Centers for Medicare & Medicaid Services Issues First HCPCS Code and Medicare DME Benefit Category Determination for Therapeutic Virtual Reality Device

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In this article, the authors explain why a recent determination by the Centers for Medicare & Medicaid Services amounts to a significant first step in pursuing Medicare coverage and reimbursement for virtual reality therapies.

In a recent trailblazing coding and benefit category determination,[1] the Centers for Medicare & Medicaid Services (CMS) has established a unique Healthcare Common Procedure Coding System (HCPCS) Level II code for a virtual reality (VR) device and associated software, RelieVRx.

CMS also issued a final benefit category determination for RelieVRx under the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) benefit category. This is the first VR therapeutic device to receive a HCPCS code and DMEPOS benefit category determination.

The Device

On March 3, 2021, AppliedVR Inc. was granted Food and Drug Administration (FDA) breakthrough status for the first FDA-authorized immersive VR medical device for home use indicated for the treatment of chronic low back pain, RelieVRx. This Class II medical device, available only pursuant to a prescription, consists of a modified proprietary headset (not available for retail sale) as

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well as a patented breathing amplifier that allows integration of bio-enabled immersive experiences, and preloaded software.

As CMS explains, the device delivers a clinically based multimodal pain self-management program that incorporates evidence-based principles of cognitive behavioral therapy (CBT) and other neuroscience-based behavioral health methods to reduce pain intensity and pain interference with daily activities, sleep, mood, and stress for patients diagnosed with moderate to severe chronic low back pain. RelieVRx therapy is administered daily as a three- to 16-minute module over the course of 56 days. It is intended to be used during an eight-week treatment program in the patient's home and involves a sequential set of immersive experiences with a mix of different components used in CBT, including pain education, diaphragmatic breathing practices, pain distraction, interceptive awareness, and mindfulness escapes. The device is locked such that it can only be used for treatment of the specified clinical indication.

Citing the applicant's assertions, CMS noted that the clinical trial evidence demonstrates that the durable VR hardware is required to deliver significantly greater reductions in pain intensity and pain interference compared to software-only or application-only methods; RelieVRx is self-administered, utilized unsupervised in the patient's home while the patient is in a seated position. The therapy is not delivered as part of a clinician service; the device is returned upon completion of the 56-day course of treatment and is available for reuse; it has an expected useful life of three years or greater, is suitable for repeated use, and does not include non-medical software or allow non-medical use.

Coding and Medicare Benefit Category Determination

Whether or not an item or service falls under an established Medicare benefit category, such as the Medicare Part B benefit category for durable medical equipment (DME), is an essential step in determining whether the item or service may be covered under the Medicare program and, if applicable, what statutory and regulatory payment rules apply to the item or service. If an item or service is excluded from coverage by the Social Security Act or does not fall within the scope of a defined Medicare benefit category, it cannot be covered under Medicare Part B. When the item is not excluded

from coverage by statute and is found to fall within a Medicare benefit category, CMS must determine what payment rules apply to the item or service.

HCPCS Level II codes are a standardized coding system used primarily to identify products, supplies, and services when used outside of a physician's office. HCPCS Level II codes may or may not have associated payments assigned to them and often, they have specific coverage guidelines that can vary by Medicare Administrative Contractors (MACs).

Effective April 1, 2023, CMS established a new HCPCS Level II code E1905, "Virtual reality cognitive behavior therapy device (cbt), including pre-programmed therapy software," to describe RelieVRx.

In determining that RelieVRx is considered DME, CMS considered the medical software and device on which it is housed to be so integral to each other that they are one whole device, not software and a separate device. CMS made this determination based on the following factors:

- The software is locked to the device;
- The software cannot be used on any personal devices and no other non-medical software can be added to the device;
- The software relies on the VR/immersive features of the device to deliver the benefit to the patient;
- The device has features that drive the effectiveness of the software;
- The breathing apparatus on the headset impacts the algorithms played by the software;
- There are no personal devices, like computers or laptops, that can achieve the same affect with this same software or interact with both the patient and the software algorithms the way RelieVRx does; and
- The FDA identified a special control (88 FR 983, January 6, 2023) that the patient-contracting components of the device must be demonstrated to be biocompatible, indicating that the hardware and software are necessary components of the product.

Because it determined that RelieVRx is a device and meets the requirements to be considered DME as set forth in 42 C.F.R.

§ 414.202, CMS issued a final benefit category determination of DME for RelieVRx.

No Coverage or Payment Determination

CMS stopped short of mandating coverage or specific payment for RelieVRx, instead deferring to the MACs to determine coverage and payment on a claim-by-claim basis. However, CMS indicated that it was interested in better understanding how a VR device would create a better outcome for patients that would not have the same effect were the software to instead be used on a non-VR device such as a computer, tablet, or phone. CMS noted that it would continue to consider RelieVRx's clinical distinction relative to other products. It referenced 42 C.F.R. § 414.238 for establishing fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history.

CMS explains that it establishes fee schedule amounts for new HCPCS codes for items and services by using existing fee schedule amounts for comparable items and services based on a comparison of physical components, mechanical components, electrical components, function and intended use, and additional attributes and features. If there are no items with existing fee schedule amounts that are comparable to the items and services under the new code, CMS may establish the fee schedule using supplier or commercial price lists. When a purchase price is greater than $150, payment would be made on a capped rental basis per 42 C.F.R. § 414.229; if the purchase price is $150 or less, then payment is made on a rental or purchase basis per 42 C.F.R. § 414.220. CMS urged AppliedVR Inc. to provide it with pricing information such as retail pricing and invoices from commercial payers, the Veteran's Administration, and state Medicaid agencies for consideration at a subsequent HCPCS public meeting.

What This Means

As digital health care solutions have continued to grow, advance, and expand, so too has the use of VR in patient care; VR digital therapeutics already treat various conditions ranging from behavioral health to physical therapy to visual impairment, and ongoing

clinical trials continue to explore the efficacy of VR in a range of areas.

This is an exciting first step in pursuing Medicare coverage and reimbursement for VR therapies. While no coverage or pricing has been mandated by CMS under this determination, it evidences that CMS is interested in considering how technological advancements in medicine and digital health could be used to generate better outcomes for patients and potentially lower the cost of care. The willingness of CMS to grant DME benefit classification to RelieVRx and to consider the device and software to be a single device may indicate that CMS is open to expanding coverage for other digital devices under existing benefit categories. The pathway for payor coverage and reimbursement for these devices is separate and apart from the assignment of an HCPCS code and benefit category determination, but this is a huge step forward in an ever-evolving, rapidly growing, and expanding arena of digital health.

Notes

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1. https://www.cms.gov/files/document/2022-hcpcs-application-summary-biannual-2-2022-non-drug-and-non-biological-items-and-services.pdf.