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Immersive Virtual Reality Therapy for Chronic Lower Back Pain

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Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.

Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

The use of U.S. Food and Drug Administration-authorized prescription virtual reality digital therapeutics for chronic lower back pain **is considered experimental, investigational and/or unproven.**

Policy Guidelines

None.

Description

Scope of Policy

This medical policy 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 policy 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; criterion as follows:

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.

Regulatory Status

In November 2021, the 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. (1, 2)

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	RelieVRx is a software-based virtual reality program delivered through a VR headset that provides an 8-week, self-	QRA	DEN210014 (De Novo)	2021

		of age and older. The device is intended for home use, to be used under the direction of a healthcare provider. RelieVRx is a prescription-use immersive VR system that provides CBT and other evidence-based behavioral methods for pain management.	administered, at-home behavioral skills-based treatment for chronic lower back pain. The program includes CBT, mindfulness, relaxation training, and interoceptive awareness techniques delivered through immersive VR experiences.			
VRNT (14, 15)	CognifiSense, Inc.	VRNT is indicated for adjunctive treatment of chronic lower back pain in patients 18 years of age and older. VRNT is a prescription-use immersive VR system for home use that provides CBT and other evidence-based behavioral methods for pain management.	VRNT 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 behavioral content incorporates cognitive behavioral therapy skills and other evidence-based behavioral methods.	QRA	K230814/ K254004	2023/ 2026

CBT: cognitive behavioral therapy; FDA: U.S. Food and Drug Administration; VR: virtual reality.

The listing noted above may not be an “all inclusive” list of prescription digital therapeutics for the treatment of chronic lower back pain and is subject to change. Refer to the FDA web site at <<https://www.fda.gov>> for additional information on devices.

NOTE: This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Rationale

Medical policies assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Chronic Lower Back Pain

Clinical Context and Therapy Purpose

Chronic lower back pain is defined as pain in the lower back region persisting for 12 weeks or longer, even after an initial injury or underlying cause has been treated. It is one of the most prevalent and disabling conditions worldwide, affecting an estimated 13%-20% of U.S. adults at any given time, (3) and is a leading cause of disability, lost work productivity, and healthcare utilization. The condition is associated with significant impairments in physical function, psychological well-being, and quality of life.

Current treatment approaches for chronic lower back pain include pharmacologic therapies (nonsteroidal anti-inflammatory drugs, acetaminophen, muscle relaxants, antidepressants, and in some cases opioids), physical therapy, exercise-based rehabilitation, cognitive behavioral therapy (CBT), multidisciplinary pain rehabilitation programs, and interventional procedures (e.g., epidural steroid injections, radiofrequency ablation). Clinical practice guidelines from the

American College of Physicians (2017) recommend that clinicians and patients initially select nonpharmacologic treatment, 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, CBT, or spinal manipulation (Grade: strong recommendation, moderate-quality evidence). (4)

Despite the availability of multiple treatment modalities, chronic lower back pain remains difficult to manage effectively, with many patients experiencing persistent symptoms and functional limitations. Barriers to accessing evidence-based behavioral therapies include limited availability of trained therapists, geographic constraints, and time demands of in-person treatment programs. Virtual reality-based behavioral interventions represent a relatively recent approach to delivering evidence-based pain management skills in a home-based, self-administered format.

The purpose of prescribed therapeutic digital applications is to provide a treatment option that is a replacement or alternative to existing therapies for individuals with chronic lower back pain.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals with chronic lower back pain.

Interventions

RelieVRx

RelieVRx (formerly EaseVRx) is a prescription-use immersive virtual reality (VR) system indicated for adjunctive treatment of chronic lower back pain in patients 18 years of age and older, to be used at home under the direction of a healthcare provider. The device delivers an 8-week, self-administered behavioral skills-based treatment program through a VR headset. The therapeutic content incorporates CBT, mindfulness, relaxation training, and interoceptive awareness techniques delivered through immersive 3D environments. Treatment sessions are designed to be completed daily and are approximately 2 to 16 minutes in duration. RelieVRx received U.S. Food and Drug Administration (FDA) De Novo authorization (DEN210014) in November 2021.

Comparators

Usual care for chronic lower back pain includes pharmacologic therapies (nonsteroidal anti-inflammatory drugs, acetaminophen, muscle relaxants, antidepressants, and opioids), physical therapy, exercise-based rehabilitation, CBT, multidisciplinary pain rehabilitation programs, and interventional procedures (e.g., epidural steroid injections, radiofrequency ablation, spinal cord stimulation).

In-person delivery of CBT for chronic pain by a trained therapist is an evidence-based treatment recommended in clinical practice guidelines. However, access to behavioral pain management

is limited by a shortage of trained providers, geographic barriers, cost, and time constraints. Self-administered digital and VR-based interventions have been proposed as a means of expanding access to evidence-based behavioral skills training for pain management.

The choice of comparator depends on whether RelieVRx is intended to replace in-person behavioral therapy or serve as an alternative in a stepped care model. If intended as a replacement, it should demonstrate noninferiority to in-person CBT for chronic pain. If intended as an alternative entry-level behavioral treatment, comparison with a sham VR control or usual care is appropriate. RelieVRx is indicated for adjunctive treatment of chronic lower back pain in patients 18 years of age and older. The pivotal trial used a sham VR comparator.

Outcomes

The general outcomes of interest are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Follow-up after treatment and at 6 to 12 months following the end of treatment is of interest to monitor outcomes.

Outcome measures for chronic lower back pain are noted in Table 2.

Table 2. Outcome Measures

Outcome	Measure (Units)	Description and Administration	Thresholds for Improvement/Decline or Clinically Meaningful Difference
DVPRS	Defense and Veterans Pain Rating Scale	A 5-item pain assessment tool that evaluates pain intensity on a 0 to 10 numeric rating scale and its interference with activity, sleep, mood, and stress.	A reduction of ≥ 1.5 points on the pain intensity item. (5)
NRS	Numeric Rating Scale for Pain Intensity	A single-item self-report measure of current pain intensity on a 0 to 10 scale, where 0=no pain and 10=worst pain imaginable.	A reduction of ≥ 2 points or $\geq 30\%$ from baseline. (6)
BPI	Brief Pain Inventory – Short Form	A validated self-report questionnaire assessing pain severity (4 items) and pain interference with daily functions (7 items) on 0 to 10 scales.	A reduction of ≥ 1 point on the interference subscale. (7)
PGIC	Patient Global Impression of Change	A single-item self-report measure of perceived change in overall status since treatment initiation, rated on a 7-point scale	A rating of “much improved” or “very much improved”.

		from “very much improved” to “very much worse.”	
ODI	Oswestry Disability Index	A 10-item self-administered questionnaire measuring functional disability related to low back pain across domains including pain intensity, personal care, lifting, walking, sitting, standing, sleeping, social life, traveling, and employment.	A change of ≥ 10 points (on a 0 to 100 scale). (8)
PROMIS	Patient-Reported Outcomes Measurement Information System	National Institutes of Health-developed validated self-report measures covering multiple health domains including physical function and sleep disturbance. Scores are T-scores standardized to the U.S. general population (mean 50, SD 10).	A difference of ≥ 2 -3 T-score points. (9)

SD: standard deviation; U.S.: United States.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach', within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

Three sham-controlled RCTs of RelieVRx (or its predecessor EaseVRx) have been published.

The pivotal RCT (NCT04415177) (10), and a larger post-launch RCT (NCT05263037) (11), were industry-funded trials. A third, independently conducted federally funded trial (NCT04409353) evaluated EaseVRx+, a version of the same skills-based VR program identical in content to RelieVRx but with an additional on-demand content library; utilization data for the on-demand library were not reported, and the degree of divergence from the commercially marketed RelieVRx in actual patient use is therefore unknown in a 3-arm design against sham

VR and distraction VR. (12) Study characteristics and results are summarized in Tables 3 and 4, respectively. Limitations in design and conduct are summarized in Tables 5 and 6.

Garcia et al. (2021) conducted the pivotal RCT (N=179 received device) where EaseVRx (now RelieVRx) produced statistically and clinically significant reductions in pain intensity (DVPRS) and pain-related interference with activity, mood, sleep, and stress (DVPRS-II), with between-group Cohen d effect sizes of 0.40-0.49 and within-group pain intensity reduction of 43% vs. 25% for sham VR. (10) EaseVRx was superior to sham for all primary outcomes ($p=0.001$ to 0.009). Improvements in sleep disturbance (Patient-Reported Outcomes Measurement Information System [PROMIS] Sleep Disturbance, $p=0.013$) and physical function (PROMIS Physical Function, $p=0.022$) were also observed. Generalizability of the pivotal trial findings is constrained by its enrollment criteria and recruitment approach. Of 1577 individuals screened, 1125 (71%) were excluded for depressive symptoms alone, using a Patient Health Questionnaire-2 (PHQ-2) threshold of ≥ 2 , a subclinical cutoff near the floor of the instrument, despite the high prevalence of depression comorbidity in the intended population. Participants were additionally recruited through Facebook advertisements and chronic pain organizations rather than clinical referral, introducing self-selection toward motivated, health-literate, and technology-comfortable individuals who may not reflect a typical clinical population.

In a follow-up study of the same cohort, Maddox et al. (2023a) reported durable between-group superiority for EaseVRx over sham VR at 24 months post-treatment for both pain intensity (effect size [ES]=0.28; $p=0.04$) and overall pain interference (ES=0.54; $p=0.002$). (13) At least 65% of EaseVRx participants maintained clinically meaningful ($\geq 30\%$) reductions at each post-treatment time point to 24 months; however, this was a research letter with 24% attrition from the already homogeneous pivotal trial cohort (see Table 5).

Maddox et al. (2023b), in a separate cohort (N=1067), reported that RelieVRx was shown to be superior to sham VR for pain intensity (between-group difference, 0.41 points on BPI; $p<0.001$) and pain interference (0.52 point; $p<0.001$). (11) The absolute between-group differences were modest and the sham VR comparator itself had therapeutic effects (relaxation, distraction), potentially attenuating the observed contrast. Engagement was higher in the RelieVRx group (mean 37.5 of 56 sessions) than in the sham group (mean 31.0 sessions; $p<0.001$), and no serious adverse events were reported.

Spiegel et al. (2026) conducted a 3-arm federally funded trial (N=385) where participants were randomized to skills-based VR (EaseVRx+; $n=131$), distraction VR (immersive 360-degree videos; $n=127$), or sham VR (2D nature videos; $n=127$). (12) The primary outcome was change in PROMIS Pain Interference (PROMIS-PI) at Day 30. No statistically significant between-group differences were observed for the primary outcome comparing either active VR arm to sham VR (skills-based vs. sham: adjusted mean difference 0.16 points; 95% confidence interval [CI], -1.12 to 1.43; $p=0.81$; distraction vs. sham: 0.47 points; 95% CI, -0.87 to 1.81; $p=0.49$). Notably, distraction VR, which delivers immersive 360-degree videos without any skills-based or CBT content, performed equivalently to skills-based VR on the primary outcome, raising a direct question about whether the therapeutic signal observed in earlier positive trials was

attributable to the CBT content that distinguishes RelieVRx as a prescription device, or to immersion and distraction alone. The trial was adequately powered and detected no clinically meaningful effect; it exceeded its planned enrollment of 360 participants and was powered (84%) to detect the pre-specified 5-point PROMIS-PI minimal clinically meaningful difference. No significant differences were observed for secondary outcomes including pain intensity, anxiety, depression, sleep, physical function, or Patient Global Impression of Change scale (PGIC). A significant reduction in daily opioid use was observed in the distraction VR group compared to sham at Day 90 ($p=0.009$), but not in the skills-based VR group. Exploratory analysis identified higher baseline anxiety as a significant predictor of response to skills-based VR at Day 60 ($p=0.025$). Adverse events were predominantly mild; cybersickness was the most common.

Table 3. Summary of Key RCT Characteristics for RelieVRx

Study	Garcia et al. (2021); Pivotal RCT (10)^a	Maddox et al. (2023b); Post-launch RCT (11)^a	Spiegel et al. (2026); Federally funded 3-arm RCT (12)
Study Design	Double-blind, sham-controlled RCT (1:1)	Double-blind, sham-controlled RCT (1:1)	3-arm, double-blind RCT (1:1:1)
Setting	In-home; U.S. (2020)	In-home; U.S. (Jan-Oct 2022)	In-home; U.S. (Oct 2020–Feb 2024)
Participants	Inclusion • Age ≥ 18 years • Chronic lower back pain ≥ 6 months duration • Average pain intensity and pain interference $\geq 4/10$ Exclusion • Depressive symptoms (PHQ-2 ≥ 2) • Epilepsy, seizure disorder, dementia, migraines, or other neurological disease preventing VR use • Medical condition predisposing to nausea or dizziness; hypersensitivity to flashing light or motion	Inclusion • Age ≥ 18 years with diverse, clinically severe sample • Self-reported nonmalignant chronic low back pain ≥ 3 months with average pain intensity and interference $\geq 4/10$ Primary Outcomes • BPI pain intensity at day 56 • BPI pain interference at day 56	Inclusion • Age ≥ 13 years with chronic lower back pain ≥ 3 months on $\geq 50\%$ of days over past 6 months • English-speaking • Smartphone/computer access Exclusion • Seizure history • Significant visual or hearing impairment • Prior VR clinical trial participation • Anticipated hospitalization >3 weeks • Recent or planned surgery • Spinal cord stimulator

	- No stereoscopic vision or severe hearing impairment; injury to eyes, face, or neck - Cancer-related pain; current pregnancy; gross cognitive impairment - Prior use of EaseVRx; current participation in other interventional studies Primary Outcomes - Pain intensity (DVPRS 0-10) at day 56 - Pain interference with activity, mood, sleep, stress (DVPRS-II 0-10) at day 56		- Back pain due to infection, cancer, or inflammatory spondylopathies Primary Outcome - PROMIS Pain Interference T-score change from baseline to Day 30
Active	EaseVRx (RelieVRx): 8-week, 56-session immersive VR program delivering CBT, diaphragmatic breathing/biofeedback, mindfulness, and pain education via VR headset (n=89 received device; 188 randomized ITT)	RelieVRx (n=536)	EaseVRx+ (skills-based VR): identical content to RelieVRx plus on-demand content library that allows patients to access modules they prefer to experience, offering greater access to the use; 56-session immersive VR program (n=131); each VR session lasts 2-16 minutes (average: 6 minutes)
Control	Sham VR: identical VR headset delivering 2D nature videos without therapeutic content (n=90 received device)	Sham VR: 2D nature content (n=531)	Distraction VR: 360-degree immersive videos, same hardware and session count (n=127); Sham VR: 2D nature footage with neutral

			music, same hardware (n=127)
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^a Industry-funded (AppliedVR).

BPI: Brief Pain Inventory; CBT: cognitive behavioral therapy; DVPRS: Defense and Veterans Pain Rating Scale; ITT: intention-to-treat; PHQ-2: Patient Health Questionnaire-2; PROMIS: Patient-Reported Outcomes Measurement Information System; RCT: randomized controlled trial; U.S.: United States; VR: virtual reality.

Table 4. Summary of Key RCT Results for RelieVRx

Study/Outcome	RelieVRx	Sham VR	Between-group Difference; p-value
Garcia et al. (2021); Day 56 (N=179) (10)			
Pain intensity (DVPRS mean change)	NR (not reported as mean change)	NR	Between-group Cohen d=0.49; p=0.001 (superiority across all timepoints); within-group reduction 42.8% (EaseVRx) vs. 25.1% (sham)
Pain interference (DVPRS-II mean change)	(multiple domains reported separately)	NR	Between-group Cohen d=0.40-0.44 across activity, mood, sleep, stress domains; p=0.004-0.009, p<0.001
Safety (SAEs)	No SAE; cybersickness (nausea/motion sickness) reported by 9.7% EaseVRx vs. 6.7% sham at 1-month follow-up (assessed retrospectively; p=0.50)		
Maddox et al. (2023b); Day 56 (N=1067) (11)			
Pain intensity (BPI mean change)	-2.0 points	-1.6 points	Difference: 0.406 (95% CI, 0.170 to 0.642), p<0.001
Pain interference (BPI mean change)	-2.3 points	1.7 points	Difference: 0.523 (95% CI, 0.285 to 0.760), p<0.001
Spiegel et al. (2026); Day 30 primary endpoint (N=385) (12)			
PROMIS-PI (primary outcome)	Skills-Based VR: -1.63 points	Sham VR: -1.79 points	Skills-Based vs. sham: adjusted mean difference 0.16 (95% CI, -1.12 to 1.43); p=0.81 (not significant); Distraction vs. sham: 0.47 (95% CI, -0.87 to 1.81), p=0.49 (not significant)
Opioid use (secondary; Day 90)	Distraction VR: significantly greater reduction	Sham VR	Distraction VR vs. sham: p=0.009; Skills-based VR vs. sham: p=0.830 (not significant)
All other secondary outcomes (anxiety, depression, sleep, physical function, PGIC, Fitbit steps)	No significant differences across any secondary outcome	NR	No significant between-group differences observed
Safety	AEs predominantly mild; cybersickness most common (68/117 total AEs); 3 severe AEs all unrelated to VR; AEs more frequent in skills-based VR (26.7%) than distraction VR (19.7%) or sham (15.0%)		

AEs: adverse events; BPI: Brief Pain Inventory; CI: confidence interval; DVPRS: Defense and Veterans Pain Rating Scale; DVPRS-II: DVPRS Interference subscale; NR: not reported as a single mean change; NRS: Numeric Rating Scale; PGIC: Patient Global Impression of Change; PROMIS-PI: Patient-Reported Outcomes Measurement Information System Pain Interference; RCT: randomized controlled trial; SAE: serious adverse event; VR: virtual reality.

Table 5. Study Relevance Limitations for RelieVRx

Study	Garcia et al. (2021) (10)	Maddox et al. (2023b) (11)	Spiegel et al. (2026) (12)
Population^a	4. Enrolled population does not reflect relevant diversity (e.g., White, 91%; female, 77%) 5. Other (depression exclusion at subclinical PHQ-2 threshold eliminated 71% of screened individuals; Facebook/chronic pain organization recruitment introduces self-selection bias (see above narrative for detail))	5. Other (self-reported diagnosis without objective confirmation of chronic lower back pain; real-world self-diagnosed population may not be generalizable to the clinically-diagnosed population)	
Intervention^b			4. Not the intervention of interest (EaseVRx+ includes an additional on-demand content library not present in the FDA-cleared RelieVRx, allowing patient-directed module selection; utilization data for the library were not reported, and the degree of divergence from RelieVRx in actual use is therefore unknown)
Comparator^c	2. Not standard or optimal (sham VR delivered 2d)	2. Not standard or optimal (sham VR comparator itself had	

	visualization without skills component which could potentially lead to unblinding)	therapeutic effects; between-group differences were modest and may not meet published clinically meaningful thresholds)	
Outcomes^d			
Duration of Follow-up^e		1. Not sufficient duration for benefit (primary endpoint at day 56)	1. Not sufficient duration for benefit (primary endpoint at Day 30; secondary endpoints to Day 90)

FDA: U.S. Food and Drug Administration; PHQ-2: Patient Health Questionnaire-2; VR: virtual reality. The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^a Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4. Enrolled populations do not reflect relevant diversity; 5. Other.

^b Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5: Other.

^c Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.

^d Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.

^e Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 6. Study Design and Conduct Limitations for RelieVRx

Study	Garcia et al. (2021) (10)	Maddox et al. (2023b) (11)	Spiegel et al. (2026) (12)
Allocation^a			
Blinding^b	4. Other (blinding efficacy not reported)	4. Other (blinding efficacy not reported)	4. Other (blinding efficacy not reported; presence scores after first use differed significantly between sham and active arms [$p<0.001$], raising questions about blinding integrity)
Selective Reporting^c		4. Other (this paper reports only 2 of 4 randomized arms to end-of-treatment, with the remaining	

		arms and all post-treatment follow-up data deferred to future publications)	
Data Completeness^d			
Power^e			
Statistical^f			

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^a Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias; 5. Other.

^b Blinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other.

^c Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other.

^d Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials); 7. Other.

^e Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other.

^f Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated; 5. Other.

Section Summary: Chronic Lower Back Pain

The evidence includes 2 industry-funded sham-controlled RCTs, a follow-up durability study, and one federally funded independent 3-arm RCT. 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=1067) 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 3-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 CBT

content that distinguishes RelieVRx as a prescription device. The divergence in outcomes and population diversity across trials contributes to overall evidence uncertainty.

Summary of Evidence

For individuals with chronic lower back pain who receive RelieVRx, the evidence includes 2 industry-funded sham-controlled randomized controlled trials (RCTs), a follow-up durability study, and a federally funded, independent 3-arm RCT. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. RelieVRx (formerly EaseVRx) received U.S. Food and Drug Administration (FDA) De Novo authorization in November 2021. The pivotal trial (N=179) demonstrated statistically significant and clinically meaningful superiority of EaseVRx over sham virtual reality (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=1067) 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 3-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.

Practice Guidelines and Position Statements

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. (4) The guideline does not specifically address VR-based therapeutics.

Medicare National Coverage

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

- On March 8, 2023, CMS established Healthcare Common Procedure Coding System (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. (14)

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this policy are listed in Table 7.

Table 7. Summary of Key Trials

NCT Number	Trial Name	Planned Enrollment	Completion Date
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.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	0770T, 0771T, 0772T, 0773T, 0774T
HCPCS Codes	E1399, E1905

*Current Procedural Terminology (CPT®) ©2025 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <<https://www.cms.hhs.gov>>.

Policy History/Revision

Date	Description of Change
11/01/2026	New medical document. The use of U.S. Food and Drug Administration-authorized prescription virtual reality digital therapeutics for chronic lower back pain is considered experimental, investigational and/or unproven.