Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome

Medicare Advantage Medical Policy #MA-217
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Applies to all products administered or underwritten by the Health Plan, unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Blue Advantage does not cover investigational or experimental services, including any drug, device, procedure, or service provided under the investigational arm of a clinical trial or study unless mandated by the Centers for Medicare and Medicaid Services. Coverage is limited to routine services for Category A IDE studies and to devices and related services for Category B IDE studies when not supplied by the trial sponsor. Approved IDE studies are posted on www.cms.gov/medicare/coverage/evidence.

Note: Louisiana is served by Novitas Solutions Inc. under Medicare Administrative Contractor (MAC) Jurisdiction H (JH). Hypoglossal Nerve Stimulation is addressed in Novitas –LCD - Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea (L38310)

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 Health Plan 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 Health Plan 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**.**

Patient Selection Criteria for Obstructive Sleep Apnea syndrome (OSA) in Adult Patients
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) greater than or equal to 15 events per hour; **OR**

- Apnea/hypopnea index (AHI), respiratory disturbance index (RDI), or respiratory event index (REI) greater than or equal to 5 events per hour with excessive daytime sleepiness, unexplained hypertension, ischemic heart disease, or history of stroke.

Based on review of available data, the Health Plan 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) greater than or equal to 5 events per hour; **OR**
- Apnea/hypopnea index (AHI), or respiratory disturbance index (RDI) greater than or equal to 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 Health Plan 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 Health Plan 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 Health Plan 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.

Based on review on available data, the Health Plan considers hypoglossal nerve stimulation with U.S. Food and Drug Administration (FDA) approved devices other than Inspire®‡ Upper Airway Stimulation device (e.g., Genio®‡ system 2.1) for the treatment of clinically significant obstructive sleep apnea (OSA) syndrome to be **investigational.***

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.

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.

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

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.

Terms	Definitions
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.
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®‡	Somnus Medical Technologies (now Olympus)	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

Interventions	Devices (predicate or prior name)	Manufacturer (previous owner)	Indication	PMA/ 510(k)	Year	FDA Product Code
Tongue base suspension	Encore™‡ (PRELUDE III)	Siesta Medical	Treatment of mild or moderate OSA and/or snoring	K111179	2011	ORY
Hypoglossal nerve stimulation	Genio®‡	Nyxoah		European CE Mark	2019	
Hypoglossal nerve stimulation	Genio®‡ System 2.1	Nyxoah	For use in treatment of moderate to severe OSA (AHI of ≥15 and ≤65). The device is intended for adult patients ≥22 years of age who have been confirmed to fail, cannot tolerate or are ineligible to be treated with current standard of care treatments including lifestyle modifications, PAP treatments (such as CPAP or BiPAP machines), oral appliances (such as	P240024	2025	MNQ

Interventions	Devices (predicate or prior name)	Manufacturer (previous owner)	Indication	PMA/ 510(k)	Year	FDA Product Code
			mandibular advancement devices), and pharmacotherapy (such as tirzepatide). PAP failure is defined as an inability to eliminate OSA (residual AHI of >15 despite PAP usage), and PAP intolerance is defined as: 1. Inability to use PAP (at least 5 nights per week of usage; usage defined as >4 hours of use per night), or 2. Unwilling-ness to use PAP (PAP therapy initiated and subsequently discontinued by choice).			

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

Genio consists of a single piece of implanted hardware that contains an antenna/receiver and two attached electrode paddles. The battery is external and transmits energy to the implant via Bluetooth. It is implanted under the chin through a single incision. There is no implanted battery, no pocket creation for the IPG, no tunneling, and no second incision.
https://www.geniosleep.com/?page_country_id=us

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 (LAUP), the evidence includes 2 systematic reviews and randomized controlled trials (RCT). Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. A 2019 systematic review involving 3,093 patients across 42 studies (4 RCTs) to assess complications of LAUP for snoring and OSA identified the most frequent complications being globus sensation (8%), dryness (7%), and velopharyngeal (VP) insufficiency (4%), with globus and VP insufficiency occurring significantly more than in the general or post-oropharyngeal surgery populations (relative risks: 1.48 and 2.25, respectively). On average, 26 complications were seen per 100 LAUP-treated patients, and pain lasted around 12 days. A earlier meta-analysis of 23 studies (717 adults) on LAUP for OSA, found an AHI mean decrease of 6.56 events/h, but only a 23% success rate and 8% cure rate; 44% of patients experienced worsening AHI, with minimal improvement in lowest O2 saturation. 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.

For individuals who have OSA who receive hypoglossal nerve stimulation (HNS), there are currently 2 FDA-approved HNS devices for the treatment of OSA: the Inspire Upper Airway Stimulation (UAS) system (addressed in Carelon Sleep Disorder Management Clinical guidelines) and the Genio system (addressed in this medical policy).

Genio System

No systematic reviews or RCTs have been published on the Genio system. The FDA approval was based on results of a nonrandomized clinical trial (DREAM: Dual-sided Hypoglossal neRvE stimulAtion for the treatMent of Obstructive Sleep Apnea). This study enrolled 113 patients across 21 centers (including 16 U.S. locations), with coprimary endpoints focused on reducing the AHI and ODI at 12 months. Woodson et al (2025) conducted this trial in adult patients with moderate-to-severe OSA who refused, failed, or did not tolerate PAP therapy underwent implantation and nightly use of the Genio device. The coprimary endpoints at 12 months were (1) a minimum of 50%

reduction in the 4% AHI from baseline with a final AHI of <20 events/h, and (2) a minimum of 25% reduction in the 4% ODI. Objective secondary endpoints included changes in mean AHI, ODI, and sleep time with blood oxygen saturation <90%. Self-reported secondary endpoints included changes in ESS, the short FOSQ, the Symptoms of Nocturnal Obstruction and Related Events score, and bedpartner assessment of snoring. The Genio device was implanted in 113 patients. Eleven serious adverse events occurred in 10 (9%) patients of which 3 (3%) were device-related, 5 (4%) were procedure-related, and 3 (3%) were unrelated to the device or the procedure. The coprimary endpoints were completed by 89 (77%) patients. AHI and ODI responses were achieved in 63.5% (73/115, p =.002) and 71.3% of patients (82/115, p <.001), respectively. Secondary endpoint analysis revealed significant changes in mean AHI (-18.3 ± 11.8 events/h, p <.001), ODI (-17.7 ± 14.6 events/h, p <.001), and sleep time with blood oxygen saturation less than 90% (6.9 ± 10.7%, p <.001). Significant changes were observed in all secondary endpoints (p <.001). Study limitations include study design was single-arm, open-label, studied population was limited (70% were male and 94% white), follow-up period was short and precluded long-term evaluation of safety and efficacy, treatment adherence was addressed by patient self-reporting, and 24% of patients did not complete the trial per protocol. Limitations of the current evidence preclude determination of who is most likely to benefit. 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 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 HNS. 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 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.

The AASM (2025) guidelines on the evaluation and management of OSA in adults hospitalized for medical care recommend that treatment of sleep-disordered breathing should be continued regardless of modality (e.g., PAP, HNS therapy, oral appliance therapy, pharmacotherapies) if feasible given the clinical setting. Recommendations to continue therapy apply not only to PAP therapy, but also to alternative non-PAP modalities including oral appliances and HNS.

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 (defined as BMI >95th percentile).

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.

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.

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. Surgical approaches are considered when CPAP fails 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			
NCT06851338a	Pediatric Down Syndrome Post-Approval Study	60	May 2030
NCT05592002a	A Multicenter Study to Assess the Safety and Effectiveness of the Genio®‡ Dual-sided Hypoglossal Nerve Stimulation System for the Treatment of Obstructive Sleep Apnea in Subjects With Complete Concentric Collapse of the Soft Palate	124	Sep 2028
NCT02413970[a]	Inspire®‡ Upper Airway Stimulation System (UAS): Post-Approval Study Protocol Number 2014-001	127	Jun 2025

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT04801771[a]	Effects of Hypoglossal Nerve Stimulation on Cognition and Language in Down Syndrome and Obstructive Sleep Apnea	57	Sept 2027
NCT02907398[a]	Adherence and Outcome of Upper Airway Stimulation (UAS) for OSA International Registry	5000	Dec 2025
NCT04950894[a]	Treating Obstructive Sleep Apnea Using Targeted Hypoglossal Neurostimulation	150	Oct 2025

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

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Policy History

Original Effective Date: 07/01/2026
Current Effective Date: 07/01/2026
04/21/2026 Utilization Management Committee review/approval. New policy.
Next Scheduled Review Date: 04/2027

Coding

The five character codes included in the Health Plan Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2025 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 the Health Plan Medical Policy Coverage Guidelines is with the Health Plan 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 the Health Plan 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 the Health Plan 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.

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

Code Type	Code
CPT	0978T, 0979T, 0980T, 21199, 21685, 31599, 41512, 41530, 42120,

	42145, 42299, 42950, 42999
HCPCS	C1889, C8011, C8012, C8013, C9727
ICD-10 Diagnosis	G47.33, G47.8, G47.9, R06.83

*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 Health Plan's 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 Health Plan 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.

NOTICE: All codes listed on the Medical Policy require prior authorization. This ensures appropriate utilization and alignment with current clinical guidelines.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Blue Advantage), Blue Advantage may honor the previous health plan's authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Blue Advantage health plan.

Medicare Advantage Members
Established coverage criteria for Medicare Advantage members can be found in Medicare coverage guidelines in statutes, regulations, National Coverage Determinations (NCD)s, and Local Coverage Determinations (LCD)s. To determine if a National or Local Coverage Determination addresses coverage for a specific service, refer to the Medicare Coverage Database at the following link: https://www.cms.gov/medicare-coverage-database/search.aspx. You may wish to review the Guide to the MCD Search here: https://www.cms.gov/medicare-coverage-database/help/mcd-benehelp.aspx.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, internal coverage criteria may be developed. This policy is to serve as the summary of evidence, a list of resources and an explanation of the rationale that supports the adoption of this internal coverage criteria.

InterQual®
Interqual® is utilized as a source of medical evidence to support medical necessity and level of care decisions. InterQual® criteria are intended to be used in connection with the independent

professional medical judgment of a qualified health care provider. InterQual® criteria are clinically based on best practice, clinical data, and medical literature. The criteria are updated continually and released annually. InterQual® criteria are a first-level screening tool to assist in determining if the proposed services are clinically indicated and provided in the appropriate level or whether further evaluation is required. The utilization review staff does the first-level screening. If the criteria are met, the case is approved; if the criteria are not met, the case is referred to the medical director.