Medical Policy Reference Manual

Medical Policy

2.01.018 Sleep Disorders

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Description

Sleep disorders include, but are not limited to the following disorders: narcolepsy, nocturnal myoclonus, hypersomnolence, insomnia, and obstructive sleep apnea. While snoring is not, in itself, considered to be a sleep disorder, heavy snoring may be a warning signal that obstructive sleep apnea exists, and that further diagnostic testing may be indicated.

- *Hypersomnolence* (hypersomnia) describes any group of sleep disorders consisting of the need for excessive amounts of sleep and of sleepiness when awake; this may be psychogenic or may have an organic cause.
- *Insomnia* is a prolonged and usually abnormal inability to obtain adequate sleep either due to a disturbance in the sleep mechanism or secondary to another disease or condition.
- *Narcolepsy* is characterized by recurrent, uncontrollable, brief episodes of sleep. It may also be accompanied by cataplexy, hypnagogic hallucinations, or sleep paralysis.
- *Nocturnal myoclonus* is the myoclonic jerking of the limbs occurring as a person is falling asleep or is asleep; in the latter case, it may disrupt sleep.
- *Obstructive sleep apnea syndrome* (OSAS) is characterized by repetitive episodes of upper airway obstruction that occur during sleep, usually associated with a reduction in blood oxygen saturation. Features of OSAS include daytime somnolence, disordered sleep, and a variety of clinical symptoms. It is also common to find decreased motor and perceptual skills while awake, which correlate with the severity of hypoxemia during sleep. The syndrome is most common in middle-aged, obese, male smokers, but also occurs in women and in children who may exhibit loud snoring, daytime somnolence and school failure.

Policy

DIAGNOSTIC TESTING FOR SLEEP DISORDERS

Certain diagnostic studies, including polysomnography, sleep staging and sleep latency tests, are considered **medically necessary** in the diagnosis of certain sleep disorders when performed in an approved sleep center, and as outlined in the Policy Guidelines.

Polysomnography:

Polysomnography is considered **medically necessary** in the diagnosis of obstructive sleep apnea in children and adults in an approved sleep center.

- Polysomnography is the polygraphic recording during sleep of multiple physiologic variables, both directly and indirectly related to the state and stages of sleep, to assess possible biological causes of sleep disorders or to evaluate the patient's response to therapy.
- A polysomnogram (CPT® code 95808) is distinguished from sleep studies (CPT® code 95807) by the inclusion of sleep staging which includes a 1-4 lead electroencephalogram (EEG), electro-oculography to monitor eye movements and REM sleep, submental electromyography, respiratory monitoring with inductance plethysmography of the chest (or diaphragmatic or intercostal myography) to determine respiratory excursions, a single lead ECG for continuous heart rhythm monitoring, ear or pulse oximetry to measure arterial oxygen saturation, electromyographic monitoring of the anterior tibialis muscle to assess sleep-associated leg movements, and nasal airflow studies.
- A "split-night" polysomnogram (CPT® code 95811) includes both the diagnostic polysomnogram and CPAP titration in a single overnight session.

Sleep Latency Testing:

Multiple sleep latency testing (MSLT) is considered **medically necessary** when performed in an approved sleep center when used to exclude or confirm narcolepsy in the diagnostic work-up of OSAS.

- Multiple sleep latency testing (MSLT) (CPT® code 95805) involves repeated measurement of sleep latency, which is the time to the onset of sleep. The test is performed in the daytime under standardized and controlled conditions following quantified nocturnal sleep. Usually two to six tests are performed, one testing every two hours, to measure daytime sleep tendency. MSLT is generally not necessary in the diagnosis of OSAS, but in some cases may be indicated to exclude or confirm narcolepsy in the diagnostic work-up of OSAS.

Quantitative electroencephalography (QEEG) (Topographic Brain Mapping):

Quantitative electroencephalogram (QEEG) mapping is considered **experimental / investigational** in the diagnosis and/or medical management of any of the sleep disorders, as it does not meet TEC criteria # 2-5. Standard electroencephalographic measurement during sleep is performed as part of the polysomnogram.

Portable Sleep Studies:

Unattended sleep studies performed in the home setting using a clinically validated Level II or Level III monitoring device is considered **medically necessary**. See Policy Guidelines for unattended home sleep studies.

Unattended Home Sleep Studies which do not meet Level II or Level III AASM clinical standards are considered **experimental / investigational** (CPT 95801) as they do not meet TEC criteria # 2-5.

Actigraphy:

Actigraphy (95803), the monitoring and recording of movement activity during the sleep / wake cycle, is considered **experimental / investigational** for the diagnosis of sleep disorders as it does not meet criteria # 2-5.

MANAGEMENT OF SLEEP DISORDERS: Medical Intervention

Narcolepsy, nocturnal myoclonus, and insomnia:
Treatment includes a combination of various pharmacologic agents and / or medical management

techniques.

Obstructive Sleep Apnea Syndrome (OSAS):
The following treatments are considered medically necessary in the medical management of obstructive sleep apnea syndrome (OSAS) when it is accompanied by excessive daytime somnolence, and when polysomnographic documentation of apneic episodes has determined that they are not of central nervous system origin:

Nasal continuous positive airway pressure (nCPAP): nCPAP devices are worn by the patient during sleep. Continuous positive airway pressure is delivered by a flow generator through a mask to supply a pressure level sufficient to keep the upper airway open. The autotitrating CPAP device automatically adjusts the pressure according to the upper airway obstruction. nCPAP is **medically necessary** for the treatment of obstructive sleep apnea.

Bi-level positive airway pressure (BiPAP): This device is also worn during sleep. It delivers a bi-level positive airway pressure in patients unable to tolerate nCPAP. BiPAP is **medically necessary** for the treatment of obstructive sleep apnea when nCPAP is not tolerated.

- There are two types of BiPAP systems: BiPAP-S and BiPAP-ST. The BiPAP-S (spontaneous) is an airway management system, and the BiPAP-ST (spontaneous / timed) is a ventilator support system.

Intra-oral prostheses, including the **Equalizer® tongue retaining device:** These devices are considered **medically necessary** for certain patients with documented sleep apnea.

Provent™ Sleep Apnea Therapy is considered experimental / investigational as it does not meet criteria #2-5.

MANAGEMENT OF SLEEP DISORDERS: Surgical Intervention

Narcolepsy, nocturnal myoclonus, and insomnia:
These disorders are not treated with surgery.

Surgical Intervention:
Surgery is not the first treatment of choice for OSAS. All forms of conservative medical management, including weight loss, nasal continuous positive airway pressure (nCPAP) and bi-level positive airway pressure (BiPAP) are appropriate treatment options prior to surgical intervention.

Obstructive Sleep Apnea Syndrome (OSAS): There are several surgical options available for the treatment of obstructive sleep apnea syndrome (OSAS):

- **Laser-assisted uvulopalatoplasty (LAUP)** (HCPCS code S2080) is considered **experimental / investigational** for the treatment of obstructive sleep apnea syndrome, as it does not meet TEC criteria # 2 - 5.
- **Mandibular and maxillary advancement (MMA)** surgery is more aggressive than uvulopalatopharynogoplasty (UPPP) and is considered **medically necessary** for the treatment of obstructive sleep apnea syndrome in patients who have failed UPPP.
- **Minimally invasive anterior suspension of the base of the tongue**, in which a percutaneous bone screw system (example: Repose™) used as anchor point for suturing the tongue base to prevent its' collapse, is considered **experimental / investigational** for the treatment of obstructive sleep apnea syndrome, as it does not meet TEC criteria # 2 - 5.

- **Palatal stiffening procedures**, including but not limited to, cautery-assisted palatal stiffening operation (CAPSO), and the implantation of palatal implants (example: The Pillar® Palatal Implant System) are considered **experimental / investigational** as a treatment for obstructive sleep apnea syndrome as these procedures do not meet TEC criteria # 2-5.
- **Radiofrequency tissue volume reduction**, (RFTVR) (example: Somnoplasty®) (41530) a technique in which excess tissue at the base of the tongue is reduced using radiofrequency energy, is considered **experimental / investigational**, as it does not meet TEC criteria # 2, 3, and 5.
- **Surgery to tonsils and / or adenoids** is considered **medically necessary** in children with documented obstructive sleep apnea.
- **Tracheostomy** is considered a **medically necessary** treatment option *only* as a last resort in those cases where all other approaches have failed.
- **Uvulopalatopharyngoplasty (UPPP**), has many variants, and may include a tonsillectomy or septoplasty. UPPP with or without inferior sagittal osteotomy (ISO) with hyoid suspension is considered **medically necessary** for the treatment of obstructive sleep apnea syndrome in patients who have not responded or do not tolerate nasal continuous positive airway pressure (nCPAP).
- Hypoglossal nerve stimulation (64999) is considered experimental / investigational for the treatment of obstructive sleep apnea as it does not meet TEC criteria # 2 - 5.

NOTE: Any surgical intervention performed for snoring in the absence of documented obstructive sleep apnea is considered not medically necessary, as snoring is not considered an illness or injury.

Policy Guidelines

Prior authorization is required for attended sleep studies to determine appropriateness and medical necessity for treatment.

Prior authorization is not required for unattended sleep studies. In CareFirst products with site of service copay differential, the site of service copayment of home setting will apply for unattended sleep studies.

See Provider Guidelines for details.

DIAGNOSTIC TESTING FOR OSAS:

Polysomnography: One polysomnogram is needed to confirm a diagnosis of OSAS. A second polysomnogram may be required to adjust the nCPAP device. Additional polysomnograms may be necessary for evaluating treatment response and making subsequent treatment management decisions. More than three polysomnograms in a 12-month period should undergo utilization review.

Certain patients may undergo both the diagnostic polysomnogram and titration of the nCPAP settings in a single overnight session in the sleep laboratory. This is known as a split-night polysomnogram.

Unattended Home Sleep Studies: In-home unattended sleep testing is considered medically necessary for patients with a high clinical suspicion for sleep apnea and no significant co-

morbidities. The following recommendations are based on the American Academy of Sleep Medicine (AASM) Guidelines (2007):

- Must be performed as part of a comprehensive sleep evaluation,
- Must be interpreted by a practitioner with board certification in sleep medicine or one who has fulfilled the eligibility criteria for the certification examination,
- Unattended portable monitoring may be used as an alternative to standard polysomnography (PSG) for diagnosis of OSAS in patients with a high pretest probability of moderate-to-severe OSAS,
- Patient does not have a significant comorbidity (examples: congestive heart failure [CHF], chronic obstructive pulmonary disease [COPD]), that may degrade the accuracy of the test.
- Patient does not have a co-existing sleep disorder of another type, such as periodic limb movement disorder,
- Unattended portable monitoring may be used to monitor the response to non-CPAP treatments for OSAS,
- At a minimum the portable device must record airflow, respiratory effort, blood oxygenation, and heart rate * and
- If the unattended portable monitoring in patients with a high pretest probability of obstructive sleep apnea is negative or indeterminate, an in-laboratory PSG is recommended

* Level II or Level III AASM clinical standards

Supervised polysomnography performed in a freestanding or hospital sleep laboratory is considered medically necessary as a diagnostic test in patients with any of the following:

- Pediatric patients (<18 years old),
- Craniofacial or upper airway soft tissue abnormalities, including adenotonsillar hypertrophy or neuromuscular disease,
- Moderate or severe congestive heart failure, stroke, transient ischemic attack, coronary artery disease, or significant tachycardia or bradycardia arrhythmias,
- Central sleep apnea,
- Chronic obstructive pulmonary disease,
- Strong suspicion of narcolepsy,
- Suspected REM Sleep Behavioral Disorder,
- Diagnostic need to distinguish between sleep related parasomnias and seizure disorders, or
- A previous non-diagnostic home study.

Rationale: 2002 (Unattended and home-based sleep studies for diagnosing sleep disorders)

Description of service:

Sleep-disordered breathing has been identified as a group of related disturbances in respiratory pattern that occur during sleep. There is a range of disorders from simple snoring, to hypopnea (a limitation of air flow), to obstructive sleep apnea (OSA) with a complete cessation of respiration for brief periods. The overnight polysomnogram (PSG) has historically been considered the gold standard for objective measurement of parameters to diagnose sleep disordered breathing problems. The PSG is conducted in a sleep laboratory, with the patient connected to a variety of sensors, under the direct care of a trained technician. This process is expensive, inconvenient for the patient, and often uncomfortable as well. Alternative methods of providing the physician with diagnostic information regarding the patient's sleep patterns has been sought for a number of years, resulting in proliferation of a variety of designs of units designed for use in the patient's home without professional attendance.

1. The technology must have final approval from the appropriate government regulatory bodies:

In the past ten years, a variety of devices for recording physiologic data at home during sleep have received FDA clearance for marketing. Most such devices have been cleared under 510(k) provisions. Such devices range from very simple devices such as pulse oximeters or phonic-type apnea monitors to relatively complex devices that measure oxygen saturation, ECG, respiratory rate, and flow.

2. The scientific evidence must permit conclusions concerning the effect on health outcomes:

This technology was previously reviewed in 1997, at which time there were numerous studies that suggested sleep studies could be successfully performed in the home setting, allowing the patient to set up and use the equipment without supervision by a technologist. It was further suggested that such studies could provide useful diagnostic information with regard to the presence of sleep apnea or other sleep disordered breathing.

The American Sleep Disorders Association (ASDA), then known as the American Academy of Sleep Medicine, published a position in 1994 addressing the question of whether home, unattended sleep studies could be considered effective for the diagnosis of sleep-related breathing disorders. At that time the problems with home-based, unattended studies were identified: 1) The variability of recording systems and techniques; 2) Lack of clinical outcomes studies that determine the reliability of such systems; 3) Lack of knowledge of how to interpret data from these studies; 4) Lack of definition of situations where the use of portable devices would be appropriate; 5) Lack of standardization of design of devices; 6) Lack of comparison studies between the portable devices and the gold standard, the laboratory based polysomnogram. The recommendations of the ASDA were that: 1) The standard polysomnogram is the accepted test for the diagnosis and determination of the severity and treatment of OSA, and 2) unattended portable recording is an acceptable alternative only in a few, strictly defined situations. The ASDA supported portable studies only when standard polysomnography was urgently needed and not readily available, or when it was not possible to study the patient in the sleep laboratory. Furthermore, the ASDA categorized the different types of sleep studies and the parameters measured into four levels, with the standard PSG being considered Level I. The following table summarizes the ASDA's definitions:

Level I: Standard PSG	Level II: Comprehensive portable PSG	Level III: Modified portable sleep apnea testing	Level IV: Continuous single or dual bioparameter recording
Minimum 7 parameters, including: EEG, EOG, EMG, ECG, airflow, respiratory effort, O_2 saturation	Minimum 7 parameters, including: EEG, EOG, EMG, ECG or heart rate, airflow, respiratory effort, O_2saturation	Minimum of 4 parameters, including ventilation (at least 2 channels), heart rate, and O_2saturation	Minimum of one parameter
Attended	Unattended	Unattended	Unattended

There have been attempts to validate the results from unattended studies against the gold standard laboratory PSG. The ASDA found that Level II portable PSG's correlated well with the laboratory standard. However, much was dependent on what particular machine was used. The Level II sleep study is able to identify and quantify stages of sleep, total sleep time, number of arousals, and, in turn, determine a respiratory disturbance index (RDI). Level III studies do not record enough information to determine wakefulness and the stages of sleep, and only a few studies evaluating them have been published. It is this category of device that has seen the most proliferation, because of the simplicity of design, ease of attachment, and the ability to determine two of the most important parameters in determining sleep disordered breathing: O_2 saturation and respiratory airflow and rate disturbances. In the validation studies, it was determined that the Level III device may not accurately determine the RDI. The majority of these products have not been subjected to rigorous validation studies. There is evidence, however, that there is considerable inconsistency in the accuracy of results obtained from this level of testing. The Level IV devices rely primarily on pulse oximetry to test for OSA. There is a great deal of variability in response characteristics in oximeter devices, and based on ASDA's evaluation the sensitivity and specificity was therefore not adequate to describe a Level IV device as more than a screening tool.

The ASDA updated their guidelines in 1998, but did not make any essential changes to their recommendations.

3. The technology must improve the net health outcome:

Whether the technology improves net health outcome is focused on whether the use of unattended sleep studies accurately provides information indicative of sleep disordered breathing. There is insufficient documentation in the literature to make this determination.

4. The technology must be as effective as any established alternatives:

The gold standard remains the overnight, in-house polysomnography. There is insufficient documentation to conclude that unattended sleep studies are as accurate in diagnosing sleep disordered breathing. Granted, some of the validation studies deal with certain devices that are quite accurate, and would likely be an effective tool for this purpose. Still others either have not been validated or show considerable discrepancies in results as compared with the gold standard. There are so many different products on the market, using such a variety of designs that it would not be possible to generalize to a conclusion that home studies are at least as effective as laboratory based polysomnography.

5. The improvement must be attainable outside the investigational settings:

Home sleep recording devices are in widespread use and treatment decisions are being made based on the data obtained from them.

<u>Rationale: 2004 Update: (Unattended and home-based sleep studies for diagnosing sleep disorders)</u>

Description of service.

In the past ten years, a variety of devices for recording physiologic data at home during sleep have received FDA clearance for marketing. Most such devices have been cleared under 510(k) provisions. Such devices range from very simple devices such as pulse oximeters or phonic-type apnea monitors to relatively complex devices that measure oxygen saturation, ECG, respiratory rate, and flow.

Since that time, the peer-reviewed literature has presented no new information that would alter the conclusions reached in the original assessment. An evidence based review co-sponsored by the American Academy of Sleep Medicine, the American College of Chest Physicians, and the American Thoracic Society (Flemons et al) concluded that Type II and III monitors are valid for

use in the home when the study is performed by a qualified technician, and that neither Type II nor III systems have been adequately validated for use in the unattended setting. Type IV monitoring systems, which are used primarily in the home setting, and which collect very limited information regarding the patient's sleep pattern, did not receive a favorable evaluation. A second evidence based review presented by Chesson et al in the same year (2003) concluded that there was insufficient evidence to recommend the use of Type II devices in attended or unattended settings, that Type III devices could be used in an attended setting could not recommend their use in the unattended setting. The use of Type IV devices were not recommended for use based on this review. A study that was specific to the SNAP® device by SNAP® Laboratories was published in 2004 by Liesching et al concluded that SNAP®, interpreted to be a Type IV device, does not appear to accurately assess the severity of obstructive sleep apnea.

Based on the information reviewed since 2002, the conclusions from the 2002 technology assessment are unchanged.

Rationale 2009 Update (Unattended and home-based sleep studies)

A considerable number of validation studies of the newest-generation models of home sleep study systems has documented sensitivity, specificity, and positive and negative predictive values for home-based systems. Although these devices measure fewer parameters than the conventional polysomnogram, reasonable correlation has been demonstrated. The home devices are designed to assist in the diagnosis of obstructive sleep apnea (OSA) and appear to be more accurate for moderate to severe OSA than for mild OSA. In late 2007 the American Academy of Sleep Medicine issued revised guidelines for the performance of home sleep studies, which CareFirst has adapted for use in determining benefit support for unattended home-based testing.

Rationale: 2005 Update (Actigraphy in insomnia and sleep disorders)

Description of service.

Actigraphy is a measurement of movement used to study sleep-wake patterns and circadian rhythms, most commonly by wearing a movement sensor on the wrist. Although the technology has been around for about twenty years, and practice guidelines from the American Academy of Sleep Medicine (AASM) have been published for a decade, concern has been raised over the proliferation of the technology in clinical practice, and whether there is evidence to support the use of actigraphy as a diagnostic tool. It has been proposed as a diagnostic aid in obstructive sleep apnea, insomnia, and circadian rhythm disorders.

1. The technology must have final approval from the appropriate government regulatory bodies:

A number of actigraphy devices have received clearance for marketing from the FDA under 510(k) provisions.

2. The scientific evidence must permit conclusions concerning the effect on health outcomes:

The Standards of Practice Committee of the American Academy of Sleep Medicine has published two relevant papers regarding the role of actigraphy in sleep disorders. Based on the evidence reviewed, the Committee concluded that actigraphy is reliable and valid for detecting sleep in normal populations, but less reliable for detecting disturbed sleep. Furthermore, the Committee reported that actigraphy is not indicated for the routine diagnosis, assessment, or management of any of the sleep disorders, but may be considered as an adjunct to evaluation of insomnia, daytime sleepiness, or circadian rhythm disturbances. The latter applications were considered potential uses, where other techniques cannot provide similar information. These applications were supported by a level of evidence generally rated low by the Committee.

There have been other expert reviews in the peer-reviewed literature that have detailed the weaknesses present in the use of such devices.

3. The technology must improve the net health outcome:

4. The technology must be as effective as any established alternatives:

Actigraph devices themselves do not show any potential for harm, but in consideration of the weak or absent evidence that the use of actigraphy can effectively improve diagnosis and / or management of sleep disorders, insomnia, or sleep-wake cycle disturbances, it is not possible to determine whether the technology can improve net health outcomes. The current standard for insomnia or circadian rhythm disturbances is for the patient to record sleep-wake logs. Although at least one expert reviewer has suggested that actigraphy could be used as an adjunct, there have been no studies to indicate improved diagnosis or patient management as a result.

5. The improvement must be attainable outside the investigational settings:

Improvement in patient outcomes has not been adequately addressed in investigational settings. Therefore it is not possible to determine an expected improvement in outcomes outside the investigational settings.

Based on the above observations, actigraphy does not meet CareFirst criteria for coverage for any proposed indication.

Rationale: 2008 Update (Palatal stiffening procedures and radiofrequency tissue volume reduction of the tongue base [RFTVR])

A search of the peer-reviewed literature from 2001 to the present retrieved minimal published data on the cautery assisted palatal stiffening operation (CAPSO) and the Pillar® palatal implant procedure. Only one study has documented a small group (n=25) of consecutive patients with OSA who underwent a CAPSO procedure. A positive response to treatment was considered to be a 50% or better reduction in the apnea-hypopnea index (AHI) and an AHI of 10 or less after surgery. In this small group only 40% were considered to have had a positive response. Results of three small, non-randomized uncontrolled studies have reported a moderate reduction in apneic episodes during sleep in patients who have undergone the Pillar® implant procedure. There have been no studies directly comparing the Pillar®procedure to other interventions for obstructive sleep apnea. An expert review (Allison, 2007) concluded that there is insufficient published evidence to determine whether palatal implants are an effective treatment option for patients with mild to moderate OSA due to palatal obstruction.

The use of radiofrequency tissue volume reduction (RFTVR) can be undertaken at the tongue base and palatal areas for multi-level treatment of the upper airway in patients with obstructive sleep apnea or upper airway resistance. Despite its being available for nearly ten years, there still have not been adequate published data to permit conclusions regarding patient outcomes. A 2002 review by Li and colleagues noted the initial success of RF tongue base reduction may diminish with time. Another evidence review by Masood and Phillips (2001) concludes that while RFTVR seems to be "moderately" effective for simple snoring, it has not been shown to be effective for significant sleep apnea. In a comparison study of RF techniques to conventional uvulopalatopharyngoplasty (UPPP) and nCPAP, nasal CPAP demonstrated somewhat better results in terms of improvement in apnea index. The study did not evaluate the durability of any improvements gained from RFTVR.

2010 Update (RFTVR):

The trend based on studies and reviews published over the past two years suggests that RFTVR applied to the tongue base may be used as an adjunct procedure in patients with multi-level obstructive sleep apnea. (Li, 2009; van den Broek et al, 2008) However, the latter author in a retrospective cohort study (n=75) reported that adding tongue reduction to UPPP did not add but a mild improvement in outcomes measures over UPPP alone. Neruntarat and Chantapant (2009) and Fernandez-Julian and colleagues observed that the effects of RF tongue reduction tended to diminish over time, that it was most effective in patients with mild to moderate sleep apnea, and that lower BMI was a major predictor of success. Fibbi and colleagues (2009) reported a small

comparison study of RFTVR of the tongue base with lingual suspension. The authors reported that the effects of both procedures diminished after two years, with long-term successful results seen in 42% and 33% of patients respectively. Despite the increasing acceptance of RFTVR of the tongue base as an adjunctive surgical intervention for sleep apnea, the evidence suggests its effects on patient outcomes are limited, probably of short duration, and are observed mainly in patients with mild to moderate obstructive sleep apnea.

2011 Update:

A review of the peer-reviewed literature was performed through March 2011. Findings in the literature do not change the conclusions regarding diagnostic testing, and the medical and surgical management of sleep disorders.

2013 Update:

A review of the peer-reviewed literature was performed for April 2011 through July 2013. Findings in the literature do not change the conclusions regarding diagnostic testing, and the medical and surgical management of sleep disorders. Therefore the policy statements are unchanged.

Rationale: 2014 Update (Provent™ Sleep Apnea Therapy)

Description of service.

Provent™ is a pair of small lightweight intranasal devices worn just inside each nostril and secured with adhesive. Its design incorporates bidirectional valves that allow inspiration with very little resistance, but produce increased resistance on expiration with back pressures of 50 to 110 cm of water per liter per second at a flow rate of 100 mL/sec. The expiratory flow resistance creates a positive airway pressure that stabilizes the pharyngeal structures and prevents the collapsing of the airway associated with obstructive sleep apnea (OSA). It is therefore an alternative to the more conventional continuous positive airway pressure (CPAP) for those individuals who are intolerant of the use of a mask or nasal device to treat their OSA. Provent™ devices are disposable, and intended for a single night's use.

1. The technology must have final approval from the appropriate government regulatory bodies:

The Provent™ Sleep Apnea Therapy, also known as Provent™ Professional Sleep Apnea Therapy, is regulated as a Class II device by the FDA. Marketing clearance was allowed under the 510(k) process to Ventus Medical Inc. initially in February of 2008, with a subsequent clearance in December, 2010.

2. The scientific evidence must permit conclusions concerning the effect on health outcomes:

Evidence for the safety and effectiveness of the Provent™ device was reported in prospective studies including two randomized controlled trials (RCT). In five prospective studies, patients served as their own controls. In the randomized controlled trials the efficacy of the Provent™ was compared with that of a sham device. Outcomes measures were consistent and included the apnea-hypopnea index (AHI), duration of apnea events, oxygen desaturation index (ODI) and sleep architecture parameters. Patient-centered measures included the Epworth Sleepiness Scores (ESS), Functional Outcomes of Sleep Questionnaire (FOSQ) and device adherence. All but one of the studies were sponsored by Ventus and some of the researchers were either directly employed by Ventus or declared a financial interest.

The initial pilot study (Colrain et al, 2008) was a small (n=26) study that documented a therapeutic effect of expiratory nasal resistance on the AHI and ODI. Standard polysomnography (PSG) was used to measure outcomes with and without the device. Another study (Rosenthal et al, 2009) utilized three varying resistance settings (50, 80 and 110 cm H2O/L/sec at 100mL/sec flow). This too was a small study (n=34 in the intent to treat analysis). This study confirmed the therapeutic effects documented in the pilot study and also demonstrated continuing improvement over a 30 day period. The study did note that patient responses were variable. The first RCT was

reported by Berry et al (2011). A total of 250 patients were randomized to Provent™ or a sham device of similar appearance and treated for a total of 3 months. The 80 cmH2O Provent™ was used; the resistance of the sham device was under 1 cm. A total of 195 patients completed the study, with dropout rates similar between the two groups. Both objective and subjective performance measures were significantly improved in the Provent™ group versus the sham group. The authors concluded that Provent™ was an efficacious treatment for mild to severe OSA in a high percentage of patients. A portion of this study population was assessed in a 12-month extension study by Kryger and colleagues (2011). This study reported sustained health benefits from continuous use of Provent™ at 12 months. The results must be interpreted with caution, however, since the number of patients studied was only about a third of the original population, so that the reported results may be biased as the dropouts likely included a high percentage of non-responders; furthermore, the reported success was based primarily on patient reports rather than objective measures.

Another randomized controlled trial (Rossi et al, 2013) tested whether Provent™ could be used successfully as an alternative to CPAP by patients who were acclimated to and regular users of CPAP. The study randomized 67 patients with OSA and who were users of CPAP to one of three groups for two weeks: continuation of CPAP, active Provent™, and placebo Provent™. From this study the authors concluded that Provent™ could not be recommended as a short term therapy alternative to CPAP, since there was no therapeutic effect of Provent™ on CPAP patients.

Although the studies support conclusions that Provent™ therapy affects patient outcomes, the evidence is of overall low quantity and quality, and in many cases patients who showed a statistically significant improvement in sleep quality measures continued to have significant OSA.

3. The technology must improve the net health outcome:

There were no serious adverse events reported in these studies. The Berry study did report a device-related adverse event rate of 45%. These included nasal congestion, cough, nasal discomfort, dry mouth and throat, exhalation difficulty and poor sleep quality. Overall, a therapeutic effect is unproven in patients unable to use standard CPAP without serious adverse effects based on limited and low-quality evidence.

4. The technology must be as effective as any established alternatives:

CPAP remains the gold standard for treatment of OSA. The available evidence, while suggestive that Provent™ therapy may have a therapeutic effect on OSA, is insufficient to conclude that it is at least as effective as the current gold standard.

5. The improvement must be attainable outside the investigational settings:

There is insufficient evidence to determine if a net improvement can be expected outside of the investigational settings.

Therefore Provent™ Sleep Apnea Therapy is considered experimental / investigational.

Rationale: 2015 Update (Hypoglossal Nerve Stimulation):

Description of the service:

Hypoglossal nerve stimulation technology is being evaluated as a treatment for OSA. The technology utilizes an implantable device that electrically stimulates the hypoglossal nerve leading to the contraction of the genioglossus muscle, the major muscle responsible for tongue protrusion. This stimulation dilates the pharyngeal region, improving the diameter of the upper airway, preventing airway collapse and the development of upper airway obstruction during sleep.

Hypoglossal nerve stimulation systems consist of three components which are surgically implanted under general anesthesia. An implantable pulse generator (IPG) is placed

subcutaneously below the clavicle and connects to the stimulation lead and the sensing lead. An implantable neurostimulator lead that delivers an electrical current to the hypoglossal nerve is positioned in a cuff around the hypoglossal nerve and connects to the IPG. A respiratory sensing lead is placed between the external and internal intercostal muscle (intercostal space). When therapy is on, the sensing lead detects the patient's respiratory effort and maintains airway patency with mild stimulation of the hypoglossal nerve. Therapy settings are stored and configured by the physician using an external programmer.

1. The technology must have final approval from the appropriate government regulatory bodies: The Inspire® II Upper Airway Stimulation (UAS) System, which includes the Model 3024 Implantable PulseGenerator, the Model 4063 Stimulation Lead, the Model 4323 Sensing Lead, the Model 2740 Physician Programmer, and the Model 3032 Patient Programmer, received premarket approval (PMA) from the U.S. Food and Drug Administration (FDA) on April 30, 2014.

In 2011, Apnex Medical, Inc., received investigational device exemption (IDE) approval from the U.S. FDA to begin a clinical study (NCT01446601) to evaluate the safety and effectiveness of its Hypoglossal Nerve Stimulation (HGNS®) System to treat OSA.

2. The scientific evidence must permit conclusions concerning the effect on health outcomes:

The published studies on hypoglossal nerve stimulation have been sponsored by the device manufacturer. A feasibility trial (Eastwood et al, 2011) examined the safety and efficacy of the HGNS® system used to treat 21 patients with moderate to severe OSA who were unable to tolerate CPAP. The system was found to have a favorable safety and efficacy profile with a high compliance rate. The safety and preliminary efficacy of the Inspire® UAS were evaluated (Van de Heyning and group, 2012) in patients with moderate to severe OSA unable to use or adhere to CPAP therapy. The small, open prospective study was uncontrolled and conducted in two consecutive parts. Part 1 had broad patient eligibility criteria (n=20) and findings from this study were used to formulate stricter eligibility criteria in Part 2 (n=6). In addition, the surgical technique was modified after Part 1. The study lacked a control group and randomization, along with different implantation techniques and eligibility requirements used in the two parts of the study hampered result interpretation. HGNS was found to produce marked dose-related increases in airflow without arousing patients from sleep (Schwartz and colleagues, 2012). The increase in airflow was of sufficient magnitude to suggest potential HGNS efficacy across a broad range of sleep apnea severity.

The largest study, the manufacturer sponsored STAR Trial (Star Trial Group, 2014), a multicenter, prospective, single-group trial design, followed by a randomized, therapy-withdrawal trial evaluated the clinical safety and effectiveness of the Inspire® device at 12 months. One hundred twenty six study participants (83% men) with moderate to severe OSA who were unable to tolerate CPAP were enrolled. The median AHI score at 12 months decreased by 68%, from 29.3 events per hour to 9.0 events per hour ($P<0.001$); the ODI score decreased 70%, from 25.4 events per hour to 7.4 events per hour ($P<0.001$). Secondary outcome measures showed a reduction in the effects of sleep apnea and improved quality of life. The first 46 patients with a positive response to therapy at 12 months were subsequently randomized to controlled use of the device (Inspire On group; n=23) or to discontinuation of the device for seven days (Inspire Off group; n=23). The mean AHI score did not differ significantly from the 12-month score in the nonrandomized phase among the 23 participants in the therapy-maintenance group (8.9 and 7.2 events per hour, respectively); the AHI score was significantly higher (indicating more severe apnea) among the 23 participants in the therapy-withdrawal group (25.8 vs. 7.6 events per hour $P<0.001$). The ODI results followed a similar pattern.

A prospective single-arm interventional trial (Kezirian and colleagues,2014) evaluated the safety, feasibility and efficacy of the HGNS® system in treating OSA in 31 subjects with moderate to severe OSA who were unable to tolerate PAP. Hypoglossal nerve stimulation was used on 86 ± 16% of nights for 5.4 ± 1.4 h per night. There was a significant improvement ($P < 0.001$) from baseline to 12 months in AHI (45.4 ± 17.5 to 25.3 ± 20.6 events h(-1)) and FOSQ score (14.2 ±

2.0 to 17.0 ± 2.4), as well as other PSG and symptom measures. Outcomes were stable compared with 6 months following implantation.

3. The technology must improve the net health outcome:

Preliminary evidence suggests that HGNS therapy improves objective measures such as AHI and ODI along with subjective measures such as daytime sleepiness and quality of life. However, the population studied was carefully selected with only a minority of patients evaluated actually undergoing implantation of the device.

4. The technology must be as effective as any established alternatives:

The available evidence, while suggestive that hypoglossal nerve stimulation therapy may have a therapeutic effect on OSA, is insufficient to conclude that it is at least as effective as established therapies. The published studies employed unblinded, prospective, open-label designs without a control group.

5. The improvement must be attainable outside the investigational settings:

There is insufficient evidence to determine if a net improvement can be expected outside of the investigational settings. The optimal patient selection criteria have not yet been established.

Provider Guidelines

An unattended sleep study with simultaneous recording of heart rate, oxygen saturation, respiratory airflow, and respiratory effort (95806) is not time-based and should be reported only one time per study.

Prior authorization is required for attended sleep studies to determine appropriateness and medical necessity for treatment.

Prior authorization is not required for unattended sleep studies. In CareFirst products with site of service copay differential, the site of service copayment of home setting will apply for unattended sleep studies.

Submit documentation for review to:

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Cross References to Related Policies and Procedures

Durable Medical Equipment with Attached Table, Policy 1.01.001
Oral - Facial Pathology or Trauma, Policy 7.01.022
Quantitative Electroencephalogram / Topographic Brain Mapping, Policy 2.01.010

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The following were among the resources reviewed and considered in developing this policy. By reviewing and considering the resources, CareFirst does not in any way

endorse the contents thereof nor assume any liability or responsibility in connection therewith. The opinions and conclusions of the authors of these resources are their own, and may or may not be in agreement with those of CareFirst.

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