Chronic pain management: Virtual reality (VR)-based home therapy

About AppliedVR's RelieVRx®

AppliedVR is creating a new reality in healthcare. AppliedVR's treatments represent a robust approach to chronic lower back pain (CLBP) that empowers patients with an intuitive device they can self-manage at home. AppliedVR's RelieVRx® program is the first VR-based, prescription therapeutic to receive FDA's Breakthrough Device Designation and De Novo authorization for CLBP. AppliedVR's demonstrates a successful DHT for evidence generation, key stakeholder engagement, regulatory navigation, and reimbursement coverage.

Let's explore AppliedVR's journey through the lens of the Integrated Evidence Plan for digital health technologies toolkit - Stage A, highlighting the process, key decisions, and concepts that shaped their success.

Stage A: Market need & product benchmarking

- **Market need evaluation:** Chronic pain affects over 100 million Americans and spends $635 billion annually in pain treatment. Current treatments, often reliant on opioids, implants, injections, surgery, can lead to possible misuse and addiction without significantly treating the problem.
- **Product benchmarking:** VR has been studied and used for acute and chronic pain conditions for decades, but widespread adoption was hindered by cost and accessibility of headset technology.
- **Competitor analysis:** AppliedVR's RelieVRx® (formerly EaseVRx) became the first FDA-authorized VR-based home therapy for CLBP. The RelieVRx® program is a 56-session in-home therapy that integrates cognitive behavioral therapy (CBT), pain education, breathing techniques, pain distraction, and mindfulness.
- **Stakeholder mapping and value proposition:** AppliedVR engaged with CMS to ensure the product fit within the regulatory and reimbursement framework. The VA has been an early adopter of VR-based healthcare solutions, demonstrating success with patient treatment using immersive technologies.
- **Initial business model development:** AppliedVR strategically pursued CMS reimbursement via the Durable Medical Equipment (DME) benefit category given the complex reimbursement landscape. This decision by CMS held the potential to influence coverage policy with commercial health plans, self-insured employers, and other payors.

By the end of Stage A, AppliedVR had:

✔ Identified the primary geographic regions (US) and understood that the product would require regulatory authorization from the FDA.	✔ **Regulatory strategy**
✔ As they set out to develop an optimized product that meets patient, clinician, payor, and public health needs, AppliedVR requested a series of pre-submission meetings with the FDA.	✔ **Regulatory strategy**
✔ Currently, many VR-specific healthcare services are not reimbursed by CMS or other insurance payors. The Veterans Administration, however, has an active innovation ecosystem that has proactively incorporated virtual and mixed reality into training and patient treatment.	✔ **Reimbursement pathway**
✔ Prioritized payor discussions and reimbursement strategy to align with market adoption needs.	✔ **Business priorities**
✔ Tracked trends in value-based care, payor interest in non-opioid solutions, and emerging reimbursement policies for digital health technologies.	✔ **Business priorities**

The case example was developed based on public information only (Website, press releases, report, & interviews).