



digital therapy (Somryst®)

EOCCO POLICY



Policy Type: PA

Pharmacy Coverage Policy: EOCCO245

Description

Somryst (digital therapy) is an FDA-authorized prescription digital therapeutic which delivers cognitive behavioral therapy (CBT) to treat chronic insomnia.

Length of Authorization

- Initial: one time authorization to cover up to 9-week treatment
- Renewal: not applicable; this is a single one-time treatment

Quantity Limits

Product Name	Dosage Form	Indication	Quantity Limit
Somryst (digital therapy)*	Each	Chronic Insomnia	1 x access, up to 9-week treatment

*Somryst NDC 96439-0030-01

Initial Evaluation

- I. Somryst (digital therapy) may be considered medically necessary when the following criteria are met:
 - A. Member is 22 years of age or older; **AND**
 - B. A diagnosis of **chronic insomnia**; **AND**
 1. Attestation by provider that all the following are met:
 - i. Member is under their supervision; **AND**
 - ii. Member is able to read and understand English; **AND**
 - iii. Member is familiar with how to use mobile apps

AND

 2. Attestation by provider member’s daily life or work does not require them to be highly alert or cautious (e.g. long-haul truck drivers, long-distance bus drivers, air traffic controllers, operators of heavy machinery, certain assembly line jobs).
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- II. Somryst (digital therapy) is considered investigational when used for all other conditions, including but not limited to:
 - A. Short-term insomnia
 - B. Parasomnia

Renewal Evaluation

Not applicable. Somryst (digital therapy) is a one-time 9-week treatment.

Supporting Evidence

- I. The American Academy of Sleep Medicine (AASM) strongly recommends cognitive behavioral therapy for insomnia (CBT-I) as part of the initial recommended approaches to treat chronic insomnia in adults.
 - CBT-I combines one or more cognitive therapies, alongside education about sleep regulation, stimulus control, and sleep restriction therapy. This can also include sleep hygiene education, relaxation training, and use of sleep diaries.
 - CBT-I is digitally delivered via the Somryst app on a tablet or smartphone.
- II. While cognitive behavioral therapy is the standard of care in the treatment of insomnia, the FDA authorization of Somryst was based on a controlled study where CBT-I was delivered by a computer. Thirty-four subjects were randomized to receive either control (sleep diary) or computer-based CBT-I. The CBT-I treatment group had a statistically significant difference in improved sleep versus control.
- III. Somryst is indicated in patients 22 years of age and older with chronic insomnia. Product claim includes improving insomnia symptoms.
- IV. Somryst use is intended as a single 9-week treatment, under the supervision of a provider.
- V. Somryst guides the user through various activities and modules over 6 to 9 weeks; there is no data to support repeat use or use beyond this time.
- VI. Since CBT-I is delivered via a digital means on a tablet or smartphone, safe and typical use requires familiarity with apps and ability to read and understand English.
- VII. Treatment with Somryst includes both sleep restriction and consolidation which can cause sleepiness, especially in the early stages of using this prescribed digital therapeutic. For individuals who must be alert or cautious to avoid serious accidents in their job or daily life, Somryst should not be used. Examples include: long-haul truck drivers, long-distance bus drivers, air traffic controllers, those who operate heavy machinery or select assembly line work.

Investigational Uses

- I. Somryst has not been FDA-authorized, or sufficiently studied for safety and efficacy for the conditions or settings listed below:
 - A. Short-term insomnia
 - B. Parasomnia



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References

1. Somryst [Clinician Information]. Boston, MA: Pear Therapeutics, Inc. March 2020.
2. Feuerstein S, Hodges SE, Keenaghan B, Bessette A, Forselius E, Morgan PT. Computerized cognitive behavioral therapy for insomnia in a community health setting. J Clin Sleep Med. 2017;13(2):267-274.
3. Edinger JD, Arnedt JT, Bertisch SM, et al. Behavioral and psychological treatments for chronic insomnia disorder in adults: an American Academy of Sleep Medicine clinical practice guideline. J Clin Sleep Med. 2021;17(2):255–262.

Policy Implementation/Update:

Action and Summary of Changes	Date
Policy created November 2021	01/2022