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April 16, 2021

Mr. Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Attention: CMS-3372-IFC

Re: Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary"; Delay of Effective Date; Public Comment Period

Dear Secretary Becerra:

The Academy of Managed Care Pharmacy (AMCP) thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to provide comments in response to its interim final rule with comment (IFC) period titled "*Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary"; Delay of Effective Date; Public Comment Period (CMS-3372-IFC)*" published on March 17, 2021. We appreciate the opportunity to leverage our members' expertise in offering feedback on this rule.

AMCP is the professional association leading the way to help patients get the medications they need at a cost they can afford. AMCP's diverse membership of pharmacists, physicians, nurses, biopharmaceutical professionals, and other stakeholders leverage their specialized expertise in clinical evidence and pharmacoeconomics to optimize medication benefit design and population health management and help patients access cost-effective and safe medications and other drug therapies. AMCP members improve the lives of nearly 300 million Americans served by private and public health plans, pharmacy benefit management firms, and emerging care models.

In recent years, AMCP has taken a leadership role in the emerging field of digital therapeutics (DTx) by convening thought leaders across the healthcare industry to determine the role that DTx play in patient care, and how to ensure that patients are able to access this new frontier of medical science. DTx have the potential to revolutionize population health management and help patients live healthier lives, and managed care pharmacists have the knowledge and skills necessary to play a primary role in their management.

On September 17-18, 2019, AMCP convened a Partnership Forum on DTx that drew national stakeholders in the digital therapy space across various industries including payers, manufacturers,

employers, providers, patient advocacy groups, and government.[1] As part of this forum, participants developed a description of DTx and noted key differences between DTx and other digital health products, such as consumer wellness apps. In August 2021, AMCP will hold another Partnership Forum on DTx to continue this important work by exploring the current market space for DTx, including the evidence for these products, place in therapy, monitoring or utilization metrics, and barriers that patients face in obtaining therapies.

Based on these discussions, a DTx describes a "high-quality digital intervention, making a medical claim, that is driven by software programs to prevent, manage, or treat a medical disorder or disease." DTx also "require approval and third-party validation of efficacy and safety claims," by a regulatory or equivalent national body, such as the Food and Drug Administration (FDA), or a recognized accreditation or health services organization. Accordingly, coverage decisions for DTx should include an examination of safety, efficacy, data security/privacy, and usability, with tiered formulary considerations based on the product's medical claim or function.

Given the unique characteristics of DTx, our discussions have also considered whether DTx may be most suitable for coverage under the medical or pharmacy benefit depending on whether DTx are designed to be furnished by a physician or self-administered by the patient. For purposes of Medicare coverage, however, this discussion is further complicated by the statutory limitations imposed on Medicare Part B and D as it pertains to coverage of items and services. These complexities have contributed to access challenges under the Medicare program for DTx as providers and suppliers are uncertain whether they can provide DTx to their Medicare beneficiaries. CMS has yet to provide any indication of how the agency views DTx in the context of Medicare coverage.

As the FDA is increasingly approving DTx with indications to prevent, manage, and treat a myriad of conditions, AMCP was hopeful that the MCIT pathway would clarify how the agency intends to approach coverage and payment for DTx. However, although the MCIT pathway represents an important step in the right direction for improving patient access to innovative technologies, we remain disappointed that CMS does not address patient access to DTx in the proposed rule, even as it proposes to codify a "reasonable and necessary" definition that serves as the linchpin for Medicare coverage determinations. AMCP urges CMS to consider providing additional clarity on the coverage of DTx in the Medicare program as it reconsiders this rule.

Rule Provision

In the final rule, CMS codifies the longstanding subregulatory definition for "reasonable and necessary" that determines when an item or service may be covered under the Medicare program.[2] Specifically, the rule requires that an item or service is "reasonable and necessary" when it is (1) safe and effective; (2) not experimental or investigational; and (3) appropriate, including the duration and frequency that is considered appropriate for the item or service in terms of whether it is.[3] CMS also proposes to incorporate commercial health insurers' coverage policies as an alternative means to

[1] "Digital Therapeutics: What Are They and Where Do They Fit in Pharmacy and Medical Benefits?," AMCP Partnership Forum (Sept. 17-18, 2019), https://www.amcp.org/Resource-Center/meeting-proceedings-findings/digital-therapeutics-what-are-they-and-where-do-they.

[2] 85 Fed. Reg. at 54331.

[3] Id.

satisfy the third condition that the item or service is considered appropriate for Medicare beneficiaries.[4]

In addition to codifying the definition of "reasonable and necessary", the rule creates the MCIT pathway that would extend a 4-year coverage period, based on the date of FDA market authorization, to devices that receive Breakthrough designation from the FDA and fall within a Medicare benefit category.[5] The agency characterizes its MCIT rule as "support[ing] and accelerat[ing] beneficiary access to certain innovative devices."[6] CMS points out throughout the rule, however, that the MCIT pathway would only be available for technologies with an applicable statutory benefit category.

AMCP Comments
AMCP supports CMS's efforts to improve beneficiary access to innovative technologies by establishing the MCIT pathway and bringing more clarity around the "reasonable and necessary" definition applicable to Medicare coverage of items and services. At the same time, however, we are disappointed that the rule makes no mention of DTx given the potential represented by this emerging area of technology.

AMCP appreciates the challenges that DTx poses for the Medicare program, and in particular the Medicare requirement that for any item to be covered under the program, it must meet a statutory benefit category. As a healthcare program first enacted in the 1960s, the Medicare statute does not expressly contemplate a benefit category comprised of software technologies that are directly providing the medical intervention, and we understand that CMS would be breaking new ground in considering coverage and payment for DTx under a rigid statutory scheme.

In the past, however, CMS has exercised its regulatory authority in innovative ways to provide access to modern technologies. For example, in 2017 CMS extended coverage to continuous glucose monitors (CGMs) under the durable medical equipment (DME) benefit category,[7] and in 2018 CMS expanded coverage and payment for remote patient monitoring (RPM) services outside of the telehealth benefit category.[8]

CMS's commitment to ensuring Medicare beneficiary access to innovative technologies has manifested itself repeatedly through creative coverage and payment frameworks that offer more

[4] Id. at 54332.
[5] 85 Fed. Reg. at 54334.
[6] Id.
[7] CMS-1682-R (January 12, 2017), available at https://www.cms.gov/regulations-and-guidance/guidance/rulings/downloads/cms1682r.pdf; see also Medicare CY 2021 Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Policy Issues and Healthcare Common Procedure Coding System (HCPCS) Level II Proposed Rule (CMS-1738-P), (released Oct. 27, 2020), https://www.cms.gov/files/document/cms-1738-p-dmepos.pdf (further expanding coverage for CGMs that do not replace a traditional blood glucose monitor).
[8] "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; Medicaid Promoting Interoperability Program; Quality Payment Program-Extreme and Uncontrollable Circumstance Policy for the 2019 MIPS Payment Year; Provisions From the Medicare Shared Savings Program-Accountable Care Organizations-Pathways to Success; and Expanding the Use of Telehealth Services for the Treatment of Opioid Use Disorder Under the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act," 83 Fed. Reg. 59452, 59487 (Nov. 23, 2018).

flexibility while adhering to the Medicare statute. The MCIT rule is another example of CMS's creative problem-solving for ensuring adequate access to innovative technologies, and CMS should use this opportunity to also provide stakeholders, including beneficiaries, with a better idea of how the agency views and will approach coverage and payment for DTx.

Conclusion

AMCP appreciates the opportunity to comment on the IFC "*Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary"; Delay of Effective Date; Public Comment Period (CMS-3372-IFC).*" We are committed to be being a valuable resource to CMS on improving access to prescription drugs at lower costs and reducing costs in the health care system for Medicare beneficiaries. If you have any questions regarding AMCP's comments or would like further information, please contact me at 703-684-2600 or scantrell@amcp.org.

Sincerely,

Susan A. Cantrell. RPh, CAE

Chief Executive Officer