

Department of Origin: Integrated Healthcare Services	Effective Date: 12/12/23
Approved by: Medical Policy Quality Management Subcommittee	Date Approved: 12/05/23
Clinical Policy Document: Neurostimulation, Hypoglossal Nerve	Replaces Effective Clinical Policy Dated: 06/06/23
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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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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- 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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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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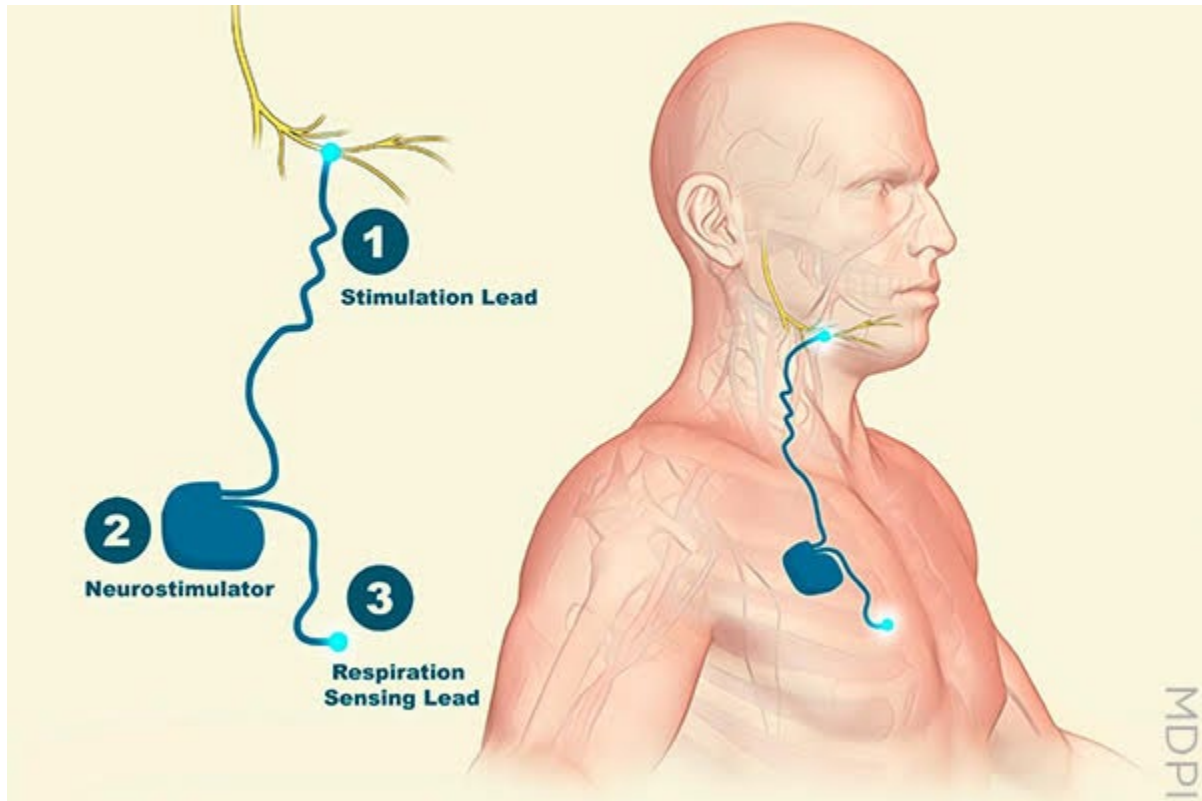
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Attachment A



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>

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Fax: 763.847.4010
customerservice@preferredone.com

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Washington, D.C. 20201
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U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
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ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1.800.940.5049 (телетайп: 763.847.4013).

បំពេញ: ប្រសិនបើ អ្នកនិយាយភាសាខ្មែរ, សេវាជំនួយភាសា ដោយមិនគិតថ្លៃ គឺអាចមានសំរាប់អ្នក។ ហៅ 1.800.940.5049 (TTY: 763.847.4013).

ማስታወሻ: የሚናገሩት ቋንቋ አማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፡ በነጻ ሊያገኙት ተዘጋጅተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 1.800.940.5049 (ማስማት ለተሳናቸው: 763.847.4013) .

ဟံသာဝတီ: နမူနာတို့ ကညီ ကျိအသိ, နမူနာ ကျိအတိအကျတို့ တလက်ကွက်လက်စွာ နှိတ်မိသည့်သို့လည်း ကိ: 1.800.940.5049 (TTY: 763.847.4013).

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.800.940.5049 (TTY: 763.847.4013).

ប្រយ័ត្ន: បើសិនជាអ្នកនិយាយភាសាខ្មែរ, សេវាជំនួយភាសា ដោយមិនគិតថ្លៃ គឺអាចមានសំរាប់អ្នក។ ហៅ 1.800.940.5049 (TTY: 763.847.4013).

ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 1.800.940.5049 (رقم هاتف الصم والبكم: 763.847.4013).

ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1.800.940.5049 (TTY: 763.847.4013).

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.800.940.5049 (TTY: 763.847.4013). 번으로 전화해 주십시오.

PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 1.800.940.5049 (TTY: 763.847.4013).