ADVAMED'S STATEMENT FOR CMS LISTENING SESSION ON TRANSITIONAL COVERAGE FOR EMERGING TECHNOLOGIES

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Good afternoon. My name is Chandra Branham, senior vice president and head of Payment & Health Care Delivery Policy at the Advanced Medical Technology Association ("AdvaMed"). On behalf of the Association, I am here to present AdvaMed's perspective on Transitional Coverage for Emerging Technologies and a potential path forward.

AdvaMed's member companies produce lifesaving and life-enhancing medical devices, diagnostic products, and health information systems that are transforming health care through early disease detection, less invasive procedures, and more effective treatments. Our members range from the largest to the smallest medical technology innovators and companies. We have two divisions – AdvaMedDx, which represents manufacturers of in vitro diagnostics tests, and AdvaMed Accel, which represents smaller to mid-sized companies, including early-stage companies and start-ups, that are developing emerging technologies.

AdvaMed has long supported policy and process improvements that would create a *predictable* pathway to Medicare coverage for new and innovative medical devices and diagnostics. We believe that CMS has a critical role in advancing access to innovations that would benefit the Medicare beneficiaries it serves. AdvaMed looks forward to collaborating with CMS as the Agency moves forward with coverage reforms for emerging technologies.

We and CMS share the goal of improving patient and provider access to emerging technologies for patients; we believe a process can be developed to ensure an expeditious and predictable pathway to coverage for devices and diagnostics that will benefit the Medicare population.

When CMS proposed to repeal the Medicare Coverage of Innovative Technology (MCIT) final rule last fall, AdvaMed offered some proposals for a revised coverage process. We've met with CMS to discuss these ideas and we intend to continue this dialogue as part of our efforts to inform CMS' thinking moving forward.

To summarize our earlier comments and our current thinking, we urge CMS to develop a voluntary, transitional coverage program that would allow for early engagement between CMS and companies that develop emerging technologies. A clearly articulated process would enable CMS to learn about the new technology, and to discuss and evaluate the existing evidence base with the manufacturer. That process could build off existing CMS processes. For example, CMS could build on elements of the process used to review and cover technologies in Investigational Device Exemption (IDE) clinical trials.

Such a process could include:

1. A ***Voluntary, Opt-in Approach for Coverage Based on Eligibility Criteria.*** Emerging technologies intended for Medicare patients should have access to an expedited pathway to coverage. CMS could create an opt-in process for new, emerging technologies seeking transitional coverage that builds on existing programs. An opt-in and early engagement process would ease CMS concerns regarding the number of devices that may seek coverage.

2. A ***Feedback Loop Between Developers and CMS.*** A feedback loop would allow CMS and companies to establish critical communication to <u>proactively</u> address any concerns regarding the existing evidence, use in the Medicare population, or other concerns. Companies could submit information to help CMS better understand the technology, such as:
    - **General Information** regarding the technology's intended use, the targeted patient population, clinical workflow, therapeutic research value, and other information.
    - **Information on Medicare Relevance or Appropriateness and Impact.** Companies can explain or demonstrate how their technology improves outcomes for the Medicare population or is generalizable to the Medicare population.
    - **Disparities/Health Equity Information.** Companies may highlight any known disparities in access to treatment for the condition addressed by their technology and suggest ways of addressing such disparities with the approved device during the transitional coverage period.
    - **Other information** as necessary to respond to CMS' evidentiary questions.

3. ***Collaboration with Device Companies on Ongoing Evidence Development During the Transitional Coverage Period to Support Long-Term/Permanent Coverage.*** This process could provide for CMS review and evaluation of the evidence developed to date for its appropriateness in the Medicare population **<u>and</u>** allow companies and CMS to

identify any remaining evidence gaps and agree on the best way to resolve those gaps during the transitional coverage period (e.g., 4 years).

4. ***Assurance of Beneficiary Protections and Appropriate Safeguards.*** The device in question should improve health outcomes of appropriately selected patients, including those in the Medicare-eligible population, and its use should be well-supported by available scientific and medical information.

5. ***Opportunity for Public Comment.*** The process should be transparent and allow for public comment (while maintaining confidentiality protections for proprietary information), which could help guide CMS and companies for future transitional coverage decisions.

6. ***Adequate Time Frame to Ensure System Readiness (coding, payment, contractor instructions, etc.)***. We understand that certain operational concerns must be addressed. The process can build in an appropriate time frame to ensure that proper coding, payment assignment, instructions to MACs and other issues can be addressed.

We look forward to discussing these issues with CMS and to participating in future opportunities to help inform CMS' coverage policy development. We greatly appreciate this opportunity to provide our input on this important issue and to work with CMS to advance our shared goals of expediting access to innovative technologies and solutions for the patients we all serve.

Thank you.

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