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## **OVERVIEW**

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.

## **MEDICAL CRITERIA**

Not applicable

## **PRIOR AUTHORIZATION**

Not applicable

## **POLICY STATEMENT**

### **Medicare Advantage Plans**

Prescription digital therapeutics for patients with substance use disorder is not covered as the evidence is insufficient to determine the effects of the technology on health outcomes.

### **Commercial Products**

Prescription digital therapeutics for patients with substance use disorder is considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

## **COVERAGE**

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage.

## **BACKGROUND**

### **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 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. 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 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.

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-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.

## Regulatory Status

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. 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®.

For individuals with substance use disorder who receive a prescription digital therapeutic, the evidence includes 2 pivotal randomized controlled trials (RCTs). 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, one 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. Given all 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 the effects of the technology on health outcomes.

### **CODING**

The following codes are not covered for Medicare Advantage Plans and not medically necessary for Commercial Products:

- 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
- 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

### **RELATED POLICIES**

None

### **PUBLISHED**

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