Behavioral Clinical Policy: Computer Based Treatment for Cognitive Behavioral Therapy (CBTCBT) for Substance Use Disorders

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**INTRODUCTION**

*Behavioral Clinical Policies* are a set of objective and evidence-based behavioral health criteria used by medical necessity plans to standardize coverage determinations, promote evidence-based practices, and support members’ recovery, resiliency, and wellbeing for behavioral health benefit plans that are managed by Optum®.

**INSTRUCTIONS FOR USE**

This guideline is used to make coverage determinations as well as to inform discussions about evidence-based practices and discharge planning for behavioral health benefit plans managed by Optum. When deciding coverage, the member’s specific benefits must be referenced.

All reviewers must first identify member eligibility, the member-specific benefit plan coverage, and any federal or state regulatory requirements that supersede the member’s benefits prior to using this guideline. In the event that the requested service or procedure is limited or excluded from the benefit, is defined differently or there is otherwise a conflict between this guideline and the member’s specific benefit, the member’s specific benefit supersedes this guideline. Other clinical criteria may apply. Optum reserves the right, in its sole discretion, to modify its clinical criteria as necessary using the process described in *Clinical Criteria*.

This guideline is provided for informational purposes. It does not constitute medical advice.

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Optum may also use tools developed by third parties that are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Optum may develop clinical criteria or adopt externally developed clinical criteria that supersede this guideline when required to do so by contract or regulation.

**BENEFIT CONSIDERATIONS**

**Before using this policy, please check the member-specific benefit plan document and any federal or state mandates, if applicable.**

**DESCRIPTION OF SERVICE**

Using technology such as the computer, internet, or cell phone to deliver outpatient cognitive behavioral therapy is considered computer-based treatment cognitive behavioral therapy (CBTCBT). This policy addresses CBTCBT for the outpatient treatment of substance use disorders. Examples of recent technology are:

**reSET**® is a 12-week duration, FDA-cleared Prescription Digital Therapeutic developed by Pear Therapeutics to be used in conjunction with standard outpatient treatment for substance use disorder related to stimulants, cannabis, cocaine, and alcohol. The application is not intended as a stand-alone treatment or to be used to treat opioid dependence.

The **reSET-O**® is an FDA-cleared mobile application that is a prescription cognitive behavioral therapy intended to be used in addition to outpatient treatment under the care of a health care professional, combined with treatment that includes buprenorphine and contingency management. Contingency management is a behavior modification intervention that establishes a connection between new, targeted behavior and the opportunity to obtain a preferred reward. The reSET-O is an application that is downloaded directly to a mobile device after a prescription is received from the treating physician. It is intended to be used while participating in an outpatient Opioid Use Disorder treatment program.

**COVERAGE RATIONALE**

**Computer Based Treatment for Cognitive Behavioral Therapy (CBTCBT) is unproven and not medically necessary as outpatient therapy to treat substance use disorders.**

A review of the clinical literature does not support CBTCBT as a significant intervention in treating substance use disorders. There is limited evidence showing CBTCBT effectiveness as an adjunct therapy when combined with other therapies.

The requested service or procedure must be reviewed against the language in the member's benefit document. When the requested service or procedure is limited or excluded from the member's benefit document, or is otherwise defined differently, it is the terms of the member's benefit document that prevails.

Per the specific requirements of the plan, health care services or supplies may not be covered when inconsistent with evidence-based clinical guidelines.

All services must be provided by or under the direction of a properly qualified behavioral health provider.
Summary of Clinical Evidence

A review of the current literature does not support CBTCBT as an outpatient therapy to treat substance use disorders.

The studies available for review are limited due to the recent development of the technology. There is limited evidence showing CBTCBT effectiveness as an adjunct therapy when combined with clinical monitoring. Though short-term benefits have been seen, long-term efficacy of CBTCBT has not been determined. CBTCBT for the treatment of substance use disorders is considered unproven until additional studies are available.

Systematic Reviews and Meta- Analyses

Hayes, Inc. (2021) completed a health technology assessment regarding mobile medical applications (MMA) for treating substance use disorders. A total of 7 studies (n=58 – 507) were reviewed. Participants ages ranged from 32.2 to 45.9 years, with treatment settings described as outpatient. Specific MMAs included in the review were reSET, reSET-O, and A-CHESS. Hayes rated the quality of 6 studies as fair and 1 was rated as poor. Limitations of the studies include lack of masking/blinding, lack of validation of self-reported data (1 study), and variability with intervention delivery. The evidence reviewed suggests that individuals with SUD treated with MMAs supplemented with conventional care could possibly be linked to improved treatment retention and increased substance abstinence. Outcomes data revealed that the impact of MMA on abstinence largely occurred in the first 2 months and was no longer reported at 3 months or later. The overall rating indicates potential, yet unproven benefit with significant questions remaining about the impact on health outcomes due to poor-quality studies, sparse data, conflicting study results, and/or other concerns.

The Emergency Care Research Institute (ECRI) completed a technology evidence report published in July 2020 regarding reSET-O for opioid use disorder. The review examined the research available that consisted of 2 single-center, open-label randomized controlled trials (RCTs) with a total of 330 patients. Studies were included of the Therapeutic Education System (an earlier version of reSET-O) used in a treatment center as an adjunct to medication-assisted treatment (MAT). The evidence conclusion is that the current research is inconclusive. The evidence report states that the available RCTs reported consistent findings and are at some risk of bias because each involved a single study center and without blinding. While blinding is not possible for users or treatment providers, data outcomes assessors could be blinded to treatment group. In addition, results from these studies are too limited in scope to assess reSET-O’s effectiveness because neither RCT reported on outcomes beyond program completion or on social functioning, quality of life, or drug-related adverse events. Results of on-site therapy with the Therapeutic Education System may not generalize to self-directed telehealth using reSET-O.

ECRI (2020) completed an evidence review of current available research of 6 full-text publications of 5 studies (2 RCTs, 1 nonrandomized comparative study, and 2 case series) reporting on 1,087 patients regarding reSET for substance use disorder. The summary states that the evidence is inconclusive with too few outcomes data. The limitation concerns addressed are 2 RCTs with moderate risk of bias, while other studies are at high risk of bias from lack of randomization or controls. Findings may not entirely generalize across studies or to specific patient groups because the studies included patient groups with mixed and varying demographic and SUD features. In addition, results may not generalize to telehealth treatment with reSET because the Therapeutic Education System was administered on site in all the studies. Follow-up on outcomes did not extend beyond program completion. Only 1 study reported on social functioning, and none reported on quality of life or SUD-related adverse events (e.g., overdoses).

Kiluk et al. (2019) completed a meta-analysis of 15 randomized controlled trials published from 1990 - 2019, that included alcohol users that met the DSM-5 disorder criteria, and also at-risk or heavy alcohol users. The mean sample size was 656 participants with the minimum of 42 and a maximum of
7935 participants. The CBT-based interventions were delivered via a computer in a web-based program or mobile device in the form of a mobile application. The CBT Technology program details varied, ranging from 4 to 62 sessions/exercises, with many programs adding components of motivational interviewing (47%). CBT Technology as a stand-alone treatment when compared to a minimal treatment control showed a positive and statistically significant (g = 0.20: 95% CI = 0.22, 0.38, k̅ = 5). Treatment as usual (TAU) effects when compared to CBT Technology were non-significant. The largest pooled effects were when CBT Tech was tested as an addition to TAU, in contrast to TAU only, the effect size was positive, significant (g = 0.30: 95% CI = 0.10, 0.50, k̅ = 7), and stable over 12-month follow-up. Two studies compared CBT Technology to in-person CBT with a therapist, and this pooled effect size was not significant. The authors conclude that the results are promising, and that CBT Technology increases the ability to reach and treat large groups of people.

Clinical Trials & Studies

Tetrault and colleagues (2020) performed a randomized clinical trial evaluating feasibility, satisfaction, and substance use outcomes regarding technology-based interventions for 58 individuals with substance use disorder (SUD). The study addressed whether technology-based interventions for SUD delivered in primary care settings are a viable method for effective treatment. Participants were randomized to standard care (n=28) or standard care plus access to a web-based SUD intervention, computer-based training in cognitive behavioral therapy, or CBT4CBT (n=30). Participants included were 18 years of age or older, met current DSM-5 criteria for current cocaine, marijuana, opioid, alcohol or other stimulant use disorder, and medically and psychiatrically stable for 8 weeks of outpatient treatment. The results revealed adherence to CBT4CBT in this setting was high; 77% of those assigned to this condition accessed the program at least once, with 77% completing all 7 modules. The program produced a high satisfaction rate. Participants reported >90% days abstinent for all classes of drugs; with no significant differences between conditions. Strengths of this feasibility trial include its randomized design, enrollment had few limitations, collection of both urine toxicology screen and self-report data from participants, and blinding of clinicians to participants' treatment assignment. The authors acknowledge lack of follow-up data as a limitation. The authors conclude that this study shows the potential of technology-based interventions for the treatment of SUD in primary care settings.

Shi and colleagues (2019) conducted a 12-week randomized pilot trial evaluating effects of CBT4CBT-Buprenorphine in retaining participants and reducing drug use when compared to standard office-based buprenorphine alone. Participants were 20 adult opioid-dependent individuals seeking treatment. Participants were randomized to standard buprenorphine treatment (n=10) or buprenorphine plus access to CBT4CBT-Buprenorphine (n=10). Individuals were excluded who had a current unstabilized psychotic disorder; were currently suicidal or homicidal; were pregnant or lactating; or had any other medical or psychiatric condition that would contraindicate outpatient buprenorphine treatment. Individuals with current cocaine, benzodiazepine, or alcohol use disorder were excluded; individuals with nicotine or marijuana use disorders were eligible. All participants received standard buprenorphine treatment, which included buprenorphine induction, completion of a buprenorphine contract, weekly meetings with a physician for medical management, and buprenorphine prescriptions. The CBT4CBT-Buprenorphine treatment included a new introductory module addressing fundamental aspects of buprenorphine treatment, followed by the existing 7-module CBT4CBT drug program. As with the existing modules, the new buprenorphine module included narration, videos, quizzes, and exercises, intended to familiarize participants with strategies for improving their outcome in buprenorphine maintenance, such as the “5As” (regular Attendance, Adherence to treatment, Abstinence from all other drugs, developing healthy Alternative activities, and Accessing social support). After completing the introductory buprenorphine module, participants could complete following CBT4CBT modules within the clinic at the time of their meetings with the physician or at home. The primary outcome indicator was percentage of urine toxicology screens negative for all drugs tested: amphetamines; barbiturates; benzodiazepines; cocaine; methamphetamine; opiates; oxycodone; tetrahydrocannabinol). Participants randomized to CBT4CBT-Buprenorphine submitted more urine samples that were negative for opioids (64% versus 91%; P = .05) as well as negative for...
all drugs tested (30% versus 82%; P < .004). The 10 participants assigned to CBT4CBT-Buprenorphine; all accessed the program at least once; the mean number of modules completed was 4.2 (SD = 2.0) of 8. Lastly, the CBT4CBT-Buprenorphine participants also completed a brief evaluation of the treatment at the posttreatment interview asking about their experience with the CBT4CBT-Buprenorphine module. All questions were rated a mean of 4 or higher on the 5-item Likert-type scale, indicating a high level of satisfaction. The authors acknowledge a preliminary and limited small sample size and imbalance in baseline characteristics. The results are noteworthy regarding effects on drug use as assessed by urine specimens. Retention was noted as high in both conditions; thus, these findings may not generalize to other settings. Results are also consistent with previous studies suggesting that CBT4CBT is well liked by a variety of individuals with substance use disorders. Future studies with a larger randomized trial with adequate power, may prove this treatment as attractive, accessible, and cost-effective means of providing evidence-based treatment and increasing access to treatment.

Kiluk and colleagues (2018) conducted a clinical trial in an outpatient clinical setting to assess the efficacy and safety of computer-based cognitive behavioral therapy (CBT4CBT). The clinical trial included a computer-generated, stand-alone treatment, delivered with only minimal clinical monitoring, and clinician-delivered cognitive behavioral therapy (CBT) compared with treatment as usual (TAU) in a heterogeneous sample of treatment-seeking outpatient individuals. Participants (n=137) with a substance abuse or dependence diagnosis were randomized to TAU, weekly individual CBT or CBT4CBT with brief weekly monitoring. The results showed the best retention in the CBT4CBT+monitoring group and the poorest in clinician CBT. The primary hypotheses were supported, with individuals receiving either delivery method of CBT (clinician or computer) decreasing frequency of substance use substantially more than those assigned to TAU. The 6-month outcomes revealed an ongoing benefit of CBT4CBT+monitoring versus TAU, but not for clinician-delivered CBT versus TAU. While those assigned to clinician-delivered CBT did show increased reductions in substance use as compared to treatment as usual, it had the lowest level of treatment retention and engagement, as well as the poorest abstinence rates during the follow-up period. The authors state that this is the first randomized clinical trial to examine a web-based intervention administered with nominal monitoring for individuals with substance use disorders within a treatment-seeking clinical sample. The results support the safety, viability, and efficacy for CBT4CBT provided with minimal clinical supervision.

Paris and associates (2018) conducted a randomized clinical trial that evaluated if adding web-based cognitive behavioral treatment (CBT) to standard outpatient psychiatric or addiction treatment improved substance use outcomes. Treatment occurred between 2014 and 2017 for 8 weeks. Participants were 92 individuals seeking substance use disorder treatment; participants’ primary language was Spanish. Participants reported that they had lived in the United States for an average of 17 years. Substance use among participants was described as 36% reported their primary substance was marijuana, 35% reported alcohol, and 25% reported cocaine; the remainder reported opioids (3%) or benzodiazepines (1%). Psychiatric co-morbidities among the participants included current major depression (47%), generalized anxiety disorder (41%), posttraumatic stress disorder (42%), and serious mental illness (SMI; schizophrenia or bipolar disorder, 32%). Standard treatment as usual was offered via standard care at clinics and then compared to (Computer Based Treatment for Cognitive Behavioral Therapy) CBT4CBT plus treatment as usual. The CBT4CBT-Spanish is a 7-session web-based program for cognitive behavioral treatment. The primary outcome measure was change in self-reported frequency of substance use. Generally, the self-reported days of abstinence from the participants’ primary drug was lower for those assigned to CBT4CBT plus TAU when compared to TAU alone throughout follow-up (83.4 vs 65.6 days, respectively; f = 6.41; P = .01), as was reported days of abstinence from all drugs and alcohol (72.1 vs 56.8; f = 3.61; P = .06). The primary outcome (change in frequency of primary substance used), there was a significant effect of treatment condition by time (t = −2.64; 95% confidence interval = −0.61, 0.09; P = .01), indicating significantly greater reductions for those assigned to Web CBT, which were durable through the 6-month follow-up. The authors report strengths of this trial to include a diverse and randomized sample while meeting diagnostic criteria for substance abuse or dependence. The authors state that the results emphasize that technology has the potential to provide easily accessible, inexpensive forms of treatment. The
authors acknowledge a weakness of the study was CBT4CBT-Spanish as an add-on to standard treatment, rather than as a separate intervention.

Kiluk and colleagues (2017) conducted a clinical trial to examine the effects of computer-based training for CBT (CBT4CBT) as additional to treatment as usual (TAU+CBT4CBT) compared to TAU alone. A subsample (N=71) completed a role play assessment to determine coping skills, the Drug Risk Response Test (DRRT), which was completed before, during (week 4), and after the 8-week treatment period. The participants were diagnosed as current (past 30 days) cocaine dependent and maintained on methadone (same dose for more than 2 months). Participant exclusion criteria were untreated or unstable psychosis or reading below the 6th grade level. TAU comprised daily methadone maintenance and weekly group/individual therapy with a substance use counselor. Participants were randomly assigned to TAU, or TAU with additional CBT4CBT for 8 continuous weeks. Those assigned to TAU+CBT4CBT were provided weekly access to a dedicated computer with CBT4CBT module videos in a private clinic room. Completion of one module video per week was required. The DRRT that was used before, during (week 4), and after the 8 weeks, is an audio-recorded verbal role play measure. Participants are asked to imagine a high-risk situation for drug use and then respond. Participant responses are recorded and then rated by a trained evaluator, blind to the treatment assignment. Results of repeated analyses revealed \( F(1, 141.26) = 4.29, p < .01 \), indicating improvement in the quality of coping skills across groups, yet no difference regarding treatments. The high-risk circumstances when individuals provided lower quality responses at baseline, those assigned to TAU+CBT4CBT showed greater improvement compared to those assigned to TAU only \( F (1, 697.65) = 6.47, p = .01 \).

Kiluk and associates (2016) performed a randomized trial of 68 treatment-seeking individuals with a current diagnosis of alcohol use disorder. The participants were assigned to one of three treatments at a community outpatient facility: (1) standard treatment-as-usual (TAU); (2) TAU plus on-site access to a computerized CBT targeting alcohol use (TAU +CBT4CBT); or (3) CBT4CBT with brief weekly clinical monitoring (CBT4CBT+monitoring). Participant alcohol use was monitored weekly during an 8-week treatment period, as well as 1, 3, and 6 post-treatment. The results showed higher rates of treatment completion in participants designated to one of the CBT4CBT conditions compared to TAU (Wald = 6.86, \( p < .01 \)). Alcohol use was reduced among all conditions within treatment, with participants assigned to TAU+CBT4CBT demonstrating greater increases in percentage of days abstinent (PDA) compared to TAU, \( t(536.4) = 2.68, p < .01, d = 0.71, 95\% \text{ CI} [0.60, 3.91] \), for the full sample. The authors report that the trial demonstrated the safety, feasibility, and preliminary efficacy of web-based CBT4CBT to treat alcohol use. CBT4CBT was superior to TAU at increasing days of abstinence when administered adjunctly. It was not significantly different from TAU or TAU+CBT4CBT when delivered with clinical monitoring only.

Budney and associates (2015) examined cannabis use disorders (CUD) and the effects of computer-assisted versions of motivational enhancement therapy (MET), cognitive-behavioral therapy (CBT), and abstinence-based contingency-management (CM) in a clinical study. Participants (n=75) diagnosed with cannabis dependence or abuse, seeking CUD treatment were randomly assigned to one of three treatment programs: 1) Brief - entailed two, individual counseling sessions; 2) Therapist – entailed 9 sessions of individual counseling; or 3) Computer – a 9-session MET/CBT intervention via an internet-delivered program. Results indicate the longest duration of abstinence (LDA) to be the treatments of Therapist and Computer as significantly greater LDA than Brief treatments (\( p's < .05 \)). The Therapist and Computer treatments presented significantly greater increases in abstinence from intake to the end of treatment than Brief treatments. At 3 months post-treatment, the Computer treatment had a considerably higher rate of abstinence than the Brief treatment. Both MET/CBT/CM conditions achieved better abstinence outcomes than the BRIEF comparison condition, revealing that both were effective for CUD. Therapist and Computer produced comparable cannabis outcomes during treatment. Lastly, the rate of relapse/change in abstinence over the post-treatment period did not differ among the three conditions, which endorses the premise that treatment effects on cannabis abstinence over time would not differ between the MET/CBT/CM treatments. The authors report that despite limitation in the study, the findings are encouraging in demonstrating that computer- or web-
Based treatments have the potential to improve access to evidence-based care, to decrease costs, and to improve effective healthcare delivery.

Carroll and colleagues (2014) completed a randomized clinical trial. The trial entailed 101 cocaine-dependent individuals maintained on methadone were randomly assigned to either basic methadone maintenance or methadone maintenance combined with weekly access to CBT4CBT, that included 7 computer modules delivered within an 8-week trial. The results showed that treatment retention and data availability were high and comparable across the treatment conditions. The participants designated to the CBT4CBT condition were significantly more likely to reach 3 or more consecutive weeks of abstinence from cocaine (36% compared with 17%; p<0.05, odds ratio=0.36). In addition, the CBT4CBT participants also had better outcomes on most aspects, including urine specimens negative for all drugs; these reached statistical significance only for individuals completing the 8-week trial (N=69). The collected data at 6 months after treatment cessation were available for 93% of the randomized sample; these data revealed ongoing improvement for those assigned to the CBT4CBT group. The authors conclude that CBT4CBT is an effective adjunct to addiction treatment with lasting effects. CBT4CBT is a viable treatment option for broadening the availability of CBT and increasing access to care for substance-dependent individuals.

Campbell and colleagues (2014) evaluated the efficacy of computer-delivered interventions to improve access to quality addiction treatment care. The Therapeutic Education System (TES) was used in the treatment of substance use disorders. They studied 507 patients from 10 addiction treatment programs. Participants were assigned 12 weeks of treatment as usual or treatment as usual with TES. The results revealed that the TES group had lower dropout rate and a greater abstinence rate. The authors concluded that TES had the potential to increase access and advance outcomes for addiction treatment. The authors concluded the study findings suggest that Internet-based TES, as well as other effective computer-assisted interventions now emerging, have the potential to help close the gap between the need for high-quality, evidence-based treatment for addiction and the capacity of the treatment system to deliver. Barriers to implementation of these interventions need to be addressed, including training clinicians to effectively prescribe and monitor computer-delivered interventions, in addition to developing reimbursement systems for payment. The authors recommended further study.

Guidelines & Consensus Statements
There are no professional guidelines or consensus statements currently regarding this topic.

U.S. FOOD AND DRUG ADMINISTRATION

On 9/15/17, Pear Therapeutics obtained FDA Clearance for the First Prescription Digital Therapeutic to Treat Disease. The reSET® device is the First Prescription Digital Therapeutic Cleared with Data Demonstrating Improved Outcomes of Abstinence and Treatment Retention in Patients with Substance Use Disorder (SUD). The release states that the U.S. Food and Drug Administration permitted marketing of the first mobile medical application to help treat substance use disorders (SUD). The ReSET application is intended to be used with outpatient therapy to treat alcohol, cocaine, marijuana, and stimulant SUDs. The application is not intended to be used as a stand-alone treatment or to treat opioid dependence.

In December, 2018 the FDA approved pre-market safety clearance via the 510(k) pathway of the reSET-O® mobile application device to Pear Therapeutics. According to the FDA pre-market review, the data from the clinical trial showed that this mobile application did not improve abstinence from opiates or decrease use overall of illicit drugs, therefore only safety marketing clearance was provided by the FDA (Christensen et al., 2014; FDA, 2018). The reSET-O is a mobile application that is a prescription cognitive behavioral therapy intended to be used in addition to outpatient treatment under the care of a health care professional, combined with treatment that includes buprenorphine and contingency management. Contingency management is a behavior modification intervention that establishes a connection between new, targeted behavior and the opportunity to obtain a preferred reward. The reSET-O is an application that is downloaded directly to a mobile device after a prescription is received from the treating physician. It is intended to be used while participating in an outpatient Opioid Use Disorder treatment program.
Please refer to the [FDA website](https://www.fda.gov) for more examples and information regarding mobile health and digital applications that are FDA cleared.

### CENTERS FOR MEDICARE AND MEDICAID SERVICES

There are no Medicare National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs) addressing CBTCBT.

### APPLICABLE CODES

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member-specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other clinical criteria may apply.

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### REFERENCES


**REVISION HISTORY**

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Additional resources considered in support of this policy:

