Health Technology Review	
Technology Ref.:	HTA23050
Technology Name:	SleepUp
Approvals by International Bodies:	SleepUp is approved by ANVISA in Brazil, as Medical Device Class II, and has authorization for commercialization under registration 82207710002
Company name:	Propharma Medical Supplies
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Short Description of the Technology:	SleepUp is a software application classified as (Software as Medical Device) that offers digital therapy with the use of clinically validated protocol of Cognitive Behavioral Therapy (CBTi) for the treatment of insomnia and subjective sleep complaints in adults. SleepUp also offers educational modules, reports, and sleep monitoring using sleep diary and clinical outcome assessment tests. SleepUp does not provide diagnostics and does not replace a doctor's consultation. The software application does not interact or change any physical and biological aspects of body and sleep physiology and SleepUp does not prescribe medication. To access SleepUp, the user must download the Application from Google Play or the Apple Store, install it on their smartphone, login and register. The SleepUp application works on physical Android and IOS devices. The minimum configuration that allows the installation and use of the SleepUp application on the Android device is Android operating system 5.0 or higher and the IOS device is operating system 13 or higher, with internet connection. The clinical protocol is based on Cognitive Behavioral Therapy for Insomnia (CBT-I). It is considered the gold standard in the treatment of chronic insomnia, being the first choice of intervention in these cases. It consists of a psychotherapeutic approach, which aims to provide the user with specific cognitive and behavioral techniques that improve sleep quality. CBT-I 2 DOH/RIC/HTA/0002 V2.1 Submission Form seeks to understand the causes and symptoms of insomnia in order to modify habits, behaviors, and beliefs, promoting more assertive attitudes and more realistic and positive thoughts for improving sleep quality. The clinical protocol comprises 7 modules, which are self-guided and take about 12 weeks to complete. The user will carry out the activities and techniques progressively in each module and will fill in the sleep diary, anamneses and clinical questionnaires periodically. The operating principle is based on user interaction with the application's functionalities through touch screens, involving text, audio and video resources. The user receives daily reminders and notifications and is guided to use the features progressively. In addition, SleepUp also offers a screening test for the Obstructive Sleep Apnea (OSA), anamneses and clinical assessment tests for the screening of insomnia, depression and other sleep related conditions. The expected result at the end

	of the protocol is that the patient identifies the causes of insomnia and reduces their sleep complaints. The clinical response is calculated based on the Insomnia Severity Index (main questionnaire for measuring insomnia symptoms). The treatment is considered effective if this Index score, at the end of treatment, is lower than the score at the start of treatment. Patients are considered to have no symptoms of insomnia if the score at the end of treatment is less than 8 points. Variables related to excessive daytime sleepiness, sleep quality, chronotype and sleep hygiene are also measured, using appropriate questionnaires for each case.

Health Technology Assessment Team Recommendation:	**Approve with limitation**

Summary of Review:

The technology consists of (Platform, Cloud Platform ("Backend"), SleepUp APP, Website, SleepUp WEB Portal and wearable device). it is a digital platform that improves user's sleep through lifestyle tips, music, guided meditation, mindfulness and virtual therapy, with the aim of monitoring, analyzing and tracking user's progress through diary, tests, reports and wearable technologies, developed for Android & IOS Operating Systems, including remote consultation service, in a secure virtual environment (online), via chat or video. The Monitoring refers to wearable technologies used to monitor sleep pattern, in order to customize guidance and monitor evolution, the app utilize AI that generate Personalized Recommendation. It's intended to treating insomnia and monitoring sleep through digital therapies, educational and relaxation resources, follow-up reports, clinical tests and a sleep diary. (Over 17 years old, or in full civil capacity.)

Advantages	Disadvantages
Digital therapy was effective in improving insomnia severity and sleep-related parameters, both alone and combined with medication. Effects sizes were greater among sleep medication users, indicating that dCBTi can be considered an effective adjunct treatment for chronic insomnia.	Digital CBT-I requires a great deal of willpower and self-discipline. Therefore, lack of adherence and non-therapist guidance are major drawbacks, next to other issues such as overgeneralized advice, technical issues, and privacy concern.
CBTi in digital platforms (or digital CBTi - dCBTi) has been proposed to overcome conventional CBTi limitations such as (availability and affordability)	Future studies are needed to analyze its clinical effectiveness and reliability; more rigorous validation studies on the therapeutic effect of the SleepUp platform, mainly based on randomized clinical trials, compared to conventional CBT-I and based on larger diverse samples.
dCBTi reduces or excludes the need for a face-to-face professional, is less expensive, and has the potential to maintain patient compliance.	The generated reports by the app shall be reviewed by healthcare professionals
Recent evidence already shows that dCBTi can reduce sleep medication use in the short and long term	The Platform does not provide diagnostics and does not replace a doctor's consultation.
	The application is limited in language for non-English users and in utilization for those who do

	not own Android and IOS devices

We recommend an **approval with limitation of using this technology** with the following conditions:

1. The approval is limited to one year only, the applicant shall return with further evidence on the platform efficacy for reevaluation.
2. Recommended a medical assessment should be done before referral to SleepUp during pregnancy and in people with comorbidities.
3. SleepUp is not intended to provide diagnostics and does not replace a doctor's consultation nor prescribe medication.
4. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
5. Provision of regular updates and reports about the product to DOH upon request.

Moreover, DOH has the right to stop the product at any stage if deemed necessary, initial conditions and any subsequent conditions must be satisfied before obtaining final approval. Failure to do so will reflect in provoking the approval.

Technology Image

Population, setting and intended user for Technology “SleepUp”

- **Population/ Intended User**;
  - The treatment of insomnia and subjective sleep complaints in adults.
- **To be prescribed by**:
  - NA
- **Clinical Setting:**
  - NA
- **Condition of use:**
  - As per Healthcare professional guidance
- **Exclusion criteria:**
  - Other conflicting medical issues