April 16, 2021

The Honorable Elizabeth Richter
Acting 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 Richter:

Biocom California appreciates the opportunity to offer comments on the Centers for Medicare and Medicaid Services' (CMS) interim final rule Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary" ("the IFR")[1]. Our comments focus on the specific concerns raised by CMS in the Medicare Coverage of Innovative Technology (MCIT) IFR. We are not commenting on the definition of reasonable and necessary.

Biocom California 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 California 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, 86 FR 14542, pp. 14542-14545, March 17, 2021.
[2] Biocom California 2020 Economic Impact Report Databook. https://www.biocom.org/eir/

Biocom California 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. 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 California urges CMS to begin implementation of this critical pathway on the already delayed date of May 15, 2021.**

CMS requested comments on the following topics within the IFR and Biocom California provides responses to CMS' concerns below:

Operational Issues
CMS notes that the IFR did not directly address operational issues, such as how the agency would establish coding and payment levels and determine benefit categories for particular devices, which are both central to prompt market access. CMS seeks comments on how they should resolve these operational issues. Biocom California notes that commentors previously raised this issue during the draft period of the document, and CMS addressed it in the final rule, noting "a detailed description of coding and payment is beyond the scope of the MCIT rule and resides in other payment rules." (86 FR 3002). CMS considered this issue in the final rule and has already responded to it therefore further delay of the MCIT rule is unwarranted. It also worth noting there is a significant amount of time between breakthrough designation and market authorization, which is adequate for developers and CMS to align on key operational issues.

New Information: Breakthrough Device Volume
CMS notes the regulatory impact analysis (RIA) published as part of the MCIT final rule was based on the expectation that the Food and Drug Administration (FDA) breakthrough device program would initially apply to a relatively small number of devices based on the low number of breakthrough devices that had become market authorized. CMS notes that recent public data suggests a larger number of market-authorized breakthrough devices may be eligible for MCIT. While more than 400 devices have been designated as breakthroughs to date, this designation is only the first step in a long process before ultimate FDA approval or clearance. **Breakthrough designation does not guarantee FDA approval and many devices designated as such will not clear FDA's rigorous hurdles to be approved under available pathways.** To date, FDA has only approved 23 breakthrough devices. The distinction between designation and approval is important when considering the impact of the MCIT on resources. It is also worth noting that many devices designated under the breakthrough pathway will not qualify for MCIT because they do not fall under an existing Medicare benefit category. Ultimately, a smaller number of breakthrough-designated technologies will achieve FDA approval or clearance each year and be eligible for MCIT. Regardless, it is also important for CMS to recognize the significant benefits to both patients and long-term savings to the health care system if the number of devices eligible for the program increases in the future.

Medicare Patient Benefit/Protection

In the IFR, CMS raised questions about how breakthrough technology may work in older patient populations and the evidence basis for Medicare coverage of these technologies. CMS also noted that some public commenters challenged CMS' premise that the MCIT coverage could result in improved care for Medicare beneficiaries absent specific evidence that the MCIT eligible devices benefit the Medicare population. CMS already addressed this concern in the MCIT final rule by encouraging stakeholders to engage with the agency early on, before and after market authorization.

In response to public comments, the MCIT final rule also gives CMS authority to remove a breakthrough device from the MCIT pathway when a medical device safety communication or warning letter is issued by the FDA, or if the FDA revokes market authorization for a device. It is a important to note that manufacturers are required to perform rigorous clinical trials to obtain marketing authorization from the FDA, including if a device goes through the breakthrough designation pathway. Further, contrary to the article CMS cites in the IFR by Neumann and Chambers, many products have long lifespans and even if the next generation of products are available, manufacturers have significant incentives to continue to assess products and provide strong clinical evidence for long-term CMS coverage after the MCIT period, as well as to obtain commercial insurer coverage.

Biocom California reminds CMS that the Agency has many pathways to establish coding and payment in an appropriate and timely way to ensure access to critical new breakthrough devices—including through the HCPCS coding and MAC payment rate processes, among others. For example, there is coding for "prostatectomy." If there is a new FDA breakthrough version of the machine, it would fall under the existing CPT codes and be cross walked by them into existing APC or DRG payments. Similarly, new FDA NGS tests are automatically covered by an NCD today the date of FDA approval, but the coding and pricing follow. We encourage CMS to solicit feedback from stakeholders, either via rulemaking or an informal comment process, on how best to address these operational issues going forward. CMS has the opportunity in this regard to create dialogue and allow and provide feedback that will achieve greater transparency in the coverage process long term, as well as facilitate better understanding by both parties of the evidence expectations over time. **Biocom California agrees that evidence is needed for continued coverage beyond the four-year MCIT coverage period and supports early manufacturer engagement with CMS to discuss and receive feedback on potential clinical study designs and clinical endpoints that can produce such evidence.**

Adequacy of Rulemaking Process

CMS seeks comments on whether there are any other procedural issues pertaining to the January 2021 MCIT rulemaking process. The MCIT rule was finalized through the appropriate process under the Administrative Procedure Act (APA), including a public notice and 60-day comment period, and has received broad support. Therefore, Biocom California does not believe that there is inadequacy in the rulemaking process that would require amending, rescinding, or further delaying the rule. **Biocom California urges CMS to proceed with implementation of the final rule on the revised May 15, 2021, effective date.**

Biocom California 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 developing the MCIT coverage pathway and urge you to begin implementation of the pathway on May 15, 2021. We look

forward to a continued dialogue as you develop the final rule. If you have any questions about these comments, please contact Isabel Omer, Regulatory Policy Associate at iomer@biocom.org.

Sincerely,

Joe Panetta
President and CEO
Biocom California