Indications for Use:
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: 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).

Please see additional Important Safety Information on back cover and accompanying Clinician Brief Summary Instructions on inside pages.
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**The 24/7 Access to reSET-O™ Can Change Everything**

**Help Close Treatment Gaps with a Prescription Digital Therapeutic Like reSET-O**

**Clinically Validated to Increase Retention**
- of patients with OUD in outpatient treatment (TES, 82.4%; TAU, 68.4%; \( P=0.0224 \))

Two study groups were:
- TAU=buprenorphine + clinician visits + contingency management
- TES=buprenorphine + clinician visits + contingency management + reSET-O

**Meets MAT Requirements for Outpatient Behavioral Therapy**
- with evidence-based and consistent delivery of cognitive behavioral therapy, contingency management, and fluency training

**Fosters Greater Engagement and Access**
- with interactive modules whose therapeutic content is available via patients’ smartphone or tablet

**Gain Deeper Insights into Your Patients’ Progress Toward Recovery with the Clinician Dashboard**

**View**
- View patient summary, personal information, prescription status, clinician-entered drug screen results, and appointment attendance

**See**
- See the severity and intensity of patient-reported cravings and triggers

**Follow**
- Follow patient-reported buprenorphine check-ins, substance use, cravings and triggers, as well as lesson completion

**Enter**
- Enter drug screen results, to further guide the conversation

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**For Patients with Opioid Use Disorder**
- Lack of access to psychosocial resources for patients
- US dies from an opioid overdose
- Medication-assisted treatment (MAT) for opioid abuse is a national public health emergency
- 1 million did not receive MAT
- Buprenorphine-containing medications combined with behavioral therapies
- MAT: the use of behavioral therapies, medications, and counseling delivered in person or as an accessory to a regulated medical device
- This clinician information leaflet 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
- Enter drug screen results, to further guide the conversation

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**Warnings:**
- 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
- The reSET-O Clinician Dashboard is optimized for desktop computer access and may contain and transmit protected health information
- The reSET-O app is supported on the Apple App Store or Google Play Store
- The reSET-O app is intended for patients whose primary language is English and who have access to an Android/iOS tablet or smartphone

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**Indications for Use Statement:**
- reSET-O is intended for patients with opioid use disorder (OUD) who own a smartphone and are familiar with use of smartphone apps (applications)
- reSET-O was validated through randomized controlled trials as an adjunct to outpatient treatment that includes transmucosal buprenorphine and contingency management, or by phone at 1-833-MY-RESET (1-833-697-7383)
- The therapy lesson facilitates transparency in patient-clinician dialogue
- The therapy lesson makes face-to-face meetings more meaningful

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**Indications for Use:**
- reSET-O is indicated for patients with opioid use disorder (OUD) who own a smartphone and are familiar with use of smartphone apps (applications)
- reSET-O is not intended to be used as a standalone therapy
- reSET-O is intended to be used as an accessory to a regulated medical device
- reSET-O is not intended for patients with opioid use disorder (OUD) who do not own a smartphone or tablet
- reSET-O is not intended for patients who do not have access to a smartphone or tablet

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**Client Direction for Use:**
- Please see full Clinician Directions for Use
- Please see additional Important Safety Information on the back cover and accompanying Clinician Brief Summary Instructions on following pages
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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 Mobile Medical Application (MMA) for patients with Opioid Use Disorder. MMAs are software applications used as an accessory to a regulated medical device or transform the mobile platform into a medical device. MMAs are regulated by the U.S. FDA. reSET-O was validated through randomized clinical trials with data to demonstrate its safety and efficacy. 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 contingency management (CM) 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, and 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 Clinician Dashboard can be accessed at any time by visiting www.pear.md.
- Using the Clinician 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 Clinician 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 Clinician 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 Clinician Dashboard.
- The reSET-O software works with outpatient therapy to support the patient’s OUD treatment.

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 8.0 and above
- Android 4.1 and above

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 use with objective measures such as urine drug screens, Breathalyzer or other laboratory tests. Clinicians should undertake standard of care 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.

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Limitations of Use:

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

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-MY-RESET (1-833-697-3738).

reSET-O, reSET Connect, Pear Therapeutics, and Sandoz trademarks are the property of their respective owners.


Issued: 12/2018
S-RSO-1368205
IMPROVE THE IMPACT OF YOUR OUD PATIENT THERAPY WITH reSET-O™

**CLINICALLY VALIDATED TO INCREASE RETENTION**

of patients with OUD in outpatient treatment (TES, 82.4%; TAU, 68.4%; \(P=0.0224\))^1¹

**TRACKS MEASURABLE RESULTS**

that help you focus on patients’ progress to make face-to-face meetings more meaningful^1¹

**IMPROVES THE IMPACT OF OUTPATIENT OUD THERAPY**

by providing 24/7 access to cognitive behavioral therapy, contingency management, and fluency training^1¹

**TRACK PATIENT-REPORTED BUPRENORPHINE CHECK-INS**

that support patients’ current therapy regimens and facilitate transparency in patient-clinician dialogue^1¹

Visit www.reSETforRecovery.com

**Ask your Sandoz Digital Therapeutics Specialist to show you a product demonstration**

For questions and technical support, contact your reSET Connect™ Patient Service Center

Call: 1-833-MY RESET (1-833-697-3738), Monday-Friday, 8 AM-6 PM ET

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Please see accompanying Clinician Brief Summary Instructions on pages on reverse side.

References: