Name of Policy:	**Clinical guidelines for titration of hypoglossal nerve stimulation device**
Policy Number:	3364-171-07-08
Department:	Sleep Disorders
Approving Officer:	Senior Hospital Administrator
Responsible Agent:	Director, Sleep Disorders Center
Scope:	The University of Toledo Medical Center Pulmonary Services Department

THE UNIVERSITY OF TOLEDO MEDICAL CENTER

Effective Date: 3/17/2023

Initial Effective Date: 3/17/2023

X New policy proposal	_____ Minor/technical revision of existing policy
_____ Major revision of existing policy	_____ Reaffirmation of existing policy

(A) Policy Statement

All qualified and trained Polysomnographic Technologists will be able to set-up and titrate patients using upper airway neurostimulation therapy with the implanted hypoglossal nerve stimulation device.

(B) Purpose of Policy

Hypoglossal nerve stimulation can be used for the treatment of Obstructive Sleep Apnea (OSA) when patients are unable to tolerate Positive Airway Pressure (PAP).

(C) Procedure

When a patient is diagnosed with OSA, after receiving an order, the Sleep Lab staff will schedule a Polysomnogram (PSG) to be performed using hypoglossal nerve stimulation ~~Inspire~~. Amplitude will be adjusted throughout the PSG to determine the optimal settings for maintaining upper airway patency. Whenever a sleep study recording is less than 6 hours in length, the sleep study will be billed using a modifier 52 (reduced charge).

American Academy of Sleep Medicine (AASM) definitions for optimal, good, adequate, and unacceptable titration:

1. Optimal titration reduces the Apnea Hypopnea Index (AHI) < 5 for at least 15 minutes duration and should include supine Rapid Eye Movement (REM) sleep at the selected pressure that is not continually interrupted by spontaneous arousals or awakenings.
2. A good titration reduces the AHI<10 or by 50% if the baseline AHI is <15 and should include supine REM that is not continually interrupted by spontaneous arousals or awakenings at the selected pressure.
3. An adequate titration does not reduce the AHI ≤ 10 but reduces the AHI by 75% from baseline (especially in severe OSA patients) or one in which the titration grading criteria for optimal or good are met with the exception that Supine REM did not occur at the selected pressure.
4. An unacceptable titration is one that does not meet any of the above definitions.

Workflow

1. ALL Inspire titration studies will be scheduled with the Inspire Sleep Support Specialist with a minimum of 4 weeks' notice to allow for Inspire to assign a Sleep Support Specialist.
2. Support will be available for all Inspire titration studies by either of the methods listed below
    a. During initial technologist training by a Sleep Support Specialist
    b. 24/7 wireless support 833-522-7747

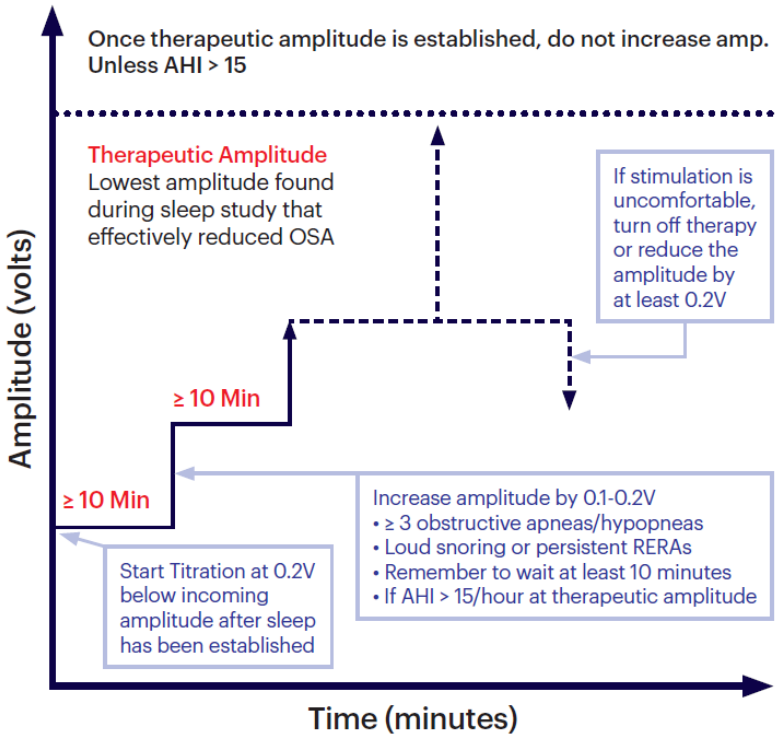
3. Explain test/expectations to the patient.
4. Discuss the patient's subjective benefits and answer any questions.
5. Complete the physical exam of the tongue and incision sites. Report any abnormal findings to the ordering physician.
    a. Neuropraxia- tongue is not midline, does not move symmetrically left, right, up, down. Discuss postponing study with ordering physician until condition resolves.
    b. Inspect for proper healing of incision sites (2 or 3 Sites depending upon insertion technique)
6. Complete a normal PSG hook-up with the exception of the following;
    a. Respiratory Inductance Plethysmography (RIP) belts. RIP belts generate a magnetic field that interferes with the Inspire telemetry. Non-RIP belts must be used.
    b. Electrocardiogram (EKG). The right arm electrode should be moved to the back to allow for attachment of the Inspire telemetry unit.
7. Connect the Inspire telemetry unit to the Inspire Pulse Generator (IPG)
8. Determine the current amplitude setting the patient is using at home. When starting the Inspire device start titration 0.2 volts (V) below current home setting.
9. Follow normal Lights Out procedures. Document the Inspire device is off.
10. Turn on the Inspire device after 15-20 minutes of consolidated sleep or if frequent events are noted and are preventing the patient from achieving consolidated sleep.
11. Refer to the attached algorithm, Standardized Fine Tune Algorithm
    - Recommended starting amplitude is 0.02V below incoming home amplitude.
    - Increase amplitude by 0.1-0.2V for apneas or hypopneas
    - Increase amplitude by 0.1V for loud snoring or persistent Respiratory Event Related Arousals (RERA)
    - If the patient raises complaints regarding stimulation, decrease amplitude by 0.2V and turn therapy off. Resume titration once consolidated sleep is achieved.
    - Flow limited events without arousals or desaturations, continue to observe only.
12. If the room air baseline oxygen saturation (SpO2) is ≤88% for a minimum duration of at least 10 consecutive minutes **in the absence of sleep disordered breathing events (including snoring)**, apply oxygen. Refer to the Sleep Lab policy titled Oxygen Administration.
13. Complete Inspire Fine Tune Recap and discuss with the Sleep Support Specialist prior to lights on.

Components:

1. Patient education
2. Patient hook-up
3. Patient hook-up
    a. International 10-20 hook-up
    b. Inspire telemetry unit
    c. Chin Electromyograph (EMG)
    d. Eye Electrooculogram (EOG)
    e. Anterior Tibialis leads right and left
    f. Chest non-RIP belt
    g. Abdomen non-RIP belt
    h. Oximeter
    i. Snore microphone
4. Patient to bed
5. Lights out
6. Impedance check
7. Machine calibration
8. Patient calibration
9. Machine calibration
10. Lights on

11. Disassemble PAP device and remove all electrodes and process each for disinfection or disposal per policy.

Standardized Fine Tune Algorithm for UAS*



*Adapted from current practice guidelines established for CPAP titration by the American Academy of Sleep Medicine, ref: Journal of Clinical Sleep Medicine, Vol. 4, No 2, 2008

Reference:
Inspire Sleep Center Guide Rev A

See Procedure Clinical Guidelines for Titration of Hypoglossal Nerve Stimulation Device

Approved by: /s/ 3/20/2023 Michael Taylor — Date Director, Pulmonary Services /s/ 3/19/2023 Andre Aguillon, M.D. — Date Medical Director /s/ 3/20/2023 Russell Smith — Date Senior Hospital Administrator *Review/Revision Completed By:* *Director, Sleep Disorders*	**Review/Revision Date:** 03/23 **Next Review Date: 03/26**
Policies Superseded by This Policy:	