Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome

Policy # 00329
Original Effective Date: 07/27/2012
Current Effective Date: 10/14/2024

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: 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 adults 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- See Policy Guidelines Section), in appropriately selected adults with clinically significant obstructive sleep apnea (OSA) 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**.**

<u>Patient Selection Criteria for Obstructive Sleep Apnea syndrome (OSA) in Adult Patients</u>
Clinically significant obstructive sleep apnea (OSA) is defined as those individuals who meet **ANY** of 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 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 individuals with clinically significant obstructive sleep apnea (OSA) and hypertrophic tonsils to be **eligible for coverage**.**

Patient Selection Criteria for Obstructive Sleep Apnea syndrome (OSA) in Pediatric Patients
Clinically significant obstructive sleep apnea (OSA) is defined as those pediatric individuals who meet **ANY** of 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 an individual with excessive daytime sleepiness, behavioral problems, or hyperactivity.

When Services Are Considered Not Medically Necessary

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

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) 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 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) to be **investigational****; snoring alone is not considered a medical condition.

Policy Guidelines

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

Mandibular-maxillary advancement involves osteotomies and advancement of both the maxilla and mandible. Candidates for this procedure should not have congenital hypoplasia of either the maxilla or the mandible. Cephalometric x-rays are typically performed to study the orientation of the maxilla and mandible and to plan the procedure. Also, drug-induced sleep endoscopy (DISE) will typically be performed prior to planning mandibular-maxillary advancement to confirm hypopharyngeal airway obstruction.

Background/Overview

Obstructive Sleep Apnea

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 individuals with OSA. Severe OSA is associated with decreased survival, presumably related to severe hypoxemia, hypertension, or an increase in automobile accidents related to overwhelming sleepiness.

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

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 effort. In adults, apnea is defined as a drop in airflow by ≥90% of the pre-event baseline for at least 10 seconds. Due to faster respiratory rates in children, pediatric scoring criteria define 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 the pre-event baseline for at least 10 seconds in association with either at least 3% or 4% decrease in arterial oxygen desaturation (depending on the scoring criteria) or arousal. Hypopneas in children are scored by a ≥50% drop in nasal pressure and either a ≥3% decrease in oxygen saturation or 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 increased respiratory effort, terminating in arousal but not otherwise meeting criteria for apnea or hypopnea
Respiratory event reporting	
AHI	The average number of apneas or hypopneas per hour of sleep
RDI	The respiratory disturbance index is the number of apneas, hypopneas, or respiratory event-related arousals per hour of sleep time. RDI is often used synonymously with the AHI.

Terms	Definitions
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	
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 <15. In children: AHI ≥1 to 5
Moderate OSA	AHI of 15 to <30. Children: AHI of > 5 to 10
Severe OSA	Adults: AHI ≥30. Children: AHI of >10
Treatment	
PAP	CPAP, APAP, or 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

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

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 (previous 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 AlRvance TM Bone Screw System is also suitable for the performance of a hyoid suspension	K122391	1999	LRK
Tongue base suspension	Encore™‡ (PRELUDE III)	Siesta Medical	Treatment of mild or moderate	K111179	2011	ORY

Interventions	Devices (predicate or prior name)	Manufacturer (previous owner)	Indication	PMA/ 510(k)	Year	FDA Product Code
			OSA and/or snoring			

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

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

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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 individuals who have failed conservative therapy, established surgical approaches may be indicated. This medical 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, and palatal stiffening procedures. This medical policy does not address conventional surgical procedures such as uvulopalatopharyngoplasty (UPPP), hyoid suspension, surgical modification of the tongue, maxillofacial surgery, or adenotonsillectomy.

Summary of Evidence

For individuals who have obstructive sleep apnea (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 that the technology results in an improvement in the net health outcome.

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 and a prospective, single-arm cohort study. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Single-stage radiofrequency to palatal tissues did not improve outcomes compared 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 prospective cohort study included 56 patients with mild-to-moderate OSA who received 3 sessions of office-based multilevel RFA. Results demonstrated improvement in AHI and Oxygen Desaturation Index (ODI) at the 6-month follow up. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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

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

Supplemental Information

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Academy of Sleep Medicine

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

American Academy of Pediatrics
The American Academy of Pediatrics (2012) published a clinical practice guideline on the diagnosis and management of childhood OSA. The Academy indicated that if a child has OSA, a clinical examination consistent with adenotonsillar hypertrophy, and does not have a contraindication to surgery, the clinician should recommend adenotonsillectomy as first-line treatment. The Academy recommended that patients should be referred for CPAP management if symptoms/signs or objective evidence of OSA persist after adenotonsillectomy or if adenotonsillectomy is not performed. Weight loss was recommended in addition to other therapy if a child or adolescent with OSA is overweight or obese.

American Academy of Otolaryngology - Head and Neck Surgery
The American Academy of Otolaryngology - Head and Neck Surgery (AAO-HNS; 2021) 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:

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

In a 2021 position statement, AAO-HNS supported 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, besides CPAP, as opposed to surgical procedures directed at the mandible or tissues of the palate. The updated 2017 guidelines reaffirmed these recommendations.

National Institute for Health and Care Excellence
The National Institute for Health and Care Excellence (NICE) 2017 guidance concluded that evidence on the safety and efficacy of hypoglossal nerve stimulation is limited in quantity and quality, and the procedure should only be used in the context of a clinical trial.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
The Centers for Medicare & Medicaid Services (CMS; 2001) 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 medical policy on the surgical management of OSA. The CMS review of the literature suggested there is a risk of hypertension with an AHI or RDI of at least 15 events per hour, and thus treatment is warranted for patients without any additional signs and symptoms. For patients with an AHI or RDI between 5 and 14 and associated symptoms, CMS concluded that the data from randomized controlled trials have demonstrated improved daytime somnolence and functioning in those treated with CPAP.

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
Ongoing			
NCT04031040[a]	A Post-market Clinical Follow up of the Genio™‡ System for the Treatment of Obstructive Sleep Apnea in Adults (EliSA)	110	Oct 2025
NCT02907398[a]	Adherence and Outcome of Upper Airway Stimulation (UAS) for OSA International Registry	5000	Dec 2025

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

References

1. Zhou N, Ho J-PTF, de Vries N, et al. Evaluation of drug-induced sleep endoscopy as a tool for selecting patients with obstructive sleep apnea for maxillomandibular advancement. J Clin Sleep Med. Apr 2022;(18)4: 1073-81. https://jcsm.aasm.org/doi/pdf/10.5664/jcsm.9802#:~:text=Prediction%20of%20surgical%20outcome,population%2C%20responders%2C%20and%20nonresponders
2. Dudley KA, Patel SR. Disparities and genetic risk factors in obstructive sleep apnea. Sleep Med. Feb 2016; 18: 96-102. PMID 26428843
3. Cohen SM, Howard JJM, Jin MC, et al. Racial Disparities in Surgical Treatment of Obstructive Sleep Apnea. OTO Open. 2022; 6(1): 2473974X221088870. PMID 35321423
4. Lee YC, Chang KY, Mador MJ. Racial disparity in sleep apnea-related mortality in the United States. Sleep Med. Feb 2022; 90: 204-213. PMID 35202926
5. Friedman M, Schalch P, Lin HC, et al. Palatal implants for the treatment of snoring and obstructive sleep apnea/hypopnea syndrome. Otolaryngol Head Neck Surg. Feb 2008; 138(2): 209-16. PMID 18241718
6. Lee LA, Yu JF, Lo YL, et al. Comparative effects of snoring sound between two minimally invasive surgeries in the treatment of snoring: a randomized controlled trial. PLoS One. 2014; 9(5): e97186. PMID 24816691

7. Patel S, Kon SSC, Nolan CM, et al. The Epworth Sleepiness Scale: Minimum Clinically Important Difference in Obstructive Sleep Apnea. Am J Respir Crit Care Med. Apr 01 2018; 197(7): 961-963. PMID 28961021
8. Ferguson KA, Heighway K, Ruby RR. A randomized trial of laser-assisted uvulopalatoplasty in the treatment of mild obstructive sleep apnea. Am J Respir Crit Care Med. Jan 01 2003; 167(1): 15-9. PMID 12502473
9. Bäck LJ, Liukko T, Rantanen I, et al. Radiofrequency surgery of the soft palate in the treatment of mild obstructive sleep apnea is not effective as a single-stage procedure: A randomized single-blinded placebo-controlled trial. Laryngoscope. Aug 2009; 119(8): 1621-7. PMID 19504550
10. Woodson BT, Steward DL, Weaver EM, et al. A randomized trial of temperature-controlled radiofrequency, continuous positive airway pressure, and placebo for obstructive sleep apnea syndrome. Otolaryngol Head Neck Surg. Jun 2003; 128(6): 848-61. PMID 12825037
11. Herman H, Stern J, Alessi DM, et al. Office-Based Multilevel Radiofrequency Ablation for Mild-to-Moderate Obstructive Sleep Apnea. OTO Open. 2023; 7(1): e19. PMID 36998558
12. Steward DL, Huntley TC, Woodson BT, et al. Palate implants for obstructive sleep apnea: multi-institution, randomized, placebo-controlled study. Otolaryngol Head Neck Surg. Oct 2008; 139(4): 506-10. PMID 18922335
13. Neruntarat C. Long-term results of palatal implants for obstructive sleep apnea. Eur Arch Otorhinolaryngol. Jul 2011; 268(7): 1077-80. PMID 21298386
14. Maurer JT, Sommer JU, Hein G, et al. Palatal implants in the treatment of obstructive sleep apnea: a randomised, placebo-controlled single-centre trial. Eur Arch Otorhinolaryngol. Jul 2012; 269(7): 1851-6. PMID 22228439
15. Thomas AJ, Chavoya M, Terris DJ. Preliminary findings from a prospective, randomized trial of two tongue-base surgeries for sleep-disordered breathing. Otolaryngol Head Neck Surg. Nov 2003; 129(5): 539-46. PMID 14595277
16. Kent D, Stanley J, Aurora RN, et al. Referral of adults with obstructive sleep apnea for surgical consultation: an American Academy of Sleep Medicine clinical practice guideline. J Clin Sleep Med. Dec 01 2021; 17(12): 2499-2505. PMID 34351848
17. Aurora RN, Casey KR, Kristo D, et al. Practice parameters for the surgical modifications of the upper airway for obstructive sleep apnea in adults. Sleep. Oct 2010; 33(10): 1408-13. PMID 21061864
18. Kent D, Stanley J, Aurora RN, et al. Referral of adults with obstructive sleep apnea for surgical consultation: an American Academy of Sleep Medicine systematic review, meta-analysis, and GRADE assessment. J Clin Sleep Med. Dec 01 2021; 17(12): 2507-2531. PMID 34351849

19. Marcus CL, Brooks LJ, Draper KA, et al. Diagnosis and management of childhood obstructive sleep apnea syndrome. Pediatrics. Sep 2012; 130(3): e714-55. PMID 22926176
20. American Academy of Otolaryngology -- Head and Neck Surgery. Position Statement: Surgical Management of Obstructive Sleep Apnea. 2021; https://www.entnet.org/resource/position-statement-surgical-management-of-obstructive-sleep-apnea/.
21. American Academy of Otolaryngology-Head and Neck Surgery. 2021 Position Statement: Hypoglossal Nerve Stimulation for Treatment of Obstructive Sleep Apnea (OSA) https://www.entnet.org/resource/position-statement-hypoglossal-nerve-stimulation-for-treatment-of-obstructive-sleep-apnea-osa/.
22. Clinical Issues Committee, American Society for Metabolic & Bariatric Surgery. Peri-operative management of obstructive sleep apnea. 2012; https://asmbs.org/resources/peri-operative-management-of-obstructive-sleep- apnea.
23. de Raaff CAL, Gorter-Stam MAW, de Vries N, et al. Perioperative management of obstructive sleep apnea in bariatric surgery: a consensus guideline. Surg Obes Relat Dis. Jul 2017; 13(7): 1095-1109. PMID 28666588
24. National Institute for Health and Care Excellence. Hypoglossal nerve stimulation for moderate to severe obstructive sleep apnoea (IPG598). 2017. https://www.nice.org.uk/guidance/ipg598/chapter/1-Recommendations.
25. Centers for Medicare & Medicaid Services. Decision Memo for Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA) (CAG-00093N). 2001; https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=19&ver=7&NcaName=Continuous+Positive+Airway+Pressure+(CPAP)+Therapy+for+Obstr uctive+Sleep+Apnea+(OSA)&TAId=50&bc=AAAAAAAAEAAA&.

Policy History

Original Effective Date: 07/27/2012
Current Effective Date: 10/14/2024

06/28/2012	Medical Policy Committee review
07/27/2012	Medical Policy Implementation Committee approval. New policy.
12/06/2012	Medical Policy Committee review
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 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 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.
02/24/2021	Coding update
08/05/2021	Medical Policy Committee review
08/11/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/17/2021	Coding Update
08/04/2022	Medical Policy Committee review
08/10/2022	Medical Policy Implementation Committee approval. Removed "syndrome" to describe obstructive sleep apnea throughout the coverage section. Changed "patients" to "individuals" throughout the coverage section. Added a reference to see Policy Guidelines in the second eligible for coverage statement. Changed coverage from not medically necessary to investigational for "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; snoring alone is not considered a medical condition".
08/03/2023	Medical Policy Committee review
08/09/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/07/2023	Medical Policy Committee review
09/13/2023	Medical Policy Implementation Committee approval. Removed hypoglossal nerve stimulation from the coverage criteria and under Medicare National Coverage.
09/05/2024	Medical Policy Committee review
09/11/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2023 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association

Policy # 00329
Original Effective Date: 07/27/2012
Current Effective Date: 10/14/2024

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	21199, 21685, 41512, 41530, 42120, 42145, 42299, 42950 Delete codes effective 01/01/2024: 64582, 64583, 64584, 64568, 64569, 64570, 95970 Add codes effective 03/01/2025: 31599, 42999 Add codes effective 07/01/2025: 0978T, 0979T, 0980T
HCPCS	C9727, S2080 Delete codes effective 01/01/2024: C1767, C1778, C1787
ICD-10 Diagnosis	G478, G479, R0683

*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 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, 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.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.