



What are digital therapeutics?

Mental health digital therapeutics involve the use of software programs to deliver evidence-based and validated interventions to treat or manage mental and behavioral health disorders, such as chronic insomnia and substance use disorders. They can be used independently or as an adjunct to medications or other therapies to optimize patient care and health outcomes. Digital therapeutics are not typically direct-to-consumer mental health apps you can download on your own.

By definition, digital therapeutics meet classification for [Software as a Medical Device](#) and, therefore, fall under FDA oversight. A digital therapeutic may require explicit FDA review and clearance which then requires a prescription in order to be offered to patients or be subject to 'enforcement discretion' depending on its claims and existing regulatory code ([Carl et al., 2020](#)). In April 2020, the FDA announced [temporarily waiving certain requirements for digital health devices for treating psychiatric disorders](#). There are currently 7 FDA approved prescription only mental health digital therapeutics, with 4 of the 7 receiving approval after June 1, 2020.

Opportunities for patients and mental & behavioral health service providers

- Increase access and options to care and potentially affordability
- Ensure products have acceptable efficacy and safety profiles
- Extend the reach of evidence-based mental & behavioral health treatments
- Provide adjunctive support to established therapeutic relationships

Challenges and concerns

- While most digital therapeutics are based in psychological science, psychologists have been largely if not entirely absent from the review and approval process for digital therapeutics at the FDA
- FDA's prescription-only medical model excludes psychologists and most other mental and behavioral health care providers from accessing and using digital therapeutics
- Potential for these devices to be used as a replacement for psychologists and/or other health professionals
- [Traditional coverage and payment approaches were not designed to fit digital health innovations](#)
- Rapidly increasing pace of FDA approvals could compromise efficacy and safety

Role of psychological science

The nascent mental health digital therapeutics industry is expanding rapidly. These mental health digital therapeutics are based on psychological science, and as such, psychology and psychologists play a critical role in this area and bring clinical and scientific expertise unique to that from physician-based organizations.

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