



December 2, 2021

Via Electronic Communication

Chiquita Brooks-LaSure
Administrator, Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Comment on Revision to the Healthcare Common Procedure Coding System (HCPCS) Code Set Public Meeting December 2021

Dear Administrator Brooks-LaSure,

Aimed Alliance is a 501(c)(3) non-profit health policy organization that seeks to protect and enhance the rights of healthcare consumers and providers. Aimed Alliance leads ACTION for PDTs, a multidisciplinary partnership that is working to expand the adoption, coverage, and access to prescription digital therapeutics (PDTs) for individuals living with chronic diseases.

We are writing to ask the Centers for Medicare and Medicaid Services (CMS) to develop a HCPCS code for PDTs to reduce barriers and improve access to these innovative treatments.

I. Background

PDTs are a new treatment that operate at the intersection of biology and technology. PDTs are Food and Drug Administration (FDA) cleared, evidence-based medical devices that deliver treatment through software that is accessible via smartphones and tablets. PDTs require a prescription from a healthcare provider before they can be used.

Used individually, or in combination with medications, PDTs can provide around-the-clock treatment and support to patients when and where they need it, leading to increased adherence and improved outcomes. This is especially important for individuals with mental health and substance use disorders, who already face significant access barriers to treatment in part due to the nationwide shortage of treatment providers and facilities - particularly in states with large rural populations and in urban health care deserts.¹ However, despite their advantages, PDTs are not widely utilized due to a variety of barriers including a lack of standardized Healthcare Common Procedure Coding System (HCPCS) codes.

¹ Digital Therapeutics Alliance, *Digital Therapeutics Reducing Rural Health Inequalities*, https://dtxalliance.org/wp-content/uploads/2021/01/DTA_Rural-Health_r13_110220.pdf; Alliance for Patient Access, *Prescription Digital Therapeutics Emerge As Health Care's Newest Frontier*, <https://instituteforpatientaccess.org/prescription-digital-therapeutics-emerge-as-health-cares-newest-frontier/>



II. PDTs Need a Unique HCPCS Level 2 Code to Ensure Adequate Access

CMS is currently considering whether PDTs should be given a HCPCS Level 1 or Level 2 code. Aimed Alliance strongly encourages CMS to provide PDTs with a HCPCS Level 2 code to ensure adequate patient access and reduce administrative coding barriers that impair or delay treatment coverage.

CMS has stated that Level 1 codes are appropriate for PDTs because they are “used in conjunction with face-to-face treatment delivered by the clinicians.”² Generally, HCPCS Level 1 codes, also referred to as Current Procedural Terminology (CPT) codes, are usually given to procedures and services *performed by* healthcare providers.³ While HCPCS Level 2 codes are given to medical devices, supplies, medications, transportation services, and other items not covered under CPT codes.⁴

HCPCS Level 2 codes are used for equipment that is used outside of the physician’s office.⁵ With regard to PDTs, the doctor prescribes the PDT, the prescription is sent to a specialty pharmacy that dispenses the PDT content to the patient, and the patient then uses the PDT content at a time and place of their convenience. PDTs are not procedures that are performed by the healthcare provider. They are medical devices that are used outside the physician’s office by a patient on their smartphone or tablet.⁶ As such, they should be given appropriate HCPCS Level 2 codes.

III. The CPT Codes Proposed by AMA do not Apply to PDTs that are Solely Software Applications

As you may know, this year, the American Medical Association – the entity in charge of creating and maintaining CPT codes – proposed in its Level 1 CPT codes to include “remote therapeutic monitoring,” for Cognitive Behavioral Therapy Monitoring.⁷ However, from our understanding, these codes are only applicable when a provider pays for the FDA-regulated medical device, dispenses it to the patient, and then bills the insurer for the device (i.e. buy and bill). This is different from PDT’s which are solely a software application; the provider never pays for or takes custody of the device and the provider never physically dispenses the device. The provider issues a prescription and the technology is dispensed by the specialty pharmacy

² CMS Agenda December 2021, <https://www.cms.gov/files/document/hcpcs-public-meeting-agenda-non-drug-and-non-biological-items-and-services-december-2-2021-updated.pdf>.

³ AAPC, *What is HCPCS*, <https://www.aapc.com/resources/medical-coding/hcpcs.aspx>.

⁴ CMS, *HCPCS – General Information*, <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo>.

⁵ CMS, *HCPCS – General Information*, <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo>.

⁶ Camargo, *Prescription Digital Therapeutics: When Software Is the Active Ingredient*, <https://camargopharma.com/resources/blog/prescription-digital-therapeutics-when-software-is-the-active-ingredient/>.

⁷ American Medical Association, *CPT Editorial Summary of Panel Actions September-October 2021*, <https://www.ama-assn.org/system/files/september-october-2021-summary-of-panel-actions.pdf>.



who then bills for the device. As such, the proposed CPT codes for cognitive behavioral therapy do not apply to PDTs that are solely software-based technology.

Aimed Alliance encourages CMS to implement appropriate HCPCS Level 2 codes for PDTs to improve access to these innovative technologies. Thank you for considering our comments on this issue.

Sincerely,

Ashira Vantrees
Policy Manager