

Evidence Discussion

(SL 2.8) **EviCore**
By EVERNORTH

Hypoglossal nerve stimulation (HGNS) was demonstrated as safe and effective by the Stimulation Therapy for Apnea Reduction Trial (STAR) and was initially approved by the Food and Drug Administration (FDA) for use in adults 22 years of age and older.^{1,2}

FDA expanded approval for patients ages 18-21 years old,³ pediatric patients with Down Syndrome ages 13-18 years,⁴ and for individuals with BMI from ≤ 32 to ≤ 40 upper apnea-hypopnea index (AHI) limit from ≤ 65 to ≤ 100 .⁶

Post-implantation polysomnogram (PSG) testing is recommended by the American Academy of Sleep Medicine (AASM) for titration of stimulation parameters to optimized outcomes for OSA.¹¹ The AASM also recommends periodic clinical assessment since OSA may recur postoperatively. In patients treated with PAP, repeat titration is indicated in the setting of significant weight gain with re-emergence of symptoms. This recommendation can be extrapolated to patients treated with HGNS.¹¹

References

1. Inspire FDA Approval 4/30/14: https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130008A.pdf
2. Strollo PJ Jr, Soose RJ, Maurer JT, de Vries N, Cornelius J, Froymovich O, Hanson RD, Padhya TA, Steward DL, Gillespie MB, Woodson BT, Van de Heyning PH, Goetting MG, Vanderveken OM, Feldman N, Knaack L, Strohl KP; STAR Trial Group. Upper-airway stimulation for obstructive sleep apnea. N Engl J Med. 2014 Jan 9;370(2):139-49. doi: 10.1056/NEJMoa1308659. PMID: 24401051.
3. Inspire FDA Approval 4/14/20: https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130008S039A.pdf
4. Inspire FDA Approval 3/20/23: https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130008S089A.pdf
5. Yu PK, et al. Evaluation of Upper Airway Stimulation for Adolescents With Down Syndrome and Obstructive Sleep Apnea. JAMA Otolaryngol Head Neck Surg. 2022;148(6):522-528.
6. Inspire FDA Approval 6/8/23: https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130008S090A.pdf
7. Bosschieter PFN, de Vries N, Mehra R, et al. Similar effect of hypoglossal nerve stimulation for obstructive sleep apnea in 5 disease severity categories. J Clin Sleep Med. 2022;18(6):1657–1665.
8. Baptista PM, Costantino A, Moffa A, Rinaldi V, Casale M. Hypoglossal Nerve Stimulation in the Treatment of Obstructive Sleep Apnea: Patient Selection and New Perspectives. Nat Sci Sleep. 2020 Feb 13;12:151-159. doi: 10.2147/NSS.S221542. PMID: 32104122; PMCID: PMC7026121.
9. Strohl MM, Yamauchi M, Peng Z, Strohl KP. Insights since FDA Approval of Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea. Curr Sleep Med Rep. 2017



Sep;3(3):133-141. doi: 10.1007/s40675-017-0088-x. Epub 2017 Aug 5. PMID: 29276665; PMCID: PMC5739331.

10. Thaler E, Schwab R, Maurer J, Soose R, Larsen C, Stevens S, Stevens D, Boon M, Huntley C, Doghramji K, Waters T, Kominsky A, Steffen A, Kezirian E, Hofauer B, Sommer U, Withrow K, Strohl K, Heiser C. Results of the ADHERE upper airway stimulation registry and predictors of therapy efficacy. *Laryngoscope*. 2020 May;130(5):1333-1338. doi: 10.1002/lary.28286. Epub 2019 Sep 14. PMID: 31520484; PMCID: PMC7217178.
11. Caples SM, Anderson WM, Calero K, Howell M, Hashmi SD. Use of polysomnography and home sleep apnea tests for the longitudinal management of obstructive sleep apnea in adults: an American Academy of Sleep Medicine clinical guidance statement. *J Clin Sleep Med*. 2021;17(6):1287–1293.
12. Woodson BT, et al. Three-year outcomes of cranial nerve stimulation for obstructive sleep apnea: the STAR trial. *Otolaryng-Head and Neck Surg*. 2016;154(1):181-188.

