

Prescription Digital Therapeutics (PDTs)

WashingtonState
Telehealth Collaborative

What is it?

A new therapeutic class that uses software to directly treat disease

Go by several names, including:

- Prescription digital applications
- Software as a medical device (SaMD)
- New drug applications (NDAs)

Intended to be complementary to the patient's current therapies and treatments



How are patients using it?

- Intended to be preventive to:
 - Stop a disease
 - Improve outcomes in chronic conditions
 - Manage conditions
 - Focus on modifying behavior to increase patient engagement or improve medication/treatment adherence

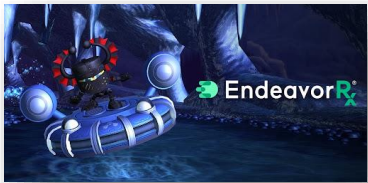
Three Categories of PDTs

Category	Example	Benefit
Physiological	Sleepio	Impacts the underlying physiological response of the patient
Behavior modifying	Reset-O	Patient behavior modification to improve one's ongoing treatment
Drug specific	Abilify My Cite	Digital solutions that lead to improved adherence tracking, disease monitoring and dose optimization during the entire treatment process

FDA-Approved PDTs

Product Name	Therapeutic Area
ReSet	Substance use disorder
Nightware	PTSD-driven traumatic nightmares
Reset-O	Opioid use disorder
EndeavorRx	Attention Deficit Hyperactivity Disorder (ADHD)
Mahana for IBS	Irritable Bowel Syndrome (IBS)
EaseVRx	Chronic lower back pain
Luminopia One	Amblyopia (decreased eyesight)

What is the evidence for clinical benefit?

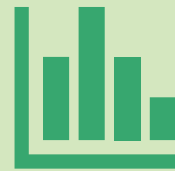


PDT	Therapeutic Area	Clinical Benefit
EndeavorRx	ADHD	Improvements in measured inattention in pediatric patients with ADHD
BlueStar Rx	Type 1 or Type 2 Diabetes	Decreased glycosylated hemoglobin levels over one year by 1.9%
reset-O	Opioid use disorder	Substance abstinence and treatment adherence

How is it being paid?



PDT insurance coverage where PDTs are part of the Pharmacy Benefit Managers' Drug Formulary



Value-based Contracting



Reimbursement through a national/state health plan



Large company coverage

References

- [Current list of Germany's approved PDTs](#)
- [Pear Therapeutics Announces Formulary Availability for its Three FDA Authorized Prescription Digital Therapeutics at OptumRx | Business Wire](#)
- [Prescription Digital Therapeutics - Medical Clinical Policy Bulletins | Aetna](#)
- [Most Payers Are Unfamiliar with Prescription Digital Therapeutics \(healthpayerintelligence.com\)](#)