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Marge Watchhorn
Director, Division of Coding & Diagnosis Related Groups
Centers for Medicare & Medicaid Services
Department of Health & Human Services
7500 Security Blvd
Baltimore, MD 21244-1850

Submitted electronically via hcpcs@cms.hhs.gov

Re: Centers for Medicare & Medicaid Services' First Biannual 2022 Healthcare Common Procedure Coding System Public Meeting

Dear Ms. Watchhorn:

The Academy of Managed Care Pharmacy (AMCP) thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to provide comments for the June 2022 Healthcare Common Procedure Coding System (HCPCS) Public Meeting regarding coding practices for prescription digital therapeutics (PDTs). AMCP does not comment on individual coding decisions but submits these comments to address macro-level coding trends.

AMCP is the nation's leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes, and ensuring the wise use of healthcare dollars. Through evidence- and value-based strategies and practices, AMCP's over 7,000 pharmacists, physicians, nurses, and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models, and government.

AMCP applauds CMS' efforts to standardize coding and billing for PDTs and believes the creation of the Level II code A9291 was an important first step. However, AMCP recommends creating additional codes for PDTs as needed because A9291 does not cover the full range of available PDTs.

Background on PDTs

Prescription digital therapeutics are an emerging class of treatments that use software applications to deliver a clinical mechanism of action, either alone or in combination with other standard-of-care treatments to improve outcomes. PDTs are approved by the Food & Drug Administration (FDA) and prescribed by a healthcare provider in the same way that patients are prescribed traditional drugs. One key factor in determining whether a health-focused software application is considered a true digital therapeutic is whether the application delivers a specific and independent clinical mechanism. For example, an application that helps patients remember to take their prescription medications does not have an independent mechanism and would not be considered a digital therapeutic. Further, not all

products described by their manufacturers or developers as digital therapeutics are prescription or undergo FDA review to establish safety and efficacy. Currently, there are 10 FDA-approved PDTs available. These therapies treat a variety of conditions, with many addressing mental health and substance use disorder through cognitive behavioral therapy. However, other therapies address different clinical conditions; use different mechanisms of action; and may augment, replace, or compete with other treatment modalities to optimize patient health outcomes impact and care costs.

For example, one FDA-approved PDT is used for the treatment of amblyopia in children aged 4 to 7. Amblyopia, colloquially referred to as "lazy eye", is treated by strengthening the muscles in the affected eye; traditionally, treatment has been wearing an eye patch over the non-affected eye. This PDT works by using a virtual reality headset, which features separate screens for each eye, to play movies and television shows that automatically stimulate strengthening exercises in the affected eye. Several diabetes treatments involve the coordinated use of an insulin pump device and continuous glucose monitoring software, sometimes considered a PDT, that allows patients to adjust their insulin pump as needed, delivering more stable insulin levels than patients performing periodic manual checks and injections. These PDTs involve equipment or devices beyond the program itself that payers will likely want to consider separately from software-only PDTs for billing purposes due to the extra cost.

Multiple HCPCS codes for PDTs are needed to adequately ensure patient access

CMS has thus far assigned HCPCS Level II code A9291 to PDT products that have requested a code irrespective of their indications.[1] In particular, CMS' preliminary determination is to reject Akili Interactive's HCPCS coding request for a separate code for the company's PDT, EndeavourRx, based on the agency's determination that A9291 adequately describes the technology. The HCPCS descriptor for A9291 currently reads: "**Prescription digital behavioral therapy, fda cleared, per course of treatment.**"

Without taking a position on the specific coding recommendation being discussed during the June HCPCS Public Meetings, AMCP generally believes that code A9291 may be overbroad and is concerned about establishing a precedent of assigning all PDTs to the same HCPCS code regardless of indication, clinical condition, or mechanism of action. Such a choice may have the unintended effect of inhibiting patient access to PDTs.

AMCP recommends modifying the descriptor for A9291 to read: "**Prescription digital therapeutic – behavioral therapy, fda cleared, per course of treatment**." AMCP believes that a more targeted indication-specific HCPCS coding for PDTs is the better coding approach at this stage for this emerging class of technologies. Additional codes following this format may be created as needed to reflect PDTs using mechanisms other than behavioral therapy or with substantially different costs.

Our proposed coding approach is informed by several policy considerations:

[1] Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Recommendations, Second Biannual, 2021 HCPCS Coding Cycle. Centers for Medicare & Medicaid Services. February 16, 2022. https://www.cms.gov/files/document/2021-hcpcs-application-summary-biannual-2-2021-non-drug-and-non-biological-items-and-services.pdf

- **A single HCPCS code fails to recognize the diversity of existing PDTs and PDTs in the pipeline.** Not all PDTs fall under the scope of "behavioral therapy." Some PDTs deliver their mechanism of action through physical exercises, as in the case of the PDT that treats amblyopia, or through coordination with a connected device, as is the case in with insulin pumps and continuous glucose monitors. Without an adequate variety of HCPCS codes for PDTs, these products may be inappropriately classified as behavioral therapies or may not receive a HCPCS assignment at all.
- **A single HCPCS code contributes to administrative burden.** Limiting PDTs to only a single HCPCS code will require the inclusion of non-standardized elements in claims billing, such as Unique Device Indicators (UDIs) or specific product names; this will lead to additional administrative burden for both providers and payers. Currently, shared HCPCS codes for medical drugs have presented an obstacle for payers regarding the misrepresentation of a product identifying modifier, where the provider submitting the billing claim uses placeholder text or non-existent NDCs. Limiting PDTs to a single HCPCS code will likely replicate these obstacles.
- **A single HCPCS code limits reimbursement flexibility.** Compressing all PDTs into a single code may also result in unnecessarily uniform reimbursement rates that do not adequately account for cost differences between individual products. Additionally, PDTs have shown promise in the context of value-based contracting, and a single HCPCS code frustrates the implementation of value-based contracts under the medical benefit.
- **A single HCPCS code restricts utilization management capabilities.** Multiple HCPCS codes enable the ability to monitor, assess, evaluate, and plan for product use. HCPCS codes allow payers to monitor for fraud and abuse, conduct evaluations of effectiveness comparing DTx treatments to drugs, services, and other treatment modalities, and to best identify the patients, settings, and policies for appropriate access for coverage and reimbursement.

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AMCP supports CMS' efforts to develop stable and consistent coding practices for digital therapeutics. Because this is an emerging class of therapies, it is crucial to develop a robust set of codes that fully cover the variety of PDTs, both in terms of clinical mechanism and diseases treated, that have been approved or are currently in the pipeline. Developing multiple codes will empower health payers to implement the most appropriate and well-tailored utilization management programs to improve the health of their beneficiaries.

AMCP appreciates your consideration of the concerns outlined above and looks forward to continuing to work on this issue with CMS. If you have any questions regarding AMCP's comments or would like further information, please contact Jennifer Mathieu at 703.286.2564 or jmathieu@amcp.org.

Sincerely,

Susan A. Cantrell RPh, CAE
Chief Executive Officer