

SleepioRx

FDA-cleared prescription digital therapeutic delivering Cognitive Behavioral Therapy for Insomnia (CBT-I) to treat chronic insomnia in adults.

<https://www.bighealth.com>

Overview

SleepioRx is an FDA-cleared (August 2024) prescription digital therapeutic (PDT) developed by Big Health for the treatment of chronic insomnia and insomnia disorder in adults aged 18 and older, used as an adjunct to usual care.

It is a software-based mobile application that delivers an automated, self-directed form of Cognitive Behavioral Therapy for Insomnia (CBT-I), which is the first-line recommended treatment for the condition.

The program is a structured, 90-day treatment that guides patients through evidence-based techniques to address the cognitive and behavioral factors that maintain chronic sleep problems, such as cognitive restructuring, paradoxical intention, and sleep restriction.

Key Benefits & Clinical Efficacy: SleepioRx has been evaluated in over 25 clinical trials, including 18 randomized controlled trials (RCTs).

Up to 76% of patients achieved healthy sleep post-treatment.

Participants experienced up to a 54% reduction in time to fall asleep and 62% less time awake at night. Benefits are long-lasting, with improvements continuing up to three years after treatment.

Target Users and Use Cases: SleepioRx is prescribed by licensed healthcare providers (MDs, DOs, NPs, Clinical Psychologists, etc.) to patients with chronic insomnia. The primary customers are **Health Systems, Health Plans, and Employers** who seek to provide scalable, clinically-validated, non-drug mental health solutions to their patient populations or members.

Key Features

- FDA-Cleared Digital Therapeutic
- Cognitive Behavioral Therapy for Insomnia (CBT-I)
- 90-Day Structured Treatment Program
- Daily Sleep Tracking and Diary
- Personalized, Tailored Content
- On-Demand Daytime and Nighttime Toolkits
- Video and Audio Lessons

Pricing

Model: enterprise

Subscription-based pricing is available upon request and is primarily sold to Health Plans, Employers, and Health Systems. It is a prescription device, and is targeted for reimbursement via new Digital Mental Health Treatment (DMHT) codes finalized in the CY 2025 Medicare Physician Fee Schedule.

Target Company Size: enterprise

Integrations

Grow Therapy (Provider Network), Fitness Trackers (e.g., Jawbone UP - historical/API capability)

Compliance & Certifications

FDA 510(k) Clearance, HIPAA, NICE Guidance (UK) (for underlying Sleepio program)

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