Case Study

Innovative Reimbursement Strategy for Digital Therapeutics

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Executive Summary

Chronic pain has a substantial economic impact on the United States, costing an estimated $635 billion annually. While VR has been studied and used in various acute and chronic pain conditions for decades, headset technology has only recently become simple to use and broadly accessible, and it continues to improve. AppliedVR, a California-based company pioneering immersive virtual reality for medical therapeutic use, has achieved a remarkable feat, working with the Centers for Medicare & Medicaid Services (CMS) to include RelieVRx® in the existing benefit category for durable medical equipment (DME), the first immersive VR therapeutic to follow this strategy to tap into existing payment authority.

Home-based VR therapies like RelieVRx® hold the potential to broaden access to effective and on-demand nonpharmacologic treatments for chronic lower back pain that are durable well beyond the end of treatment. Understanding reimbursement as a combination of coding, coverage, and payment provides the context for the hurdles all new technologies must clear. Regulatory strategy may be underappreciated in terms of its influence on reimbursement success, and this was certainly key to the decisions related to code assignment and granting the benefit category as DME for RelieVRx®.

Understanding the intricacies of reimbursement codes and benefit categories is crucial for innovators seeking to navigate the evolving landscape of virtual reality in healthcare. It is essential to keep an eye on emerging trends and codes to make informed decisions and leverage opportunities for reimbursement in this rapidly evolving field. Founders of VR healthcare companies should vigilantly monitor the evolving reimbursement landscape and how changes may influence their business model. By capitalizing on these established reimbursement options and staying attuned to emerging trends, healthcare providers can harness the full potential of VR technology in delivering innovative and effective treatments.

Introduction

AppliedVR, a California-based company pioneering immersive virtual reality for medical therapeutic use, has developed an immersive therapeutic device called RelieVRx® (formerly known as EaseVRx), with an indication to reduce pain and pain interference in patients living with chronic lower back pain (CLBP). AppliedVR has achieved a remarkable feat, working with the Centers for Medicare & Medicaid Services (CMS) to include RelieVRx® in the existing benefit category for durable medical equipment (DME), the first immersive VR therapeutic to follow this strategy to tap into existing payment authority. CMS granted a unique Healthcare Common Procedure Coding System (HCPCS) Level II code for AppliedVR's RelieVRx® device and published a purchase price, paving the way for reimbursement and adoption of this novel approach to CLBP management[1]. This decision by CMS holds the potential to influence coverage policy with commercial health plans, self-insured employers, and other payors[2].

The RelieVRx® program was also the first VR-based therapeutic to receive FDA breakthrough designation and market authorization for treating CLBP[3]. The program follows a 56-session in-home treatment course, utilizing modules based on principles of cognitive behavioral therapy (CBT) and other evidence-based behavioral methods encompassing pain education, breathing techniques, pain distraction, and mindfulness. Clinical studies have demonstrated the program's ability to yield lasting effects on the severity of various pain indicators.

Chronic pain has a substantial economic impact on the United States, costing an estimated $635 billion annually[4]. The prevalence of CLBP alone affects about 8% of American adults – roughly 16 million individuals – and stands as a leading cause of disability[5]. It is widely recognized that chronic pain sufferers benefit from a biopsychosocial approach to pain management[6]; these therapeutic methods have not previously been incorporated into an easy-to-use curriculum. While VR has been studied and used in various acute and chronic pain conditions for decades[7], headset technology has only recently become simple to use and broadly accessible, and it continues to improve. The timing was right to bring these two opportunities together in the RelieVRx® therapeutic VR program.

Section 2: Trials, evidence, and outcomes of the RelieVRx® program

Treatment Group Performance

AppliedVR executed a fully decentralized, double-blind, parallel-arm, randomized, placebo-controlled trial of the 56-session self-administered behavioral skills RelieVRx® program for CLBP during the COVID-19 pandemic[8]. This study's nationwide sample consisted of individuals with moderate to severe chronic non-malignant low back pain with a duration of three months or longer. The sample of 188 participants were enrolled and randomly assigned to either the RelieVRx® immersive VR pain relief skills program or the sham VR program, both delivered via the same model VR headset. The immersive RelieVRx® program delivered theraputic VR experiences lasting 2 to 16 minutes (averaging 6 minutes per session), while the sham VR delivered 2D, non-immersive nature content with similar duration. The study's main

goals were to assess differences between the RelieVRx® and sham VR groups and to measure changes in pain intensity and pain-related interference with activity, sleep, mood and stress from baseline to the end of the treatment, and ultimately to 24-months post-treatment.

Nearly **2 out of 3 patients** (65%) in the treatment group had a clinically meaningful reduction in pain intensity

Nearly half of patients (46%) in the treatment group experienced a **71% reduction** in pain intensity on average

Results of the study showed that baseline variables and treatment engagement were similar between the two groups. The RelieVRx® group had higher user satisfaction ratings compared to the sham VR (P<.001). At the end of treatment, relative to baseline, the RelieVRx® group showed statistically significant reductions in pain intensity and pain interference with activity, sleep, mood, and stress compared to sham. In addition, the average RelieVRx® pain reduction was clinically meaningful[9-10] (i.e., at least a 2-point reduction) for average pain intensity (2.2) and pain-related interference with activity (2.6), sleep (2.5), mood (2.5), and stress (2.6). The RelieVRx® group also demonstrated superiority over the sham VR in terms of Physical Function and Sleep Disturbance reductions from baseline to end-of-treatment. Participants were encouraged to contact study staff with any adverse events experienced during treatment; however, no participants contacted study staff to report adverse events of any type, including nausea and motion sickness.

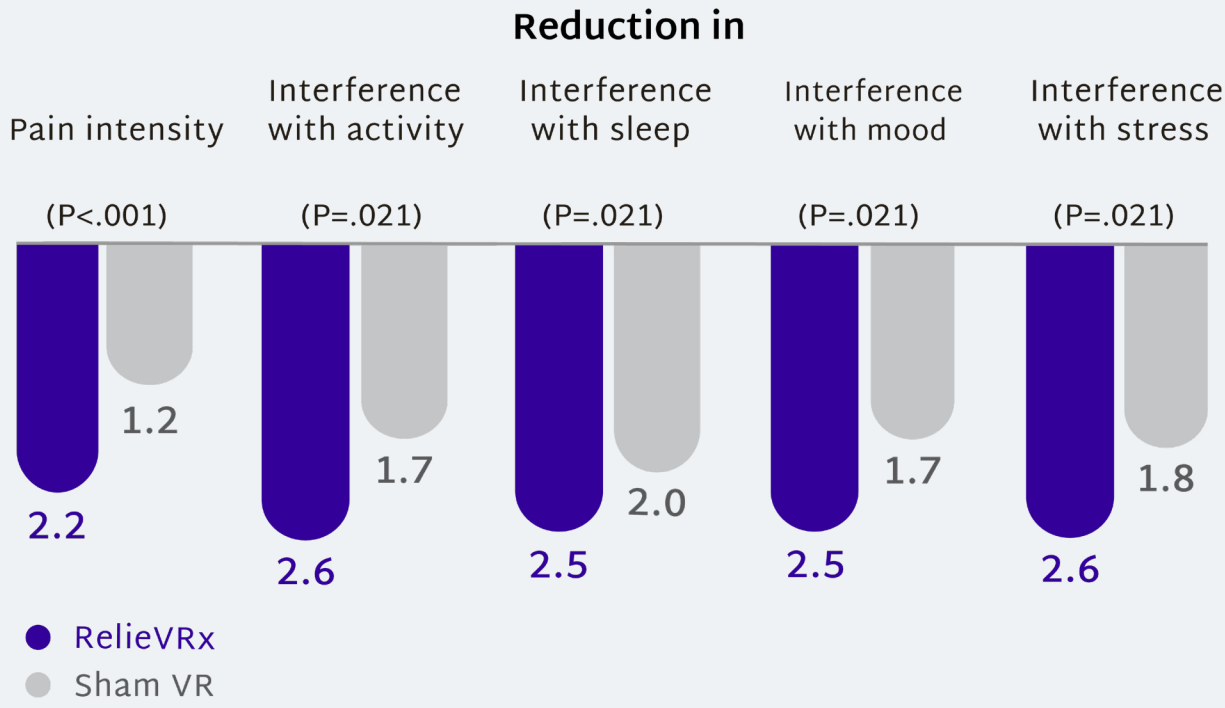
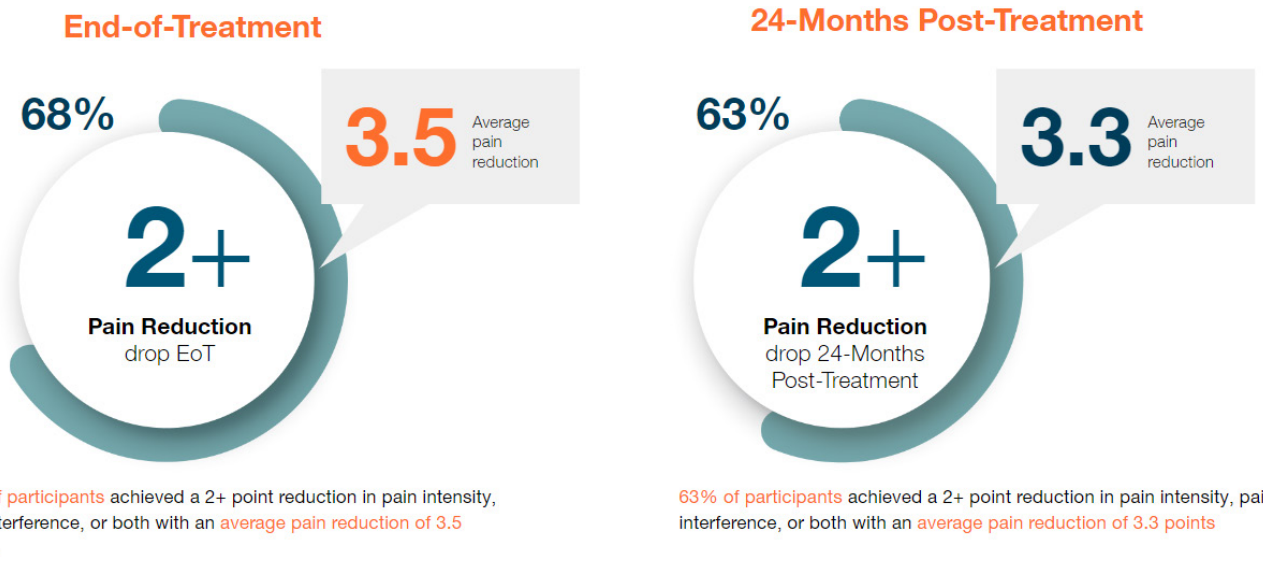


Figure 1. Pivotal Study: EoT Graph

Individual Participant Performance and Treatment Durability

RelieVRx® led to clinically meaningful pain reductions at the group level, but it is important to determine whether they are also reflected at the individual participant level. To address this question, a responder analysis was performed to assess the percentage of RelieVRx® participants who met or exceeded a 2-point pain intensity or interference reduction. The results were clear at the end of treatment, with nearly 7 in 10 participants achieving a 2-point reduction in pain intensity, pain interference or both, with an average pain reduction of nearly 3.5 in this group. This result was quite robust with just over 6 in 10 participants achieving a 2-point reduction in pain intensity, pain interference or both, at 24-months post-treatment [11], with an average pain reduction of 3.3 in this group.

A key takeaway here is that home-based VR therapies like RelieVRx® hold the potential to broaden access to effective and on-demand nonpharmacologic treatments for chronic lower back pain that are durable well beyond the end of treatment.



68% of participants achieved a 2+ point reduction in pain intensity, pain interference, or both with an average pain reduction of 3.5 points.

63% of participants achieved a 2+ point reduction in pain intensity, pain interference, or both with an average pain reduction of 3.3 points

The role of evidence in establishing reimbursement?

Evidence is crucial when seeking reimbursement from CMS or other payors for a new medical device. The quality and quantity of evidence provided can impact CMS' decision-making process regarding whether to grant reimbursement and under what conditions. Manufacturers need to present a comprehensive case that demonstrates the device's clinical benefits, comparative effectiveness, safety, economic value, and impact on patient outcomes. Manufacturers seeking reimbursement should provide robust clinical evidence that reflects the characteristics of the patient population. This typically involves data from clinical trials, studies, and real-world evidence that establish the device's clinical benefits and outcomes. When planning for discussions with CMS, consider the number of the patients in clinical studies that reflect the age, gender and diversity of Medicare beneficiaries. FDA authorization is a prerequisite for seeking reimbursement.

Section 3: The reimbursement landscape for virtual reality therapeutics

Understanding reimbursement as a combination of coding, coverage, and payment provides the context for the hurdles all new technologies must clear. At present, many VR-specific healthcare services are not reimbursed by CMS or other insurance payors. The Veterans Administration, however, has an active innovation ecosystem[12] that has proactively incorporated virtual and mixed reality into training and patient treatment. Only recently, in March 2023, did CMS approve a VR-specific billing code – HCPCS code E1905[13]. A payment rate was subsequently published[14]. The specifics of how this process unfolded are instructive for manufacturers of devices for use in the home that might be eligible for the DME benefit category.

Why is a code important?

What does a code represent? Healthcare is a complex ecosystem described entirely in countless combinations of alphanumeric descriptors we call "codes". Very simply, these different types of codes are used to describe a clinical condition or a procedure, and the location of care, primarily for payment purposes. Given this link to payment, there are many reasons a code is important for new technologies[20].

Patient Access

Reimbursement is a critical aspect in the U.S. healthcare landscape for any new technology. It directly impacts patient access, as lack of insurance coverage might hinder patients from affording the technology needed for care.

Business and Revenue Model

Reimbursement considerations play a role in shaping your business and revenue model. Evaluating reimbursement possibilities helps you gauge customer affordability and communicate fees more effectively.

Provider Adoption

Highlighting available reimbursement options aids customers in understanding the potential return on investment achievable by using your new technology. This, in turn, can encourage greater provider adoption.

Investment Opportunities

Available reimbursement avenues can also boost your investment prospects. Investors seek viable revenue streams as part of assessing market fit and long-term potential. Reimbursement demonstrates a concrete way to exhibit this.

What is a Benefit Category?

Medicare is a defined benefit program[15]. One of the critical steps in obtaining reimbursement from CMS is to determine that there is an existing benefit category the product fits into. Benefit categories are defined in statute, and Congress would have to pass legislation to establish a new benefit category. A good example of this was the establishment of the Part D drug benefit in Medicare in 2006 as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)[16]. This can be a critical strategic decision with significant implications for your regulatory and reimbursement planning.

Regulatory strategy may be underappreciated in terms of its influence on reimbursement success, and this was certainly key to the decisions related to code assignment and granting the benefit category as DME for RelieVRx®.

How is payment determined?

With an understanding of what benefit category the technology fits into and what type of code will describe your new technology, the way payment is determined will become more clear. For example, a VR device used in a hospital procedure might fall under an existing DRG, one used in an office setting will be subject to the CPT coding system managed by the American Medical Association (AMA) with a defined process for determining the Relative Value Units (RVUs) of the service which determines the payment rate. If the device is used in the home setting and it meets the requirements for durable medical equipment (DME), the Medicare payment rate is set in one of two ways: 1) crosswalk payment to a similar item; or 2) use the "gap fill" methodology in which the current purchase price of the product is deflated to 1986/87 then reinflated to the current year to set the Medicare payment rate. (see 42CFR§414.238).

What is Coverage?

Once the code, benefit category and payment rate are established, coverage is dependent on a determination that the product or service is "reasonable and necessary" for the individual patient. In the early days for a new product this might be determined on a case-by-case basis either by the Medicare Administrative Contractors (MACs) or by the insurance company's medical team. As the new technology gains market share, coverage policy can be written to clearly define the conditions for coverage. Coverage policy may include diagnostic or procedure codes or specific patient characteristics that must be documented for the technology to be covered and ultimately paid for.

Section 4: The RelieVRx® reimbursement success story

In November 2021, AppliedVR's RelieVRx® device received market authorization[17] via the De Novo regulatory pathway; a pathway for the classification and authorization of certain low- to moderate-risk medical devices that do not have a predicate device on the market.

When a novel medical device is not substantially equivalent to any existing device, it cannot be cleared through the traditional 510(k) premarket notification process. If this is the case, a De Novo application may be submitted to the FDA. The level of evidence required for a De Novo submission varies depending on the device's complexity and risk. The review of these applications evaluates the device's safety and effectiveness, which involves assessing the device's intended use, technology, and potential risks. Early consideration regarding proof of concept and evidence generation processes is extremely important, as the FDA may require clinical data, bench testing, performance evaluations, and other relevant information to demonstrate the device's safety and effectiveness.

Regulatory strategy may be underappreciated in terms of its influence on reimbursement success, and this was certainly key to the decisions related to code assignment and granting the benefit category as DME for RelieVRx®. The FDA's authorization of AppliedVR's De Novo submission was instrumental in facilitating future marketing and distribution of the RelieVRx® program in the United States. This approval also established a new device classification, which other manufacturers can use as a predicate for future 510(k) submissions, again, demonstrating how AppliedVR is paving the way for future VR therapeutic devices entering the field.

Approaching CMS for a code

If a HCPCS code is the appropriate code type for your new technology, the strategy should be elucidated in conjunction with the regulatory strategy. A key indicator that HCPCS coding may be appropriate is that the location of care is outside of the qualified healthcare provider office or the inpatient or outpatient setting. Independent use in the home setting commonly indicates a HCPCS code is appropriate. The following steps are a good rule-of-thumb for ensuring you understand how best to tap into existing payment pathways within CMS:

1. **What is the location of care, and what is the predominant payment type in this setting?**
2. **What products are similar in nature and how have they been treated by CMS?**
3. **What are the statutory requirements for this benefit category, and does my product meet them? If not, can a product modification or regulatory approach remedy this?**
4. **What is the application process and timeline for the code application?**
5. **What are the evidence requirements for the application?**
6. **How will pricing be determined in this pathway?**

DME Categorization

The RelieVRx® device is intended for use in the home independent of direct clinician involvement. This is similar to items of durable medical equipment (DME), and this is the existing benefit category AppliedVR pursued. The statutory definition (42 CFR §414.202) of DME requires that the following criteria be met:

1. **Can withstand repeated use**
2. **Has an expected life of at least 3 years**
3. **Is primarily and customarily used to serve a medical purpose**
4. **Generally is not useful to an individual in the absence of an illness or injury; and**
5. **Is appropriate for use in the home**

In March of 2023, CMS established the new HCPCS Level II code E1905, "Virtual reality cognitive behavioral therapy device (CBT), including pre-programmed therapy software" to describe RelieVRx®. While AppliedVR initiated the application that led to this code, it can potentially apply to other platforms meeting its criteria.

These details are critically important to communicate in the HCPCS application. As defined, only software IN a medical device (SiMD) but not software AS a medical device (SaMD) would qualify for this benefit category, and CMS has published this in decisions under code A9291 ("Prescription digital behavioral therapy, FDA cleared, per course of treatment"). As shown by the assignment of code A9291[18] and code A9292[19] ("Prescription digital visual therapy, software-only, FDA cleared, per course of treatment"), not meeting the requirements for the DME benefit category does

not preclude HCPCS code assignment, though there is not a statutorily defined way for Medicare to pay for items that fall outside this benefit.

This groundbreaking coding decision positions the RelieVRx® program as the first ITx or digital therapeutic (DTx) to be integrated into an existing benefit category. Fulfilling all five of CMS' requirements for DME categorization allows a clearer path to Medicare coverage eligibility, thereby influencing wider commercial coverage. The official DME determination from CMS clarified their reasoning: "The medical software and the device on which it is housed are so integral to each other that we consider them to be one whole device, not software and a separate device[1]."

Why CMS granted code E1905 and what it means now and in the future?

In March of 2023, CMS established the new HCPCS Level II code E1905, "Virtual reality cognitive behavioral therapy device (CBT), including pre-programmed therapy software" to describe RelieVRx®. While AppliedVR initiated the application that led to this code, it can potentially apply to other platforms meeting its criteria.

It is worth revisiting the regulatory decisions that allowed for this unique outcome when compared to those where software run on a phone, tablet or laptop have not met the criteria. A VR headset is essentially a head mounted computer system that displays visual data in an immersive 360-degree format. It was critical that the RelieVRx® device be configured and tested to meet the requirements for a medical device used in the home and the definition of DME. This includes modification of the operating system to be gaze-based instead of controller operated, the addition of a patented shield to capture breath and incorporate it into the patient experience, and testing to ISO 60601 electrical standards for medical equipment in the home. Additionally, the FDA authorization includes special controls specific to its use as a medical device. It should be expected that CMS will consult with the FDA if they have questions regarding the status of hardware as a medical device.

The final step in the HCPCS process is determination of the payment rate. Again, CMS is confined to two methods for setting payment rates by statute (42CFR§414.238). The first is to "crosswalk" the DME item to a similar item. This method can lead to painfully low payment rates for new technologies that may have much higher manufacturing and marketing costs than the old items they are compared to. This assessment should be part of the strategic plan to understand what points of differentiation will avoid untenable payment rates. The second method, and the one that was applied to RelieVRx®, is called the backfill method. In this case, invoices are provided to CMS for them to determine an appropriate (weighted) purchase price. This price is then deflated to the 1986/87 fiscal year and is reinflated to the current decision year. This will typically result in a final price that is 60-65% of the baseline. One final challenge for RelieVRx® is that because the course of therapy is only 56 sessions, the device is rented and returned, and is not intended to be purchased by the patient. However, there is not an appropriate payment methodology for rental items, so the purchase price had to be imputed from published rental prices and established under the capped rental model where CMS reimburses 10% of the purchase price in months 1-3 and 7.5% of the purchase price in months 4-13 after which time the ownership of the device would pass to the beneficiary. Because the prescription would only cover the 56-session therapy, the device will only be billed for the months it is used.

Conclusion

Understanding the intricacies of reimbursement codes and benefit categories is crucial for innovators seeking to navigate the evolving landscape of virtual reality in healthcare. It is essential to keep an eye on emerging trends and codes to make informed decisions and leverage opportunities for reimbursement in this rapidly evolving field. Founders of VR healthcare companies should vigilantly monitor the evolving reimbursement landscape and how changes may influence their business model. By capitalizing on these established reimbursement options and staying attuned to emerging trends, healthcare providers can harness the full potential of VR technology in delivering innovative and effective treatments.

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[20] Your Guide to Virtual Reality Reimbursement in the U.S. Healthcare Market

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