

Medical Policy

Hypoglossal Nerve Stimulation for Obstructive Sleep Apnea

Policy Number: 028

Contents

Overview.....	1
Medicare Variation.....	1
Mass General Brigham ACO Variation.....	2
One Care and Senior Care Options Variation.....	2
Commercial and Qualified Health Plans Variation.....	2
Codes.....	3
Effective Dates.....	3
References.....	4

Overview

The purpose of this document is to describe the guidelines Mass General Brigham Health Plan utilizes to determine medical necessity for implantation of an FDA approved hypoglossal nerve stimulation (HGNS) device, for obstructive sleep apnea (OSA).

Medicare Variation

Prior authorization is required for code 64568. Prior authorization is not required for any of the other codes listed in this policy.

Mass General Brigham Health Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) for medical necessity determinations for its Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs), and documentation included in the Medicare manuals are the basis for medical necessity determinations. When there is no guidance from CMS for the requested service, Mass General Brigham Health Plan's medical policies are used for medical necessity determinations. **At the time of Mass General Brigham Health Plan's most recent policy review, Medicare has the following LCDs:**

- [Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea \(L38387\)](#)
- [Hypoglossal Nerve Stimulation for Obstructive Sleep Apnea \(L38276\)](#)
- [Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea \(L38307\)](#)
- [Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea \(L38310\)](#)
- [Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea \(L38398\)](#)
- [Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea \(L38312\)](#)
- [Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea \(L38385\)](#)
- [Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea \(L38528\)](#)

Mass General Brigham ACO Variation

Prior authorization is required for code 64568. Prior authorization is not required for any of the other codes listed in this policy.

Mass General Brigham Health Plan uses guidance from MassHealth for medical necessity determinations for its Mass General Brigham ACO members. When MassHealth does not have guidance available for specific DME, refer to the Medicare Advantage section for the relevant LCD. If no relevant LCD exists, refer to the Commercial and Qualified Health Plans section for medical necessity information. **As of Mass General Brigham Health Plan's most recent policy review, MassHealth did not have medical necessity guidelines for HGNS to treat OSA. Refer to the Medicare Variation for medical necessity information.**

One Care and Senior Care Options Variation

Prior authorization is required for code 64568. Prior authorization is not required for any of the other codes listed in this policy.

Mass General Brigham Health Plan uses guidance from CMS for medical necessity determinations for its One Care and SCO plan members. NCDs, LCDs, LCAs, and documentation included in the Medicare manuals are the basis for medical necessity determinations. When there is no guidance from CMS for the requested service, Mass General Brigham Health Plan uses medical necessity guidelines from MassHealth. When there is no guidance from CMS or from MassHealth, Mass General Brigham Health Plan's medical policies are used for medical necessity determinations. **Refer to the Medicare Variation for medical necessity information.**

Commercial and Qualified Health Plans Variation

Prior authorization is required for code 64568. Prior authorization is not required for any of the other codes listed in this policy.

Coverage Guidelines

Mass General Brigham Health Plan covers implantation of an FDA approved HGNS device for OSA in members when ALL the following are met:

- The member is 18 years of age or older with a diagnosis of OSA; and
- The member's apnea hypopnea index (AHI) is 15-100 with predominantly obstructive events (defined as central and mixed apneas less than 25% of the total AHI); and
- There is absence of complete concentric collapse at the soft palate level as seen on a drug-induced sleep endoscopy procedure; and
- The member's body mass index (BMI) is less than 32 kg/m²; and
- There is documentation by a Board-Certified Sleep Medicine Specialist of continuous positive airway pressure (CPAP) trial and failure or intolerance (defined as use less than four hours per night, five nights per week).

Additionally, Mass General Brigham Health Plan covers implantation of an FDA approved HGNS device for OSA in members when ALL the following are met:

- The member is 13-18 years of age with Down Syndrome; and
- The member has persistent severe OSA with AHI 10-50 with predominantly obstructive events (defined as central and mixed apneas less than 25% of the total AHI); and



- The member has previously had adenotonsillectomy or lacks clinical indication for adenotonsillectomy; and
- The member has BMI less than or equal to 95th percentile for age; and
- There is absence of complete concentric collapse at the soft palate level as seen on a drug-induced sleep endoscopy procedure; and
- There is either nighttime tracheostomy dependence or documentation by a Board-Certified Sleep Medicine Specialist of CPAP trial with failure or intolerance (defined as use less than 4 hours per night, five nights per week).

Exclusions

- When the member does not meet the coverage criteria;
- The device is not an FDA-approved hypoglossal nerve stimulation system.

Codes

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage or reimbursement.

Authorized Code	Code Description
64568	Open implantation of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator
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
C8007	Open implantation of hypoglossal nerve neurostimulator array and pulse generator, not requiring insertion of a separate distal respiratory sensor electrode or electrode array
C8008	Revision or replacement of hypoglossal nerve neurostimulator array including connection to existing pulse generator
C8009	Removal of hypoglossal nerve neurostimulator array and pulse generator
C8011	Open implantation of hypoglossal nerve(s) neurostimulator electrode array(s) and receiver, including external power source and all system components
C8012	Revision or replacement of hypoglossal nerve(s) neurostimulator electrode array(s) and receiver
C8013	Removal of hypoglossal nerve(s) neurostimulator electrode array(s) and receiver

Effective Dates

December 1, 2026: Ad hoc review. Updated ACO section.

July 1, 2026: Annual review. Reformatted policy. Updated code list.

January 2026: Ad hoc review. Updated prior authorization table and added variation for One Care and SCO members. Added MassHealth variation. Fixed code disclaimer.

July 2025: Annual review. LCDs added.



January 2025: Ad hoc review. Prior authorization requirement removed.

July 2024: Annual review.

July 2023: Annual review. Medicare Advantage added to table. Added new indication and medical necessity language for members 13-18 years of age with down syndrome. Medicare Variation language added. References updated.

July 2022: Annual review. References updated.

January 2022: Ad hoc review. Code update.

July 2021: Annual review. Under coverage guidelines, changed member age requirement from 22 to 18 years of age.

July 2020: Annual review. References updated.

January 2020: Effective date.

References

- American Academy of Otolaryngology-Head and Neck Surgery. Position Statement: Hypoglossal Nerve Stimulation for Treatment of Obstructive Sleep Apnea (OSA). 2016; <http://www.entnet.org/content/position-statement-hypoglossal-nerve-stimulation-treatment-obstructive-sleep-apnea-osa>. Accessed August 28, 2018.
- Barbé F, Masa JF. Hypoglossal neurostimulation for obstructive sleep apnoea. *Eur Respir J*. 2013 Feb;41(2):257-8. doi: 10.1183/09031936.00132312. PubMed PMID: 23370799.
- Certal VF, Zaghi S, Riaz M, et al. Hypoglossal nerve stimulation in the treatment of obstructive sleep apnea: A systematic review and meta-analysis. *Laryngoscope*. May 2015;125(5):1254-1264. PMID 25389029.
- Costantino A, Rinaldi V, Moffa A, et al. Hypoglossal nerve stimulation long-term clinical outcomes: a systematic review and meta-analysis. *Sleep Breath*. 2020;24(2):399-411. doi:10.1007/s11325-019-01923-2.
- Op de Beeck S, Wellman A, Dieltjens M, et al; STAR Trial Investigators. Endotypic Mechanisms of Successful Hypoglossal Nerve Stimulation for Obstructive Sleep Apnea. *Am J Respir Crit Care Med*. 2021 Mar 15;203(6):746-755. doi: 10.1164/rccm.202006-2176OC. PMID: 32970962; PMCID: PMC7958511.
- Eastwood PR, Barnes M, Walsh JH, et al. Treating obstructive sleep apnea with hypoglossal nerve stimulation. *Sleep* 2011;34:1479-86. PMID: 22043118.
- Eastwood PR, Barnes M, MacKay SG, et al. Bilateral hypoglossal nerve stimulation for treatment of adult obstructive sleep apnoea. *Eur Respir J*. 2020 Jan 9;55(1):1901320. doi: 10.1183/13993003.01320-2019. PMID: 31601716; PMCID: PMC6949509.
- Goding GS, Wondimeneh T, Kezirian EJ, et al. Hypoglossal nerve stimulation and airway changes under fluoroscopy. *Otolaryngol Head Neck Surg* 2012; 146:1017-22. PMID: 22307575.
- Hayes, Inc. Health Technology Assessment. Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea. Published October 30, 2018. Accessed November 1, 2019.
- Hong SO, Chen YF, Jung J, Kwon YD, Liu SYC. Hypoglossal nerve stimulation for treatment of obstructive sleep apnea (OSA): a primer for oral and maxillofacial surgeons. *Maxillofac Plast Reconstr Surg*. 2017;39(1):27. Published 2017 Sep 25. doi:10.1186/s40902-017-0126-0.
- Kezirian EJ, Goding GS Jr, Malhotra A, et al. Hypoglossal nerve stimulation improves obstructive sleep apnea: 12-month outcomes. *J Sleep Res*. Feb 2014;23(1):77-83. PMID 24033656.



Kompelli AR, Ni JS, Nguyen SA, et al. The outcomes of hypoglossal nerve stimulation in the management of OSA: A systematic review and meta-analysis. *World J Otorhinolaryngol Head Neck Surg*. 2018;5(1):41-48. Published 2018 Sep 25. doi:10.1016/j.wjorl.2018.04.006.

Liu P, Kong W, Fang C, Zhu K, Dai X, Meng X. Hypoglossal nerve stimulation in adolescents with down [sic] syndrome and obstructive sleep apnea: A systematic review and meta-analysis. *Front Neurol* 2022; 13:1037926. PMCID: PMC9640576; PMID: [36388229](#). National Government Services. Local Coverage Determination (LCD): Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea (L38387). Revision Effective Date: 04/01/2020. Available: Medical Policies - NGS MEDICARE.

Olson MD, Junna MR. Hypoglossal Nerve Stimulation Therapy for the Treatment of Obstructive Sleep Apnea. *Neurotherapeutics*. 2021 Jan;18(1):91-99. doi: 10.1007/s13311-021-01012-x. Epub 2021 Feb 8. PMID: 33559036; PMCID: PMC8116425.

Pascoe M, Wang L, Aylor J, et al. Association of Hypoglossal Nerve Stimulation With Improvements in Long-term, Patient-Reported Outcomes and Comparison With Positive Airway Pressure for Patients With Obstructive Sleep Apnea. *JAMA Otolaryngol Head Neck Surg*. 2022 Jan 1;148(1):61-69. doi: 10.1001/jamaoto.2021.2245. PMID: 34762105; PMCID: PMC8587218.

Pordzik J, Ludwig K, Seifen C, et al. Insomnia in Patients Undergoing Hypoglossal Nerve Stimulation Therapy for Obstructive Sleep Apnea. *Biology (Basel)*. 2023 Jan 9;12(1):98. doi: 10.3390/biology12010098. PMID: 36671790; PMCID: PMC9856015.

Schwartz, AR, Barnes M, Hillman D, et al. Acute upper airway responses to hypoglossal nerve stimulation during sleep in obstructive sleep apnea. *Am J Respir Crit Care Med* 2012; 185; 4:420-6. PMID: 22135343.

Seay EG, Keenan BT, Schwartz AR, Dedhia RC. Evaluation of Therapeutic Positive Airway Pressure as a Hypoglossal Nerve Stimulation Predictor in Patients With Obstructive Sleep Apnea. *JAMA Otolaryngol Head Neck Surg*. 2020 Aug 1;146(8):691-698. doi: 10.1001/jamaoto.2020.1018. PMID: 32496539; PMCID: PMC7273315.

Steffen A, Heiser C, Galetke W, et al. Hypoglossal nerve stimulation for obstructive sleep apnea: updated position paper of the German Society of Oto-Rhino-Laryngology, Head and Neck Surgery. *Eur Arch Otorhinolaryngol*. 2022 Jan;279(1):61-66. doi: 10.1007/s00405-021-06902-6. Epub 2021 Jun 21. PMID: 34151387; PMCID: PMC8738404.

Strollo PJ Jr, Soose RJ, Maurer JT, et al. Upper-airway stimulation for obstructive sleep apnea. *N Engl J Med*. Jan 9 2014;370(2):139-149. PMID 24401051.

U.S. Food and Drug Administration (FDA), Center for Devices and Radiologic Health (CDRH). Inspire Upper Airway Stimulation (UAS) System, Model 3028 IPG. Summary of Safety and Effectiveness Data. PMA No. P130008/S021. Rockville, MD: FDA; June 23, 2017. Available at: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P130008S021> Accessed November 1, 2019.

U.S. Food and Drug Administration (FDA), Center for Devices and Radiologic Health (CDRH). Inspire Upper Airway Stimulation (UAS) System, Model 3028 IPG. Summary of Safety and Effectiveness Data. PMA No. P130008/S089. Rockville, MD: FDA; March 30, 2023. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130008S089A.pdf.

U.S. Food and Drug Administration (FDA). FDA News Release: FDA Roundup. Rockville, MD: FDA; June 9, 2023. Available at <https://www.fda.gov/news-events/press-announcements/fda-roundup-june-9-2023>



Withrow K, Evans S, Harwick J, Kezirian E, Strollo P. Upper Airway Stimulation Response in Older Adults with Moderate to Severe Obstructive Sleep Apnea. *Otolaryngol Head Neck Surg.* 2019;161(4):714-719. doi:10.1177/0194599819848709.

Yu PK, Sternson M, Ishman SL, 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. doi:10.1001/jamaoto.2022.0455.

