



United Behavioral Health

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

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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®¹.

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.

¹ Optum is a brand used by United Behavioral Health and its affiliates.

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 Level of Care Guidelines and/or evidence-based clinical guidelines.

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

CLINICAL EVIDENCE

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 and the devices are for sale in the United States.

Clinical Trials & Studies

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 seven 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.

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 [$F(1, 697.65) = 6.47, p = .01$].

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.

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.

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% 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.

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.

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.

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.

Procedure Codes	Description
	There are no procedure codes regarding CBTCBT

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Diagnosis Codes	Description
F10.10	Alcohol abuse, uncomplicated
F10.20	Alcohol dependence, uncomplicated
F11.1 - F11.9	Opioid abuse and dependence
F12.10	Cannabis abuse, uncomplicated
F12.20	Cannabis dependence, uncomplicated
F14.10	Cocaine abuse, uncomplicated
F14.20	Cocaine dependence, uncomplicated
F15.10	Other stimulant abuse, uncomplicated
F15.20	Other stimulant dependence, uncomplicated

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REVISION HISTORY

Date	Action/Description
04/11/2018	• Version 1. New policy approved by UMC.
10/21/2019	• Annual Update
06/15/2020	• Interim update