

Medical Policy

Policy: 201914

SUBJECT: Hypoglossal Nerve Stimulation for Treatment of Obstructive Sleep Apnea

Effective Date: 04/01/2024

Annual Review Date: 02/21/2024

Last Revised Date: 04/15/2024

Prior approval is required for some or all procedure codes listed in this Corporate Medical Policy.

Definition: Obstructive sleep apnea (OSA) is a condition characterized by the repetitive collapse of the upper airway during sleep. Symptoms of untreated OSA include excessive daytime sleepiness, loud snoring, headaches, nocturnal choking and fatigue. Positive airway pressure (PAP) treatment is the most effective and common treatment of OSA. However, there are individuals who are unable or unwilling to use a PAP device. Hypoglossal nerve stimulation (e.g. Inspire Upper Airway Stimulation System) is a treatment option for patients with moderate to severe OSA in whom PAP treatment has failed to provide relief. The Inspire System consists of three fully implanted components that together sense breathing patterns and deliver mild electrical stimulation to maintain airway patency during sleep. This results in the improvement of upper airway obstruction without arousal or discomfort.

Medical Necessity: The Company considers hypoglossal nerve stimulation for the treatment of obstructive sleep apnea **medically necessary** and eligible for reimbursement providing that *all* of the following medical criteria are met:

- Age is \geq 18 years old; and
- Body Mass Index (BMI) is \leq 40 kg/m²; and
- Apnea-hypopnea index (AHI) is between 15 and 100 events per hour; and
- Minimum of one month documentation confirming failure or intolerance of positive airway pressure (PAP) treatments[†]; and
- Absence of complete concentric collapse at the soft palate level (please see **NOTE** below for information regarding drug-induced sleep endoscopy^{††}); and
- The member has predominantly obstructive events (defined as central and mixed apneas less than 25% of the total AHI); and
- Individual has no contraindications as outlined below.

Contraindications:

- Other implanted device that could interact with the Inspire system
- Pregnancy or planned pregnancy
- Required or planned magnetic resonance imaging (MRI)

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- Patient unable or does not have the necessary assistance to operate the sleep remote
- Any condition or procedure that has compromised neurological control of the upper airway
- No anatomical finding that would compromise the performance of upper airway stimulation

†PAP failure is defined as an AHI of greater than 15 despite PAP usage. PAP intolerance is defined as inability to use PAP at least 5 nights per week for greater than 4 hours of use per night.

††**NOTE:** Drug-induced sleep endoscopy (DISE) (**CPT Code 42975**) is considered **medically necessary** and eligible for reimbursement when requested to evaluate for complete concentric collapse at the soft palate level, providing that **all** other medical necessity criteria above are met **and** that the DISE is intended to assess for appropriateness of hypoglossal nerve stimulation for treatment of obstructive sleep apnea. DISE is considered investigational and not eligible for reimbursement for *all* other indications.

NOTE: Replacement of implanted hypoglossal nerve stimulator is appropriate if the device is no longer functioning and is not under warranty

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member, and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results, and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply, and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

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Sources of Information:

- American Academy of Otolaryngology – Head and Neck Surgery. Position Statement: Treatment of Obstructive Sleep Apnea. Adopted May 3, 2010. Revised April 22, 2021. Retrieved from: <https://www.entnet.org/resource/position-statement-hypoglossal-nerve-stimulation-for-treatment-of-obstructive-sleep-apnea-osa/>
- Epstein LJ, Kristo D, Strollo PJ Jr, et al.; Adult Obstructive Sleep Apnea Task Force of the American Academy of Sleep Medicine. Clinical guideline for the evaluation, management and long-term care of obstructive sleep apnea in adults. *J Clin Sleep Med.* 2009;5(3):263-276.
- Gillespie, MB, Soose RJ, Woodson BT, et al. (2017). Upper airway stimulation for obstructive sleep apnea: patient-reported outcomes after 48 months of follow-up. *Otolaryngol Head Neck Surg.* 156(4):765-771.
- Hayes, Inc. (2018, October 30). *Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea.* (Annual Review 2022, December 27). Lansdale, PA: Author.
- Inspire System Implant Manual Model 3028, 4063, 4323. Retrieved from: https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130008d.pdf
- Qaseem A, Holty, JE, Owens DK, et al.; Clinical Guidelines Committee of the American College of Physicians. Management of obstructive sleep apnea in adults: a clinical practice guideline from the American College of Physicians. *Ann Intern Med.* 2013;159(7):471-483
- Schwartz AR, Jacobowitz O, Eisele DW, Mickelson SA, Miller MB, Oliven A, Certal V, Hopp ML, Winslow DH, Huntley TC, Nachlas NE, Pham LV, Gillespie MB, Weeks BH, Lovett EG, Shen J, Malhotra A, Maurer JT. Targeted Hypoglossal Nerve Stimulation for Patients With Obstructive Sleep Apnea: A Randomized Clinical Trial. *JAMA Otolaryngol Head Neck Surg.* 2023 Jun 1;149(6):512-520.
- Soose RJ, Woodson BT, Gillespie MB et al. (2016). Upper airway stimulation for obstructive sleep apnea: self-reported outcomes at 24 months. *J Clin Sleep Med.* 12(1): 43-48.
- Steffen A, Abrams N, Suurna MV, Wollenberg B, Hasselbacher K. Upper-Airway Stimulation Before, After, or Without Uvulopalatopharyngoplasty: A Two-Year Perspective. *Laryngoscope.* 2019 Feb;129(2):514-518.
- Strohl, M, Strohl, K, Palomo, JM, Ponsky, D. (2016). Hypoglossal nerve stimulation rescue surgery after multiple multi-level procedures for obstructive sleep apnea. *Am J Otolaryngol.* 37(1): 51-53.
- U.S. Food and Drug Administration (FDA). Inspire Upper Airway Stimulation - P130008/S089. Silver Spring, MD: FDA; March 20,2023.
- Woodson, BT, Strohl, KP, Soose, RJ, et al. (2018). Upper airway stimulation for obstructive sleep apnea: 5-year outcomes. *Otolaryngol Head Neck Surg.* 159(1): 194-202.

Applicable Code(s):	
CPT:	42975, 64582, 64583, 64584
HCPCS:	L8680, L8681, L8688
ICD10 Procedure Codes:	

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