

Prescription Digital Therapeutics (PDTs) Need A HCPCS Code

To ensure patients have access to prescription digital therapeutics (PDTs), health plans must provide comprehensive coverage of PDTs. A foundational administrative requirement for plans to begin providing coverage of PDTs is the creation of a standard insurance code for PDTs. Creating a standard code for PDTs can help remove roadblocks for PDT coverage and help provide a pathway for patient access to these innovative treatments.

What Are Prescription Digital Therapeutics?

PDTs are a new category of therapeutics at the intersection of biology and technology. Cleared by the Food and Drug Administration (FDA) as medical devices, they are evidence-based medical interventions that use software accessed via an electronic device, such as a tablet or smartphone, to prevent, manage, or treat a range of diseases and disorders. As FDA cleared medical devices, PDTs are developed using strict quality standards, tested for safety and efficacy, and labeled according to FDA requirements. Like traditional therapeutics, PDTs are only available to patients when prescribed by a licensed healthcare provider and must be used under clinician supervision. Currently, PDTs are FDA-cleared or in clinical trials for a wide range of diseases including Type 2 diabetes, chronic stroke, multiple sclerosis, Parkinson's disease, autism, chronic insomnia, ADHD, and many mental health conditions.

What Benefits Do PDTs Provide to Patients and Providers?

Used individually or in combination with other treatment interventions, PDTs can provide around-the-clock treatment and support to patients when and where they need it, leading to increased treatment adherence and improved outcomes. This is especially important for individuals with mental health and substance use disorders, who already face significant 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.

In addition, PDTs allow patients to receive treatment during hours in which providers are typically unavailable. For example, studies have shown that patients often use apps between 7 PM and 7 AM, when provider offices are typically closed. PDTs can also aid providers in treating patients. With patient consent, some PDT software can collect and report real-time data on patient adherence to treatments and medications. This can be particularly beneficial for providers treating patients with substance use disorders who need to establish new habits and patterns.

Why Can't Patients Currently Access PDTs?

Despite their advantages, PDTs are not widely utilized due to a variety of barriers, including lack of payer coverage. While PDTs are eligible to be priced and reimbursed similarly to traditional therapeutics via federal, state, and commercial insurers, many payers currently do not cover PDTs. A major contributing factor to this barrier is the current lack of reimbursement codes for PDTs.

What Are CPT and HCPCS Codes?

The Healthcare Common Procedure Coding System (HCPCS) is the standardized coding system used by medical providers to submit claims to Medicare and other health plans. There are HCPCS Level 1 codes, also referred to as Current Procedural Terminology (CPT) codes; and HCPCS Level 2 codes. Generally, HCPCS Level 1 codes are given to procedures and services performed by healthcare providers. Meanwhile, HCPCS Level 2 codes are given to medical devices, supplies, medications, transportation services, and other items that are used outside the clinician's office and not covered under CPT codes.

This year, the American Medical Association – the entity in charge of creating and maintaining CPT codes – proposed that Level 1 CPT codes include “remote therapeutic monitoring,” for Cognitive Behavioral Therapy Monitoring. However, these new CPT codes are only applicable when a provider pays for the FDA-cleared medical device, dispenses it to the patient in the office, and then bills the insurer for the device (i.e., buy and bill).

PDTs Require a HCPCS Level 2 Code

PDTs that are solely software applications require a HCPCS Level 2 code because these PDTs are not dispensed in the provider's office. In the case of 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 practitioner's office by a patient on their smartphone or tablet. As such, they should be given an appropriate HCPCS Level 2 code.

Current CPT Codes Are Not Appropriate for Software-Only PDTs

The established CPT codes for cognitive behavioral therapy only apply to medical devices that can be physically provided to patients in a physician's office. For example, a medical device that may qualify for this CPT code would be an asthma inhaler that has software installed to monitor the patient's use of the inhaler. In this hypothetical, the provider would prescribe the patient the inhaler; dispense the inhaler to the patient in the provider's office; and later analyze the data provided by the software within the inhaler. This type of monitoring would be CPT code eligible because the initial delivery of the medical device, the asthma inhaler, occurred within the providers' office.

Meanwhile, unlike the above example, PDTs that are software-only medical devices would not qualify to use these codes because with PDTs, the provider never pays for or takes custody of the device, nor does the provider ever physically dispense the device. Instead, for software-only PDTs, the provider issues a prescription, and the technology is dispensed by the specialty pharmacy, which 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. Therefore, PDTs are still in need of a HCPCS Level 2 code.

The Centers for Medicare and Medicaid Services (CMS) Must Create a HCPCS Level 2 Code for PDTs

As patients and providers begin utilizing these innovative treatments to address chronic disease, we must ensure our administrative coding system moves with them. Continuing to use a dated categorization system will impede the ability for patients to access PDTs as covered benefits. By creating a HCPCS Level 2 code for PDTs, CMS can reduce administrative coding barriers that impair or delay treatment coverage and improve patient access to these treatments .

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