

A Closer Look: Payer Treatment of Prescription Digital Behavior Therapy

In April 2022, the Center for Medicare and Medicaid Services (CMS) implemented a new HCPCS code A9291: Prescription digital behavioral therapy, FDA cleared, per course of treatment. As we discussed previously, payers have been reluctant to cover digital therapeutics, often citing insufficient clinical evidence as a reason. This is in spite of manufacturers of the technology providing adequate evidence to be granted FDA 510K, DeNovo and/or Breakthrough designation for digital therapeutics.

To illustrate this, we examined the coverage rationale of some top payers for two specific computerized therapeutics: reSET and reSET-O. In this update, we provide a summary of those findings, and will offer a deeper dive into coverage information from Policy Reporter's database in an upcoming update.

Regulatory Background

- Under 21 CFR 882.5801, FDA approved reSET via De Novo classification (DEN160018) in May 2016, as a prescription-only treatment for patients as an adjunct to outpatient treatment for substance use disorder who are NOT currently on opioid replacement therapy.
- In May 2019, FDA provided 510K clearance (K173681) for the use of reSET-O for patients with opioid use disorder who ARE receiving buprenorphine treatment.

Prescription Digital Therapy (PDT) and Cognitive Behavioral Therapy (CBT) for Substance Use and Opioid Use Disorder

reSET is an FDA-cleared software application providing cognitive behavioral therapy (CBT) for substance use disorder in patients 18 years or older who are enrolled in outpatient treatment. Specifically, reSET is intended to treat alcohol, cocaine, marijuana, and stimulant use disorders (Brett, 2021). reSET uses a form of intensive validated neurobehavioral therapy for substance use disorder called the community reinforcement approach (CRA), and augments learning through reinforcement concept mastery (Aetna, 2022). CRA is based on operant conditioning, with a goal of helping patients rearrange their lifestyles to focus on rewarding, substance-free social activities and community (Meyers et al., 2011). reSET modules include skill building exercises and a CBT component, and are delivered through a combination of videos, animations, and graphics (BCBS Illinois, 2022). reSET modules may take 10 to 20 minutes to complete, and there are a total of 62 modules: 32 core and 30 supplemental modules, which focus on specific topics such as relationship skills and living with hepatitis C (Aetna, 2022).

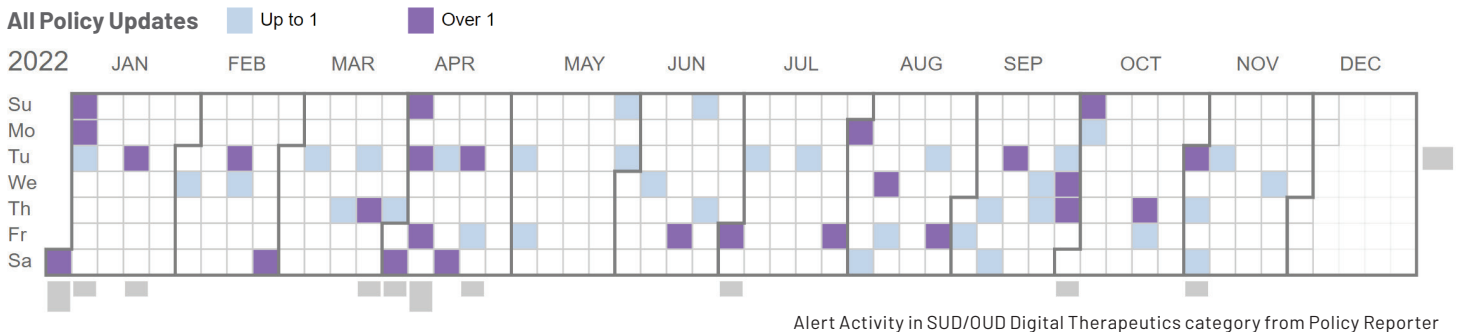
reSET-O, meanwhile, focuses on providing cognitive behavioral therapy via CRA for opioid use disorder as an adjunct to transmucosal buprenorphine and contingency management outpatient treatment to aid patient retention. This is FDA-cleared for patients 18 years of age or older, under the supervision of a healthcare provider.

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Payer Coverage of Prescription Digital CBT

Both reSET and reSET-O require a prescription from a licensed healthcare provider, which will support a 12-week therapy program. The apps allow patients to self-report cravings and triggers (and in the case of reSET-O, buprenorphine use), and clinicians can check in on patient module sequence and progress. reSET and reSET-O are supported on mobile devices such as smartphones and tablets (BCBS Illinois, 2022).

Together, these two apps may increase patient access to substance abuse treatments for indications SUD or OUD, though this heavily depends on payers' willingness to provide coverage for prescription digital therapeutics for addiction. Most payers we examined were hesitant to provide coverage for digital therapeutics, including reSET and reSET-O. However, we do see policy updates in this area, as you can see by the visual below that shows the alerts we have sent in 2022, as of the writing of this publication. This can be an indication that payers are monitoring this space and keeping up with new studies.



Next, we will provide a report with a deeper dive into coverage information from Policy Reporter's database, including a few of the ways in which these technologies may be covered by some payers.

References

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