Submitted Electronically at www.regulations.gov

March 13, 2023

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-0057-P
P.O. Box 8013
Baltimore, MD 21244

Re: Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-facilitated Exchanges (QHPs), Merit-based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program (CMS-0057-P)

Dear Administrator Brooks-LaSure,

I am pleased to submit these comments on behalf of the Association for Clinical Oncology (ASCO) in response to the Electronic Prior Authorization proposed rule, which was published in the Federal Register on December 13, 2022.

ASCO is a national organization representing nearly 45,000 physicians and other health care professionals specializing in cancer treatment, diagnosis, and prevention. We are also dedicated to conducting research that leads to improved patient outcomes, and we are committed to ensuring that evidence-based practices for the prevention, diagnosis, and treatment of cancer are available to all Americans.

ASCO supports the intent of the rule in taking important steps to streamline prior authorization within Medicare Advantage (MA), Medicaid, Children's Health Insurance Program (CHIP), and Qualified Health Plans (QHPs), and we commend the agency for including MA plans in this rule. Including MA ensures consistency across different payers, especially as MA continues to grow. With the rising cost of health care and prescription drugs, policymakers, providers, and payers are strategizing to find more cost-effective ways to manage resources. Although tools like prior authorization can play a role in managing cost when implemented appropriately and transparently, we urge the agency

to avoid the restriction of or delay in accessing care, resulting in harmful outcomes. ASCO members have repeatedly raised concerns about prior authorization as a barrier to appropriate care. In our updated position statement on prior authorization, "ASCO Position Statement: Prior Authorization" we outline recommendations to facilitate appropriate implementation of prior authorization policies.[1]

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Burden of Prior Authorization and Cancer Care

Our organization recently published the results of a survey[2] of our members in the United States to assess the impact of prior authorization on cancer care. The survey results show three main takeaways: prior authorization is delaying patient care, impacting cancer care outcomes, and diverting providers from patient care.

Nearly all survey participants reported 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 were 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%).

The survey responses also reflected the difficulties of the prior authorization process. Nearly all respondents report experiencing burdensome administrative requirements, delayed payer responses, and a lack of clinical validity in the process. The survey also found that, on average:

- It takes a payer five business days to respond to a prior authorization request.
- A prior authorization request is escalated beyond the staff member who initiates it 34% of the time.
- Prior authorizations are perceived as leading to a serious adverse event for a patient with cancer 14% of the time.
- Prior authorizations are "significantly" delayed (by more than one business day) 42% of the time.

Over the past several years, members of Congress have become increasingly concerned about the use of prior authorization in MA plans. The House of Representatives unanimously passed the Improving Seniors' Timely Access to Care Act (S. 3018/H.R. 3173) (the Bill) in September 2022. This bipartisan legislation, developed with input from ASCO, finished the 117th Congress with 380 combined co-sponsors — 53 senators and 327 representatives — supporting the legislation. Importantly, more than 500 organizations representing patients, health care providers, the medical technology and

[1] https://old-prod.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2022-PA-Statement-FINAL.pdf
[2] ASCO Prior Authorization Survey Summary. Available at: https://old-prod.asco.org/sites/new-www.asco.org/files/ASCO-Prior-Auth-Survey-Summary-November-2022.pdf

biopharmaceutical industry, health plans, and others endorsed the legislation. Despite overwhelming bipartisan support, the estimated cost of the legislation created barriers to advancing the bill.

ASCO commends the agency for taking steps to improve the prior authorization process and believes the changes and recommendations discussed below will improve beneficiary access to necessary and life-saving services and ease the administrative burden on physicians and payers. This rule aligns with many of the provisions included in the legislation, which if passed would have gone into effect in 2024. Both this proposed rule and the legislation:

- Establish an electronic prior authorization program.
- Standardize and streamline the prior authorization process.
- Increase transparency around MA prior authorization requirements and their use.

We support the efforts CMS is making to streamline prior authorization; however, we strongly urge CMS to address two overarching concerns with the proposed rule in order to maintain current regulatory and legislative momentum to address prior authorization:

1) **We strongly urge CMS to expedite the implementation timeline of provisions finalized in this rule for all plans and require compliance with finalized proposals in contract year 2024.**
2) **We strongly urge CMS to include drugs—which are currently excluded--in the electronic prior authorization program and application programming interface (API) requirements.**

1) ASCO strongly urges CMS to implement the finalized changes in this rule in contract year 2024. Patient outcomes are heavily affected by current prior authorization practices.[3,4,5,6] Allowing current prior authorization practices for several additional years (until 2026 as proposed in this rule), would limit progress, and continue to put patients in harm's way. Furthermore, plans have already been put on notice of potential changes given previous regulatory proposals as well as the legislative efforts noted above. And finally, CMS itself states that MA plans would not face a "substantial burden" because of the provisions in this rule. **To protect patients from delays in and restricted access to cancer care, and as payers have anticipated moving toward electronic prior authorization processes for the last several years, we strongly urge CMS to implement electronic prior authorization requirements in 2024.**

2) ASCO strongly urges CMS to require payers to include drugs in all provisions of this proposed rule. CMS states in the rule that drugs are excluded "because the processes and standards for prior authorization applicable to drugs differ from the other 'items and services' for which we propose

[3] https://www.mgma.com/getmedia/099f8c3b-1e4b-4a36-ac2e-18c9215eb2dc/2022_MGMA-Regulatory-Burden-Report-FINAL.pdf.aspx?ext=.pdf
[4] American Medical Association. 2021 AMA prior authorization (PA) physician survey. https://www.ama-assn.org/system/files/prior-authorization-survey.pdf
[5] ASCO Prior Authorization Survey Summary. Available at: https://old-prod.asco.org/sites/new-www.asco.org/files/ASCO-Prior-Auth-Survey-Summary-November-2022.pdf
[6] https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf

regulation." However, the National Council for Prescription Drug Programs (NCPDP) Telecommunication Standard Implementation Guide Version D.0 for retail pharmacy drugs to which CMS is referring applies only to Part D drugs, leaving Part B drugs without standards.

A significant portion of cancer treatment requires patient access to life-saving drugs and the prior authorization requirements associated with these drugs are extremely burdensome for oncologists and their patients. The omission of drugs from this rule is deeply concerning and provides no relief for the provider and their patients, who will continue to experience delays in obtaining necessary therapy. ASCO strongly encourages CMS to require payers to include drugs as it does for other items and services discussed in the rule.

When the Improving Seniors' Timely Access to Care Act stalled in Congress, focus immediately shifted to this proposed rule in hopes of relief from the burden of prior authorization. However, when learning that drugs were omitted from all proposals – the streamlined electronic prior authorization process, the transparency requirements, the ease of information transfer – our members were left dismayed. If CMS finalizes this rule as proposed (i.e., omitting drugs) oncologists will be left with a fragmented workflow and inconsistent prior authorization processes at the patient level. For example, an imaging request could be done through the electronic process, but then practices will still be working with inefficient systems – phone, fax, email – trying to get prior authorization approval for drugs. To ease the burden of prior authorization for oncologists, CMS must require that payers include drugs in this rule in 2024.

ASCO Comments and Recommendations on Specific Proposals

Time-consuming, labor-intensive prior authorization processes adds significant burden on patients and providers. While many prior authorization requests 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. We commend the agency for taking steps to require electronic prior authorization among several payers, and we offer our comments and recommendations on select provisions below. Many of these recommendations can also be found in the American Society of Clinical Oncology's position statement[7] and prior comment letters to federal agencies, including CMS and ONC.

Proposed Requirement for Payers: Implement an API for Prior Authorization Requirements, Documentation, and Decision

ASCO strongly supports CMS' proposal to require impacted payers to build and maintain a FHIR Prior Authorization Requirements, Documentation and Decision (PARDD) API that would automate the

[7] American Society of Clinical Oncology Position Statement: Prior Authorization. Available at https://old-prod.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2022-Prior-Authorization-Statement.pdf

process for providers to determine whether prior authorization is required, identify prior authorization information and documentation requirements, as well as facilitate the exchange of prior authorization requests and decisions from their electronic health records (EHRs) or practice management system.

ASCO does not support a phased-in implementation strategy as such an approach would fragment care and increase burden on physicians and other providers. We urge the agency to implement the proposals and recommendations discussed in this letter for all items and services, including drugs, to reduce burden and streamline prior authorization into a physician's workflow. We agree with CMS that a phased-in approach could delay the availability of electronic prior authorization for certain items and services, which may in turn reduce the overall adoption of the PARDD API by providers who do not see their specialties and services represented in the initial rollout of the available PARDD API. It is for exactly this reason that we strongly urge CMS to require payers use the PARDD API for prior authorization requests for drugs also. We strongly urge the CMS to require full implementation of the PARDD API in 2024.

Reason for Denial of Prior Authorization

ASCO strongly supports CMS' proposal to require impacted payers to provide a clear, concise, and specific reason for denied prior authorization decisions regardless of the method used to send the prior authorization request. 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 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 National Comprehensive Cancer Network (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.

Finally, while not specifically addressed in this rule, ASCO submitted comments (see Appendix A) in response to the MA and Part D proposed rule highlighting the burden associated with peer-to-peer review. Peer-to-peer communication is usually conducted over the telephone so the physician can share more in-depth clinical information with a healthcare provider, rarely an oncologist, 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 "peer" who lacks expertise in the specific clinical area under discussion (i.e., in the case of cancer treatment, a non-oncologist). **ASCO urges CMS to 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.

Requirements for Prior Authorization Decision Timeframes and Communications

CMS is proposing to require impacted payers (except QHP issuers) to send prior authorization decisions within 72 hours for expedited (i.e., urgent) requests and seven calendar days for standard (i.e., non-urgent) requests. CMS is also seeking comment on alternative time frames with shorter turnaround times, for example, 48 hours for expedited requests and five calendar days for standard requests.

Delays to lifesaving treatment caused by prior authorization are unacceptable; therefore, we do not support the proposed timelines for expedited prior authorization decisions: within 48 or 72 hours of receipt or within 5 or 7 calendar days after receiving a request for standard decision. Instead, **ASCO supports the establishment of more 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.**

Medically appropriate cancer care demands patient access to the most appropriate drug at the most appropriate time, and this proposal does not ensure patient access in a timely manner. The proposed timeframe changes of 72 hours for expedited requests does not alter existing MA timelines and would continue to result in delays in care for patients. Furthermore, patients who have purchased health care coverage on the Exchanges should not have to accept longer wait times for a prior authorization request. We strongly urge CMS to also include QHP issuers on the FFEs in its requirements for response timelines. ASCO supported the prior authorization legislation that was previously mentioned, which included a 24-hour timeframe for urgent prior authorization requests, and we strongly recommend that CMS adopt the same standard to ensure that urgent care needs are met. Given providers typically operate around the clock to care for patients, we encourage plans to work towards similar timeframes.

ASCO is extremely concerned with the following statement[8], "If a **payer fails** to meet the timeline for approval or other decision, **providers should contact the payer to obtain the status of the request and determine if supporting documentation is needed** to complete processing of the authorization or if there are other reasons for the delay in a decision." The purpose of this rule is to "tackle process challenges related to prior authorization to increase efficiencies in health care"; however, the lack of consequences when a payer does not comply undermines the intent of the rule and only makes the burden more egregious on providers. Putting the onus back on a provider when the payer fails to comply with timelines established in this rule only reinforces the current burden associated with prior authorization and provides little incentive to plans for process improvements. Providers will still initiate prior authorization requests electronically, but subsequent interactions will be conducted via fax or phone, leading to delayed communication, slower response times, and delays in patient care. Payers need to be held accountable and provide prior authorization notifications within the set timeframe. **If**

[8] Page 184 of display copy

the physician does not receive a decision within the set timeframe, the default response should be an approval of the prior authorization request.

We strongly urge CMS and other regulatory agencies to hold payers accountable for the timeliness of prior authorization determinations.

Public Reporting of Prior Authorization Requirements

ASCO agrees with CMS that the following information should be made available and transparent; however, we believe the information should be available at the most granular level. Aggregate reporting of the following metrics would not provide meaningful insight into prior authorization patients or providers. ASCO supports CMS' proposal to require impacted payers to report annually on the following metrics, and we strongly urge CMS to include drugs in the list of items and services:

- A list of all items and services that require prior authorization.
- The percentage of standard prior authorization requests that were approved.
- The percentage of standard prior authorization requests that were denied.
- The percentage of standard prior authorization requests that were approved after appeal.
- The percentage of prior authorization requests for which the timeframe for review was extended, and the request was approved.
- The percentage of expedited prior authorization requests that were approved.
- The percentage of expedited prior authorization requests that were denied.
- The average and median time that elapsed between the submission of a request and a determination by the payer, plan, or issuer, for standard prior authorizations.
- The average and median time that elapsed between the submission of a request and a decision by the payer, plan or issuer, for expedited prior authorizations.

In earlier communications to CMS, we have emphasized the need for transparency and accountability of payers. To align data on prior authorization and other utilization management techniques, ASCO believes that payers should also report their metrics to the agency about, but not limited to, plan accountability for timeliness of determinations, requiring plans to report the extent of prior authorization use, and the prohibition of additional prior authorization requirements for added medical necessary services performed during an invasive procedure that already received prior authorization. In addition to the aforementioned, **we urge CMS to 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.**

While we support the transparency noted above, we recognize that aggregating this data across all items and services may fail to provide meaningful and actionable information for specific specialties, patients undergoing complex treatments, and even for CMS. A better approach would be for the plan to provide specific data points related to certain specialties, like oncology treatment. Without more granular information, we are concerned that the data will be too broad to show how often specific

treatments and services are impacted by payer policies and CMS will be unable to effectively monitor the adverse impact of plan prior authorization policies, including suboptimal clinical outcomes, increases in adverse events and disparities in treatments.

Any patient or provider, as well as all other interested parties, should have meaningful access to prior authorization information metrics, including whether prior authorization is required, and if so, the number of times the request for a particular services or drug has been denied, approved, or approved after appeal. The information should be available immediately at the most granular level at an individual's request, though not necessarily posted. An individual should be able to query a search function and return the information they are looking for at the level of aggregation they request.

"Gold-Carding" Programs for Prior Authorization and Health Equity

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. To this extent, ASCO has long supported state and federal regulations and legislation that seek to set a threshold for prior authorizations where the item or service is approved a vast majority of the time, such as gold carding.

ASCO recommends that state and federal governments strengthen oversight and require insurers to implement gold carding when providers have a proven track record of prior authorization approvals. Gold carding programs have the potential to resolve many provider concerns related to prior authorization. However, monitoring and real-world experience will be required before the cancer care community can consider them a panacea. For additional information, please read our policy brief on gold carding.

Mounting evidence[9,10,11,12] 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. 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. To ensure the widest beneficial impact of electronic prior authorization technology and protect against further exacerbation of current health disparities, CMS and other

[9] 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-toaddressing-health-care-disparities

[10] 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://abcardio.org/wp-content/uploads/2019/03/AB-20190227-PA-White-Paper-Survey-Results-final.pdf.

[11] American College of Cardiology. Cardiologist Perceptions of Access to New Therapies. October 2016.

[12] 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

regulatory agencies should explore incentives to support smaller, under-resourced providers in adopting and implementing standard electronic prior authorization technology.

Electronic Prior Authorization for the Merit-based Incentive Payment System (MIPS) Promoting Interoperability Performance Category and the Medicare Promoting Interoperability Program

To encourage providers to adopt the electronic prior authorization processes, CMS is proposing a new measure for eligible hospitals and critical access hospitals (CAHs) under the Medicare Promoting Interoperability Program and for Merit-based Incentive Payment System (MIPS) eligible clinicians under the Promoting Interoperability performance category. The providers would report the number of prior authorizations (excluding drugs) that are requested electronically from a PARDD API using certified EHR technology under these newly proposed measures.

ASCO strongly opposes requiring hospitals, CAHs, and MIPS eligible clinicians to report on this measure and that the score be reflected in the Promoting Interoperability performance category. Adopting this new measure increases physician burden, which acts in opposition to the intent of this rule. If CMS is interested in collecting this type of data, the payers should have it readily available. ASCO is also concerned that without enforcement or oversight of the proposals included in this rule, it could leave physicians unfairly penalized if a payer's API is not fully functional or operating efficiently. Finally, the reforms in this proposed rule apply to payers outside of the traditional Medicare fee-for-service program, yet CMS is proposing to implement traditional Medicare reporting programs to assess compliance. These efforts appear to be misaligned with one another and should not be conflated.

ASCO strongly opposes the new measure and disagrees with CMS that this is an appropriate way to encourage provider adoption.

As mentioned earlier in the rule, our members strongly supported the Improving Seniors' Timely Access to Care Act, and when that stalled, they immediately looked to this proposed rule for prior authorization reforms. Our members want to use this technology and these APIs; they are extremely hopeful that this rule will address many of the burdens they and their patients face and ease information exchange. **To encourage physician use, we strongly recommend that CMS:**

- **Require drugs to be included in the provisions of this rule**. Much of the burden of prior authorization is associated with attempts to get coverage for the appropriate drugs or cancer therapies.
- **Hold payers accountable for the response timelines established in this rule. If a payer fails to respond within the set timeframe, the default response should be an approval of the prior authorization request.** As currently proposed, if payers do not adhere to the timelines, the burden of manual follow up reverts to the physician.
- **Develop and implement a provider complaint portal to report and monitor payer practices that negatively impact patients**. A process for enforcement and oversight in the establishment of the proposed APIs must be addressed to effect change through these proposals.
- **Adopt an implementation date of 2024**.

Patient Access API

Under previous regulations, plans were required to implement and maintain a standards-based Patient Access API that would allow patients to access their claims and encounter information as well as clinical data, provider remittances, and enrollee cost-sharing pertaining to such claims, if maintained by the impacted payer. Under this proposed rule, CMS would add information about prior authorization requests and decisions to the Patient Access API. The intent is to allow patients to track this information, not just payers and providers. The proposed rule would also require payers to report annual metrics to CMS about patient use of this API. **ASCO supports the proposal to require payers to include prior authorization information in the Patient Access API, to make this information available within one business day, and to require payers to report metrics to CMS annually. ASCO strongly recommends that CMS make this policy effective in 2024 and require payers to *include* drugs in the Patient Access API.**

According to CMS, the primary goal of the Patient Access API is to give patients access to their health information. ASCO agrees with CMS that expanding patient access to prior authorization information will help patients be more informed decision makers and true partners in their healthcare; however, to make this possible, prior authorization information for cancer treatments, drugs, and therapies must be included in the Patient Access API. Furthermore, as CMS states, payers have already established Patient Access APIs; therefore, prior authorization information should be included as soon as the 2024 contract year. Payers currently have the technology to provide this information and patients deserve access to this information immediately.

ASCO supports CMS' proposal to require that information about prior authorizations be available via the Patient Access API for as long as the authorization is active and at least 1 year after the last status change. We believe this will reduce physician, patient, and payer burden while complementing the provision in the MA and Part D rule, which would prohibit MA plans from requiring (additional?) prior authorization during an already-approved course of treatment. In our comments on the MA and Part D rule, ASCO strongly supported CMS' proposal to make a prior authorization approval valid for the duration of the approved course of treatment and/or the duration of the prescribed order, as decided on by the physician and patient.

To support all patients and to improve health equity, CMS should ensure that payers provide communication materials, including APIs, that are culturally appropriate and address the specific communication and language assistance needs of their enrollees. ASCO supported CMS' proposal in the MA and Part D proposed rule which would require MA organizations and Part D sponsors to translate materials into any non-English language on a standing basis that is the primary language of at least 5 percent of the individuals in a plan benefit package service area. ASCO has supported proposals requiring payers to communicate with enrollees using their language of choice.

Provider Access API

CMS is proposing to require impacted payers to implement and maintain an API that makes patient data

available to in-network providers who have a treatment relationship with the patient. The Provider Access API would allow a provider to initiate a request when the provider needs access to a patient's data prior to or during a patient visit. It would require payers to share information related to prior authorization requests and decisions (including related administrative and clinical documentation) for items and services. The payer would then be required to share the requested data no later than one business day after the provider initiates this request. The Provider Access API would allow the exchange of adjudicated claims and encounter data but not include provider remittances and enrollee cost-sharing information. A provider access API would be extremely beneficial in exchanging information with other in-network providers. Having a thorough understanding of a cancer patient's health care history is imperative in developing and maintaining continuity of care. **ASCO supports this proposal, and again we strongly urge CMS to include drugs in the Provider Access API and to implement the policy updates in 2024.**

Payer-to-Payer API

To facilitate patient information exchange when a patient changes health plans or has dual coverage, the proposed rule establishes a Payer-to-Payer API. Data would include claims and encounter data (excluding cost information), data elements in the USCDI, and prior authorization requests and decisions. If an enrollee has concurrent coverage with multiple payers, payers must make the enrollee data available at least quarterly. **ASCO supports this proposal and urges CMS to include drugs and to expedite the implementation date to 2024.**

Request for Information: Accelerating the Adoption of Standard Related to Social Risk Factor Data

Since its founding more than 50 years ago, our affiliate, the American Society of Clinical Oncology (The Society), has been committed to addressing cancer health equity and continually works to improve understanding, advance scientific knowledge, and develop solutions to eliminate disparities in cancer care and outcomes. The Society strives, through research, education, and promotion of the highest quality equitable patient care, to create a world where cancer is prevented, and every survivor is healthy. In this pursuit, cancer health equity remains a guiding institutional principle that applies to all its activities across the cancer care continuum. The Society's statement[13] on health equity affirms its commitment to moving beyond descriptions of differences in cancer outcomes and toward the achievement of cancer health equity. This includes a focus on improving equitable access to care, improving clinical research, addressing structural barriers, and increasing awareness that results in measurable and timely action toward achieving cancer health equity for all.

Physicians in under resourced practices and/or communities have expressed hesitation to ask questions about SDOH when the physician or practice does not have specific resources to address identified needs, or if a community resource is unavailable to assist the patient. To better understand how ASCO can best support our members in addressing these issues, ASCO recently surveyed its U.S. members about their understanding and interest in addressing health equity issues in their professional practices. One key

[13] https://ascopubs.org/doi/full/10.1200/JCO.20.00642?af=R

finding is that ASCO members do not currently feel completely or very prepared to address health disparities. They want to be empowered through practical resources and support that they can use with their patients, such as scripts for discussing equity, as well as additional training on social determinants of health.[14]

We strongly support understanding and addressing the SDOH of patients with cancer. It is important to remember that screening for social needs is useful only insofar as resources to address those needs exist in the community, are available for referral, and patients can be successfully navigated to those resources. Additionally, meeting individual social needs is not by itself sufficient to addressing underlying social structures (and therefore, SDOH more broadly). ASCO remains committed to advocacy work to continue the goals of health care reform, to reduce the financial toxicity of cancer care, and to improve the policy landscape to reduce the burden of cancer for individual patients and their families.

CMS should understand the potential administrative burdens that may accompany more robust SDOH data collection. Physicians or other staff collecting the SDOH information may need training on how to best collect SDOH information, why it is important to do so, and appropriate strategies for initiating such conversations with their patients. Gathering SDOH information may require significant additional time to capture and then code into the patient's EHR, which will require additional staff time and resources. Because patient's social needs and SDOH are always changing, SDOH screening should happen continually, which also demands additional time, staff, and resources to stay current.

We question whether Z codes are the most effective method to recognize severity of illness, complexity of illness, and/or utilization of resources. According to a Medicare study[15], most beneficiaries with Z codes reported were white (approximately 75%), and only 1.4% of claims included coding. Codes should also be evaluated for duplicity and ambiguity. Multiple codes describe insufficient housing situations (homelessness, instability, etc.). One code describing "insufficient social insurance and welfare support" is generally reported for patients without medical/health insurance. However, it may be difficult to determine whether this code could be reported for situations where patients have insufficient insurance coverage or need additional services but cannot access them either due to eligibility or resource limits. In summary, ASCO supports the understanding and addressing of SDOH of patients with cancer, and we recommend the following measures related to the collection of such data:

- **ASCO recommends that CMS define the scope of information collection burden on physicians and other providers that will be required to report SDOH data.**
- **ASCO recommends that CMS work with the provider community on the technical issues of streamlining data collection efforts.**
- **ASCO recommends CMS work with the provider community to develop guidance on SDOH data collection as well as strategies to address SDOH issues when appropriate resources are not available in their community.**

[14] ASCO Domestic Member Survey: Perceptions of Health Equity, December 2020 – February 2021, https://www.asco.org/news-initiatives/current-initiatives/health-equity
[15] https://www.cms.gov/files/document/z-codes-data-highlight.pdf

Currently, social risk data are often fragmented and duplicative due to a lack of clear standards for recording and exchanging these data. We look forward to sharing our work and participating with CMS and others to establish standardized social risk data elements.

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We commend the agency for taking steps to streamline prior authorization and appreciate the opportunity to comment on this proposed rule. Please contact Gina Hoxie (gina.hoxie@asco.org) or Karen Hagerty (karen.hagerty@asco.org) with any questions or for further information.

Sincerely,

Lori Pierce, MD, FASTRO, FASCO
Chair of the Board
Association for Clinical Oncology

ASCO
ASSOCIATION FOR CLINICAL ONCOLOGY
KNOWLEDGE CONQUERS CANCER

Appendix A: ASCO Comments Regarding Prior Authorization in the 2024 Medicare Advantage and Part D Proposed Rule

Utilization Management Requirements: Clarifications of Coverage Criteria for Basic Benefits and Use of Prior Authorization, Additional Continuity of Care Requirements, and Mandate Annual Review of Utilization Management Tools

Prior Authorization

Many provider organizations have reported that the prior authorization process is a significant source of burden for patients, providers, and payers. It contributes to provider burnout and poses a health risk to patients when it delays their care. Disparate payer policies, provider workflow challenges, and technical barriers all contribute to this burden.

As highlighted in the April 2022 report by the Office of Inspector General (OIG) prior authorization policies can limit beneficiaries' access to care.[16] To strengthen beneficiary access, CMS needs to take significant action to streamline prior authorization (PA). Plans use utilization management techniques, including prior authorization, to restrict or deny coverage, undermining patient access to diagnostics and medically necessary care. Patients with cancer often face delays in approval for treatment, and many oncology drugs do not have substitutes that are both equally effective and less expensive for a given patient. Consequently, policies that attempt to incentivize, force, or coerce patients to accept anti-cancer therapy alternatives that are not recommended by their oncologist can threaten both the outcomes for patients and the well-being of their families or caretakers.

ASCO recently published the results of a survey[17] of our members in the United States to assess the impact of prior authorization on cancer care. The survey results show three main takeaways: prior authorization is delaying patient care, impacting cancer care outcomes, and diverting providers from patient care.

Nearly all survey participants reported 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 were 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%).

[16] 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. Available at https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf
[17] ASCO Prior Authorization Survey Summary. Available at: https://old-prod.asco.org/sites/new-www.asco.org/files/ASCO-Prior-Auth-Survey-Summary-November-2022.pdf

We commend CMS for taking initial action to address concerns governing prior authorization, utilization management, and medical necessity determinations in MA. We offer our comments and recommendations on select proposals below. ASCO would like to collaborate closely with the agency to ameliorate prior authorization policies to protect beneficiary access to appropriate, life-saving care and to relieve administrative burden.

CMS has proposed to codify standards for coverage criteria to ensure that basic benefits coverage for MA enrollees is no more restrictive than Traditional Medicare. MA Plans must comply with National Coverage Determinations (NCD), Local Coverage Determinations (LCD), and general coverage and benefit conditions included in Traditional Medicare statutes and regulations as interpreted by CMS. This includes coverage instructions and guidance in Medicare manuals, instructions, and other guidance documents. ASCO supports this proposal.

We agree with CMS that MA organizations should follow and comply with CMS's interpretation of Medicare laws and coverage requirements as reflected in the manuals, guidance, and instructions issued by CMS to ensure that all Medicare beneficiaries have access Medicare covered services regardless of the plan in which they are enrolled. The OIG report found that 13 percent of prior authorization denials within the MA program were for service requests that met Medicare fee-for-service coverage rules, likely delaying or preventing necessary patient care. Medicare beneficiaries should have equal access to the same services, regardless of the plan they choose.

We agree with CMS that when an MA organization is deciding whether an item or service is reasonable and necessary for an individual patient, MA organizations should make medically necessary decisions in a manner that most favorably provides access to services for beneficiaries and aligns with CMS's definition of reasonable and necessary.

ASCO supports CMS' proposal to limit MA organizations' discretion to require alternate services or settings. When care can be delivered in more than one way or setting, and a contracted provider has ordered or requested Medicare covered items or services for an MA enrollee, the MA organization may not deny coverage of the services or setting unless they fail to meet the regulatory criteria described above. The patient and physician work together to determine the best care plan, including where the patient will receive the services. These determinations are made for personal reasons and should not be dictated by the MA organization.

CMS has proposed that in situations when no applicable Medicare statute, regulation, NCD, or LCD establishes when an item or service must be covered, MA organizations must include current evidence in widely used treatment guidelines or clinical literature when creating internal clinical coverage criteria. MA organizations must make this evidence publicly available to CMS, enrollees, and providers. CMS solicits comment on the definition of widely used treatment guidelines and clinical literature that would justify internal coverage criteria used in the absence of NCDs, LCDs, or Traditional Medicare statutes or regulations.

The Medicare Benefit Policy Manual, Chapter 15, §50.4.5 instructs Medicare Part B contractors to not deny coverage of an FDA approved drug or biological, used in an anti-cancer chemotherapy regimen, if such drug's use is supported by any of the following compendia and not listed as unsupported by any of the following compendia: American Hospital Formulary Service-Drug Information, National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Micromedex DrugDex, Clinical Pharmacology, and Lexi-Drugs. MA organizations must follow off-label, medically accepted indications included in these compendia to ensure that basic benefits coverage for MA enrollees is no more restrictive than Traditional Medicare. **ASCO supports policy that requires MA organizations to cover all off-label indications supported by the approved compendia for anti-cancer chemotherapy regimens.**

§50.4.5 further allows contractors to identify additional indications through use of peer-reviewed medical literature from a list of 26 publications. §50.4.5 provides guidance on how to evaluate evidence within medical literature. **ASCO supports policy that requires MA organizations to consider peer-reviewed medical literature included in the list of approved publications for anti-cancer chemotherapy regimens.**

If finalized, MA organizations must provide publicly available information that discusses the factors the MA organization considered in making coverage criteria for medical necessity determinations. MA plans should provide a publicly accessible summary of evidence that was considered during the development of the internal coverage criteria used to make medical necessity determinations, a list of the sources of such evidence, and include an explanation of the rationale that supports the adoption of the coverage criteria used to make a medical necessity determination. **ASCO supports policy that requires payers to disclose the process by which they evaluate and determine prior authorization, including the evidence on which these decisions are based.**[18]

ASCO recommends that ASCO guidelines[19] be included in establishing clinical coverage criteria and that prior authorization should not be required for pathway and/or guideline concordant care. "Clinical practice guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances."[20] Clinical guidelines contain recommendations that are based on evidence from a rigorous systematic review and synthesis of the published, peer-reviewed, medical literature. Physicians follow guidelines for the same reason that CMS is proposing that payers use them when establishing coverage criteria. Prior authorization should not be required in this instance, obviating the need for payers to spend resources developing internal coverage criteria based on guidelines practitioners are already following.

[18] https://old-prod.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2022-PA-Statement-FINAL.pdf
[19] https://old-prod.asco.org/practice-patients/guidelines
[20] Institute of Medicine (US) Committee to Advise the Public Health Service on Clinical Practice Guidelines. Clinical Practice Guidelines: Directions for a New Program. Field MJ, Lohr KN, editors. Washington (DC): National Academies Press (US); 1990. PMID: 25144032.

ASCO strongly supports CMS' proposal to make a prior authorization approval valid for the duration of the approved course of treatment and/or the duration of the prescribed order, as decided on by the physician and patient. CMS proposes to provide a minimum 90-day transition period when an enrollee switches plans; however, ASCO recommends that CMS prohibit mandatory substitution or interruptions in treatment that is already underway.

Cost control methods employed by payers interfere with the doctor-patient relationship—and, ultimately, quality of care.[21] When a provider plans a course of therapy, it requires careful consideration and collaboration with the patient and should not be interrupted by a payer for cost-control reasons. When an enrollee changes plans and must resubmit a prior authorization request, this can delay or interrupt treatment that has already been deemed clinically appropriate. Requiring both payers and providers to repeat an already burdensome process creates additional strain on the healthcare system.

CMS has proposed to require that the healthcare professional conducting a medical necessity review have expertise in the field of medicine that is appropriate for the item or service being requested before an MA organization or applicable integrated plan issues an adverse determination. While we support a review prior to a denial of a prior authorization request, ASCO is concerned that the physician or other appropriate health care professional reviewing the request need not, in all cases, be of the same specialty or subspecialty as the treating physician or other health care provider.

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 "peer" who lacks expertise in the specific clinical area under discussion (i.e., in the case of cancer treatment, a non-oncologist). **ASCO urges CMS to 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.**

ASCO supports CMS' proposal to require all MA Plans to establish a Utilization Management Committee to review all utilization management, including prior authorization, policies annually and ensure they are consistent with current, traditional Medicare's national and local coverage decisions and guidelines; **however, we believe that CMS needs to take a more proactive role in the enforcement and oversight of the proposals in this rule.**

ASCO recommends that CMS and other regulatory agencies should monitor and remedy the predictable, adverse consequences that individuals with cancer may experience from barriers or

[21] 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/contentfiles/advocacy-and-policy/ASCO-Position-Statement-PBMs-Aug.-2018.pdf?et_cid=40510620&et_rid=1760459169&linkid=the+statement.

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. Additionally, regulators should develop and implement a provider complaint portal to report and monitor payer practices that negatively impact patients. While we appreciate that CMS is making changes to improve prior authorization in MA, CMS and other regulators need to take action to ensure payer compliance with these policies.

CMS solicits comment on whether a utilization management (UM) committee should be required to ensure that the UM policies and procedures are developed in consultation with contracted providers; whether the UM committee should ensure that MA organization communicates information about practice guidelines and UM policies to providers and, when appropriate, to enrollees.

ASCO agrees with CMS that physicians participating in a MA Plan's network should be well represented on the Plan's UM Committee.

The Proposed Rule requires that a MA Plan must revise UM policies and procedures as necessary, and at least annually. The governing statute requires a MA plan to disclose to potential enrollees the services subject to prior authorization "at the time of enrollment." Allowing MA Plans to add prior authorization requirements to additional services during the plan year would undermine the intent of this statutory provision. **For this reason, we urge CMS to clarify that only new services not available at the time of enrollment can be added to the list of services that require PA.**

CMS solicits comment on whether the proposed regulatory provisions sufficiently address the requirements and limits that the agency describes in the preamble. We thank CMS for addressing prior authorization in MA. We understand these proposals come in the wake of the April 2022 report by the Office of Inspector General (OIG) raising concerns about MA plans' denials of requests for prior authorization. We urge CMS to also incorporate ASCO and other stakeholder feedback in this rule and in future rule-making cycles as we continue working to prevent delays in patient care and improve cancer care outcomes. For additional information, please read our affiliate The Society's, Position Statement on Prior Authorization, which can be found here.[22]

ASCO strongly urges CMS and other regulatory agencies to:

- 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. ASCO will submit comments in response to the Electronic – Prior Authorization proposed rule, but we reiterate our comments here. Payers need to be held accountable and provide prior authorization notifications within the set timeframe. **If the physician does not receive a decision within the set timeframe, the default response should be an approval of the prior authorization request.**

[22] https://old-prod.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2022-PA-Statement-FINAL.pdf

- 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. Any delay in appropriate cancer care can be devastating to patients and result in disease progression or serious impairment of quality of life.
- 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. 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.[23] Consistent with a previous survey conducted by the American College of Cardiology in 2016,[24] 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%).[25] To prevent exacerbating health disparities and to bolster the work of the agency[26] and the Administration to reduce health disparities, the need for a more transparent, efficient prior authorization process is critical—especially for smaller, under-resourced providers and their patient populations.

[23] 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
[24] American College of Cardiology. Cardiologist Perceptions of Access to New Therapies. October 2016.
[25] 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://abcardio.org/wp-content/uploads/2019/03/AB-20190227-PA-White-Paper-Survey-Results-final.pdf.
[26] https://www.cms.gov/about-cms/agency-information/omh/health-equity-programs/cms-framework-for-health-equity