

CLINICIAN INFORMATION

Brief Summary Instructions

reSET-O®

Prescription Digital Therapeutic

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.

Important Safety Information:

Warnings: reSET-O is intended for patients whose primary language is English and who have access to an Android/iOS tablet or smartphone. reSET-O is intended only for patients who own a smartphone and are familiar with use of smartphone apps (applications).

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.

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 does not represent a substitution for a patient's medication. Patients should continue to take their medications as directed by their healthcare provider. The ability of reSET-O to prevent potential relapse after therapy discontinuation has not been studied.

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. PDTs are regulated by the U.S. FDA. reSET-O is available by prescription-use only and is intended to provide 12 week (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 via the enrollment form, which includes an email address for the patient.
- A patient care specialist from reSET Connect™ by Pear Therapeutics, Inc. contacts the patient via telephone with an access code, and guides the patient through downloading the app from the Apple App Store or Google Play Store.
- The patient downloads the application and enters the access code and email address from 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 win 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. Appointment compliance must occur every 30 days or less during the 12-week (84-day) therapy period, as determined by the entries in the Dashboard. After 30 days, the patient will no longer be able to access their CM rewards via the reSET-O app. Access will be restored after a recent appointment compliance is entered via the Dashboard.
- The reSET-O software works with outpatient therapy to support the patient's OUD.

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 reduce the amount of face-to-face clinician time. 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 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. reSET-O may contain and transmit protected health information and/or personally identifiable information.

reSET-O has not been shown to decrease illicit drug use or improve abstinence in patients with OUD. Please see the clinical summary section of the DFU for more details on the study design and results.

Please see full Clinician Directions for Use 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.

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, you can contact reSET Connect™ via email at pearconnect@peartherapeutics.com or by phone at 1-833-4RESETO (1-833-473-7386).



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¹ Christensen 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. ² 510(k) Notification for reSET-O. K173681. May 23, 2019. https://www.accessdata.fda.gov/cdrh_docs/pdf17/K173681.pdf. Accessed July 23, 2019.