TITLE: IMPLANTED HYPOGLOSSAL NERVE STIMULATION FOR TREATMENT OF OBSTRUCTIVE SLEEP APNEA

EFFECTIVE DATE: June 17, 2019

This policy was developed with input from specialists in sleep medicine and endorsed by the Medical Policy Committee.

IMPORTANT INFORMATION – PLEASE READ BEFORE USING THIS POLICY

These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare and Minnesota Health Care Programs, this policy will apply unless these programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica utilization management policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica utilization management policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

PURPOSE

To promote consistency between reviewers in utilization management decision-making by providing the criteria that generally determine the medical necessity of implanted hypoglossal nerve stimulation. The Benefit Considerations box below outlines the process for addressing the needs of individuals who do not meet these criteria.

BACKGROUND

I. Definitions

A. Apnea is a cessation of airflow for 90% or greater of baseline for 10 or more seconds.
B. Apnea-Hypopnea Index (AHI) is calculated as the number of episodes of apnea plus hypopnea per hour of sleep.
C. Central Sleep Apnea results when the brain temporarily stops sending signals to the muscles that control breathing. This causes the body to decrease or stop the effort of breathing during sleep. The condition may occur in individuals as a result of medical problems, e.g., heart failure and stroke. This condition is different from obstructive sleep apnea.
D. Continuous Positive Airway Pressure (CPAP) Devices deliver air under continuous pressure through a nasal mask or face mask. This opens the airway and prevents collapse of the oropharynx that occurs during sleep by forming a pneumatic splint.
E. Hypopnea as defined by the Centers for Medicare and Medicaid Services (CMS) is an abnormal respiratory event lasting at least 10 seconds with at least a 30 percent reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4 percent oxygen desaturation.
F. Hypoglossal Nerve Stimulation stimulates the hypoglossal nerve (cranial nerve XII) at the base of the tongue. A lead in the chest consists of a pressure sensor that detects breathing. Respiratory information is relayed to the device, which stimulates the hypoglossal nerve in the tongue, and the tongue moves forward, opening the airway. The device is operated by remote control, which the patient activates before going to sleep.
G. Mixed Apnea is a combination of both obstructive and central sleep apnea symptoms.
H. Obstructive Sleep Apnea/Hypopnea Syndrome (OSAHS) is a condition in which individuals experience pauses of breathing (apnea) during sleep. It is associated with partial or complete closure of the throat when the muscles in the back of the throat fail to keep the airway open. Epidemiologic data indicate that approximately two percent of women and four percent of men in the middle-aged work force meet the minimal diagnostic criteria for OSAHS.
1. The syndrome is confirmed by test results that indicate the following:
   a. AHI greater than or equal to 15 events per hour confirmed by polysomnography (PSG).
   b. AHI greater than or equal to 5 and less than or equal to 14 events per hour confirmed by PSG and
      accompanied by symptoms of OSAHS, which include unexplained excessive daytime sleepiness,
      mood disorders, insomnia; impaired cognition, or documented hypertension, ischemic heart
      disease, or history of stroke.
2. Severity of OSAHS is categorized as:
   a. Mild: AHI of 5 to 15.
   b. Moderate: AHI of 16 to 30.
   c. Severe: AHI greater than 30.

I. Polysomnography (PSG) refers to multimodal measurement of physiologic indicators during phases of
   sleep. Most consensus statement definitions of facility-based polysomnography assume the measurement
   of at least seven parameters including measurement of brain activity, heart and respiratory function,
   oxygen saturation, eye movement, and movement of abdominothoracic muscles. PSGs are administered
   over a full night or split-night. In a split-night study, the presence and severity of sleep apnea is confirmed
   during the first half of the study. During the remainder of the night, positive airway pressure devices are
   titrated to determine therapeutic pressure levels.

BENEFIT CONSIDERATIONS
1. Prior authorization is required for implanted hypoglossal nerve stimulation. Please see the prior authorization
   list for product specific prior authorization requirements.
2. Coverage may vary according to the terms of the member’s plan document.
3. If the Medical Necessity and Coverage Criteria are met, Medica will authorize benefits within the limits in the
   member’s plan document.
4. If it appears that the Medical Necessity and Coverage Criteria are not met, the individual’s case will be
   reviewed by the medical director or an external reviewer. Practitioners are reminded of the appeals process in
   their Medica Provider Administrative Manual.

MEDICAL NECESSITY CRITERIA
I. Indications for implanted hypoglossal nerve stimulation
   Documentation in the medical records indicates that all of the following criteria are met:
   A. The device to be implanted is FDA-approved
   B. The member is age 22 or older
   C. Obstructive sleep apnea is present with an apnea-hypopnea index (AHI) greater than or equal to 20 and
      less than or equal to 65
   D. There is a documented history of failed CPAP after a trial of at least eight weeks or the patient cannot
      tolerate CPAP
      1. If the patient is unable to tolerate standard CPAP, alternative therapies such a flexible CPAP, various
         models of facial masks and nasal pillows should be tried prior to consideration of hypoglossal nerve
         stimulation.
   E. Other non-surgical options, such as mandibular advancement device, have been considered and
      excluded.
II. Contraindications
   None of the following are present:
   A. Body mass index (BMI) greater than 32
   B. Anatomic finding that would compromise the performance of upper airway stimulation, such as the
      presence of complete concentric collapse of the soft palate
   C. Any condition or procedure that has compromised neurological control of the upper airway
   D. Central plus mixed apneas greater than 25% of the total AHI
   E. The patient is pregnant or plans to become pregnant
   F. The patient is unable or does not have the necessary assistance to operate the sleep remote.
III. Written documentation
   Documentation in the medical record must include all of the following:
   A. A summary of the most recent PSG that includes the AHI
   B. A description of all trials of noninvasive medical treatments including the length and results of the trials.
Implanted Hypoglossal Nerve Stimulation for Treatment of Obstructive Sleep Apnea
Medica Policy No. III-SUR.43

CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS)
- For Medicare members, refer to the following, as applicable at: http://www.cms.hhs.gov/mcd/search.asp?

DOCUMENT HISTORY

<table>
<thead>
<tr>
<th>Original Effective Date</th>
<th>August 21, 2017</th>
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<tbody>
<tr>
<td>MPC Endorsement Date(s)</td>
<td>06/2017, 4/2018, 04/2019</td>
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References

Pre-02/2017 MTAC:

02/2017 MTAC

06/2017 MPC:
No new references
04/2018 MPC:

04/2019 MPC: