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 C, highlighting the process, key decisions, and concepts that shaped their success.

Stage C: Commercial strategy & market access

- **Assess the landscape of reimbursement for DHTs:** The reimbursement landscape for DHTs is complex, requiring a combination of coding, coverage, and payment approvals.

- **Refine targeted value story:** AppliedVR identified its primary customer segments as Medicare, the VA, self-insured employers, and commercial health insurers.

- **Business strategy & reimbursement pathway:**

  - Focused on **Medicare** reimbursement and collaboration with the **Veterans Health Administration** innovation ecosystem.

  - AppliedVR pursued HCPCS Level II code E1905 under the DME category. The VR headset was designated durable medical equipment, qualifying it for Medicare reimbursement under the DME benefit category. The coverage is not separate for software and hardware but as a whole: *"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."*

  - RelieVRx® was added to the Department of Veterans Affairs' Federal Supply Schedule (FSS), the Defense Logistics Agency's Electronic Catalogue for Medical Supply Chain (ECAT), and the Department of Defense's Distribution and Pricing Agreement (DAPA), allowing government customers to make streamlined purchases.

  - VA Immersive, a Veterans Health Administration (VHA) division, extended its

contract with AppliedVR to facilitate accelerated uptake.
- Expanded into the Workers' Compensation market.

- **Secure long-term market access and reimbursement:** Securing CMS reimbursement opened doors to engage with commercial insurers and self-funded employers to expand coverage.
  - E.g. Highmark, a leading commercial health insurance plan will now cover RelieVRx and be accessible as a covered therapeutic to 4+ million Highmark members across its commercial lines of business.

- **Foster adoption through education, advocacy, and evidence dissemination:** Collaborated with healthcare professionals and policy stakeholders to educate decision-makers on VR therapy for chronic pain. The company published clinical trial results demonstrating significant pain reduction, reinforcing RelieVRx® 's efficacy and safety.

By the end of stage C, AppliedVR had:

✔ Successfully obtained FDA market authorization for RelieVRx® via the De Novo regulatory pathway, facilitating future marketing and distribution in the US.

✔ **Regulatory strategy**

✔ Achieved reimbursement eligibility by securing a Healthcare Common Procedure Coding System (HCPCS) Level II code (E1905) under the DME benefit category.

✔ **Reimbursement pathway**

✔ Established the first commercial payor partnership with Highmark, making RelieVRx® accessible for its members.

✔ **Reimbursement pathway**

✔ Strengthened strategic partnerships with government agencies and commercial payors.

✔ **Business priorities**

✔ They continue to build research and evidence for the clinical and health economic impacts, foster new partnerships, and educate clinicians.

✔ **Business priorities**

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