DRAFT Medical Coverage Policy | Immersive Virtual Reality Therapy for Chronic Lower Back Pain

EFFECTIVE DATE: 03|01|2027
POLICY LAST REVIEWED: 11|18|2026

OVERVIEW
This 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 addressed 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.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
Medicare Advantage Plans
The use of U.S. Food and Drug Administration-authorized prescription virtual reality digital therapeutics for chronic lower back pain is not covered as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Commercial Products
The use of U.S. Food and Drug Administration-authorized prescription virtual reality digital therapeutics for chronic lower back pain is not medically necessary as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

COVERAGE
Benefits may vary between groups/contracts. Please refer to the Evidence of Coverage or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage.

BACKGROUND
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, 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 (eg, 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).

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.

For individuals with chronic lower back pain who receive RelieVRx, the evidence includes 2 industry-funded sham-controlled randomized controlled trials (RCTs) with follow-up publications from the post-launch cohort, a separate durability study of the pivotal trial cohort, 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 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; 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 12-month follow-up of the post-launch cohort reported sustained between-group superiority for pain intensity and interference, with average reductions approaching but not reaching the 2-point clinically meaningful threshold and small between-group effect sizes. A secondary analysis of the RelieVRx arm only found significantly larger and clinically meaningful reductions in the high-impact chronic pain subgroup at 1 and 2 years posttreatment; these findings do not resolve the primary evidentiary limitations of the parent trial. 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.

For individuals with chronic lower back pain who receive Virtual Reality Neuroscience-based Therapy (VRNT), the evidence includes a single waitlist-controlled RCT (N=61). VRNT received FDA 510(k) clearance in October 2023, supported by this trial, which was originally available as a preprint prior to peer publication. The trial reported statistically significant reductions in pain intensity and interference versus waitlist control, with medium-to-large effect sizes for both outcomes. The evidence is limited by small sample size, absence of a sham or active comparator, lack of blinding, limited generalizability (sample 92% White, recruited from a single geographic area), and follow-up limited to 2 weeks post-treatment; nonspecific effects

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cannot be excluded. No post-market effectiveness data are available. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

CODING

Medicare Advantage Plans and Commercial Products

The following CPT code(s) are not covered for Medicare Advantage Plans and not medically necessary Commercial Products:

E1905 Virtual reality cognitive behavioral therapy device (CBT), including preprogrammed therapy software

RELATED POLICIES

None

PUBLISHED

Provider Update, January 2027

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