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MedTech STRATEGIST

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FROM DURABLE TO DIGITAL: HOW TO HARNESS THE RISE OF DIGITAL DME

The increasing integration of digital technologies into durable medical equipment is revolutionizing patient care by offering novel treatment options. This enables manufacturers and investors to gain insights into the potential of digital DME to address unmet medical needs and learn best practices in commercialization, helping them capitalize on these technologies to drive new market opportunities and ensure their innovation reaches patients.

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In 2023, we published a paper titled, "Where Does MedTech End and Digital Begin?" highlighting how the increasing convergence of medtech and digital health technologies is creating new opportunities to personalize patient care. As we reflect on the market's evolution in 2025, digital durable medical equipment (DME) is a segment we find poised to similarly transform patient outcomes by offering new therapeutic modalities. To fully understand these impending market changes, it is important to understand the current digital DME landscape and how this traditional market segment is evolving. Here we highlight five critical

elements of commercialization planning to achieve ROI and make sure patients benefit from digital DME innovations.

What Is Digital DME and What Value Does It Bring?

Durable medical equipment has long been a cornerstone of the US healthcare system, traditionally encompassing products designed to withstand repeated use over three years. Historically, this category has been dominated by items such as assistive devices (that help with speech, orthopedics, and activities of daily living or ADLs), wheelchairs, hospital beds, respiratory devices, and wound care equipment. However, the landscape of DME is evolving. The "D" in DME is beginning to stand for more than just "durable"; it now also signifies "digital." The rise of digital DME ushers in a new era, transforming DME from mere support and assistance to ground-breaking therapeutic intervention.

Digital DME is a durable medical device where integrated software drives value in terms of patient outcomes. This new generation of home device innovations offers the potential for personalization to meet patient needs and to improve access to care in areas with limited practitioner availability or rural healthcare resources. This shift can drive cost savings and reduce patient and caregiver burden. Additionally, these devices introduce novel noninvasive treatment modalities for conditions with high unmet needs, such as Alzheimer's, multiple sclerosis, Parkinson's, and pain management. These therapeutic technologies may address symptoms in areas where traditional treatments have failed to consistently show improvement or reduce the need for invasive procedures and interventions. It's particularly exciting that digital DME is being explored for its potential to drive survival benefits or slow disease progression in chronic conditions.

Key Innovations in Digital DME

Over the last five years, there has been an acceleration in development of innovative digital DME products that blend traditional durability with cutting-edge digital technology to treat patients' symptoms.

Some early examples of DME as a treatment are *LifeVest* and *Optune*:

- *LifeVest,* which was introduced by **Zoll** in 2001, is a wearable defibrillator designed to protect patients at risk of sudden cardiac arrest who are not candidates for or refuse an implanted defibrillator. If a life-threatening arrhythmia is detected, the device delivers a treatment shock to restore normal heart rhythm. The *LifeVest* provides a safety net for patients who are not immediate candidates for an implantable device, offering a noninvasive solution that can improve outcomes while long-term treatment plans are being developed.
- *Optune*, developed by **Novocure** and FDA approved in 2011, is a medical device designed for the treatment of glioblastoma, an aggressive form of brain cancer. Since its initial approval this product line has expanded into mesothelioma and non-small cell lung cancer. It delivers low intensity, alternating electric fields to disrupt cancer cell division and inhibit tumor growth.

In the last five years, we've started to see more launches of digital DME, where the integrated software is driving additional value in terms of patient outcomes. These new products include:

- The *Leva* Pelvic Health System, launched by **Axena Health** in 2019, aims to address urinary and fecal incontinence in women by using motion-based technology to guide women through pelvic floor muscle training (PFMT), providing real-time biofeedback and patient coaching on an app, and enhancing patient privacy and convenience through home delivery.
- **Cala Health**'s wearable TAPS (Transcutaneous Afferent Patterned Stimulation) devices *Cala Trio/Cala kIQ*, introduced in 2021 and 2022, respectively, for essential tremor and Parkinson's disease seek to improve symptoms. By delivering targeted electrical stimulation to the wrist, Cala's devices aim to help reduce tremors, improving the quality of life for patients.
- **Applied VR**'s *EaseVRx*, launched in 2021, leverages virtual reality to manage chronic pain, offering an alternative to traditional pain management methods for chronic lower back pain. This approach is particularly relevant in the context of the need for safer and effective non-pharmacological approach amid the opioid epidemic.
- **MedRhythm**'s *InTandem* system, commercialized in 2023, uses music therapy combined with digital sensors to improve gait and mobility in patients with neurological conditions such as multiple sclerosis and stroke. The technology exemplifies how digital interventions can address specific symptoms and enhance rehabilitation outcomes.

The Future of Digital DME

Looking ahead to the digital DME product pipeline, emerging technologies and companies are continuing to push the boundaries of what is possible, including exciting innovations in neurology. These include:

- **Neuroelectrics** and **Flow Neuroscience:** These companies are exploring the use of brain stimulation technologies (Transcranial Electrical Stimulation [tES] and Transcranial Direct Current Stimulation [tDCS], respectively) to treat various neurological and psychiatric conditions. These interventions have the potential to offer personalized and adaptive solutions to overcome unmet needs with current treatments. They can also be used in the comfort of patients' homes.
- **Cognito Therapeutics** is developing a device that aims to be disease-modifying for Alzheimer's. This technology represents a significant leap forward, offering the potential to alter the course of the disease rather than merely managing symptoms.

The integration of digital technologies into durable medical equipment is revolutionizing patient care by offering innovative treatment options. From wearable defibrillators to virtual reality pain management, these advancements are addressing unmet medical needs and improving the quality of life for patients with conditions such as Alzheimer's, multiple sclerosis, Parkinson's, and chronic pain. The future of digital DME is bright, with emerging technologies continuing to push the boundaries of what is possible.

Five Key Success Factors for Digital DME Development and Commercialization

For companies developing new digital DME technologies, understanding the commercialization landscape is crucial. From our recent work in digital DME and 30+ years of partnering with digital and medtech clients on market access and commercialization, the following themes of successful companies have emerged (see *Figure 1*):

1. Market-Focused R&D to Ensure ROI

Developing a robust understanding of the market's unmet needs to align early on a winning product concept drives early fundraising and ultimately will facilitate faster adoption, cost savings, and ROI of R&D investments. To reduce uncertainty, investors are increasingly more likely to invest in digital DME technologies that have built a strong business case for the revenue potential for their innovation and have a clear path to revenue generation.

2. Aligning Regulatory Planning With Optimal Reimbursement Pathway

To that end, one of the primary challenges for digital DME is identifying the optimal reimbursement and payment pathways. Aligning on the pathways early in the development process is necessary to ensure that investments in development will set up the digital DME to meet the necessary criteria.

Choosing the right reimbursement pathway requires a clear understanding of the distinction between Software as a Medical Device (SaMD) and Software in a Medical Device (SiMD). While SaMD has limited but growing reimbursement pathways, SiMD can often qualify for the well-worn DME track, facilitating reimbursement. This distinction is crucial for digital health companies as it significantly impacts their business models, go-to-market strategies, and overall revenue generation (see *Figure 2*).

3. Early Planning for Coding and Payment Rates

A significant pitfall in the medical device industry is the financial impact of missing coding. For instance, there have been cases where a product's cost of goods sold (COGS) exceeded the existing code reimbursement, rendering the product financially unviable. These risks underscore the importance of aligning product development and pricing strategies with appropriate coding and reimbursement pathways. To overcome these hurdles, DME manufacturers can explore methods such as HCPCS (Healthcare Common Procedure Coding System) coding and novel evidence generation to ensure their products are covered by payors at an attractive payment rate.

Figure 1

5 Key Success Factors for Digital DME Development and Commercialization

Source: Health Advances interviews and analysis

Ensuring that a product is economically sustainable requires careful planning and consideration of the reimbursement landscape from the early stages of development. Companies must understand the specific requirements for obtaining coding, coverage, and reimbursement for their products. This involves not only meeting the technical and clinical criteria, but also engaging with patient advocacy groups, clinicians, and payors to demonstrate the value of the device, since some uptake and demand is required to request new coding. The process can be expensive and time-consuming, often requiring investment in reimbursement consultants, market access experts, and legal support; but failing to budget for this expertise can lead to delays in revenue generation and lost revenue down the line.

Spotlight: Coding and Coverage Case Study

- Novocure's *Optune* gained approval of a HCPCS code two years after launch, with private payor coverage starting to pick up five years after launch and CMS coverage at eight years, driven by strong additional evidence generation (*see Figure 3*). While it took time, its ultimate success in obtaining reimbursement and market access and continued expansion covering new indications highlights the potential for innovative digital DME to achieve clinical adoption and improve patient outcomes. Since its first launch in glioblastoma (GBM), Novocure gained follow-on approvals of the product line in mesothelioma, non-small cell lung cancer, and is pursuing additional indications in pancreatic cancer and brain metastasis.

4. Integrated Value Proposition, Market Access, and Evidence Generation Plan

Market access for digital DME involves several critical considerations that must be addressed early, most notably:

- *Robust Studies; Clinical Trials and Beyond:* Demonstrating robust clinical evidence that shows the device's effectiveness and safety is essential to gain the trust of clinicians, payors, and regulatory bodies. However, it will also be critical to generate additional evidence that supports a strong value proposition, which clearly articulates the benefits of the device, such as improved patient outcomes, cost savings, and enhanced quality of life, and is necessary to justify its adoption and reimbursement. Manufacturers can succeed by investing in comprehensive clinical trials, engaging with key opinion leaders, and highlighting the device's value through HEOR (health economics and outcomes research).

- *Targeted Value Proposition by Stakeholder:* Additionally, aligning the device's benefits with the priorities of key populations will drive value. The Medicare population can be a crucial stakeholder for digital DME companies because Medicare may drive the coding committee's assessment of unmet need for a device and the need for CMS (Centers for Medicare and Medicaid Services) to take action. The creation of an HCPCS code and the corresponding reimbursement sets the standard for reimbursement and coverage, influencing other payors' decisions, particularly for companies targeting older individuals with chronic conditions. Securing Medicare reimbursement can expedite market access and adoption, providing a pathway for revenue generation. For example, interventions that show benefits in the Medicare population and address unmet medical needs can further strengthen the value proposition and facilitate market access.

- *Evidence Beyond the Trial:* Companies can add value by investing in HEOR or real-world evidence (RWE) to build a strong case for coverage and reimbursement.

Figure 2

SiMD Definition

To qualify as a software in a medical device (SiMD), which has a distinct reimbursement pathway, companies must show the software drives value in a hardware medical device.

Software must drive value in the device to be classified as SiMD.

Software that is integral to, or embedded in, a medical device or *in vitro* diagnostic

The FDA differentiates between SiMD and "software as a medical device" (SaMD), which is software that meets the definition of a device but is not part of the overall device's hardware.

However, both both SaMD and SiMD are "device software functions."

Source: Health Advances interviews and analysis

Applied VR is an example of a company that invested heavily in hiring experienced market access and HEOR professionals, which helped them navigate the complex reimbursement landscape effectively.

- *Continued Evidence Building After Launch:* Continuing to collect long-term data and strengthening the value proposition is a key driver of expanding coverage and uptake.

5. Multi-Stakeholder Go-to-Market Strategy to Drive Access and Clinical Adoption

To truly succeed in the market requires a plan to engage with and address hurdles for all key stakeholders—including payors, clinicians, patients, and providers. Engaging with payors and demonstrating the value of digital interventions to drive coverage is essential. Since it is a more nascent category, changing the perception of clinicians toward digital DME will be required. Companies must provide robust clinical evidence and engage with key opinion leaders to drive adoption and build the case for new codes or coverage. In addition, helping practices overcome hurdles to obtaining reimbursement and integrating the technology is necessary to ensure eligible patients are not lost. For example:

- Novocure handles everything from shipping to patient training to billing, reducing friction for oncologists to prescribe *Optune* and accelerating adoption. Novocure likely leveraged its operational capabilities to drive uptake as the product line has expanded into new indications.
- Zoll also assumed a comprehensive operating model to enable more frictionless uptake across provider specialties.

Navigating a Shifting Healthcare Landscape

The evolution of DME from traditional durable products to innovative digital interventions marks a significant shift in the healthcare landscape. Novel companies are demonstrating the potential of digital DME to improve patient outcomes and quality of life. As we look to the future, emerging technologies promise to further transform the field.

For investors and companies developing these new technologies, understanding the commercialization landscape and navigating the challenges of reimbursement, market access, and clinical adoption will be key to their success. By embracing these strategies, digital DME products can achieve widespread adoption and make a meaningful impact on patient care.

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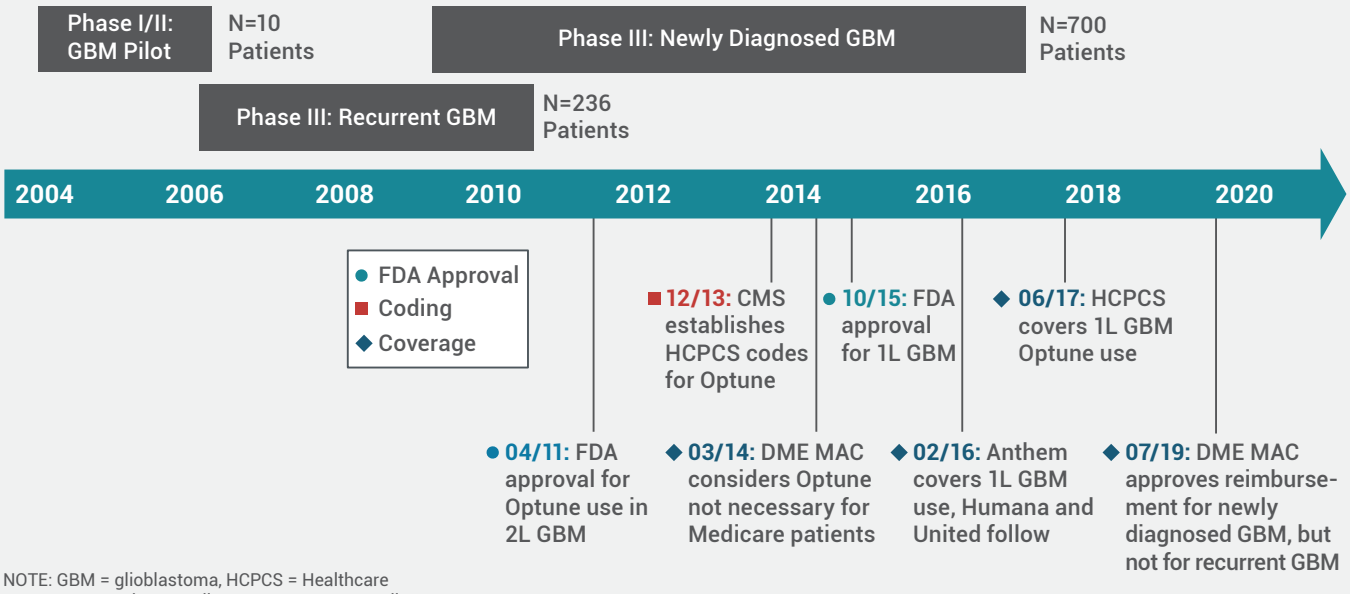
Figure 3

Novocure Optune Approval, Coding and Coverage Timeline



NOTE: GBM = glioblastoma, HCPCS = Healthcare Common Procedures Coding System, MAC = Medicare Administrator Contractor.

Sources: Health Advances analysis; clinicaltrials.gov; press releases; OncLive; company websites