

# Executive Summary: Payer Skepticism about Digital Therapeutics

One thing we notice in market access is that technical capabilities and FDA approval do not always align with payer willingness to cover and pay for diagnostics and therapeutics.

For instance, FDA has created a regulatory pathway and Center for Excellence focused on digital health: <https://www.fda.gov/medical-devices/digital-health-center-excellence>, yet a recent survey of payer policy shows most payers do not provide coverage or reimbursement for most of the products in this class.

## Defining a New Class of Therapeutics

Digital therapeutics are evidenced-based, software-driven interventions that are used to evaluate, diagnose, or treat a particular illness, injury, disease, or its symptoms. Many work as an app on a mobile phone or tablet. Currently available FDA-approved digital therapeutics span a broad spectrum of behavioral health, and physical diseases and disorders, but evidence for their effectiveness is limited. A list of some are on the next page.

Because digital therapeutics claim to serve such a broad range of patient populations, we were curious to see how top payers discuss and cover these therapies. After examining over a dozen FDA-approved digital therapeutics, it became clear that FDA approval does not equal coverage.

## Findings

We found that most payers create a blanket digital therapeutics policy, which may have titles such as Anthem's "Mobile Device-Based Health Management Applications" or Aetna's "Prescription Digital Therapeutics". Some payers choose instead to mention digital therapeutics within the context of a specific treatment policy for a given indication, such as Centene's pharmacy policy for Insulin Delivery Systems.

### Challenges

- The multi-payer system in the United States makes researching payer policy extremely time-consuming
- Complex payment and reimbursement rules for drugs, devices, and diagnostics vary by payer
- Information changes daily

### Policy Examples:

**Aetna.com.** "Prescription Digital Therapeutics - Medical Clinical Policy Bulletins | Aetna," January 07, 2022. [https://www.aetna.com/cpb/medical/data/900\\_999/0999.html](https://www.aetna.com/cpb/medical/data/900_999/0999.html).

**Anthem.com.** "CG-ANC-08 Mobile Device-Based Health Management Applications," September 28, 2022. [https://www.anthem.com/dam/medpolicies/abcbs/active/guidelines/gl\\_pw\\_e000367.html](https://www.anthem.com/dam/medpolicies/abcbs/active/guidelines/gl_pw_e000367.html).

**Centene.com** "CP.PHAR.534 Clinical Policy: Insulin Delivery Systems," June 01, 2021. <https://www.centene.com/content/dam/centene/policies/pharmacy-policies/CP.PHAR.534.pdf>.

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## Digital Therapeutics on the Market in the US

Some examples of FDA-approved digital therapeutics that payers have addressed on policy are summarized in the table below. This is not an exhaustive list. If you would like a sample report that details coverage, please contact us at [info@policyreporter.com](mailto:info@policyreporter.com).

Company	Product	Indication	FDA Approval
<b>Livmor</b>	Halo AF Detection System	Atrial Fibrillation	K201208 09/23/2020
<b>Akili Interactive</b>	EndeavorRx	Attention Deficit Hyperactivity Disorder	DeNovo 06/15/2020
<b>CanvasDx</b>	Cognoa ASD Diagnosis Aid	Autism Spectrum Disorder	DeNovo 06/02/2021
<b>Glooko</b>	Glooko Mobile Insulin Dosing System (MIDS)	Diabetes Management	K171450 02/02/2018
<b>Voluntis S.A.</b>	Insulia Diabetes Management Companion	Diabetes Management	K172177 11/07/2017
<b>Hygieia</b>	d-Nav System	Diabetes Management	K181916 02/04/2019
<b>Welldoc</b>	BlueStar Rx	Diabetes Management	K193654 4/7/2020
<b>electrocore</b>	gammaCore	Episodic Cluster Headache	DeNovo 10/15/2015
<b>Pear Therapeutics</b>	Somryst	Insomnia	K191716 03/23/2020
<b>Mahana Therapeutics</b>	Parallel Digital Cognitive Behavioral Therapy (CBT) M	Irritable Bowel Syndrome	K211372 06/02/2021
<b>metaMe Health</b>	Regulora	Irritable Bowel Syndrome	K211463 11/24/2021
<b>Theranica Bio-Electronics</b>	Nervio	Migraine Headache	K203181 01/22/2021
<b>Pear Therapeutics</b>	re-SET-0	Opioid Use Disorder	DeNovo 12/10/2018
<b>Palo Alto Health Sci-ences</b>	Freespira	Panic Disorder (PD) & Post-traumatic Stress Disorder (PTSD)	K180173 08/23/2018
<b>Resonea</b>	Drowzle	Sleep Apnea Screening	K173974 07/14/2019
<b>Nightware, Inc.</b>	NightWare	Sleep Disturbance related to PTSD	Breakthrough / DeNovo 11/06/2020
<b>Renovia</b>	Ileva Pelvic Digital Health System	Urinary Incontinence	K212495 09/08/2021

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