November 2, 2020

Via Electronic Communication Only

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3372-P, Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-3372-P – Proposed Rule To Establish Medicare Coverage To Provide Medicare Beneficiaries With Faster Access FDA Breakthrough Medical Devices

Dear Centers for Medicare & Medicaid Services (CMS), HHS Team,

On behalf of the Medullan Digital Health Consulting Firm, we write to support CMS-3372-P (the "Proposed Rule"). CMS has proposed meaningful improvements for access to FDA "breakthrough medical devices." While the Proposed Rule will do much good, we write to ask that CMS ensure the Proposed Rule appropriately covers digital therapeutics (also referred to as software as a medical device) — evidence-based treatments powered by quality software programs to prevent, manage, or treat a medical disorder or disease — as well as certain other issues with regard to the Medicare population.

A. The Medicare Coverage of Innovative Technology (MCIT) Pathway Should Thoroughly Cover Digital Therapeutics and Software as a Medical Device — And Not Be Confined to the Traditional Durable Medical Equipment Interpretation

This section is written in response to CMS's request: "[w]e seek public comment on the proposed MCIT pathway, the considerations described, whether any of the existing coverage pathways should be modified to achieve the goals set out by the E.O. [13890], and alternatives to these proposals."

Although CMS has specifically stated its intention for the Proposed Rule to cover existing benefit categories, such as durable medical equipment (DME), its approach to digital therapeutics (DTx) and software as a medical device (SaMD) remains unsettled. At present, Section I (D) — "MCIT Pathway" — of the Proposed Rule addresses current coverage and reimbursement policies for existing benefit categories without specifically addressing DTx and SaMD.[1]

Without appropriately outlining a framework for how innovative technologies such as DTx and SaMD would be covered under current or proposed pathways, there remains a lack of solid scaffolding for coverage and reimbursement under the Proposed Rule.

[1] As noted in Section I (D) of the Proposed Rule, "CMS proposes to rely on FDA's breakthrough device designation and market authorization of those devices to define the universe of devices eligible for MCIT, except for those particular devices CMS determines do not have a Medicare benefit category or are statutorily excluded from coverage under Part A or Part B."

By attempting to repeatedly stuff coverage of innovative technologies under the traditional benefit categories, such as DME, there remains an odd fit between DTx/SaMD and appropriate coverage and reimbursement. This piecemeal and patchwork approach should be replaced with a sturdy foundation and systemic construct of how innovative, evidence-based treatments — whether a traditional benefit category exists or not — will be covered and reimbursed by the Proposed Rule.

For example, Germany's Federal Institute for Drugs and Medical Devices (BfArM) is implementing an entire suite of regulations related to reimbursement of digital therapeutics. While the new Digital Healthcare Act (DVG) was a legislative initiative, it was focused in large part on ensuring that regulatory processes for reimbursement are accelerated and designed to reflect the innovation potential of digital health – not restricting it to DME.

We advise CMS expand its understanding of DME from a rigid, concrete interpretation to a more flexible, limber interpretation and specifically address how innovative, evidence-based treatments — whether a traditional benefit category exists or not — can be covered and reimbursed under the Proposed Rule. Specifically, we agree with several of the recommendations in the Advanced Medical Technology Association's (AdvaMed) proposed roadmap for expanding coverage policies for DTx/SaMD:[2]

> ***Using the COVID-19 public health emergency waivers as a model, CMS should explore the expansion of coverage policies for new and currently non-covered digital health technologies.***
>
> CMS should evaluate the potential of new and emerging digital health technologies to expand access to care, to improve quality and health outcomes, to promote patient safety, and to decrease Medicare program costs.
>
> Using these as measures of potential impact, flexibilities for coverage of the following types of technologies should be explored… coverage of Software as a Medical Device (SaMD)…

We also recognize and appreciate that Section II (A) — "Defining 'Reasonable and Necessary'" — provides a separate basis for which an item or service may be deemed "reasonable and necessary."[3] In response to the request for comment regarding this proposed codification language, we agree and support this proposed codification language. We also agree with the assumption that the number of devices granted breakthrough status is increasing as stated in Section IV — "Regulatory Impact Statement."

And just as the revamped Food and Drug Administration (FDA) Software Precertification (Pre-Cert) Program aims to facilitate both timely development and review of SaMD, we believe the Proposed Rule can also foster meaningful development and review of SaMD.

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[2] Modernizing Medicare Coverage of Digital Health Technologies, Pg. 39-42 (September 2020), https://www.advamed.org/sites/default/files/resource/advamed-modernizing-medicare-coverage-of-digital-health-technologies-september-2020.pdf.

[3] "We seek comment on whether beneficiaries, providers, innovators, or others wishing to gain coverage for an item or service demonstrate that the item or service is covered by at least one commercial insurance plan policy. If they can provide CMS with evidence of commercial coverage or if CMS or its MACs identify such coverage from its review of compilations of health insurance offerings or data from other sources, CMS would consider factor (3) to be satisfied."

In other words, we implore CMS to provide a clear and concise framework for DTx/SaMD coverage and reimbursement. Secondly, we recommend CMS evolve its DME interpretation to explicitly include and address DTx and SaMD.

B. MCIT's National Coverage Should Address Rural or Indigent Populations, Social Determinants of Health Factors, and Access to Care Issues

Under the Proposed Rule, CMS seeks to establish a Medicare coverage pathway to provide Medicare beneficiaries nationwide with faster access to new, innovative medical devices designated as breakthrough by the FDA.

Too often, in our public and private quest for efficiency improvements and scalable treatments, we tend to lose focus of the unique problems posed by rural or indigent populations, social determinants of health (SDoH) factors, and access to care issues.

Reimagining how breakthrough medical devices can be covered and reimbursed via a national lens presents a powerful opportunity to address disparate access to care, treatment, and outcomes in our society. CMS, as the single largest payer for health care in the United States, has the capability to act as a force multiplier for positive change in how we envision coverage and reimbursement for innovative technologies, including DTx and SaMD.

Evidence-based treatments — whether a traditional benefit category exists or not — should be covered and reimbursed under the Proposed Rule because rural or indigent populations, SDoH factors, and access to care can all be better addressed by an evolving, flexible framework for innovative technologies.

Conclusion

We support the Proposed Rule to establish a Medicare coverage pathway to provide Medicare beneficiaries nationwide with faster access to new, innovative medical devices designated as breakthrough by the FDA — and ask that CMS make a determination, which specifically addresses DTx/SaMD coverage and reimbursement to ensure that the Proposed Rule adequately covers innovative, evidence-based treatments — whether a traditional benefit category exists or not.

Respectfully Submitted,

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