

SomnoGuard™ Coding Recommendations

Oral Appliance Therapy for Snoring & Obstructive Sleep Apnea

Background discussion

Loud disruptive SNORING negatively impacts the sleep health and lives of an estimated 40% of the US population (134 million people directly or indirectly) and 4% of women and 8% of men suffer from Obstructive Sleep Apnea. Oral appliances, also referred to as Mandibular Advancement Devices, Oral Splints and Airway Stabilization Devices, have emerged as a proven solution to maintain an open and stable airway during sleep to reduce or eliminate snoring and prevent the airway from obstructing which leads to significant cardiovascular morbidity, complications and increased risk of stroke or heart attack and many other negative health impacts, and as a result are often recognized as medically necessary for the treatment of Obstructive Sleep Apnea when diagnosed and meeting criteria.

ICD-10 Diagnosis Codes	Description
G47.33	Obstructive Sleep Apnea (Adult & Pediatric)
R06	Snoring

There are **3** categories of Oral Appliances. (only FDA Cleared, custom fitted appliances are eligible for insurance coverage).

1. Over The Counter, non-FDA cleared, non-custom fitted, appliances for Snoring only (Not indicated for OSA). (ie. Z-Quiet, ZYPHAH, SilentNight, etc)
2. Prefabricated, Custom-fitted, FDA Cleared, Titratable Oral Appliances indicated for Snoring & OSA (SomnoGuard AP2, SPX, SG 3)
3. Custom Lab Manufactured, FDA cleared, Titratable Oral Appliances indicated for Snoring & OSA (SomnoGuard AP Pro, SomnoMed, Tap III, etc.)

1500 Codes	Description. (Only One code is appropriate per service) All are global, including device & fitting.
HCPCS E0485	Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, <u>prefabricated</u> , includes fitting and adjustment. (ie. SG AP2, SPX)
HCPCS E0486	Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, <u>custom fabricated (in a lab)</u> , includes fitting and adjustment. (ie. AP Pro)
CPT 21085*	Impression and custom preparation; oral surgical splint Oral maxillofacial prostheses used in the treatment of obstructive sleep apnea (OSA) will be covered when specifically fashioned to the needs and measurements of individual patients when used to treat essential sleep apnea and obstructive sleep apnea. <i>NOTE:</i> Use CPT Code 21085 to represent this prosthesis and the work to develop it. (MP.138.PC Oral Maxillofacial Prosthesis Apr 17 & AAOMS Guidelines)

* Most insurers have settled on E0485 being the preferred code for prefabricated appliances. Only occasionally still referenced (2019), use only when E0485 is not recognized (as opposed to not covered). **NEVER** bill both.

Possible Modifiers	Description (Should not be required, but occasionally requested)
-NU	New Unit (Typically only referenced in CPAP therapy, but erroneously requested occasionally.)
-KX	Requirements specified in the medical policy have been met
-GZ	Item or service expected to be denied as not reasonable and necessary

Statement of Financial Responsibility (SOFR)

Due to the highly variable criteria of each patient's indications and circumstances and multiple insurer medical policies, each with its own criteria for establishing Medical Necessity (general guidelines presented on Page 2), it is highly recommended to present each patient with a Statement of Financial Responsibility that documents that the SomnoGuard Oral Appliance is an appropriate therapy solution, and that a claim will be submitted on their behalf for any services that are eligible for coverage (ie. not Snoring), but that they are responsible for the specified fee if for any reason it is not covered. SOFR available from customer service (866-720-8080)

OSA Severity Index:

Insurers require copy of the Sleep Study to establish Medical Necessity

AHI/RDI*	Severity	Notes
<5	Not clinically significant - snoring	Not covered- cash for snoring
5 ≥ 14	Mild	Typically requires comorbidity**
15 ≥ 29	Moderate	Typical covered 1 st line option
≥ 30	Severe	CPAP first or conjunctive therapy***

* If both AHI and RDI are provided on Sleep Study, insurers typically reference **AHI** for determination of medical necessity.

** Mild OSA requires documentation of associated comorbidity:

Epworth Score >10, Loud Disruptive Snoring, Hypertension (>140/90), history of Stroke/heart attack, cognitive dysfunction, etc.

*** Oral appliance therapy can be used conjunctively to substantially reduce PAP pressure and help resolve Leak and pressure sore issues from too high a PAP pressure.