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STATEMENT
Of
The Advanced Medical Technology Association (AdvaMed)

Centers for Medicare & Medicaid Services
Medicare Evidence Development and Coverage Advisory Committee
(MEDCAC)

February 13-14, 2023

Good afternoon. My name is Tara Burke, Vice President of Payment and Health Care Delivery Policy of the Advanced Medical Technology Association, or AdvaMed. AdvaMed is the national trade association representing manufacturers of medical devices and diagnostic products.

AdvaMed's member companies produce the life-saving and life-enhancing medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies. We appreciate the opportunity to comment today in this public forum on CMS coverage with evidence development (CED).

CMS held a MEDCAC meeting on Evidentiary Characteristics for CED in 2012 before updating its existing CED guidance. We said then that the medical device industry has long-supported the use of sound evidence to inform medical practice. We also said we become concerned when a CMS decision that requires CED in order to allow certain Medicare beneficiaries access to a medical technology adds significant requirements for manufacturers and providers and delays access for other Medicare beneficiaries. These statements hold true today.

Today's MEDCAC meeting centers around the recent AHRQ report on CED criteria. We submitted specific comments on the draft AHRQ report last year and we also provided those comments to CMS in advance of this MEDCAC. Our comments today reflect more overarching concerns regarding the potential implications for future CMS coverage decision-making, for example in the context of the forthcoming Transitional Coverage for Emerging Technologies (TCET) proposed regulation.

AdvaMed supports policy and process improvements that will result in a predictable pathway to Medicare coverage for new medical devices and diagnostics. Advancing access to technologies that improve health outcomes for a wide array of Medicare beneficiaries is also critical to ensuring CMS' goals of advancing health equity.

We have often said that CED should be used to expand, and not restrict coverage. AdvaMed has advocated for a coverage pathway for emerging technologies that is separate and distinct from the existing National Coverage Determination process, or NCD with CED process. Therefore, any evidence generation requirements under TCET should ensure a "least burdensome" process, distinct from the CED process, that ensures timely access to new and innovative technologies.

CED Principles

With respect to CED, when additional data collection is deemed necessary, the process must involve collaboration between CMS and its stakeholders, such as medical device companies, to identify the data collection objectives, appropriate study endpoints and the duration of the data collection. Whenever possible, such policies must minimize administrative burden.

We reiterate previous comments to CMS that when Medicare coverage is contingent on the collection of additional clinical or scientific evidence (beyond Food and Drug Administration (FDA) requirements for safety and efficacy), CMS should:

1) collaborate with stakeholders to clearly identify the data collection objectives;
2) consider the minimum data necessary to achieve those objectives;
3) clearly identify, with input from interested stakeholders, scientifically supported study endpoints and the duration of data collection in advance (including clear stopping rules for data collection under CED); and
4) identify an appropriate mechanism to ensure continuous coverage of an item or service after a study ends, to avoid disruption in coverage and continue to allow Medicare beneficiaries to benefit from important FDA-approved technologies and services until a new or revised coverage determination is issued.

Additionally, as CED generates evidence supporting a new innovation or service as reasonable or necessary, Medicare's coverage policies should be updated in a timely manner to reflect these outcomes while minimizing additional administrative burdens and simplifying program requirements where possible.

Again, AdvaMed submitted more detailed comments to AHRQ on its Draft CED Report and appreciates that the final report reflects several of those comments. We believe that CMS' decisions about coverage criteria and the CED process should be clear and should not result in delayed access to promising medical technologies.

We appreciate the opportunity to discuss this important issue and we welcome further discussion.

Thank you.

Tara Burke, PhD
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