Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome

Policy # 00329
Original Effective Date: 07/27/2012
Current Effective Date: 09/12/2022

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

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

Note: Actigraphy is addressed separately in medical policy 00330.

When Services May Be Eligible for Coverage

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

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

Based on review of available data, the Company may consider palatopharyngoplasty (e.g., uvulopalatopharyngoplasty (UPPP), uvulopharyngoplasty, uvulopalatal flap, expansion sphincter pharyngoplasty, lateral pharyngoplasty, palatal advancement pharyngoplasty, relocation pharyngoplasty) for the treatment of clinically significant obstructive sleep apnea (OSA) syndrome in appropriately selected 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.**
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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 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 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.

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

Patient Selection Criteria
Coverage eligibility will be met for hypoglossal nerve stimulation in adults with obstructive sleep apnea (OSA) under the following conditions:
- Age ≥ 22 years; AND
- Apnea/hypopnea index (AHI), respiratory disturbance index (RDI), or respiratory event index (REI) ≥ 15 with less than 25% central apneas; AND
- Continuous positive airway pressure (CPAP) failure (residual apnea/hypopnea index [AHI], respiratory disturbance index (RDI), or respiratory event index (REI) ≥ 15 or failure to use CPAP ≥ 4 hr per night for ≥ 5 nights per week) or inability to tolerate CPAP; AND
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- Body mass index ≤ 32 kg/m2; AND
- Non-concentric retropalatal obstruction on drug-induced sleep endoscopy (see Policy Guidelines).

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

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

- Age 10 to 21 years; AND
- Apnea/hypopnea index (AHI) or respiratory event index (REI) > 10 with less than 25% central apneas after prior adenotonsillectomy; AND
- Have been ineffectively treated with continuous positive airway pressure (CPAP) due to noncompliance, discomfort, 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 (See Policy Guidelines).

When Services Are Considered Not Medically Necessary
Based on review on available data, the Company considers surgical treatment of obstructive sleep apnea (OSA) 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 absence of documented obstructive sleep apnea (OSA) to be investigational**; snoring alone is not considered a medical condition.

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

**Policy Guidelines**
Continuous positive airway pressure is the preferred first-line treatment for obstructive sleep apnea for most individuals. A smaller number of individuals may use oral appliances as a first-line treatment (see medical policy 00328). 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.

The hypoglossal nerve (cranial nerve XII) innervates the genioglossus muscle. Stimulation of the nerve causes anterior movement and stiffening of the tongue and dilation of the pharynx.
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Hypoglossal nerve stimulation reduces airway collapsibility and alleviates obstruction at both the level of the soft palate and tongue base.

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

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, 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>
<thead>
<tr>
<th>Terms</th>
<th>Definitions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Respiratory Event</strong></td>
<td></td>
</tr>
<tr>
<td>Apnea</td>
<td>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.</td>
</tr>
<tr>
<td>Hypopnea</td>
<td>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.</td>
</tr>
</tbody>
</table>
### Terms and Definitions

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<tr>
<td>RERA</td>
<td>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.</td>
</tr>
<tr>
<td><strong>Respiratory event reporting</strong></td>
<td></td>
</tr>
<tr>
<td>Apnea/Hypopnea Index (AHI)</td>
<td>The average number of apneas or hypopneas per hour of sleep.</td>
</tr>
<tr>
<td>Respiratory Disturbance Index (RDI)</td>
<td>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.</td>
</tr>
<tr>
<td>Respiratory event index (REI)</td>
<td>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.</td>
</tr>
<tr>
<td>Diagnosis</td>
<td></td>
</tr>
<tr>
<td>OSA</td>
<td>Repetitive episodes of upper airway obstruction due to the collapse and obstruction of the upper airway during sleep.</td>
</tr>
<tr>
<td>Mild OSA</td>
<td>In adults: AHI of 5 to &lt;15. In children: AHI ≥1 to 5</td>
</tr>
<tr>
<td>Moderate OSA</td>
<td>AHI of 15 to &lt; 30. Children: AHI of &gt; 5 to 10</td>
</tr>
<tr>
<td>Severe OSA</td>
<td>Adults: AHI ≥30. Children: AHI of &gt;10</td>
</tr>
<tr>
<td>Treatment</td>
<td></td>
</tr>
<tr>
<td>Positive airway pressure (PAP)</td>
<td>Positive airway pressure may be continuous (CPAP) or auto-adjusting (APAP) or Bi-level (Bi-PAP).</td>
</tr>
<tr>
<td>PAP Failure</td>
<td>Usually defined as an AHI greater than 20 events per hour while using PAP</td>
</tr>
</tbody>
</table>
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<td>PAP Intolerance</td>
<td>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.</td>
</tr>
</tbody>
</table>

EEG: electroencephalogram; OSA: obstructive sleep apnea; 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**

<table>
<thead>
<tr>
<th>Interventions</th>
<th>Devices (predicate or prior name)</th>
<th>Manufacturer (previous owner)</th>
<th>Indication</th>
<th>PMA/510(k)</th>
<th>Year</th>
<th>FDA Product Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>LAUP</td>
<td>Various</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radiofrequency ablation</td>
<td>Somno-plasty®‡</td>
<td></td>
<td>Simple snoring and for the base of the tongue for OSA</td>
<td>K982717</td>
<td>1998</td>
<td>GEI</td>
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<tr>
<td>Palatal Implant</td>
<td>Pillar® Palatal Implant</td>
<td>Pillar Palatal (Restore Medical/ Medtronic)</td>
<td>Stiffening the soft palate which may reduce the severity of snoring and incidence of airway obstructions in patients with mild-to-moderate OSA</td>
<td>K040417</td>
<td>2004</td>
<td>LRK</td>
</tr>
<tr>
<td>Tongue base suspension</td>
<td>AIRvance® (Repose)</td>
<td>Medtronic</td>
<td>OSA and/or snoring. The AIRvance TM Bone Screw System is also suitable for the performance of a hyoid suspension</td>
<td>K122391</td>
<td>1999</td>
<td>LRK</td>
</tr>
<tr>
<td>Tongue base suspension</td>
<td>Encore™ (PRELUDE III)</td>
<td>Siesta Medical</td>
<td>Treatment of mild or moderate OSA and/or snoring</td>
<td>K111179</td>
<td>2011</td>
<td>ORY</td>
</tr>
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</thead>
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<tr>
<td>Hypoglossal nerve stimulation</td>
<td>Inspire® II Upper Airway Stimulation</td>
<td>Inspire Medical Systems</td>
<td>Patients ≥ 18 years with AHI ≥15 and ≤65 who have failed (AHI &gt;15 despite CPAP usage) or cannot tolerate (&lt;4 h use per night for ≥5 nights per week) CPAP and do not have complete concentric collapse at the soft palate level. Patients between ages 18 and 21 should also be contraindicated for or not effectively treated by adenotonsillectomy.</td>
<td>P130008, S039</td>
<td>2014</td>
<td>MNQ</td>
</tr>
<tr>
<td>Hypoglossal nerve stimulation</td>
<td>aura6000®‡</td>
<td>ImThera Medical</td>
<td></td>
<td>IDE</td>
<td>2014</td>
<td></td>
</tr>
<tr>
<td>Hypoglossal nerve stimulation</td>
<td>Genio™‡</td>
<td>Nyxoa</td>
<td></td>
<td>European CE Mark</td>
<td>2019</td>
<td></td>
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<tr>
<td>Hypoglossal nerve stimulation</td>
<td>Apnex System®‡</td>
<td>Apnex</td>
<td>Apnex</td>
<td>AHI: Apnea/Hypopnea Index; CPAP: continuous positive airway pressure; IDE: investigational device exemption; LAUP: Laser-assisted uvulopalatoplasty; OSA: obstructive sleep apnea.</td>
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</tr>
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</table>

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

**Rationale/Source**
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 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 medical policy does not address conventional surgical procedures such as uvulopalatopharyngoplasty.
Summary of Evidence

For individuals who have OSA who receive laser-assisted uvulopalatoplasty, the evidence includes a single randomized controlled trial (RCT). Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The trial indicates reductions in snoring, but limited efficacy on the Apnea/Hypopnea Index (AHI) or symptoms in patients with mild-to-moderate OSA. The evidence is insufficient to determine 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. 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 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 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 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 UPPP and showed success rates of 50% to 57% for both procedures. RCTs
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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, the evidence includes a systematic review, 1 RCT, nonrandomized prospective studies, nonrandomized studies with historical controls, and prospective single-arm studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. A double-blind, multicenter RCT of 89 adults with moderate-to-severe OSA who did not tolerate continuous positive airway pressure (CPAP) found significant short-term improvement in AHI, Epworth Sleepiness Scale, and quality of life measures with HNS compared to sham stimulation. The study was limited by a short duration of follow-up and lack of diverse individuals included in the trial. Hypoglossal nerve stimulation has shown success rates for about two-thirds of a subset of patients who met selection criteria that included AHI, body mass index, and favorable pattern of palatal collapse across nonrandomized trials. These results were maintained out to 5 years in the pivotal single-arm study. The single prospective comparative study of patients who received HNS versus patients who were denied insurance coverage for the procedure has a high potential for performance bias. For children and adolescents with OSA and Down Syndrome who are unable to tolerate CPAP, the evidence includes a safety study with 20 patients who were treated at tertiary care centers. The success rate was 70% with 2 adverse events of the leads, which were resolved with further surgery. A larger study of 42 individuals with Down Syndrome and OSA found a similar success rate of 73.2% with 4 device extrusions corrected with replacement surgery. Limitations of the current evidence base preclude determination of who is most likely to benefit from this invasive procedure. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Additional Information

2018 Input
Clinical input was sought to help determine whether the use of hypoglossal nerve stimulation for individuals with OSA 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.
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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 patients. One subgroup includes adult patients with a favorable pattern of non-concentric palatal collapse. The alternative treatment for this anatomical endotype is maxillo-mandibular advancement (MMA), which is associated with greater morbidity and lower patient acceptance than HNS. The improvement in AHI with HNS, as shown in the Stimulation Therapy for Apnea Reduction (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

**Supplemental Information**

**Clinical Input From Physician Specialty Societies and Academic Medical Centers**

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

**2018 Input**

Clinical input was sought to help determine whether the use of hypoglossal nerve stimulation (HNS) for individuals with obstructive sleep apnea (OSA) would provide a clinically meaningful improvement in net health outcome and whether the use is consistent with generally accepted medical practice. In response to requests, clinical input was received from 2 respondents, including 1 specialty society-level response and physicians with academic medical center affiliation.

For individuals who have OSA who receive HNS, clinical input supports that this use provides a clinically meaningful improvement in net health outcome and indicates this use is consistent with...
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generally accepted medical practice in subgroups of appropriately selected patients. One subgroup includes adult patients with a favorable pattern of non-concentric palatal collapse. The alternative 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 Apnea/Hypopnea Index (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 continuous positive airway pressure (CPAP). The following patient selection criteria are based on information from clinical study populations and clinical expert opinion.

- Age $\geq 22$ years in adults or adolescents with Down's syndrome age 10 to 21; AND
- Diagnosed moderate to severe OSA (with less than 25% central apneas); AND
- CPAP failure or inability to tolerate CPAP; AND
- Body mass index $\leq 32$ kg/m$^2$ in adults; AND
- Favorable pattern of palatal collapse

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,
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- genioglossal advancement,
- hyoid myotomy,
- midline glossectomy,
- tongue suspension,
- maxillary and mandibular advancement.

In a 2021 position statement, AAO-HNS supported hypoglossal nerve stimulation as an effective second-line treatment of moderate-to-severe OSA.

American Society for Metabolic and Bariatric Surgery  
The American Society for Metabolic and Bariatric Surgery (2012) published guidelines on the perioperative management of OSA. The guideline indicated that OSA is strongly associated with obesity, with the incidence of OSA in the morbidly obese population reported as between 38% and 88%. The Society recommended bariatric surgery as the initial treatment of choice for OSA in this population, 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 review on the surgical management of OSA. The CMS review of the literature suggested there is a risk of hypertension with an AHI or Respiratory Disturbance Index of at least 15 events per hour, and thus treatment is warranted for patients without any additional signs and symptoms. For patients with an AHI or Respiratory Disturbance Index 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.

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

**Ongoing and Unpublished Clinical Trials**
Some currently unpublished trials that might influence this review are listed in Table 3.

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
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<tr>
<td>NCT02413970a</td>
<td>Inspire®‡ Upper Airway Stimulation System (UAS): Post-Approval Study Protocol Number 2014-001</td>
<td>127</td>
<td>Jun 2025</td>
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<tr>
<td>NCT03868618a</td>
<td>A Multicenter Study to Assess the Safety and Effectiveness of the Genio Dual-sided Hypoglossal Nerve Stimulation System for the Treatment of Obstructive Sleep Apnea in Adults Subjects</td>
<td>134</td>
<td>Jun 2027</td>
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<tr>
<td>NCT02263859a</td>
<td>ImThera Medical Targeted Hypoglossal Neurostimulation Study #3 (THN3)</td>
<td>138</td>
<td>Dec 2022</td>
</tr>
<tr>
<td>NCT03763682a</td>
<td>A Multicentre, Prospective, Open-label, 2 Groups Study to Assess the Safety and Performance of the Genio™ Bilateral Hypoglossal Nerve Stimulation System for the Treatment of Obstructive Sleep Apnoea in Adult Patients With and Without Complete Concentric Collapse of the Soft Palate</td>
<td>42</td>
<td>Dec 2023</td>
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<td>NCT04801771a</td>
<td>Effects of Hypoglossal Nerve Stimulation on Cognition and Language in Down Syndrome and Obstructive Sleep Apnea</td>
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<td>NCT04031040a</td>
<td>A Post-market Clinical Follow up of the Genio™ System for the Treatment of Obstructive Sleep Apnea in Adults (ElISA)</td>
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<td>Adherence and Outcome of Upper Airway Stimulation (UAS) for OSA International Registry</td>
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<td>NCT04950894a</td>
<td>Treating Obstructive Sleep Apnea Using Targeted Hypoglossal Neurostimulation</td>
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<td>Jul 2023</td>
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<td>NCT04928404</td>
<td>Barbed Suspension of the Tongue Base for Treatment of Obstructive Sleep Apnea Patients</td>
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Unpublished

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<td>NCT03760328</td>
<td>Effect of Upper Airway Stimulation: A Randomized Controlled Crossover Study</td>
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<td>NCT03359096</td>
<td>Cardiovascular Endpoints for Obstructive Sleep Apnea With Twelfth Nerve Stimulation (CARDIOSA-12): A Randomized, Sham-Controlled, Double-Blinded, Crossover Trial</td>
<td>63</td>
<td>Jan 2022</td>
</tr>
</tbody>
</table>

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

References

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06/28/2012 Medical Policy Committee review
07/27/2012 Medical Policy Implementation Committee approval. New policy.
12/06/2012 Medical Policy Committee review
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
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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


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
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“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 absence of documented obstructive sleep apnea (OSA) syndrome; snoring alone is not considered a medical condition”.

Next Scheduled Review Date: 08/2023

Coding

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:
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*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;
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B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and

C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

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

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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.