November 2, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary"

Submitted electronically

Dear Administrator Verma:

Biocom appreciates the opportunity to offer comments on the Centers for Medicare and Medicaid Services' (CMS) proposed rule Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary" ("the Proposed Rule")[1]. Our comments focus on the new Medicare Coverage of Innovative Technology (MCIT) pathway. We are not commenting on the definition of reasonable and necessary.

Biocom is the largest, most experienced leader and advocate for California's life science sector, which includes biotechnology, pharmaceutical, medical device, genomics and diagnostics companies of all sizes, as well as research universities and institutes, clinical research organizations, investors and service providers. With more than 1,300 members dedicated to improving health and quality of life, Biocom drives public policy initiatives to positively influence the state's life science community in the research, development, and delivery of innovative products. California's life sciences industry generates $372 billion in annual economic output, boosts the state's total gross product by $212 billion, supports over 1.4 million jobs, and increases labor income by more than $115 billion per year[2].

[1] Federal Register, Vol. 85, No. 170, pp. 54327-39, September 1, 2020.
[2] Biocom 2020 Economic Impact Report Databook. https://www.biocom.org/eir/

Biocom thanks CMS for its continued efforts to identify more appropriate ways to reimburse transformative technologies, keep pace with emerging technologies, and remove barriers that prevent Medicare beneficiaries from accessing critical, life-saving products. **Biocom commends CMS on its proposed MCIT pathway, which would provide four years of automatic national Medicare coverage for medical devices and diagnostics that have been designated as breakthrough by the Food and Drug Administration (FDA), starting on the date of FDA market authorization.**

These medical technologies are revolutionizing health care by enhancing delivery options and improving outcomes. The 21st Century Cures Act of 2016 led to the creation of the Breakthrough Devices Program to expedite the review and approval process for innovative devices and diagnostics. However, it did not provide a pathway for the coverage, coding, and payment of these technologies, which is effectively delaying patients' access to these advancements. **Biocom is very supportive of this part of the proposal and urges CMS to finalize the MCIT pathway, with the following recommended changes:**

Inclusion of Diagnostic Technologies

Section 515B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360e-3) defines medical devices eligible for the Breakthrough Devices Program as medical devices and device-led combination products that "provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions," rendering diagnostic technologies eligible for the Program. However, language from the proposed rule pertaining to diagnostics eligibility is not consistent throughout the proposed rule.

In Section I- Background, CMS states "at this time, we are limiting MCIT to medical devices because that is a category of products explicitly identified in E.O. 13890, and we have identified that breakthrough devices can experience variable coverage across the nation shortly after market authorization," which appears to exclude diagnostics. Yet, in Section II.B – Provision of Proposed Regulations, CMS states "this application of the "reasonable and necessary" standard in this way would ensure that the MCIT pathway can provide a fast-track to Medicare coverage of innovative devices that may more effectively treat or diagnose life-threatening or irreversibly debilitating human disease or conditions," which includes diagnostics.

Recommendation: Biocom urges CMS to clarify that FDA-approved breakthrough diagnostic technologies are eligible for the MCIT Pathway, as they are for FDA's Breakthrough Devices Program. Throughout our comments, breakthrough devices refer to both medical devices and diagnostic technologies.

Expansion of Medicare Benefit Categories

The proposed rule would automatically cover FDA-approved breakthrough technologies under the MCIT pathway, unless CMS determines that a device does not have a Medicare benefit category. While we recognize that CMS doesn't have the authority to include technologies that do not fit a benefit category, we want to emphasize that, in the case of breakthrough devices, this is a major barrier to providing these technologies to patients. Indeed, given the transformative and unique nature of these

devices, it is highly common that several of these technologies would get approved by the FDA but not fit within an existing benefit category. Therefore, we encourage you to work with legislators and stakeholders to facilitate the coverage of these most innovative technologies.

In addition, we urge CMS to consider changes to Medicare regulations that would expand coverage within Medicare's existing benefit categories to ensure that technologies not currently covered could be under an existing benefit category. For example, breakthrough devices are increasingly using digital health technologies or components that are digital technologies, such as apps or algorithms, but there is a lack of clarity as to whether these technologies are covered under Medicare's existing benefit categories. We recommend that a clearer pathway be established for these technologies through regulation.

Recommendation: Biocom urges CMS to work with legislators and stakeholders to facilitate the coverage of breakthrough devices that, given their transformative nature, do not fit within an existing benefit category, and to establish a clearer pathway through regulation to ensure that digital health technologies fit within an existing benefit category and are therefore eligible for MCIT coverage.

Four-Year Coverage

The proposed rule establishes an MCIT coverage period of four years. Biocom understands the need for a time limit during which the breakthrough technology is considered new for purposes of MCIT coverage. We believe that four years is an adequate time to provide immediate coverage to patients while allowing manufacturers to develop clinical evidence and demonstrate the value of these new technologies in the marketplace.

Biocom also supports starting the four-year coverage period on the date of FDA market authorization, which is consistent with the methodology used by CMS to determine the start of coverage for new technology add-on payments (NTAP) under the Inpatient Hospital Prospective Payment System (IPPS) or transitional pass-through payments (TPT) under the Hospital Outpatient Prospective Payment System (OPPS). These were CMS' first steps toward providing coverage for breakthrough devices, which Biocom has supported in previous comments to the agency.

Lastly, we urge CMS to provide breakthrough devices that have already obtained FDA market authorization four years of coverage starting on the date this proposed rule becomes effective or the date of FDA-market availability, whichever comes second. Indeed, manufacturers should not be penalized for being the firsts to be part of FDA's Breakthrough Devices Program.

Recommendation: Biocom supports the four-year MCIT coverage period and starting coverage on the date of FDA market authorization. For early entrants to the Breakthrough Devices Program that have already received market authorization, we urge CMS to provide the full four years of coverage, beginning on the date the final rule becomes effective, or the date of market availability, whichever comes second.

Flexibility for Coverage Post-MCIT

At the end of the four-year coverage period, manufacturers should be given the option to pursue a National Coverage Determination (NCD) or Local Coverage Determination (LCD), based on their reimbursement needs, the technology, and the needs of the patient population they serve.

Biocom does not support an automatic initiation of a national coverage analysis if a Medicare Administrative Contractor (MAC) has not issued an LCD for a breakthrough device within six months of the expiration of the four-year MCIT coverage period, as proposed by CMS. The MCIT pathway is voluntary and products have unique specificities; therefore, manufacturers should have the flexibility to pursue the coverage option that suits them.

We would also like to suggest that CMS include an option to extend MCIT coverage for a period of time to be determined to allow manufacturers to complete studies to support coverage beyond the initial four years. This extension would be allowed on a case-by-case basis. It would prevent abrupt disruptions in beneficiary access to breakthrough technologies following the expiration of the MCIT coverage period.

Recommendation: Biocom urges CMS to provide manufacturers with flexibility to determine their approach to continued coverage after the four-year MCIT coverage period ends, including pursuing an NCD or LCD, and opposes initiating a national coverage analysis, triggered automatically or by inaction on the part of a MAC.

Inclusion of Process to Receive Appropriate Coding and Payment

Biocom urges CMS to implement processes to ensure appropriate coding and payment categories are in place for products in the MCIT pathway. Those should be established early in the coverage period to allow manufacturers to generate the evidence CMS expects for continuation of coverage beyond that initial period. We also support CMS' plan to establish a new office to coordinate coverage, coding and payment and look forward to working with the agency to define the priorities for this new office

In addition, we support ensuring that a process is in place for assigning codes specifically to MCIT devices, as a code is essential to getting payment. Currently, codes are assigned by CMS or the American Medical Association (AMA). CMS should clarify whether the code assignment process will be administered through the MCIT program, under existing programs, or a combination of approaches. We also suggest implementing a process to assign temporary codes immediately upon approval for coverage.

Recommendation: Biocom urges CMS to implement processes to ensure appropriate coding and payment categories are in place for MCIT technologies, including clarifying the process for code assignment for MCIT technologies, and considering implementing a process to assign temporary codes immediately upon approval for coverage.

Engagement with Manufacturers regarding Continued Evidence Generation

Biocom supports CMS' proposal that manufacturers not be mandated by CMS to conduct clinical studies during the initial coverage period. Indeed, technologies are different and across-the-board requirements could result in unnecessary data collection requirements. In addition, CMS' mandate for data collection could be inconsistent with FDA postmarked studies that some manufacturers will be conducting. Manufacturers will already be incentivized to gather data that might be needed to justify coverage beyond the initial period of automatic coverage.

We also agree with CMS that further evidence may be needed for continued coverage beyond the four-year coverage period and support CMS' encouragement of continued evidence generation. However, we strongly urge CMS to ensure that the agency engage with manufacturers early on to discuss potential clinical study designs and clinical endpoints that can produce such evidence, consider the minimum data necessary to achieve those objectives, make clear expectations regarding the evidence necessary, and work with stakeholders in an open and transparent manner.

Recommendation: Biocom supports not mandating manufacturers to conduct clinical studies during the initial coverage period while supporting CMS' encouragement of continued evidence generation to achieve permanent coverage at the end of the four-year MCIT coverage period. We urge CMS to create opportunities for dialogue with manufacturers early on and make clear expectations regarding the production of evidence necessary for continued coverage beyond the initial four-year coverage period.

Biocom is dedicated to improving patient access to innovative technologies and thanks you again for the opportunity to provide these comments. We applaud the agency for proposing the MCIT coverage pathway and urge you to finalize this portion of the proposed rule. We look forward to a continued dialogue as you develop the final rule. If you have any questions about these comments, please contact Laure Fabrega, Director of Federal Policy and Government Affairs at lfabrega@biocom.org.

Sincerely,

Joe Panetta
President and CEO
Biocom California