Somryst digital therapy for insomnia

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Next review date: 12/2025

Policy contains: cognitive behavioral therapy, digital therapeutics, insomnia, Somryst

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Coverage policy

Somryst® digital therapy (Nox Health, Alpharetta, Georgia, formerly Pear Therapeutics) is investigational/not clinically proven and, therefore, not medically necessary for chronic insomnia.

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

- Cognitive behavioral therapy.
- Light box therapy.
- Prescription medications.

Background

Insomnia is the most common sleep disorder, affecting about one-third of Americans. Insomnia is marked by difficulty falling asleep, staying asleep, or poor sleep quality despite adequate opportunity and circumstance for sleep, resulting in daytime dysfunction. Insomnia may occur on a short-term basis — sometimes caused by stress or changes in schedule or environment — but may also become chronic (Roth, 2019). The International Classification of Sleep Disorders (3rd edition) classifies chronic insomnia as a sleep disturbance that occurs at least three times a week and lasts more than three months (Kaur, 2023).

Psychiatric comorbidities, notably depression, are common in persons with chronic insomnia. Chronic insomnia is associated with increased risk of hypertension, coronary heart disease, diabetes, and cancer (National Heart, Lung, and Blood Institute, 2022a). In addition, it is a factor in accidents, falls and other injuries, reduced work productivity, and increased health care use and costs (Forma, 2022a).

Treatment of chronic insomnia includes behavioral modifications, including avoidance of alcohol, caffeine, and nicotine; increasing regular physical activity; making sleep habits routine; eating meals on a regular schedule; limiting fluids before bedtime; avoiding naps; stress management; and avoiding certain medicines. In addition, cognitive behavioral therapy, prescription and off-label medicines, and light therapy can be used as treatments (National Heart, Lung, and Blood Institute, 2022b).

While each of the above treatments can be successful, some cases of chronic insomnia persist. Recently, Somryst, a prescription digital therapy used on mobile devices (e.g., smartphones and tablets), has been proposed for treating such cases. Patients download the Somryst app, and treatment is rendered for nine weeks under supervision of a health care provider. Somryst treatment includes six core approaches focused on cognitive behavioral therapy concepts, including sleep restriction/consolidation, stimulus control, and cognitive restructuring. Patients complete a daily diary during treatment (Digital Therapeutics Alliance, 2024).

In March 2020, Pear Therapeutics received regulatory approval to market Somryst for treating adults age 22 and older for insomnia; Somryst remains the only approved digital therapy for insomnia (U.S. Food and Drug Administration, 2020). Digital cognitive behavioral therapy for insomnia in pediatric populations has shown potential to be effective, but as of the writing, no products are approved for use in the United States (Tsai, 2022).

Findings

Guidelines

Currently, no professional medical association guideline recommends digital therapy to treat chronic insomnia. The American College of Physicians (Qaseem, 2016) and American Academy of Sleep Medicine (Edinger, 2021; Sateia, 2017) support cognitive behavioral therapy as first-line treatment. Both groups offer weak support for treatment with certain prescription medications.

A guideline from the United Kingdom recommends Sleepio, a digital therapeutic similar to Somryst, as a cost-saving option for treating insomnia compared to sleep hygiene and sleeping pills. The guideline, which used 28 studies (12 randomized), noted research is needed comparing Sleepio with face-to-face cognitive behavioral therapy, and cited high drop-out rates as a concern (National Institute for Health and Care Excellence, 2022).

Evidence reviews

Regulatory approval of Somryst for insomnia was based on two studies, both using Sleep Healthy Using the Internet (SHUTi) digital therapy, a precursor to Somryst. One was a review (n = 1,149) of persons with depression and insomnia; depression was reduced ($P < .0001$) with digital therapy versus placebo (Christensen, 2016). The other study (n = 303) showed that digital therapy improved insomnia ($P < .001$) compared with an educational

program (Ritterband, 2017). Limitations were high drop-out rates and absence of a comparison group given standard treatment for insomnia. Another larger review (n = 7,216) also assessed ability of Sleep Healthy Using the Internet to treat insomnia. Moderate-to-large improvements reported in patient diaries were observed for sleep onset latency and wake after sleep onset. Of the article's 10 authors, eight are affiliated with former owner and manufacturer Pear Therapeutics (Ritterband, 2022).

A network meta-analysis of 20 studies showed improvements in insomnia severity were greatest for Somryst compared with cognitive behavioral therapy, approved prescription medications (eszopiclone and zolpidem), or placebo. All interventions were superior to placebo for improving wake after sleep onset, but not sleep onset latency. Authors were affiliated with the manufacturer (Forma, 2022a).

A study (n = 248) determined that after nine weeks of treatment with Somryst, the insomnia severity index declined by 37.2% (19.1 to 12.0); 58.5% of these patients achieved responder status. After two years, reductions were observed in emergency department visits (reduced by 53%), hospitalizations (reduced by 21%), and hospital outpatient visits (reduced by 13%). Ambulatory surgery center visits and office visits both increased by 2%. Total two-year cost reductions were $2,059 per patient (Forma, 2022b).

As of this writing, two National Institutes of Health clinical trials of Somryst are in progress. One recently completed trial, conducted by Yale University and the Mayo Clinic, randomized 100 patients with insomnia to groups with and without a nine-week trial with Somryst; final analysis is pending (ClinicalTrials.gov ID NCT04909229, 2024). The other trial (n = 350) is testing the ability to reduce self-reported insomnia symptoms (ClinicalTrials.gov ID NCT04325464, 2023).

A network meta-analysis of 54 randomized controlled trials (n = 11,815) found treatment of chronic insomnia with web-based cognitive behavioral therapy (compared with usual care) produced longer total sleep time (23.19 minutes), shorter sleep onset latency (18.76 minutes), lower wake after sleep onset (31.40 minutes), and increased sleep efficiency (10.37%) than other digital cognitive behavioral therapy approaches, including mobile-app-based approaches. Authors consider web-based cognitive behavioral therapy with therapists as the optimal intervention for insomnia. Somryst was not specifically mentioned in the analysis (Hasan, 2022).

In 2024, we added no newly published, relevant literature to the policy. No policy changes are warranted.

References

On June 21, 2024, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were "cognitive behavioral therapy," "digital therapeutics," "insomnia," and "Somryst." We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

8/2023: initial review date and clinical policy effective date: 10/2023

8/2024: Policy references reviewed.