


<b>MEDICAL POLICY</b>	<b>Sleep Disorder Treatment: Surgical (Medicare Only)</b>
<b>Effective Date: 12/1/2022</b>   12/1/2022	Medical Policy Number: 244
	Medical Policy Committee Approved Date: 9/19; 2/2020; 10/2020; 9/2021; 11/2021; 9/2022
Medical Officer	Date

**See Policy CPT/HCPCS CODE section below for any prior authorization requirements**

**SCOPE:**

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayn Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

**APPLIES TO:**

Medicare Only

<b>MEDICARE POLICY CRITERIA</b>	
<p>The following Centers for Medicare &amp; Medicaid Services (CMS) guidelines should be utilized for medical necessity coverage determinations. Click the link provided in the table below to access applicable medical necessity criteria. All listed guidelines apply.</p>	
Service	Medicare Guidelines
<i>Hypoglossal Nerve Stimulation – Initial Placement</i>	Local Coverage Determination (LCD): Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea ( <a href="#">L38312</a> ).
<i>Hypoglossal Nerve Stimulation – Removal, revision, and replacement</i>	<p>For <b>removal only</b> of previously placed devices:</p> <ul style="list-style-type: none"> <li>Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, <a href="#">§180 - Services Related to and Required as a Result of Services Which Are Not Covered Under Medicare</a></li> </ul> <p><b>Note:</b> Even if initial placement of a device did not meet medical necessity coverage criteria and the complication or subsequent medical condition is the result of a prior non-covered service, coverage may be allowed in certain circumstances for the removal of the device. Note, individuals who reasonably expect or plan to become pregnant or who will require the use of MRIs may not meet the medical necessity criteria found in the above LCD for</p>

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	<p>initial implantation of these devices.</p> <p>For <b>revision/replacement</b> requests of previously placed devices:</p> <ul style="list-style-type: none"> <li>• Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, <a href="#">§120 - Prosthetic Devices, D. Supplies, Repairs, Adjustments, and Replacement</a></li> </ul> <p><b>Note:</b> A procedure or device that did <b>not</b> meet medical necessity criteria when initially placed would have been non-covered, thus any revision or replacement to allow for the <i>continued</i> use of the non-covered device would not meet Medicare’s general requirements for coverage. Replacement of previously placed medically necessary devices or their components that are nonfunctioning and irreparable (e.g., device malfunction, etc.) may be considered medically necessary in accordance with the above Medicare reference if the stimulator continues to be medically indicated and is no longer under manufacturer warranty or if the component is not included under the warranty. (See “Policy Guidelines” below)</p>
<p><i>All Other Surgical Treatments for Sleep Disorders, Including the Following Procedures:</i></p> <ul style="list-style-type: none"> <li>• <i>Uvulopalatopharyngoplasty (UPPP)</i></li> <li>• <i>Hyoid myotomy and suspension with or without osteotomy and/or genioglossus advancement</i></li> <li>• <i>Mandibular-maxillary advancement (MMA)</i></li> <li>• <i>Laser-assisted uvulopalatoplasty (LAUP)</i></li> <li>• <i>Radiofrequency volume tissue reduction of the soft palate, uvula, tongue base or turbinates (e.g., Somnoplasty™)</i></li> <li>• <i>Palatal stiffening procedures/palatal implants (e.g., the Pillar Procedure™)</i></li> </ul>	<p>Company medical policy for Sleep Disorder Treatment: Surgical (All Lines of Business Except Medicare)</p> <ol style="list-style-type: none"> <li>I. These services may be considered <b>medically necessary</b> for Medicare when the Company medical policy criteria are met.</li> <li>II. These services are considered <b>not medically necessary</b> for Medicare Plan members either when the Company medical policy criteria are <b>not met</b> <u>or</u> when a service is deemed “investigational” by the Company policy. <u>Services deemed “investigational” are considered not medically necessary for Medicare Plan members. See Policy Guidelines below.</u></li> </ol>

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<ul style="list-style-type: none"> <li>• <i>Tongue suspension systems (e.g. AIRvance® or Encore™)</i></li> <li>• <i>Expansion sphincter pharyngoplasty</i></li> </ul>	
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**POLICY GUIDELINES**

While implantation of nerve stimulators involves the implantation of a “device,” they are not considered durable medical equipment (DME). Implanted nerve stimulators are considered to be “prosthetic devices” under the Medicare Program.<sup>1</sup> Therefore, similar guidelines regarding the *replacement* of prostheses would also apply to implanted nerve stimulation devices. This includes consideration of whether the device itself continues to be medically reasonable and necessary for the individual, as well as confirming the device is no longer under manufacturer warranty.<sup>1</sup>

Medicare and Medical Necessity

The Company policy for *PHA Medicare Medical Policy Development and Application* (MP50) provides details regarding Medicare’s definition of medical necessity and the hierarchy of Medicare references and resources during the development of medical policies, as well as the Plan’s use of evidence-based processes for policy development. In the absence of Medicare coverage policies (e.g., manual, national coverage determination [NCD], local coverage determination [LCD], article [LCA], etc.) which addresses the medical necessity of a given medical service, Medicare regulatory guidelines do allow Medicare Advantage Organizations (MAOs) to make their own coverage determinations, as long as the MAO applies an objective, evidence-based process, based on authoritative evidence. (*Medicare Managed Care Manual, Ch. 4, §90.5*)

Following an evidence-based assessment of current peer-reviewed medical literature, the Company may consider certain medical services or technologies to be “investigational.” The term “investigational” is not limited to devices or technologies which have not received the appropriate governmental regulatory approval (e.g., U.S. Food and Drug Administration [FDA]), but rather may also mean the procedure, device, or technology does not meet all of the Company’s technology assessment criteria, as detailed within the Company policy for *Definition: Experimental/Investigational* (MP5).

For Medicare, only medically reasonable and necessary services or items which treat illness or injury are eligible for Medicare coverage, as outlined in *Title XVIII of the Social Security Act, §1862(a)(1)(A)*. Thus, services which lack scientific evidence regarding safety and efficacy because they are investigational are “not medically reasonable or necessary” for Medicare Plan members. (*Medicare Claims Processing Manual, Ch. 23, §30 A*)

## BILLING GUIDELINES

### General

Please see the following Local Coverage Articles (LCAs) for applicable billing guidelines related to hypoglossal nerve stimulation:

- Local Coverage Article: Billing and Coding: Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea ([A57949](#))

### Surgical Treatments of Sleep Apnea

The following codes should not be used for surgical treatments of sleep apnea as they are used for surgical procedures:

- 21121
- 21122
- 21248
- 21249
- 30930

CPT codes 30140, 30801, 30802, 41530 and 42160 are **not medically necessary** when billed with obstructive sleep apnea (OSA) diagnosis codes (G47.33, G47.39).

CPT codes 42225 and 42226 may be considered **medically necessary** when billed with the following diagnosis codes:

Q35.1	Q37.0	Q37.5
Q35.3	Q37.1	Q37.8
Q35.5	Q37.2	Q37.9
Q35.7	Q37.3	
Q35.9	Q37.4	

CPT codes 42225 and 42226 are considered **not medically necessary** when billed with expansion sphincter pharyngoplasty or for any other indication not represented by the above diagnosis codes.

### Laser-Assisted Uvulopalatoplasty (LAUP)

Like all S-codes, the *National Physician Fee Schedule Relative Value File (NPF SRVF)*, which is published by Medicare<sup>2</sup>, indicates HCPCS code S2080 has been assigned a Status Indicator of "I." This is defined as "Not valid for Medicare purposes." In addition, HCPCS code S2080 is not recognized as a valid code for claim submission as indicated in the relevant Company Coding Policy (*HCPCS S-Codes and H-Codes*, 22.0). Providers need to use alternate available CPT or HCPCS codes to report for the service. If no specific CPT or HCPCS code is available, then an unlisted code may be used. Note that unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. Thus, if an unlisted code is

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billed related to a non-covered service addressed in this policy, it will be denied as not covered. Note that CPT code 42145 (*Palatopharyngoplasty [e.g., uvulopalatopharyngoplasty, uvulopharyngoplasty]*) is not appropriate for this procedure.

Somnoplasty™

Somnoplasty™ is a trade name for palate reduction with the Somnoplasty™ System of Somnus Medical Systems. Somnoplasty™ must not be billed as 42145. This code is not appropriate for this procedure. If Somnoplasty™ is reported, unlisted CPT code 42299 (*Unlisted procedure, palate, uvula*) should be used.

Pillar Procedure™

The Pillar Procedure™ is a trade name for palatal implants. This procedure would be appropriately reported by the physician using CPT code 42299 (*Unlisted procedure, palate, uvula*). Hospital outpatient department services for this procedure would be reported using HCPCS code C9727.

**CPT/HCPCS CODES**

Medicare Only	
Prior Authorization Required	
<del>0466F</del>	TERMED 12/31/2021 <del>Insertion of chest wall respiratory sensor electrode or electrode array, including connection to pulse generator (List separately in addition to code for primary procedure)</del>
<del>0467F</del>	TERMED 12/31/2021 <del>Revision or replacement of chest wall respiratory sensor electrode or electrode array, including connection to existing pulse generator</del>
<del>0468F</del>	TERMED 12/31/2021 <del>Removal of chest wall respiratory sensor electrode or electrode array</del>
21110	Application of interdental fixation device for conditions other than fracture or dislocation, includes removal
21141	Reconstruction midface, lefort i; single piece, segment movement in any direction (eg, for long face syndrome), without bone graft
21142	Reconstruction midface, LeFort I; 2 pieces, segment movement in any direction, without bone graft
21143	Reconstruction midface, LeFort I; 3 or more pieces, segment movement in any direction, without bone graft
21145	Reconstruction midface, lefort i; single piece, segment movement in any direction, requiring bone grafts (includes obtaining autografts)
21146	Reconstruction midface, LeFort I; 2 pieces, segment movement in any direction, requiring bone grafts (includes obtaining autografts) (eg, ungrafted unilateral alveolar cleft)
21147	Reconstruction midface, LeFort I; 3 or more pieces, segment movement in any direction, requiring bone grafts (includes obtaining autografts) (eg, ungrafted bilateral alveolar cleft or multiple osteotomies)

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21196	Reconstruction of mandibular rami and/or body, sagittal split; with internal rigid fixation
21198	Osteotomy, mandible, segmental
21199	Osteotomy, mandible, segmental; with genioglossus advancement
21206	Osteotomy, maxilla, segmental (eg, Wassmund or Schuchard)
21685	Hyoid myotomy and suspension
42120	Resection of palate or extensive resection of lesion
42145	Palatopharyngoplasty (eg, uvulopalatopharyngoplasty, uvulopharyngoplasty)
42235	Repair of anterior palate, including vomer flap
42950	Pharyngoplasty (plastic or reconstructive operation on pharynx)
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

#### No Prior Authorization Required

Note: Diagnosis code restrictions may apply to the following codes. See "Billing Guidelines" above for details.

21193	Reconstruction of mandibular rami, horizontal, vertical, C, or L osteotomy; without bone graft
21194	Reconstruction of mandibular rami, horizontal, vertical, C, or L osteotomy; with bone graft (includes obtaining graft)
42140	Uvulectomy, excision of uvula
30140	Submucous resection inferior turbinate, partial or complete, any method
30801	Ablation, soft tissue of inferior turbinates, unilateral or bilateral, any method (eg, electrocautery, radiofrequency ablation, or tissue volume reduction); superficial
30802	Ablation, soft tissue of inferior turbinates, unilateral or bilateral, any method (eg, electrocautery, radiofrequency ablation, or tissue volume reduction); intramural (ie, submucosal)
41530	Submucosal ablation of the tongue base, radiofrequency, 1 or more sites, per session
42160	Destruction of lesion, palate or uvula (thermal, cryo or chemical)
42225	Palatoplasty for cleft palate; attachment pharyngeal flap
42226	Lengthening of palate, and pharyngeal flap

#### Not Covered

41512	Tongue base suspension, permanent suture technique
C9727	Insertion of implants into the soft palate; minimum of three implants
S2080	Laser-assisted uvulopalatoplasty (LAUP)

#### Unlisted Procedure

All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy then **prior-authorization is required.**

41599	Unlisted procedure, tongue, floor of mouth
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42299	Unlisted procedure, palate, uvula
64999	Unlisted procedure, nervous system

**INSTRUCTIONS FOR USE**

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days’ notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

**REGULATORY STATUS**

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

**REFERENCES**

1. Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, §40.4 - Items Covered Under Warranty; Available at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c16.pdf> [Last Cited 10/21/2021]
2. Medicare Physician Fee Schedule (PFS) Relative Value Files; Available at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files>