November 2, 2020

Administrator Seema Verma
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1734-P
P.O. Box 8016
Baltimore, MD 21244-801

Re: Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary" (CMS-3372-P)

Submitted electronically on regulations.gov

Dear Administrator Verma,

As the only organization completely dedicated to advancing telehealth, the ATA is committed to ensuring everyone has access to safe, affordable and appropriate care when and where they need it, enabling the system to do more good for more people. The ATA commends CMS's recent actions to expand Medicare beneficiaries' access to telehealth and remote care during the ongoing COVID-19 Public Health Emergency (PHE) and looks forward to working with the agency and Congress to ensure these services remain available even after the PHE ends. While we continue to work together to support telehealth services, the ATA also urges CMS to consider how the agency can use its regulatory authority to expand access to and directly cover digital health technologies that are not traditionally covered by Medicare. To that end, the ATA is pleased to submit the following brief comments to the proposed rule on Medicare Coverage of Innovative Technology (CMS-3372-P).

The ATA appreciates CMS's efforts to expand access to innovative technologies, including new medical devices designated as breakthrough by the Food and Drug Administration (FDA) through this proposed rule. Technology innovation occurs at a rapid pace, and it is essential that regulators—both at the FDA and CMS—keep up with innovation to ensure timely access to and reimbursement of technologies that can improve patients' care. The ATA appreciates this rule's intent to help speed access to innovative technologies, streamline coverage determinations across regions, and address the detrimental "valley of death" between a technology's FDA approval and CMS coverage determination that can delay access to care and disincentivize future investments by developers. The communication proposed by this rule between the agencies to ensure innovative products that have been shown to be safe and effective can then be available to Medicare patients encourages further lifesaving and life-improving innovation.

However, there is a critical piece missing from this proposed rule. CMS indicates that only devices or services with an existing Medicare benefit category qualify for coverage. This leaves out many new technologies and services that Medicare has

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failed to assign to an existing benefit category. For example, digital therapeutics – app or virtual-based services that have proven clinical benefit – would not be eligible for this new pathway. This is a growing field that has potential to provide treatment to patients in novel ways, which is why FDA has granted breakthrough device status to multiple digital therapeutics, including for substance use disorder applications. However, under this proposed rule as it is currently written, those breakthrough devices would not qualify for payment even if they are market-authorized by FDA.

The ATA believes CMS's opinion that the agency's ability to cover digital technologies is limited because of the absence of a specific statutorily defined benefit category is misguided. According to the FDA, digital health technologies "use computing platforms, connectivity, software, and sensors for health care" and "have the vast potential to improve our ability to accurately diagnose and treat disease and enhance the delivery of health care for the individual."[1] Unfortunately, CMS's interpretation means this proposed rule, if finalized, would leave out countless new digital health technologies that could improve the health outcomes of millions of Medicare beneficiaries. As discussed in a September 2020 white paper released by AdvaMed entitled "Modernizing Medicare Coverage of Digital Health Technologies"[2], CMS has multiple avenues within its jurisdiction to address this problem. The ATA urges CMS to use the MCIT proposed rule to include FDA breakthrough-designated digital products without existing benefit categories in this rule by clarifying that an existing benefit category, like the category used for durable medical equipment, can include digital therapeutics and software.

During the COVID-19 PHE, it is more prudent than ever that the agency uses every authority it has to ensure access to care, including remote care that can be safely administered from a distance. Because of the aging population, Medicare beneficiaries have been disproportionately impacted by the pandemic. Further, the PHE has uncovered significant health equity gaps in our nation, underscoring the need for public payers like Medicare to extend coverage and reimbursement to innovative technologies, like digital therapeutics, that have been approved by the FDA and even covered by some of our nation's private payers.

Without specific actions by CMS that clarify digital therapeutics could fall into an existing benefit category, the MCIT proposed rule—while encouraging and potentially helpful to spur innovation and improve timely access to some care—will not help Medicare beneficiaries who need access to these technologies. Thank you very much for the opportunity to provide our feedback to this proposed rule. If you have any questions or would like to further discuss our recommendations, please contact Kyle Zebley, Director, Public Policy at kzebley@americantelemed.org.

Kind regards,

[1] https://www.fda.gov/medical-devices/digital-health-center-excellence/what-digital-health
[2] https://www.advamed.org/sites/default/files/resource/advamed-modernizing-medicare-coverage-of-digital-health-technologies-september-2020.pdf

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