Regence

Medical Policy Manual Medicine, Policy No. 175.03

Digital Therapeutic Products for Chronic Low Back Pain

Effective: January 1, 2025

Next Review: September 2025
Last Review: December 2024

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Digital health products are technologies, platforms, and systems that engage consumers for lifestyle, wellness, and health-related purposes. A digital therapeutic product is a specific type of digital health product that is practitioner-prescribed software that delivers evidence-based therapeutic intervention directly to a patient to prevent, manage, or treat a medical disorder or disease. Digital therapeutic products have been proposed to supplement or replace established treatments for chronic low back pain.

MEDICAL POLICY CRITERIA

Notes:

- Member contracts for covered services vary. Member contract language takes precedence over medical policy.
- This policy addresses the use of practitioner-prescribed software applications for therapeutic intervention.
- This policy does not address:
  - Software that is used for the function or control of an FDA-cleared or approved stand-alone medical device (e.g., external insulin pump or pacemaker).

- Applications operated by a health care practitioner for remote health monitoring.
- Products not meeting the definition of a digital therapeutic (see Policy Guidelines in Digital Therapeutic Products, Medicine, Policy No. 175).

The use of a digital therapeutic product for the treatment of chronic low back pain either as a stand-alone treatment or as an adjunct to standard treatment, is considered **investigational**, including but not limited to the RelieVRx device.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

1. Digital Therapeutic Products, Medicine, Policy No. 175

BACKGROUND

REGULATORY STATUS

In March 2021, RelieVRx (formerly EaseVRx) received FDA Breakthrough Device designation through the De Novo premarket review pathway. No other virtual reality devices have been FDA authorized or approved. RelieVRx is a prescription device intended to treat chronic low back pain.

EVIDENCE SUMMARY

Systematic Reviews

Henríquez-Jurado (2024) published a systematic review and meta-analysis of 25 RCTs on the effect of virtual reality based therapy (VRBT) on reducing pain intensity, kinesiophobia, associated disability, and health-related quality of life in patients with chronic neck pain or chronic low back pain.[1] VRBT was compared to therapeutic exercise, sham, or no intervention. Data from 19 RCTs (n=1,415) showed a large immediate effect in pain response with VRBT for chronic low back pain (Standard Mean Difference [SMD]=−1.27, 95% CI: −1.45 to −0.8, p<0.001). Heterogeneity was high (I^2=63.9%; Q=66.5; df=24; p=0.87). For chronic neck pain, five RCTs (n=417) showed a large immediate effect in pain response (SMD=−0.45, 95% CI: −0.68 to −0.21, p<0.001) in favor of VRBT with low risk of publication bias or heterogeneity (I^2=0%; Q=4.4; df=6; p=0.62). Improvements in kinesiophobia, associated disability, and health-related quality of life were also reported. On average, the reviewers concluded that risk of bias was moderate across studies; two RCTs were of high quality and low risk of bias, and nine RCTs were of moderate quality and medium risk of bias. Limitations of this study include high heterogeneity in pain intensity analysis and VR treatment type, lack of long-term follow-up, and not all outcomes were reported for control groups.

Brea-Gomez (2021) published a systematic review for the use of virtual reality for the treatment of chronic low back pain which included 14 studies, 11 of which were included in the meta-analysis.[2] Significant differences were found in favor of VR compared to no VR in pain intensity postintervention (p< 0.00001) and follow-up (p< 0.00001); and kinesiophobia postintervention (p=0.04) and follow-up (p=0.006). No significant differences were found in disability. The authors concluded that VR can significantly reduce pain intensity and

kinesiophobia in patients with chronic low back pain. There was significant heterogeneity in the included studies. Additionally, the studies had small sample sizes and the interventions provided in the studies had a broad range of type, duration, and frequency which makes it difficult to interpret meaningful differences and make generalizable conclusions.

Randomized Controlled Trials

Groenveld (2023) published a single-center pilot RCT of 40 adult participants with non-specific chronic low back pain, reporting an average pain score of 4 and higher on an 11 point Likert scale in the week before enrollment.[3] Participants were randomized to receive self-administered behavioral therapy with a novel virtual reality application (Reducept) for at least 10 minutes per day for 4 weeks (n=20) or standard care (n=20). The primary outcome was quality of life measured by the short form-12 at four weeks. Secondary outcomes were short form-12 scores at four months and daily pain scores and analgesic use at four weeks and four months. Six patients did not complete the questionnaires and were lost to follow-up. Short form-12 scores did not differ between treatment groups at four weeks for the physical scale (mean difference -2.56, 95% confidence interval [CI] -5.60 to 0.48, p=0.96) or mental scale (mean difference -1.75, 95% CI -6.04 to 2.53, p=0.41). A significant treatment effect was observed for daily worst pain score (F [1, 91.425] = 33.3, p<0.001) and daily least pain score (F [1, 30.069] = 11.5, p=0.002). Due to low sample size, most secondary outcomes could not be measured due to insufficient statistical power.

Garcia (2021) published a double-blind RCT with 179 participants chosen from a national online convenience sample.[4] The participants had self-reported low back pain with duration of six months or more with average pain intensity of four or greater (out of 10) and were randomized to a 56-day EaseVRx program or a Sham VR. The sham VR group was exposed to a 2D nature content delivered through a VR headset. The primary outcome was the effects of EaseVRx versus the Sham VR representing change in average pain intensity and pain-related interference with activity, stress, mood, and sleep from baseline to end of treatment at 56 days. Change was measured using the Defense and Veterans Pain Rating Scale (DVPRS) and the DVPRS interference scale (DVPRS-II). Twice-weekly surveys were obtained with a final survey at treatment completion. EaseVRx was superior to Sham VR for all primary outcomes with greater reductions in average pain intensity and pain-related interferences with activity, mood, and stress. Between-group comparisons for physical function and sleep disturbance demonstrated superiority for the EaseVRx versus the Sham VR (p=0.022 and 0.012, respectively). However, pain catastrophizing, pain self-efficacy, pain acceptance, and prescription opioid use did not reach statistical significance for either group. Use of over-the-counter analgesic use was reduced for EaseVRx but not for Sham VR (p<0.01).

A three-month follow-up study by Garcia (2022) analyzed data for 188 participants who were surveyed at one, two, and three months after the original 56-day trial.[5] 168 of the participants from the original trial completed the 56-day treatment and remained blinded during the follow-up period. The authors reported that the EaseVRx had lower pain intensity, lower pain-interference with activity, sleep, and stress than the Sham VR through three months. There was no significant difference between EaseVRx and Sham VR for sleep disturbance at three months. A six-month follow-up study by Garcia (2022) demonstrated similar results.[6]

A 24-month follow-up study of the Garcia (2021) RCT was published by Maddox (2023).[7] The Defense and Veterans Pain Rating Scales (DVPRS, DVPRS-II) were used to collect 24-month post-treatment data among VR- and sham-treated participants. 127 out of 168 participants

(76%) completed the 24-month post-treatment survey (81% of the VR group and 70% of the sham group). Skills-Based VR participants had lower pain intensity ratings (p=0.04, ES=0.28) and overall pain interference (p=0.002, ES=0.54) compared to sham participants. Pain interference subcomponents, including activity, sleep, mood, and stress, were also significantly lower for Skills-Based VR participants. At the end of treatment, 62% of VR participants achieved a clinically meaningful reduction in both pain intensity and pain interference, compared to 37% of sham participants. Similar results were reported in an 18-month follow-up study.[8]

The original trial and the follow-up studies are limited in their recruitment protocol, collection of self-reported data including the inclusion criteria (e.g., self-reported back pain and medication usage), lack of diversity in the sample collected, and lack of generalizability. Additional high-quality randomized trials are needed to establish the effectiveness of virtual reality as a treatment of chronic low back pain.

Section Summary

The evidence for those with chronic low back pain who receive virtual reality as a treatment modality includes systematic reviews and one randomized controlled trial with four follow-up studies at three months, six months, 18 months, and 24 months, and one randomized controlled trial with a four-week follow-up. Relevant outcomes are pain scores, quality of life, and medication utilization. Several questions remain concerning the efficacy of this treatment based on the limitations of the included trials which demonstrates a need for high-quality randomized trials with long-term follow-up to establish the effectiveness and durability of the treatment. At this time, the digital therapy is not recommended as an alternative or adjunct to established treatments. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

PRACTICE GUIDELINE SUMMARY

No clinical practice guidelines were identified which addressed the use of a digital therapeutic for the treatment of chronic low back pain.

SUMMARY

There is not enough research to show that digital therapeutic products for the treatment of chronic low back pain improves net health outcomes. No clinical guidelines based on research recommend digital therapeutic products for the treatment of chronic low back pain. Therefore, digital therapeutic products for the treatment of chronic low back pain are considered investigational.

REFERENCES

1. Henríquez-Jurado JM, Osuna-Pérez MC, García-López H, et al. Virtual reality-based therapy for chronic low back and neck pain: a systematic review with meta-analysis. *EFORT Open Rev.* 2024;9(7):685-99. PMID: 38949175
2. Brea-Gómez B, Torres-Sánchez I, Ortiz-Rubio A, et al. Virtual Reality in the Treatment of Adults with Chronic Low Back Pain: A Systematic Review and Meta-Analysis of

Randomized Clinical Trials. *Int J Environ Res Public Health.* 2021;18(22). PMID: 34831562
3. Groenveld TD, Smits MLM, Knoop J, et al. Effect of a Behavioral Therapy-Based Virtual Reality Application on Quality of Life in Chronic Low Back Pain. *Clin J Pain.* 2023;39(6):278-85. PMID: 37002877
4. 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.* 2021;23(2):e26292. PMID: 33484240
5. Garcia LM, Birckhead BJ, Krishnamurthy P, et al. Three-Month Follow-Up Results of a Double-Blind, Randomized Placebo-Controlled Trial of 8-Week Self-Administered At-Home Behavioral Skills-Based Virtual Reality (VR) for Chronic Low Back Pain. *J Pain.* 2022;23(5):822-40. PMID: 34902548
6. Garcia L, Birckhead B, Krishnamurthy P, et al. Durability of the Treatment Effects of an 8-Week Self-administered Home-Based Virtual Reality Program for Chronic Low Back Pain: 6-Month Follow-up Study of a Randomized Clinical Trial. *J Med Internet Res.* 2022;24(5):e37480. PMID: 35612905
7. 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.* 2023;24(10):1200-03. PMID: 37220894
8. Maddox T, Garcia H, Ffrench K, et al. In-home virtual reality program for chronic low back pain: durability of a randomized, placebo-controlled clinical trial to 18 months post-treatment. *Reg Anesth Pain Med.* 2024;49(5):373-75. PMID: 36427904

CODES

NOTE: Not all digital health products will have a specific code. These are examples of codes that may be relevant.

Codes	Number	Description
CPT	98978	Remote therapeutic monitoring (eg, therapy adherence, therapy response); device(s) supply with scheduled (eg, daily) recording(s) and/or programmed alert(s) transmission to monitor cognitive behavioral therapy, each 30 days
	99199	Unlisted special service, procedure or report [when specified as a digital health management software application]
HCPCS	A9291	Prescription digital behavioral therapy, FDA cleared, per course of treatment
	E1399	Durable medical equipment, miscellaneous [when specified as a digital health management software application]
	E1905	Virtual reality cognitive behavioral therapy device (cbt), including pre-programmed therapy software
	G0552	Supply of digital mental health treatment device and initial education and onboarding, per course of treatment that augments a behavioral therapy plan
	G0553	First 20 minutes of monthly treatment management services directly related to the patient's therapeutic use of the digital mental health treatment (dmht) device that augments a behavioral therapy plan, physician/other qualified health care professional time reviewing information related to the use of the dmht device, including patient observations and patient specific inputs in a calendar month and requiring at least one interactive communication with the patient/caregiver during the calendar month

Codes	Number	Description
	G0554	Each additional 20 minutes of monthly treatment management services directly related to the patient's therapeutic use of the digital mental health treatment (dmht) device that augments a behavioral therapy plan, physician/other qualified health care professional time reviewing data generated from the dmht device from patient observations and patient specific inputs in a calendar month and requiring at least one interactive communication with the patient/caregiver during the calendar month

Date of Origin: *March 2023*