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VIA EMAIL: Benjamin.Eloff@fda.hhs.gov

Mr. Benjamin Eloff
Associate Director for Innovation Policy and Processes
Accelerate Clinical Innovation
U.S. Department of Health & Human Services
Humbert H. Humphrey Building
200 Independence Ave., SW
Room 749D
Washington, DC  20201

RE:  Reimagining HHS: Accelerate Clinical Innovation Initiative

Dear Mr. Eloff:

The Advanced Medical Technology Association (AdvaMed) is pleased to submit these comments in support of the Department of Health & Human Services’ (HHS) recently announced initiative to accelerate certain processes for clinical innovation in the United States. For many years, AdvaMed has advocated for changes that will improve processes that can speed access to new and innovative medical technologies for clinicians and patients. We are particularly interested in the Department’s request for information about the role of the Federal government in making the coverage decision process more efficient.

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.

Overview and Problem

Rapid innovation in medical technology has delivered huge gains to patients and the U.S. health care system, but AdvaMed believes that coverage reforms are needed to more fully realize the promise of modern medical technologies.

Today, to be covered by Medicare, an item or service must be “reasonable and necessary” for Medicare beneficiaries. Understanding whether a technology is “reasonable and necessary” can be very complex and uncertain – especially for new and innovative technologies. In general, a product must

- Improve health outcomes;

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• Be safe and effective;
• Not be deemed experimental or investigational; and
• Have FDA approval or clearance.

Many companies develop evidence supporting the safety, effectiveness and value of an innovation but later may find that the evidence they have collected does not meet the Centers for Medicare & Medicaid Services (CMS’s) expectations. The specific outcomes, types of evidence and information that CMS and its contractors want in order to make a positive coverage decision are often ill-defined and subjective.

When a company is told it does not have the evidence necessary to reach a coverage determination, the company often finds that it can then be difficult to gather the evidence because of the lack of coverage or limited access to patients needed to develop it. This creates a seemingly insurmountable challenge for companies that want to develop evidence for coverage purposes.

The lack of certainty regarding market access and the resulting challenge in developing the necessary evidence has resulted in real harm to the innovation ecosystem. Venture capital and private investors are increasingly hesitant to back start-up medical technology companies and development of breakthrough innovations because the path to Medicare coverage and reimbursement is so unclear. Without a healthy ecosystem that fosters these breakthrough innovations, future treatments, diagnostics and cures are at risk.

The medical technology industry has made vital contributions to the two-year gain in life expectancy realized in the most recent decade. It employs nearly 519,000 people at wages almost 40 percent higher than average, indirectly generates over 1.44 million additional jobs and generates a favorable balance of trade. Policy changes that strengthen the medtech innovation ecosystem will have direct benefits for patients, the health care system, and the entire U.S. economy.

Promise and Challenges

Today, medical technologies are poised to drive unprecedented value for patients and the health care system, through exponential advances in scientific knowledge and powerful convergences across engineering, materials, sensors, diagnostics, biomechanical interfaces, communications, data collection and analytics, machine learning, robotics, and more.

The potential rewards ahead for patients are breathtaking, but the medtech ecosystem in the U.S. is severely stressed. American leadership in medical technology has eroded, early-stage investment has been in decline, payment
systems can be inhospitable to emerging technologies, and there are disincentives to value-based care.

There are specific policy changes, however, that can and should be adopted now to accelerate progress for patients and help ensure that a robust pipeline of medical technology innovations delivers maximum benefit to patients, the health care system, and society at large.

**Solutions**

**Cover FDA Breakthrough Devices**

The FDA’s Breakthrough Device Program is intended to provide patients more timely access to a limited set of the most innovative and disruptive medical technologies by expediting their development, assessment, and review while still meeting statutory standards for safety and effectiveness. Yet the medical technologies that FDA determines are most important for patients can languish at CMS without Medicare coverage – defeating the purpose of accelerating their FDA approval. Changes to ensure that Medicare patients actually have timely access to breakthrough technologies are needed to leverage the benefits of FDA’s breakthrough program.

Two key administrative changes can dramatically improve patient access to these technologies and remove unnecessary regulatory red tape that currently slows the process. First, we have advocated that breakthrough technologies should be automatically covered for 3-5 years for Medicare patients and, secondly, as breakthrough technologies represent new and substantial improvements over existing care options, they also should receive automatic approval for inpatient New Technology Add-on Payments (NTAP) and hospital Outpatient Passthrough payments. We applaud CMS’s recent proposal in the Fiscal Year 2020 Inpatient hospital rule to consider new medical technologies that are designated as breakthroughs by the FDA to be deemed to be “new” and “substantial clinical improvements” for the purposes of receiving the NTAP under Medicare, and we are developing our comments to CMS in support of that proposal.

AdvaMed would support consideration of new, breakthrough technologies being eligible to receive the NTAP under Medicare, as well as the provision of immediate three-year transitional coverage with additional data collection as may be required to make a long-term coverage determination.

**Expand Medicare’s Coverage with Evidence Development Process**

For technologies that do not receive automatic access to Medicare coverage or have an established payment pathway, a new evidence development process should be created
to provide coverage certainty by detailing up front CMS’s desired evidence expectations for a specific medical technology, including study outcomes and metrics. Medicare coverage should be available to help support the post-FDA evidence development process for at least three years. This can be done by a new, voluntary process that would provide certainty on the type of evidence and outcomes CMS wants for determining whether a new technology meets the agency’s definition of “reasonable and necessary” and provides coverage and reimbursement for a limited time to develop the evidence.

- **Establish Evidence Advisory Process.** — Create a voluntary evidence advisory meeting process to address evidence development expectations and recommendations, including a written summary of CMS evidence expectations related to desired outcomes and evidence development plan which will provide a path to coverage for medtech innovators and a measured level of certainty and reliable expectations to manufacturers and investors.

- **Establish Coverage for Evidence Development Program.** — Create a voluntary new program allowing Medicare coverage and payment for three years for evidence development of new approved/cleared technologies, outside of the National Coverage Decision process.

- **Presumption of Coverage.** — Upon meeting the previously agreed upon evidence plan and patient outcomes determined by CMS and the manufacturer, the technology and related services would have a long-term coverage plan either through the national or local coverage process.

Again, we applaud this new HHS initiative and look forward to working with the Department as it continues this effort. If you have questions regarding these comments or if you require additional information, please contact me or Chandra Branham, JD, Vice President, Payment and Health Care Delivery Policy, at (202) 434-7219 or cbranham@AdvaMed.org.

Sincerely,

Donald May  
Executive Vice President  
Payment and Health Care Delivery Policy