PERSONALIZED MEDICINE COALITION

January 5, 2024

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS–4205–P
7500 Security Boulevard
Baltimore, MD 21244-1850

BY ELECTRONIC DELIVERY

Re: Medicare Program; Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, etc. (CMS–4205–P)

Dear Administrator Brooks-LaSure:

The Personalized Medicine Coalition (PMC), a multi-stakeholder group comprising more than 200 institutions from across the health care spectrum, thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to submit comments on policies related to utilization management (UM) and health equity under the *Contract Year (CY) 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, etc.* proposed rule.[i] The proposed rule acknowledges barriers certain patients can face in accessing necessary treatments and services in Medicare Advantage (MA). CMS' proposals can help address these barriers by introducing new health equity requirements for MA organizations' UM Committees and enhancing transparency and data collection on UM practices. Our comments support these proposals and reiterate previous recommendations for how CMS can mitigate barriers created by UM practices, like prior authorization and step therapy, in patient access to personalized medicine.

Personalized medicine is a rapidly evolving field in which physicians use diagnostic tests to determine which medical treatments will work best for each patient or use medical interventions to alter molecular mechanisms that impact health. By combining data from diagnostic tests with an individual's medical history, circumstances, and values, health care providers can develop targeted treatment and prevention plans with their patients.

Personalized medicine is helping to shift the patient and provider experiences away from trial-and-error toward a more streamlined process for making clinical decisions, which will lead to improved patient outcomes, a reduction in unnecessary treatment costs, and better patient and provider satisfaction. PMC and its members are leading the way in personalized medicine and in developing evidence showing how patients and the health care system can benefit from appropriate testing and tailored treatment

as soon as possible during their clinical experiences.

Statement of Neutrality

PMC's members may present their own responses to CMS' *CY 2025 Policy and Technical Changes to the Medicare Advantage Program, etc.* proposed rule and actively advocate for those positions. PMC's response is designed to provide feedback so that the general concept of personalized medicine can advance, and is not intended to impact adversely the ability of individual PMC members, alone or in combination, to submit separate responses to CMS on this proposed rule.

Support for health equity analyses and data collection on utilization management under MA

MA plans offer Medicare beneficiaries an alternative to original Medicare through a private sector payer. MA organizations are permitted by CMS to employ UM practices like prior authorization and step therapy to reduce inappropriate utilization of services and promote cost efficiency in care, but these practices can present barriers for patients and their providers in accessing treatments and services under MA plans. Prior authorization practices have come under increased scrutiny for decreasing access, delaying care, decreasing patient satisfaction and outcomes, and increasing clinician burnout.[ii, iii, iv, v] In fact, a 2020 study conducted by PMC identified complex administrative policies and prior authorization requirements as an obstacle to the consistent utilization of genomic testing approaches including comprehensive genomic profiling of tumors in patients with advanced cancer. [vi] With more than half of eligible Medicare beneficiaries now enrolled in MA as of 2023 and this number projected to increase over the next decade,[vii] improvements to the MA program are critical to ensure patients can access personalized medicine.

Building on its CY 2024 final rule requiring all MA plans to establish a UM Committee for reviewing policies annually and ensuring consistency with traditional Medicare's national and local coverage decisions and guidelines,[viii] CMS' proposed rule for CY 2025 would introduce additional requirements for these UM Committees to (1) include at least one member with expertise in health equity and (2) conduct annual health equity analyses evaluating the impact of prior authorizations on individuals who receive a low-income subsidy, are dually eligible, or have a disability in order to identify potential health disparities. For all items and services at the plan level, CMS proposes that the health equity analysis compare the levels of prior authorization approvals, denials, appeals, and their timeliness for enrollees with these "specified social risk factors" versus enrollees who are not in these categories. CMS also proposes a requirement that MA organizations make the results of the annual health equity analyses publicly available on their websites.

PMC generally supports CMS' proposals to include at least one member with expertise in health equity on MA organizations' UM Committees and to require annual health equity analyses. The proposed health equity analysis has the potential to help identify disproportionate impacts of UM policies and procedures on enrollees from underserved populations. We commend CMS' focus on health equity in the proposed rule, which aligns with CMS' *Strategic Plan*[ix] and *Framework for Health Equity.*[x] **We recommend that in future rulemaking CMS also require Part D plan sponsors to establish UM Committees and extend these health equity requirements.**

We appreciate CMS' interest in feedback on additional populations that should be considered in the proposed health equity analyses. Considering additional social risk factors and patient characteristics can

help ensure that the unique circumstances of underserved populations are accounted for when assessing the impact of UM policies. Later this year, PMC will release findings from a recent project convening leaders from underrepresented communities who identified the importance of improved health data collection and use in personalized medicine research to mitigate disparities and promote equity in the United States health care system. **In finalizing the scope of the proposed health equity analyses, PMC encourages CMS to prioritize feedback received from commenters who work directly with underrepresented populations. We would support analyses that consider additional patient characteristics — including but not limited to enrollees' race, ethnicity, sex, and geography to make the annual analyses more inclusive.**

In order to quickly recognize and ameliorate problems caused by certain UM protocols, CMS needs better inbound data. In the proposed rule, CMS also proposes to enhance transparency and data collection by amending reporting requirements imposed upon MA organizations and Part D plan sponsors to include procedures relating to coverage, utilization, and the actions required of beneficiaries to obtain covered items or services. By solidifying its authority to collect this information, CMS states it intends to lay the groundwork for new and increased data collection to "have better line of sight" on UM and prior authorization practices and to better understand the circumstances under which plans choose whether to provide or pay for an item or service. We applaud this approach. Better insight into prior authorization practices will improve our understanding of the impacts of UM on patients and help ensure beneficiaries are getting access to medically necessary care, including personalized medicine. We hope this data will be available both to CMS policymakers and to extramural health services researchers as appropriate. **We therefore support CMS' proposal to solidify its authority to collect information on prior authorization and utilization management practices from MA organizations and Part D plan sponsors.**

<u>Additional recommendations to facilitate MA enrollees' access to personalized medicine</u>

We appreciate CMS' efforts through recent rulemaking to respond to stakeholder concerns that UM practices can create barriers for patients in accessing medically necessary care. Although we believe CMS has made significant progress in implementing policy changes to help address these barriers, we reiterate the following recommendations to accelerate patient access to personalized medicine, which we previously shared with CMS in our response to the agency's 2022 request for information on opportunities to improve health care for patients covered by MA plans.[xi]

In 2019, CMS began to permit MA plans to use step therapy as a UM tool for Part B drugs, [xii] even though these practices are prohibited in traditional Medicare. PMC previously opposed CMS' implementation of this policy.[xiii] UM practices like step therapy require a patient to try a lower-cost treatment before working up to a more expensive product if the initial treatment is ineffective. Access to the right treatment at the right time is critical for patients dealing with progressive and chronic diseases, such as cancer or autoimmune diseases, for which many Part B drugs are intended. By facilitating the same treatment protocol for every patient, regardless of their biological differences, step therapy pre-empts the use of personalized treatments that have a high likelihood of working for a patient, robbing patients of time and reducing the quality of their lives.[xiv, xv] With personalized medicines accounting for more than a quarter of all new drugs approved by the U.S. Food and Drug Administration since 2015,[xvi] the pipeline for personalized therapies becoming available to patients remains robust. **We therefore urge CMS to reinstate the prohibition of step therapy for Part B drugs and ensure equitable access to these drugs among individuals with traditional Medicare or MA coverage.**

In addition, MA plans typically do not allow the laboratory servicing provider to participate in the prior authorization process, instead requiring the ordering physician to do so. This can create a natural roadblock in MA beneficiaries' access to the testing services underpinning personalized medicine. In cases when a health plan delegates prior authorization to a third party, the ability of the laboratory service provider to participate in prior authorization may also depend on the MA plan's arrangement with that third party. The laboratory service provider can be better positioned to obtain prior authorization for the test it performs using information provided by the ordering physician, especially when the laboratory is billing for the test. **PMC believes that laboratory service providers should be able to participate in MA plans' prior authorization process to help streamline patients' access to necessary testing services.** Improving laboratory service providers' participation in prior authorization can reduce the burden of this practice on patients and providers as well as improve the timeliness of UM decisions.

Finally, in our previous comments to CMS, we raised that some MA plans have used prior authorization to delay or decline coverage for testing already covered under a National Coverage Determination (NCD) by requiring documentation in excess of what CMS requires to determine medical necessity. We also called on CMS to ensure that in instances where an item or service is already covered by an NCD, prior authorizations should not contain additional criteria beyond what is already included in the NCD. We applaud CMS for establishing regulation in its CY 2024 final rule that requires MA plans to comply with NCDs, local coverage determinations (LCDs), and general coverage and benefit conditions included in traditional Medicare regulations. **While we believe these new regulations in the CY 2024 final rule can help prevent MA plans from denying coverage for certain laboratory services covered by NCDs and LCDs, including those essential to the timely delivery of personalized medicine, in future rulemaking we also urge CMS to address the misuse of burdensome document requests for laboratory services clearly covered under NCDs and LCDs and to establish a streamlined mechanism for reporting and resolving suspected violations.**

Conclusion

PMC appreciates CMS' continued commitment to improving health care for beneficiaries enrolled in the MA program with a focus on UM and health equity. We look forward to working with you and your colleagues to facilitate Medicare beneficiaries' and MA enrollees' access to personalized medicine. If you have any questions about the content of this letter, please contact me at 202-499-0986 or cbens@personalizedmedicinecoalition.org, or David Davenport, PMC's Manager of Public and Science Policy, at ddavenport@personalizedmedicinecoalition.org or 804-291-8572.

Sincerely,

Cynthia A. Bens
Senior Vice President, Public Policy

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[xv] Stephanie Lomas. "The Debate Over Step Therapy." *Applied Policy*. June 10, 2023. https://www.appliedpolicy.com/step-therapy/ (accessed January 2, 2024).
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