RESET-O

Clinical Policy ID: CCP.1429

Recent review date: 10/2025

Next review date: 2/2027

Policy contains: Opioid use disorder; community reinforcement approach; prescription digital therapeutic; RESET-O.

AmeriHealth Caritas has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas' clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered, on a case-by-case basis, by AmeriHealth Caritas when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas' clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas will update its clinical policies as necessary. AmeriHealth Caritas' clinical policies are not guarantees of payment.

Coverage policy

Use of RESET-O® (PursueCare, Middletown, Connecticut, formerly Pear Therapeutics) is investigational/not clinically proven and, therefore, not medically necessary as an adjunctive treatment for opioid use disorder.

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

- Cognitive behavioral therapy.
- Buprenorphine (Subutex) pharmacological therapy.
- Methadone pharmacological therapy.
- Inpatient drug detoxification rehabilitation treatment.
- Opioid drug addiction support groups (Substance Abuse and Mental Health Services Administration, 2021).

Background

In the United States, drug overdoses have risen over the past several decades and remain one of the leading causes of injury death in adults. In the United States in 2023, 105,000 people died from drug overdose and nearly 76% involved opioids. Deaths from synthetic opioids have also increased in recent years (Substance Abuse and Mental Health Services Administration, 2021).

Treatment with medications for opioid use disorder can be combined with counseling and participation in social support programs. Drugs such as buprenorphine and naltrexone can be given in an office, community hospital, health department, or correctional facility, while dispensing of methadone is limited to certain clinics (Substance Abuse and Mental Health Services Administration, 2025).

Medication treatment and behavior modification for opioid use disorder continue to evolve. In 2019, the U.S. Food and Drug Administration issued 510(k) class II marketing clearance to Pear Therapeutics for RESET-O as the first prescription digital therapeutic for opioid use disorder. A prescription digital therapeutic is clinically validated software, regulated as a medical device, available on tablets or smartphones, and prescribed to prevent, manage, or treat disease. RESET-O is intended to increase retention of patients with opioid use disorder in outpatient treatment by providing cognitive behavioral therapy as an adjunct to the outpatient treatment, which may include transmucosal buprenorphine and contingency management, for patients 18 years or older who are currently under the supervision of a clinician (U.S. Food and Drug Administration, 2019).

RESET-O is a self-guided, 12-week cognitive behavioral therapy tool modeled on the Community Reinforcement Approach, and can serve as a training, monitoring, and reminder tool for health care providers and patients. After installing the application, the patient can complete lessons, answer quiz questions, report medication usage, and report substance use, cravings, and triggers, making it more likely that a patient will seek treatment when needed. In 2024, PursueCare acquired Pear Therapeutics and its two products RESET, which is a similar intervention for substance use disorders, and RESET-O (PursueCare, 2024).

Findings

Guidelines

No professional guidelines on treating opioid addiction address RESET-O. The American Society of Addiction Medicine guideline includes psychosocial treatment as a component of the overall treatment program for opioid use disorder. In the context of shared decision-making with the patient and in consideration of available resources, clinicians should determine the optimal type of psychosocial treatment to which to refer patients to ensure treatment adherence. The guideline does not mention RESET-O or any other web-based or internet-based approach specifically (American Society of Addiction Medicine, 2020).

A Canadian guideline on opioid addiction treatment does not mention RESET-O, and only recommends that psychosocial therapies be routinely offered — but not viewed as mandatory — as an alternative or adjunct means of treatment (Bruneau, 2018). A guideline from the College of Family Physicians in Canada on opioid addiction stated that cognitive behavioral therapy has not demonstrated efficacy in retention, and the guideline recommends only brief psychosocial interventions such as counseling. The guideline does not mention RESET-O or other prescription digital therapeutics (Korownyk, 2019).

Evidence review

Longer retention on medications for opioid use disorder reduces morbidity and mortality, but improving retention remains a challenge. Studies assessing interventions to support medications for opioid use disorder rarely report retention as a primary outcome, and there is no consensus on its definition. The evidence supporting retention strategies is often conflicting. The reasons for different findings are multifactorial, and the superiority of any one

strategy cannot be determined (Chan, 2021). RESET-O may offer a new strategy for improving retention in outpatient treatment, but current evidence is limited, and the effects on important health outcomes are uncertain.

A review of comparative clinical effectiveness of RESET-O and two other digital health technologies for opioid use disorder concluded that existing evidence does not show a net health benefit. While retention may improve, long-term cost-effectiveness beyond a 12-week duration is less certain due to the gap in evidence and is highly dependent on the effects of RESET-O on retention. The report also calls on manufacturers to provide evidence of effectiveness of these new technologies (Institute for Clinical and Economic Review, 2020).

The findings from the Campbell and Christensen randomized trials described below used an intervention with a mechanism of action similar to RESET-O and were the basis of the regulatory approval of RESET-O as an adjunctive treatment for opioid addiction. A trial of 507 adults in a substance abuse program randomized subjects into those receiving 12 weeks of treatment as usual (individual and group counseling) with or without two hours of weekly care with the Therapeutic Education System. The group with additional care had a lower dropout rate (hazard ratio = .72) and a higher abstinence rate (odds ratio = 1.62) (Campbell, 2014).

A randomized controlled trial of 170 opioid-dependent adults examined the efficacy of buprenorphine plus contingency management (i.e., patients could earn up to $997.50 each during the study to reward urine tests negative for opioids). Trial subjects were randomized into groups with and without an in-clinic, internet-based community reinforcement approach. Clinic visits to administer buprenorphine and test urine for opioids occurred three times a week for 12 weeks. Retention over the course of treatment was defined as longest continuous abstinence, total abstinence, and days retained in treatment (Christensen, 2014).

The group with the internet reinforcement averaged a significant 9.7 more days of abstinence (P = .011), and a significantly lower dropout rate from treatment (19.6% versus 35.9%, P = .013). For those who experienced prior treatment, internet reinforcement had longer continuous abstinence and longer total abstinence weeks than the contingency management-alone group, while among treatment-naïve participants, the two treatment groups did not differ statistically on abstinence. The authors noted that the study may have been underpowered to detect a difference in longer continuous abstinence of three weeks between the two groups, because the differences were approximately one-third of expected, although trending in the right direction. The relationship between retention and relevant health outcomes was uncertain, and adverse events were not reported (Christensen, 2014).

A secondary analysis of the Christensen study found participants with a digital therapeutic were more likely to have opioid abstinence during weeks nine through 12 (77.3% versus 62.1%, P = .02), and were less likely to stop treatment (hazard ratio 0.49, 95% confidence interval 0.26 to 0.92). No significant difference in the rate of adverse events occurred (P = .42) (Maricich, 2021).

An analysis of 351 participants (82.6% Medicaid) with opioid use disorder treated with buprenorphine compared utilization six months before and after RESET-O initiation. Significant decreases occurred in inpatient admissions (P = .024), drug tests (P < .001), psychiatry visits (P = .036), and other pathology/laboratory (P = .039). Insignificant decreases occurred for alcohol/substance rehabilitation visits (P = .348), office/other outpatient visits (P = .302), other rehabilitation visits (P = .387), emergency department visits (P = .247), and surgery visits (P = .070). Insignificant increases included behavioral rehabilitation (P = .124) and mental health rehabilitation (P = .097) (Velez, 2021).

After 12-month follow-up, when compared to the control group (n = 978), in a retrospective analysis, the RESET-O group (n = 901) experienced greater use of clinician services, a 9% increase in buprenorphine adherence, and lower overall costs, which were driven by significant reductions in inpatient stays (P = .026), hospital readmissions (P = .033), and nonsignificant reductions in unique hospital encounters and emergency department visits. A greater reduction in overall costs occurred among Medicaid participants (Velez, 2022).

A retrospective analysis compared healthcare resource utilization before and after initiation of RESET-O in 101 participants with opioid and non-opioid substance use disorders. Use of RESET-O was associated with reductions in healthcare resource utilization and lower healthcare costs over a six month period. These reductions were attributed to significant decreases in inpatient stays ($P = .003$), partial hospitalizations ($P = .021$), emergency room visits ($P < .004$), some clinician services, and facility encounters (Shah, 2022). However, RESET-O has not been approved for use in non-opioid substance use disorders.

In 2023, we added two manufacturer-sponsored studies. One trial updates findings presented previously with longer follow-up data (Velez, 2022 update of 2021), and the other includes participants with non-opioid substance use disorders (Shah, 2022). Both studies compared healthcare resource utilization and cost data with and without the use of RESET-O. The results confirm previous findings and no policy changes are warranted.

In 2024, we updated the references and found no newly published, relevant information to add to the policy. No policy changes are warranted.

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References

On August 5, 2025, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “community reinforcement approach,” “opioids,” “prescription digital therapeutic,” and “RESET-O.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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PursueCare. PursueCare introduces RESET® and RESET-O®—FDA-authorized digital therapeutics for addiction treatment. https://www.pursuecare.com/pursuecare-introduces-reset-and-reset-o-fda-authorized-digital-therapeutics-for-addiction-treatment/. Published October 16, 2024.

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Policy updates

9/2019: initial review date and clinical policy effective date: 11/2019

10/2020: Policy references updated.

10/2021: Policy references updated.

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