Medical Policy

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Title: Surgical Treatment of Snoring and Obstructive Sleep Apnea (OSA) Syndrome

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Populations	Interventions	Comparators	Outcomes
Individuals: • With obstructive sleep apnea	Interventions of interest are: • Laser-assisted uvulopalatoplasty	Comparators of interest are: • Continuous positive airway pressure • Established surgical procedures	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity
Individuals: • With obstructive sleep apnea	Interventions of interest are: • Tongue base suspension	Comparators of interest are: • Continuous positive airway pressure • Established surgical procedures	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity

Populations	Interventions	Comparators	Outcomes
Individuals: • With obstructive sleep apnea	Interventions of interest are: • Radiofrequency volumetric reduction of palatal tissues and base of tongue	Comparators of interest are: • Continuous positive airway pressure • Established surgical procedures	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity
Individuals: • With obstructive sleep apnea	Interventions of interest are: • Palatal stiffening procedures	Comparators of interest are: • Continuous positive airway pressure • Established surgical procedures	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity
Individuals: • With obstructive sleep apnea	Interventions of interest are: • Hypoglossal nerve stimulation	Comparators of interest are: • Established surgical procedures	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity

DESCRIPTION

Obstructive sleep apnea (OSA) syndrome is characterized by repetitive episodes of upper airway obstruction due to the collapse of the upper airway during sleep. For patients who have failed conservative therapy, established surgical approaches may be indicated. This policy addresses minimally invasive surgical procedures for the treatment of OSA. They include laser-assisted uvuloplasty, tongue base suspension, radiofrequency volumetric reduction of palatal tissues and base of tongue, palatal stiffening procedures, and hypoglossal nerve stimulation. This policy does not address conventional surgical procedures such as uvulopalatopharyngoplasty, hyoid suspension, surgical modification of the tongue, maxillofacial surgery, or adenotonsillectomy.

OBJECTIVE

The objective of this policy is to determine whether the use of minimally invasive surgical procedures improve the net health outcome for patients being treated for obstructive sleep apnea.

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, adult patients with OSA-associated daytime somnolence are thought to be at higher risk for accidents involving motorized vehicles (ie, 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 also associated with decreased survival, presumably related to severe hypoxemia, hypertension, or an increase in automobile accidents related to overwhelming sleepiness.

REGULATORY STATUS

The regulatory status of minimally invasive surgical interventions is shown in Table 1.

Table 1. Minimally Invasive Surgical Interventions for Obstructive Sleep Apnea

Interventions	Devices (predicate or prior name)	Manufacturer (previously owner)	Indication	PMA/ 510(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 TM Bone Screw System is also suitable for the performance of a hyoid suspension	K122391	1999	LRK
	Encore™ (PRELUDE III)	Siesta Medical	Treatment of mild or moderate OSA and/or snoring	K111179	2011	ORY
Hypoglossal nerve stimulation	Inspire II Upper Airway Stimulation	Inspire Medical Systems	"a subset of patients with moderate to severe obstructive sleep apnea" (AHI >=20 and <=65) in adults >=22 years who have failed (AHI >20 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. Failure includes unwillingness to use CPAP.	P130008	2014	MNQ
	aura6000®	ImThera Medical		IDE	2014	

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

POLICY

A. Palatopharyngoplasty (eg, uvulopalatopharyngoplasty, uvulopharyngoplasty, uvulopalatal flap, expansion sphincter pharyngoplasty, lateral pharyngoplasty, palatal advancement pharyngoplasty, relocation pharyngoplasty) may be considered **medically necessary** for the treatment of clinically significant obstructive sleep apnea syndrome (OSA) in appropriately select adults who have failed an adequate trial of continuous positive airway pressure (CPAP) (see Policy Guidelines) or failed an adequate trial of an oral appliance. Clinically significant OSA is defined as those patients who have:

   1. An Apnea/Hypopnea Index (AHI) or Respiratory Disturbance Index (RDI) of 15 or more events per hour, **OR**

   2. An AHI or RDI of 5 or more events and 14 or less events per hour with documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or documented hypertension, ischemic heart disease, or history of stroke.

B. Hyoid suspension, surgical modification of the tongue, and/or maxillofacial surgery, including mandibular-maxillary advancement (MMA), may be considered **medically necessary** in appropriately selected adults with clinically significant OSA and objective documentation of hypopharyngeal obstruction who have failed an adequate trial of CPAP (see Policy Guidelines) or failed an adequate trial of an oral appliance. Clinically significant OSA is defined as those patients who have:

   1. An AHI or RDI of 15 or more events per hour, **OR**

   2. An AHI or RDI of 5 or more events and 14 or less events per hour with documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or documented hypertension, ischemic heart disease, or history of stroke.

C. Adenotonsillectomy may be considered **medically necessary** in pediatric patients with clinically significant OSA and hypertrophic tonsils. Clinically significant OSA is defined as those pediatric patients who have:

   1. An AHI or RDI of at least 5 per hour, **OR**

   2. An AHI or RDI of at least 1.5 per hour in a patient with excessive daytime sleepiness, behavioral problems, or hyperactivity.

D. Hypoglossal nerve stimulation may be considered **medically necessary** in adults with OSA under the following conditions:

1. Age ≥22 years; AND

2. AHI ≥20 with less than 25% central apneas; AND

3. CPAP failure (residual AHI ≥20 or failure to use CPAP ≥4 hours per night for ≥5 nights per week) or inability to tolerate CPAP; AND

4. Body mass index ≤32 kg/m^2; AND

5. Non-concentric retropalatal obstruction on drug-induced sleep endoscopy (see Policy Guidelines).

E. Hypoglossal nerve stimulation may be considered **medically necessary** in adolescents or young adults with Down's syndrome and OSA under the following conditions:

1. Age 10 to 21 years; AND

2. AHI >10 and <50 with less than 25% central apneas after prior adenotonsillectomy; AND

3. Have either tracheotomy or be ineffectively treated with CPAP due to noncompliance, discomfort, undesirable side effects, persistent symptoms despite compliance use, or refusal to use the device; AND

4. Body mass index ≤95^{th} percentile for age; AND

5. Non-concentric retropalatal obstruction on drug-induced sleep endoscopy (see Policy Guidelines).

F. Surgical treatment of OSA that does not meet the criteria above would be considered **not medically necessary**.

G. The following minimally-invasive surgical procedures are considered **experimental / investigational** for the sole or adjunctive treatment of OSA or upper airway resistance syndrome (UARS):

1. Radiofrequency volumetric tissue reduction of the tongue, with or without radiofrequency reduction of the palatal tissues

2. Laser-assisted palatoplasty (LAUP) or radiofrequency volumetric tissue reduction of the palatal tissues

3. Palatal stiffening procedures including, but not limited to, cautery-assisted palatal stiffening operation, injection of a sclerosing agent, and the implantation of palatal implants

4. Tongue base suspension

5. All other minimally-invasive surgical procedures not described above.

H. Implantable hypoglossal nerve stimulators are considered **experimental / investigational** for all indications.

I. All interventions, including LAUP, radiofrequency volumetric tissue reduction of the palate, or palatal stiffening procedures, are considered **not medically necessary** for the treatment of snoring in the absence of documented OSA; snoring alone is not considered a medical condition.

Policy Guidelines

1. CPAP is the preferred first-line treatment for most patients. A smaller number of patients may use oral appliances as a first line treatment.
2. The AHI is the total number of events (apnea or hypopnea) per hour of recorded sleep. The RDI is the total number of events (apnea or hypopnea) per hour of recording time. An obstructive apnea is defined as at least a 10-second cessation of respiration associated with ongoing ventilatory effort. Hypopnea is defined as an abnormal respiratory event lasting at least 10 seconds with at least a 30% reduction in thoracoabdominal movement or airflow as compared with baseline, and with at least a 4% oxygen desaturation.
3. 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.
4. 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 criteria from the Food and Drug Administration.
5. A trial of CPAP is defined as utilization for 60 days or greater.

RATIONALE

This policy was originally based on TEC Assessments on the surgical management and radiofrequency volumetric tissue reduction of obstructive sleep apnea (OSA).[1,2] The most recent update was performed through May 2, 2018.

This review was informed by TEC Assessments on the surgical management and radiofrequency volumetric tissue reduction for obstructive sleep apnea (OSA).[1, 2,]

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to functionincluding benefits and harms. Every clinical condition has specific outcomes that are important to patients and 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.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Obstructive Sleep Apnea

Clinical Context and Therapy Purpose

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.[3,] Nonsurgical treatment for OSA or upper airway resistance syndrome includes continuous positive airway pressure (CPAP) or mandibular repositioning devices. 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 question addressed in this evidence review is: Do the surgical interventions addressed in this evidence review improve the net health outcome in patients with OSA?

The following PICOTS were used to select literature to inform this review.

Patients

The population of interest includes patients with OSA who have failed or are intolerant of positive airway pressure. Definitions of terms for OSA are shown in Table 2. Indications for the various procedures are described in Table 3 and in the Regulatory Status section.

Table 2. Definitions of Terms for Obstructive Sleep Apnea

Terms	Definition
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 >=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 4% arterial oxygen desaturation or an arousal. Hypopneas in children are scored by a >=50% drop in nasal pressure and either a >=3% decrease in oxygen saturation or an associated arousal.
Apnea/Hypopnea Index (AHI)	The average number of apneas or hypopneas per hour of sleep
Obstructive sleep apnea (OSA)	Repetitive episodes of upper airway obstruction due to the collapse and obstruction of the upper airway during sleep
Mild OSA	In adults: AHI of 5 to <15In children: AHI >=1.5 is abnormal
Moderate OSA	AHI of 15 to < 30
Severe OSA	Adults: AHI >=30Children: AHI of >=15
Continuous positive airway pressure (CPAP)	Positive airway pressure may be continuous (CPAP) or auto-adjusting (APAP) or Bi-level (Bi-PAP). CPAP is a more familiar abbreviation and will refer to all types of PAP devices.
CPAP Failure	Usually defined as an AHI greater than 20 events per hour while using CPAP
CPAP Intolerance	CPAP 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

Interventions

The interventions addressed in this review are laser-assisted uvulopalatoplasty (LAUP), radiofrequency (RF) volumetric reduction of palatal tissues and base of tongue, palatal stiffening procedures, tongue base suspension, and hypoglossal nerve stimulation (HNS) (see Table 3).

Table 3. Minimally Invasive Surgical Interventions for OSA

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 reshapedDoes not alter tonsils or lateral pharyngeal wall tissuesTissue ablation can be titrated	Snoring with or without OSA

Interventions	Devices	Description	Key Features	Indications
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 implanted submucosally in the soft palate	Up to 5 implants may be used	Snoring
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.

Comparators

The following therapies and practices are currently being used to treat OSA:

For patients with mild OSA who are intolerant of CPAP, the comparator would be oral appliances or an established upper airway surgical procedure.

For patients with moderate-to-severe OSA who have failed CPAP or are intolerant of CPAP, the comparator would be maxillofacial surgeries that may include UPPP, hyoid suspensions, maxillary and mandibular osteotomies, and modification of the tongue. UPPP alone has limited efficacy.[4,] UPPP may be modified or combined with a tongue base procedure such as uvulopalatopharyngoglossoplasty, depending on the location of the obstruction. UPPP variants would not be the most appropriate comparator for HNS, since the procedures address different sources of obstruction.

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

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 Questionnaire (FOSQ) (see Table 4).

Table 4. Health Outcome Measures Relevant to OSA

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 >=50% and an AHI <20Alternative 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
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

AHI: Apnea/Hypopnea Index; VAS: visual analog score.

Timing

The effect of surgical treatment of OSA should be observed on follow-up PSG that would be performed from weeks to months after the surgery. Longer term follow-up over 2 years is also needed to determine whether the effects of the procedure are durable or change over time.

Setting

Referral for a surgical procedure would be given by a primary care physician or sleep specialist following a laboratory PSG or home sleep study and home trial of CPAP.

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 RCT (Ferguson et al 2003,) on LAUP has been identified.[7,] This trial compared LAUP with no treatment, finding treatment success (AHI <10) to be similar between LAUP (24%) and no treatment controls (17%) (see Tables 5 and 6). 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 nonblinded study (see Tables 7 and 8). Adverse events of the treatment

included moderate-to-severe pain and bleeding in the first week and difficulty swallowing at follow-up.

Table 5. Summary of Key Randomized Controlled Trial Characteristics

Study	Countries	Sites	Participants	Interventions[1]	NA
				Active	Comparator
Ferguson et al (2003)[7,]	Canada	1	46 patients with mild-to-moderate symptomatic OSA (AHI of 10 to 25) and loud snoring	21 patients treated with LAUP every 1-2 mo1	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 6. 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)[7,]							
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.

The purpose of the gaps tables (see Tables 7 and 8) is to display notable gaps identified in each study. This information is synthesized as a summary of the body of evidence following each table and provides the conclusions on the sufficiency of evidence supporting the position statement.

Table 7. Relevance Gaps

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Ferguson et al (2003)[7,]	1. Entry criteria includes populations with mild OSA (AHI between 10 and 15) for whom an improvement to AHI <10 is not clinically significant		3. Controls had no treatment	6. The definition of success (AHI <10) combined with the eligibility criteria (AHI >10) can lead to clinically insignificant improvements being labeled success	

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 8. Study Design and Conduct Gaps

Study	Allocation[a]	Blinding[b]	Selective Reporting[d]	Data Completeness[e]	Power[d]	Statistical[f]
Ferguson et al (2003)[7,]		1.-3. No blinding				4. Comparison of primary outcome not reported

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: 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 with no treatment controls. Patients in this nonblinded study did not report an improvement in ESS or quality of life 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.[2,] All studies were nonrandomized.

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 9-11).[8,] The second trial (Woodson et al 2003,), provided a mean of 4.8 sessions of RF to the tongue and palate.[9,] This trial found a statistically significant improvement from baseline to posttreatment for ESS and FOSQ. However, the improvement in the 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 Table 12).

Table 9. Summary of Key Randomized Controlled Trial Characteristics

Study	Countries	Sites	Participants	Interventions	NA
				Active	**Comparator**
Black et al (2009)[8,]	Finland	1	32 patients with symptomatic mild OSA and habitual snoring	Single-stage RF to palatal tissues	Sham control with local anesthetic and multiple insertions of

Study	Countries	Sites	Participants	Interventions	NA
			with only velopharyngeal obstruction		an applicator needle without the RF
Woodson et al (2003)[9,]	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 10. 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)**	
Black et al (2009)[8,]					
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	0.628	0.064	0.941	0.746	No significant differences after 6 d
	Change Score (SD)		Change Score (SD)	FOSQ Score (SD)	
Woodson et al (2003)[9,]					
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=0.005 for baseline to posttreatment.

Tables 11 and 12 display notable gaps identified in each study.

Table 11. Relevance Gaps

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Black et al (2009)[8,]	4. Included patients with mild OSA and snoring	4. Single treatment with RFA			
Woodson et al (2003)[9,]					

The evidence gaps 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 12. Study Design and Conduct Gaps

Study	Allocation[a]	Blinding[b]	Selective Reporting[d]	Data Completeness[e]	Power[d]	Statistical[f]
Black et al (2009)[8,]		2. Surgeons also performed follow-up assessments				.
Woodson et al (2003)[9,]						3. Comparative treatment effects not reported

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: Radiofrequency Volumetric Reduction of Palatal Tissues and Base of Tongue
The evidence on RF volume reduction includes 2 randomized trials, both sham-controlled. Single-stage RF to palatal tissues did not improve outcomes compared with 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.

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 operation are intended for snoring, and are not discussed here. Palatal implants are cylindrically shaped devices that are implanted in the soft palate.

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 13). 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 14). 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.[10,] In the study by Friedman et al (2008), there was greater success in AHI (45% vs 0%, $p<0.001$), improvement in snoring (-4.7 vs -0.7 on a 10-point VAS, $p<0.001$), and improvement in ESS (-2.4 vs -0.5, $p<0.001$) with palatal implants compared with sham controls.[5,] Patient selection criteria were different in the 2 studies. In the trial by Friedman et al (2008), patients with a Friedman tongue position of IV and palate of 3.5 cm or longer were

excluded, whereas, in the trial by Steward et al (2008), selection criteria included patients with primarily retropalatal pharyngeal obstruction.

Table 13. Summary of Key Randomized Controlled Trial Characteristics

Study	Countries	Sites	Participants	Interventions	NA
				Active	Comparator
Steward et al (2008)[10,]	U.S.	3	100 patients with mild-to-moderate OSA (AHI >=5 and <=40), and primarily retropalatal pharyngeal obstruction, BMI <=32 kg/m2	50 received the office-based insertion of 3 palatal implants	50 received the sham procedure
Friedman et al (2008)[5,]	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/m2	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 14. 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
Steward et al (2008)[10,]					
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	0.04	0.052	NS	0.05	
Friedman et al (2008)[5,]		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 15 and 16). Compared with nonresponders, responders had lower body mass index, 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 17 and 18 summarize the limitations of the studies described above.

Table 15. Summary of Key Case Series Characteristics

Study	Country	Participants	Follow-Up
Neruntarat et al (2011)[11,]	Thailand	92 patients with mild-to-moderate symptomatic OSA and palate >2 cm	Minimum 24 mo

OSA: obstructive sleep apnea.

Table 16. Summary of Key Case Series Results

Study	N	AHI (SD)	Snoring (SD) (10-point VAS)	ESS (SD)	Implant Extrusion
Neruntarat et al (2011)[11,]	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		<0.001	<0.001	<0.001	

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

Table 17. Relevance Gaps

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Neruntarat et al (2011)[11,]			2. No comparator		
Steward et al (2008)[10,]					1, 2. 3 mo
Friedman et al (2008)[5,]					1, 2. 3 mo

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 18. Study Design and Conduct Gaps

Study	Allocation[a]	Blinding[b]	Selective Reporting[d]	Data Completeness[e]	Power[d]	Statistical[f]
Neruntarat et al (2011)[11,]	Retrospective	None (case series)				
Steward et al (2008)[10,]						
Friedman et al (2008)[5,]						

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: Palatal Stiffening Procedures

Two sham-controlled trials have assessed palatal implants for the treatment of snoring and OSA. The 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. One preliminary RCT with 17 patients was identified that compared UPPP plus tongue suspension with UPPP plus tongue advancement (see Table 19).[12,] Success rates using the Sher criteria ranged from 50% to 57% (see Table 20). Both treatments improved snoring and reduced ESS to below 10. The major limitations of the trial were the number of subjects (n=17) in this feasibility study and the lack of blinding (see Tables 21 and 22). In addition, there was no follow-up after 16 weeks.

Table 19. Summary of Key Randomized Controlled Trial Characteristics

Study	Countries	Sites	Participants	Interventions	NA
				Active	**Comparator**
Thomas et al (2003)[12,]	U.S.	1	17 patients with moderate-to-severe OSA who failed conservative treatment	UPPP with tongue suspension Mean AHI=46 (n=9)	UPPP with tongue advancementMean AHI=37.4 (n=8)

AHI: Apnea/Hypopnea Index; OSA: obstructive sleep apnea; UPPP: uvulopalatopharyngoplasty.

Table 20. Summary of Key Randomized Controlled Trial Results

Study	AHI Success (Sher Criteria)	Snoring (SD)	ESS (SD)	Pain, Speech, Swallowing
Thomas et al (2003)[12,]				
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=0.02.b Baseline to posttreatment p=0.007.c Baseline to posttreatment p=0.04.d Baseline to posttreatment p=0.004.

Table 21. Relevance Gaps

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Thomas et al (2003)[12,]					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 22. Study Design and Conduct Gaps

Study	Allocation[a]	Blinding[b]	Selective Reporting[d]	Data Completeness[e]	Power[d]	Statistical[f]
Thomas et al (2003)[12,]	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 with tongue advancement plus UPPP and reported 50% to 57% success rates for the 2 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 patients 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.

Comparative Studies

No RCTs have been identified on HNS. Comparative evidence consists of 2 studies that compared HNS with historical controls treated with UPPP or a variant of UPPP (expansion sphincter pharyngoplasty, see Table 23). AHI success by the Sher criteria ranged from 87% to 100% in the HNS group compared with 40% to 64% in the UPPP group (see Table 24). 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 regards to the pattern of palatal collapse and from patients who did not return for postoperative PSG (see Tables 25 and 26). UPPP may not be the most appropriate comparator for HNS, because UPPP is less effective for patients with obstruction arising primarily from the tongue base (the primary target for HNS).

Table 23. Summary of Observational Comparative Study Characteristics

Study	Study Type	Country	Dates	Participants	HNS	Traditional Surgery	Follow-Up
Shah et al (2018)[13,]	Retrospective series with historical controls	U.S.	HNS 2015-2016UPPP 2003-2012	40 OSA patients with AHI >20 and <65, BMI <=32 kg mg/m2, failed CPAP, favorable pattern	35% had previously had surgery for OSA	UPPP 50% of patients had additional surgical procedures	2-13 mo

Study	Study Type	Country	Dates	Participants	HNS	Traditional Surgery	Follow-Up
				of palatal collapsea			
Huntley et al (2018)[14,]	Retrospective series with historical controls	U.S.	HNS 2014-2016Modified 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

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 24. 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)[13,]					
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)[14,]					
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	0.003	0.003	0.008	0.565	NS

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<0.05.b Baseline vs posttreatment p<0.001.

Table 25. Relevance Gaps

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Shah et al (2018)[13,]			2. UPPP may not be preferred treatment for patients with primarily lingual obstruction		
Huntley et al (2018)[14,]	4. Study populations not comparable		1. Not clearly defined, few ESP patients had follow-up PSG		
Steffen et al (2018)[15,]			No comparator		
STAR trial[16, 17, 18, 19, 20, 21,]			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 26. Study Design and Conduct Gaps

Study	Allocation[a]	Blinding[b]	Selective Reporting[d]	Data Completeness[e]	Power[d]	Statistical[f]
Shah et al (2018)[13,]	1. Not randomized (retrospective)4. Inadequate control for selection bias	1.-3. No blinding				4. Comparative treatment effects not calculated
Huntley et al (2018)[14,]	1. Not randomized (retrospective)	1.-3. No blinding				
Steffen et al (2018)[15,]	1. Not randomized	1.-3. No blinding				
STAR trial[16, 17, 18, 19, 20, 21,]	1. Not randomized	1.-3. No blinding				

The evidence gaps 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

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 27 and 28). 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 29).

Table 27. Summary of Prospective Single-Arm Study Characteristics

Study	Country	Participants	Treatment Delivery	Follow-Up
STAR trial[16, 17, 18, 19, 20, 21,]	EU, U.S.	126 patients with AHI >20 and <50, BMI <=32 kg/m2, failed CPAP, favorable pattern of palatal collapsea	Stimulation parameters titrated with full PSG	5 y
Postmarket studies: Heiser et al (2017)[22,] Steffen et al (2018)[15,]	3 sites in Germany	60 patients with AHI >=15 and <=65 on home sleep study, BMI <=35 kg/m2, failed CPAP; favorable pattern of palatal collapsea		12 mo

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 28. 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[16, 17, 18, 19, 20, 21,]						
Baseline	126		32.0 (11.8)	28.9 (12.0)	14.3 (3.2)	11.6 (5.0)

Study	N	Percent of Patients With AHI Success (Sher criteria)	Mean AHI Score (SD)	Mean ODI Score (SD)	FOSQ Score (SD)	ESS Score (SD)
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	116a	65%	14.2 (15.9)	9.1 (11.7)	17.4 (3.5)b	7.0 (5.0)b
5 years	97c	63%	12.4 (16.3)	9.9 (14.5)	18.0 (2.2)	6.9 (4.7)
Postmarket studies: Heiser et al (2017)[22], Steffen et al (2018)[15],						
Baseline	60		31.2 (13.2)	27.6 (16.4)	13.7 (3.6)	12.8 (5.3)
12 months	56f	68%	13.8 (14.8)e	13.7 (14.9)e	17.5 (3)e	6.5 (4.5)e

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.a Ninety-eight participants agreed to undergo PSG at 36 months, of the 17 participants who did not undergo PSG at 36 months, 54% were nonresponders 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<0.001.e p< 0.05.

Table 29. 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[21],							
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

Section Summary: Hypoglossal Nerve Stimulation

The evidence on HNS for the treatment of OSA includes nonrandomized studies with historical controls and prospective single-arm studies. For patients with moderate-to-severe OSA who had failed conservative therapy (CPAP) and had a favorable pattern of palatal collapse, about two-thirds met the study definition of success. Results observed at the 12-month follow-up were maintained at 5 years in the pivotal study. Clinical input supplements and informs the interpretation of the published evidence. Clinical input indicates that HNS leads to a meaningful improvement in health outcomes in appropriately selected 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. Clinical input also supports that HNS results in a meaningful improvement in health outcomes in appropriately selected adolescents with OSA and Down's syndrome who have difficulty in using CPAP.

SUMMARY OF EVIDENCE

For individuals who have OSA who receive laser-assisted uvulopalatoplasty, the evidence includes a single 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 the effects of the technology on health outcomes.

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. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Single-stage radiofrequency to palatal tissues did not improve outcomes compared with 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 was not clinically significant. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have OSA who receive palatal stiffening procedures, the evidence includes two sham-controlled randomized trials. 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 study is needed to corroborate the results of the more successful trial and, if successful, define the appropriate selection criteria. The evidence is insufficient to determine the effects of the technology on health outcomes.

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 and showed success rates of 50% to 57% for both procedures. 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 the effects of the technology on health outcomes.

For individuals who have OSA who receive hypoglossal nerve stimulation, the evidence includes two nonrandomized studies with historical controls and prospective single-arm studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Hypoglossal nerve stimulation has shown success rates for about two-thirds of a subset of patients who met selection criteria that included AHI, body mass index, and favorable pattern of palatal collapse. These results were maintained out to five years in the pivotal single-arm study. Clinical input supplements and informs the interpretation of the published evidence. Clinical input indicates that HNS leads to a meaningful improvement in health outcomes in appropriately selected 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. Clinical input also supports that HNS results in a meaningful improvement in health outcomes in

appropriately selected adolescents with OSA and Down's syndrome who have difficulty in using CPAP. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome for patients meeting the following selection criteria which 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 <= 35 kg/m2 in adults; AND
- Favorable pattern of palatal collapse

CLINICAL INPUT FROM PHYSICIAN SPECIALTY SOCIETIES AND ACADEMIC MEDICAL CENTERS

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2018 Input

In response to requests, clinical input on moderate-to-severe and mild obstructive sleep apnea was received from 2 respondents, including 1 specialty society-level response and physicians with academic medical center affiliation, while this policy was under review in 2018.

Based on the evidence and independent clinical input, the clinical input supports that the following indication provides a clinically meaningful improvement in the net health outcome and is consistent with generally accepted medical practice:

- Use of hypoglossal nerve stimulation for individuals with moderate-to-severe obstructive sleep apnea who have failed an adequate trial of (or are unable to tolerate) continuous positive airway pressure.

Based on the evidence and independent clinical input, the clinical input does not support that the following indication provides a clinically meaningful improvement in the net health outcome and is consistent with generally accepted medical practice:

- Use of hypoglossal nerve stimulation for individuals with mild obstructive sleep apnea who have failed an adequate trial of (or are unable to tolerate) continuous positive airway pressure.

PRACTICE GUIDELINES AND POSITION STATEMENTS

American Academy of Sleep Medicine

The American Academy of Sleep Medicine (2010) published practice parameters for surgical modifications of the upper airway for obstructive sleep apnea (OSA).[4,] The AASM practice parameters were based on a systematic review of the evidence that found the published literature was comprised primarily of case series, with few controlled trials and varying approaches to preoperative evaluation and postoperative follow-up.[23,] Using the change in Apnea/Hypopnea Index as the primary measure of efficacy, substantial and consistent reductions were observed following mandibular-maxillary advancement, and adverse events were uncommonly reported. Outcomes following pharyngeal surgeries were less consistent, and adverse events were more commonly reported. The review found that outcomes of studies with newer pharyngeal techniques and multilevel procedures, performed in small numbers of patients,

appear promising. The practice parameters noted the lack of rigorous data evaluating surgical modifications of the upper airway, resulting in a recommendation of "option" (uncertain clinical use) for mandibular-maxillary advancement, uvulopalatopharyngoplasty as a sole procedure, or multilevel or stepwise surgery if patients failed uvulopalatopharyngoplasty as a sole treatment. Use of radiofrequency ablation was recommended as an "option" for patients with mild-to-moderate OSA who cannot tolerate or are unwilling to adhere to continuous positive airway pressure (CPAP), or in whom oral appliances have been found ineffective or undesirable. Palatal implants were recommended as an "option" for patients with mild OSA who failed medical therapy. Laser-assisted uvulopalatoplasty was not recommended as a routine treatment for OSA (standard). The practice parameters recommended as "standard" the need to determine the presence and severity of OSA before initiating surgical therapy, discussion of success rates, complications, and alternative treatments with the patient, and a postoperative follow-up evaluation, which includes a clinical evaluation and an objective measure of the presence and severity of sleep-disordered breathing and oxygen saturation. However, little guidance was available in the medical literature to recommend any particular monitoring strategy. The optimal interval and duration of this follow-up were also not clear from the available literature.

American Academy of Pediatrics

The American Academy of Pediatrics (2012) published a clinical practice guideline on the diagnosis and management of childhood OSA.[24,] 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 OAS 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.

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.[25,] 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:

- tracheotomy,
- nasal and pharyngeal airway surgery,
- tonsillectomy and adenoidectomy,
- palatal advancement,
- uvulopalatopharyngoplasty,
- uvulopalatoplasty (including laser-assisted and other techniques),
- genioglossal advancement,
- hyoid myotomy,
- midline glossectomy,
- tongue suspension,
- maxillary and mandibular advancement.

In a position statement, AAO-HNS (2016) supported hypoglossal nerve stimulation as an effective second-line treatment of moderate-to-severe OSA in patients who are intolerant or unable to achieve benefit with CPAP.[26,] AAO-HNS noted that not all patients are candidates for upper

airway stimulation therapy and require a number of assessments to ensure proper patient selection.

American Society for Metabolic and Bariatric Surgery

The American Society for Metabolic and Bariatric Surgery (2012) published guidelines on the perioperative management of OSA.[27,] 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.

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 30.

Table 30. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT02344108a	A Pilot Study to Evaluate the Safety and Efficacy of the Hypoglossal Nerve Stimulator in Adolescents and Young Adults With Down Syndrome and Obstructive Sleep Apnea	50	Sep 2020
NCT02907398a	Adherence and Outcome of Upper Airway Stimulation (UAS) for OSA International Registry	2500	Sep 2019
NCT03359096	Cardiovascular Endpoints for Obstructive Sleep Apnea With Twelfth Nerve Stimulation (CARDIOSA-12): A Randomized, Sham-Controlled, Double-Blinded, Crossover Trial	80	Jun 2020
NCT02413970a	Inspire® Upper Airway Stimulation System (UAS): Post-Approval Study Protocol Number 2014-001	127	Dec 2021
NCT02263859a	ImThera Medical Targeted Hypoglossal Neurostimulation Study #3 (THN3)	141	Dec 2022

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CPT/HCPCS

21199	Osteotomy, mandible, segmental; with genioglossus advancement
41512	Tongue base suspension, permanent suture technique
41530	Submucosal ablation of the tongue base, radiofrequency, 1 or more sites, per session
42145	Palatopharyngoplasty (eg, uvulopalatopharyngoplasty, uvulopharynogoplasty)
42299	Unlisted procedure, palate, uvula

42820	Tonsillectomy and adenoidectomy; younger than 12
42821	Tonsillectomy and adenoidectomy; age 12 or over
42825	Tonsillectomy, primary or secondary; younger than age 12
42826	Tonsillectomy, primary or secondary; age 12 or over
42830	Adenoidectomy, primary; younger than age 12
42831	Adenoidectomy, primary; age 12 or over
42835	Adenoidectomy, secondary; younger than age 12
42836	Adenoidectomy, secondary; age 12 or over
64568	Incision for implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator
0466T	Insertion of chest wall respiratory sensor electrode or electrode array, including connection to pulse generator (List separately in addition to code for primary procedure)
0467T	Revision or replacement of chest wall respiratory sensor electrode or electrode array, including connection to existing pulse generator
0468T	Removal of chest wall respiratory sensor electrode or electrode array
S2080	Laser-assisted uvulopalatoplasty (LAUP)

ICD-10 Diagnoses

G47.33	Obstructive sleep apnea (adult) (pediatric)

REVISIONS

10-01-2015	Policy added to the bcbsks.com web site on 09-01-2015 and effective 10-01-2015.
	The new policy replaced two policies titled: "Laser Assisted Uvulopalatopharyngoplasty (LAUP)" and "Uvulopalatopharyngoplasty (UPPP) and Tongue Base Reduction Surgery"
05-13-2016	In Policy section: ▪ In Item A, added "(see Policy Guidelines)" to read "Uvulopalatopharyngoplasty (UPPP) may be considered medically necessary for the treatment of clinically significant obstructive sleep apnea syndrome (OSA) in appropriately selected adult patients who have failed an adequate trial of continuous positive airway pressure (CPAP) (see Policy Guidelines) or failed an adequate trial of an oral appliance. Clinically significant OSA is defined as those patients who have:" ▪ In Item B, added "(see Policy Guidelines)" to read "Hyoid suspension, surgical modification of the tongue, and/or maxillofacial surgery, including mandibular-maxillary advancement (MMA), may be considered medically necessary in appropriately selected adult patients with clinically significant OSA and objective documentation of hypopharyngeal obstruction who have failed an adequate trial of CPAP (see Policy Guidelines) or failed an adequate trial of an oral appliance. Clinically significant OSA is defined as those patients who have:" ▪ In Policy Guidelines, added "3. A trial of CPAP is defined as utilization for 60 days or greater."
	Updated References section.
01-18-2017	Updated Description section.
	In Policy section: ▪ In Item A, added "Palatopharyngoplasty (eg" and "uvulopharyngoplasty, uvulopalatal flap, expansion sphincter pharyngoplasty, lateral pharyngoplasty, palatal advancement pharyngoplasty, relocation pharygoplasty)" and removed "(UPPP)" to read, "Palatopharyngoplasty (eg, uvulopalatopharyngoplasty, uvulopharyngoplasty, uvulopalatal flap, expansion sphincter pharyngoplasty, lateral pharyngoplasty, palatal

	advancement pharyngoplasty, relocation pharyngoplasty) may be considered medically necessary for the treatment of clinically significant obstructive lseep apnea syndrome (OSA) in appropriately selected adult patients who have failed an adequate trial of continuous positive airway pressure (CPAP) (see Policy Guidelines) or failed an adequate trial of an oral appliance. Clinically significant OSA is defined as those patients who have:" ▪ In Item B, added an "s" and removed "patients" to read, "Hyoid suspension, surgical modification of the tongue, and/or maxillofacial surgery, including mandibular-maxillary advancement (MMA), may be considered medically necessary in appropriately selected adults with clinically significant OSA and objective documentation of hypopharyngeal obstruction who have failed an adequate trial of CPAP (see Policy Guidelines) or failed an adequate trial of an oral appliance. Clinically significant OSA is defined as those patients who have:" ▪ In Item B 1, added "of" to read, "AHI or RDI of 15 or more events per hour," ▪ In Item B 2, added "of" to read, "AHI or RDI of 5 or more events and 14 or less events per hour with documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or documented hypertension, ischemic heart disease, or history of stroke."
	Updated Rationale section.
	In Coding section: ▪ Added CPT code: 64568. ▪ Added CPT codes: 0466T, 0467T, 0468T *(new codes, effective January 1, 2017)*.
	Updated References section.
10-25-2017	Updated Description section.
	Updated Rationale section.
	Updated References section.
02-01-2019	Updated Description section.
	In Policy section: ▪ In Item A, removed "patients" to read, "Palatopharyngoplasty (eg, uvulopalatopharyngoplasty, uvulopharyngoplasty, uvulopalatal flap, expansion sphincter pharyngoplasty, lateral pharyngoplasty, palatal advancement pharyngoplasty, relocation pharyngoplasty) may be considered medically necessary for the treatment of clinically significant obstructive sleep apnea syndrome (OSA) in appropriately select adults who have failed an adequate trial of continuous positive airway pressure (CPAP) (see Policy Guidelines) or failed an adequate trial of an oral appliance. Clinically significant OSA is defined as those patients who have:" ▪ Added new Item D, "Hypoglossal nerve stimulation may be considered medically necessary in adults with OSA under the following conditions: 1. Age ≥22 years; AND 2. AHI ≥20 with less than 25% central apneas; AND 3. CPAP failure (residual AHI ≥20 or failulre to use CPAP ≥4 hours per night for ≥5 nights per week) or inability to tolerate CPAP; AND 4. Body mass index ≤32 kg/m^2; AND 5. Non-concentric retropalatal obstruction on drug-induced sleep endoscopy (see Policy Guidelines)." ▪ Added new Item E, "Hypoglossal nerve stimulation may be considered medically necessary in adolescents or young adults with Down's syndrome and OSA under the following conditions: 1. Age 10 to 21 years; AND 2. AHI >10 and <50 with less than 25% central apneas after prior adenotonsillectomy; AND 3. Have either tracheotomy or be ineffectively treated with CPAP due to noncompliance, discomfort, undesirable side effects, persistent symptoms despite compliance use, or refusal to use the device; AND 4. Body mass index ≤95^{th} percentile for age; AND 5. Non-concentric retropalatal obstruction on drug-induced sleep endoscopy (see Policy Guidelines). ▪ In Item H (previously Item F), removed "including, but not limited to, the treatment of OSA" and added "other than listed above" to read, "Implantable hypoglossal nerve

	stimulators are considered experimental / investigational for all indications other than listed above." ▪ Updated Policy Guidelines.
	Updated Rationale section.
	In Coding section: ▪ Removed CPT code: 41599. ▪ Removed ICD-9 codes.
	Updated References section.

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