Anthem

Medical Policy

Subject: Virtual Reality-Assisted Therapy Systems
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Description/Scope

This document addresses the use of virtual reality systems in the management of pain, cognitive or motor rehabilitation, treatment of procedural anxiety, promotion of weight control, or other medical purposes. Several virtual reality-assisted therapy systems are being investigated for medical use including, but not limited to: RelieVRx (formerly EaseVRx) and SootheVR. Over-the-counter virtual reality systems such as the Oculus headset have also been proposed for therapeutic uses.

Position Statement

Investigational and Not Medically Necessary:

Use of virtual reality systems for screening, diagnosis, or treatment of a health condition is considered**investigational and not medically necessary** for all indications.

Rationale

Virtual reality (VR) systems (for example, RelieVRx™ (formerly EaseVRx) and SootheVR) use a computer capable of providing interactive 3-dimensional (3-D) visualization, a controller for interaction with the virtual environment, a position tracker, and a head-mounted, immersive display to deliver output. VR-assisted therapy systems have been proposed as a tool for the non-pharmacological management of pain, in cognitive, motor, and orthopedic rehabilitation, and in the management of procedural anxiety and weight control.

Pain Management

Fouks and colleagues (2022) published the results of a prospective, open-label, randomized controlled trial evaluating the effectiveness of VR as a distraction technique in the management of acute pain during operative hysteroscopy in the outpatient setting. The study involved 82 individuals randomly assigned to undergo operative hysteroscopy either with the use of VR (n=44, VR group) or with standard treatment (n=38, control group). The VR group viewed VR content administered for the duration of the procedure through the SootheVR system (AppliedVR, Van Nuys, CA). SootheVR is a clinically oriented therapeutic VR platform. Neither analgesia nor anesthesia was administered to either group. The primary outcome was the assessment of intraoperative pain. A pre- and post-operative pain assessment was conducted using a numeric scale from 0 to 10. A pre-procedural anxiety score was collected using the State-Trait Anxiety Inventory where 0 to 4 represent a range from “not at all anxious” to “very much so anxious”. Objective measurements included pulse rate and respiratory rate. There were no significant differences in pre-procedural anxiety ($p=0.26$) or anticipated pain between groups ($p=0.94$). Likewise, there were no statistically significant differences between reported pain scores during the procedure for either group ($p=0.67$). Post-operatively, participants in the VR group reported lower rates of pain than the control group ($p=0.04$) and comparable scores for the descriptor “feel comfortable” ($p=0.925$). While neither intraoperative heart rate nor respiratory rate differed between groups ($p=0.77$ and $p=0.7$, respectively), the increase in heart rate from the pre-procedural to the intraprocedural measurement was greater in the VR group ($p=0.01$). The gynecologist performing the procedure reported that the operative intervention was almost stopped due to pain reported by the participant in 7 (18.2%) control group procedures and 2 (4.5%) VR group procedures ($p=0.04$). The results of this study did not demonstrate significant differences in pain scores as perceived by participants in the VR group compared to the standard of care group during the procedure. However, the use of the VR system appears to provide some benefit as a distraction technique for some individuals undergoing outpatient interventional hysteroscopy. The authors note that this study may be subject to a selection bias as individuals elect to undergo hysteroscopy with or without anesthesia. Individuals who are less anxious and resistant to pain may have been more likely to agree to participate in this intervention.

In an industry-sponsored and led double-blind, randomized, sham-controlled trial, Garcia and colleagues (2021) evaluated a self-administered behavioral skills-based VR program in community-based individuals with self-reported chronic low back pain. The participants consisted of a national online convenience sample recruited remotely through various chronic pain organizations and social media advertisements. Inclusion criteria consisted of self-reported nonmalignant low back pain with a duration of 6 months or more and with an average pain intensity of 4 or more on a scale with a maximum rating of 10. Participants (n=179) were randomized 1:1 to receive either a 56-day, pain relief, skills-based VR program using the EaseVRx system (AppliedVR, Inc., Van Nuys, CA) or a 56-day, 2-dimensional (2-D) control sham VR program (Sham VR). Both treatment groups used the commercially available Pico G2 4K all-in-one head-mounted VR device (Pico Immersive, San Francisco, CA). The EaseVRx system presented an immersive pain management program addressing pain management education and self-help skills such relaxation, mindfulness, and distraction techniques. The Sham VR group viewed 2-dimensional nature images with neutral music as background. Results were collected through on-line surveys that included use of the Defense and Veterans Pain Rating Scale (DVPRS) to measure perceived pain intensity. Participants were paid for each survey they returned. Participants could also receive a gift VR headset if they completed 16 surveys. No significant between-group differences were found for baseline variables or treatment engagement. User satisfaction ratings were higher for the EaseVRx group than the Sham VR group ($p<0.001$). Though there was a significant improvement over time for both treatment groups ($p<0.001$), there was a significant treatment effect favoring EaseVRx for all primary outcomes which included a change in average pain intensity ($p=0.001$) and pain-related interference with activity ($p=0.004$), stress ($p=0.009$), mood ($p=0.005$), and sleep ($p=0.004$). Between-group Cohen’s d effect sizes ranged from 0.40 to 0.49 indicating that the differences were moderately clinically significant. For EaseVRx, pre-post effect sizes ranged from 1.17 to 1.3 and met moderate to substantial definitions of clinical importance for all primary outcomes. Of note, the Sham VR group effect size also met the definition of moderate clinical importance for all primary outcomes except average pain intensity (minimal clinical importance). Secondary outcome measurements included a between-group comparison of physical function and sleep disturbance measured using the National Institute of Health Physical Function and Sleep Disturbance (PROMIS) tool. Both treatment groups demonstrated a significant improvement in physical function and sleep disturbance throughout the study. However, there was a significant treatment effect favoring the EaseVRx group for both outcomes ($p=0.022$ and $p=0.013$, respectively). For other secondary outcomes, neither group achieved a statistically significant change in pain catastrophizing, pain self-efficacy, pain acceptance, or prescription opioid use, but

there was a reduction in the use of over-the-counter analgesics in the EaseVRx group (p<0.01). The EaseVRx system had high user satisfaction ratings and participants experienced clinically meaningful symptom reduction for average pain intensity and pain-related interference with activity, mood, and stress compared to Sham VR. However, apart from device use metrics, all data were self-reported from a convenience sample of participants. The investigators were not able to confirm the reported pain diagnoses, physical function, or medication use. Additionally, the study was not designed to show whether use of VR to present pain management education is more effective than other methods, such as written, audio, or 2-dimensional visual presentation of this material. Evidence in the form of well-designed trials is needed to confirm the characteristics of those who would benefit from this therapy system and the clinical significance and durability of the effects of this strategy on chronic low back pain management.

In 2022, Garcia and colleagues published 3- and 6-month follow-up results of the 8-week trial described above. These follow up studies continued to be conducted remotely and involved no in-person procedures. The sample size in the previous study excluded those who did not receive a virtual reality device (n=3), returned an unopened device (n=1), and those who withdrew (n=5). The posttreatment survey completion rates were 83% (n=156) for 1 month, 82% (n=155) for 2 months, 85% (n=159) for 3 months, and 74% (n=139) for 6 months. In the 3-month follow up, the mean pain intensity improvement for the EaseVRx group was 30.3% (median=25.9%) and 15.8% (median=10.7%) for the Sham VR group. The mean physical function improvement was 8.9% (median=9.2%) for the EaseVRx group and 5.2% (median=5.1%) for the Sham VR group. In the 6-month follow up for pain intensity, 52.1% (37/71) of the EaseVRx group and 25% (17/68) of the Sham VR group achieved the threshold for moderate clinical meaningfulness (> 30%) and 38% (27/71) and 13.2% (9/68) for substantial clinical meaningfulness (≥ 50%). For physical function, 12.7% (9/71) of the EaseVRx group and 4.4% (3/68) of the Sham VR group reached a moderate clinical meaningfulness. The authors concluded that a therapeutic virtual reality program for chronic low back pain has clinically meaningful and enduring impacts and supports continued research in virtual reality treatment efficacy with diverse samples. These follow-up studies share the limitations of the initial trial, including the inability to validate diagnoses, physical function, or medication use, and the lack of comparison to other methods of providing pain management education.

Wong and colleagues (2021) reported the results of an open-label, randomized controlled trial evaluating the effects of VR on pain in pregnant individuals in labor. The study involved 40 participants with a pain score of 4 to 7, having regular contractions at least every 5 minutes. Individuals were excluded if they had received any pharmacologic pain relief or experienced pain not due to contractions. Participants randomized to the VR group (n=21) received up to 30 minutes of either a labor-specific visualization developed by AppliedVR or another program of their choice. The control group (n=19) did not receive any additional intervention other than standard of care. The primary outcome was the difference from pre- to post-intervention pain score. Post-intervention pain scores were obtained at 2- and 4-hours after the intervention. Following the intervention period, those assigned to the control arm had a statistically significant increase in pain of 0.58 and those in the VR group a reduction in pain of 0.52 (p=0.03). There was also a difference in the proportion of individuals who had a minimum clinically important difference in pain (0% control group and 23.8% VR group; p=0.049). Those in the control group were more likely to use position changes during the intervention (p=0.002) and on average had a higher heart rate following the intervention than those in the VR group (p=0.01). There was no significant difference in the time to first pain treatment between groups (p=0.27). The results indicate that VR could be an effective pain reduction strategy for some laboring individuals compared to no intervention. However, the majority of individuals in the VR group did not achieve a minimum clinically important difference in pain and there were no significant differences in the time to first pain treatment between groups. Additionally, it remains unclear if the visual and auditory isolation of the VR system or this labor-specific VR protocol yielded these outcomes. Further evidence is needed to clarify the optimal features of the VR strategy and the characteristics of individuals who are most likely to benefit from its use.

Darnall and colleagues (2020) published the results of a pilot study investigating feasibility and user satisfaction for a self-administered, home-based, VR cognitive behavioral therapy (CBT) program as an intervention for chronic pain. Secondary aims of the study were to determine the preliminary effects of the VR program on average pain intensity, pain-related interference with activity, stress, mood, and sleep, and its impact on pain-related cognition and self-efficacy. The study involved a convenience sample of 97 participants with self-reported, chronic, nonmalignant low back pain or fibromyalgia with chronic pain for a duration longer than 6 months. Participants were randomly assigned to either a 21-day, skills-based VR software program for chronic pain developed by AppliedVR and implemented using the Oculus Go virtual reality headset (Facebook Technologies, LLC, Menlo Park, CA), or the audio only version of the 21-day VR program. Of those that were randomized, only 74 participants (VR group=35, audio group=39) completed baseline measures and at least one of the eight follow-up surveys during the 21-day treatment phase. High satisfaction rates were reported for both the VR (n=21/25, 84%) and audio only groups (n=21/29, 72%). Individual-level session launch data was not recorded for the audio only group limiting the description of engagement. Results for the VR group indicate that participants launched an average of 34.4 sessions. For the VR group, there was a significant improvement in each of the five pain indicators (p<0.001). The effect sizes for the VR group met or exceeded the > 30% threshold of clinical importance for all indicators except pain-related mood interference which met the threshold for substantial clinical importance of > 50%. There was an improvement in indicators for both groups over time. Significant time and group effects were found in favor of the VR group for average pain intensity (p=0.04), pain-related inference with activity (p=0.005), sleep (p<0.001), mood (p<0.001), and stress (p=0.003). Both groups demonstrated improvements in pain catastrophizing and self-efficacy over time, and no significant between-group differences were noted. While high engagement, satisfaction, and a significant reduction in pain outcomes over the course of the 21-day treatment period indicate that this VR intervention may have the potential to assist in the management of chronic pain in this group of individuals, the study had several limitations. Although high satisfaction and engagement were reported based on the analyzed sample, only 25 of 35 participants in the VR group and 29 of 39 participants in the audio only group completed the day 22 survey at the end of the treatment period. With the exception of engagement data in the VR group, all data were self-reported from a convenience sample of participants recruited through web-based social media advertisements and a digital health community. There was no confirmation of diagnosis, duration of pain, or medication use. While the pain medication or complimentary therapies were not assessed, they were also not controlled and represent a major limitation. The analytic data set included only those participants who completed at least one study survey, but not all. Additionally, although participants were randomly assigned to an intervention group, blinding posed a challenge due to the modality used for the comparison condition.

Tejera and colleagues (2020) conducted a single-blinded, randomized controlled trial evaluating the effects of VR on pain intensity, conditioned pain modulation, temporal summation, and functional and somatosensory outcomes in individuals with non-specific chronic neck pain (NS-CNP). A total of 44 individuals with NS-CNP were randomized to receive VR treatment or traditional neck exercises only. The VR intervention consisted of 2 treatment sessions per week, for 4 weeks for a total of 8 sessions. Two VR programs were delivered through a VR headset. The VR programs, of a first and second degree of difficulty, presented individuals with immersive environments in which they were required to make a variety of neck movements. Both the control and VR interventions started with the aid of a physical therapist. Gradually, the physical therapist was removed from the VR intervention. Participants in the control group received exercise instruction delivered by a physical therapist for the entire length of treatment. Measurements were collected at baseline, immediately after intervention, and at 1 and 3 months after intervention. The main primary outcomes were pain intensity, conditioned pain modulation and temporal summation. Significant effects were shown for time factor (p<0.05) but not for group and time interaction for pain intensity, rotation range of motion, Neck Disability Index, pain catastrophizing, fear-avoidance beliefs, left side pressure pain threshold, and anxiety. There were no significant differences across time or between groups for conditioned pain modulation, temporal summation, pressure pain threshold, flexo-extension, and lateral-flexion range of motion. There

was a statistically significant difference for time factor ($p<0.01$) and group and time interaction for kinesiophobia ($p=0.01$). Kinesiophobia was the only outcome that showed differences between VR and exercise alone at 3 months after intervention. The use of complimentary pain management was not controlled or assessed and represents a major limitation in this study. Based on these results, it is unclear if the addition of VR therapy provides an enhanced benefit to individuals with NS-CNP over traditional exercise therapy.

Bani Mohammed and colleagues (2019) published the results of a randomized controlled trial assessing the effectiveness of immersive VR distraction technology in reducing pain and anxiety among individuals with breast cancer. Participants (n=80) were randomly assigned to receive usual care including the use of pharmacological interventions or usual care plus immersive VR. The individuals in the VR group completed a 15-minute VR session using a non-specific virtual environment. Assessments were completed just before administering morphine and 15 minutes after the peak time effect of administration in both groups. There was a significant difference in pain scores post-intervention between the two groups favoring the VR intervention ($p<0.001$). There was also a significant difference in anxiety levels post-intervention favoring the VR intervention ($p<0.001$). There was a significant difference in the mean pre- and post-intervention anxiety levels and pain scores for the intervention group and the control group. The results indicate that immersive VR may help reduce pain and anxiety among this group of individuals. Some limitations of this study are that the VR intervention was administered for a single, short session, outcomes were evaluated at a single timepoint post-intervention, and other than morphine, other forms of pain management were not recorded or controlled. Additional evidence is needed to confirm the long-term impact and sustained effects of this intervention on pain and anxiety in individuals with breast cancer.

Spiegel and colleagues (2019) reported the results of a randomized comparative effectiveness trial evaluating the impact of on-demand VR compared to 2-D television programming on pain in hospitalized individuals. The study involved 120 participants with an average pain score ≥ 3 out of a total of 10 points. Participants in the VR group (n=61) received a library of 21 VR experiences (produced by AppliedVR) administered using the Samsung Gear Oculus headset (Ridgefield Park, NJ). Participants were advised to complete 10-minute sessions, 3 times daily, and as needed for breakthrough pain over 48-hours. Individuals in the control group (n=59) viewed specialized television programming designed to promote health and wellness for 10-minute sessions, 3 times daily, and as needed for breakthrough pain. Use of the study interventions was not standardized per protocol which allowed participants to use their assigned intervention on their own schedule. Participants were allowed have pain managed according to usual practice and the protocol did not specify on whether to substitute VR for opioids or any other analgesic therapy. The primary outcome was self-reported pain using a numeric rating scale, as recorded by nursing staff during usual care. Pre- and post-intervention pain scores were compared immediately after the initial treatment and after 48 and 72 hours. The mean within-subject difference in immediate pre- and post-intervention pain scores was larger in the VR group (-1.72 points; standard deviation [SD] 3.56) than in the control group (-0.46 points; SD 3.01). The difference was significant in favor of VR ($p<0.04$). When limited to the subgroup of participants with severe baseline pain (defined as ≥ 7 points), the effect of VR was more pronounced than the control intervention (-3.04 points, SD 3.75 compared to -0.93 points, SD 2.16, respectively; $p=0.02$). After adjusting for age, gender, and type of pain using linear regression analysis, exposure to VR conferred a 1.17-point incremental reduction in pain compared to the control intervention ($p=0.048$). Age was also a significant predictor, with each additional 10-years of age predicting a 0.6-point reduction in pain ($p=0.001$). In regression analyses adjusting for pre-intervention pain, time, age, gender, and type of pain, the VR intervention yielded a 0.59 ($p=0.03$) and 0.56 ($p=0.04$) point incremental reduction in pain compared to the control intervention at the 48- and 72-hour post-intervention periods, respectively. There was no difference in the quantity of opioids consumed between groups in either the pre- or post-intervention periods. The results of this study support that there may be some promise to the use of VR as an adjunctive therapy to complement traditional pain management protocols in hospitalized individuals. However, although the effect of VR was statistically significant, the absolute reduction in pain scores was relatively small and below the threshold of minimal clinical importance. The authors also note that despite evaluating 591 individuals for participation, only 120 enrolled and completed the protocol. This emphasizes that many individuals are either ineligible or uninterested in using this novel health technology while hospitalized.

Tashjian and colleagues (2017) reported the results of a non-randomized, comparative cohort study evaluating the impact of a one-time, 3-D VR intervention compared to a 2-D distraction video on pain in hospitalized individuals. The study involved 100 individuals with a pain score of ≥ 3 on a 10-point scale and without nausea, vomiting, dementia, motion sickness, stroke, seizure, and epilepsy. Approximately two thirds of the individuals who met criteria for inclusion were unwilling to try the VR technology. Participants in the VR cohort (n=50) received a 15-minute VR experience called Pain RelieVR (AppliedVR, Van Nuys, CA), a 3-D immersive experience specifically designed to treat pain in individuals with limited mobility. The experience was delivered using the Samsung Gear Oculus headset fitted with a Samsung Galaxy S7 smart phone. Individuals in the control group viewed a 15-minute 2-D high-definition video on a 14-inch computer screen. The proportion of individuals admitted for pulmonary reasons was higher in the control group while the number of individuals admitted for orthopedic reasons was higher in the VR group. There was a significant reduction in pain scores for both the VR group and the control group. The mean pain reduction in the VR cohort (-1.3 points) was greater than in the control group (-0.6; $p=0.008$). A total of 35 individuals (65%) in the VR cohort achieved a pain response compared to 40% of controls ($p=0.01$;). The results indicate that VR may be effective as an adjunct to traditional pain management in hospitalized individuals. However, the findings are limited by a lack of randomization, the short duration of the intervention, and a lack of follow-up to evaluate if there are any long-term effects. Additionally, several variables that could impact the outcome, including the use of pain medication or complimentary pain management therapies, were not addressed.

Garcia-Palacios and colleagues (2015) published the results of a randomized controlled trial evaluating the preliminary efficacy of VR as an adjunct to activity management in individuals with fibromyalgia syndrome (FMS). The study included 61 individuals diagnosed with FMS randomly assigned to receive VR treatment or treatment as usual. A total of 9 individuals dropped out prior to treatment allocation because they considered the treatment sessions too time consuming. The VR treatment was a group CBT program for FMS supported by VR as an adjunct to the activity pacing component of traditional interventions. The VR treatment was administered as 2-hour group sessions, twice a week, for a total of 6 sessions. Participants in the VR group were told not to modify medication while participating, and none made medication alterations for the duration of the study. The usual care group was not given the same instruction. There were no significant between group differences in baseline characteristics. Regarding the primary outcome measure, participants in the VR group reported a significant reduction in the Fibromyalgia Impact Questionnaire (FIQ) score compared with the control group ($p<0.01$). Secondary outcome measures were pain intensity and interference, depression and quality of life. The improvement was significant in favor of the VR strategy with regard to perceived quality of life ($p<0.001$) task persistence ($p<0.01$) and exercise ($p<0.02$). However, there were no differences in pain intensity ($p=0.675$), interference ($p=0.145$), or depression ($p=0.205$) and several of the coping strategies (guarding, resting, asking for assistance, and relaxation). Participants reported high satisfaction with the VR component. The findings suggest that VR treatment had a positive effect on reducing the impact of FMS on the life of participants as measured by the FIQ.

In 2021, the FDA granted a De Novo classification as a Class II medical device to the EaseVRx system. The EaseVRx system is a prescription-use, immersive, virtual reality system intended for use at home to provide adjunctive treatment for the reduction of pain and pain-interference associated with chronic lower back pain. AppliedVR renamed EaseVRx to RelieVRx in March 2022.

In summary, published evidence for VR systems as a pain management modality consists primarily of small short-term studies with methodologic limitations. These include convenience sampling, lack of controls on concurrent treatments, lack of randomization or control groups, and use of subjective measures. Key questions remain about the characteristics of VR system protocols that elicit a

desired response and the characteristics of individuals that predict an enhanced response to VR therapy. Larger randomized controlled trials with longer follow-up are needed before conclusions can be made about the effectiveness of VR for pain management.

Cognitive, Motor, and Orthopedic Rehabilitation

Gianola and colleages (2020) conducted a randomized controlled trial assessing the efficacy of an early VR-based rehabilitation program compared to traditional rehabilitation provided by physical therapists after primary total knee arthroplasty (TKA). The study involved 85 individuals, randomized 3 to 4 days after TKA, to receive an inpatient VR-based rehabilitation program (n=44) or traditional rehabilitation (n=41). Specifics regarding the VR-based rehabilitation conditions and devices used were not described. Participants in both groups received 60-minute sessions daily until discharge (approximately 10 days after surgery). The primary outcome was the effect on pain intensity. Secondary outcomes included knee disability, health related quality of life, global perceived effect, functional independence, medication use, isometric strength of quadriceps and hamstrings, flexion range of motion, and ability to perform proprioception exercises. Outcomes were assessed at baseline and at discharge. A total of 11 participants (12.9%) dropped out of the study. Of those 11 participants, 9 were participants from the VR group that declined treatment because they felt uncomfortable with the device. There was no statistically significant pain reduction between groups ($p=0.266$) or in any other outcome except for global proprioception where there was a statistically significant improvement in favor of the VR group ($p=0.002$). The results indicate that VR-based rehabilitation enhanced proprioception in this group of individuals with TKA. However, it did not result in improved pain control or other functional outcomes when compared to traditional rehabilitation.

Feng and colleagues (2019) published the results of a single-blinded, randomized controlled study investigating the effects of VR technology on balance and gait in individuals with Parkinson's disease (PD). The study involved 28 hospitalized individuals with PD diagnosed according to the United Kingdom Brain Bank Criteria. Participants were between age 50 and 70 years old and needed to have an improved Hoehn-Yahr classification grade 2.5 to 4. This score indicates that the individual has balance dysfunction but can walk independently. Individuals were excluded from participation if they had other causes of tremor, bone and joint diseases, serious diseases affecting organ function, or visual or hearing disorders. Participants were randomly assigned to receive either VR training in the experimental group (n=14) or conventional physical therapy in the control group (n=14). The VR system used in this study was not described. Participants performed 45-minute treatment sessions, 5 days a week, for 12 weeks. Treatment was continued in the outpatient setting if participants met criteria for hospital discharge. Individuals were assessed pre- and post-rehabilitation using the Berg Balance Scale (BBS), Timed Up and Go Test (TUGT, a measurement of dynamic balance ability), the third part of the Unified Parkinson's Disease Rating Scale (UPDRS3), and the Functional Gait Assessment. After treatment, BBS, TUGT, and FGA scores improved significantly in both groups and the UPDRS3 improved in the experimental group ($p<0.05$). The control group showed no significant difference between the pre- and post-rehabilitation data on the UPDRS3. Scores on the BBS, TUGT, UPDRS3, and FGA were better for the experimental group than those in the control group ($p<0.05$). The results of this study indicate that VR technology is a promising strategy for the rehabilitation of gait, balance, and mobility in this group of individuals with PD compared to conventional therapy. Further study evaluating the long-term impact of this strategy in a larger sample of individuals with PD is needed to confirm these findings.

Schuster-Amft and colleagues (2018) published the results of a multicenter, randomized controlled trial directly evaluating the effects of virtual reality-based training on upper-limb motor function in individuals with a previous stroke. The study involved 54 eligible participants who were at least 6 months after the onset of their first-ever stroke and had a persistent motor deficit of the arm and hand. Participants were randomly assigned to receive VR-based training (n=22) or conventional therapy (n=32). Conventional therapy consisted of physical and occupational therapy. VR-based training was delivered using the Bi-Manu Trainer (Reha-Stim Medtec Inc., New York, NY), a game-based VR training system that was specifically developed for individuals with upper-limb sensorimotor impairments. Both conventional therapy and VR-based training were delivered in 45-minute training sessions 4 times per week over a 4-week period. Outcomes were assessed twice at baseline, once during intervention, and twice after the intervention up to the 2-month follow-up. While both the VR and control groups showed significant improvement with their treatment, there was no significant between-group difference in the primary outcome, improvement in dexterity from pre-intervention (T0) to completion of intervention (T2), as assessed by the Box and Block Test (control group: $p=0.02$, VR group: $p=0.003$). At the 2-month follow-up (FU), improvement in dexterity remained significant for the control group ($p=0.001$). While statistically significant, these changes did not meet criteria for clinically relevant improvement. The secondary outcome was the measurement of bilateral arm function assessed using the Chedoke-McMaster Arm and Hand Activity Inventory (CAHAI). Participants in both groups demonstrated significant improvements in CAHAI scores from T0 to FU (control group: $p=0.001$, VR group: $p=0.002$) with no between-group differences. The results indicate that the use of VR-based training did not confer a significant difference in outcomes over conventional therapy. However, the authors note that individuals who were less impaired at baseline (Box and Block test score of 18 to 72) showed higher improvements in favor of the experimental group. Future studies evaluating the impact of this technology in that subgroup are necessary to support its benefit over conventional therapy.

In and colleagues (2016) published the results of a randomized controlled trial investigating the effects of virtual reality reflection therapy (VRRT) on postural balance and gait ability in individuals with chronic stroke admitted to a hospital setting. The study involved participants who had suffered a stroke at least 6 months prior to participation, scored over 21 on the Mini Mental State Examination (MMSE), had a Brunnstrom score (a staging measurement of motor recovery) between stage I and IV, had no apraxia or hemineglect, and had no orthopedic or neurological conditions in their lower extremities such as fractures or digital neuropathy. Participants (n=30) were randomly assigned to receive either VRRT or a VRRT placebo program for 30 minutes along with an individualized conventional rehabilitation program for 30 minutes 5 times a week for 4 weeks. During the 4-week intervention period, 5 participants dropped out of the study leaving a total of 13 participants in the VRRT group and 12 participants in the control group. Unlike immersive VR systems, individuals in the VRRT group inserted an affected lower limb into a VRRT box through which a mirrored live recording of their unaffected limb was displayed on an incorporated monitor. Outcome measures included the BBS, the Functional Reaching Test (FRT), and the TUGT, postural sway (a measurement of static balance ability) and the 10-meter walking velocity (10 mWV) test for gait ability. While both the VRRT and control group demonstrated significant improvements in BBS scores, the VRRT group scores were statistically better ($p<0.05$) than the control group. Confidence intervals overlapped for the VRRT and control group in every measure. The VRRT group showed significant improvements compared to baseline ($p<0.05$) in the FRT, TUG, and 10 mWV measurements, but the control group did not. Regarding static balance ability measured by the changes of postural sway distance, all conditions with eyes open, and medial-lateral sway with eyes closed the VRRT group showed significant improvement ($p<0.05$), but the control group did not. Additionally, while both groups showed improvements in the anterior-posterior sway and medial-lateral sway distance with eyes open, the VRRT group showed significant improvement compared to the control group. The results indicate that VRRT could lead to improvements in balance, range of motion, functional activity, dynamic balance, and flexibility. Larger controlled trials elucidating the impact and delivery of this intervention are necessary to understand how individuals benefit from its use compared to existing modalities and if benefits are sustained. Since the VRRT intervention used in this trial is based on the principles of mirror therapy, it would be important to compare VRRT to conventional mirror therapy.

Duque and colleagues conducted a randomized controlled study evaluating the effects of a virtual reality system designed to assess balance and provide balance training in community-dwelling older individuals with a known history of falls. The study involved 60 participants 65 years of age or older who had experienced at least one fall in the 6 months prior to assessment and showed poor

performance in their balance. Participants were randomly assigned to a usual care (n=30) or VR training (n=30) using the Balance Rehabilitation Unit (BRU). The BRU is a validated method used to assess and train balance using 3-D virtual-reality goggles. The assessment component of the BRU (posturography) evaluates postural control responses to different types of visual and visual-vestibular stimulation on standing surfaces of different firmness. Both groups received a posturography assessment at baseline and at 9 months after intervention. Participants in the BRU-training group were scheduled for 2 sessions of balance training per week for 6 weeks under the guidance of a physiotherapist. Each training sessions lasted 30 minutes. Change in balance parameters were assessed in the BRU-training group at the end of the 6-week training program. Adherence to the BRU-training program was 97%. Balance parameters were significantly improved in the BRU-training group ($p<0.01$). Both groups showed a statistically significant reduction in the incidence of falls ($p<0.05$). The average number of falls in the prior 6 months for VR group fell from 3.7 ± 1.3 before training to 1.1 ± 0.7 after training. The average number of falls in the prior 6 months for the control group fell from 3.8 ± 2.0 before their course of regular care to 2.0 ± 0.2 afterwards. The difference between the VR and usual care groups in the post-study average number of falls was statistically significant. Some components of balance that were improved by BRU training showed a return to pre-training levels after 9 months post-training. The results indicate the BRU training may be a promising balance training strategy for community-dwelling older adults with a history of falls, but the benefits may not be sustained. As this study was not powered to assess the intervention's effect on fall prevention, larger controlled trials are needed to evaluate the impact of this strategy on fall outcomes in this group of individuals.

Procedural Anxiety and Weight Management

Hendricks and colleagues (2020) reported on a randomized controlled trial investigating the effects of immersive virtual reality treatment on perceptions of anxiety compared to a tabled-based control treatment in individuals undergoing a sternotomy for the first time. The study involved 20 individuals randomly assigned to either a VR group or control intervention. The VR intervention was a game module developed by AppliedVR using a Samsung Gear Oculus VR headset fitted with a Samsung Galaxy S7 smart phone to deliver VR content. The control intervention was a tablet-based game application with comparable audio, visual, and tactile components. Both interventions were delivered for a total of 20 minutes. Changes in self-reported anxiety measures using the State-Trait Anxiety Inventory pre- and post-intervention were the key outcome variables. Individuals in the VR group experienced significant reductions in feeling tense and strained, and significant improvements in feeling calm when compared to the control group ($p<0.05$). They also experienced significant reductions in feeling strained, upset, and tense when compared with their own self-reported anxiety measure pre- and post-intervention ($p<0.05$). Individuals in the control group had no significant changes in these categories. However, those in the control group reported a significant increase in feeling steady ($p=0.02$) while those in the VR group reported significant decreases in feeling steady ($p=0.01$). Those in the control group also reported a significant reduction in feeling frightened post-intervention ($p=0.04$). When evaluating the impact of VR on clinically relevant outcomes, the investigators found that the administration of anxiolytics was slightly lower between the end of the VR session and the induction for surgery, though not significantly ($p=0.08$). The results of this study suggest that, in this preoperative environment, non-immersive technologies have a modest impact on anxiety states compared to baseline while VR technologies have a greater impact on a broader range of anxiety states compared to baseline. Larger, well-controlled studies are needed to provide objective data as well as to confirm the outcomes and parameters of the VR intervention including the duration of treatment and optimization of the VR environment.

Eijlers and colleagues (2019) published the results of a randomized controlled single-blind trial investigating VR exposure as a preparation tool for elective day surgery in children and its effects on anxiety, pain, and emergence delirium. The study involved 200 children between 4 and 12 years of age undergoing elective maxillofacial, dental, or ear-nose-throat day surgery under general anesthesia. Participants were randomly assigned to receive either VR exposure plus usual care or usual care alone. On the day of surgery, those in the VR group received a VR intervention designed to familiarize them with a realistic, child-friendly, immersive virtual version of the surgical environment and procedures. The intervention was presented to the child for approximately 15 minutes using the HTC Vive (HTC Corporation, Xindian, New Taipei, Taiwan) head-mounted display. The primary outcome was anxiety during induction of anesthesia measured using the modified Yale Pre-operative Anxiety Scale (mYPAS). Secondary outcomes were self-reported anxiety, self-reported and observed pain, emergence delirium, need for rescue analgesia and parental anxiety. Of those randomized, 9 children were excluded because of accidental unblinding, noncompliance, lack of data collection, or cancelled surgery. A total of 191 participants were included in the analyses (VR group: n=94, control group: n=97). Outcomes were measured at 5 timepoints across the surgical care continuum from hospital admission (T1) and ending at home (T5). Regarding child anxiety, mYPAS scores were similar between groups at baseline (T1, $p=0.697$), in the holding area (T2, $p=0.765$), and during induction of anesthesia (T3, $p=0.862$). Self-reported anxiety scores on a visual analog scale were also similar between conditions. The only significant predictor of anxiety during induction of anesthesia was pre-operative parental state anxiety ($p=0.027$). While there were no differences in parental anxiety during induction of anesthesia between groups, higher parental anxiety levels prior to surgery were related to higher child anxiety levels during induction in the VR group. No differences in pain levels or symptoms of emergence delirium were found between groups. There were no significant predictors of postoperative pain. Overall, there was no difference in the need for rescue analgesia between groups. However, those in the VR group who underwent adenoidectomy or tonsillectomy needed significantly less frequent rescue analgesia than comparable individuals in the control group ($p=0.002$). There were also no differences in parental anxiety during induction of anesthesia between groups. The results of this study indicate that VR exposure did not have an effect on anxiety, pain, emergence delirium, or parental anxiety. Additionally, there were 21 of the 94 children in the VR group that discontinued the intervention early by taking off the headset. The majority of these children (71.4%) were 4 or 5 years of age. Future studies are needed to understand the effects of this intervention on procedures that are considered to be more painful and in a study sample with higher baseline levels of anxiety.

Shetty and colleagues (2019) conducted a randomized controlled trial assessing the impact of VR as a distraction technique on pain and anxiety during short invasive dental procedures in children aged 5 to 8 years. The study involved 120 children who scored less than 25 points on the SCARED questionnaire (a screening tool designed to evaluate the likelihood of trait anxiety) and required short invasive dental treatment. Participants were randomized to receive either usual care in the control group (n=60) or VR distraction (n=60) administered using the i-Glasses 920HR (Ilixco, Inc., Menlo Park, CA). The device occludes the visual field from the dental environment. The children viewed cartoon shows for 5 minutes prior to the start of dental treatment and were asked to relax and continue watching while the dental treatment was carried out. State anxiety levels were assessed using a revised version of the Modified Child Dental Anxiety Scale, before and after the dental procedure. Pain perceived during treatment was assessed using the Wong Baker Faces pain rating scale at the end of treatment. Salivary cortisol levels were also assessed before, during, and after the dental procedure. There was a significant reduction in pain perception ($p<0.001$) and state anxiety ($p=0.002$) in the VR group. The decrease in salivary cortisol levels was significantly greater in children using VR distraction ($p<0.001$). However, the pre-treatment cortisol level was higher in the VR group than in the controls. The results of this study showed a significant decrease in state anxiety in children using a VR distraction technique undergoing short invasive dental procedures. However, there were certain limitations related to the design of the VR intervention. Participants reported that certain sounds from the dental operator were audible at times. Future studies are needed to confirm the results and evaluate the impact of the device's design, including the effects of noise cancellation. As this was a study on participants aged 5 to 8 years and the intervention was a recorded video, additional studies are necessary to evaluate the effects of the strategy and optimization for those with different developmental needs.

Cesa and colleagues (2013) published the results of a randomized controlled trial evaluating the brief and long-term effects of VR-

enhanced experiential cognitive therapy (ECT) aimed at unlocking the negative memory of the body in individuals with morbid obesity and binge eating disorders (BED) compared with standard CBT and with an inpatient multimodal treatment (IP). Outcomes of interest included weight loss, weight loss maintenance, BED remission, and body satisfaction improvement, including psychonutritional groups, a low-calorie diet (1200 kcal/day), and physical training. Although 90 obese (body mass index [BMI] > 40 kg/m^2) individuals with BED were randomized (31 to ECT, 30 to standard CBT, and 29 to IP), 24 participants discharged themselves from the hospital prior to treatment completion (4 in ECT, 10 in standard CBT, and 10 in IP). The remaining 66 participants received either 15 sessions of ECT, 15 sessions of standard CBT, or no additional treatment over a 5-week usual care inpatient regimen. All individuals participated in an integrated, multimodal, medically managed inpatient program. Participants allocated to the ECT group received 5 weekly group sessions similar to those provided to the standard CBT group and an additional 10 biweekly VR sessions. NeuroVR open-source software was used for the VR sessions. NeuroVR includes 14 virtual environments used by the therapist during a 60-minute session with the participant. Participants were blinded to conditions. Data was captured at baseline, upon completion of inpatient treatment, and at 1 year follow-up. Weight significantly decreased for all three treatment groups ($p<0.001$) without any significant between-group differences and the number of binge eating episodes decreased to zero in all three groups. Body satisfaction improved in all groups with no difference between them. Body image concerns improved only in the ECT group. A total of 22 participants who received all sessions did not provide follow-up data (n=9 in ECT, n=6 in standard CBT, and n=7 in IP). Lost to follow-up rates and baseline characteristics of those participants were similar for each group except for a statistically significant difference in baseline binge eating episodes. Intention-to-treat (ITT) analysis revealed statistically significant weight and BMI increases at 1-year follow-up in the IP group ($p<0.001$), but not in the CBT or ECT groups. There were significant differences in weight and median BMI scores across the three groups favoring ECT, which was the only modality to further improve weight loss at 1-year follow-up. Analysis on subjective follow-up data was not calculated due to a critical lack of information from individuals that were lost to follow-up. The ECT and CBT groups were also successful in maintaining a low rate of monthly binge eating episodes. Although the results indicate that VR-based treatment may provide a potential benefit to individuals with morbid obesity and binge eating disorders, several major limitations impact their reliability. The study used a non-standard CBT program. Outcomes were imputed for the one third of participants in the ECT and IP groups that did not provide data at the 1-year follow up. Larger trials with complete data sets are needed to confirm the health outcomes associated with the use of this strategy.

The available evidence includes several trials evaluating the clinical utility of VR-assisted therapy systems for the management of pain; motor, cognitive, and orthopedic rehabilitation; procedural anxiety; and weight management. Results of these trials have been inconsistent. Available evidence does not show consistent benefits compared to existing therapies, durable benefits over long time periods, or consensus among experts regarding the optimal method, duration, and frequency of treatment delivery. Future studies are needed to understand how VR systems achieve their outcomes, the optimal form of therapy, and population characteristics that predict enhanced response to VR-assisted therapy.

Background/Overview

Virtual Reality (VR)-assisted systems use a computer capable of providing interactive three-dimensional visualization, a controller for interaction with animations, a position tracker, and a head-mounted, immersive display to deliver visual output. The position tracker monitors the position and orientation of the user in space and provides information to the computer that updates the display images in real-time. The technology allows an individual to hear and feel stimuli that corresponds with a visual image and allows interaction with the virtual world in real-time. The configuration of VR system technology can be immersive, as previously described, or non-immersive. Non-immersive VR systems display a virtual environment on a computer monitor which allows users to maintain concurrent interaction with their real-world surroundings.

VR-assisted therapy can either be passive or interactive. Interactive therapy requires an individual's input either by playing a game or completing assigned tasks. The interactive aspects of specifically designed VR programs have been suggested to help acclimate individuals with new environments, develop new skills and coping strategies, and to assist with motor and cognitive rehabilitation. Indication-specific, interactive programs using VR's entertaining effects have also been used to redirect attention away from noxious experiences and reduce discomfort. Passive VR-assisted therapy systems, either specific or non-specific to a proposed indication, can include guided imagery meant to soothe, calm, or provide distraction. As a passive technique, VR-assisted therapy has been proposed as a tool to distract individuals during painful procedures or to reduce anxiety.

Definitions

Chronic stroke: Refers to a period of recovery at least 6 months after the initial stroke event.

Kinesiophobia: A condition in which there is excessive, irrational, and debilitating fear of physical movement and activity resulting from a feeling of vulnerability due to painful injury or reinjury.

Mirror therapy: A rehabilitation modality in which patients view the unaffected side of their body in a mirror in place of the affected side while attempting movement. The illusion provides visual feedback that may facilitate therapy.

State anxiety: Situational anxiety

Temporal summation: The phenomenon in which repeated and equal-intensity noxious stimuli at a specific frequency cause an increase in the pain experienced.

Virtual reality: A computer-generated simulation of a 3-D environment that can be interacted with in a seemingly real or physical way by a person using special electronic equipment, such as a helmet or goggles with a screen inside or gloves fitted with sensors.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:
For the following procedure code, or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

CPT	
0770T	Virtual reality technology to assist therapy

0771T	Virtual reality (VR) procedural dissociation services provided by the same physician or other qualified health care professional performing the diagnostic or therapeutic service that the VR procedural dissociation supports, requiring the presence of an independent, trained observer to assist in the monitoring of the patient's level of dissociation or consciousness and physiological status; initial 15 minutes of intraservice time, patient age 5 years or older
0772T	Virtual reality (VR) procedural dissociation services provided by the same physician or other qualified health care professional performing the diagnostic or therapeutic service that the VR procedural dissociation supports, requiring the presence of an independent, trained observer to assist in the monitoring of the patient's level of dissociation or consciousness and physiological status; each additional 15 minutes of intraservice time
0773T	Virtual reality (VR) procedural dissociation services provided by a physician or other qualified health care professional other than the physician or other qualified health care professional performing the diagnostic or therapeutic service that the VR procedural dissociation supports; initial 15 minutes of intraservice time, patient age 5 years or older
0774T	Virtual reality (VR) procedural dissociation services provided by a physician or other qualified health care professional other than the physician or other qualified health care professional performing the diagnostic or therapeutic service that the VR procedural dissociation supports; each additional 15 minutes of intraservice time

HCPCS

E1399	Durable medical equipment, miscellaneous [when specified as a virtual reality-assisted therapy system]
E1905	Virtual reality cognitive behavioral therapy device (CBT), including pre-programmed therapy software [for example, RelieVRx]

ICD-10 Diagnosis

All diagnoses

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Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Revised	05/11/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated list of examples in the Description/Scope section. Removed list of examples in the Position Statement section. Updated Rationale and References sections.
	03/29/2023	Updated Coding section with 04/01/2023 HCPCS changes; added E1905.
	12/28/2022	Updated Coding section with 01/01/2023 CPT changes; added 0770T, 0771T, 0772T, 0773T, 0774T.
New	05/12/2022	MPTAC review. Initial document development.

Applicable to Commercial HMO members in California: When a medical policy states a procedure or treatment is investigational, PMGs should not approve or deny the request. Instead, please fax the request to Anthem Blue Cross Grievance and Appeals at fax # 818-234-2767 or 818-234-3824. For questions, call G&A at 1-800-365-0609 and ask to speak with the Investigational Review Nurse.

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. The member's contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.