VIEWPOINT

Refocusing Medication Prior Authorization on Its Intended Purpose

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Viewpoint

Author Audio Interview

During the 1980s, prospective utilization review programs deployed by US health plans focused on screening the appropriateness of hospital admissions and high-cost procedures. As prescription drug coverage became more widespread and spending on pharmaceuticals increased, commercial and public insurers expanded utilization management to include medication prior authorization, quantity and dosage limits, and step therapy requirements. Applied in concert with restricted formularies and tiered patient cost sharing, these measures were initially directed during the 1990s and early 2000s at a narrow set of newer, high-cost drugs that insurers judged to offer limited benefit or higher risk over existing, less expensive alternatives.

However, prior authorization has expanded during the last decade to involve larger shares of formularies in commercial and government plans. Prior authorization requirements increased from 8% to approximately 24% of covered drugs on Medicare Part D plans between 2007 and 2019.[1] In 4 therapeutic classes (including antidepressants, autoimmune disease immunotherapies, multiple sclerosis agents, and antineoplastic drugs for chronic myeloid leukemia), application of prior authorization/step therapy on commercial formularies increased from 35% of single-source drugs approved for at least 1 year in 2011 to 67% in 2016.[2] Physicians expect challenges when prescribing newer specialty drugs, but major formularies in some instances now require prior authorization/step therapy even for established generic products that have no obvious lower-cost substitutes, including topical corticosteroids, oral immunosuppressive agents, HIV antiretroviral medications, sulfonylureas for diabetes, and oral antineoplastic drugs for cancer.

Although prior authorization programs may help insurers address outlier prescribers who choose higher-cost brand-name options without medical justification at rates far higher than their peers when there are similarly effective alternatives, those practicing medicine based on evidence and experience and attempting to be good stewards of resources may be unable to avoid the substantial work involved in gaining plan approval for appropriate prescriptions. A 2018 survey of 1000 practicing physicians across multiple specialties found that they reported completing a mean of 31 prior authorizations for medications and procedures per week, with a mean of 15 hours in time spent seeking authorizations.[3] A national online prior authorization submission platform reported a 55% increase in prescriptions requiring prior authorization each January and February due simply to formulary modifications and patients switching plans.[4] Of 8.1 million Medicare Part D prior authorization requests for medications in 2017, 35% were initially rejected, but 73% of appealed denials were ultimately overturned,[5] suggesting that many initial denials of coverage are inappropriate.

The extensive friction that prior authorization has created, affecting patients, physicians, and practices, can have adverse consequences, even when requests or appeals are ultimately approved. The opacity of frequently changing formularies and prior authorization requirements means that prescribing physicians do not know which treatment options will be filled without delays. Patients arriving at pharmacies to pick up medications and initiate treatment are sometimes surprised to learn that further action is required by their physician to seek health plan approval. Thus begins a process that often includes faxes sent from physician offices to health plans, initial rejections, written appeals, and "peer-to-peer" telephone calls with adjudicators who sometimes are not familiar with the disease or the disputed medication or who may suggest inappropriate alternatives. According to one report, during this prior authorization process, 37% of prescriptions initially rejected at the pharmacy are abandoned, never to be picked up by patients.[6] This may explain why prescription prior authorization implementation for medications to treat diabetes, depression, schizophrenia, and bipolar disorder has been associated with worsening disease status, increased hospitalization, and higher net medical costs.[7,8]

Medication prior authorization does not operate in isolation and is tied to other US health care trends. The accelerating introduction of high-cost specialty drugs, slow entry of biosimilars delayed by patent litigation, and increasing prices for protected brands and even some generics have driven insurers to expand cost-containment strategies. The business model of pharmacy benefit managers retaining a percentage of the confidential rebates they negotiate from manufacturer list prices can incentivize preferred formulary status for drugs with larger rebates even when their costs are higher. Lack of transparency with rebates and the resulting formulary unpredictability exacerbate the difficulties prescribers face selecting drugs that are likely to be covered. The United States consumes far more of its heath expenditures on administrative tasks than virtually any other country in the world,[9] and work by both prescribers and health plans to manage the large volume of prior authorization requests likely contributes to those expenditures.

Under the expanded use of medication prior authorization, both physicians and patients are experiencing a challenging and often exhausting burden that has raised calls for prior authorization to be rightsized and simplified. A few states have passed, and several others are contemplating, legislation that mandates public disclosure of prior authorization requirements and denial statistics, sets time limits for determinations,

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implements minimum approval durations, or requires acceptance of electronically transmitted requests. Congressional bills have been introduced that mirror many of these provisions. The Centers for Medicare & Medicaid Services is exploring regulatory changes to reduce prior authorization workload through its "Patients Over Paperwork" initiative. In January 2018, organizations representing physicians, pharmacists, hospitals, and health plans signed a consensus statement agreeing to strategies for improving the prior authorization process and reducing needless administrative work.[10] However, the recommendations of the initiative have not been substantially implemented by the health plan signatories.

The following reasonable changes could reduce the burden of prior authorization while preserving the ability of health plans to focus utilization review efforts on the outlier prescribers and high-cost therapies with unwarranted variation for which they were designed.

First, focus prior authorization on its intended purpose. Health plans should eliminate prior authorization requirements for medications that have very low final denial rates, lack evidence of unwarranted variation in utilization, or for which lower cost or safer but effective alternatives do not exist. Health plans should also deploy programs that selectively implement prior authorization based on an individual prescriber's or group's prior approval rates and should focus on outliers rather than putting all clinicians through the same high level of review and burden. Similar to the government's Pre-Check program for airline passengers, health plans have historical data that could be used to stratify and exempt low-risk prescribers with established track records and periodically reevaluate them for program renewal.

Second, protect continuity of patient care. For patients who are stable with chronic treatment, insurers should offer protections to minimize disruptions and inefficiencies that occur when patients change health plans or when plans add new prior authorization/step therapy requirements to existing formularies. These could include consistent grace periods for patients switching plans, protection from new prior authorization/step therapy restrictions implemented outside beneficiary enrollment periods, and protection from requirements to retry previously failed therapies.

Third, promote transparency, efficiency, and fairness. Technology exists to enable prescribers to view the formulary status, prior authorization requirements, and cost sharing for medications and alternatives in electronic health records (EHRs) while face-to-face with a patient at the point of care; however, this information remains unavailable for most patient-physician encounters because health plans, pharmacy benefit managers, and EHR vendors have not yet agreed to finalize universal electronic standards or make all of the necessary data accessible. Individual health plan websites with myriad downloadable formulary documents are impractical, as are proprietary real-time pharmacy benefit check tools that exist outside prescribing workflows and only work with certain plans, pharmacy benefit managers, or EHRs. Prescribers should be able to see formulary, prior authorization/step therapy, and cost status in a single real-time pharmacy benefit check tool integrated into their workflow and submit prior authorization requests via secure electronic transmissions directly from their EHR interface. When prior authorization rejections require appeals, cases should be reviewed in a timely fashion by someone of the same specialty who has knowledge of the condition and medication.

Conclusions

Rather than an unrealistic call to abolish prior authorization, these are balanced proposals intended to refocus medication utilization review tools on the appropriate use of high-cost new drugs for which the benefits, risks, and value are still being evaluated. The unconstrained expansion of prior authorization as a blunt cost-saving tool applied to an increasing number of medications across formularies has unnecessarily exacerbated care delays for patients and further redirected physician time and effort away from patient care toward burdensome administrative duties that foster frustration and consume resources.

ARTICLE INFORMATION

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Conflict of Interest Disclosures: Dr Resneck serves as immediate past chair of the Board of Trustees of the American Medical Association. Dr Resneck also serves on the board of directors of the National Quality Forum. Dr Resneck reported serving as an expert witness within the last 3 years; however, none of the cases was focused on the topic of prior authorization.

Disclaimer: The views expressed are those of the author and do not necessarily represent the views of the American Medical Association.

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