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MEDICAL POLICY – 3.03.501

Prescription Digital Therapeutics for Substance Use Disorders

Effective Date:	Nov. 1, 2026
Last Revised:	Oct. 13, 2026
Replaced:	5.01.643

RELATED MEDICAL POLICIES:

2.04.522	Drug Testing in Pain Management and Substance Use Disorder Treatment Settings
3.03.03	Prescription Digital Therapeutics for Attention Deficit/Hyperactivity Disorder
3.03.500	Prescription Digital Therapeutics
3.03.523	Prescription Digital Health Diagnostic Aid for Autism Spectrum Disorder

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POLICY CRITERIA | CODING | EVIDENCE REVIEW | REFERENCES | HISTORY

∞ Clicking this icon returns you to the hyperlinks menu above.

Introduction

Prescription digital therapeutics (PDTs) are a type of treatment that use mobile software applications to help prevent, manage, or treat medical and behavioral health conditions. PDTs can be accessed on a tablet or smartphone when it is convenient for the individual. For substance use disorders, PDTs are designed to work with other types of treatment, such as face-to-face counseling that uses cognitive-behavioral therapy (CBT). The use of PDTs for the treatment of substance use disorders is considered investigational. That means it is still being studied.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Service	Investigational
Prescription digital therapeutics	**Prescription digital therapeutics for individuals with substance use disorders are considered investigational (e.g., reSet and reSet-O).**

Coding

Code	Description
CPT	
99199	Unlisted special service, procedure or report
HCPCS	
A9291	Prescription digital cognitive and/or behavioral therapy, FDA cleared, per course of treatment
A9294	Prescription digital cognitive and/or behavioral therapy, biofeedback, FDA cleared, per course of treatment (new code effective 04/01/26)
A9999	Miscellaneous DME supply or accessory, not otherwise specified
E1399	Durable medical equipment, miscellaneous

Related Information

Vorvida and Modia (Orexo) are digital therapies that do not require a prescription and are not addressed in this policy.

Evidence Review

Description

The World Health Organization (WHO) defines substance use disorder as "the harmful or hazardous use of psychoactive substances", which include alcohol, cocaine, marijuana,

stimulants, benzodiazepines and opiates. Treatments for drug addiction include behavioral counseling and skills training, which can be given as part of a cognitive-behavioral approach. The first prescription mobile app, developed to supplement or replace individual or group therapy, delivers a cognitive-behavioral approach developed specifically for substance use disorder in a series of interactive lessons.

Background

Substance Use Disorder

The WHO defines substance use disorder as "the harmful or hazardous use of psychoactive substances, including alcohol and illicit drugs", which include alcohol, cocaine, marijuana, stimulants, benzodiazepines and opiates. The American Psychiatric Association, in the Diagnostic and Statistical Manual of Mental Disorders, details 11 problematic patterns of use that lead to clinically significant impairment or distress. Mild substance use disorder (SUD) is defined as meeting two to three criteria, moderate as four to five criteria, and severe as six or more criteria.

- Often taken in larger amounts or over a longer period than was intended
- A persistent desire or unsuccessful efforts to cut down or control use
- A great deal of time is spent on activities necessary to obtain, use, or recover from the substance's effects
- Craving or a strong desire or urge to use the substance
- Recurrent use resulting in a failure to fulfill major role obligations at work, school, or home
- Continued use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by its effects
- Important social, occupational, or recreational activities are given up or reduced because of use
- Recurrent use in situations in which it is physically hazardous
- Continued use despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance
- Tolerance

- Withdrawal

Treatment

Treatments for substance use disorder include behavioral counseling, skills training, medication, treatment for withdrawal symptoms, treatment for co-occurring mental health issues, and long-term follow-up to prevent relapse. For individuals with primary opioid use disorder (OUD), medication-assisted treatment is the most common approach. US Food and Drug Administration (FDA) approved drugs for opioid use treatment include a full opioid agonist (methadone), a partial opioid agonist (buprenorphine), and an opioid antagonist (naltrexone). These are used to suppress withdrawal symptoms and reduce cravings and may be used in combination with counseling and behavioral therapies.

One common psychosocial intervention is cognitive-behavioral therapy (CBT). CBT is an established therapy based on social learning theory that addresses an individual's thinking and behavior. CBT has proven positive effects for the treatment of SUD.[1] There are two main goals of CBT: first, recognize thoughts and behaviors that are associated with substance abuse, and second, expand the repertoire of effective coping responses. Specific goals for SUD and OUD include a better understanding of risk factors for use, more accurate attributions of cause and effect, increased belief in the ability to address problems, and coping skills. Specific skills may include motivation, drink/drug refusal skills, communication, coping with anger and depression, dealing with interpersonal problems, and managing stress.

The community reinforcement approach (CRA) is a form of CBT that has a goal of making abstinence more rewarding than continued use. CRA increases non-drug reinforcement by teaching skills and encouraging behaviors that help improve employment status, family/social relations and recreational activities. CRA was originally developed for alcohol dependence and cocaine use and has been shown to be more effective than usual care in reducing the number of substance use days.

Contingency management may also be a component of addiction treatment. Contingency management, also known as motivational incentives, provides immediate positive reinforcement to encourage abstinence and attendance. Positive reinforcement may range from a verbal/text acknowledgement of completion of a task to monetary payment for drug-negative urine specimens. Contingency management is based on the principles of operant conditioning as formulated by B.F. Skinner, which posits that rewarding a behavior will increase the frequency of that behavior. Contingency management is typically used to augment a psychosocial treatment such as CRA.

The combination of CRA plus contingency management was shown in a 2018 network meta-analysis of 50 RCTs to be the most efficacious and accepted intervention among 12 structured psychosocial interventions, including contingency management alone, in individuals with cocaine or amphetamine addiction.[2] Positive reinforcement with voucher draws (e.g., from a fishbowl) of variable worth that range from a congratulatory message to an occasional high dollar value are as effective as constant monetary vouchers. Studies conducted by the National Drug Abuse Treatment Clinical Trials Network have shown that intermittent reinforcement with incentives totaling $250 to $300 over eight to 12 weeks both increases retention in a treatment program and reduces stimulant drug use during treatment.[3]

Software as a Medical Device

The International Medical Device Regulators Forum, a consortium of medical device regulators from around the world, which is led by the FDA, distinguishes between 1) software in a medical device and 2) software as a medical device (SaMD). The Forum defines SaMD as "software that is intended to be used for one or more medical purposes that perform those purposes without being part of a hardware medical device".[4]

FDA's Center for Devices and Radiological Health is taking a risk-based approach to regulating SaMD. Medical software that "supports administrative functions, encourages a healthy lifestyle, serves as electronic patient records, assists in displaying or storing data, or provides limited clinical decision support, is no longer considered to be and regulated as a medical device".[5]

Regulatory review will focus on mobile medical apps that present a higher risk to individuals.

- Notably, FDA will not enforce compliance for lower risk mobile apps such as those that address general wellness.
- FDA will also not address technologies that receive, transmit, store, or display data from medical devices.

The agency has launched a software pre-certification pilot program for SaMD that entered its test phase in 2019. Key features of the regulatory model include the approval of manufacturers prior to evaluation of a product, which is based on a standardized "Excellence Appraisal" of an organization, and its commitment to monitor product performance after introduction to the US market. Criteria include excelling in software design, development, and validation. Companies that obtain pre-certification participate in a streamlined pre-market review of the SaMD. Pre-certified organizations might also be able to market lower-risk devices without additional

review. In 2017, FDA selected 9 companies to participate in the pilot program, including Pear Therapeutics.

Evaluation Framework for Digital Health Technologies

SaMDs, as defined by FDA, are subject to the same evaluation standards as other devices; the Blue Cross and Blue Shield Association Technology Evaluation Criterion are as follows:

- The technology must have final approval from the appropriate governmental regulatory bodies.
- The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.
- The technology must improve the net health outcome.[a]
- The technology must be as beneficial as any established alternatives.
- The improvement must be attainable outside the investigational settings.[b]

[a] The technology must assure protection of sensitive individual health information as per the requirements of The Health Insurance Portability and Accountability Act of 1996 (HIPAA)

[b] The technology must demonstrate usability in a real-world setting

Other regulatory authorities such as the United Kingdom's National Institute for Health and Care Excellence (NICE) have proposed standards to evaluate SaMD.[6]

Summary of Evidence

For individuals with SUD other than OUD who receive a prescription digital therapeutic, the evidence includes one pivotal randomized controlled trials (RCT) and secondary analyses of data from the trial. Relevant outcomes are symptoms, morbid events, change in disease status, quality of life, and medication use. Mobile digital technology is proposed as an adjunct to outpatient treatment; however, there are a number of limitations in the current evidence base that limit any conclusions regarding efficacy. The RCT assessed the combined intervention of computer-based learning and a reward for abstinence. Since reward for abstinence alone has been shown to increase both abstinence and retention, the contribution of the web-based program to the overall treatment effect cannot be determined. The treatment effect on

abstinence was not observed at follow-up, raising further questions about the relative effects of the rewards and the web program. While the RCT reported a positive effect on the intermediate outcome of retention, the relationship between retention and relevant health outcomes in this trial is uncertain. A retrospective secondary analysis of data from the trial reported an association between engagement with the app and abstinence at nine to 12 weeks, but study design limitations preclude drawing conclusions from this study. Given these limitations, further study in well-designed trials is needed to determine the effects of prescription digital therapeutics on relevant outcomes in individuals with SUD. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with OUD who receive a prescription digital therapeutic, the evidence includes one pivotal RCT and analysis of data of more than 3000 individuals from the mobile app. Relevant outcomes are symptoms, morbid events, change in disease status, quality of life, and medication use. Mobile digital technology is proposed as an adjunct to outpatient treatment that includes transmucosal buprenorphine and contingency management; however, there are a number of limitations in the current evidence base that limit any conclusions regarding efficacy. The RCT did not meet a primary objective of longest days of abstinence. While there was a positive effect on the intermediate outcome of retention, the relationship between retention and relevant health outcomes in this trial is uncertain. Retrospective observational studies found that participants who completed more modules with the mobile app had greater abstinence during weeks 9 to 12 and, in a subgroup of individuals who received a refill prescription, during weeks 21 to 24, but the retrospective design and lack of a control group with comparable motivation limits interpretation of these results. Given these limitations, further study in well-designed trials is needed to determine the effects of prescription digital therapeutics on relevant outcomes in individuals with OUD. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently ongoing trials that might influence this review are listed in **Table 1**.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT05766631	Treating Polysubstance Use in Methadone Maintenance: Application of Novel Digital Technology	240	Sept 2027
NCT06346431[a]	Efficacy of Digital Problem Solving Application in Reduction of Anxiety, Depression and Substance Use Disorder Symptoms	100	Dec 2026 not yet recruiting
NCT04927143	Encouraging Abstinence Behavior in a Drug Epidemic: Optimizing Dynamic Incentives	600	Sep 2026
NCT07178158	Enhancing Addiction Treatment Through Psychoeducation: Evaluating the Feasibility and Acceptability of a Neuroscience-Informed Mobile App	40	April 2027
Unpublished			
NCT04129580[a]	A Randomized Clinical Trial of Comprehensive Cognitive Behavioral Therapy (CBT) Via reSET-O for a Hub and Spoke Medication Assisted Treatment (MAT) System of Care	100	Sep 2024
NCT04907045	Digital Therapeutics for Opioids and Other Substance Use Disorders in Primary Care Pilot (DIGITS Trial Pilot)	1552	Dec 2023
NCT05160233	Digital Treatments for Opioids and Other Substance Use Disorders (DIGITS) in Primary Care: A Hybrid Type-III Implementation Trial	13,000	Sep 2024
NCT06212557	Evaluation of KIOS in a 12-week Randomized Controlled Trial	116	Dec 2025
NCT05521854	Encouraging Abstinence Behavior in a Drug Epidemic: Does Age Matter?	62	May 2026

NCT: national clinical trial. [a] Denotes industry-sponsored or cosponsored trial.

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a U.S. professional society, an international society with U.S. representation, or NICE.

Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Society of Addiction Medicine

In 2020, the American Society of Addiction Medicine (ASAM) published a focused update of their National Practice Guideline for the Treatment of Opioid Use Disorder.[31] The guideline recommended that psychosocial treatment should be considered in conjunction with pharmacological treatment for opioid use disorder and noted, "At a minimum, the psychosocial treatment component of the overall treatment program should include assessment of psychosocial needs; individual and/or group counseling; linkages to existing support systems; and referrals to community-based services." They also noted that "psychosocial treatment may also include more intensive individual counseling and psychotherapy, contingency management, and mental health services" and, "while questions remain about which specific psychosocial therapies work best with which pharmacological treatments, there is widespread support for recommending psychosocial treatment as an important component of a patient's opioid use disorder treatment plan." The guideline did not address digital health therapies.

National Institute on Drug Abuse

The 2018 Principles of Drug Addiction and Treatment from the National Institute on Drug Abuse describes evidence-based approaches to drug addiction treatment.[21] Behavioral therapies include cognitive-behavioral therapy (alcohol, marijuana, cocaine, methamphetamine, nicotine), contingency management (alcohol, stimulants, opioids, marijuana, nicotine), Community Reinforcement Approach (CRA) plus vouchers (alcohol, cocaine, opioids), motivational enhancement therapy (alcohol, marijuana, nicotine), the matrix model (stimulants), 12-step facilitation therapy (alcohol, stimulants, opiates) and family behavior therapy. The guidelines did not address digital health therapies for substance use disorders.

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

In 2017, reSET (Pear Therapeutics), received de novo marketing clearance from the FDA to provide cognitive behavioral therapy (CBT) as an adjunct to contingency management, for patients with substance use disorder who are enrolled in outpatient treatment under the supervision of a clinician (DEN160018). This is the first prescription digital therapeutic to be approved by the FDA.. reSET is indicated as a 12-week (90 days) prescription-only treatment intended to increase abstinence from a patient's substances of abuse during treatment and increase retention in the outpatient treatment. FDA product code: PWE.

In 2018, reSET-O (Pear Therapeutics) was cleared for marketing by the FDA through the 510(k) pathway as a prescription-only digital therapeutic to "increase retention of patients with opioid use disorder (OUD) in outpatient treatment by providing cognitive behavioral therapy, as an adjunct to outpatient treatment that includes transmucosal buprenorphine and contingency management" (K173681). FDA determined that this device was substantially equivalent to existing devices. The predicate device was reSET.

In December 2023, PursueCare, a virtual addiction treatment provider, acquired the digital therapeutics reSET and reSET-O from Pear Therapeutics.

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History

Date	Comments
02/01/24	New policy, approved January 9, 2024. Prescription digital therapeutics for individuals with substance use disorders are considered investigational. (For previous history content, see deleted policy 5.01.35).
11/01/25	Annual Review, approved October 13, 2025. Literature search completed September 26, 2025. No References updated. Policy statements unchanged.
02/06/26	Minor update to related policy section. Updated policy number 2.04.513 Drug Testing in Pain Management and Substance Use Disorder Treatment Settings to 2.04.522 Drug Testing in Pain Management and Substance Use Disorder Treatment Settings.
04/01/26	Coding update. Added new HCPCS code A9294, effective April 1, 2026.
09/01/26	Minor update to related medical policy section. Updated 13.01.500 Prescription Digital Therapeutics to 3.03.500 Prescription Digital Therapeutics.
11/01/26	Policy 3.03.501 Prescription Digital Therapeutics for Substance Use Disorders replaced 5.01.643 Prescription Digital Therapeutics for Substance Use Disorders to align with the Digital Health categorization, approved October 13, 2026. Annual review performed. Reference added. Clinical trials table updated. Policy statement unchanged.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review

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Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.