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Subject: Medical & Surgical Management of Sleep Apnea, Snoring, and Other Conditions of the Soft Palate and Nasal Passages

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

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DESCRIPTION:

This policy addresses various methods for the management of sleep apnea. CPAP, APAP, BiPAP, and Sleep Testing are addressed in separate policies.

Treatment of obstructive sleep apnea (OSA), an interrupted breathing pattern occurring during sleep, involves both medical and surgical means. Medical management of OSA in adults may include weight loss, avoidance of stimulants, body position adjustment, oral appliances, and use of various types of positive airway pressure therapy (i.e., fixed CPAP, bilevel positive airway pressure [BiPAP], or APAP) during sleep.

Oral appliances can be broadly categorized as mandibular advancing or positioning devices or tongue retaining devices. Oral appliances can either be “off the shelf” or custom made by a dental laboratory or similar provider.

A condition related to OSA has been termed upper airway resistance syndrome (UARS). UARS is characterized by a partial collapse of the airway resulting in increased resistance to airflow. It has been proposed that UARS is a distinct syndrome from OSA that may be considered a disease of arousal.

Traditional surgeries for OSA or UARS include **uvulopalatopharyngoplasty (UPPP)** and a variety of maxillofacial surgeries such as mandibular-maxillary advancement (MMA). **UPPP** involves surgical resection of the mucosa and submucosa of the soft palate, tonsillar fossa, and the lateral aspect of the uvula. The amount of tissue removed is individualized for each patient, as determined by the potential space and width of the tonsillar pillar mucosa between the two palatal arches. UPPP enlarges the

oropharynx but cannot correct obstructions in the hypopharynx; thus, patients who fail UPPP may be candidates for additional procedures, depending on the site of obstruction. Additional procedures include hyoid suspensions, maxillary and mandibular osteotomies, or modification of the tongue. Drug-induced sleep endoscopy and/or cephalometric measurements have been used as methods to identify hypopharyngeal obstruction in these patients. The first-line treatment in children is usually adenotonsillectomy.

Several minimally invasive surgical approaches are being evaluated for OSA in adults including:

- **Laser-Assisted Uvulopalatoplasty (LAUP)** - An outpatient procedure proposed as a treatment of snoring with or without associated OSA. In this procedure, superficial palatal tissues are sequentially reshaped using a carbon dioxide laser. The extent of the surgery is typically different from standard UPPP because only part of the uvula and associated soft palate tissues are reshaped. The procedure does not remove or alter tonsils or lateral pharyngeal wall tissues. The patient undergoes from 3 to 7 sessions at 3- to 4-week intervals. One purported advantage of LAUP is that the amount of tissue ablated can be titrated so treatment can be discontinued once snoring is eliminated. LAUP cannot be considered an equivalent procedure to the standard UPPP, with the laser simply representing a surgical tool that the physician may opt to use. LAUP is considered a unique procedure, which raises its own issues of safety and, in particular, effectiveness.
- **Tongue Base Suspension** - The base of the tongue is suspended with a suture that is passed through the tongue and fixated with a screw to the inner side of the mandible, below the tooth roots. The aim of the suspension is to make it less likely for the base of the tongue to prolapse during sleep.
- **Radiofrequency Ablation of Palatal Tissues and Base of Tongue** - Similar in concept to LAUP, although a different energy source is used. Radiofrequency is used to produce thermal lesions within the tissues rather than using a laser to ablate the tissue surface, which may be painful. For this reason, radiofrequency ablation appears to be growing in popularity as an alternative to LAUP. In some situations, radiofrequency of the soft palate and base of tongue are performed together as a multilevel procedure.
- **Palatal stiffening procedures** - Include insertion of palatal implants, injection of a sclerosing agent (snoreplasty), or a cautery-assisted palatal stiffening operation. The operation uses cautery to induce a midline palatal scar designed to stiffen the soft palate to eliminate excessive snoring. The palatal implant device is a cylindrically shaped segment of braided polyester filaments that is permanently implanted submucosally in the soft palate.
- **Hypoglossal Nerve Stimulation** - Contracts the genioglossus muscle, the largest upper airway dilator muscle. This causes tongue protrusion and stiffening of the anterior pharyngeal wall, potentially decreasing apneic events. Hypoglossal nerve stimulation systems include an implantable neurostimulator, stimulating leads, and electrodes. Stimulation systems include respiratory sensing leads that permit intermittent stimulation during inspiration. Stimulation parameters are titrated during an in-laboratory polysomnography and can be adjusted by the patient during home use. The device is turned on only during sleep periods.
- **Atrial overdrive pacing** - This approach is being tried because of the bradycardia generally noted during episodes of apnea.

Central sleep apnea (CSA) is characterized by repetitive cessation or decrease in both airflow and ventilatory effort during sleep. Central sleep apnea may be idiopathic or secondary (associated with a medical condition such as congestive heartfailure, drugs, or high altitude breathing). The use of positive airway pressure devices is currently the most common form of therapy for CSA. An implantable device that stimulates the phrenic nerve in the chest is a potential alternative treatment. The battery-powered device sends signals to the diaphragm in order to stimulate breathing and normalize sleep-related breathing patterns.

A variety of devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process for the treatment and management of sleep apnea.

POSITION STATEMENT:

The following procedures or devices **meet the definition of medical necessity** when the associated criteria are met:

- **Intraoral appliances (tongue-retaining devices or mandibular advancing/positioning devices)** – in members with clinically significant obstructive sleep apnea (defined in Definition section below) who have failed a trial of continuous positive airway pressure (CPAP) or is contraindicated, the device is prescribed by a treating physician, the device is custom-fitted by qualified dental personnel, **AND** there is absence of temporomandibular dysfunction or periodontal disease.
- **Palatopharyngoplasty** (e.g., uvulopalatopharyngoplasty, uvulopharyngoplasty, uvulopalatal flap, expansion sphincter pharyngoplasty, lateral pharyngoplasty, palatal advancement pharyngoplasty, relocation pharyngoplasty)- when performed for the treatment of clinically significant obstructive sleep apnea (defined in Definition section below) in appropriately select members who have failed an adequate trial of CPAP **OR** failed an adequate trial of an oral appliance.
- **Hyoid suspension, surgical modification of the tongue, or maxillofacial surgery, including mandibular-maxillary advancement (MMA)** – in appropriately selected members with clinically significant OSA and objective documentation of hypopharyngeal obstruction who have not responded to or do not tolerate CPAP **OR** failed an adequate trial of an oral appliance.
- **Adenotonsillectomy**- in pediatric members with clinically significant obstructive sleep apnea (defined in Definition section below) and hypertrophic tonsils.

Surgical treatment of obstructive sleep apnea (OSA) that does not meet the criteria above **does not meet the definition of medical necessity**.

An FDA-approved hypoglossal nerve stimulation device **meets the definition of medical necessity** in adults with OSA who meet **ALL** of the following criteria:

- Age \geq 22 years;
- AHI \geq 15 with less than 25% central apneas;
- CPAP failure (residual AHI \geq 15 or failure to use CPAP \geq 4 hr per night for \geq 5 nights per week) or inability to tolerate CPAP;

- Body mass index ≤ 32 kg/m²; **AND**
- Absence of complete concentric collapse at the soft palate level on drug-induced sleep endoscopy (DISE).

Hypoglossal nerve stimulation is considered **experimental or investigational** for all other indications. The evidence is insufficient to determine the effects of the technology on health outcomes.

The use of a non-FDA-approved hypoglossal nerve stimulation device is considered **experimental or investigational** for all indications. The evidence is insufficient to determine the effects of the technology on health outcomes.

The following are considered **experimental or investigational** for the sole or adjunctive treatment of OSA or upper airway resistance syndrome:

- Laser-assisted palatoplasty (LAUP) or radiofrequency volumetric tissue reduction of the palatal tissues
- Tongue base suspension
- Radiofrequency volumetric tissue reduction of the tongue (with or without radiofrequency reduction of the palatal tissues; i.e. Somnoplasty)
- Palatal stiffening procedures including, but not limited to, cautery-assisted palatal stiffening operation, injection of a sclerosing agent, and the implantation of palatal implants
- Radiofrequency ablation of the nasal passages, soft palate, tonsils, adenoids, or turbinates (i.e. Coblation)
- Atrial overdrive pacing
- Palate and mandible expansion devices
- All other minimally invasive surgical procedures not described above.

There is a lack of clinical data to permit conclusions on net health outcomes.

All devices or interventions, including LAUP, radiofrequency volumetric tissue reduction of the palate, or palatal stiffening procedures, **do not meet the definition of medical necessity** for the treatment of snoring in the absence of documented OSA; snoring alone is not considered a medical condition.

The use of daytime electrical stimulation of the tongue (e.g. eXciteOSA®) is considered **experimental or investigational** for the treatment of obstructive sleep apnea. The evidence is insufficient to determine the effects of the technology on health outcomes.

The use of phrenic nerve stimulation (e.g. remedē® System) for the treatment of central sleep apnea is considered **experimental or investigational**. The evidence is insufficient to determine the effects of the technology on health outcomes.

BILLING/CODING INFORMATION:

CPT Coding:

21199	Osteotomy, mandible, segmental; with genioglossus advancement
30801	Ablation, soft tissue of inferior turbinates, unilateral or bilateral, any method (e.g., electrocautery, radiofrequency ablation, or tissue volume reduction); superficial
30802	Ablation, soft tissue of inferior turbinates, unilateral or bilateral, any method (e.g., electrocautery, radiofrequency ablation, or tissue volume reduction); intramural (i.e., submucosal)
41512	Tongue base suspension, permanent suture technique
41530	Submucosal ablation of the tongue base, radiofrequency, 1 or more sites, per session (Investigational)
42145	Palatopharyngoplasty (e.g., uvulopalatopharyngoplasty, uvulopharyngoplasty)
64582	Open implantation of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array
64583	Revision or replacement of hypoglossal nerve neurostimulator array and distal respiratory sensor electrode or electrode array, including connection to existing pulse generator
64584	Removal of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array
0424T	Insertion or replacement of neurostimulator system for treatment of central sleep apnea; complete system (transvenous placement of right or left stimulation lead, sensing lead, implantable pulse generator) (Investigational)
0425T	Insertion or replacement of neurostimulator system for treatment of central sleep apnea; sensing lead only (Investigational)
0426T	Insertion or replacement of neurostimulator system for treatment of central sleep apnea; stimulation lead only (Investigational)
0427T	Insertion or replacement of neurostimulator system for treatment of central sleep apnea; pulse generator only (Investigational)
0428T	Removal of neurostimulator system for treatment of central sleep apnea; pulse generator only (Investigational)
0429T	Removal of neurostimulator system for treatment of central sleep apnea; sensing lead only (Investigational)
0430T	Removal of neurostimulator system for treatment of central sleep apnea; stimulation lead only (Investigational)
0431T	Removal and replacement of neurostimulator system for treatment of central sleep apnea, pulse generator only (Investigational)
0432T	Repositioning of neurostimulator system for treatment of central sleep apnea; stimulation lead only (Investigational)
0433T	Repositioning of neurostimulator system for treatment of central sleep apnea; sensing lead only (Investigational)
0434T	Interrogation device evaluation implanted neurostimulator pulse generator system for central sleep apnea (Investigational)

0435T	Programming device evaluation of implanted neurostimulator pulse generator system for central sleep apnea; single session (Investigational)
0436T	Programming device evaluation of implanted neurostimulator pulse generator system for central sleep apnea; during sleep study (Investigational)

HCPCS Coding:

C1823	Generator, neurostimulator (implantable), non-rechargeable, with transvenous sensing and stimulation leads (Investigational)
E0485	Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, prefabricated fabricated, includes fitting and adjustment
E0486	Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, custom fabricated, includes fitting and adjustment
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 (Investigational)
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 (Investigational)
S2080	Laser-assisted uvulopalatoplasty (LAUP) (Investigational)

ICD-10 Diagnosis Codes That Support Medical Necessity:

G47.30 – G47.39	Sleep apnea
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REIMBURSEMENT INFORMATION:

Reimbursement for oral appliances is limited to one (1) in a 12-month period. Services in excess of the limitation are subject to medical review of documentation supporting medical necessity (The following information may be required documentation to support medical necessity: physician history and physical, initial assessment, procedure note, visit note).

LOINC Codes:

DOCUMENTATION TABLE	LOINC CODES	LOINC TIME FRAME MODIFIER CODE	LOINC TIME FRAME MODIFIER CODES NARRATIVE
Physician history and physical	28626-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Physician Initial Assessment	18736-9	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Physician procedure note	11505-5	18805-2	Include all data of the selected type that represents observations made six months or

			fewer before starting date of service for the claim.
Attending physician visit note	18733-6	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products:

The following National Coverage Determination (NCD) was reviewed on the last guideline reviewed date: Phrenic Nerve Stimulator (160.19) located at cms.gov.

The following Local Coverage Determinations (LCDs) were reviewed on the last guideline reviewed date:

- Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea (L38398) located at fcso.com.
- Oral Appliances for Obstructive Sleep Apnea (L33611) located at cgsmedicare.com.

DEFINITIONS:

Clinically significant obstructive sleep apnea is defined as those members who have:

1. Apnea/Hypopnea Index (AHI), Respiratory Event Index (REI), or Respiratory Disturbance Index (RDI) of 15 or more events per hour, **OR**
2. AHI, REI, or RDI of 5 or more events per hour in a member with one or more signs or symptoms associated with OSA (eg, excessive daytime sleepiness, hypertension, cardiovascular heart disease, or stroke).

Clinically significant OSA is defined as those pediatric members who have:

1. AHI or RDI of at least 5 per hour, **OR**
2. AHI or RDI of at least 1.5 per hour in a member with excessive daytime sleepiness, behavioral problems, or hyperactivity.

RELATED GUIDELINES:

[Positive Airway Pressure Devices, 09-E0000-21](#)

[Sleep Testing, 01-95828-01](#)

OTHER:

None applicable.

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16. Blue Cross Blue Shield Association Evidence Positioning System®. 8.01.67 Medical Management of Obstructive Sleep Apnea Syndrome, 07/22.
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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 08/25/22.

GUIDELINE UPDATE INFORMATION:

05/17/01	MCG reformatted; revised to include information for somnoplasty.
01/01/02	Annual HCPCS coding update: added S2080.
06/15/02	Reviewed; clarification statement added for LAUP vs. laser-assisted UPPP; references updated.
02/15/03	Revised; added information regarding oral orthotic devices for treating OSA.
06/15/03	Reviewed; no changes.
06/15/04	Scheduled review, no revisions.
01/15/05	Annual HCPCS coding update (0088T added).
03/15/05	Scheduled review; no change in coverage statement; add procedure code 0088T.
10/15/05	Revision consisting of adding information regarding palatal stiffening procedures and hyoid suspension.
01/01/06	Annual HCPCS coding update: revise descriptor for 0088T. Add E0485 and E0486.
03/15/06	Scheduled review; no change in coverage statement; remove Program Exception for Medicare Advantage.
04/01/06	2 nd Quarter HCPCS coding update: removed S8260.
03/15/07	Scheduled review; added information for atrial pacing; updated references, revised Description section.
06/15/07	Reformatted guideline; updated references.
04/15/08	Scheduled review; no change in position statement; updated ICD-9 coding section and references.
01/01/09	Annual HCPCS coding update: removed 0088T; added 41512 and 41530.
04/15/09	Scheduled review; added position statement regarding somnoplasty; reformatting changes; references updated.
01/01/10	Annual HCPCS coding update: simple revision to descriptor for 41530.
03/15/10	Revision of Position Statement to include additional coverage criteria for UPPP.
10/15/10	Revision; related ICD-10 codes added.
07/15/11	Revision; formatting changes.
03/15/12	Review; position statement revised to include information regarding coblation; references updated.
02/15/13	Review of position statement for Somnoplasty and Coblation; position statement revised for clarification; references updated.

03/15/14	Position statement for coblation reviewed with literature search; no change in position statement; Program Exceptions section updated; references updated.
02/15/15	Revision: added CPT codes 30801 and 30802.
07/30/15	Revision; position statement section and references updated.
11/01/15	Revision: ICD-9 Codes deleted.
02/15/16	Revision; position statement section updated.
11/15/17	Review; description, position statements, coding, program exception, and references updated.
02/15/19	Revision; phrenic nerve stimulation for CSA position statement added; title, description, coding, and references updated.
03/15/19	Review; Implantable hypoglossal nerve stimulators experimental or investigational position maintained.
10/15/19	Review; hypoglossal nerve stimulation position statement maintained; definitions section and references updated.
08/15/20	Review; hypoglossal nerve stimulation position statement updated; all other position statements maintained; coding and references updated.
09/15/21	Review; Position statements maintained and references updated.
01/01/22	Annual CPT/HCPCS coding update. Codes 64582-64584 added; 0466T-0468T deleted.
09/15/22	Review: Use of daytime electrical stimulation of the tongue investigational statement added; coding and references updated.