Digital Therapeutics: Taxonomy, Regulatory Status, Observations

Vinfen's Innovative Technology in Behavioral Health Conference

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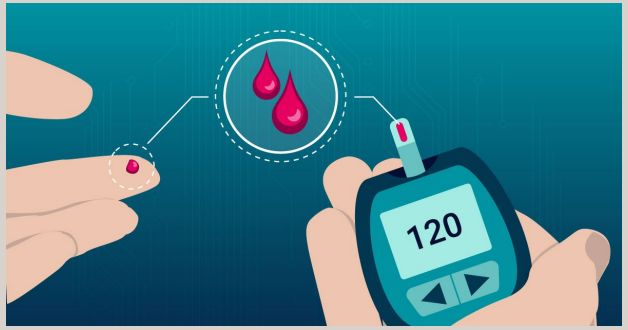
Objectives

- Describe the taxonomy for digital therapeutics
- Review current regulatory status
- Provide payer insight

Disclosures

- I have nothing to disclose



Digital Health

Digital Medicine

Digital Therapeutics

Prescription Digital Therapeutics

Product Data

- Approximately 30 companies produce digital therapeutics
- 13 have FDA approval
- 8 in approval process

Therapeutic Areas

- Behavioral Health
- Oncology
- Neurology
- Chronic Diseases (Diabetes)

Product	Maker	Therapeutic Area
BlueStar®	Welldoc	Diabetes
d-Nav®	Hygieia	Diabetes
Dario®	DarioHealth	Diabetes
Daylight®	Big Health	Anxiety
EndeavorRx	Akili	ADHD
Freespira®	Freespira	PTSD, Panic
Insulia®	Voluntis	Diabetes
Kaia Health®	Kaia Health	Pain
Kaiku Health®	Kaiku Health	Oncology
leva®	Renovia	Urology
Nerivio®	Theranica	Migraine
Propeller®	Propeller Health	Pulmonary
reSET®	Pear	SUD
reSET-O®	Pear	OUD
Sleepio®	Big Health	Insomnia
Somryst®	Pear	Insomnia
SparkRx®	Limbix	Depression
vorvida®	Orexo	Alcohol Use

https://dtxalliance.org/understanding-dtx/product-library/

Product Manufacturer Data

https://www.healthxl.com/blog/healthxl-exit-outcomes-pdt-report 2/19/21

Regulatory Status

- Regulated by the FDA as Software as a Medical Device (SaMD)
- 21st Century Cures Act of 2016
  - Allowed approvals through 510(k) pathway (substantially equivalent to an existing device)
  - Clarified alternate pathways – De Novo and New Drug Applications (eg 505[b][2] combination products)
  - Breakthrough Devices Program – prioritized digital therapeutics product reviews
- FDA Digital Health Innovation Action Plan
  - https://www.fda.gov/medical-devices/digital-health-center-excellence
  - Software Precertification Pilot Program
- Access to Prescription Digital Therapeutics Act of 2022 (S. 3791/H.R. 7051)
  - Proposed national coverage for Medicare

Payer Considerations

- Level of evidence
- Acceptance/Uptake
  - Impact on workflow
- Value
- Operational/Budget
  - Pharmacy vs Medical benefit
- Value-based Contracting

Questions

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