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

March 31, 2022

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 the path forward for a Transitional Coverage for Emerging Technologies proposed rule.

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 appreciates these opportunities to inform CMS's efforts regarding Transitional Coverage for Emerging technologies. We strongly support creation of a new process – distinct from the National Coverage Determination (NCD) process – that would create an efficient, *predictable* Medicare coverage pathway for innovative medical devices and diagnostics. All patients, and especially those suffering from severe, debilitating conditions, will benefit from more timely access to emerging technologies.

At the February 17 Listening Session, we suggested that a new process could build on successful elements of existing CMS processes – such as the process currently used to review and cover technologies in Investigational Device Exemption (IDE) clinical trials. For example, the process should be voluntary, and could include an application, a period of CMS review and evaluation, and opportunity for discussion about important aspects, such as the evidence and the impact on the Medicare population.

CMS has asked for specific input on several important questions, which I will address.

First, regarding CMS guidance, we do know that manufacturers are able to request informal guidance – sometimes referred to as "informal parallel review" – and that this can be very useful, as CMS can and has provided helpful signals to companies. This informal process, while helpful, also can be drawn out and unpredictable, in part due to limitations on CMS staff time and other resource constraints. More formalized guidance by therapy area could be helpful, but CMS should retain some flexibility, given the potential range of medical devices and therapy areas.

Second, regarding engagement with CMS, we believe that voluntary engagement should occur earlier, and well before the results of the pivotal clinical trials are available. Early engagement, with the opportunity to receive feedback from CMS on the evidence developed to date, would enable companies and CMS to proactively address any outstanding questions. Engagement and feedback could:

- Identify evidence gaps,
- Provide information on how the technology improves health outcomes for Medicare beneficiaries or is generalizable to the Medicare population
- Highlight any known disparities in access to treatment for the condition addressed by the technology and ways to address inequities.

Third, as we've already stated, early feedback on the available evidence base is a good idea, but it will be important to allow manufacturers to respond and provide additional information if necessary. Manufacturers should be able to propose, and to collaborate with CMS, to develop a fit-for-purpose evidence development plan to resolve evidence gaps. The question posed by CMS is whether this should be part of the national coverage determination process. In response, we do believe that improvements could be made to the NCD process. However, given the NCD process can take six to nine months and CMS typically issues only 3-5 NCDs every year, the NCD process may not be a good fit for many emerging technologies. Again, we urge CMS to separately develop a new process for transitional coverage for emerging technologies that is distinct from the NCD process, that can be flexibility to provide expeditious coverage for new products and treatments for patients.

Finally, the fourth question regarding similar devices that are FDA-market authorized after a coverage with evidence development decision is finalized is a good one, and we would like to work with CMS to think through the issues associated with the question. An important related issue is the definition of similar devices. However, again, the question seems to assume an NCD with CED would be in place, and we urge CMS to move forward with a new process, apart from the NCD process, for emerging technologies.

As we stated during the previous listening session, any new program should ensure appropriate safeguards are in place to protect beneficiaries, there should be transparency and opportunities for the public to weigh in. We also recognize that appropriate time is needed to ensure system readiness – so that proper coding assignment, payment levels, instructions to the MACs and other issues can be addressed.

We look forward to working with CMS to achieve these goals.
Thank you.

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