



Louisiana

Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome

Policy # 00329

Original Effective Date: 07/27/2012

Current Effective Date: 09/14/2020

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome is addressed separately in medical policy 00328.

Note: Actigraphy is addressed separately in medical policy 00330.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member’s contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider palatopharyngoplasty (e.g., uvulopalatopharyngoplasty (UPPP), uvulopharyngoplasty, uvulopalatal flap, expansion sphincter pharyngoplasty, lateral pharyngoplasty, palatal advancement pharyngoplasty, relocation pharyngoplasty) for the treatment of clinically significant obstructive sleep apnea (OSA) syndrome in appropriately selected adult patients who have failed an adequate trial of continuous positive airway pressure (CPAP) or failed an adequate trial of an oral appliance (OA) to be **eligible for coverage.****

Based on review of available data, the Company may consider hyoid suspension, surgical modification of the tongue, and/or maxillofacial surgery, including mandibular-maxillary advancement (MMA), in appropriately selected adult patients with clinically significant obstructive sleep apnea (OSA) syndrome and objective documentation of hypopharyngeal obstruction who have failed an adequate trial of continuous positive airway pressure (CPAP) or failed an adequate trial of an oral appliance (OA) to be **eligible for coverage.****

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Patient Selection Criteria for Obstructive Sleep Apnea syndrome (OSA) in Adult Patients

Clinically significant obstructive sleep apnea (OSA) syndrome is defined as those patients who meet the following criteria:

- Apnea/hypopnea index (AHI), respiratory disturbance index (RDI), or respiratory event index (REI) ≥ 15 events per hour; OR
- Apnea/hypopnea index (AHI), respiratory disturbance index (RDI), or respiratory event index (REI) ≥ 5 events per hour in a patient with excessive daytime sleepiness, unexplained hypertension, ischemic heart disease, or history of stroke.

Based on review of available data, the Company may consider adenotonsillectomy in pediatric patients with clinically significant obstructive sleep apnea (OSA) syndrome and hypertrophic tonsils to be **eligible for coverage**.**

Patient Selection Criteria for OSA in Pediatric Patients

Clinically significant obstructive sleep apnea (OSA) syndrome is defined as those patients who meet the following criteria:

- Apnea/hypopnea index (AHI), or respiratory disturbance index (RDI) ≥ 5 events per hour; OR
- Apnea/hypopnea index (AHI), or respiratory disturbance index (RDI) ≥ 1.5 events per hour in a patient with excessive daytime sleepiness, behavioral problems, or hyperactivity.

Based on review of available data, the Company may consider hypoglossal nerve stimulation in adults with obstructive sleep apnea (OSA) syndrome to be **eligible for coverage**.**

Patient Selection Criteria

Coverage eligibility will be met for hypoglossal nerve stimulation in adults with obstructive sleep apnea (OSA) syndrome under the following conditions:

- Age ≥ 22 years; AND
- Apnea/hypopnea index (AHI), respiratory disturbance index (RDI), or respiratory event index (REI) ≥ 15 with less than 25% central apneas; AND
- Continuous positive airway pressure (CPAP) failure (residual apnea/hypopnea index [AHI], respiratory disturbance index (RDI), or respiratory event index (REI) ≥ 15 or failure to use CPAP ≥ 4 hr per night for ≥ 5 nights per week) or inability to tolerate CPAP; AND

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- Body mass index \leq 32 kg/m²; AND
- Non-concentric retropalatal obstruction on drug-induced sleep endoscopy (see Policy Guidelines).

Based on review of available data, the Company may consider hypoglossal nerve stimulation in adolescents or young adults with Down syndrome and obstructive sleep apnea (OSA) syndrome to be **eligible for coverage**.**

Patient Selection Criteria

Coverage eligibility will be met for hypoglossal nerve stimulation in adolescents or young adults with Down syndrome and obstructive sleep apnea (OSA) syndrome under the following conditions:

- Age 10 to 21 years; AND
- Apnea/hypopnea index (AHI) or respiratory event index (REI) $>$ 10 with less than 25% central apneas after prior adenotonsillectomy; AND
- Have been ineffectively treated with continuous positive airway pressure (CPAP) due to noncompliance, discomfort, un-desirable side effects, persistent symptoms despite compliance use, or refusal to use the device; AND
- Body mass index \leq 95th percentile for age; AND
- Non-concentric retropalatal obstruction on drug-induced sleep endoscopy (See Policy Guidelines).

When Services Are Considered Not Medically Necessary

Based on review on available data, the Company considers surgical treatment of obstructive sleep apnea (OSA) syndrome that does not meet the criteria above to be **not medically necessary**.**

Based on review on available data, the Company considers all interventions, including laser-assisted palatoplasty (LAUP), radiofrequency volumetric tissue reduction of the palate, or palatal stiffening procedures for the treatment of snoring when criteria have not been met or in the in the absence of documented obstructive sleep apnea (OSA) syndrome to be **not medically necessary****; snoring alone is not considered a medical condition.

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When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the following minimally-invasive surgical procedures for the sole or adjunctive treatment of obstructive sleep apnea (OSA) syndrome or upper airway resistance syndrome (UARS) to be **investigational**.*

- Laser-assisted palatoplasty (LAUP) or radiofrequency volumetric tissue reduction of the palatal tissues; and
- Radiofrequency volumetric tissue reduction of the tongue, with or without radiofrequency reduction of the palatal tissues; and
- Palatal stiffening procedures including, but not limited to, cautery-assisted palatal stiffening operation (CAPSO), injection of a sclerosing agent, and the implantation of palatal implants; and
- Tongue base suspension; and
- All other minimally-invasive surgical procedures not described above.

Based on review of available data, the Company considers implantable hypoglossal nerve stimulators for all indications other than listed above to be **investigational**.*

Policy Guidelines

Continuous positive airway pressure is the preferred first-line treatment for most patients. A smaller number of patients may use oral appliances as a first-line treatment (see medical policy 00328). The Apnea/Hypopnea Index is the total number events (apnea or hypopnea) per hour of recorded sleep. The Respiratory Disturbance Index is the total number 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 compared with baseline, and with at least a 4% oxygen desaturation.

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.

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Hypoglossal nerve stimulation reduces airway collapsibility and alleviates obstruction at both the level of the soft palate and tongue base.

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 U.S. Food and Drug Administration.

Background/Overview

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 impair daytime activity. For example, adults 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 associated with decreased survival, presumably related to severe hypoxemia, hypertension, or an increase in automobile accidents related to overwhelming sleepiness.

Terminology and diagnostic criteria for OSA are shown in Table 1

Table 1. Terminology and Definitions for Obstructive Sleep Apnea

Terms	Definitions
Respiratory Event	
Apnea	The frequency of apneas and hypopneas is measured from channels assessing oxygen desaturation, respiratory airflow, and respiratory

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Terms	Definitions
	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 4% arterial oxygen desaturation 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	Respiratory event-related arousal is defined as an event lasting at least 10 seconds associated with flattening of the nasal pressure waveform and/or evidence of increasing respiratory effort, terminating in an arousal but not otherwise meeting criteria for apnea or hypopnea
Respiratory event reporting	
Apnea/Hypopnea Index (AHI)	The average number of apneas or hypopneas per hour of sleep
Respiratory Disturbance Index (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.
Respiratory event index (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

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Terms	Definitions
Mild OSA	In adults: AHI of 5 to <15. In children: AHI \geq 1 to 5
Moderate OSA	AHI of 15 to < 30. Children: AHI of > 5 to 10
Severe OSA	Adults: AHI \geq 30. Children: AHI of >10
Treatment	
Positive airway pressure (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 20 events per hour while using PAP
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

OSA: obstructive sleep apnea; PSG : Polysomnographic

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

The regulatory status of minimally invasive surgical interventions is shown in Table 2.

Table 2. 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

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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
	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	Patients \geq 18 years with $AHI \geq 15$ 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	P130008, S039	2014	MNQ

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			between ages 18 and 21 should also be contraindicated for or not effectively treated by adenotonsillectomy.			
Hypoglossal nerve stimulation	aura6000 ^{®‡}	ImThera Medical		IDE	2014	
Hypoglossal nerve stimulation	Genio ^{™‡}	Nyxoa		European CE Mark	2019	

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

The expanded indication for hypoglossal nerve stimulation in patients age 18 to 21 was based on patients with Down Syndrome and is contingent on a post-approval study of the Inspire^{®‡} UAS in this age group. The post-approval study will be a multicenter, single-arm, prospective registry with 60 pediatric patients age 18 to 21. Visits will be scheduled at pre-implant, post-implant, 6 months, and yearly thereafter through 5 years.

Rationale/Source

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 evidence review 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 (HNS). This evidence review does not address conventional surgical procedures such as

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uvulopalatopharyngoplasty, hyoid suspension, surgical modification of the tongue, maxillofacial surgery, or adenotonsillectomy.

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 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 2 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

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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 2 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 5 years in the pivotal single-arm study. Prospective comparative trials are needed. For children and adolescents with OSA and Down Syndrome who are unable to tolerate CPAP, the evidence includes a safety study with 20 patients who were treated at tertiary care centers. The success rate was 70% with 2 adverse events of the leads, which were resolved with further surgery. Study in a larger number of patients with Down Syndrome is ongoing. The evidence is insufficient to determine the effects of the technology on health outcomes.

Supplemental Information

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

Clinical input was sought to help determine whether the use of hypoglossal nerve stimulation for individuals with obstructive sleep apnea 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, clinical input was received from 2 respondents, including 1 specialty society-level response and physicians with academic medical center affiliation.

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

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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 \geq 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 \leq 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 (2010) published practice parameters for surgical modifications of the upper airway for obstructive sleep apnea (OSA). 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. 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

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"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. 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 position statement on surgical management of OSA. 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.

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In a 2019 position statement, AAO-HNS supported hypoglossal nerve stimulation as an effective second-line treatment of moderate-to-severe OSA.

American Society for Metabolic and Bariatric Surgery

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

National Institute for Health and Care Excellence

2017 guidance from the U.K.'s National Institute for Health and Care Excellence (NICE) concluded that evidence on the safety and efficacy of hypoglossal nerve stimulation is limited in quantity and quality.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

The Centers for Medicare & Medicaid Services (CMS; 2008) published a decision memorandum that addressed how to define moderate-to-severe OSA as a guide for a coverage policy on CPAP. Because surgical approaches are considered when CPAP fails, CMS policy was adapted to this evidence review on the surgical management of OSA. The CMS review of the literature suggested there is a risk of hypertension with an Apnea/Hypopnea Index or Respiratory Disturbance Index of at least 15 events per hour, and thus treatment is warranted for patients without any additional signs and symptoms. For patients with an Apnea/Hypopnea Index or Respiratory Disturbance Index between 5 and 14 and associated symptoms, CMS concluded that the data from RCTs have demonstrated improved daytime somnolence and functioning in those treated with CPAP.

There is no national coverage determination for hypoglossal nerve stimulation. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

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Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 3.

Table 3. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT03760328	Effect of Upper Airway Stimulation: A Randomized Controlled Crossover Study	100	Jun 2020
NCT02344108 ^a	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 2021
NCT03359096	Cardiovascular Endpoints for Obstructive Sleep Apnea With Twelfth Nerve Stimulation (CARDIOSA-12): A Randomized, Sham-Controlled, Double-Blinded, Crossover Trial	80	Dec 2021
NCT02413970 ^a	Inspire Upper Airway Stimulation System (UAS): Post-Approval Study Protocol Number 2014-001	127	Dec 2021
NCT03868618 ^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 Adults Subjects	136	Jun 2022
NCT02263859 ^a	ImThera Medical Targeted Hypoglossal Neurostimulation Study #3 (THN3)	138	Dec 2022

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NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT04031040 ^a	A Post-market Clinical Follow up of the Genio System for the Treatment of Obstructive Sleep Apnea in Adults.	110	Oct 2023
NCT02907398 ^a	Adherence and Outcome of Upper Airway Stimulation (UAS) for OSA International Registry	5000	Sep 2025
<i>Unpublished</i>			
ACTRN12614000338662	Multi-level airway surgery in patients with moderate-severe Obstructive Sleep Apnoea (OSA) who have failed medical management to assess change in OSA events and daytime sleepiness.	102	Aug 2018

NCT: national clinical trial. ACTRN: Australian New Zealand Clinical Trials Registry

^a Denotes industry-sponsored or cosponsored trial.

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Policy History

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06/28/2012 Medical Policy Committee review

07/27/2012 Medical Policy Implementation Committee approval. New policy.

12/06/2012 Medical Policy Committee review

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12/19/2012	Medical Policy Implementation Committee. Coverage eligibility statement amended to clarify that the denial is not medically necessary when criteria are not met.
06/27/2013	Medical Policy Committee review
07/17/2013	Medical Policy Implementation Committee. No change to coverage.
07/10/2014	Medical Policy Committee review
07/16/2014	Medical Policy Implementation Committee approval. Changed the language throughout the “May Be Eligible for Coverage” section from “not responded to or do tolerate nasal continuous positive airway pressure (CPAP)” to “failed an adequate trial of continuous positive airway pressure (CPAP) or failed an adequate trial of an oral appliance (OA)”. Added that “surgical treatment of obstructive sleep apnea syndrome (OSA) that does not meet the criteria above” to the “Not Medically Necessary” section. Added investigational statement for hypoglossal nerve stimulation.
06/25/2015	Medical Policy Committee review
07/15/2015	Medical Policy Implementation Committee. No change to coverage.
06/30/2016	Medical Policy Committee review
07/20/2016	Medical Policy Implementation Committee. No change to coverage.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
02/02/2017	Medical Policy Committee review
02/15/2017	Medical Policy Implementation Committee. Updated rationale and references. Coverage statement revised to include variants of palatopharyngoplasty. RDI removed from criteria for clinically significant OSA Updated rationale and references.
02/01/2018	Medical Policy Committee review
02/21/2018	Medical Policy Implementation Committee approval. Deleted 2 sentences from the “Notes” in the coverage section regarding the use of oral appliances and the definition of the Respiratory Disturbance Index. Coverage eligibility unchanged.
02/07/2019	Medical Policy Committee review
02/20/2019	Medical Policy Implementation Committee approval. Added Respiratory Disturbance Index (RDI) and Respiratory Event Index (REI) to the Patient Selection Criteria for adult patients to further define clinically significant obstructive sleep apnea. Added Respiratory Disturbance Index (RDI) to the Patient Selection Criteria for pediatric patients to further define clinically significant

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obstructive sleep apnea. Hypoglossal nerve stimulation for obstructive sleep apnea changed from investigational to eligible for coverage with criteria, for adults and for adolescents or young adults. Investigational statement added for implantable hypoglossal nerve stimulators for all other indications. Moved the *Notes* after the investigational statements to a Policy Guidelines section that includes all BCBSA Policy Guidelines. Added definitions for RDI and REI to Table 2.

02/06/2020 Medical Policy Committee review

02/12/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

08/06/2020 Medical Policy Committee review

08/12/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 08/2021

Coding

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Code Type	Code
CPT	0466T, 0467T, 0468T, 21199, 21685, 41512, 41530, 42145, 42299, 42950, 64568, 64569, 64570, 95970
HCPCS	C1767, C1778, C1787, C9727, S2080
ICD-10 Diagnosis	G47.10, G47.30-G47.37, G47.9, R06.00, R06.09, R06.1, R06.3, R06.81, R06.83, R06.89

***Investigational** – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

****Medically Necessary** (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment,

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would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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