drug costs over a 2-year period after implementation of a step edit to encourage use of generic selective serotonin reuptake inhibitors (SSRIs). In this health maintenance organization program, neither PA nor medical exception was allowed and patients had their copay waived for the first fill of a preferred generic medication. Results demonstrated that the average drug cost per day decreased by 9% among a program of about 440,000 members. This amounted to $0.36 PMPM in 2005 dollars in the first year of intervention. Although the researchers noted a 1.5% reduction in antidepressant utilization among affected members, no other outcomes were assessed.

Another area of study has been in the use of antihypertensives. Yokoyama et al[6] assessed the effect of a step edit requiring use of angiotensin-converting enzyme inhibitors before coverage of ARBs. Results demonstrated that over a 12-month period the program saved 13% in direct drug costs for all antihypertensives. The pharmacy benefit savings was calculated to be $0.03 PMPM across 1 million members, which amounted to annual savings in drug costs of at least $360,000 in 2002 to 2003 dollars. However, the researchers

Table. Overview of Studies

Authors (Year)	Disease Area or Drug Class	Type of Formulary Restriction	Outcomes Measured	Key Findings	Limitations
Murawski and Abdelgawad (2005)[3]	Cardiovascular patients	Preferred drug list	• Drug utilization • Hospital visits • Physician visits	• Inpatient days increased • Outpatient hospital days increased • Physician visits increased • Drug cost reductions of 25% were necessary to offset increased utilization of care	• Database only included a fraction of all patients • Small sample size • Only examined visits and costs for patients on antihypertensive medications
Dunn et al (2006)[5]	Antidepressants	Step therapy	Drug costs	• Average drug cost per day decreased by 9% • Drug utilization decreased by 1.9%	• Only measured direct drug costs • Savings likely influenced by dose-optimization intervention for generic fluoxetine started in 2005
Yokoyama et al (2007)[6]	Antihypertensives	Step therapy	Drug costs	• Program saved 13% in drug costs • 69.5% of patient received restricted drug within 12 months after failing initial edit • 6.6% of patients received no antihypertensive drug	• Only included pharmacy claims data, so could not assess effect on clinical outcomes • Did not measure pharmacy and prescriber costs associated with requesting a prior authorization or changing drug therapy
Motheral et al (2004)[7]	PPIs, SSRIs, NSAIDs	Step therapy	• Drug costs • Patient survey of end result	• Varying drug savings across all 3 classes • 17% of responders received no drug • 16% of responders paid out-of-pocket for drug • 29% of responders switched to preferred therapy	• Study reflects experience of 1 employer • Small sample size • Did not include evaluation of medical claims costs
Cox et al (2004)[8]	Subanalysis of data from Motheral et al[7]	Step therapy	Patient survey of end result	• 44% of responders received a different medication than was originally prescribed • 11% of responders received no drug	• Potential response bias • Study relied heavily on patient recall • Small sample size; only 1 health plan
Ganther-Urmie et al (2004)[9]	None specifically	Multitier copayments	Patient survey of attitudes	• 54% of responders paid extra for nonformulary drugs • 13% of responders received no drug	• Low response rate • Potential lack of generalizability to other health plans • Study focused on patient's willingness to switch to an alternative product, and actual decisions may change when faced with a product change
Hsu et al (2006)[10]	None specifically	Two-tier plan with benefit caps	• Drug costs • Total medical costs • Clinical outcomes for patients with hypertension, diabetes, hyperlipidemia	• Drug costs were 31% lower for members with benefit caps • Total costs were 1% lower for members with benefit caps • Members with benefit caps who had select conditions were more nonadherent to long-term drug therapy • Members with benefit caps who had select conditions had worse physiologic outcomes	• Nonrandomized design • Could not assess out-of-system drug use and may have underestimated total drug consumption • Limited precision when evaluating cost differences between groups

Authors (Year)	Disease Area or Drug Class	Type of Formulary Restriction	Outcomes Measured	Key Findings	Limitations
Panzer et al (2005)[11]	Anti-depressants	Step therapy	• Total medical costs • Drug costs • Drug utilization	• Total medical costs increased by $0.32 PMPM • Drug costs decreased by $0.26 PMPM • More patients switched medication within 6 months • Fewer patients received continuous therapy at 6 months	• Model assumes 100% conversion from branded to generically available products • Pharmacy costs may not accurately reflect health plan pharmacy costs • Administrative and other costs for implementing the program were excluded
Abourjaily et al (2005)[12]	None specifically	Formulary restrictions	Clinician survey of attitudes	• 11-19 minutes per drug switch • 11-37 switches per month • Calculated as $100-$400 in opportunity costs per month	• Small sample size; providers all from 1 institution • Patients' nondrug costs such as time and cost of outcomes were not included
Shrank et al (2006)[13]	Six drug classes	Three-tier plan	Adherence to therapy	• Adherence ranged from 21% to 65% across 6 drug classes • Adherence was greatest for patients initiated on tier 1 and lowest for patients on nonpreferred medication	• Use of pharmacy claims to measure patient adherence • Patients were relatively young and most lived in 1 of 2 Western states
Landsman et al (2005)[14]	Nine classes for 5 conditions	Two-tier to 3-tier plan	Drug utilization	• Significant reductions in adherence found for 7 of 9 classes • Medication discontinuation rates increased significantly in 5 of 9 classes, ranging from 4% to 26%	• Data inaccuracies with administrative claims data • Discontinuation rates may have been overestimated if patients switched to an alternative in another drug class or OTC alternative • Limited only to users of retail pharmacies
Goldman et al (2004)[15]	Multiple classes	Increase in copayments	Drug utilization	Reductions in use occurred in 8 classes	• Results for insured, working-age population may not be generalizable • Beneficiaries did not have a choice of drug benefits
Taira et al (2006)[16]	None specifically	Multitier systems	• Drug utilization • Patient adherence	Patients taking antihypertensives on tier 3 were 52% more likely to be nonadherent than patients taking medications on tier 1	• Study population reflects a single health plan in Hawaii • Medication compliance was determined indirectly from pharmacy claims • Clinical outcomes were not assessed
Cranor et al (2003)[17]	Diabetes	Waiver of copayments	• Clinical status • Total medical cost per patient year	• Mean A1C values decreased • Amounts paid per patient per year was lower in each year of follow-up	• Missing or unreported clinical data • Neither patients nor providers followed a specific protocol or documentation format
Mahoney (2005)[18]	Diabetes	Reduction in tier system	• Adherence • Drug costs • Healthcare utilization	• Adherence improved • Total pharmacy costs decreased • ED visits decreased • Overall direct costs decreased	• Included only 1 employer group • Benefit design with no tiers is not typical of most benefit designs

A1C indicates glycosylated hemoglobin; ED, emergency department; NSAIDs, nonsteroidal anti-inflammatory drugs; OTC, over-the-counter; PMPM, per member per month; PPI, proton pump inhibitor; SSRIs, selective serotonin reuptake inhibitors.

also noted that approximately half of the population received ARB therapy within 12 months after failing the initial edit and that 6.6% of patients did not receive any antihypertensive therapy in the subsequent year.

Other Costs to Payers and Patients. Step edits may lead to scenarios where patients do not fill prescriptions, underutilize medication, or circumvent restrictions. For example, Yokoyama et al[6] reported that 45% of patients received an ARB through a PA, and Dunn et al[5] reported a decrease in antidepressant utilization after implementation of a step edit. Other recent studies have reported that less than half of patients who initially face a step edit actually start on the first-line medication as intended. Motheral et al[7] assessed utilization of proton pump inhibitors, SSRIs, and nonsteroidal anti-inflammatory drugs (NSAIDs) after implementation of step edits in a plan of 20,000 members. The step edit for all 3 therapy classes required trial of generic medication before coverage of branded medication. The researchers reported drug savings across all 3 classes. Also, during a 4-month period, 212 members were surveyed regarding the step edits. Of those surveyed, 17% reported they did not fill their prescription as a result of the edit. Approximately 22% reported receiving a medical exception to receive their desired drug, and 16% paid out-of-pocket for the brand medication. Another 10% received a sample or an over-the-counter alternative to circumvent the step edit. Only 29% went through the step edit and switched to the program's preferred generic therapy.

In an extended analysis of the Motheral et al data,[7] Cox et al[8] assessed surveys of 201 responders. A total of 44% indicated they had received a different medication than was originally prescribed, but 15% obtained a PA and 11% paid full price for their desired drug. Another 11% received no medication, 4% received drug samples, and 8% purchased an over-the-counter medication. Similar findings were reported by Ganther-Urmie et al[9] in a random sample survey of 3816 members in a large managed care organization. Among survey responders, 54% paid extra to purchase nonformulary medication, 9.9% obtained a PA from the plan, 13% did not get any medication, and 23% received a formulary medication.

Total Healthcare Costs. Although formulary restrictions may decrease drug costs, several studies have demonstrated that total healthcare costs remained the same or increased. Hsu et al[10] compared economic outcomes among almost 200,000 Medicare beneficiaries with or without drug benefit caps. Although drug spending was 31% lower among patients whose benefits were capped, total medical costs, including drugs, decreased by only 1%. The essentially null effect on total costs was largely a result of the fact that patients with drug benefit caps incurred higher rates of emergency department (ED) visits and hospitalizations.

Panzer et al[11] assessed generic step therapy with SSRIs compared with an open formulary and found that a higher number of patients switched medications within 6 months and that a lower percentage of patients received continuous therapy at 6 months with a generic step-therapy program in place. Whereas pharmacy costs decreased by $0.26 PMPM with generic step therapy, total medical costs, including hospitalizations, outpatient visits, and ED visits, increased by $0.32 PMPM.

Formulary restrictions also may have differing financial outcomes depending on the types of patients affected. Soumerai[19] cautioned that vulnerable populations such as the elderly or poor may be especially burdened by cost sharing and other drug therapy restrictions. In a study of Medicaid patients with cardiovascular disease, Murawski and Abdelgawad[3] assessed prescriptions, hospital visits, and physician visits over a 12-month period following implementation of a PDL. They reported that the average number of inpatient days increased by 37% to 42%, depending on the demographic controls included in the regression model, among Medicaid patients compared with non-Medicaid patients. Outpatient hospital visits also increased by 35% to 41%, and physician visits increased by 66% to 78%. Because of data limitations the authors could only estimate that additional medical costs outweighed drug savings from the PDL. It was estimated that the PDL program needed to realize prescription cost reductions of more than 25% before total healthcare savings were achieved, not including the cost of program administration.

Additional Administrative Costs to Providers. In cases of increased costs associated with step edits, the cost increases are not limited to patients. Healthcare providers, including physicians, nurses, and pharmacists, spend significant time and resources navigating through varying plans. In one of the few assessments of nondrug costs associated with formulary restrictions, Abourjaily et al[12] conducted an Internet-based survey of clinicians at an urban tertiary care hospital. Survey responses to scenarios involving outpatient switches for angiotensin-converting enzyme inhibitors, HMG-CoA reductase inhibitors (statins), and SSRIs were evaluated. A total of 91 physicians and nurses indicated they spent about 11 to 19 minutes making medication switches and experienced 11 to 37 switches per month. The researchers concluded that the productivity loss associated with formulary restrictions amounted to average monthly costs of more than $400 for

nurses and more than $100 for physicians.

Pharmacists also report spending significant time liaising between patient, physician, and payer to resolve barriers to prescription fills. In 1999, a study of pharmacists' time found 20% of a pharmacist's workday is spent handling activities related directly to administrative and claims processing procedures.[20] Implementation of Medicare drug coverage has resulted in pharmacists spending more time navigating through various plans.[21] Many pharmacists bypass exceptions and appeals processes, and can be overwhelmed with dozens of plans requiring different processes for step edits or PAs. Long telephone hold times for resolving claims encourages pharmacists and physicians to change a prescription to a drug with fewer or no restrictions. This in turn may lead to increased risk of adverse drug events, decreased medication adherence, or therapeutic failure.

Utilization and Clinical Outcomes

Ideally, formulary restrictions such as step edits provide therapeutically equivalent options that do not adversely affect clinical outcomes or therapy adherence. Several lines of inquiry, however, have demonstrated lower therapy adherence following formulary restrictions. Shrank et al[13] assessed treatment adherence to 6 classes of chronic medications among 7532 new prescriptions in a 3-tier benefit program. They found adherence was greatest among patients initiated on tier 1 followed by patients on tier 2, compared with patients receiving nonpreferred medications. Adherence among the 6 classes of drugs ranged from 21% to 65%. These results illustrate patients' sensitivity to out-of-pocket costs, as dose-sparing activities and delayed refills likely reduce compliance rates for high-cost medications.

Landsman et al[14] investigated the effect of changing a 2-tier program to 3 tiers on utilization of 9 therapeutic classes for 5 conditions. They found significant reductions in patient adherence to therapy in 7 of 9 classes following benefit changes. Average copayments increased from 16% to 129% across all classes, whereas medication discontinuation rates increased significantly in 5 of 9 classes, ranging from 4.1% to 25.7%. The authors concluded that switching to the 3-tier design had a negative effect on patient persistence and drug utilization.

Goldman et al[15] studied the effect of drug utilization following an increase in patient copayments. They found reductions in use occurred in 8 therapeutic classes, with the largest decrease in use among NSAIDs (45%) and antihistamines (44%). Among medications to treat chronic illnesses, use of antidepressants decreased by 8%, use of antihypertensives decreased by 10%, and use of antidiabetic drugs decreased by 23% as a result of the benefit change.

Taira et al[16] found comparable results in an analysis of the effect of copayments on patient adherence to antihypertensives in Hawaii. They found that in 3-tier designs, higher-tier drugs had lower adherence rates across all therapeutic classes. In addition, patients taking antihypertensives listed on tier 3 were 52% more likely to be nonadherent than patients taking medications on tier 1.

Decreases in drug utilization may be a result of underutilization or of not filling prescriptions. Studies assessing the effect of various benefit restrictions have reported no-fill rates of 11% for NSAIDs or proton pump inhibitors,[8] 7% for ARBs,[6] and 13% among numerous agents with formulary restrictions.[9] Step edits in particular have demonstrated similar results. Motheral et al[7] found 17% of patients in an Express Scripts patient population with prescriptions for NSAIDs, proton pump inhibitors, or SSRIs failed to fill any prescription after the introduction of a step edit. As a consequence, patient health may be adversely affected. In the study by Hsu et al,[10] drug benefit caps with antihypertensives, lipid-lowering agents, and antidiabetic drugs led to declines in drug utilization by 15%, 27%, and 21%, respectively. In addition, members with capped benefits were more likely to have elevated blood pressure, elevated low-density lipoprotein cholesterol, and elevated glycosylated hemoglobin (A1C).

Patient and Provider Inconvenience and Dissatisfaction. The time required to navigate programs can be substantial for patients and providers. Cox et al[8] found 16% of patients spent at least 4 hours trying to resolve coverage issues. Specifically, 12% of patients surveyed spent 3 to 4 hours, 30% spent 1 to 2 hours, and 43% spent less than 1 hour. The time spent resolving barriers to drug access leads to delays in medication use and additional costs to patients. The researchers also found that 37.9% of patients who switched to a covered medication experienced a delay of 5 or more days from the time the step edit was implemented to the actual receipt of covered medication. Only 20.7% of patients who switched medications received the medication on the same day. Also, more than 50% of patients who received a PA experienced a delay of 5 or more days from the time of the step edit to receipt of medication. The majority of patients who received the noncovered medication on the same day were those who chose to pay out-of-pocket.

The delays associated with navigating a pharmacy benefit plan can have a negative effect on patient–provider relations. According to Abourjaily et al,[12] only 3 of

91 survey responders thought medication switches improved patient–provider relations. As a result, member and provider dissatisfaction with plans can ensue. Motheral et al[7] found dissatisfaction was highly dependent on the outcome of the step edit. Higher patient satisfaction was reported for those who received a branded medication (95%) compared with those who received a generic medication (53%). A lower level of satisfaction also was observed among patients paying out-of-pocket or receiving no drug compared with those who received a generic product. These less tangible outcomes are rarely included in analyses of the effect of formulary controls.

Removing Barriers to Medication Access. Growing evidence indicates removal of formulary restrictions is associated with improved outcomes, especially in patients with diabetes. Cranor et al[17] reported on outcomes of the Asheville Project, which allowed patients to receive a waiver of copayments for diabetes-related drugs and supplies, along with pharmaceutical care services provided by community-based pharmacists. Results showed that mean A1C values decreased at every follow-up, and the number of patients with optimal A1C increased. From an economic perspective, the amount paid per patient per year for insurance claims was lower in each year of follow-up compared with baseline. Although separating the effects of pharmacy services and copayment waivers was not possible, efforts to ease patient burden in obtaining medication and supplies appeared to improve clinical outcomes.

Mahoney[18] also reported improved outcomes and lower total costs following modification of a pharmacy benefit plan for participants with diabetes in an employer-based setting. In a large-scale effort to improve patient health and reduce costs, Pitney Bowes Inc reduced its previous 2-tier or 3-tier formulary status to a 1-tier system for diabetes drugs and supplies. With 2 to 3 years of longitudinal data, results demonstrated that adherence improved, total pharmacy costs decreased, ED visits decreased, and overall direct healthcare costs per plan participant with diabetes decreased. The author concluded tight cost controls are barriers to diabetes management and represent a "huge burden" to patients.[22]

DISCUSSION

In an attempt to assess the effect of step edits on financial and clinical outcomes, we sought to review the literature published between 2003 and 2007. Fifteen studies were identified that assessed various outcomes, including drug costs, total medical costs, drug utilization and adherence, patient satisfaction, and provider time. In the 15 studies examined, step edits and formulary restrictions were successful in reducing pharmacy spending and creating pharmacy cost savings. Of the 15 studies, 3 measured drug costs as the primary outcome. Of those studies, 1 included a member survey regarding drug utilization[7] and reported that one third of responders paid for their drug out-of-pocket or did not fill their prescription. Two additional studies assessed total healthcare costs and found mixed results. Hsu et al[10] reported a minimal decrease in total costs, largely because pharmacy spending savings were offset by increased healthcare utilization following implementation of capped drug benefits. However, in a study of antidepressant therapy restrictions, Panzer et al[11] reported a significant increase in total medical costs. These findings demonstrate that although drug costs decrease following formulary restrictions, increased medical costs may outweigh those savings and, in essence, result in cost shifting rather than true cost savings. Furthermore, researchers who report drug savings actually may have observed cost reductions owing to patient nonadherence and decreased medication utilization rather than an effective program design.

The assumption has been made that formulary restrictions do not adversely affect clinical outcomes. However, evidence indicates patient outcomes are affected. Of the 15 studies, 9 measured adherence, prescription fill rates, and clinical outcomes of patients with various illnesses.[8-16] These studies assessed multitier plans, step edits, drug caps, and PDLs. All 9 reported adverse results of these restrictions, including decreased medication utilization, significant no-fill rates, circumvention or increased expenditures to obtain nonpreferred drugs, and increased discontinuation rates. Hsu et al[10] also reported that patients with hypertension, diabetes, or hyperlipidemia were more likely to have worse physiologic outcomes associated with capped drug plans.

Formulary restrictions often are imposed on medications for chronic illnesses, although nonadherence among patients with chronic illness can have a significant financial effect. The portion of members with claim rejections who go on to have no claims for medication to treat that condition is of growing concern.[23] Two studies reviewed in this article assessed the effect of eliminating formulary restrictions for patients with diabetes.[17,18] Both reported improved financial and clinical outcomes of the restriction reversals: mean A1C values, drug costs, ED visits, and total direct medical costs decreased when barriers to care were removed.

Several limitations of this review are of note. We identified few studies that assessed step edits apart from other pharmacy benefit changes; however, step therapy is similar to other policies (eg, multitier designs, PAs) that

can impose a barrier to care that affects patient behavior. Therefore, the review was expanded to include other formulary restrictions that are similar to or often included in step edits. The effect of these programs may be generalizable to step edits in a broader sense; however, it must be noted that step edits are aimed at new users of a medication, whereas the other programs can involve all plan members. Further, the ability to draw conclusions based solely on the reviewed studies is hindered because plan restrictions, included costs, and disease types varied by study. Outcomes can be affected by a number of factors, including the patient population affected by the program (eg, disease type, sex, age, socioeconomic status), the degree of restriction imposed by the program, and plan-specific factors such as negotiated prices for pharmaceuticals. In many cases, the preferences and past experiences of the physicians greatly affect the outcome of a step edit or formulary restriction.

Admittedly, the level of medication adherence in the general population is poor. The net consequences of step edits and formulary restrictions would be an interesting line of study that requires additional research, given that current medication adherence rates are suboptimal.

Limitations of using administrative and pharmacy claims data include possible data inaccuracies and potential medication switches to over-the-counter medications, which would not be captured in the administrative claims database. Additionally, the use of pharmacy claims to indirectly determine compliance may overestimate or underestimate compliance, as actual patient consumption of medication was not assessed. Another limitation is the potential of a response bias, as survey data are limited by patient recall of the events and outcomes of step edits. In some cases, patients may not have been fully aware that step therapy was in effect and of the steps that were taken by healthcare providers to remedy the situation. Some of the studies were limited in scope owing to sample size; thus, responses may reflect the practice structure and patterns of the group of providers that were included in the study.

CONCLUSION

Formulary restrictions have developed as a response to rising prescription drug costs and the availability of multiple products with similar perceived safety and efficacy. However, few studies provide evidence demonstrating that formulary controls and restrictive drug benefit designs achieve the intended goal of reducing total costs while maintaining quality care. Formulary restrictions and step edits may hinder patient access and adherence, and may increase total costs of care. Further research is needed to quantify the total financial implications of step edits to better understand their effect on patient behavior and adherence to therapy, and to support the claims that restrictions do not adversely affect patient health.

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