PDT Name	Description	FDA Indication(s) for Use	Target Population	Proprietary Hardware?	Available Clinical Evidence and Notes	Reference(s)
AspyreRx	Prescribed in 90-day increments, the software delivers CBT through a mobile application in a weekly, step-by-step process to help patients improve glycemic control	Provide CBT to patients 18 years or older with type 2 diabetes who are under the care of a HCP.	Patients ≥18 y.o. with T2DM under care of HCP	No; delivered through an app through an iPhone/iPad OR Android	(1) RCT (2) Health economics analysis (3) Cohort study	(1) empr.com/home/news/fda-clears-prescription-digital-behavioral-therapeutic-for-type-2-diabetes/ (2) Hmpgloballearningnetwork.com/site/frmc/commentary/prescription-digital-therapeutics-ongoing-efforts-expand-awareness-integrate (3) bettertx.com/research
Canvas Dx	Uses an AI algorithm to receive input from parents or caregivers, video analysts and health care providers to assist physicians evaluate a patient at risk of Autism Spectrum Disorder	Aid in the diagnosis of ASD for patients 18 months through 5 years of age who are at risk of developmental delay based on concerns of a parent, caregiver, or health care provider.	Patients ages 18 m.o. through 72 m.o. who are at risk for developmental delay based on concerns of a parent, caregiver, or healthcare provider	No; delivered through an app through an iPhone/iPad OR Android	Several key milestones: foundational early stage development research, clinical validation, post-FDA authorization algorithmic optimization, real-world perfomance (pragmatic analysis).	(1) cognoa.com/clinical-research/ (2) prnewswire.com/news-releases/cognoa-receives-fda-marketing-authorization-for-first-of-its-kind-autism-diagnosis-aid-301304351.html
CT-155	This product received an FDA breakthrough device designation in January 2024. Delivered through a smartphone app, the product is designed to treat the negative	This product received a breakthrough device designation in January 2024, thus an FDA indication for use is unavailable at this time.	Patients ≥18 y.o. diagnosed with schizophrenia.	No; delivered through an app through an iPhone/iPad OR Android	Currently undergoing a randomized, multicenter, 16-week study evaluating the efficacy of CT-155 in addition to SOC therapy for the treatment of schizophrenia. The estimated study	(1) businesswire.com (2) clinicaltrials.gov

	symptoms of schizophrenia, in conjunction with standard of care (SOC) pharmaceutical therapy. (1)				completion date is June 2024. (2)	
CureSight	Blue-red light glasses that allow a child to watch any digital content with the intent to improve visual and stero acuity in patients with amblyopia; supported by an integrated cloud platform that processes data from the CureSight system, eye care provider receives a comprehensive patient vision summary	Improvement in visual acuity and stereo acuity in amblyopia patients, aged 4-<9 years, associated with anisometropia and/or with mild strabismus, having received treatment instructions (frequency and duration) as prescribed by a trained eyecare professional. CureSight™ is intended for both previously treated and untreated patients and is intended to be used as an adjunct to full-time refractive correction, such as glasses, which should also be worn	Patients aged 4-9 y.o. with amblyopia	Yes; blue-red light glasses (anaglyph conversion) that can must utilized with any digital content	(1) Pilot prospective study (2) One-year follow-up study (3) Several posters published online	(1) accessdata.fda.gov /cdrh_docs/pdf22 /K221375.pdf (2) nova-sight.com /publications-and-medical -posters/

		under the anaglyph glasses during CureSight™ treatment.				
d-Nav	Combines FDA-cleared mobile app enabled by AI technology, and virtual clinical support to make autonomous adjustments to a patient's insulin prescription based on their historical and current glucose levels; patients use d-Nav Technology before every insulin injection by entering their most recent sugar reading, and then receiving a personalized dose recommendation.	Calculates the next dose of insulin to aid in optimizing insulin management. The d-Nav Program is indicated for adults with type 2 diabetes who are injecting insulin.	Patients who inject insulin to manage their T2DM; no specific age identified at time of review	No; iPhone/iPad, Android required	(1) Multicenter randomized controlled study (2) Observational studies (3) Prospective cost analysis (4) Prospective study	(1) dtxalliance.org/products/d-nav/

EndeavorRx	Delivered through an action video game; designed to challenge pediatric patient's attentional control throughout gameplay. Requires focus, flexibility, and ability to manage multiple tasks at one time	Improve attention function as measured by computer-based testing in children ages 8-12 y.o. with primarily inattentive or combined-type ADHD, who have a demonstrated attention issue.	Patients ages 8-12 y.o.	No; delivered through an app through an iPhone/iPad OR Android	Supported by a total of 5 clinical studies, total of 600 pediatric patients with ADHD. **Highlights:** (1) Multicenter, open-label effectiveness study AND (2) Randomized controlled trial	(1) endeavorrx.com /the-research/ (2) dtxalliance.org/products /endeavor/
FibriCheck	Medical device software that determines heart rhythm conditions, with a primarily focus on the detection of Afib that makes use of optical sensing from a mobile device to collect photoplethysmogram (PPG) data; these recordings can be shared optionally with a physician or monitoring service	Self-testing by patients who have been diagnosed with, or are susceptible to developing, atrial fibrillation and who would like to monitor and record their heart rhythms on an intermittent basis.	Patients $\geq$18 y.o. that have been diagnosed with or are susceptible to developing Afib	No; delivered through an app through an iPhone/iPad OR Android	Various studies performed: algorithim validation, PPG interpretation, usability for HCPs, usability for patients	(1) accessdata.fda.gov /cdrh_docs/pdf17 /K173872.pdf (2) https://www.fibricheck .com/clinical-studies/
Freespira	After completing training with a HCP or a Freespira coach, patients will complete a 28-day home-delivered protocol with two 17-min breathing sessions/day; there are	Adjunctive treatment of symptoms associated with panic disorder (PD) and/or posttraumatic stress disorder (PTSD), to	Patients over 13 years old with PTSD, panic disorder, or suffering from panic attacks associated with other medical or behavioral health conditions	Yes; patient will receive Freespira device, which is self-contained & does not require additional equipment. Patient will need to send	(1) Two real-world evidence studies (pragmatic) (2) Cost-savings study with Allegheny Health Network (3) Multisite benchmarking study	(1) accessdata.fda.gov /cdrh_docs/pdf18 /K180173.pdf (2) frontiersin.org/articles /10.3389/fdgth.2022. 976001/full (3) freespira.com/resources /

	four additional weekly virtual coaching sessions	be used under the direction of a healthcare professional, together with other pharmacological and/or non-pharmacological interventions		device back after completion of therapy.		
Glooko Mobile Insulin Dosing System (MIDS)	Glooko MIDS provides directions to the patient based on a pre-planned treatment program as suggested by their HCP for titrating long acting insulin doses; to be used for titrating long acting insulin doses only	Management of type 2 diabetes by calculating appropriate long-acting basal insulin doses for titrating insulin levels based on configuration by a physician or healthcare provider knowledgeable in the care and management of diabetes.	Patients ≥18 y.o. with T2DM being treated with long-acting insulin analogs to manage their diabetes.	No; iPhone/iPad, Android required	Various retrospective studies, cost/outcomes studies	(1) accessdata.fda.gov/cdrh_docs/pdf17/K171450.pdf
Halo AF	Consists of algorithm that filters and detects irregular pulse rhythm that may be suggestive of atrial fibrillation (AF) from photoplethysmograph (PPG) data, a patient user interface to notify the patient of data collection, and a	For use by patients who have been diagnosed with or are susceptible to developing atrial fibrillation and who like to monitor and record their pulse rhythms on an intermittent basis so that their physician	Patients ≥18 y.o. that have been diagnosed with or are susceptible to developing Afib	No; delivered through compatible Samsung Smartwatch	None identified at time of review	(1) accessdata.fda.gov/cdrh_docs/pdf20/K201208.pdf

	physician user interface to alert the physician when irregular pulse rhythm suggestive of AF is detected; interfaces with the LIVMOR Halo+ Home Monitoring System and compatible smartwatch to capture PPG data and sync to servers	can be alerted of detected irregular heart rhythms				
Insulia	Software medical device that supports insulin titration for people using any brand of basal insulin	Provide secure capture, storage and transmission of diabetes related healthcare information, to enhance data management, to display reports and graphs, and to aid the HCP and the patient in the review, analysis, and evaluation of patient data in order to support effective diabetes management.	Patients ≥18 y.o. with T2DM being treated with long-acting insulin analogs to manage their diabetes.	No; iPhone/iPad, Android required	(1) Randomized controlled study with two arms	(1) dtxalliance.org/products/insulia/

InTandem (MR-001)	Evidence-based neurorehabilitation system to improve walking and ambulation in adults with chronic stroke walking deficits. The system delivers an intervention based on the principle of Rhythmic Auditory Stimulation (RAS), a well-researched clinical intervention utilizing the mechanism of auditory-motor entrainment, through which the motor and auditory systems in the brain subconsciously synchronize to an external cue, such as music.[1]	Indicated to improve walking and ambulation in adult chronic stroke patients.[2]	Adults (>18 y/o) with chronic stroke walking deficits.	Yes. Patient will receive a package including shoe-worn sensors (one for each shoe), a touchscreen device pre-loaded with InTandem, a headset, and charging components for the applicable devices.	(1) Feasibility study (2) Randomized controlled trial of safety and clinical efficacy (3) A budget impact model that estimates cost savings to payers was also created.[3]	(1) https://www.prnewswire.com (2) https://intandemrx.com/ (3) https://rehab.jmir.org/2023/1/e50438
Leva	Intended for pelvic floor strengthening to improve fecal & urinary incontinence; users are guided by the app to perform exercise sessions twice a day for 8-12 weeks (or until satisfied with their results); Leva motion sensor is placed	1) Strengthening of the pelvic floor muscles; 2) Rehabilitation and training of weak pelvic floor muscles for the treatment of stress, mixed and mild to moderate urgency urinary incontinence	Women with urinary incontinence, chronic fecal incontinence, and/or pelvic floor muscle weakness who want to improve or resolve these symptoms with at-home pelvic floor muscle training	No; delivered through an app through an iPhone/iPad OR Android	(1) 4 RCTs (2) Retrospective cohort study (3) Single-arm trial	(1) dtxalliance.org/products/leva/

	intravaginally for the duration of the exercise session and is removed immediately after use. Exercise sessions are performed in a standing position.	(including overactive bladder) in women, and 3) Rehabilitation and training of weak pelvic floor muscles for the first-line treatment of chronic fecal incontinence (>3-month uncontrolled passage of feces) in women.				
Luminopia One	Digital therapy device for amblyopia; incorporates dichoptic presentations on visual displays through therapeutic algorithms to treat amblyopia or to improve visual acuity of patients with amblyopia	Improvement in visual acuity in amblyopia patients 4-7 y.o., associated with anisometropia and/or with mild strabismus as prescribed by a trained eye-care professional. Intended for both previously treated and untreated patients; however, patients with >12 months of prior treatment (other than refractive correction) have not been studied	Patients 4-7 y.o. with amblyopia, associated with anisometropia and/or with mild strabismus	No; designed to be used with commercially available Head-Mounted Displays that are compatible with software application	(1) RCT (2) Open-label pilot study (3) Single-center, open-label design (4) Modelling study - no patient involvement	(1) accessdata.fda.gov/cdrh_docs/reviews/DEN210005.pdf (2) luminopia.com/hcp/clinical-data

Mahana IBS (Previously known as Parallel)	Three-month, patient tailored interactive program designed to reduce severity of IBS symptoms through cognitive behavioral therapy	Indicated as 3-month treatment for patients with IBS	Adults ≥22 y.o. with IBS	No; delivered through an app through an iPhone/iPad OR Android	(1) Multicenter randomized clinical trial	(1) assets.website-files.com/61f48988f687c00c6032c430/61f48988f687c071e032c514_03-0007-002%20Rev%20B_Parallel%20Mobile%20US_Labeling_Clinician%20Information%20Sheet.pdf (2) https://gut.bmj.com/content/68/9/1613.long
MindMotion GO	Focuses on maximizing the recovery potential of patients after a stroke or brain injury. Software includes rehabilitation exercises for the upper extremity, trunk, and lower extremity; audio-visual feedback and graphic movement representations for patients; and patient performance metrics for the medical professional. Patient assessment, exercise guidance, and approval by the medical professional is required prior to use.	Medical device software used in combination with the Microsoft Kinect v2 and Leap Motion controller that supports the physical rehabilitation of adults in the clinic and at home.	Patients that have experienced a stroke or brain injury; no specific age identified at time of review	No; software delivered through Microsoft Kinect v2 and Leap Motion controller	None identified at time of review	(1) accessdata.fda.gov/cdrh_docs/pdf17/K173931.pdf (2) accessgudid.nlm.nih.gov/devices/03760272650019

myVisionTrack	Vision function test provided as a downloadable app on to the user's supplied cell phone or tablet which implements a shape discrimination hyperacuity vision test which allows patients to perform their own vision test at home; if a significant worsening of vision function is detected the physician will be notified and provided access to the vision self-test results so that they can decide whether the patient needs to be seen sooner than their next already scheduled appointment	Detection and characterization of central 3 degrees metamorphopsia (visual distortion) in patients with maculopathy, including age-related macular degeneration and diabetic retinopathy, and as an aid in monitoring progression of disease factors causing metamorphopsia.	Patients with age-related macular degeneration, diabetic retihnopathy, and other retinal conditions; no specific age identified at time of review	No; delivered through an app through an iPhone/iPad OR Android	(1) Observational, case-only study	(1) accessdata.fda.gov /cdrh_docs/pdf14 /K143211.pdf (2) classic.clinicaltrials.gov /ct2/show/record /NCT01728883
Nerivio	Wireless wearable battery-operated stimulation unit controlled by a smartphone software application; treatments are self-administered by the user at the onset of a migraine attack.	Non-pharmacological, non- invasive, wireless, wearable, battery-operated, remote electrical neuromodulation (REN) stimulation device for the treatment of migraine. Nerivio is	For migraine patients with or without aura, ≥12 y.o. For those seeking a clinically-proven drug-free solution, or those that do not respond to prescribed medications and/or cannot tolerate AEs	No; delivered through an app through an iPhone/iPad OR Android	(1) Pragmatic trial (2) Prospective, multi-center, open-label trial (3) Retrospective, survey study (4) Several (>5) prospective, open-label studies (5) Several sham-controlled studies	(1) dtxalliance.org/products /nerivio/

		self-administered by the patient, controlled by a smartphone app, and FDA cleared for acute treatment of migraine with or without aura in patients 12 years of age or older.				
NightWare	Digital therapeutic system that temporarily reduces sleep disturbance related to nightmares through vibrotactile feedback during sleep cycle	Provide vibrotactile feedback on an Apple Watch based on an analysis of heart rate and motion during sleep for the temporary reduction of sleep disturbance related to nightmares	Adults ≥22 y.o who suffer from nightmare disorder or have nightmares from PTSD	No; software delivered through AppleWatch and iPhone	(1) Randomized sham-controlled clinical trial	(1) nightware.com/ scientific-literature/
Regulora	Three-month treatment for patients with abdominal pain due to IBS that is designed to induced deep physical autonomic relaxation followed by metphorical storytelling with a combination of direct/indirect suggestions at somatic control mechanisms	Provide behavioral therapy through gut-directed hypnotherapy for adults ≥22 y.o. and older who have been diagnosed with IBS	Adults ≥22 y.o. with IBS	No; delivered through an app through an iPhone/iPad OR Android	No studies specific to device; rather, efficacy and safety built on previous research that descibes efficacy of hypontherapy and behavioral therapy for IBS	(1) accessdata.fda.gov /cdrh_docs/pdf21 /K211463.pdf (2) regulorahcp.com/ resources/

RelieVRx (Previously known as EaseVRx)	Virtual reality device intended to provide behavioral therapy for patients with pain; treatment is self-administered over 8 weeks in the comfort of a patient's home with an average daily session of 7 mins	Provide adjunctive treatment based on cognitive behavioral therapy skills and other evidence-based behavioral methods for patients (age 18 and older) with a diagnosis of chronic lower back-pain (defined as moderate to severe pain lasting longer than three months)	Adults ≥18 y.o. with a diagnosis of chronic lower back-pain (moderate to severe pain lasting longer than three months)	Yes; RelieVRx kit includes the optimized device for VRx, headset/controller, screen, face pan, amplifier, and platform	(1) Randomized, controlled, double-blind trial *FYI Class 2 Active recall as of 06/2023 due to device malfunctioning	(1) appliedvr.io/product (2) relievrx.com/ clinical-results#trial-design
reSET	Delivers behavioral therapy modeled on the Community Reinforcement Approach (CRA), which is a specific form of CBT designed for patients with SUD; combines CRA and fluency training in conjunction with Contingency Management to support and incentivize patients with SUD in achieving abstinence and retention in outpatient SUD treatment.	Provide cognitive behavioral therapy, as an adjunct to a contingency management system, for patients 18 years of age and older, enrolled in outpatient treatment under the supervision of a clinician.	Patients with SUD and concurrently under treatment for addiction to stimulants, alcohol plus another substance, marijuana, cocaine, opioids (when not the primary substance of abuse), and other substances	No; delivered through an app through an iPhone/iPad OR Android	(1) Randomized controlled design (2) Multisite randomized controlled design	(1) dtxalliance.org/products /reset/

reSET-O	12-week (84-day) software application to be used as an adjunct to outpatient treatment using transmucosal buprenorphine and contingency management to increase retention of patients with OUD	Intended to increase retention of patients with OUD in outpatient treatment by providing CBT, as an adjunct to outpatient treatment that includes transmucosal buprenorphine and contingency management, for patients 18 years or older who are currently under the supervision of a clinician.	Patients with OUD, as an adjunct to outpatient treatment that includes transmucosal buprenorphine and contingency management, for patients ≥18 y.o. who are currently under the supervision of a clinician	No; delivered through an app through an iPhone/iPad OR Android	(1) Block-randomized, unblinded, parallel, 12-week treatment trial	(1) dtxalliance.org/products/reset-o/
Somryst	9-week device for chronic insomnia; delivers CBT-I which focuses on addressing the maladaptive behaviors, routines, and dysfunctional thoughts that perpetuate sleep problems, regardless of the original source of the sleep problem	Provide a neurobehavioral intervention (CBT for Insomnia — CBT-I) to patients 22 years of age and older with chronic insomnia. Intended to improve a patient's insomnia symptoms.	Patients ≥22 y.o. with chronic insomnia	No; delivered through an app through an iPhone/iPad OR Android	(1) Randomized controlled trial	(1) accessdata.fda.gov/cdrh_docs/pdf19/K191716.pdf (2) dtxalliance.org/products/somryst/