Medical Policy

PARAMOUNT

HMO AND PPO
ELITE (MEDICARE ADVANTAGE)
MARKETPLACE

Prescription Digital Therapeutics (PDTs) Health Products

Policy Number: PG0506
Last Review: 08/01/2024

GUIDELINES:

- **This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder terms, conditions, exclusions, and limitations contract. It does not constitute a contract or guarantee regarding coverage or reimbursement/payment. Self-Insured group specific policy will supersede this general policy when group supplementary plan document or individual plan decision directs otherwise.**
- **Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards.**
- **This medical policy is solely for guiding medical necessity and explaining correct procedure reporting used to assist in making coverage decisions and administering benefits.**

SCOPE:

X Professional
X Facility

DESCRIPTION:

Digital health refers to the use of information and communications technologies in medicine and other health professions to manage illnesses and health risks and to promote wellness. Digital health technologies computing platforms, connectivity, software, and sensors for health care and related uses engaging consumers in lifestyle, wellness, and health-related purposes. These technologies span a wide range of uses, from applications in general wellness to applications as a medical device. They include technologies intended for use as a medical product, in a medical product, as companion diagnostics, or as an adjunct to other medical products (devices, drugs, and biologics). Digital health technologies include devices such as smart phones, social networks, and internet applications.

Digital therapeutic products differ from digital health products in that they are practitioner-prescribed software that delivers evidence-based therapeutic interventions to prevent, manage, or treat a medical disorder or disease.

Prescription digital therapeutics (PDTs) possess the following unique characteristics:

- PDTs deliver evidence-based and high-quality software-driven therapeutic interventions that diagnose, prevent, manage, or treat a medical disorder or disease independently or in combination with medications, devices, or other treatments to optimize patient care and health outcomes; and
- PDTs are authorized by the FDA (i.e., cleared or approved) with approved directions for use; and
- PDTs undergo rigorous evaluation for safety and effectiveness in clinical trials with clinically meaningful results published in peer-reviewed journals; and
- PDTs are prescribed and initiated by a qualified and licensed healthcare practitioner.

POLICY:

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans

This policy addresses the non-covered use of practitioner-prescribed software applications for therapeutic intervention.

NonCovered Digital Health Therapies; not an all-inclusive listing, are listed in the table below.

This policy does not address:

- Software that is used for the function or control of an FDA-cleared or approved stand-alone medical device (e.g., external insulin pump or pacemaker).
- Applications operated by a health care practitioner for remote health monitoring.

Note: Additional specific digital product devices may be addressed in other medical policies, not all inclusive:

- Vision therapy, PG0318, procedures 0687T, 0688T, 0704T-0706T, A9292
- Urinary Incontinence/ Voiding Dysfunction Treatment and Devices, PG0497, Athena pelvic muscle trainer, Gyneflex, Kegelmaster, Leva Pelvic Floor Trainer, or similar devices for the treatment of urinary incontinence
- Cognitive Rehabilitation, PG0402, procedures 0702T, 0703T

Non-participating providers are required to obtain prior authorization BEFORE any services are rendered.

COVERAGE CRITERIA:

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans

The following general Criteria are applied to digital health products, including digital therapeutic products, not already addressed in any other Medical Policy.

The use of a digital health product in the treatment or prevention of any health condition may be considered medically necessary when all of the following criteria are met:

- The digital health product has been prescribed by a healthcare practitioner providing medical oversight; and
- The digital health product has been Food and Drug Administration (FDA) approved for the requested indication; and
- High-quality evidence demonstrates the digital health product improves clinically meaningful net health outcomes as much or more than an established alternative; and
- The improved net health outcome provided by the digital health product is attainable outside of experimental/investigational settings.

The use of a digital health product in the treatment or prevention of any health condition is considered experimental/investigational/unproven when the above criteria is not met; including but not limited to general wellness and fitness application, which are not considered therapeutic in nature.

Paramount considers the following prescription digital therapeutics (PDTs) experimental/investigational because there is insufficient evidence in the published peer-reviewed literature to support their effectiveness; not an all-inclusive listing:

BlueStar Rx	**Canvas Dx**	**d-Nav**	**Endeavor Rx**	**Freespira**	**Halo AF Detection System**
Insulia	**Ieva Pelvic Health System**	**Nerivio**	**NightWare**	**reSET**	**reSET-O**
Somryst	**Glooko Mobile Insulin Dosing System**	**Go Dose System**	**My Dose Coach**	**Mahana IBS (formerly Parallel or Regul8)**	**Digital infrared thermal imaging**
GammaSense Stimulation System	**Prescription digital visual therapy and software**				

Note, the fact a new service or procedure has been issued a CPT/HCPCS code or is FDA approved for a specific indication does not support the procedure medically reasonable and necessary.

Digital Health Products for Attention Deficit Hyperactivity Disorder

The purpose of digital therapeutic products is to provide a treatment option that is an alternative to or an improvement on existing therapies for patients with attention-deficit/hyperactivity disorder (ADHD).

The use of a digital health product (including digital therapeutics) for the treatment of attention-deficit/hyperactivity disorder (ADHD), either as a stand-alone treatment or as an adjunct to standard treatment, is considered investigational, including but not limited to EndeavorRx® (AKL-T01). The digital therapy is not recommended as an alternative or adjunct to established treatments. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. There is not enough research to show that digital health products for the treatment of attention-deficit/hyperactivity disorder (ADHD) improves net health outcomes.

Digital Health Products for Substance Use Disorders

Digital therapeutic products have been proposed to supplement or replace individual or group therapy and/or to deliver cognitive-behavioral therapy for the treatment of substance use disorders.

There is not enough research to show that digital health products for the treatment of substance use disorders improves net health outcomes. No clinical guidelines based on research recommend digital health products for the treatment of substance use disorders. The use of a digital health product (including digital therapeutics) for the treatment of a substance use disorder, either as a stand-alone treatment or as an adjunct to standard treatment, is considered investigational, including but not limited to reSET® and reSETO®. Vorvida® and Modia® (Orexo) provide support for individuals with problematic drinking and opioid use disorder (OUD). These digital technologies have not received marketing clearance by U.S. Food and Drug Administration.

Digital Health Products for Panic Disorder and/or Posttraumatic Stress Disorder (PTSD)

Freespira (Freespira Inc.) is a digital therapeutic device available by prescription only and indicated as adjunctive treatment for panic disorder and/or posttraumatic stress disorder (PTSD). It is a biofeedback device, which according to its regulatory guidance is an "instrument that provides a visual or auditory signal corresponding to the status of one or more of a patient's physiological parameters … so that the patient can control voluntarily these physiological parameters".

Clinical studies with larger sample sizes that compare the Freespira device with standard treatment options, such as cognitive behavioral therapy, exposure therapy, or drug therapy, are necessary before its effectiveness can be verified and to inform selection of Freespira among competing alternatives.

Prescription Digital Therapeutics for Management of Type 1 Diabetes Mellitus (T1DM)

Prescription digital therapeutics (PDTs) are a mobile technology that offer patients with diabetes mellitus (DM) the ability to monitor daily trends in blood glucose (BG) levels and make appropriate modifications to therapy to reduce the likelihood of exceeding or falling below the target glycemic range. In addition, PDTs offer the ability to share real-time clinically relevant data with healthcare providers (HCPs), allowing for immediate intervention. Six prescription digital therapeutics for management of T2DM have been approved or cleared by the U.S. Food and Drug Administration (FDA); Insulia Diabetes Management Companion (Voluntis S.A.), D-Nav system (Hygieia Inc.), BlueStar Rx System (WellDoc Inc.), Glooko Mobile Insulin Dosing System (Glooko Inc.), Go Dose System (Eli Lilly and Company), and My Dose Coach (Sanofi Inc.).

The overall body of evidence for the use of PDTs in the management of T1DM was considered to be of very low quality.

Note: computer software for analyzing blood glucose monitor test results is an integral part of a blood glucose monitor and not separately reimbursable. In addition, software or hardware required for downloading data from a

blood glucose monitor to a computer is considered an integral part of the blood glucose monitor and not separately reimbursable.

Prescription Digital Therapeutics for Management of Type 2 Diabetes Mellitus (T2DM)

Prescription digital therapeutics (PDTs) offer patients with diabetes mellitus (DM) the ability to monitor daily trends in blood glucose (BG) levels and make appropriate modifications to therapy to reduce the likelihood of exceeding or falling below the target glycemic range. In addition, PDTs offer the ability to share real-time clinically relevant data with healthcare providers (HCPs), allowing for timely intervention. Six prescription digital therapeutics for management of T2DM have been approved or cleared by the U.S. Food and Drug Administration (FDA); Insulia Diabetes Management Companion (Voluntis S.A.), D-Nav system (Hygieia Inc.), BlueStar Rx System (WellDoc Inc.), Glooko Mobile Insulin Dosing System (Glooko Inc.), Go Dose System (Eli Lilly and Company), and My Dose Coach (Sanofi Inc.).

The overall body of evidence for the use of PDTs in the management of T2DM was considered to be of low quality. While PDTs appear to be safe and efficacious, uncertainty remains due to variability in treatment protocols, including procedure protocols and outcome measures, population heterogeneity, and the lack of long-term studies. In addition, questions remain regarding the effectiveness of PDTs due to variable levels of patient adherence reported across studies. Additional well-designed comparative studies with longer-term follow-up periods are required to provide more robust support of potential benefits, taking note of patient compliance. In addition, further research should seek to establish the comparative effectiveness of different PDTs, evaluate the impact on patient quality of life (QOL) and diabetes-related morbidity, and provide a basis for optimizing patient selection criteria.

Prescription Digital Therapeutic (Mahana Therapeutics) for Treatment of Irritable Bowel Syndrome

Mahana IBS (formerly Parallel or Regul8) is a prescription digital therapeutic mobile application designed to deliver cognitive behavioral therapy (CBT) to patients with irritable bowel syndrome (IBS). The Mahana IBS 3-month program intends to teach patients how to track symptoms, manage flare-ups, change unhelpful behaviors and thoughts, and build personalized techniques for IBS relief.

Parallel [Mahana IBS] is available by prescription only and is intended to provide 3 months of CBT for adult patients, aged 22 years and older, with IBS. Parallel [Mahana IBS] is intended to provide CBT, as an adjunct to any other IBS treatments. The Parallel [Mahana IBS] mobile application uses the patient’s mobile phone or tablet to deliver therapy on demand as a complement to the provider's care. Typical length of the therapy period is 3 months and is composed of 10 sessions. The first session explains IBS symptoms, the key features of the brain-gut axis, and the personalization of the rationale for CBT. The next 9 sessions provide personalized treatment for IBS by asking patient’s questions and getting them to complete interactive tasks. Each session contains several pages of content, which may be text, audio files, video files, or interactive components. During the program, patients are provided short tasks to complete during the week. Patients are also asked to complete questionnaires from time-to-time to rate the severity of their IBS symptom, and the impact symptoms are having on their life and mood. There is not enough research to show that digital health products for the treatment of irritable bowel syndrome improves net health outcomes.

Prescription Digital Therapeutic for Management of Traumatic Nightmares in Adults

The NightWare Kit is a prescription digital therapeutic device that uses an Apple Watch and an Apple iPhone to monitor body movement and heart rate during sleep via a proprietary software application and the NightWare server. The server creates a sleep profile for the patient as it gathers patient data each night, using an artificial intelligence (AI) algorithm to calculate the patient's "stress index threshold" (not a clinically validated stress measurement). When NightWare detects that a patient is experiencing a nightmare (stress index threshold is exceeded), the Apple Watch provides vibrotactile feedback based on the analysis of the wearer’s heart rate and movement. The kit is intended to reduce sleep disturbance associated with nightmare disorder or nightmares related to PTSD in adults. NightWare is available by prescription only and is intended for home use.

A review of abstracts suggests that there currently is insufficient published, peer-reviewed, literature to evaluate the evidence related to NightWare for the management of traumatic nightmares in a full assessment.

GammaSense Stimulation System

The GammaSense Stimulation System is an investigational device that delivers non-invasive electroencephalogram (EEG)-calibrated auditory and visual stimulation to entrain gamma frequency neural activity (oscillations) in the brain. It is proposed for the treatment of mild to moderate Alzheimer disease (AD). Gamma frequency oscillations are the fastest brainwaves in humans and are associated with numerous higher-level cognitive functions. These oscillations are believed to also trigger microglia immune cell-mediated removal of amyloid beta (Aβ) and tau proteins in the brain. Disruptions in gamma oscillations are observed in patients with AD and may contribute to the pathogenesis of the disease by decreasing microglial phagocytic activity.

Published reports on larger studies with longer follow-up are needed to better characterize the safety and efficacy of GammaSense for the treatment of Alzheimer disease.

Somryst- Prescription Digital Therapeutic for Treatment of Chronic Insomnia

Somryst delivers digital Cognitive Behavioral Therapy for Insomnia (CBT-I) therapeutic content. CBT-I is a neurobehavioral treatment, which focuses on addressing the maladaptive behaviors, routines, and dysfunctional thoughts that perpetuate sleep problems, regardless of the original source of the sleep problem. Somryst includes a daily sleep diary that is completed by the patient. The clinician-facing dashboard includes information about patient use of the device, the Insomnia Severity Index, the Patient Health Questionnaire, and sleep metrics derived from sleep diaries. Somryst may be downloaded to an iPhone, iPad, or Android phone or tablet and is compatible with mobile devices with an iOS version 9.0 or higher or an Android version 5.0 or higher. Somryst has patient- and clinician-facing dashboards.

CODING/BILLING INFORMATION:

The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

CPT CODE	
Note: Not all digital health products will have a specific code.	
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 health care professional, with report, per calendar month**
0702T	**Remote therapeutic monitoring of a standardized online digital cognitive behavioral therapy program ordered by a physician or other qualified health care professional; supply and technical support, per 30 days**
0703T	**Remote therapeutic monitoring of a standardized online digital cognitive behavioral therapy program ordered by a physician or other qualified health care professional; management services by physician or other qualified health care professional, per calendar month**
99199	**Unlisted special service, procedure, or report [when specified as a digital health management software application]**
HCPCS CODE	
A9291	**Prescription digital behavioral therapy, FDA cleared, per course of treatment**
A9292	**Prescription digital visual therapy, software-only, FDA cleared, per course of treatment**
E1399	**Durable medical equipment, miscellaneous [when specified as a digital health management software application]**

REVISION HISTORY EXPLANATION: ORIGINAL EFFECTIVE DATE: 06/01/2022

Date	Explanation & Changes
06/01/2022	• Policy created to industry standards
07/22/2022	• Added GammaSense Stimulation System to the list of prescription digital therapeutics (PDTs) experimental and investigational
03/09/2023	• Medical Policy updated to reflect Medicaid coverage to Anthem as of 02/01/2023
12/20/2023	• Added non-covered HCPCS Code A9292

07/18/2024	• Added documentation addressing Somryst - Prescription Digital Therapeutic for Treatment of Chronic Insomnia (Note medical policy PG0499 Somryst - Prescription Digital Therapeutic for Treatment of Chronic Insomnia archived and the policies documentation/information added to this policy, which already listed Somryst)

Paramount reserves the right to review and revise our policies periodically when necessary. When there is an update, we will publish the most current policy to https://www.paramounthealthcare.com/providers/medical-policies/policy-library

REFERENCES/RESOURCES

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs

NCDs https://www.cms.gov/medicare-coverage-database/searchresults.aspx?keyword=&keywordType=starts&areaId=s29&docType=NCD&contractOption=all

LCDs https://www.cms.gov/medicare-coverage-database/searchresults.aspx?keyword=&keywordType=starts&areaId=s29&docType=F,P&contractOption=all

American Medical Association, *Current Procedural Terminology (CPT®)* and associated publications and services https://www.ama-assn.org/amaone/cpt-current-procedural-terminology

Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update

U.S. Preventive Services Task Force, https://www.uspreventiveservicestaskforce.org/uspstf/
Industry Standard Review

Hayes, Inc., Lansdale, PA: Author. Health Technology Assessments. https://www.hayesinc.com/

Industry Standard Review