# Medical Coverage Policy

**Effective Date.....12/15/2025**
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**Coverage Policy Number..... 0565**

# Prescription Digital Therapeutics

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## Related Coverage Resources

Remote Patient Monitoring
Category III Current Procedural Terminology (CPT®) codes
Preventive Care Services

***INSTRUCTIONS FOR USE***

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*will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.*

## Overview

This Coverage Policy addresses prescription digital therapeutics (PDTs) in the adult and pediatric populations. PDTs utilize software-based interventions designed to prevent, manage, or treat various medical conditions. These interventions are delivered through mobile apps, wearable devices, or other digital platforms. Digital therapeutics (DTx) use digital technology to provide personalized, evidence-based therapies that complement conventional approaches to treatment and are used independently or in conjunction with medications, devices, or other therapies.

For the purposes of this CP, a PDT requires a prescription by a healthcare provider, is approved by the Food and Drug Administration (FDA), and the safety and effectiveness is supported by published peer-reviewed clinical evidence for treating, managing, and/or preventing a disease or disorder. Software-based programs utilized for general health promotion, wellness, or fitness or solely to inform, monitor, or diagnose are not considered to be a PDT because they do not treat diseases. DTXs that can be obtained without a prescription are not addressed in this policy and may be subject to benefit determination.

Components of a prescription digital therapeutic may include devices, accessories, software, smart phone apps and other components necessary to provide the prescription digital therapy.

## Coverage Policy

**Coverage for prescription digital therapy varies across plans. Please refer to the customer's benefit plan document for coverage details.**

**When a customer's benefit plan includes coverage for a prescription digital therapeutic (PDT), the PDT* is considered medically necessary only when ALL of the following criteria are met:**

- requires a prescription by a licensed healthcare practitioner
- has been approved by the Food and Drug Administration (FDA) and used in accordance with the FDA indications
- required to treat an illness, injury, disease or its symptoms
- demonstrated, through existing peer-reviewed, evidence-based, scientific literature to be safe and effective for treating the condition or sickness for which its use is proposed
- not primarily for the convenience of the patient, physician or other health care provider

***Note: Remote therapeutic monitoring is considered an integral part of prescription digital therapeutics and is not separately reimbursable.**

**When the criteria above are not met, a PDT is considered experimental, investigational and unproven.**

**ALL of the following are considered experimental, investigational and unproven:**

| | |
|---|---|
| **E0738** | **IpsiHand™ (Neurolutions, Santa Cruz, CA)** |

| | |
|---|---|
| **E0739** | **Motus Hand and Motus Foot (MotoNova, Atlanta, GA)** |
| **E1905** | **RelieVRx (AppliedVR, Van Nuys, CA)** |

## Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation, and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

Digital therapy has been proposed as a treatment option for those residing in rural areas without access to healthcare (Digital Therapeutics Alliance, 2020). In a retrospective analysis of data from the National Vital Statistics System, Yaemsiri, et al. (2019) compared rural and urban progress towards national targets for the seven major causes of death (i.e., coronary heart disease (CHD), cancer, diabetes related, stroke, chronic obstructive pulmonary disease (COPD), unintentional injury, suicide) identified by Healthy People 2020. The term "urban" was defined as a county with an urban core of ≥ 50,000 people. The term "rural" was based on county of residence using the Office of Management and Budget's 2013 county-based classification system. 2007 and 2017 rural and urban collective death rates were categorized as having met or exceeded, improving, getting worse, or having little or no detectable change as compared to the Health People 2020 targets.

The authors found that age-adjusted death rates were higher in rural areas for all seven major causes of death tracked by Healthy People 2020 and that in rural areas national death rate targets were not met for any of the seven causes of death. In both areas, worsening performance was observed in the categories of unintentional injury and suicide mortality rates while rural areas also saw worsening performance in the categories of diabetes related and COPD death rates. Comparing national rural and urban death rates, the authors found a growing disparity between the two areas for COPD, suicide, diabetes related, CHD and cancer. COPD and suicide death rates were 45% higher in rural areas compared to urban.

The authors noted that reduced access to health services contributed to the numerous public health challenges facing rural America. In an effort to reduce access to care challenges, the Community Preventive Services Task Force (2017a; 2017b) recommends interactive digital and digital media interventions for those with high blood pressure and to supplement the care of individuals with chronic diseases affected by diet (e.g., cardiovascular disease, diabetes) respectively as part of the Healthy People 2030 initiative.

## General Background

Digital health is a nonspecific term that includes different types of technology including digital medicine. Digital medicine includes digital therapeutics (DTx). Products in these categories make different levels of claims, have different levels of risk and require various levels of clinical evidence and regulatory oversight.

Platforms that engage consumers for lifestyle, wellness, and health-related purposes; that capture, store, or transmit data; and/or support life science and clinical operations are classified

as digital health. Regulatory oversight and clinical evidence are not required. Examples of digital health products include but are not limited to:

- fitness trackers
- nutrition applications
- electronic medical record systems
- telemedicine virtual visits

The category of digital medicine includes products that measure and/or intervene in the delivery of human health and require clinical evidence. Regulatory oversight requirements vary depending on whether or not the product is classified as a medical device or if the product is being used as a tool to develop other drugs, devices, or medical products. Examples of digital medicine products include but are not limited to:

- Software-driven technologies that detect, confirm, or identify subtypes of a disease or condition
- Remote patient monitoring (e.g., monitoring tools, medication adherence tools, sensor technologies)
- Injestible sensors
- Insulin pump
- Artificial pancreas
- Pacemaker

(Healthxl, 2019)

FDA-approved prescription digital therapeutics (PDTs) have been proposed for numerous indications as discussed below but have been found to be primarily for the convenience of the patient, physician, or other health care provider; are not required to treat an illness, injury, disease, or its symptoms; or have not been compared to standard treatment options and are therefore, considered not medically necessary for any indication.

DTx utilize software-based interventions designed to prevent, manage, or treat various medical conditions. These interventions are delivered through mobile apps, wearable devices, or other digital platforms. DTx use digital technology to provide personalized, evidence-based therapies that complement conventional approaches to treatment and are used independently or in conjunction with medications, devices, or other therapies. They differ from wellness apps in that wellness apps typically focus on general well-being, lifestyle improvement, or promoting healthy habits; do not address specific medical conditions; don't require medical supervision; are not based on evidence-based medicine; do not require regulatory oversight (i.e., FDA approval or clearance); and are not integrated with healthcare providers and/or systems (Digital Therapeutics Alliance, 2022a).

Reported potential benefits of DTx include accessibility, increased engagement, convenience, personalization, and cost-effectiveness. Widespread use of smartphones and internet connectivity means that DTx has the potential to reach individuals in remote areas with limited access to healthcare facilities. DTx can collect and analyze data such as patient-reported outcomes, physiological measurements, and behavioral patterns allowing treatment to be personalized and tailored to the individual's specific needs. It is also reported that DTx can be more cost effective than traditional therapies by reducing the need for physical infrastructure and face-to-face interactions with healthcare providers, making DTx a viable option for individuals who may not be able to afford conventional treatments.

Considerations related to the use of DTx include concerns over the protection of privacy and security, regulatory challenges related to the rapid expansion and evolution of DTx applications, ensuring user adherence and training, and access to the internet (Digital Therapeutics Alliance, 2023a). Identifying those patients who can benefit from DTx includes considering whether or not the individual has access to the components required for the software to deliver its proposed value (e.g., smartphone, hardware, medication, internet connection) and literacy considerations (e.g., language, health, digital health, technology) to ensure product usability (Digital Therapeutics Alliance, 2022a).

DTx are available with or without a prescription. DTx that treat a serious disease, use higher-risk devices, are used for conditions that require a secure diagnosis by a trained professional, and/or require monitoring and follow-up may require a prescription as governed by state-level health authorities. These are referred to as prescription digital therapeutics (PDTs) (Watson, et al., 2023).

PDTs are proposed for numerous conditions including but not limited to physical rehabilitation such as after stroke and treatment of chronic low back pain. Other conditions proposed for which use of DTx has been proposed include diabetes, attention deficit hyperactivity disorder, PTSD, panic disorder, chronic pain, incontinence, migraine, substance use disorder, opioid use disorder, and insomnia.

The interventions utilized to treat, manage, or prevent a disease or disorder vary. For example, PDTs may include cognitive-behavioral therapy, mindfulness exercises, or the use of sensors to measure and display exhaled carbon dioxide level and respiration rates. Other PDTs may utilize robotics and brain-computer interface through electroencephalogram.

Comparators to individual PDTs vary depending on the disease or condition being treated and can include pharmaceuticals, medical devices (e.g., physical therapy devices, diagnostic tools), and/or behavioral or lifestyle interventions (e.g., dietary changes, stress management interventions). In a more broad sense, alternatives to PDTs may include clinician-delivered care, activity and fitness trackers, online consumer health information sources, non-medical grade clinical decision support tools, engagement tools (e.g., social media, online communities), wellness and fitness applications, or remote monitoring tools (Digital Therapeutics Alliance, 2022b).

**U.S. Food and Drug Administration (FDA):** PDTs are defined by the FDA as "Software as a Medical Device" (SaMD) and as such, are regulated by the FDA, categorized as Class II devices, and authorized via either the de novo or 510(k) clearance pathway (Watson, et al., 2023). SaMD is defined as "software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device" (Watson, et al., 2023).

**Professional Societies/Organizations:** The Digital Therapeutics Alliance (DTA) developed a flowchart (2022c) to assist individuals with determining which products are classified as DTx verses other types of digital health technology. The following list contains criteria derived from this flowchart that can be used to identify DTx:

- The product provides an intervention that is used in the context of healthcare.
- The intervention is used to treat, manage, or prevent a disease or disorder.
- The software is responsible for providing the intervention to the patient via a technology platform, medical device, or pharmaceutical.
- The product has been designed and manufactured using quality best practices.
- Product development engaged end users in product development and usability processes.
- The product incorporates patient privacy and security protection mechanisms.
- The product manufacturers have applied product deployment, management, and maintenance best practices.

- The product manufacturers have published trial results inclusive of clinically meaningful outcomes in a peer-reviewed journal.
- The product has been authorized by a regulatory body as required to support product claims of risk, efficacy, and intended use.
- The product manufacturer has made claims appropriate to clinical evaluation and regulatory status.
- The product manufacturer has collected, analyzed, and applied real-world evidence and/or product performance data to patient care.

**IpsiHand™ Upper Extremity Rehabilitation System (Neurolutions, Van Nuys, CA) (HCPCS Code E0738)**
Brain–computer interface (BCI), also known as brain-machine interface is an emerging technology that facilitates communication between brain and computer. BCI has been used in a wide variety of industries including entertainment and gaming, automation control, education, neuromarketing and neuroergonomics. It seeks to transform brain signals into human actions, independent of peripheral nerves or muscles. It is hypothesized to provide direct communication between the brain and an external device, such as a computer and robotic limbs (Maiseli,2023). BCI technology is being studied for a variety of conditions including motor rehabilitation after stroke, Parkinson's disease, and diagnosis of epilepsy, neurodegenerative disorders, motor disabilities and ADHD, among others.

The IpsiHand™ Upper Extremity Rehabilitation System is an FDA-cleared device brain-computer interface (BCI) device indicated for use in individuals with a history of chronic stroke (six months or more post-stroke) who are 18 years or older, undergoing stroke rehabilitation to facilitate muscle re-education and for maintaining or increasing range of motion in the upper extremities. The device utilizes the uninjured or ipsilateral side of the brain to improve arm and hand function. The system consists of a microprocessor, biometric electroencephalogram (EEG) headset for use of the unaffected hemisphere, a powered upper extremity range of motion assist device, and a microprocessor control unit containing therapy software (Neurolutions, 2025).

According to the manufacturer's website, IpsiHand™ is a non-surgical, non-invasive therapeutic device. It leverages contralesional-controlled BCI-therapy to effectively enable recovery for chronic hemiparesis.

The electroencephalogram (EEG) headset identifies cortical signals from hand regions in the primary cortex of the ipsilateral cerebral hemisphere, sending them to the computer processor to make the handpiece move in real time. The manufacturer reports that with regular use following exercise prompts on their tablet, IpsiHand™ users show the presence of biomarkers in the brain that demonstrates motor remodeling.

**US Food and Drug Administration (FDA)**
The FDA authorized marketing of the IpsiHand™ Upper Extremity Rehabilitation System in April, 2021, granting Breakthough Device designation. The FDA reviewed the device through the De Novo premarket review pathway, a regulatory pathway for low- to moderate-risk devices of a new type.

It is intended for use in patients 18 years and older undergoing stroke rehabilitation to facilitate muscle re-education and for maintaining or increasing range of motion. The FDA notes it assists in rehabilitation for stroke patients with upper extremity—or hand, wrist and arm—disability. The IpsiHand System device should not be used by patients with severe spasticity or rigid contractures in the wrist and/or fingers that would prevent the electronic hand brace from being properly fit or positioned for use or those with skull defects due to craniotomy or craniectomy.

**Literature Review**
There is insufficient published, peer-reviewed scientific literature demonstrating the effectiveness of the IpsiHand™ Upper Extremity Rehabilitation System to improve health outcomes.

Using a prospective trial design, Rustamov et al. (2022) investigated the effectiveness of contralesionally-controlled BCI therapy in chronic stroke patients with impaired upper extremity motor function. Investigators also explored neurophysiological features of motor recovery driven by BCI. Although 100 chronic stroke patients with upper-limb hemiparesis consented to participate in the study, only 30 patients completed BCI therapy for 12 weeks. Authors note that the high number of dropouts was attributed to the trial requirements and the influence of the coronavirus disease 2019 (COVID-19) pandemic. Thirty-one patients did not meet inclusion/exclusion criteria. Fifteen patients were unable to consistently generate identifiable BCI control signals across 2 EEG screenings. According to the authors, the trial was heavily impacted by COVID-19 and twenty-four patients withdrew from the study.

Inclusion criteria were stroke at least 6 months prior to the study with unilateral upper extremity weakness. Exclusion criteria were severe visual, cognitive, or psychiatric impairment; severe aphasia, ataxia, unilateral neglect; impaired tactile; or proprioceptive sensation in the affected upper extremity. Baseline motor function was assessed by physical and occupational therapists before starting the therapy and participants were trained on the use of the BCI system. Participants were instructed to use the device for 1 hour/day, 5 days/week, over the course of 12 weeks. EEG data were acquired using 6 wireless dry electrodes mounted on an EEG headset. Usage was entered by the participant on a tracking sheet. The usage of BCI varied, with an average of 41.6 hours. There were no adverse events.
Median move and rest success rates were 71.8% and 39.8%, respectively. A definition of a successful trial was reaching the BCI activation threshold for at least 1 second for move trials or staying under the activation threshold for the entire trial duration for rest trials.

The upper extremity Fugl-Meyer (UEFM) served as a primary motor outcome assessment tool. The mean increase in UEFM score was 8.1points which exceeded the minimal clinically significant difference (MCID) threshold of 5.25 points increase (P<.001). Eighteen of 26 participants reached the MCID. None of the patients exhibited a decline in motor function. The researchers noted several limitations, including the lack of a control group for comparison with BCI therapy, and a small sample size with high dropout. Lack of assessor blinding is also noted as a study limitation. Despite

Humphries et al. (2022) published a prospective study of eight individuals with upper limb hemiparesis at least six months post stroke. The objective of the study was to evaluate whether an EEG-driven BCI controlled by motor signals from the unaffected hemisphere reorganized brain networks for motor control. Researchers hypothesized that motor recovery achieved during BCI therapy would change motor network connectivity, and that these resting-state functional connectivity (rsFC) changes in motor systems would correlate with the strength of recovery.

After screening sessions over 1–2 weeks, pre-therapy motor assessments and resting-state fMRI , participants trained to use the BCI device and performed 12 weeks of at-home BCI therapy. The sessions were 1 hour per day, five days per week, totaling 60 hours. Usage varied among participants. Clinicians assessed motor function once per month. After 12 weeks of BCI therapy, participants received a post-therapy motor assessment and second resting-state fMRI scan. Patients in the comparison group received intensive physical therapy in an eight week task-specific training program.

The upper extremity portion of the Fugl-Meyer Assessment functioned as the primary motor outcome, Secondary outcomes included grip strength, Motricity Index, Modified Ashworth Scale

(MAS), and Arm Motor Ability Test (AMAT). Assessments occurred at four-week intervals during therapy, and at six-months post-therapy completion. MRI scanning sessions occurred within two weeks of initiating and completing the 12-week therapy protocol.

All BCI patients showed an increase in UEFM score after 12 weeks of contralesional BCI therapy. Clinically meaningful recovery occurred in seven of the eight patients who reached a minimal clinically important difference (MCID) threshold of at least a 5.2 point score increase. Median increase in UEFM score was 7.25. Wilcoxon signed-rank tests also found significant improvement ($p < 0.05$) in grip strength, Motricity Index score, and AMAT scores. Median changes included increased grip strength (3.75 pounds, $p = 0.0234$), Motricity Index (2 points, $p = 0.0156$), and AMAT (5 points, $p = 0.0156$). The Modified Ashworth Scale, a measure of spasticity, showed median changes of 0 at the elbow and 0.125 at the wrist. Ipsilesional primary motor cortex in BCI patients was the only region of interest that showed a statistically significant change in suprathreshold voxels. No correlations were observed between the degree of motor recovery and the change in ipsilesional M1 connectivity extent. Data suggest that motor recovery correlated with reductions in motor FC strength; however, small study population and non-randomized design preclude the ability to determine improved health outcomes.

**Professional Societies/Organizations** No relevant information

**Motus Hand and the Motus Foot Mentor(Motus Nova, Atlanta, GA)(HCPCS E0739)**
The Motus Hand and Motus Foot Mentor is a FDA Class 1 at-home stroke rehab robot. According to the manufacturer's website, Motus technology uses gaming as a means for high-dose repetitive task practice to help stroke survivors improve activities of daily living by improving range of motion and strength and functional capacity of the arm. The system includes the Motus Hand and/or Motus Foot devices and a touch screen.

The manufacturer reports that inclusion criteria is any diagnosis that would benefit from repetitive task practice. The device can be used from days to decades post injury or diagnosis. The manufacturer notes that the device can be used by an individual with no active movement to those who are working on precision movements/fine motor skills in those with flaccid to high tone. The game complexity can be adjusted to fit various cognitive levels. Exclusion criteria is noted to be an individual who cannot follow basic commands and wrist or ankle fusion, or any condition where assisted range or motion is contraindicated.

**Literature Review**
There is insufficient evidence in the published, peer-reviewed scientific literature to demonstrate improved health outcomes with the use of the Motus Hand or Motus Foot Mentor. Although home use of robot-assist arm and foot training is feasible, evidence is of low quality and study outcomes are of a short-term duration. In some studies, improvement is noted for both home exercise programs and for home exercise program + robot assist device.

Mehrholz et al. (2018) performed a systematic review of 34 randomized controlled trials comparing electromechanical and robot-assisted arm training for recovery of arm function with other rehabilitation, placebo interventions or no treatment, for an individual after stroke.

Electromechanical and robot-assisted arm training improved activities of daily living scores ($P = 0.005$, $I^2 = 62\%$), arm function ($P < 0.0001$, $I^2 = 36\%$), and arm muscle strength ($P = 0.04$, $I^2 = 72\%$), but the quality of the evidence was low to very low. Electromechanical and robot-assisted arm training did not increase the risk of participant drop-out ($P = 0.84$, $I^2 = 0\%$) with moderate-quality evidence. Adverse events were rare.

The researchers note that data suggest that electromechanical and robot-assisted arm and hand training after stroke might improve activities of daily living, arm and hand function, and arm and hand muscle strength. However, due to low and very low quality evidence and variations in the trials related to intensity, duration, amount of training, type of treatment and participant characteristics, the results must be interpreted with caution.

Kutner et al. (2010) published results of an RCT involving 17 individuals, who were three to nine months post stroke, The study examined the change in patient-reported, health-related quality of life associated with robotic-assisted therapy combined with reduced therapist-supervised training. Sixty hours of therapist-supervised repetitive task practice (RTP) was compared with a combined therapy group (30 hours of RTP combined with 30 hours of robotic-assisted therapy). Participants completed the Stroke Impact Scale (SIS) at baseline, immediately post-intervention, and two months post-intervention. Both groups had statistically significant improvement in activities of daily living scores, instrumental activities of daily living scores, and hand function from pre-intervention to post-intervention. The combined therapy group had a greater increase in rating of mood from pre-intervention to post-intervention, and the RTP-only group had a greater increase in rating of social participation from preintervention to follow-up. The combined therapy group had significant improvements in stroke recovery rating post-intervention and at follow-up.

The authors concluded that robotic-assisted therapy may be an effective alternative or adjunct to therapist supervised task practice to enhance function recovery in individuals with a history of stroke. Study limitations include different amounts of RTP in the combined therapy group The authors cited a limitation of the study was that the two groups received different numbers of RTP and the low number of study participants.

Wolf et al. (2015) conducted a multisite, single-blinded RCT to examine the efficacy of home-based telemonitored robotic-assisted therapy (Hand Mentor Pro) as part of a home exercise program (HEP) compared with a dose-matched HEP-only intervention among individuals less than six months post-stroke and characterized as underserved. The study included 99 hemiparetic participants with limited access to upper extremity rehabilitation. The participants were randomized to an experimental group which received combined HEP and HMP or a control group which received HEP only at an identical dosage.

The interventions were controlled for frequency (3 hours, 5 times per week) and duration (8–12 weeks); participants were asked to complete 120 hours in an 8-week period. Both groups represented a similar ratio of functional activities with the main difference being that the control group participants completed approximately two hours of traditional impairment-based exercises and 1 hour of functional activities while the experimental group participants completed two hours of robotic-based exercises and one hour of functional-based activities.

The Action Research Arm Test and Wolf Motor Function Test along with the Fugl Meyer Assessment (upper extremity) were primary and secondary outcome measures respectively, undertaken before and after the interventions. Both groups demonstrated improvement across all upper extremity outcomes including the Action Research Arm Test, Wolf Motor Function Test, and the Fugl Meyer Assessment (upper extremity). There was no change between groups in motor function over time.

The authors noted multiple limitations to the study. The participants were less than six months post-stroke, and thus, spontaneous recovery may have contributed to functional motor improvement. The authors concluded that although the telerehabiliation component may be valuable in individuals post-stroke with limited resources. Additional research is needed to determine the appropriate dosage of HEP and HMP and a more detailed selection of users will be required before this approach could become better than a home based exercise program.

**Professional Societies/Organizations**
**The Veterans Health Administration and the Department of Defense's** clinical practice guideline for the management of stroke rehabilitation (2010) stated that "[t]here is no sufficient evidence supporting use of robotic devices during gait training in patients post stroke" (regarding gait training strategies for lower extremities).

**RelieVRx (AppliedVR, Inc, Van Nuys, CA) (HCPCS Code E1905)**
RelieVRx is proposed as an adjunctive virtual reality treatment for chronic lower back pain aimed at long-term behavioral pain management skills acquisition. After a provider prescribes the device, a virtual reality headset is delivered to the individual's home. The device is self-administered in the individual's home over the course of eight weeks with average daily sessions of seven minutes duration. Pain treatment is targeted through mindful escapes, pain education, diaphragmatic breathing, and relaxation.

**U.S. Food and Drug Administration (FDA):** RelieVRx (formerly EaseVRx) (AppliedVR, Inc., Van Nuys, CA) received FDA approval on November 16, 2021 via the DeNovo pathway. The device is indicated as a prescription-use immersive virtual reality system intended to provide adjunctive treatment based on cognitive behavioral therapy skills and other evidence-based behavioral methods for patients (age 18 and older) with a diagnosis of chronic lower back-pain (defined as moderate to severe pain lasting longer than three months). The device is intended for in-home use for the reduction of pain and pain interference associated with chronic lower back pain.

**Literature Review**
There is insufficient evidence to demonstrate the effectiveness of a self-administered virtual reality program for the treatment of chronic back pain. Improvements in PROMIS Physical Functio and PROMIS sleep score were noted in both groups. Limitations include short-term outcomes of up to 56 days.

Garcia et al. (2021) conducted a double-blind randomized controlled trial (RCT) to evaluate the safety and efficacy of a self-administered, virtual reality (VR) program for the treatment of chronic low back pain (CLBP). Participants were recruited nationally through chronic pain organizations and online Facebook advertisements. There were 179/188 adults included in the study analysis with 76.5% being female, 90.5% Caucasian, and a mean age of 51.5 years. Individuals were eligible for inclusion in the study if they: were aged 18–85, self-reported a diagnosis of CLBP without radicular symptoms of ≥ six months duration, had an average pain intensity of 4/10 for the past month, and possessed access to Wi-Fi. Individuals were not eligible for inclusion in the study if they: had a gross motor impairment, had a current or prior diagnosis of a condition that would prevent the use of VR or result in adverse effects (e.g., epilepsy, migraines, dementia), were hypersensitive to flashing light or motion, had no stereoscopic vision or a severe hearing impairment, had an injury to the head that would impede use of the VR headset, had cancer-related pain, or had a Patient Health Questionnaire-2 depression score of ≥ 2.

The active arm of the trial consisted of engagement in a once daily immersive pain relief skills program (EaseVRx) delivered with a VR headset for 56 days. Each daily session ranged in length from two to sixteen minutes with an average of six minutes. The comparator was a once daily non-interactive sham VR that displayed 2D nature content once daily for 56 days. The length of each session mimicked the active arm. The primary outcomes evaluated were the difference between groups for average pain intensity (Defense and Veterans Pain Rating Scale (DVPRS)) and pain-related interference with activity, stress, mood, and sleep (DVPRS-II). Secondary outcomes evaluated included: the global impression of change (Patient's Global Impression of Change (PGIC)), change in physical function and sleep disturbance (NIH Physical Function and Sleep Disturbance (PROMIS)), pain self-efficacy (2-item Pain Self-Efficacy Questionnaire (PSEQ-2)), pain

catastrophizing (13-item Pain Catastrophizing Scale (PCS)), chronic pain acceptance (8-item Chronic Pain Acceptance Questionnaire (CPAQ-8)), pain medication use (yes/no question), and user satisfaction (6-point scale). Follow-up occurred via remote survey completion, twice weekly for eight weeks along with a final survey at the end of the eight-week treatment period.

Authors reported significant improvements in pain intensity (P=0.001), pain interference with activity (p=0.004), pain interference with mood (p<0.005), pain interference with sleep (p=0.004), and pain interference with stress (p=0.009) in the active group compared to the sham group. Average pain intensity decreased significantly in the active group by 42.8% and 25.1% in the sham group. Average pain interference with activity decreased by 51.6% in the active group and 32.4% in the sham group. Pain interference with mood was reduced by an average of 55.7% in the active group and 40.04% in the sham group. Pain interference with sleep reduced by an average of 54% in the active group and 39.2% in the sham group. Pain interference with stress reduced in the active group by an average of 59.9% and 39.3% in the sham group. A significant improvement in the PGIC score was observed in the active group compared to the sham group (4.13 vs 3.11, respectively; p=0.002). Between-group statistical significance was not reached in changes in pain catastrophizing, pain self-efficacy, and pain acceptance from baseline to post-treatment.

Compared to baseline, both groups improved significantly in the PROMIS Physical Function score; however, the active group improvement was significantly superior to the sham group (p=0.002). While both groups experienced significant reductions on the PROMIS sleep disturbance score, a significant decrease in the score was noted in the active group compared to the sham group (p=0.035). Neither group observed a significant change in prescription opioid dose from baseline to post-treatment. Sixty-one participants in the active group reported using over the counter (OTC) analgesic medication at baseline compared to 50 participants at post-treatment follow-up (p=0.01). The sham group observed an increase in OTC analgesic medication use from baseline to post-treatment (55 vs 56, respectively). Significantly higher ratings were reported in the active group compared to sham for treatment satisfaction, likelihood to recommend, and likelihood to continue use (p<0.001). Nausea and motion sickness were reported by 7 participants in the active group and 5 from the sham group. The author note that additional research is needed to determine durability of treatment effects and to characterize mechanisms of treatment effects.

Garcia et al. (2022) reported on 3-month post-treatment follow-up data for their 2021 double-blind RCT evaluating the safety and efficacy of a self-administered, VR program for the treatment of CLBP. Follow-up occurred at one-, two-, and three-months post-treatment.

Authors concluded that the improvements observed immediately post-treatment in the active group were sustained at three months for pain intensity, pain-related interference, and physical function and were superior to sham.

Limitations of the study included the self-reported nature of data metrics and an inability to generalize findings to the disparate demographic population or other chronic pain conditions. Additional limitations of the study include participant attrition, short-term follow-up, small patient population, a failure to compare the intervention to established treatment options, and the use of inconsistent data analysis methods between various time points. Additional, high-quality studies are needed to establish the role of a self-administered, VR program for the treatment of CLBP.

## Medicare Coverage Determinations

| | Contractor | Determination Name/Number | Revision Effective Date |
|---|---|---|---|
| NCD | National | N/A | |
| LCD | Local | N/A | |

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

## Coding Information

**Notes:**

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare & Medicaid Services (CMS) code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

**Considered Experimental, Investigational, Unproven:**

| HCPCS Codes | Description |
|---|---|
| E0738 | Upper extremity rehabilitation system providing active assistance to facilitate muscle re-education, includes microprocessor, all components and accessories |
| E0739 | Rehabilitation system with interactive interface providing active assistance in rehabilitation therapy, includes all components and accessories, motors, microprocessors, sensors |
| E1905 | Virtual reality cognitive behavioral therapy device (CBT), including preprogrammed therapy software |



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## Revision Details

| Type of Revision | Summary of Changes | Date |
|---|---|---|
| Focused Review | No clinical policy statement changes | 12/15/2025 |
| New Coverage Policy | N/A | 9/15/2025 |