

**ASCO Position Statement: Prior Authorization****Approved by the ASCO Board of Directors October 21, 2022****Introduction**

The last decade has seen immense progress in the development of new cancer therapeutics, which have greatly improved outcomes for patients and survivors. Despite life-saving advancements in the treatment of cancer, barriers remain in access and affordability of drugs vital to patient treatment. With rising costs of health care and prescription drugs, policymakers, providers, and payers are seeking strategies for achieving cost-effective use of resources. One such approach from payers and PBMs is the use of prior authorization. Prior authorization is used by a variety of sponsors, including commercial health plans, self-insured employer plans, Medicare Part D and Medicare Advantage plans, and the Federal Employees Health Benefits Program. Prior authorization is a paper-based or electronic process by which payers require providers and/or patients to obtain approval for a prescribed procedure, service, or medication in advance of its delivery.<sup>1</sup>

While prior authorization is being conducted, patients are left waiting to receive care that their clinician has determined they need. These waits can be significant, leading to increased suffering and elevated risk for a negative health outcome. Although insurers acknowledge that prior authorization can be burdensome to providers, they describe it as a necessary process to lower costs and to avoid potentially dangerous medication combinations and unnecessary procedures.<sup>2</sup> There are many umbrella terms used to describe prior authorization, depending on which stakeholder is involved. The umbrella term “utilization management” does not accurately convey the urgency or negative impact of how prior authorization is currently imposed on ASCO members and patients.

ASCO members, as well as countless provider and patient organizations, increasingly cite prior authorization as a significant impediment to patient care. For years, ASCO has advocated at the federal and state level for a more streamlined prior authorization process to stop delays in care that negatively impact patients with cancer and contribute to administrative burden. In 2017, ASCO and 16 other organizations representing physicians, medical groups, hospitals, pharmacists, and patients issued principles on utilization management programs, including prior authorization, to reduce the negative impact on patients, providers, and the health care system.<sup>3</sup> ASCO has separately issued a policy statement on the impact of utilization management policies for cancer drug therapies.<sup>4</sup>

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<sup>1</sup> American Medical Association. Prior Authorization. <https://www.ama-assn.org/practice-management/prior-authorization/prior-authorization>

<sup>2</sup> America’s Health Insurance Plans. Prior Authorization. <https://www.ahip.org/prior-authorization-helping-patients-receive-safe-effective-and-appropriate-care>

<sup>3</sup> Prior Authorization Reform Workgroup (2017). Prior Authorization and Utilization Management Reform Principles, available at <https://www.ama-assn.org/sites/default/files/media-browser/principles-with-signatory-page-for-slsc.pdf>.

<sup>4</sup> American Society of Clinical Oncology. American Society of Clinical Oncology policy statement on the impact of utilization management policies for cancer drug therapies. *J Oncol Pract* 13:758-762, 2017.

Despite significant concerns from physicians across the medical community, the burden and impact of prior authorization continues to grow. It is having increasingly negative impacts on practices and patients while providing unclear benefit to their care or to the health care system overall. Efforts to provide guidance and work collaboratively with payers on process and system improvements have failed to yield any concrete benefits. The purpose of this ASCO Position Statement is to provide policy recommendations and a summary of issues our members have raised about prior authorization imposed by payers in oncology and their impact on physicians and patients. ASCO is concerned that a previous statement calling for action on Utilization Management is no longer sufficient to convey the urgency and gravity of the impact prior authorization has on cancer patients and survivors.<sup>4</sup>

## Background

Beginning in the 1950s, the growing supply of hospital resources began to be perceived as a source of rising health care costs; health planning was seen as a way to limit excessive capital investment.<sup>5</sup> Insurers warned that unless hospitals cooperated with public or voluntary health system planning, they would not pay full reimbursement or continue a contract with a hospital.<sup>6</sup> At that time, hospitals used committees to conduct retrospective utilization review to identify fee-for-service payments spent on unnecessary and inappropriate hospital services.<sup>7</sup> Eventually, challenges in implementation led to dismantling much of the federal and state legal framework supporting these programs.<sup>8</sup>

The 1960s saw a rapid increase in expenditures for hospital care, and the federal government began to pressure health insurance companies and hospitals to decrease length of stay. By that time, more than sixty Blue Cross plans had implemented programs to review hospital claims for the appropriateness of admissions, and more than fifty targeted length of stay. Some insurers required physicians to certify at admission that hospital care was necessary for certain cases (such as diagnostic and dental admissions), and more than two dozen required physicians to certify the need for continued hospital care after a specified length of stay.<sup>7</sup> Federal government interest in cost containment strategies also began in the 1960s, largely because of federal investment in the new Medicare and Medicaid programs. Both programs were a response to gaps in private group insurance, providing coverage for high-risk or low-income individuals. As a result, the government's stake in health costs increased.<sup>7</sup> One condition of participation in Medicare programs for hospitals and extended-care facilities was a requirement to establish utilization review committees tasked with assuring medical necessity and quality of care.

In 1972, amendments to the Social Security Act established Professional Standards Review Organizations (PSROs) to monitor the quality and appropriateness of care provided to Medicare and Medicaid

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<sup>5</sup> Institute of Medicine. 1989. *Controlling Costs and Changing Patient Care?: The Role of Utilization Management*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/1359>.

<sup>6</sup> Somers, Herman M., and Somers, Anne R., *Doctors, Patients, and Health Insurance*, Washington, DC: The Brookings Institution, 1961.

<sup>7</sup> Institute of Medicine (US) Committee on Utilization Management by Third Parties; Gray BH, Field MJ, editors. *Controlling Costs and Changing Patient Care? The Role of Utilization Management*. Washington (DC): National Academies Press (US); 1989. 2, Origins of Utilization Management. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK235002/>

<sup>8</sup> Schwartz, Michael, et al., "The Effect of a Thirty Percent Reduction in Physician Fees on Medicaid Surgery Rates in Massachusetts," *American Journal of Public Health*, 1981, pp. 370-375.

beneficiaries.<sup>9</sup> In 1975, the Joint Commission on the Accreditation of Hospitals added the requirement that hospitals perform a specified number of medical record audits in order to be accredited, encouraging the wider use of utilization review.<sup>9</sup> By the mid-1970s, both the hospital industry's own accrediting body and the federal government—the single largest purchaser of health care in the country—mandated utilization review programs. By 1976, 90 percent of the nation's hospitals had utilization review programs in place.<sup>9</sup>

As the Medicare program became the largest single payer of care in the US, approaches to management of cost were copied by private payers to bring about modifications in patterns of care.<sup>10</sup> As the healthcare market place evolved, purchasers became a strong presence and were in a powerful position to impose utilization management requirements on health care providers.<sup>10</sup> This enabled private payers to be more aggressive about pre-emptively detecting and eliminating inappropriate use of medical services.

### **Patient and Provider Impact of Prior Authorization**

While the original prior authorization programs were focused on keeping institutions accountable and overall system costs low, they evolved over time into a service-specific hurdle for health care personnel. A 2022 report conducted by U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) found that 13% of PA denials in the Medicare Advantage (MA) program were for service requests that met Medicare fee-for-service coverage rules, likely delaying or preventing necessary patient care. The report on the impact of prior authorization within MA found that imaging services, stays in post-acute facilities, and injections were three prominent service types among the denials that met Medicare coverage rules, meaning that they would have been covered under traditional, fee-for-service Medicare. In oncology care, the report featured several cases of denials based on incorrect determinations, clerical errors, and inaccurate data review.

In several instances Medicare Advantage Organizations (MAOs), which contract with PBMs, were found to have misapplied Medicare coverage rules to justify denial of injections for pain management—a critical component of cancer care. While many of the denials were reversed on appeal (some after identification by the OIG), the appeals process can be arduous and time consuming, on top of delays the prior authorization process can cause in the first place. Any delay in appropriate cancer care can be devastating to patients and result in disease progression or serious impairment of quality of life. Additional mistakes by PBMs include errors in filling prescriptions, alterations in treatment dosages for patients without consulting their oncology care provider, incomplete dispensing resulting in duplicate patient copays, and delays in treatment related to prior authorization demands and other problems.<sup>11</sup>

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<sup>9</sup> Payne, Susan M. C., "Identifying and Managing Inappropriate Hospital Utilization," Health Services Research, December 1987, pp. 709-769

<sup>10</sup> Institute of Medicine (US) Committee on Utilization Management by Third Parties. Controlling Costs and Changing Patient Care? The Role of Utilization Management. Gray BH, Field MJ, editors. Washington (DC): National Academies Press (US); 1989. PMID: 25144100.

<sup>11</sup> U.S. Department of Health and Human Services Office of Inspector General. "Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care. OEI-09-18-00260. April 2022. <https://oig.hhs.gov/oei/reports/OEI-09-18-00260.asp>.

These findings were consistent with OIG’s 2018 Report.<sup>12</sup> The American Hospital Association (AHA) submitted a letter to the Department of Justice (DOJ) regarding OIG’s findings, noting the suspicious nature of several denials occurring in a single week.<sup>13</sup> In the letter, the AHA urges the DOJ to “focus more directly on the commercial insurers who commit this fraud” by investigating MAOs that are “failing to live up to the commitments they make to the federal government and the Medicare beneficiaries they have been entrusted to serve.”

Many provider organizations have identified the concerns, administrative burdens, and impacts providers face with prior authorization. In an ASCO survey of oncology practices, nearly all survey participants report a patient has experienced harm because of prior authorization processes, including significant impacts on patient health such as disease progression (80%) and loss of life (36%). The most widely cited harms to patients reported are delays in treatment (96%) and diagnostic imaging (94%); patients being forced onto a second-choice therapy (93%) or denied therapy (87%); and increased patient out-of-pocket costs (88%). Respondents also reported that 14% of prior authorization delays have led to a serious adverse event with 42% reporting significant delays in receiving prior authorization, with an average payer response time of 5 business days.<sup>14</sup>

In our 2018 ASCO Practice Census Survey, the Society’s largest survey of oncology practices that aims to capture and describe changes in cancer care and oncology practices, respondents identified prior authorization as the top payer pressure (78%).<sup>15</sup> This is consistent with annual physician surveys issued by the American Medical Association (AMA) documenting prior authorization burdens.<sup>16</sup> In 2021, the AMA reported that 93% of physicians experienced delays to necessary care because of prior authorization, with 82% reporting that prior authorization can lead to abandoning treatment altogether. The survey findings since 2016 report an increase in the number of prior authorizations per week from 36.6% to 41%, care delays associated with prior authorization from 90% to 93%, and prior authorization physician burden from 75% to 88%, respectively. Prior authorization has led to serious adverse events for patients in their care leading to hospitalization, life-threatening events, or required intervention to prevent permanent impairment or damage, disability and permanent bodily damage, congenital anomaly/birth defect, and even death.<sup>17</sup>

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<sup>12</sup> U.S. Department of Health and Human Services Office of Inspector General. “Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns about Service and Payment Denials,” OEI-09-16-00410. September 2018.

<sup>13</sup> American Hospital Association. Letter to the Department of Justice. <https://www.aha.org/system/files/media/file/2022/05/aha-to-department-of-justice-re-false-claims-act-investigations-letter-5-19-22.pdf>

<sup>14</sup> American Society of Clinical Oncology. ASCO Prior Authorization Survey. <https://old-prod.asco.org/sites/new-www.asco.org/files/ASCO-Prior-Auth-Survey-Summary-November-2022.pdf>

<sup>15</sup> Kirkwood MK, Hanley A, Bruinooge SS, Garrett-Mayer E, Levit LA, Schenkel C, Seid JE, Polite BN, Schilsky RL. The State of Oncology Practice in America, 2018: Results of the ASCO Practice Census Survey. *J Oncol Pract*. 2018 Jul;14(7):e412-e420. doi: 10.1200/JOP.18.00149. Epub 2018 Jun 15. PMID: 29906211. <https://ascopubs.org/doi/10.1200/jop.18.00149>

<sup>16</sup> American Medical Association. 2016 AMA Prior Authorization Physician Survey. <https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/government/advocacy/2016-pa-survey-results.pdf>

<sup>17</sup> American Medical Association. 2021 AMA prior authorization (PA) physician survey. <https://www.ama-assn.org/system/files/prior-authorization-survey.pdf>

Delays associated with prior authorization add to the increasingly negative impact on providers and patients. As providers spend more staff time and administrative resources on prior authorization, less time is spent with patients while adding costs to the healthcare system. AMA's prior authorization physician survey reports that physicians complete an average of 41 prior authorizations per physician per week with 40% of physicians indicating they have hired practice staff solely to handle prior authorization.<sup>18</sup> A report evaluating two similar studies calculates that the mean annual projected cost per full-time equivalent physician for prior authorization activities ranged from \$2,161 to \$3,430.<sup>19</sup> An administrative report from the Council for Affordable Quality Healthcare (CAQH) found that providers' prior authorization processing cost was \$528 million in 2019 and prior authorization time per manual transaction increased from 16 minutes in 2018 to 21 minutes in 2019.<sup>20</sup>

Despite these alarming consequences, requirements for prior authorization are on the rise. As shown in a March 2022 survey released by the Medical Group Management Association, 79% of respondents said that prior authorization requirements increased over the past year.<sup>21-22</sup> MGMA members reported their most significant challenges are lack of response or slow response from payers for approvals, increased time spent by practice staff working to obtain prior authorizations, and a lack of automation in payers' prior authorization processes. The American Society for Radiation Oncology has identified prior authorization as the greatest challenge facing radiation oncology.<sup>23</sup> In its 2019 survey, ASTRO found that nearly all radiation oncologists (93%) said their patients are delayed from life-saving treatments, and a third (31%) said the average delay lasts longer than five days. The American Cancer Society Cancer Action Network (ACSCAN) issued a report on their 2019 survey findings showing that 1 in 3 (34%) cancer patients and more than half (56%) of doctors reported having to wait for approval of a cancer treatment, test, or prescription drug because of utilization management policies resulting in delayed patient care with the most common barrier being prior authorization (96%).<sup>24</sup>

### Concerns with the Process of Prior Authorization

When prior authorization is denied by a payer, providers report that the reason for the denial often is unclear. Failure to provide a detailed response with clear reasons for the denial requires additional

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<sup>18</sup> American Medical Association. What is prior authorization? <https://www.ama-assn.org/practice-management/prior-authorization/what-prior-authorization>

<sup>19</sup> The Impact of Prior Authorization Requirements on Primary Care Physicians' Offices: Report of Two Parallel Network Studies. Christopher P. Morley, David J. Badolato, John Hickner, John W. Epling  
The Journal of the American Board of Family Medicine Jan 2013, 26 (1) 93-95; DOI: 10.3122/jabfm.2013.01.120062

<sup>20</sup> 2019 CAQH INDEX, Conducting Electronic Business Transactions: Why Greater Harmonization Across the Industry is Needed

<sup>21</sup> Ernst, C. Virtually all medical groups say payer prior authorization requirements aren't improving. MGMA STAT, March 2, 2022. Available at: <https://www.mgma.com/data/data-stories/virtually-all-medical-groups-say-payer-prior-ortho>.

<sup>22</sup> Southwick, R. Prior authorization demands are getting worse, survey finds. Chief Healthcare Executive, March 4, 2022. Available at <https://www.chiefhealthcareexecutive.com/view/prior-authorization-demands-are-rising-survey-finds>.

<sup>23</sup> American Society for Radiation Oncology. Prior Authorization and Cancer Patient Care. <https://www.astro.org/ASTRO/media/ASTRO/News%20and%20Publications/PDFs/ASTROPriorAuthorizationPhysician-SurveyBrief.pdf>

<sup>24</sup> American Cancer Society Cancer Action Network. New Survey: Utilization Management Delays Cancer Care; Leads to More Stress and Contributes to Worse Outcomes. <https://www.fightcancer.org/releases/new-survey-utilization-management-delays-cancer-care-leads-more-stress-and-contributes>

follow up and only worsens an already heavy administrative burden on physicians and their staff. If, for example, an oncologist is adhering to ASCO or NCCN guidelines in the care of a patient but is not aware that the payer bases decisions on different sources of clinical information in its determinations, this will significantly impact the appeals process and is something the provider should be made aware of immediately.

Many payers give status updates that simply read, “pending,” with no indication of what further information might be needed for a final decision. An explanation of the cause for delay and the information anticipated to be needed for a final decision would help to streamline the process and potentially decrease the number of denials and appeals. Providers have noted that this lack of specific feedback earlier in the process plays a significant role in persistent denials for lack of relevant information, and that this same information provided later in the process often overturns a denial.

A significant burden within the prior authorization process is “peer-to-peer” communication, usually conducted over the telephone, with the physician sharing more in-depth clinical information with a healthcare provider employed by the payer. For many providers, this is the step in the process that can be the most time-consuming and frustrating, in many cases occurring with a non-oncologist. Improving the more routine, earlier steps employed in the process could avoid the need for “peer-to-peer” consultation, reserving those instances for situations where they are truly needed.

In addition to committing to a transparent process, payers should be accountable for prior authorization efficiency and impact. The Centers for Medicaid & Medicare Services (CMS) should require reporting on patient experience, timeliness of determinations, and extent of prior authorization use. Payers—public and private—should be prohibited from imposing piecemeal prior authorization requirements for individual medically necessary services performed during an invasive procedure that has already received prior authorization.

### **Electronic Prior Authorization**

Time-consuming, labor-intensive prior authorization processes adds significantly to its overall burden and the impact on physicians and patients. While many prior authorizations may be initiated electronically via individual payer portals, subsequent interactions and requests for additional information are frequently conducted via fax or phone, leading to delayed communication, slower response times, and delays in patient care. These additional requirements and interactions drive the need for staff dedicated to processing and responding to prior authorization requests.

Earlier studies have shown the benefits of implementation of electronic prior authorization, including decreased faxes and phone calls and faster time to patient care.<sup>25</sup> However, according to a recent report from the Council for Affordable Quality Healthcare (CAQH) only 26% of prior authorization requests are

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<sup>25</sup> America’s Health Insurance Plans. Press Release: New Analysis Shows Benefits of Electronic Prior Authorization for Patients and Providers, March 24, 2021. Available at <https://www.ahip.org/news/press-releases/new-analysis-shows-benefits-of-electronic-prior-authorization-for-patients-and-providers>.

handled fully electronically.<sup>26-27</sup> CAQH also found that 39% of prior authorizations were partially electronic in 2021, while 35% were still fully manual (submitted by phone, fax, e-mail, or mail). CAQH estimates that if all prior authorization claims were submitted fully electronically, the healthcare industry would save \$437 million annually.<sup>26</sup>

The electronic prior authorization process has the potential to improve transparency, efficiency, and physician burden. However, it is not a complete solution. The electronic prior authorization process requires providers to extract data from electronic health records into individual payer portals, often leading to entry errors and minimal change to overall burden. Even when prior authorization requests can be submitted electronically, the majority of responses are not received electronically. These manual responses (fax, mailed letters, calling for updates) add unnecessary delay to the process, especially when the response contains a request for additional information, which must also be exchanged manually. Instead of obtaining necessary documentation or data elements directly from the electronic medical record without additional manual entry from the user, physicians and their care teams are faced with additional forms or templates that create an unnecessary step and is still burdensome.

The barriers imposed by prior authorization will not be resolved by simply implementing an electronic submission standard. If the underlying problems inherent to prior authorization remain (e.g., lack of transparency, unnecessary and routine use across vast swathes of items and services, etc.), then a prior authorization electronic system will simply continue to facilitate those abuses.

### **Disparities in Prior Authorization**

Mounting evidence indicates that prior authorization requirements may be discriminatory and worsen health disparities. Additionally, individuals who face challenges accessing and paying for care may not be aware of how the prior authorization process works, or how it may disadvantage them.

As one example, Hispanic and Latinx patients were less likely to fill a prescription compared to White patients (31% vs 44%) after a claim was rejected by prior authorization.<sup>28</sup> In a survey examining the disproportionate impact on cardiovascular care for Black and other patients of color, the Association of Black Cardiologists found that almost all physicians (98%) experience a barrier when prescribing new evidence-based therapy, with the most prevalent issues being cost (78%) and prior authorization documentation/administrative burden (75%).<sup>29</sup> These data are consistent with a previous survey conducted by the American College of Cardiology in 2016.<sup>30</sup> In a study published by the Journal of the American Medical Association examining access to treatment for HIV pre-exposure prophylaxis (PrEP),

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<sup>26</sup> 2021 CAQH Index. Working Together: Advances in Automation During Unprecedented Times. Available at: <https://www.caqh.org/sites/default/files/explorations/index/2021-caqh-index.pdf>.

<sup>27</sup> Southwick, R. Healthcare companies do more electronically, but there's room to improve, study finds. Chief Healthcare Executive, February 1, 2022. Available at: <https://www.chiefhealthcareexecutive.com/view/healthcare-companies-do-more-electronically-but-there-s-room-to-improve-study-finds>.

<sup>28</sup> American Journal of Managed Care. Expert Panel Offers Insight Into Multifaceted Approach to Addressing Health Care Disparities. <https://www.ajmc.com/view/expert-panel-offers-insight-into-multi-faceted-approach-to-addressing-health-care-disparities>

<sup>29</sup> The ABC Access to Care Initiative Prior Authorization Work Group. Identifying How Prior Authorization Impacts Treatment of Underserved and Minority Patients. Association of Black Cardiologists. 2019. Available from: <http://abcario.org/wp-content/uploads/2019/03/AB-20190227-PA-White-Paper-Survey-Results-final.pdf>.

<sup>30</sup> American College of Cardiology. Cardiologist Perceptions of Access to New Therapies. October 2016.

researchers found that, compared with other qualified health plans (QHPs) in the Northeast, QHPs in the South were almost 16 times as likely to require prior authorization for PrEP, and the reasons for the disparities are unknown.<sup>31</sup>

To protect against further exacerbating current health disparities, the need for a more transparent, efficient prior authorization process is critical—especially for smaller, under-resourced providers and their patient populations.

## Transparency

The lack of transparency with which payers, including PBMs, operate has caught the attention of many stakeholders in the healthcare community, including plan sponsors who are employers. Stakeholders have been challenged in achieving any detailed understanding of the prior authorization process, partly because of the proprietary and confidential environment in which payers operate.

Beyond public and private insurance issuers, ASCO is also focused on the impact of Pharmacy Benefit Manager (PBMs) policies.<sup>32</sup> Our 2018 statement notes that as PBMs have grown, so have their restrictions and requirements on pharmacies, providers, and patients. The opaque manner in which PBMs operate is a known concern. Within the context of prior authorization, providers and patients often are unaware of prior authorization requirements and drug formulary changes imposed by PBMs. ASCO has called upon legislators and regulatory agencies to require PBMs to incorporate accurate formulary data and prior authorization requirements into electronic health records (EHRs). To avoid continuing significant delays and denials for care resulting from prior authorization, it is critical that providers and patients have the necessary information at the point of care.<sup>3</sup>

The lack of transparency in the prior authorization process makes it difficult for providers and patients to evaluate the effectiveness, potential impact, and costs of prior authorization processes. Currently, there is limited availability of public information for research and analysis. To ensure that patients and health care providers are fully informed while purchasing a product and/or making care decisions, payers need to be transparent about all coverage and formulary restrictions and the supporting clinical documentation needed to meet prior authorization requirements. Knowing what requirements are needed in advance of providing vital health care services is vital to ensuring timely access to care for patients.

The lack of transparency noted in prior authorization processes is also found in payer and PBM financial arrangements.<sup>32</sup> Stakeholders, including the U.S. Congress, have also failed to achieve detailed understanding of PBM practices because of the proprietary and confidential environment in which PBMs

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<sup>31</sup> McManus KA, Powers S, Killelea A, Tello-Trillo S, Rogawski McQuade E. Regional Disparities in Qualified Health Plans' Prior Authorization Requirements for HIV Pre-exposure Prophylaxis in the United States. *JAMA Netw Open*. 2020;3(6):e207445. doi:10.1001/jamanetworkopen.2020.7445

<sup>32</sup> American Society of Clinical Oncology: American Society of Clinical Oncology Position Statement: Pharmacy benefit managers and their impact on cancer care. [https://www.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/ASCO-Position-Statement-PBMs-Aug.-2018.pdf?et\\_cid=40510620&et\\_rid=1760459169&linkid=the+statement](https://www.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/ASCO-Position-Statement-PBMs-Aug.-2018.pdf?et_cid=40510620&et_rid=1760459169&linkid=the+statement).

operate.<sup>33-34</sup> On June 7, 2022, the Federal Trade Commission (FTC) launched an inquiry to investigate PBM business practices.<sup>35</sup> As part of their investigation, the FTC seeks to investigate the prevalence of prior authorization and is seeking comments from the public. The FTC is currently reviewing comments, with 24,100 comments received by the end of the comment period.<sup>36</sup>

### **Interference with Doctor-Patient Relationship**

One important concern physicians have expressed related to prior authorization is that certain cost control methods employed by payers interfere with the doctor-patient relationship—and, ultimately, quality of care.<sup>32</sup> Prior authorization denial of patient care disrupts this relationship. When a provider plans a course of therapy, it requires careful consideration and collaboration with the patient. Frequently, prior authorizations do not provide specific justification for denials nor indicate a covered alternative treatment or detail available appeal options.

### **State Efforts to Combat Prior Authorization**

Many states have proposed or implemented legislation to limit the burden that prior authorization has placed on physicians and other health care providers.<sup>37</sup> Increasingly, states are imposing required response times for prior authorization and mandating use of a standard or universal form. Several states also are considering “gold card” laws that would require health plans to waive prior authorization on services and prescription drugs ordered by providers with a good track record of prior authorization approvals. Texas passed such a law, the first of its kind, where physicians who have a 90% prior authorization approval rate over a period of six months on certain services will be exempt from prior authorization requirements for those services. However, insurers will have the ability to reevaluate exemptions in January and July to determine if the exemption can be revoked. A January 2018 consensus statement on prior authorization signed by the American Health Association, America’s Health Insurance Plans, American Medical Association, American Pharmacists Association, BlueCross BlueShield Association, and Medical Group Management Association expressed support for “the use of programs that implement prior authorization requirements based on stratification of health care providers’ performance and adherence to evidence-based medicine.” However, these principles generally have not been implemented by payers. Despite this consensus statement, the Pharmaceutical Care Management Association and America’s Health Insurance Plans, the PBMs’ and insurers’ largest lobbying groups, both pushed back against the States’ legislation.<sup>38</sup> These advocacy groups assert that prior authorization are used to encourage appropriate use of medications, which reduces drug costs for all beneficiaries. Further, AHIP argues that reasoning for adverse determinations on prior authorization requests are based on evidence-based guidelines. That assertion is not consistent with the growing body of evidence noted above.

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<sup>33</sup> Centers for Medicare and Medicaid Services. Medicare Part D – Direct and Indirect Remuneration (DIR). 2017. <https://www.cms.gov/newsroom/mediareleasedatabase/fact-sheets/2017-fact-sheetitems/2017-01-19-2.html>

<sup>34</sup> Robert Goldberg, Drug Costs Driven by Rebates, Center for Medicine in the Public Interest. <http://bionj.org/wp-content/uploads/2015/11/drug-costs-driven-by-rebates.pdf>.

<sup>35</sup> United States of America Before the Federal Trade Commission. Order to File a Special Report. [https://www.ftc.gov/system/files/ftc\\_gov/pdf/P221200PBMMModelOrder.pdf](https://www.ftc.gov/system/files/ftc_gov/pdf/P221200PBMMModelOrder.pdf)

<sup>36</sup> <https://www.regulations.gov/docket/FTC-2022-0015>

<sup>37</sup> <https://www.aafp.org/dam/AAFP/documents/advocacy/legal/administrative/BKG-PriorAuthorization.pdf>

<sup>38</sup> <https://www.tdi.texas.gov/health/hb3459comments.pdf>

## **Conclusion**

Prior authorization is consistently identified as the largest barrier to care for insured patients. The administrative burdens associated with prior authorization contribute to major delays and denials of necessary, appropriate—in many cases, lifesaving—care. Providers and patients have offered to collaborate on reforms to prior authorization processes, but these calls have largely gone unheard. To address these barriers, ASCO provides the following recommendations to improve the prior authorization process:

### **Federal and State governments should strengthen oversight of prior authorization practices:**

- Amend the Medicare Modernization Act (MMA) to grant states the authority for insurance commissioners to review insurance company marketing practices, pursue market conduct reviews, and penalize payers who are not acting in good faith.
- Require prior authorization to be electronic, use universal forms, and be embedded in electronic health records within 24 hours of the submitted claim.
- Establish a Department of Justice task force to conduct False Claims Act investigations into commercial health insurance companies.
- Require insurers to implement prior authorization bypass (i.e., gold carding) when providers have a proven track record of prior authorization approvals.
- Prohibit payers from piecemeal prior authorization, e.g., requiring prior authorizations for individual medications and medically necessary services that are components of a larger invasive procedure.
- Prior authorization should not be required for pathway and/or guideline concordant care. Payers that require prior authorization for these situations, but ultimately approve it, should be required to reimburse practices for the time spent in obtaining approval.
- Require third party arbitration to adjudicate disputes involving prior authorizations and require insurer payments be made to the practice when arbitration decisions uphold the physician treatment plan.

### **Regulatory Agencies should:**

- Monitor and remedy the predictable, adverse consequences that individuals with cancer may experience from barriers or delays in receiving preferred oncology therapies as a result of prior authorization requirements, including suboptimal clinical outcomes, increases in adverse events, increases in emergency department visits, and disparities in treatment or outcomes.
- For patients enrolling in a new health plan, prohibit mandatory substitution or interruptions in treatment that is already underway.
- Require payers to improve transparency by mandating payers to report to CMS and the public on the extent to which they use prior authorization by disclosing the process by which they evaluate and determine prior authorization and hold payers accountable for the timeliness of determinations.
- Require payers to ensure that during “peer-to-peer” discussions or other discussions of clinical circumstances, the treating oncologist has direct access to an oncologist employed by or otherwise authorized by the payer to make prior authorization determinations in cancer care.

- Establish efficient and responsive appeals processes, including 48-hour completion of review/decision on appeals for oncology and expedited review for patients whose clinical circumstances require urgent treatment.
- Develop and implement a provider complaint portal to report and monitor payer practices that negatively impact patients.

**ASCO and other Stakeholders should:**

- Continue to explore incentives to support smaller, under-resourced providers in adopting and implementing a more streamlined prior authorization process.
- Ensure evidence-based care through education, clinical decision support tools, and quality improvement campaigns – such as Choosing Wisely – that improve physician-patient communication of treatment goals and reduce or eliminate unnecessary medical tests and procedures.

*Questions? Contact [policy@asco.org](mailto:policy@asco.org)*