

iNAP Coding Guide

Product Description

The iNAP One Sleep Therapy System is a nonsurgical device indicated for home use in the treatment of obstructive sleep apnea (OSA) in adults manufactured by Somnics Health, Inc. iNAP delivers a light, oral vacuum to comfortably open the airway while you breathe through your nose during sleep.

The complete device includes the following:

1. Oral interface: is a soft, non-allergenic soft polymer mouthpiece that contains a lip shield and a straw that has multiple ports along its sides and at the tip, sitting midway in the oral cavity, directed toward the back of the throat.
2. Tubing: is a thin, flexible polymer tube that connects between the console and the oral interface.
3. Saliva container: attaches directly to the console. It retains saliva up to 100 ml and has a membrane at the bottom of the container that covers a small opening, allowing the negative pressure to move through the unit.
4. Console: generates a gentle negative pressure and is driven by a built-in rechargeable Lithium battery, fully charged battery will last up to 48 hours of operation. In addition to the battery, the console contains the pressure pump, electronics and sensors that detect the amount of negative pressure.
5. iNAP Care software application for mobile devices: Patients download and install the iNAP Care application onto a smartphone to help patients and clinicians track their usage (treatment and sealing-leakage time) and progress while using iNAP. This information also is stored in our online platform Somnics Cloud.
6. Power Adapter: Input Volt Range: 100-240V.
7. Saliva absorbent DryPad: it's a small, disposable saliva absorbent contained within cellophane wrapping. A new DryPad should be inserted into the saliva container each night to collect saliva pulled from the mouth. The DryPad retains over 30 ml of saliva.



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Warranty

Somnics Health, Inc. provides a warranty to the original purchaser for the period listed below: iNAP console - 2 years; Other components – 1 month.

This warranty does not apply to “Wear and tear” that would normally occur with usage. The warranty does not include any misuse, abuse or tampering with the unit.

FDA Indications for Use

The FDA has classified iNAP as a prescription device with the following indications for use: iNAP is a removable intraoral pressure gradient device, electrically powered and operates by reducing the pressure in the oral cavity (by way of tubing and a noninvasive oral interface) to create a continuous positive pressure gradient from the airway to the oral cavity that urges the soft palate and tongue forward. It is intended to be used while a patient is sleeping to treat obstructive sleep apnea. For patients 18 and older only. FDA Classification Device Class 2.

iNAP Coding

The Healthcare Common Procedure Coding System (HCPCS) Level II Codes for Durable Medical Equipment, Prosthetic, Orthotics, and Supplies (DMEPOS) applies to medical devices used in the home. Medicare’s Pricing Data and Analysis Contractor (PDAC) granted the use of the following HCPCS codes, effective November-29-2023.

HCPCS Code	Description
TBD	iNAP console
A7001	Saliva container
A7002	Tubing
A9900	Dry pads
A7047	Oral interface

The iNAP console being the class II device and the other items being its accessories, positive coverage might not be granted to accessories unless the class II device is covered.

For additional information call us at 1 888.766.6427 (1.888.SOMNICS) The reimbursement information is being provided on an “as is” basis with no express or implied warranty of any kind and should be used solely for informational purposes only. The information does not constitute professional or legal advice on reimbursement and should be used at your sole liability and discretion. Before filing any claims, it is the provider’s sole responsibility to verify current requirements and policies with the payor.

All coding, coverage policies and reimbursement information are subject to change without notice. Somnics Health does not represent or warrant that any of the information being provided is true or correct and you agree to indemnify Somnics Health in the event of any loss, damage, liabilities or claims arising from the use of the reimbursement information provided to you.