MASSACHUSETTS

Blue Cross Blue Shield of Massachusetts is an Independent Licensee of the Blue Cross and Blue Shield Association

Medical Policy

Surgical and Non-CPAP Treatment of Snoring and Obstructive Sleep Apnea Syndrome

Table of Contents

Policy Number: 130

BCBSA Reference Number: 7.01.101; 2.01.18 (For Plan internal use only)

Related Policies

Home Cardiorespiratory Monitoring, #224

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue℠ and Medicare PPO Blue℠ Members

Palatopharyngoplasty

Palatopharyngoplasty (eg, uvulopalatopharyngoplasty, uvulopharyngoplasty, uvulopalatal flap, expansion sphincter pharyngoplasty, lateral pharyngoplasty, palatal advancement pharyngoplasty, relocation pharyngoplasty) may be considered **MEDICALLY NECESSARY** for the treatment of clinically significant obstructive sleep apnea (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. Clinically significant OSA is defined as those individuals who have:

- Apnea/hypopnea Index (AHI) or Respiratory Disturbance Index (RDI) 15 or more events per hour, **OR**
- AHI or RDI 5 or more events and 14 or less events per hour with documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or documented hypertension, ischemic heart disease, or history of stroke.

Hyoid suspension

Hyoid suspension, surgical modification of the tongue, and/or maxillofacial surgery, including mandibular-maxillary advancement (MMA), may be considered **MEDICALLY NECESSARY** in appropriately selected adult individuals with clinically significant 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. Clinically significant OSA is defined as those individuals who have:

- AHI or RDI 15 or more events per hour, **OR**
- AHI or RDI 5 or more events and 14 or less events per hour with documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or documented hypertension, ischemic heart disease, or history of stroke.

Adenotonsillectomy

Adenotonsillectomy may be considered **MEDICALLY NECESSARY** in children (2 -18 years of age) with obstructive sleep apnea and hypertrophic tonsils as determined through individual history and clinical exam. A polysomnography is recommended in individuals with sleep-disordered breathing in certain conditions[1], see below:

The American Academy of Otolaryngology - Head and Neck Surgery Clinical Practice Guideline: Polysomnography for Sleep-Disordered Breathing Prior to Tonsillectomy in Children recommends a polysomnography in the following clinical circumstances.

- The clinician should refer children with sleep-disordered breathing for polysomnography if they exhibit certain complex medical conditions such as obesity, Down syndrome, craniofacial abnormalities, neuromuscular disorders, sickle cell disease, or mucopolysaccharidoses.
- The clinician should advocate for polysomnography prior to tonsillectomy for sleep-disordered breathing in children without any of the comorbidities listed in statement 1 for whom the need for surgery is uncertain or when there is discordance between tonsillar size on physical examination and the reported severity of sleep-disordered breathing.

Hypoglossal nerve stimulation

Hypoglossal nerve stimulation may be considered **MEDICALLY NECESSARY** in adults with OSA under the following conditions:

- Age ≥ 22 years; AND
- AHI ≥ 15 with less than 25% central apneas; AND
- CPAP failure (residual AHI ≥ 15 or failure to use CPAP ≥ 4 hr per night for ≥ 5 nights per week) or inability to tolerate CPAP; AND
- Body mass index ≤ 32 kg/m^2; AND
- Non-concentric retropalatal obstruction on drug-induced sleep endoscopy.

Hypoglossal nerve stimulation may be considered **MEDICALLY NECESSARY** in adolescents or young adults with Down syndrome and OSA under the following conditions:

- Age 10 to 21 years; AND
- AHI >10 and <50 with less than 25% central apneas after prior adenotonsillectomy; AND
- Have either tracheotomy or be ineffectively treated with CPAP due to noncompliance, discomfort, undesirable side effects, persistent symptoms despite compliance use, or refusal to use the device; AND
- Body mass index ≤ 95th percentile for age; AND
- Non-concentric retropalatal obstruction on drug-induced sleep endoscopy.

Implantable hypoglossal nerve stimulators are considered **INVESTIGATIONAL** for all indications other than listed above.

Surgical treatment of OSA

Surgical treatment of OSA that does not meet the criteria above would be considered **NOT MEDICALLY NECESSARY**.

The following minimally-invasive surgical procedures are considered **INVESTIGATIONAL** for the sole or adjunctive treatment of OSA or upper airway resistance syndrome:

- Laser-assisted palatoplasty or radiofrequency volumetric tissue reduction of the palatal tissues
- Radiofrequency volumetric tissue reduction of the tongue, with or without radiofrequency reduction of the palatal tissues
- Palatal stiffening procedures including, but not limited to, cautery-assisted palatal stiffening operation, injection of a sclerosing agent, and the implantation of palatal implants

- Tongue base suspension
- All other minimally-invasive surgical procedures not described above.

All interventions, including laser-assisted palatoplasty, radiofrequency volumetric tissue reduction of the palate, or palatal stiffening procedures, are **NOT MEDICALLY NECESSARY** for the treatment of snoring in the absence of documented OSA; snoring alone is not considered a medical condition.

Non-CPAP Medical Treatment of OSA[2]

The use of an abbreviated daytime sleep session for acclimation to CPAP (PAP-NAP) is considered **INVESTIGATIONAL**.

The use of a sleep positioning trainer with vibration is considered **INVESTIGATIONAL** for the treatment of positional OSA.

The use of daytime electrical stimulation of the tongue is considered **INVESTIGATIONAL** for the treatment of OSA.

Nasal expiratory positive airway pressure (EPAP) and oral pressure therapy devices are considered **INVESTIGATIONAL**.

For medically necessary indications on APAP, CPAP, BPAP, see AIM Clinical Appropriateness Guidelines for Sleep Disorder Management.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is **required** for sleep apnea surgery (CPT codes 42145, 21193-21199, 21206 and 21685). Prior authorization is **not required** for adenoidectomy and tonsillectomy procedures (CPT codes 42820-42821, 42825-42826, 42830-42831 and 42835-42836). Prior authorization is **not required** for hypoglossal nerve stimulation (CPT codes 64568, 64582; 64583; 64584).
Commercial PPO	Prior authorization is **required** for sleep apnea surgery, adenoidectomy or tonsillectomy. (CPT codes 42145, 21193-21199, 21206 and 21685). Prior authorization is **not required** for adenoidectomy and tonsillectomy procedures (CPT codes 42820-42821, 42825-42826, 42830-42831 and 42835-42836). Prior authorization is **not required** for hypoglossal nerve stimulation (CPT codes 64568,64582; 64583; 64584).
Medicare HMO Blue[SM]	Prior authorization is **required** for sleep apnea surgery (CPT codes 42145, 21193-21199, 21206 and 21685).

	Prior authorization is **not required** for adenoidectomy and tonsillectomy procedures (CPT codes 42820-42821, 42825-42826, 42830-42831 and 42835-42836).
Medicare PPO Blue℠	Prior authorization is **required** for sleep apnea surgery (CPT codes 42145, 21193-21199, 21206 and 21685). Prior authorization is **not required** for sleep apnea surgery, adenoidectomy or tonsillectomy procedures (CPT codes 42820-42821, 42825-42826, 42830-42831 and 42835-42836).

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

CPT Codes

CPT codes:	Code Description
21193	Reconstruction of mandibular rami, horizontal, vertical, C, or L osteotomy; without bone graft
21194	Reconstruction of mandibular rami, horizontal, vertical, C, or L osteotomy; with bone graft (includes obtaining graft)
21195	Reconstruction of mandibular rami and/or body, sagittal split; without internal rigid fixation
21196	Reconstruction of mandibular rami and/or body, sagittal split; with internal rigid fixation
21198	Osteotomy, mandible, segmental
21199	Osteotomy, mandible, segmental; with genioglossus advancement
21206	Osteotomy, maxilla, segmental (e.g., Wassmund or Schuchard)
21685	Hyoid myotomy and suspension
42145	Palatopharyngoplasty (eg, uvulopalatopharyngoplasty, uvulopharyngoplasty)
42820	Tonsillectomy and adenoidectomy; younger than age 12
42821	Tonsillectomy and adenoidectomy; age 12 or over
42825	Tonsillectomy, primary or secondary; younger than age 12
42826	Tonsillectomy, primary or secondary; age 12 or over
42830	Adenoidectomy, primary; younger than age 12
42831	Adenoidectomy, primary; age 12 or over
42835	Adenoidectomy, secondary; younger than age 12
42836	Adenoidectomy, secondary; age 12 or over

ICD-10 Diagnosis Codes

ICD-10-CM Diagnosis codes:	Code Description
G47.30	Sleep apnea, unspecified
G47.33	Obstructive sleep apnea (adult) (pediatric)

ICD-10 Procedure Codes

ICD-10-PCS procedure codes:	Code Description
0CQ70ZZ	Repair Tongue, Open Approach
09QN0ZZ	Repair Nasopharynx, Open Approach
09QN3ZZ	Repair Nasopharynx, Percutaneous Approach
09QN4ZZ	Repair Nasopharynx, Percutaneous Endoscopic Approach
09QN7ZZ	Repair Nasopharynx, Via Natural or Artificial Opening
09QN8ZZ	Repair Nasopharynx, Via Natural or Artificial Opening Endoscopic
09RN0JZ	Replacement of Nasopharynx with Synthetic Substitute, Open Approach
09RN7JZ	Replacement of Nasopharynx with Synthetic Substitute, Via Natural or Artificial Opening
09RN8JZ	Replacement of Nasopharynx with Synthetic Substitute, Via Natural or Artificial Opening Endoscopic
09UN0JZ	Supplement Nasopharynx with Synthetic Substitute, Open Approach
09UN7JZ	Supplement Nasopharynx with Synthetic Substitute, Via Natural or Artificial Opening
09UN8JZ	Supplement Nasopharynx with Synthetic Substitute, Via Natural or Artificial Opening Endoscopic
0CQ20ZZ	Repair Hard Palate, Open Approach
0CQ23ZZ	Repair Hard Palate, Percutaneous Approach
0CQ30ZZ	Repair Soft Palate, Open Approach
0CQ33ZZ	Repair Soft Palate, Percutaneous Approach
0CQ73ZZ	Repair Tongue, Percutaneous Approach
0CQ7XZZ	Repair Tongue, External Approach
0CQM0ZZ	Repair Pharynx, Open Approach
0CQM3ZZ	Repair Pharynx, Percutaneous Approach
0CQM4ZZ	Repair Pharynx, Percutaneous Endoscopic Approach
0CQM7ZZ	Repair Pharynx, Via Natural or Artificial Opening
0CQM8ZZ	Repair Pharynx, Via Natural or Artificial Opening Endoscopic
0CQN3ZZ	Repair Uvula, Percutaneous Approach
0CQNXZZ	Repair Uvula, External Approach
0CS20ZZ	Reposition Hard Palate, Open Approach
0CS30ZZ	Reposition Soft Palate, Open Approach
0CTP0ZZ	Resection of Tonsils, Open Approach
0CTQ0ZZ	Resection of Adenoids, Open Approach
0CU207Z	Supplement Hard Palate with Autologous Tissue Substitute, Open Approach
0CU20JZ	Supplement Hard Palate with Synthetic Substitute, Open Approach
0CU20KZ	Supplement Hard Palate with Nonautologous Tissue Substitute, Open Approach
0CU237Z	Supplement Hard Palate with Autologous Tissue Substitute, Percutaneous Approach
0CU23JZ	Supplement Hard Palate with Synthetic Substitute, Percutaneous Approach
0CU23KZ	Supplement Hard Palate with Nonautologous Tissue Substitute, Percutaneous Approach
0CU307Z	Supplement Soft Palate with Autologous Tissue Substitute, Open Approach
0CU30JZ	Supplement Soft Palate with Synthetic Substitute, Open Approach
0CU30KZ	Supplement Soft Palate with Nonautologous Tissue Substitute, Open Approach
0CU337Z	Supplement Soft Palate with Autologous Tissue Substitute, Percutaneous Approach
0CU33JZ	Supplement Soft Palate with Synthetic Substitute, Percutaneous Approach
0CU33KZ	Supplement Soft Palate with Nonautologous Tissue Substitute, Percutaneous Approach
0CUM07Z	Supplement Pharynx with Autologous Tissue Substitute, Open Approach
0CUM0JZ	Supplement Pharynx with Synthetic Substitute, Open Approach

0CUM0KZ	Supplement Pharynx with Nonautologous Tissue Substitute, Open Approach
0CUM77Z	Supplement Pharynx with Autologous Tissue Substitute, Via Natural or Artificial Opening
0CUM7JZ	Supplement Pharynx with Synthetic Substitute, Via Natural or Artificial Opening
0CUM7KZ	Supplement Pharynx with Nonautologous Tissue Substitute, Via Natural or Artificial Opening
0CUM87Z	Supplement Pharynx with Autologous Tissue Substitute, Via Natural or Artificial Opening Endoscopic
0CUM8JZ	Supplement Pharynx with Synthetic Substitute, Via Natural or Artificial Opening Endoscopic
0CUM8KZ	Supplement Pharynx with Nonautologous Tissue Substitute, Via Natural or Artificial Opening Endoscopic
0NQT0ZZ	Repair Right Mandible, Open Approach
0NQT3ZZ	Repair Right Mandible, Percutaneous Approach
0NQT4ZZ	Repair Right Mandible, Percutaneous Endoscopic Approach
0NQTXZZ	Repair Right Mandible, External Approach
0NQV0ZZ	Repair Left Mandible, Open Approach
0NQV3ZZ	Repair Left Mandible, Percutaneous Approach
0NQV4ZZ	Repair Left Mandible, Percutaneous Endoscopic Approach
0NQVXZZ	Repair Left Mandible, External Approach
0NUT07Z	Supplement Right Mandible with Autologous Tissue Substitute, Open Approach
0NUT0JZ	Supplement Right Mandible with Synthetic Substitute, Open Approach
0NUT0KZ	Supplement Right Mandible with Nonautologous Tissue Substitute, Open Approach
0NUT37Z	Supplement Right Mandible with Autologous Tissue Substitute, Percutaneous Approach
0NUT3JZ	Supplement Right Mandible with Synthetic Substitute, Percutaneous Approach
0NUT3KZ	Supplement Right Mandible with Nonautologous Tissue Substitute, Percutaneous Approach
0NUT47Z	Supplement Right Mandible with Autologous Tissue Substitute, Percutaneous Endoscopic Approach
0NUT4JZ	Supplement Right Mandible with Synthetic Substitute, Percutaneous Endoscopic Approach
0NUT4KZ	Supplement Right Mandible with Nonautologous Tissue Substitute, Percutaneous Endoscopic Approach
0NUV0JZ	Supplement Left Mandible with Synthetic Substitute, Open Approach
0NUV0KZ	Supplement Left Mandible with Nonautologous Tissue Substitute, Open Approach
0NUV3JZ	Supplement Left Mandible with Synthetic Substitute, Percutaneous Approach
0NUV3KZ	Supplement Left Mandible with Nonautologous Tissue Substitute, Percutaneous Approach
0NUV4JZ	Supplement Left Mandible with Synthetic Substitute, Percutaneous Endoscopic Approach
0NUV4KZ	Supplement Left Mandible with Nonautologous Tissue Substitute, Percutaneous Endoscopic Approach

The above <u>medical necessity criteria MUST</u> be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

CPT Codes

CPT codes:	Code Description
64568	Incision for implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator
64582	Hypoglossal nerve neurostimulator implantation; open
64583	Hypoglossal nerve neurostimulator revision or replacement

64584	Hypoglossal nerve neurostimulator removal

The following ICD Diagnosis Codes are considered medically necessary when submitted with the CPT codes above if medical necessity criteria are met:

ICD-10 Diagnosis Codes

ICD-10-CM Diagnosis codes:	Code Description
G47.33	Obstructive sleep apnea (adult) (pediatric)
Q90.0	Trisomy 21, nonmosaicism (meiotic nondisjunction)
Q90.1	Trisomy 21, mosaicism (mitotic nondisjunction)
Q90.2	Trisomy 21, translocation
Q90.9	Down syndrome, unspecified

The following CPT and HCPCS codes are considered investigational for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

CPT Codes

CPT codes:	Code Description
41512	Tongue base suspension, permanent suture technique
41530	Submucosal ablation of the tongue base, radiofrequency, 1 or more sites, per session

HCPCS Codes

HCPCS codes:	Code Description
A7047	Oral interface used with respiratory suction pump, each
K1001	Electronic positional obstructive sleep apnea treatment, with sensor, includes all components and accessories, any type
K1028	Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle for the reduction of snoring and obstructive sleep apnea, controlled by phone application
K1029	Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by phone application, 90-day supply
S2080	Laser-assisted uvulopalatoplasty (LAUP)

According to the policy statement above, the following HCPCS codes are considered investigational for the conditions listed for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

HCPCS Codes

HCPCS codes:	Code Description
E0600	Respiratory suction pump, home model, portable or stationary, electric
A7002	Tubing, used with suction pump, each

Description

Obstructive sleep apnea (OSA) is characterized by repetitive episodes of upper airway obstruction due to the collapse and obstruction of the upper airway during sleep. 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.

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 pre-event baseline for at least 10 seconds. Due to faster respiratory rates in children, pediatric scoring criteria define an apnea as ≥2 missed breaths, regardless of its duration in seconds.
Hypopnea	Hypopnea in adults is scored when the peak airflow drops by at least 30% of pre-event baseline for at least 10 seconds in association with either at least 4% arterial oxygen desaturation or an arousal. Hypopneas in children are scored by a ≥50% drop in nasal pressure and either a ≥3% decrease in oxygen saturation or an associated arousal.
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
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	
Positive airway pressure (PAP)	Positive airway pressure may be continuous (CPAP) or auto-adjusting (APAP) or Bi-level (Bi-PAP).

Terms	Definitions
Respiratory Event	
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 individuals with mild, moderate, or severe OSA

OSA: obstructive sleep apnea; PSG: Polysomnographic

Summary

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 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 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 individuals 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 individuals 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 individuals. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The single RCT compared tongue suspension plus uvulopalatopharyngoplasty with tongue advancement plus uvulopalatopharyngoplasty and showed success rates of 50% to 57% for both procedures. RCTs with a larger number of subjects are needed to determine whether tongue suspension alone or added to uvulopalatopharyngoplasty improves the net health outcome. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have OSA who receive hypoglossal nerve stimulation, the evidence includes 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 individuals 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 individuals 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 individuals with Down Syndrome is ongoing. The evidence is insufficient to determine the effects of the technology on health outcomes.

Additional Information
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 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 individuals. One subgroup includes adult individuals with a favorable pattern of non-concentric palatal collapse. The alternative treatment for this anatomical endotype is maxillo-mandibular advancement (MMA), which is associated with greater morbidity and lower patient acceptance than HNS. The improvement in AHI with HNS, as shown in the STAR trial, is similar to the improvement in AHI following MMA. Another subgroup includes appropriately selected adolescents with OSA and Down's syndrome who have difficulty in using CPAP. The following patient selection criteria are based on information from clinical study populations and clinical expert opinion.

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

MEDICAL TREATMENT OF OSA
Source: MPRM 2.01.18 Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome.

Daytime Tongue Stimulation
For individuals who have OSA who receive novel OSA treatments (eg, ~~palate expansion~~, EPAP, oral pressure therapy, tongue stimulation, supine vibration), the evidence includes RCTs, prospective single arm studies, and a meta-analysis of case series. Relevant outcomes are symptoms, functional outcomes, and QOL. The evidence on nasal EPAP devices in individuals with OSA has been reported in prospective case series, an industry-sponsored RCT, and a systematic review that did not include the RCT. The main finding of the RCT was a decrease in the Apnea/Hypopnea Index (AHI), with minor impact on oxygenation, and a decrease in Epworth Sleepiness Scale (ESS) score. One small RCT with 22 individuals found no benefit of an oral EPAP therapy device when added to an oral appliance. One comparative trial with historical controls and a retrospective chart review evaluated daytime sleep study (PAP-NAP) to reduce resistance to CPAP titration or use.

Additional study is needed to evaluate the efficacy of this intervention. Single arm studies suggest that daytime tongue stimulation may improve snoring, but the effect on OSA is uncertain. Several RCTs have been published with a sleep positioning device that vibrates when the individual is in a supine position. Drop-out rates were high and long-term compliance is unknown. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Daytime sleep study (PAP-NAP)
PAP-NAP uses a desensitization program to facilitate adaptation to pressurized air and test advanced PAP modes for intolerance to PAP. The evidence on the PAP-NAP includes 1 comparative trial with historical controls and a case series of individuals who were resistant to CPAP titration. These studies do not provide sufficient evidence to form conclusions on the efficacy of this approach in improving compliance with CPAP. The patient population in the comparative study was highly selected and the behavioral intervention may be dependent on the specific clinicians providing treatment. In addition, historical controls were used, and they were not well-matched to the study population. For these reasons, the internal validity and generalizability of the results are uncertain.

Nasal Expiratory Positive Airway Pressure
The evidence on nasal EPAP devices in individuals with OSA has been reported in several prospective case series, an industry-sponsored RCT, and a systematic review that did not include the RCT. The main finding of the RCT was a decrease in AHI with a minor impact on oxygenation and ESS scores. An oral EPAP device did not have significant benefit when added to an oral appliance.

eXciteOSA
eXciteOSA (previously named Snoozeal) is intended to reduce snoring and mild OSA by increasing tongue muscle tone with daytime neuromuscular electrical stimulation. No controlled trials on eXciteOSA were identified. The evidence includes 2 prospective single arm studies in individuals with primary snoring or mild OSA. The available evidence suggests that when used for 20 min a day over 6 weeks, the treatment may reduce snoring. In the overall population, the effects on AHI were not clinically significant. For the subgroup of individuals with mild OSA, the improvement in AHI in these uncontrolled trials remained modest. With a mean ESS of less than 10, this group of individuals might not be considered symptomatic. Controlled studies are needed to evaluate whether individuals who meet criteria for treatable OSA improve and whether individuals would continue use after the 6-week trial period.

NightBalance Sleep Position Trainer
The evidence on the NightBalance Sleep Positioning Trainer Includes RCTs and single arm studies. The RCTs suggest that the device may be as effective as oral appliances and more comfortable than positive airway pressure in individuals with positional OSA. However, the studies are limited by a high dropout rate and short follow-up. A 6-month prospective study found that 64% of individuals used the sleep position trainer for more than 4 h per night, but another observational study found that only a quarter of individuals may be both able to tolerate the device and have a reduction in supine AHI in the short-term. Further study is needed to evaluate who may receive benefit and continue utilization after the trial period.

Policy History

Date	Action
6/2022	Prior authorization information clarified for PPO plans. Effective 6/1/2022.
4/2022	Clarified coding information.
1/2022	Clarified coding information and prior authorization table.
11/2021	Annual policy review. New investigational indications described for Non-CPAP Medical Treatment of OSA: Daytime Tongue Stimulation; Daytime sleep study (PAP-NAP); Nasal Expiratory Positive Airway Pressure; eXciteOSA; and NightBalance Sleep Position Trainer. Clarified coding information. Title changed. Effective 11/2021.
1/2021	Medicare information removed. See MP #132 Medicare Advantage Management for local coverage determination and national coverage determination reference.
8/2020	Annual policy review. Description, summary and references updated. Policy statement(s) unchanged.
4/2020	Local Coverage Determination (LCD): Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea (L38387) added. Effective 4/1/2020.
8/2019	Annual policy review. The indication for hypoglossal nerve stimulation was clarified to indicate apnea/hypopnea index of ≥15 for alignment with the Food and Drug Administration-approved indication.
5/2019	Annual policy review. New medically necessary indications described. Hypoglossal nerve stimulation is medically necessary under specified conditions. Clarified coding

	information. Effective 5/1/2019.
2/2019	Policy statements on adenotonsillectomy in children with obstructive sleep apnea and hypertrophic tonsils revised. Effective 2/1/2019.
6/2018	Clarified coding information.
1/2018	Clarified coding information.
10/2017	New references added from Annual policy review.
5/2017	Annual policy review. Medically necessary policy statement revised to include variants of palatopharyngoplasty. New references added. Effective 5/1/2017.
1/2017	Clarified coding information for the 2017 code changes.
6/2016	Clarified coding information.
10/2014	Annual policy review. New investigational indications described. Coding information clarified. Effective 10/1/2014.
5/2014	Updated Coding section with ICD10 procedure and diagnosis codes. Effective 10/2015.
3/2014	Coding information clarified.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
12/2010	Annual policy review. Changes made to policy statement.
9/1/2010	Annual policy review. Changes made to policy statement.
8/1/2009	Medical Policy 130 developed effective 8/1/2009.
5/2008	Updated to clarify coverage exclusion of radiofrequency volumetric tissue reduction of the palatal tissues with coblation technology.
2/2008	Annual policy review. No changes to policy statements.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:
Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

References

Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome

1. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Surgical management of sleep apnea. TEC Assessments. 1995;Volume 10:Tab 32.
2. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Radiofrequency volumetric tissue reduction for sleep-related breathing disorders. TEC Assessments. 2000;Volume 15:Tab 15.
3. 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
4. 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
5. 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
6. 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
7. Back 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

8. 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
9. 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
10. Neruntarat C. Long-term results of palatal implants for obstructive sleep apnea. Eur Arch Otorhinolaryngol. Jul 2011; 268(7): 1077-80. PMID 21298386
11. 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
12. 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
13. Yu JL, Mahmoud A, Thaler ER. Transoral robotic surgery versus upper airway stimulation in select obstructive sleep apnea patients. Laryngoscope. Jan 2019; 129(1): 256-258. PMID 30208225
14. Shah J, Russell JO, Waters T, et al. Uvulopalatopharyngoplasty vs CN XII stimulation for treatment of obstructive sleep apnea: A single institution experience. Am J Otolaryngol. May 2018; 39(3): 266-270. PMID 29540289
15. Huntley C, Chou DW, Doghramji K, et al. Comparing Upper Airway Stimulation to Expansion Sphincter Pharyngoplasty: A Single University Experience. Ann Otol Rhinol Laryngol. Jun 2018; 127(6): 379-383. PMID 29707958
16. Steffen A, Sommer JU, Hofauer B, et al. Outcome after one year of upper airway stimulation for obstructive sleep apnea in a multicenter German post-market study. Laryngoscope. Feb 2018; 128(2): 509-515. PMID 28561345
17. Strollo PJ, Soose RJ, Maurer JT, et al. Upper-airway stimulation for obstructive sleep apnea. N Engl J Med. Jan 09 2014; 370(2): 139-49. PMID 24401051
18. Strollo PJ, Gillespie MB, Soose RJ, et al. Upper Airway Stimulation for Obstructive Sleep Apnea: Durability of the Treatment Effect at 18 Months. Sleep. Oct 01 2015; 38(10): 1593-8. PMID 26158895
19. Woodson BT, Soose RJ, Gillespie MB, et al. Three-Year Outcomes of Cranial Nerve Stimulation for Obstructive Sleep Apnea: The STAR Trial. Otolaryngol Head Neck Surg. Jan 2016; 154(1): 181-8. PMID 26577774
20. Soose RJ, Woodson BT, Gillespie MB, et al. Upper Airway Stimulation for Obstructive Sleep Apnea: Self-Reported Outcomes at 24 Months. J Clin Sleep Med. Jan 2016; 12(1): 43-8. PMID 26235158
21. Woodson BT, Gillespie MB, Soose RJ, et al. Randomized controlled withdrawal study of upper airway stimulation on OSA: short- and long-term effect. Otolaryngol Head Neck Surg. Nov 2014; 151(5): 880-7. PMID 25205641
22. Kezirian EJ, Goding GS, Malhotra A, et al. Hypoglossal nerve stimulation improves obstructive sleep apnea: 12-month outcomes. J Sleep Res. Feb 2014; 23(1): 77-83. PMID 24033656
23. Gillespie MB, Soose RJ, Woodson BT, et al. Upper Airway Stimulation for Obstructive Sleep Apnea: Patient-Reported Outcomes after 48 Months of Follow-up. Otolaryngol Head Neck Surg. Apr 2017; 156(4): 765-771. PMID 28194999
24. Woodson BT, Strohl KP, Soose RJ, et al. Upper Airway Stimulation for Obstructive Sleep Apnea: 5-Year Outcomes. Otolaryngol Head Neck Surg. Jul 2018; 159(1): 194-202. PMID 29582703
25. Heiser C, Maurer JT, Hofauer B, et al. Outcomes of Upper Airway Stimulation for Obstructive Sleep Apnea in a Multicenter German Postmarket Study. Otolaryngol Head Neck Surg. Feb 2017; 156(2): 378-384. PMID 28025918
26. Hasselbacher K, Hofauer B, Maurer JT, et al. Patient-reported outcome: results of the multicenter German post-market study. Eur Arch Otorhinolaryngol. Jul 2018; 275(7): 1913-1919. PMID 29808422
27. Caloway CL, Diercks GR, Keamy D, et al. Update on hypoglossal nerve stimulation in children with down syndrome and obstructive sleep apnea. Laryngoscope. Apr 2020; 130(4): E263-E267. PMID 31219619
28. Boon M, Huntley C, Steffen A, et al. Upper Airway Stimulation for Obstructive Sleep Apnea: Results from the ADHERE Registry. Otolaryngol Head Neck Surg. Aug 2018; 159(2): 379-385. PMID 29557280
29. Kent DT, Carden KA, Wang L, et al. Evaluation of Hypoglossal Nerve Stimulation Treatment in Obstructive Sleep Apnea. JAMA Otolaryngol Head Neck Surg. Sep 26 2019. PMID 31556927

30. Huntley C, Steffen A, Doghramji K, et al. Upper Airway Stimulation in Patients With Obstructive Sleep Apnea and an Elevated Body Mass Index: A Multi-institutional Review. Laryngoscope. Oct 2018; 128(10): 2425-2428. PMID 30098035
31. Caples SM, Rowley JA, Prinsell JR, et al. Surgical modifications of the upper airway for obstructive sleep apnea in adults: a systematic review and meta-analysis. Sleep. Oct 2010; 33(10): 1396-407. PMID 21061863
32. 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
33. American Academy of Otolaryngology -- Head and Neck Surgery. Position Statement: Surgical Management of Obstructive Sleep Apnea. 2014; http://www.entnet.org/Practice/policySurgicalMgmtApnea.cfm. Accessed May 18, 2020.
34. American Academy of Otolaryngology-Head and Neck Surgery. 2019 Position Statement: Hypoglossal Nerve Stimulation for Treatment of Obstructive Sleep Apnea (OSA) http://www.entnet.org/content/position-statement- hypoglossal-nerve-stimulation-treatment-obstructive-sleep-apnea-osa. Accessed May 18, 2020.
35. 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. Accessed September 1, 2017.
36. 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. Accessed May 18, 2020.

Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome

1. Krakow B, Ulibarri V, Melendrez D, et al. A daytime, abbreviated cardio-respiratory sleep study (CPT 95807-52) to acclimate insomnia patients with sleep disordered breathing to positive airway pressure (PAP-NAP). J Clin Sleep Med. Jun 15 2008; 4(3): 212-22. PMID 18595433
2. Ulibarri VA, Krakow B, McIver ND. The PAP-NAP one decade later: patient risk factors, indications, and clinically relevant emotional and motivational influences on PAP use. Sleep Breath. Dec 2020; 24(4): 1427-1440. PMID 31898192
3. Berry RB, Kryger MH, Massie CA. A novel nasal expiratory positive airway pressure (EPAP) device for the treatment of obstructive sleep apnea: a randomized controlled trial. Sleep. Apr 01 2011; 34(4): 479-85. PMID 21461326
4. Kryger MH, Berry RB, Massie CA. Long-term use of a nasal expiratory positive airway pressure (EPAP) device as a treatment for obstructive sleep apnea (OSA). J Clin Sleep Med. Oct 15 2011; 7(5): 449-53B. PMID 22003339
5. Riaz M, Certal V, Nigam G, et al. Nasal Expiratory Positive Airway Pressure Devices (Provent) for OSA: A Systematic Review and Meta-Analysis. Sleep Disord. 2015; 2015: 734798. PMID 26798519
6. Kureshi SA, Gallagher PR, McDonough JM, et al. Pilot study of nasal expiratory positive airway pressure devices for the treatment of childhood obstructive sleep apnea syndrome. J Clin Sleep Med. Jun 15 2014; 10(6): 663-9. PMID 24932147
7. Lai V, Tong BK, Tran C, et al. Combination therapy with mandibular advancement and expiratory positive airway pressure valves reduces obstructive sleep apnea severity. Sleep. Aug 01 2019; 42(8). PMID 31180512
8. Kotecha B, Wong PY, Zhang H, et al. A novel intraoral neuromuscular stimulation device for treating sleep-disordered breathing. Sleep Breath. Mar 26 2021. PMID 33772397
9. Baptista PM, Martinez Ruiz de Apodaca P, Carrasco M, et al. Daytime Neuromuscular Electrical Therapy of Tongue Muscles in Improving Snoring in Individuals with Primary Snoring and Mild Obstructive Sleep Apnea. J Clin Med. Apr 27 2021; 10(9). PMID 33925376
10. Srijithesh PR, Aghoram R, Goel A, et al. Positional therapy for obstructive sleep apnoea. Cochrane Database Syst Rev. May 01 2019; 5: CD010990. PMID 31041813
11. Eijsvogel MM, Ubbink R, Dekker J, et al. Sleep position trainer versus tennis ball technique in positional obstructive sleep apnea syndrome. J Clin Sleep Med. Jan 15 2015; 11(2): 139-47. PMID 25515276
12. de Ruiter MHT, Benoist LBL, de Vries N, et al. Durability of treatment effects of the Sleep Position Trainer versus oral appliance therapy in positional OSA: 12-month follow-up of a randomized controlled trial. Sleep Breath. May 2018; 22(2): 441-450. PMID 28913630

13. Berry RB, Uhles ML, Abaluck BK, et al. NightBalance Sleep Position Treatment Device Versus Auto-Adjusting Positive Airway Pressure for Treatment of Positional Obstructive Sleep Apnea. J Clin Sleep Med. Jul 15 2019; 15(7): 947-956. PMID 31383231
14. van Maanen JP, de Vries N. Long-term effectiveness and compliance of positional therapy with the sleep position trainer in the treatment of positional obstructive sleep apnea syndrome. Sleep. Jul 01 2014; 37(7): 1209-15. PMID 25061249
15. Beyers J, Dieltjens M, Kastoer C, et al. Evaluation of a Trial Period With a Sleep Position Trainer in Patients With Positional Sleep Apnea. J Clin Sleep Med. Apr 15 2018; 14(4): 575-583. PMID 29609712
16. Buyse B, Ciordas S, Hoet F, et al. Positional obstructive sleep apnoea: challenging findings in consecutive patients treated with a vibrating position trainer. Acta Clin Belg. Dec 2019; 74(6): 405-413. PMID 30433857

Endnotes

[1] Based on expert opinion and the American Academy of Otolaryngology - Head and Neck Surgery Clinical Practice Guideline: Polysomnography for Sleep-Disordered Breathing Prior to Tonsillectomy in Children. Ootolaryngology Head Neck Surg. 2011 Jul;145.