



FAQs

Prescribing of Oral Appliance Therapy for Obstructive Sleep Apnea (OSA) & Snoring

How much does the SomnoGuard AP2 cost?

The **SomnoGaurd AP2** is available only by prescription for **\$279** (+\$8.95 s/h). This compares to \$2500-\$5000 (and up) for a comparable appliance fabricated in a dental lab.

Is the SomnoGuard covered by insurance?

Sometimes. Virtually all insurers recognize Oral Appliance Therapy as Medically Necessary based upon the severity of the OSA. The SomnoGuard is FDA cleared for OSA which is a criteria needed to make it eligible for reimbursement. The SomnoGuard AP2 is classified as a Prefabricated/Custom Fit appliance, recognized under insurance HCPCS Code E0485. Some insurers, including Medicare/Medicaid only recognize lab-made appliances under HCPCS Code E0486 as well as specifying several other restrictive criteria, and thus do not help cover the cost of the SomnoGuard. All coverage is subject to deductibles, copays and coinsurance. The information needed to submit to your insurer for potential reimbursement is provided upon purchase, but coverage is between you and your insurer. No guarantee of coverage/reimbursement is made or implied.

Can I use HSA/FSA Funds to purchase the SomnoGuard?

Yes. 1st Line Medical can process the purchase with an HSA/FSA credit card by contacting Customer Service at 866-720-8080. While there are QR codes provided to conveniently purchase the appliance, HSA/FSA cards have to be processed separately and therefor require calling.

How does the SomnoGuard AP2 compare to Lab-Made?

The SomnoGuard achieves precisely the same clinical objective of lab-made appliances, stabilizing the jaw and associated musculature and moving them forward when/if necessary in very small increments to maintain an open airway at night. It is custom fit to both the upper teeth (Maxilla) and lower teeth (Mandible) with a mechanism to connect the two trays. In the case of the AP2, the mechanism allows almost unrestricted freedom of movement and the ability to mouth breathe, optimizing comfort and encouraging consistent use (Compliance). The rigid trays of the SomnoGuard AP2 are "one size fits most", and are therefor a little larger than is required for each specific individual, making them slightly larger in the mouth than an appliance tailored specifically to each individual. This extra material is typically considered minimal, and the fitting process positions most of it on the inside of the teeth, making it virtually undetectable in actual use.

How long does it take to get?

The SomnoGuard is sent Priority US Mail from our facility in New Hampshire, transit times range from 2-5 days based upon destination in the US. Some OSA-focused practices make them available for purchase through their office, while others offer it as a service.

Who is a good candidate for the SomnoGuard?

The SomnoGuard is FDA cleared and indicated for the treatment of both OSA & Snoring. It is best suited for those with mild-to-moderate OSA (AHI from Sleep Study from 5-29), but can be useful for patients with Severe OSA (AHI>30) when CPAP is not tolerated or often in conjunction with CPAP to lower the PAP pressure to more comfortable levels. Anyone looking to address their snoring can benefit from the therapy, but should be tested for OSA first to see if the snoring is an indicator of the more negatively-health-impacting OSA.

Who is not a good candidate for the SomnoGuard?

Oral Appliance Therapy places the forces of holding your jaw and associated musculature stable all night, on your teeth, therefore you must have healthy teeth with a minimum of 8 teeth on both the upper and lower arch (16 total). Patients should also be able to move their jaw forward and back at least 7mm, in order to be able to tolerate the forward protrusion that may be needed to optimize efficacy. Healthy teeth and gums are required and therefore regular dental care is encouraged. Dentures are not able to withstand these forces, but any permanent dental work is permissible (caps, fillings, crowns, etc.) Partials are permissible, as long as 8 teeth on the impacted arch remain after removal of the partial and the fitting is performed with the partial removed. Any dental work raises the possibility that it may be impacted (loosened, or separated) and the responsibility for repairing/replacing it is considered a dental issue and in no way is the responsibility of 1st Line Medical, Inc., Tomed GmbH or anyone other than the patient.

Is there a warranty on the SomnoGuard?

Yes. There is a one (1) year limited warranty on the SomnoGuard AP2 Oral Appliance that is applicable to Workmanship & Materials. As the materials are quite durable and design proven quite robust, the majority of claims are often caused by excessively high forces exceeding those of normal wear and tear, typically associated with dental conditions of grinding (Bruxism) and clenching of the teeth. Bruxism/Clenching are not considered warranty-claim conditions, though there is an individual tray replacement program available for those that prematurely wear through either tray of the appliance faster than normal as a result.

How long does the SomnoGuard AP2 last?

2 years is the anticipated useful life of the SomnoGuard AP2 Oral Appliance. Some last considerably longer if well maintained and not subject to excessive dental forces. As mentioned previously, severe bruxism may lead to excessive wear and tear reducing the lifespan of the appliance to as little as 6 months, but such circumstances are typically anticipated as patients have been prescribed a Bruxguard previously to prevent the damage to the teeth that this grinding condition creates.

How do you care for the SomnoGuard AP2?

Brushing promptly with toothpaste and a toothbrush every morning after use. The SomnoGuard is made up of 2 components - a rigid outer tray and a moldable copolymer to obtain the impression of the teeth. It is important to NEVER SOAK the appliance in any liquid (denture cleaner, mouthwash, etc) when not in use as this can permeate the junction between the 2 materials, weakening the bond between them and lead to premature cracking and shorten useful life. Whitening toothpaste and a medium bristle brush can optimize appearance over the life of the appliance. Conditions such as GERD, smoking, or synthetic moisteners (ie. Biotene) can lead to discoloration of the device over time which does not impact its efficacy but can contribute to an undesirable discoloration.

How does the SomnoGuard AP2 get custom fit?

The SomnoGuard AP2 can be self-administered by the patient or assisted by a member of the providers staff proficient in the 3-step process to custom fit the appliance. The 2-part trays are submerged in boiling water for 3 ½ minutes and then fit in a way to record both the upper and lower impressions as well as how the Upper (maxilla) and Lower (mandible) relate to each other at the bite closed point (several millimeters of material still between the teeth), called the bite Registration. The copolymer is molded to the inner side of the teeth with the tongue while holding firmly in place, dictating the degree to which the appliance secures to the teeth (Retention). Once the impression/registration is obtained, the connection mechanism is put in place to initiate therapy without any advancement of the jaw and when/if necessary move the jaw forward in small increments until the desired result is obtained.

How does the SomnoGuard AP2 get adjusted?

The Lower tray of the SomnoGuard AP2 contains a screw that engages with a groove (C-Channel) on the Upper tray. By advancing the screw OUT of the lower post, it in turn pushes the lower tray forward when engaged with the groove of the upper tray. While initiated with no advancement - simply stabilizing the anatomy - turning the screw 2.5 turns counterclockwise, with the provided Allen key, results in a 1mm advancement. It is recommended to only advance the lower tray 1mm per week through this process to achieve the best combination of comfort and efficacy. It is not unusual to require 3-4mm of advancement, or more (up to 1cm is possible), to achieve optimal efficacy, so this process can take 3-4 weeks or more to attain and remains dynamic (subject to further +/- adjustment) throughout the lifespan of the appliance.

When do I wear the SomnoGuard AP2?

The Oral Appliance is strictly a therapy to use while sleeping. There is no benefit to wearing the appliance when awake (no muscle training or memory is imparted).

Is there an impact to my teeth or bite?

Because the adjustment (titration) process is undertaken so gradually, there is typically very little sense of any bite mis-alignment in the morning. When this presents, it is typically resolved by jaw exercise during the brushing of teeth or rarely beyond (ie. chewing gum or eating breakfast). If a significant (>4mm) amount of protrusion is required to achieve efficacy and there is a prolonged feeling of bite mis-alignment in the morning, there is a device called a morning repositioner that can be obtained to return the bite to it's normal resting position briefly until the muscle memory is restored each morning. Contact 1st Line Medical Customer Service for access to this device when/if necessary.

As the copolymer records the position of your teeth at the time of fitting, it will serve to maintain this position, much like a retainer, when the appliance is in use.

Can the SomnoGuard AP2 be refit if I get dental work?

Yes. Unlike lab-made appliances, if you should need any dental work (ie fillings, crowns, veneers, etc.) during the life of the appliance, the impacted tray can be reheated and remolded to the teeth to accommodate it. No need to purchase a whole new tray/appliance.

How do I know if the SomnoGuard AP2 is working?

Bed Partners are usually the best way to assess efficacy. If no bed partner exists, there are several ways to assess Snoring and any residual Sleep Apnea through a variety of downloadable smartphone apps (some free, others require a subscription). Typical initial adjustment is assessed subjectively by patient bed partner or patient response (feeling more rested/alert, etc.) and once achieved should be quantified by participating in a follow up sleep study. New technologies have been developed to routinely and inexpensively test for Obstructive Sleep Apnea (ie. NightOWL HST) enabling you and your physician to test on a frequent (weekly/monthly) basis to optimize outcomes. Contact 1st Line Medical for more information on the NightOWL HST if interested.

Is there a return policy on the SomnoGuard AP2?

Yes. Any Appliance purchased and ultimately not custom fit or used is eligible for return for a full refund within one (1) year. The packaging and appliance must be in unused/unopened condition. Once opened and/or custom fit to a specific patient, the appliance is considered contaminated and not eligible for return.

Will the SomnoGuard AP2 replace my CPAP?

Many mild to moderate OSA patients have achieved ample reduction of their apnea with Oral Appliance Therapy to be able to discontinue CPAP. There are many factors contributing to each specific patients airway however, so no guarantee can be made or implied that you will achieve this level of efficacy. Some patients will achieve a significant reduction in their OSA but not fully eradicate it, but can only comfortably tolerate a certain degree of advancement of the mandible. Dramatically reducing the OSA, even if not curing, has been found to improve long-term health outcomes in most patients and is vastly superior to not addressing the OSA at all. Some patients find that the Oral Appliance Therapy provides substantial mechanical support of the airway which makes the pressures needed for CPAP use much more comfortable, and therefore successfully use the two in conjunction. The more severe the Obstruction is in the airway, the less likely that Oral Appliance Therapy alone will successfully address it and options should be explored with your physician.

The most beneficial therapy in the world is worthless if not routinely used, thus you should be applauded for using whatever therapy solution works best for you to reduce/eliminate the debilitating effects of untreated OSA.

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