A Proposed Way Forward From the Prior Authorization Crisis in Radiation Oncology

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Abstract

The use of prior authorization (PA) by medical payers has expanded in recent years beyond its initial focus on limiting the use of unproven, high-cost treatments and is now more frequently being used to limit access to guideline-concordant treatments and generic medications. This has been accompanied by a similar expansion of administrative demands for physicians to comply with PA requests, requiring hours of additional time per week, especially for resource-intensive specialties like radiation oncology. Here, we discuss the current landscape of PA use in radiation oncology and propose actionable steps that can be taken to improve the process for patients, clinicians, and payers alike. By streamlining electronic practitioner-payer communication, increasing transparency around payers' PA requirements, and providing a path to waiving PA requirements for select cases, we can establish a system in which patients are able to receive the best possible care in a timely, cost-efficient, and evidence-based fashion.

Keywords: radiation oncology, prior authorization, preauthorization, medical economics, health care spending, advocacy, insurance, reimbursement

Introduction: Prior Authorization Defined

Prior authorization (PA) is a management process applied by health care insurers to a list of services and medications that requires case-bycase review to determine whether a proposed treatment will be covered.1 The expanding set of services subject to PA is determined unilaterally by the payer. These policies vary by insurer and are changed frequently, creating a system of low predictability for physicians and their patients.2 Given the burdens this process also creates for the insurers themselves, many have turned to third-party businesses known as resource benefits managers (RBMs) to carry out their policies.3

The ubiquitous PA requirements of the current practice environment

have created a medical system where, for each patient, physicians must first determine whether a proposed service will require PA and, if so, whether it is likely to qualify for payment through the particular insurer. ^{2,4,5} If a proposed service is unlikely to be approved, physicians might decide not to pursue the medically superior treatment and instead pivot to a more easily approved alternative. If they do elect to pursue PA for a service, physicians are generally required to submit documentation — in some circumstances, remarkably, on paper

via fax — regarding the patient's characteristics and proposed treatment. This will often include completing forms or entering data that is already present in the medical record, creating a wasteful burden on clinicians and their staff without providing reimbursement for additional time spent.² The required information, the timeliness of its submission, and the timeliness of payer's response are all unilaterally decided by the insurers/ RBMs and vary across the industry, creating a chaotic experience for clinicians and patients alike.

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If authorization is denied, a peerto-peer consultation is often the next step.6 In this process, the physician will discuss the case with a physician employee of the insurer or an RBM to explain the justification of the proposed treatment. However, the effectiveness and collaborative nature of this process varies widely. First, the scheduling of this conversation is often established by the insurers without regard for the physician's availability. Physicians may be expected to interrupt a sensitive consultation with a patient, an important meeting, or an after-hours family gathering to accommodate the payer's schedule. In addition, the qualifications of the "peer" with whom the provider discusses the case can be highly variable and may not even be from the same field (eg, primary care doctors reviewing radiation oncology requests), which obviously makes the review far less substantive and representative of the state-of-the-art. Lastly, the authority of the "peer" to authorize treatment also varies greatly, with some simply able to reiterate that the proposed care is not covered without any insight into the individual case, creating only a façade of case review.

Finally, if the proposed care is still not approved after peer-to-peer review, the physician can either file an appeal or pursue an alternative treatment option. Again, this appeals process is unilaterally under the control of payers and is inconsistently defined and managed across the industry. This phase of the process can be exceptionally long and creates a dilemma: since a delay in treatment can negatively impact prognosis, physicians must weigh whether fighting for their perceived optimal care is worth the impact of delays on patient outcomes.

Radiation oncology is a resource-intensive field that is heavily impacted by PA, causing professional societies like the American Society for Radiation Oncology (ASTRO) and American College of Radiation

Oncology (ACRO) to devote significant efforts to highlight the burden of PA in the field and to engage with government stakeholders to advocate for PA reform.7-10 To illustrate the extent of this impact, a recent study analyzing claims from a wide variety of specialties found that radiation oncology had the highest rate (97%) of services that require PA.4 Here, we review the background behind the establishment of PA, detail the radiation-oncology-specific burdens and consequences associated with the current system, and present concrete proposals for improving the PA process so that payers and practitioners are better aligned to support patient access to timely, cost-effective, and high-quality cancer care.

Seamless coordination and cooperation between physicians and payers in this process is crucial to optimizing outcomes, allowing patients to receive the best possible care without concern for treatment delays or financial toxicity. However, PA continues to drive a deepening wedge between physicians and payers, becoming increasingly burdensome for both from year to year¹¹ and frequently delaying initiation of treatment, which results in direct patient harm.12 PA thus challenges clinicians' autonomy to enact the shared medical decisions they make with their patients and instead implies that payers are the final decision-makers on how care is delivered, in many ways allowing payers themselves to practice medicine.

Background and Payer Rationale for PA

Overuse of expensive, unnecessary medical services has been a key driver of the ongoing unsustainable growth seen in US health care costs. Berwick et al listed the overuse of low-value tests and treatments as one of the 6 primary domains of health care waste, accounting for \$75.7 to 101.2 billion in excess costs per year. Thus,

limiting or eliminating the delivery of low-value care through strict third-party oversight of health care practices or "utilization management" (UM) is logically accepted by the payer community as a fundamental cost-containment strategy. Prior authorization (PA) has become an increasingly common form of UM, defined as a "set of techniques designed to manage health care costs by influencing patient care decision-making through case-by-case assessments of the appropriateness of care prior to its provision."14 In addition to bending the cost curve, UM is also viewed by payers as an essential tool to maximize patient safety and promote evidence-based care, UM initially emerged in the 1960s and saw rapid adoption by private payers early in the managed care era of the 1980s.14 Among the largest 776 employers in the US, the proportion of employers who worked with payers to implement UM had increased from 47% in 1985 to 75% by 1990.15

Despite mounting pressure from health care practitioners to scale back PA, payers have remained committed to the necessity and effectiveness of a robust PA process in optimizing value. In 2014, after UnitedHealthcare instituted a PA process specifically for cancer treatments in Florida, they found that Florida chemotherapy costs decreased by 9% that year.5 Because average chemotherapy expenditures across the US increased by 11% in 2014, United credits the PA program with the savings generated in Florida. In a 2019 survey from the advocacy group America's Health Insurance Providers (AHIP), 91% of payers felt their PA programs had a positive impact on the quality and affordability of care, while 84% felt PA improved patient safety.16

Challenges With Navigating the PA Process

While payers clearly have a strong rationale for developing and adopting PA (ie, limiting wasteful spending and

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promoting evidence-based practice), PA as it is currently employed has evolved beyond its well-intentioned origins into an intrusive, inconsistent, resource-intensive system that does not promote evidenced-based, stateof-the-art care. To wit, PA was named as "the greatest challenge facing the field" by radiation oncologists in the ASTRO annual survey.7 Moreover, 94% of physicians in a 2020 American Medical Association (AMA) survey reported that PA can lead to treatment delays and 79% reported that PA can lead to treatment abandonment.17 The current PA system has multiple flaws that cause frustration and fatigue for all stakeholders, with 2 of the most prominent being its poor transparency and its drain on time and resources.

Lack of Transparency

Payers' policies typically state that it is the clinician's responsibility to know whether a particular service will require PA. However, each payer's unique coverage guidelines are often not available at the point of care. Accordingly, 58% of physicians polled in a recent AMA survey report that it is challenging to determine whether a given medical service requires PA.17 Predicting when PA will be required can also be complicated by inconsistencies between payer coverage guidelines and professional society recommendations. To illustrate, a recent single-institution study examining PA determinations for proton therapy found no significant association between insurance approval and compliance with ASTRO guidelines on clinically appropriate uses of proton therapy.18 Similarly, while the use of endocrine therapy in hormone-receptor positive breast cancer is supported by level 1 evidence, generic endocrine therapies accounted for 15% of 2015 PA requests submitted by the breast oncology division at Dana-Farber Cancer Institute,2 further suggesting that PA requests are not

simply serving to rein in wasteful medical spending.

As a result of this unpredictability, physicians are often unable to prepare their patients when a treatment will be subject to PA and thus potentially delayed by appeals, denied by their insurer, or both. Instead, physicians are routinely alerted after having already engaged in thoughtful shared decision-making with the patient. Physicians at this point must then inform patients that they are unable to offer the agreed-upon treatment, undermining patients' trust and confidence in their physicians. In addition, practitioners and patients are typically not provided with regular updates on the status of PA requests, adding anxiety and uncertainty to an already challenging diagnosis.

Drain on Time and Resources

Prior authorization ranked as the no. 1 burden reported by physicians in a survey by the Medical Group Management Association (MGMA), with 88% of respondents describing PA as a "very" or "extremely" burdensome process hampered by increasing requirements and delays.19 Another recent survey found that physicians average 1 hour per week on PA, while nurses average over 13 hours.20 Nearly one-fifth of physicians in the ASTRO survey reported that at least 10% of their workday is spent addressing PA issues, which represents valuable time diverted away from direct patient care.7

A major factor underlying the burden of PA is the highly manual nature of completing and submitting PA requests. Even when payers adopt electronic PA (ePA), physicians must still access each payer's unique web portal, manually input answers to each inquiry, and then pull individual notes and reports from the patient's medical record, because ePA systems and electronic medical records (EMRs) frequently lack integration.²¹ A 2020 survey by

AHIP found that 58% of physicians do not use EMRs integrated with ePA.16 Furthermore, the significant variation in coverage guidelines and PA processes between different payers limits the ability of physicians and staff to achieve efficiency in completing PA requests. Beyond the burden of submitting multiple nonstandardized forms, 85% of ASTRO survey respondents reported that they were required to generate multiple distinct treatment plans for individual PA requests, demanding a significant amount of unreimbursed time and resources from physicians, dosimetrists, and physicists.7

Even once a PA request is successfully submitted, communication between payers and physicians regarding the status of the submission is often slow and inefficient, adding to treatment delays. Notably, only 21% of medical plans have adopted fully electronic PA communication, with 79% of plans still requiring communication by fax or phone.22 In addition, the current system of peerto-peer phone calls serves as another major burden for clinicians. Despite the significant time commitment required to schedule these calls, the discussions themselves may be quite short and unproductive. This is because peer physicians often lack the specialty-specific knowledge and expertise required to engage in a thoughtful dialogue or to appreciate the rationale for a treatment approach that may on its surface appear inconsistent with coverage guidelines. Specifically, 44% of radiation oncologists responding to the ASTRO survey indicated that peer reviews typically are not conducted by a licensed radiation oncologist.7

Long-term Consequences

The most critical concern with the current PA system is its potential to adversely impact patient health. First, the time required for a PA process — which can be prolonged if a denial must be appealed — can

significantly delay or deny access to necessary care. In the ASTRO survey, 93% of the participants reported PA-related delays in life-saving treatments, with 31% indicating that the average delay lasts longer than 5 days. In a study examining the insurance approval process for proton therapy, 2/3 of PA denials were ultimately reversed on appeal, suggesting that the majority of PA-related care delays are avoidable.

Unfortunately, delayed care directly translates into harm for cancer patients. The AMA survey showed that PA-related care delays lead to increased morbidity, with 39% of respondents indicating that delays led to either hospitalization or an intervention preventing permanent impairment.17 PA-related delays can also mean the difference between life and death for cancer patients: A National Cancer Database study showed that each 1-week delay in the initiation of cancer treatment was associated with a 3.2% increase in absolute risk of mortality for early stage breast, lung, renal, and pancreas cancers.12 Thus, these delays in cancer care are not merely an inconvenience; they have a lifeand-death impact.

The burdens of the PA system may also exacerbate pre-existing socioeconomic and racial disparities in access to high-quality oncologic care. For example, smaller community practices and freestanding hospitals caring for rural or underserved populations may lack the resources to efficiently navigate the PA process, ultimately limiting access to treatment options available at large health systems with full-time staff dedicated to the PA process. The ASTRO survey found that, relative to academic physicians, a significantly higher percentage of community practice physicians reported PA-related treatment delays lasting longer than 1 week (34% vs 28%).7 In cardiology, another resource-intensive medical specialty subject to

significant PA burden, PA rejection rates have been shown to be higher for minorities and low-income groups. ²⁴ As ASTRO, ACRO, and other professional medical societies have prioritized reducing health care disparities, tackling the flaws in the current PA system will be an important step toward health equity.

In addition to delaying access to existing evidence-based treatment options, the PA process also frequently stands in the way of innovation in radiation oncology by hindering clinical trial enrollment. Because payers do not automatically waive PA requirements for new treatments being investigated on clinical trials, the time-intensive process of submitting PA requests and appealing coverage denials serves as a major barrier to patient accrual, leading to premature trial closures. A recent study on phase 3 clinical trials of proton therapy found that 64% of PA requests were initially denied, and that 67% of these initial denials remained denied after appeal.18 This creates a catch-22 whereby payers inhibit the generation of the very evidence needed to demonstrate value and justify payment coverage of the latest treatments. More importantly, these practices prevent the improvement of cancer care, causing progress to stagnate and resulting in unnecessary continued patient suffering that potentially could have been prevented by research had it continued uninhibited.

Finally, while strict PA policies were intended to control health care costs by limiting use of expensive treatments, there is evidence that their burdensome requirements and rigid coverage guidelines may ultimately increase overall health care expenditures. Excessive administrative costs – driven in part by the complex, inefficient PA system – are a top reason the US spends significantly more per capita on health care than any other higher-income country. In the 2020 AMA survey,

40% of physicians report having at least 2 full-time staff dedicated entirely to PA.17 Moreover, it is estimated that practices spend \$31 billion per year on PA-related tasks.26 Another recent study estimated the total annual PA-related spending for all US academic radiation oncology centers to be more than \$40 million, of which 86% is associated with navigating the PA process for treatments that are ultimately approved.27 Thus, the current PA system paradoxically generates new waste in the form of unnecessary administrative time and costs.

Excessively stringent PA practices may also further increase health expenditures in the long-term if the savings generated from treatment denials are offset or surpassed by the downstream costs of treating complications that arise from delayed or inferior care. An analysis of PA claims for type 2 diabetes medications found that plans spent significantly more on patients who did not receive a requested drug (either via denial or delays) vs patients approved for the medication.28 A similar analysis of patients with bipolar disorder or schizophrenia found that prescription prior authorization led to significantly increased hospitalizations, 23% higher inpatient costs, and 16% higher spending overall.29

Fixing the Prior Authorization Crisis

Leveraging Technology to Streamline PA

If the purpose of PA is truly to decrease waste in medicine — and not simply to delay or deny care — increased automation of the intricate, multistep PA process is critical to reduce clinician burden and minimize delays in care. Ideally, software can be designed to accomplish this either as an integrated part of the EMR or as a stand-alone app that can communicate with the EMR.

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For example, the steps required to achieve payment coverage could be seamlessly integrated into clinical workflows in the EMR. Specifically, physicians could be alerted at the point of care if a given service requires PA and be informed upfront of all necessary supporting documentation, based on the unique coverage requirements of the payer. If PA is required, the EMR could communicate the pertinent clinical data from the patient's chart to the payer. Similarly, the payer could communicate its response to the physician though the EMR. These capabilities are eminently achievable with software capabilities and should be developed; however, realistically, a government mandate will likely be required to achieve this.

Some progress has been made to enable an integrated health IT ecosystem that permits secure communication between a practitioner's EMR and payers' ePA systems. One approach to facilitate interoperability between traditionally siloed health information systems has been the development of a new common language or "standard" for health data exchange called Fast Healthcare Interoperability Resources (FHIR).30 Under the FHIR standard, discrete data elements such as individual diagnostic reports or medications can be communicated between different health information systems via web-based application programming interfaces (APIs). These APIs allow a particular software program, such as a practitioner's EMR, to access data or content generated and housed by another program, such as an insurance plan's coverage policy rules.

The CMS Interoperability and Prior Authorization proposed rule (CMS-9123-P) is a landmark policy effort that seeks to accelerate PA automation by promoting FHIR-enabled APIs.³¹ The proposed rule requires payers in Medicaid, the Children's Health Insurance Program, and qualified health plans on federal

exchanges to build and maintain an FHIR-enabled document requirement look-up service API, which would allow providers to retrieve the unique PA requirements of specific payers directly within the EMR. CMS-9123-P also requires payers to build and maintain an FHIR-enabled prior authorization support API that will allow clinicians to "send PA requests and receive responses electronically within their existing workflow," while complying with HIPAA standards. CMS-9123-P is proposed to take effect January 1, 2023.

The bipartisan Improving Seniors' Timely Access to Care Act of 2021 also seeks to streamline the PA process by mandating that Medicare Advantage plans establish ePA programs that meet specified standards, including coverage determination decisions, in real time for routinely approved services.32 Close collaboration between policymakers, practitioners, health plans, and EMR vendors will be essential to ensure that the technological solutions promoted by the above policy initiatives are deployed in the private market as well to spur broad PA automation.

Increasing Transparency of the PA Process

In addition to streamlining the documentation process, another key step to ease the current PA burden will be to increase transparency around payers' coverage determination requirements and processes. Physicians should be aware of different treatments' PA requirements before engaging with patients to formulate a management plan. Insight into the PA process empowers physicians to set appropriate expectations regarding the potential hurdles to overcome prior to arriving at the optimal treatment. Greater clarity can help avoid patients' frustration and anxiety stemming from abrupt and unexpected delays or changes in the initial care plan. If a treatment is held up by the PA process, both the patient and physician should be able to conveniently obtain status updates and receive a specific deadline by which a coverage decision will be made.

The Improving Seniors' Timely Access to Care Act of 2021 also aims to increase transparency in the PA process by mandating that Medicare Advantage plans grant physicians and patients with upfront access to criteria used for making coverage decisions along with details regarding the supporting documentation that must be submitted as part of the PA request.³² Private health technology companies are also developing machine learning solutions that continuously scan the dynamic coverage policies and medical necessity rules of different health plans, so physicians can be accurately informed of a plan's most up-to-date coverage requirements for a particular service.33

Once PA requests are submitted, the CMS-9123-P rule requires participating plans to enable patients and physicians to track all pending and active PA decisions through FHIR-enabled APIs. Multipayer, web-based portals are also being developed in the private market to serve as a onestop hub for practitioners to monitor the status of all PA requests in real time, eliminating the need for inefficient and repeated phone calls to insurance companies for updates.³⁴

Both the CMS-9123-P proposed rule and the Improving Seniors' Timely Access to Care Act of 2021 will also open a window into how plans manage the use of different services by mandating that plans publish PA metrics, including rates of initial PA approval, denial, and approval after appeal. The Improving Seniors' Timely Access to Care Act of 2021 also strives to increase transparency by requiring Medicare Advantage plans to provide data on the extent to which software decision support tools and clinical evidence standards are being factored into PA coverage determinations. This information will enable patients and

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practitioners to hold plans accountable for ensuring a clear and consistent application of their internal coverage guidelines during the PA process.

Shortening Turnaround Times for PA Approvals

A central goal of streamlining the PA process through ePA systems is to accelerate time to PA approval. New technologies have shown promise, as a new machine-learning-based solution was shown to reduce PA approval time by 60% at a regional medical center. 33 Similarly, the FASTPATH initiative, which enabled clinicians to navigate the PA process electronically through a multipayer web-based portal, reduced the median time to a PA decision by threefold. 34

Regulatory measures are an equally (if not more) important strategy for shortening the PA process. The CMS-9123-P proposed rule applies strict time-frame constraints for decisions, requiring participating health plans to respond within 72 hours of urgent requests and within 7 calendar days of standard requests. ASTRO's commentary on the proposed rule encourages CMS to update the maximum response time to urgent requests to 48 hours. Rather than imposing fixed deadlines on PA decisions, the Improving Seniors' Timely Access to Care Act of 2021 aims to incentivize timely PA determinations by requiring Medicare Advantage plans to report average response times to PA requests. This allows patients and practitioners to hold payers accountable for PA practices that result in unacceptably long delays in care.

Selective Waiving of PA Requirements

While the prospect of eliminating PA is unrealistic, expanding the services and physicians that are selectively exempted from PA requirements has greater buy-in from health plans based on a consensus statement signed by multiple stakeholder groups including

the AMA and AHIP.35 Plans can significantly cut their own administrative costs by adopting the practice of "gold carding," in which practitioners with historically high PA approval rates for certain services are exempted from having to repeat the PA process for those services in the future. A Texas law, H.B. No. 3459, that took effect in October 2021, gold cards physicians who have a 90% PA approval rate over 6 months on certain services.36 Ideally, future legislation should also look to award gold card status to medical groups that establish their own utilization management process and demonstrate high compliance with internal, evidence-based care pathways. In addition to rewarding practitioners who have a proven record of high-value, guideline-concordant care, physicians who have embraced value-based payment models are already assuming financial risk and should be exempt from restrictive utilization management practices.

Thought should also be given to exempting certain services from PA regardless of the ordering physician. For example, in Sunset PA programs, specific services with particularly high rates of initial or ultimate approval are phased out of the PA process completely. Treatments being investigated in well-designed prospective clinical research trials should also be exempt from PA requirements to facilitate trial accrual, which is crucial for innovation and for aligning payer coverage policies with up-to-date practice guidelines.

Advocacy of Practicing Physicians

Finally, it is important to note that the major PA-related policy changes that have been enacted or proposed thus far^{32,33} have been achieved in large part by the political advocacy efforts of radiation oncologists in professional societies like ASTRO and ACRO. On Notably, the additional systems-level changes proposed in this article are unlikely to be implemented without further advocacy

efforts at the state or federal level. Thus, it is essential to recognize that additional effort and involvement of practicing radiation oncologists and affiliated stakeholders will be needed to bring ongoing issues to the attention of government officials and to advocate for change.

Conclusion

Ultimately, physicians and payers are ideally both working to ensure that patients receive the best possible care that is grounded in evidence and delivered cost-effectively. When applied appropriately, PA is an invaluable tool for payers to limit medical waste and ensure that patients receive guideline-concordant care. However, there is valid concern that the current PA system has expanded its scope beyond medical waste and is now being used as a general cost-containment tool, particularly within specialties like radiation oncology.7 When PA is applied broadly and with limited transparency, patients face frequent delays and denials for proven treatments while physicians face ever-expanding administrative burdens. We hope the solutions offered here - with a focus on leveraging technology to make the process more efficient and more transparent - can help practitioners and payers find a balance that provides reasonable oversight where appropriate while limiting unnecessary treatment delays/denials and minimizing administrative burden.

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