Safe Step Act: does it undermine step therapy?

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Abstract

Drug expenditure in the United States has continued to increase unsustainably; the specialty of dermatology has been particularly affected. Resources are limited — someone has to make decisions about what treatments will be covered and how they will be reimbursed. Step therapy is a cost-control method used by insurers to encourage the use of the most cost-effective treatments before more expensive options are attempted. However, a rigid step therapy policy can be problematic when protocols are out of date, or delay necessary treatment leading to unnecessary suffering, increased morbidity, and overall cost. To address some of these concerns, the proposed Safe Step Act (S. 2546 and H.R. 2279) attempts to create a requirement that insurers provide a transparent, expeditious exceptions process for step therapy protocols. Increased flexibility in this process will allow for the unique circumstances of individual patients and improve access to expensive drugs for special cases. However, this bill may be exploited, further weakening insurers' ability to negotiate on cost. We should be cautious about measures that reduce the effectiveness of this tool, particularly if we, as a society, aim to expand access to basic care to all Americans.

Keywords: step therapy, prior authorization, Safe Step Act, cost-control, insurers, insurance

Introduction

With new (and often expensive) medication to treat disease, drug expenditure continues to spiral upward. The specialty of dermatology, with its high-priced topicals and biologics, has seen substantial increases in drug spending [1]. Resources are limited and someone has to decide which treatments will be covered and how they will be reimbursed. Some countries manage limited resources by making top-down choices using cost-effectiveness and opportunity cost analyses, but in the United States our decentralized system is based on competition to control cost. Patients are, to a large extent, insulated from the cost of healthcare by their insurers. This leaves insurers in the position to negotiate with healthcare providers (hospitals, pharmaceutical companies, physicians) to provide patients quality healthcare at an affordable price.

Step therapy

One tool insurers use to control cost is step therapy (**Table 1**). Step therapy is a cost-control method that is being used by most commercial insurers and more recently, Medicare Part D to encourage the use of the most cost-effective treatments before more expensive options are attempted [2, 3]. Step therapy reduces drug costs by encouraging greater use of lower-cost options [4]. Insurers restricting access to expensive options put pressure on pharmaceutical companies to lower prices to make these options more cost-effective and more viable. This helps control the price of insurance for all people and leaves more resources available to fund access to other treatment needs [5].

Disease in individuals is complex with no one-size-fits-all treatment. A rigid step therapy policy can be problematic when protocols are out of date or delay necessary treatment leading to unnecessary suffering, or worse, irreversible disease progression,

Table 1. *Step therapy advantages and disadvantages [2, 5].*

Advantages	Disadvantages
Reduces drug costs by encouraging greater use of lower-cost options	Could delay necessary treatment leading to increased morbidity and cost
Restricting access to expensive options puts pressure on pharmaceutical companies to lower prices	Administrative burden (time and cost)
Leaves more resources available to fund access to other treatment needs	Out of date protocols

increased morbidity, and overall cost. Step therapy increases the already heavy administrative burden at all levels of our system for the provider, staff, and insurer — which equates to further delay in treatment and increased costs [5].

Safe Step Act

To address some of these downsides, a proposed amendment (Safe Step Act; S. 2546 and H.R. 2279) to the Employee Retirement Income Security Act of 1974, is attempting to create a requirement that insurers provide a transparent, expeditious exceptions process for any medication step therapy protocol. Although many states have already passed similar legislation, this bill takes this regulation nationally. This bill requires decisions to be made within a reasonable time frame (72 hours). Increased flexibility in the step therapy process will allow for accounting for the unique circumstances of individual patients and more access to expensive drugs for special cases. The Safe Step Act makes changes providing a path to exception if treatment is contraindicated, is expected to be ineffective, will cause an adverse reaction, or will decrease the ability to perform daily activities, occupational responsibilities, or adhere to the treatment plan. An exception will be also be granted if a patient is already stable on a treatment already selected [6].

Limitations

The Safe Step Act was created with the best of intentions and does standardize a step therapy exceptions process. However, these changes are vaguely written and depending on how they are interpreted, could be exploited, weakening insurers' ability to negotiate on cost. One example is §716(b)(4)(B), which states that exemptions to step therapy may be made if the provider believes that a therapy will have poor adherence. Exemptions that could allow almost anyone to bypass cost control steps may unintentionally worsen the cost problem. Additionally, this bill fails to streamline the administrative burden of step therapy and will likely not reduce the paperwork or cost burden on providers. Specialized medicines like biologics are inherently expensive, even if insurers are successful at transparently reducing their unit cost. There is no free lunch and ultimately, if we want to maintain access to these medicines, we as a society must pay. Weakening step therapy will likely increase costs and may not much improve outcomes.

We want the best for *all* patients, but resources are limited. To optimize care for the entire population, the use of the most cost-effective options has advantages. Physicians have to be focused on giving each patient the best available care, a goal that, at times, may conflict with the need to ration resources for the optimal benefit of all patients. In the United States, insurers have a role in making difficult cost-conscious decisions. Whether insurers should be making these decisions is an important question, but someone must. Will the patients, the doctors, the payors, or the government take on the responsibility for considering costs? There is not an ideal answer. Step therapy is a mechanism by which insurers currently encourage cost-effective care. We should be cautious about measures that reduce the effectiveness of this tool, particularly if we, as a society, wish to expand some level of basic care to all Americans.

Potential conflicts of interest

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Menlo, Merck, Novartis, Regeneron, Sanofi, Novan, Qurient, National Biological Corporation, Caremark, Advance Medical, Sun Pharma, Suncare Research, Informa, UpToDate and National Psoriasis Foundation. He is founder and majority owner of www.DrScore.com and founder and part owner of Causa Research, a company dedicated to enhancing patients' adherence to treatment. Arjun M. Bashyam and Phillip M. Williford have no conflicts of interest to disclose.

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