

CANCER LEADERSHIP COUNCIL

A PATIENT-CENTERED FORUM OF NATIONAL ADVOCACY ORGANIZATIONS
ADDRESSING PUBLIC POLICY ISSUES IN CANCER

August 31, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

RE: CMS-4203-NC – Request for Information on Medicare

Dear Administrator Brooks-LaSure:

The undersigned cancer patient, health care professional, and research organizations appreciate the opportunity to comment on the Vision for Medicare and how Medicare Advantage (MA) plans can achieve the vision that “puts the person at the center of care and drives towards a future where people with Medicare receive more equitable, high quality, and whole-person care that is affordable and sustainable.” There are currently substantial obstacles to access to whole-person care in MA plans, as many plan policies and strategies delay or deny access to high-quality care. In addition, many MA plans fall short in achieving health equity. We recommend policies below to address the serious obstacles to quality cancer care that many MA enrollees experience.

Ensure Coverage for Quality Cancer Care

The United States Department of Health and Human Services Office of Inspector General (IG) recently released a report on Medicare Advantage Organization (MAO) denials of prior authorization requests and denials of payment requests. The IG noted that some of the denials – prior authorization request denials and payment denials – were ultimately reversed by MAOs.¹ However, both kinds of denials (even if reversed) may have an adverse effect on Medicare beneficiary access to medically necessary care. As the IG gently noted, “Denying requests that meet Medicare coverage rules may prevent or delay beneficiaries from receiving medically

¹ U.S. Department of Health and Human Services Office of Inspector General, Report in Brief, April 2022, OEI-09-18-00260, Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care. The IG found that 13 percent of prior authorization denials met Medicare coverage rules and 18 percent of payment requests that were denied met Medicare coverage and payment rules.

necessary care and can burden providers.”² The IG continued, “Although some of the denials that we reviewed were ultimately reversed by the MAOs, avoidable delays and extra steps create friction in the program and may create an administrative burden for beneficiaries, providers, and MAOs.” The IG notes that denials of coverage involved advanced imaging services (MRIs) and stays in post-acute facilities.

The IG report confirms the experience of cancer patients and health care professionals who receive and provide care in MA plans, respectively. However, the report understates the barriers to quality care that cancer patients in MA plans encounter. The report focuses on denials of prior authorization and payment (acknowledging that some denials are reversed), and we agree that the pattern of denials is an obstacle to patient access to care. However, the use of prior authorization – even when there is no denial – serves to delay care, if it does not absolutely block access to care. For cancer patients, delays in care have an impact on quality of care, outcomes of care, and cost of care. Delays in care may increase the risk of death from cancer. Research shows that there is a 1.2 to 3.2 percent increased risk of death with each week of delay in cancer treatment initiation.³

The expansive use of prior authorization to control costs in MA plans is at odds with the needs of cancer patients and puts them at great risk. In addition, we suggest that the use of prior authorization to control costs is short-sighted and counterproductive for plans and not just for patients. Delaying medically necessary care may result in subsequent expenditures for care that are greater than they might have been with early and appropriate intervention with medically necessary care.

The coronavirus pandemic has resulted in delays in screening and diagnosis of cancer, with patients diagnosed with later stage cancer and with outcomes adversely affected as a result. Large employers have recently reported that for the first time in the history of their annual survey, cancer has overtaken musculoskeletal conditions as the top cost driver. Of the employers participating in the survey, 13% are seeing a higher prevalence of late-stage cancers, and another 44% anticipate seeing an increase in the future.⁴ We acknowledge that prior authorization and diagnosis of later stage cancer are distinct and different events. However, they may be alike in their adverse effects on patients AND on health care spending, including the costs borne by MAOs that aggressively utilize prior authorization.

Because it is critically important that Medicare beneficiaries in MA plans have access to medically appropriate care that is reimbursed equitably, we recommend that MA plans adhere to professionally developed clinical practice guidelines and prior authorization model policies.

² U.S. Department of Health and Human Services Office of Inspector General, Report in Brief, April 2022, OEI-09-18-00260, pages 9-12.

³ Khorana AA, Tullio K, Elson P, Pennell NA, Grobmyer SR, et al. (2019) Correction: Time to initial cancer treatment in the United States and association with survival over time: An observational study. PLOS One 14(4): e0215108. <https://doi.org/10.1371/journal.pone.0215108>.

⁴ 2023 Large Employers' Health Care Strategy and Plan Design Survey, Business Group on Health, August 22, 2022. Accessed on August 25, 2022, at <https://www.businessgrouphealth.org/en/resources/2023-large-employers-health-care-strategy-survey-intro>.

These policies should include an electronic prior authorization process to streamline approvals; limits on the time allowed for the prior authorization process; a requirement that MA plans report their use of prior authorization, approvals, and denials; and adherence to evidence-based guidelines.⁵

Our reservations about prior authorization also relate to the fact that the authorization process can undermine cancer care planning and coordination that features shared decision-making. We believe that cancer care planning should be a core feature of MA plans for people diagnosed with cancer, as described below.

Cancer Care Planning to Ensure People with Cancer Receive the Care They Need

The first question in the Request for Information (RFI) on Medicare asks about the steps that CMS should take to “better ensure that ALL (emphasis added) MA enrollees receive the care they need...” The inquiry also identifies specific groups of enrollees, to ensure that their needs are assessed and addressed. We think that this is the appropriate first question of the RFI, and we have a clear answer about the FIRST step that CMS can take to ensure that cancer patients in MA plans receive the care they need. In offering this answer, we stress that we are addressing first and foremost the needs of cancer patients, although we think a comparable recommendation is appropriate for other MA enrollees with serious or chronic diseases. We recommend that, upon receiving a cancer diagnosis, a cancer patient should have access to a cancer care planning process that includes shared decision-making.

The Institute of Medicine (IOM), in a 2013 report, *Delivering High-Quality Cancer Care: Charting a New Course for a System in Crisis*, identified the elements of a care management plan.⁶ This planning process was included in the Oncology Care Model alternative payment model tested by the Centers for Medicare & Medicaid Services from July 1, 2016, through June 30, 2022. The provision of a cancer care plan, according to the standards of the Institute of Medicine, was one of the patient-focused elements of the Oncology Care Model and one of the practice improvement activities required of participating oncologists. The cancer care planning requirement will also be an element of the Enhancing Oncology Model due to launch in 2023.

⁵ The Seniors’ Timely Access to Care Act of 2022 (HR 3173) would modernize and streamline prior authorization policies and permit physicians to provide the best care for patients. This legislation has been approved by the House Ways and Means Committee. We support enactment of this legislation to set prior authorization standards that will protect patients and permit their physicians to provide medically appropriate care without delay or bureaucratic hassle.

⁶ Institute of Medicine. 2013. *Delivering High-Quality Cancer Care: Charting a New Course for a System in Crisis*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/18359>.

The 13 components within the IOM's Care Management Plan include:

1. Patient demographic information, medication list, and allergy list
2. Diagnosis, including specific tissue information, relevant biomarkers, and staging information
3. Prognosis
4. Treatment goals (curative, life-prolonging, symptom control, palliative care)
5. Initial plan for treatment and proposed duration, including specific chemotherapy drug names, doses, and schedules, as well as surgery and radiation therapy if applicable
6. Expected response to treatment
7. Treatment benefits and harms, including common and rare toxicities, how to manage them, and short-term and late effects of treatment
8. Quality-of-life information and patient's likely experience with treatment
9. Outline of who will take care of specific aspects of patient's care (cancer care team, geriatrics care team, other teams)
10. Advance care plans, including advanced directives and other legal documents
11. Estimated total and out-of-pocket costs of cancer treatment
12. Psychosocial health plan, including psychological, vocational, disability, legal, or financial concerns
13. Detailed survivorship care plan, including a summary of treatment and information on recommended follow-up activities and surveillance, as well as risk reduction and health promotion activities

The cancer care planning process that has been identified by the Institute of Medicine, incorporated into oncology delivery models, and adopted by many cancer care professionals, provides cancer patients with information and tools to help them better manage their care. The plan also helps patients understand the financial burdens of care and provides tools for managing the psychosocial, vocational, disability, legal, or financial concerns associated with a cancer diagnosis and cancer care. Cancer care planning incorporates a conversation between the patient and cancer care team and a shared decision-making process. Oncology professionals acknowledge the challenges associated with shared decision-making but the significant opportunities it presents for fostering patient-centered care.⁷

A cancer care planning process, if of high quality and equitably provided to all MA enrollees who are diagnosed with cancer, can be a core element of an efforts to address diversity, equity, and inclusion issues in MA plans. There is evidence from a randomized clinical trial that survivorship care plans provided to Latina breast cancer survivors show benefits in clinical outcomes.⁸ We strongly encourage the requirement of a cancer care planning process, with a plan in written or electronic form provided to the patient, for all MA enrollees diagnosed with cancer.

⁷ Katz SJ, Belkora J, Elwyn G. Shared Decision Making for Treatment of Cancer: Challenges and Opportunities. *Journal of Oncology Practice* 10, no. 3 (May 1, 2014).

⁸ Maly RC, Liang LJ, Griggs JJ, et al. Randomized Controlled Trial of Survivorship Care Plans Among Low-Income, Predominantly Latina Breast Cancer Survivors. *Journal of Clinical Oncology*. Volume 35, No. 15, July 1, 2017.

MA Enrollees Should be Protected from Cost-Sharing if Enrolled in a Clinical Trial

Since 2000, a Medicare coverage decision governing the routine patient care costs for those enrolled in clinical trials has been in place.⁹ Under the terms of this coverage policy, a Medicare beneficiary who enrolls in a clinical trial will have Medicare coverage for the routine patient care costs that they incur as a result of participation in the trial.¹⁰

Because this particular barrier to clinical trials participation has been removed, Medicare beneficiaries can consider participation in a trial without the responsibility for paying out of pocket for routine patient care costs. A clinical trial may represent the best or even the only treatment option for certain cancer patients. It should be noted that there remain additional economic and other barriers to clinical trials participation, but at least Medicare beneficiaries are not burdened by routine patient care costs. That is, some Medicare beneficiaries.

Unfortunately, MA enrollees do not easily or routinely enjoy clinical trial enrollment opportunities. Many MA plans do not communicate clearly in patient educational materials about the possibility of clinical trial enrollment if that is appropriate for the patient. Neither do those plans openly encourage MA enrollees to participate in trials. Finally, if patients work against all of these odds to identify clinical trials in which they wish to participate, they face uncertainty about their financial responsibilities associated with trial participation. Will their clinical trial participation be considered out-of-network care for which they will bear cost-sharing responsibilities, a financial burden that they will not be able to meet easily because they do not have supplemental Medicare insurance because of their MA enrollment?

MA plans' inaction and actions related to clinical trial enrollment are not consistent with the best interests of MA participants. But these actions regarding clinical trials are also at odds with the best interests of MA plans. Care in clinical trials may not only be the best option for clinical trial participants but also for the payer if it means that the patient is getting effective treatment in the trial. In addition, MA plans and the entire cancer care system benefit from clinical trials that tell us which investigational agents and care are effective and which are not.

We urge CMS to require MA plans to make clinical trial enrollment opportunities available to patients without imposing on them out-of-network cost-sharing responsibilities. We also recommend that enrollee educational materials on this topic be developed and disseminated.

⁹ National coverage policy of 2000 accessed on August 25, 2022:

<https://www.cms.gov/medicare/coverage/clinicaltrialpolicies/downloads/finalnationalcoverage.pdf>.

¹⁰ Version 2 of the coverage policy, updated in 2007, is available online at

<https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=1&ncdver=2&keyword=clinical%20trials&keywordType=starts&areald=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1>.

Accessed on August 25, 2022.

We appreciate the opportunity to offer advice regarding actions that MA plans can take to improve access to patient-centered care for cancer patients and other MA enrollees.

Sincerely,

Cancer Leadership Council

Academy of Oncology Nurse & Patient Navigators
American Society for Radiation Oncology
Association for Clinical Oncology
CancerCare
Cancer Support Community
Children's Cancer Cause
Hematology/Oncology Pharmacy Association
International Myeloma Foundation
LUNgevity Foundation
Lymphoma Research Foundation
National Coalition for Cancer Survivorship
Ovarian Cancer Research Alliance
Prevent Cancer Foundation
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