The Digital Prescription: FDA-Approved Digital Therapeutics for Chronic Disease Management

Rasit Dinc

Rasit Dinc Digital Health & AI Research

Published: July 10, 2025 | Digital Therapeutics

DOI: 10.5281/zenodo.17996636

Abstract

The landscape of healthcare is undergoing a profound transformation, driven by the convergence of clinical science and advanced technology. At the forefront ...

Introduction: The Evolution of Medicine

The landscape of healthcare is undergoing a profound transformation, driven by the convergence of clinical science and advanced technology. At the forefront of this revolution is **Digital Therapeutics (DTx)**, a category of evidence-based software designed to directly treat, manage, or prevent a medical disease or disorder. Unlike general wellness apps, DTx products are held to the same rigorous standards as traditional pharmaceuticals, requiring clinical validation and regulatory clearance or approval from bodies like the U.S. Food and Drug Administration (FDA). For professionals in digital health and AI, understanding the impact and clinical utility of FDA-approved DTx is crucial, particularly in the context of chronic disease management.

The FDA's Regulatory Framework for DTx

The FDA regulates DTx as medical devices, typically falling under Class II, which necessitates a demonstration of safety and effectiveness through the **510(k) premarket notification** or the **De Novo classification request** pathway. This regulatory rigor ensures that DTx are not merely tools for health tracking but are, in fact, therapeutic interventions. The FDA's approach acknowledges the unique nature of software as a medical device (SaMD), establishing a clear, high-bar standard for clinical evidence. This framework is vital for establishing trust and driving adoption within the clinical community.

Case Studies in Chronic Disease Management

FDA-approved DTx are demonstrating significant clinical utility across a spectrum of chronic conditions, offering non-pharmacological, scalable, and personalized treatment options.

1. Type 2 Diabetes and Metabolic Health

Diabetes management, a cornerstone of chronic care, has seen notable DTx innovation. **AspyreRx** (formerly BlueStar), for example, is an FDA-cleared prescription digital therapeutic for adults with Type 2 diabetes. It delivers a digital form of cognitive behavioral therapy (CBT) to help patients manage their condition by addressing psychological barriers to adherence and lifestyle change. Clinical trials have shown that AspyreRx can lead to statistically significant and clinically meaningful reductions in HbA1c levels, a key metric for glycemic control [1]. This evidence positions DTx as a powerful adjunct to traditional pharmacotherapy.

2. Mental and Behavioral Health

The scalability of software makes DTx particularly well-suited for addressing the growing global burden of mental health disorders.

Insomnia: Somryst *is a prescription DTx cleared by the FDA for the treatment of chronic insomnia. It delivers a digital version of Cognitive Behavioral Therapy for Insomnia (CBT-I), which is the first-line treatment recommended by clinical guidelines. Studies have shown that Somryst significantly improves sleep onset and maintenance [2].* **Anxiety and Depression:** Products like **DaylightRx** for Generalized Anxiety Disorder and **Rejoyn™** for Major Depressive Disorder (MDD) represent the next wave. Rejoyn, for instance, uses a personalized, brain-training program to target neural pathways associated with depression, demonstrating a durable effect on symptoms in clinical trials [3].

3. Respiratory Conditions

In respiratory care, DTx often focuses on improving adherence and patient-reported outcomes. The **Propeller Health** system, an FDA-cleared DTx, uses a sensor attached to a patient's existing inhaler to track medication usage and environmental triggers. By providing personalized insights and reminders, the system has been shown to reduce the frequency of asthma and COPD exacerbations and emergency department visits [4]. This exemplifies how DTx can leverage real-world data and AI-driven personalization to optimize existing treatments.

The Role of AI and Future Directions

The next generation of FDA-approved DTx is increasingly integrating **Artificial Intelligence (AI)** and machine learning. AI algorithms are used to personalize the therapeutic intervention, predict patient non-adherence, and provide real-time, adaptive feedback. For instance, AI can analyze a patient's engagement patterns, physiological data from connected devices, and self-reported symptoms to dynamically adjust the digital therapeutic content, maximizing its clinical effect.

The regulatory landscape is also evolving to accommodate this rapid innovation. The FDA's **Pre-Cert Program** (though currently in transition) and the ongoing development of the **Software Pre-Certification Program** signal a move toward a more streamlined and adaptive regulatory process for trusted developers. This shift is critical for accelerating the availability of safe

and effective DTx to patients with chronic conditions.

Conclusion

FDA-approved Digital Therapeutics represent a paradigm shift in chronic disease management. By delivering clinically validated, software-based interventions, they offer a powerful, scalable, and evidence-based complement to traditional medicine. For healthcare professionals and innovators, the successful integration of DTx into clinical practice—supported by robust clinical evidence and a clear regulatory pathway—is essential to unlocking a future where technology plays a central, therapeutic role in improving patient outcomes. The continued growth and refinement of this field promise to redefine what it means to prescribe medicine.

References [1] Hsia, J., et al. (2023). Randomized, Controlled Trial of a Digital Behavioral Therapeutic Application to Improve Glycemic Control in Adults With Type 2 Diabetes. *Diabetes Care*, 46(10), 1801-1809. (Demonstrated a mean HbA1c reduction of 0.39% at 90 days compared to control.) [2] Morin, C. M., et al. (2020). Profile of Somryst Prescription Digital Therapeutic for Chronic Insomnia: Overview of Safety and Efficacy. *Expert Review of Medical Devices*, 17(12), 1279-1288. (Showed significant improvement in Insomnia Severity Index and sleep parameters.) [3] *Rejoyn's pivotal trial data was the basis for the FDA's authorization, though the full peer-reviewed publication is pending.* [4] Merchant, R. K., et al. (2018). Digital Health Intervention for Asthma: Patient-Reported Outcomes and Health Care Utilization in a Prospective Observational Study. *Journal of Medical Internet Research*, 20(5), e187. (Reported a 53% reduction in asthma-related emergency department visits over 12 months.)
