BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Digital Health Therapies for Substance Use

Policy #: 736
Latest Review Date: August 2022
Category: DME

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat **digital health therapies for patients with substance use disorder** as a **non-covered** benefit and as **investigational**.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

The World Health Organization defines substance use 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.

Substance Use Disorder

The World Health Organization defines substance abuse 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 2 to 3 criteria, moderate as 4 to 5 criteria, and severe as 6 or more criteria.

1. Often taken in larger amounts or over a longer period than was intended.
2. A persistent desire or unsuccessful efforts to cut down or control use.
3. A great deal of time is spent in activities necessary to obtain, use, or recover from the substance's effects.
4. Craving or a strong desire or urge to use the substance.
5. Recurrent use resulting in a failure to fulfill major role obligations at work, school, or home.
6. Continued use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by its effects.
7. Important social, occupational, or recreational activities are given up or reduced because of use.
8. Recurrent use in situations in which it is physically hazardous.

9. 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.
10. Tolerance.
11. 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 patients with primary opioid use disorder (OUD), medication assisted treatment is the most common approach. U.S. 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 a patient's thinking and behavior. CBT has proven positive effects for the treatment of SUD. 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. 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 8 to 12 weeks both increases retention in a treatment program and reduces stimulant drug use during treatment.

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

- 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 U.S. 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.

BCBSA 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 BlueShield 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 patient 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.

KEY POINTS:

This evidence review was created with a search of the PubMed database through June 6, 2022.

Author, year, country	Study Design	Population Characteristics	Interventions	Comparators	Clinical Outcomes, Length of Follow-Up
Marichich et al (2021)	Observational Study	3144 patients with buprenorphine medication for OUD who were under the care of a clinician and filled a 12-weekprescription for reSET-O	Four 30 min modules per week for a total of 31 core modules and 36 supplemental modules on a mobile device; Total treatment time 12 weeks	None	12 weeks
Marichich et al (2021)	Observational Study	643 individuals from the above cohort who had completed a 12-week prescription	Same as above; with a total treatment time of 24 weeks	None	24 weeks
Campbell et al (2014) FDA Summary DEN160018	RCT	507 adult patients with self-report of drug use, with a subset of 305 who did not have primary use of opioids treated at community	12 weeks of TAU + CCRA (62 modules on a desktop) + CM for module completion and negative drug screen	12 weeks of TAU consisting > 2 individual or group therapy sessions	TES reduced drop-out from the treatment program (hazard ratio=.72 [95% CI: 0.57 to 0.92], P=.010), and the odds of

		health centers	(n=255)	per week (n=252)	achieving abstinence was 1.62 fold greater in the group with CCRA and contingency management group (p=.010). TES benefit was only observed in pts who were not abstinent at baseline. 6 month follow up
Christensen et al (2014) FDA summary K173681	RCT	170 opioid-dependent adults	12 weeks of CCRA (69 modules on a desktop in the clinic) + CM + buprenorphine/ naloxone (n=92)	12 weeks of CM +buprenorphine/ naloxone (n=78)	9.7 more days of abstinence in 84 days, in the CCRA group (67.1 days) than in the control group (57.4 days, P=.01), No significant difference between the two groups in the longest abstinence (5.5 days P=.214). No significant improvement on the overall Addiction Severity Index (P>16). 12 week follow up

Summary of Evidence:
For individuals with SUD other than OUD who receive a prescription digital therapeutic, the evidence includes 1 pivotal CT 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 analyses of data from the trial reported an association between engagement with the app and abstinence at 9 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 1 pivotal RCT and analysis of data of more than 3000 patients 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.

Practice Guidelines and Position Statements:
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.

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. Behavioral therapies include cognitive-behavioral therapy (alcohol, marijuana, cocaine, methamphetamine, nicotine), contingency management (alcohol, stimulants, opioids, marijuana, nicotine), community reinforcement approach 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.

U.S. Preventive Services Task Force Recommendations
Not applicable.

KEY WORDS:
reSET-O®, reSET®, substance use disorder, prescription mobile app,deprexis, vorvida, Modia, cognitive behavioral therapy, CBT

APPROVED BY GOVERNING BODIES:
In 2017, reSET® (Pear Therapeutics), received de novo marketing clearance from the FDA to provide 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.

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 July 2020, deprexis®(Orexo Digital Therapuetics) received FDA EUA approval. Deprexis is a 12 week digital cognitive behavioral therapy program for mild to moderate to severe depression.

In July 2020, VORV!DA®(Orexo Digital Therapuetics) received FDA EUA approval. VORV!DA is a 24 week digital cognitive behavioral therapy program for problematic drinking.

Modia™ (Orexo Digital Therapuetics) is currently in development for use in patients with opioid use disorder. This includes a 24 week digital therapy support program.

Vorvida® and Modia® (Orexo) provide support for individuals with problematic drinking and OUD. These digital technologies have not received marketing clearance by U.S. Food and Drug Administration and are not reviewed here. They are currently available in the U.S. through the Enforcement Policy for Digital Health Devices for Treating Psychiatric Disorders During COVID-19.

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT:

98978	Remote therapeutic monitoring; device supply, recording, transmission to monitor cognitive behavioral therapy, each 30 days (Effective 01/01/23)

HCPCS:

A9291	Prescription digital behavioral therapy, FDA cleared, per course of treatment (Effective 04/01/22)
E1399	Durable Medical Equipment Miscellaneous

PREVIOUS CODING:

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 (Deleted 12/31/2022)
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 (Deleted 12/31/2022)

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POLICY HISTORY:

Adopted for Blue Advantage, October 2020.
Medical Policy Group, March 2021
Medical Policy Group, July 2021
Medical Policy Group, November 2021: 2022 Annual Coding Update. Added CPT 0702T-0703T.
Medical Policy Group, March 2022: Quarterly Coding Update. Added HCPCS A9291 to Current Coding section.
Medical Policy Group, August 2022
Medical Policy Group, November 2022: 2023 Annual Coding Update. Added CPT 98978 to the Current Coding section. Moved CPT 0702T/0703T code from Current Coding section. Created Previous Coding section to include code 0702T/0703T.
Medical Policy Group, November 2022: 2023 Annual Coding Update. Added CPT 98978 to the Current Coding section. Moved CPT 0702T/0703T code from Current coding section. Created Previous Coding section to include code 0702T/0703T.
