Sleep Disorder Treatment: Surgical

MEDICARE MEDICAL POLICY NUMBER: 244

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INSTRUCTIONS FOR USE: Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. 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.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

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

☒ Medicare Only

MEDICARE COVERAGE CRITERIA

IMPORTANT NOTE: More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

Service	Medicare Guidelines
Hypoglossal Nerve Stimulation – Initial Placement	Local Coverage Determination (LCD): Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea (L38312).
Hypoglossal Nerve Stimulation – Removal, revision, and replacement	For ***removal only*** of previously placed devices: • Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, §180 - Services Related to and Required as a Result of Services Which Are Not Covered Under Medicare **Note**: 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 initial implantation of these devices. For ***revision/replacement*** requests of previously placed devices: • Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, §120 - Prosthetic Devices, D. Supplies, Repairs, Adjustments, and Replacement **Note**: A procedure or device that did **not** meet medical necessity criteria when initially placed would have been non-covered, thus any revision or replacement to allow for the *continued* 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)*
Submucous resection inferior turbinate (CPT 30140) and Destruction of lesion, palate or uvula (CPT 42160) for obstructive sleep apnea (OSA)	These services may be considered **medically necessary** for Medicare Plan members.
All Other Surgical Treatments for Sleep Disorders, Including the Following Procedures: • *Uvulopalatopharyngoplasty (UPPP)* • *Hyoid myotomy and suspension with or without osteotomy and/or genioglossus advancement* • *Mandibular-maxillary advancement (MMA)* • *Laser-assisted uvulopalatoplasty (LAUP)* • *Somnoplasty™* • *Palatal stiffening procedures/palatal implants (e.g., the Pillar Procedure™)* • *Radiofrequency submucosal ablation of the tongue base (CPT 41530)* • *Tongue suspension systems (e.g. AIRvance® or Encore™)* • *Expansion sphincter pharyngoplasty*	Company medical policy for Sleep Disorder Treatment: Surgical I. These services may be considered **medically necessary** for Medicare when the Company medical policy criteria are met. II. These services are considered **not medically necessary** for Medicare Plan members either when the Company medical policy criteria are **not** met ***or*** when a service is deemed "investigational" by the Company policy. *Services deemed "investigational" are considered not medically necessary for Medicare Plan members.* See Policy Guidelines below.

IMPORTANT NOTICE: While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member's benefit plan. Such excluded services or items by Medicare and member EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A).* If there is uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form **cannot** be used for Medicare Advantage members. *(Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021)*

POLICY CROSS REFERENCES

None

The full Company portfolio of Medicare Medical Policies is available online and can be accessed here.

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.[1] Therefore, similar guidelines regarding the *replacement* of protheses 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.[1]

MEDICARE AND MEDICAL NECESSITY

Noridian Healthcare Solutions (Noridian) Jurisdiction F (J-F) is the designated Medicare Administrative Contractor (MAC) with oversight over the states of Oregon and Washington. With respect to CPT codes 30140 and 42160, while there is no LCD or LCA for the Company service area for these procedures, the single Medicare Contractor who does have a relevant LCD provides coverage criteria for these services when performed for OSA. Therefore, these procedures may be considered medically necessary by the Company for Medicare Plan members.

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)*

REGULATORY STATUS

U.S. FOOD & DRUG ADMINISTRATION (FDA)

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, including but not limited to, the availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

BILLING GUIDELINES AND CODING

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 30801, 30802, and 41530 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 (NPFSRVF)*, which is published by Medicare[2], 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 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.

CODES*		
CPT	~~0466T~~	**TERMED 12/31/2021** ~~Insertion of chest wall respiratory sensor electrode or electrode array, including connection to pulse generator (List separately in addition to code for primary procedure)~~
	~~0467T~~	**TERMED 12/31/2021** ~~Revision or replacement of chest wall respiratory sensor electrode or electrode array, including connection to existing pulse generator~~
	~~0468T~~	**TERMED 12/31/2021** ~~Removal of chest wall respiratory sensor electrode or electrode array~~
	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)
	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)
	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
	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)
	41512	Tongue base suspension, permanent suture technique
	41530	Submucosal ablation of the tongue base, radiofrequency, 1 or more sites, per session
	41599	Unlisted procedure, tongue, floor of mouth
	42120	Resection of palate or extensive resection of lesion
	42140	Uvulectomy, excision of uvula
	42145	Palatopharyngoplasty (eg, uvulopalatopharyngoplasty, uvulopharyngoplasty)
	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
	42235	Repair of anterior palate, including vomer flap
	42950	Pharyngoplasty (plastic or reconstructive operation on pharynx)
	42299	Unlisted procedure, palate, uvula
	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
	64999	Unlisted procedure, nervous system
HCPCS	C9727	Insertion of implants into the soft palate; minimum of three implants
	S2080	Laser-assisted uvulopalatoplasty (LAUP)

***Coding Notes:**

- The code list above is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit. According to Medicare, "presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare." The issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does **not** make a procedure medically reasonable or necessary or a covered benefit by Medicare. *(Medicare Claims Processing Manual, Chapter 23 - Fee Schedule*

Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician's Fee Schedule, A. Physician's Services)

- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company [Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website] for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

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

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
12/2022	Annual review (converted to new format 2/2023)