

Department of Origin: Integrated Healthcare Services	Effective Date: 06/05/24
Approved by: Medical Policy Quality Management Subcommittee	Date Approved: 06/04/24
Clinical Policy Document: Neurostimulation, Hypoglossal Nerve	Replaces Effective Clinical Policy Dated: 12/12/23
Reference #: MC/I012	Page: 1 of 6

PURPOSE:

The intent of this clinical policy is to ensure services are medically necessary.

Please refer to the member's benefit document for specific information. To the extent there is any inconsistency between this policy and the terms of the member's benefit plan or certificate of coverage, the terms of the member's benefit plan document will govern.

POLICY:

Benefits must be available for health care services. Health care services must be ordered by a provider. Health care services must be medically necessary, applicable conservative treatments must have been tried, and the most cost-effective alternative must be requested for coverage consideration.

GUIDELINES:

Medical Necessity Criteria – Requests for hypoglossal nerve stimulation with the use of an FDA-approved device (eg, Inspire) for the specific indication - Must satisfy any of the following: I or II

I. Initial placement - must satisfy any of the following: A or B

- A. The member is greater than or equal to 13 years of age and less than or equal to 17 years of age – must satisfy all of the following: 1 – 5
 1. The member has a diagnosis of Down Syndrome; and
 2. Presence of obstructive sleep *apnea* (OSA) with an *AHI/RDI/REI* score of greater than or equal to 10 and less than or equal to 50 events per hour; and
 3. Absence of complete concentric velopharyngeal collapse on screening sleep endoscopy; and
 4. Documentation of failure of or contraindication to adenotonsillectomy; and
 5. Failure or intolerance of positive airway pressure treatments – any of the following: a or b
 - a. PAP failure is defined as an inability to eliminate OSA (*AHI* of greater than 15 despite PAP usage); or
 - b. PAP intolerance is defined as either of the following – 1) or 2)
 - 1) Inability to use PAP (greater than 5 nights per week of usage [usage defined as greater than 4 hours of use per night]); or
 - 2) Unwillingness to use PAP (eg, a patient returns the PAP system after attempting to use it)
- B. The member is greater than or equal to 18 years of age – must satisfy all of the following: 1 - 5
 1. The member has a BMI less than or equal to 40kg/m²; and
 2. Presence of obstructive sleep *apnea* (OSA) with an *AHI/RDI/REI* score of greater than or equal to 15 and less than or equal to 100 events per hour; and
 3. Presence of predominantly obstructive events (central and mixed *apneas* less than or equal to 25% of *AHI*); and

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Reference #: MC/I012	Page: 2 of 6

4. Failure or intolerance of positive airway pressure (PAP, CPAP) treatments – any of the following: a or b
 - a. PAP failure is defined as an inability to eliminate OSA (AHI of greater than 15 despite PAP usage); or
 - b. PAP intolerance is defined as either of the following – i or ii
 - i. Inability to use PAP (greater than 5 nights per week of usage [usage defined as greater than 4 hours of use per night]); or
 - ii. Unwillingness to use PAP (eg, a patient returns the PAP system after attempting to use it)
 5. Absence of complete concentric velopharyngeal collapse on screening sleep endoscopy.
- II. Replacement or revision of stimulator generator/battery, lead or electrode, or patient programmer (controller) – must satisfy the following: A, and B or C, as applicable
- A. The indication for initial placement meets indications under I.; and
 - B. Request is for replacement of the existing generator/battery or patient programmer (controller) – must satisfy any of the following: 1 - 2
 1. The battery life is less than 1 year; or
 2. The device must be *malfunctioning* and no longer under warranty.
 - C. Request is for replacement and/or revision of lead/electrode due to migration and/or no longer functioning properly is considered medically necessary.

EXCLUSIONS (not limited to):

Refer to member's Certificate of Coverage or Summary Plan Description.

The following are considered investigative for the treatment of obstructive sleep apnea (see Investigative List): I – XXI

- I. Adjustable tongue-advancement device (eg, Advance system)
- II. Apnea triggered muscle stimulation (does not include hypoglossal nerve stimulation)
- III. Cardiac (Atrial) Pacing
- IV. Cautery-Assisted Palatal Stiffening Operation (CAPSO)
- V. Epiglottidectomy
- VI. Expansion sphincteroplasty
- VII. Flexible Positive Airway Pressure (pressure-relief C-PAP [C-Flex, Respironics])
- VIII. Genioplasty/genial tubercle advancement
- IX. Glossectomy, partial
- X. Injection Snoreplasty
- XI. Laser assisted Uvuloplasty (LAUP)
- XII. Mandibular distraction osteogenesis (MDO)
- XIII. Nasal dilators
- XIV. Obstructive Sleep Apnea (OSA) oral appliance to restore proper mandibular alignment after use of overnight sleep apnea appliance, for prevention of temporomandibular joint dysfunction (such as, but not limited to, the Direct AM Positioner, Morning Repositioner [SomnoMed])
- XV. Palatal Implants (Pillar Procedure)

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Clinical Policy Document: Neurostimulation, Hypoglossal Nerve	Replaces Effective Clinical Policy Dated: 12/12/23
Reference #: MC/I012	Page: 3 of 6

- XVI. Provent Sleep Apnea Therapy
- XVII. Radiofrequency Volumetric Tissue Reduction of the palate, tongue, or uvula (Somnoplasty/Coblation)
- XVIII. Remotely controlled mandibular positioner
- XIX. Tongue based reduction surgery
- XX. Tongue Based Suspension (eg, Repose or AIRvance)
- XXI. Winx therapy system/oral pressure therapy

DEFINITIONS:

Apnea:

Transient cessation of respiration

Apnea Hypopnea Index (AHI):

Average number of episodes of *apnea* and/or *hypopnea* per hour of sleep

Malfunctioning:

The failure of a device to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims made in the labeling for the device.

Obstructive Sleep Apnea Types (from AASM):

- *AHI* of 5-14: Mild OSA; Involuntary sleepiness during activities that require little attention (eg, watching TV, reading)
- *AHI* of 15-29: Moderate OSA; Involuntary sleepiness during activities that require some attention (eg, meetings, presentations)
- *AHI* of 30 or greater: Severe OSA; Involuntary sleepiness during activities that require more active attention (eg, talking, driving)

Respiratory Disturbance Index (RDI):

Average number of respiratory disturbances per hour (*apneas*, *hypopneas*, and respiratory event-related arousals [RERAs])

Respiratory Event Index (REI):

Average number of episodes of *apnea* and/or *hypopnea* per total recording time in hours

BACKGROUND:

Obstructive Sleep Apnea (OSA) is a disorder in which complete or partial obstruction of the airway during sleep causes loud snoring, oxyhemoglobin desaturations, and frequent arousals.

Upper airway stimulation is performed using an implanted neurostimulation device that stimulates the hypoglossal nerve to activate the protrusion muscles of the tongue. The patient controls the start and stop times for therapy using a handheld device while the stimulation device gathers information from the sensor throughout therapy to determine the most beneficial time to deliver the stimulation.

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Reference #: MC/I012	Page: 4 of 6

Prior Authorization: Yes, per network provider agreement.

CODING:

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

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Clinical Policy Document: Neurostimulation, Hypoglossal Nerve	Replaces Effective Clinical Policy Dated: 12/12/23
Reference #: MC/I012	Page: 5 of 6

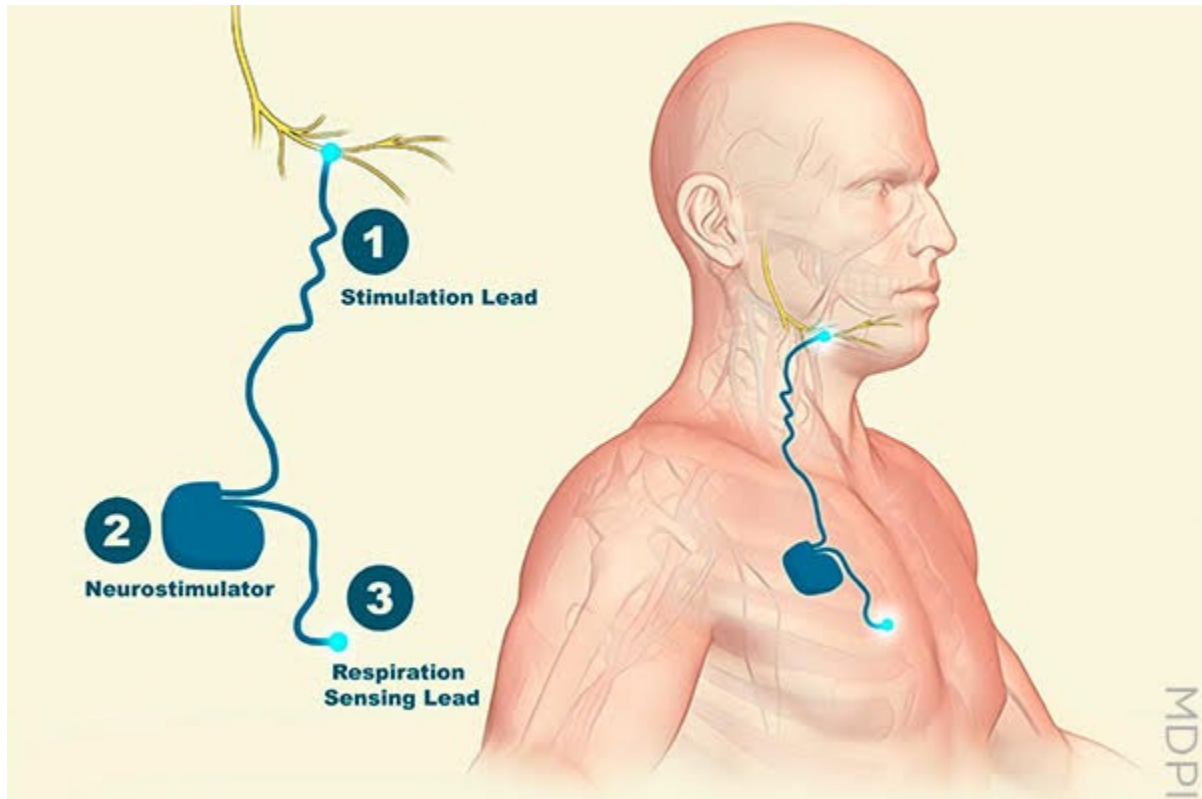
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Department of Origin: Integrated Healthcare Services	Effective Date: 06/05/24
Approved by: Medical Policy Quality Management Subcommittee	Date Approved: 06/04/24
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Reference #: MC/I012	Page: 6 of 6

Attachment A



Retrieved from MedPage Today: Moskowitz, B. Excessive Sleepiness and Associated Risks with Obstructive Sleep Apnea. OSA: What Role for Hypoglossal Nerve Stimulation?
<https://www.medpagetoday.com/resource-centers/excessive-sleepiness-and-associated-risks-with-obstructive-sleep-apnea/osa-role-hypoglossal-nerve-stimulation/2720>

Nondiscrimination & Language Access Policy



Discrimination is Against the Law. Aspirus Health Plan, Inc. complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex, (including sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation, gender identity and sex stereotypes), consistent with the scope of sex discrimination described at 45 CFR § 92.101(a)(2). Aspirus Health Plan, Inc. does not exclude people or treat them less favorably because of race, color, national origin, age, disability, or sex.

Aspirus Health Plan, Inc.:

Provides people with disabilities reasonable modifications and free appropriate auxiliary aids and services to communicate effectively with us, such as:

- Qualified sign language interpreters.
- Written information in other formats (large print, audio, accessible electronic formats, other formats).

Provides free language assistance services to people whose primary language is not English, which may include:

- Qualified interpreters.
- Information written in other languages.

If you need reasonable modifications, appropriate auxiliary aids and services, or language assistance services, contact the Nondiscrimination Grievance Coordinator at the address, phone number, fax number, or email address below.

If you believe that Aspirus Health Plan, Inc. has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a *grievance* with:

Nondiscrimination Grievance Coordinator
Aspirus Health Plan, Inc.
PO Box 1890
Southampton, PA 18966-9998
Phone: 1-866-631-5404 (TTY: 711)
Fax: 763-847-4010
Email: customerservice@aspirushealthplan.com

You can file a *grievance* in person or by mail, fax, or email. If you need help filing a *grievance*, the Nondiscrimination Grievance Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1.800.368.1019, 800.537.7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>. This notice is available at Aspirus Health Plan, Inc.'s website: https://aspirushealthplan.com/webdocs/70021-AHP-NonDiscrim_Lang-Assist-Notice.pdf.

Language Assistance Services

Albanian: KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë. Telefononi në 1-800-332-6501 (TTY: 711).

Arabic: تنبيه: إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية متاحة لك مجاناً. اتصل بن أعلى رقم الهاتف 1-800-332-6501 (رقم هاتف الصم والبك : 711)

French: ATTENTION: Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1-800-332-6501 (ATS: 711).

German: ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1-800-332-6501 (TTY: 711).

Hindi: यान द : य द आप िहंदी बोलते ह तो आपके िलए मु त म भाषा सहायता सेवाएं उपल थ ह 1-800-332-6501 (TTY: 711) पर कॉल कर ।

Hmong: LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1-800-332-6501 (TTY: 711).

Korean: 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1-800-332-6501 (TTY: 711) 번으로 전화해 주십시오.

Polish: UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 1-800-332-6501 (TTY: 711).

Russian: ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1-800-332-6501 (телетайп: 711).

Spanish: ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1-800-332-6501 (TTY: 711).

Tagalog: PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1-800-332-6501 (TTY: 711).

Traditional Chinese: 注意：如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 1-800-332-6501 (TTY: 711)

Vietnamese: CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1-800-332-6501 (TTY: 711).

Pennsylvania Dutch: Wann du Deutsch (Pennsylvania German / Dutch) schwetzscht, kannst du mitaue Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1-800-332-6501 (TTY: 711).

Lao: ໂປດຊາບ: ຖ້າວ່າທ່ານເວົ້າພາສາລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາໂດຍບໍ່ເສັຽຄ່າ, ຄວນມີພ້ອມໃຫ້ທ່ານ. ໂທ 1-800-332-6501 (TTY: 711).