EVERSANA™

Anindita Banerjee
SVP, Client Services,
EVERSANA™ INTOUCH Engage

In the Emerging World of Prescription Digital Therapeutics (PDTs), Can You Really be Prescriptive?

Breaking Down the 5Cs of Clinical and Commercial Success

The past 2+ years of my 12-year career as a client strategy and services lead has thrown me into the ever-evolving world of prescription digital therapeutics (PDTs). The top thing that has stood out to me on this recent journey is that ***there is little to no prescription (no pun intended) or clear directives for driving promotional communication in this emerging world of PDTs***.

Fundamentally, for market access stakeholders, it starts with…

- How do you ***define*** PDTs?
- What ***improved and augmentative value*** do PDTs bring to patients, providers and payers that current treatments and management do not?
- How are they ***clinically meaningful and differentiated*** from other digital wellness and fitness applications?

At EVERSANA™ INTOUCH Engage, we are at the forefront of co-creating and articulating the value proposition for PDTs. These engagements have been wonderful collaborations with our marquee clients, partners, SMEs and in-house Field Advisory Team, bringing our collective voice to the table in this creative process.

Several factors have accelerated the process to adopt and evaluate the clinical viability and validity of prescription-driven digital therapeutic solutions and offerings in the past five years, most notably, brewing pharma investments and partnerships with digital health companies, and consumer (pre- and, more so, post-pandemic) demand for personalized health solutions.

To drive both **clinical** and **commercial** success, we need to start focusing on the basic principles of these **5Cs** to overcome challenges and competitions associated with PDTs.

1. Communication

The cornerstone of any creative promotional narrative starts with developing a clear, succinct and compelling communication blueprint with the right value message architecture – focused on both external and internal stakeholders.

2. Coverage

Invest in proactive early-on dialogue with HCDMs (payers – both private and government, provider networks, employers, providers and policymakers) to prime the market and drive clarity within coverage benefit design, reimbursement stage, coding pathway, and identifying evidence and criteria for Medical Necessities.

As an agency, we initiate pre-approval information exchange (PIE), containing information on product usability (SaMD, hardware devices, wearables, etc.), clinical and technical evaluation frameworks through appropriate review channels (i.e., P&T review, HTA review) to gain early formulary consideration and intended preferred access on digital formularies at product launch.

KEY OBSERVATION — Stakeholder buy-in for PDT value proposition expands and extends beyond key healthcare decision makers and external influencers impacting coverage and policy. It requires collective alignment from the internal leadership team, data science and product development teams, investors and Board of Directors, to resonate with their corporate vision, strategy, business and investment objectives.

3. Contracting

For the appropriate uptake and utilization, PDT manufacturers need to perform clinically oriented (preferably peer-reviewed) but economically driven analyses that go beyond the rebate stream. Specifically, in this category, compared to traditional therapies, PDTs have the unique ability to inform and enable HCDMs to conduct cost analyses with data that is generated in real-time by the product and provides specific insights at the individual and patient population levels to help manage the category with innovative contracting solutions.

4. Consumer Centricity

"The pandemic pushed both digital health and telehealth forward by 15 years in a matter of three weeks," says Rick Anderson, president and general manager of North America at Dario Health. It's all about timing!. I believe the world that we are currently living in has tremendously helped to homogenize efforts to integrate healthcare and technology to drive personalized, adaptive and immersive experiences and platforms to improve patient health.

We want the **CONSUMER** in this case, the one who is using the technology, the one who is prescribing the technology, the one who is benchmarking and evaluating the technology and the one who is paying for the technology to be more visible and feel empowered to manage their conditions, patients, members and populations to help improve outcomes for all.

CONSUMER

(n): A consumer is a person or a group who intends to order, or use purchased goods, products, or services primarily for personal, social, family, household and similar needs —

5. Combination Criteria

As the categorization of the digital health technology ecosystem continues to evolve with new solutions and offerings becoming available to patients, caregivers, clinicians and payers, I think it's time to shift the narrative and evaluate and approve coverage* for PDTs as a combination of clinical effectiveness, member experience, and financial considerations.

As a microbiologist and biochemist by trade, I want to reinforce that it is time to amalgamate biology and technology to open a whole new world of care and digital possibilities for the pharmaceutical industry.

It's TIME!!!

- To include and make room to articulate the value of **Mechanism of Technology (MoT)** beyond the traditional Mechanism of Action (MoA).
- To move from product-centric traditional delivery to **LIVE demonstration** of how the technology/ device works.
- To choose **digital prescription delivery** over in-person therapy or Rx pickup.
- To consider a **safe risk profile** with no/few SAEs.
- To access rich, **continuous real-time data** to visualize benefits and gain insights than wait to observe limited data on disease progression or lack of progression thereof, before change of course/therapy.

*Given the time it typically takes to gain payer coverage, it is common for PDT manufacturers to pursue a self-pay model in parallel while trying to gain payer coverage and reimbursement.

GLOSSARY:

AE=Adverse Events; HCDMs=Healthcare Decision Makers; HTA=Health Technology Assessment;

P&T=Pharmacy & Therapeutics review;
SaMD= Software as Medical Device