PERSONALIZED MEDICINE COALITION

January 24, 2025

Jeff Wu
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS–4208–P
P.O. Box 8013
Baltimore, MD 21244–8013

BY ELECTRONIC DELIVERY

Re: Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (CMS-4208-P)

Dear Administrator Wu:

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 prior authorization and other utilization management (UM) policies under the *Contract Year (CY) 2026 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 requirements for MA organizations' UM Committees and data reporting, strengthening non-discrimination guardrails over the use of artificial intelligence (AI), and enhancing rules related to internal coverage criteria. Our comments generally support these proposals, encourage further enhancements, 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 and individual details about a person and their health 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 2026 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 more granular reporting in UM Committee's health equity analyses

MA plans offer Medicare beneficiaries an alternative to Traditional 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 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] Evidence also suggests that prior authorization does not consistently achieve cost savings and may increase overall health care expenses due to delayed or disrupted care.[vii, viii] 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,[ix] improvements to the MA program are critical to ensure patients can access personalized medicine.

In the CY 2024 final rule, CMS required 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.[x] In order to evaluate the impact of prior authorizations on enrollees with certain social risk factors and identify potential health disparities, CMS' CY 2025 final rule added requirements for UM Committees to conduct annual health equity analyses reporting the levels of prior authorization approvals, denials, appeals, and timeliness for enrollees who receive a low-income subsidy, are dually eligible, or have a disability.[xi] For CY 2026, CMS is proposing to require more granularity in the annual health equity analyses conducted by MA plans' UM Committees by requiring these prior authorization metrics to be reported by each item or service, rather than in aggregate.

PMC supports CMS' proposals to require MA organizations' UM Committees to conduct more granular health equity analyses. We also recommend CMS require each item or service be reported by Current Procedural Terminology (CPT) code. In 2024, PMC published recommendations from leaders of underrepresented and rural communities who identified the importance of improved health data collection to mitigate disparities and promote equity in the United States' health care system. We believe disaggregating the reported metrics for all items and services will increase transparency and provide more accurate data on how prior authorization practices can contribute to systemic health inequities impacting patient access to personalized medicine. Reporting for each item or service by CPT

code will also allow CMS policymakers, health services researchers, and other stakeholders to more quickly recognize and address access issues caused by prior authorization practices. **We recommend that in future rulemaking CMS also require Part D plan sponsors to establish UM Committees and require similar health equity analyses.**

Support for establishing guardrails for MA plans' use of AI

An October 2024 report from the U.S. Senate Permanent Subcommittee on Investigations found that, during the implementation of AI algorithms between 2020 and 2022, one MA plans' prior authorization denial rate for post-acute care more than doubled from 10.9 to 22.7 percent.[xii] To ensure health care decisions appropriately reflect individual patients' needs and preferences, the use of AI in health care decision-making must not supplant human decision-making, patient preferences, and clinician knowledge. PMC shares growing concerns among stakeholders that, without human oversight and depending on biases in how data may be trained and used, the use of AI algorithms in handling prior authorization requests may improperly delay or deny access to personalized medicine.

PMC supports CMS' proposal to establish guardrails for MA plans' use of AI algorithms by reiterating the applicability of existing non-discrimination and equitable access standards, whether through human or automated systems, and by requiring MA plans to ensure that AI or automated systems, if utilized, are used in a manner that preserves equitable access to MA services.

CMS provides examples for how MA organizations could maintain compliance with this proposal, such as by mitigating the input of biased data, regularly reviewing use of the automated system, and not using outputs with a known discriminatory bias, such as expected utilization or predictability of payment. We support CMS' effort to ensure that MA plans' use of AI does not result in inequitable treatment and/or bias within the health care system, and instead is used to promote access to care. Human oversight, transparency in how and when AI algorithms are used, and other bias mitigation strategies can help ensure health care decisions appropriately reflect individual patients' needs and preferences. **To ensure MA plans' compliance with CMS non-discrimination and equitable access standards**, **we urge CMS to monitor denials and explore when algorithms were used as part of the decision-making process leading to the denials.**

Comments on regulations clarifying MA plans' use of internal coverage criteria

In its CY 2024 final rule, CMS required MA plans to comply with national coverage determinations (NCDs), local coverage determinations (LCDs), and general coverage and benefit conditions included in Traditional Medicare regulations.[xiii] For CY 2026, CMS is proposing to enhance its regulations related to MA plans' use of internal coverage criteria when Traditional Medicare coverage criteria are not fully established by defining "internal coverage criteria," establishing policy guardrails to ensure enrollee access to benefits, and adding more specific rules about publicly posting internal coverage criteria content on MA organization websites.

PMC believes CMS' proposals to define and clarify the appropriate use of internal coverage criteria provide another step forward in addressing variability in patients' access to items and services between MA and Traditional Medicare, while promoting transparency, equity, and timely access to personalized medicine. In particular, we support CMS' proposal to clarify in regulation that MA plans' internal coverage criteria may not be used to add new coverage criteria for an item

or service that already has established coverage criteria, such as an NCD or LCD. Aligning MA coverage criteria with Traditional Medicare can reduce inconsistencies in coverage policy that complicate treatment decision-making and hinder patient access to personalized medicine, especially patients from underserved communities who often face disproportionate barriers to care and challenges with appeals processes.

CMS is proposing two new policy guardrails that will apply to all internal coverage criteria: that using an internal coverage criterion is prohibited when the criterion does not have any clinical benefit or when the criterion is used to automatically deny coverage of basic benefits without the MA organization making an individual medical necessity determination. **PMC supports these policy guardrails, and we recommend CMS clarify that an internal coverage criterion is prohibited <u>either</u> when there is no clinical benefit or when it is used to deny coverage automatically— not when both conditions are present— by amending the proposed regulation at § 422.101(b)(6)(iv) and replacing the period at the end of clause (A) with "; or".**

Technical refinements related to molecular diagnostic tests

Currently over half of U.S. states participate in the Molecular Diagnostic Services (MolDX®) program, administered by Palmetto GBA, with other participating Medicare Administrative Contractors (MACs) including Noridian Healthcare Solutions, Wisconsin Physician Services Corp (WPS), and CGS Administrators, LLC. MACs that participate in the MolDX® program issue and administer similar (often identical) "foundational" LCDs for molecular diagnostic tests, for which laboratories are required to obtain unique Z-Code identifiers in the proprietary DEX® Diagnostics Exchange database.

PMC is concerned that CMS' proposed language at § 422.101(b)(6)(i)(A) does not align with the practical realities of Medicare coverage policies, particularly molecular diagnostic tests underpinning personalized medicine that are managed under the MolDX® program. Here, to clarify that internal coverage criteria cannot be used to add new, unrelated coverage criteria for an item or service that already has existing coverage policies under Traditional Medicare, CMS proposes revised language permitting MA plans to apply internal coverage criteria when "additional, unspecified criteria are needed to interpret or supplement the *plain language* of applicable Medicare coverage and benefit criteria in order to determine medical necessity consistently." CMS asserts that it is only in the "rare instance" when an NCD or LCD is lacking in specificity or clarity that internal coverage criteria would be permissible, and that information contained in LCD articles, such as billing and coding articles, do not contain coverage criteria.

While we agree that it is only in rare instances that internal coverage criteria should be permissible, there are many laboratory LCDs whose coverage policies are neither specific nor clear, so such internal coverage criteria are not "rare instances". By their nature, the foundational LCDs issued by the MolDX® program are lacking in specificity and clarity in their "plain text" because they focus on high-level information about the process and criteria that the MolDX® program will apply in the future to determine whether or not a test is covered.[xiv, xv] Clinical laboratory tests can be identified at the code level— a CPT® code, a Proprietary Laboratory Analysis (PLA) code, and/or a "Z-code" issued by the MolDX® program.[xvi] Foundational LCDs themselves, however, do not specify which laboratory tests are covered. Instead, MolDX® LCDs explicitly direct stakeholders to consult supplemental resources to interpret and operationalize test-specific coverage decisions, such as the billing or coding articles associated with the LCD or supplemental resources like the DEX® Diagnostics Exchange database. These external resources,

which are integral to MolDX® coverage determinations, are not captured within the "plain language" of the LCDs. In fact, CMS' *Medicare Program Integrity Manual* even states that CPT codes may not be included in an LCD and shall be placed instead in billing and coding articles or Policy Articles.[xvii]

Requiring MA plans to rely solely on explicit criteria within LCDs will lead to confusion, misinterpretation, and potential gaps in coverage for important diagnostic tests. It is important for CMS to acknowledge and account for the unique process for coverage of molecular diagnostic tests under MolDX® LCDs where the billing article and proprietary contractor databases are necessary. **To recognize the role of supplemental resources in operationalizing coverage policies via LCDs for molecular diagnostic tests, CMS should clarify in the final rule that**

- **coverage and benefit criteria may be found not only in statutes, regulations, NCDs, and LCDs, but also in billing articles and in supplemental contractor resources (such as the DEX® Diagnostics Exchange database for molecular diagnostics under the MolDX® system);**
- **prior to developing internal coverage criteria, MA plans should look to <u>all</u> such sources for evidence of Traditional Medicare coverage of a laboratory test or other item or service, including billing articles and supplemental contractor resources; and**
- **if an item or service is listed in the billing article or supplemental resource, then it is covered, but MA plans cannot use lack of inclusion in the billing article or supplemental resource as the basis for denying coverage.**

Clarifying the sources that MA plans should look to prior to developing internal coverage criteria will help reduce variabilities in patient access to items and services, including molecular diagnostic tests, and ensure that MA plans cover all items and services for which benefits are available under Medicare Parts A and B.

Enhancing public accessibility and enforcement

PMC supports CMS' proposals to revise its public accessibility requirements to ensure that MA organizations make information regarding their internal coverage criteria and the evidence supporting an internal coverage criterion publicly available in a manner that is routinized and easy to follow. We agree it should be clear to all enrollees and stakeholders the items and services for which a MA plan has internal coverage criteria that supplement LCDs or NCDs, and that it should be easy to find those criteria. We urge CMS to finalize these policies to promote transparency across MA organizations and to ensure that any stakeholder can easily access this information without barriers such as requirements to establish a user account and password or to accept terms. The website that contains such information should also be user friendly to empower patients, providers, and other stakeholders with the information needed to navigate prior authorization and appeals processes more effectively. **In addition, we recommend the internal coverage criteria be posted with a publicly accessible list of payable diagnosis codes to increase transparency and efficiency in determining which items or services satisfy a MA plan's criteria.**

PMC members have observed that MA organizations and their third-party intermediaries are increasingly adopting and implementing internal coverage criteria that do not meet the regulatory requirements at § 422.101(b)(6). Specifically, MA organizations, or laboratory benefit managers on behalf of or at the bequest of MA organizations, are adopting and implementing internal coverage criteria that are not "publicly accessible" and are not based on "current evidence" in "widely used" treatment guidelines or clinical literature as required by § 422.101(b)(6). Although we support CMS' efforts to provide greater

transparency and clarity by defining and establishing guardrails for internal coverage criteria, these policies will not meaningfully address variabilities in MA enrollees' access to treatments and services without enforcement. **PMC urges CMS to educate MA organizations and their associated third-party intermediaries about the regulatory requirements relevant to internal coverage criteria, clearly communicate CMS' intent to enforce the requirements, and consistently enforce them.**

To facilitate monitoring and enforcement of these regulatory requirements, PMC supports annual reporting by MA plans to CMS of the internal coverage criteria information that must be made publicly available. CMS should be monitoring MA plans' compliance with internal coverage criteria requirements, and receiving this information directly from MA plans will simplify CMS' oversight. We also believe that being required to report this information directly to CMS may encourage MA plans to comply with these requirements.

In addition, we recommend that CMS require MA plans, along with the internal criteria on their websites, to disclose which, if any, third-party organizations were involved in the development or implementation of the individual coverage criteria. Making such information publicly accessible will offer stakeholders, including providers, much-needed transparency into internal coverage policies and will help CMS better understand the roles that third-party organizations play in developing, implementing, and overseeing internal coverage criteria on behalf of a MA plan.

In previous comments to CMS, PMC raised that some MA plans have used prior authorization to delay or decline coverage for testing already covered under a NCD by requiring documentation in excess of what CMS requires to determine medical necessity,[xviii] such as burdensome medical records requests when a simpler test requisition form provides sufficient information. While we believe CMS' proposed guardrails for internal coverage criteria could help prevent MA plans from denying coverage for certain laboratory services covered by NCDs and LCDs, **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.** Currently, there is no clear mechanism to escalate issues where MA plans are not covering services in line with Traditional Medicare. **We recommend CMS create a provider-specific electronic form for reporting suspected MA violations to CMS and establish a clear process to allow providers to escalate suspected violations and resolve disputes between providers and MA organizations.**

Addressing internal coverage criteria narrowing access to CAR T-cell therapy

Chimeric Antigen Receptor (CAR) T-cell therapy represents a significant advancement in personalized medicine. Some cancer patients with very poor prognoses have experienced life-improving and life-extending outcomes resulting from CAR T-cell therapy, including patients with certain forms of lymphoma, leukemia, and multiple myeloma. Since 2018, PMC has supported Medicare coverage and reimbursement policies that ensure timely beneficiary access to these potentially life-saving personalized treatments.[xix]

We are concerned that some MA plans are establishing internal coverage criteria through accreditation requirements that limit the delivery of CAR T-cell therapy to a narrower set of treatment centers than Traditional Medicare. These accreditation requirements are in conflict with Medicare's 2019 NCD 110.24 that establishes the criteria for coverage of CAR T-cell therapies.[xx] In some cases, MA plans

provide coverage of CAR T-cell therapy administration only at treatment centers with Foundation for Accreditation of Cellular Therapy (FACT) accreditation, even though CMS' NCD Decision Memo explicitly considered but rejected FACT accreditation.[xxi] Notably, MA plans characterize this requirement as a condition of coverage, even though it more closely resembles a network requirement since it governs a provider's ability to furnish CAR T-cell therapy irrespective of the patient's eligibility for the treatment.

MA plans' use of FACT accreditation to limit the delivery of CAR T-cell therapy to a narrower set of treatments centers is in conflict with CMS' NCD 110.24 and creates a barrier to enrollee access that, in effect, represents the kind of internal coverage criteria that CMS' proposed regulatory clarifications should specifically address and curtail. In its NCD Decision Memo, CMS indicated that the agency decided not to require FACT accreditation in order to provide uniform national coverage of CAR T-cell therapies. FACT was not developed nor intended to be used as a tool to restrict delivery of CAR T-cell therapies. Furthermore, FDA labeling for CAR T-cell therapies do not require that treatment be delivered at FACT-accredited centers. Ensuring that MA beneficiaries can receive treatment at the same centers as Traditional Medicare beneficiaries will provide for more widespread and equitable access to CAR T-cell therapy, particularly for patients in underserved and/or rural communities who may have limited access to specialized inpatient facilities.

Enabling laboratory service providers to participate in the prior authorization process

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 essential 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.

Reinstating CMS' prohibition of step therapy for Part B drugs

In 2019, CMS began to permit MA plans to use step therapy as a UM tool for Part B drugs, [xxii] even though these practices are prohibited in Traditional Medicare. PMC previously opposed CMS' implementation of this policy.[xxiii] 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.[xxiv, xxv]

Since CMS permitted MA plans' use of step therapy for Part B drugs in 2019, MA enrollees are increasingly subject to step therapy requirements. Analyses from the American Cancer Society revealed a

growing trend in the use of step therapy by Medicare Advantage-Prescription Drug plans (MA-PDs) for certain breast cancer treatments and that MA-PDs were embedding step edits dependent on patient characteristics and treatment choice into their prior authorization criteria.[xxvi,xxvii] Embedding step therapy in prior authorization requirements may obscure CMS's formulary review process for ensuring appropriate beneficiary access to drugs. Another analysis found that, by 2023, more than half of MA enrollees were in plans that applied step therapy to the ten commonly used disease-modifying rheumatoid arthritis drugs covered under Part B, which play a pivotal role in improving patient's quality of life and prognosis. An average of 27 percent of MA enrollees were in plans requiring two or more steps, with up to 44% for certain drugs.[xxviii]

PMC is concerned that MA plans' use of step therapy does not follow clinical guidelines, limits shared decision-making between a patient and their provider, and impedes patients' access to medically necessary care. For example, starting January 1, 2025, Humana is instituting an onerous step therapy policy for its MA members that will limit treatment options for patients diagnosed with metastatic PD-1/PD-L1 non-small cell lung cancer (NSCLC) by requiring the use of a singular, preferred immunotherapy (IO) product first over all other PD-1/PD-L1 IOs, even though current guidelines from the National Comprehensive Cancer Network (NCCN) do not recommend treatment with an IO or IO combination in second line after treatment with an IO in first line. LUNGevity Foundation and 27 other patient organizations have called on CMS to review Humana's policy change and to take action to ensure alignment with clinical guidelines.[xxix]

With personalized medicines accounting for more than a quarter of all new drugs approved by the U.S. Food and Drug Administration since 2015,[xxx] the pipeline for personalized therapies becoming available to patients remains robust. Step therapy requirements, however, undermine the ability of physicians and patients to make treatment decisions tailored to each patient's unique medical needs and desired outcomes. **We therefore urge CMS to reinstate the prohibition of step therapy for Part B drugs and ensure consistent access to these drugs among individuals with Traditional Medicare or MA coverage.**

Conclusion

PMC appreciates CMS' continued commitment to improving health care for beneficiaries enrolled in the MA program with a focus on prior authorization, internal coverage criteria, and consistent beneficiary access. 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 Director 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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