TITLE: IMPLANTED HYPOGLOSSAL NERVE STIMULATION FOR TREATMENT OF OBSTRUCTIVE SLEEP APNEA MP9636

EFFECTIVE DATE: May 1, 2024

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

IMPORTANT INFORMATION – PLEASE READ BEFORE USING THIS POLICY

These services may or may not be covered by Prevea360 Health Plan. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member's plan document for other 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, Medicaid, and other government programs, this policy will apply unless these programs require different coverage. Members may contact Prevea360 Health Plan Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions may call the Provider Service Center. Please use the Quick Reference Guide on the Provider Communications page for the appropriate phone number. https://www.prevea360.com/Providers/Provider-communications-library

Prevea360 Health Plan medical 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 utilization management reviewers by providing the criteria that determines the medical necessity.

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. **CPAP intolerance** defined as inability to use CPAP for less than an average of four hours per night or less than 70 percent of nights (i.e., less than five nights per week).
F. **PAP failure** is defined as an inability to eliminate OSA (AHI of greater than 15 despite PAP usage).
G. **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.
H. **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.
I. **Mixed Apnea** is a combination of both obstructive and central sleep apnea symptoms.
J. **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.
K. **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. Implanted hypoglossal nerve stimulation *is investigative and therefore, not covered* for all other indications not specifically mentioned in the Medical Necessity Criteria section.
4. If the Medical Necessity Criteria and Benefit Considerations are met, Medica will authorize benefits within the limits in the member's plan document.
5. If it appears that the Medical Necessity Criteria and Benefit Considerations 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 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. There is a documented history of failed CPAP after a trial of at least eight weeks or the patient cannot tolerate CPAP.

Note: 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.

C. Documented history of failed or reasons for exclusions of other alternative treatments (e.g.mandibular advancement device).

D. Documentation in the medical records indicates that one of the following criteria are met

1. Members 22 years of age or older, when **all of the following** criteria have been met:
   a. Apnea-hypopnea index (AHI) greater than or equal to 15 and less than or equal to 100, and
   b. Body mass index (BMI) equal to or less than 40, and
2. Members between 18 and 21 years of age, when **all of the following** criteria have been met:
   a. AHI greater than or equal to 15 and less than or equal to 100, and

b. BMI equal to or less than 40, and
c. With contraindications for, or not effectively treated by, adenotonsillectomy.

3. Members between 13 to 18 years of age with Down syndrome, when **all of the following** criteria have been met:
   a. AHI greater than 10 and less than 50, and
   b. BMI equal to or less than 40
   c. With contraindications for, or not effectively treated by, adenotonsillectomy.

II. Contraindications

None of the following are present:

A. Anatomic finding that would compromise the performance of upper airway stimulation, such as the presence of complete concentric collapse of the soft palate

B. Any condition or procedure that has compromised neurological control of the upper airway

C. Central plus mixed apneas greater than 25% of the total AHI

D. The patient is pregnant or plans to become pregnant

E. 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.

CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS)

- For Medicare members, refer to the following, as applicable at: https://www.cms.gov/medicare-coverage-database/new-search/search.aspx

WISCONSIN BADGERCARE PLUS

- For members with State of Wisconsin BadgerCare Plus Insurance review the Forward Health website for coverage and prior authorization requirements. (Forward Health WI Portal

DOCUMENT HISTORY

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