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.

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.

Policy Statement on Prescription Digital Therapeutics (PDTs) Efficacy Information

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

General Medical Necessity Criteria

Initial Indication-Specific Criteria

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 / Not Medically Necessary

Prescription Digital Therapeutics (PDTs) for any indication or use are considered experimental, investigational, and unproven 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[1]:

- 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)

[1] *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

Service(s) name	
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
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]
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]
ICD-10 codes considered medically necessary if criteria are met:	
Code	*Description*
	All diagnoses

Appendix A

Table 1*: 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™	Improve visual acuity of patients with amblyopia

by NovaSight	
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® by Theranica	Migraine
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 2*: 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.*

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