Medicare Medical Policy

Sleep Disorder Surgery

MEDICARE MEDICAL POLICY NUMBER: 244

Effective Date: 2/1/2025

Last Review Date: 1/2025

Next Annual Review: 9/2025

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

PRODUCT AND BENEFIT APPLICATION

☒ 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/removal with 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.
Medicare Coverage Criteria: "MA organizations may create publicly accessible internal coverage criteria… when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs." *(§ 422.101(b)(6) – see Policy Guidelines below*) • **Medicare Coverage Manuals:** Medicare does not have criteria for the sleep disorder surgeries listed below in a coverage manual. • **National Coverage Determination (NCD):** Medicare does not have an NCD for the sleep disorder surgeries listed below. • **Noridian J-F Local Coverage Determination (LCD)/Local Coverage Article (LCA):** As of the most recent policy review, only one Medicare Administrative Contractor (MAC) has an LCD for sleep disorder surgery (Wisconsin Physician Services, or WPS); however, WPS is **not** the MAC with jurisdiction over the Company service area. • Therefore, in the absence of established Medicare coverage criteria in a manual, NCD, LCD, or other regulatory guidance for the health plan's service area, Company criteria below are applied for medical necessity decision-making. In this case, Medicare coverage criteria are considered "not fully established" as defined under CFR § 422.101(6)(i)(C) as there is no Medicare coverage criteria available. • ***NOTE:*** *The summary of evidence, as well as the list of citations/references used in the development of the Company's internal coverage criteria, are publicly available and can be found using the Company medical policy link below [CFR § 422.101(6)(ii)(A) and (B)].*	
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)*	Company medical policy for Sleep Disorder Surgery 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 "not medically necessary" by the Company policy. See *Policy Guidelines below.*

• *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*	

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

IMPLANTABLE NERVE STIMULATORS

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

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)*.

Fully established Medicare coverage criteria is available for hypoglossal nerve stimulation, for the placement, as well as for removal and revision.

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 (Wisconsin Physician Services, WPS) provides coverage criteria for these services when performed for OSA. Therefore, these procedures may also be considered medically necessary for Medicare Plan members.

For all other sleep disorder surgical procedures, MA organizations (MAOs) make medical necessity determinations based on coverage and benefit criteria, current standards of care, the member's unique personal medical history (e.g., diagnoses, conditions, functional status, co-morbidities, etc.), physician recommendations, and clinical notes, as well as involvement of a plan medical director, where appropriate. *(§ 422.101(c)(1))*

In addition:

> "MA organizations may create publicly accessible internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs. Current, widely-used treatment guidelines are those developed by organizations representing clinical medical specialties, and refers to guidelines for the treatment of specific diseases or conditions. Acceptable clinical literature includes large, randomized controlled trials or prospective cohort studies with clear results, published in a peer-reviewed journal, and specifically designed to answer the relevant clinical question, or large systematic reviews or meta-analyses summarizing the literature of the specific clinical question." *(§ 422.101(b)(6) and Medicare Managed Care Manual, Ch. 4, §90.5)*

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.

Since there are not fully established coverage criteria for sleep disorder surgery available in applicable Medicare statutes, regulations, NCDs or LCDs, then Company medical policy criteria will be applied. See the Medicare Coverage Criteria table above for more information regarding the use of internal coverage criteria when Medicare coverage criteria are not fully established.

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, all S-codes, including HCPCS code S2080, are not recognized as valid codes 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. It should also be noted that CPT code 42145 *(Palatopharyngoplasty [e.g., uvulopalatopharyngoplasty, uvulopharyngoplasty])* is not appropriate as a replacement code 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.

HYPOGLOSSAL NERVE STIMULATION (HNS)

In 2024, the FDA approved an updated model of the Inspire® system (Inspire V). While this next-generation model is similar to its predecessor (Inspire IV), it no longer includes the respiratory sensor lead. As a result of this difference between the two models, the manufacturer may advise providers to use CPT code 64582 when Inspire **IV** is used, and CPT 64568 when Inspire **V** is used.

However, the Plan has determined providers should use CPT 64582 regardless of model as follows:

- 64582 – Inspire IV
- 64582**-52** – Inspire V

**Other modifier(s) should also be used as appropriate.*

Rationale

Prior to 2022, CPT 64568 was used to report some elements of this procedure. However, since 2022 and the development of CPT 64582, a CPT code specific to the hypoglossal nerve stimulator implantation procedure now exists. Because it is more specific than CPT 64568, it is felt to be the more appropriate code, regardless of the device model.

Modifier -52 is used to identify a "reduced service," and it is defined by the American Medical Association (AMA) as follows:

> "Under certain circumstances a service of procedure is partially reduced or eliminated at the discretion of the physician or other qualified healthcare professional. Under these circumstances the service provided can be identified by its usual procedure number and the

addition of modifier 52, signifying that the service is reduced. **This provides a means of reporting reduced services without disturbing the identification of the basic service**..."

In the case of the two Inspire models, while there is no longer a respiratory sensor lead, the "basic service" remains unchanged as it is still a hypoglossal nerve stimulator implantation service. The same nerve is targeted for stimulation regardless of which model device (Inspire IV or Inspire V) is used.

By using modifier 52 with CPT 64582, the provider maintains the basic service, while indicating the full description of the CPT code isn't met. It is felt by the Plan that using the CPT code 64568 changes the "basic service" rendered. While the hypoglossal nerve is technically a "cranial nerve," the existing CPT code specific to the hypoglossal nerve more accurately represents the service.

Finally, the use of modifier -52 is consistent with instructions from the local MAC for HNS revision, replacement, or removal services when the entire description of the HNS code is not performed (see Noridian LCA A57949). The Plan is applying the same logic to the implantation procedure.

CODES*		
CPT	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) *(CMS-assigned Status "I" code – See above billing guidelines)*

***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)
12/2023	Annual review; no criteria changes but language revision due to policy changes from "Investigational" to "not medically necessary", update title
10/2024	Annual review; no criteria changes
2/2025	Interim update; update coding/billing guidelines for Inspire IV and Inspire V models