iNAP® Sleep Therapy System

Information for Physicians

What is iNAP?

iNAP is a new alternative, non-surgical device for the treatment of obstructive sleep apnea in adults. The system uses a soft, flexible mouthpiece, thin tubing, and a quiet battery-powered console. The size of a smartphone, iNAP delivers a light vacuum in the oral cavity that comfortably opens the airway during sleep as the patient breathes naturally through the nose.

How does iNAP work?

iNAP delivers a gentle suction inside the oral cavity, moving the tongue forward and away from the airway. When iNAP activates, it helps the patient establish a seal within the mouth. Once the seal is set, iNAP's intermittent negative airway pressure turns off, effectively eliminating the apnea while saving battery. Should the tongue move out of the



optimal position, the device provides negative pressure again, helping the patient re-establish the seal and keeping the airway open (Seal = open airway). Vacuum in the oral cavity occurs when the patient closes their lips around the tubing portion of the oral interface, bringing the tongue forward and up toward the palate, thereby creating the seal. The device's external lights indicate when the patient is or is not in "seal time."

Is iNAP effective?

With over 25 clinical studies, iNAP significantly improved the apnea-hypopnea index (AHI), a common measurement of sleep apnea severity across people with all OSA severity levels- mild, moderate, and severe obstructive sleep apnea. Participants were highly compliant, using iNAP for a median of six hours per night. Both participants and bed partners reported high satisfaction and preference for iNAP over other therapy options. To view our research, visit <u>https://www.inapsleep.online/clinical-evidence</u>

Who is a likely candidate?

iNAP is not for every patient. Most adults are candidates, and the exclusion criteria are minimal except for a small number of patients who do not have front teeth or are unable to breathe through their noses during sleep. Those who demonstrate high motivation for this alternative therapy are the most successful with long-term use.

What is the initial patient experience with iNAP?

Whether purchasing out of pocket, or choosing the subscription model, Somnics Health will ship the device and accessories to the patient's home. Our iNAP Customer Success Team will handle the product orientation, technical support, adherence coaching, compliance tracking. Refills of consumables each quarter is



part of a subscription monthly fee. We suggest that patients stay with the treatment for at least three months. Afterward, they are free to cancel their subscription and return the device. Patients who purchase out of pocket receive the same service from Somnics Health, except for the automatic refills of consumables which they purchase on our website when convenient to them.

What are the costs?

1) **Membership**- for those who would like to try and use iNAP at a lower initial price point, membership is a fixed price per month. This allows cancellation anytime during the 24 months after the initial 3 months period. Resupplies are sent to the customer every three months and include shipping. Pricing is subject to changes, please see prices on our online store, <u>https://www.inapsleep.online/shop</u>. Patient can elect to purchase the device at a reduced price after the initial three months.

2) **Purchase**-includes three months of supplies, shipping and a 2-year warranty. Purchasers may order new supplies as needed by visiting our online store, <u>https://www.inapsleep.online/shop</u>. Patients can return the device within the first 90 days and will be reimbursed minus a \$250 restocking fee.

Is iNAP Covered by Insurance?

Not at this time. Somnics, the manufacturer of iNAP, will soon work with private and federal insurance companies, to establish coverage for the product. Currently, patients pay out-of-pocket for this therapy. The good news is that iNAP is eligible for coverage under HSA/FSA employer plans. We also have been granted with HCPCS code by CMS' s PDAC. Please contact us to inquire about these codes.

How do I refer patients for iNAP treatment?

Prescribing iNAP is easy. Once we receive a prescription, we notify

the patient to sign disclosure forms and submit payment securely on our website. Once they've registered, we will contact the patient, answer any questions, arrange shipment, and coordinate a telehealth onboarding session with them. We suggest that your staff provide a copy of the prescription to the patient for their records. Please use the prescription template below or your usual Rx form.

Are there any published studies?

Many! Over 30 iNAP efficacy studies have been published in peer-reviewed manuscripts and abstracts around the world. A list of clinical studies is available on our website at <u>https://www.inapsleep.online/clinical-evidence</u>.



What services are provided by Somnics Health?

Once your patient is ready to start iNAP, our iNAP Customer Support team will handle the product orientation and pair the device with their smartphone to track their progress. We also provide continual technical assistance, adherence coaching, troubleshooting, compliance tracking, and new supplies replenishment. We will notify your office should patients need further medical management and support. As the prescribing physician, you can follow the progress of each of your patients (compliance, treatment time per night, etc.) by logging on to our platform <u>www.somnics.cloud</u> after an initial setup. Please contact us for this setting.

What if the patient has not had a recent sleep study?

When speaking with patients, please feel free to reevaluate the patient to obtain an updated baseline sleep report. Some sleep physicians may also be interested in comparing the baseline study results while the patient is using INAP and undergoes a new HST.

If you or your staff have any questions or would like to meet with us on Zoom, please contact iNAP Customer Service at 833.SOMNICS (833.766.6427) or visit inapsleep.online.





| FAX- Confidential | | | | | |
|---|---|--|--|--|--|
| To: Somnics Health | Fax # 833-847-2009 | | | | |
| From: Phone: Re: INAP Sleep Therapy Request | Pages- | | | | |
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| Certificate of Medical Necessity /Prescription for the INAP Sleep Therapy System | | | | | |
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Prescription and Certificate of Medical Necessity

This document serves as a Prescription and Statement of Medical Necessity for the patient referenced below for the Somnics iNAP Sleep Therapy System and any items indicated.

| Patient Information | | | | |
|-------------------------------|----------------|-----|--|--|
| Patient First Name, Last Name | Gender | DOB | | |
| Primary Phone | Initial AHI | BMI | | |
| Street Address | City/State/Zip | | | |
| Email Address | | | | |

| Diagnosis | | | | |
|---|----------------------------|---|------------------------------|----------|
| () G47.33 Obstructive Sleep Ap () Depression | nea () Hypert () Stroke | tension () Hypersomnolence () Other: | () Ischemic Heart Disease () | Insomnia |

| NAP Sleep Therapy System |
|---|
|) iNAP Starter Kit (container, oral Interface, tubing, 93 Day's Supply of Dry Pads) |
| Replenishment: ()Oral Interface ()Tubing ()DryPad (3 months' supply)()Other |

| Physician Information | | | | | |
|-----------------------|-----------------------|-------|-----|--|--|
| Name | | NPI# | | | |
| Address | City: | State | Zip | | |
| Phone # | Fax # | | | | |
| Signature | Date | | | | |
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| | Email (non PHI only): | | | | |
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When referred by qualified referral sources, all patients will be admitted by Somnics Health for continuing services. Should services be requested that Somnics does not provide, we will direct patients to the appropriate resource. Prices for all products and services are available upon request. Somnics provides sleep therapy products In California only until further notice.