

reSET-O® Prescription Digital Therapeutic Software

This clinician information leaflet does not include all the information needed to use reSET-O safely and effectively. Please see the full reSET-O Clinician Directions for Use within the reSET-O Clinician Dashboard for complete Important Safety Information.

Indications for Use Statement:

reSET-O is intended 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, for patients 18 years or older who are currently under the supervision of a clinician. reSET-O is indicated as a prescription-only digital therapeutic.

Important Safety Information Warnings:

Safety:

reSET-O should not be used by individuals outside active OUD treatment. It is not intended to replace treatment by you, the patient's medical provider. It should be used as an adjunct to clinician treatment, buprenorphine treatment and contingency management.

reSET-O is not intended to be used as a stand-alone therapy for Opioid Use Disorder (OUD). reSET-O does not replace care by a licensed medical practitioner.

reSET-O is not intended to replace or reduce the frequency or duration of in-person therapy.

Clinicians should not use reSET-O to communicate with their patients about emergency medical issues. Patients should be clearly instructed not to use reSET-O to communicate to their clinician any urgent or emergent information. In case of an emergency, patients should dial 911 or go to the nearest emergency room.

Patients with opioid use disorder experience mental health disease and co-morbid medical problems at higher rates than the general population. Patients with opioid use disorder have higher baseline rates of suicidal ideation, and suicide attempts and suicide completion. Clinicians should undertake standard of care to monitor patients for medical problems and mental health disease, including risk for harming others and/or themselves.

The therapy lesson-use tracking data collected by reSET-O is not intended to be used as a stand-alone assessment of overall treatment progress. Clinicians should use their best judgment when considering self-reported data about use

and cravings and seek to verify and validate use with objective measures such as a urine drug screens (UDS), Breathalyzer or other laboratory tests.

Patient reported data on buprenorphine use/non-use is a tool to allow the clinician more insight into their patient's behavior and actions between in person visits. It is not intended to advise on dosing or titration of buprenorphine.

reSET-O is not intended to be used as a stand-alone assessment for making determinations regarding a patient's opioid use disorder.

Treatment decisions should be based on all a patient's medical history and data.

Effectiveness:

The buprenorphine notification feature is voluntary and must be set up correctly by the patient if they wish to receive accurate daily notifications.

reSET-O has not been shown to decrease illicit drug use or improve abstinence in patients with OUD.

Additional 12-week prescriptions may benefit patients, as OUD is a chronic disease; however, the benefits of prescription extensions have been evaluated.

The long-term benefit of using reSET-O has not been evaluated in studies with buprenorphine lasting beyond 12-weeks (84 days) in the OUD population. The ability of reSET-O to prevent potential relapse after treatment discontinuation has not been studied.

Patient Eligibility:

reSET-O should only be used by individuals who are enrolled or participating in an OUD treatment program. It should be used with outpatient clinician treatment, buprenorphine treatment, and contingency management (a program that provides incentives for achieving behavior goals).

reSET-O is intended for patients whose primary language is English or Spanish, and whose reading level is at or above 7th grade English or Spanish.

Patients should have access to an Android/iOS tablet or smartphone and are familiar with use of smartphone apps (applications).

Patients should be able to upload data periodically, i.e., have internet/wireless connection access.

Security:

reSET-O may contain and transmit protected health information and/or personally identifiable information.

Please see full Clinician Directions for Use for complete Important Safety Information.

What is reSET-O?

reSET-O is a Prescription Digital Therapeutic (PDT) for patients with Opioid Use Disorder. PDTs are software applications used in supporting therapies for disease. reSET-O is available by prescription-use only and is intended to provide 12 weeks (84 days) of cognitive behavioral therapy as an adjunct to a contingency management (CM) system, for patients 18 years of age and older who are currently enrolled in outpatient treatment under the supervision of a clinician. The reSET-O software uses the patient's smartphone or tablet to deliver content on demand as a complement to outpatient treatment.

How to Start Using reSET-O:

The following steps will help guide your use of reSET-O and the Clinician Dashboard correctly:

- A licensed clinician prescribes reSET-O.
- The patient receives a text from Pear's Patient Service Center with an access code and instructions to download the app from Apple or Google Play Store.
- The patient downloads the application and enters the access code and email address from the prescription, then sets a password to use for subsequent login in the case of deleting/reinstalling the app, getting a new phone or tablet.
- The patient begins working and learning with reSET-O, completes lessons, answers quiz questions (fluency training), and reports substance use, cravings, and triggers. reSET-O also notifies patients with reminders to take their buprenorphine (note: this feature is voluntary)
- reSET-O includes a CM system that gives the patient a chance to earn* rewards for lessons completed and negative drug screens achieved during the 12-week (84-day) therapy period.

- The clinician receives an email sent to the email address provided on the enrollment form. The email contains a link to verify the account and set a password. Once an account is created, the Dashboard can be accessed at any time by visiting www.pear.md.
- Using the Dashboard, the clinician can monitor the patient's progress, use of reSET-O app, and view patient-reported substance use, cravings and triggers.
- The clinician can also enter drug screen results and appointment compliance dates using the Dashboard. Patients will have continued access to any unused retail gift cards through the reSET-O app after their prescription expires.
- The therapy lesson-use tracking data collected by reSET-O is not intended as a stand-alone assessment of overall treatment progress.
- The reSET-O software works with outpatient therapy to support the patient's OUD treatment. Please see full Patient Directions for Use for complete instructions on how to use reSET-O and how to share information with your clinician.

*At the discretion of the provider, the rewards earned may be virtual (nonmonetary) or in the form of retail gift cards. Subject to pre-programmed limits.

Please see full Clinician Directions for Use (DFU) for complete instructions on how to use the reSET-O Clinician Dashboard and how patients can share information with their clinician using reSET-O.

What Operating Systems and Browsers Does reSET-O Support?

The reSET-O app is supported on the following mobile operating systems:

- iOS
- Android

The reSET-O Clinician Dashboard is optimized for desktop computer access and is supported on the following web browsers:

- Google Chrome
- Firefox
- Microsoft Internet Explorer
- Microsoft Edge
- Safari

General Information about the Safe and Effective Use of reSET-O:

Individuals outside active enrollment in an OUD treatment program should not use reSET-O. It should only be used as an adjunct to face-to-face counseling and contingency management. reSET-O is not intended to replace or reduce the frequency or duration of in-person therapy. The therapy lesson use tracking data collected by reSET-O is not intended to be used as a stand-alone assessment of therapy progress or for making determinations regarding a patient's OUD treatment. Treatment decisions should be based on all medical history and data pertaining to a patient. Clinicians should use their best judgment when considering self-reported data about substance use and cravings and seek to verify and validate with objective measures such as urine drug screens, Breathalyzer or other laboratory tests. Clinicians should engage in their normal care practices to monitor patients for medical problems and mental health disorders, including risk for harming others and/or themselves.

It is recommended that the patient completes a minimum of 4 therapy lessons per week. Lessons that the clinician deems important may be repeated. Patients complete the Core Lessons in a specific order. A patient can only advance to the next core lesson after successfully completing the prior lesson.

Please see full Clinician Directions for Use for complete Important Safety Information

Additional Information Available:

The clinical study summary is available in publication¹ and a summary of the clinical study results is available on the FDA website.²

Additional Support Available:

For additional support with any aspect of the reSET-O app, contact Pear's Patient Service Center via email at support@pearconnect.com or by phone at 1-833-697-3738.

Rx Only

¹Christensen DR, Landes RD, Jackson L, et al. Adding an Internet-delivered treatment to an efficacious treatment package for opioid dependence. *J Consult Clin Psychol*. 2014;82(6):964-972. doi:10.1037/a0037496.

²510(k) Notification for reSET-O. K173681. May 23, 2019. https://www.accessdata.fda.gov/cdrh_docs/pdf17/K173681.pdf.

Accessed July 23, 2019.