STATEMENT OF

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ON

EXAMINING POLICIES TO IMPROVE SENIORS' ACCESS TO INNOVATIVE DRUGS, MEDICAL DEVICES, AND TECHNOLOGY

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Statement of Dora Hughes on
"Examining Policies to Improve Seniors' Access to Innovative Drugs, Medical Devices, and Technology**"**
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Chairs McMorris Rodgers and Guthrie, Ranking Members Pallone and Eshoo, and Members of the Subcommittee, thank you for the opportunity to discuss the Centers for Medicare & Medicaid Services' (CMS's) efforts to ensure that Medicare beneficiaries have timely coverage of innovative treatments and medical technologies that treat life-threatening or irreversibly debilitating diseases and improve patients' quality-of-life.

CMS is committed to fostering innovation while ensuring that Medicare has fast and consistent coverage processes for emerging treatments and technologies that will improve health outcomes. CMS's goal is to enhance coverage of new treatments and technologies, while maintaining appropriate safeguards and rigorous evidence standards essential to the health of Medicare beneficiaries. We must also ensure that these innovative treatments and technologies improve health outcomes for Medicare beneficiaries. CMS will continue supporting innovative approaches to improving quality, accessibility, and affordability, while finding the best ways to use advanced treatments and technology to support person-centered care.

CMS is committed to building on the work we have done to date, and we are continuing to find ways to improve and streamline Medicare coverage policies in a manner that allows us to advance health equity, foster access, improve health outcomes, and increase transparency.

Medicare Coverage Determination Process

Medicare covers a wide range of medically necessary items and services. Medicare coverage and payment policies are provided in statute. In order to be covered under Part A and Part B, an item or service must fall within a statutory benefit category and must not be excluded from coverage. In addition, for an item or service to be covered under Medicare, it usually must meet the standard described in section 1862(a)(1)(A) of the Social Security Act (the Act) — that is, it must be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member. CMS makes reasonable and necessary coverage decisions through various pathways to facilitate expeditious beneficiary access to items and services that meet the statutory standard for coverage. It is longstanding policy that CMS does not take cost into consideration when making national coverage determinations. Additionally, Medicare payment rates and coding are determined outside of the national coverage determination process.

National coverage determinations (NCDs) are made using a transparent, evidence-based process, with opportunities for public participation as specified in statute. NCDs serve as generally applicable rules to ensure that similar claims for items or services are covered in the same manner. Often, an NCD is written in terms of defined clinical characteristics that identify a population that may or may not receive Medicare coverage for a particular item or service. In some cases, CMS's own research is supplemented by an outside technology assessment and/or consultation with the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC).

In the absence of a national coverage policy, reasonable and necessary coverage determinations are made by the Medicare contractors. By statute, Medicare contractors may establish a local coverage determination (LCD) or adjudicate claims on a case-by-case basis. The case-by-case adjudicatory model permits consideration of a beneficiary's particular factual circumstances described in the medical record. The case-by-case model affords more flexibility to consider a particular individual's medical condition than is possible when the agency establishes a generally applicable rule.

For medical devices, it is also important to note that while FDA and CMS have a well-established history of collaboration in review of evidence for emerging medical technologies, FDA and CMS must consider different legal authorities and apply different statutory standards when making marketing authorization and coverage decisions, respectively. Generally, FDA marketing authorization and clearance authorization decisions are based on whether the relevant statutory standard for safety and effectiveness is met, while CMS generally makes NCDs based on whether an item or service is reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member for individuals in the Medicare population. FDA generally reviews a device to ensure it meets the applicable safety and effectiveness standard. In making a reasonable and necessary determination, CMS focuses on whether the treatment is clinically beneficial for Medicare patients. We believe that consideration of the health impact on the Medicare population is a key factor in determining national coverage for Part A and Part B.

National Coverage Determination Review Process

An NCD review can be initiated by CMS, or a request can be initiated by an individual, (including a beneficiary), or an entity (including a medical professional society or business interest). Any request for an NCD review must be a written, complete, formal request, as described in the August 7, 2013 Federal Register notice (78 FR 48164).[1] Typically, a requester is a Medicare beneficiary, a manufacturer, a physician or a physician professional association. A request may be to establish, reconsider, limit, or entirely remove coverage.

When a formal evidence review is undertaken, CMS determines whether the available evidence base supports or refutes the requested coverage in whole or in part. A proposed decision is normally issued for public comment within six months of opening the NCD review. Consistent with statute,[2] CMS provides 30 days for public comment on the proposal. Typically, no later than 60 days after the close of the 30-day public comment period, CMS issues a final NCD. The statutory timeframes, however, can vary depending on whether CMS commissions a technology assessment from an outside entity, convenes the MEDCAC to discuss the quality of the evidence, or requests a clinical trial. The final NCD decision memorandum includes a summary of the public comments on the proposed decision as well as responses to those comments. The proposed and final memoranda also include the scientific and clinical evidence basis for our coverage determination and an analysis and summary of the evidence considered.

CMS strives to make the NCD process open, transparent, and accessible to medical innovators and other stakeholders. CMS recently updated the public NCD Dashboard, which displays the

[1] Available at: https://www.cms.gov/medicare/coverage/determinationprocess/downloads/fr08072013.pdf
[2] Section 1862(l)(3)(B) of the Social Security Act

list of accepted NCD requests, often referred to as the "NCD Wait List" on the CMS Website.[3] The NCD Dashboard shows the list of NCDs currently under review as well as those for which CMS has issued a final NCD within the previous 12 months.

All of the potential NCDs that CMS is currently working on, and the corresponding request letters, are available online through the tracking sheet. The tracking sheet is a key element in making the NCD process efficient, open, and accessible to the public. CMS also publishes an annual Report to Congress that lists all NCDs completed in a specific year. The most recent Report to Congress for 2021[4] is available online, and the 2022 Report to Congress is under development. This year, CMS has also published online the CMS Guide for Medical Technology Companies and Other Interested Parties to provide information to medical innovators on coding, coverage, and payment information for Medicare Part A and B Fee-For-Service.

When the number of NCD requests exceeds CMS staffing capacity and requests are added to the waitlist, CMS prioritizes NCD requests from the waitlist based on the magnitude of the potential impact on the Medicare program and beneficiaries. CMS has leveraged operational efficiencies to streamline and standardize the evidence review process whenever possible and has augmented available resources with contractor support to complete the NCD process when possible.

Coverage with Evidence Development

[3] Available at: https://www.cms.gov/Medicare/Coverage/DeterminationProcess/index.html
[4] Available at: https://www.cms.gov/Medicare/Coverage/InfoExchange/Reports

In some cases, CMS decides to provide Medicare coverage for items and services on the condition that they are furnished in the context of approved clinical studies or with the collection of additional clinical data. Coverage with evidence development (CED) is a coverage policy innovation intended to get certain approved treatments to beneficiaries more quickly while collecting information about health outcomes. In making coverage decisions involving CED, CMS decides after a formal review of the medical literature to cover an item or service only in the context of an approved clinical study or when additional clinical data are collected to assess the appropriateness of an item or service for use in the Medicare population.

CMS has issued a total of 26 NCDs requiring CED over the last two decades to provide Medicare beneficiaries coverage of promising items and services that could not otherwise be covered under current law.[5] CMS has approved 109 CED studies and five national registries to facilitate evidence development for these CED-NCDs. Forty-two of these studies have generated evidence across 14 topics covered under CED. Three CED-NCD topics have had the CED requirement removed following an NCD reconsideration and have received national coverage.

Transitional Coverage for Emerging Technologies (TCET)

CMS recognizes that new approaches are needed to make decisions more quickly on certain new items and services, such as medical devices, to provide expedited access to new and innovative medical technologies.

[5] Section 1862(a)(1)(A) of the Social Security Act

CMS took an additional step to ensure Medicare beneficiaries are able to access emerging technologies by proposing a new Medicare coverage pathway. In June of this year, CMS issued a proposed procedural notice[6] outlining this new coverage pathway to achieve more timely and predictable national coverage for certain eligible Breakthrough Devices that are FDA market authorized or cleared. The new Transitional Coverage for Emerging Technologies (TCET) pathway is voluntary and supports innovation by providing an efficient, predictable, and transparent coverage review process while developing robust safeguards for the Medicare population. Simultaneously, the TCET pathway intends to reduce uncertainty about coverage by evaluating early the potential benefits and harms of technologies with innovators seeking national coverage of emerging technologies, thereby promoting innovation.

As part of CMS's broader coverage modernization initiative, TCET focuses on certain medical devices designated as Breakthrough Devices by the FDA. This program aims to accelerate the development of new medical devices that meet certain criteria for patients with life-threatening or irreversibly debilitating diseases or conditions, while preserving the statutory standards for marketing authorization or clearance, consistent with FDA's public health mission. Smaller studies using nontraditional study designs and data analysis methods, surrogate outcomes, and empirical evidence may be used for market authorization or clearance of these devices. At the time of FDA market authorization or clearance, devices that use these strategies may have important evidence gaps relative to the reasonable and necessary legal standard required for Medicare coverage. For national coverage decisions, CMS usually requires evidence of benefit in

[6] "Medicare Program; Transitional Coverage for Emerging Technologies," https://www.federalregister.gov/documents/2023/06/27/2023-13544/medicare-program-transitional-coverage-for-emerging-technologies

the Medicare population, which is often older and/or disabled, has more complex medical needs, and may be inadequately represented in clinical studies used to obtain FDA market authorization. The TCET pathway will support coverage for promising new technologies as manufacturers develop additional evidence after the devices enter the market. The pathway also includes safeguards that protect Medicare beneficiaries while promoting high-quality care.

When developing premarket clinical studies, we believe that manufacturers will be better positioned for multiple product development stages if they anticipate both FDA and CMS requirements. Therefore, we have updated the CMS National Coverage Analysis Evidence Review guidance document and Coverage with Evidence Development study requirements to more clearly allow fit-for-purpose study designs and efficiently demonstrate appropriateness of their technology for Medicare beneficiaries. Fit-for-purpose studies include a study design, analysis plan, and study data that are appropriate for the research question and often rely on empirical data. We expect to publish detailed fit-for-purpose guidance later this year.

The TCET pathway may begin as early as one year before the anticipated FDA decision on market authorization for eligible devices. The pathway aims to initiate benefit category and coding reviews before market to improve the coordination of these functions. It also includes a focused evidence review that will inform discussions between CMS and manufacturers about the state of the evidence and available coverage options. For technologies with a well-developed evidence base, manufacturers may pursue an accelerated NCD. For others, the review will identify specific evidence gaps that may be addressed through an CED-NCD to make the process

more collaborative with manufacturers. The NCD process will remain open and transparent, and the public will have opportunities to comment.

The TCET pathway represents a substantial advancement in CMS's approach to CED. Furthermore, CMS agrees with stakeholder feedback that CED requirements should not be open-ended and will commit to reviewing the available evidence again after an approved Evidence Development Plan is completed. At the prespecified review date, CMS will systematically review the published evidence against the agreed objective success criteria in the CED-NCD. Then, CMS will expedite the NCD reconsideration consistent with statutory requirements, and the public will have an opportunity to comment on the proposed decision. After transitional coverage, TCET devices may have coverage at the national level, as appropriate.

Moving Forward

CMS remains committed to modernizing its coverage pathways to deliver efficient, predictable, and transparent coverage of emerging treatments and medical technologies. We are equally committed to covering treatments and devices based on scientifically sound clinical evidence and with appropriate safeguards. As we move forward, CMS will continue to engage with stakeholders to ensure that Medicare promotes access to emerging treatments and medical technologies while maintaining the protections and rigorous evidence standards essential to the health of Medicare beneficiaries.