Diagnostic Testing Pre- and Post-Hypoglossal Nerve Stimulator Implantation Diagnostic Testing Pre- and Post- Hypoglossal Nerve Stimulator Implantation (SL-2.8)

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General Information

A hypoglossal nerve stimulator is a surgically implanted device that delivers stimulating electrical pulses to the hypoglossal nerve, which controls upper airway musculature.

With a sensing lead, the device permits synchronization with ventilatory effort. The Stimulation Treatment for Apnea Reduction (STAR) trial was a prospective, multicenter trial of 126 participants with a body mass index (BMI) less than 32, moderate to severe obstructive sleep apnea (AHI 20-50), and difficulty tolerating/adhering to CPAP. Participants, who served as their own control, experienced a significant reduction in Apnea Hypopnea Index with hypoglossal nerve stimulation (68% decrease) and oxygen desaturation index (70% decrease) at 12 months, as well as a reduction in self- reported outcomes at 12 and 24 months. These improvements were maintained at 3, 4, and 5 years. During the trial, a response to hypoglossal nerve stimulation was defined as a reduction of AHI by at least 50% from baseline and an AHI of less than 20 events per hour at one year. A prospective, single arm study conducted in Germany utilized an inclusion criteria of AHI of 15 to 65 per hour and BMI less than 35 kg/m2. Significant reduction in AHI was achieved with median AHI decreasing from 28/h to 8.3/h at 6 months and sustained improvement at one year. In June 2017, the Food and Drug administration revised the criteria to include individuals with AHI between 15 and 65. Retrospectively, no differences have been found for post-operative AHI, oxygen saturation nadir, daytime sleepiness or surgical success with BMI greater than or less than 32.

Indications

PSG (CPT® 95810) is indicated for the following:

Pre-implantation

See also Background and Supporting Information below

No prior sleep testing:

- **Individuals with a high pre-test likelihood for moderate to severe obstructive sleep apnea who have not undergone prior sleep testing should undergo home sleep apnea testing, if appropriate per guidelines, and a PAP trial before consideration of facility testing for possible hypoglossal nerve stimulator implantation. Please see sections General Guidelines (SL-1.0): Site of care for sleep testing requests (home versus facility), Home Sleep Testing (HSAT) Indication (SL-2.1), prior sections in In-Laboratory Polysomnography - OSA Indications (SL-2.2), and In-Laboratory Polysomnography - Other Indications (SL-2.2.1) for guidelines for individuals who have not undergone prior testing.**

Prior diagnosis of OSA based on polysomnography:

- **Individuals who have recently undergone polysomnography (within 24 months), do not need a repeat study unless there have been changes in weight or symptoms to suggest a clinically significant change in sleep study results. In the setting of recent significant changes in weight or symptoms, repeat polysomnography (CPT® 95810) could be considered if the following criteria are met (BOTH):**
  - **BMI <35**
  - **Previous intolerance to CPAP and/or bi-level PAP during a minimum of one- month trial**

Prior diagnosis of OSA based on home sleep apnea testing:

- **In the setting of a known diagnosis of obstructive sleep apnea based on home sleep apnea testing, the following criteria must be met prior to performance of polysomnography (CPT® 98510) for pre-implantation evaluation (ALL):**
  - **BMI <35**
  - **AHI or REI <65 on home sleep testing**
  - **Intolerance to CPAP and/or bi-level PAP during a minimum of one-month trial**

Post-implantation:

- **As per the clinical trial, polysomnography (CPT® 95810) can be performed post- implantation (at approximately 2-3 months post-implantation) for the purpose of titrating device parameters and determining therapeutic stimulation settings.**
- **Following the initial post-implantation study, retesting (either HSAT or PSG CPT® 95810) can be performed if any of the following occurs:**

- **Clinical response is insufficient despite regular treatment with hypoglossal nerve stimulator.**
- **Substantial weight gain with return of symptoms.**
- **Results of previously medically necessary sleep test were inadequate due to limited sleep time or other variables.**

- **Following the initial post-implantation study, the choice of home sleep apnea testing or facility polysomnography for repeat testing will be based on indications and co- morbidities outlined in General Guidelines (SL-1.0), Home Sleep Testing (HSAT) Indication (SL-2.1), prior sections in In-Laboratory Polysomnography- OSA Indications (SL-2.2), and In-Laboratory Polysomnography- Other Indications (SL-2.2.1).**

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