March 6, 2020

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: Docket Number CMS-2020-0003
200 Independence Avenue, SW
Washington, DC 20201

Via electronic submission at www.regulations.gov


Dear Administrator Verma:

I am pleased to submit these comments on behalf of the Association for Clinical Oncology (the Association) in response to the Advance Notice of Methodological Changes for Calendar Year (CY) 2021 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies – Part II.

The Association is a national organization representing more than 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 are committed to ensuring that evidence-based practices for the prevention, diagnosis, and treatment of cancer are available to all Americans.

Prior Authorization: CMS’ Request for Related Quality Measures

In the Advance Notice - Part II, CMS acknowledges that prior authorizations can affect access to needed patient care and solicits feedback from stakeholders on any potential quality measures that could assess the performance of plans related to how well they administer and automate electronic prior authorizations. Specifically (from page 73 of the Advance Notice):

Prior Authorizations (Part C). CMS is beginning work to develop a measure for the display page related to prior authorizations and is considering proposing it in the future as a Star Ratings measure to support beneficiary access to necessary and reasonable care. Prior authorization is a critical aspect of plan performance since it affects how quickly plan enrollees can get needed care and services. Although prior authorization has proven to be an effective process for controlling
improper payments and managing costs, CMS recognizes that when processes are not in place to quickly review and approve requests for tests, services and supplies that may be medically necessary for the beneficiary, this can affect access to needed patient care. We are also interested in feedback from stakeholders on any potential quality measures that could assess the performance of plans related to how well they administer and automate electronic prior authorizations.¹

Our affiliate organization, the American Society of Clinical Oncology (the Society), has earlier expressed concerns and provided recommendations regarding improved processes and implementation for required prior authorization.²,³,⁴,⁵ Below we highlight some of the challenges faced by physicians and patients when navigating prior authorization requirements and summarize recommendations from the Society’s policy statement⁶ on utilization management.

**Prior Authorization Policies Must be Streamlined and Transparent to Avoid Unnecessary Barriers, Delays in Care, and Other Administrative Burdens**

The considerable length and complexity of the prior authorization process can cause unnecessary administrative burdens, drawing time and resources away from patient care. These barriers and complexities include, but are not limited to, the variation in processes and forms used by multiple payers; lack of knowledge and use of the most current clinical evidence to inform decisions; inefficiencies in response times and appeals; and lack of automation. Ultimately, the failure to consider the potential of poor outcomes resulting from prior authorization policies is detrimental to the patient. Additionally, payers may use a variety of information sources in making prior authorization determinations, including FDA labeling, clinical practice guidelines, clinical compendia, published clinical literature, and independent medical review, but they often do not disclose the process or basis for prior authorization decisions.

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authorization determinations. Personnel making prior authorization determinations may not be readily accessible to the prescribing provider and may have limited knowledge in oncology.

Seventy-eight percent of oncology practices responding to the 2016 ASCO Practice Trends Survey cited prior authorization as a significant pressure associated with payers. In a separate survey conducted by the American Medical Association (AMA), medical practices indicated that on average they conduct 37 prior authorization requests per week, accounting for approximately 16 hours—or two business days. Payers can mitigate these barriers to care by limiting the focus of prior authorization requirements to specific areas of concern and by providing an efficient, transparent prior authorization process within a reasonable timeline. Specifically, the Society recommends that payers:

- Develop and use standardized prior authorization request forms and processes to alleviate the administrative burdens placed on treating oncology teams or practices
- Use a public process by which they determine prior authorization policies for cancer treatment, reflecting the most up-to-date standards of care and including consultation with oncologists
- Restrict prior authorization policies to drugs where specific concerns about inappropriate use and/or undesirable variation exist
- Ensure oncologists make prior authorization determinations in cancer care and provide treating oncologists with direct access to that oncologist to discuss the clinical circumstances as necessary
- Integrate prior authorization processes into electronic health records to support authorization at the points of care, minimizing delays in treatment and administrative burden on providers
- 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
- Do not use the appeals mechanisms to compensate for underlying deficiencies in prior authorization policies or process
- 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, and increases in emergency department visits
- Ensure continuity for patients receiving a course of therapy upon enrollment in a health plan to prevent mandatory substitution or interruptions in treatment

Using these established recommendations as a starting point, we suggest some potential quality measures related to prior authorization below. These potential measures are organized into three areas: program design, administrative burden, and avoidance of patient harm.

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Potential Areas for Quality Measurement of Prior Authorization

The following factors may be considered as markers of quality in prior authorization program design, administration, and impact on patients.

Program Design

- The length of time for review through all phases (e.g. initial and subsequent requests, appeals, final appeals) of the process, including standard and expedited appeals
- The routine availability of specialists from the same specialty for peer-to-peer review in a timely/expedited process
- Plan consultation with relevant specialists prior to implementation of prior authorization for specific items / services in areas related to that specialty
- A process for developing prior authorization for items / services that is inclusive of stakeholders, free of conflicts (or potential conflicts appropriately disclosed), reflects expert specialist opinion, and relies on the latest evidence
- The plan provides reason(s) for any denials; does not base denials on administrative errors; and provides opportunity for correction of documentation prior to a decision
- A transparent and comprehensive appeals process is clearly spelled out by the plan
- Prior authorization requirements and criteria are readily available to providers and their staffs
- Prior authorization requirements and information are readily available to patients, in patient-friendly language
- The prior authorization process relies on the electronic transfer of information

Administrative Burden

- For each item or service requiring prior authorization, the plan makes available data on which of these items or services are routinely approved and implements processes to remove unnecessary prior authorizations
- The plan is able to show that for any particular item or service requiring a prior authorization, that prior authorization reflects valid concerns regarding undesirable variation in use
- For ongoing therapy or courses of treatment, the plan is able to justify and make publicly available requirements for repeat prior authorizations
- For each item or service requiring prior authorization, the plan makes available data on the percent of items or services which are initially denied but then approved upon appeal
- For each item or service receiving prior authorization, the plan makes available data on the number of times/percent of authorizations that are subsequently reversed
- The prior authorization process utilizes standardized forms and processes which are, to the extent possible, fully integrated into a physician’s electronic health record
Avoidance of Patient Harm

- The plan has a process in place for reviewing and initiating corrective action in instances of suspected patient harm reported by providers (e.g. suboptimal outcomes or disease progression) due to delays in prior authorization
- The plan has a process in place for reviewing and initiating corrective action in instances of other complications reported by providers arising from delays in treatment (e.g. the exacerbation of nausea due to poor initial emesis control or avoidable hospitalizations or emergency department visits due to poor symptom control)
- The plan allows newly enrolled beneficiaries to continue an established course of treatment without it being interrupted due to prior authorization requirements under the beneficiary’s new plan

While we believe all the processes and activities noted above are important for the efficient and equitable implementation of any required prior authorization requirements, we would like to especially highlight here the importance of rapid responses to prior authorization requests. From the time of notification of a required prior authorization through to an ultimate decision being rendered, precious hours and days—sometimes weeks—are slipping away from a patient whose disease may be progressing, whose symptoms may be spiraling out of control, and who may be losing hope for a cure. For patients with cancer this is especially true: treatments delayed may be treatments that are now less effective; delayed imaging studies may also allow time for tumor burden to increase; and otherwise controllable symptoms such as nausea and vomiting associated with some chemotherapy treatments may lead to uncontrollable anticipatory nausea and vomiting or even hospitalization if not addressed in a timely fashion. We therefore recommend that CMS pay close attention to the issue of timeliness when considering potential quality measures in the area of prior authorization.

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The Association appreciates the opportunity to provide comments on this Advance Notice. Please contact Gina Baxter (gina.baxter@asco.org) or Karen Hagerty (karen.hagerty@asco.org) with any questions or for further information.

Sincerely,

Monica Bertagnolli, MD, FACS, FASCO
Chair of the Board
Association for Clinical Oncology