

Subject: Hypoglossal Nerve Stimulation for OSA **Revision Date:** 6/24

DESCRIPTION

Obstructive Sleep Apnea (OSA) is defined as the obstruction of the upper airway during sleep that occurs because of inadequate motor tone of the tongue and/or airway dilator muscles resulting in temporary cessation of breathing. The optimal approach for treatment is lifestyle changes (weight loss) and education, and then Positive Airway Pressure (PAP). After the failure of PAP or refusal to use PAP machine, the clinical guidelines indicate the order as behavioral/positional therapy, oral appliances, and then surgical therapy. Another viable option after failure of PAP is Hypoglossal nerve stimulation. The goal of Hypoglossal nerve stimulation (HGNS) is to restore the tone of upper airway dilator muscles, including the genioglossus, thus preventing obstruction of the airway. The HGNS system consists of an implantable device, similar to a pacemaker, which contains a neurostimulator, a lead in the patient's chest, and a lead that is attached to the hypoglossal nerve at the base of the tongue. The lead in the chest detects breathing by a pressure sensor and relays respiration rate information to the device, which stimulates the hypoglossal nerve in the tongue. When stimulated, the tongue moves forward, thus opening the airway. The device, which can be operated by a remote control, turns on after 20 minutes to minimize disrupting the patient's sleep onset; the device turns off via remote when the patient wakes up. The decision to perform Hypoglossal nerve stimulation to treat Obstructive Sleep Apnea should be made on a case-by-case basis.

POLICY

The OSU Health Plan considers Hypoglossal nerve stimulation procedures medically necessary for the treatment of Obstructive Sleep Apnea when the ALL of the following criteria are met:

- 1. Apnea-Hypopnea Index (AHI) between 15 and 65, documented by polysomnography within the past 24 months.
- 2. Failure of Lifestyle changes and Positive Airway Pressure (PAP) therapy, as indicated by ALL of the following:

- a) Weight not a concern, or weight loss tried and failed in obese patient.
- b) PAP trial (usage greater than 5 nights per week and greater than 4 hours per night for a minimum of 1 month) with well-supported follow-up and involvement by qualified sleep specialist has clearly failed due to 1 or more of the following:
 - Failure to improve symptoms as evidenced by AHI of greater than 15 despite PAP usage; or
 - 2. Claustrophobia; or
 - 3. Difficulty tolerating pressure; or
 - 4. Intolerance to device
- 3. BMI \leq 35 kg/m²
- 4. Drug-induced sleep endoscopy (DISE) shows incomplete concentric collapse at the level of soft palate.
- 5. No contraindications are present:
 - a) Central and mixed apneas greater than 25% of the total AHI
 - b) Any anatomical finding that would affect the performance of upper airway stimulation, such as the presence of complete concentric collapse of the soft palate.
 - c) Any condition or procedure that would affect neurological control of the upper airway.
 - d) Patients who are unable or do not have the necessary assistance to operate the sleep remote.
 - e) Patients who are pregnant or plan to become pregnant.
 - f) Patients who will require magnetic resonance imaging (MRI).
 - g) Patients with an implantable device that may have unintended interactions with the HGNS system such as Inspire system.
- 6. One of the following FDA approved devices will be utilized:
 - a) Inspire® Upper Airway Stimulation device (Inspire Medical)

EXCLUSIONS

The OSU Health Plan considers Hypoglossal nerve stimulation experimental and investigational for all other indications. Prospective studies should seek to identify specific clinical settings where patients would be most likely to benefit from this procedure.

PRIOR AUTHORIZATION

Prior authorization is required.

RELATED CPT/HCPC CODES

CPT codes covered if selection criteria are met:

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
C1767	Generator, neurostimulator (implantable), nonrechargeable
C1778	Lead, neurostimulator (implantable)
C1787	Patient programmer, neurostimulator
L8680	Implantable neurostimulator electrode, each
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
L8682	Implantable neurostimulator radiofrequency receiver

REFERENCES

Aetna. (2024). Obstructive Sleep Apnea in Adults.

https://www.aetna.com/cpb/medical/data/1_99/0004.html

American Academy of Otolaryngology-Head and Neck Surgery. (2021). Position statement: Hypoglossal nerve stimulation for treatment of obstructive sleep apnea (OSA).

 $\underline{https://www.entnet.org/resource/position-statement-hypoglossal-nerve-stimulation-for-treatment-of-obstructive-sleep-apnea-osa/}$

- American Medical Association. CPT Assistant, Nov 2016. Vol 26, Issue 11. Page 6—Hypoglossal Nerve Stimulator. Retrieved from https://www.inspiresleep.com/wp-content/uploads/2017/01/AMA-Coding-Document.pdf [Link no longer active]
- Baptista, P.M., Constantino, A., Moffa, A., Rinaldi, V. & Casale, M. (2020). Hypoglossal nerve stimulation in the treatment of obstructive sleep apnea: patient selection and new perspectives.

 Nature and Science of Sleep, 12, 151-159.
- Boroosan, A., Salapatas, A.M., & Friedman, M. (2022). Clinical predictors of OSA treatment success following implantation of a hypoglossal nerve stimulation device. *Otolaryngology Head and Neck Surgery*, 167(5), 891-895. https://doi.org/10.1177/01945998221087594
- Certal, V. F., Zaghi, S., Riaz, M., Vieira, A. S., Pinheiro, C. T., Kushida, C., Capasso, R. and Camacho, M. (2015), Hypoglossal nerve stimulation in the treatment of obstructive sleep apnea: A systematic review and meta-analysis. *The Laryngoscope, 125*: 1254–1264. doi:10.1002/lary.25032
- Chang, J.L., et al. (2023). International consensus statement on obstructive sleep apnea. *Allergy & Rhinology*, 13(7), 1061-1482. https://doi.org/10.1002/alr.23079
- Cigna Healthcare. (2023). Surgical Treatments for Obstructive Sleep Apnea.

 https://static.cigna.com/assets/chcp/pdf/coveragePolicies/medical/mm_0158_coveragepositionc
 riteria_obstructive_sleep_apnea_diag_trtment_svc.pdf
- Corr, F., Kilinc, F., Oros, J., Qasem, L.-E., Al-Hilou, A., Jussen, D., Czabanka, M., & Quick-Weller, J. (2023). Increased body mass index correlates with less favorable postoperative outcomes after hypoglossal nerve stimulation for obstructive sleep apnea: A retrospective cohort study. World Neurosurgery, 180, e210-e218. https://doi.org/10.1016/j.wneu.2023.09.027
- Costantino, A., et al. (2020). Hypoglossal nerve stimulation long-term clinical outcomes: a systematic review and meta-analysis. *Sleep and Breathing*, *24*, 399-411. Doi: 10.1007/s11325-019-01923- 2
- CMS. (2020). Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea, LCD L38398. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=38398&ver=6 Curado, T.F, Oliven, A., Sennes, L.U., Polotsky, V.Y., Eisele, D. and Schwartz, A.R. (2018).
- Neurostimulation treatment of OSA. Chest, 154(6), 1435-1447. https://doi.org/10.1016/j.chest.2018.08.1070
- Friedman, M., Jacobowitz, O., Hwang, M. S., Bergler, W., Fietze, I., Rombaux, P., Mwenge, G. B., Yalamanchali, S., Campana, J. and Maurer, J. T. (2016), Targeted hypoglossal nerve stimulation for the treatment of obstructive sleep apnea: Six-month results. *The Laryngoscope, 126*: 2618–2623. doi:10.1002/lary.25909

- Heiser, C., Steffen, A., Hofauer, B., Mehra, R., Strollo, P.J., Vanderveken, O.M., & Maurer, J.T. (2021). Effect of upper airway stimulation in patients with obstructive sleep apnea (EFFECT): A randomized controlled crossover trial. *Journal of Clinical Medicine, 10*(13), 2880. https://doi.org/10.3390/jcm10132880
- Heiser, C., Steffen, A., Strollo, P.J., Giaie-Miniet, C., Vanderveken, O.M., & Hofauer, B. (2022).

 Hypoglossal nerve stimulation versus positive airway pressure therapy for obstructive sleep apnea. *Sleep and Breathing*, 27, 693-701. https://doi.org/10.1007/s11325-022-02663-6
- Hofauer, B., Philip, P., Wirth, M. et al. Sleep Breath (2017) 21: 901. https://doi.org/10.1007/s11325-017-1519-0
- Hong, S., Chen, Y.-F., Jung, J., Kwon, Y.-D., & Liu, S. Y. C. (2017). Hypoglossal nerve stimulation for treatment of obstructive sleep apnea (OSA): a primer for oral and maxillofacial surgeons.
 Maxillofacial Plastic and Reconstructive Surgery, 39(1), 27. http://doi.org/10.1186/s40902-017-0126-0
- Kim, D.H., Kim, S.W., Han, J.S., Kim, G.-J., Park, J.H., Basurrah, M.A., Kim, S.H., & Hwang, S.H. (2023). Comparative effectiveness of hypoglossal nerve stimulation and alternative treatments for obstructive sleep apnea: A systematic review and meta-analysis. *Journal of Sleep Research*, 33(3), e14017. https://doi.org/10.1111/jsr.14017
- Kompelli, A.R., Ni, J.S., Nguyen, S.A., Lentsch, E.J., Neskey, D.M. and Meyer, T.A. (2019) The outcomes of hypoglossal nerve stimulation in the management of OSA: a systematic review and meta-analysis. *World Journal of Otorhinolaryngology-Head and Neck Surgery, 5*, 41-48. https://doi.org/10.1016/j.wjorl.2018.04.006
- Kryger, MH. Management of obstructive sleep apnea in adults. In: UpToDate, UpToDate, Waltham, MA.
- Lara, F.R., Carnino, J.M., Cohen, M.B., & Levi, J.R. (2023). Advances in the use of hypoglossal nerve stimulator in adolescents with down syndrome and persistent obstructive sleep apnea A systematic review. *Annals of Otology, Rhinology & Laryngology, 133*(3), 317-321. https://doi.org/10.1177/00034894231216287
- Liu, P., Kong, W., Fang, C., Zhu, K., Dai, X., & Meng, X. (2022). Hypoglossal nerve stimulation in adolescents with down syndrome and obstructive sleep apnea: A systematic review and meta-analysis. *Front Neurol*, 13, 1037926. https://doi.org/10.3389/fneur.2022.1037926
- Mashaqi, S., et al. (2021). The hypoglossal nerve stimulation as a novel therapy for treating obstructive sleep apnea a literature review. *International Journal of Environmental Research and Public Health,* 18, 1642. Doi: 10.3390/ijerph18041642
- Nord, R., Fitzpatrick, T., DeShazo, J.P., & Reiter, E.R. (2022). Comparison of readmission and complication rates between traditional sleep surgery and hypoglossal nerve stimulation.

- Laryngoscope Investigative Otolaryngology, 7(5), 1659-1666. https://doi.org/10.1002/lio2.883
- Ramaswamy, A. T., Li, C. and Suurna, M. V. (2017), A case of hypoglossal nerve stimulator-resistant obstructive sleep apnea cured with the addition of a chin strap. *The Laryngoscope*. doi:10.1002/lary.27010
- Serghani, M.-M., Heiser, C., Schwartz, A.R., & Amatoury, J. (2024). Exploring hypoglossal nerve stimulation therapy for obstructive sleep apnea: A comprehensive review of clinical and physiological upper airway outcomes. *Sleep Medicine Reviews, 76*, 101947. https://doi.org/10.1016/j.smrv.2024.101947
- Soose RJ, Woodson BT, Gillespie MB, Maurer JT, de Vries N, Steward DL, Strohl KP, Baskin JZ, Padhya TA, Badr MS, Lin H, Vanderveken OM, Mickelson S, Chasens E, Strollo Jr PJ, STAR Trial Investigators. Upper airway stimulation for obstructive sleep apnea: self-reported outcomes at 24 months. *J Clin Sleep Med* 2016;12(1):43–48.
- Steffen, A., Heiser, C., Galatke, W., Herkenrath, S.-D., Maurer, J.T., Günther, E., Stuck, B.A., Woehrle, H., Löhler, J., & Randerath, W. (2022). Hypoglossal nerve stimulation for obstructive sleep apnea: Updated position paper of the German Society of Oto-Rhino-Laryngology, Head and Neck Surgery. *European Archives of Oto-Rhino-Laryngology, 279*, 61-66. https://doi.org/10.1007/s00405-021-06902-6
- Steffen, A., Sommer, J. U., Hofauer, B., Maurer, J. T., Hasselbacher, K. and Heiser, C. (2018), Outcome after one year of upper airway stimulation for obstructive sleep apnea in a multicenter German post-market study. *The Laryngoscope*, 128: 509–515.
- Suurna, M.V., et al. (2021). Impact of body mass index and discomfort on upper airway stimulation:

 ADHERE registry 2020 update. *The Laryngoscope, 131*(11), 2616-2624.

 https://doi.org/10.1002/lary.29755
- Upper Airway Stimulation.
 - $\frac{http://www.fda.gov/MedicalDevices/Products and MedicalProcedures/DeviceApprovals and Cleara}{nces/Recently-ApprovedDevices/ucm398321.htm}$
- Woodson BT, Soose RJ, Gillespie MB, et al. Three-Year Outcomes of Cranial Nerve Stimulation for Obstructive Sleep Apnea: The STAR Trial. *Otolaryngol Head Neck Surg.* 2016;154(1):181-8. https://www.doi.org/10.1177/0194599815616618
- Xiao, R., Trask, D.K., & Kominsky, A.H. (2020). Preoperative predictors of response to hypoglossal nerve stimulation for obstructive sleep apnea. *Otolaryngology Head and Neck Surgery, 162*(3), 400-407. https://doi.org/10.1177/0194599820901499