



CLINICAL MEDICAL POLICY	
Policy Name:	Prescription Digital Therapeutics
Policy Number:	MP-112-MD-PA
Responsible Department(s):	Medical Management
Provider Notice/Issue Date:	03/01/2026; 01/01/2025; 02/01/2024; 12/01/2022; 01/21/2022 ; 11/23/2020
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Next Annual Review:	10/2026
Revision Date:	10/15/2025; 10/16/2024; 10/18/2023; 09/22/2022; 08/18/2021
Products:	Highmark Wholecare SM Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 9

Policy History

Date	Activity
05/01/2026	Provider Effective date
12/08/2025	PARP Approval
10/15/2025	QI/UM Committee review
10/15/2025	Annual Review: Added medical necessity guidelines for Prescription digital therapeutics (PDTs). Added Program Exception guidance for Somryst [®] PDT. Added list of PDT products that are considered unproven and experimental/investigational. Added the following ICD-10 diagnosis codes for Somryst [®] : F51.01, F51.02, F51.03, F51.04, F51.05, F51.09, F51.8, G47.00, G47.01, G47.8, & G47.9. Updated 'Summary of Literature' and 'Reference Sources' sections.
02/01/2025	Provider Effective date
11/25/2024	PARP Approval
10/16/2024	QI/UM Committee review
10/16/2024	Annual Review: No changes to clinical criteria. Updated 'Summary of Literature' and 'Reference Sources' sections.
03/01/2024	Provider Effective date
01/08/2024	PARP Approval
10/18/2023	QI/UM Committee review
10/18/2023	Annual Review: No changes to clinical criteria. Updated 'Summary of Literature' and 'Reference Sources' sections.
01/01/2023	Provider Effective date
11/22/2022	PARP Approval

10/19/2022	QI/UM Committee review
08/11/2020	Initial policy developed

Disclaimer

Highmark WholecareSM medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

Policy Statement

Highmark WholecareSM may provide coverage under the digital prescription therapy benefits of the Company's Medicaid products for medically necessary as an outpatient adjunctive therapy..

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

(Current applicable Pennsylvania HealthChoices Agreement Section V. Program Requirements, B. Prior Authorization of Services, 1. General Prior Authorization Requirements.)

Definitions

Prior Authorization Review Panel (PARP) - A panel of representatives from within the PA Department of Human Services who have been assigned organizational responsibility for the review, approval and denial of all PH-MCO Prior Authorization policies and procedures.

Buprenorphine – A semisynthetic narcotic analgesic that is used to control moderate to severe pain and treat opioid dependence.

Opioid Use Disorder (OUD) – A problematic pattern of opioid use leading to problems or distress and include taking larger amounts of drug, taking drugs over a long period of time, desire or unsuccessful efforts to cut down or control opioid use, craving to use opioids, problems fulfilling obligations, continued opioid use despite recurring social and interpersonal problems, reducing or giving up activity because of opioid use, using opioids in physically hazardous situations, continued opioid use despite ongoing physical or psychological problems likely caused by opioids, tolerance of opioids, and experiencing withdrawal or taking opioids to relieve withdrawal symptoms.

Substance Use Disorder (SUD) - A disease that affects an individual's brain and behavior and is characterized by the persistent use of drugs (both prescription and illegal as well as alcohol) despite substantial harm and adverse consequences.

Prescription Digital Therapeutics (PDT) – A type of software-generated therapeutic interventions delivered directed to patients to prevent, manage, or treat a medical disorder or disease. These systems

differ from wellness or fitness apps, wearable devices or remote care programs as they require rigorous clinical evidence to substantiate intended use and impact on disease states.

Procedures

Program Exception

The Pennsylvania Department of Health has determined that the prescription digital therapeutics (PDTs) reSET®, reSET-O® and Somryst® require a Program Exception, the ordering healthcare professional must provide ALL of the following:

- a supporting statement indicating why a requested therapy or device is medically necessary, and the alternative options have been or are likely to be ineffective, adversely affect patient compliance, or cause an adverse reaction., AND
- documentation that medical necessity criteria are met.

Note: Please see the manufacturer guidelines for additional information for reSET®, reSET-O® and Somryst® .

1. Medical Necessity Guidelines

U.S. FDA approved PDTs prescribed by a licensed healthcare professional for therapeutic intervention may be considered medically necessary when the following criteria are met:

- A. The PDT is used within its approved indications; AND
- B. The PDT is prescribed by a provider for whom the condition is within the scope of their practice; AND
- C. The user must be at least 18 years of age; AND
- D. The PDT is only used for outpatient care; AND
- E. The user must be able to reasonably interact with the software in order to receive a prescription for any PDT treatment or intervention; AND
- F. The PDT is not primarily for the convenience of the member, or the member's healthcare provider.

2. PDTs are considered not medically necessary, and therefore not covered, when ANY of the following are true:

- A. The individual is not enrolled in outpatient treatment under the supervision of a clinician, OR
- B. The individual is noncompliant with, or does not complete their outpatient treatment plan,
- C. The following PDTs are considered experimental/investigational and therefore noncovered because the technology has not been proven (this list is not all-inclusive):
 - BlueStar®Rx System (WellDoc®)
 - Canvas Dx™ autism diagnosis aid (Cognoa, Inc.)
 - CureSight™ (NovaSight)
 - d-Nav® Insulin Management Program (Hygieia , Inc.)
 - Drowzle™ (Resonea)
 - EndeavorRx™ (Akili Interactive Labs, Inc.)
 - Freespira® (PaloAlto Health Sciences, Inc.)
 - Halo™AF Detection System (LIVMOR, Inc.)
 - Home Vision Monitor® (HVM) (Vital Art and Science, LLC)
 - Insulia® Diabetes Management Companion (Voluntis)

- INVU™ (Nuvo™)
- leva® Pelvic Digital Health System (Renovia, Inc.)
- MindMotion™ GO (MindMaze S.A.)
- My Dose Coach™ (Sanofi, Inc.)
- NightWare™ (Apple, Inc.)
- Parallel™ (Mahana Therapeutics, Inc.)
- Regulora® (metaMe Health, Inc.)
- RelieVRx (AppliedVR, Inc.)
- RevitalVision (NeuroVision, Inc.)

3. Post-payment Audit Statement

The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark WholecareSM at any time pursuant to the terms of your provider agreement.

4. Place of Service

The place of service for PDT use is outpatient.

Governing Bodies Approval

On September 14, 2017, Pear Therapeutics received FDA premarket approval for reSET, a mobile medical application, as the result of a De Novo request. The reSET application is intended to be used with outpatient therapy to treat alcohol, cocaine, marijuana and stimulant substance use disorders. This application is not intended to be used to treat opioid dependence. The application also includes a series of incentives to reward patients for adherence to their treatment program.

On December 18, 2018, Pear Therapeutics received FDA premarket approval for reSET as the result of a 510(k) approval. The intended users are patients with a substance use disorder who are not currently on opioid replacement therapy, abuse alcohol solely or whose primary substance of abuse is opioids. The approval indicates that this application is an adjunctive application to treatment as usual (TAU) that includes outpatient treatment and contingency management.

On May 23, 2019, the FDA approved reSET-O with a Regulation Name of computerized behavioral therapy device for psychiatric disorders, Class II. The intended users are patients with an opioid use disorder. The approval indicates that the use of reSET-O is an adjunctive application to treatment as usual (TAU) that includes transmucosal buprenorphine in addition to outpatient treatment and contingency management.

On March 23, 2020, the FDA approved Somryst (Pear Therapeutics) for the treatment of chronic insomnia in adults. The software used cognitive behavioral therapy and data-based sleep restrictions to treat insomnia. The Somryst app uses technology to provide customized sleep restriction and consolidation recommendations, stimulus control and cognitive restructuring. The company states the app also includes a physician dashboard to track patients' sleep metrics and progress.

The Pennsylvania Department of Human Services Technology Assessment Group (TAG) workgroup meets quarterly to discuss issues revolving around new technologies and technologies or services that were previously considered to be a program exception. During this meeting, decisions are made as to whether or not certain technologies will be covered and how they will be covered. TAG's decisions are as follow:

- Option #1: Approved - Will be added to the Fee Schedule
- Option #2: Approved as Medically Effective - Will require Program Exception
- Option #3: Approved with (or denied due to) Limited/Minimal Evidence of Effectiveness - Will require Program Exception
- Option #4: Denied - Experimental/Investigational

The TAG workgroup gave reSET/reSET-O and Somryst an Option # 3, specifically for HCPCS code A9291. reSET/reSET-O® and Somryst® require a Program Exception. The ordering healthcare professional must provide a supporting statement indicating why the requested therapy or device is medically necessary, and the alternative options have been or are likely to be ineffective, adversely affect patient compliance, or cause an adverse reaction.

Summary of Literature

According to the Substance Abuse and Mental Health Services Administration (SAMHSA), prescription digital therapeutics (PDTs) are digital therapeutics (DTx) in the United States that are cleared or approved (depending upon risk level) for prescription use by the FDA as software-based medical devices intended to prevent, manage, or treat a medical condition. Benefits of DTx may include:

- Patients can use DTx remotely on a smartphone or computer and can use DTx independently or in combination with clinician consultation and other treatments, reducing client-provider, in-person interaction.
- Remote access of DTx can facilitate anonymity and honest responses and minimize the need to seek in-person care.
- DTx are rigorously developed and tested.
- DTx can decrease required client-provider interaction, and therefore lessen out-of-pocket costs for clients.
- DTx have demonstrated effectiveness in engaging hard-to-reach populations (SAMHSA, 2022).

Use of DTx may improve behavioral health outcomes, but there are risks related to access, acceptability, and cost that providers and developers must consider to ensure DTx are improving health equity rather than creating more pronounced disparities, including:

- **Access to technology, broadband, and sufficient data plans:** limited access to broadband may impact individuals living in rural areas, as well as individuals located in urban and suburban areas. It is important to ensure users have multiple mechanisms to DTx based on their unique needs.
- **Digital and health literacy:** individuals' understanding of common health terminologies and ability to use digital technologies vary and cannot be anticipated simply from an individual's age, cultural background, or geographic location.
- **Cultural and linguistic appropriateness:** DTx platforms should include culturally representative examples and vignettes and be available in the individual's native language. Providers should also confirm the DTx product has been validated with the user population.
- **Affordability:** to ensure equitable access to DTx, the cost of participation should not be prohibitive, particularly for those who lack access and financial support to smartphones, computers, broadband, and data plans (SAMHSA, 2022).

A study suggests that Internet-based TES, as well as other efficacious computer-assisted interventions now emerging, have the potential to help bridge the gap between the enormous need for high-quality

evidence-based treatment for addiction and the capacity of the treatment system to deliver. Barriers to implementation of such interventions need to be addressed, including training clinicians to effectively prescribe and monitor computer-delivered interventions and developing reimbursement systems to fund them (Campbell 2018).

A recent study examined the benefits of adding an Internet-delivered behavior therapy to a buprenorphine medication program. The study provided results that showed an increased overall abstinence and retention efficacy in an internet-delivered computerized CRA+ group over motivational incentives and buprenorphine, and increased continuous abstinence for those CRA+ individuals who engaged in prior treatment. The study also indicated that CRA appears to build on previous treatment episodes despite research that suggests people who previously entered substance abuse treatment have greater drug problems, higher psychiatric co-morbidities, and suffer more life challenges than those without previous treatment experience (Christensen, 2014).

Coding Requirements

Procedure Code

HCPCS Code	Description
A9291*	Prescription digital behavioral therapy, FDA-cleared, per course of treatment

*TAG Determination, requires a Program Exception.

Diagnosis Codes for reSET

This is not an all-inclusive list of covered diagnosis codes.

ICD-10 Code	Description
F10.10	Alcohol abuse, uncomplicated
F10.11	Alcohol abuse, in remission
F10.20	Alcohol dependence, uncomplicated
F10.21	Alcohol dependence, in remission
F10.230	Alcohol dependence with withdrawal, uncomplicated
F11.21	Opioid dependence, in remission
F11.23	Opioid dependence with withdrawal
F11.90	Opioid use, unspecified, uncomplicated
F11.93	Opioid use, unspecified with withdrawal
F12.10	Cannabis abuse, uncomplicated
F12.11	Cannabis abuse, in remission
F12.20	Cannabis dependence, uncomplicated
F12.21	Cannabis dependence, in remission
F12.23	Cannabis dependence with withdrawal
F12.90	Cannabis use, unspecified, uncomplicated
F12.93	Cannabis use, unspecified with withdrawal
F13.10	Sedative, hypnotic or anxiolytic abuse, uncomplicated
F13.11	Sedative, hypnotic or anxiolytic abuse, in remission
F13.20	Sedative, hypnotic or anxiolytic dependence, uncomplicated

F13.21	Sedative, hypnotic or anxiolytic dependence, in remission
F13.230	Sedative, hypnotic or anxiolytic dependence with withdrawal, uncomplicated
F13.90	Sedative, hypnotic, or anxiolytic use, unspecified, uncomplicated
F13.930	Sedative, hypnotic or anxiolytic use, unspecified with withdrawal, uncomplicated
F13.939	Sedative, hypnotic or anxiolytic use, unspecified with withdrawal, unspecified
F14.10	Cocaine abuse, uncomplicated
F14.11	Cocaine abuse, in remission
F14.20	Cocaine dependence, uncomplicated
F14.21	Cocaine dependence, in remission
F14.23	Cocaine dependence with withdrawal
F14.90	Cocaine use, unspecified, uncomplicated
F15.10	Other stimulant abuse, uncomplicated
F15.11	Other stimulant abuse, in remission
F15.20	Other stimulant dependence, uncomplicated
F15.21	Other stimulant dependence, in remission
F15.23	Other stimulant dependence with withdrawal
F15.90	Other stimulant use, unspecified, uncomplicated
F16.10	Hallucinogen abuse, uncomplicated
F16.11	Hallucinogen abuse, in remission
F16.20	Hallucinogen dependence, uncomplicated
F16.21	Hallucinogen dependence, in remission
F18.10	Inhalant abuse, uncomplicated
F18.11	Inhalant abuse, in remission
F18.20	Inhalant dependence, uncomplicated
F18.21	Inhalant dependence, in remission
F18.90	Inhalant use, unspecified, uncomplicated
F19.10	Other psychoactive substance abuse, uncomplicated
F19.11	Other psychoactive substance abuse, in remission
F19.20	Other psychoactive substance dependence, uncomplicated
F19.21	Other psychoactive substance dependence, in remission
F19.230	Other psychoactive substance dependence with withdrawal, uncomplicated
F19.90	Other psychoactive substance use, unspecified, uncomplicated
F19.930	Other psychoactive substance use, unspecified with withdrawal, uncomplicated
Z71.41	Alcohol abuse counseling and surveillance of alcoholic
Z71.51	Drug abuse counseling and surveillance of drug abuser

Diagnosis Codes for reSET-O

This is not an all-inclusive list of covered diagnosis codes.

ICD-10 Code	Description
F11.10	Opioid abuse, uncomplicated
F11.11	Opioid abuse, in remission
F11.20	Opioid dependence, uncomplicated
F11.21	Opioid dependence, in remission

F11.23	Opioid dependence with withdrawal
F11.90	Opioid use, unspecified, uncomplicated
F11.93	Opioid use, unspecified with withdrawal

Diagnosis Codes for Somryst

This is not an all-inclusive list of covered diagnosis codes.

ICD-10 Code	Description
F51.01	Primary insomnia
F51.02	Adjustment insomnia
F51.03	Paradoxical insomnia
F51.04	Psychophysiologic insomnia
F51.05	Insomnia due to other mental disorder
F51.09	Other insomnia not due to a substance or known physiological condition
F51.8	Other sleep disorders not due to a substance or known physiological condition
G47.00	Insomnia, unspecified
G47.01	Insomnia due to medical condition
G47.8	Other sleep disorders
G47.9	Sleep disorder, unspecified

Reimbursement

Participating facilities will be reimbursed per their Highmark WholecareSM contract.

Reference Sources

Pennsylvania Department of Human Services. Technology Assessment Group (TAG) Coverage Decisions. Managed Care Operations Memorandum: OPS. August 5, 2020. MCOPS Memo #6/2021-05. reSET and reSET-O Option #3 for both TAG decisions. Accessed on September 22, 2022.

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The Centers for Medicare and Medicaid Services (CMS). Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Recommendations Second Biannual, 2021 HCPCS Coding Cycle. April 1, 2022. Accessed on September 22, 2022.

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