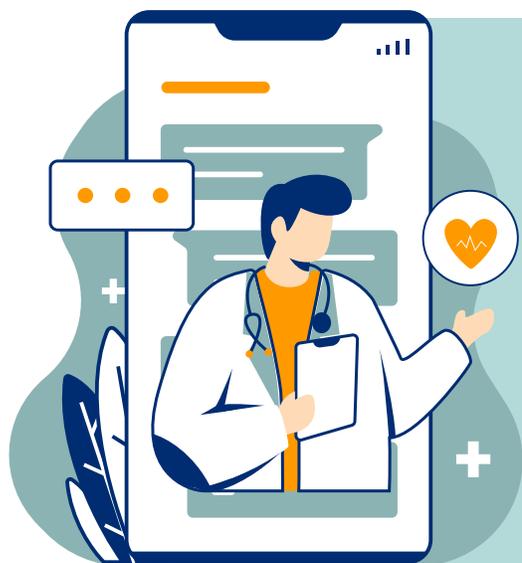


# Prescription Digital Therapeutics (PDTs): Addressing Treatment Gaps & Equitable Access

Prescription digital therapeutics (PDTs) are software-based therapies used to treat and manage a broad spectrum of diseases and disorders. PDTs can improve patient health, reduce the overall cost of care, address health disparities, and expand access to needed care, especially in the mental health space. These software therapies require the immediate attention of policymakers to ensure Americans and their healthcare providers have appropriate access to them.



## What Are PDTs?

- PDTs are software-based treatments prescribed by healthcare professionals either in combination with prescription medications – or independently – to treat or manage a disease or a condition.
- PDTs generate and deliver medical interventions directly to patients through their smart mobile device, tablet, or digital headset.
- PDTs are evaluated for safety and efficacy in clinical trials by the U.S. Food and Drug Administration (FDA).
- PDTs comply with FDA enforced patient privacy and security protections.<sup>1</sup>

## PDTs Are Cleared by the FDA

PDTs are therapeutic products categorized as **Software as a Medical Device (SaMD)** by the FDA and undergo rigorous evaluation for safety and efficacy before they can be made available to patients.

- ✓ PDTs are generally evaluated as Class II medical devices, meaning they pose a low-to-moderate risk to consumers. Manufacturers must submit a product application for review to the FDA based on the classification of their device.
- ✓ PDTs are evaluated by the FDA through one of two pathways: 510(k) or De Novo. PDTs are FDA-cleared through 510k Premarket authorization or granted authorization through De Novo classification.<sup>3</sup>

## 2023 PDT U.S. Market Landscape<sup>2</sup>



PDTs ARE CURRENTLY ON-MARKET



HAVE THE POTENTIAL TO LAUNCH IN THE NEXT FEW YEARS.



PDTs WITH U.S. MARKET INTENTIONS.



SCAN TO LEARN MORE

### References

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3. FDA. Premarket Notification 510(k). 2022.
4. S.723 - 118th Congress (2023-2024): Access to Prescription Digital Therapeutics Act of 2023. 2023, March 8.
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# A Roadmap to Equitable Access of PDTs



As demand for PDTs grows among the medical community and the public, efforts are still underway to ensure equitable access to these novel therapeutics. Government agencies and policymakers should consider the following solutions:

## Payer Coverage

PDTs have not yet been included in a benefit category for the Medicare or Medicaid programs, which excludes communities that could benefit most from them. We encourage CMS to offer clear guidance on creating standardized reimbursement practices to allow for the expansion of public and commercial insurance coverage of these therapies.

Recommendations:

- Support broad health coverage and reimbursement of PDTs, including the development of new codes, to enable healthcare providers to prescribe these alternative treatment methods.
- Cosponsor the **Access to Prescription Digital Therapeutics Act of 2023 (H.R. 1458/S.723)**, bipartisan legislation that would establish the first ever Medicare and Medicaid PDT benefit category.<sup>4</sup>

## Other Considerations

- Expand resources for widened device and internet access, such as strengthening broadband services, to ensure ease of access for rural and underrepresented populations.
- Educate healthcare providers on how PDTs can address critical gaps in care, especially for high-risk, undertreated, and underrepresented populations.

## How PDTs Can Transform Healthcare

### BENEFITS FOR PROVIDERS AND SYSTEMS



Extend providers' ability to care for patients through remote, customizable therapies.



Provide an adjunct or stand alone therapy for un- or undertreated conditions that require either supplemental care or do not have an existing treatment option.



Offer an adaptable and personalized approach to care for improved patient health outcomes and lower total healthcare costs.

### BENEFITS FOR PATIENTS



Enable access to treatment anytime and anywhere, reducing barriers to care.



Reduce stigma associated with traditional therapies by delivering care directly to a patient's private device.



Provide a person-centered approach to care that maintains and improves patient health and well-being.

In cases of Schizophrenia, PDTs can serve as an adjunct or stand alone therapy to address patient symptoms. Medications are traditionally used to treat positive symptoms including hallucinations, disorganized speech, and behavior agitation.<sup>5</sup> PDTs may be used to treat negative symptoms including lack of motivation, lack of pleasure, and feelings of isolation from the people and things around them.<sup>6</sup>