
Medical Policy



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***Current Policy Effective Date: 11/1/26**
(See policy history boxes for previous effective dates)

Title: Obstructive Sleep Apnea and Snoring - Surgical Treatment

Description

Obstructive sleep apnea (OSA) is characterized by repetitive episodes of upper airway obstruction due to the collapse and obstruction of the upper airway during sleep. For individuals who have failed conservative therapy, established surgical approaches may be indicated.

Medical Policy Statement

Certain surgical procedures, as stated in the inclusionary criteria below, are **established** for the treatment of clinically significant obstructive sleep apnea (OSA) when criteria are met. The procedure selected should be based on the patient's anatomy and the OSA etiology.

Adenotonsillectomy in pediatric patients with OSA and hypertrophic tonsils is **established** when criteria are met.

Hypoglossal nerve stimulation for treatment of OSA, using the Inspire FDA-approved device, is **established** when criteria are met.

Drug-induced sleep endoscopy (DISE) to evaluate appropriateness of FDA-approved hypoglossal nerve stimulation is **established** when criteria for hypoglossal nerve stimulation are met.

Other surgical procedures and submucosal cryolysis therapy for the treatment of clinically significant OSA are **experimental/investigational**. There is insufficient evidence to determine that the technology results in an improvement in net health outcomes.

Inclusionary and Exclusionary Guidelines

Inclusions:

- Palatopharyngoplasty (e.g., uvulopalatopharyngoplasty, uvulopharyngoplasty, uvulopalatal flap, expansion sphincter pharyngoplasty, lateral pharyngoplasty, palatal advancement pharyngoplasty, relocation pharyngoplasty) for the treatment of clinically significant** obstructive sleep apnea syndrome (OSA) in adult patients who have not responded to or do not tolerate continuous positive airway pressure (CPAP) or failed an adequate trial of an oral appliance.
- Hyoid suspension, surgical modification of the tongue, and/or maxillofacial surgery, including mandibular-maxillary advancement (MMA) in adult patients with clinically significant** OSA and objective documentation of hypopharyngeal obstruction who have not responded to or do not tolerate CPAP or failed an adequate trial of an oral appliance.

***Clinically significant OSA is defined as patients who have:*

- *AHI (Apnea/Hypopnea Index) or RDI (Respiratory Disturbance Index) of 15 or more events per hour, or*
 - *AHI or RDI of at least 5 events per hour with 1 or more signs or symptoms associated with OSA (e.g., excessive daytime sleepiness, hypertension, cardiovascular heart disease, or stroke).*
- Adenotonsillectomy in pediatric patients with OSA and hypertrophic tonsils, AND:
 - AHI or RDI of at least 5 per hour, OR
 - AHI or RDI of at least 1.5 per hour in a patient with excessive daytime sleepiness, behavioral problems, or hyperactivity
 - Hypoglossal nerve stimulation for treatment of OSA using the Inspire FDA approved device:

Adults:

ALL of the following must be met:

- Individual is 18 years of age or older;
- Home sleep apnea test (HSAT) Type II or Type III or attended in-laboratory polysomnography (PSG) sleep study within the preceding 18 months shows **all** of the following:
 - AHI or REI is ≥ 15 and ≤ 100 prior to HNS implantation
 - Total number of central apneas are $\leq 25\%$ of the total AHI;
 - Patients who have experienced significant weight loss (defined as 10% of body weight or more) since the most recent sleep study must have a repeat sleep study showing AHI or RDI is ≥ 15 and ≤ 100 prior to HNS implantation
- Within the prior year the patient has **EITHER** failed PAP therapy or been tolerant of PAP therapy as defined below:
 - Failure of PAP therapy is defined as:
 - AHI > 15 despite compliant use of PAP (more than 4 hours per night on $\geq 70\%$ of nights during a consecutive 30-day period) supported by a download from the PAP machine
 - Intolerance of PAP therapy is defined by **BOTH** of the following:

- Inability to tolerate compliant use of PAP therapy (more than 4 hours per night on $\geq 70\%$ of nights during a consecutive 30-day period) supported by a download from the PAP machine **AND**
 - Attempted use of PAP therapy for a period of at least 8 weeks under the direction of a physician board certified in sleep medicine (including but not limited to pressure adjustment, interface optimization, and treatment of fixed upper airway obstruction, if present)
- Absence of complete concentric retropalatal collapse on drug induced sleep endoscopy. Absence of complete concentric retropalatal collapse confirmation can be performed via drug-induced sleep endoscopy at the time of implantation of the hypoglossal nerve stimulator if a prior in-office volitional snore, during flexible laryngoscopy, demonstrated anterior-posterior velum collapse;
- Body mass index (BMI) is less than or equal to 35 kg/m^2 ;
- There are no exclusions to hypoglossal nerve stimulation use (see below)

Adolescent or young-adult with Down syndrome:

ALL of the following must be met:

- Individual is 13 to 21 years of age;
 - Individual had a prior adenotonsillectomy or has a contraindication to an adenotonsillectomy;
 - HSAT (Type II or Type III) or PSG sleep study within the preceding 18 months shows **all** of the following:
 - AHI is greater than 10 and less than 50; AND
 - Total number of central apneas are less than 25% of the total AHI;
 - Individual has either:
 - had a tracheotomy, OR
 - ineffective treatment with CPAP due to nonadherence, discomfort, undesirable side effects, persistent symptoms despite adherent use, or refusal to use the device;
 - Body mass index (BMI) at the 95th percentile or lower for age,
 - Absence of complete concentric retropalatal collapse on drug induced sleep endoscopy. Absence of complete concentric retropalatal collapse confirmation can be performed via drug-induced sleep endoscopy at the time of implantation of the hypoglossal nerve stimulator if a prior in-office volitional snore during flexible laryngoscopy demonstrated anterior-posterior velum collapse.
 - There are no exclusions to hypoglossal nerve stimulation use (see below)
- Drug-induced sleep endoscopy (DISE):
 - To evaluate the appropriateness of FDA-approved hypoglossal nerve stimulation when all the criteria for hypoglossal nerve stimulation are met.

Exclusions:

- Laser-assisted palatoplasty (LAUP)
- Midline glossectomy (MLG)
- Palatal stiffening procedures including, but not limited to, cautery-assisted palatal stiffening operation, injection of a sclerosing agent, and the implantation of palatal implants
- Radiofrequency volumetric tissue reduction (RVTR) of the tongue
- Radiofrequency reduction of the palatal tissues (i.e., Somnoplasty)

- Tongue base suspension (i.e., Repose system)
- Submucosal cryolysis therapy
- All other minimally invasive surgical procedures not described above
- All interventions for the treatment of snoring in the absence of documented OSA; snoring alone is not considered a medical condition
- DISE when above criteria are not met
- Surgical treatment of OSA when above criteria are not met

Exclusions for hypoglossal nerve stimulation:

- Fixed upper airway obstruction (e.g., tonsil size 3 or 4 per standardized tonsillar hypertrophy grading scale) or any other anatomical finding that would compromise the performance of the device
- Hypoglossal nerve palsy
- Current rhabdomyolysis
- Neuromuscular or neurologic disease (e.g., Parkinsons disease, muscular dystrophy, myasthenia gravis) that could compromise control of the upper airway
- Prior upper airway surgery that could compromise control of the upper airway
- Prior radiation to the larynx, tongue or throat that could compromise control of the upper airway
- Physical condition, intellectual impairment, or mental illness resulting in inability to operate the controller (when no assistance is available)
- Individuals who are pregnant or plan to become pregnant
- Moderate to severe cardiopulmonary disease including **ANY** of the following:
 - Recent myocardial infarction (within the past 180 days)
 - Severe valvular heart disease
 - NYHA class III or IV heart failure
 - Sustained ventricular arrhythmia (within the past 180 days)
 - Uncontrolled hypertension
 - Severe restrictive or obstructive pulmonary disease
 - Moderate to severe pulmonary hypertension (PA systolic pressure > 55 mmHg)
 - Obesity hypoventilation syndrome
- Members who are known to require magnetic resonance imaging (this does not apply to a model that is MR compatible)
- Members with an implantable device that may be susceptible to unintended interaction with the device
- Any other hypoglossal nerve stimulators with or without U.S. Food and Drug Administration (FDA) approval, including the bilateral hypoglossal nerve stimulator (e.g., Genio)

CPT/HCPCS Level II Codes

Established codes:

21120	21121	21122	21123	21141	21142
21143	21145	21146	21193	21196	21198
21199	21685	42140	42145	42975	64568*
64582**	64583	64584	C8007	C8008	C8009

Other codes (investigational, not medically necessary, etc.):

0978T	0979T	0980T	41512	41530	42299
S2080	C8011	C8012	C8013		

****When this code represents Inspire V it is established, for all other devices, this code is experimental/investigational***

***** When this code represents Inspire IV***

Notes:

- Code(s) may not be covered by all contracts or certificates. Please consult customer or provider inquiry resources at BCBSM or BCN to verify coverage.*
- Individual policy criteria determine the coverage status of the CPT/HCPCS code(s) on this policy. Codes listed in this policy may have different coverage positions (such as established or experimental/investigational) in other medical policies.*

Background

Obstructive sleep apnea (OSA) is characterized by repetitive episodes of upper airway obstruction due to the collapse and obstruction of the upper airway during sleep. The hallmark symptom of OSA is excessive daytime sleepiness, and the typical clinical sign of OSA is snoring, which can abruptly cease and be followed by gasping associated with a brief arousal from sleep. The snoring resumes when the patient falls back to sleep, and the cycle of snoring/apnea/arousal may be repeated as frequently as every minute throughout the night. Sleep fragmentation associated with the repeated arousal during sleep can lead to impairment of daytime activity. For example, adults with OSA-associated daytime somnolence are thought to be at higher risk for accidents involving motorized vehicles (i.e., cars, trucks, heavy equipment). OSA in children may result in neurocognitive impairment and behavioral problems. In addition, OSA affects the cardiovascular and pulmonary systems. For example, apnea leads to periods of hypoxia, alveolar hypoventilation, hypercapnia, and acidosis. This in turn can cause systemic hypertension, cardiac arrhythmias, and cor pulmonale. Systemic hypertension is common in patients with OSA. Severe OSA is associated with decreased survival, presumably related to severe hypoxemia, hypertension, or an increase in automobile accidents related to overwhelming sleepiness.

There are racial and ethnic health variations seen for OSA, impacting the prevalence of disease and accessibility to treatment options, particularly affecting children. Black children are 4 to 6 times more likely to have OSA than White children.¹ Among young adults 26 years of age or younger, African American individuals are 88% more likely to have OSA compared to White individuals. Another study found that African American individuals 65 years of age and older were 2.1 times more likely to have severe OSA than White individuals of the same age group. These health disparities may affect accessibility to treatment for OSA and impact health outcomes. One analysis of insurance claims data, including over 500,000 patients with a diagnosis of OSA, found that increased age above the 18- to 29- year range ($p<.001$) and Black race ($p=.020$) were independently associated with a decreased likelihood of receiving surgery for sleep apnea.² Lee et al (2022) found that Black men had a continuous mortality increase specifically related to OSA over the study period (1999 to 2019; annual percentage change 2.7%; 95% confidence interval, 1.2 to 4.2) compared to any other racial group.³

Continuous positive airway pressure is the preferred first-line treatment for obstructive sleep apnea for most individuals. A smaller number of individuals may use oral appliances as a first-line treatment.

Obstructive sleep apnea (OSA) is associated with a heterogeneous group of anatomic variants producing obstruction. The normal pharyngeal narrowing may be accentuated by anatomic factors, such as a short, fat “bull” neck, elongated palate and uvula, and large tonsillar pillars with redundant lateral pharyngeal wall mucosa. In addition, OSA is associated with obesity. OSA may also be associated with craniofacial abnormalities, including micrognathia, retrognathia, or maxillary hypoplasia. Obstruction anywhere along the upper airway can result in apnea. The severity and type of obstruction may be described with the Friedman staging system.⁵ Nonsurgical treatment for OSA or UARS includes positive airway pressure (CPAP) or mandibular repositioning devices, which are addressed in the BCBSM medical policy “Sleep Disorders, Diagnosis and Medical Management”. Patients who fail conservative therapy may be evaluated for surgical treatment of OSA.

Traditional surgeries for OSA or upper airway resistance syndrome include uvulopalatopharyngoplasty (UPPP) and a variety of maxillofacial surgeries such as mandibular-maxillary advancement. UPPP involves surgical resection of the mucosa and submucosa of the soft palate, tonsillar fossa, and the lateral aspect of the uvula. The amount of tissue removed is individualized for each patient, as determined by the potential space and width of the tonsillar pillar mucosa between the 2 palatal arches. UPPP enlarges the oropharynx but cannot correct obstructions in the hypopharynx. Patients who have minimal hypoglossal obstruction have greater success with UPPP. Patients who fail UPPP may be candidates for additional procedures, depending on the site of obstruction. Additional procedures include hyoid suspensions, maxillary and mandibular osteotomies, or modification of the tongue. Drug-induced sleep endoscopy and/or cephalometric measurements have been used as methods to identify hypopharyngeal obstruction in these patients. The first-line treatment in children is usually adenotonsillectomy. Minimally invasive surgical approaches are being evaluated for OSA in adults.

The hypoglossal nerve (cranial nerve XII) innervates the genioglossus muscle. Stimulation of the nerve causes anterior movement and stiffening of the tongue and dilation of the pharynx. Hypoglossal nerve stimulation reduces airway collapsibility and alleviates obstruction at both the level of the soft palate and tongue base.

They are currently 2 FDA-approved HNS devices for the treatment of OSA. Both are implanted devices that stimulate a nerve to keep the airway open during sleep, though they have different technological designs.

- The Inspire Upper Airway Stimulation (UAS) system (Inspire Medical Systems) was initially approved by the FDA in April 2014, for adults aged 22 and older with moderate to severe OSA who failed or could not tolerate PAP therapy and did not have complete concentric collapse at the soft palate (PMA: P130008). Subsequent supplements broadened its indications: S039 included adolescents aged 18 to 21, S089 added pediatric patients with Down syndrome aged 13 to 18, and S090 further expanded eligibility to adults 18 and older with an AHI ≥ 15 and ≤ 100 . S090 also raised the BMI upper limit for available safety and effectiveness data from BMI ≤ 32 to BMI ≤ 40 . The latest supplement, S098, approved in August 2024, introduced the Inspire V system, featuring an advanced neurostimulator and Bluetooth-enabled patient remote and

physician programmer, representing the most current generation of the device. Inspire V includes two implantable components: an implantable programmable pulse generator (IPG) placed in the chest wall and a stimulation lead in the neck. The procedure requires two incisions, pocket creation for the IPG and tunneling to connect the lead to the IPG.

- The Genio system (Nyxoah) was approved by the FDA in August 2025 and is designed for adults aged 22 and older with moderate to severe OSA (AHI of ≥ 15 and ≤ 65). It is intended for patients who have failed, cannot tolerate, or are not eligible for standard treatments such as lifestyle changes, PAP devices (including CPAP and BiPAP), oral appliances, or medications like tirzepatide. PAP failure is defined as an inability to eliminate OSA (residual AHI of >15 despite PAP usage), while PAP intolerance is defined as either being unable to use PAP consistently (at least 5 nights per week, usage defined as >4 hours of use per night) or unwillingness to use PAP. Genio consists of a single piece of implanted hardware that contains an antenna/receiver and two attached electrode paddles. The battery is external and transmits energy to the implant via Bluetooth. It is implanted under the chin through a single incision. There is no implanted battery, no pocket creation for the IPG, no tunneling, and no second incision.⁶⁰

The third device, the aura6000 system (LivaNova) is currently an investigational implantable HNS device undergoing clinical evaluation for the treatment of adult patients with moderate to severe OSA. The aura6000 system is an HNS device which utilizes six electrodes placed on the proximal trunk of the hypoglossal nerve, offering broad access to the muscles controlling the airway and providing customized titration. LivaNova completed its premarket approval submission to FDA for the aura6000 device based on meeting the primary safety and efficacy endpoints (AHI and ODI) following six months of treatment.⁶¹ This submission was based on a U.S. multi-center, open-label, prospective, RCT (NCT04950894, N=150 patients, see Table 37, Summary of Key Trials).

The review of evidence in this medical policy will focus on the two approved FDA devices: Inspire UAS system and Genio system.

A drug-induced sleep endoscopy (DISE) replicates sleep with an infusion of propofol. A DISE will suggest either a flat, anterior-posterior collapse or complete circumferential oropharyngeal collapse. Concentric collapse decreases the success of hypoglossal nerve stimulation and is an exclusion criterion from the U.S. Food and Drug Administration.

Terminology and diagnostic criteria for OSA are shown in Table 1

Table 1. Terminology and Definitions for Obstructive Sleep Apnea

Terms	Definition
Respiratory Event	
Apnea	The frequency of apneas and hypopneas is measured from channels assessing oxygen desaturation, respiratory airflow, and respiratory effort. In adults, apnea is defined as a drop in airflow by $\geq 90\%$ of pre-event baseline for at least 10 seconds. Due to faster respiratory rates in children, pediatric scoring criteria define an apnea as ≥ 2 missed breaths, regardless of its duration in seconds.
Hypopnea	Hypopnea in adults is scored when the peak airflow drops by at least 30% of pre-event baseline for at least 10 seconds in association with either at least 3% or 4% decrease in arterial oxygen desaturation (depending on the scoring criteria) or an arousal.

	Hypopneas in children are scored by a $\geq 50\%$ drop in nasal pressure and either a $\geq 3\%$ decrease in oxygen saturation or an associated arousal.
RERA	RERA is defined as an event lasting at least 10 seconds associated with flattening of the nasal pressure waveform and/or evidence of increased respiratory effort, terminating in arousal but not otherwise meeting criteria for apnea or hypopnea.
Respiratory event reporting	
AHI	The average number of apneas or hypopneas per hour of sleep
RDI	The respiratory disturbance index is the number of apneas, hypopneas, or respiratory event-related arousals per hour of sleep time. RDI is often used synonymously with the AHI.
REI	The respiratory event index is the number of events per hour of monitoring time. Used as an alternative to AHI or RDI in-home sleep studies when actual sleep time from EEG is not available.
Diagnosis	
Obstructive sleep apnea (OSA)	Repetitive episodes of upper airway obstruction due to the collapse and obstruction of the upper airway during sleep
Mild OSA	Adults: AHI 5 to <15 Children: AHI ≥ 1 to 5
Moderate OSA	Adults: AHI 15 to <30 Children: AHI >5 to 10
Severe OSA	Adults: AHI ≥ 30 Children: AHI >10
Treatment	
PAP	Positive airway pressure may be continuous (CPAP) or auto-adjusting (APAP) or Bi-level (Bi-PAP).
PAP Failure	Usually defined as an AHI greater than or equal to 15 events per hour while using CPAP
PAP Intolerance	PAP use for less than 4 h per night for 5 nights or more per week, or refusal to use CPAP. CPAP intolerance may be observed in patients with mild, moderate, or severe OSA

AHI: Apnea/Hypopnea Index; APAP: auto-adjusting positive airway pressure; Bi-PAP: Bi-level positive airway pressure; CPAP: continuous positive airway pressure; EEG: electroencephalogram; OSA: obstructive sleep apnea; PAP: positive airway pressure; RDI: Respiratory Disturbance Index; REI: Respiratory Event Index; RERA: respiratory event-related arousal

Summary of Evidence

For individuals who have obstructive sleep apnea (OSA) who receive laser-assisted uvulopalatoplasty (LAUP) the evidence includes a single randomized controlled trial randomized controlled trial (RCT). Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The trial indicates reductions in snoring, but limited efficacy on the Apnea/Hypopnea Index (AHI) or symptoms in patients with mild-to-moderate OSA. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have OSA who receive a radiofrequency volumetric reduction of palatal tissues and base of tongue, the evidence includes 2 sham-controlled randomized trials and a prospective, single-arm cohort study. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Single-stage radiofrequency to palatal tissues did not improve outcomes compared to sham. Multiple sessions of radiofrequency to the palate and base of tongue did not significantly (statistically or clinically) improve AHI, and the improvement in functional outcomes were not clinically significant. The prospective cohort study included 56 patients with mild-to-moderate OSA who received 3 sessions of office-based multilevel RFA. Results demonstrated improvement in AHI and Oxygen Desaturation

Index (ODI) at the 6-month follow up. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have OSA who receive palatal stiffening procedures, the evidence includes 2 sham-controlled randomized trials and several case studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The 2 RCTs differed in their inclusion criteria, with the study that excluded patients with Friedman tongue position of IV and palate of 3.5 cm or longer reporting greater improvement in AHI (45% success) and snoring (change of -4.7 on a 10-point visual analog scale) than the second trial. Additional studies are needed to corroborate the results of the more successful trial and, if successful, define the appropriate selection criteria. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have OSA who receive tongue base suspension, the evidence includes a feasibility RCT with 17 patients. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The single RCT compared tongue suspension plus uvulopalatopharyngoplasty with tongue advancement plus uvulopalatopharyngoplasty (UPPP) and showed success rates of 50% to 57% for both procedures. Additional RCTs with a larger number of subjects are needed to determine whether tongue suspension alone or added to uvulopalatopharyngoplasty improves the net health outcome. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have OSA who receive hypoglossal nerve stimulation, they are currently 2 FDA-approved HNS devices for the treatment of OSA: the Inspire Upper Airway Stimulation (UAS) system and the Genio system. The evidence on the Inspire device for the treatment of OSA includes systematic reviews, 3 RCTs, nonrandomized prospective studies, nonrandomized studies with historical controls, and prospective single-arm studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. A double-blind, multicenter RCT of 89 adults with moderate-to-severe OSA who did not tolerate continuous positive airway pressure (CPAP) found significant short-term improvement in the apnea/hypopnea index (AHI), Epworth Sleepiness Score (ESS), and quality of life measures with hypoglossal nerve stimulation (HNS) compared to sham stimulation. The study was limited by a short duration of follow-up and lack of diversity among included participants. Another RCT including 138 patients with moderate-to-severe OSA who did not tolerate CPAP compared outcomes for patients who received HNS therapy at 1 or 4 months after implant for the treatment and control groups, respectively. Results demonstrated significant short-term improvement in AHI and ODI when comparing HNS to no HNS at month 4. However, after 11 months of active therapy, the difference between the treatment and control groups was not statistically significant for AHI but remained significant for ODI in favor of the treatment group. This trial was also limited by a lack of diverse individuals, as well as a lack of a true control group for long-term outcomes. Hypoglossal nerve stimulation has shown success rates for about two-thirds of a subset of patients who met selection criteria that included AHI, BMI (≤ 32 or ≤ 35 kg/m²), and favorable pattern of palatal collapse across nonrandomized trials. These results were maintained out to 5 years in the pivotal single-arm study. The single prospective comparative study of patients who received HNS versus patients who were denied insurance coverage for the procedure has a high potential for performance bias. For children and adolescents with OSA and Down Syndrome who are unable to tolerate CPAP, the evidence includes a systematic review and a prospective study of 42 individuals. The systematic review

investigated HNS in adolescents with Down Syndrome and OSA and demonstrated significant improvement in AHI and OSA-18 survey scores after HNS. The study of 42 individuals with Down Syndrome and OSA found a success rate of 73.2% with 4 device extrusions corrected with replacement surgery. For the Inspire device, the evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

The evidence on the Genio device is limited to results of a nonrandomized clinical trial. This study enrolled 113 individuals across 21 centers (including 16 U.S. locations), with coprimary endpoints focused on reducing the AHI and ODI at 12 months. Serious adverse events occurred in 9% of individuals, with only a small proportion attributed directly to the device or procedure. Of the individuals who completed the study, 63% met the AHI reduction endpoint and 71% achieved the ODI reduction. Secondary outcomes showed significant improvements in mean AHI, ODI, nocturnal oxygen saturation, and patient-reported sleep quality measures. Limitations of the current evidence-base preclude determination of who is most likely to benefit from this minimally invasive procedure. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Rationale

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to individuals and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms. The following is a summary of the key literature to date.

The purpose of minimally invasive surgery in individuals who have OSA is to provide a treatment option that is an alternative to or an improvement on existing therapies.

Table 2. Minimally Invasive Surgical Interventions for Obstructive Sleep Apnea

Interventions	Devices	Description	Key Features	Indications
LAUP	Various	Superficial palatal tissues are sequentially reshaped over 3 to 7 sessions using a carbon dioxide laser	- Part of the uvula and associated soft-palate tissues are reshaped - Does not alter tonsils or lateral pharyngeal wall tissues - Tissue ablation can be titrated	Snoring with or without OSA
RF volumetric reduction of palatal tissues and base of tongue	Somnoplasty	Radiofrequency is used to produce thermal lesions within the tissues	- Similar to LAUP - Can include soft palate and base of tongue	Simple snoring and base of tongue OSA
Palatal Implant	Pillar Palatal Implant	Braided polyester filaments that are	Up to 5 implants may be used	Snoring

		implanted submucosally in the soft palate		
Tongue base suspension	AIRvance Encore	A suture is passed through the tongue and fixated with a screw to the inner side of the mandible, below the tooth roots	The aim of the suspension is to make it less likely for the base of the tongue to prolapse during sleep	Snoring and/or OSA
Hypoglossal nerve stimulation (HNS)	Inspire II Upper Airway Stimulation	Stimulation of the hypoglossal nerve which contracts the tongue and some palatal tissue	The device includes an implanted stimulator and a sensor implanted in the ribs to detect respiration.	A subset of patients with moderate-to-severe OSA who have failed or cannot tolerate CPAP (see Regulatory Status section)

CPAP: positive airway pressure; LAUP: laser-assisted uvulopalatoplasty; OSA: obstructive sleep apnea; RF: radiofrequency.

Established surgical procedures are associated with adverse effects such as dysphagia. In addition, the surgical procedures are irreversible should an adverse effect occur. Therefore, an improvement in effectiveness and/or a decrease in adverse events compared to standard surgical procedures would be the most important outcomes.

The outcomes of interest are a decrease in Apnea/Hypopnea Index (AHI) and Oxygen Desaturation Index on polysomnography (PSG) and improvement in a measure of sleepiness such as the Epworth Sleepiness Scale (ESS) or Functional Outcomes of Sleep (FOSQ) (see Table 3).

Table 3. Health Outcome Measures Relevant to Obstructive Sleep Apnea

Outcome	Measure (Units)	Description	Clinically Meaningful Difference (If Known)
Change in AHI	AHI	Mean change in AHI from baseline to post-treatment	Change from severe to moderate or mild OSA
AHI Success	Percentage of patients achieving success.	Studies may use different definitions of success; the most common definition of AHI success is the Sher criteria	Sher criteria is a decrease in AHI $\geq 50\%$ and an AHI < 20 Alternative measures of success may be AHI < 15 , < 10 , or < 5
Oxygen Desaturation Index	Oxygen levels in blood during sleep	The number of times per hour of sleep that the blood oxygen level drops by ≥ 4 percentage points	More than 5 events per hour
Snoring	10-point visual analog score	Filled out by the bed partner to assess snoring intensity or frequency	There is no standard for a good outcome. Studies have used 50% decrease in VAS ⁵ or final VAS of < 5 or < 3 ⁶ .
Epworth Sleepiness Score (ESS)	Scale from 0 to 24	The ESS is a short, self-administered questionnaire that asks patients how likely they are to fall asleep in 8 different situations such as watching TV, sitting quietly in a car, or sitting and talking to someone	An ESS of ≥ 10 is considered excessively sleepy. The MCID has been estimated at -2 to -3. ⁴
Functional Outcomes of Sleep Questionnaire	30 questions	Disease-specific quality of life questionnaire that evaluates functional status related to excessive sleepiness	A score of ≥ 18 is the threshold for normal sleep-related functioning, and a change of ≥ 2 points is considered to be a clinically meaningful improvement

OSA-18	18 item surveys graded from 1 to 7	Validated survey to assess quality of life in child	Change score of 0.5 to 0.9 is a small change, 1.0 to 1.4 a moderate change, and 1.5 a large change
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AHI: Apnea/Hypopnea Index; MCID: minimum clinically import difference; VAS: visual analog score.

Laser-Assisted Uvulopalatoplasty

LAUP is proposed as a treatment of snoring with or without associated OSA. LAUP cannot be considered an equivalent procedure to the standard UPPP, with the laser simply representing a surgical tool that the physician may opt to use. LAUP is considered a unique procedure, which raises its own issues of safety and, in particular, effectiveness.

One RTC (Ferguson et al [2003]) on LAUP has been identified.⁸ This study compared LAUP with no treatment, finding treatment success (AHI <10) to be similar between LAUP (24%) and no treatment controls (17%) (see Tables 4 and 5). The primary benefit of LAUP was on snoring as rated by the bed partner. Subjective improvements in ESS and quality of life were not greater in the LAUP group in this non-blinded study (see Tables 6 and 7). Adverse effects of the treatment included moderate-to-severe pain and bleeding in the first week and difficulty swallowing at follow-up.

Table 4. Summary of Key Randomized Controlled Trial Characteristics

Study	Countries	Sites	Participants	Interventions ¹	
Ferguson et al (2003)	Canada	1	46 patients with mild-to-moderate symptomatic OSA (AHI of 10 to 25) and loud snoring	<i>Active</i> 21 patients treated with LAUP every 1-2 mo ¹	<i>Comparator</i> 25 patients received no treatment

AHI: Apnea/Hypopnea Index; LAUP: laser-assisted uvulopalatoplasty.

¹ The LAUP procedure was repeated at 1- to 2-month intervals until either the snoring was significantly reduced, no more tissue could safely be removed, or the patient refused further procedures. There was a mean of 2.4 procedures (range, 1-4).

Table 5. Summary of Key Randomized Controlled Trial Results

Study	Treatment Success (AHI <10)	Change in Snoring (10- point VAS)	Change in ESS	Change in SAQLI Quality of Life	Moderate-to-Severe Pain in First Week	Bleeding in First Week	Difficulty Swallowing at Follow-up
Ferguson et al (2003)							
N	45	45	45	45	45	45	45
LAUP	24%	-4.4	-1.4	+0.4	81%	19%	19%
No treatment	17%	-0.4	+0.8	+0.2			
p	NR	<0.001	NS	NS			

AHI: Apnea/Hypopnea Index; ESS: Epworth Sleepiness Scale (maximum of 24); LAUP: laser-assisted uvulopalatoplasty; NS: not significant; NR: not reported; SAQLI: Sleep Apnea Quality of Life Index (maximum of 7); VAS: visual analog scale.

Study limitations are described in Tables 6 and 7. The major flaw is the uncertain clinical significance of the outcome measure.

Table 6. Relevance Limitations

Study	Population ^a	Intervention ^b	Comparator ^c	Outcomes ^d	Follow-Up ^e
Ferguson et al (2003)	1. Entry criteria includes populations with mild OSA (AHI between 10 and 15)		3. Controls had no treatment	6. The definition of success (AHI <10) combined with the eligibility criteria (AHI	

for whom an improvement to AHI <10 is not clinically significant	>10) can lead to clinically insignificant improvements being labeled success
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The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment. AHI: Apnea/Hypopnea Index; OSA: obstructive sleep apnea.

^a Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.

^b Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.

^c Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.

^d Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.

^e Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 7. Study Design and Conduct Limitations

Study	Allocation ^a	Blinding ^b	Selective Reporting ^c	Data Completeness ^d	Power ^e	Statistical ^f
Ferguson et al (2003)		1.-3. No blinding				4. Comparison of primary outcome not reported

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^a Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.

^b Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.

^c Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.

^d Follow-Up key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).

^e Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.

^f Statistical key: 1. Intervention is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Intervention is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Section Summary: Laser-Assisted Uvulopalatoplasty

A single RCT has been identified on LAUP for the treatment of mild-to-moderate OSA. LAUP improved snoring as reported by the bed partner but did not improve treatment success in terms of AHI when compared to no treatment controls. Patients in this non-blinded study did not report an improvement in ESS or QOL after LAUP.

Radiofrequency Volumetric Reduction of Palatal Tissues and Base of Tongue

RF is used to produce thermal lesions within the tissues rather than using a laser to ablate the tissue surface. In some situations, RF of the soft palate and base of tongue are performed together as a multilevel procedure.

The analysis of RF volumetric tissue reduction was informed by a TEC Assessment (2000) that evaluated 4 primary studies on palatal radiofrequency ablation (RFA) and 1 study on tongue base RFA.⁹ All studies were nonrandomized.

Review of Evidence

Randomized Controlled Trials

Two RCTs have subsequently been identified on RF volumetric reduction of the palate and tongue. One of the trials (Back et al [2009]) gave a single RF treatment to palatal tissues and found no statistical difference in scores on the AHI, VAS for snoring, ESS, or FOSQ between

RF and sham (see Tables 8-10).¹⁰ The second trial (Woodson et al [2003]), provided a mean of 4.8 sessions of RF to the tongue and palate. This trial found a statistically significant improvement from baseline to post-treatment for ESS and FOSQ.¹¹ However, the improvement in FOSQ score (1.2; standard deviation, 1.6) was below the threshold of 2.0 for clinical significance and the final mean score in ESS was 9.8, just below the threshold for excessive sleepiness. AHI decreased by 4.5 events per hour, which was not statistically or clinically significant. The statistical significance of between-group differences was not reported (see Tables 9 and 11).

Table 8. Summary of Key Randomized Controlled Trial Characteristics

Study	Countries	Sites	Participants	Interventions	
				Active	Comparator
Back et al (2009)	Finland	1	32 patients with symptomatic mild OSA and habitual snoring with only velopharyngeal obstruction	Single-stage RF to palatal tissues	Sham control with local anesthetic and multiple insertions of an applicator needle without the RF
Woodson et al (2003)	U.S.	2	90 patients with symptomatic mild-to-moderate OSA, randomized to RF, sham, or CPAP	30 subjects received up to 7 sessions (mean, 4.8) of RF to tongue base and palate	30 subjects received sham procedure to tongue for 3 sessions, including local anesthetic and multiple insertions of an applicator needle without the RF

CPAP: continuous positive airway pressure; OSA: obstructive sleep apnea; RF: radiofrequency.

Table 9. Summary of Key Randomized Controlled Trial Results

Study	AHI	Snoring	ESS	Function	Adverse Events
	Median (Range)	Snoring Median (Range)	Median (Range)	Compound End Point Score ^a Median (Range)	
Back et al (2009)					
N	32	30	32	32	32
RF	13.0 (2.0-26.0)	5.0 (2.0-8.0)	7.0 (0-20.0)	6 (3-9)	
Sham	11.0 (1.0-29.0)	6.0 (3.0-8.0)	5.0 (2.0-15.0)	7 (4-10)	
p	.628	.064	.941	.746	No significant differences after 6 d
	Change Score (SD)		Change Score (SD)	FOSQ Score (SD)	
Woodson et al (2003)					
N	52		54	54	54
RF	-4.5 (13.8)		-2.1 (3.9) ^b	1.2 (1.6) ^b	
Sham	-1.8 (11.5)		-1.0 (3.1)	0.4 (2.0)	
Effect size	0.34		0.50	0.66	No significant differences after 1 wk

AHI: Apnea/Hypopnea Index; ESS: Epworth Sleepiness Scale (maximum of 24); FOSQ: Functional Outcomes of Sleep Questionnaire; MCS: Mental Component Summary score; PCS: Physical Component Summary score; SD: standard deviation; SF-36: 36-Item Short-Form Health Survey.

^a The compound end point scored added points derived from AHI, ESS, SF-36 PCS, and SF-36 MCS;

^b p=.005 for baseline to posttreatment.

^c Effect size=post-treatment mean - baseline mean.

Tables 10 and 11 display notable limitations identified in each study.

Table 10. Relevance Limitations

Study	Population ^a	Intervention ^b	Comparator ^c	Outcomes ^d	Follow-Up ^e
Back et al (2009)	4. Included patients with mild OSA and snoring	4. Single treatment with RFA			
Woodson et al (2003)					

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment. OSA: obstructive sleep apnea; RFA: radiofrequency ablation.

^a Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.

^b Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.

^c Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.

^d Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.

^e Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 11. Study Design and Conduct Limitations

Study	Allocation ^a	Blinding ^b	Selective Reporting ^c	Data Completeness ^d	Power ^e	Statistical ^f
Back et al (2009)		2. Surgeons also performed follow-up assessments				.
Woodson et al (2003)						3. Comparative treatment effects not reported

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^a Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.

^b Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.

^c Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.

^d Follow-Up key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).

^e Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.

^f Statistical key: 1. Intervention is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Intervention is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Observational Studies

Herman et al (2023) published a prospective, open-label, single-arm, nonrandomized trial that investigated multilevel RFA as an alternative therapy for patients with mild-to-moderate OSA (AHI 10 to 30) with intolerance or inadequate adherence to CPAP.¹² Patients were treated with 3 sessions of office-based RFA to the soft palate and tongue base. Of the 56 patients recruited for the study, 43 completed the protocol. Overall, 22/43 (51%) were considered complete responders with a $\geq 50\%$ reduction in baseline AHI and an overall AHI < 20 at study completion. A statistically significant reduction in mean and median AHI was observed at 6 months follow-up ($p=.001$ for both); the mean AHI decreased from 19.7 to 9.86 and the median AHI decreased from 17.8 to 7.5. Likewise, ODI scores were significantly reduced at 6 months follow-up; the mean ODI score decreased from 12.79 to 8.36 ($p=.006$) and the median ODI score decreased from 11.65 to 6.23 ($p=.008$).

Section Summary: Radiofrequency Volumetric Reduction of Palatal Tissues and Base of Tongue

The evidence on radiofrequency volume reduction includes 2 randomized trials, both sham controlled, and a prospective, single-arm cohort study. Single-stage RF to palatal tissues did not improve outcomes compared to sham. Multiple sessions of RF to the palate and base of tongue did not significantly (statistically or clinically) improve AHI, while the improvement in functional outcomes did not achieve a level of clinical significance. The prospective cohort study included 56 patients with mild-to-moderate OSA who received 3 sessions of office-based multilevel RFA. Results demonstrated improvement in AHI and Oxygen Desaturation Index (ODI) at the 6-month follow up.

Palatal Stiffening Procedures

Palatal stiffening procedures include insertion of palatal implants, injection of a sclerosing agent (snoreplasty), or a cautery-assisted palatal stiffening operation. Snoreplasty and cautery-assisted palatal stiffening operations are intended for snoring and are not discussed here. Palatal implants are cylindrically shaped devices that are implanted in the soft palate.

Review of Evidence

Randomized Controlled Trials

Two double-blind sham-controlled randomized trials with over 50 patients have evaluated the efficacy of palatal implants to improve snoring and OSA (see Table 12). AHI success by the Sher criteria ranged from 26% to 45% at 3-month follow-up. AHI success was observed in 0% to 10% of the sham control patients (see Table 13). In 1 study (Steward et al [2008]), the statistical significance of AHI success was marginal and there was no statistical difference in snoring or change in ESS between the 2 groups.¹³ In the study by Friedman et al (2008), there was greater success in AHI (45% vs 0%, $p<.001$), improvement in snoring (-4.7 vs -0.7 on a 10-point VAS, $p<.001$), and improvement in ESS (-2.4 vs -0.5, $p<.001$) with palatal implants compared with sham controls.⁵ Patient selection criteria were different in the 2 studies. In Friedman et al (2008), patients with a Friedman tongue position of IV and palate of 3.5 cm or longer were excluded. In the trial by Steward et al (2008), selection criteria included patients with *primarily* retropalatal pharyngeal obstruction.

Table 12. Summary of Key Randomized Controlled Trial Characteristics

Study	Countries	Sites	Participants	Interventions	
				Active	Comparator
Steward et al (2008)	U.S.	3	100 patients with mild-to-moderate OSA (AHI ≥ 5 and ≤ 40), and primarily retropalatal pharyngeal obstruction, BMI ≤ 32 kg/m ²	50 received the office-based insertion of 3 palatal implants	50 received the sham procedure
Friedman et al (2008)	U.S.	1	62 patients with mild-to-moderate OSA (AHI ≥ 5 and ≤ 40), soft palate ≥ 2 cm and < 3.5 cm, Friedman tongue position I, II, or III, BMI ≤ 32 kg/m ²	31 received the office-based insertion of 3 palatal implants	31 received the sham procedure

AHI: Apnea/Hypopnea Index, BMI: body mass index; OSA: obstructive sleep apnea.

Table 13. Summary of Key Randomized Controlled Trial Results

Study	AHI Success (Sher criteria)	Snoring (10-point VAS)	Change in ESS (95% CI) or (SD)	Change in FOSQ Score (95% CI)	Foreign Body Sensation/Extrusion
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Steward et al (2008)					
N	97	43	96	98	100
Palatal implants	26%	6.7	-1.8 (-0.8 to -2.9)	1.43 (0.84 to 2.03)	18%/4 extruded
Sham control	10%	7.0	-1.5 (-.04 to -2.5)	0.6 (0.01 to 1.20)	2%
p	.04	.052	NS	.05	
Friedman et al (2008) Change in VAS					
N	55	62	62		
Palatal implants (SD)	44.8%	-4.7 (2.1)	-2.4 (2.2)		2 extruded
Sham control (SD)	0%	-0.7 (0.9)	-0.5 (1.5)		
MD (95% CI)		4.0 (3.2 to 4.9)	1.9 (1.0 to 2.9)		
p	<0.001	< 0.001	<0.001		
Summary: Range	26%-44.8%				

CI: confidence interval; ESS: Epworth Sleepiness Score; MD: mean difference; NS: not significant; RCT: randomized controlled trial; RR: relative risk; SD: standard deviation; VAS: visual analog scale.

Case Series

Uncontrolled series have provided longer follow-up data on patients treated with palatal implants. Using criteria of 50% improvement in AHI and final AHI of less than 10 events hour, Neruntarat et al (2011) reported a success rate of 52% at a minimum of 24 months (see Tables 14 and 15).¹⁴ Compared with non-responders, responders had lower body mass index (BMI), lower baseline AHI and a lower percentage of patients with a modified Mallampati classification of III or IV (obscured visualization of the soft palate by the tongue). Tables 16 and 18 summarize the limitations of the studies described above.

Table 14. Summary of Key Case Series Characteristics

Study	Country	Participants	Follow-Up
Neruntarat et al (2011)	Thailand	92 patients with mild-to-moderate symptomatic OSA and palate >2 cm	Minimum 24 mo

OSA: obstructive sleep apnea.

Table 15. Summary of Key Case Series Results

Study	N	AHI (SD)	Snoring (SD) (10-point VAS)	ESS (SD)	Implant Extrusion
Neruntarat et al (2011)	92				
Baseline		21.7 (6.8)	8.2 (1.2)	12.3 (2.6)	
29 months		10.8 (4.8)	3.8 (2.3)	7.9 (1.8)	7 (7.6%)
p		<.001	<.001	<.001	

AHI: Apnea/Hypopnea Index; ESS: Epworth Sleepiness Score; SD: standard deviation; VAS: visual analog scale.

Table 16. Relevance Limitations

Study	Population ^a	Intervention ^b	Comparator ^c	Outcomes ^d	Follow-Up ^e
Neruntarat et al (2011)			2. No comparator		
Steward et al (2008)					1, 2, 3 mo
Friedman et al (2008)					1, 2, 3 mo

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^a Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.

^b Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.

^c Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.

^d Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.

^e Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 17. Study Design and Conduct Limitations

Study	Allocation ^a	Blinding ^b	Selective Reporting ^c	Data Completeness ^d	Power ^e	Statistical ^f
Neruntarat et al (2011)	Retrospective	None (case series)				
Steward et al (2008)						
Friedman et al (2008)						

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^a Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.

^b Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.

^c Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.

^d Follow-Up key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).

^e Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.

^f Statistical key: 1. Intervention is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Intervention is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Section Summary: Palatal Stiffening Procedures

Two sham-controlled trials and several case series have assessed palatal implants for the treatment of snoring and OSA. The sham-controlled studies differed in the inclusion criteria, with the study that excluded patients with Friedman tongue position of IV and palate of 3.5 cm or longer reporting greater improvement in AHI (45% success) and snoring (change of -4.7 on a 10-point VAS) than the second trial.

Tongue Base Suspension

In this procedure, the base of the tongue is suspended with a suture that is passed through the tongue and fixated with a screw to the inner side of the mandible, below the tooth roots. The aim of the suspension is to make it less likely for the base of the tongue to prolapse during sleep.

Review of Evidence

One preliminary RCT with 17 patients was identified that compared UPPP plus tongue suspension to UPPP plus tongue advancement (see Table 18).¹⁵ Success rates using the Sher criteria ranged from 50% to 57% (see Table 19). Both treatments improved snoring and reduced ESS to below 10. The major limitations of the study were the number of subjects (n=17) in this feasibility study and the lack of blinding (see Tables 20 and 21). In addition, there was no follow-up after 16 weeks.

Table 18. Summary of Key Randomized Controlled Trial Characteristics

Study	Countries	Sites	Participants	Interventions	Comparator
Thomas et al (2003)	U.S.	1	17 patients with moderate-to-severe	Active UPPP with tongue suspension Mean AHI=46 (n=9)	UPPP with tongue advancement

OSA who failed conservative treatment	Mean AHI=37.4 (n=8)
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AHI: Apnea/Hypopnea Index; OSA: obstructive sleep apnea; UPPP: uvulopalatopharyngoplasty.

Table 19. Summary of Key Randomized Controlled Trial Results

Study	AHI Success (Sher Criteria)	Snoring (SD)	ESS (SD)	Pain, Speech, Swallowing
Thomas et al (2003)				
N	11	17	17	17
UPPP plus tongue suspension	57%	3.3 (2.1)a	4.1 (3.4)b	
UPPP plus tongue advancement	50%	5.0 (0.6)c	5.4 (3.5)d	No significant differences between groups

AHI: Apnea/Hypopnea Index; ESS: Epworth Sleepiness Score; SD: standard deviation; UPPP: uvulopalatopharyngoplasty.

^a Baseline to posttreatment p=.02.

^b Baseline to posttreatment p=.007.

^c Baseline to posttreatment p=.04.

^d Baseline to posttreatment p=.004.

Table 20. Study Relevance Limitations

Study	Population ^a	Intervention ^b	Comparator ^c	Outcomes ^d	Follow-Up ^e
Thomas et al (2003)					1, 2. Follow-up was to 16 wk

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^a Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.

^b Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.

^c Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.

^d Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.

^e Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 21. Study Design and Conduct Limitations

Study	Allocation ^a	Blinding ^b	Selective Reporting ^c	Data Completeness ^d	Power ^e	Statistical ^f
Thomas et al (2003)	3. Allocation concealment unclear	1.-3. Not blinded			1. Feasibility study	4. Comparative treatment effects not calculated

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^a Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.

^b Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.

^c Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.

^d Follow-Up key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).

^e Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.

^f Statistical key: 1. Intervention is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Intervention is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Section Summary: Tongue Base Suspension

One feasibility study with 17 patients was identified on tongue suspension. This study compared tongue suspension plus UPPP to tongue advancement plus UPPP and reported 50% to 57% success rates for the two procedures. RCTs with a larger number of subjects are

needed to determine whether tongue suspension alone or added to UPPP improves the net health outcome.

Hypoglossal Nerve Stimulation

Stimulation of the hypoglossal nerve causes tongue protrusion and stiffening of the anterior pharyngeal wall, potentially decreasing apneic events. For individuals with moderate-to-severe sleep apnea who have failed or are intolerant of CPAP, the alternative would be an established surgical procedure, as described above.

Review of Evidence

Inspire Upper Airway Stimulation (UAS) System

Systematic Reviews

A summary of systematic reviews is included in Tables 22 and 23.

Costantino et al conducted a systematic review and meta-analysis of 6- to 60-month outcomes following HNS¹⁷ They identified 12 studies with a total of 350 patients (median BMI, 29.8 [IQR, 28.8 to 31.6 kg/m²] with OSA who were treated with the Inspire, ImThera, or Apnex HNS systems. Only the Inspire device has obtained FDA approval as of April 2021 and contributed the largest number of patients to the meta-analysis. In addition to the trials described below by Steffen et al (2015, 2018)^{18,19} and Strollo et al (Stimulation Therapy for Apnea Reduction [STAR] Trial, 2014, 2018),^{20,21} several other trials with the Inspire system were included in the meta-analysis. At 6 mo follow-up, the overall change in AHI was -17.74 with an improvement in ESS of -5.36. At 12 mo follow-up, the change in AHI was -17.50 with an improvement in ESS of -5.27. Sixty-month data were provided only by the STAR trial as reported by Woodson et al (2018) and are described below.²²

Kim et al (2023) compared HNS to other OSA treatments in a systematic review and meta-analysis.²³ A total of 10 studies with 2209 patients (mean BMI ≤ 30 kg/m² in every study) who were treated with HNS or alternative interventions were included. HNS improved post-treatment AHI <10 and <15 events/hour compared with other surgical options including uvulopalatopharyngoplasty, expansion sphincterpharyngoplasty, or tongue-based surgery (odds ratio [OR]; 5.33; 95% CI, 1.21 to 23.42). Other results are summarized in Table 23.

Table 22. Meta-analysis Characteristics

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Constantino et al (2020)	Through 2018	12	Adult patients with moderate to severe OSA	350 (8-124)	Cohort	6, 12, and 60 mo
Kim et al (2023)	Through March 2023	10	Adults with moderate to severe OSA with inadequate CPAP adherence	2209 (23-698)	RCT (n=2)/cohort (n=8)	NR

OSA: obstructive sleep apnea

Table 23. Meta-analysis Results

Study	AHI Change at 6 mo (95% CI)	AHI Change at 12 mo (95% CI)	ESS Change at 6 mo (95% CI)	ESS Change at 12 mo (95% CI)	AHI Success n
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					(%) Sher Criteria ^a
Constantino et al (2020)					
Total N	210	255	210	255	
Inspire	-17.74 (-24.73 to -10.74)	-17.50 (-20.01 to -14.98)	-5.36 (-6.64 to -4.08)	-5.27 (-6.18 to -4.35)	115 (70%)
ImThera	-9.50 (-19.14 to 0.14)	-24.20 (-37.39 to -11.01)	-3.70 (-5.65 to -1.75)	-2.90 (-6.97 to 1.17)	46 (35%)
Apnex	-24.20 (-30.94 to -17.45)	-20.10 (-29.62 to -10.58)	-3.87 (-5.53 to -2.21)	-4.20 (-6.30 to -2.10)	115 (59.8%)
<i>P</i> (p)	68% (.004)	0% (.77)	25% (.25)	27% (.24)	
Range of N	8 to 56	13 to 124	21 to 56	13 to 124	
Kim et al (2023)					
HNS vs all other airway surgeries	AHI MD (95% CI)	ESS MD (95% CI)	ODI (95% CI)		
HNS vs no treatment	-8.0 (95% CI, -12.0344 to -3.9656)	0.3968 (95% CI, -1.5231 to 2.3167)			
HNS vs CPAP	-12.8394 (95% CI, -16.1475 to -9.5312)	-5.3929 (95% CI, -6.6078 to -4.1781)	-11.8384 (95% CI, -17.4476 to -6.2292)		
	1.5000 (95% CI -1.0145 to 4.0145)	-1.8236 (95% CI, -4.5634 to 0.9163)			

AHI: Apnea/Hypopnea Index; CI: confidence interval; CPAP: continuous positive airway pressure; ESS: Epworth Sleepiness Score. HNS: hypoglossal nerve stimulation; MD: mean difference; ODI: oxygen desaturation index.

^aSurgical success according to Sher criteria is defined as a 50% reduction in AHI and overall AHI < 20.

Randomized Controlled Trials

Several RCTs have been identified on the effect of HNS in patients with OSA. Study characteristics and a summary of results are described in Tables 24 and 25, respectively.

Schwartz et al (2023) published results from the ImThera Medical Targeted Hypoglossal Neurostimulation Study #3 (THN3), which investigated the efficacy and safety of targeted HNS of the proximal hypoglossal nerve in patients with moderate-to-severe OSA (AHI 20-60 events per hour) and a BMI of 35 kg/m² or less.²⁴ This was a multicenter, randomized trial where all patients (N=138) were implanted with the HNS system (aura6000; ImThera Medical), and randomly assigned 2:1 to HNS device activation at 1 or 4 months after implant for the treatment and control groups, respectively. Efficacy was measured at month 4, as well as after 11 months of therapy (study months 12 and 15 for treatment and control groups, respectively). The study included mostly males (86.2%) and White individuals (91.3%). The results demonstrated that at month 4, the treatment group had significantly better outcomes compared to the control group for AHI and ODI scores. However, after 11 months of active therapy, the difference between the treatment and control groups was not statistically significant for AHI (RR, -7.5; 95% CI, -16 to 1.4) but remained significant for ODI (RR, 10.4; 95% CI, 1.6 to 18.8). The authors noted that the results should only be applied to patients with moderate-to-severe OSA and a BMI of 35 kg/m² or less.

Heiser et al (2021) conducted The Effect of Upper Airway Stimulation in Patients With Obstructive Sleep Apnea (EFFECT) trial, a multicenter, randomized, double-blind, crossover design study in adult patients with moderate-to-severe OSA (defined as AHI ≥ 15) who were intolerant to CPAP.²⁵ All individuals included in the study were White. All patients received implantation of HNS device (Inspire Medical Solutions) at least 6 months prior to enrollment. Baseline AHI before implantation was 32.2 events/h; after implantation, baseline AHI was approximately 8.3 events/h. All participants received therapeutic stimulation during the

baseline visit. Patients were then randomized to 1 of 2 treatment groups: HNS-Sham (n=45) or Sham-HNS (n=44). After randomization, the HNS-Sham group received therapeutic stimulation, and the Sham-HNS received sham stimulation for 1 week. During the second week, the HNS-Sham group received sham stimulation while the Sham-HNS group received therapeutic stimulation. Changes in AHI over time showed a statistically significant decrease in AHI with stimulation compared to sham stimulation during the baseline, week 1, and week 2 visits. This meant that during week 1 when the HNS-Sham group received stimulation, they had significantly lower AHI; during week 2, when the Sham-HNS group received stimulation, they had significantly lower AHI. Similarly, participants reported a lower ESS with stimulation compared to sham stimulation during all visits. The change of AHI and ESS from baseline to the 1-week and 2-week visits was analyzed between the groups and investigators found no evidence of a carryover effect for AHI or ESS.

Dedhia et al (2024) conducted a double-blind, randomized, crossover study comparing cardiovascular outcomes in patients (N=60) with severe OSA who had an HNS device implanted.²⁶ Patients were randomized to a 4-week period of active HNS and a 4-week period of sham HNS. The primary endpoint was mean 24-hour systolic blood pressure. In patients with a BMI of 30 kg/m² or more, the decrease in SBP (+0.5 mmHg vs. -0.64 mmHg) and DBP (-0.17 mmHg vs. -0.25 mmHg) measurements were numerically smaller than those who had a lower BMI; however, the clinical importance of this is unclear).

Table 24. Summary of Key RCT Characteristics

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Schwartz et al (2023) THN3	US, Belgium, Israel, Germany, France, Portugal	20	2015-2018	Adults with moderate-to-severe OSA (AHI 20 to 65 events/hr), intolerant to CPAP; 91.3% of participants were White; mean BMI, 29.84 kg/m ² (SD, 3.03)	HNS (aura6000 device) starting at 1 month post implant with follow up at 12 months (n=92)	HNS (aura6000 device) starting at 4 months post implant with follow up at 15 months (n=46)
Heiser et al (2021); EFFECT	Germany	3	2018-2019	Adults with moderate-to-severe OSA (AHI ≥15), intolerant to CPAP; 100% of participants were White; mean BMI, 29.2 kg/m ² (SD, 4.4)	HNS (Inspire device) for week 1 followed by crossover to sham in week 2 (n=45)	Sham stimulation for week 1 followed by crossover to HNS (Inspire device) in week 2 (n=44)

Dedhia et al (2024) CARDIOSA-12	US	3	2018-2022	Adults with severe OSA who had an HNS device; mean BMI, 28.7 kg/m ² (SD, 4.6)	HNS (Inspire device) for 4 weeks before crossover (n=29 received active treatment first)	Sham for 4 weeks (n=31 received sham first)
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AHI: Apnea/Hypopnea Index; CPAP: continuous positive airway pressure; HNS: hypoglossal nerve stimulation; OSA: obstructive sleep apnea; RCT: randomized controlled trial.

Table 25. Summary of Key RCT Results

Study	AHI response at month 4 (≥50% reduction to 20 or fewer events/hr)	ODI response at month 4 (≥25% reduction)	
Schwartz et al (2023) THN3	N=138	N=138	
HNS therapy starting at 1 month post implant (treatment)	72/138 (52.3%)	86/138 (62.5%)	
HNS therapy starting at 4 months post implant (control)	27/138 (19.6%)	57/138 (41.3%)	
RR (95% CI)	32.7 (15.2 to 49.0)	21.2 (3.3 to 38.1)	
	AHI response after 1 week (AHI ≤15 events/h)	Change in ESS after 1 week	Overall change from baseline in FOSQ across treatment modalities
Heiser et al (2021);²⁴ EFFECT	N=89	N=89	N=86
HNS	73.3%	0.4 ± 2.3	0.2 (-0.5 to 0.9)
Sham	29.5%	5.0 ± 4.6	-1.9 (-2.6 to -1.2)
Difference (95% CI)	43.8% (25.1 to 62.5)	4.6 (3.1 to 6.1)	2.1 (1.4 to 2.8)
p-value	<.001	.001	<.001
AHI events per hour (SD)	24 hour SBP, mean (SD)	24 hour DBP, mean (SD)	
Dedhia et al (2024);²⁶ CARDIOSA-12			
HNS	18.1 (14.8)	122.8 mmHg (11.8)	71.9 mmHg (7.8)
Sham	23.0 (15.6)	123.0 mmHg (10.8)	72.1 mmHg (7.0)
Difference (95% CI)	-4.9 (-8.8 to -1.0)	-0.18 (-2.21 to 1.84)	-0.22 (-1.27 to 0.83)
p-value	NR	NR	NR

AHI: Apnea/Hypopnea Index; CI: confidence interval; ESS: Epworth Sleepiness Scale; FOSQ: Functional Outcomes of Sleep Questionnaire; HNS: hypoglossal nerve stimulation; HR: hazard ratio; NNT: number needed to treat; ODI: oxygen desaturation index; OR: odds ratio; RCT: randomized controlled trial; RR: relative risk.

Notable study limitations are described in Tables 26 and 27.

Table 26. Study Relevance Limitations

Study	Population ^a	Intervention ^b	Comparator ^c	Outcomes ^d	Duration of Follow-up ^e
Schwartz et al (2023) THN3	4. Study population was predominantly male and exclusively White		2. Both groups received treatment but at different starting points		
Heiser et al (2021); EFFECT	4. Study population was predominantly male and exclusively White				1., 2. Limited follow-up period precluded long-term evaluation of safety and efficacy
Dedhia et al (2024); CARDIOSA-12	4. Study population was predominantly male and White			1. Primary outcomes were cardiovascular focused	1. Total duration of 10 weeks

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment. ^a Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4. Enrolled populations do not reflect relevant diversity; 5. Other. ^b Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5. Other. ^c Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other. ^d Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other. ^e Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 27. Study Design and Conduct Limitations

Study	Allocation ^a	Blinding ^b	Selective Reporting ^c	Data Completeness ^d	Power ^e	Statistical ^f
Schwartz et al (2023)		1. Open-label trial				
Heiser et al (2021); EFFECT		4. Most participants randomized to sham stimulation became aware of the group allocation, possibly impacting subjective outcomes				
Dedhia et al (2024); CARDIOSA-12						

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment. ^a Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias; 5. Other. ^b Blinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other. ^c Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other. ^d Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials); 7. Other. ^e Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other. ^f Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated; 5. Other.

Comparative Studies

Study characteristics and results are described in Tables 28 and 29. Limitations in relevance and design and conduct, including comparative studies and 2 single-arm studies, are described in Tables 30 and 31.

Besides the RCT described above, comparative evidence consists of 3 studies that compared HNS (using the Inspire device) to historical controls treated with UPPP or a variant of UPPP (expansion sphincter pharyngoplasty) and a study that compared HNS groups with transoral robotic surgery. AHI success by the Sher criteria ranged from 87% to 100% in the HNS group compared to 40% to 64% in the UPPP groups. Posttreatment ESS was below 10 in both groups. It is not clear from these studies whether the patients in the historical control group were similar to the subset of patients in the HNS group, particularly in regard to the pattern of palatal collapse and from patients who did not return for postoperative PSG.

Several comparative studies have addressed these concerns by only including patients who meet the criteria for HNS in the control group. Yu et al (2019) compared outcomes for patients who met the criteria for both HNS (non-concentric collapse on drug-induced sleep endoscopy) and transoral robotic surgery (retroglossal obstruction).²⁷ When patients with similar anatomic criteria were compared, HNS led to significantly better improvements in AHI, cure rate (defined as AHI < 5), and the percentage of time that oxygen saturation fell below 90%. Huntley et al (2021) selected patients in the control group who met criteria for HNS (non-concentric collapse on drug-induced sleep endoscopy and BMI criteria) but had been treated at their institutions by single or multi-level palatal and lingual surgery.²⁸ There was no explanation of why the different treatments were given during the overlap period of 2010 to 2019, but the HNS patients were older and heavier. HNS resulted in a modestly greater decrease in AHI (HNS: -21.4 vs -15.9, $p < .001$), but not in ESS (HNS: -4.7 vs -5.8, $p = .06$). More patients in the HNS group achieved success by the Sher criteria (70% vs 48 to 49%) suggesting that there might be a clinical benefit for some patients.

Another report from Adherence and Outcome of Upper Airway Stimulation for OSA International Registry (ADHERE) registry investigators (Mehra et al, 2020) compared outcomes from HNS patients with patients who met criteria but had been denied insurance coverage.²⁹ In a post-hoc multivariate analysis, previous use of PAP and prior surgical procedures were predictors of insurance approval. In the group of patients who received HNS, the average use downloaded from the device was 5.6 h/night and 92% of patients had usage greater than 20 h/week. A majority of the comparator group (86%) were not using any therapy at follow-up. The remaining 14% were using PAP, an oral appliance, or underwent OSA surgery. The AHI decreased to 15 events/h (moderate OSA) on the night of the sleep test in patients with HNS, with only modest improvement in patients who did not receive HNS. The hours of use on the night of the post-operative sleep study were not reported, and the HNS patients may have been more likely to use their device on the test night. In addition, the use of a home sleep test for follow-up may underestimate the AHI. The ESS improved in the HNS group but worsened in the controls. This suggests the possibility of bias in this subjective measure in patients who were denied coverage.

Additional non-comparative reports from the ADHERE registry are described below.

Table 28. Summary of Observational Comparative Study Characteristics

Study	Study Type	Country	Dates	Participants	HNS	Traditional Surgery	Follow-Up
Shah et al (2018)	Retrospective series with historical controls	U.S.	HNS 2015-2016 UPPP 2003-2012	40 OSA patients with AHI >20 and <65, BMI ≤32 kg mg/m ² , failed CPAP, favorable pattern of palatal collapse ^a	35% had previously had surgery for OSA	UPPP 50% of patients had additional surgical procedures	2-13 mo
Huntley et al (2018)	Retrospective series with historical controls	U.S.	HNS 2014-2016 Modified UPPP 2011-2016	Retrospective review included treated patients who had a postoperative PSG	75 patients age 61.67 y with a favorable pattern of palatal collapse	33 patients age 43.48 y treated by ESP	To post-operative PSG
Yu et al (2019)	Retrospective series with historical controls	U.S.	HNS 2014-2016 TORS 2011-NR	OSA patients with AHI >20 and <65, BMI ≤32 kg mg/m ² , failed CPAP, favorable pattern of palatal collapse ^a	27 patients age 62 with retroglossal collapse amenable to TORS	20 patients age 53 y who would have qualified for HNS and were treated by TORS	NR
Huntley et al (2020)	ADHERE registry compared to retrospective controls	US, EU	• HNS 2010- 2019 • Modified UPPP 2003-2019	OSA patients who were intolerant to CPAP and met HNS criteria of AHI 15 to 65, BMI < 35, and favorable pattern of palatal collapse ^a	465 registry patients treated with HNS who had 12 mo follow-up	233 patients who would have qualified for HNS and were treated by single level (68%) or multilevel (31%) surgery	173 days after surgery 383 days after HNS
Mehra et al (2020)	ADHERE registry	US, EU	2017-2019	OSA patients who were intolerant to CPAP and met HNS criteria of AHI 15 to 65, BMI < 35, and favorable pattern of palatal collapse ^a	250 registry patients treated with HNS	100 patients who qualified for HNS but were denied insurance coverage	6 to 24 months

AHI: Apnea/Hypopnea Index; BMI: body mass index; CPAP: continuous positive airway pressure; ESP: expansion sphincter pharyngoplasty; HNS: hypoglossal nerve stimulation; OSA: obstructive sleep apnea; PSG: polysomnography; UPPP: uvulopalatopharyngoplasty.

^a A favorable pattern of palatal collapse is not concentric retropalatal obstruction on drug-induced sleep endoscopy.

Table 29. Summary of Key Observational Comparative Study Results

Study	Baseline AHI (SD)	Posttreatment AHI (SD)	AHI Success (%) Sher Criteria	Baseline ESS (SD)	Posttreatment ESS (SD)
Shah et al (2018)					
HNS	38.9 (12.5)	4.5 (4.8) ^b	20 (100%)	13 (4.7)	8 (5.0) ^b
UPPP	40.3 (12.4)	28.8 (25.4) ^a	8 (40%)	11 (4.9)	7 (3.4) ^b
Huntley et al (2018)					

HNS	36.8 (20.7)	7.3 (11.2)	86.7	11.2 (4.2)	5.4 (3.4)
ESP	26.7 (20.3)	13.5 (19.0)	63.6	10.7 (4.5)	7.0 (6.0)
p	.003	.003	.008	.565	NS
Yu et al (2018)		Average AHI Reduction	% Cure Rate	Change in SaO ₂ <90%	
HNS		33.3	70.4%	14.1	
TORS		12.7	10.0%	1.3	
p-value		0.002	<0.001	0.02	
Huntley et al (2020)					
HNS	35.5 (15.0)	14.1 (14.4)	70	11.9 (5.5)	7.3 (4.7)
Single or multi-level UPPP	35.0 (13.1)	19.3 (16.3)	48 to 49	11.3 (5.1)	5.9 (4.0)
p-Value	.88	<.001	<.001	.22	.06
Mehra et al (2020)					
HNS	33.7 (13.4)	14.7 (13.8)		12.3 (5.5)	7.2 (4.8)
No HNS	34.9 (16.4)	26.8 (17.6)		10.9 (5.4)	12.8 (5.2)
p-Value	.95	<.001		.06	<.001

AHI: Apnea/Hypopnea Index; ESP: expansion sphincter pharyngoplasty; HNS: hypoglossal nerve stimulation; NS: not significant; Sher criteria: 50% decrease in AHI and final AHI <20; SD: standard deviation; UPPP: uvulopalatopharyngoplasty.

^a Baseline vs posttreatment p<.05.

^b Baseline vs posttreatment p<.001.

Table 30. Study Relevance Limitations

Study	Population ^a	Intervention ^b	Comparator ^c	Outcomes ^d	Follow-Up ^e
Shah et al (2018)			2. UPPP may not be preferred treatment for patients with primarily lingual obstruction		
Huntley et al (2018)	4. Study populations not comparable		1. Not clearly defined, few ESP patients had follow-up PSG		
Yu et al (2018)					1,2 Duration of follow-up unclear
Huntley et al (2020)	4. Study populations not comparable				1. The timing of follow-up was different (173 days after surgery and 383 days after HNS)
Mehra et al (2020)	4. Study populations not comparable		3. Hours of use on the test night was not reported. This may not represent the normal use of the device.		1. The timing of follow-up was different
Steffen et al (2018)			No comparator		
STAR trial			No comparator		

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment. ESP: expansion sphincter pharyngoplasty; PSG: polysomnography; STAR: Stimulation Therapy for Apnea Reduction; UPPP: uvulopalatopharyngoplasty.

a Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.

b Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.

c Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.

d Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.

e Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 31. Study Design and Conduct Limitations

Study	Allocation ^a	Blinding ^b	Selective Reporting ^c	Data Completeness ^d	Power ^e	Statistical ^f
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Shah et al (2018)	1. Not randomized (retrospective) 4. Inadequate control for selection bias	1.-3. No blinding	4. Comparative treatment effects not calculated
Huntley et al (2018)	1. Not randomized (retrospective)	1.-3. No blinding	
Yu et al (2018)	1. Not randomized (retrospective)		
Huntley et al (2020)	1. Not randomized (retrospective)	1.-3. No blinding	
Mehra et al (2020)	1. Not randomized	1.-3. No blinding	1. Power calculations not reported
Steffen et al (2018)	1. Not randomized	1.-3. No blinding	
STAR trial	1. Not randomized	1.-3. No blinding	

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment. STAR: Stimulation Therapy for Apnea Reduction.

^a Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.

^b Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.

^c Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.

^d Follow-Up key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).

^e Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.

^f Statistical key: 1. Intervention is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Intervention is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Single-Arm Studies

Characteristics and results of single-arm studies are described in Tables 32 to 34. Limitations are mentioned in Tables 30 and 31, above.

Results of prospective single-arm studies show success rates in 66% to 68% of patients who had moderate to severe sleep apnea and a favorable pattern of palatal collapse (see Tables 26 and 27). Mean AHI was 31 to 32 at baseline, decreasing to 14 to 15 at 12 months. ESS scores decreased to 6.5 to 7.0. All improvements were maintained through 5 years of follow-up. Discomfort due to the electrical stimulation and tongue abrasion were initially common but were decreased when stimulation levels were reduced (see Table 28). In the post-market study, a normal ESS (≤ 10) was obtained in 73% of patients. A FOSQ score of at least 19 was observed in 59% of patients compared to 13% at baseline. At the 12-month follow-up, 8% of bed partners regularly left the room due to snoring, compared to 75% of bed partners at baseline. The average use was 5.6 + 2.1 h per night. Use was correlated with the subjective outcomes, but not with AHI response. Two- and 3-year follow-up of this study were reported by Steffen et al (2020),¹⁹ but the percentage of patients at follow-up was only 68% at 2 years and 63% at 3 years, limiting conclusions about the longer-term efficacy of the procedure. A comparison of the populations who had 12-month versus 2- or 3-year results showed several differences between the patients who followed up and those who dropped out, including higher baseline AHI, higher baseline ODI, and trends towards lower usage per night and a lower responder rate at 12 months.

Table 32. Summary of Prospective Single-Arm Study Characteristics

Study	Country	Participants	Treatment Delivery	Follow-Up
STAR trial	EU, U.S.	126 patients with AHI >20 and <50, BMI ≤ 32 kg/m ² , failed CPAP, favorable pattern of palatal collapse ^a	Stimulation parameters titrated with full PSG	5 y
Postmarket studies: Heiser et al (2017) Steffen et al (2018) Hasselbacher et al (2018) Steffen et al (2020)	3 sites in Germany	60 patients with AHI ≥15 and ≤65 on home sleep study, BMI ≤35 kg/m ² , failed CPAP; favorable pattern of palatal collapse ^a		12 mo, 2 yr, and 3 yr

AHI: apnea/hypopnea index; BMI: body mass index; CPAP: continuous positive airway pressure; STAR: Stimulation Therapy for Apnea Reduction.

^a A favorable pattern of palatal collapse is non-concentric retropalatal obstruction on drug-induced sleep endoscopy.

Table 33. Summary of Prospective Single-Arm Study Results

Study	N	Percent of Patients With AHI Success (Sher criteria)	Mean AHI Score (SD)	Mean ODI Score (SD)	FOSQ Score (SD)	ESS Score (SD)
STAR trial						
Baseline	126		32.0 (11.8)	28.9 (12.0)	14.3 (3.2)	11.6 (5.0)
12 months	124	66%	15.3 (16.1) ^d	13.9 (15.7) ^d	17.3 (2.9) ^d	7.0 (4.2) ^d
3 years	116 ^a	65%	14.2 (15.9)	9.1 (11.7)	17.4 (3.5) ^b	7.0 (5.0) ^b
5 years	97 ^c	63%	12.4 (16.3)	9.9 (14.5)	18.0 (2.2)	6.9 (4.7)
Post market studies: Heiser et al (2017) Steffen et al (2018) Hasselbacher et al (2018) Steffen et al (2020)						
Baseline	60		31.2 (13.2)	27.6 (16.4)	13.7 (3.6)	12.8 (5.3)
6 months					17.5 (2.8) ^d	7.0 (4.5) ^d
12 months	56 ^f	68%	13.8 (14.8) ^e	13.7 (14.9) ^e	17.5 (3) ^e	6.5 (4.5) ^e
Normalized at 12 months					59%	73%

AHI: Apnea/Hypopnea Index; ESS: Epworth Sleepiness Scale; FOSQ: Functional Outcomes of Sleep Questionnaire; ODI: Oxygen Desaturation Index; PSG: polysomnography; SD: standard deviation; STAR: Stimulation Therapy for Apnea Reduction.

Ninety-eight participants agreed to undergo PSG at 36 months of the 17 participants who did not undergo PSG at 36 months, 54% were non-responders and their PSG results at 12 or 18 months were carried forward. ^b The change from baseline was significant at p<0.001. ^c

Seventy-one participants agreed to a PSG. ^f Four patients lost to follow-up were analyzed as treatment failures. ^d p<.001. ^e p<.05.

Table 34. Device-Related Adverse Events From Prospective Single-Arm Studies

Study	N	Discomfort due to Electrical Stimulation ^a	Tongue Abrasion	Dry Mouth	Mechanical Pain From Device	Internal Device Usability	External Device Usability
STAR trial							
0 to 12 months	126	81	28	10	7	12	11
12 to 24 months	124	23	12	5	2	8	11
24 to 36 months	116	26	4	2	3	1	8
36 to 48 months	97	7	3	0	1	3	9

> 48 months	5	3	3	1	1	6
Participants with event, n of 126 (%)	76 (60.3)	34 (27.0)	19 (15.1)	14 (11.1)	21 (16.7)	33 (26.2)

STAR: Stimulation Therapy for Apnea Reduction.

a Stimulation levels were adjusted to reduce discomfort

Down Syndrome

Caloway et al (2020) reported a safety study of HNS in 20 children with Down Syndrome and severe OSA (AHI of 10 or greater) treated at 3 tertiary care centers.³⁹ Included were non-obese (BMI < 95%) children and adolescents aged 10-21 years who were refractory to tonsillectomy and either unable to tolerate CPAP or dependent on a tracheostomy. Patients were included whose AHI was between 10 and 50 on baseline PSG; the median baseline AHI was 24.15 (interquartile range [IQR] of 19.88 to 35.10). All of the patients tolerated the stimulation, and at 2 months after implantation the median AHI was 3.56 (IQR 2.61 to 4.40). Success, defined as an AHI of 5 or less (mild) with HNS, was achieved in 14 of 20 patients (70%). The median percent reduction in AHI was 85% with a median usage of 9.21 h (IQR: 8.29 to 9.50) per night. The OSA-18 score improved by 1.15 (IQR: 0.02 to 1.97), indicating a moderate but clinically significant change. There were 2 adverse events related to extrusion or connectivity of the stimulation or sensation leads, which were both corrected with wound exploration surgery.

Liu et al (2022) published a systematic review investigating HNS in adolescents with Down Syndrome and OSA.⁴⁰ A total of 9 studies were included with a follow up period ranging from 2 to 58 months; 6 studies had sample sizes fewer than 10 patients. The largest of the included studies was a prospective cohort study published by Yu et al (2022), which is summarized below. In an analysis that included 104 patients, AHI scores were significantly reduced in patients after HNS (mean AHI reduction, 17.43 events/h; 95% CI, 13.98 to 20.88 events/h; $p < .001$). Similarly, in an analysis that included 88 patients, OSA-18 survey scores were significantly reduced after HNS (mean OSA-18 reduction, 1.67; 95% CI, 1.27 to 2.08; $p < .001$).

Yu et al (2022) reported on the safety and effectiveness of HNS in 42 adolescents with Down Syndrome and severe OSA (AHI of 10 events/h or greater).⁴¹ This was a single-group, multicenter, cohort study with a 1-year follow-up that included non-obese (BMI < 95%) children and adolescents aged 10 to 21 years who were refractory to adenotonsillectomy and unable to tolerate CPAP. Patients who were included had an AHI between 10 and 50 on baseline PSG; the mean baseline AHI was 23.5 (SD, 9.7). All patients included tolerated HNS without any intraoperative complications. The most common complication was tongue or oral discomfort or pain, which occurred in 5 (11.9%) patients and was temporary, lasting weeks or rarely, months. Four patients (9.5%) had device extrusion resulting in readmissions to replace the extruded device. At 12 months, there was a mean decrease in AHI of 12.9 (SD, 13.2) events per hour (95% CI, -17.0 to -8.7 events/h). At the 12-month PSG, 30 of 41 patients (73.2%) had an AHI of less than 10 events/h, 14/41 patients (34.1%) had an AHI of less than 5 events/h, and 3/41 patients (7.3%) had an AHI of less than 2 events/h. There was also a significant improvement in quality of life outcomes. The mean improvement in the OSA-18 total score was 34.8 (SD, 20.3; 95% CI, -42.1 to -27.5) and the ESS improved by 5.1 (SD, 6.9; 95% CI, -7.4 to -2.8).

Registry

Boon et al (2018) reported results from 301 patients in the multicenter Adherence and Outcome of Upper Airway Stimulation for OSA International Registry (ADHERE).⁴² The

ADHERE registry included both retrospective and prospectively collected data from the U.S. and Germany between October 2016 and September 2017. Data were collected from PSG prior to implantation and between 2 and 6 months after implantation, or from home sleep tests which were often performed at 6 and 12 months after implantation as part of routine care. Mean AHI decreased from 35.6 (SD: 15.3) to 10.2 (SD: 12.9) post-titration with 48% of patients achieving an AHI of 5 or less. ESS decreased from 11.9 (5.5) to 7.5 (4.7) ($P < .001$).

Kent et al (2019) pooled data from the ADHERE registry plus data from 3 other studies to evaluate factors predicting success.⁴³ Over 80% of the 584 patients were men, and most were overweight. Seventy-seven percent of patients achieved treatment success, defined as a decrease in AHI by at least 50% and below 20 events/per hour. AHI decreased to below 5 in 41.8% of patients. Greater efficacy was observed in patients with a higher preoperative AHI, older patient age, and lower BMI. A report of data from the ADHERE registry by Thaler et al (2020) included 640 patients with 6-month follow-up and 382 with 12-month follow-up.⁴⁴ AHI was reduced from 35.8 at baseline to 14.2 at 12 months ($p < .001$), although the number of hours of use during the sleep test was not reported and home sleep studies may underestimate AHI. ESS was reduced from 11.4 at baseline to 7.2 at 12 months ($p < .001$), and patient satisfaction was high. In a multivariate model, only female sex (odds ratio: 3.634, $p = .004$) and lower BMI (odds ratio: 0.913, $p = .011$) were significant predictors of response according to the Sher criteria. In sensitivity analysis, higher baseline AHI was also found to be a negative predictor of success.

Suurna et al (2021) evaluated the impact of BMI on HNS using the ADHERE registry ($N=1849$).⁴⁵ The mean BMI of all patients in the registry was 29.3 kg/m². All patients had a BMI of 35 kg/m² or lower and were categorized as those with BMI of 32 kg/m² or less and those with a BMI greater than 32 kg/m² and less than or equal to 35 kg/m². At 12 months, both groups had reduced AHI events/hour compared with baseline, although the mean change was greater in the lower BMI group (-21.4) compared with the higher BMI group (-20.3; mean difference 1.05 with the upper 97.5% CI at 4.5 which fell within the noninferiority margin). The difference in ESS scores between groups was also non-inferior.

In a retrospective analysis by Huntley et al (2018) of procedures at 2 academic institutions, patients with a BMI of greater than 32 did not have lower success rates than patients with a BMI less than 32.⁴⁶ However, only patients who had palpable cervical landmarks and carried most of their weight in the waist and hips were offered HGNS. Therefore, findings from this study are limited to this select group of patients with BMI greater than 32.

Patel et al (2024) conducted a retrospective cohort study at a single academic institution evaluating the effects of BMI on response to HNS.⁴⁷ A total of 76 patients with an average age of 61 years and a median BMI of 28.9 kg/m² were identified. Patients with a BMI of 32 to 35 kg/m² had 75% lower odds of a response to HNS (OR, 0.25; 95% CI, 0.07 to 0.90). Further analysis revealed an approximate 17% decrease in odds of being a responder for each 1-unit BMI increase.

Genio System

No systematic reviews or RCTs have been published on the Genio system. The FDA approval was based on results of a nonrandomized clinical trial (DREAM: Dual-sided Hypoglossal neRvE stimulation for the treatment of Obstructive Sleep Apnea). Woodson et al (2025) conducted this trial in adult patients with moderate-to-severe OSA who refused, failed, or did

not tolerate PAP therapy underwent implantation and nightly use of the Genio device.⁶² The coprimary endpoints at 12 months were (1) a minimum of 50% reduction in the 4% AHI from baseline with a final AHI of <20 events/h, and (2) a minimum of 25% reduction in the 4% ODI. Objective secondary endpoints included changes in mean AHI, ODI, and sleep time with blood oxygen saturation <90%. Self-reported secondary endpoints included changes in ESS, the short FOSQ, the Symptoms of Nocturnal Obstruction and Related Events score, and bedpartner assessment of snoring. The Genio device was implanted in 113 patients. Eleven serious adverse events occurred in 10 (9%) patients of which 3 (3%) were device-related, 5 (4%) were procedure-related, and 3 (3%) were unrelated to the device or the procedure. The coprimary endpoints were completed by 89 (77%) patients. AHI and ODI responses were achieved in 63.5% (73/115, $p = .002$) and 71.3% of patients (82/115, $p < .001$), respectively. Secondary endpoint analysis revealed significant changes in mean AHI (-18.3 ± 11.8 events/h, $p < .001$), ODI (-17.7 ± 14.6 events/h, $p < .001$), and sleep time with blood oxygen saturation less than 90% ($6.9 \pm 10.7\%$, $p < .001$). Significant changes were observed in all secondary endpoints ($p < .001$). Study Limitations are described in Tables 35 and 36.

Table 35. Study Relevance Limitations

Study	Population ^a	Intervention ^b	Comparator ^c	Outcomes ^d	Duration of Follow-up ^e
Woodson et al (2025)	4. Study population was predominantly male (70%) and exclusively White (94%)				1, 2. Limited follow-up period precluded long-term evaluation of safety and efficacy

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^a Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4. Enrolled populations do not reflect relevant diversity; 5. Other

^b Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5. Other.

^c Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.

^d Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.

^e Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 36. Study Design and Conduct Limitations

Study	Allocation ^a	Blinding ^b	Selective Reporting ^c	Data Completeness ^d	Power ^e	Statistical ^f
Woodson et al (2025)	1. Single-arm, open-label design	1. Single-arm, open-label design	4. Treatment adherence assessed by patient self-reporting	1. 24% of patients did not complete the trial per protocol		

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^a Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias; 5. Other.

^b Blinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other.

^c Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other.

^d Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials); 7. Other.

^e Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other.

^f Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated; 5. Other.

Section Summary: Hypoglossal Nerve Stimulation

They are currently 2 FDA-approved HNS devices for the treatment of OSA: the Inspire Upper Airway Stimulation (UAS) system and the Genio system. The evidence on the Inspire device for the treatment of OSA includes systemic reviews, 3 RCTs, nonrandomized prospective studies, nonrandomized studies with historical controls and prospective single arm studies. An RCT of

89 adults with moderate-to-severe OSA who did not tolerate CPAP found significant short-term improvement in AHI, ESS, and quality of life measures with HNS compared to sham stimulation. The study was limited by short duration of follow-up and lack of diverse individuals included in the trial. Another RCT, including 138 patients with moderate-to-severe OSA who did not tolerate CPAP compared outcomes for patients who received HNS therapy at 1 or 4 months after implant for the treatment and control groups, respectively. Results demonstrated significant short-term improvement in AHI and ODI when comparing HNS to no HNS at month 4. However, after 11 months of active therapy, the difference between the treatment and control groups was not statistically significant for AHI but remained significant for ODI in favor of the treatment group. This trial was also limited by a lack of diverse individuals, as well as a lack of a true control group for long-term outcomes. In nonrandomized studies, about two-thirds of patients with moderate-to-severe OSA who had failed conservative therapy (CPAP) and had a favorable pattern of palatal collapse met the study definition of success. Results observed at the 12-month follow-up were maintained at 5 years in the pivotal study. A prospective study that compared outcomes in patients who had received HNS to patients who were denied insurance coverage reported significant differences in both objective and subjective measures of OSA. However, there is a high potential for performance bias in this non-blinded study.

For children and adolescents with OSA and Down Syndrome who are unable to tolerate CPAP, the evidence includes a systematic review and a prospective study of 42 individuals. The systematic review investigated HNS in adolescents with Down Syndrome and OSA and demonstrated significant improvement in AHI and OSA-18 after HNS. The study of 42 individuals with Down Syndrome and OSA found a similar success rate of 73.2% with 4 device extrusions corrected with replacement surgery.

The evidence on the Genio device is limited to results of a nonrandomized clinical trial. This study enrolled 113 patients across 21 centers (including 16 U.S. locations), with coprimary endpoints focused on reducing the AHI and ODI at 12 months. Serious adverse events occurred in 9% of patients, with only a small proportion attributed directly to the device or procedure. Of the patients who completed the study, 63% met the AHI reduction endpoint and 71% achieved the ODI reduction. Secondary outcomes showed significant improvements in mean AHI, ODI, nocturnal oxygen saturation, and patient-reported sleep quality measures. Limitations of the current evidence-base preclude determination of who is most likely to benefit from this minimally invasive procedure.

Supplemental Information

2018 Input

BCBSA sought clinical input (2018) to help determine whether the use of hypoglossal nerve stimulation for individuals with (OSA) would provide a clinically meaningful improvement in net health outcome and whether the use is consistent with generally accepted medical practice. In response to requests, BCBSA received clinical input from 2 respondents, including 1 specialty society-level response and physicians with academic medical center affiliation. At the time of the clinical input, the Inspire UAS system was the only HNS device that had received FDA approval.

For individuals who have OSA who receive HNS, clinical input supports that this use provides a clinically meaningful improvement in net health outcome and indicates this use is consistent with generally accepted medical practice in subgroups of appropriately selected patients. One subgroup includes adult patients with a favorable pattern of non-concentric palatal collapse. The alternative treatment for this anatomical endotype is maxillo-mandibular advancement (MMA), which is associated with greater morbidity and lower patient acceptance than HNS. The improvement in AHI with HNS, as shown in the STAR trial, is similar to the improvement in AHI following MMA. Another subgroup includes appropriately selected adolescents with OSA and Down's syndrome who have difficulty in using CPAP. The following patient selection criteria are based on information from clinical study populations and clinical expert opinion.

- Age ≥ 22 years in adults or adolescents with Down's syndrome age 10 to 21; AND
- Diagnosed moderate to severe OSA (with less than 25% central apneas); AND
- CPAP failure or inability to tolerate CPAP; AND
- Body mass index ≤ 32 kg/m² in adults; AND
- Favorable pattern of palatal collapse

Practice Guidelines and Position Statements

American Academy of Sleep Medicine

The American Academy of Sleep Medicine (AASM, 2021) published practice guidelines on when to refer patients for surgical modifications of the upper airway for OSA.⁴⁸ These guidelines replaced the 2010 practice parameters for surgical modifications.⁴⁹ The AASM guidelines note that positive airway pressure (PAP) is the most efficacious treatment for OSA, but effectiveness can be compromised when patients are unable to adhere to therapy or obtain an adequate benefit, which is when surgical management may be indicated. The AASM guideline recommendations are based on a systematic review and meta-analysis of 274 studies of surgical interventions, including procedures such as uvulopalatopharyngoplasty (UPPP), modified UPPP, MMA, tongue base suspension, and hypoglossal nerve stimulation.⁵⁰ The systematic review deemed most included data of low quality, consisting of mostly observational data. The AASM strongly recommends that clinicians discuss referral to a sleep surgeon with adults with OSA and body mass index (BMI) <40 kg/m² who are intolerant or unaccepting of PAP. Clinically meaningful and beneficial differences in nearly all critical outcomes, including a decrease in excessive sleepiness, improved quality of life (QOL), improved Apnea/Hypopnea Index (AHI) or respiratory disturbance index (RDI), and sleep quality, were demonstrated with surgical management in patients who are intolerant or unaccepting of PAP. The AASM makes a conditional recommendation that clinicians discuss referral to a sleep surgeon with adults with OSA, BMI <40 kg/m², and persistent inadequate adherence due to pressure-related side effects, as available data (very low-quality), suggests that upper airway surgery has a moderate effect in reducing minimum therapeutic PAP level and increasing PAP adherence. In adults with OSA and obesity (class II/III, BMI ≥ 35) who are intolerant or unaccepting of PAP, the AASM strongly recommends discussion of referral to a bariatric surgeon, along with other weight-loss strategies.

American Academy of Pediatrics

The American Academy of Pediatrics (2012) published a clinical practice guideline on the diagnosis and management of childhood OSA.⁵¹ The Academy indicated that if a child has OSA, a clinical examination consistent with adenotonsillar hypertrophy, and does not have a contraindication to surgery, the clinician should recommend adenotonsillectomy as first-line

treatment. The Academy recommended that patients should be referred for CPAP management if symptoms/signs or objective evidence of OSA persist after adenotonsillectomy or if adenotonsillectomy is not performed. Weight loss was recommended in addition to other therapy if a child or adolescent with OSA is overweight or obese (defined as BMI >95th percentile).

American Academy of Otolaryngology–Head and Neck Surgery

The American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS; 2014) has a revised position statement on surgical management of OSA.⁵² Procedures AAO-HNS supported as effective and not considered investigational when part of a comprehensive approach in the medical and surgical management of adults with OSA include:

- tracheostomy,
- nasal and pharyngeal airway surgery,
- tonsillectomy and adenoidectomy,
- palatal advancement,
- uvulopalatopharyngoplasty,
- genioglossal advancement,
- hyoid myotomy,
- midline glossectomy,
- tongue suspension,
- maxillary and mandibular advancement.

In a 2021 position statement, AAO-HNS supported hypoglossal nerve stimulation as an effective second-line treatment of moderate to severe OSA.⁵³

American Society for Metabolic and Bariatric Surgery

The American Society for Metabolic and Bariatric Surgery (2012) published guidelines on the perioperative management of OSA.⁵⁴ The guideline indicated that OSA is strongly associated with obesity, with the incidence of OSA in the morbidly obese population reported as between 38% and 88%. The Society recommended bariatric surgery as the initial treatment of choice for OSA in this population, as opposed to surgical procedures directed at the mandible or tissues of the palate. The updated 2017 guidelines reaffirmed these recommendations.⁵⁵

U.S. Preventive Services Task Force Recommendations

Not applicable.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 37

Table 37. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05592002 ^a	A Multicenter Study to Assess the Safety and Effectiveness of the Genio® Dual-sided Hypoglossal Nerve Stimulation System for the Treatment of Obstructive Sleep Apnea in Subjects With Complete Concentric Collapse of the Soft Palate	124	Sept 2028
NCT02413970 ^a	Inspire® Upper Airway Stimulation System (UAS): Post-Approval Study Protocol Number 2014-001	127	Jun 2025
NCT03868618 ^a	A Multicenter Study to Assess the Safety and Effectiveness of the Genio Dual-sided Hypoglossal Nerve Stimulation System	115	Feb 2028

for the Treatment of Obstructive Sleep Apnea in Adults Subjects			
NCT04801771 ^a	Effects of Hypoglossal Nerve Stimulation on Cognition and Language in Down Syndrome and Obstructive Sleep Apnea	57	Sept 2027
NCT04031040 ^a	A Post-market Clinical Follow up of the Genio™ System for the Treatment of Obstructive Sleep Apnea in Adults (EliSA)	110	Oct 2030
NCT02907398 ^a	Adherence and Outcome of Upper Airway Stimulation (UAS) for OSA International Registry	5000	Dec 2025
NCT04950894 ^a	Treating Obstructive Sleep Apnea Using Targeted Hypoglossal Neurostimulation	150	Oct 2025
NCT06008626	Clinical Trial of the Cryosa System for the Treatment of Obstructive Sleep Apnea (ARCTIC-3)	25	Mar 2028
NCT06851338 ^a	Pediatric Down Syndrome Post-Approval Study	60	May 2030

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

Regulatory Status

The regulatory status of minimally invasive surgical interventions is shown in Table 38.

Table 38. Minimally Invasive Surgical Interventions for Obstructive Sleep Apnea

Interventions	Devices (predicate or prior name)	Manufacturer (previously owned by)	Indication	PMA/ 501(k)	Year	FDA Product Code
LAUP	Various					
Radiofrequency ablation	Somnoplasty®		Simple snoring and for the base of the tongue for OSA	K982717	1998	GEI
Palatal implant	Pillar® Palatal Implant	Pillar Palatal (Restore Medical/ Medtronic)	Stiffening the soft palate which may reduce the severity of snoring and incidence of airway obstructions in patients with mild to moderate OSA	K040417	2004	LRK
Tongue base suspension	AIRvance® (Repose)	Medtronic	OSA and/or snoring. The AIRvance™ Bone Screw System is also suitable for the performance of a hyoid suspension	K122391	1999	LRK
Tongue base suspension	Encore™ (PRELUDE III)	Siesta Medical	Treatment of mild or moderate OSA and/or snoring	K111179	2011	ORY
Hypoglossal nerve stimulation (HNS)	Inspire® (Inspire Upper Airway Stimulation)	Inspire Medical Systems	Patients ≥ 18 years with AHI ≥15 and ≤ 65 who have failed (AHI >15 despite CPAP usage) or cannot tolerate (<4 h use per night for ≥5 nights per week) CPAP and do not have complete concentric collapse at the soft palate level. Patients between ages 18 and 21 should also be contraindicated for or not effectively treated by adenotonsillectomy	P130008 S039	2020	MNQ
HNS	Inspire Upper Airway Stimulation System	Inspire Medical Systems	Patients ≥ 18 years with AHI ≥15 and ≤100 who have failed (AHI >15 despite CPAP usage) or cannot tolerate (<4 h use per night for ≥5 nights per week) CPAP and do not have complete concentric collapse at the soft	P130008/S090	2023	MNQ

			palate level. Patients between ages 18 and 21 should also be contraindicated for or not effectively treated by adenotonsillectomy. Inspire is also indicated in pediatric patients ages 13 to 18 years with Down Syndrome and severe sleep apnea (AHI >10 and <50).			
HNS	Inspire V Model 3150 Implantable Pulse Generator (IPG)	Inspire Medical Systems	As above	P130008/S090	2024	MNQ
HNS	aura6000®	LivaNova (ImThera Medical)		IDE	2014	
HNS	Genio™	Nyxoah		European CE Mark	2019	
HNS	Genio® System 2.1	Nyxoah	For use in treatment of moderate to severe OSA (AHI of ≥15 and ≤65). The device is intended for adult patients ≥22 years of age who have been confirmed to fail, cannot tolerate or are ineligible to be treated with current standard of care treatments including lifestyle modifications, PAP treatments (such as CPAP or BiPAP machines), oral appliances (such as mandibular advancement devices), and pharmacotherapy (such as tirzepatide). PAP failure is defined as an inability to eliminate OSA (residual AHI of >15 despite PAP usage), and PAP intolerance is defined as: 1. Inability to use PAP (at least 5 nights per week of usage; usage defined as >4 hours of use per night), or 2. Unwillingness to use PAP (PAP therapy initiated and subsequently discontinued by choice).	P240024	2025	MNQ

AHI: Apnea/Hypopnea Index; CPAP: continuous positive airway pressure; IDE: investigational device exemption; LAUP: Laser-assisted uvulopalatoplasty; OSA: obstructive sleep apnea, PAP: positive airway pressure.

The Cryosa system, which uses cryolysis to treat obstructive sleep apnea (OSA), is currently investigational and not available for sale in the United States; it is limited to investigational use in approved investigational device exemption (IDE) studies.

Government Regulations

National:

There is no NCD addressing surgical treatment for obstructive sleep apnea.

Local:

L34526 Surgical Treatment of Obstructive Sleep Apnea (OSA)

Original effective date 10/01/2015; Revision effective date 6/26/2025

Sleep-Disordered Breathing, often referred to as Obstructive Sleep Apnea (OSA), is characterized by frequent episodes of hypopnea or apnea during sleep. Multiple detrimental physiologic changes may result from these hypopneic and apneic episodes. Non-surgical and surgical approaches to obstructive apnea and hypopnea have been developed. Continuous Positive Airway Pressure (CPAP) breathing is the treatment of choice for OSA. Some patients do not tolerate CPAP or are not benefited from it. The level of obstruction in OSA (retropalatal, retrolingual, and retropalatal and retrolingual) is variable.

Uvulopalatopharyngoplasty (UPPP) is an accepted means of surgical treatment for this disorder but is curative in less than 50% of patients. Scientific evidence suggests that UPPP is useful in retropalatal and combination retropalatal and retrolingual obstruction.

Mandibular Maxillary Osteotomy and Advancement is a procedure developed for those patients with retrolingual obstruction, or those patients with retropalatal and retrolingual obstruction who have not responded to CPAP and uvulopalatopharyngoplasty. Medical data on the efficacy of this treatment has been reported from only a small number of centers, but the information appears to show good results for those patients who meet certain criteria. It is unknown whether the technique will result in similar results outside specialized centers.

Tracheostomy remains the surgical approach with the greatest effectiveness since it bypasses all areas of obstruction in the nasal, palatal, lingual, and pharyngeal areas. However, tracheostomy is associated with significant morbidity and is usually reserved for patients who have failed other medical or surgical methods of treatment, or who are unsuitable for other methods of treatment for various reasons.

Various other anatomic abnormalities (such as, but not limited to, enlarged tonsils or tongue) sometimes cause OSA also. Surgical approaches to these abnormalities will vary according to the anatomic defect and the procedure/procedures needed to correct the defined problem.

Genioglossal advancement, with or without resuspension of the hyoid bone, may be performed with uvulopalatopharyngoplasty, but this procedure is not always successful, and there is little definitive information on its benefit.

A. Uvulopalatopharyngoplasty (UPPP) is covered for those patients who have **all** of the following:

1. Obstructive sleep apnea diagnosed (prior to any proposed surgery) in a certified sleep disorders laboratory (certification body recognized by the American Academy of Sleep Medicine)
2. A Respiratory Disturbance Index of 15 or higher
3. Failed to respond to Continuous Positive Airway Pressure therapy or cannot tolerate CPAP or other appropriate non-invasive treatment

4. Documented counseling by a physician, with recognized training in sleep disorders, about the potential benefits and risks of the surgery; **and**
 5. Evidence of retropalatal or combination retropalatal/retrolingual obstruction as the cause of the obstructive sleep apnea
- B. Mandibular Maxillary Osteotomy and Advancement and /or genioglossus advancement with or without hyoid suspension is covered for those patients who have **all** of the following
1. Obstructive sleep apnea diagnosed (prior to any proposed surgery) in a certified sleep disorders laboratory (certification body recognized by the American Academy of Sleep Medicine)
 2. A Respiratory Disturbance Index of 15 or higher
 3. Failed to respond to Continuous Positive Airway Pressure therapy or cannot tolerate CPAP or other appropriate non-invasive treatment
 4. Documented counseling by a physician, with recognized training in sleep disorders, about the potential benefits and risks of the surgery; **and**
 5. Evidence of retrolingual obstruction as the cause of the obstructive sleep apnea, or previous failure of UPPP to correct the obstructive sleep apnea.
- Regarding the Mandibular Maxillary Osteotomy and Advancement operation
- a. Separate repositioning of teeth would not be necessary except under unusual circumstances; but, if necessary, the dental work would be covered
 - b. Application of an interdental fixation device is occasionally necessary, and is a covered service (see Documentation Requirements)
- C. Tracheostomy is covered for obstructive sleep apnea that is in the judgment of the attending physician, unresponsive to other means of treatment or in cases where other means of treatment would be ineffective or not indicated.
- D. When obstructive sleep apnea is caused by discrete anatomic abnormalities of the upper airway (such as, but not limited to, enlarged tonsils or an enlarged tongue), surgery to correct these abnormalities is covered if medically necessary based on adequate documentation in the medical records supporting the significant contribution of these abnormalities to OSA. Submucous radiofrequency reduction of hypertrophied turbinates is covered as an appropriate treatment for nasal obstruction due to turbinate hypertrophy that significantly contributes to OSA or significantly compromises CPAP therapy.
- E. The following procedures are not covered at this time.
1. Laser-assisted uvulopalatoplasty (LAUP) is not covered at this time since it is not considered effective for OSA. LAUP **must not** be billed as 42145, Palatopharyngoplasty (e.g., uvulopalatopharyngoplasty, uvulopharyngoplasty). This code is not appropriate for this procedure. If LAUP is billed for denial purposes, it should be coded as 42299, (unlisted procedure, palate, uvula) with "LAUP" in the electronic narrative 2400/SV101-7 equivalent to line 19 of the CMS 1500 form. The claim is denied as not proven effective.
 2. Somnoplasty™ is a trade name for palate reduction with the Somnoplasty™ System of Somnus Medical Systems. This is not a term recognized by this Contractor as a covered procedure under Medicare Part B. Therefore, Somnoplasty™ must not be billed as 42145. This code is not appropriate for this procedure. If Somnoplasty™ is billed for denial purposes, it should be coded as 42299, (unlisted procedure, palate, uvula) with "Somnoplasty™" in the electronic narrative 2400/SV101-7 equivalent to line 19 of the CMS 1500 form. The claim is denied as not proven effective.

3. The Pillar Procedure™ is a trade name for palatal implants. Palatal implants have not been shown effective for the treatment of obstructive sleep apnea and are not covered. This procedure should be billed by the physician as 42299 (unlisted procedure, palate, uvula) with "Pillar Procedure™" or "palatal implant" in the electronic narrative 2400/SV101-7 equivalent to line 19 of the CMS 1500 form. This claim will then be denied as not proven effective. Hospital outpatient would use code C9727.
4. Submucosal ablation of the tongue base, radiofrequency, one or more sites, per session. (41530) will be denied as investigational and experimental.

L38528 Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea (OSA). Original effective date 06/14/20; Revision effective date 4/25/24

Covered Indications

FDA-approved hypoglossal nerve neurostimulation is considered medically reasonable and necessary for the treatment of moderate to severe obstructive sleep apnea when all of the following criteria are met:

1. Beneficiary is 22 years of age or older; **and**
2. Body mass index (BMI) is less than 35 kg/m²; **and**
3. A polysomnography (PSG) is performed within 24 months of first consultation for HGNS implant; **and**
4. Beneficiary has predominantly obstructive events (defined as central and mixed apneas less than 25% of the total AHI); **and**
5. AHI is 15 to 65 events per hour; **and**
6. Beneficiary has documentation that demonstrates CPAP failure (defined as AHI greater than 15 despite CPAP usage) or CPAP intolerance (defined as less than 4 hours per night, 5 nights per week or the CPAP has been returned) including shared decision making that the patient was intolerant of CPAP despite consultation with a sleep expert: **and**
7. Absence of complete concentric collapse at the soft palate level as seen on a drug-induced sleep endoscopy (DISE) procedure; **and**
8. No other anatomical findings that would compromise performance of device (e.g., tonsil size 3 or 4 per standardized tonsillar hypertrophy grading scale).

Limitations

The following are considered not reasonable and necessary and therefore will be denied:

1. Hypoglossal nerve neurostimulation is considered not medically reasonable and necessary for all other indications.
2. Non-FDA-approved hypoglossal nerve neurostimulation is considered not medically reasonable and necessary for the treatment of adult obstructive sleep apnea due to insufficient evidence of being safe and effective.
3. Hypoglossal nerve neurostimulation is considered not medically reasonable and necessary when any of the following contraindications are present:
 - Beneficiaries with central and mixed apneas that make up more than one-quarter of the total AHI.
 - Beneficiaries with an implantable device could experience unintended interaction with the HGNS implant system.
 - BMI equal to or greater than 35

- Neuromuscular disease
 - Hypoglossal-nerve palsy
 - Severe restrictive or obstructive pulmonary disease
 - Moderate-to-severe pulmonary arterial hypertension
 - Severe valvular heart disease
 - New York Heart Association class III or IV heart failure
 - Recent myocardial infarction or severe cardiac arrhythmias (within the past 6 months)
 - Persistent uncontrolled hypertension despite medication use
 - An active, serious mental illness that reduces the ability to carry out Activities of Daily Living (ADLs) and would interfere with the patient's ability to operate the HNS and report problems to the attending provider.
 - Coexisting non-respiratory sleep disorders that would confound functional sleep assessment.
 - Beneficiaries who are, or who plan to become pregnant.
 - Beneficiaries who require Magnetic Resonance Imaging (MRI) with model 3024.
 - Beneficiaries, who require MRI with model 3028, can undergo MRI on the head and extremities if certain conditions and precautions are met. Please refer to the Manufacturer Guidelines for this model and future models for more information.
 - Beneficiaries who are unable or do not have the necessary assistance to operate the sleep remote.
 - Beneficiaries with any condition or procedure that has compromised neurological control of the upper airway.
4. Drug Induced Sleep Endoscopy (DISE):
- Due to documented inconsistency in determining if complete concentric collapse (CCC) is present, the inserting provider shall be certified by the FDA approved manufacturer's second opinion service of validation via video clip submissions of at least 80% agreement in at least 15 consecutive studies. Inserting providers shall have documentation to submit to this contractor if necessary.
5. Shared Decision Making (SDM):
- SDM shall be documented in the patient's record by the referring physician and the implanting physician. Both shall provide these documents if requested by this contractor.

A56905 Billing and Coding: Surgical Treatment of Obstructive Sleep Apnea (OSA)

Original Effective Date: 08/29/19 Revision Effective Date: 06/26/25

The billing and coding information in this article is dependent on the coverage indications, limitations and/or medical necessity described in the associated LCD L34526.

Sleep-Disordered Breathing, often referred to as OBSTRUCTIVE SLEEP APNEA (OSA), is characterized by frequent episodes of hypopnea or apnea during sleep. Multiple detrimental physiologic changes may result from these hypopneic and apneic episodes. Non-surgical and surgical approaches to obstructive apnea and hypopnea have been developed.

The following procedures are not covered at this time.

1. Laser-assisted uvulopalatoplasty (LAUP) is not covered at this time since it is not considered effective for OSA. LAUP must not be billed as 42145, Palatopharyngoplasty (e.g., uvulopalatopharyngoplasty, uvulopharyngoplasty). This code is not appropriate for this procedure. If LAUP is billed for denial purposes, it should be coded as 42299, (unlisted procedure, palate, uvula) with "LAUP" in the electronic narrative 2400/SV101-7

equivalent to line 19 of the CMS 1500 form. The claim will be denied as not proven effective.

2. Somnoplasty™ is a trade name for palate reduction with the Somnoplasty™ System of Somnus Medical Systems. This is not a term recognized by this Contractor as a covered procedure under Medicare Part B. Therefore, Somnoplasty™ must not be billed as 42145. This code is not appropriate for this procedure. If Somnoplasty™ is billed for denial purposes, it should be coded as 42299, (unlisted procedure, palate, uvula) with "Somnoplasty™" in the electronic narrative 2400/SV101-7 equivalent to line 19 of the CMS 1500 form. This claim will be denied as not proven effective.
3. The Pillar Procedure™ is a trade name for palatal implants. Palatal implants have not been shown effective for the treatment of OBSTRUCTIVE SLEEP APNEA and are not covered. This procedure should be billed by the physician as 42299 (unlisted procedure, palate, uvula) with "Pillar Procedure™" or "palatal implant" in the electronic narrative 2400/SV101-7 equivalent to line 19 of the CMS 1500 form. This claim will then be denied as not proven effective. Hospital outpatient departments would use code C9727.
4. Submucosal ablation of the tongue base, radiofrequency, one or more sites, per session. (41530) will be denied as investigational and experimental.

A57944 Billing and Coding: Hypoglossal Nerve Stimulation for Treatment of Obstructive Sleep Apnea. Original Effective Date: 06/14/20 Revision Effective Date: 1/1/25

Refer to the Proposed Local Coverage Determination (LCD) DL38528, **HYPOGLOSSAL NERVE STIMULATION FOR THE TREATMENT OF OBSTRUCTIVE SLEEP APNEA**, for reasonable and necessary requirements.

The Current Procedural Terminology (CPT)/Healthcare Common Procedure Coding System (HCPCS) code(s) may be subject to National Correct Coding Initiative (NCCI) edits. This information does not take precedence over NCCI edits. Please refer to NCCI for correct coding guidelines and specific applicable code combinations prior to billing Medicare.

Coding Guidelines

Implantation of a Hypoglossal Nerve Stimulator (HSN) for treatment of OSA CPT code:

- **CPT code 64582** - Open implantation of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array

Revision or replacement of HSN for treatment of OSA is reported with:

- **CPT code 64583** - Revision or replacement of hypoglossal nerve neurostimulator array and distal respiratory sensor electrode or electrode array, including connection to existing pulse generator

Reduced services-Use modifier 52 for revision or replacement of either the hypoglossal nerve stimulator electrode array or distal respiratory sensor, and bill at a reduced rate.

Removal of HSN for treatment of OSA is reported with:

- **CPT code 64584** - Removal of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode array

Reduced services- Use modifier 52 for removal of one or two components of the hypoglossal nerve stimulator electrode array, pulse generator, or distal respiratory sensor, and bill at a reduced rate.

Coding Guidance

- Do not bill CPT code 64582 in conjunction with 64583, 64584, or 61888
- Do not bill CPT code 64583 in conjunction with 64582, 64584, or 61888
- Do not bill CPT code 64584 in conjunction with 64582, 64583, or 61888

Documentation Requirements

1. All documentation must be maintained in the patient's medical record and made available to the contractor upon request.
2. Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, dates of service[s]). The documentation must include the legible signature of the physician or non-physician practitioner responsible for and providing the care to the patient.
3. The submitted medical record must support the use of the selected diagnosis code(s).

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicaid Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Actigraphy
- Cosmetic and Reconstructive Surgery
- Diagnosis Sleep Disorders
- Obstructive Sleep Apnea — Non-surgical Treatment

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through September 19, 2025, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
7/10/02	7/10/02	7/10/02	Joint policy established
1/22/04	1/22/04	3/1/04	Routine maintenance
5/7/04	5/7/04	6/22/04	Addition of procedure codes and descriptions
1/14/05	1/14/05	1/14/05	Code updated effective 1/1/05
7/15/05	7/15/05	9/22/05	Routine maintenance
1/1/08	10/16/07	11/15/07	Routine maintenance
5/1/09	2/10/09	2/10/09	Routine maintenance
1/1/11	10/12/10	10/27/10	Routine maintenance; removed codes E0485 and E0486
7/1/12	6/7/12	5/18/12	Routine maintenance
5/1/14	2/18/14	3/3/14	Routine maintenance; added “and Snoring” to the policy title; added “All other minimally-invasive surgical procedures not described above” to the exclusions.
7/1/16	4/19/16	4/19/16	Routine maintenance Hypoglossal nerve stimulation added to exclusions References and rationale updated
7/1/17	4/18/17	4/18/17	Routine maintenance Added procedure codes 0466T-0468T References and rationale updated
7/1/18	4/17/18	4/17/18	Routine maintenance Added procedure codes 21685 and 64568.
5/1/19	2/19/19		Routine maintenance Position change: HNS covered with criteria.
5/1/20	2/18/20		Routine maintenance. Ref #13 and 24 added.

5/1/21	3/2/21		Routine maintenance. Ref #4, 27, 28, 29, 30, 37, and 38 added. Added LCD L38528 and A57944. Updated change to Inspire HGNS under Table 1: Inspire HGNS is now also indicated for use in patients between the ages of 18 and 21 with moderate to severe OSA (AHI 15-65) who: are contraindicated for, or not effectively treated by, adenotonsillectomy - to reflect FDA language. ▪ Added the below under inclusion under Hypoglossal nerve stimulation coverage – to reflect FDA language: ○ Adolescent or young-adult member: ○ Between the ages of 18 and 21; AND ○ Moderate to severe OSA ($15 \leq \text{AHI} \leq 65$); AND ○ Non-concentric retropalatal obstruction on drug-induced sleep endoscopy; AND ○ A contraindication to, or not effectively treated by, adenotonsillectomy; AND ○ Has been confirmed to fail, or cannot tolerate, PAP therapy despite attempts to improve compliance; AND ** ○ Has followed standard of care in considering all other alternative/adjunct therapies
5/1/22	2/15/22		• Routine maintenance • 0466T, 0467T and 0468T replaced with 64582, 64583, 64584
7/1/22	4/19/22		• Added code 49275 under Established. • Added the below language under the MPS: ○ Drug-induced sleep endoscopy (DISE) replicates sleep with an

			infusion of propofol. DISE will suggest either a flat, anterior-posterior collapse or complete circumferential oropharyngeal collapse. Concentric collapse decreases the success of hypoglossal nerve stimulation and is an exclusion criterion from the U.S. Food and Drug Administration. ○ The use of the DISE procedure is considered established to evaluate appropriateness of FDA-approved hypoglossal nerve stimulation when all the criteria for hypoglossal nerve stimulation are met. ○ The DISE procedure is considered experimental/investigational for all other indications. ● Added the below language under Inclusions: ○ Drug-induced sleep endoscopy (DISE): ▪ The DISE procedure is established to evaluate the appropriateness of FDA-approved hypoglossal nerve stimulation when all the criteria for hypoglossal nerve stimulation are met. ● Added the below language under Exclusions: ○ The DISE procedure is considered experimental/investigational for all other indications ● Removed procedure code 64568 which was revised on 1/1/22 from Incision for implantation of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator to Open implantation of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse
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			generator. This policy does not speak to cranial nerve. • Revised the definition of hypopnea to “at least 3% or 4% decrease in arterial oxygen saturation” to reflect both AASM and Medicare requirements.
7/1/23	4/18/23		• Routine Maintenance • BCBSA updated policy 7.01.101 - Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome on 6/9/22 • References added, policy statements unchanged • Vendor: N/A (ky)
7/1/24	4/16/24		• Noted Hypoglossal nerve stimulation Inspire FDA approval P130008/S090 on 6/8/23 but this approval was based on a registry – which could be biased. Elected to maintain JUMP policy guidelines on initial FDA approval which was based on a study. • Removed section Under Adolescent or young-adult member Between the ages of 18 and 21 and updated Under Hypoglossal nerve stimulation member 22 years of age or older to Individual is 18 years of age or older; • Updated the below: ○ From AHI is ≥ 15 events per hour to AHI is 15-65 events per hour. • Added the below language to align with FDA and Carelon: ○ Has been confirmed to fail, or cannot tolerate, PAP therapy despite attempts to improve compliance**; ** PAP failure is defined as an inability to eliminate OSA (AHI of greater than 15 despite PAP usage), and PAP intolerance is defined as:

			▪ <i>Inability to use PAP for greater than or equal to 5 nights per week of usage; usage defined as greater than 4 hours of use per night, or</i> ▪ <i>Unwillingness to use PAP (for example, a patient returns the PAP system after attempting to use it).</i> • Added the below after Non-concentric retropalatal obstruction on drug-induced sleep endoscopy: ○ Non-concentric retropalatal obstruction confirmation can be performed via drug-induced sleep endoscopy at the time of implantation of the hypoglossal nerve stimulator if a prior in-office volitional snore during flexible laryngoscopy demonstrated anterior-posterior velum collapse. • Under Adolescent or young-adult member with Down syndrome Member is 10 to 21 years of age: ○ Updated age from 10 to 13 years of age per FDA guidance. • Added the below after Non-concentric retropalatal obstruction on drug-induced sleep endoscopy: ○ Non-concentric retropalatal obstruction confirmation can be performed via drug-induced sleep endoscopy at the time of implantation of the hypoglossal nerve stimulator if a prior in-office volitional snore during flexible laryngoscopy demonstrated anterior-posterior velum collapse. • To align the codes on the cover page and the coding section in the body of the policy: added code 21193 under EST to the cover page and added code 21685 under EST to the coding section of the policy. • Medical policy statements updated:
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			○ Added these two statements: ▪ Adenotonsillectomy in pediatric patients with OSA and hypertrophic tonsils is established when criteria are met. ▪ The use of the DISE procedure is considered established to evaluate appropriateness of FDA-approved hypoglossal nerve stimulation when all the criteria for hypoglossal nerve stimulation are met. ○ Removed these two statements: ▪ Hypoglossal nerve stimulation for those not meeting the inclusion criteria is considered experimental/investigational ▪ Hypoglossal nerve stimulators that are not FDA-approved are considered experimental/investigational ○ Moved this statement to under the Description/ Background section: ▪ Drug-induced sleep endoscopy (DISE) replicates sleep with an infusion of propofol. DISE will suggest either a flat, anterior-posterior collapse or complete circumferential oropharyngeal collapse. Concentric collapse decreases the success of hypoglossal nerve stimulation and is an exclusion criterion from the U.S. Food and Drug Administration. • References added • Vendor: Codes 64582, 64583, and 64584 are managed by Carelon for both PPO and HMO. Carelon policy Sleep Disorder Management 10/20/24 (ky)
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7/1/25	4/15/25		• Routine Maintenance • Updated to align with BCBSA under Hypoglossal nerve stimulation Adult individual: • Updated AHI is 15-65 events per hour to AHI is ≥ 15 and ≤ 100 events per hour. • Updated Total number of central and mixed apneas are less than 25% of the total AHI to Total number of central apneas are $\leq 25\%$ of the total AHI. • Updated Body mass index (BMI) is less than or equal to 32 kg/m² to 35 kg/m² • Updated the below language to align with BCBSA: ** CPAP failure is defined as residual AHI ≥ 15 despite CPAP use or failure to use CPAP ≥ 4 hr per night for ≥ 5 nights per week. • Combined 2 exclusion statements to the below statement to align with BCBSA under Exclusions: • Palatal stiffening procedures including, but not limited to, cautery-assisted palatal stiffening operation, injection of a sclerosing agent, and the implantation of palatal implants; • Added codes 21142, 21143, 21145, and 21146 under established. • Added codes 0978T, 0979T, and 0980T (submucosal cryolysis therapy) eff 7/1/25 as E/I. • Added information about Cryosa submucosal cryolysis therapy under the regulatory section, MPS, exclusions section, and added Cryosa's clinical trial under the clinical trial section. • Vendor: Carelon (ky)
1/1/26	10/21/25		• Annual review moved to Oct • Vendor: Carelon (slp) • Policy reformatted • 64568 added for Inspire V

			• “Residual” removed from the inclusion note referencing residual AHI: CPAP failure is defined as AHI ≥ 15 despite CPAP use or failure to use CPAP ≥ 4 hr per night for ≥ 5 nights per week.
5/1/26	2/17/26		• Off cycle review to: ○ Add Genio exclusion ○ Clarified coverage is for “Inspire” FDA approved devices • Added exclusion ○ Surgical treatment of OSA when above criteria are not met • Removed mixed apneas from prior adenotonsillectomy inclusion bullets • Changed tracheostomy to tracheotomy in inclusion criteria
11/01/26	8/18/26		• Updates to MPS, Inclusions, and Exclusions • Codes added established: C8007, C8008, C8009 • Codes added E/I: C8011, C8012, C8013 (rh/mk)

Next Review Date: 4th Qtr, 2026

Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN: 12/1/99	Revised: 3/14/01, 1/4/02
BCBSM: 1/1/97	Revised: 11/14/00

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: OBSTRUCTIVE SLEEP APNEA AND SNORING - SURGICAL TREATMENT

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Policy criteria apply.
BCNA (Medicare Advantage)	See Government Regulations section. If there is no NCD or LCD, medical policy criteria apply.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate, and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.