Policy Number	**PSY301.023**
Policy Effective Date	**06/15/2025**
Policy End Date	**12/31/2025**

Digital Health Therapies for Chronic Insomnia

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Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

This medical policy has become inactive as of the end date above. There is no current active version and this policy is not to be used for current claims adjudication or business purposes.

Digital health therapies for patients with chronic insomnia **are considered experimental, investigational and/or unproven.**

Policy Guidelines

None.

Description

Insomnia
A common sleep disorder, insomnia is defined as persistent difficulty with sleep initiation, duration, consolidation or quality that occurs despite adequate opportunities for normal sleep,

and results in some form of daytime impairment such as malaise and fatigue, memory and concentration difficulties, and/or mood disturbances. (1) Environmental, physiological, and psychological factors can all play a role in insomnia, including the following:

- Ingestion or consumption of substances that negatively affect sleep (e.g., alcohol, caffeine, etc…);
- Health conditions that can make it harder to fall and/or remain asleep; and
- Behavioral and mental health disorders.

Treatment

Common treatments for insomnia include establishing healthy sleep habits, medications, and cognitive behavioral therapy.

Prescription digital therapeutics (PDTs) are a new class of software-based medical devices that are being used and evaluated for a variety of medical and behavioral health conditions.

Software as a Medical Device

The International Medical Device Regulators Forum, a consortium of medical device regulators from around the world which is led by the U.S. Food and Drug Administration (FDA), distinguishes between 1) software in a medical device and 2) software as a medical device (SaMD). The Forum defines SaMD as "software that is intended to be used for one or more medical purposes that perform those purposes without being part of a hardware medical device". (2)

The FDA's Center for Devices and Radiological Health is taking a risk-based approach to regulating SaMD. Medical software that "supports administrative functions, encourages a healthy lifestyle, serves as electronic patient records, assists in displaying or storing data, or provides limited clinical decision support, is no longer considered to be and regulated as a medical device". (3)

Regulatory review will focus on mobile medical apps that present a higher risk to patients.

- Notably, the FDA will not enforce compliance for lower risk mobile apps such as those that address general wellness.
- The FDA will also not address technologies that receive, transmit, store, or display data from medical devices.

Regulatory Status

In March 2020, Somryst® (Nox Health) received marketing clearance by the U.S. FDA through the 510(k) premarket approval process (K191716). Somryst is a prescription software application intended to provide a neurobehavioral intervention in patients 22 years of age and older with chronic insomnia. Somryst is based on “principles of cognitive behavioral therapy for insomnia (CBT-I), sleep restriction, and other proven psychosocial treatment elements, which are delivered in a sequence of “cores” of patient education, training, and skill building. The therapy is delivered via a mobile application intended to be used on a patient’s mobile device and consists of text, video, animation and graphics. Clinicians, as part of a patient’s general

treatment program, have access to a clinician dashboard that shows patient utilization and engagement with the application." (4)

FDA product code: QVO.

Rationale

Medical policies assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Digital Therapies for Insomnia

Although there are no published RCTs for Somryst®, a number of RCTs on SHUTi (the web-based platform of Somryst) were identified.

Ritterband et al. (2017) compared internet cognitive behavior therapy for insomnia (CBT-I) with internet patient education at set time intervals over the course of 12 months. (5) The primary sleep outcomes were self-reported online ratings of insomnia severity (Insomnia Severity Index) and online sleep diary-derived values for sleep-onset latency and wake after sleep onset, collected prospectively for 10 days at each assessment period. Among 303 participants, the mean (SD) age was 43.28 (11.59) years, and 71.9% (218 of 303) were female. Of these, 151 were randomized to the SHUTi group and 152 to the online patient education group. Results of the 3 primary sleep outcomes showed that the overall group × time interaction was significant for all variables, favoring the SHUTi group (Insomnia Severity Index [$F_{3,1063} = 20.65$, $P < .001$], sleep-onset latency [$F_{3,1042} = 6.01$, $P < .001$], and wake after sleep onset [$F_{3,1042} = 12.68$, $P < .001$]). Treatment effects were maintained at the 1-year follow-up (SHUTi Insomnia Severity

Index d = 2.32 [95% CI, 2.01-2.63], sleep-onset latency d = 1.41 [95% CI, 1.15-1.68], and wake after sleep onset d = 0.95 [95% CI, 0.70-1.21]), with 56.6% (69 of 122) achieving remission status and 69.7% (85 of 122) deemed treatment responders at 1 year based on Insomnia Severity Index data.

Hagatun et al. (2019) evaluated the short-term efficacy of an unguided internet-based CBT-I program called SHUTi. (6) Participants were randomly allocated to the SHUTi or a web-based patient education condition. Both groups were assessed before and after the nine-week intervention period (online sleep diaries and questionnaires). The SHUTi participants were reassessed in a six-month nonrandomized follow-up. Primary outcome measures were the Insomnia Severity Index (ISI) and the Bergen Insomnia Scale (BIS). A total of 181 participants were included in the study; SHUTi (n = 95), patient education (n = 86). Intention-to-treat mixed-model repeated-measures analysis revealed that the SHUTi group had better short-term outcomes compared with the patient education group on most sleep measures. Improvements were maintained among the completing SHUTi participants at the six-month nonrandomized follow-up. However, dropout attrition was high.

Vedaa et al. (2020) conducted a parallel-group superiority RCT comparing digital CBT-I with online patient education about sleep. (7) The interventions were available through a free-to-access website, which incorporated automated screening, informed consent, and randomization procedures, as well as outcome assessments. Adults (age ≥18 years) who had regular internet access and scored 12 or higher on the ISI were eligible for inclusion and were allocated (1:1) to receive digital CBT-I (consisting of six core interactive sessions to be completed over 9 weeks) or patient education (control group). Between February 26, 2016, and July 1, 2018, 5349 individuals commenced the online screening process, of which 1497 were ineligible or declined to participate, 2131 discontinued the screening process, and 1721 were randomly allocated (868 to receive digital CBT-I and 853 to receive patient education). At 9-week follow-up, 584 (67%) participants in the digital CBT-I group and 534 (63%) in the patient education group completed the ISI assessment. The latent growth model showed that participants in the digital CBT-I group had a significantly greater reduction in ISI scores from baseline to 9-week follow-up than those in the patient education group. Compared with patient education, the number needed to treat with digital CBT-I was 2·7 (95% CI 2·4 to 3·2) for treatment response (ISI score reduction ≥8) and 3·2 (2·8 to 3·8) for insomnia remission (ISI score <8).

Shaffer et al. (2020) compared participants (N=303) randomized to an internet-based CBT-I program (SHUTi-Sleep Healthy Using the Internet) or internet-based patient education (PE). (8) Participants reported daily bedtimes and rising times on 10 online sleep diaries collected over 2 weeks at baseline and 9-week post-intervention assessment. Participants completed the ISI at post-assessment and 6-month follow-up; symptom remission was defined by ISI < 8. Mixed effects location scale modeling was used to examine the effect of SHUTi on bedtime and rising time IIV; a novel two-staged analysis examined the effect of bedtime and rising time IIV on insomnia symptom remission. At post-assessment, SHUTi participants reported about 30% less bedtime and 32% less rising time variability compared to PE. Bedtime and rising time IIV was

not independently associated with likelihood of insomnia symptom remission at the subsequent time point, nor did sleep schedule IIV moderate treatment response. Findings demonstrate that an Internet-delivered CBT-I program can effectively increase users' sleep schedule consistency relative to an educational control. This consistency, however, was not related to treatment outcome when defined by insomnia symptom remission, suggesting that enforcing rigid sleep schedules for patients may not be necessary for treatment success.

Kjorstad et al. (2022) studied the effects of digital CBT-I (dCBT-I) on work productivity and activity levels and the mediational role of insomnia symptoms: Data from a randomized controlled trial with 6-month follow-up. (9) Cognitive behavioral therapy for insomnia (CBT-I) is a well-established treatment for insomnia, but few studies have explored its impact on work and activity impairment. The data compared 1721 participants enrolled in a randomized controlled trial comparing the efficacy of digital CBT-I compared with Patient Education (PE). Digital CBT-I was found to be associated with reduced activity impairment compared with PE (by 5.6%) but not presenteeism, absenteeism, or changes in employment status. Mediation analysis showed that changes in insomnia severity largely mediated improvements in presenteeism (by 5.4%) and activity impairment (by 5.5%). There were no significant mediational effects on absenteeism or employment status. The study acknowledged that the findings need confirmation and future studies designed to specifically examine work and social impairment are also needed. Limitations included significant participant attrition at the 6-month follow (approximately 60%) and some of the participants were unemployed at baseline. Further, the included measure of absenteeism in the present study is a proxy measure with participants only reporting the number of hours absent from work, and, therefore, the authors noted they were unable to calculate, e.g., percentage of work hours absent.

Forma et al. (2022) conducted a meta-analysis to compare the effectiveness of the only Food and Drug Administration-authorized prescription digital therapeutic (PDT) Somryst versus face-to-face cognitive behavioral therapy for insomnia (CBT-I), or FDA-approved prescription medications for insomnia. (10) A Bayesian network meta-analysis (NMA) was conducted to examine 1) mean change in insomnia severity index (ISI); 2) proportional change in ISI remitters; 3) mean change in wake after sleep onset (WASO); and 4) mean change in sleep onset latency (SOL). Twenty studies provided data on the PDT, CBT-I, CBT-I in combination with self-help (SH), or two prescription medications (eszopiclone and zolpidem). The PDT was associated with significant mean change in ISI (–5.77, 95% Credible Interval [CrI]-8.53, -3.07) and ISI remitters (OR 12.33; 95% CrI 2.28, 155.91) compared to placebo, and had the highest probability of being the most effective treatment overall for ISI mean change (56%), and ISI remitters (64%). All evaluated interventions significantly outperformed placebo for WASO but no significant differences were observed for SOL (five interventions). Sensitivity analyses excluding medications and meta-regression (assessing type, duration, delivery method for CBT-I) did not affect NMA results. This network meta-analysis demonstrated that a PDT delivering CBT-I had the highest probability of being most effective compared to face-to-face CBT-I, prescription sleep medications, or placebo, as measured by reductions in mean ISI score from baseline and ISI-determined remittance. Further research with longer follow-up time including broader treatment types and additional outcome metrics, are needed to further delineate the most

effective and cost-effective treatments for chronic insomnia. Further research with longer follow-up time including broader treatment types and additional outcome metrics, are needed to further delineate the most effective and cost-effective treatments for chronic insomnia.

Ritterband et al. (2022) conducted a retrospective investigation to evaluate outcome and patient engagement data of SHUTi. (11) This real-world dataset analysis included 7216 adults who purchased access to SHUTi between December 2015 and February 2019. The Insomnia Severity Index (ISI) was given at the start of each of six treatment Cores of the intervention. Users recorded sleep diaries between Cores to track changes in sleep over time and obtain tailored sleep recommendations. Program usage was determined from the number of Cores completed and sleep diaries recorded. Users demonstrated a reduction in mean ISI scores and a corresponding increase in effect size at the start of each subsequent Core (compared to Core 1) (range: d = 0.3-1.9). Effect sizes at the last Core relative to the first were moderate-to-large for diary derived sleep onset latency and wake after sleep onset. A reduction in number of medicated nights was also noted, with those with severe insomnia displaying the largest reduction from last-to-first week of treatment (d = 0.3). At the last Core, 61% met criteria for meaningful treatment response (reduction of >7 points on ISI) and 40% met criteria for remission (ISI<8). Engagement was comparable to SHUTi research trials. The findings of this real-world analysis should be considered in light of several limitations. Heterogeneity of the sample cannot be fully determined given the limited demographic information collected from the digital therapeutic users. In addition, heterogeneity is likely also reduced given users were required to purchase SHUTi. A major challenge for interpreting this dataset is due to the number of participants who stopped using the program early. The researchers concluded that additional research is needed on this challenge of data missingness and overall adherence to digital health programs.

Summary of Evidence

For individuals who have chronic insomnia who receive digital health therapies, the evidence includes a meta-analysis and several RCTs. Relevant outcomes include symptoms, functional outcomes, and quality of life. Although results were largely positive, it should be noted that there were a number of limitations associated with these trials. Some had small sample sizes, several had high attrition rates, and most recognized the need for longer studies. It is unknown as to whether there are differences in the patient experience using the Somryst application on a mobile device. More studies comparing Somryst with in-person cognitive behavior therapy for insomnia (CBT-I) as an alternative or adjunct to sleep medication would be useful. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this policy are listed in Table 1.

Table 1. Summary of Key Trials

NCT Number	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT04325464[a]	A Remote, 9-week Insomnia Treatment Trial to Collect Real World Data for a Digital Therapeutic (DREAM)	1590	Oct 2024
NCT04909229	Prescription Digital Therapeutic for the Treatment of Insomnia (SLEEP-I)	100	Mar 2024

NCT: national clinical trial.

[a] Denotes industry-sponsored or cosponsored trial.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	99199
HCPCS Codes	A9291, A9999, E1399, G0552, G0553, G0554

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
12/31/2025	Document became inactive.
06/15/2025	Reviewed. No changes.
04/01/2024	Document updated with literature review. Coverage unchanged. Added reference 11.
06/01/2023	Document updated with literature review. Coverage unchanged. References 9 and 10 added.
10/15/2022	Reviewed. No changes.
04/15/2022	New medical document. Digital health therapies for patients with chronic insomnia are considered experimental, investigational and/or unproven.