Hypoglossal Nerve Stimulation
Clinical Coverage Criteria

Overview

Sleep-Disordered Breathing, often referred to as obstructive sleep apnea (OSA), is characterized by frequent episodes of apnea or hypopnea during sleep. Multiple detrimental physiologic changes may result from these apneic and hypopneic episodes. Non-surgical and surgical approaches to obstructive apnea and hypopnea have been developed.

Hypoglossal nerve stimulation is an alternative for those who have failed or cannot tolerate CPAP. The system consists of 3 different components implanted with a neurostimulator placed on the hypoglossal nerve to control stimulation to moderate the patient's breathing cycle. The patient can control this system via a remote before and after sleeping.

Policy

This Policy applies to the following Fallon Health products:

☒ Fallon Medicare Plus, Fallon Medicare Plus Central (Medicare Advantage)

☒ MassHealth ACO

☒ NaviCare HMO SNP (Dual Eligible Medicare Advantage and MassHealth)

☒ NaviCare SCO (MassHealth-only)

☒ PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)

☒ Community Care (Commercial/Exchange)

Fallon Health requires prior authorization for hypoglossal nerve stimulation including insertion/implantation, replacement or revision and removal of hypoglossal nerve neurostimulator and or related components.

Fallon Health Clinical Coverage Criteria

Fallon Health Clinical Coverage Criteria apply to MassHealth ACO and Community Care members.

Effective for dates of service on or after November 1, 2025, Fallon Health will use InterQual® Criteria when making medical necessity determinations for hypoglossal nerve stimulation using the Inspire® Upper Airway Stimulation System (Inspire Medical Systems, Inc.) for MassHealth ACO and Community Care plan members 18 years of age and older:

For coverage criteria, refer to the InterQual® Criteria in effect on the date of service:

- InterQual® CP:Procedures, Hypoglossal Nerve Stimulator (HNS) Implantation
- InterQual® CP:Procedures, Hypoglossal Nerve Stimulator (HNS) Revision or Removal and/or Replacement

Additionally, hypoglossal nerve stimulation using the Inspire® Upper Airway Stimulation System (Inspire Medical Systems, Inc.) may be considered medically necessary for MassHealth ACO and Community Care plan members ages 13 to 18 years with Down syndrome and severe OSA (AHI≥10 and ≤50) who:

- Do not have complete concentric collapse at the soft palate level, and
- Are contraindicated for, or not effectively treated by, adenotonsillectomy, and

- Have been confirmed to fail, or cannot tolerate, PAP therapy despite attempts to improve compliance, and
- Have followed standard of care in considering all other alternative/adjunct therapies.

Medicare Variation

Medicare statutes and regulations do not have coverage criteria for surgery for hypoglossal nerve stimulation. Medicare does not have an NCD for hypoglossal nerve stimulation. National Government Services, Inc., the Part A and B Medicare Administrative Contractor with jurisdiction in the Plan's service area has an LCD for Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea (L38387) (Medicare Coverage Database search 09/20/2025). Coverage criteria for surgery for hypoglossal nerve stimulation are fully established by Medicare; therefore, the Plan's coverage criteria are not applicable.

Link: LCD Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea (L38387)

MassHealth Variation

MassHealth does not have Guidelines for hypoglossal nerve stimulation (MassHealth website search 09/20/2025), therefore, the Plan's coverage criteria are applicable.

Exclusions

- Hypoglossal nerve stimulation (unilateral) using the Inspire Upper Airway Stimulation System (Inspire Medical Systems) is considered experimental/investigational and not medically necessary when coverage criteria in this medical policy are not met.
- Hypoglossal nerve stimulation (bilateral) using the Genio 2.1 System (Nyxoah, Inc., Wilminton, DE) is considered experimental/investigational and not medically necessary.

Summary of Evidence

Background

The diagnosis of obstructive sleep apnea (OSA) involves measuring breathing during sleep, based upon polysomnogram (PSG). Due to the high prevalence of OSA, there is significant cost associated with evaluating all patients suspected of having OSA with PSG (currently considered the gold standard diagnostic test). Further, there also may be limited access to in-laboratory testing in some areas. Home sleep apnea testing (HSAT), which has limitations, is an alternative method to diagnose OSA in adults, and may be less costly and more efficient in some populations. Measurement error is inevitable in HSAT, compared against PSG, as standard sleep staging channels are not typically monitored in HSAT (e.g., EEG, EOG and EMG monitoring are not typically performed), which results in use of the recording time rather than sleep time to define the denominator of the respiratory event index (REI; the term used to represent the frequency of apneas and hypopneas derived from HSAT) (Kapur et al., 2017).

The third edition of the International Classification of Sleep Disorders (ICSD-3) defines OSA as a PSG-determined obstructive respiratory disturbance index (RDI) ≥ 5 events per hour associated with the typical symptoms of OSA (e.g., unrefreshing sleep, daytime sleepiness, fatigue or insomnia, awakening with a gasping or choking sensation, loud snoring, or witnessed apneas), or an obstructive RDI ≥ 15 events per hour (even in the absence of symptoms). In addition to apneas and hypopneas that are included in the AHI, the RDI includes respiratory effort-related arousals (RERAs) (AASM, 2014).

The scoring of respiratory events is defined in The AASM Manual for the Scoring of Sleep and Associated Events: Rules, Terminology and Technical Specifications, Version 2.3 (AASM Scoring Manual). However, it should be noted that there is variability in the definition of a hypopnea event. The AASM Scoring Manual recommended definition requires that changes in flow be associated with a 3% oxygen desaturation or a cortical arousal but allows an alternative definition that requires association with a 4% oxygen desaturation without consideration of cortical arousals. Depending on which definition is used, the AHI may be considerably different in a given individual. The discrepancy between these and other hypopnea definitions used in research

studies introduces complexity in the evaluation of evidence regarding the diagnosis of OSA (AASM, 2016).

AHI is the average number of episodes of apnea and hypopnea per hour of sleep without the use of a positive airway pressure (PAP) device and can only be measured in a type 1 (facility-based polysomnogram) or type II home-based sleep study. RDI is the episodes of apnea and hypopnea per hour of recording without the use of PAP and is reported in type III or IV home sleep study (Kapur et al., 2017).

Hypoglossal Nerve Stimulation Regulatory Status

Inspire® Upper Airway Stimulation System

The Inspire® Upper Airway Stimulation System (Inspire Medical Systems) received FDA PMA approval on April 30, 2014 (P130008) to treat a subset of patients with moderate to severe obstructive sleep apnea (apnea-hypopnea index [AHI] greater than or equal to 20 and less than or equal to 65). Product code: MNQ. In June 2017, approval was granted to expand the AHI range from 20 to 65, to 15 to 65 events per hour (P130008 S021). In April 2020, Inspire® received approval to expand the indications to include adolescent patients age 18 to 21 with moderate to severe OSA (15 ≤ AHI ≤65) who:

- Do not have complete concentric collapse at the soft palate level
- Are contraindicated for, or not effectively treated by, adenotonsillectomy
- Have been confirmed to fail, or cannot tolerate, PAP therapy despite attempts to improve compliance
- Have followed standard of care in considering all other alternative/adjunct therapies

For this approval, existing adult clinical data was leveraged to support the reasonable assurance of safety and effectiveness of the device in the pediatric subpopulation of adolescents aged 18 to 21 (P130008 S039). The primary study to support expansion in indications for use is the STAR trial in adult patients which was used to support the original PMA. In March 2023, the FDA expanded the indications further to include pediatric patients ages 13 to 18 years with Down syndrome and severe OSA (10 ≤ AHI ≤ 50 (P13008 S089). Data from the pediatric Down syndrome study was used to support the expanded indications for use. In June 2023, Inspire® received approval for expanding the indications for use to OSA patients with an upper limit baseline AHI to 100 (increase from ≤ 65 to ≤ 100) and increasing the upper limit body mass index (BMI) warning to 40 (increase from ≤ 32 to ≤ 40). Real world evidence data from Inspire Medical's ADHERE Registry (ongoing observational study) was used to support the expanded indication for use and update to the BMI warning.

As part of the conditions of approval of the original PMA, two post-approval studies were initiated. One study was a continuation of the original IDE cohort of the STAR trial out to 5 years. A new enrollment study was also initiated in a new cohort of patients to be studied out to 5 years. In addition, Inspire has established a registry (ADHERE) which has been considered as part of this evaluation.

On August 1, 2024, the Inspire® Upper Airway Stimulation System received approval for a new implant device, the Inspire V Model 3150 Implantable Pulse Generator. The Model 3150 IPG is the new version of the currently approved Model 3028 IPG. The Inspire V only has 2 implanted components, consisting of the Inspire V Model 3150 IPG and the Inspire stimulation lead.

Genio® System 2.1

On August 8, 2025, the Genio® System 2.1 (Nyxoah, Inc., Wilminton, DE) received FDA PMA approval (P240024) for use in the treatment of moderate to severe Obstructive Sleep Apnea (OSA) (apnea-hypopnea index [AHI] of greater than or equal to 15 and less than or equal to 65). The Genio® System 2.1 is intended for adult patients 22 years of age and older who have been confirmed to fail, cannot tolerate or are ineligible to be treated with current standard of care treatments including lifestyle modifications, positive airway pressure (PAP) treatments (such as continuous positive airway pressure [CPAP] or bi-level positive airway pressure [BiPAP] machines), oral appliances (such as mandibular advancement devices), and pharmacotherapy (such as tirzepatide). Product code: MNQ. Results from the Premarket Approval (PMA) study

(Dual-sided Hypoglossal neRvE stimulAtion for the treatMent of Obstructive Sleep Apnea [DREAM]) for the Genio® System 2.1 (Clinicaltrials.gov NCT03868618, IDE G190068) were used to establish a reasonable assurance of safety and effectiveness of bilateral hypoglossal nerve stimulation with the Genio® System 2.1 to treat adult subjects with moderate to severe OSA. The results of DREAM are available online ahead of print (Woodson et al., 2025) and in the FDA Summary of Safety and Effectiveness.

The conditions of the PMA approval include:

1. Extended Follow-up of the Premarket Cohort (DREAM Study): This is a prospective, single-arm cohort study designed to evaluate the long-term safety and efficacy of the Genio® system in 115 subjects previously implanted under the premarket study, with follow-up extending to 5 years post-surgery.
2. New enrollment study (Post-Approval Study): This study will be conducted according to CL-DREAMON-2024 Protocol dated March 12, 2025. This multicenter, prospective, single-arm, post-approval study aims to demonstrate the long-term safety and effectiveness of the Genio® System (IS Model #2954) in treating subjects diagnosed with moderate to severe obstructive sleep apnea (OSA) who are intolerant to or have failed/refused positive airway pressure (PAP) treatments.

Clinical Studies for Inspire® Upper Airway Stimulation System

Strollo et al., 2014 published 12 month results of the STAR (Stimulation Therapy for Apnea Reduction) Premarket Approval (PMA) study. (ClinicalTrials.gov NCT01161420). The STAR trial was a multi-center, prospective trial with a 12-month single arm study and a randomized controlled therapy withdrawal study at 13 months. The STAR trial was conducted at 15 clinical sites in the United States and 7 in Europe. The STAR trial subjects were evaluated prior to implant to ensure the following:
1) that their pre-implant AHI (as scored during an in-laboratory sleep study prior to implant) was between 20 and 50 events per hour,
2) that any AHI contribution from central or mixed sleep apnea was less than 25%,
3) that subjects did not have primarily lateral OSA (defined as limited sleep apnea when lying on their side), and
4) that the subjects did not have a complete concentric collapse at the level of the soft palate while observed during a drug-induced sleep endoscopy (DISE).

Of 929 participants enrolled in STAR, 205 were excluded before undergoing a screening test. An additional 598 participants were excluded after the screening assessment, which included polysomnography, consultation with the surgeon, and endoscopy during sleep; 56 of these participants were excluded after the endoscopy was performed during drug-induced sleep (25% of the 222 participants who underwent the procedure).

The study population in STAR consisted of 126 participants (83% of whom were men), with a mean age of 54.5 years (range, 31 to 80) and mean BMI of 28.4 (range, 18.4 to 32.5). Per protocol, all participants had a history of nonadherence to CPAP therapy. A total of 124 of 126 participants (98%) completed the follow-up at 12 months (1 patient died from a cardiac event thought to be unrelated to the device and 1 patient elected to remove device).

STAR had two (2) co-primary effectiveness endpoints based on patient-level reductions in the AHI and the ODI from baseline to month 12.

- For the first co-primary endpoint, the study defined a responder to the Inspire® UAS therapy as a patient with at least a 50% reduction in the AHI compared to the mean of the pre-implant screening and 1-month visit (post-implant but prior to therapy activation) and AHI less than 20 events per hour.
- For the second co-primary endpoint, the study defined a responder as a patient with a 25% or greater reduction in ODI at the 12-Month visit compared to baseline (i.e., the mean of the pre-implant screening and 1-month visit).

Secondary outcome measures in STAR included self-reported sleepiness and disease-specific quality of life as assessed with the use of the Epworth Sleepiness Scale (scores range from 0.0 to

24.0, with higher scores indicating more daytime sleepiness), disease-specific quality of life, as assessed with the use of the Functional Outcomes of Sleep Questionnaire (FOSQ; scores range from 5.0 to 20.0, with higher scores indicating greater functioning), and the percentage of sleep time with the oxygen saturation less than 90%.

Following the 12-month visit, the first 46 consecutive responding subjects were randomized 1:1 to either a therapy maintenance group (ON group) or a therapy withdrawal group (OFF group). This design filtered out persons who had not had a response to therapy. The therapy-withdrawal group had the device turned off for 7 days, whereas the therapy-maintenance group continued with the device turned on. Polysomnography was performed after the randomization period to measure the effects of therapy withdrawal, as compared with continued use of the therapy. A subsequent sleep study of the two randomized groups was conducted, and results were compared between the two groups. Blinding was not possible during the study since the stimulation therapy evokes a physiological response in the subjects. However, the primary endpoints were based on the objective measures of AHI and oxygen desaturation index (ODI) which were collected during an overnight sleep study using PSG.

The Inspire® Upper Airway Stimulation system consists of implanted components including the implantable pulse generator, stimulation lead and sensing lead, and external components such as the physician programmer and the patient programmer. Inspire® was successfully implanted in all 126 participants. A total of 124 of 126 participants (98%) completed the follow-up at 12 months.

The STAR Pivotal Trial met all primary and secondary effectiveness outcomes. At the 12-month visit, the criteria for the coprimary outcome of a reduction of at least 50% in the AHI score from baseline and an AHI score of less than 20 events per hour were met by 66% of the participants (83 of 126 participants; lower boundary of the 97.5% confidence interval [CI], 57). The criterion for the coprimary outcome of a reduction of at least 25% in the ODI score from baseline was met by 75% of participants (94 of 126; lower boundary of the 97.5% CI, 66). Both primary efficacy outcomes exceeded the predefined study objectives.

The scores on the AHI and ODI (primary outcome measures) were lower (indicating fewer episodes of sleep apnea) at 12 months than at baseline. The median AHI score decreased 68%, from the baseline value of 29.3 events per hour to 9.0 events per hour (P<0.001). The median ODI score decreased 70%, from 25.4 events per hour to 7.4 events per hour (P<0.001).

Among the 46 consecutive participants with a response to therapy who underwent randomization, the demographic and clinical characteristics at baseline were similar with regard to age, BMI, neck size, and AHI and ODI scores. By design, participants who had not had a response were not included in this part of the study. The AHI and ODI scores were similar in the two groups at 12 months (baseline of the randomized portion of the trial). There was a significant difference between the therapy-withdrawal group and the therapy-maintenance group with respect to the change in AHI scores from the beginning of the randomization period at 12 months to the assessment 1 week later. Among the 23 participants in the therapy-withdrawal group, the AHI score was significantly higher at the 1-week assessment than it was at the start of the randomized phase (25.8 vs. 7.6 events per hour, P<0.001). The average increase in the AHI score in the therapy-withdrawal group was 18.2 events per hour, whereas the average increase in the therapy-maintenance group was 1.7 events per hour (difference in changes in mean scores, 16.4±12.0 events per hour (P<0.001). A similar effect was observed with respect to the mean ODI scores. A similar effect was observed with respect to the mean ODI scores.

Two participants had a serious device-related adverse event requiring repositioning and fixation of the neurostimulator to resolve discomfort. A total of 33 serious adverse events not considered to be related to the implantation procedure or implanted devices were reported. Most of nonserious adverse events related to the procedure (88%) occurred within 30 days after implantation and were expected postsurgical events, including sore throat from intubation, pain at the incision site, and muscle soreness.

Yu et al., 2022 reported results of A Pilot Study to Evaluate the Hypoglossal Nerve Stimulator in Adolescents With Down Syndrome and Obstructive Sleep Apnea (ClinicalTrials.gov Identifier:

NCT02344108). The prevalence of obstructive sleep apnea (OSA) in children with Down syndrome is as high as 80% compared with less than 5% in the general pediatric population. Although adenotonsillectomy is the first-line treatment for pediatric OSA, only 16% to 33% of children with Down syndrome have resolution of OSA after adenotonsillectomy alone. Many require subsequent continuous positive airway pressure (PAP) support, which is often poorly tolerated owing to coincident sensory integrative disorders.

This study was a Phase 1, single-group, multicenter clinical trial of the safety and effectiveness of hypoglossal nerve stimulation for adolescent patients with Down syndrome and persistent severe OSA. The study was conducted at Massachusetts Eye and Ear, Cincinnati Children's Hospital Medical Center, Children's Healthcare of Atlanta, Children's Hospital of Pittsburgh, and Children's Hospital of The King's Daughters. The US Food and Drug Administration (FDA) also issued an investigational device exemption for the study.

Patients with Down syndrome were included if they were adolescents (at least 10 years of age and younger than 22 years of age, per American Academy of Pediatrics definition) and had persistent severe OSA, defined as an AHI of 10 events/h or more after adenotonsillectomy and either the inability to tolerate PAP or nighttime tracheostomy dependence. Children were not excluded if they were autistic or nonverbal, or if they had any baseline sensory processing disorders.

If patients did not have a polysomnogram in the 6 months prior to enrollment, they underwent polysomnography at baseline to confirm eligibility. Patients meeting inclusion criteria then underwent drug-induced sleep endoscopy under sedation with propofol and/or dexmedetomidine. The velum, oropharynx, tongue base, epiglottis (VOTE) classification scheme was used to score the drug-induced sleep endoscopy examination. Videos of the drug-induced sleep endoscopy were reviewed independently by 3 of the investigators, and patients were excluded if they had circumferential palatal collapse as determined by at least 2 of the 3 reviewers.

Eligible patients then received a hypoglossal nerve stimulator implant using techniques as previously described. One month after the implant, the nerve stimulators were activated in the clinic and then turned off. The evening of activation, patients initially underwent polysomnography to ensure that they could tolerate the stimulation, after which they were discharged from the hospital to use the therapy nightly. Follow-up polysomnograms were subsequently obtained at 2, 6, and 12 months. The 12-month polysomnography was completed as a full-night effectiveness study to assess OSA outcome measures at the incoming stimulation settings.

Of the 67 patients screened to reach the enrollment goal of 42 patients. All 42 patients (28 male patients [66.7%]; mean [SD] age, 15.1 [3.0] years) underwent a hypoglossal nerve stimulator implant without intraoperative complications, and no patients subsequently had the device removed. Most patients were discharged from the hospital on postoperative day 1, with the exception of 1 patient who was discharged the same day and 1 patient who was observed for 3 nights prior to hospital discharge owing to some concurrent upper respiratory infection symptoms.

The mean (SD) change in AHI at 12 months was a decrease of 12.9 (13.2) events/h (95% CI, –17.0 to –8.7 events/h). The mean (SD) percentage change in AHI was –51.2% (95% CI, –35.3% to –67.0%). There were 27 of 41 patients (65.9%) who were classified as therapy responders, defined as at least a 50% postoperative decrease in AHI. At the 12-month polysomnogram, 30 of 41 patients (73.2%) had an AHI of less than 10 events/h, 14 of 41 patients (34.1%) had an AHI of less than 5 events/h, and 3 of 41 patients (7.3%) had an AHI of less than 2 events/h. There was a mean (SD) increase in hypopnea predominance of 5.6% (33.9%) (95% CI, –5.2% to 16.5%), with a mean hypopnea predominance of 74.5% at baseline compared with a mean hypopnea predominance of 80.3% at 12 months. One patient at baseline had a tracheostomy for OSA; this patient was able to have the tracheostomy tube removed after upper airway stimulation. There was a mean (SD) decrease in the percentage of time with oxygen saturation below 90% of 0.8% (3.1%) (95% CI, –1.7% to 0.2%) and a mean (SD) increase in the oxygen saturation nadir of 3.2% (4.6%) (95% CI, 1.8%-4.7%). Sex, age, baseline AHI, and overweight body mass index percentile (adjusted for age and sex) were not associated with therapy response.

Although there was a high overall therapy response rate, most patients in this study still had an AHI of more than 5 events/h at the end of the study, or residual moderate sleep apnea. The mean (SD) nightly duration of therapy was 9.0 (1.8) hours. A total of 40 patients (95.2%) used the upper airway stimulation device at least 4 hours a night for 70% of the nights (the definition of PAP adherence as defined by the Center for Medicare & Medicaid Services); the 2 patients who did not were both therapy nonresponders.

The most common complication was tongue or oral discomfort or pain, which occurred in 5 patients (11.9%) and was temporary, lasting weeks or rarely months. One patient had worsening of central apnea based on the 1-month activation polysomnogram suggestive of post-obstructive central hypoventilation. Four patients (9.5%) had device- or surgery-related readmissions. The readmissions were the result of device extrusion due to the patient picking at the submental incision (resolved after replacement of the extruded device), surgical site infection at the chest incision exacerbated by patient picking (resolved with antibiotics), poorly controlled postoperative pain, and discomfort from sensing the stimulation in the jaw and chest (resolved without intervention).

This study elucidated the challenges associated with upper airway stimulation for pediatric patients with Down syndrome and OSA. There was a higher rate of readmission than previously published in the adult literature. The authors suggest that this finding may be partially due to a low threshold for readmission for a high-risk pediatric population. One patient experienced worsening of central apnea after device activation, so polysomnography the night of activation is recommended for this population. Another contributing factor is the increased prevalence of sensory processing disorders in children with Down syndrome.

Clinical Studies for Genio® System 2.1

Results of the Premarket Approval (PMA) study for the Genio® System 2.1 (Clinicaltrials.gov NCT03868618) are available online ahead of print (Woodson et al., 2025) and are summarized in the FDA Summary of Safety and Effectiveness (P240024B).

The Genio® System 2.1 consists of one implanted device, the implantable stimulator, and three external devices: the activation chip, the disposable patch and the charging unit. This implant is surgically implanted under the chin during a surgical procedure close to the hypoglossal nerve. Electrodes in the implantable stimulator allow energy to flow to the hypoglossal nerve, resulting in the stimulation of the nerve and contraction of the tongue muscles. This process can help maintain open airway and normalize breathing while sleeping. The activation chip is the power source of the implantable stimulator. The activation chip contains a rechargeable battery and is programmed with therapy settings as determined by the health care provider. The charging unit and its power adapter are used to charge the activation chips battery during the day, in order to be ready for the next night. The disposable patch is a single-use adhesive patch that is placed on the skin under the chin. When the activation chip is snapped into the disposable patch’s clip, they work together to transmit stimulation energy to the implantable stimulator. Participants with beards are counseled that facial hair needs to be trimmed to enable the patch to adhere to the skin. The Genio® Smartphone Application communicates with the Activation Chip and allows the patient to pause and resume treatment, adjust stimulation intensity within a pre-defined safe range, and access usage information.

The DREAM study was a multi-center, prospective, open-label, non-randomized, single arm clinical study to demonstrate the safety and effectiveness of the Genio® dual-sided hypoglossal nerve stimulation system in treating moderate to severe OSA over a period of 12 months post-surgery.

The DREAM study was conducted using the first generation model of the implantable stimulator. Although the original implantable stimulator and implantable stimulator Model 2954 differ in certain characteristics, the two versions of the Genio® System 2.1 implant were considered functionally equivalent in key areas such as: electronic circuitry, stimulation parameters used, active stimulation area of the electrodes, mode of communication with the activation chip Model 2364, and use of external components. Based on all the non-clinical and pre-clinical testing conducted for implantable stimulator Model 2954, it was concluded that the changes made for the

implantable stimulator Model 2954 did not impact the performance or functionality of the implant when compared to the original implantable stimulator. Considering both the similarities between the original implantable stimulator and the implantable stimulator Model 2954 as well as the assessment of the design changes, the clinical data obtained with the original implantable stimulator during the DREAM IDE study was considered leverageable for the implantable stimulator Model 2954.

The DREAM study had two co-primary efficacy endpoints: the first measured the percentage of responders at 12 months based on a 50% reduction in AHI4 (Apnea-Hypopnea Index based on 4% oxygen desaturation) and a remaining AHI4 of less than 20, and the second measured the percentage of responders based on a 25% reduction in ODI4 (Oxygen Desaturation Index based on 4% desaturation), both assessed with fixed therapeutic settings on full-night Polysomnography (PSG).

The objective was to demonstrate at least 50% responders for both AHI4 and ODI4 at 12 months, with the study considered successful if the null hypotheses were rejected for both endpoints. Patient success was defined as clinically significant reduction in OSA and improvements in overall sleep quality.

There were six secondary effectiveness endpoints, focusing on: OSA-specific quality of life measured by the SNORE-25 instrument; hypoxemic burden measured by the percentage of sleep time with oxyhemoglobin saturation< 90%; intermittent hypoxia measured by the ODI4; the sleep-specific function measured by the Functional Outcomes of Sleep Questionnaire (FOSQ-10); the sleep propensity measured by the Epworth Sleepiness Scale (ESS) and change in OSA severity.

With regards to safety, evaluation was conducted using the incidence of device and/or procedure serious events recorded during the study for a period of 12 months post-surgery.

The patients were scheduled for screening and baseline evaluations before implant and follow up post-surgery up to 12 months. At the 6-month visit, the investigator assessed if the therapy was optimized based on a positive change in AHI and ODI from baseline. If therapy was considered optimized, study visits were scheduled at 9- and 12-months. If the therapy was not optimized, study visits were scheduled at 8-, 10- and 12-months.

Between October 14, 2020, and March 3, 2023, the DREAM study enrolled 687 participants. These participants were evaluated against predefined patient selection criteria, which included adults with moderate to severe obstructive sleep apnea (OSA) that had failed or not tolerated Positive Airway Pressure (PAP) treatments, having a BMI less than or equal to 32, without complete concentric collapse at the soft palate level (evaluated by performing a Drug Induced Sleep Endoscopy [DISE]). A total of 568 subjects (82.7%) were screen failures and did not receive an implant. Drug-induced sleep endoscopy excluded 64 participants with complete concentric collapse of the soft palate. Forty-two participants were excluded for being unwilling to comply with study requirements. Ultimately, 119 patients met inclusion criteria, but the study was capped at 115 participants, leading to 4 participants being excluded after the 115th participant was implanted. A total of 115 subjects (16.7%) from 19 investigative sites had an attempted implant with 113 (16.4%) of those successfully implanted with the Genio® System.

Safety and effectiveness in the following groups have not been established with the Genio® System 2.1:

- Patients below 22 or above 75 years of age
- Patients with a Body Mass Index (BMI) above 32 kg/m2
- Patients with an Apnea Hypopnea Index (AHI) below 15 or over 65 events/hr
- Patients with Complete Concentric Collapse (CCC) at the soft palate level

The following sets of population were used in the analysis of the DREAM study: the Enrolled set (n=687), the Safety (SAF) set (n=115), the Full Analysis (FA) set (n=110), and the Per Protocol (PP) set (n=88). The FA set included all subjects who successfully completed the implant procedure. Three subjects successfully implanted in Australia were not included in FA set due to the unmonitored status of their data (Good Clinical Practice (GCP) deviation). They were subsequently excluded from the effectiveness analyses. The per-protocol set (PP) included all

subjects from the FA set who performed the 12-month PSG with available values for primary endpoints (AHI4 and ODI4) and without any critical major protocol deviations.

The analysis of effectiveness was based on the full analysis set (FAS) of 110 with worst-case imputation, and per protocol set (PPS) of 88 evaluable patients at the 12-month time point. Additional sensitivity analysis was performed in the safety analysis set (SAF) of 115 subjects.

The primary effectiveness objective of the DREAM trial was to evaluate if the Genio® System provided a clinically significant reduction in OSA in adult subjects. This evaluation was performed by comparing the AHI and ODI at baseline and at the 12-month follow-up visit.

After the 6-month study visit, fifty-six (48.7%) participants were deemed not yet optimized with treatment and went on to have 8- and 10-month PSGs. Over the course of the study, 70 participants underwent at least one unscheduled study visit.

At the 12-month post-implant PSG, the AHI and ODI co-primary outcome responder rates across participants in the SAF set (n=115) were 63.5% (73/115, p = 0.002) and 71.3% (82/115, p<0.001), respectively using the worst-case imputation method with missing data considered a non-response. The improvement occurred in all sleeping positions, which reflected in the non-supine and supine AHI of 12.7±12.8 events/hr and 48.9±19.6 events/hr, respectively (n=110) being reduced to 5.2±8.2 events/hr and 22.7±19.9 events/hr (n=89, p<0.001). In summary, overall median AHI reduction (70.8%), median reduction in supine (66.6%) and median AHI reduction in non-supine (71.0%) sleep positions were comparable.

The AHI and ODI co-primary outcome responder rates in the PP set (n=88) were 81.8% (72/88, p = 0.001) and 92.0% (81/88, p<0.001).

In the FA set (n=110), the AHI and ODI co-primary outcome responder rates were 66.4% (73/110, p <0.001) and 74.5% (82/110, p <0.001).

Both co-primary effectiveness endpoints exceeded the pre-specified performance goal of 50%, confirming the clinical benefit of bilateral hypoglossal nerve stimulation.

Twelve month objective secondary outcomes were assessed in the 89 participants who completed the 12 month PSG. While one of the remaining participants was withdrawn from the study by the site investigator for failure to maintain compliance with nightly therapy use, many of the remaining 26/115 (22.6%) participants missed or did not complete the 12 month PSG per protocol for other quantifiable reasons. All six secondary effectiveness endpoints demonstrated clinically meaningful improvements from baseline to 12 months, including OSA-specific quality of life (SNORE-25), hypoxemic burden (percentage of sleep time with oxygen saturation <90%), intermittent hypoxia (ODI4), functional outcomes (FOSQ-10), daytime sleepiness (ESS), and overall OSA severity (AHI4). These comprehensive improvements indicate broad therapeutic benefit beyond primary efficacy measures.

Out of the 115 patients in whom implant was attempted, 85 (73.9%) experienced a total of 252 non-serious device and/or implant procedure-related AEs. The most common non-serious procedure-related AEs were difficulty swallowing/dysphagia (11.7% of patients) and incision site swelling (12.2% of patients). Among device-related non-serious events, local skin irritation from the Disposable Patch occurred in 24.3% of patients, while stimulation-related discomfort affected 14.8% and tongue discomfort occurred in 12.2% of patients. There were 16 serious adverse events, of which 3 events (2.6%) were unrelated to the device/procedure, while 13 events (11.3%) were device and/or procedure related.

Nyxoah sponsored a prospective, open-label, non-randomized, single arm treatment study of bilateral hypoglossal nerve stimulation using the Genio System at eight centers in three countries (Australia, France and the UK). BiLAteral Hypoglossal Nerve Stimulation for Treatment of Obstructive Sleep Apnoea (BLAST OSA) (NCT03048604) assessed the safety and effectiveness of the Genio System at 6 months post-implantation. BLAST OSA enrolled patients age 21–75 years; body mass index (BMI) ≤32 kg·m2; AHI 20–60 events/hour; no positional OSA (defined as nonsupine AHI <10 events/hour and supine AHI ≥ non-supine AHI×2); absence of soft palate

complete concentric collapse (CCC) during drug-induced sleep endoscopy; and had not tolerated or accepted PAP treatments.

The primary outcome measures were the incidence of device-related serious adverse events (SAEs) and the change in AHI. The secondary outcome measure was the change in the 4% oxygen desaturation index (ODI). Between April 2017 and February 2018, seven centers in France and Australia screened 93 participants into the study (one center was activated in the UK but did not enroll any participants), 66 participants failed the screening after consent and did not receive an implant, 27 participants were implanted with the Genio System.

Among the 27 implanted participants, 22 reached the 6-month follow-up visit. Two participants exited the study prior to the first post-implant PSG due to procedure-related infections. One participant was withdrawn from the study due to non-study-related behavioral issues. Another one should not have been implanted, since only limited hypoglossal nerve stimulation response was observed during the surgery, and was subsequently withdrawn from the study. Finally, one participant was withdrawn as they failed to return for the 6-month end-point visit despite numerous attempts from the center to re-establish contact with the participant.

No device-related SAEs occurred during the 6 months post-implantation. Three out of the 27 implanted participants experienced four SAEs related to the surgical procedure: three were local infections at the surgical site necessitating explantation of the devices at 2 and 3 months after implantation, including two participants at the same center. The corresponding SAEs were resolved without further sequelae. The fourth procedure-related SAE was impaired swallowing, which led to a 1-day prolongation of implantation-related hospitalization. This SAE resolved spontaneously without further sequelae. The most frequent procedure-related non-serious adverse events that occurred in implanted participants were impairment or painful swallowing (30% of participants), dysarthria (26% of participants), hematoma (19% of participants) and swelling or bruising around the incision site (19% of participants). Among the device-related non-serious adverse events, 30% of participants experienced local skin irritation due to the disposable patch, which resolved in all cases except one, which remained present at the 6-month visit. Despite these side-effects, usage of the therapy was high, with 91% of participants using the system >5 days a week and 77% reporting using it >5 h per night.

Mean AHI decreased from baseline to the 6-month PSG from 23.7 ± 12.2 to 12.9 ± 10.1 events/hour ($p<0.0001$); the mean individual percentage decrease was 47.3% (median 48.6%). Additionally, the therapy resulted in 11 participants with a residual AHI <15 events/hour, four participants with AHI <10 events/hour and three participants with AHI <5 events/hour. Mean ODI decreased from baseline to the 6-month PSG from 19.1 ± 11.2 to 9.8 ± 6.9 events/hour ($p<0.0001$); the mean individual percentage decrease was 43.3% (median 47.2%).

Upon CE Mark approval of the Genio® System, Nyxoah initiated the EliSA trial (NCT04031040), a post market clinical follow up study. The purpose of this study is to assess the long-term safety and performance of the Genio® System and to identify any potential new risks not previously encountered during the pivotal study. The EliSA study aims to include 110 implanted patients with a 5-year follow-up period. As of December 12, 2024, 101 patients have been implanted in Germany, the Netherlands, Belgium and Switzerland. The enrollment is ongoing.

American Academy of Sleep Medicine

The American Academy of Sleep Medicine (AASM, 2021) published practice guidelines on the referral of adults with OSA for surgical consultation (Kent et al., 2021). These guidelines replaced the 2010 Parameters for the Surgical Modifications of the Upper Airway for Obstructive Sleep Apnea in Adults (Aurora et al., 2010). The AASM commissioned a task force of experts in sleep medicine, otolaryngology, and bariatric surgery to develop recommendations and assign strengths based on a systematic review of the literature and an assessment of the evidence using the GRADE process. The task force evaluated the relevant literature and the quality of evidence, the balance of benefits and harms, patient values and preferences, and resource use considerations that support the recommendations. The AASM Board of Directors approved the final recommendations. Each recommendations statement is assigned a strength ("Strong" or "Conditional"). A Strong recommendation is one that clinicians should follow under most

circumstances. A Conditional recommendation is one that requires that the clinician use clinical knowledge and experience and strongly consider the patient's values and preferences to determine the best course of action.

The treatment of adults with OSA should be based on a diagnosis of OSA established using objective testing performed in conjunction with a comprehensive sleep evaluation. The AASM guidelines note that positive airway pressure (PAP) is the most efficacious treatment for OSA, but effectiveness can be compromised when patients are unable to adhere to therapy or obtain adequate benefit, which is when surgical management may be indicated. It is expected that surgery proceed only once the surgeon and patient have mutually agreed upon an acceptable risk profile. Inherent to this evaluation is the understanding that some referred patients will not be appropriate for surgical interventions and are expected to be counseled as such by surgical colleagues.

The AASM strongly recommends that clinicians discuss referral to a sleep surgeon with adults with OSA and body mass index (BMI) < 40 kg/m^2 who are intolerant or unaccepting of PAP. The strong recommendation to discuss surgical referral with patients with a BMI < 40 kg/m^2 is not a recommendation against (and does not preclude) discussion of surgical referral with patients with a BMI ≥ 40 kg/m^2 if the health care provider deems it an appropriate management discussion point.

For patients within the BMI range of 35–40 kg/m^2 who are intolerant or unaccepting of PAP, the AASM strongly recommends discussion regarding a referral to both sleep and bariatric surgeons to discuss management options. Other organizations, such as the National Heart, Lung, and Blood Institute, recommend consideration of bariatric surgery for individuals suffering from obesity (class II/III, BMI ≥ 35 kg/m2) and OSA, regardless of PAP adherence status.

The AASM guideline recommendations are based on a systematic review and meta-analysis of 274 studies of surgical interventions, including procedures such as uvulopalatopharyngoplasty (UPPP), modified UPPP, maxillomandibular advancement (MMA), tongue base suspension, and hypoglossal nerve stimulation. The systematic review deemed most included data of low quality, consisting of mostly observational data (Kent et al., 2021a).

A total of 4 RCTs and 239 observational studies investigated the use of surgery as rescue therapy for participants who were intolerant or unaccepting of PAP to improve 1 or more of the following outcomes: excessive sleepiness, quality of life (QOL), sleep quality, snoring, blood pressure (BP), perioperative death, permanent dysphagia, apnea-hypopnea index (AHI), respiratory disturbance index (RDI),lowest oxygen saturation (LSAT), and oxygen desaturation index (ODI). Participants included in the studies had a BMI <40 kg/m^2. Participants in the RCTs had moderate to severe OSA and received UPPP with or without tonsillectomy. Participants in the control group originally received no treatment but were eventually treated with the same procedure(s). Participants in the observational studies represented a broad population of adults undergoing a wide variety of surgical interventions for OSA including palatal modification, tongue base resection, multilevel pharyngeal airway surgery, nasal surgery, maxillomandibular advancement, and hypoglossal nerve stimulation. The Task Force determined that the overall quality of evidence for the use of surgical treatments in patients who are intolerant or unaccepting of PAP was low based on the critical outcomes and downgrading of the evidence due to risk of bias associated with observational studies and imprecision within the RCTs.

Based on their combined clinical experience and the substantial effects of surgery on objective and subjective measures of disease, the Task Force judged that the potential benefits of a discussion regarding referral to a sleep surgeon with patients' intolerant or unaccepting of PAP therapy outweigh the potential harms of untreated OSA. The Task Force observed that the balance of risks vs benefits for upper airway surgery is variable and dependent upon an individual patient's OSA severity, symptoms, medical comorbidities, and selected surgical therapy but noted that a discussion of individualized risks and benefits is a standard component of the preoperative informed consent process.

American Academy of Otolaryngology-Head and Neck Surgery Position Statement: Hypoglossal Nerve Stimulation for Treatment of Obstructive Sleep Apnea (OSA)

The American Academy of Otolaryngology-Head and Neck Surgery considers upper airway stimulation (UAS) via the hypoglossal nerve for the treatment of adult obstructive sleep apnea syndrome to be a safe and effective second-line treatment of moderate to severe obstructive sleep apnea in patients who are intolerant or unable to achieve benefit with positive pressure therapy.

Analysis of Evidence (Rational for Determination)

Evidence from single-arm, open label, industry sponsored studies that unilateral hypoglossal nerve stimulation using the Inspire Upper Airway Stimulation System (Inspire Medical Systems) is associated with improvements in apnea-hypopnea index (AHI) scores in carefully selected patients with moderate-to-severe obstructive sleep apnea (OSA) who have failed or cannot tolerate positive air pressure (PAP) therapy. It will be useful to conduct more definitive randomized, controlled studies or comparative-effectiveness trials in the future. Given the proven safety and efficacy of PAP therapy in patients with OSA, surgery is not a first line therapy.

A bilateral hypoglossal nerve stimulation device, the Genio 2.1 System (Nyxoah, Inc., Wilminton, DE) received FDA PMA approval on August 8, 2024. Results of the pivotal trial (DREAM) are available online ahead of print (Woodson et al., 2025) and in the FDA Summary of Safety and Effectiveness (P240024B). Twenty-seven (27) participants (23.5%) did not complete the trial per protocol, and it is unknown whether a lower degree of attrition would have materially altered the observed per protocol efficacy. Additional studies of bilateral hypoglossal nerve are required to definitively assess safety and efficacy in comparison to unilateral hypoglossal nerve stimulation. At this time, bilateral hypoglossal nerve stimulation using the Genio 2.1 System is considered experimental/investigational and not medically necessary.

Coding

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage or reimbursement.

Inspire® Upper Airway Stimulation System Hypoglossal Nerve Stimulation

For Medicare members, claims for Inspire® Upper Airway Stimulation System hypoglossal nerve stimulation must include primary diagnosis code G47.33 (Obstructive sleep apnea) and a secondary diagnosis code indicating the Body Mass Index (BMI) is less than 35 kg/m2 as set forth in the LCD (i.e., Z68.1-Z68.34).

Implantation

For dates of service on or after 01/01/2022, use CPT code 64582 to report open implantation of the Inspire IV™ Upper Airway Stimulation System.
Note: Hypoglossal nerve stimulation (CPT 64582) is not payable for MassHealth ACO members when performed in an Ambulatory Surgical Center. CPT 64582 is only payable for MassHealth ACO members when performed in an acute outpatient hospital setting.

Code	Description	Device Components
64582	Open implantation of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array	Generator, Stimulation Lead and Breathing Sensor Lead

Revision, Removal and Replacement

For dates of service on or after 01/01/2022, following CPT codes should be used to report revision, removal or replacement of the Inspire IV™ Upper Airway Stimulation System.

Note: Hypoglossal nerve stimulation (CPT 64583 and 64584) are not payable for MassHealth ACO members when performed in an Ambulatory Surgical Center. CPT 64583 and 64584 are only payable when performed in an acute outpatient hospital setting.

Code	Description	Device Components
61886	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to 2 or more electrode arrays	Generator
61888	Revision or removal of cranial neurostimulator pulse generator or receive	Generator
64583	Revision or replacement of hypoglossal nerve neurostimulator array and distal respiratory sensor electrode or electrode array, including connection to existing pulse generator	Stimulation Lead and Breathing Sensor Lead
64584	Removal of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array	Generator, Stimulation Lead, and Breathing Sensor Lead

For dates of service on or after 08/01/2024, CPT code 64568 should be used to report open implantation of the Inspire V™ Upper Airway Stimulation System:

CPT code	Description	Device Components
64568	Open implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator	Generator and Stimulation Lead

For implant/revision or replacement procedures performed in an acute outpatient hospital setting and reimbursed under Medicare OPPS payment methodology, hospitals should report HCPCS code C1767 for the generator, C1778 for the stimulation lead, and C1787 for the patient programmer, as appropriate. Note that pass-through status for these codes expired on 12/31/2002, therefore no separate reimbursement will be made.

For implant/revision/replacement procedures performed in an ASC and reimbursed under Medicare ASC payment methodology, it is not recommended to include separate claim lines for the device components.

For implant/revision/replacement procedures performed under MassHealth acute outpatient hospital payment methodology, reimbursement to the facility is an all-inclusive payment (APEC) that includes all items directly related to the provision of the surgical procedure.

HCPCS code	Description
C1767	Generator, neurostimulator (implantable), non-rechargeable
C1778	Lead, neurostimulator (implantable)
C1787	Patient programmer, neurostimulator
L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
L8680	Implantable neurostimulator electrode, each

Analysis and Programming
Code 95970 is not assigned for device analysis when performed at the time of generator implantation. CPT Manual instructions state that code 95970 describes only “subsequent” electronic analysis of “a previously implanted” generator.

Code 95976 is defined for simple programming and code 95977 is defined for complex programming. Simple programming refers to changing three or fewer parameters. Complex programming refers to changing four or more parameters.

CPT Code	Description	Service
95970	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group(s), interleaving, amplitude, pulse	Device analysis only, without programming, subsequent visits only (not at the time of generator implantation)

	width, frequency (Hz), on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve neurostimulator pulse generator/transmitter, without programming	
95976	Electronic analysis of implanted neurostimulator pulse generator/ transmitter (eg, contact group(s), interleaving, amplitude, pulse width, frequency (Hz), on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional	Device analysis and simple programming (not at the time of generator implantation)
95977	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group(s), interleaving, amplitude, pulse width, frequency (Hz), on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex cranial nerve neurostimulator pulse generator/ transmitter programming by physician or other qualified health care professional	Device analysis and complex Programming (not at the time of generator implantation)

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Policy history

Origination date:	10/15/2024
Review/Approval(s):	Technology Assessment Committee: 07/23/2024, 09/24/2024 (annual review, criteria for hypoglossal nerve stimulation previously included in Surgery for Obstructive Sleep Apnea, updated to include criteria for hypoglossal nerve stimulation for members between the ages of 18 and 21 with moderate to severe OSA, and members ages 13 to 18 with Down syndrome and AHI > 10 and < 50), 9/23/2025 (annual review, adopted InterQual® Criteria for Hypoglossal Nerve Stimulation for MassHealth ACO and Community Care plan members 18 years of age and older effective for dates of service on or after November 1, 2025, added Exclusion for bilateral hypoglossal nerve stimulation using the Genio 2.1 System, updated Coding).

UM Committee: 10/15/2024 (annual review, approved with addition of criteria for members between the ages of 18 and 21 with moderate to severe OSA, and members ages 13 to 18 with Down syndrome and AHI > 10 and < 50), 9/23/2025 (annual review, approved with adoption of InterQual® Criteria for MassHealth ACO and Community Care plan members 18 years of age and older effective for dates of service on or after November 1, 2025 and addition of Exclusion for hypoglossal nerve stimulation using the Genio 2.1 System).

Instructions for Use

Fallon Health complies with CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations for Medicare Advantage members. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health may create internal coverage criteria under specific circumstances described at § 422.101(b)(6)(i) and (ii).

Fallon Health generally follows Medical Necessity Guidelines published by MassHealth when making medical necessity determinations for MassHealth members. In the absence of Medical Necessity Guidelines published by MassHealth, Fallon Health may create clinical coverage criteria in accordance with the definition of Medical Necessity in 130 CMR 450.204.

For plan members enrolled in NaviCare, Fallon Health first follows CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, or if the NaviCare member does not meet coverage criteria in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health then follows Medical Necessity Guidelines published by MassHealth when making necessity determinations for NaviCare members.

Each PACE plan member is assigned to an Interdisciplinary Team. PACE provides participants with all the care and services covered by Medicare and Medicaid, as authorized by the interdisciplinary team, as well as additional medically necessary care and services not covered by Medicare and Medicaid. With the exception of emergency care and out-of-area urgently needed care, all care and services provided to PACE plan members must be authorized by the interdisciplinary team.

Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans.