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overview

Impact of Prior Authorization on Patient Access to Cancer Care

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Prior authorization (PA) is a type of utilization review that health insurers apply to control service delivery, payments, and reimbursements of health interventions. The original stated intent of PA was to ensure high-quality standards in treatment delivery while encouraging evidence-based and cost-effective therapeutic choices. However, as currently implemented in clinical practice, PA has been shown to affect the health workforce, adding administrative burden to authorize needed health interventions for patients and often requiring time-consuming peer-to-peer reviews to challenge initial denials. PA is presently required for a wide range of interventions, including supportive care medicines and other essential cancer care interventions. Patients who are denied coverage are commonly forced to receive second-choice options, including less effective or less tolerable options, or are exposed to financial toxicity because of substantial out-of-pocket expenditures, affecting patient-centric outcomes. The development of tools informed by national clinical guidelines to identify standard-of-care interventions for patients with specific cancer diagnoses and the implementation of evidence-based clinical pathways as part of quality improvement efforts of cancer centers have improved patient outcomes and may serve to establish new payment models for health insurers, thereby also reducing administrative burden and delays. The definition of a set of essential interventions and guidelines- or pathways-driven decisions could facilitate reimbursement decisions and thus reduce the need for PAs. Structural changes in how PA is applied and implemented, including a redefinition of its real need, are needed to optimize patient-centric outcomes and support high-quality care of patients with cancer.

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Accepted on April 26, 2023 and published at ascopubs.org on May 23, 2023: DOI https://doi.org/10.1200/EDBK_100036

INTRODUCTION: PRIOR AUTHORIZATION IN HEALTH CARE

Utilization review is an established component of cost management in health care, broadly implemented to control service delivery, payments, and reimbursements.[1] Such services and treatments can include diagnostics, medications, and surgical procedures. When utilization review is required by health insurers before patients can receive services or treatments, it is called prior authorization (PA).[2,3] (Table 1) Stated goals of PA include screening for appropriateness and efficiency and reducing the overutilization of unnecessary services or medications, thereby reducing health care costs. Historically, one aim of PA has been to catalyze the uptake of generic drugs; when coupled with policies facilitating use of generic medications and biosimilars, utilization management may yield improved system sustainability by exerting downward price pressure on medications.[4] In an era of growing innovation, the rising costs of oncology care have been concerning for sustainability.[5] As a consequence, PA has been applied more broadly to a larger set of health interventions. Although such a process may be viewed as legitimately grounded in some respects, it places a significant burden on patients and health care providers, contributing to negative outcomes with further strains on the already-stressed health care workforce. Indeed, the PA process raises essential questions about the proper roles of insurers and health care providers in the care of oncology patients and everyday medical practice. This article focuses on the PA process in the United States, but the issues raised also illuminate some of the tradeoffs faced throughout the world in controlling health spending on the one hand and striving for optimal care of individuals facing cancer on the other hand.

PRIOR AUTHORIZATION IN CANCER CARE

Rationale for PA in Oncology: Improving Efficiency in Health Care Spending

The fast pace of innovation in oncology has not only brought improvements in patient outcomes but also increased costs and overuse of non–cost-effective therapies.[6] US health expenditure accounted for $4.3 trillion US dollars (USD) in 2021, that is, $12,914 USD per person, corresponding to 18.3% of gross domestic product.[7] Of such an expenditure, 5.33% is allocated to cancer care alone, that is, more than $200 USD billion annually ($16,346 USD pro capita). This is four times than those for patients treated for noncancer conditions.[8] Oncology drugs

PRACTICAL APPLICATIONS

- Prior authorization (PA) is a type of utilization review that health insurers use to make decisions on the coverage of health interventions for individual patients.
- PA has been originally introduced as a mechanism to rationalize health expenditures toward more affordable and evidence-based treatment choices, including to improve uptake of generics and biosimilars, reduce inappropriate use of off-label therapies, and reduce overuse of expensive medications outside of their intended use.
- PA is subject to insurers' review: Patients experiencing denials as the outcome of PA review may yield adverse health outcomes and financial toxicity, as receiving less effective therapy, therapy with higher risk for toxicity, and/or less optimal supportive care.
- PA is associated with adjunctive administrative burden for health care providers, including the need for peer-to-peer review, and leads to delays in access to care for patients.
- The harmonization of the PA process with national cancer treatment clinical guidelines could help rationalize and simplify the process and reduce costs and treatment delays.
- The establishment of a set of regularly updated, evidence-based essential interventions, the use of national guidelines to inform coverage decisions, a global rethinking of the proper scope of PA requirements, attention to administrative burden and costs, safeguards to protect against abuse of PA requirements, and better implementation science can reshape the PA process as it is applied now.

account for the largest spending of any specialty and exceed 15%-30% of the overall cancer budget.[9] PA has been touted as a way to encourage high-value and cost-efficient budget allocation in oncology.[10] When implemented in the context of treatment guidelines aligned with best practice, PA policies have the potential to increase the quality of cancer care.[1]

From the perspective of payers, the PA process gives health insurance companies a chance to review how necessary a medical treatment or medication may be.[11] Examples of medications that may require PA are those that have dangerous side effects, are harmful when combined with other drugs, are often misused or abused, or should be used only for certain health conditions.[12] Cost is an explicit factor to be considered, for example in the case of medical treatments that have lower cost but equally effective, alternatives available.[11] Step therapy is frequently also built into the PA process to prioritize more cost-effective options. When used judiciously, PA can minimize the use of overly toxic treatments and enhance adherence to established clinical guidelines. For instance, a retrospective analysis of more than 13,000 chemotherapy treatment requests (CTRs) submitted by oncologists for PA has been cited as an example of how a pathway-driven PA process may improve medical oncology quality.[13] In this study, 11.6% of requests were denied even after peer-to-peer review with a board-certified oncologist employed by the insurer: Denials concerned supportive care and antineoplastic agents in the same proportion. One third of denials were due to lack of compendia support, one quarter due to clinical criteria, and 22.8% for problems with dose/frequency. In 10.7% of cases, clinical tests did not support use. A difficulty in assessing this analysis is a lack of granular data on the clinical scenario, the source of guidelines/compendia used, and the outcomes of patients in whom CTRs were denied. Indeed, the implicit assumption in analyses of this type is that the health insurer's assessment is the gold standard for oncology care, which may not be the case always.

Rationale for PA in Oncology: Improving Quality of Cancer Care

Quality improvement can be achieved with the disengagement from low-value clinical interventions or overuse.[14,15] PA can serve as a firewall against the misuse of medical interventions and improve adherence to best practices. A key example is the use of granulocyte colony-stimulating factors (CSFs) in patients receiving chemotherapy. It is reported that up to 30%-50% of patients receiving high-risk regimens for febrile neutropenia are not put under the appropriate CSFs prophylaxis while 30%-40% are prophylaxed outside current indications.[16] In an attempt to rationalize the use of CSFs, a site-wide program initiative was implemented for patients with metastatic colorectal cancer receiving care at a multicenter oncology practice network.[17] The intervention included educational materials, appropriate nonuse recommendations, and PA requirements. The preimplementation versus postimplementation comparison showed that use of CSFs was significantly reduced from 13.5% to 4.5%, with no change in short-term mortality because of complications of neutropenia.[17] However, because of the multipronged intervention, it is unclear to what extent the PA component per se contributed to the reduction in CSF use or if implementation of consistent internal guidelines was instead the primary driver of the observed changes. Another study reported that inclusion of a CSF decision support tool as part of the PA process for women with breast cancer receiving chemotherapy resulted in higher alignment with clinical guidelines.[18] After implementation, a significant decrease in

TABLE 1. Overview of the Main Definitions and Procedures Used in Prior Authorizations by Health Insurances in the United States

Term	Definition
Utilization review	A process of evaluation of the care plan of a patient. It is intended to determine the medical necessity, taking into consideration the treatment standards for a certain health condition, the availability of alternative treatments, and the cost implications
Preauthorization (or prior authorization)	A type of utilization review that health insurances apply to control service delivery, payments, and reimbursements of health interventions
Denial	An adverse determination of a previous request for a health intervention through preauthorization
Peer-to-peer review	A process in which the requests for coverage for a health intervention are discussed between the ordering physician or advanced health provider and another physician employed by the health insurance. The intent of the peer review is to discuss the medical necessity and obtain an authorization or appeal of a request previously denied
Appeal	A request for a second review of the original coverage determination
Medicare Advantage Organizations	A private contractor that can give benefits for Medicare, including part D
Medicare Compendia	A set of authoritative sources for use in the determination of a medically accepted indication of health interventions used by Medicare as a reference to decide on coverage decisions. The National Comprehensive Cancer Network Drugs and Biologics Compendium is the source used by the Centers for Medicare & Medicaid Services to determine coverage for cancer interventions
Clinical pathways	Evidence-informed algorithms developed by multidisciplinary expert committees to define tasks and/or type and sequence of interventions that should encompass most of the clinical practices used in specific clinical scenarios

the proportion of patients with CSF use was observed in the intervention states (75%-69%) compared with no significant change in the nonintervention state (72%-71%), without an increase in the incidence of febrile neutropenia.

How Prior Authorization Is Conducted

PA is a multistep process. Common scenarios requiring almost automatic requirements for PA include advanced imaging, expensive medications (including supportive care treatments), indications where alternative, cheaper, and equally active treatments exist, drugs historically prescribed outside their on-label use, and drugs with cosmetic indications. Specific coverage determination is often not reached through initial submission of medical information to the insurer, resulting in denials. Insurers can communicate reasons for denials and provide the opportunity to request a peer-to-peer review (^Fig 1). The stated intention of peer-to-peer review is to provide an objective and transparent forum for the appealing health care provider, to critically review the evidence with their assigned peer, and to assess the appropriateness of the proposed intervention in relation to accepted standard of care. In some instances, the decision for denial can be appealed, resulting in a second review of the original coverage determination. Submissions for PA, the peer-to-peer reviews, and the appeals are time-intensive procedures. As such, PA and linked procedures are associated with extra administrative work for health providers, including physicians and advanced care providers. There have also been widespread complaints about the qualifications and expertise of assigned peer reviewers, leading to calls by the American Medical Association and other professional organizations to enforce standards for peer reviewers regarding specialty training and clinical experience.[19]

Potential Implications of PA Requirements on Patients' Access to Cancer Treatments

PA is a time-intensive procedure that can increase the workload of health providers and result in delayed access to treatments. A 2022 landmark survey of approximately 1,000 US physicians from the American Medical Association described physician-reported delays in the delivery of interventions requiring PA, with 82% of the respondents reporting they had experience of treatment abandonment as a result of a denial.[20] One third of responders claimed that the delays because of the PA had resulted in serious adverse events for patients, including hospitalization (25%) and life-threating events (19%). Two thirds of physicians reported that PA led to ineffective initial treatment owing to requirements for step therapy. In addition, 31% of respondents considered the criteria for PA rarely or never mirroring best clinical practice, perceiving most of the peer-to-peer review and appeals as avoidable if internal insurance guidelines were regularly reviewed by providers who are topic experts.[15,20] Seeking to understand the impact of PA requirements in oncology specifically, in 2022, ASCO conducted a survey[22] among ASCO members. Nearly all survey participants reported a patient who had experienced harm because of the PA process, including delays in treatment (96%) and diagnostic imaging (94%), being forced into second-choice therapy (93%), increased out-of-pocket costs (88%), denial of recommended therapy (87%), disease progression (80%), and even loss of life

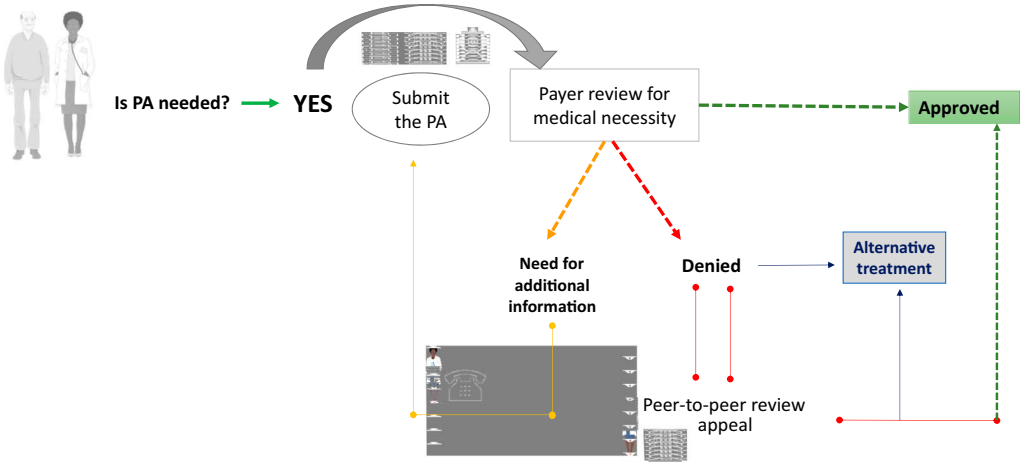

FIG 1. An overview of the current process of PA. PA, prior authorization.

(36%).[21] Ultimately, a potential detriment on overall survival was reported by 36% of the oncologists.[21]

Although very concerning, survey studies on the basis of provider self-report risk the potential for recall bias and have been criticized in this regard. There are relatively few studies in the oncology literature where access to detailed medical records was available to understand the nature of PA requests and denials. One such study conducted within a large US-based academic cancer center in Massachusetts from a cohort of patients with breast cancer reported that initial denials were received not only for antineoplastic agents but also for guideline-concordant use of supportive care medicines, such as CSFs and antiemetics, with extensive evidence supporting their use.[22] Delays could be as long as 14 days.[22] Notably, 13.6% of PA requests were for generic hormonal therapy used according to long-established standards of care. Overall, 97.5% PA requests were approved on the first request, suggesting that PA requirements added multiple layers of administrative complexity without any major impact on medication choice utilization. Another facility-based survey in the gynecology-oncology setting showed that PA was broadly requested for key interventions for cancer management such as imaging (54% of all PAs), supportive care medications (29%), and chemotherapy (17%).[23] Approvals occurred in 79%. Time to care delivery varied substantially, with a mean of 16 days and a broad range up to 98 days. As expected, patients whose requests were denied were forced into alternative options, with substantial changes in their previously recommended treatment plan.[23]

The often unpredictable variability in the decisions of insurers to cover certain procedures and denials can increase inequities in the delivery of cancer care. In addition, the additional workload and personnel requirements imposed by the PA process may deter providers from advocating for the best options for their patients. This is particularly of concern in less-resourced practice settings, which often serve the most vulnerable and historically underserved patients. Arguably, denial of PA is not a denial of treatment but of payment. Still, without insurance coverage, cancer treatments would be unaffordable to most patients. Indeed, it is estimated that 40%-50% of adults with a cancer history experience financial hardship.[24] When patients are denied high-value and important clinical procedures, they will often need to provide for their care with out-of-pocket expenditure, resulting in financial distress and risk of impoverishment.

Patients' perspectives. We explored the lived experience with PA from patients' perspectives and asked patients to share their stories, in conjunction with a long-standing patient advocate (L.K.), highlighting the implications on cancer care and capturing their emotions, when forced to change the treatment plan previously discussed with their providers (Table 2). Patients themselves experience vivid distress because of the intense efforts needed to advocate for their best care. The emotion reported is that of a fight against denials and of navigating many challenges to secure health insurer's approval. The experience of delays of life-saving treatment has been commonly reported, aggravated by the lack of transparency in the overall process of PA and the perception that who is making the decisions is not competent in the matter: deciding on the lives of people. Patients also underlined that not all patients are able to advocate for themselves through active efforts to have their treatments approved: Those who are too sick or those not experienced with insurance processes are left behind, leading to a chain of inequities, detrimental outcomes, and avoidable sorrow. "That's the last thing that I need as I fight for every minute of my life." "Patients deserve a medical system that works without patient intervention." "Insurance and ultimately cancer, won."

Potential Implications of PA Requirements on Patients' Access to Supportive and Palliative Care

At present, numerous supportive medicines require PA for coverage, even if broadly indicated in cancer management and frequently of low costs.[22,25,26] A notable trend in restricting

TABLE 2. Patients' Lived Experience on Pre-authorization

Patient Story	Narrative of Experience
Story 1	"While I've heard many different stories about how a prior authorization affects patients, I was living in blissful ignorance as to the mess that can ensue until a recent experience with getting a new **prior authorization for a** medication that I've been on for more than a year. This medication, **Capecitabine**, is an oral chemotherapy treatment for those of us with terminal cancer. Taking this medication is quite literally life or death for someone like me and the **psychological burden** of knowing that cancer could be growing out of control without medication can be extremely debilitating My private insurance company (through my husband's employer) requires that I use a specialty pharmacy that mails me my medication, for any medication taken long term. All of the pharmacy literature urges patients to use the website or application to refill medication. Dutifully, I went to the website to refill my prescription on 2/13 (a Monday) needing the meds the following Friday to start my next cycle. I get a call at 3:45 p.m. on Friday saying that a prior authorization was needed and so the medication can't be shipped and that the online system only checks for insurance paperwork needed at the time of mailing the medication Despite the fact that it was after the clinic closed at my doctor's office that Friday, I was able to get them to send in the paperwork to get the prior authorization via fax. The following week, **I began following up with everyone**. Took about a week for my doctor's office to discover that **they'd been using the wrong fax number**. Ironically, my insurance company kept sending back faxes saying that they needed more information, never mentioning it was the wrong number Once my doctor's office discovered that they'd been using the wrong fax number, my insurance company allowed one of the pharmacists to use the electronic prior authorization form and the information was received and processed within the time period allotted in my insurance contract. The pharmacy at my cancer center advanced me medication and my insurance company authorized the medication to be sent overnight and an extra dose ahead of the regular refill schedule, so I'd have medication on-hand The **burdens of living with a terminal cancer diagnosis** are many and varied. I already live in constant pain, have many side effects from the medication I'm on right now as well as the four other lines of treatment I've been on since 2017, take medication to manage depression and anxiety, have PTSD from all of the experiences thus far, see a variety of doctors and specialists and get regular bloodwork. **Being a forever patient is truly at least one full time job**. Adding on the trauma of knowing that I don't have the medication ie, quite literally keeping me alive and it can be just untenable. **"Patients deserve a medical system that works without patient intervention"**
Story 2	"My father passed away on March 28, 2022 after a long battle with Stage IV Oral Squamous Cell Carcinoma, which was overlooked by medical professionals and diagnosed in a very late stage. His form of cancer was very aggressive and progressed/further metastasized four times after initial diagnosis. I spent 3 years, from the time of diagnosis until his death, **waging a battle against cancer along with my Dad and unexpectedly, his own insurance company**. While my time should have been spent making memories in the final stages of my Dad's life, I spent that precious time advocating on behalf of my Dad. This cancer diagnosis felt like my own as it was trying to take something so precious. I advocated without hesitation, but at many points in time I thought about those who had no advocate. I saw them in the waiting room often. Knowing my father's experience, their **fate against cancer and equally against their insurance** was beyond worrisome While undergoing standard treatments, my Dad's cancer progressed again. In an effort to save his life, my Dad's oncologist switched gears and started a new regimen of zoledronic acid and pembrolizumab within just 6 days. We knew time was not on our side and while his oncologist set the expectation that he was unsure if/how my Dad's cancer would respond to this new treatment, we took the chance. Despite its aggressive nature, **2 doses of this new combination therapy stalled the progression of his cancer and visibly improved his quality of life** As infusions continued, each scan looked better than the last so I remained optimistic. While my Dad's cancer wasn't NED, we were inching closer to that milestone after each treatment. This continuation was necessary as stopping infusions could have caused it to come back with a vengeance. Based on his oncologist's medical expertise, and need for future treatment planning, he ordered a biopsy taken and sent it for genomic sequencing, analyzed through an FDA-approved test. I advocated on my Dad's behalf to get this test approved because his life absolutely depended on it. **After numerous denials, the nurse practitioner overseeing my Dad's care was scheduled for a peer-to-peer review** with insurance in order to get approval. The nurse practitioner called me immediately after the review concluded and quoted *"**physician admitted to him that he was not an oncologist and is unfamiliar with impact on genomic testing for cancer treatment** planning and therefore could not approve the test."* I was shocked. How is this a peer-to-peer review if the peer is not an oncology expert? Who decided that this physician (who lacked relevant experience and knowledge of genomic testing) was a suitable candidate to discuss the efficacy and medical necessity of the test? **My Dad's fate lay in the hands of someone who by his own admission didn't know the implications of the test**. My Dad's oncologist submitted a second request for the test to be approved and I called his insurance company many times questioning them as to why a physician insurance provider, not involved in his direct care, had greater oversight and influence over my Dad's health than my Dad's team of leading oncology experts. As we continued to contest the denial, scans showed that a new area was growing. While the rest of his body continued to respond favorably to his ongoing treatment, it was evident that his latest cancer development was resistant to the regiment. With no approval in sight, we ultimately gave up and opted for surgery on this new area in hopes that the cancer could be removed while still receiving pembrolizumab, as it continued to be effective in the rest of my Dad's body Following surgery, we marked 2 years on Keytruda. Then came yet another denial, this time for the very treatment keeping him alive. Insurance stated that the FDA and NCCN recommend a total treatment duration of 24 months for his diagnosis and my Dad had completed the recommended treatment cycle. Any future treatment was effectively denied. Despite a mountain of evidence supporting the efficacy in continued treatment **my Dad received 3 denials. The final letter was sent from an obstetrician-gynecologist**. Even pleas to the drug manufacturer were unsuccessful. I finally realized I could do no more **"Insurance and ultimately cancer, won"**

(Continued on following page)

TABLE 2. Patients' Lived Experience on Pre-authorization (Continued)

Patient Story	Narrative of Experience
Story 3	"I have had multiple experiences over my five years with metastatic colorectal cancer where pre-authorizations have either **limited my care or added a lot of extra effort and work** by my expert care team to provide me with their recommended care. One area where this has really become a challenge is in **scans**. I have disease in some organs that's only visible on CT scans and in other organs only visible on PET scans. Therefore, PET/CT is the only way to understand the full nature of my disease and at my center this combined scan is an option. However, my insurance will only approve one scan at a time. This includes **countless hours of my oncologist's team going through peer-to-peer reviews** and my going through my 'navigator' at the insurance company to try to resolve. Surprisingly, it is not always the less expensive scan, and it is **unclear** why sometimes when my team submitted for pre-authorization of a PET/CT the CT is approved and the PET is denied and other times the PET is approved, and the CT is denied. The insurance also does not require additional information from this chosen scan to justify the next scan. So, this preauthorization game does not at all relate to need or financial considerations, or any other logical rationale that I can tell, but rather that it is a policy, and therefore it is followed. What this has led to has been either needing to choose which portion of my disease we would like to see first or most often, and then filling in with the other scan on alternate dates or I have gotten one of the scans and as soon as it's completed, my team submits for the other scan, which then I get a week or two later. This two-step process not only can delay treatment decisions. It also adds **additional time toxicity** to my care of needing to go to the center multiple times to get the scan, scheduling, etc as well as more radiation exposure since the PET scan does include a low-resolution CT anyway. This also turns out to be more expensive for the insurance company as the scans are usually approved at different locations with different staff and adds additional common needs like bloodwork or accessing in my port that are therefore duplicated. While we've learned how to play this game over time, in the beginning **it was quite exhausting** to try to navigate and now **it's simply frustrating** that I as the patient and my team has to deal with all of this **extra complication for no reason**. And to think **all of this isn't actually to treat the cancer** but to understand what needs to be treated. The extra delays this has caused in terms of actually treating the cancer are quite **nerve wracking**. That's the last thing that I need as I fight for every minute of my life"

Abbreviations: FDA, the US Food and Drug Administration; NCCN, National Comprehensive Cancer Network; NED, no evidence of disease; PTSD, post-traumatic stress disorder.

the access to supportive care medicines has been reported for opioids, an essential treatment for neoplastic pain control.[27] In the period 2015-2021, the requirement for PA for two common formulations of long-acting opioids increased from no need for PA to 50% of Medicare prescription drug plans.[28] Additionally, many insurers reclassified four opioids of six available from lower tiers to tier 3 or specialty tier (ie, higher copayment requested) in Medicare part D coverage.[28] As a result, the out-of-pocket expenditure for optimal control of neoplastic pain increased up to four-fold. It is reported that such a restriction of the pain medications occurred in response to the opioid crisis in the United States; however, regulating cancer pain medications using the same tools as for opioids in the noncancer setting has had serious collateral consequences.[27,29] Denial of high-value drugs and supportive care management can increase the out-of-pocket expenditure and result in detriment for patients. Patients who are exposed to financial distress experience poorer quality of life and ultimately inferior survival outcomes.[30-32] Although evidence are limited on the impact of excluding supportive palliative care medicines from PA, we believe that a minimum set of essential interventions should be assured to all patients, with minimal administrative barriers.

Impact of PA Requirements on Health Care Providers and Health Systems

PA does not occur as an automated process but requires time and expertise from a highly skilled health workforce. It is reported that PA yields a substantial increase of the physicians' workload, corresponding to more than $68,000 USD time-equivalent per physician per year interacting with health plans, that is, $20 USD-$30 billion USD in the United States, annually.[33] Bingham et al created a time-driven activity-based model, estimating annual costs associated with obtaining PA for radiation treatment-related services[35] of $491,989 USD per institution.

Much of the dissatisfaction with the PA process is related to the time spent in supporting treatment decisions for patients, including peer-to-peer reviews and appeals. Physicians report frustration regarding the quality and flow of communications with insurers and the amount of documentation required.[35] Turnaround times for PA can widely vary. In the ASCO survey,[21] oncologists reported to have completed up to 50 PAs weekly, dedicating up to 40 hours every week. It is interesting to note that such an amount of time, 40-50 hours per week, corresponds to a full-time equivalent doctor's workload[36]: In substance, PA can double the average weekly workload. Bingham et al[34] estimated an overall time burden ranging from 92 to 95 minutes per PA event for radiation oncologists, when peer-to-peer discussion was required.

Half of the providers surveyed by ASCO had up to two staff in their practice dedicated to PA. Much of the bureaucratic hurdle was due to the burden of evidence requested to prove the clinical necessity of the interventions. The oncologist often perceived a lack of expertise of the authorization reviewers as a driver of denials and unsuccessful appeals and felt discouraged by the lack of transparency, especially on the criteria for coverage decisions.[21,35] Although some authorizations are smoothly managed and completed within 1 hour from the initial submission, escalation to peer-to-peer review occurs in a third of the

requests, and delays of ≥1 day occur in nearly a half of the cases.[21]

Oncology trainees are not spared: A survey circulated among medical physicians in training in the United States in 2019 showed that 70% of them were involved in some extent in the PA process.[35] The participation to this activity was associated with decreased enthusiasm for work and choice of the medical profession: Such a dissatisfaction was maximally reported by 83% of the medical oncology trainees.

In medical practice, dissatisfaction and challenges impeding the effective care delivery related to PA can result in clinician burnout and contribute to technology-induced and administrative burden-related distress.[37] Burnout is a substantial determinant of the workforce shortages, resulting in providers leaving oncology practice and changing their career paths.[38,39]

Taken together, the evidence suggests that while conceptualized to be a cost-containment and efficiency-improving procedure, PA is now a burden in terms of unfunded, adjunctive administrative labor. From a whole-health system perspective, the original intent appears to be ultimately corroded and possibly detrimental.

The Fundamental Question: Who Should Direct a Patient's Care and How Should Reimbursement Decisions Be Made?

One of the major problems exacerbated by the PA process is the fragmentation of patient-centered care. Rather than the locus of care centered on the patient, with shared decision making in concert with the oncology provider(s), many treatments and services must be precleared by insurers, each with their own policies and rules. Health insurers can formulate their own pathways for coverage decisions, although overarching regulations exist to govern their scope.[28] For example, the Medicare Advantage Organizations (MAOs) are private contractors that can give benefits for Medicare, including part D (drugs). In principle, MAOs should align with the initial criteria for service coverage set by Medicare. However, important divergences have been reported. In April 2022, the Office of Inspector General of the US Department of Health and Human Services issued a Report on the MAOs denials of procedures and medicines requested via PA.[40] The Inspector showed that MAOs had used decisional criteria beyond the Medicare coverage rules, putting adjunctive barriers to services that should not require extensive discussions. MAOs have requested adjunctive and unnecessary documentation to formulate their decisions to cover or not specific health interventions, restricting or delaying the access to cancer care while increasing the administrative burden for health providers.[40] The major determinants of inappropriate denials were errors during manual claims-processing reviews and system processing errors: 18% of all denials were about interventions meeting the Medicare rules for billing, which should have been covered.[40]

The PA system was ostensibly developed to optimize care delivery with a focus on noninferior, cost-effective options. However, the report of the Office of Inspector General portrays an alarming status quo: Insurance organizations have demanded unnecessary adjunctive workload for interventions of common practice and included in the basic services that Medicare has established on the basis of clinical relevance, impact, and cost-effectiveness. In short, given that insurance coverage is in many cases required for a patient to realistically access a treatment or service, insurers and MAOs are de facto governing the practice of medicine as it relates to individual patients. It can be debated if insurers are the most objective adjudicators because they have an inherent conflict of interest between optimizing revenues and supporting optimal patient care. In addition, there are controversies related to the choice of the adjudicators regarding their subject matter expertise, as well a relative lack of real-time oversight into internal reference guidelines adopted by insurers to make coverage determinations. Such variability in multiple critical decisional points generates more barriers and creates a mist of uncertainty, yielding frustration because of the arbitrary nature of some coverage requirements and the irreproducibility of final decisions. Finally, emerging reports of potential abuse including the use of automated algorithms to deny coverage of tests, medications, or treatments without true medical review only further erode trust between patients, health care providers, and insurers as to the true purpose of PA requirements.[41] The unpredictable or highly burdensome requirements for PA, in substance, can affect the clinical decision-making process and undermine the patient-doctor relationship.

BARRIERS, FACILITATORS, AND POTENTIAL SOLUTIONS

In the short term, health care providers can restructure systems to handle the current PA process more effectively, although it should be acknowledged that such efforts cost time and money. A pharmacy-based survey from 2022 reported that health benefits formulary management attitudes, differences in requirements between managed care organizations, and miscommunications seemed to drive many of the approval delays.[42] Additional determinants of delayed approvals have been reported in a recent, single-institution study with oral anticancer drugs.[43] A key factor that appeared to accelerate the time to approvals was the availability of a hospital-based specialty pharmacy. The proportion of patients who could eventually get treated within 7 days of prescription increased modestly from 47% versus 54% (adjusted odds ratio [aOR], 1.29; 95% CI, 1.00 to 1.68; $P = .05$) when the hospital-based specialty pharmacy was available. Although a positive study, it is important to note that despite the intervention, nearly half of adult oncology patients faced >1-week delays in medication approvals. Of note, a specialty pharmacy and dedicated

workforce to handle PA paperwork and other related services are not commonly available and not billable to insurers. As a result, although implementation of ad hoc services to manage PAs can be a short-term solution, a better long-term solution must be simplification of the process and reduction of the administrative burden. Reliance on specific services that only few centers can implement would yield to even more inequities in access to cancer care, with patients referred to smaller or less well-resourced centers left behind and systematically forced into second choices because of barriers imposed by the PA process. Solutions in this area should pursue simplification and efficiency first.

Specialty-Oriented, National Clinical Guidelines–Informed Tools Can Facilitate PA

A key driver of dissatisfaction is the burden for health providers to justify therapies and services broadly viewed as standard of care. A (sub)specialty-oriented, tool-based approach has the potential to support up-to-date, guideline-concordant care, while mitigating the problems associated with the frequent lack of disease specialists to review requests and reduce turnaround time to decisions.[35] Such an approach is concordant with the original intent of PA: to reduce the use of nonstandard interventions that can harm patients and assure efficiency in health expenditure. PA tools incorporating real-time decision support on the basis of the National Comprehensive Cancer Network Clinical (NCCN) Practice Guidelines in Oncology as the content for decision making have been piloted in one program of a large national payer.[44] The advantages of a structured tool-based approach for PA is in the data minimization to make the request and the transparent criteria for decision making, on the basis of national, most updated guidelines. The NCCN-based, pilot project for assisted PA reported a saving of $5.3 million USD for the state of Florida in 1 year, by aligning clinical decisions to best practices and requesting peer-to-peer review only in selected cases.[44] As with many policy prescriptions, the devil is in the details. Given the large number of insurance plans, there is the potential for such tool-based approaches to generate greater administrative burden if plans each use different decision tools and custom decision guidelines (^Fig 2).[45] As one oncologist has expressed, "If we're facing a situation where I have to use a different pathway based on whether my patient is a Blue Cross patient or an Aetna patient or Medicare Advantage patient, and each one of those has a different order set and different priority, that is going to create significant frustration and blowback from the oncology community."

Potential of Clinical Pathways to Facilitate PA

Clinical pathways are evidence-informed tools developed by multidisciplinary expert committees to define tasks and/or type and sequence of interventions that should encompass most of the clinical practice on the basis of a specific cancer type and stage.[46] It is well documented that adherence to best practices results in improved survival and quality of life for patients with cancer.[47] Alignment to common standards of treatment could improve efficiency and reduce discrepant decisions across decision makers. When clinical decisions are based on national treatment guidelines that are accepted by

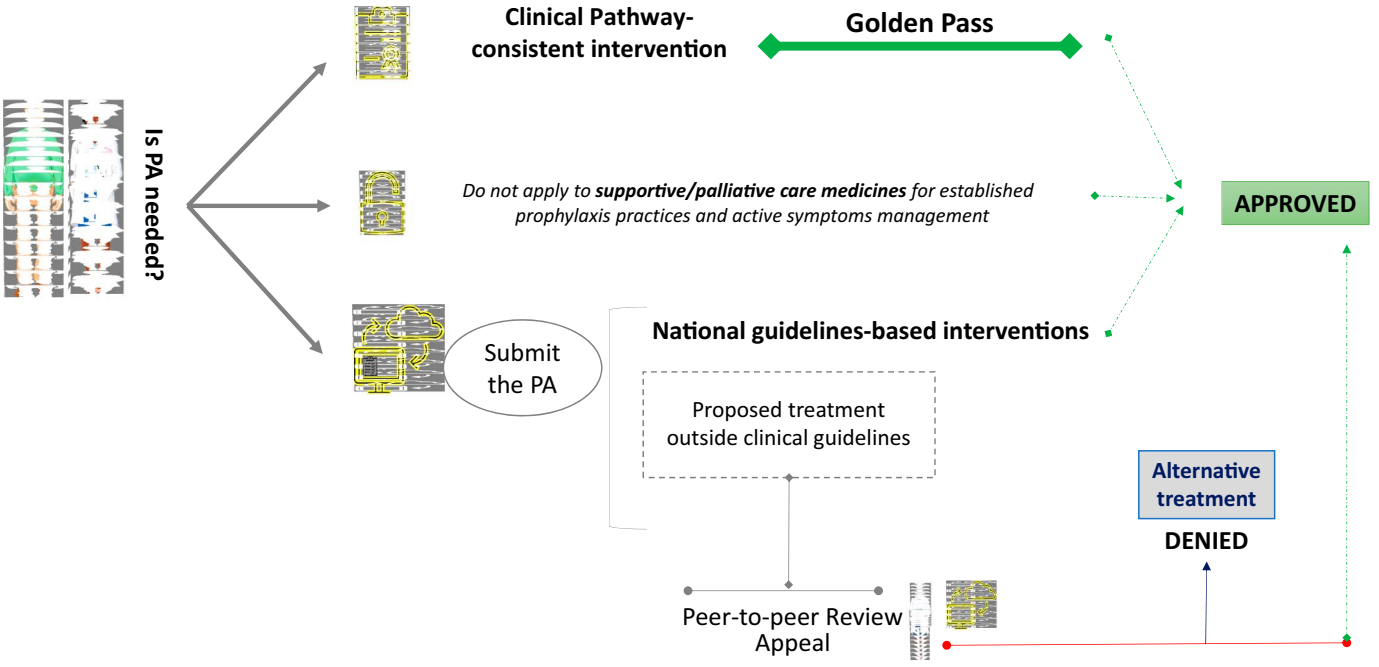

FIG 2. A proposed scheme for an evidence-informed next-generation PA process. PA, prior authorization.

Medicare as part of their compendia to inform reimbursement decisions, PA could be automatized and embedded in a transparent, web-based, consistent, and universal tool that should assist physicians in requesting cancer care interventions while assuring timely care delivery. In addition, with the widespread implementation of clinical pathways as quality enhancers at the institutional level, insurers should consider reducing the administrative burden when physicians can document that they navigated the pathways, instead of duplicating the efforts to align to institutional and then noninstitutional quality standards. Adherence-related metrics are broadly recognized as a key component of quality of care, with an acceptable threshold of $\geq$80% to state good quality.[48] This 80% threshold still provides space for patient-centered care and adjustment of the treatment plan according to patient preferences and comorbidities. Notably, the 80% threshold has been used by some health insurers, such as Blue Cross Blue Shield, to describe high pathways adherence.[49] Institutions with an adherence above such an established threshold of 80%, for example, may grant the benefit for a golden pass for facilitated preauthorization. A golden pass could bring benefits for high-quality institution to have their requests minimally scrutinized through preauthorization. Institutions may save workload and costs while investing in quality, and insurers would save costs.

Revisiting the Scope of PA

From multiple lines of evidence, it seems clear that tools supporting decision making on the basis of transparent criteria can enhance progress toward high-value care.[18] However, many groups have also demonstrated that implementation of internal clinical guidelines and pathways can deliver higher-quality care in the absence of coupled PA requirements.[50] In general, insurance-led PA efforts alone seem unlikely to deliver major benefits to patients, when not coupled with quality-oriented policy interventions. Accordingly, one could question if PA is truly needed in an era of rapid therapeutic advancements, institutional quality policies, and more attention toward sustainability.

The larger question at hand relates to the scope of PA, that is, what criteria should properly dictate where a particular treatment or service requires PA at all in the setting of oncologic care? Cost? Toxicity? Availability of generic or biosimilar substitutes? Evidence of overuse, misuse, or abuse? Just as importantly, what treatments or services should be *excluded* from PA requirements? Indeed, drastically restricting the scope of treatment or services subject to PA could go a long way in reducing negative impacts to patients, health care providers, and health care systems.

For supportive care medicines, we believe that a waiver of PA requirements should be granted because they are commonly requested when patients receive treatments with a moderate-to-high likelihood of adverse effects as prophylaxis or proactive treatments, making the timeliness a critical variable to minimize impact on quality of life. Where no misuse of supportive care medicines is well documented, insurers should not place barriers on their use. Supportive care drugs should be put under facilitated pathways for coverage without additional administrative requirements.

Experiences and Analogies From Other Countries' Experiences

Similarities in the PA process can be identified in countries outside the United States.[51] In Italy, a public fund covers antineoplastic treatments in the public setting. For some high-cost medicines, specific rules for prescription are in place to ensure the alignment with the on-label regulatory approvals. Although there is no formal PA process, providers must prove the appropriateness of their prescriptions for a set of drugs falling under a special monitoring scheme (commonly high-cost medicines) on the basis of an online registry.[52,53] These appropriateness registries enhance consistent prescription patterns while also help control the overall expenditure by informing value-based reimbursement models. Such an approach rhymes with the broader body of literature supporting quality improvement tools to enhance efficiency, especially if operationalized as consistent tools on the basis of consensus guidelines.

Policy Actions

ASCO has launched a campaign to urge the US Congress to pass PA reform.[54] ASCO's approach echoes the broad policy call to action of the American Medical Society on the basis of the need to define the appropriateness of PA, to deliver clinical validity and preserve continuity of care, enhance transparency in the process, and promote timely access to health service, including alternative billing strategies and exemptions for patients in need. In 2022, ASCO launched a campaign to endorse the passage of the Improving Seniors' Timely Access to Care Act to establish improved requirements and standards relating to PA processes under MAOs plans.[55] In September 2022, the US House of Representatives unanimously voiced the urgent need to facilitate access to health care, including cancer care, through efficient health policies aiming at reducing adverse impacts on patients deriving from unnecessary, non–evidence-based, and inappropriate bureaucratic procedures. The bill calls for an electronic authorization process. In addition, it calls the US Department of Health & Human Services to establish a process for real-time decisions for services that are part of the routine clinical practice. Such an item aims at facilitating clinical guidelines-driven or pathway-informed decisions. Approvals and denials are requested to be fully disclosed and reported to the Centers for Medicare & Medicaid Services to prompt review of the MAOs' decisions, encouraging these organizations to adopt evidence-based medical guidelines, developed, or adopted in consultation with physicians.

The Improving Seniors' Timely Access to Care Act has potential for broad impact on access to cancer care. Advocating to facilitate timely access to high-value cancer treatments is a policy and advocacy priority to ensure best care for all patients in need.

IMPLEMENTATION CHALLENGES AND FUTURE DIRECTIONS

The implementation phase of innovative and potentially transforming policies deserves strong efforts to turn commitment into impact. The implementation of the policy solutions outlined in the recently passed Access to Care Act and the ASCO agenda may present challenges at two levels.

First, there is a *structural* problem: The need to establish an online platform on the basis of common data standards, strong privacy data-sharing rules, and consistent web-based tools. It is critical to automatize a more efficient process: Health insurances manage PA and peer-to-peer review largely by phone and fax.[20] Yet, turning a fax-based procedure into an online form is not sufficient to streamline the process. Actions to tackle pragmatic issues, such as the need to manually input patient data to submit requests and lack of any linkage with the electronic medical records, can be instrumental. Moving online means thinking smart and approaching with innovative solutions, including prefilled fields and artificial intelligence support.

Then, there is an *ontology* question. Presently, PA appears closer to a chimera, with multiple layers of intentions and goals accumulated over the years that jeopardize the delivery of safest, effective, cost-effective health care. PA is still missing the opportunity to catalyze patient-relevant policy toward improved quality and sustainability. In the era of value-based health care, there is no excuse to restrict broad access to essential cancer care: Essential cancer interventions should be moved under facilitated reimbursement pathways,[56] as outlined in the *Cancer Moonshot* initiative[57] that aims at reducing cancer mortality through broadening equitable access to quality care. The challenge to cancer control, in substance, cannot disregard how patients access care.[58] In few words it means reducing bureaucracy, ending inefficiency, and delivering sustainable health impact. We would argue that in the current environment, there are insufficient barriers to imposing additional PA requirements under the assumption that PA policies save costs and reduce inappropriate care without negative consequences. By contrast, advocating to reduce PA requirements appears to require a higher burden of proof demonstrating evidence of harm and strong advocacy efforts.

Nevertheless, limitations of the evidence presented are acknowledged. The available data are mostly observational and derived from cross-sectional, survey-type studies. Better studies should be designed to capture and quantify the real impact of PA policies on patient outcomes and identify actionable barriers to result in renovated PA or alternative mechanisms to PA. Research approaches include the development of pragmatic clinical trials or ad hoc longitudinal policy case studies aiming at evaluating the impact of innovative PA and its alternatives on patient-centric outcomes.

In conclusion, the PA process for cancer management is a major barrier for the timely access to best care. The original role of PA to enhance efficiency, safeguard patients, and assure cost-savings appears nebulized in the complex world of its bureaucracy. In the short to medium term, a recent bill passed by the US House of Representatives has outlined specific policy goals to improve efficiency of the PA and to reduce nontransparent procedures. In the longer term, a fundamental reshaping of the PA process should be based on nationwide cancer control goals, as outlined by the *Cancer Moonshot* initiative, delivering equitable cancer care, through access to high-value essential cancer interventions while always keeping patients at the center.

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The following represents disclosure information provided by authors of this manuscript. All relationships are considered compensated. Relationships are self-held unless noted. I = Immediate Family Member, Inst = My Institution. Relationships may not relate to the subject matter of this manuscript. For more information about ASCO's conflict of interest policy, please refer to www.asco.org/rwc

Hope S. Rugo
Consulting or Advisory Role: Napo Pharmaceuticals, Scorpion Therapeutics, Blueprint Medicines, Puma Biotechnology
Research Funding: OBI Pharma (Inst), Pfizer (Inst), Novartis (Inst), Lilly (Inst), Genentech (Inst), Merck (Inst), Daiichi Sankyo (Inst), Sermonix Pharmaceuticals (Inst), AstraZeneca (Inst), Gilead Sciences (Inst), Astellas Pharma (Inst), Pionyr (Inst), Taiho Oncology (Inst), Veru (Inst), GlaxoSmithKline (Inst)

Travel, Accommodations, Expenses: Merck, AstraZeneca, Gilead Sciences

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Stock and Other Ownership Interests: Artera
Consulting or Advisory Role: Seagen, Puma Biotechnology, Daiichi Sankyo, Denali Therapeutics, AstraZeneca, Prelude Therapeutics, Voyager Therapeutics, Affinia Therapeutics, Pfizer, Olema Pharmaceuticals, Aleta Biotherapeutics, Artera, Johnson & Johnson/Janssen, Blueprint Medicines,
Research Funding: Genentech (Inst), Pfizer (Inst), Seagen (Inst), Merck (Inst), Zion Pharma (Inst), Olema Pharmaceuticals (Inst)

Patents, Royalties, Other Intellectual Property: Royalties for chapter in UpToDate regarding management of breast cancer brain metastases, Royalties, Jones & Bartlett

No other potential conflicts of interest were reported.

ACKNOWLEDGMENT

We sincerely thank the dearest Erin Kondvar, Abigail Johnston Esquire, and Julie Clauer for sharing their stories and contributing to this work in the strict interest of patients and the broader oncology community.

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