

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

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| Program Number | 2021 P 2235-1 |
| Program | Prior Authorization/Medical Necessity – Digital Applications |
| Medication | EndeavorRx, reSET, reSET-O, Somryst |
| P&T Approval Date | 4/2021 |
| Effective Date | 7/1/2021; Oxford Only: 7/1/2021 |

1. Background:

The program is for prescription digital applications, including but not limited to EndeavorRx, reSET, reSET-O and Somryst.

EndeavorRx is an FDA-cleared digital application intended to improve attention function as measured by computer-based testing in children ages 8 to 12 years old with primarily inattentive or combined-type Attention Deficit Hyperactivity Disorder (ADHD).

reSET and reSET-O are FDA-cleared mobile applications that are pharmacy prescription-based cognitive behavioral therapy treatments for various substance use disorders. The applications are intended to increase retention of patients in outpatient treatment under the care of a health care professional by providing cognitive behavioral therapy.

Somryst is an FDA-cleared digital application intended to provide neurobehavioral intervention in patients 22 years of age and older with chronic insomnia.

A review of the current literature does not support Computer Based Treatment for Cognitive Behavioral Therapy (CBTCBT) for the treatment of ADHD, as an outpatient therapy to treat alcohol, cocaine, marijuana, and/or stimulant substance use disorders, or for the treatment of chronic insomnia.

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 is considered unproven until additional studies are available and the devices are for sale in the United States.

2. Coverage Criteria:

A. Authorization

1. Computer Based Treatment for Cognitive Behavioral Therapy (CBTCBT) such as **EndeavorRx***, **reSET***, **reSET-O*** and **Somryst*** are unproven and not medically necessary.

All requests for authorization will be **denied by OptumRx**. All requests for therapy must be submitted through the appeals process to the UnitedHealthcare Pharmacy appeals team for consideration.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

*Digital Application devices are typically excluded from coverage.

4. References:

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2. U.S. Food and Drug Administration. FDA permits marketing of mobile medical application for substance use disorder. Last updated 9/14/2017. Retrieved from <https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-mobile-medical-application-substance-use-disorder>. Accessed March 2021.
3. U.S. Food and Drug Administration. FDA permits marketing of first game-based digital therapeutic to improve attention function in children with ADHD. Last updated 6/15/2020. Retrieved from <https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-first-game-based-digital-therapeutic-improve-attention-function-children-adhd>. Accessed March 2021.
4. U.S. Food and Drug Administration. March 2020 510(K) Clearances. Last updated 4/06/2020. <https://www.fda.gov/medical-devices/510k-clearances/march-2020-510k-clearances> Accessed March 2021.
5. Budney, A.J., et. al. (2015). Computer-assisted behavioral therapy and contingency management for cannabis use disorder. *Psychology of Addictive Behaviors*, 29(3): 501–511.
6. Campbell, A.N.C., et al. (2014). Internet-delivered treatment for substance abuse: A multisite randomized controlled trial. *American Journal of Psychiatry*, 171:6.
7. Carroll, K.M., et. al. (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.
8. Kiluk, B.D., et. al. (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.
9. Kiluk, B.D., et al. (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.

10. Sonuga-Barke, E., et. al. (2014). Computer-based cognitive training for ADHD: A review of the current evidence. Child Adolesc Psychiatric Clin N Am 23 (2014) 807–824.

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| Program | Prior Authorization/Medical Necessity- Digital Applications |
| Change Control | |
| 4/2021 | New program. |