Clinical policy title: ReSET-O

Clinical policy ID: CCP.1429
Recent review date: October 1, 2019
Next review date: February 2021

Policy contains: opioid use disorder; community reinforcement approach; reSET-O.

About this policy: 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 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 is investigational and, therefore, not medically necessary.

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

- Behavioral therapy.
- Buprenorphine (Subutex).

Background

In 2017, 70,237 Americans died of drug overdoses, up from about 17,000 in 1999. The current age-adjusted rate was more than triple than in 1999 (6.1 to 21.7 deaths per 100,000 persons). The rate of drug overdose deaths involving synthetic opioids other than methadone (e.g., fentanyl, fentanyl analogs, and tramadol) increased 30-fold between 1999 and 2017, from 0.3 to 9.0 deaths per 100,000 persons, with the large majority occurring since 2013 (Hedegaard, 2018).

Preliminary data issued in July 2019 by the U.S. Centers for Disease Control and Prevention estimate that in 2018, the rate of drug overdose deaths, including overdoses of synthetic opioids, fell about 5 percent, the first annual decline since the 1990s. Still, drug overdoses, especially from synthetic opioids, remain a pressing public health issue (National Center for Health Statistics, 2019).

A variety of interventions are being used to prevent overdoses from synthetic opioids. One of these is buprenorphine, approved by the Food and Drug Administration in 2002, at relatively high doses, i.e., 16 mg/day or more. The treatment failure rate for buprenorphine has been reported at 25 percent, versus 100 percent for placebo (National Institute on Drug Abuse, 2018). High-dose buprenorphine suppresses illicit opioid use at rates similar to methadone, according to a Cochrane study of 5,430 subjects (Mattick, 2014).
Treatment of opioid addiction with buprenorphine can be combined with counseling and participation in social support programs. The drug can be given in an office, community hospital, health department, or correctional facility, while methadone is given only in clinics (Substance Abuse and Mental Health Service Administration, 2019). In a 24-week study of 140 opioid addicts, those with drug and cognitive behavioral therapy had over twice the average number of weeks of abstinence for all drugs ($7.6$ versus $3.6$, $P = .02$) than those assigned to drug therapy only (Moore, 2016).

Drugs and behavior modification for opioid addiction therapy continue to evolve. On December 10, 2018, the Food and Drug Administration approved reSET-O, a software application that can be downloaded to a patient’s mobile device and used along with drug treatment and contingency management (behavior modification, based on rewards) for opioid addiction. reSET-O, classified as a cognitive behavioral therapy tool, can serve as a training, monitoring and reminder tool for health care providers and patients in maintaining an outpatient treatment program (Food and Drug Administration, 2018).

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 it is needed. In January 2019, Sandoz Inc. and Pear Therapeutics Inc. made reSET-O available by prescription, for 12 weeks of treatment (Coppock, 2019).

**Findings**

No professional guidelines on treating opioid addiction address reSET-O. The American Society of Addiction Medicine includes cognitive behavioral therapy as one treatment of the disorder, but does not mention reSET-O (or any other web-based or internet-based approach), as the guideline was published over three years before federal approval for use (American Society of Addiction Medicine, 2015). 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).

Computer-based treatment for opioid addiction is a relatively new approach. An early study involved 97 persons with depression and alcohol/cannabis misuse given a brief intervention and randomized to no further treatment or nine sessions of motivational interviewing and cognitive behavior therapy (either delivered by a psychologist or a computer-based program). Twelve months after baseline, those with extra sessions from a computer showed the greatest improvement in reducing cannabis/hazardous substance use (Kay-Lambkin, 2009).

An early trial to evaluate the effect of a web-based behavioral therapy intervention on opioid dependence included 135 subjects taking buprenorphine. Subjects were reviewed for 23 weeks, and randomized into three groups: 1) no additional treatment; 2) additional treatment using therapist-delivered community reinforcement approach; and 3) additional treatment using computer-assisted community reinforcement approach. Both groups with additional treatment had significantly ($P < 0.05$) more weeks of abstinence from opioids, and the computer-assisted group had many fewer minutes of encounters with therapists (264, versus 647 for no additional treatment and 1,198 for the therapy-assisted group (Bickel, 2008).

The Therapeutic Education System is one of the first technology-based behavioral interventions for substance abuse, based on the prior Community Reinforcement Approach and Cognitive Behavior Therapy approaches. The system is an interactive, web-based, self-directed tool composed of 65 modules addressing a broad array of skills and behavior
designed to help substance-abusing individuals successfully stop their substance use, gain life skills, and establish new behavioral abilities.

A trial involved treatment of 160 opioid-dependent (mostly heroin) patients with methadone, randomized to groups that did or did not replace some of the methadone with the Therapeutic Education System. Over a 12-month period, the group with intervention had a significantly greater rate of opioid abstinence (48 percent versus 37 percent, \( P < .05 \)), which was even more significant on weeks when participants provided urine samples (59 percent versus 43 percent, \( P < .01 \)). Drop-out rates were high for both groups (Marsch, 2014).

A trial of 170 opioid-dependent adults studied 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 internet-based community reinforcement approach. Clinic visits to administer buprenorphine and test urine for opioids occurred three times a week for 12 weeks. 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 percent versus 35.9 percent, \( P = .013 \)) (Christensen, 2014).

The Christensen article was the basis of the 2018 Food and Drug Administration approval of reSET-O as an adjunctive treatment for opioid addiction. The research also showed a statistically significantly higher retention (time a patient participates) of subjects who used the desktop computer version of reSET-O (82.4 percent) compared with 68.4 percent for those who did not (Food and Drug Administration, 2018).

A study comparing medicinal therapy alone versus combined with the Therapeutic Education System for addiction showed combination therapy initially showed an improved percent of patients who abstained. However, the percentage of both groups was equal after six months, negating any early improvement (National Institute of Drug Abuse, 2018).

A Cochrane review of five studies (\( n = 278 \)) assessed the ability of acupuncture, mindfulness, and cognitive behavioral therapy interventions to reduce opioid consumption, misuse of opioids, or maintenance of chronic non-cancer pain management treatments. Findings were mixed; that is, reductions in opioid consumption in intervention and also control groups were observed (Eccleston, 2017). Little empirical data to guide practitioners was found in a study of 56 trials psychosocial interventions for opioid misuse in chronic non-cancer pain (Hruschak, 2018).

A systematic review of 30 publications studied effects of psychosocial interventions in conjunction with medications for opioid addiction (mostly methadone), in particular contingency management and cognitive behavioral therapy. This combination was judged to generally be effective in improving outcomes for opioid addiction (Dugosh, 2016).

A systematic review of 24 articles on contingency management, 11 of which focused on opioid treatment programs and methadone clinics, declared contingency management to be one of the most effective behavioral interventions for substance use but is not as widespread as might be expected (Ainscough, 2017; Oluwoye, 2019).

An umbrella systematic review (39 systematic reviews plus 26 randomized controlled trials) revealed that retention rates in opioid use disorder treatment:

- Improve when buprenorphine or methadone is used (64 percent to 73 percent versus 22 percent to 39 percent for control).
- Improve when treated in primary care (86 percent versus 67 percent) in specialty care.
- Improve when counseling is added to drug therapy (74 percent versus 62 percent for controls).
• Improve with naltrexone (33 percent versus 25 percent for controls).
• Decline with medication-related contingency management (68 percent versus 77 percent for no contingency) (Korowynk, 2019).

A systematic review of 55 articles on retention rates for opioid addiction concluded contingency management showed promise to increase retention, but other behavioral therapies, such as supervision of medication consumption, or additional counseling, education, or support, produced no differences with controls (Timko, 2016).

**Billing and coding**

Below are National Coverage Determinations, Local Coverage Determinations, and the most commonly submitted codes subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate Centers for Medicare & Medicaid Services references and coding manuals, and bill accordingly.

**National coverage determinations**

No National Coverage Determinations were identified as of the writing of this policy.

**Local coverage determinations**

No Local Coverage Determinations were identified as of the writing of this policy.

**ICD-10 diagnosis codes**

N/A

**CPT procedure codes**

N/A

**HCPCS level II codes**

N/A

**References**

On July 23, 2019, 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,” 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.


Policy updates

09/2019: Initial review date.
11/2019: Effective date.

Appendix

No additional information was identified for this section during the writing of this policy.