

A Closer Look: Prescription Digital Therapeutics – By the Numbers – Payer Survey

We have recently talked about payer skepticism about prescription digital therapeutics, and this summary provides a deeper dive into two specific digital Cognitive Behavior Therapy products, reSET and reSET-O. These have been on the market since 2016 and 2019 respectively. These products are just beginning to gain traction for payer coverage with some important limitations.

We examined the coverage rationale of some top payers for these computerized behavioral health therapeutics to see the early payer coverage that is emerging. In this update, we provide a summary of those findings and offer a deeper dive into coverage information from Policy Reporter's library. In the Policy Reporter library, there are hundreds of documents that are in scope for understanding payer treatment of digital therapeutics and/or treatment for substance use disorder. We analyzed 115 digital therapeutics policy documents for 48 payers, and found only 5 payer policies explicitly provide coverage.

Here are some other highlights, with more statistics on the next page:

- We note that when payers explicitly state non-coverage for digital therapeutics, they cite that these FDA-approved products are still considered experimental and investigational.
- The first two payer policies with positive coverage were state-specific Medicaid exceptions to general non-coverage policy, where state rules made reSET and reSET-O covered for medicaid beneficiaries in a specific state (Pennsylvania). This applied to 0.6 million Medicaid covered lives.
- The next three policies (all from Highmark subsidiaries) were added in November 2022, which appear to be the first commercial policies with coverage. This applies to 3.2 million commercial beneficiaries covered lives.
- Coverage criteria includes a number of important considerations, including that the therapeutic must be used within FDA-approved indications, prescribed by a provider that has this condition within their scope of practice (which can be a variety of licensed provider types with rules that may vary by state), used only for outpatient care, and the patient must be able to reasonably interact with the software.

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Mental health digital therapeutics involve the use of software programs to deliver evidence-based and validated interventions to treat or manage mental and behavioral health disorders, such as chronic insomnia and substance use disorders. They can be used independently or as an adjunct to medications or other therapies to optimize patient care and health outcomes. Digital therapeutics are not typically direct-to-consumer mental health apps you can download on your own. By definition, digital therapeutics meet classification for Software as a Medical Device and, therefore, fall under FDA oversight. A digital therapeutic may require explicit FDA review and clearance which then requires a prescription in order to be offered to patients or be subject to "enforcement discretion", depending on its claims and existing regulatory code (Carl et al., 2020). In April 2020, the FDA announced temporarily waiving certain requirements for digital health devices for treating psychiatric disorders. There are currently 7 FDA-approved prescription-only mental health digital therapeutics, with 4 of the 7 receiving approval after June 1, 2020.

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Here are some additional statistics from our survey, which included payers across multiple lines of business including 75 commercial policies, 23 Managed Medicaid policies, 14 Medicare Advantage policies, and 2 policies from plans for federal employees. Beyond policy, we also found 121 places where these products are mentioned on formulary published by the Prescription Benefit Managers (PBMs).

reSET & reSET-0 by the Numbers

Many payers are hesitant to provide coverage for digital therapeutics, including reSET and reSET-0

Out of 115 policies, only 5 provide coverage to reSET and reSET-0

75	Commercial
23	Managed Medicaid
14	Medicare Advantage
2	Federal Employees
1	Dual Eligible



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Payers with Positive Coverage

3.8 Million
Covered Lives

0.6 Million
Medicaid

3.2 Million
Commercial

Example Policies (not an exhaustive list)

Aetna. (2022). Prescription digital therapeutics. Retrieved December 2, 2022, from https://www.aetna.com/cpb/medical/data/900_999/0999.html

Highmark Pennsylvania (2022). Prescription Digital Therapeutics. Retrieved December 2, 2022, from <https://securecms.highmark.com/content/medpolicy/en/highmark/pa/commercial/policies/Miscellaneous/Z-105/Z-105-001.html>

Be the first to find out about payer coverage positions on new and existing digital therapeutics with Policy Reporter's email alerts! Book a demonstration here:

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