



Transitional Coverage for Emerging Technologies (TCET) (06/12/2023)

Overview

Rapid innovation in medical technology benefits patients and the U.S. healthcare system, but the lack of certainty and potentially long delays regarding Medicare coverage for new medical technologies creates an unnecessary barrier to patient access. Delays between FDA approval and CMS coverage mean that patients, including underserved populations, are denied access to state-of-the-art, breakthrough medical technologies and diagnostics.

AdvaMed has long supported both policy and process improvements that would result in a predictable pathway to national Medicare coverage for new medical devices and diagnostics. In late 2021, CMS announced it would propose a new rule called “Transitional Coverage for Emerging Technologies” (TCET) after repealing the Medicare Coverage of Innovative Technology (MCIT) rule. AdvaMed has remained committed to engaging with CMS and other stakeholders on TCET’s creation. We were encouraged by CMS holding two listening sessions in 2021 but remain concerned that CMS failed to meet its self-imposed April deadline to provide a proposed TCET rule. Medicare beneficiaries deserve timely rulemaking on coverage policies affecting their well-being.

We believe AdvaMed and CMS share a common goal – the establishment of a clear and expeditious coverage process, based on scientifically sound clinical evidence with appropriate safeguards, for emerging technologies that will benefit Medicare-eligible patients. AdvaMed has communicated to CMS a framework for TCET, which will ensure Medicare coverage promptly following FDA market authorization, but at the same time is transparent and includes appropriate safeguards.

A Conceptual Framework

The framework for this pathway should include:

- **Opt-In.** A voluntary, opt-in approach for eligible products that allows for early engagement between manufacturers and CMS to identify evidence needs in a timely manner.
- **Evidence Generation.** Alignment around a plan for evidence generation in the Medicare population, with agreement regarding methodologies and types of data CMS will require.
- **Beneficiary Protections.** Appropriate safeguard to protect Medicare beneficiaries.
- **Transparency.** Opportunity for public comment.
- **System Readiness.** Adequate time frame to ensure system readiness (e.g., coding, payment, contractor instructions, and any other operational needs).
- **Follow-on Devices.** A thoughtful approach to providing transitional coverage to follow-on products.

AdvaMed urges CMS to release the TCET policy as soon as possible. AdvaMed looks forward to working together with CMS to finalize a workable TCET policy that achieves the goals of rapid coverage and patient access to innovative breakthrough technologies that are approved by the FDA.



Scott Whitaker, President & CEO, AdvaMed

- Scott Whitaker is President and CEO of AdvaMed, the world's largest medical technology association. AdvaMed members make the medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments, to help people live longer, healthier lives. AdvaMed members range from the largest to the smallest medical technology innovators and companies.
- As CEO of AdvaMed, Whitaker is the voice of the medical technology industry. He is widely recognized as a top health care advocate and policy expert with experience across multiple health policy sectors, having worked successfully with diverse stakeholder groups – including hospital, patient and physician groups, regulators, public and private payers, and global trade organizations – to advance medical technology innovation and timely patient access to next-generation treatments and cures.
- Prior to AdvaMed, Whitaker was chief operating officer of the Biotechnology Innovation Organization (BIO), the world's largest trade association representing biotechnology companies, and president of the BIO International Convention, the world's largest biotech conference. Having served as COO of BIO since 2005, Whitaker brings a deep knowledge of the medical technology innovation ecosystem, a wealth of health care advocacy expertise, and strong working relationships with patient groups and other industry stakeholders.
- Whitaker also previously served as chief of staff of the U.S. Department of Health & Human Services (HHS) – a cabinet agency with 67,000 employees and a budget of \$550 billion – from 2003 to 2005. As HHS Chief of Staff, Whitaker managed the day-to-day operations of the department; led the department's activities on all major policy and management issues and initiatives; and served as the top liaison to the White House on policy, management and political matters. He also served as assistant secretary for legislation at HHS from 2001 to 2003. Whitaker began his Washington career on Capitol Hill, where he worked for U.S. Senator Don Nickles (R-Okla.).
- Whitaker holds a master's degree in government from Johns Hopkins University and a degree in political science from Palm Beach Atlantic University.



Lishan Aklog, President & CEO, PAVmed

- Dr. Lishan Aklog has been PAVmed's Chairman and CEO since the company's inception. Dr. Aklog previously served as Chairman and Chief Technology Officer of Vortex Medical Inc. from its inception in 2008 to its acquisition in 2012 by AngioDynamics. Prior to entering the medical device industry full-time, Dr. Aklog was Associate Professor of Surgery, Chief of Cardiovascular Surgery and Chair of the Cardiovascular Center at St. Joseph's Hospital and Medical Center's Heart and Lung Institute.
- Dr. Aklog currently serves as a member of the Board of Directors of AdvaMed. He has previously served on the Scientific Advisory Boards of numerous leading medical device companies, including Medtronic, St. Jude Medical, Guidant Cardiac Surgery (now, Maquet Cardiovascular), and Cardioventions (then, a division of Johnson & Johnson). He has previously served on the Board of Directors of the International Society for Minimally Invasive Cardiothoracic surgery and as President of the 21st Century Cardiothoracic Surgery Society. Dr. Aklog is a member of numerous professional societies and has been elected to the American Association of Thoracic Surgery.
- Dr. Aklog received his clinical training in general and cardiothoracic surgery at Brigham and Women's Hospital and Boston Children's Hospital. He received his A.B., magna cum laude, in Physics from Harvard University, and his M.D., cum laude, from Harvard Medical School.



Carl J. St. Bernard, Jr., President & CEO, Alta Biomaterials

- Carl St. Bernard is currently the President & Chief Executive Officer of Alta Biomaterials. Alta Biomaterials is a private equity funded, start-up medical device company focused on developing and commercializing unique polymer technologies designed to address unmet clinical needs in interventional cardiology, interventional oncology, and other emerging medical applications. Prior to joining CeloNova Biosciences, Carl was President & Chief Executive Officer of Tryton Medical, a start-up interventional medicine company that was successfully exited in 2019.
- Carl has over 30 years of experience in the life sciences field, including pharmaceutical, consumer, medical device, and diagnostics markets. Carl has broad leadership experience in Cardiology, Ophthalmology, Vascular Surgery, Orthopedics, Radiology, General Surgery, and Plastic Surgery and has held senior executive positions at healthcare leaders such as Johnson & Johnson, Abbott Labs, and GE Healthcare. While at GE Healthcare, Carl led the African American Forum affinity organization which focused on recruitment, development and promotion of GE's African American business talent. Additionally, the GE African American Forum launched a business-wide initiative to address existing healthcare disparities in communities of color.

- Carl earned a bachelor's degree in Economics and Studio Art from Lafayette College and a master's degree in business administration from Pepperdine University. Carl and his wife, Terry, live in Manhattan Beach, CA.



Nadim Yared, President & CEO, CVRx

- Nadim Yared is the President and Chief Executive Officer of CVRx®. Mr. Yared previously served as Vice President and General Manager of Medtronic Navigation, a supplier of integrated image-guided surgery products, from 2002 to 2006.
- He also worked at GE Medical for ten years, where he was Vice President of Global Marketing for OEC Medical Systems, Inc. and Vice President and General Manager of General Electric Company's European X-ray business based in Paris.
- Mr. Yared is a member of the boards of directors of AdvaMed, Lightpoint Medical, the Medical Device Innovation Consortium ("MDIC"), NanoWear, Inc., North American Science Associates, Inc. ("NAMSAS") and CVRx. In addition, Mr. Yared is currently the Chairman of the NAMSAS Board of Directors and has recently served as Chairman of the AdvaMed Board of Directors and the MDIC Board of Directors. Mr. Yared has an engineering degree from Ecole Nationale Supérieure des Télécommunications and an M.B.A. from INSEAD, France.