Evidence-Based Prescription Digital Therapeutics for Mental Health Care

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Prescription Digital Therapeutics Require Clinical Validation and Regulatory Oversight[1,2]

	Digital Therapeutic[1,*]	Prescription Digital Therapeutic[2]
EVIDENCE-BASED	Clinical trial data may not be available	Clinical trial data required for safety and effectiveness
REGULATORY OVERSIGHT	May not have received US Food and Drug Administration (FDA) authorization	Has received FDA authorization
HEALTH CARE PROFESSIONAL (HCP) OVERSIGHT	Not required	Only available with prescription and HCP supervision

*This information is based on observation in the marketplace.

Prescription Digital Therapeutics Available for Mental Health Care in the US[3-11]

2017
- Substance use disorder[3]

2018
- Opioid use disorder[4]

2020
- Post-traumatic stress disorder[4]
- Attention-deficit/hyperactivity disorder[5]
- Insomnia[6]

2021
- Panic disorder[8]
- Attention deficit[9]

2024
- Major depressive disorder[10]
- Generalized anxiety disorder[11]

Development and Approval of Prescription Digital Therapeutics[12]

Development
Developed using Good Manufacturing Practices

- FDA oversight
- Clinical trial data

Regulatory Review
Must pass regulatory clearance

- Safety and effectiveness
- Review of labeled claims

Payor Coverage
Many are eligible for reimbursement

- Health insurance
- Regional health systems

Provider Oversight
*May be prescribed as a **standalone** or **add-on** to other treatments*

Summary

Prescription digital therapeutics are[13]:

- Evidence-based
- Software-driven
- Approved for a number of mental health conditions

Prescription digital therapeutics are typically regulated as a Class II medical device.[13]

- Clinical validation
- De Novo or FDA 510(k) pathway to approval

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