TRIANGLE INSIGHTS GROUP
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Launching Digital Therapeutics Vol 2

Evidence Package Needed to Support Market Access

Data-driven access is optimized with digital therapeutics (DTx) as these products are often designed to track and measure adherence and clinical outcomes. However, there are a few potential challenges with DTx data:

1. Portability given patient privacy concerns,
2. Compatibility of data sources and potential destinations i.e., different medical record systems of various providers and payer databases, and
3. Reliability / integrity of data from patients.

Moreover, the evidence package needed to support access differs from non-digital therapeutics, but if successful, could enhance care delivery in many therapeutic areas. In this second piece from Triangle Insights, we will examine access barriers, posit DTx specific evidence generation improvement, and discuss approaches to launch through unique examples.

While DTx products have been studied through randomized control trials (RCT) resulting in FDA approval, many US government programs have yet to cover or fully recognize the value of DTx. This is partly a coding issue as limited precedence for use of DTx and past reimbursement challenges have stifled the commercial viability of individual products and entire companies. Existing remote therapeutic and patient monitoring (RTM and RPM) codes could be used and billed for services related to digital therapeutics, but reimbursement is often insufficient to cover the cost of these technologies. On the other hand, unique codes like the one AppliedVR received for RelieVRx in the first quarter of 2023 may be viewed as anticompetitive due to narrow or limited use, but are a positive sign towards acceptance of DTx by CMS.

Some payers have developed overall policies not covering any prescription digital therapeutics despite existing evidence. Many commercially available and FDA-approved therapies are considered *"experimental, investigational, and unproven due to insufficient clinical evidence and peer-reviewed medical literature establishing long-term safety, efficacy, and effect on net health outcome."* (Molina Clinical Policy 2023).

To address the reservations of payers regarding DTx effectiveness, the following recommendations may bolster coverage of products already on the market:

- Follow-on studies that are better powered by larger cohorts with comparable control groups to demonstrate statistically significant and meaningful differences in clinical outcomes
- Collecting data over longer periods of time to measure the ability of DTx to impact patient outcomes through positive habit-forming engagement with the technology
- Developing different validated measures or PRO (patient reported outcome) tools than non-digital therapies to support efficacy claims
- Economic studies including cost benefit analyses in relevant patient populations, perhaps leveraging health system partnerships

Appropriately tested and clinically relevant patient assessments through DTx could widen use through broader applicability, support future reimbursement by US government programs, and additional coverage by commercial plans or employers through quantifiable impact. As an example, Freespira, an FDA-cleared treatment that can reduce or stop panic attacks and PTSD symptoms, recently announced a partnership with Lovell® Government Services. As of June 23, 2023, federal healthcare systems including the Veterans Health Administration (VHA) and Military Health System (MHS) can provide access to Freespira's at-home treatment. Freespira was previously studied in partnership with Allegheny Health Network and demonstrated cost benefits resulting in expanded access by Highmark Health plans after a 12-month pilot program in 2017. Access barriers for DTx may be overcome with time, through similar approaches including unique strategic partnerships and different agreements with plans, providers, and even government contracted organizations.

Reach out to Triangle Insights Group to learn more about our approaches to optimizing market access and tune in for our next installment in the series, focused on appropriately-sized field force and selling models for DTx.