Oscar Clinical Guideline: Prescription Digital Therapeutics (PG142, Ver. 3)

Prescription Digital Therapeutics

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

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Summary

Prescription Digital Therapeutics (PDTs) are a novel class of software-driven therapeutic interventions that aim to diagnose, prevent, manage, or treat medical disorders or diseases. They are authorized by the FDA, and their safety and effectiveness are evaluated through clinical trials, with clinical results published in peer-reviewed journals. PDTs can be used independently or in combination with medications, devices, or other treatments to optimize patient care and health outcomes. PDTs are prescribed and initiated by qualified and licensed healthcare practitioners.

Despite the potential benefits and growing interest in PDTs, it is essential to acknowledge the limitations in the current body of evidence supporting their effectiveness. The published peer-reviewed literature on PDTs is limited, with studies often having small sample sizes, short durations, or lacking control groups. Additionally, with the rapid pace of technological advancements, the clinical trial results often outpaces the publication of the findings, creating a gap in the available evidence.

Given the insufficient evidence in the published peer-reviewed literature, the Plan considers PDTs to be experimental and investigational. Further research, including large-scale, well-designed clinical trials and long-term follow-up studies, is necessary to establish the efficacy of PDTs and provide clear guidance for their integration into clinical practice. Until such evidence becomes available, it is essential for healthcare providers and patients to exercise caution when considering the use of PDTs in clinical treatment plans.

Both PDTs and OTC digital therapeutics harness the power of technology to improve patient care, enhance self-management, and support healthcare providers in delivering personalized treatment plans. However, there is an important distinction between the two, with PDTs having a more rigorous evaluation process and a higher standard of evidence required for their authorization and use (See Appendix A, Table 1).

In contrast, Over-the-Counter (OTC) digital therapeutics are health and wellness mobile applications (commonly referred to as apps), web-based programs, software for wearable devices, desktop software, devices paired with software or virtual reality platforms. These programs are available to consumers without a prescription. They provide general health information, help track or manage health conditions, and offer support in maintaining a healthy lifestyle. OTC digital therapeutics may not undergo the same level of clinical evaluation or FDA authorization/approval as PDTs, and they often serve as complementary monitoring or screening tools, rather than primary treatment options. While healthcare professionals may prescribe these technologies, they can often be acquired without a prescription as over-the-counter (OTC) products. As a result, they are generally not covered under a member's insurance plan. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage (See Appendix A, Table 2).

Definitions

"Artificial intelligence (AI)" involves the integration of computer systems, databases, and advanced algorithms to mimic human capabilities, such as decision-making and problem-solving. Common applications include customer service, facial and voice recognition, and recommendation/search engines. AI is being explored for various clinical purposes, such as detecting medical conditions or diagnosing illnesses based on medical imaging or histopathology (disease-induced changes in cells or tissues). AI is also used to augment the analysis of facial phenotypes related to genetic syndromes.

"Augmented reality (AR)" and "virtual reality (VR)" employ computer simulation and modeling to enable interaction with an artificial three-dimensional (3D) environment. AR blends digital imagery with the real world and can be viewed through a camera or display, such as a smartphone or head-mounted or heads-up display (HUD). Users typically wear equipment (gloves, goggles, headset) that provides sensory feedback to the computer based on their movements. AR has been utilized as a surgical training tool for medical students and is being explored to guide surgical techniques by overlaying images onto patients. VR is being investigated as an adjunctive treatment tool for cognitive rehabilitation, enhanced physical therapy, memory improvement, and pain reduction. VR applications for mental health under study include augmenting therapy for anxiety, depression, phobias, and post-traumatic stress disorder.

"Digital Health Technology (DHT)" encompasses applications, software, and programs utilized within the healthcare and social care sectors. These technologies can function independently or be integrated with other products such as medical devices or diagnostic tests.

"Digital Therapeutic (DTx)" are treatment interventions delivered to patients through high-quality software programs. These interventions aim to treat, manage, or prevent diseases or disorders and can be used independently or alongside medications, devices, or other therapies to enhance patient care and health outcomes.

"Health Technology Assessment (HTA)" is a systematic, multidisciplinary evaluation of the properties, effects, and impacts of health technology. The assessment considers social, economic, organizational, and ethical aspects of a health intervention or technology with the primary goal of informing policy decisions.

"Mobile applications (apps, mobile apps)" are software programs specifically designed for use on mobile devices like smartphones. Mobile health (mHealth) apps offer a broad range of personal health management options for wellness and chronic conditions (e.g., fitness tracking, meditation guidance, stress reduction, weight management). Mobile medical apps (MMAs) are medical devices that function as mobile apps, meet the definition of a medical device, and either serve as an accessory to a regulated medical device or transform a mobile platform into a regulated medical device. Both MMAs and mHealth apps may incorporate games or use gamification to establish and maintain desired health behaviors.

"Prescription digital therapeutics (PDTs)" are a category of digital health products that utilize software applications to treat medical conditions or improve health outcomes. These products require a prescription from a healthcare provider and often engage patients via mobile apps or web platforms. PDTs can be used independently or alongside conventional treatments like medications or therapy. These digital tools can provide personalized treatment plans, monitor patient progress, and offer real-time feedback.

"Real-World Data (RWD)" comprises information about a patient's health status and/or healthcare delivery, routinely gathered from various sources.

"Real-World Evidence (RWE)" pertains to the clinical evidence concerning a medical product's usage and potential benefits or risks, derived from the analysis of real-world data. RWE can be produced through various study designs or analyses, including but not limited to, randomized trials, large simple trials, pragmatic trials, and observational studies (prospective and/or retrospective).

"Software as a Medical Device (SaMD)" refers to software intended to be used for medical purposes without being part of a hardware medical device. PDTs are a specific category of SaMD that provide therapeutic interventions.

"[s]" indicates state mandates may apply.

Policy Statement on Prescription Digital Therapeutics (PDTs) Efficacy Information[s]

The Plan recognizes the potential of Prescription Digital Therapeutics (PDTs) in healthcare. PDTs are software-based interventions designed to prevent, manage, or treat medical disorders or diseases. While the FDA has authorized several PDTs, and numerous clinical trials have been conducted, the current body of peer-reviewed literature does not provide sufficient evidence to conclusively support their effectiveness across all applications.

Many studies on PDTs have limitations such as small sample sizes, short durations, lack of control groups, or inconsistent results across different clinical settings. The rapid pace of technological advancements often outpaces the publication of clinical trial results, creating a gap in available evidence. Additionally, the diversity of PDTs in terms of target conditions, platforms, and therapeutic approaches makes it challenging to draw firm conclusions on their overall effectiveness.

Some PDTs have shown promise for specific conditions, but the current evidence base lacks robust long-term outcomes data and comparative effectiveness studies against standard treatments. The Plan will continue to monitor emerging evidence and update this policy as new research becomes available.

Clinical Indications

Medical Necessity Criteria for Clinical Review[s]

Prescription Digital Therapeutics (PDTs)

The Plan acknowledges that some PDTs have demonstrated potential benefits in clinical trials and received FDA authorization. However, current published peer-reviewed literature does not provide

sufficient evidence to establish long-term safety, efficacy, and effect on net health outcomes across all PDT applications. Therefore, the Plan does not currently have medical necessity criteria for PDTs.

The Plan will continue to monitor emerging evidence on the use of PDTs. The plan may update this policy as new research becomes available, including data which demonstrates:

- Long-term safety and efficacy in well-designed clinical trials.
- Comparative effectiveness against standard treatments.
- Sustained benefits in real-world settings.
- Cost-effectiveness.

Individual case reviews may be considered for specific clinical scenarios where standard treatments have been exhausted or are contraindicated.

Experimental or Investigational or Unproven / Not Medically Necessary[s]

Prescription Digital Therapeutics (PDTs) for any indication or use are considered experimental, investigational, unproven, or not medically necessary due to insufficient clinical evidence and peer-reviewed medical literature establishing long-term safety, efficacy, and effect on net health outcomes. This includes but is not limited to all current FDA-authorized PDTs for[tt]:

- ADHD (including EndeavorRx)
- Amblyopia (including CureSight, Luminopia One)
- Anxiety disorders
- Chronic pain management (including RelieVRx)
- Depression (including SparkRx)
- Hypertension management
- Insomnia (including Somryst)
- Irritable Bowel Syndrome (including Mahana IBS)
- Migraine (including Nerivio)
- Obesity and weight management
- Pregnancy monitoring (including INVU)
- PTSD and nightmare disorder (including NightWare)
- Substance use disorders (including reSET and reSET-O)
- Type 1 and 2 diabetes (including BlueStar Rx, AspyreRx, d-Nav, Insulia)
- Urinary/fecal incontinence (including Leva)

[tt] *This list is not exhaustive, and the Plan maintains its position that PDTs for any indication or use are considered experimental, investigational, or unproven until:*

1. *Robust clinical evidence demonstrates long-term efficacy.*
2. *Well-designed comparative effectiveness studies show clear benefit over standard treatments.*
3. *Real-world evidence confirms sustainable positive health outcomes.*

4. *Professional society guidelines provide strong recommendations based on high-quality evidence.*

Applicable Billing Codes

Table 1	
CPT/HCPCS Codes considered medically necessary if criteria are met: *Please note that the provided list may not cover every digital health product, as some may not have a specific code assigned to them.*	
Code	*Description*
0687T	Treatment of amblyopia using an online digital program; device supply, educational set-up, and initial session
0688T	Treatment of amblyopia using an online digital program; assessment of patient performance and program data by physician or other qualified healthcare professional, with report, per calendar month
0704T	Remote treatment of amblyopia using an eye tracking device; device supply with initial set-up and patient education on use of equipment
0705T	Remote treatment of amblyopia using an eye tracking device; surveillance center technical support including data transmission with analysis, with a minimum of 18 training hours, each 30 days
0706T	Remote treatment of amblyopia using an eye tracking device; interpretation and report by physician or other qualified healthcare professional, per calendar month
0731T	Augmentative AI-based facial phenotype analysis with report
0740T	Remote autonomous algorithm-based recommendation system for insulin dose calculation and titration; initial set-up and patient education
0741T	Remote autonomous algorithm-based recommendation system for insulin dose calculation and titration; provision of software, data collection, transmission, and storage, each 30 days
0770T	Virtual reality technology to assist therapy (List separately in addition to code for primary procedure)
0771T	Virtual reality (VR) procedural dissociation services provided by the same physician or other qualified health care professional performing the diagnostic or therapeutic service that the VR procedural dissociation supports, requiring the presence of an independent, trained observer to assist in the monitoring of the patient's level of dissociation or consciousness and physiological status; initial 15 minutes of intraservice time, patient age 5 years or older

Table 1	
CPT/HCPCS Codes considered medically necessary if criteria are met: *Please note that the provided list may not cover every digital health product, as some may not have a specific code assigned to them.*	
0772T	Virtual reality (VR) procedural dissociation services provided by the same physician or other qualified health care professional performing the diagnostic or therapeutic service that the VR procedural dissociation supports, requiring the presence of an independent, trained observer to assist in the monitoring of the patient's level of dissociation or consciousness and physiological status; each additional 15 minutes intraservice time (List separately in addition to code for primary service)
0773T	Virtual reality (VR) procedural dissociation services provided by a physician or other qualified healthcare professional other than the physician or other qualified healthcare professional performing the diagnostic or therapeutic service that the VR procedural dissociation supports; initial 15 minutes of intraservice time, patient age 5 years or older
0774T	Virtual reality (VR) procedural dissociation services provided by a physician or other qualified healthcare professional other than the physician or other qualified healthcare professional performing the diagnostic or therapeutic service that the VR procedural dissociation supports; each additional 15 minutes intraservice time (List separately in addition to code for primary service)
99091	Collection and interpretation of physiologic data (e.g. ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified healthcare professional, qualified by education, training, licensure/ regulation (when applicable) requiring a minimum of 30 minutes of time, each 30 days
99453	Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow Billed once per rate), initial; set-up and patient education on use of episode of care. equipment.
99454	Device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days.
99457	Remote physiologic monitoring treatment management services, 20 minutes or more of clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month
99458	Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; additional 20 minutes.
99199	Unlisted special service, procedure or report [when specified as a mobile-based health management software application]

Table 1	
CPT/HCPCS Codes considered medically necessary if criteria are met: *Please note that the provided list may not cover every digital health product, as some may not have a specific code assigned to them.*	
A9291	Prescription digital behavioral therapy, FDA cleared, per course of treatment
A9292	Prescription digital visual therapy, software-only, FDA cleared, per course of treatment
A9999	Miscellaneous DME supply or accessory, not otherwise specified
E1399	Durable medical equipment, miscellaneous [when specified as a mobile-based health management software application]
E1905	Virtual reality cognitive behavioral therapy device (CBT), including pre-programmed therapy software
T1505	Electronic medication compliance management device, includes all components and accessories, not otherwise classified [when specified as a mobile-based health management software application]

Table 2	
ICD-10 codes considered medically necessary if criteria are met:	
Code	*Description*
	All diagnoses

Appendix A

Table 3*: Prescription (Rx) Digital Therapeutics (PDTs), i.e., for prescription use only

Prescription DTx Products	Intended Use/Indications for Use *(Abbreviated descriptions, please see Table 1b in Appendix for detailed summary)*
AspyreRx by Better Therapeutics Inc.	Type 2 diabetes
BlueStar Rx® by Welldoc	Type 1 and 2 diabetes
Canvas Dx by Cognoa	Autism Spectrum Disorder (ASD) diagnosis aid for pediatrics

CT-132 by Click Therapeutics	Episodic migraines
CT-155 by Click Therapeutics, Boehringer Ingelheim	Schizophrenia
CureSight™ by NovaSight	Improve visual acuity of patients with amblyopia
DaylightRx By Big Health	generalized anxiety disorder (GAD)
d-Nav® by Hygieia	Type 2 diabetes
Drowzle Pro by Resonea	Prescreening tool for obstructive sleep apnea
EndeavorRx® by Akili	Attention-deficit/hyperactivity disorder (ADHD)
Halo AF Detection System by LIVMOR	AF detection using photoplethysmography
Home Vision Monitor (HVM), fka myVisionTrack by Vital Art and Science	Home vision test for maculopathy
Insulia® by Voluntis	Type 2 diabetes
INVU by Nuvo	Fetal heart rate and uterine activity monitoring
Leva® by Axena Health	Urinary and fecal incontinence
Luminopia One by Luminopia	Improve amblyopia vision in children
Mahana IBS by Mahana Therapeutics	Irritable Bowel Syndrome (IBS)
MamaLiftPlus by Curio Digital Therapeutics, Inc.	Postpartum depression
MindMotion GO by MindMaze	physical rehabilitation for adults.
Modia by Orexo GAIA	Opioid Use Disorder
My Dose Coach by Sanofi	Type 2 diabetes
Nerivio®	Migraine

by Theranica	
NightWare Kit by NightWare	Nightmare relief device for adults
Regulora by metaMe Health	Irritable Bowel Syndrome (IBS)
RelieVRx, fka EaseVRx by AppliedVR	Chronic low back pain (CLBP)
Rejoyn by Otsuka Pharmaceutical	Major Depressive Disorder (MDD)
reSET® by Pear Therapeutics	Substance use disorder (SUD)
reSET-O® by Pear Therapeutics	Opioid use disorder (OUD)
SleepioRx by Big Health	Chronic insomnia/insomnia disorder
Somryst® by Pear Therapeutics	Insomnia
SparkRx® by Limbix	Depression
Stanza by Swing Therapeutics	Fibromyalgia
Tidepool Loop by Tidepool	Auto insulin control for diabetes

*The data presented in the table is provided for informational purposes only and is accurate as of [12/2025]. It does not constitute a comprehensive or exhaustive list.

Table 4*: Over-the-Counter (OTC) Digital Therapeutics (DTx), i.e., a prescription is not required

DTx Products	Intended Use
BlueStar®, by Welldoc	Type 1 and 2 diabetes
Dario® Blood Glucose Monitoring System, by DarioHealth	Type 1 and 2 diabetes
Daylight®, by Big Health	Generalized anxiety disorder

Deprexis®, by Orexo	Depression
EndeavorOTC®, by Akili Interactive	Attention-deficit/hyperactivity disorder (ADHD)
Freespira®[#], by Freespira, Inc.	pPost-traumatic stress disorder (PTSD), panic disorder, and panic attack
HelloBetter® Chronic Pain, by GET.ON Institut für Online Gesundheitstrainings GmbH	Chronic pain
HelloBetter® Diabetes and Depression, by GET.ON Institut für Online Gesundheitstrainings GmbH	Depression in people with diabetes
HelloBetter® Panic, by GET.ON Institut für Online Gesundheitstrainings GmbH	Panic disorder with or without agoraphobia
HelloBetter® Stress and Burnout, by GET.ON Institut für Online Gesundheitstrainings GmbH	Stress and burnout
HelloBetter® Vaginismus Plus, by GET.ON Institut für Online Gesundheitstrainings GmbH	vaginismus, dyspareunia and genito pelvic pain/penetration disorder (GPPPD)
Kaiku Health, by Kaiku Health	Cancer care
Propeller®, by Propeller Health	Asthma and chronic obstructive pulmonary disease (COPD)
Sleepio®, by Big Health	Insomnia
Vvorvida®, by Orexo	Reduce Alcohol Use Disorder

[#]Permission from a licensed healthcare professional is needed, but a prescription is not required.

[*]The data presented in the table is provided for informational purposes only and is accurate as of [12/2025]. It does not constitute a comprehensive or exhaustive list.

NOTE: This Clinical Guideline addresses FDA-cleared or approved clinician-prescribed software apps on mobile devices (e.g. phone, laptop, smartwatch, tablet) for health management with the aim of evaluating, diagnosing, or treating medical conditions or symptoms. It does not cover mobile software not cleared or approved by the FDA, including OTC or consumer-available apps for general wellness or used by healthcare professionals for remote health monitoring.

References

1. "Better Therapeutics Announces New Data Highlighting Concurrent Use of AspyreRx and GLP-1 Receptor Agonists to Treat Type 2 Diabetes." BioSpace, 11 Oct. 2023, https://www.biospace.com/better-therapeutics-announces-new-data-highlighting-concurrent-use-of-aspyrerx-and-glp-1-receptor-agonists-to-treat-type-2-diabetes.

2. "Proposed New Medicare Billing Codes Could Boost Digital Mental Health Treatment." Healthcare IT News, 13 Aug. 2024, https://www.healthcareitnews.com/news/proposed-new-medicare-billing-codes-could-boost-digital-mental-health-treatment.
3. Abbas H, Garberson F, Glover E, Wall DP. Machine learning approach for early detection of autism by combining questionnaire and home video screening. J Am Med Inform Assoc. 2018; 25(8):1000-1007. https://doi.org/10.1093/jamia/ocy039.
4. Abbas H, Garberson F, Liu-Mayo S, et al. Multi-modular AI approach to streamline autism diagnosis in young children. Sci Rep. 2020; 10(1):5014. https://doi.org/10.1038/s41598-020-61213-w.
5. Academy of Managed Care Pharmacy. AMCP is helping to define digital therapeutics for coverage decisions. Alexandria, VA: Academy of Managed Care Pharmacy; November 21, 2019. Available at https://www.amcp.org/Resource-Center/blog/amcp-helping-define-digital-therapeutics-coverage-decisions. Accessed March 31, 2023.
6. Agarwal P, Mukerji G, Desveaux L, et al. Mobile app for improved self-management of type 2 diabetes: multicenter pragmatic randomized controlled trial. JMIR Mhealth Uhealth. 2019. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6329896/. Accessed March 31, 2023.
7. Ailani J, et al. The American Headache Society consensus statement: Update on integrating new migraine treatments into clinical practice. Headache. 2021 Jul;61(7):1021-1039. Doi: 10.1111/head.14153. Epub 2021 Jun 23. PMID: 34160823.
8. Akili Interactive Labs, Inc. EndeavorRx: Indications, safety & cautions. Boston, MA: Akili Interactive Labs; 2021. Available at: https://www.endeavorrx.com/regulations/. Accessed March 31, 2023.
9. Akili Interactive Labs, Inc. EndeavorOTC: A Digital Treatment for Adult ADHD. Boston, MA: Akili Interactive Labs. 2025. Available at: https://www.endeavorotc.com/. Accessed 9 Oct 2025.
10. American Academy of Ophthalmology. Amblyopia Preferred Practice Pattern®. Ophthalmology. 2018;125(1):P105-P142. Doi:10.1016/j.ophtha.2017.10.008.
11. American Diabetes Association Professional Practice Committee. 7. Diabetes Technology: Standards of Care in Diabetes-2024. Diabetes Care. 2024 Jan 1;47(Suppl 1):S126-S144. doi: 10.2337/dc24-S007. PMID: 38078575; PMCID: PMC10725813.
12. American Medical Association (AMA). Proposed guidelines aim for safe, effective mobile health apps. Chicago, IL: AMA; January 22, 2018. Available at https://www.ama-assn.org/practice-management/digital/proposed-guidelines-aim-safe-effective-mobile-health-apps. Accessed March 31, 2023.
13. American Psychiatric Association (APA). Mental health apps. Washington, DC: APA; 2021. Available at https://www.psychiatry.org/psychiatrists/practice/mental-health-apps/the-app-evaluation-model. Accessed March 31, 2023.
14. Anderson, ByMaia. "What CMS's Proposed Reimbursement Codes Could Mean for the Digital Therapeutics Industry." Healthcare Brew, https://www.healthcare-brew.com/stories/2024/07/22/cms-proposed-reimbursement-codes-digital-therapeutics-industry. Accessed 3 Dec. 2024.
15. AppliedVR, Inc. Discover RelieVRx. About RelieVRx. Van Nuys, CA.: AppliedVR; 2022. Available at: https://www.relievrx.com/about#discover. Accessed March 31, 2023.
16. Batterham PJ, Christensen H, Mackinnon AJ, et al. Trajectories of change and long-term outcomes in a randomised controlled trial of internet-based insomnia treatment to prevent depression. BJPsych Open. 2017; 3(5):228-235.
17. Bergenstal RM, Johnson M, Passi R, et al. Automated insulin dosing guidance to optimise insulin management inpatients with type 2 diabetes: A multicentre, randomised controlled trial. Lancet. 2019; 393(10176):1138-1148.

18. Brezing CA, Brixner DI. The Rise of Prescription Digital Therapeutics in Behavioral Health. Adv Ther. 2022 Dec;39(12):5301-5306. doi: 10.1007/s12325-022-02320-0. Epub 2022 Oct 15. PMID: 36242730; PMCID: PMC9569000.
19. Campbell AN, Nunes EV, Matthews AG, et al. Internet-delivered treatment for substance abuse: A multisite randomized controlled trial [published correction appears in Am J Psychiatry. 2014 Dec 1;171(12):1338]. Am J Psychiatry. 2014;171(6):683-690. Doi: 10.1176/appi.ajp.2014.13081055. Erratum in: Am J Psychiatry. 2014 Dec 1;171(12):1338. PMID: 24700332; PMCID: PMC4079279.
20. Carl JR, Miller CB, Henry AL, Davis ML, Stott R, Smits JAJ, Emsley R, Gu J, Shin O, Otto MW, Craske MG, Saunders KEA, Goodwin GM, Espie CA. Efficacy of digital cognitive behavioral therapy for moderate-to-severe symptoms of generalized anxiety disorder: A randomized controlled trial. Depress Anxiety. 2020 Dec;37(12):1168-1178. doi: 10.1002/da.23079. Epub 2020 Jul 29. PMID: 32725848.
21. Catalá-López F, Hutton B, Núñez-Beltrán A, et al. The pharmacological and non-pharmacological treatment of attention deficit hyperactivity disorder in children and adolescents: A systematic review with network meta-analyses of randomised trials. PLoS One. 2017;12(7):e0180355.
22. Cheng, Mira. "FDA Clears First Digital Treatment for Depression, but Experts Caution That Research Is Still Early." CNN, 2 Apr. 2024, https://www.cnn.com/2024/04/02/health/fda-rejoyn-depression-digital-treatment/index.html.
23. Christensen DR, Landes RD, Jackson L, et al. Adding an internet-delivered treatment to an efficacious treatment package for opioid dependence. J Consult Clin Psychol. 2014; 82(6):964-972. Doi: 10.1037/a0037496.
24. Christensen H, Batterham PJ, Gosling JA, et al. Effectiveness of an online insomnia program (SHUTi) for prevention of depressive episodes (the GoodNight Study): a randomised controlled trial. Lancet Psychiatry. 2016; 3(4):333-341.
25. Click Therapeutics. Episodic Migraine CT-132. New York, New York. 2025. Available at: https://www.clicktherapeutics.com/products/ct-132. Accessed 9 Oct 2025.
26. Click Therapeutics. Schizophrenia CT-155. New York, New York. 2025. https://www.clicktherapeutics.com/products/ct-155. Accessed 9 Oct 2025.
27. Cognoa. Hcp user guide. Canvas Dx. Palo Alto, CA: Cognoa; 2021. Available at: https://cognoa-production-cms.s3.amazonaws.com/documents/HCP+Portal+User+Guide+Rev+J.pdf. Accessed March 31, 2023.
28. Cognoa. Pipeline. Palo Alto, CA: Cognoa; 2023. Available at: https://cognoa.com/our-science/pipeline/. Accessed March 31, 2023.
29. Cui L, Schroeder PR, Sack PA. Inpatient and outpatient technologies to assist in the management of insulin dosing. Clin Diabetes. 2020;38(5):462-473. Doi:10.2337/cd20-0054.
30. Curio Digital Therapeutics Inc. MamaLiftPlus. Princeton, NJ. 2025. Available at:https://www.mymamalift.com/. Accessed 9 Oct 2025.
31. Dang A, Arora D, Rane P. Role of digital therapeutics and the changing future of healthcare. J Family Med Prim Care. 2020;9(5):2207-2213.
32. Davenport ND, Werner JK. A randomized sham-controlled clinical trial of a novel wearable intervention for trauma-related nightmares in military veterans. J Clin Sleep Med. 2023 Feb 1;19(2):361-369. doi: 10.5664/jcsm.10338. PMID: 36305584; PMCID: PMC9892731.
33. Davison, N.J., Guthrie, N.L., Medland, S. et al. Cost-Effectiveness Analysis of a Prescription Digital Therapeutic in Type 2 Diabetes. Adv Ther 41, 806–825 (2024). https://doi.org/10.1007/s12325-023-02752-2
34. Digital Therapeutics Alliance. DTx product profile BlueStar and BlueStar Rx. Arlington, VA: Digital Therapeutics Alliance; 2023. Available at: https://dtxalliance.org/products/bluestar/.
35. Digital Therapeutics Alliance. DTx product profile CureApp HT Hypertension Treatment Aid App. Arlington, VA: Digital Therapeutics Alliance; 2023. Available at: https://dtxalliance.org/products/cureapp-ht/.
36. Digital Therapeutics Alliance. DTx product profile d-Nav. Arlington, VA: Digital Therapeutics Alliance; 2023. Available at: https://dtxalliance.org/products/d-nav/.

37. Digital Therapeutics Alliance. DTx product profile Dario® Blood Glucose Monitoring System. Arlington, VA: Digital Therapeutics Alliance; 2023. Available at: https://dtxalliance.org/products/dario-blood-glucose-monitoring-system/.
38. Digital Therapeutics Alliance. DTx product profile Daylight. Arlington, VA: Digital Therapeutics Alliance; 2023. Available at: https://dtxalliance.org/products/daylight/.
39. Digital Therapeutics Alliance. DTx product profile deprexis. Arlington, VA: Digital Therapeutics Alliance; 2023. Available at: https://dtxalliance.org/products/deprexis/.
40. Digital Therapeutics Alliance. DTx product profile EndeavorRx. Arlington, VA: Digital Therapeutics Alliance; 2023. Available at: https://dtxalliance.org/products/endeavor/.
41. Digital Therapeutics Alliance. DTx product profile Freespira. Arlington, VA: Digital Therapeutics Alliance; 2023. Available at: https://dtxalliance.org/products/freespira/.
42. Digital Therapeutics Alliance. DTx product profile HelloBetter® Chronic Pain. Arlington, VA: Digital Therapeutics Alliance; 2023. Available at: https://dtxalliance.org/products/hellobetter-chronicpain/.
43. Digital Therapeutics Alliance. DTx product profile HelloBetter® Diabetes and Depression. Arlington, VA: Digital Therapeutics Alliance; 2023. Available at: https://dtxalliance.org/products/hellobetter-diabetes-and-depression/.
44. Digital Therapeutics Alliance. DTx product profile HelloBetter® Panic. Arlington, VA: Digital Therapeutics Alliance; 2023. Available at: https://dtxalliance.org/products/hellobetter-panic-and-agoraphobia/.
45. Digital Therapeutics Alliance. DTx product profile HelloBetter® Stress and Burnout. Arlington, VA: Digital Therapeutics Alliance; 2023. Available at: https://dtxalliance.org/products/hellobetter-stress-and-burnout/.
46. Digital Therapeutics Alliance. DTx product profile HelloBetter® Vaginismus Plus. Arlington, VA: Digital Therapeutics Alliance; 2023. Available at: https://dtxalliance.org/products/hellobetter-vaginismus/.
47. Digital Therapeutics Alliance. DTx product profile Insulia. Arlington, VA: Digital Therapeutics Alliance; 2023. Available at: https://dtxalliance.org/products/insulia/.
48. Digital Therapeutics Alliance. DTx product profile Kaiku Health. Arlington, VA: Digital Therapeutics Alliance; 2023. Available at: https://dtxalliance.org/products/kaiku-health/.
49. Digital Therapeutics Alliance. DTx product profile leva. Arlington, VA: Digital Therapeutics Alliance; 2023. Available at: https://dtxalliance.org/understanding-dtx/product-library/.
50. Digital Therapeutics Alliance. DTx product profile Nerivio. Arlington, VA: Digital Therapeutics Alliance; 2023. Available at: https://dtxalliance.org/understanding-dtx/product-library/.
51. Digital Therapeutics Alliance. DTx product profile Propeller. Arlington, VA: Digital Therapeutics Alliance; 2023. Available at: https://dtxalliance.org/products/propeller/.
52. Digital Therapeutics Alliance. DTx product profile reSET-O. Arlington, VA: Digital Therapeutics Alliance; 2023. Available at: https://dtxalliance.org/products/reset-o/.
53. Digital Therapeutics Alliance. DTx product profile reSET. Arlington, VA: Digital Therapeutics Alliance; 2023. Available at: https://dtxalliance.org/products/reset/. Accessed October 1, 2021i.
54. Digital Therapeutics Alliance. DTx product profile SC Nicotine Addiction Treatment App and CO Checker®. Arlington, VA: Digital Therapeutics Alliance; 2023. Available at: https://dtxalliance.org/products/scnicotineaddictiontreatment/.
55. Digital Therapeutics Alliance. DTx product profile Sleepio. Arlington, VA: Digital Therapeutics Alliance; 2023. Available at: https://dtxalliance.org/products/sleepio/.
56. Digital Therapeutics Alliance. DTx product profile Somryst. Arlington, VA: Digital Therapeutics Alliance; 2023. Available at: https://dtxalliance.org/products/somryst/.
57. Digital Therapeutics Alliance. DTx product profile SparkRx®. Arlington, VA: Digital Therapeutics Alliance; 2023. Available at: https://dtxalliance.org/products/sparkrx/.
58. Digital Therapeutics Alliance. DTx product profile TALi®. Arlington, VA: Digital Therapeutics Alliance; 2023. Available at: https://dtxalliance.org/products/tali/.
59. Digital Therapeutics Alliance. DTx product profile vorvida®. Arlington, VA: Digital Therapeutics Alliance; 2023. Available at: https://dtxalliance.org/products/vorvida/.

60. Digital Therapeutics Alliance.Digital therapeutics definition and core principles. Arlington, VA: Digital Therapeutics Alliance; 2021. Available at https://dtxalliance.org/wp-content/uploads/2021/01/DTA_DTx-Definition-and-Core-Principles.pdf.
61. Everitt HA, Landau S, O'Reilly G, et al. Cognitive behavioural therapy for irritable bowel syndrome: 24-month follow-up of participants in the ACTIB randomised trial. Lancet Gastroenterol Hepatol. 2019b; 4(11):863-872.
62. First Smartphone App to Gain FDA Approval for Depression. https://www.aafp.org/pubs/afp/afp-community-blog/entry/first-smartphone-app-to-gain-fda-approval-for-depression.html. Accessed 5 Dec. 2024.
63. Franc S, Joubert M, Daoudi A et al. Efficacy of two telemonitoring systems to improve glycaemic control during basal insulin initiation in patients with type 2 diabetes: The TeleDiab-2 randomized controlled trial. Diabetes Obes Metab. 2019; 21(10):2327-2332.
64. Fulford D, Marsch LA, Pratap A. Prescription Digital Therapeutics: An Emerging Treatment Option for Negative Symptoms in Schizophrenia. Biol Psychiatry. 2024 Oct 15;96(8):659-665. doi: 10.1016/j.biopsych.2024.06.026. Epub 2024 Jul 1. PMID: 38960019; PMCID: PMC11410508.
65. Grosberg B, Rabany L, Lin T, et al. Safety and efficacy of remote electrical neuromodulation for the acute treatment of chronic migraine: An open-label study. Pain Rep. 2021;6(4):e966. Doi: 10.1097/PR9.0000000000000966.
66. Hagatun, S, Vedaa, Ø, Nordgreen, T, et al. The short-term efficacy of an unguided internet-based cognitive-behavioral therapy for insomnia: A randomized controlled trial with a six-month nonrandomized follow-up. Behav Sleep Med. 2019;17(2):137-155. https://doi.org/10.1080/15402002.2017.1301941.
67. Helne, Taru. Prescription Digital Therapeutics | AMCP.Org. https://www.amcp.org/policy-advocacy/legislative-regulatory-issues/prescription-digital-therapeutics. Accessed 2 Dec. 2024.
68. Hershey AD, Irwin S, Rabany L, et al. Comparison of remote electrical neuromodulation (REN) and standard-care medications for acute treatment of migraine in adolescents: a post-hoc analysis. Pain Med. 2022;23(4):815-820.
69. Hershey AD, Irwin S, Rabany L, et al. Comparison of remote electrical neuromodulation and standard-care medications for acute treatment of migraine in adolescents: A post hoc analysis. Pain Med. 2022 Apr 8;23(4):815-820. Doi: 10.1093/pm/pnab197.
70. Hsia J, Guthrie NL, Lupinacci P, et al. Randomized, Controlled Trial of a Digital Behavioral Therapeutic Application to Improve Glycemic Control in Adults with Type 2 Diabetes. Diabetes Care. 2022 Dec 1;45(12):2976-2981. doi: 10.2337/dc22-1099. PMID: 36181554; PMCID: PMC9862458.
71. Hygieia. The d-Nav way. Livonia, MI: Hygieia; 2021. Available at: https://hygieia.com/the-d-nav-way/.
72. Institute for Clinical and Economic Review (ICER). Digital health technologies as an adjunct to medication assisted therapy for opioid use disorder. November 6, 2020. Available at: https://icer.org/wp-content/uploads/2020/08/ICER_Digital_Therapeutics_for_OUD_Evidence_Report.pdf. Accessed March 30 2023.
73. International Medical Device Regulators Forum (IMDRF). Software as a Medical Device (SaMD): Key Definitions. IMRDF; December 9, 2013. Available at http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-samd-key-definitions-140901.pdf.
74. Kanne SM, Carpenter LA, Warren Z. Screening in toddlers and preschoolers at risk for autism spectrum disorder: Evaluating a novel mobile-health screening tool. Autism Res. 2018;11(7):1038-1049. doi:10.1002/aur.1959.
75. Kaplan A, Mannarino AP et al. Evaluating the impact of Freespira on panic disorder patients' health outcomes and healthcare costs within the Allegheny Health Network. Appl Psychophysiol Biofeedback. 2020;45(3):175-181. Doi: 10.1007/s10484-020-09465-0.

76. Khirasaria R, Singh V, and Batta A. Exploring digital therapeutics: The next paradigm of modern healthcare industry. Perspect Clin Res. 2020;11(2):54-58.
77. Kollins S, DeLoss D, Canadas E, et al. A novel digital intervention for actively reducing severity of paediatric ADHD(STARS-ADHD): A randomised controlled trial. Lancet. 2020;2(4):e168-e178.
78. Kollins SH, Childress A, Heusser AC, Lutz J. Effectiveness of a digital therapeutic as adjunct to treatment with medication in pediatric ADHD. NPJ Digit Med. 2021; 4(1):58.
79. Korot E, Pontikos N, Drawnel FM, et al. Enablers and barriers to deployment of smartphone-based Home Vision Monitoring in clinical practice settings. JAMA Ophthalmol. 2022; 140(2):153-160.
80. Kumar A, Ross JS, Patel NA, Rathi V, Redberg RF, Dhruva SS. Studies Of Prescription Digital Therapeutics Often Lack Rigor And Inclusivity. Health Aff (Millwood). 2023 Nov;42(11):1559-1567. doi: 10.1377/hlthaff.2023.00384. PMID: 37931187.
81. LIVMOR, Inc. LIVMOR receives FDA clearance for the world's first prescriptible wearable for continuous heart monitoring. Frisco, TX: LIVMOR; October 15, 2020.
82. Lum JW, Bailey RJ, Barnes-Lomen V, et al. A real-world prospective study of the safety and effectiveness of the Loop open source automated insulin delivery system. Published online April 20, 2021. Diabetes Technology & Therapeutics doi:10.1089/dia.2020.0535.
83. Mahana Therapeutics, Inc. Mahana Therapeutics obtains FDA marketing authorization for the first prescription digital therapeutic to treat irritable bowel syndrome. Press Release. San Francisco, CA: Mahana Therapeutics; December 8, 2020.
84. Maricich YA, Bickel WK, Marsch LA, Gatchalian K, Botbyl J, Luderer HF. Safety and efficacy of a prescription digital therapeutic as an adjunct to buprenorphine for treatment of opioid use disorder. Curr Med Res Opin. 2021 Feb;37(2):167-173. Doi: 10.1080/03007995.2020.1846022. Epub 2020 Dec 7. PMID: 33140994; PMCID: PMC8666102.
85. Maricich YA, Xiong X, Gerwien R, et al. Real-world evidence for a prescription digital therapeutic to treat opioid use disorder. Curr Med Res Opin. 2021b;37(2):175-183.
86. MindMaze. Digital therapies for neurorehabilitation. MindMotion GO. Lausanne, Switzerland: MindMaze; 2022. Available at: https://www.mindmaze.com/digital-therapies-for-neurorehabilitation/#mindmotion-go.
87. Moisset X, Pereira B, et al. Neuromodulation techniques for acute and preventive migraine treatment: A systematic review and meta- analysis of randomized controlled trials. J Headache Pain. 2020;21(1):142. Published 2020 Dec 10. Doi:10.1186/s10194-020-01204-4.
88. Narayan S, Shivdare P, Niranjan T, et al. Noncontact identification of sleep-disturbed breathing from smartphone-recorded sounds validated by polysomnography. Sleep Breath. 2019; 23(1):269-279.
89. Nierenburg H, Vieira JR, Lev N, et al. Remote electrical neuromodulation for the acute treatment of migraine in patients with chronic migraine: An open-label pilot study. Pain Ther. 2020;9(2):531-543.
90. NightWare, Inc. Product. Hopkins, MN: NightWare; 2021. Available at: https://nightware.com/product/. Accessed March 31, 2023.
91. Patel NA, Butte AJ. Characteristics and challenges of the clinical pipeline of digital therapeutics. NPJ Digit Med. 2020;3(1):159.
92. Orexo. Modia Patient Instruction for Use. Morristown, NJ.2024. Available at: https://us.modia.pro/instructions-for-use. Accessed 9 Oct 2025.
93. Pear Therapeutics, Inc. reSET & reSET-O. Boston, MA: Pear Therapeutics; 2021. Available at: https://peartherapeutics.com/products/reset-reset-o/. Accessed March 31, 2023.
94. Pear Therapeutics, Inc. Somryst. Boston, MA: Pear Therapeutics; 2021. Available at: https://peartherapeutics.com/products/somryst/. Accessed March 31, 2023.
95. Quinn CC, Shardell MD, Terrin ML, et al. Cluster-randomized trial of a mobile phone personalized behavioral intervention for blood glucose control. Diabetes Care. 2011;34(9):1934-1942. Doi: 10.2337/dc11-0366.
96. Resonea, Inc. Drowzle Pro Home Sleep Test. Products. Scottsdale, AZ: Resonea; 2021. Available at: https://drowzle.com/products/drowzle-pro-home-sleep-test/. Accessed March 31, 2023.

97. Ritterband LM, Thorndike FP, Gonder-Frederick LA, et al. Efficacy of an internet-based behavioral intervention for adults with insomnia [published correction appears in Arch Gen Psychiatry. 2010 Mar;67(3):311]. Arch Gen Psychiatry. 2009;66(7):692-698. Doi:10.1001/archgenpsychiatry.2009.66.
98. Ritterband LM, Thorndike FP, Ingersoll KS, et al. Effect of a web-based cognitive behavior therapy for insomnia intervention with 1-year follow-up: A randomized clinical trial. JAMA Psychiatry. 2017;74(1):68-75.
99. Rosenblatt P, McKinney J, Rosenberg RA, Iglesias RJ, Sutherland RC, Pulliam SJ. Evaluation of an accelerometer-based digital health system for the treatment of female urinary incontinence: A pilot study. Neurourol Urodyn. 2019;38(7):1944-1952.
100. Salsabili M, Tesell M, Alcusky M, Greenwood BC, Huang D, Lenz K, Dave J. Prescription digital therapeutics: Applying Medicaid experience to value assessment and formulary management. J Manag Care Spec Pharm. 2023 Jun;29(6):685-691. doi: 10.18553/jmcp.2023.29.6.685. PMID: 37276040; PMCID: PMC10387922.
101. Sapanel Y, Tadeo X, Brenna CTA, Remus A, Koerber F, Cloutier LM, Tremblay G, Blasiak A, Hardesty CL, Yoong J, Ho D. Economic Evaluation Associated With Clinical-Grade Mobile App-Based Digital Therapeutic Interventions: Systematic Review. J Med Internet Res. 2023 Aug 1;25:e47094. doi: 10.2196/47094. PMID: 37526973; PMCID: PMC10427932.
102. Shafai G, Aungst TD. Prescription digital therapeutics: A new frontier for pharmacists and the future of treatment. J Am Pharm Assoc (2003). 2023 Jul-Aug;63(4):1030-1034. doi: 10.1016/j.japh.2023.03.012. Epub 2023 Apr 3. PMID: 37019379.
103. Shaffer, KM, Hedeker, D, Morin, CM, et al. Intra-individual variability in sleep schedule: Effects of an internet-based cognitive- behavioral therapy for insomnia program and its relation with symptom remission. Sleep. 2020; 43(12). https://doi.org/10.1093/sleep/zsaa115.
104. Suttiratana SC, Wong JJ, Lanning MS, et al. D. Qualitative study of user experiences with loop, an open-source automated insulin delivery system. Diabetes Technol Ther. 2022 Jun;24(6):416-423. doi: 10.1089/dia.2021.0485. Epub 2022 May 12.
105. Swing Therapeutics. Stanza. San Francisco, CA. 2025. Available at: https://swingtherapeutics.com/stanza/. Accessed 9 Oct 2025.
106. Tackling biases in clinical trials to ensure diverse representation and effective outcomes. Nat Commun 15, 1407 (2024). https://doi.org/10.1038/s41467-024-45718-w
107. Theranica USA. Nerivio by Theranica. Montclair, NJ: Therannica; 2021. Available at: https://nerivio.com/. Accessed March 31, 2023.
108. Thorndike FP, Morin CM, Ojile J, Edington S, Gerwien R, Ong JC, Wickwire EM, Ritterband LM, Riney H. Effect of a prescription digital therapeutic for chronic insomnia on post-treatment insomnia severity, depression, and anxiety symptoms: results from the real-world DREAM study. Front Psychiatry. 2024 Sep 10;15:1450615. doi: 10.3389/fpsyt.2024.1450615. PMID: 39319356; PMCID: PMC11420038.
109. Tolin DF, McGrath PB, Hale LR, et al. A multisite benchmarking trial of capnometry guided respiratory intervention for panic disorder in naturalistic treatment settings. Appl Psychophysiol Biofeedback. 2017;42(1):51-58. Doi: 10.1007/s10484-017-9354-4.
110. U. S. Food and Drug Administration (FDA). Developing the software precertification program: Summary of learnings and ongoing activities: 2020 Update. Silver Spring, MD: FDA; September 2020. Available at: https://www.fda.gov/media/142107/download. Accessed March 31, 2023.
111. U.S. Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH). Cognoa ASD Diagnosis Aid. 513(f)(2)(De Novo) DEN200069. Silver Spring, MD: FDA; June 2, 2021. Available at: https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN200069.pdf. Accessed March 31, 2023.
112. U.S. Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH). CureSight (NovaSight, Ltd.) No. K221375. Silver Spring, MD: FDA; September 29, 2022. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf22/K221375.pdf. Accessed March 31, 2023.

113. U.S. Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH). d-Nav System®. (Hygieia, Inc.; Livonia, MI). No. K181916. Silver Spring, MD: FDA; February 04, 2019. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf18/K181916.pdf. Accessed March 31, 2023.
114. U.S. Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH). Drowzle sleep apnea pre screening device. 510 no. K173974. Silver Spring, MD: FDA; July 14, 2019. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf17/K173974.pdf. Accessed March 31, 2023.
115. U.S. Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH). EndeavorRxTM. (Akili Interactive Labs Inc.; Philadelphia, PA). No. 21 CFR 882.5803. Silver Spring, MD: FDA; June 15, 2020. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf20/DEN200026.pdf. Accessed March 31, 2023.
116. U.S. Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH). Freespira®. (Palo Alto Health Sciences, Inc.; Palo Alto, CA). No. K180173. Silver Spring, MD: FDA; August 23, 2018. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf18/K180173.pdf. Accessed March 31, 2023.
117. U.S. Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH). HaloTM AF Detection System. (LIVMOR, Inc., Frisco, Tx). No. K201208. Silver Spring, MD: FDA; September 23, 2020. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf20/K201208.pdf. Accessed March 31, 2023.
118. U.S. Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH). Insulia®. (Voluntis S.A. Suresnes, France). No. K161433. Silver Spring, MD: FDA; November 9, 2016. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf16/K161433.pdf. Accessed March 31, 2023.
119. U.S. Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH). Luminopia One (Luminopia, Inc). No. DEN210005. Silver Spring, MD: FDA; October 20, 2021. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf21/DEN210005.pdf. Accessed March 31, 2023.
120. U.S. Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH). Mahana Parallel digital cognitive behavioral therapy (CBT) mobile application for irritable bowel syndrome (IBS). 510 no. K211372. Silver Spring, MD: FDA; June 2, 2021. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf21/K211372.pdf. Accessed March 31, 2023.
121. U.S. Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH). MindMotion GO. 510 no. K173931. Silver Spring, MD: FDA; May 17, 2018. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf17/K173931.pdf. Accessed March 31, 2023.
122. U.S. Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH). My Dose Coach. 510 no. K171230. Silver Spring, MD: FDA; May 26, 2017. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf17/K171230.pdf. Accessed March 31, 2023.
123. U.S. Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH). myVisionTrack. 510 no. K121738. Silver Spring, MD: FDA; July 7, 2017. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf12/K121738.pdf. Accessed March 31, 2023.
124. U.S. Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH). NightWareTM. (NightWare, Inc.; Minneapolis, MN). No. DEN200033. Silver Spring, MD: FDA; November 6, 2020. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf20/DEN200033.pdf. Accessed March 31, 2023.
125. U.S. Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH). ParallelTM. (Mahana Therapeutics; San Francisco, CA). No. K211372. Silver Spring, MD: FDA; June 02, 2021. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf21/K211372.pdf. Accessed March 31, 2023.
126. U.S. Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH). Regulora. 510 no. K211463. Silver Spring, MD: FDA; November 24, 2021. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf21/K211463.pdf. Accessed March 31, 2023.

127. U.S. Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH). RelieVRx (formerly EaseVRx) No. DEN 210014. 2021. Silver Spring, MD: FDA; November 16, 2021. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf21/DEN210014.pdf. Accessed March 31, 2023.
128. U.S. Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH). Reset-O®. (Pear Therapeutics, Inc.; Boston, MA). No. K173681. Silver Spring, MD: FDA; May 23, 2019. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf17/K173681.pdf. Accessed March 31, 2023.
129. U.S. Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH). Reset®. (Pear Therapeutics, Inc.; Boston, MA). No. DEN160018. Silver Spring, MD: FDA; May 16, 2016. Available at: https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN160018.pdf. Accessed March 31, 2023.
130. U.S. Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH). Somryst®. (Pear Therapeutics, Inc.; Boston, MA). No. K191716. Silver Spring, MD: FDA; March 23, 2020. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf19/K191716.pdf. Accessed March 31, 2023.
131. U.S. Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH). Tidepool Loop (Tidepool; Palo Alto). No. K203689. Silver Spring, MD: FDA; January 23, 2023. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf20/K203689.pdf. Accessed March 31, 2023.
132. U.S. Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH). WellDoc® BlueStar®, BlueStar® Rx. 510 no. K162532. Silver Spring, MD: FDA; January 12, 2017. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf16/k162532.pdf. Accessed March 31, 2023.
133. U.S. Food and Drug Administration (FDA). Digital health innovation action plan. Silver Spring, MD: FDA; undated. Available at https://www.fda.gov/media/106331/download. Accessed March 31, 2023.
134. U.S. Food and Drug Administration (FDA). Digital health software precertification (pre-cert) program. Silver Spring, MD: FDA; May 6, 2021. Available at https://www.fda.gov/medical-devices/digital-health-center-excellence/digital-health-software-precertification-pre-cert-program. Accessed March 31, 2023.
135. U.S. Food and Drug Administration (FDA). Guidance document. Enforcement policy for digital health devices for treating psychiatric disorders during the Coronavirus disease 2019 (COVID-19) public health emergency. Silver Spring, MD: FDA; April 14, 2020. Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-digital-health-devices-treating-psychiatric-disorders-during-coronavirus-disease. Accessed March 31, 2023.
136. U.S. Food and Drug Administration. (2024). Daylight 510(k) Summary (K233872). Retrieved from FDA Website
137. U.S. Food and Drug Administration. (2024). Rejoyn 510(k) Summary (K231209).
138. U.S. Food and Drug Administration. (2024). Sleepio 510(k) Summary (K233577). Retrieved from FDA Website
139. U.S. Food and Drug Administration. (FDA). Device software functions including mobile medical applications. Silver Spring, MD: FDA; updated November 5, 2019. Available at https://www.fda.gov/medical-devices/digital-health-center-excellence/device-software-functions-including-mobile-medical-applications. Accessed March 31, 2023.
140. US Food and Drug Administration (FDA). Policy for device software function and mobile medical applications: Guidance for industry and Food and Drug Administration Staff. Silver Spring, MD: FDA; September 27, 2019. Available at: https://www.fda.gov/media/80958/download. Accessed March 31, 2023.
141. Vedaa Ø, Kallestad H, Scott J. et al. Effects of digital cognitive behavioural therapy for insomnia on insomnia severity: a large-scale randomized controlled trial. Lancet Digit Health. 2020 Aug;2(8):e397-e406. Doi: 10.1016/S2589-7500(20)30135-7. PMID: 33328044.

142. Vedaa, Ø, Hagatun, S, Kallestad, H, et al. Long-term effects of an unguided online cognitive behavioral therapy for chronic insomnia. J Clin Sleep Med. 2019;15(1):101-110. PMID: 30621837.
143. Velez FF, Colman S, Kauffman L, et al. Real-world reduction in healthcare resource utilization following treatment of opioid use disorder with reSET-O, a novel prescription digital therapeutic. Expert Rev Pharmacoecon Outcomes Res. 2021;21(1):69-76.
144. Voluntis. Chronic diseases. Cambridge, MA: Voluntis; 2021. Available at: https://www.voluntis.com/therapeutic-areas/chronic-diseases/. Accessed March 31, 2023.
145. Wang L, Nielsen K, Goldberg J, et al. Association of wearable device use with pulse rate and health care use in adults with atrial fibrillation. JAMA Netw Open. 2021;4(5): e215821.
146. Weinstein MM, Collins S, Quiroz L, et al. Multicenter randomized controlled trial of pelvic floor muscle training with a motion-based digital therapeutic device versus pelvic floor muscle training alone for treatment of stress-predominant urinary incontinence. Female Pelvic Med Reconstr Surg. 2022 Jan 1;28(1):1-6. Doi: 10.1097/SPV.0000000000001052. PMID: 33787561.
147. WellDoc. BlueStar Rx. [website] Columbia, MD: WellDoc.; 2021. Available at: http://www.welldoc.com/indications-for-use/. Accessed March 31, 2023.
148. What Is the Access to Prescription Digital Therapeutics Act? https://www.alextherapeutics.com/post/what-is-the-access-to-prescription-digital-therapeutics-act. Accessed 3 Dec. 2024.
149. Wong JJ, Suttiratana SC, Lal RA, et al. Discontinued use of the loop insulin dosing system: A mixed-methods investigation. Diabetes Technol Ther. 2022 Apr;24(4):241-248. doi: 10.1089/dia.2021.0362.
150. Wygnanski-Jaffe T, Kushner BJ, Moshkovitz A., et al. An eye-tracking based dichoptic home treatment for amblyopia: a multicenter randomized clinical trial. Ophthalmology. 2022; Oct 25: S0161-6420(22)00835-1. Online ahead of print. PMID: 36306974.
151. Xiao S, Angjeli E, Wu HC, Luminopia Pivotal Trial Group, et al. Randomized controlled trial of a dichoptic digital therapeutic for amblyopia. Ophthalmology. 2022 Jan;129(1):77-85. Doi: 10.1016/j.ophtha.2021.09.001. Epub 2021 Sep 14. Erratum in: Ophthalmology. 2022 May;129(5):593. PMID: 34534556.
152. Yarnitsky D, Dodick DW, Grosberg BM, et al. Remote electrical neuromodulation (REN) relieves acute migraine: A randomized, double-blind, placebo-controlled, multicenter trial. Headache. 2019;59(8):1240-1252.
153. Yarnitsky D, Volokh L, Ironi A, et al. Nonpainful remote electrical stimulation alleviates episodic migraine pain. Neurology. 2017;88(13):1250-1255. Doi:10.1212/WNL.0000000000003760.

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