



June 15, 2026

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Administrator

Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
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Re: Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability Standards and Prior Authorization for Drugs for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges (CMS-0062-P)

Dear Administrator Oz:

The Personalized Medicine Coalition (PMC), a multi-stakeholder group established 20 years ago and comprising more than 160 institutions from across the health care spectrum to promote the understanding and adoption of personalized medicine concepts, services, and products for the benefit of patients and the health care system, thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to submit comments on the Medicare and Medicaid Interoperability Standards and Prior Authorization for Drugs Proposed Rule.¹ PMC applauds CMS for recognizing the need for reforms to prior authorization and we encourage the agency to focus on inappropriate practices that unnecessarily limit access to care and increase provider burden. While PMC recognizes that there are numerous important policy issues addressed in the proposed rule, our comments are limited to CMS' request for information on prior authorization for laboratory services and highlight how prior authorization impacts Medicare beneficiaries by often delaying access to personalized medicine.

PMC defines personalized medicine as an 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

Many of PMC's members will present their own responses to the Medicare and Medicaid Interoperability Standards and Prior Authorization for Drugs Proposed Rule and will actively advocate for those positions. PMC's comments are designed to provide feedback so that the general concept of personalized medicine can advance, and are not intended to impact adversely the ability of individual PMC members, alone or in combination, to pursue separate comments with respect to the proposed rule.

CMS Prior Authorization Considerations for Tests Underpinning Personalized Medicine

Data collection and analysis of prior authorization for biomarker and other laboratory testing

Biomarker tests are essential clinical tools that can identify disease at a molecular level enabling earlier intervention and more precise therapeutic decision-making. In oncology, for example, biomarker testing informs treatment selection for targeted therapies and immunotherapies. 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}

Delays in obtaining test results can directly delay the initiation of life-saving treatment. Similarly, biomarker and other laboratory testing facilitate early identification and monitoring across a range of serious conditions and rare genetic disorders. Molecular and genetic laboratory testing, including hereditary cancer panels, pharmacogenomics, multianalyte assays with algorithmic assays (MAAAs), and companion diagnostics, are essential to personalized medicine but are often subject to utilization management practices. These practices can delay or prevent early detection and limit access to timely targeted treatments. Delays are particularly detrimental in clinical contexts where early detection is closely linked to improved survival and treatment outcomes.

We believe CMS should collect information on prior authorization denial rates for biomarker and other laboratory testing supporting personalized medicine. This data would equip CMS with further evidence to evaluate whether current prior authorization practices are clinically appropriate or whether additional enforcement, safeguards, exemptions, or reforms are warranted to ensure that utilization management does not impede timely diagnosis and patient access to evidence-based treatment.

Furthermore, if CMS' intent with the proposed rule is to accelerate the use of electronic prior authorization tools, required data fields should encompass those required for laboratory testing. Electronic prior authorization tools that fit laboratory workflows and capture data such as the exact test ordered, specimen type, diagnosis and procedure codes, coverage parameters, and others would be helpful in streamlining prior authorization. Without consideration for difference in data collection needs, ongoing patterns of claim denial may continue.^{vii}

Inappropriate application of Date of Service policy for clinical laboratory tests

CMS has developed a detailed framework for determining the date of service and place of service for molecular pathology testing with associated billing rules. PMC and the broader stakeholder community expressed concern that certain aspects of the billing rules were impeding beneficiary access.^{viii ix x} In response CMS established regulations to revise its date of service policy for clinical laboratory tests to allow a laboratory, rather than the hospital, to bill Medicare directly for molecular pathology tests, certain advanced diagnostic laboratory tests

(ADLTs), and certain MAAAs performed on specimens collected from hospital outpatients. These changes improved reimbursement and patient access to these innovative tests, which are often used to guide personalized medicine.

PMC appreciates CMS acknowledging in the proposed rule that the date of service policy has not been consistently applied by Medicare Advantage plans. This practice has resulted in disparities among Medicare beneficiaries and adds complexity and burden for laboratories. **In the final rule, we strongly urge CMS to maintain that the practice of plans inappropriately applying the date of service policy to deny prior authorization is not compliant with rules in the Medicare Advantage program and that plans should be required to recognize exceptions already established in regulation. Furthermore, CMS should clarify that prior authorization requests should be accepted any time up until claim submission.**

While CMS specifically addresses the misuse of the date of service policy, a broader concern is that some Medicare Advantage organizations continue to use administrative or procedural criteria to deny, void, or cancel prior authorization requests. CMS has appropriately recognized that prior authorization may only be used to access coverage and medical necessity requirements. When prior authorization is denied, the subsequent claim may be denied for administrative reasons even if the service was medically necessary. Plans often treat such claim denials as ineligible for appeal or external review, preventing meaningful review of whether the service was medically necessary and met applicable coverage requirements. **PMC encourages CMS to clarify that claims for laboratory services should remain eligible for appeal on medical necessity grounds regardless of the outcome of a prior authorization determination and upheld denials should be forwarded for external review.**

Enabling laboratory service providers to request prior authorization

In response to concerns raised by stakeholders that laboratory professional should be able to participate in Medicare Advantage plans' prior authorization process, CMS clarified that laboratories are providers with standing to be actors in the prior authorization process.^{xi} Unfortunately, some Medicare Advantage organizations or their delegated entity do not permit laboratories to file prior authorization for the services they perform and provide for beneficiaries, thus creating a pathway for plans to deny claims for covered and medically necessary testing. PMC thanks CMS for citing in the proposed rule that current regulation confirms the ability of laboratories to initiate requests as it states that an enrollee, enrollee's representative, or any provider that furnishes, or intends to furnish, services to the enrollee can request prior authorization.

Plans that do not allow laboratory professionals to participate in the prior authorization process create an unnecessary roadblock to the essential testing services underpinning personalized medicine, where timely results are often critical to inform treatment decisions for patients. Ensuring laboratory service providers can participate in prior authorization can reduce administrative burden on providers, improve the timeliness of determinations, and help avoid unnecessary delays in patient care. **CMS should further ensure that plans cannot restrict prior authorization to ordering providers or primary care providers; they must allow enrollees, an enrollee's representative, and any provider, including laboratory professionals, to request prior authorization.**

Clarifying valid medical documentation for clinical laboratory tests

In addition to prior authorization, Medicare Advantage plans and other payers employ utilization management techniques, such as pre-pay medical documentation requests to delay or deny payment for necessary services. These services include those for beneficiaries with advanced cancer and other time-sensitive treatment needs. Excessive medical records review creates significant burden for providers when the information needed to

determine medical necessity has often already been provided to the Medicare Advantage plan when submitting the claim.

For laboratory testing, complete information is often provided in the Test Requisition Form (TRF). However, in previous comments to CMS PMC has highlighted that laboratories often experience situations in which there are demands for additional documents for services clearly covered under national and local coverage determinations.^{xiii} For laboratories who are not the ordering provider their ability to acquire the requested medical documentation may be limited when it is outside of the specific coverage requirements for the service. These situations further contribute to delays and/or denials. The proposed rule highlights that some Medicare Advantage plans and Medicare Administrative contractors may not be accepting a TRF as valid medical documentation. **PMC urges CMS to clarify that TRFs are a valid form of medical documentation and additional documentation should not be requested when complete medical necessity information is already provided in the TRF.** Broader adoption of TRFs by Medicare Advantage organizations and other payers would promote greater alignment in documentation requirements, reduce redundant requests for medical records, facilitate timely and efficient coverage determinations, and help ensure that utilization management processes are targeted toward information necessary to evaluate medical necessity.

Limiting prior authorization for covered services and ensuring consistent application of Medicare coverage requirements

PMC appreciates CMS' ongoing efforts to ensure that Medicare Advantage organizations implement coverage and utilization management policies that are consistent with Medicare requirements. **More broadly, PMC encourages CMS to evaluate whether prior authorization is appropriate for laboratory services that are already covered under applicable National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs).** Where CMS or Medicare Administrative Contractors have already established coverage criteria for a test, prior authorization requirements may create unnecessary administrative burden and delay patient access to evidence-based care without providing meaningful program integrity benefits. Unlike Traditional Medicare fee-for-service, which generally does not require prior authorization for laboratory services, Medicare Advantage beneficiaries face additional administrative barriers to accessing laboratory services already covered under NCDs and LCDs. PMC's laboratory members report a significantly higher denial rate by Medicare Advantage organizations for services covered under NCDs/LCDs compared to Medicare fee-for-service for the same services, highlighting that many of these denials for covered services are inappropriate.

Effective oversight and enforcement of Medicare coverage requirements is important to ensuring that beneficiaries have appropriate access to personalized medicine. When utilization management practices are repeatedly applied in ways that are inconsistent with Medicare requirements or that impede access to medically necessary testing, CMS should use its oversight authority and take corrective action to promote compliance and consistent implementation of Medicare policy. To facilitate this, **CMS should establish a clear mechanism for laboratories and other providers to report suspected systemic violations involving prior authorization and coverage determinations and to resolve disputes.** While existing processes may allow providers to raise concerns regarding individual claims, they are not sufficient to identify and resolve broader patterns of noncompliance.

Conclusion

Thank you for your commitment to ensuring that Medicare beneficiaries have timely access to transformative technologies. We look forward to collaborating with you and your colleagues at CMS to improve access to personalized medicine and continuing to foster innovation for patients with unmet needs.

If you have any questions about the content of this letter, please contact me at 202-499-0986 or cbens@personalizedmedicinecoalition.org.

Sincerely,



Cynthia A. Bens
Senior Vice President, Public Policy

ⁱ Centers for Medicare & Medicaid Services. Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability Standards and Prior Authorization for Drugs for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges (CMS-0062-P). April 14, 2026. <https://www.govinfo.gov/content/pkg/FR-2026-04-14/pdf/2026-07205.pdf> (Accessed June 9, 2026)

ⁱⁱ Neil A. Busis et al. "Streamlining Prior Authorization to Improve Care." *JAMA Neurol.* November 20, 2023. <https://jamanetwork.com/journals/jamaneurology/article-abstract/2812278> (accessed June 9, 2026)

ⁱⁱⁱ American Medical Association. *2025 AMA Prior Authorization (PA) Physician Survey.* 2025. <https://www.ama-assn.org/system/files/prior-authorization-survey.pdf> (accessed June 9, 2026)

^{iv} Jeannie Fuglesten Biniak and Nolan Sroczyński. *Over 53 Million Prior Authorization Requests Were Submitted to Medicare Advantage Plans in 2024.* Kaiser Family Foundation. January 28, 2026. <https://www.kff.org/medicare/medicare-advantage-insurers-made-nearly-53-million-prior-authorization-determinations-in-2024/> (accessed June 11, 2026)

^v 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).* April 27, 2022. <https://oig.hhs.gov/oei/reports/OEI-09-18-00260.asp> (accessed June 9, 2026)

^{vi} Personalized Medicine Coalition. *Understanding Genomic Testing Utilization and Coverage in the US.* June 2020. https://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/PMC_Understanding_Genomic_Testing_Utilization_and_Coverage_in_the_US2.pdf (accessed June 9, 2026)

^{vii} Discoveries in Health Policy. "What? CMS Runs RFI on Why Labs Hate Prior Authorization" May 10, 2026. <https://www.discoveriesinhealthpolicy.com/2026/05/what-cms-runs-rfi-on-why-labs-hate.html> (accessed June 11, 2026)

^{viii} Personalized Medicine Coalition. Hospital Outpatient Prospective Payment System, Notice of Proposed Rulemaking — Potential Revisions to the Laboratory Date of Service Policy (CMS-1678-P) Comment Letter. September 11, 2027. https://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/PMC_comments_CMS-1678-P.pdf (accessed June 11, 2026)

^{ix} Personalized Medicine Coalition. CY 2020 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS-1717-P) — Potential Revisions to the Laboratory Date of Service Policy Comment Letter. September 27, 2029. https://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/PMC_Lab_DOS_Policy_2019.pdf (accessed June 11, 2026)

^x Personalized Medicine Coalition, Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; and Physician owned Hospitals Comment Letter. October 5, 2020. https://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/PMC_on_CY_2021_OPSP_Proposed_Rule.pdf (accessed June 11, 2026)

^{xi} §422.566(c)(1) <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-422/subpart-M/section-422.566> (accessed June 11, 2026)

^{xiii} Personalized Medicine Coalition. 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) Comment Letter. January 24, 2025. <https://www.personalizedmedicinecoalition.org/wp-content/uploads/2024/11/PMC-Comment-Letter-CY26-MA-Proposed-Rule-FINAL.pdf> (accessed June 11, 2026).