

CLINICIAN INFORMATION

Brief Summary Instructions

reSET® Prescription Digital Therapeutic Software

This clinician information leaflet does not include all the information needed to use reSET safely and effectively. Please see the full reSET Clinician Directions for Use within the reSET Clinician Dashboard for complete important safety information.

Important Safety Information:

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

Clinicians should not use reSET to communicate with their patients about emergency medical issues. Patients should be clearly instructed not to use reSET 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 is not intended to be used as a stand-alone therapy for substance use disorder (SUD). reSET does not replace care by a licensed medical practitioner. reSET does not represent a substitution for a patient's medication. Patients should continue to take their medications as directed by their healthcare provider.

The long-term benefit of treatment with reSET on abstinence has not been evaluated in studies lasting beyond 12-weeks in the SUD population. The ability of reSET to prevent potential relapse after treatment discontinuation has not been studied.

What is reSET?

reSET is the first prescription digital therapeutic (PDT) to treat Substance Use Disorder (SUD). PDTs are a new class of treatment using software to treat medical diseases. PDTs are regulated by the U.S. FDA and validated through randomized clinical trials, with data to demonstrate their safety and efficacy.¹ reSET is available by prescription-use only and is intended to provide 12 weeks (90 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 software uses the patient's smartphone or tablet to deliver therapy on demand as a complement to outpatient treatment.

How to Start Using reSET:

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

- A licensed clinician prescribes reSET 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, completes lessons, answers quiz questions (fluency training), and reports substance use, cravings, and triggers. reSET 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 (90-day) treatment 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 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 (90-day) treatment 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 app. Access will be restored after a recent appointment compliance is entered via the Dashboard.
- The reSET software works synergistically with outpatient therapy to treat the patient's SUD.

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

What Operating Systems and Browsers Does reSET Support?

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

- iOS 8.0 and above
- Android 4.1 and above

The reSET 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
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General Information about the Safe and Effective Use of reSET:

Individuals outside active enrollment in an SUD treatment program should not use reSET. It should only be used as an adjunct to face-to-face counseling and contingency management. reSET is not intended to reduce the amount of face-to-face clinician time. The therapy lesson use tracking data collected by reSET is not intended to be used as a stand-alone assessment of treatment progress or making determinations regarding a patient's SUD. 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 a 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 may contain and transmit protected health information and/or personally identifiable information.

The effectiveness of reSET has not been demonstrated in patients reporting opioids as their primary substance of abuse. Patients enrolled in the study who reported opioids as their primary substance of abuse were not on, and specifically excluded if, enrolled in standard-of care, opioid treatment programs (OTPs) and/or on opioid replacement therapy (ORT). 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 is intended to provide cognitive behavioral therapy, as an adjunct to a contingency management system, for patients 18 years of age and older, who are currently enrolled in outpatient treatment under the supervision of a clinician. reSET is indicated as a 12-week (90-day) prescription-only treatment for patients with substance use disorder (SUD), who are not currently on opioid replacement therapy, who do not abuse alcohol solely, or who do not abuse opioids as their primary substance of abuse.

It is intended to:

- increase abstinence from a patient's substances of abuse during treatment, and
 - increase retention in the outpatient treatment program.
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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 app, contact reSET Connect™ via email at pearconnect@peartherapeutics.com or by phone at 1-833-MYRESET (1-833-697-3738).



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¹Campbell ANC, Nunes E V, Matthews AG, et al. Internet-delivered treatment for substance abuse: a multisite randomized controlled trial. *Am J Psychiatry*. 2014;171(6):683-690.doi:10.1176/appi.ajp.2014.13081055. ²De Novo Classification Request for reSET. DEN160018. May 16, 2017. https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN160018.pdf