

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.

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.

Important Safety Information Warnings:

Safety:

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, critical, 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 is not a substitute for a patient's medication. Patients should continue to take their medications as directed by their healthcare provider.

reSET should not be used by individuals outside active enrollment in a SUD treatment program. 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.

Patients with substance use disorder experience mental health disease and co-morbid medical problems at higher rates than the general population. Patients with substance use disorder also have higher baseline rates of suicidal ideation, and suicide attempts, and suicide completion. 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.

The therapy lesson use tracking data collected by reSET is not progress. Clinicians should use their best judgment when considering self-reported data about use and cravings and seek to verify and validate with objective measures such as a urine drug screens (UDS), Breathalyzer or other laboratory tests.

reSET is not intended to be used as a stand-alone assessment for making determinations regarding a patient's substance use disorder. Treatment decisions should be based on all medical history and data pertaining to a patient.

Effectiveness:

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.

The effectiveness of reSET has not been demonstrated in patients currently reporting opioids as their primary substance of abuse.

The duration of each prescription interval is 12 weeks (90 days). Additional 12-week (90 day) access intervals to the reSET therapy may benefit patients, as SUD is a chronic disease; however, the benefits of prescription extension have not been evaluated.

The safety and effectiveness of reSET has not been established in patients enrolled in opioid treatment programs.

The effectiveness of reSET has not been demonstrated in patients currently reporting opioids as their primary substance of abuse.

Patient Eligibility:

reSET is intended for patients whose primary language is English or Spanish and whose reading level is at the 7th grade level or above and who have access to an Android/iOS tablet or smartphone.

reSET is intended only for patients who own or have access to a 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.

When issuing a prescription, the clinician should review the Privacy Policy and Terms of Service and confirm verbally that the patient understands the system, the Terms of Service and the Privacy Policy. If for any reason the clinician is concerned the patient cannot understand these, they should not pre-scribe reSET.

Security:

reSET 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?

reSET is the first prescription digital therapeutic (PDT) designed to deliver behavioral therapy to treat Substance Use Disorder (SUD). PDTs are a new class of treatment using software to treat medical diseases. reSET is available by prescription only and is intended to provide 12-week (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. It is intended to be used in conjunction with face-to-face treatment delivered by you, the clinician.

How to Start Using reSET:

The following steps will help guide the clinician's use of reSET and the Clinician Dashboard correctly:

- A licensed clinician prescribes reSET.
- 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 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 earn *rewards for lessons completed and negative drug screens achieved during the 12-week (90-day) treatment period.
- The clinician receives a message via 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. Patients will have continued access to any unused retail gift cards through the reSET app after their prescription expires.
- The reSET software works synergistically with out patient therapy to treat the patient's SUD.

*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 Clinician Dashboard and how patients can share information with their clinician using reSET.

What Operating Systems and Browsers Does reSET Support?

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

- iOS
- Android

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

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 for 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 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.

Patients enrolled in the study used to demonstrate the safety and effectiveness of reSET 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.

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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 Pear's Patient Service Center via email at support@pearconnect.com or by phone at 1-833-697-3738.

Rx Only

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. September 14, 2017. https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN160018.pdf.

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