FirstChoice VIP CARE
by Select Health of South Carolina

Prescription digital therapeutics for insomnia

Clinical Policy ID: CCP.1530

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Policy contains: Cognitive behavioral therapy, digital therapeutics, insomnia, Sleepio; Somryst.

FirstChoice VIP Care has developed clinical policies to assist with making coverage determinations. FirstChoice VIP Care's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered, on a case by case basis, by FirstChoice VIP Care when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. FirstChoice VIP Care's clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. FirstChoice VIP Care's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, FirstChoice VIP Care will update its clinical policies as necessary. FirstChoice VIP Care's clinical policies are not guarantees of payment.

Coverage policy

The following prescription digital therapeutics for chronic insomnia are investigational/not clinically proven and, therefore, not medically necessary:

- Somryst® digital therapy (Nox Medical, Alpharetta, Georgia, formerly Pear Therapeutics).
- Sleepio® (Big Health, San Francisco, California).

Limitations

Contraindications to prescription digital therapeutics for chronic insomnia include, but are not limited to (Big Health, Inc., 2025; Nox Medical, 2025):

- Any disorder exacerbated or worsened by sleep restriction (e.g. bipolar disorder, schizophrenia, other psychotic spectrum disorders).
- History of seizure disorder.
- Excessive daytime sleepiness.
- Sleep-related breathing disorder / sleep apnea.
- At high risk for falls.
- Pregnancy.

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 (McNamara, 2025).

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, 2022b). 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 to help fall asleep and stay asleep. In addition, cognitive behavioral therapy, prescription and off-label medicines, and light therapy can be used as treatments. The first-line treatment for long-term insomnia is cognitive behavioral therapy, but access to the intervention can be limited (National Heart, Lung, and Blood Institute, 2022a).

Prescription digital therapeutics have emerged as potential treatments for a range of conditions, including insomnia. They are clinically validated, software-based therapies delivered on smartphones or tablets intended to treat or alleviate a medical condition either alone or in combination with other treatments. They have the potential to increase access to important non-pharmacological behavioral health interventions (Digital Therapeutics Alliance, 2024).

The U.S. Food and Drug Administration has issued 510(k) approval to two prescription digital therapeutics for insomnia. They are Class II, prescription-only devices intended to provide a computerized version of condition-specific behavioral therapy as an adjunct to clinician-supervised outpatient treatment to patients with psychiatric conditions. In March 2020, Pear Therapeutics (now Nox Medical, Alpharetta, Georgia) received regulatory approval to market Somryst for treating adults age 22 and older for insomnia (U.S. Food and Drug Administration, 2020). Sleepio was approved recently for the treatment of chronic insomnia/insomnia disorder as an adjunct to usual care in patients aged 18 years and older (U.S. Food and Drug Administration, 2024). As of the writing, no products have been approved for pediatric use in the United States.

Both products use the behavioral therapy of sleep restriction. This therapy limits the time a patient spends in bed to generally match the amount of time they sleep but also can increase the risk of excessive daytime sleepiness. Therefore, patients with the following conditions should not use Somryst or Sleepio: any medical condition worsened or exacerbated by sleep restriction (e.g., degenerative illness, bipolar disorder, schizophrenia, other psychotic spectrum disorders); untreated obstructive sleep apnea; parasomnias; epilepsy; individuals at high risk of falls; or individuals who are pregnant (Big Health, Inc., 2025; Nox Medical, 2025).

Findings

Guidelines

Early American sleep guidelines published by American professional organizations support cognitive behavioral therapy delivered by different methods as a first-line treatment for chronic insomnia (Edinger, 2021; Qaseem, 2016; Sateia, 2017). However, publication of these guidelines preceded regulatory approval of prescription digital therapeutics for insomnia.

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 review

Evidence of the effectiveness of cognitive behavioral therapy for insomnia is strongest for modes using synchronous communication (e.g., face-to-face individual or group therapy, telephone, or web-based communication). The evidence for self-help alternatives such as Somryst and Sleepio is less certain, showing superiority to placebo but varying effectiveness relative to synchronous modes. In most cases, the evidence comprises multiple publications by the same investigator group and is sponsored by the manufacturer.

Somryst

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).

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. Because few comparative studies have examined mobile application-based cognitive behavioral therapy, additional high-quality, large-scale randomized controlled trials are warranted to confirm these findings (Hasan, 2022).

In a real-world sample of 1,565 U.S. adults, investigators examined the effect of Somryst use on insomnia, depression, and anxiety over a nine-week intervention period (ClinicalTrials.gov ID NCT04325464). Fifty-eight percent completed four of the six interactive treatment cores, and 48.4% completed all six cores. The Insomnia Severity Index decreased by nearly nine points from baseline to Core 6 (Cohen's d = 1.7), seven points from baseline to six-month follow-up (d = 1.4), and 6.6 points from baseline to one-year follow-up (d = 1.1); all classified as large in magnitude. When classifying patient severity according to the baseline Insomnia Severity Index score (mild, moderate, or severe severity), each group achieved significant improvements (Thorndike, 2024).

At post-intervention Day 63, six-month follow up, and one-year follow-up time points, the proportion of insomnia treatment responders, defined as a reduction of > 7 Insomnia Severity Index score points, were 49.2%, 46.4%, and 37.8%, respectively, and the proportion of participants in remission, defined as an Insomnia Severity Index < 8 on follow up, were 32.3%, 28.7%, and 24.7%, respectively. Participants who adhered to treatment as prescribed showed greater effect size improvement in insomnia severity, higher clinically meaningful response rates, and higher rates of remission. Participants also showed a significant reduction in symptoms of depression and anxiety. In this real-world sample, the authors noted greater symptomatology at baseline and fewer participants reaching full remission than observed in randomized controlled trials, emphasizing the importance for clinicians to evaluate the benefit of the intervention and determine if additional clinical support is needed (Thorndike, 2024).

Sleepio

Multiple studies have compared Sleepio to sleep hygiene education or usual care across a range of clinical populations. Two large randomized controlled trials in the United Kingdom that used intention-to-treat analysis provided early evidence of effectiveness (Espie, 2019; Freeman, 2017). All enrolled participants aged 18 and older with insomnia, the majority of whom were white and female. Sleepio was safe and effective in reducing symptoms of insomnia for up to one year and may help improve other behavioral health comorbidities such as depression and anxiety.

One trial (n = 1,711) found Sleepio was effective in improving functional health, psychological well-being, and sleep-related quality of life in people reporting insomnia symptoms over a 24-week duration (Espie, 2019; ISRCTN.org identifier ISRCTN60530898). The second trial enrolled 3,755 college students. At 10 weeks, Sleepio use reduced insomnia, paranoia, and hallucinations (all $P < .0001$). Insomnia was a mediator of change in paranoia and hallucinations (Freeman, 2017; ISRCTN.org identifier ISRCTN61272251). Using data from these two trials, sub-analyses revealed additional benefits. Sleepio use resulted in statistically significant gains in quality-adjusted life years over time compared with controls (Stokes, 2022), mediated the effects of clinically significant depressive symptoms (Henry, 2021), and may mediate comorbid anxiety symptoms (Henry, 2023).

Another community-based randomized controlled trial in the United Kingdom recruited 205 participants aged 22 to 65 years with clinically significant insomnia and depression. Compared to participants receiving sleep hygiene education, at 10 weeks, Sleepio users experienced greater improvements in clinical insomnia severity and depressive symptoms, although changes in the perception of facial expressions after treatment that can modify negative bias did not occur (Tamm, 2025; ISRCTN.org identifier ISRCTN17117237).

In the United States, the U.S. Food and Drug Administration based approval of Sleepio on the results of the Digital CBT-I for Insomnia Disorder Trial (CrEDIT; ClinicalTrials.gov identifier NCT05541055), which demonstrated substantial equivalence to the predicate device Somryst. Response was defined as a change of ≥ 6 points from baseline, and remission was defined as a score of < 8. Compared to sleep hygiene education, Sleepio participants had 2.52 odds of response ($P < .001$, 99% confidence interval 1.33 to 4.75), and 5.8 odds of remission ($P < .001$, 99% confidence interval 2.11 to 15.84) at 10 weeks. In a post-hoc response analysis using a change of ≥ 8 points from baseline to define response, Sleepio participants had 3.30 odds of response (95% confidence interval 1.92 to 5.69). No adverse or serious adverse events were reported (U.S. Food and Drug Administration, 2024).

A Markov simulation model examined the cost effectiveness and potential net monetary benefit of Sleepio use for insomnia compared with no insomnia treatment or other therapy, estimating direct and indirect costs from a U.S. perspective in 2019 dollars. Simulations randomized 100,000 individuals equally to one of five arms — Sleepio, pharmacotherapy, individual cognitive behavioral therapy, group cognitive behavioral therapy, or no insomnia treatment. Sleepio was the most cost-effective insomnia treatment followed by group cognitive behavioral therapy, pharmacotherapy, and individual cognitive behavioral therapy. Sleepio achieved cost

effectiveness through lower healthcare expenditure, less workplace accident risk, and improved work productivity (Darden, 2021).

A randomized controlled trial enrolled U.S. pregnant women (up to 28 weeks gestation) to receive six weekly sessions of Sleepio for approximately 20 minutes each (n = 105) or standard treatment (n = 103) for insomnia; investigators provided follow up data at three and six months postpartum (ClinicalTrials.gov identifier: NCT02805998). From baseline to 10 weeks post-intervention, Sleepio users experienced significantly greater improvements in insomnia symptom severity ($P < .001$) and in secondary outcomes of sleep efficiency, global sleep quality, depressive symptom severity, and anxiety symptom severity, but not sleep duration. Changes in outcomes from baseline to 18 weeks follow-up revealed similar patterns (Felder, 2020).

Sleepio participants experienced higher rates of insomnia remission and lower rates of diagnostic criteria-defined insomnia at six months postpartum, greater improvements in depressive symptom severity from baseline, and greater improvements in anxiety symptom severity from baseline to three months postpartum. The proportion of participants with probable major depression at three months postpartum was significantly higher among standard care than Sleepio participants (18% versus 4%, $P = .006$), particularly among those with minimal depressive symptoms at baseline (18% vs 0%) (Felder, 2022).

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

In 2025, we updated the literature, including a new prescription digital therapeutic for chronic insomnia (Sleepio), and added Sleepio and contraindications to the coverage section.

References

On June 19, 2025, 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 "sleep initiation and maintenance disorders/therapy" (MeSH), ("mobile applications" (MeSH), "cognitive behavioral therapy," "digital therapeutics," "insomnia," "Somryst," and "Sleepio." 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.

8/2025: Policy references reviewed. Coverage updated.