Immersive Virtual Reality Therapy for Chronic Lower Back Pain

Medicare Advantage Medical Policy # MA-238
Original Effective Date: 12/01/2026
Current Effective Date: 12/01/2026

Applies to all products administered or underwritten by the Health Plan, unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Blue Advantage does not cover investigational or experimental services, including any drug, device, procedure, or service provided under the investigational arm of a clinical trial or study unless mandated by the Centers for Medicare and Medicaid Services. Coverage is limited to routine services for Category A IDE studies and to devices and related services for Category B IDE studies when not supplied by the trial sponsor. Approved IDE studies are posted on www.cms.gov/medicare/coverage/evidence.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Health Plan considers the use of U.S. Food and Drug Administration-authorized prescription virtual reality digital therapeutics for chronic lower back pain (e.g., RelieVRx) to be **investigational.***

Background/Overview

Scope of Review

This review addresses a specific subset of U.S. Food and Drug Administration (FDA)-authorized prescription digital therapeutics (PDTs) that deliver their primary therapeutic effect through integrated hardware-software systems utilizing immersive visual stimulation. Covered products may have received De Novo classification or 510(k) clearance, depending on the availability of a legally marketed predicate device.

The scope of this review is restricted to prescription virtual reality therapeutics for management of chronic lower back pain that meet the following 3 criteria:

1. Must be a PDT: software that performs one or more medical purposes as the primary therapeutic component of a hardware-software system, excluding software used solely to store or transmit medical information.
2. Must have received marketing clearance or approval by the FDA and,
3. Must be prescribed by a healthcare provider.

Evaluation Framework for Digital Health Technologies

FDA-authorized PDTs are subject to the same evaluation standards as other devices:

1. The technology must have final approval from the appropriate governmental regulatory bodies.
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.

3. The technology must improve the net health outcome.[a]
4. The technology must be as beneficial as any established alternatives.
5. The improvement must be attainable outside the investigational settings.[b]

[a] The technology must assure protection of sensitive patient health information as per the requirements of The Health Insurance Portability and Accountability Act of 1996 (HIPAA).
[b] The technology must demonstrate usability in a real-world setting.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In November 2021, the U.S. Food and Drug Administration (FDA) granted De Novo marketing authorization (DEN210014) for EaseVRx (AppliedVR, Inc.), subsequently renamed RelieVRx, for adjunctive treatment of chronic lower back pain, as summarized in Table 1.

RelieVRx is currently the only FDA-authorized prescription virtual reality therapeutic indicated for chronic lower back pain management in the United States.

Table 1. Prescription Virtual Reality Therapeutics for Chronic Lower Back Pain

Application	Manufacturer	FDA Cleared Indication	Description	FDA Product Codes	Clearance	Date
Chronic Lower Back Pain						
RelieVRx	AppliedVR	RelieVRx (formerly EaseVRx) is indicated for adjunctive treatment of chronic lower back pain in patients 18 years of age and older. The device is intended for home use, to be used under the direction of a healthcare provider. RelieVRx is a	RelieVRx is a software-based virtual reality program delivered through a VR headset that provides an 8-week, self-administered, at-home behavioral skills-based treatment for chronic lower back pain. The program includes CBT,	QRA	DEN210014 (De Novo)	2021

		prescription-use immersive VR system that provides CBT and other evidence-based behavioral methods for pain management.	mindfulness, relaxation training, and interoceptive awareness techniques delivered through immersive VR experiences.			

VR: virtual reality; CBT: cognitive behavioral therapy

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Description

This medical policy addresses prescription digital therapeutics (PDTs) that deliver therapeutic benefit through immersive virtual reality (VR) hardware-software systems intended for management of chronic lower back pain. Unlike software-only PDTs, the products reviewed here require dedicated hardware, a VR headset, through which proprietary software delivers the primary therapeutic intervention. To be within scope, a product must: 1) be a PDT in which software performs one or more medical purposes as the primary therapeutic component of a hardware-software system, excluding software used solely to store or transmit medical information; 2) have received marketing clearance or approval by the U.S. Food and Drug Administration (FDA); and 3) be prescribed by a healthcare provider.

Summary of Evidence

For individuals with chronic lower back pain who receive RelieVRx, the evidence includes two industry-funded sham-controlled RCTs, a follow-up durability study, and one federally funded independent three-arm RCT. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. RelieVRx (formerly EaseVRx) received FDA De Novo authorization in November 2021. The pivotal trial (N=179) demonstrated statistically significant and clinically meaningful superiority of EaseVRx over sham VR for pain intensity and pain interference across most domains, with moderate between-group effect sizes (Cohen d=0.40-0.49); secondary outcomes including physical function and sleep disturbance also favored EaseVRx. The larger post-launch trial (N=1,067) confirmed statistical superiority for pain intensity and interference, with clinically meaningful within-group reductions for RelieVRx; however, between-group differences

were modest (0.41 and 0.52 points) and did not meet thresholds for clinical importance, partly attributable to therapeutic effects of the active sham comparator. Secondary outcomes also favored RelieVRx. A follow-up study of the pivotal trial cohort reported durable between-group superiority at 24 months post-treatment, though the durability cohort carried forward the demographic limitations of the pivotal trial sample. A federally funded independent three-arm RCT (N=385) found no significant superiority of skills-based VR (RelieVRx plus on-demand content library, EaseVRx+) over sham VR for the primary pain outcome or secondary outcomes; a secondary signal favored distraction VR (360-degree immersive videos) for opioid use reduction. The trial was adequately powered and detected no clinically meaningful effect. Distraction VR performed equivalently to skills-based VR on the primary outcome, raising a direct question about whether the therapeutic signal in earlier positive trials was driven by immersion and distraction rather than the cognitive behavioral therapy content that distinguishes RelieVRx as a prescription device. The divergence in outcomes and population diversity across trials contributes to overall evidence uncertainty. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

No relevant clinical practice guidelines specifically addressing RelieVRx were identified. Relevant society guidance on non-pharmacological pain management modalities is noted below where applicable.

American College of Physicians

The American College of Physicians (ACP) clinical practice guideline for noninvasive treatments for acute, subacute, and chronic low back pain (2017) recommends nonpharmacologic treatments as initial therapy for chronic low back pain, including exercise, multidisciplinary rehabilitation, acupuncture, mindfulness-based stress reduction, tai chi, yoga, motor control exercise, progressive relaxation, electromyography biofeedback, low-level laser therapy, operant therapy, cognitive behavioral therapy, and spinal manipulation. The guideline does not specifically address VR-based therapeutics.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage
There is no National Coverage Determination (NCD) for prescription digital therapeutics in the pain management category. However, CMS has established a national reimbursement framework specific to RelieVRx through the durable medical equipment (DME) pathway:

- On March 8, 2023, CMS established HCPCS Level II code E1905, "Virtual reality cognitive behavioral therapy device (cbt), including pre-programmed therapy software," to describe RelieVRx, effective April 1, 2023. CMS determined that RelieVRx meets the requirements for classification as durable medical equipment (DME) under 42 CFR §414.202. Coverage determinations under the DME pathway are made by Medicare Administrative Contractors (MACs) on a claim-by-claim basis.

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT06248216	Implementation of an At-Home Multimodal Integrative Therapy Via Virtual Reality for Patients With Cancer-Treatment Associated Symptoms	30	Dec 2027

NCT: national clinical trial.

References

1. Food and Drug Administration (FDA). EaseVRx. DEN210014. November 16, 2021.
2. AppliedVR Renames Its FDA-approved Virtual Reality Therapeutic 'RelieVRx' and Announces Three-month Durability Study Results (Mar 2022).
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5. Buckenmaier CC, Galloway KT, Polomano RC, et al. Preliminary validation of the Defense and Veterans Pain Rating Scale (DVPRS) in a military population. Pain Med. Jan 2013; 14(1): 110-23. PMID 23137169
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7. Cleeland CS, Ryan KM. Pain assessment: global use of the Brief Pain Inventory. Ann Acad Med Singap. Mar 1994; 23(2): 129-38. PMID 8080219
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10. Garcia LM, Birckhead BJ, Krishnamurthy P, et al. An 8-Week Self-Administered At-Home Behavioral Skills-Based Virtual Reality Program for Chronic Low Back Pain: Double-Blind, Randomized, Placebo-Controlled Trial Conducted During COVID-19. J Med Internet Res. Feb 22 2021; 23(2): e26292. PMID 33484240
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12. Spiegel BMR, Eberlein SA, Persky S, et al. Randomized-controlled trial of skills-based vr vs. distraction vr vs. sham VR for chronic low back pain. NPJ Digit Med. Feb 16 2026; 9(1). PMID 41699236
13. Maddox T, Sparks C, Oldstone L, et al. Durable chronic low back pain reductions up to 24 months after treatment for an accessible, 8-week, in-home behavioral skills-based virtual reality program: a randomized controlled trial. Pain Med. Oct 03 2023; 24(10): 1200-1203. PMID 37220894
14. Centers for Medicare & Medicaid Services. (DHHS). Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Level II Final Coding, Benefit Category and Payment Determinations. First Biannual (B1), 2023 HCPCS Coding Cycle.

Policy History

Original Effective Date: 12/01/2026
Current Effective Date: 12/01/2026
09/15/2026 Utilization Management Committee review/approval. New policy.
Next Scheduled Review Date: 09/2027

Coding

The five character codes included in the Health Plan Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2025 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of the Health Plan Medical Policy Coverage Guidelines is with the Health Plan and no endorsement by the AMA is intended or should be implied. The AMA

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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	0770T
HCPCS	E1905
ICD-10 Diagnosis	N/A

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the Health Plan's Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Health Plan recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

NOTICE: All codes listed on the Medical Policy require prior authorization. This ensures appropriate utilization and alignment with current clinical guidelines.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Blue Advantage), Blue Advantage may honor the previous health plan's authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Blue Advantage health plan.

Medicare Advantage Members

Established coverage criteria for Medicare Advantage members can be found in Medicare coverage guidelines in statutes, regulations, National Coverage Determinations (NCD)s, and Local Coverage

Determinations (LCD)s. To determine if a National or Local Coverage Determination addresses coverage for a specific service, refer to the Medicare Coverage Database at the following link: https://www.cms.gov/medicare-coverage-database/search.aspx. You may wish to review the Guide to the MCD Search here: https://www.cms.gov/medicare-coverage-database/help/mcd-benehelp.aspx.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, internal coverage criteria may be developed. This policy is to serve as the summary of evidence, a list of resources and an explanation of the rationale that supports the adoption of this internal coverage criteria.

InterQual®
Interqual® is utilized as a source of medical evidence to support medical necessity and level of care decisions. InterQual® criteria are intended to be used in connection with the independent professional medical judgment of a qualified health care provider. InterQual® criteria are clinically based on best practice, clinical data, and medical literature. The criteria are updated continually and released annually. InterQual® criteria are a first-level screening tool to assist in determining if the proposed services are clinically indicated and provided in the appropriate level or whether further evaluation is required. The utilization review staff does the first-level screening. If the criteria are met, the case is approved; if the criteria are not met, the case is referred to the medical director.