



Louisiana

Digital Health Therapies for Substance Abuse

Policy # 00756

Original Effective Date: 12/13/2021

Current Effective Date: 12/13/2021

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Drug Testing in Pain Management and Substance Use Disorder Treatments addressed separately in medical policy 00387.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers digital health therapies for patients with substance use disorders to be **investigational**.*

Policy Guidelines

Vorvida^{®‡} and Modia^{®‡} (Orexo) provide support for individuals with problematic drinking and opioid use disorder. These digital technologies have not received marketing clearance by U.S. Food and Drug Administration (FDA) 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 COVID19 (U.S. Food and Drug Administration, 2020).

Background/Overview

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.

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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 drug addiction 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. 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 2 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.

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The community reinforcement approach is a form of CBT that has a goal of making abstinence more rewarding than continued use. Community reinforcement approach increases non-drug reinforcement by teaching skills and encouraging behaviors that help improve employment status, family/social relations and recreational activities. Community reinforcement approach 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 community reinforcement approach.

The combination of community reinforcement approach 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 (eg, 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".

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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-cert 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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

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 SUD 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. 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.

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Rationale/Source

The World Health Organization defines substance abuse 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.

Summary of Evidence

For individuals with substance use disorder who receive a prescription digital therapeutic, the evidence includes 2 pivotal randomized controlled trials (RCTs) 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 to increase access to evidence-based cognitive-behavioral treatments, particularly in rural areas or where there are other limitations to specialist care. Although it is theoretically appealing to replace in-person counseling with computer-based therapy, there are a number of limitations in the current evidence base that limit any conclusions regarding efficacy. Specifically, 1 of the trials 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. The second trial, conducted in patients with primary opioid use disorder, did not meet a primary objective of longest days of abstinence. While both RCTs reported a positive effect on the intermediate outcome of retention, the relationship between retention and relevant health outcomes in these trials is uncertain. In addition, both trials were conducted with an earlier technology (a desktop in a clinic) and were unblinded, so there are issues of possible performance bias and questions about generalizability of these results. The observational study shows that participants who complete more modules with the mobile app have greater abstinence during weeks

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9 to 12, but the lack of a control group with comparable motivation limits interpretation of results. Given all of these limitations, further study in well designed trials is needed to determine the effects of prescription digital therapeutics on relevant outcomes in patients with substance use disorder and opioid use disorder. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (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.

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

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

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

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Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
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	200	Sep 2021

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

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11/04/2021 Medical Policy Committee review

11/10/2021 Medical Policy Implementation Committee approval. New policy.

Next Scheduled Review Date: 11/2022

Coding

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contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	No codes
HCPCS	No codes
ICD-10 Diagnosis	F10.1-F19.99

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment,

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would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

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