Introduction

Sleep apnea is characterized by recurrent narrowing and closure of the upper airway. Untreated or inadequately treated obstructive sleep apnea syndrome can lead to abnormal physiology that can have serious implications including increased cardiovascular disease, stroke, metabolic disease, excessive daytime sleepiness, work-place errors, traffic accidents, decreased quality of life, general decreased function, and death, which are the health outcomes of interest. Although continuous positive airway pressure (CPAP) can mitigate the risks, effectiveness can be reduced by inadequate adherence to treatment for whatever reason. In accessing treatments for these events, current measures used in clinical trials as primary outcome measures are the Apnea – Hypopnea Index (AHI) and Oxygen Desaturation Index (ODI). Secondary outcome measures are usually Epworth Sleepiness Score (ESS), and Functional Outcomes of Sleep Questionnaire (FOSQ). The use of Hypoglossal Nerve Stimulation has been proposed as an alternative treatment for those patients who have difficulty with CPAP treatment.

Upper airway stimulation: Qualified participants undergo a surgical procedure to implant the upper airway stimulation system. The upper airway stimulation system consists of two leads and a neurostimulator. A stimulation electrode is placed on the hypoglossal nerve to recruit tongue protrusion function. A sensing lead is placed between the internal and external intercostal muscles to detect ventilatory effort, and the neurostimulator is implanted in the right ipsilateral mid-infraclavicular region.

Voting Questions

For each voting question, please use the following scale identifying your level of confidence - with a score of 1 being low or no confidence and 5 representing high confidence.

1 — 2 — 3 — 4 — 5

Low Confidence — Intermediate — High Confidence

Questions for consideration:

1. How confident are you of the validity and reliability of currently used clinical trial measures in representing the health outcomes of interest in the treatment of sleep apnea: Disease specific Quality of Life (QOL) (FOSQ- data), Oxygen Desaturation Index, ESS, in addition to AHI.

Outcome	**Score**
FOSQ	
ODI	
AHI	

ESS	

2. If the answer to #1 is ≥ 2.5, based on the evidence, how confident are you that HNS improves the four overall health outcomes of interest listed above?

3. How confident are you that the short term adverse events are well-characterized? How confident are you that long term events are characterized?

4. Based on the literature, how confident are you that definitive patient selection criteria have been determined for the use of HNS therapy?

- AHI 15-50
- Adults 22 years of age or older who have failed or cannot tolerate CPAP
- Must have complete concentric collapse on drug induced sleep endoscopy (DISE)
- BMI ≤ 32
- No documentation of –
    - Neuromuscular disease
    - Hypoglossal nerve palsy
    - Severe restrictive or obstructive pulmonary disease
    - Moderate to severe pulmonary arterial hypertension
    - Severe valvular heart disease or uncontrolled BP
    - Class III or IV heart failure
    - Recent Myocardial infarction
    - Severe cardiac arrhythmias within the past 6 months
    - Active psychiatric disease
    - Coexisting confounding non-respiratory sleep disorders.

5. How confident are you that the evidence supports initially an independent review of the Drug Induced Sleep Examination prior to implantation? If ≥ 2.5 how many test should be reviewed and what is a satisfactory agreement percentage?

6. How confident are you that the STAR results are generalizable to practice outside of a clinical trial?

7. How confident are you that the evidence supports specialized training being necessary for:

- Implantation
- Evaluation prior to referral to implantation provider
- For post implantation follow-up

8. How confident are you that the results are applicable to the Medicare population?

9. Overall, how confident are you that the evidence shows that health outcomes of interest are improved by HNS?