## **EDITORIAL COMMENT**

# **Prior Authorization**

## Overwhelming Burden and Critical Need for Reform\*

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igh health care expenditures in the United States have prompted health insurance carriers to increasingly rely on utilization management strategies such as prior authorization (PA) to lower costs. This process is plagued by inefficiency and overwhelming administrative burden at the expense of patient safety. Patients wait for decisions regarding coverage approval for days or weeks, only to find that their coverage is denied. Unfortunately, the patients who most require these services can least afford care delays.

In this issue of *JACC: Case Reports*, Chowdhury et al. (1) describe a case of a patient who developed drug rash with eosinophilia and systemic symptoms syndrome leading to eosinophilic myocarditis and cardiogenic shock. The patient did not respond to high-dose steroids and immunosuppression but quickly improved with tofacitinib, a *JAK1/3* (Janus kinase 1/3) inhibitor. Following discharge, the insurance carrier denied further coverage of this medication. The patient could not afford its cost, stopped taking it, and then needed to be rehospitalized for recurrent cardiogenic shock. Tofacitinib was reinitiated with rapid clinical improvement.

Reports of adverse patient outcomes resulting from PA requirements are not uncommon. In a recent

American Medical Association survey on PA (2), 91% of physicians reported that patients requiring necessary care experienced care delays, and 75% of patients abandoned their treatments because of obstacles associated with the PA process. Overall, 91% of physicians believed that PA negatively impacted patient outcomes. Recent studies have demonstrated how PA directly results in patient harm. When PCSK9 (proprotein convertase subtilisin kexin type 9) inhibitors were first introduced, over 45,000 patients received prescriptions within the first year of Food and Drug Administration approval. Only half received coverage approval and one-third of those approved abandoned treatment because of high copays (3). Patients who were denied coverage or discontinued treatment had significantly higher rates of acute coronary syndrome, coronary intervention, stroke, and cardiac arrest compared with those who took the medication (4).

To prevent these adverse outcomes, clinicians invest significant resources to ensure that appropriate care is accessible to patients. Physicians and staff spend over 20 h/week interacting with health plans. That translates to an annual opportunity cost of approximately \$70,000 per practice and \$31 billion nationally (5). The amount of time wasted on these nonclinical activities is a leading cause of physician burnout (6,7).

In response to the heavy load PA places on clinicians, the American College of Cardiology (ACC) has been actively working to find solutions. The ACC Prior Authorization Reporting Tool (PARTool) was developed to collect PA denial information. Preliminary data establish that many PA requests are denied even though such services are deemed "appropriate" based on appropriate use criteria. Over 50% of denied services either do not lead to further peer-to-peer discussion or are denied despite appeals (8). In response, the ACC established guiding

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	State	Bill	Status	Requirements					
Year				Disclose PA Services and Requirements	Specify Notification Time of PA Changes	Specify Duration of PA Validity	Prohibit Retrospective Denial of Previously Approved PA	Prohibit PA for Emergency Services	Deadline for
2016	Ohio	SB 129	Signed	Х	Х		Х		Х
2016	Delaware	HB 381	Signed	Х	Х	Х	Х		Х
2018	New Jersey	A3845	Introduced	Х			Χ	Χ	Х
2019	Colorado	HB 19-1221	Signed	Х	Х				Х
2019	Kentucky	SB 54	Signed	Χ	Х	X			
2019	Montana	HB 555	Signed	Х	Х	X			Х
2019	Virginia	SB 1607	Signed						Х
2019	West Virginia	HB 2351	Signed	Х		X			Х
2019	New York	A04521	Introduced		Χ	Χ			
2019	Pennsylvania	SB 920 HB 1194	Introduced	Х					Х
2019	National	HR 3107	Introduced	Х					
2020	Washington	SB 6404	Signed						
2020	Illinois	HB 510	Introduced	Х			Χ	Χ	Х
2020	Minnesota	SF 3204	Introduced	Х	Х		Х	Х	Х
2020	Oregon	HB 4102 A	Introduced						
2020	Florida	SB 820	Died	Х	Х				Х
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principles for PA reform (9) and has set a foundation for advocacy efforts at the state and national levels.

In 2016, the first bill (Senate Bill [SB] 129) addressing PA reform was passed in Ohio (10). SB 129 improved transparency and streamlined the PA process. Insurance carriers are mandated to

disclose requirements for PA approval and provide 30-day notice of any new requirements before implementation. Insurers must provide approval decisions within specified deadlines, and once PA requests are approved, they cannot be retroactively denied. Converting PA to an electronic format also streamlined the appeals process. By engaging key

stakeholders including state medical societies, the Ohio bill passed without significant opposition.

Delaware also enacted PA reform (House Bill [HB] 381) following a 2011 case that garnered national attention when a patient was denied nuclear stress testing despite 2 physician appeals (11). Thirty-five days later, the patient presented to the emergency department and underwent urgent coronary artery bypass surgery. HB 381 carries many similar provisions to SB 129, but one key difference is that it specifies the duration of validity for approved PAs: medications for 1 year and services for 60 days (12).

In recent years, PA reform has gained traction in many states, with bills progressing through various stages of the legislative process (Table 1) (1) Most states have not achieved the same success as Ohio and Delaware because the bills are undermined by insurance lobbyists. Washington SB 6404 only requires carriers to provide data regarding approved, denied, and appealed requests (13). Other states have passed bills that are limited in scope but introduce new elements. Colorado HB 19-1211 urges carriers to limit the use of PA to providers whose practice patterns differ significantly from their peers (14). Virginia SB 1607 maintains continuity of care when patients transition between plans by mandating that previously approved PAs must be honored for a specified period (15), while West Virginia HB 2351 stipulates that PA appeals must be performed by a practitioner in a similar specialty (16). Additional states have introduced new legislation in the past 2 years (17-26).

At the national level, H.R. 3107 was introduced in 2019 (27). It strives to improve efficiency of the PA process for Medicare Advantage program participants. Under this bill, health plans would be mandated to standardize PA requirements, make the process electronic, automate decisions for routinely approved services, and increase transparency by reporting PA request statistics.

As this case report highlights, prior authorization can cause harm to patients and places overwhelming burdens on clinicians. To ensure patient access to timely, evidence-based care, PA must be regulated and standardized. Although several states have made progress in improving this process, many others still face considerable obstacles. Bringing key stakeholders together, including state medical societies, patient advocacy groups, and insurance plans, is critical to implementing meaningful PA reform. Now is the time.

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