

Optum Health Behavioral Solutions of California (OHBS-CA) Behavioral Clinical Policy

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

Policy Number: BH727CBTBCP112025 Annual Review Date: November 18, 2025

Interim Review Date: N/A

Table of Contents	Page
Instructions for Use	<u>1</u>
Coverage Rationale	1
Description of Service	<u>2</u>
Clinical Evidence	
U.S. Food and Drug Administration	
Centers for Medicare and Medicaid Services	
Applicable Codes	
References	
Revision History	
Appendix	_

Instructions for Use

Instructions for Use

This Behavioral Health Policy is used to make coverage determinations for behavioral health services in accordance with the member-specific health benefit plan document (e.g., Evidence of Coverage) and applicable federal and state laws.

All reviewers must first confirm member eligibility, and identify the member-specific benefit plan document, and any applicable federal or state law(s) governing benefit coverage prior to using this Policy. In the event of a conflict between this Policy and the member-specific benefit plan document, the member-specific benefit plan document governs. In the event of conflict between the member-specific health benefit plan document and applicable law, the applicable law governs.

Optum reserves the right, in its sole discretion, to modify its Behavioral Health Policies and guidelines as necessary. This Policy is provided for informational purposes. It does not constitute medical advice.

Optum may also use tools developed by third parties, such as ASAM, LOCUS or CALOCUS-CASII criteria, to assist in administering behavioral health benefits. Optum Behavioral Health Policies 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.

Coverage Rationale

Computer Based Treatment for Cognitive Behavioral Therapy (CBTCBT) is investigational for the treatment of substance use disorders.

A review of the clinical literature does not support CBTCBT as a safe and effective intervention for 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.

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 offered by PursueCare 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 offered by PursueCare 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.

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. While short-term benefits have been observed, replication through rigorously designed trials is needed to establish its efficacy and identify durable outcomes.

Systematic Reviews and Meta-Analyses

Gushken and colleagues (2025) completed a systematic review of five randomized controlled trials (RCTs) regarding internetbased cognitive behavioral therapy for alcohol use disorder (AUD). Participant sample size ranged from 55-301, all 18 years or older, all with an AUD diagnosis. Intervention modalities were self-guided iCBT (2 studies); therapist-guided iCBT (1 study); blended iCBT (2 studies, combining digital modules with face-to-face clinical monitoring), typically lasting 2-3 months with follow-ups from 1-12 months. Primary outcome measures were alcohol consumption metrics: drinking days, binge days, drinks per day/week, and abstinence rates. Results for primary outcomes revealed that iCBT was non-inferior to treatment-as-usual (TAU) in reducing weekly alcohol consumption at 6 months; the iCBT group mean of standard drinks per week: 12.33 compared to the TAU group mean of 11.43 standard drinks per week. There was also a large effect size d=0.89. Superiority trials demonstrated that iCBT was more effective than treatment-as-usual (TAU) in reducing alcohol use. One study reported significantly greater reductions in alcohol consumption and higher abstinence rates in the iCBT group, with a large effect size (d = 0.71). One study found that participants receiving iCBT+TAU had significantly lower weekly alcohol intake than controls (d = 0.42). However, another study observed no significant difference in drinking days at 3-month follow-up. Limitations noted among the studies includes a small number of RCTs, heterogeneity for intervention methodology, and varied follow-up durations. The authors of this review conclude that the iCBT studies suggests improvement in clinical symptoms. Further investigation is warranted to develop standardized protocols that can support the clinical applicability and integration of iCBT into routine AUD care.

Computer Based Treatment for CBT for Substance Use Disorders Optum Behavioral Clinical Policy

UptoDate (2025) completed a review of the current literature regarding the psychosocial management of alcohol use disorder. The review concludes that there is limited data evidence with low strength of data to support internet- or video-delivered psychotherapies as a treatment for alcohol use disorder.

Johanssen et al. (2024) conducted a comprehensive review of digital interventions including 271 studies regarding cognitive behavioral therapy for treating SUD. Various study designs were reviewed, and most studies were randomized. Participants were categorized as adults, young adults, and adolescents. Internet-based CBT (iCBT) was delivered via web platforms online modules, self-guided or therapist-guided formats compared to TAU of minimal interventions or face-to-face CBT, typically for 4-12 weeks with follow-ups from 3-13 months. Findings for the meta-analysis for CBT for alcohol use showed small to moderate effect sizes; compared to minimal control: g = 0.20 (95% CI: 0.22–0.38); as adjunct to usual treatment: g = 0.30 (95% CI: 0.10–0.50). Limitations noted that many studies lacked detailed descriptions of CBT interventions, inconsistent digital terminology across studies, and limited number of CBT studies targeting illicit drug use or specific populations. The authors of this review conclude that digital interventions are effective in reducing substance use, though evidence remains inconclusive for specific intervention types and populations. Future research is needed to address the limitations including establishing a standard terminology for this topic.

Loya et al. (2024) conducted a meta-analysis of five randomized clinical trials examining CBT4CBT and/or pharmacological treatments for substance use. There were 405 participants with a diagnosis of cocaine use disorder and with a history of criminal justice involvement (CJI). The participants were 57.8% male and 44% Caucasian and assigned to CBT4CBT or treatment as usual. Participants assigned to CBT4CBT (n=245), were more likely to report greater than 3 weeks of continuous cocaine abstinence, p = 0.015; exhibited a higher number of negative cocaine urine specimens, p = 0.036; and higher number of days abstinent from cocaine use, p = 0.001. Among all those with CJI who participated in only one of the trials (n=164), those assigned to CBT4CBT were more likely to demonstrate greater than 3 weeks of continuous abstinence from cocaine, p = 0.015; a higher percentage of cocaine-negative urine specimens, p = 0.003; a higher number of days abstinent from cocaine, p = 0.018 when compared to participants with CJI that were assigned the standard treatment. Follow-ups were at 6 months, participants assigned to CBT4CBT revealed a lower legal score (p = 0.017) on the Addiction Severity Index when compared to standard treatment. Limitations include a lack of control groups and not addressing adverse effects. The authors of this meta-analysis report CBT4CBT as an effective approach for SUD and participants associated with CJI. Future large-scale well-designed clinical trials are needed to establish validity of results and clinical benefit.

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 opioid use varied and included DSM criteria, urine drug screening (UDS), hair drug test, self-reporting, substance screening tools, and an addiction severity index. Most studies in this review were among participants receiving medication for opioid use disorder. 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 twenty studies, ten reported statistically significant differences between the treatment and control groups for opioid abstinence, and four had significant differences in favor of treatment retention. Participant acceptability and satisfaction of the intervention were addressed in nine 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 eight of the studies, with many studies reporting low system use. For example, one study (n=36) with a system available for daily use reported daily calls with 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 of this systematic review 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 eighteen 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. Many studies were treatment for alcohol with the bulk of interventions using cognitive 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 seventeen out of eighteen studies regarding days of use and decreased feelings of addiction magnitude. However, four out of nine studies reported differences of utility between groups or conditions, and three 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 of this systematic review 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, updated in 2024) completed a health technology assessment regarding mobile medical applications (MMA) for treating substance use disorders. Specific MMAs included in the review were reSET, reSET-O, and A-CHESS. Hayes rated the quality of studies as fair to poor. Limitations of the studies include lack of masking/blinding, lack of validation of self-reported data, and variability with intervention delivery. The evidence reviewed suggests that individuals with SUD treated with MMAs supplemented with conventional care could be linked to improved treatment retention and increased substance abstinence. Outcomes data revealed that the impact of MMA on abstinence occurred in the first 2 months and was no longer reported 3 months 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.

Clinical Trials & Studies

Downie et al. (2025) investigated the efficacy of Cognitive Behavioral Therapy (CBT4CBT) is for individuals diagnosed with substance use disorder (SUD). The study was primarily qualitative with non-randomization and without a comparison group. There was a total of fifty-one participants diagnosed with SUD, ages 22-72 years. The CBT4CBT intervention consisted of seven online CBT modules. The program allowed participants to self-direct their learning by choosing modules and setting their own pace with treatment duration of 8 weeks. Numerous measurement tools were employed to include the Distress Tolerance Scale, Change Assessment Inventory, Severity of Dependence Scale, Drug-Taking Confidence Questionnaire, World Health Organization Quality of Life Assessment, and the Change Strategies Inventory. Quantitative results showed statistically significant improvements across several areas: a small reduction in SUD severity, a moderate increase in CBT-related coping strategies, and a small improvement in distress tolerance. Additionally, all quality-of-life domains improved, with small to medium effect sizes. Participants' self-assessed readiness to change or confidence in resisting drug use did not produce statistical significance. Limitations include small sample size, lack of empirical study design, qualitative analysis renders subjective interpretation, and lack of follow-up data. The researchers of this study propose that subsequent research should investigate the enduring outcomes of CBT4CBT, emphasizing the need for larger samples and prolonged post-treatment evaluation.

Kiluk et al. (2024) conducted a three-arm randomized clinical trial comparing the efficacy of digital CBT (CBT4CBT), clinician-delivered CBT, and standard treatment for reducing alcohol use. There was a total of 99 adult participants, with the mean age of 45 years old and a diagnosis of alcohol use disorder (AUD). Participants were randomized into 1 of 3 groups: treatment as usual (TAU) counseling, clinician CBT weekly manual-guided CBT sessions, or digital CBT weekly self-guided modules (CBT4CBT) plus brief (10-minute) clinical monitoring. Interventions were delivered over 8 weeks and follow-ups of 1-6 months. Primary outcomes were measured by percentage of days abstinent (PDA) from alcohol. Results showed that PDA increased from baseline to 6-month follow-ups across all groups; TAU increased from 49.3% to 69.6%, clinician-CBT from 53.7% to 70.2%, and digital CBT from 47.6% to 82.6%. No statistically significant difference was found between treatment groups during the 8-week treatment period. Limitations include sample size and no direct comparison of digital versus clinician CBT. The researchers conclude that this RCT supports the efficacy of digital CBT with brief clinical support at increasing abstinence. The researchers endorse future research to define the most effective methods in routine clinical practice, in addition to investigating patient characteristics that may impact outcomes.

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 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 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 as on-site 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 the rapist 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-toface 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 of this trial include a high attrition rate, measuring outcomes only 3 times periodically, and lack of generalizability due to many participants being 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 secluded 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 of this study 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. Most 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 < 0.001 for reductions in methamphetamine dependence, depression/anxiety, biopsychosocial impairment, with improvements in quality of life. Comparable 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 < 0.001. 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 findings, and a dose response was identified, indicating that some participants may benefit from digital programs. Larger, methodologically rigorous RCTs are needed to validate these findings and more accurately assess the effectiveness of digital CBT.

Guidelines & Consensus Statements

- American Society of Addiction Medicine (ASAM)
 - The Clinical Practice Guideline on the Management of Stimulant Use Disorder (2023) states that there is "insufficient evidence to recommend CBT4CBT as a standalone treatment for stimulant use disorder."
- 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 <u>FDA website</u> for more examples and information regarding mobile health and digital applications that have received FDA clearance.

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

CPT® is a registered trademark of the American Medical Association

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
F19.10	Other psychoactive substance abuse, uncomplicated
F19.20	Other psychoactive substance dependence, uncomplicated

References

American Society of Addiction Medicine (ASAM). (2023). The Clinical Practice Guideline on the Management of Stimulant Use Disorder. ASAM website: https://www.asam.org/quality-care/clinical-guidelines.

Bonfiglio, N.S., Mascia, M.L., Cataudella, S., & Penna, M.P. (2022). Digital help for substance users (SU): A systematic review. *International Journal of Environmental Research and Public Health*, 19(18), 11309.

Department of Veterans Affairs and Department of Defense (VA/DoD). (2021). Clinical Practice Guidelines for the Management of Substance Use Disorder. U.S. Department of Veterans Affairs website: https://www.healthquality.va.gov/guidelines/mh/sud/index.asp.

Elison-Davies, S., Newsome, J., Jones, A., Davies, G., & Ward, J. (2022). Associations between psychosocial risk factors, and changes in substance dependence and psychosocial functioning, during engagement with digital cognitive behavioral therapy for methamphetamine use: Use of 'Breaking Free from Substance Abuse' by incarcerated people during the COVID-19 pandemic. *Health & Justice*, 10(1), 1-16.

Downie, D., Patel, A., Corman, M., de Oliveira, C., Jain, E., Patterson, M., . . . & Quilty, L.C. (2025). Computer-based training for cognitive behavioral therapy (CBT4CBT): A mixed methods investigation. *Digital Health*, *11*, 1-12.

Food and Drug Administration. (2018). FDA clears mobile medical app to help those with opioid use disorder stay in recovery programs. FDA website: https://www.fda.gov/news-events/press-announcements/fda-clears-mobile-medical-apphelp-those-opioid-use-disorder-stay-recovery-programs.

Gushken, F., Costa, G. P., de Paula Souza, A., Heringer, D., & Anand, A. (2025). Internet-based cognitive behavioral therapy for alcohol use disorder: A systematic review of evidence and future potential. *Journal of Substance Use and Addiction Treatment*, 17(2025), 1-8.

Hayes, Inc. (2021). Health technology assessment: Mobile medical applications for substance use disorder. Updated June 3, 2024.

Johansson, M., Romero, D., Jakobson, M., Heinemans, N., & Lindner, P. (2024). Digital interventions targeting excessive substance use and substance use disorders: A comprehensive and systematic scoping review and bibliometric analysis. *Frontiers in Psychiatry*, *15*, 1-15.

Johansson, M., Sinadinovic, K., Gajecki, M., Lindner, P., Berman, A.H., Hermansson, U., & Andréasson, S. (2021). Internet-based therapy versus face-to-face therapy for alcohol use disorder, a randomized controlled non-inferiority trial. *Addiction*, 116(5), 1088-1100.

Kelpin, S.S., Parlier-Ahmad, A.B., Jallo, N., Carroll, K., & Svikis, D.S. (2022). A pilot randomized trial of CBT4CBT for women in residential treatment for substance use disorders. *Journal of Substance Abuse Treatment*, 132(108622), 1-9.

Kiburi, S.K., Ngarachu, E., Tomita, A., Paruk, S., & Chiliza, B. (2022). Digital interventions for opioid use disorder treatment: A systematic review of randomized controlled trials. *Journal of Substance Abuse Treatment*, 144(108926), 1-16.

Kiluk, B.D., Benitez, B., DeVito, E.E., Frankforter, T.L., LaPaglia, D.M., O'Malley, S.S., & Nich, C. (2024). A digital cognitive behavioral therapy program for adults with alcohol use disorder: a randomized clinical trial. *JAMA Network Open*, 7(9), 1-12.

Loya, J., Babuscio, T., Nich, C., & Kiluk, B. (2024). Treatment outcomes from computerized CBT for substance use disorders among people with criminal justice involvement. *Drug and Alcohol Dependence*, 260, 110615.

Luderer, H.F., Campbell, A.N., Nunes, E.V., Enman, N.M., Xiong, X., Gerwien, R., & Maricich, Y.A. (2022). Engagement patterns with a digital therapeutic for substance use disorders: Correlations with abstinence outcomes. *Journal of Substance Abuse Treatment*, 132(108585), 1-6.

PursueCare. (2025). reSET and reSET-O. PursueCare website: https://www.pursuecare.com/digital-therapeutics/.

UptoDate, Inc. (2025). Psychosocial management of alcohol use disorder. UptoDate database website: https://uptodate.com.

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.
10/15/2024	Annual Review: updated Reference and Appendix lists.
11/18/2025	Annual Review: updated Reference and Appendix lists.

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.

Campbell, A.N.C., Nunes, E.V., Matthews, A.G., Stitzer, M., Miele, G.M., Polsky, D., . . . Ghitza, U.E. (2014). Internet-delivered treatment for substance abuse: A multisite randomized controlled trial. *American Journal of Psychiatry*, 171(6), 683-690.

Carroll, K.M., Kiluk, B.D., Nich, C., Gordon, M.A., Portnoy, G.A., Marino, D.R., & Ball, S.A. (2014). Computer-assisted delivery of cognitive-behavioral therapy: Efficacy and durability of CBT4CBT among cocaine-dependent individuals maintained on methadone. *American Journal of Psychiatry*, 171(4), 436–444.

Emergency Care Research Institute (ECRI). (2020). ECRI clinical evidence assessment on reSET for opioid use disorder. Updated July 22, 2020.

Emergency Care Research Institute (ECRI). (2020). ECRI clinical evidence assessment on reSET for substance use disorder. Updated July 21, 2020.

Kiluk, B.D., Devito, E.E., Buck, M.B., Hunkele, K., Nich, C., & Carroll, K.M. (2017). Effect of computerized cognitive behavioral therapy on acquisition of coping skills among cocaine-dependent individuals enrolled in methadone maintenance. *Journal of Substance Abuse Treatment*, 82, 97-92.

Kiluk, B.D., Devore, K.A., Buck, M.B., Nich, C., Frankforter, T.L., LaPaglia, D.M., Yates, B.T., Gordon, M.A., & Carroll, K.M. (2016). Randomized trial of computerized cognitive behavioral therapy for alcohol use disorders: Efficacy as a virtual standalone and treatment add-on compared with standard outpatient treatment. *Alcoholism: Clinical and Experimental Research*, 40(9), 1991-2000.

Kiluk, B.D., Nich, C., Buck, M.B., Devore, K.A., Frankforter, T.L., LaPaglia, D.M., . . . Carroll, C. (2018). Randomized clinical trial of computerized cognitive behavioral therapy and clinician-delivered CBT in comparison with standard outpatient treatment for substance use disorders: Primary within-treatment and follow-up outcomes. *American Journal of Psychiatry*, 175(9), 853–863.

Kiluk, B.D., Ray, L.A., Walthers, J., Berstein, M., Tonigan, J.S., & Magill, M. (2019). Technology-delivered cognitive-behavioral interventions for alcohol use: A meta-analysis. *Alcoholism: Clinical and Experimental Research*, 43(11), 2285-2295.

Paris, M., Silva, M., Añez-Nava, L., Jaramillo, Y., Kiluk, B.D., Gordon, M.A., Nich, C., Frankforter, T., Devore, K., Ball, S.A., & Carroll, K.M. (2018). Culturally adapted, web-based cognitive behavioral therapy for Spanish-speaking individuals with substance use disorders: A randomized clinical trial. *American Journal of Public Health*, 108, 1535-1542, doi:10.2105/AJPH.2018.304571.

Shi, J.M., Henry, S.P., Dwy, S.L., Orazietti, S.K., & Carroll, K.M. (2019). Randomized pilot trial of web-based cognitive-behavioral therapy adapted for use in office-based buprenorphine maintenance. *Substance Abuse*, 40(2), 132–135, doi:10.1080/08897077.2019.1569192.

Tetrault, J.M., Hold, S.R., Cavallo, D.A., O'Connor, P.G., Gordon, M.A., Corvino, J.K., Nich, C., & Carroll, K.M. (2020). Computerized cognitive behavioral therapy for substance use disorders in a specialized primary care practice: A randomized feasibility trial to address the RT component of SBIRT. *Journal of Addiction Medicine*, 14, e303-e309.

U.S. Food and Drug Administration. (2024). Center for Devices and Radiological Health (CDRH): Digital health innovation action plan. FDA website: https://www.fda.gov/about-fda/fda-organization/center-devices-and-radiological-health.