Alliance FOR AGING RESEARCH
Catalyzing Innovation for Healthy Aging

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November 2, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

**Re: CMS-3372-P: Medicare Program: Medicare Coverage of Innovative Technology and Definition of Reasonable and Necessary**

Dear Administrator Verma,

The Alliance for Aging Research (Alliance) appreciates the opportunity to provide input on the Centers for Medicare & Medicaid Services' (CMS) proposed rule on Medicare Coverage of Innovative Technology (MCIT) and the Definition of "Reasonable and Necessary."

The Alliance for Aging Research (Alliance) is the leading nonprofit organization dedicated to accelerating the pace of scientific discoveries and their application to vastly improve the universal human experience of aging and health. The Alliance believes that advances in research help people live longer, happier, more productive lives and reduce healthcare costs over the long term. The Alliance strives to advance science and enhance lives through a variety of activities and initiatives – from policy issues to provider and consumer health programs – that generate knowledge and action on age-related matters.

The Alliance serves as a valued patient-focused voice in policy development, including for medical device coverage. We serve as conveners for the *Heart Valve Disease Task Force,* which convenes patient advocacy organizations to improve access, research, and awareness of heart disease detection and treatment. We are also engaged as a stakeholder in medical device priorities with the Food and Drug Administration (FDA), including multiple reauthorization cycles for the Medical Device User Fee Act.

**We support the proposal to align Medicare coverage for breakthrough medical devices with FDA market approval for a period of up to four years**. This change would improve access to innovative devices for which there are no equivalent therapies, or for which outcomes are superior in clinical trials. However, **we have grave concerns and are opposed to CMS's proposal to codify and add criteria to the definition of "reasonable and necessary."** Defining reasonable and necessary as outlined in the rule would fundamentally shift the relationship between Medicare and commercial insurers' coverage decisions, with the potential to curb patient access in the future.

**Medicare Coverage of Innovative Technology Pathway**

The FDA's breakthrough status provides expedited review for devices that provide "more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions."[1] These devices often provide a treatment option when no clear alternatives exist or that have significant advantages over existing treatments. In many circumstances, a breakthrough device may deliver a therapeutic pathway for a patient when pre-existing technologies for an indication are not clinically appropriate.

For patients that have a life-threatening or irreversibly debilitating condition, time is of the essence. However, the current national coverage decision (NCD) and local coverage decision (LCD) pathways typically are completed nine to twelve months after an FDA market authorization.[2] For Medicare patients that would benefit from an FDA-approved breakthrough device, this interim period can have real-world impacts on rates of long-term complications and mortality.

**The Alliance supports CMS's proposal to begin Medicare coverage upon FDA approval for breakthrough devices and provide a coverage period of up to four years.** This coverage period will provide access for Medicare beneficiaries while providing an appropriate amount of time to develop an evidence base to support a subsequent NCD or LCD determination**. We also support the proposed opt-in approach for the MCIT pathway**, rather than an opt-out approach. Given the innovative nature of the MCIT coverage pathway and the fact that there may be some devices for which the NCD or LCD pathway is preferable, an opt-in approach is appropriate.

As a device's coverage period in the MCIT pathway winds down, the manufacturer will need to apply for an NCD, LCD, or revert to claim-by-claim adjudication by a Medicare Administrative Contractor (MAC). In the proposed rule, CMS requested feedback on whether an NCD should be initiated automatically in the absence of the issuance of an LCD. The Alliance favors uniformity in coverage whenever feasible to ensure equitable access for patients. However, we are concerned that an automatic initiation of an NCD process could inadvertently create an excess of NCD requests. A surplus of coverage assessments could contribute to delays in review and increase the typical timeline for a NCD determination. We encourage CMS to work closely with manufacturers to ensure how to best ensure continuity in coverage and for the agency to provide appropriate support for the Coverage and Analysis Group.

**Definition of Reasonable and Necessary**

The proposed rule includes a second and distinct policy proposal that would codify an updated definition of "reasonable and necessary" for the purpose of coverage in Medicare. The proposal would formally adopt the current subregulatory definition found in the Medicare Program Integrity Manual and expand the definition to allow Medicare to include consideration of commercial plans' coverage policies for non-Medicare

[1] U.S. Food and Drug Administration. Breakthrough Devices Program. 16 May 2019. https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program#s1
[2] Centers for Medicare and Medicaid Services. CMS-3372-P: Medicare Program: Medicare Coverage of Innovative Technology and Definition of Reasonable and Necessary. Federal Register. Vol. 85, No. 170. 1 September 2020. https://www.govinfo.gov/content/pkg/FR-2020-09-01/pdf/2020-19289.pdf

populations. CMS explicitly notes that this definition would not be limited to the MCIT pathway and would be used for other NCDs and coverage decisions.[3]

CMS acknowledges that commercial insurers may impose restrictions on certain items or services in their coverage determinations. The agency also states that the policy intends to expand coverage, rather than restrict access. However, the policy would establish the precedent that CMS can and should include considerations of commercial insurance coverage policies moving forward. This expectation is troublesome, as Medicare has historically offered comparatively greater levels of coverage. This standard, once codified and operationalized, could be used to more closely align Medicare with commercial coverage.

This proposal has troubling implications for patient access. **Codifying the Program Integrity Manual definition of "reasonable and necessary" breaks from long-standing precedent and could adversely affect patient access to devices and potentially pharmaceutical products through future rulemaking**. CMS has traditionally avoided a blanket definition of "reasonable and necessary" because it is a question without a single answer.

Relying on commercial insurers in the development of Medicare coverage determinations introduces concerns about transparency. Insurers are not required to publicly release information on their coverage determination processes, nor must they publicly share data or rationale for their determinations. Further, variability in coverage determinations and processes between insurers undermines the concept of an external commercial market standard that Medicare should reference in defining coverage standards. We are also concerned about the implications for MACs if they are required to monitor and incorporate coverage policies made by commercial insurers. This policy could lead MACs to focus on monitoring commercial plans' policies and restrictions, rather than LCDs and claims-specific determinations. This diverted focus may result in the incorporation of private insurance coverage determinations that are not appropriate for the Medicare population and infringe upon Medicare's historically patient-centered coverage determination process.

Finally, the use of commercial insurers' coverage determinations could introduce methodologies that could curb access in Medicare for certain populations. Many commercial insurers consider cost-effectiveness utilizing the quality-adjusted life year (QALY) in their coverage determinations.[4] However, the use of QALYs in healthcare decision-making has the potential to limit access to medications and treatments for older adults, people with disabilities, and patients with chronic conditions. QALY relies upon the discriminatory assumption that the value of a year of life of a person not in perfect health is lower in comparison to an individual in perfect health. QALY also fails to account for health disparities, thereby incorporating a bias that can adversely impact minority and low-income communities. The National Council on Disability has established the discriminatory impact of QALY-based calculations and recommended that the QALY be prohibited from use in health care coverage determinations in the Medicare and Medicaid programs.[5] Further, the Affordable Care Act bans the use of comparative effectiveness research "in determining coverage, reimbursement, or incentive programs … in a manner that treats extending the life of an elderly, disabled, or terminally ill

[3] Centers for Medicare and Medicaid Services. Proposed Medicare Coverage of Innovative Technology (CMS-3372-P). 31 August 2020. https://www.cms.gov/newsroom/fact-sheets/proposed-medicare-coverage-innovative-technology-cms-3372-p
[4] Dubois, Robert W. CVS To Restrict Patient Access Using Cost-Effectiveness: Too Much, Too Soon. Health Affairs. 17 September 2018. https://www.healthaffairs.org/do/10.1377/hblog20180913.889578/full/
[5] National Council on Disability. Quality-Adjusted Life Years and the Devaluation of Life with Disability. November 2019. https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf

individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill."[6] In 1992, President George H.W. Bush's Administration established that it constitutes a violation of the Americans with Disabilities Act for states to use cost-effectiveness standards in Medicaid out of concern it would discriminate against people with disabilities. CMS should not open the door to the use of QALYs in the Medicare program through the adoption of this definition.

**The Alliance strongly urges CMS to fully withdraw the section of the proposed rule that codifies the definition of "reasonable and necessary."** Further, given the implications for this policy beyond medical devices – including for pharmaceuticals and selected procedures – we express disappointment that CMS has included the proposal as an ancillary policy within the MCIT proposed rule. Policies that impact multiple stakeholders should be publicly presented and released to a full audience of affected stakeholders, rather than a subset. We ask CMS to allow the public to consider substantial, cross-cutting changes in Medicare policy through distinct regulations in future rulemaking to ensure transparency and appropriate input through the regulatory process.

**Conclusion**

Thank you for the opportunity to provide feedback on CMS's proposals for the MCIT coverage pathway and the definition of "reasonable and necessary." The Alliance appreciates the agency's proactive approach to increasing access to innovative breakthrough technologies that hold promise for improving patient health. At the same time, we urge the agency to dismiss its proposal to codify a definition of reasonable and necessary, especially the problematic inclusion of commercial insurers' coverage determinations.

If you have any questions, please do not hesitate to contact us. Inquiries can be directed to the Alliance for Aging Research's Director of Public Policy, Michael Ward, at mward@agingresearch.org.

Sincerely,

Sue Peschin
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Alliance for Aging Research

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[6] 42 U.S. Code § 1320e-1(e). Limitations on Certain Uses of Comparative Clinical Effectiveness Research.