



Understanding Digital Therapeutics and the Regulatory Landscape

Disease State Education

This program is paid for by Otsuka
Pharmaceutical Development &
Commercialization, Inc. (OPDC)

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Suicide Prevention Hotline/Lifeline

1-800-273-TALK(8255)

Or text:

Crisis Text Line

741-741

Dial 988

Objectives

Distinguish the Different Digital Tools



Compare Benefits and Barriers of Digital Therapeutics

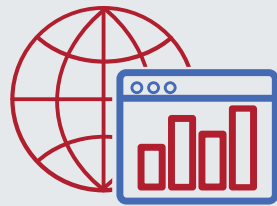


Review the US Regulatory and Reimbursement Pathways for Digital Therapeutics

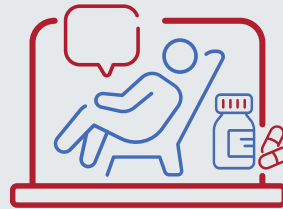
Digital Therapeutics Overview

Understanding Digital Therapeutics

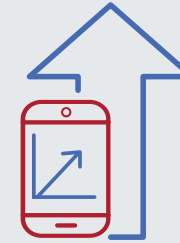
DTx deliver **SOFTWARE-BASED INTERVENTIONS** to patients to **TREAT and ALLEVIATE** a disease or condition³



DTx are supported by **clinical data** and should be guided by **real-world evidence**¹



Some DTx can be used **independently**, while others are used **alongside medications or other devices or therapies**¹



DTx may **increase access** to clinically validated therapies that may **improve patient outcomes**²

DTx, digital therapeutics.

1. Digital Therapeutics Alliance. November 2019. Accessed February 7, 2023. https://dtxalliance.org/wp-content/uploads/2021/01/DTA_DTx-Definition-and-Core-Principles.pdf.
2. Digital Therapeutics Alliance. Accessed March 6, 2023. <https://dtxalliance.org/>.
3. Digital Therapeutics Alliance. June 2023. Accessed October 9, 2023. <https://dtxalliance.org/wp-content/uploads/2023/06/Guidance-to-Industry-Classification-of-Digital-Health-Technologies-2023Jun05.pdf>

Distinguishing Between Digital Mental Health Tools

Digital mental health tools are technologies that use computing platforms, connectivity, software, and sensors for mental health care.¹ These tools can be categorized, among other things, as a health and wellness app, a patient monitoring and assessment tool, or a digital therapeutic.²

HEALTH AND WELLNESS APPS²

Promote general well-being and health living

Not permitted to make claims to treat, improve, or diagnose a medical condition

No regulatory oversight

Examples:

- Meditation app
- Relaxing sleep sounds app
- Medication reminder app

PATIENT MONITORING AND ASSESSMENT TOOLS²

Can be used to monitor specific health data

May make non-clinical claims to assess patient data

May require regulatory approval and labeling

Examples:

- Mood diary
- Sleep cycle tracker
- Digital sensor that sends data to an app

DIGITAL THERAPEUTICS²

Delivers software-based interventions to treat or alleviate a disease or condition

Makes a clinical claim to treat or alleviate a specific disease or medical condition

Regulated solution with label for indication, usage, evidence, warnings

Examples:








- CBT app for SUD
- Sleep disturbance device for nightmare disorder
- Game-based treatment for ADHD

1. US Food & Drug Administration. What is Digital Health? September 2020. Accessed October 9, 2023. <https://www.fda.gov/medical-devices/digital-health-center-excellence/what-digital-health>

2. Digital Therapeutics Alliance. June 2023. Accessed October 9, 2023. <https://dtxalliance.org/wp-content/uploads/2023/06/Guidance-to-Industry-Classification-of-Digital-Health-Technologies-2023Jun05.pdf>

Identifying DTx in Mental Health Care

Is this a digital therapeutic?^{1,2}

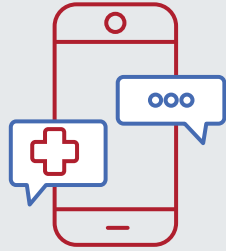
Psychotherapy app	 Yes , if the app has been authorized by a regulatory body. The app—not a clinician—delivers the intervention.
An AI virtual therapist that responds to the patient’s mental health cues	 Yes , if it has been authorized by a regulatory body. Patients engage with the virtual therapist—not a live clinician.
Sleep and activity tracker	 No . The tracker does not treat, manage, or prevent a disease or condition.
A sensor integrated with an oral drug to detect medication ingestion	 No . The drug—not the sensor—provides the treatment. If it is supported by clinical evidence, the sensor and drug combination would be considered digital medicine.
Medication reminder app	 No . The app does not treat, manage, or prevent a disease or condition.
Telehealth platform	 No . A clinician—not the software—delivers the intervention.
Electronic health record (EHR)	 No . It does not treat, manage, or prevent a disease or condition.

AI, artificial intelligence; DTx, digital therapeutics.

1. Digital Therapeutics Alliance. June 2022. Accessed February 7, 2023. https://dtxalliance.org/wp-content/uploads/2022/09/DTA_FS_Is-This-Product-a-DTx.pdf.

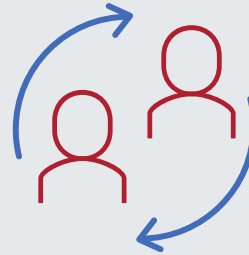
2. Goldsack J, et al. November 10, 2019. Accessed February 7, 2023. <https://www.dimesociety.org/digital-health-digital-medicine-digital-therapeutics-dtx-whats-the-difference/>.

DTx May Be Accessed in Different Ways



“OVER THE COUNTER”

Patients obtain the DTx from an app store or product website, with no prescription, referral, or authorization required



BY REFERRAL

Referral by an HCP or DTx license holder (eg, health plan) is required before the patient can access the DTx



BY PRESCRIPTION

The DTx must be prescribed by an HCP (this requirement may vary by individual countries)

DTx **may or may not be covered by insurance or state-run healthcare**

Some DTx are provided as an **employer or health plan benefit**

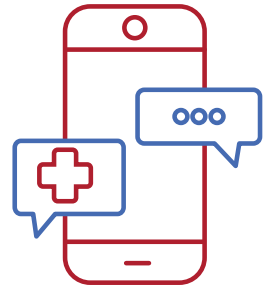
DTx, digital therapeutic(s); HCP, healthcare professional.

1. Digital Therapeutics Alliance. September 2022. Accessed April 10, 2023. <https://dtxalliance.org/understanding-dtx/what-is-a-dtx/>.

Benefits and Barriers of Digital Therapeutics

Benefits and Barriers of DTx for Patients

BENEFITS¹



- Improved access to mental health care
 - Care is available when patients need it
 - Flexibility and convenience of DTx allow patients to fit care into their schedules
 - Reduced wait time despite the shortage of mental health care providers
- Potential to address healthcare disparities, especially in healthcare deserts
- May offer additional or alternative support to nonpharmacologic options
- May help address stigma by providing discreet care
- May improve patients' engagement in their care and empower them in self-management

BARRIERS

- Patients may^{2,3}:
 - Be uncomfortable with or uninterested in using technology
 - Lack access to a computer, smartphone, or the internet
 - Have cognitive impairment or mobility limitations
 - Be concerned about sharing personal information over the internet
 - Have language restrictions
 - Feel that DTx deliver impersonal care
- Commercial insurance plans are starting to cover certain DTx, but coverage remains a challenge⁴

In countries with state-run healthcare systems, DTx are increasingly being assessed to make them available to patients^{5,6}

DTx, digital therapeutics.

1. Duerr HA. *Psychiatr Times*. 2022;39(10):14-15.

2. Whitelaw S, et al. *Eur Heart J Digit Health*. 2021;2(1):62-74.

3. Appold K. August 17, 2021. Accessed February 27, 2023. <https://www.enttoday.org/article/closing-the-digital-divide-ensuring-patients-have-access-to-healthcare-technology-is-a-priority>.

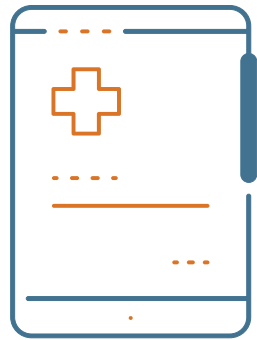
4. Lovett L. October 26, 2022. Accessed February 17, 2023. <https://bhbusiness.com/2022/10/26/clarity-on-digital-therapeutics-reimbursement-could-lead-to-more-behavioral-health-adoption/>.

5. Digital Therapeutics Alliance. June 2021. Accessed March 20, 2023. https://dtxalliance.org/wp-content/uploads/2021/06/DTA_DTx-Overview_UK.pdf.

6. GlobalData Healthcare. January 22, 2021. Accessed March 20, 2023. <https://www.pharmaceutical-technology.com/comment/digital-therapeutics-germany/>.

Benefits and Barriers of DTx for HCPs

BENEFITS¹



- May directly impact disease state measures and patients' clinical outcomes
- May expand HCPs' ability to provide safe and effective treatment by:
 - Providing therapies for previously untreated or undertreated conditions
 - Extending their ability to care for patients
 - Closing gaps in care between appointments
- May help optimize HCP-patient engagement

BARRIERS

- HCPs may^{2,3}:
 - Lack awareness of and knowledge about DTx
 - Feel that DTx are not comparable to traditional treatments
 - Fear that DTx will create more work and responsibility for themselves
 - Fear that DTx will increase patient burden
 - Experience technology challenges
 - Hesitate to use DTx if they do not integrate with EHRs or have customizable features
 - Have data privacy and security concerns
 - Have concerns about reimbursement

DTx, digital therapeutics; EHR, electronic health record; HCP, healthcare professional.

1. Digital Therapeutics Alliance. Accessed February 27, 2023. <https://dtxalliance.org/value-of-dtx/clinicians/>.

2. Secker-Johnson R, et al. February 2, 2022. Accessed February 27, 2023. <https://www.zs.com/insights/barriers-to-broad-dtx-adoption-and-ways-to-overcome>.

3. Whitelaw S, et al. *Eur Heart J Digit Health*. 2021;2(1):62-74.

Benefits and Barriers of DTx for Payers

BENEFITS¹

DTx may help:

- Enhance, support, and optimize current medical treatments
- Reduce the overall cost of care
- Improve provider network efficiency
- Support value- and outcomes-based care initiatives
- Expand care delivery outside of traditional clinic settings
- Improve member experience and satisfaction



BARRIERS²

Payers may:

- Lack familiarity with DTx
- Be uncomfortable with the regulatory process since DTx are typically reviewed as medical devices
- Desire more clinical evidence
- Be unwilling to pay for “convenience”
- Believe there is a lack of clinical value
- Believe that DTx are a low priority for patients and HCPs

DTx, digital therapeutics; HCP, healthcare professional.

1. Digital Therapeutics Alliance. Accessed February 27, 2023. <https://dtxalliance.org/value-of-dtx/payors/>.

2. Melillo G. May10, 2022. Accessed February 27, 2023. <https://www.ajmc.com/view/what-s-behind-lagging-payer-uptake-of-prescription-digital-therapeutics->.

Regulatory and Reimbursement Pathways

Regulatory Pathways in the United States

IN THE US, DTx ARE SUBJECT TO REGULATION AS MEDICAL DEVICES BY THE FDA¹

The FDA categorizes medical devices into 3 classes based on their risk and required level of regulatory control¹⁻⁴:

	CLASS I	CLASS II	CLASS III
Level of risk	Low risk	Moderate risk	High risk
Most likely pathway to regulatory clearance	None—most Class I devices are exempt from regulatory review	510(k) pathway Demonstrates that the device is substantially equivalent ^a to a legally marketed predicate device	PMA pathway Like an NDA, a PMA is the required process of scientific review to ensure the safety and effectiveness of devices

To increase access to care during the COVID-19 public health emergency, the FDA allowed digital psychiatric health devices to be marketed prior to obtaining regulatory clearance⁵

This enforcement discretion expired in 2023⁶

^aA substantially equivalent device has (a) the same intended use as the predicate and (b) the same technological characteristics or different technological characteristics but does not raise different questions of safety and effectiveness. This information submitted to the FDA demonstrates that the device is as safe and effective as the legally marketed predicate device.² FDA, US Food & Drug Administration; NDA, New Drug Application; PMA; Premarket Approval Application.

1. US Food & Drug Administration. December 19, 2017. Accessed February 17, 2023. <https://www.fda.gov/about-fda/cdrh-transparency/overview-medical-device-classification-and-reclassification>.
 2. US Food & Drug Administration. October 3, 2022. Accessed February 17, 2023. <https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k>.

3. US Food & Drug Administration. December 16, 2021. Accessed February 17, 2023. <https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/pma-approvals>.

4. Digital Therapeutics Alliance. Accessed February 19, 2023. <https://dtxalliance.org/wp-content/uploads/2022/01/US-Regulatory-and-Reimbursement-Pathways.pdf>.

5. US Food & Drug Administration. April 2020. Accessed February 17, 2023. <https://www.fda.gov/media/136939/download>.

6. US Department of Health & Human Services. Accessed February 17, 2023. <https://www.fda.gov/media/136939/download>.

Reimbursement Pathways in the United States

GOVERNMENT-SPONSORED HEALTH INSURANCE

- **DTx generally are not covered** by government-sponsored health insurance, but steps are being taken to address this
 - The **Access to Prescription Digital Therapeutics Act of 2023**, originally introduced in the US Senate in March 2022 and updated in March 2023, aims to amend the Social Security Act to provide Medicare coverage for PDT^{1,2}
 - The **Medicaid and CHIP Access to Prescription Digital Therapeutics Act**, introduced in the US Senate in December 2022, would require CMS to provide guidance on coverage for DTx under Medicaid and the State Children's Health Insurance Program³
 - Some **state Medicaid programs** have announced partnerships to cover certain DTx⁴

COMMERCIAL HEALTH INSURANCE

- Commercial insurance plans are starting to cover certain DTx, but coverage remains a challenge⁴

US DEPARTMENT OF VETERANS AFFAIRS

- Some DTx are covered by the Veterans Benefits Administration^{5,6}

CHIP, Children's Health Insurance Program; CMS, Centers for Medicare & Medicaid Services; DTx, digital therapeutics; PDT, prescription digital therapeutics.

1. US Congress. March 10, 2022. Accessed February 17, 2023. <https://www.congress.gov/bill/117th-congress/senate-bill/3791/text>.
2. . AMCP. March 9, 2023. Accessed March 20, 2023. <https://www.amcp.org/About/Media/Press-Releases/amcp-applauds-access-prescription-digital-therapeutics-act>
3. US Congress. December 12, 2022. Accessed February 17, 2023. <https://www.congress.gov/bill/117th-congress/senate-bill/5238/text>.

4. Lovett L. October 26, 2022. Accessed February 17, 2023. <https://bhbusiness.com/2022/10/26/clarity-on-digital-therapeutics-reimbursement-could-lead-to-more-behavioral-health-adoption/>.
5. Freespira. Accessed February 10, 2023. <https://freespira.com/>.
6. Military.com. Accessed March 27, 2023. <https://www.military.com/military-life/smartwatch-app-ptsd-related-nightmares-now-available-prescription-va-dod.html>.

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