

How does the Safe Step Act impact patient care in dermatology?

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BACKGROUND ON STEP THERAPY

- In the US, prescription drug expenditures have continued to rise, especially in the field of dermatology with expensive topical and biologic treatments for conditions such as psoriasis and psoriatic arthritis
- To contain costs, insurers are using strategies like step therapy
 - Requires the trial of cost-effective treatments prior to more expensive ones in a systematic manner
- While step therapy can provide large savings in drug expenditure, this may be offset by increases in healthcare costs from outpatient visits and hospitalizations
- Negative views regarding step therapy more common among physicians in medical subspecialties compared to primary care physicians

SAFE STEP ACT

- The Safe Step Act is a bipartisan bill introduced in 2019 requiring insurers to provide a transparent, expedient exception process for any medical step therapy protocols
- Five circumstances for exemptions:
 - 1) Treatment expected to be ineffective
 - 2) Treatment contraindicated
 - 3) Delay in treatment would cause severe consequences
 - 4) Treatment prevents individuals from fulfilling ADLs
 - 5) Individual is already stable on a treatment previously approved by insurer

	Impacts of Step Therapy	Impacts of Safe Step Act
Patients	<ul style="list-style-type: none"> • Reduce the cost of medications • Delays patients from obtaining necessary medications in a timely manner • Undesired adverse reactions from drugs in intermediary stages • Associated with lower odds of treatment effectiveness and adherence in patients 	<ul style="list-style-type: none"> • Quicker access to necessary medications • Prevents severe or irreversible harm to patients due to treatment delays or adverse effects of preliminary drugs
Physicians	<ul style="list-style-type: none"> • Insurance formulary often does not agree with first-line choice of dermatologists • Creates dissatisfaction amongst community dermatologists • Consumes the time of physicians • Creates additional administrative and financial burden to dermatology practices 	<ul style="list-style-type: none"> • Enables physicians to bypass the step therapy protocol to provide patients with necessary medications • Exceptions process may not mitigate administrative burden and costs faced by dermatology clinics
Insurers	<ul style="list-style-type: none"> • Large savings in drug expenditure due to greater use of lower-cost alternatives • Provides leverage to negotiate lower costs for prescription drugs 	<ul style="list-style-type: none"> • If exemption process is exploited, weakens step therapy and decreases ability of insurers to control costs and negotiate prices

Figure 1. Impacts of step therapy and the Safe Step Act on patients, physicians, and insurers.

DISCUSSION

- The Safe Step Act addresses some of the downsides of step therapy:
 - Provides quicker access to necessary medications for patients
 - Prevents severe or irreversible harm to patients due to treatment delays or adverse effects of preliminary drugs
- However, the bill could do more to reduce the administrative burden and costs faced by dermatology clinics undergoing the prior authorization process
- Given the inherently high costs of novel targeted and biologic therapies, there is no ideal solution
 - Some entity, whether patients, providers, insurers, or the government, must take responsibility for these costs

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