Increasing Burden of Prior Authorizations in the Delivery of Oncology Care in the United States

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Over the past decade, advances in the field of oncology have resulted in improved outcomes for patients with early and advanced cancer.[1] These advances have occurred in concert with increases in the cost and complexity of delivering oncology care.[2] To address costs, many insurers have implemented prior authorization (PA) requirements for multiple aspects of cancer care, including surgery, imaging, molecular testing, infusional and oral antineoplastic agents, and supportive care medications. However, whether PAs reduce overall health care expenditures is unclear, particularly when considering that not paying for one service (eg, growth factor) could lead to greater spending for associated administrative and downstream services (eg, hospitalization for febrile neutropenia).[3-6]

In 2017, ASCO conducted an oncology practice census survey that 395 practices (18%) completed, representing 58% of the US hematologist/oncologist workforce (n = 7,203).[7] Results of the survey are sobering: Payer pressures rose to the top of practice pressures (up from fourth position in 2016) and were felt acutely by academic, physician-owned, rural, and urban practices alike. Of payer pressures, PAs (78%) and coverage denials/appeals (62%) were the most frequently cited pain points (Fig 1).

The administrative burden for PAs cannot be overemphasized. A 2017 American Medical Association survey of 1,000 physicians (40% primary care, 60% specialists) found that medical practices completed approximately 29 PAs per physician weekly and took an average of 16 hours of physician or staff time.[8] More than 90% of physicians reported care delays as a result of PAs, 78% reported that PAs led to treatment plan abandonment at least some of the time, and 61% reported a significant effect on patients. Processes and forms can be cumbersome and vary tremendously among health plans. To procure outpatient medications, the breast oncology team at one academic health center documented 17 process steps and 10 decision points that involved four to five staff members, including nurses, pharmacists, and physicians, for each PA.[9] Of note, 97.5% of PA requests were approved on the first attempt, almost one quarter of requests were for on-label use of growth factors in the setting of curative intent chemotherapy, and nearly 15% of requests were for generic endocrine therapy. In addition, the delays and uncertainties associated with PAs impose significant stress on patients at a vulnerable point in their lives.

The initial clinical review typically is managed by a registered nurse, who in our experience, often seems unfamiliar with oncology and/or is not empowered to deviate from basic scripts. In addition, despite requirements to send medical records and detailed clinical information, the initial reviewer often has not reviewed medical records in advance. If a case is not approved at the initial review, it is typically sent for peer-to-peer review. Some insurers schedule peer-to-peer reviews in advance, but more frequently, clinicians must either call

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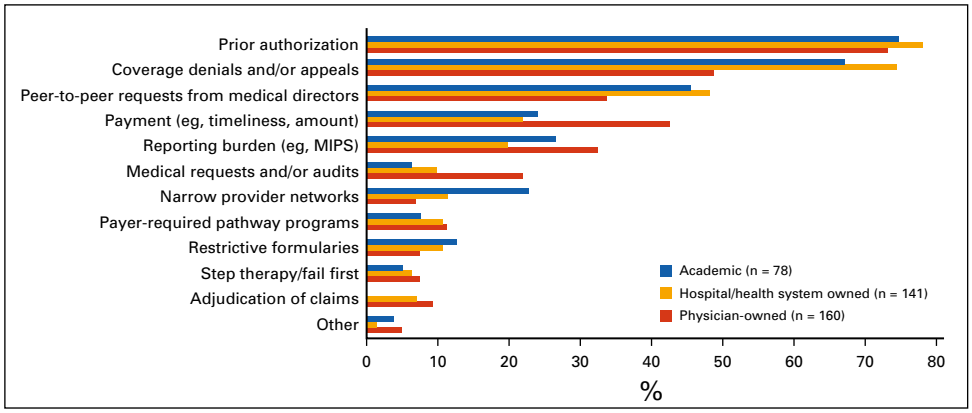

Fig 1. Payer pressures by ownership type. Reprinted with permission from Kirkwood et al.[7]

and wait on hold or interrupt a busy clinic day to speak with a reviewer. Either way, the process requires clinicians to take precious time away from their clinical practices. In many cases, the physician-reviewer approves the peer-to-peer request upon provision of 100% identical information (and no additional information) submitted in the initial request. Moreover, like nurse-reviewers, many physician-reviewers often do not seem to have oncology expertise.

A number of studies have estimated that US practices spend nearly four times as much money in interacting with payers than do Canadian practices, and these costs may be as high as $80,000 to $90,000 per 1.0 full-time equivalent (FTE) physician per year.[10-12] Thus, perhaps not surprising is that in the 2017 ASCO survey, hematology/oncology practices reported a requirement for an average of 6.1 FTE staff (range, 0 to 100 staff members) to manage PAs.[7] The administrative burden and frustrations can and do lead to burnout among providers and staff. Although not scientific, it is telling that a Google search (June 26, 2018) using the key words burnout, prior authorization, and oncology returns 150,000 hits, with many describing in the first person clinicians' negative experiences with the current PA process.

Finally, although we understand the impetus to require PAs for expensive new medications, payers also are requiring approval for supportive care or antineoplastic medicines that have been on the market for a long time and/or the use of which falls squarely within ASCO and National Comprehensive Cancer Network treatment guidelines. For example, in 2015, nearly 15% of outpatient medication PAs processed in the breast oncology practice at Dana-Farber Cancer Institute were for generic endocrine therapies (inexpensive medications) for which there is category 1 evidence for survival benefit and for which small barriers (eg, copayments) substantially reduce adherence rates.[9,13] In addition, payers' coverage criteria and step guidelines sometimes conflict with best available evidence and/or consensus clinical guidelines. For example, many insurers require opioid treatment failure before covering topical lidocaine patches (which in the setting of a national opioid epidemic seems particularly self-defeating) or require both opioid and gabapentin treatment failure before covering duloxetine for peripheral neuropathy, despite a stronger evidence base for the latter and endorsement by ASCO guidelines.[14,15]

Clearly, the system is broken. Although PAs may reduce spending on targeted medications or procedures, a legitimate concern exists that PAs may worsen outcomes for patients. Specifically, PAs may contribute to treatment abandonment, treatment delay, patient stress, clinician/staff burnout, and administrative costs/burden.[7,8,11,16,17] Perversely, PAs may create barriers to the use of proven and effective medications; limit clinicians' abilities to deliver optimal supportive care; and, in some cases, incentivize financially the use of more-toxic, less-patient-centered, and sometimes more-expensive alternatives. More studies should look at the effect of PAs on patient outcomes, overall costs for the health care system, and financial toxicity experienced by patients.

How can we move forward? We believe that everyone involved in the delivery of cancer care, including providers, payers, and patients, would agree that the goals of cancer care are to deliver timely, high-quality care that includes cure and/or prolongation of life when possible and that optimizes quality of life for all. In addition, the locus of cancer care should rest with the oncology team and the patient. We also believe that there is widespread agreement about the need to address the

financial effect of cancer care for the system and for each individual patient as well as the belief that payer-based coverage guidelines should be the exception rather than the rule.

The challenge is translating cost containment into clinical practice (Table 1). First, how and who decides what services are covered? Second, how are those decisions operationalized and enforced? Third, what approaches can be taken to mitigate the high unit costs of individual services?

Value frameworks from ASCO, the National Comprehensive Cancer Network, and others and the ASCO choosing wisely guidelines may help to guide coverage determinations and provide targets for cost reduction efforts that are clinically justified.[18,19] Oncology providers

Table 1. Key Principles to Guide Cost-Containment Strategies in Oncology

Principle	Comments
The goals of cancer care are to deliver timely, high-quality care to patients with cancer. This includes cure and/or prolongation of life when possible and optimizes quality of life for all.	Burdensome, inflexible processes contribute to treatment delays, abandonment of therapy plans, and potential for significant patient harm.
The locus of cancer care should rest with the oncology team and the patient.	Direct interactions between patients and clinicians provide a level of information and capture patient preferences in a way that is critical to the delivery of optimal care.
A real need exists to address the financial effect of cancer care both for the patient and for the system as a whole.	Value frameworks, such as those from ASCO, the National Comprehensive Cancer Network, and other organizations, may help to prioritize targets for utilization reduction efforts that are clinically justified. Alternative payment models, such as clinical pathways and bundled payments, are being piloted. However, as with any other cost-containment measure, before widespread adoption, a key question will be whether new approaches achieve the dual goals of reducing costs and supporting high-quality cancer care. In addition, it will be critical to ensure that new models do not further increase already high administrative burdens. Finally, although PAs or other mechanisms to reduce utilization may reduce some costs, they do not address per-unit costs for drugs, procedures, and services.
Payer-based coverage guidelines should be the exception rather than the rule and when they do exist, should be held to the same standards as for providers and reflect the best and most up-to-date evidence.	Utilization reduction efforts should focus on expensive medications, testing, or procedures for which there is evidence of overuse in the oncology population. Robust systems to incorporate high-level evidence regularly should reduce unnecessary paperwork and appeals.
To the extent that payers continue to require PAs, they should improve, simplify, and standardize methods of requesting and granting PAs.	When the majority of PAs for a specific intervention are approved, payers should consider waiving PAs for that intervention. Simplified or waived processes for supportive care medications may help to avoid emergency department use or hospitalizations. PA requirements that take providers out of direct patient care are disruptive to clinical care. Burnout of physicians, nurses, and medical staff is real and has negative downstream consequences.
Greater collaboration among oncology organizations, providers, patients, and payers has the potential to reduce the adversarial nature of many current physician-payer interactions and to improve the delivery of cancer care.	Focusing on shared goals, developing innovative strategies together, and being committed to evaluating and learning from the successes and failures of new approaches have the potential to alter the current adversarial dynamic in a way that provides benefits to patients while constraining increases in health care expenditures.

Abbreviation: PA, prior authorization.

ideally would be positioned to weigh in on coverage decisions both on an individual case-by-case basis and on a larger policy basis.

To the extent that payers continue to require PAs, they should improve, simplify, and standardize the methods of requesting and granting PAs. When PAs are required, they should focus on areas where there is evidence of inappropriate overuse and reflect the best, most up-to-date evidence. Many oncologists hope that participating in value-based models and clinical pathways will eliminate the need for PAs. However, these may create different burdens, particularly if imposed by payers rather than designed and implemented by the clinical practice. As with the proposal to increase standardization around PAs, pathways programs must avoid the need for clinicians to adhere to multiple payers' individual pathways. The alternative is not practically feasible, medically safe, or medically justified in a busy clinical practice. Alternative payment models, such as the Oncology Care Model developed by the Center for Medicare & Medicaid Innovation, place more financial risk in the hands of providers. As with other cost-containment strategies, a key question will be whether these or other approaches will achieve the dual goals of reducing costs and supporting high-quality cancer care.

Finally, recognition that PAs and other utilization management strategies do not lower per-unit drug or procedure costs is important. Given the high per-unit costs for drugs and services in the United States, effective cost-containment strategies likely will require reductions not only in utilization but also in the unit cost of necessary and appropriate medical services.

Oncology is advancing on many fronts. Physicians and medical providers are not blameless in the escalating costs of oncology care, and insurers want to do right by patients. Rather than perpetuating what has become a somewhat adversarial relationship between clinicians and insurers, the time is right to consider new, collaborative models in which medical teams and insurers are aligned with patients to achieve timely, appropriate, and cost-effective care. JOP

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