

**Generic:** (FDA approved 09/14/2017)

**Company:** Pear Therapeutics

**Agent for:** Substance use disorders (SUD): stimulants, cannabis, cocaine, and alcohol

**Indications:** Adjunct therapy for adult patients with SUD who are not on opioid replacement therapy, do not abuse only alcohol, or whose primary substance of abuse is not opioids

**Mechanism of Action:** reSET is a mobile application that contains a patient application and clinician dashboard. The goal is to deliver behavioral therapy to patients to increase abstinence from substance use and increase retention in outpatient therapy programs. reSET is meant to be used in addition to standard outpatient treatment.

#### COMPARABLE DRUG:

#### COST PER MONTH (WAC)

#### ADVANTAGES:

- First FDA approved prescription digital device and introduction of a new class of treatment
- Has been proven to help patients increase abstinence adherence and increase retention in programs

#### DISADVANTAGES:

- Has not been shown to be effective in patients with opioids as substance of abuse
- FDA approval was based mainly on one study of about 400 patients; further studies should be done

**MOST IMPORTANT RISKS/ADVERSE EVENTS:** Based on data from clinical trial, there were no side effects associated with the device. The adverse effects seen were typical of patients with SUD.

**MOST COMMON ADVERSE EVENTS:** Common side effects occurred mainly from treatments of SUD and not the digital device. Side effects include cardiovascular disease, gastrointestinal events, depression, mania, and suicidal behaviors, ideas or attempts.

**USUAL DOSAGE:** Patients will install the application on their smartphone and use it in conjunction with their outpatient treatment for 12 weeks.

**PRODUCT:** Treatment is a 12-week program that utilizes cognitive behavior therapy to focus on relations between thoughts, feelings and behaviors. Interventions and assessment tools are provided to the patient via a mobile app and data is collected that can be assessed by a clinician. The app prompts patients with questions that will educate them about ways to deal with their disorder and abstain from using the substance. Patients are taught practical skills to help remain abstinent and continue their rehabilitation programs. It works as an incentive based program. Patients can also report their status and any lapses in abstinence, which is sent to the clinician.

**COMMENTS:** Substance use disorder replaces the terms substance abuse and substance abuse disorder. It is a condition where use of a substance leads to impairment of one's daily life. According to the *Diagnostic and Statistical Manual of Mental Disorder, Fifth Edition*, there are eight types of substance use disorders: alcohol, cannabis, hallucinogens, inhalants, opioid, sedatives, stimulants, and tobacco. According to WHO, about 5.4% of the world population is affected by SUD. The opioid epidemic has been declared a public health emergency in the US in 2017 with more than 90 Americans dying everyday. Current treatments for SUD include counseling, group support, and medications such as naltrexone, nicotine patches, and buprenorphine. In a 12 week clinical trial, patients who used reSET were 40.3% compliant versus to patients who had standard treatment (face-to-face therapy) and were 17.6% compliant. In a subgroup of non-abstinent patients at the beginning of the study, patients using reSET had almost a five-fold improvement in abstinence. Abstinence, retention, and engagement were measured in the clinical study. reSET-O is currently in development for treatment of opioid use disorder.