

# Emphasize Shared Decision-Making Between Physicians and Patients to Improve Diabetes Outcomes

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**D**isruptive innovation and a growing emphasis on value are reshaping diabetes treatment across the United States. In recent years, as the population of patients with diabetes continues to grow and as the cost of treatment continually rises, pharmacy benefit managers (PBMs) have gone beyond the traditional (ie, progressive formulary tiers, prior authorization, step edits) management techniques by using more aggressive restrictions in an effort to control spending on pharmacy. We propose, however, that it is time for payers to respond to this innovation with innovation of their own to advance diabetes care, improve patient satisfaction, and deliver measurable quality outcomes. Diabetes is a journey, and short-term cost-savings do not support the Triple Aim.

## Formulary Management Trends—Cause and Effect

The Academy of Managed Care Pharmacy defines formulary management as “an integrated patient care process which enables physicians, pharmacists and other health care professionals to work together to promote clinically sound, cost-effective medication therapy and positive therapeutic outcomes.”<sup>1</sup> Ideally, drug formulary management should facilitate quality patient care through the selection of medications that maximize value relative to cost. In addition, physicians should play an integral role throughout the formulary development process and should have the opportunity to request modifications to formulary utilization policies to avoid the common perception that formularies diminish physician autonomy and authority.<sup>2</sup>

Despite genuinely held commitments supporting patients and providers through effective formulary management, the fact remains that health insurers’ and PBMs’ primary function is to contain costs.<sup>3</sup> Payers’ purchasing

power is the primary counterweight against excessive pricing by drug manufacturers during a drug’s market exclusivity.<sup>4</sup> As payers and PBMs have gained influence, they have extracted substantial rebates and other price concessions from pharmaceutical manufacturers in exchange for favorable formulary positioning.

This practice creates a widening gap between the price of a drug (set by the manufacturer) and the heavily discounted price PBMs receive. Although the rebates and discounts favor PBMs, which can profit from the price spread, the growing list prices of drugs are a challenge for members who pay full price, including patients who are uninsured, those with high-deductible health plans, those who fall into the Medicare Part D donut hole, and patients whose medications are excluded from formularies.<sup>5</sup>

## PBM Exclusion Lists

Formulary exclusion lists have emerged as a powerful tool used by PBMs to gain negotiating leverage against pharmaceutical manufacturers by blocking access to certain medications. PBMs essentially “force” manufacturers to offer greater rebates or risk being excluded from their formularies. Express Scripts’ 2017 formulary exclusion list consists of 85 drugs (versus 87 in 2016), and CVS Health’s 2017 list has 154 drugs (compared with 124 in 2016).<sup>6</sup>

It is important to remember that these formulary restrictions are part of a PBM’s recommended national formulary; these are suggestions, not mandates. Plan sponsors (ie, health plans, unions, and employers) have the option to customize their formularies, and should ask potential PBMs specific questions about formulary exclusions before entering into a contract. Potential questions include:

- What drugs are excluded, and how does that differ from the previous year?
- Can our members keep using their current therapy to promote adherence?
- How many members will be affected, and what are the estimated associated medical costs related to switching drugs?

The formulary exclusion lists are promoted by the largest PBMs (ie, Express Scripts and CVS Health), and

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their credibility on this issue is called into question by several healthcare stakeholders, because in several therapeutic areas one PBM prefers a drug that the other excludes. For example, CVS Health excludes several insulin drugs from Eli Lilly, and prefers drugs from Novo Nordisk instead, whereas Express Scripts does the opposite.<sup>7</sup>

Although PBMs play a crucial role in negotiating with pharmaceutical manufacturers on behalf of health plans, unions, and employers to contain ever-rising drug costs, PBMs also generate controversy because of a lack of transparency. Some of their sponsors have expressed concerns that PBMs include more costly medications on their formularies than less expensive options to enhance their own rebate revenues.<sup>8</sup> PBMs have also been challenged on the extent to which they pass along their rebates, and on pocketing those funds instead.<sup>9</sup>

Because these negotiations take place behind closed doors, the extent to which these practices take place is unclear. Results from a study conducted by the Tufts Center for the Study of Drug Development predict that payers and PBMs will continue to embrace aggressive approaches to formulary management, which will challenge the pharmaceutical industry to provide evidence of their drugs' clinical superiority and cost-effectiveness.<sup>10</sup> The Tufts study investigators note, however, that no comparative clinical or cost-effectiveness studies were conducted for 10 of the 16 drugs excluded by CVS Caremark and by Express Scripts.<sup>10</sup>

### Nonmedical Switching of Drugs

Drug switching for nonmedical reasons occurs when a health plan or a PBM makes changes to the formulary to put monetary pressure on patients whose diseases stabilized to cease filling their prescribed medication, and instead switch to a preferred or a less expensive therapeutic equivalent, but not necessarily generic, drug.<sup>11</sup> The switch is often done without the knowledge of, or notice to, the prescribing physician.<sup>12</sup> Reasons for doing so could include<sup>13</sup>:

- Increase the profits of a private insurer
- Reduce costs for a government agency or an employer
- An arrangement between the payer and a specific drug manufacturer to favor said manufacturer's drug.

Many patients with complex or chronic conditions have undergone years of a painful trial-and-error period to find the treatment that produces the best outcomes with the fewest side effects. For these patients, nonmedical drug switching may put their health at risk by causing adverse events or decreasing the efficacy of their therapy. These unintended health consequences may also result in increased emergency department visits, hospitalizations, physician visits, and laboratory tests, which drive up overall healthcare spending.<sup>14</sup>

An additional irony of nonmedical switching is that, in some cases, the consequences may cost more than would the coverage of the original drug, despite a difference in price. A patient whose disease is stabilized with a particular regimen, and who is then "forced" to find a different medication, may require multiple visits to the physician's office, and in some cases may even end up in the emergency department before a suitable alternative is found (if one exists). Nonmedical switching places payers' profits ahead of good medicine and disrupts physician-patient relationships, which are particularly crucial for patients with chronic conditions.<sup>12</sup>

**If payers do not address concerns about drug exclusion lists and the resulting nonmedical switching, the government will step in to protect its citizens.**

If payers do not address concerns about drug exclusion lists and the resulting nonmedical switching, the government will step in to protect its citizens. Several states have already begun the process of implementing legislation to protect healthcare consumers from the well-intentioned, but potentially harmful, actions of cost-focused payers.<sup>12</sup>

When patients select a health plan, which is a major purchase, they typically plan to stay with that plan for several years. The benefits offered by those plans should also last for years.<sup>12</sup>

### Case Study: Basaglar

Diabetes was the second most expensive therapeutic class in Express Scripts' 2016 *Drug Trend Report*; insulin drugs accounted for 40% of drug spending for patients with diabetes.<sup>5</sup> The billions of dollars spent on diabetes medications annually include new drugs, price increases, and a growing population of Americans living with diabetes—approximately 28 million people.<sup>5</sup>

Although Basaglar (insulin glargine injection), which was approved by the US Food and Drug Administration (FDA) in December 2015, is often referred to as a biosimilar to Lantus (insulin glargine injection) and has been classified as such in Europe, it has not received a biosimilar designation in the United States. Instead, the FDA calls it a "follow on" (ie, a therapeutic equivalent but not identical) to Lantus. Basaglar was the first insulin drug approved through the FDA's 505(b)(2) pathway, which is an abbreviated approval process that allows some of the information about the drug's active ingredient to come from clinical trials that were not conducted with the drug in question.<sup>5</sup>

**Table** Survey Results: Impact of Medication Switching on Patients with Chronic Diseases

Survey respondents (N = 62) , %	Patient responses
61	Tried several medications before finding the one that worked for me
58	The new medication switched to was less effective than the original drug
77	Had side effects after switching to the new drug
84	Had "negative physical impact" from nonmedical switch, and missed work or was hospitalized
88	Reduced disease control when formulary changes delayed access to the original drug prescribed

*Source:* Global Healthy Living Foundation. Survey finds insurance companies are forcing Floridians off prescribed medications during the plan year, providing a need for new legislation to fix the problem. Press release. January 17, 2017.

The maker of Basaglar achieved an impressive victory even before it was launched officially, when CVS Caremark excluded Lantus and Levemir (insulin detemir [rDNA origin] injection) from its national formulary, making Basaglar the only covered basal insulin and resulting in nonmedical switching of patients from Lantus or Levemir to Basaglar. Although the CVS national formulary does not affect all patients, it does affect individual states' markets and small group health plans. UnitedHealthcare made a decision similar to that of CVS Caremark and placed Basaglar on its preferred formulary tier. Express Scripts, however, opted to keep Lantus and Levemir on its national preferred formulary tier.<sup>5</sup>

**Payers maintain strict formularies to guard against prescribing that strays too far from clinical guidelines, but it is possible to develop more flexible formularies that include clinically justifiable therapies that account for patients' clinical attributes and preferences.**

These decisions by CVS Caremark and UnitedHealthcare will force some prescribers to switch some of their patients, including those whose conditions are currently well-controlled, from a branded insulin drug to the follow-on Basaglar. This nonmedical switch is not well-received by many clinicians and their patients, because they will have little—if any—say about which drug is dispensed unless they bear the full cost of their current medication. According to Yehuda Handelsman, MD, endocrinologist in Tarzana, CA, and past president of the American Academy of Clinical Endocrinology, forced switching could be harmful to patients whose disease was stable and well-controlled with use of an

existing insulin drug.<sup>5</sup> According to the FDA, "Switching insulin should always be done in consultation with a physician and requires close medical supervision, and if possible, close monitoring of blood glucose."<sup>15</sup>

### Advantages of Physician–Patient Shared Decision-Making

In traditional economic terms, value is in the eye of the consumer, but healthcare value for consumers has been defined by how patients perceive it rather than by how much they actually pay for it. Healthcare is financed in an arrangement that separates patients and payers. Patient assessments of healthcare treatments and services are made based on more than efficacy and direct costs.<sup>16</sup> Patients care about a range of outcomes, including productivity in the workplace, burden on family members and caregivers, and the ability (or inability) to enjoy their activities. Collecting evidence of patient desires and wishes reveals which attributes patients truly care about, such as a treatment's safety, efficacy, route of administration, dosing frequency, and side effects, among others. A recent survey of patients with chronic diseases captured the impact of medication switching on patients (Table).<sup>17</sup>

Patients care about opportunities to improve medically, or about the risks of doing worse than anticipated. They do not single-mindedly consider each healthcare decision but rather how each decision will affect their ability to live well. Individual patients also think differently about their condition, even when grappling with similar health scenarios. Currently, most approaches to value assessment seek a common denominator, or identify a single indicator of value. Although this is relevant to payers who make coverage decisions at a population level, it is not helpful for patients as they decide how to allocate their time, effort, and financial resources, or to physicians who seek to customize care to their patients' individualized needs.<sup>16</sup>

Value assessments need to take into account the preferences and circumstances of individual patients.<sup>16</sup> Patients need timely, usable information about their financial responsibilities and about the potential benefits and side effects of various treatment alternatives. Payers, too, can benefit from this redefined approach to evaluating value-based care. Payers maintain strict formularies to guard against prescribing that strays too far from clinical guidelines, but it is possible to develop more flexible formularies that include clinically justifiable therapies that account for patients' clinical attributes and preferences. A range of therapies may be clinically indicated for an individual patient, but that patient's preference could vary based on nonclinical dimensions. A flexible formulary would allow patients and physicians to choose among clinically valid formularies based on attributes that matter to the patient.<sup>16</sup>

Such a flexible approach to formulary design would go hand in hand with the increasing financial responsibility shouldered by patients in terms of high deductibles and copayments. As patients take on a greater portion of the cost of their own healthcare, it is reasonable to expect that their preferences and values be better represented in coverage decisions.

Ultimately, a patient-centered approach to assessing value will serve all healthcare stakeholders. Providers can better meet the needs of their patients through shared decision-making, payers can compete more effectively by generating higher levels of member satisfaction, and policymakers can benefit from marketplace decisions that line up more closely with value.<sup>16</sup>

### Recommendations for Improvement

Health plans and PBMs have an obligation to protect commercially insured patients who have complex, chronic, and rare medical conditions from the risks associated with practices that limit access to medically necessary treatments or interfere with the physician–patient relationship in favor of cutting costs (eg, drug exclusion lists and nonmedical switching).

Several states have already begun to explore legislative options to protect such patients. Payers should consider voluntarily implementing the following strategies to protect their members:

- Take action to return decision-making about drug therapy to physicians and patients, using management techniques that provide affordable options to the “right” medications, and eliminate nonmedical switching
- Create an independent, multidisciplinary panel of clinical experts not affiliated with the payer to provide input and evidence throughout the formulary development process
- Provide physicians with the opportunity to request modifications to formulary utilization policies to avoid the common perception that formularies diminish physician autonomy and authority to improve shared decision-making
- Ensure consistent coverage of previously approved medications that have successfully stabilized the patient’s condition when no generic equivalent is available
- Enable continued use of previously approved medications by maintaining consistent formulary coverage and out-of-pocket costs throughout the respective plan
- Eliminate exclusion lists for drugs that represent a therapeutic equivalence but are not identical; instead,

consider implementing a single-tier difference in formulary design to suggest, rather than mandate, use of a preferred drug.

By taking such steps, payers can still manage costs, while also ensuring that physicians’ and patients’ definitions of value are adequately being considered. ■

### Author Disclosure Statement

Mr Branning and Ms Vater are with Managed Market Resources, which provides consulting services to many pharmaceutical companies. Ms Worthy has no conflicts of interest to report.

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