Value Assessment of Prescription Digital Therapeutics

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BACKGROUND

Digital Therapeutics (DTx) are evidence-based disease management interventions that yield long-term health outcomes through behaviour modulation, psychoeducation and high-quality software programs. These products are classified as Software as Medical Devices and undergo a rigorous clinical evaluation and regulatory scrutiny ensuring the highest standard of safety and efficacy. Unlike conventional wellness applications, these products target specific disease conditions particularly chronic long-term diseases/disorders using methods such as cognitive behavioural therapy, med intake alerts, mindfulness, exercise plans, tech-based tools etc. For instance, patients are encouraged to follow a prescribed regimen, exercise and diet plan, thus preventing disease progression and promoting efficient disease management. The global digital therapeutic market, which was valued at 3.5 billion USD in 2020, is projected to reach $9 billion (USD) by 2025. At present, digital therapeutics are highly employed for diabetes and obesity, followed by cardiovascular diseases and respiratory diseases. The FDA acknowledges these products' growing demand and has introduced the Digital Health Innovation Action Plan 2023, to accelerate the design and development of these software-based technologies. Although the regulatory landscape for DTx is still evolving, the healthcare sector's rapid digital transformation provides DTx with endless possibilities.

KEY PLAYERS IN THE US DTx MARKET

Device name & Company Name	Indication of Use	Features	Approval Pathway and Decision date
Somryst **Pear Therapeutics**	Treatment of patients 22 years of age and older with chronic insomnia	• Cognitive behavioral therapy for insomnia • Tailored neurobehavioral interventions, • Algorithm-driven sleep restriction	510K FDA clearance March 23, 2020
Freespira **Freespira Inc.**	Reduce and treat PTSD, panic disorder, panic attacks	• Guided Breathing Exercises • Respiration Rate Sensor. • Physiological Feedback Display	510k FDA clearance August 23, 2018
Endeavor Rx **Akili Interactive**	Video-game digital therapeutic for children aged 8 to 12 years with ADHD	• Sensory stimuli and motor challenges to target areas of the brain • Algorithm-driven patient performance measurement	De novo Clearance April 16, 2020
Oleena™ **Voluntis**	Adjunct treatment for cancer patients to self-manage their symptoms, using evidence-based algorithms, and medical devices)	• Remote patient monitoring • Clinical algorithms offering real-time personalized insights • Actionable recommendations for symptom management	Pre-Market Authorization (PMA) July 31, 2019

RESULTS

Enhancing patient health

- Targets a wide range of health conditions like chronic illnesses, neurological disorders, lifestyle disorders, behavioural conditions.
- A DTx approved for treating substance addiction showed a 40% abstinence rate in patients as compared to those receiving standard therapy.
- Improves outcomes in neurological disorders like Parkinson's. Platforms like MedRhythms can extend the benefits of physical therapy in a real-world setting.
- These can drive behavioural change and have shown advancements in lifestyle modification programs for diabetes and are recognized by the US Centers for Disease Control and Prevention.

Engaging Experiences

- Focuses on user engagement by providing intrinsic motivation, personalized feedback and frequent interaction with healthcare providers.
- VR technology has shown advancements in treating conditions including anxiety disorders, gait dysfunction, etc. Example: Endeavor Rx has shown improved adherence, feasibility and acceptability in adolescents with ADHD.

Personalization of Treatment

- Advancements in sensor technology and machine learning algorithms have enabled the collection of real-time data and delivery of individualized treatment.
- For instance, Diabefly-Pro collects data on glycemic responses to provide personalized recommendations on nutritional intake and exercise regimen.

Improved adherence

- Enhances medication adherence for a range of illnesses including stroke, renal disease congestive heart failure, diabetes etc.
- Optimizes engagement rates by providing frequent reminders, personalized feedback, online coaching and quality interactions with clinicians.
- DTx programs for tele-cardiac rehabilitation during COVID-19 demonstrated adherence rates of 94.7% and 88.4% due to user-friendly and accessible interventions.

Direct measurement of clinical outcomes

- Digital endpoints can provide real-time data at lower costs.
- AI technology can be used to analyze the outcomes and provide targeted treatment.
- For example, mobile ECG monitors, wearable ECG devices that enable patient data collection and integration.

Outreach of HCPs

- Convenient for patients due to the remote monitoring of outcomes.
- Scalability of treatment through wearables, sensors and devices.
- Increases access to treatment in vulnerable populations by combating logistical issues.
- Enables sharing of data with health care providers for goal setting and in-app interaction between patients and doctors.

Patient-centric approach

- Improves patient satisfaction and outcomes by measuring and incorporating Patient Reported Outcomes (PROs).

Inciting Regulatory Pathways

- DTx products are recognized as SaMDs and are regulated by FDA's Center for Devices and Radiological Health (CDRH).
- During COVID-19, the FDA permitted the distribution and use of these devices without fulfilling the condition of submitting a 510(k) application.
- Guidance documents on the regulation of DTx, focussing on device software upgrades, clinical research, and products with multifunctionality (i.e. products with software functions that fall under FDA oversight and others that do not).
- As an initiative to promote sofware based medical devices, the FDA introduced the software Pre-Cert program which ran between 2017-2021.

Advancements in reimbursement

- The Access to Prescription Digital Therapeutics Act of 2022 has been proposed with the aim of broadening the coverage of DTx for the populations covered by Medicare and Medicaid.
- The Centers for Medicare & Medicaid Services (CMS) have added a new Level II Healthcare Common Procedure Coding System (HCPCS) code for digital behavioural therapy to increase the convenience of reimbursement.

SUMMARY: VALUE TO STAKEHOLDERS

Patients & Caregivers

- Improved patient health
- Engaging and user-friendly experience
- Personalized treatment options
- Scalability, accessibility and convenience
- Patient safety
- Data privacy

Healthcare providers

- Direct measurement of clinical outcomes
- Expanded access to safe & effective treatment
- Targeting untreated & undertreated conditions

Payers

- Reduced healthcare costs
- Value-based outcomes
- Optimized healthcare
- Improved access to healthcare
- Remote treatment options
- Patient Satisfaction

Policymakers

- Safe & effective treatment
- Increased access to treatment for vulnerable populations

FUTURE IMPLICATIONS

- Covid-19, rising consumerism & advancements in technologies are factors that have fueled the market growth of DTx products
- The revenue projection by 2030 is 11.2 billion USD
- As the FDA has recognized the potential of DTx, increased investments can be expected due to the development of regulatory frameworks and extended support
- Digital therapeutics catering to the treatment of diabetes, CNS disorders and mental health disorders are expected to grow
- In addition to the patient end-user segments, employer end-user segments will also occupy larger market shares due to increased focus on the management of employee healthcare costs

CONCLUSIONS

With rapid technological advancements, DTx is set to revolutionize the face of healthcare and deliver optimum results in disease management. Currently, regulatory agencies and healthcare stakeholders are working towards building a robust regulatory standard for efficient commercialization, thereby ensuring improved public access to these. With increasing R&D investments, developers must ensure that their products are safe, effective, and ethical. By prioritizing patient well-being, involving healthcare professionals in developing and overseeing their products, and practising self-regulation, developers can help ensure that DTx products are successful.

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