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

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Introduction & Instructions for Use

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.

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 this 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.

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.

Systematic Reviews and Meta-Analyses

Kiburi et al. (2023) conducted a systematic review for digital interventions for opioid use disorder treatment. There were twenty studies included, the participants were adults aged 18 years and older in all except one study, which had participants ages 12–25 years. The sample sizes ranged from 20 to 1426. The methods of assessing for opioid use varied and included DSM criteria, urine drug screening (UDS), hair drug test, self-reporting, substance screening tools and an addiction severity index. The majority of studies in this review were among participants receiving medication for opioid use disorder (MOUD). The digital interventions reviewed were web-based, computer based, telephone calls, video conferencing, automated self-management system, mobile applications, and text messaging. The various interventions were based on therapeutic education systems, community reinforcement approaches, cognitive behavior therapy, relapse prevention, brief interventions, supportive counselling, and motivational interviewing. The results varied and revealed that of the 20 studies, 10 reported statistically significant differences between the treatment and control groups for opioid abstinence, and 4 had significant differences in favor of treatment retention. Participant acceptability and satisfaction of the intervention were addressed in 9 of studies, measuring with questions and rating scales; digital intervention was rated as acceptable, and high satisfaction reported by all participants. The digital intervention utilization was reported in 8 of the studies, with a majority of studies reporting low system use. For example, one study (n=36) with a system available for daily use reported daily calls as a mean of 9.9 out of the 28 days, with a mean of 14 calls, and only 27 % of calls were made during the participant's selected two-hour call window. The authors conclude that these results show that digital interventions can be effective in opioid use disorder and can improve patients' experience when delivered in conjunction with other therapist-delivered measures. However, intervention delivery, participant access and utilization are components in the efficacy. Future research should focus on addressing limitations within this review such as standardizing protocols, lack of durability data, and investigating implementation of digital interventions for low income participants.

Bonfiglio et al. (2022) completed a systematic review of 18 studies with a total sample size of 25,475 subjects. The average age for the participants was 40.9 years old. Participants were formally diagnosed or self-identified with current or past problem substance use. The studies included specific digital interventions for substance users with various substances. The majority of studies were treatment for alcohol with a majority of interventions using cognitve behavior therapy models. Outcomes were measured with standardized questionnaires such as the Alcohol Use Disorders Identification Test (AUDIT). Most of the studies (n=16) utilized a follow-up assessment. Positive results were noted for 17 out of 18 studies regarding days of use and decreased feelings of addiction magnitude. However, 4 out of 9 studies reported differences of utility between groups or conditions, and 3 studies did not compare groups or conditions. The results at post-treatment show that digital interventions decrease the frequency of use, enhance abstinence, and decrease the feelings of addiction magnitude for most of the studies. Post-treatment effects assessed at follow-up indicated sustained intervention effects for up to 3 months. The authors acknowledge limitations such as heterogeneity of variables such as substance type, digital tool used, and interventions and treatments; these factors lead to reduced generalizability of the results. Additional limitations include lack of long-term follow-ups beyond 3 months, lack of randomization and blinding. Future clinical studies are needed to address these limitations and to determine effective protocols.

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 one 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, kes = 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, kes = 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

Luderer et al. (2022) completed an open label clinical trial to evaluate patient engagement with a digital therapeutic for substance use disorder (SUD) delivered at clinics and the associated abstinence outcomes. There were 206 participants enrolled in a treatment program for SUDs related to cocaine, alcohol, cannabis, or other stimulants. Most participants reported alcohol (28.2%) as their primary substance, followed by cannabis (26.2%), cocaine (25.7%), stimulants (16.0%), or other drugs. Participants were 18 years or older; using illicit substances in the 30 days prior to study entry; were within 30 days of enrollment in a community treatment program; and were not receiving medications for opioid use disorder. The participants were randomized to receive treatment as usual (TAU) or reduced TAU plus the digital Therapeutic Education System (TES) for 12 weeks. There were initially 206 participants with 157 completing the 12-week treatment period. Participants completed a mean of 38.8 (range 0–72) total TES Modules (core + supplemental; total includes repeated modules) over 12 weeks of treatment, including a mean of 27.1 (range = 0–32) unique 42.2%) completed the recommended 4 modules per week during the 12-week treatment period. Seventy-eight participants (37.9%) completed 48 unique modules in 12 weeks. The mean TES module completion was 45.5 (range 9–72) for study completers (n = 157) and 17.4 (range 0–45) for study non-completers (n = 49). A significant positive correlation between completed number of modules and number of days participants remained in the study, with a wide variation in total number of modules completed among participants that completed the study. The

researchers conclude that intensive participant engagement measured by number of modules complete was positively associated with abstinence in the last 4 weeks of treatment among those that completed. Limitations include that participants accessed the TES modules on-site, which could be interpreted that those participants were more engaged whether treatment was remote or not. In addition, there was a lack of follow-up assessment and durability data. Future well-designed RCTs are needed to fully evaluate efficacy, including long-term effectiveness.

Johansson and associates (2021) conducted a two-armed, randomized controlled, non-inferiority trial, addressing alcohol use disorder (AUD). The study compared internet-delivered cognitive–behavioral therapy (ICBT) (n = 150) with face-to-face CBT (n = 151), at 3- and 6-month follow-up assessment. The 301 adult participants were randomized into therapist guided ICBT or to 5 modules of face-to-face CBT, delivered over 12 weeks. The CBT program content was the same for both groups, with paper printouts given to the face-to-face group. The primary outcome identified was standard drinks of alcohol consumed during the previous week at 6-month follow-up. The secondary outcomes were alcohol consumption at the 3-month follow-up, measured by the total number of standard drinks consumed during the previous week. The non-inferiority maximum was 5 standard drinks of alcohol and d = 0.32 for secondary outcomes. The results yielded that the difference in drinks of alcohol between the internet and the face-to-face group was non-inferior in the intention-to-treat analysis of data from the 6-month follow-up (internet = 12.33 and face-to-face = 11.43, difference = 0.89, 95% confidence interval (CI) = 1.10 to 2.88). The secondary outcome, Alcohol Use Disorder Identification Test (AUDIT) score, the internet treatment was inferior when compared to face-to-face in the intention-to-treat analysis at 6-month follow-up (internet = 12.26 and face-to-face = 11.57, d = 0.11, 95% CI = –0.11 to 0.34). Limitations noted by the authors include a high attrition rate, measuring outcomes only 3 times periodically, and lack of generalizability due to the majority of participants were well-educated, employed, and with stable housing. While internet interventions are promising, there is a need for future large scale, well-designed research comparing internet interventions with other standard AUD treatments.

Kelpin and colleagues (2022) examined computer-based training for cognitive behavioral therapy (CBT4CBT) as an adjunct to residential treatment for substance use disorder (SUD). The study was a two-arm pilot RCT comparing randomized groups of standard residential treatment plus access to the CBT4CBT program (N = 34) or residential treatment as usual (TAU; n=29) The participants were women 18 years of age or older, met DSM-5 diagnostic criteria for SUD, and expected to have a residential length of stay ≥ 4 weeks. Comprehensive services of the residential treatment program were available to all study participants. The CBT4CBT group had access to the CBT4CBT program on a tablet in a private area on-site; the schedule consisted of a minimum of two sessions/week over the 3.5 weeks post-randomization. The TAU group engaged in standard residential treatment for SUDs. Participants were assessed at baseline, discharge from residential treatment, as well as 1-, 2-, and 3-weeks post-discharge (by phone); and 4- and 12-weeks post-discharge (in person). The results indicated that 44 participants completed the study with no significant difference in length of residential treatment between groups ($p > 0.05$), with women in the TAU condition completing a mean of 50.9 days (SD = 21.8, range 20–111), and women in the CBT4CBT group completing a mean of 42.8 days (SD = 20.25; range 3–81). Results for CBT4CBT and TAU groups time to relapse to any substance did not differ in time, $p=0.71$. The mean survival time for the CBT4CBT group was 57.4 days (SD = 6.8) compared to 51.8 days (SD = 7.5) for women in the TAU condition, suggesting a CBT4CBT lower relapse rate over time. Results for CBT4CBT and TAU groups time to relapse to the primary substance did not differ in time, $p=0.23$. The mean survival time for the CBT4CBT group was 67.0 days (SD = 6.1) compared to 53.2 days (SD = 7.1) for women in the TAU condition. The researchers acknowledge that limitations include as a small feasibility pilot study, the study was not powered to detect a statistically significant effect, participant substance use was self-reported, and post-discharge follow-up rates were 60%. The researchers recommend future large, well-designed RCTs to expand and support the use of CBT4CBT in outpatient settings.

Elison-Davies and colleagues (2022) conducted an observational study of 2187 participants within the Ohio Department of Rehabilitation and Correction system. The majority of participants were adults 25 years to 65 years old. Participants experienced numerous psychosocial risk factors, such as moderate to severe substance dependence; depression and anxiety; interpersonal conflict; aggressive behavior; paranoia; and difficulties with work and education. The participants utilized the digital CBT program to address their methamphetamine use between May 2020 and September 2021. The digital CBT program was available via secure tablet computers, participants used their unique sign-in to the tablet to access the program. Several assessment tools were completed at baseline: Severity of Dependence Scale; Patient Health Questionnaire-4; Five items (1, 2, 17, 18, 20) from the World Health Organization Quality of Life measure; Recovery Progression Measure. Results for comparing baseline and progress check assessments (every 2 weeks) revealed $p < .001$ for reductions in methamphetamine dependence, depression/anxiety, biopsychosocial impairment, with improvements in quality of life. Similar results identified a dose response with the total number of program components completed being significantly negatively associated with substance dependence,

depression/anxiety, biopsychosocial impairment, with improvements in quality of life, all p < .001. Limitations are acknowledged by the researchers as this study was an exploratory observational study, rather than a randomized controlled trial (RCT). Only 50% of participants completed a Progress Check assessment. In addition, the researchers report difficulty establishing whether changes in assessment scores were due to the clinical impact of the digital CBT program or because some participants were highly motivated with readiness to change. The participants experienced notable reductions in substance dependence, depression/anxiety, and biopsychosocial impairment, with significant improvements in quality of life. The digital CBT program was associated with these developments and a dose response was identified, indicating that some participants may benefit from digital programs. Larger RCTs with improved study methodology are needed to expand upon these results and evaluate the effectiveness of digital CBT.

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-Buprenophine 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-Buprenophine 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.

Guidelines & Consensus Statements

- *Department of Veterans Affairs and Department of Defense (VA/DoD)*
  - The VA/DoD Clinical Practice Guidelines for the Management of Substance Use Disorders (2021) states, "There is insufficient evidence to recommend for or against the use of computer-delivered behavioral treatments, either alone or in combination with usual care, for substance use disorders."

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 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.

Procedure Codes	Description
A9291	Prescription digital cognitive and/or behavioral therapy, FDA-cleared, per course of treatment

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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	Summary of Changes
10/19/2020	Annual Update
10/19/2021	Annual Update
10/18/2022	Annual Review: updated references/sources.
10/17/2023	Annual Review: updated references/sources.

Appendix

Additional resources considered in support of this policy:

Budney, A.J., Stanger, C., Tilford, M., Scherer, E., Brown, P.C., Zhongze, L., . . . Walker, D. (2015). Computer-assisted behavioral therapy and contingency management for cannabis use disorder. *Psychology of Addictive Behaviors*, 29(3), 501–511.

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