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

Policy History

Date	Activity
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
10/19/2022	Annual Review: No changes to clinical criteria. Updated 'Summary of Literature' and 'Reference Sources' sections. Removed generic HCPCS code A9999, replaced with updated HCPCS code A9291 (*Prescription digital behavioral therapy, FDA-cleared, per course of treatment*) according to CMS HCPCS guidance. New code effective as of 4/1/2022.
02/21/2022	Provider effective date
12/14/2021	PARP approval
08/18/2021	QI/UM Committee review
08/18/2021	Annual Review: Updated Summary of Literature and Reference Sources sections. Added 'Program Exception' language.
12/21/2020	Provider effective date
10/16/2020	PARP approval
09/16/2020	QI/UM Committee review
08/11/2020	Initial policy developed

Disclaimer

Highmark Wholecare℠ 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 Wholecare℠ may provide coverage under the digital prescription therapy benefits of the Company's Medicaid products for medically necessary as an outpatient adjunctive therapy in patients with substance use disorder (SUD).

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.

Cognitive Behavioral Therapy (CBT) - A type of psychotherapy in which negative patterns of thought about the self and the world are challenged in order to alter unwanted behavior patterns or treat mood disorders such as depression.

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
reSET and reSET-O requires a Program Exception, the ordering physician 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.

1. Medical Necessity Criteria
    A. **reSET®** may be considered medically necessary for a 90 day period (12 week) when ALL of the following conditions are met:
        1) The individual must currently be enrolled in outpatient treatment for SUD under the supervision of a clinician; AND
        2) reSET is prescribed by a clinician; AND
        3) The individual is in the treatment of SUD, who are not currently on opioid replacement therapy, who do not abuse alcohol solely, or who do not abuse opioids as their primary substance of abuse; AND
        4) The individual must be 18 years of age or older.

    B. **reSET-O®** may be considered medically necessary for an 84 day period (12-week)in patients with opioid use disorder (OUD) when ALL of the following conditions are met:
        1) The individual must currently be enrolled in outpatient treatment for OUD under the supervision of a clinician; AND
        2) reSET-O is prescribed by a clinician; AND
        3) The individual must be 18 years of age or older, AND
        4) The outpatient treatment currently includes transmucosal buprenorphine.

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

2. Contraindications
    A. Per the manufacturer contraindications of reSET include individuals who are not currently on opioid replacement therapy, who do not abuse alcohol solely, or who do not abuse opioids as their primary substance of abuse.
    B. Both reSET and reSET-O are not intended to be used as a stand-alone therapy.

3. reSET and reSET-O 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 does not complete their outpatient treatment plan, OR
    C. The individual is noncompliant with, does not complete, or does not refill buprenorphine.

4. Post-payment Audit Statement
   The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Wholecare℠ at any time pursuant to the terms of your provider agreement.

5. Place of Service
   The place of service for reSET and reSET-O is outpatient.

6. Length of Coverage
   - reSET and reSET-O are only intended to be utilized once per lifetime.
   - The long-term benefit of treatment with reSET on abstinence has not been evaluated in studies lasting beyond 12 weeks in the SUD population.
   - The ability of reSET/reSET-O to prevent potential relapse after treatment discontinuation has not been studied.

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.

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 and reSET-O an Option # 3.

reSET/reSET-O requires a Program Exception. The ordering physician 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 National Survey on Drug Use and Health (NSDUH), 19.7 million American adults (aged 12 and older) battled substance use disorder in 2017. Nearly 74% of adults suffering from substance use disorder I n 2017 struggled with an alcohol use disorder. The National Institute on Drug Abuse (2020) reports that abuse of tobacco, alcohol and illicit drugs cost our Nation more than $740 billion annually in costs related to crime, lost work productivity and health care.

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 common health terminologies and ability to use digital technologies vary and cannot be anticipated simply from a 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 that 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 2014 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).

Hayes, Inc.

- Mobile Medical Applications for Substance Use Disorder
    - **C Rating**- For use of mobile medical applications (MMAs) used in conjunction with conventional treatment in adult patients for treatment of substance use disorders (SUDs). The body of low quality evidence suggests that patients with SUD treated with MMAs in addition to conventional care might be associated with improved treatment retention and increased substance abstinence; however, the impact of MMA on abstinence occurred generally in the first 2 months and was no longer seen at 3 months or later. This conclusion is further weakened by individual study limitations and inconsistencies among studies. Evidence does not inform whether MMAs work better for particular types of SUD, if any single MMA is better than another, or provide a basis for optimizing patient selection criteria. Information regarding any potential harms related to using MMAs for SUD was missing from the reviewed studies.

Coding Requirements

Procedure Code

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

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

Reimbursement

Participating facilities will be reimbursed per their Highmark Wholecare℠ 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.

Campbell AN, Nunes EV, Matthews AG, et al. Internet-delivered treatment for substance abuse: a multisite randomized controlled trial. American Journal of Psychiatry. December 2014. Accessed on September 22, 2022.

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. Accessed on September 22, 2022.

reSET-O. Clinician directions for use. Pear Therapeutics, Inc. 2020. Accessed on August 12, 2020.

reSET. Clinician directions for use. Pear Therapeutics, Inc. 2020. Accessed on August 12, 2020.

The American Addiction Centers. Alcohol and drug abuse statistics. Reviewed by Scot Thomas, MD on June 1, 2020. Accessed on August 12, 2020.

National Survey on Drug Use and Health. 2017 NSDUH Annual National Report. September 14, 2018. Accessed on August 12, 2020.

National Institute on Drug Abuse (NIH). Trends & Statistics: Cost of substance abuse. April 6, 2020. Accessed on August 12, 2020.

Hayes Inc. Health Technology Assessment. Mobile Medical Applications for Substance Use Disorder. May 7, 2021. Annual Review date June 22, 2023. Accessed on October 2, 2023.

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.

Substance Abuse and Mental Health Services Administration (SAMHSA). SAMHSA Advisory: Digital Therapeutics for Management and Treatment in Behavioral Health. July 2023. Accessed on October 2, 2023.