Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome

Description

Obstructive sleep apnea (OSA) syndrome is characterized by repetitive episodes of upper airway obstruction due to the collapse of the upper airway during sleep. For patients who have failed conservative therapy, established surgical approaches may be indicated. This evidence review addresses minimally invasive surgical procedures for the treatment of OSA. They include laser-assisted uvuloplasty, tongue base suspension, radiofrequency volumetric reduction of palatal tissues and base of tongue, palatal stiffening procedures, and hypoglossal nerve stimulation (HNS). This evidence review does not address conventional surgical procedures such as uvulopalatopharyngoplasty, hyoid suspension, surgical modification of the tongue, maxillofacial surgery, or adenotonsillectomy.

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OBJECTIVE

The objective of this evidence review is to determine whether the use of minimally invasive surgical procedures improve the net health outcome for patients being treated for obstructive sleep apnea.

POLICY STATEMENT

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 select 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 patients who have:

- Apnea/Hypopnea Index (AHI) or Respiratory Disturbance Index (RDI) of 15 or more events per hour, or
- AHI or RDI of at least 5 events per hour with one or more signs or symptoms associated with OSA (eg, excessive daytime sleepiness, hypertension, cardiovascular heart disease, or stroke).

Hyoid suspension, surgical modification of the tongue, and/or maxillofacial surgery, including mandibular-maxillary advancement (MMA), may be considered medically necessary in appropriately selected adults with clinically significant OSA and objective documentation of hypopharyngeal obstruction who have failed an adequate trial of CPAP or failed an adequate trial of an oral appliance. Clinically significant OSA is defined as those patients who have:

- AHI or RDI of 15 or more events per hour, or
- AHI or RDI of at least 5 events per hour with one or more signs or symptoms associated with OSA (eg, excessive daytime sleepiness, hypertension, cardiovascular heart disease, or stroke).

Adenotonsillectomy may be considered medically necessary in pediatric patients with clinically significant OSA and hypertrophic tonsils. Clinically significant OSA is defined as those pediatric patients who have:

- AHI or RDI of at least 5 per hour, or
- AHI or RDI of at least 1.5 per hour in a patient with excessive daytime sleepiness, behavioral problems, or hyperactivity.

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/m²; AND
- Non-concentric retropalatal obstruction on drug-induced sleep endoscopy (see Policy Guidelines).

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, un-desirable 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).

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.

Implantable hypoglossal nerve stimulators are considered **not medically necessary** for all indications other than listed above.

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

**POLICY GUIDELINES**

Continuous positive airway pressure is the preferred first-line treatment for most patients. A smaller number of patients may use oral appliances as a first-line treatment (see evidence review 2.01.18). The Apnea/Hypopnea Index is the total number events (apnea or hypopnea) per hour of recorded sleep. The Respiratory Disturbance Index is the total number events (apnea or hypopnea) per hour of recording time. An obstructive apnea is defined as at least a 10-second cessation of respiration associated with ongoing ventilatory effort. Hypopnea is defined as an abnormal respiratory event lasting at least 10 seconds with at least a 30% reduction in thoracoabdominal movement or airflow compared with baseline, and with at least a 4% oxygen desaturation.

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

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

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Obstructive sleep apnea (OSA) is characterized by repetitive episodes of upper airway obstruction due to the collapse and obstruction of the upper airway during sleep. The hallmark symptom of OSA is excessive daytime sleepiness, and the typical clinical sign of OSA is snoring, which can abruptly cease and be followed by gasping associated with a brief arousal from sleep. The snoring resumes when the patient falls back to sleep, and the cycle of snoring/apnea/arousal may be repeated as frequently as every minute throughout the night. Sleep fragmentation associated with the repeated arousal during sleep can impair daytime activity. For example, adults with OSA-associated daytime somnolence are thought to be at higher risk for accidents involving motorized vehicles (ie, cars, trucks, heavy equipment). OSA in children may result in neurocognitive impairment and behavioral problems. In addition, OSA affects the cardiovascular and pulmonary systems. For example, apnea leads to periods of hypoxia, alveolar hypoventilation, hypercapnia, and acidosis. This, in turn, can cause systemic hypertension, cardiac arrhythmias, and cor pulmonale. Systemic hypertension is common in patients with OSA. Severe OSA is associated with decreased survival, presumably related to severe hypoxemia, hypertension, or an increase in automobile accidents related to overwhelming sleepiness.

Terminology and diagnostic criteria for OSA are shown in Table 1

Table 1. Terminology and Definitions for Obstructive Sleep Apnea

<table>
<thead>
<tr>
<th>Terms</th>
<th>Definitions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory Event</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 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 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.</td>
</tr>
<tr>
<td>Hypopnea</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 increasing respiratory effort, terminating in an arousal but not otherwise meeting criteria for apnea or hypopnea.</td>
</tr>
<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 increasing respiratory effort, terminating in an arousal but not otherwise meeting criteria for apnea or hypopnea.</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>Obstructive sleep apnea (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>
</tbody>
</table>
Terms
Moderate OSA  \hspace{1cm} \text{AHI of 15 to < 30. Children: AHI of > 5 to 10}
Severe OSA  \hspace{1cm} \text{Adults: AHI \geq 30. Children: AHI of > 10}

Treatment
Positive airway pressure (PAP)  \hspace{1cm} \text{Positive airway pressure may be continuous (CPAP) or auto-adjusting (APAP) or Bi-level (Bi-PAP). Usually defined as an AHI greater than 20 events per hour while using PAP}
PAP Failure  \hspace{1cm} \text{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}
PAP Intolerance

OSA: obstructive sleep apnea; PSG: Polysomnographic

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 (previously 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>Somnoplasty</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>
</tr>
<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>Encore™  (PRELUDE III)</td>
<td>Siesta Medical</td>
<td></td>
<td>Treatment of mild or moderate OSA and/or snoring</td>
<td>K111179</td>
<td>2011</td>
<td>ORY</td>
</tr>
<tr>
<td>Hypoglossal nerve stimulation</td>
<td>Inspire II Upper Airway Stimulation</td>
<td>Inspire Medical Systems</td>
<td>Patients \geq 18 years with AHI \geq 15 and \leq 65 who have failed (AHI &gt;15 despite CPAP usage) or cannot tolerate (&lt;4 h use per night for \geq 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></td>
<td></td>
</tr>
<tr>
<td>Hypoglossal nerve stimulation</td>
<td>Genio™</td>
<td>Nyxo</td>
<td>European CE Mark</td>
<td>2019</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
AHI: Apnea/Hypopnea Index; CPAP: continuous positive airway pressure; IDE: investigational device exemption; LAUP: Laser-assisted uvulopalatoplasty; OSA: obstructive sleep apnea.

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

Rationale

Summary of Evidence

For individuals who have obstructive sleep apnea (OSA) who receive laser-assisted uvulopalatoplasty, the evidence includes a single randomized controlled trial (RCT). Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The trial indicates reductions in snoring, but limited efficacy on the Apnea/Hypopnea Index (AHI) or symptoms in patients with mild-to-moderate OSA. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have OSA who receive radiofrequency volumetric reduction of palatal tissues and base of tongue, the evidence includes 2 sham-controlled randomized trials. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Single-stage radiofrequency to palatal tissues did not improve outcomes compared with sham. Multiple sessions of radiofrequency to the palate and base of tongue did not significantly (statistically or clinically) improve AHI, and the improvement in functional outcomes was not clinically significant. The evidence is insufficient to determine the effects of the technology on health outcomes.

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

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

For individuals who have OSA who receive hypoglossal nerve stimulation, the evidence includes 2 nonrandomized studies with historical controls and prospective single-arm studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Hypoglossal nerve stimulation has shown success rates for about two-thirds of a subset of patients who met selection criteria that included AHI, body mass index, and favorable pattern of palatal collapse. These results were maintained out to 5 years in the pivotal single-arm study. Prospective comparative trials are needed. For children and adolescents with OSA and Down Syndrome who are unable to tolerate continuous positive airway pressure (CPAP), the evidence includes a safety study with 20 patients who were treated at tertiary care centers. The success rate was 70% with 2 adverse events of the leads, which were resolved with further surgery. Study in a larger number of patients with Down Syndrome is ongoing. The evidence is insufficient to determine the effects of the technology on health outcomes.
SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

American Academy of Sleep Medicine

The American Academy of Sleep Medicine (AASM-2010) published practice parameters for surgical modifications of the upper airway for obstructive sleep apnea (OSA). The AASM practice parameters were based on a systematic review of the evidence that found the published literature was comprised primarily of case series, with few controlled trials and varying approaches to preoperative evaluation and postoperative follow-up. Using the change in Apnea/Hypopnea Index as the primary measure of efficacy, substantial and consistent reductions were observed following mandibular-maxillary advancement, and adverse events were uncommonly reported. Outcomes following pharyngeal surgeries were less consistent, and adverse events were more commonly reported. The review found that outcomes of studies with newer pharyngeal techniques and multilevel procedures, performed in small numbers of patients, appear promising. The practice parameters noted the lack of rigorous data evaluating surgical modifications of the upper airway, resulting in a recommendation of "option" (uncertain clinical use) for mandibular-maxillary advancement, uvulopalatopharyngoplasty as a sole procedure, or multilevel or stepwise surgery if patients failed uvulopalatopharyngoplasty as a sole treatment. Use of radiofrequency ablation was recommended as an "option" for patients with mild-to-moderate OSA who cannot tolerate or are unwilling to adhere to continuous positive airway pressure (CPAP), or in whom oral appliances have been found ineffective or undesirable. Palatal implants were recommended as an "option" for patients with mild OSA who failed medical therapy. Laser-assisted uvulopalatoplasty was not recommended as a routine treatment for OSA (standard). The practice parameters recommended as "standard" the need to determine the presence and severity of OSA before initiating surgical therapy, discussion of success rates, complications, and alternative treatments with the patient, and a postoperative follow-up evaluation, which includes a clinical evaluation and an objective measure of the presence and severity of sleep-disordered breathing and oxygen saturation. However, little guidance was available in the medical literature to recommend any particular monitoring strategy. The optimal interval and duration of this follow-up were also not clear from the available literature.

American Academy of Pediatrics

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

American Academy of Otolaryngology - Head and Neck Surgery

The American Academy of Otolaryngology - Head and Neck Surgery (AAO-HNS; 2014) has a position statement on surgical management of OSA. Procedures AAO-HNS supported as effective and not considered investigational when part of a comprehensive approach in the medical and surgical management of adults with OSA include:

- tracheotomy,
• nasal and pharyngeal airway surgery,
• tonsillectomy and adenoidectomy,
• palatal advancement,
• uvulopalatopharyngoplasty,
• uvulopalatoplasty (including laser-assisted and other techniques),
• genioglossal advancement,
• hyoid myotomy,
• midline glossectomy,
• tongue suspension,
• maxillary and mandibular advancement.

In a 2019 position statement, AAO-HNS supported hypoglossal nerve stimulation as an effective second-line treatment of moderate-to-severe OSA.34

American Society for Metabolic and Bariatric Surgery

The American Society for Metabolic and Bariatric Surgery (2012) published guidelines on the perioperative management of OSA.35 The guideline indicated that OSA is strongly associated with obesity, with the incidence of OSA in the morbidly obese population reported as between 38% and 88%. The Society recommended bariatric surgery as the initial treatment of choice for OSA in this population, as opposed to surgical procedures directed at the mandible or tissues of the palate.

National Institute for Health and Care Excellence

2017 guidance from the U.K.’s National Institute for Health and Care Excellence (NICE) concluded that evidence on the safety and efficacy of hypoglossal nerve stimulation is limited in quantity and quality.36

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

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

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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.

REFERENCES


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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
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<tbody>
<tr>
<td>December 2011</td>
<td>New policy</td>
<td>Policy updated with literature search, adding references 13, 14, 29, 30, 35-38, and 40. New FDA approved device, Hypoglossal Nerve Stimulator has been added to policy. Policy statement has been updated to indicate it is not medically necessary.</td>
</tr>
<tr>
<td>September 2014</td>
<td>Replace policy</td>
<td>Policy statement has been updated to indicate it is not medically necessary.</td>
</tr>
<tr>
<td>September 2015</td>
<td>Replace policy</td>
<td>Policy updated with literature review; reference 31 added; policy statements unchanged.</td>
</tr>
<tr>
<td>December 2016</td>
<td>Replace policy</td>
<td>Policy updated with literature review, adding references 17-20. Medically necessary policy statement revised to include variants of palatopharyngoplasty.</td>
</tr>
<tr>
<td>December 2017</td>
<td>Replace policy</td>
<td>Policy updated with literature review through July 20, 2017; reference 26 added; reference 27 updated. Policy statements unchanged except Hypoglossal Nerve Stimulator policy statement corrected from investigational (as noted in Dec. 2016 version) back to not medically necessary per 2014 OPM guidance regarding devices with Premarket Approval.</td>
</tr>
<tr>
<td>March 2018</td>
<td>Replace policy</td>
<td>Policy updated with literature review through October 29, 2018; Clinical input added for hypoglossal nerve stimulation. References added and some references removed. Hypoglossal nerve stimulation is considered medically necessary under specified conditions. (FDA cleared 510k) minimally invasive surgical procedures are considered investigational for the sole or adjunctive treatment of OSA or upper airway resistance syndrome.</td>
</tr>
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</table>
## FEP 7.01.101 Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>September 2019</td>
<td>Replace policy</td>
<td>Policy updated with literature review through April 22, 2019; references added. The indication for hypoglossal nerve stimulation changed to apnea/hypopnea index of ≥ 15 for alignment with the Food and Drug Administration-approved indication. Edits were also made to the Policy section regarding signs and symptoms in mild OSA to align with BCBSA policy #2.01.18. Policy statements otherwise unchanged.</td>
</tr>
<tr>
<td>September 2020</td>
<td>Replace policy</td>
<td>Policy updated with literature review through May 11, 2020; references added. Policy statements unchanged.</td>
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</table>

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