

January 27, 2025

Acting Administrator Dorothy Fink
Centers for Medicare & Medicaid Services
7500 Security Blvd
Baltimore MD 21244

RE: Response to 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 Acting Administrator,

We appreciate the opportunity to provide a response to the proposed Medicare and Medicaid Programs Policy. We are, in particular, providing comment on Item 10, Improving Access—Enhancing Rules on Internal Coverage Criteria.

At Stanford Biodesign, we believe that a disciplined approach to innovation across the continuum of care is the key to solving healthcare challenges in the U.S. and across the globe. For more than two decades, we've demonstrated that innovation can be taught, learned, practiced, and perfected. The Biodesign innovation process has been adopted by more than 100 universities and training programs around the world. Our trainees learn to observe patient needs and care delivery to identify the right opportunities for transformative impact. Over 13 million people have been helped by technologies invented during Stanford Biodesign training.

With our position at the metaphorical and physical start line for healthcare innovation, we have observed the often decade-long journey for a novel health technology to become the standard of care treatment for a disease state. At the Stanford Biodesign Policy Program, we have focused our research on qualitative and quantitative evidence that elucidates this process from FDA authorization through clinical evidence generation to commercial viability with an emphasis on how federal policy balances speed and risk. In 2023, we published "Time From Authorization by the US Food and Drug Administration to Medicare Coverage for Novel Technologies."¹ The composite endpoint of Medicare coverage was defined as the achievement of a National Coverage Determination (NCD), 3 or more Local Coverage Determinations (LCDs), or a permanent code. Fewer than 50% of the 64 technologies profiled achieved an endpoint, and the average time to coverage was at least 5.7 years. Innovators commonly refer to the time between FDA authorization and widespread coverage as the "valley of death" because many companies fail to generate enough revenue or raise enough capital to stay in business while

navigating the requirements to establish coding, coverage and payment. It is these novel technologies that we will focus on for our comments.

Novel technologies support a new procedure, diagnostic test or intervention. They may be authorized by the Food and Drug Administration (FDA) through one of multiple review pathways and may have been selected for prioritized FDA reviewer focus by being selected for FDA Breakthrough Device Designation. Upon receiving FDA authorization, the manufacturer is granted access to commercial distribution in the US. However, the broad uptake of a novel technology depends on establishing coding, payment, and coverage, as well as the support of specialty medical societies and individual physicians who adopt the technology into their practice. Establishing coding, coverage and payment is far more complex than achieving FDA authorization. It requires building sufficient clinical evidence to convince physicians, specialty societies, healthcare institutions, and payers of the safety, efficacy, and value of the novel technology related to specific patient populations. No one set of standards apply, and no single organization is wholly responsible for the decision-making. The American Medical Association (AMA) and Centers for Medicare and Medicaid Services (CMS) share responsibility for assigning codes. CMS plays an active role in the coverage of novel technology through the NCD and LCD processes. Each commercial payer also uses a health technology assessment process for coverage policies and a specific administrative process for requesting modification or reevaluation.

We applaud the Centers' efforts through the April 2023 final rule, the February 2024 HPMS memo, and the current proposed rulemaking to clarify the obligations of Medicare Advantage (MA) plans to cover basic benefits and use coverage criteria in a way that aligns with Traditional Medicare. Section 1852 of the Social Security Act and Sections 422.100 and 422.101 of the Code of Federal Regulations require MA organizations to furnish all items and services for which benefits are available under Parts A and B of Medicare. In addition, MA plans are also allowed to implement utilization management programs, prior authorization, and provider network restrictions to the benefits that Medicare beneficiaries receive. Your goal with the new provisions is to "build upon and enhance the regulations from the April 2023 final rule."

CMS has specifically solicited comments on three elements of internal coverage criteria in the proposed rulemaking, including:

1. *"on replacing the existing requirement at § 422.101(b)(6)(i)(A) [...] with a requirement that the MA organization must demonstrate through evidence that the additional criteria explicitly support patient safety, and on whether this approach is clearer than the current standard and how we could define patient safety in a way that MA organizations understand how to comply with the rule".*

Additional internal coverage criteria must be based on clinical evidence. Medicare LCD and NCDs are developed using an extensive and public process for the development of

the coverage policy. This solicited comment seeks to explore a situation in which the internal coverage criteria do not fall within the category explicitly prohibited in the proposed §§ 422.101(b)(6)(iv)(A) and (B), and that the LCD or NCD developed by Medicare was insufficient to describe an additional safety risk applicable to the Medicare beneficiary.

Studies have shown that Traditional Medicare and Medicare Advantage beneficiaries do not differ significantly in terms of race, ethnicity, income, or chronic conditions when Special Needs Plans are excluded from analysis.² It is challenging, then, to envision a situation where the Medicare coverage determination did not appropriately take into account an element of patient safety. In order to demonstrate patient safety as a reason for an internal coverage criteria, **MA plans should publish a clinical evidence review that cites specific examples of adverse events or negative healthcare outcomes that justify a restriction in coverage.** These evidence reviews should be in context relative to the available alternative therapies this subgroup of patients may or may not have, as risk/benefit is a relative framework and not absolute. Such transparency would help clinicians understand the patient population where technology use is best supported by evidence (and thus prevent administrative burdens of delays and denials), help companies design the most appropriate studies for continuing evidence development, and provide visibility to beneficiaries.

2. “on whether there are other prohibitions on internal coverage criteria that CMS should consider that support and promote access to medically necessary care in the MA program.”

Under the statutory mandates of the 21st Century Cures Act of 2016,³ CMS has advanced policies to streamline and speed the LCD process. These initiatives included a revised, transparent, and public process for developing LCD, relocation of codes, and specific instructions to retire Non-coverage LCDs for Category III codes.⁴ According to the revised LCD process, the MACs must analyze the evidence and provide a rationale for any changes in coverage. The Local Coverage Determination (LCD) Process Modernization Qs & As⁵ stated, “MACs must follow the established LCD process when developing LCDs that articulate when an item/service/technology is considered reasonable and necessary (R & N) or use claim by claim medical record review to determine R & N coverage.” The new proposed statements in §§ 422.101.6(iii) and (iv) clarify the circumstances under which an MA plan can apply internal coverage criteria. However, they do not explicitly require MA plans to evaluate Category III codes on a claim-by-claim basis. **We recommend additional explicit language that ensures MA plans use claim-by-claim evaluation of new technologies where no Medicare LCD or NCD exists.**

Why? We can imagine a future where immediate action on the part of the MA plan results in a non-coverage policy rapidly following the effective date of the new code. An extremely short window between the creation of a code and the publication of a non-coverage policy cripples physicians who wish to evaluate the technology or replicate clinical results through independent clinical trials and stymies product developers from collecting real-world effectiveness data or assessing health economic outcomes – all of which are evidence used in a typical health technology assessment for writing coverage policies. This situation sets up a Catch-22 in which new technology can't achieve coverage because sufficient utilization outside of clinical studies cannot be demonstrated.

Rapid publication of internal coverage criteria stating that a technology is unproven, experimental, or investigational leads to inequitable beneficiary access to emerging technologies that use Category III codes as a route to commercialization. The Traditional Medicare beneficiary can access the new technology through claim-by-claim medical record review until an LCD or NCD has been developed, while the MA beneficiary will face an immediate denial of coverage. For example, the United Healthcare (UHC) Medical Advantage Medical Policy MMP043.40⁶ titled Category III CPT Codes lists ninety-nine Category III codes. Sixty-five (65%) codes do not have applicable NCD or LCD coverage criteria, and are listed with the conclusion "Unproven" with a hyperlink to a reference UHC commercial policy. For seven additional codes (7%), an LCD exists for 1 or 2 MACs, and the UHC commercial policy is linked for states and territories where no LCD exists.

In contrast, under a claim-by-claim scenario, the physician is responsible for appropriately documenting the patient's condition and providing a justification for how the use of the technology meets the reasonable and necessary threshold for coverage. Physicians are also responsible for informing the patient, through an Advanced Beneficiary Notice, that Medicare may not cover the cost of the claim. These administrative steps ensure that protections exist for Medicare beneficiaries and support shared decision-making with physicians about whether using a new technology is the right next step in their treatment plan. Equivalent administrative steps should be available to MA plan beneficiaries and their physicians.

3. *"on whether CMS should require a specific format for the information posted on the MA organization website and whether a standard template for the posted information would be helpful."*

We agree that a specific format for the information posted on the MA organization website would be helpful. Coverage policy formats, titles, and organizational schema vary across plan administrators, and the lack of standards increases the administrative burden of verifying coverage eligibility. Additionally, Item 2 (Definition of Internal

Coverage Criteria) called for MA plans to explicitly describe each internal coverage criteria that would apply to a coverage decision. Thus, listing internal coverage criteria and providing references to the commercial policy in a table format alongside the applicable Medicare NCD or LCD will facilitate side-by-side comparison. The UHC MA coverage policy for technologies utilizing Category III codes referenced above demonstrates an example of clarified formatting. A table of applicable coverage has been created with a column to indicate, for each code, if a Medicare NCD or LCD(s) exists and which UHC coverage policy is applicable. Such an update makes coverage policies immediately understandable and accessible to physicians, coding and billing specialists, and beneficiaries. In addition, using a pre-specified format for the information provided by MA plans will ensure that this emerging technology, like LLMs, appropriately accesses and compiles results. Currently, LLMs are not well trained on table-based data sets, but the pace of innovation in this space suggests that models will rapidly advance.

In conclusion, we recommend MA plans should publish a clinical evidence review that cites specific examples of adverse events or negative healthcare outcomes that justify a restriction in coverage, and recommend explicit language be added that ensures MA plans use claim-by-claim evaluation of new technologies. We agree that a specific format for the information posted on the MA organization website would be helpful.

Thank you for your consideration of these public comments.

Sincerely,



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¹ Sexton et al. "Time From Authorization by the US Food and Drug Administration to Medicare coverage for Novel Technologies" JAMA Health Forum 2023; 4(8):e232260. doi:10.1001/jamahealthforum.2023.2260

² "Medicare Advantage vs. Traditional Medicare: How Do Beneficiaries' Characteristics and Experiences Differ?" Commonwealth Fund Issue Briefs October 14, 2021. <https://www.commonwealthfund.org/publications/issue-briefs/2021/oct/medicare-advantage-vs-traditional-medicare-beneficiaries-differ>

³ <https://www.congress.gov/bill/114th-congress/house-bill/34>

⁴ A Category III CPT code is a code assigned by the AMA, typically for emerging technology. <https://www.ama-assn.org/practice-management/cpt/criteria-cpt-category-i-and-category-iii-codes>

⁵ Local Coverage Determination (LCD) Process Modernization Qs & As

https://www.cms.gov/medicare/coverage/determinationprocess/downloads/lcd_qsas.pdf

⁶ <https://www.uhcprovider.com/content/dam/provider/docs/public/policies/index/mamp/category-iii-cpt-codes-08012024.pdf>