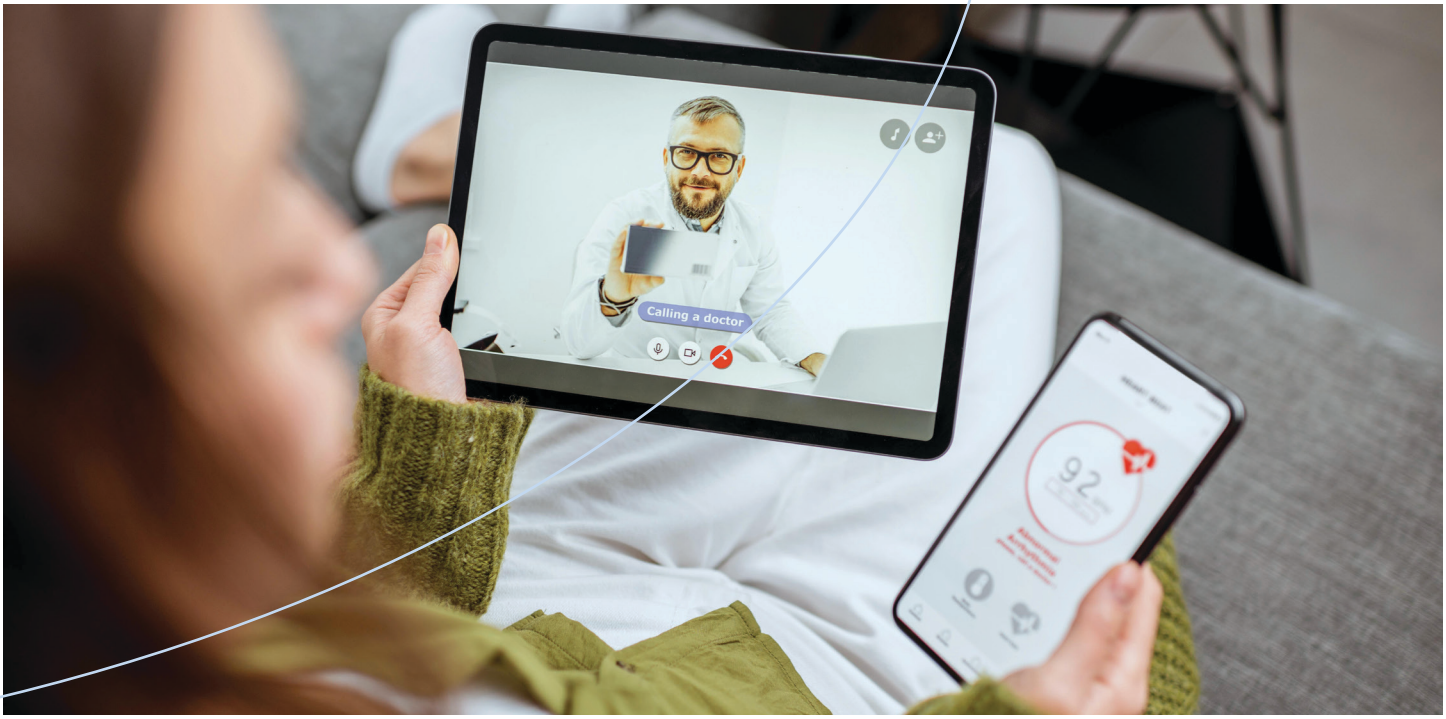
Gallagher

Insurance | Risk Management | Consulting

Digital Health: Assessing Prescription Digital Therapeutics

By Eric McKinley, PharmD; and Dino Conti, PharmD, MBA



What Are Prescription Digital Therapeutics?

By definition, digital therapeutics are therapeutic interventions driven by software that deliver medical interventions using computer software to treat, manage, and prevent diseases and disorders. These can include wearable devices, telehealth checkups and remote patient monitoring. IQVIA reports that there were more than 90,000 new digital health apps released in 2020, but a subset of these is considered digital therapeutics. A smaller subset, ones that are prescription only, is considered prescription digital therapeutics (PDTs).

FDA-Approved PDTs	
NAME	INDICATIONS
EndeavorRx	Attention-deficit hyperactivity disorder (ADHD), pediatric
Ensemble	Major depressive disorder, generalized anxiety disorder
reSET	Substance use disorder
reSET-O	Opioid use disorder
Modia	Opioid use disorder
Somryst	Insomnia
Parallel	Irritable bowel syndrome
Regulora	Irritable bowel syndrome
Freespira	PTSD, panic attacks in adults and adolescents
Luminopia One	Ambylopia in children aged 4 to 7 years old
Nightware	PTSD-driven traumatic nightmares
RelieVRx	Pain reduction in patients 18 years of age and older with diagnosed chronic lower back pain

Source: IPD Analytics

The FDA and Access to Care

PDTs are reviewed through FDA medical device clearance pathways, including 510(k) and De Novo, which hold products to some degree of evidentiary standards—although these aren't as rigorous as those required for pharmaceuticals. These clearance pathways are required to demonstrate evidence of clinical effectiveness and patient safety through well-controlled clinical trials that are reviewed by the FDA, which regulates PDTs as medical devices in order to be authorized for sale. The regulatory rigor governing this review process is the same as any other medical device, but the regulatory oversight is evolving.

PDTs have the potential to provide care to patients and expand access to treatment in scenarios when access to care, especially in mental health, is challenging. This was recently highlighted by the effects of the COVID-19 pandemic, which left many individuals without convenient access to healthcare—specifically in a virtual capacity. Leveraging software technology to address gaps in care could possibly provide safer and more effective methods to prevent, manage and treat diseases, and mitigate any future healthcare gaps that arise in the future.

> Common therapeutic areas for existing PDTs (noting that behavioral health is a consistent theme) include opioid abuse disorder, ADHD, insomnia and depression.

One barrier that PDTs face is that they require a written prescription for patients to gain access, but applying a prescription-based approval methodology to PDTs for mental health could limit broad accessibility, which contradicts the primary appeal to improve access to care. For example, the majority of behavioral and mental health providers do not have prescribing authority. Thus, under existing United States regulations, they would be unable to authorize making PDTs available to their patients. This is more concerning, given that most PDT for mental health purposes are based on behavioral and psychological science. Yet psychologists wouldn't be able to incorporate these innovations into their practice due to prescribing authority restrictions.

Benefit Plan Design Impact

Most payers do not cover PDTs at this point, citing a lack of outcome data on effectiveness. Reimbursement challenges also exist, which would further dissuade prescribers from implementing them in practice. Awareness challenges, among both prescribers and patients, also exist.

There is also controversy about whether the pharmacy or medical benefit is best for reimbursement. The fact that these are tangible products and require a prescription order from a healthcare professional makes some feel that the pharmacy benefit is the optimal benefit. Conversely, PDTs tend to be a substitute or compliment to services commonly reimbursed under the medical benefit—such as a doctor visit or therapeutic test. If reimbursed under pharmacy, payer budgets should account for these new expenditures, as they would be completely new and not a result of a shift in dollars from medications already available. Companies that produce PDTs will likely prefer coverage through the pharmacy benefit given more streamlined access. We've recently seen this with other products, such as V-Go and Omnipod on-body insulin release devices, where the manufacturers are not distributing through traditional durable medical equipment channels and solely relying on a pharmacy distribution network.

Rebates and discounts could apply, particularly for diseases with multiple products. Value-based agreements could be a good opportunity in this area to objectively evaluate the outcomes, given there is little real-world evidence to determine the significance of these products being a covered benefit. We may also see quicker adoption of these products if they have features such as electronic medical record integration. This would create efficiencies on patient monitoring in regards to ongoing data collection to determine if there is any objective value in a real-world setting.

The Centers for Medicare & Medicaid Services (CMS) has thus far only assigned a Healthcare Common Procedure Coding Systems (HCPCS) Level II code A9291 to prescription digital therapeutics irrespective of their indications. An HCPCS is a collection of standardized codes that represent medical procedures, supplies, products and services. The HCPCS descriptor for A9291 currently reads: "Prescription digital behavioral therapy, FDA cleared, per course of treatment." CMS will need to allow HCPCS coding to be more targeted and indication specific in order to allow for better reimbursement and differentiation of the different PDT products. Having a single HCPCS code contributes to administrative burden, limits reimbursement flexibility and restricts utilization management capabilities.

PDTs in Development

NAME	MANUFACTURER	MECHANISM OF ACTION	INDICATIONS
CT-155	Click Therapeutics Boehringer Ingelheim	Cognitive behavioral therapy	Cognitive impairment associated with schizophrenia (CIAS)
AKL-T02	Akili Interactive Shionogi	Neurocognitive therapy	Autism spectrum disorder
AKL-T04	Akili Interactive	Neurocognitive therapy	Major depressive disorder
Autism Therapeutic	Cognoa	Cognitive behavioral therapy	Autism spectrum disorder
CT-152	Click Therapeutics Otsuka	Cognitive behavioral therapy	Major depressive disorder
AKL-T03	Akili Interactive	Neurocognitive therapy	Major depressive disorder
Pear-004	Pear Therapeutics Novartis	Cognitive behavioral therapy	Schizophrenia
Pear-006	Pear Therapeutics Novartis	Cognitive behavioral therapy	Multiple sclerosis
FemmeRhythm	Biofourmis Chugai	Physiology biomarker monitoring	Endometriosis
Tempo	Swing Therapeutics	Cognitive behavioral therapy	Fibromyalgia
MR-001	MedRhythms	Rhythmic auditory stimulation	Motor deficits post-ischemic stroke

Source: IPD Analytics

Evaluating PDTs for Consideration

Payers will need to determine whether PDTs deserve a place on their benefits as their use continues to expand and more products reach the market. We suggest a thorough evaluation of the clinical evidence to support the coverage be done by any payer who is charged with benefit decision-making relative to PDTs.

KEY QUESTIONS WHEN EVALUATING PDTS FOR CONSIDERATION

1. Should only FDA-authorized products be considered for coverage?
2. What clinical evidence is available to support their use?
3. Which products have the best data to support their use?
4. Where do these products best fit for coverage (medical benefit, pharmacy benefit, case/disease management, etc.)?
5. Should there be preferential products within the benefit?
6. Should there be any prior authorization requirements and, if so, what should they be?
7. How do the products fit into place in therapy considering existing treatments and coverage requirements?
8. Should there be any benefit design updates to ensure that coverage for PDTs are appropriate?
9. Should there be any proactive communication to patients or providers to raise awareness about these products and how they can potentially help with specific conditions?

For questions about prescription digital therapeutics or pharmacy benefit management, contact your Gallagher consultant or visit **ajg.com/Pharmacy** to learn more.

Connect With Us

Firstname Lastname
Job title
Team/practice area/division

Address

Address Line 2 (optional)

T: 123.456.7890

E: firstname_lastname@ajg.com

Firstname Lastname
Job title
Team/practice area/division

Address

Address Line 2 (optional)

T: 123.456.7890

E: firstname_lastname@ajg.com