Value Assessment of Prescription Digital Therapeutics

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RESULTS
• Enhances medication adherence for a range of illnesses including stroke, renal disease, cognitive 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 measurements of clinical outcomes
• Digital endpoints can provide real-time data at any time point.
• AI technology can be used to analyze the outcomes and provide targeted treatment.
• For example, mobile ECG devices are used to detect arrhythmias.

Patient-centric approach
• Improves patient satisfaction and outcomes by measuring and incorporating Patient Reported Outcomes (PROMs).

Inclining Regulatory Pathways
• DTx products are recognized as MAbs 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 submission of a 510(k) application.
• Guidance documents on the regulation of DTx, focusing on device software upgradations, 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 software 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.

FUTURE IMPLICATIONS
• Covid-19, rising consumerism & advancements in technologies are factors that have fueled the market growth of DTx products
• The global market size of DTx in 2030 is USD 11.2 billion.

As the FDA has recognized the potential of DTx, increased investments are expected due to the development of frameworks and extended support.

Digital therapeutics catering to the treatment of diabetes, CNS disorders and mental health disorders are expected to grow.

In addition, 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 pace 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 practicing self-regulation, developers can help ensure that DTx products are successful.

REFERENCES
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