MEDICAL POLICY

POLICY TITLE	DIAGNOSIS AND MEDICAL MANAGEMENT OF OBSTRUCTIVE SLEEP APNEA
POLICY NUMBER	MP-2.045

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I. POLICY

Diagnostic testing for obstructive sleep apnea

Unattended (unsupervised) Home Sleep Studies

Initial Testing Unattended (unsupervised) Testing

A single unattended (unsupervised) home sleep study with a minimum of 4 recording channels (including oxygen saturation, respiratory movement, airflow and EKG or heart rate) may be considered **medically necessary** for adult patients (≥ 18)who are at risk for OSA when **ALL** of the following are met:

- Clinical need for sleep study, as indicated by **at least 2** of the following:
  - Observed apneas during sleep
  - Sleepiness that interferes with daily activities and is not explained by other conditions,;
  - Habitual snoring or gasping/choking episodes associated with awakenings
  - Hypertension;
  - Body mass index (BMI) greater than 35
- The medical professional who will interpret the home sleep study should have training in sleep medicine.
- Agency providing in-home sleep study testing uses equipment that is FDA approved for home use.
- No evidence by history and physical examination of a health condition that might alter ventilation or require alternative treatment including, but not limited to, one of the following:
  - central sleep apnea
  - moderate to severe heart failure (NYHA Class III or IV)

- chronic pulmonary disease including moderate to severe asthma.
- established diagnosis of obesity hypoventilation syndrome
- moderate to severe neuromuscular/neurodegenerative disorder causing restrictive lung diseases (e.g. kyphoscoliosis, myasthenia gravis, amyotropic lateral sclerosis (ALS), post-polio syndrome, polymositis, Guillian Barre syndrome).
- stroke/transient ischemic attack within the preceding 30 days
- tachycardia or bradycardic arrhythmias

Note: For patients with sleep-related movement disorders (e.g., restless legs syndrome [RLS], periodic limb movement disorder [PLMD]), narcolepsy or injurious or potentially injurious parasomnias see MP 2.335 Polysomnography for Non-Respiratory Sleep Disorders

A single unattended (unsupervised) home sleep study with a minimum of 4 recording channels (see above) may be considered **medically necessary** as a screening tool in patients who are scheduled for bariatric surgery and have no evidence by history and physical examination of a health condition that might alter ventilation or require alternative treatment (see Policy Guidelines).

Unattended home sleep studies are considered **investigational** in children (younger than 18 years of age). There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Repeat Unattended (unsupervised) Testing

Repeat unattended (unsupervised) home sleep studies with a minimum of four recording channels (including oxygen saturation, respiratory movement, airflow, and EKG/heartrate) may be considered **medically necessary** for adult patients under the following circumstances:

- To assess efficacy of surgery or oral appliances/devices; OR
- To re-evaluate the diagnosis of OSA and need for continued positive airway pressure (PAP) therapy, e.g., if there is significant change in weight or change in symptoms suggesting that PAP therapy should be adjusted or possibly discontinued.

Multiple consecutive nights of supervised or unattended (unsupervised) sleep studies that do not meet the above criteria for repeat studies are **not medically necessary**.

Unattended (unsupervised) home sleep studies are considered **investigational** in pediatric patients (i.e. less than 18 years of age). There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Supervised Polysomnography performed in a sleep laboratory

Initial Testing performed in a sleep laboratory

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Supervised Polysomnography or sleep study performed in a sleep laboratory is considered **medically necessary** in patients at risk for OSA in the following situations.

- Clinical need for sleep study, as indicated by **at least 2** of the following:
  - Observed apneas during sleep
  - Sleepiness that interferes with daily activities and is not explained by other conditions, (this may be expressed as learning difficulties or other daytime neurobehavioral problems in young children);
  - Habitual snoring or gasping/choking episodes associated with awakenings
  - Hypertension;
  - Body mass index (BMI) greater than 35

AND ONE or more of the following:

- Pediatric patients age < 18; OR
- When patients do not meet criteria for an unattended home sleep study as described above; OR
- A previous home study failed to establish the diagnosis of OSA in a patient with a high pretest probability of OSA; OR
- A previous home study was technically inadequate; OR
- Failure of resolution of symptoms or recurrence of symptoms during treatment; OR
- To reevaluate the diagnosis of OSA and need for continued positive airway pressure (PAP) therapy,e.g., if there is a significant change in weight or change in symptoms suggesting that CPAP should be retitrated or possibly discontinued; OR
- When testing is done to rule out central sleep apnea,
- Presence of a co-morbidity that might alter ventilation or decrease the accuracy of a home sleep study including, but not limited to one of the following:
  - central sleep apnea
  - moderate to severe heart failure (NYHA Class III or IV)
  - chronic pulmonary disease including moderate to severe asthma.
  - established diagnosis of obesity hypoventilation syndrome
  - moderate to severe neuromuscular/neurodegenerative disorder causing restrictive lung diseases (e.g. kyphoscoliosis, myasthenia gravis, amyotropic lateral sclerosis (ALS), post-polio syndrome, polymositis, Guillian Barre syndrome).
  - stroke/transient ischemic attack within the preceding 30 days
  - tachycardia or bradycardic arrhythmias

Note: For patients with sleep-related movement disorders (e.g., restless legs syndrome [RLS], periodic limb movement disorder [PLMD]), narcolepsy or injurious or potentially injurious parasomnias see MP 2.335 Polysomnography for Non-Respiratory Sleep Disorders

Repeat Testing performed in a sleep laboratory

A repeat supervised polysomnography performed in a sleep laboratory* is considered **medically necessary** for any **ONE** of the following circumstances**:**

- To initiate and titrate PAP therapy in pediatric patients age <18 who have
    - An AHI or RDI of at least 5 per hour, OR
    - AHI or RDI of at least 1.5 per hour with excessive daytime sleepiness, behavioral problems or hyperactivity.
- To initiate and titrate continuous positive airway pressure (CPAP), bilevel positive airway pressure (BiPAP) or therapy in adult patients age ≥ 18 who have
    - An apnea/hypopnea index (AHI) or respiratory disturbance index (RDI) of at least 15 per hour, OR
    - An AHI or RDI of at least 5 per hour in a patient with excessive daytime sleepiness or unexplained hypertension.
- To re-evaluate the diagnosis of OSA, for retitration, or for reconsideration of need for continued CPAP, BiPAP or APAP therapy, (this includes patients with a significant change in weight or change in symptoms suggesting that therapy should be retitrated or possibly discontinued**).
- To reevaluate the diagnosis of OSA and need for continued use of an oral appliance for a patient that does not meet the criteria for an unattended home sleep study described above. (e.g., if there is a significant change in weight or change in symptoms suggesting an adjustment is required or the use of the appliance can be discontinued.

*A split-night study, in which severe OSA is documented during the first portion of the study using polysomnography, followed by PAP therapy during the second portion of the study, can eliminate the need for a second study to titrate PAP therapy. (See Policy Guidelines).

* *This statement does not imply that supervised studies are needed routinely following unattended studies. This statement means a re-evaluation based on a substantial change in symptoms or in the clinical situation.

Supervised or unattended home sleep studies that do not meet the above criteria are **not medically necessary**.

Video EEG monitoring

Video EEG monitoring performed concurrently with polysomnography is considered **investigational.** There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Abbreviated Daytime Sleep Study (PAP-NAP)

The use of abbreviated daytime sleep study (PAP-NAP) as a supplement to standard sleep studies is considered **investigational**. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Multiple Sleep Latency Testing

Multiple sleep latency testing is considered **not medically necessary** in the diagnosis of OSA.

Medical Management of Obstructive Sleep Apnea (OSA)

Management of patients diagnosed with OSA should be initiated and monitored by a professional with training in sleep medicine.

Continuous Positive Airway Pressure (CPAP),

Initial Application of CPAP

Initial application of Continuous Positive Airway Pressure (CPAP) may be considered **medically necessary** in the medical management of patients when ONE of the following is met:

- For **adult patients** who are diagnosed with obstructive sleep apnea when **ONE** of the following is met:
    - AHI or RDI is greater than or equal to 15 events per hour; **OR**
    - AHI or RDI greater than or equal to 5 events per hour and less than or equal to 14 events per hour with documentation of ONE or MORE of the following;
        - excessive daytime sleepiness
        - hypertension
        - mood disorders
        - impaired cognition
        - ischemic heart disease
        - history of stroke
        - insomnia
- For adult patients who are diagnosed with clinically significant upper airway resistance when ONE of the following is met:
    - Greater than 10 EEG arousals per hour
    - Presence of abnormally negative intrathoracic pressures (i.e., more negative than 10 cm) in conjunction with the EEG arousals

  Note: The measurement of intrathoracic pressures requires the use of an esophageal manometer as an adjunct to a polysomnogram.

- For **pediatric patients** who are diagnosed with obstructive sleep apnea when ONE of the following is met:
    - AHI or RDI of at least 5 per hour, OR

- AHI or RDI of at least 1.5 per hour in a patient with excessive daytime sleepiness, behavioral problems or hyperactivity.

Bi-level Positive Airway Pressure (BiPAP), Auto-adjusting Positive Airway Pressure (APAP)

Initial application of Bi-level Positive Airway Pressure (BiPAP) or Auto-adjusting Positive Airway Pressure (APAP) may be considered medically necessary in the medical management of patients when ONE of the following is met:

- After an episode of respiratory failure at time of discharge from the hospital.
- For patients with neurologic conditions that effect respiratory muscles.
- For **adult patients** who are diagnosed with clinically significant obstructive sleep apnea when **BOTH** of the following are met:
  - AHI or RDI measurement is ONE of the following
    - Greater than or equal to 15 events per hour
    - Greater than or equal to 5 events per hour and less than or equal to 14 events per hour with documentation of ONE or MORE of the following;
      - excessive daytime sleepiness
      - hypertension
      - mood disorders
      - impaired cognition
      - ischemic heart disease
      - history of stroke
      - insomnia
  - The ordering practitioner has determined that BiPAP or APAP will provide optimal benefit for the management of OSA.

    NOTE: The patient is NOT required to have tried or failed CPAP prior to implementation of BiPAP, or APAP.

- For **adult patients** who are diagnosed with clinically significant upper airway resistance syndrome (UARS) when **BOTH** of the following are met:
  - Clinical condition meets ONE of the following
    - Greater than 10 EEG arousals per hour
    - Presence of abnormally negative intrathoracic pressures (i.e., more negative than 10 cm) in conjunction with the EEG arousals
  - The ordering practitioner has determined that BiPAP or APAP will provide optimal benefit for the management of UARS.

NOTE: The patient is NOT required to have tried or failed CPAP prior to implementation of BiPAP, or APAP.

- For **pediatric patients** who are diagnosed with clinically significant obstructive sleep apnea when **BOTH** of the following are met:
  - AHI or RDI measurement is ONE of the following
    - AHI or RDI of at least 5 per hour,
    - AHI or RDI of at least 1.5 per hour in a patient with excessive daytime sleepiness, behavioral problems or hyperactivity.
  - The ordering practitioner has determined that BiPAP or APAP will provide optimal benefit for the management of OSA.

NOTE: The patient is NOT required to have tried or failed CPAP prior to implementation of BiPAP or APAP.

Humidification

Note: A humidifier (either heated or non-heated) and tubing **is medically necessary** for use with a medically necessary PAP device when prescribed by the treating physician to meet the needs of the individual patient.

Continued Application of Therapy

Continued CPAP, BiPAP or APAP therapy is considered **medically necessary** when ALL the following indications are met.

- Device has been utilized for a minimum of 30 days.
- The following should be monitored by a professional with training in sleep medicine.
  - Symptoms of obstructive sleep apnea or upper airway resistance syndrome
  - Adherence to prescribed treatment

Other Therapy

Intraoral appliances

Custom fabricated intraoral appliances (tongue-retaining devices or mandibular advancing/positioning devices) may be considered **medically necessary** in patients with clinically significant OSA under the following conditions:

- For adult patients who are diagnosed with clinically significant upper airway resistance when ONE of the following is met:

- OSA, defined by an apnea/hypopnea index (AHI) of at least 15 per hour **or**
- an AHI of at least 5 events per hour in a patient with one of the following
  - excessive daytime sleepiness
  - hypertension
  - mood disorders
  - impaired cognition
  - ischemic heart disease
  - history of stroke
  - insomnia

- For pediatric patients who are diagnosed with obstructive sleep apnea when ONE of the following is met:
  - AHI or RDI measurement is ONE of the following
    - AHI or RDI of at least 5 per hour,
    - AHI or RDI of at least 1.5 per hour in a patient with excessive daytime sleepiness, behavioral problems or hyperactivity.

AND (for both adult and pediatric patients)

- A trial with CPAP, BiPAP, or APAP has failed, contraindicated, or refused, AND
- The device is prescribed by a treating physician, AND
- The device is custom-fitted by qualified dental personnel, AND
- There is absence of temporomandibular dysfunction or periodontal disease

Prefabricated or off the shelf intraoral appliances are considered **not medically necessary.**

Note: CPAP has been shown to have greater effectiveness than oral appliances in general. This difference in efficacy is more pronounced for patients with severe OSA, as oral appliances have been shown to be less efficacious in patients with severe OSA than they are in patients with mild-moderate OSA. Therefore, it is particularly important that patients with severe OSA have an initial trial of CPAP and that all reasonable attempts are made to continue treatment with CPAP, prior to the decision to switch to an oral appliance.

Palate and Mandible Expansion Devices

Palate and mandible expansion devices are considered **investigational** for the treatment of OSA. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Nasal Expiratory Positive Airway Pressure (EPAP)

A nasal expiratory positive airway pressure (EPAP) device is considered **investigational**. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Flexible Positive Airway Pressure (PAP)
The use of flexible positive airway pressure (PAP) devices, (such as C-Flex) is considered **investigational**. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Policy Guidelines

Risk Factors for OSA
Although not an exclusive list, patients with all four of the following symptoms are considered to be at high risk for OSA:

- habitual snoring;
- observed apneas;
- excessive daytime sleepiness;
- a body mass index greater than 35

If no bed partner is available to report snoring or observed apneas, other signs and symptoms suggestive of OSA, (e.g., age of the patient, male gender, thick neck, craniofacial or upper airway soft tissue abnormalities, or unexplained hypertension) may be considered. Objective clinical prediction rules are being developed; however, at the present time, risk assessment is based primarily on clinical judgment.1, 2

The STOP-BANG questionnaire is a method developed for non-sleep specialists to assess the signs and symptoms of OSA (**S**nore, **T**ired, **O**bserved apnea, blood **P**ressure, **B**MI, **A**ge, **N**eck, **G**ender) and has been shown to have 97% sensitivity and a negative predictive value of 96% (specificity of 33%) for the identification of patients with severe OSA (AHI >30).3 Overnight oximetry has been used by some sleep specialists as a component of the risk assessment but is not adequate for the diagnosis of OSA. Therefore, a follow-up PSG or home sleep study would still be required to confirm or exclude a diagnosis of OSA.

OSA in Children

The presentation of OSA in children may differ from that of adults. Children frequently exhibit behavioral problems or hyperactivity rather than daytime sleepiness. Obesity is defined as a body mass index greater than the 90th percentile for the weight/height ratio. Although the definition of severe OSA in children is not well established, an AHI greater than 1.5 is considered abnormal (an AHI of 10 or more may be considered severe). In addition, the first-line treatment in children is usually adenotonsillectomy. CPAP is an option for children who are not candidates for surgery or who have an inadequate response to surgery.

Bariatric Surgery Patients

Screening for OSA should be performed routinely in patients scheduled for bariatric surgery, due to the high prevalence of OSA in this population. The optimal screening approach is not certain. An in-laboratory PSG or home sleep study is the most accurate screening method. Some experts recommend a symptom-based screening instrument, followed by PSG in patients who exceed a certain threshold, as an alternative to performing PSG in all patients. It should be noted that there is a high prevalence of obesity hypoventilation syndrome in patients who are candidates for bariatric surgery. Therefore, obesity hypoventilation syndrome should be ruled out prior to home sleep testing in this population.

SIGNIFICANT WEIGHT CHANGE

There is no established threshold for significant change in weight. Studies have reported improvements in OSA with an average weight loss of 20 kg or 20% of body weight.

Multiple Sleep Latency Test

The multiple sleep latency test (MSLT) is an objective measure of the tendency to fall asleep in the absence of alerting factors, while the maintenance of wakefulness test (MWT) is an objective measure of the ability to stay awake under soporific conditions (used to assess occupational safety).4 The MSLT and MWT are not routinely indicated in the evaluation and diagnosis of OSA or in assessment of change following treatment with CPAP. The MSLT may be indicated as part of the evaluation of patients with suspected narcolepsy to confirm the diagnosis (often characterized by cataplexy, sleep paralysis, and hypnagogic/hypnopompic hallucinations) or to differentiate between suspected idiopathic hypersomnia and narcolepsy. Narcolepsy and OSA can co-occur.4, 5 Since it is not possible to differentiate the excessive sleepiness caused by OSA and narcolepsy, the OSA should be treated before confirming a diagnosis of narcolepsy with the MSLT.

Specialist Training

The medical professional who is interpreting a polysomnogram or home sleep study should have training in sleep medicine and should review the raw data from polysomnography (PSG) and home sleep studies in order to detect artifacts and data loss. In addition, the treatment of patients diagnosed with OSA should be initiated and monitored by a professional with training in sleep medicine. It is important to monitor symptoms and adherence to positive airway pressure (PAP) treatment, e.g., review of symptoms and device utilization between 30 and 90 days.

Split Night Studies

American Academy for Sleep Medicine (AASM) Practice Parameters indicate that a split-night study (initial diagnostic PSG followed by CPAP titration during PSG on the same night) is an

alternative to 1 full night of diagnostic PSG followed by a second night of titration if the following 4 criteria are met:

a. An AHI of at least 40 is documented during a minimum of 2 hours of diagnostic PSG. Split-night studies may sometimes be considered at an AHI of 20 to 40, based on clinical judgment (e.g., if there are also repetitive long obstructions and major desaturations). However, at AHI values below 40, determination of CPAP pressure requirements, based on split-night studies, may be less accurate than in full-night calibrations.

b. CPAP titration is carried out for more than 3 hours (because respiratory events can worsen as the night progresses).

c. PSG documents that CPAP eliminates or nearly eliminates the respiratory events during rapid eye movement (REM) and non-REM (NREM) sleep, including REM sleep with the patient in the supine position.

d. A second full night of PSG for CPAP titration is performed if the diagnosis of a sleep-related breathing disorder (SRBD) is confirmed, but criteria b and c are not met.

Categorization of Polysomnography and Portable Monitoring

There is not full correspondence between the CPT codes and the most current categorization scheme for the different types of studies. In the 2005 practice parameters of AASM, 1 there are 4 types of monitoring procedures: type 1, standard attended in-lab comprehensive PSG; type 2, comprehensive portable PSG; type 3, modified portable sleep apnea testing (also referred to as cardiorespiratory sleep studies), consisting of 4 or more channels of monitoring; and type 4, continuous single or dual bioparameters, consisting of 1 or 2 channels, typically oxygen saturation, or airflow. Types 1 and 2 would be considered polysomnographic studies, and types 3 and 4 would be considered polygraphic sleep studies. The terms sleep studies and PSG are often used interchangeably. CPT coding makes a distinction between sleep studies that do not include electroencephalographic (EEG) monitoring, and PSG, which includes EEG monitoring. PSG is usually conducted in a sleep laboratory and attended by a technologist, but may also be conducted with type 2 portable monitoring. The type of study is further characterized as attended (supervised) or unattended by a technologist. Home or portable monitoring implies unattended sleep studies, typically conducted in the patient's home. There are no specific codes for remotely monitored home sleep studies. They would likely be reported with the CPT code for the sleep study with the GT modifier ("via interactive audio and video telecommunications systems") appended. There is no CPT code for "unattended" PSG.

Cardiorespiratory sleep studies without EEG may be called polygraphic studies and can either be attended or unattended by a technologist. The CPT codes 95807 and 95806 distinguish polygraphic sleep studies that are attended or unattended, but there are no codes that distinguish between type 3 and type 4 sleep studies. A wide variety of portable monitors and proprietary automated scoring systems are being tested and marketed, but the optimum combination of sensors and scoring algorithms is currently unknown. Current recommendations are that the portable monitoring device have 4 channels (oxygen saturation, respiratory effort, respiratory airflow, and heart rate) and allow review of the raw data. Type IV monitors with fewer than 3

channels are not recommended due to reduced diagnostic accuracy and higher failure rates. As with attended PSG, it is important that the raw data from home sleep studies be reviewed by a professional with training in sleep medicine in order to detect artifacts and data loss.

Cross-references:

MP 2.087 Actigraphy
MP 1.128 Surgical Treatment of Snoring and Obstructive Sleep Apnea
MP 2.062 Temporomandibular Joint Dysfunction (TMJ)
MP 1.101 Orthognathic Surgery
MP 2.335 Polysomnography for Non-respiratory Sleep Disorders

II. PRODUCT VARIATIONS TOP

This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

FEP PPO: Refer to FEP Medical Policy Manual MP-2.01.18 Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome. The FEP Medical Policy manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

III. DESCRIPTION/BACKGROUND TOP

Obstructive Sleep Apnea

Obstructive sleep apnea (OSA) syndrome is characterized by repetitive episodes of upper airway obstruction due to the collapse of the upper airway during sleep. This causes a drop in blood oxygenation and a brief arousal, and can occur as frequently as every minute throughout the night. The most common signs and symptoms in adults are snoring, excessive daytime sleepiness, and hypertension. Excessive daytime sleepiness may be subjective, and is assessed by questionnaires such as the Epworth Sleepiness Scale (ESS), a short self-administered questionnaire that asks patients how likely they are to fall asleep in different scenarios such as watching TV, sitting quietly in a car, or sitting and talking to someone. Daytime sleepiness is uncommon in young children with OSA. Symptoms in children may include disturbed sleep and daytime neurobehavioral problems. In otherwise healthy children, OSA is usually associated with adenotonsillar hypertrophy and/or obesity.

A hallmark sign of OSA is snoring. The snoring abruptly ceases during the apneic episodes and during the brief period of patient arousal and then resumes when the patient again falls asleep. Upper airway resistance syndrome (UARS) is a variant of OSA that is characterized by a partial collapse of the airway, resulting in increased resistance to airflow. The increased respiratory effort is associated with multiple sleep fragmentations, as measured by very short alpha

electroencephalographic (EEG) arousals ("respiratory event-related arousals" [RERAs]). The sleep fragmentation associated with repeated sleep disruption can lead to impairment of daytime activity. Adult patients with OSA-associated daytime somnolence are thought to be at higher risk for accidents involving motorized vehicles, i.e., cars, trucks, or heavy equipment, while OSA in children may result in neurocognitive impairment and behavioral problems.

OSA can also affect the cardiovascular and pulmonary systems. For example, apnea leads to periods of hypoxemia, alveolar hypoventilation, hypercapnia, and acidosis. This in turn can cause systemic hypertension, cardiac arrhythmias, pulmonary hypertension, and cor pulmonale. Systemic hypertension is common in patients with OSA. Severe OSA is also associated with decreased survival, presumably related to severe hypoxemia, hypertension, or an increase in automobile accidents related to daytime sleepiness. It is estimated that about 7% of adults have moderate or severe OSA, and 20% have at least mild OSA and that the referral population of OSA patients represents a small proportion of patients who have clinically significant and treatable disease.(1)

Diagnosis

The standard diagnostic criterion for sleep disorders is a polysomnogram performed in a sleep laboratory.[2,] A standard polysomnogram includes electroencephalogram(EEG), submental electromyogram, and electro-oculogram (to detect rapid eye movement sleep) for sleep staging. Polysomnography also typically includes electrocardiography and monitoring of respiratory airflow, effort, snoring, oxygen desaturation, and sleep position. An attended study ensures that the electrodes and sensors are functioning adequately and do not dislodge during the night. In addition, an attendant is able to identify severe OSA in the first part of the night and titrate continuous positive airway pressure (CPAP) in the second part of the night, commonly known as a "split-night" study. If successful, this strategy eliminates the need for an additional polysomnography for CPAP titration.

AHI: Apnea/hypopnea Index; APAP: auto-adjusting positive airway pressure; CPAP: continuous positive airway pressure; EEG: electroencephalogram; OSA: obstructive sleep apnea; RDI: Respiratory Disturbance Index; REI: Respiratory Event Index; RERA: respiratory event-related arousal: UARS: upper airway resistance syndrome.

Due to faster respiratory rates in children, pediatric scoring criteria define an apnea as 2 or more missed breaths, regardless of its duration in seconds. In pediatric patients, an AHI greater than 1.5 events per hour is considered abnormal, and an AHI of 10 or more may be considered severe.

A variety of devices have been developed specifically to evaluate OSA at home. They range from portable full polysomnography systems to single-channel oximeters. Available devices evaluate different parameters, which may include oximetry, respiratory and cardiac monitoring, and sleep/wake activity, but most portable monitors do not record EEG activity.

Treatment

Medical management of OSA in adults may include weight loss, avoidance of stimulants, body position adjustment, oral appliances, and use of various types of positive airway pressure therapy (ie, fixed CPAP, bilevel positive airway pressure, or auto-adjusting positive airway pressure) during sleep. This evidence review, addresses CPAP, oral appliances, and novel devices including the Daytime-Nighttime Appliance (BioModeling Solutions), the mandibular Repositioning Nighttime Appliance (BioModeling Solutions), Provent and Winx. Provent is a single-use nasal expiratory resistance valve device containing valves inserted into the nostrils and secured with adhesive. The Winx system uses oral pressure therapy to treat OSA.

Surgical management of OSA (ie, adenotonsillectomy, uvulopalatopharyngoplasty, orthognathic surgery) is discussed in evidence review 7.01.101 (surgical treatment of snoring and OSA syndrome).

Regulatory Status

A variety of oral appliances have been cleared for marketing by U.S. Food and Drug Administration (FDA) through the 510(k) process for treatment of snoring and mild-to-moderate OSA, including the Narval™ CC, Lamberg Sleep Well Smartrusion, 1st Snoring Appliance, Full Breath Sleep Appliance, PM Positioner, Snorenti, Snorex, Osap, DeSRA, Elastomeric Sleep Appliance, Snoremaster Snore Remedy, Snore-no-More, Napa, Snoar™ Open Airway Appliance, and The Equalizer Airway Device. FDA product code: LQZ.

In 2014, the mRNA Appliance® (BioModeling Solutions) was cleared for marketing by FDA through the 510(k) process(K130067) for the treatment of snoring and mild-to-moderate OSA. FDA product code: LRK.

Various CPAP devices have been cleared by FDA through the 510(k) process since 1977. Bilevel positive airway pressure devices were first cleared for marketing in 1996. FDA product codes: BZD, MNT.

In 2010, a nasal expiratory resistance valve (Provent®, Ventus Medical) was cleared for marketing by FDA through the 510(k) process for the treatment of OSA. The Winx™ system received marketing clearance in 2012. The manufacturer of the Winx Therapy system, Apnicure, went out of business in late 2017. The device and its associated supplies, which require a prescription, are not currently available for purchase from the manufacturer. FDA product codes: OHP, OZR.

IV. RATIONALE

TOP

POLICY TITLE	DIAGNOSIS AND MEDICAL MANAGEMENT OF OBSTRUCTIVE SLEEP APNEA
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SUMMARY OF EVIDENCE

Diagnosis

For individuals who have suspected OSA who receive home sleep testing with at least 4 recording channels, the evidence includes RCTs. Relevant outcomes are test accuracy, symptoms, functional outcomes, and resource utilization. RCTs have reported that home sleep testing with type 3 monitors (those with ≥4 recording channels) is noninferior to testing in the sleep lab for adults with a high pretest probability of OSA and absence of comorbid conditions as determined by clinical evaluation. A positive portable monitoring study with channels that include arterial oxygen saturation, airflow, and respiratory effort has a high positive predictive value for OSA and can be used as the basis for a CPAP trial to determine the efficacy of treatment. A negative portable monitoring study cannot be used to rule out OSA. Patients who have a negative result from portable monitoring or have a positive study but do not respond to CPAP should undergo further evaluation. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have suspected OSA who receive limited channel home sleep testing, the evidence includes studies on diagnostic accuracy. Relevant outcomes are test accuracy, symptoms, functional outcomes, and resource utilization. The ability to detect clinically significant OSA without sensors for heart rate, respiratory effort, airflow, and oxygen saturation lacks support in the literature. The evidence is insufficient to determine the effects of the technology on health outcomes.

Treatment

For individuals who have OSA who receive positive airway pressure devices or oral appliances, the evidence includes RCTs and systematic reviews of RCTs. Relevant outcomes are symptoms, functional outcomes, and quality of life. Conventional medical management of OSA includes weight loss, avoidance of stimulants, body position adjustment, oral appliances, and use of CPAP during sleep. A diagnostic sleep study may be followed by a trial of auto-adjusting positive airway pressure to evaluate the efficacy and adjust pressure. Auto-adjusting positive airway pressure or bilevel positive airway pressure may also be indicated if the patient is intolerant of CPAP. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have OSA who receive novel OSA treatments (e.g., palate expansion, expiratory positive airway pressure, oral pressure therapy), the evidence includes an RCT and a meta-analysis of case series. Relevant outcomes are symptoms, functional outcomes, and quality of life. The evidence on palate and mandible expansion devices includes a few small series. Further study with well-designed trials is needed to evaluate this treatment. The evidence on expiratory positive airway pressure devices in patients with OSA has been reported in prospective case series, an industry-sponsored RCT, and a systematic review that did not include

the RCT. The main finding of the RCT was a decrease in the Apnea/Hypopnea Index, with minor impact on oxygenation, and a decrease in Epworth Sleepiness Scale score. One comparative trial with historical controls used a positive airway pressure nap to study patients with complex insomnia resistant to CPAP titration or use. Additional study is needed to evaluate with greater certainty the efficacy of this intervention. No evidence was identified on use of the oral therapy device. The evidence is insufficient to determine the effects of the technology on health outcomes.

V. DEFINITIONS TOP

510 (K) is a premarketing submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent (SE), to a legally marketed device that is not subject to premarket approval (PMA). Applicants must compare their 510(k) device to one or more similar devices currently on the U.S. market and make and support their substantial equivalency claims.

AHI - The apnea/hypopnea index is the average number of apneas or hypopneas per hour of sleep

APAP - Auto-adjusting positive airway pressure may be used either to provide treatment or to determine the most effective pressure for CPAP

APNEA - The frequency of apneas and hypopneas is measured from channels assessing oxygen desaturation, respiratory airflow, and respiratory effort. In adults, apnea is defined as a drop in airflow by 90% or more of pre-event baseline for at least 10 seconds. Due to faster respiratory rates in children, pediatric scoring criteria define an apnea as 2 or more missed breaths, regardless of its duration in seconds.

BILEVEL POSITIVE AIRWAY PRESSURE VENTILATION, ALSO KNOWN AS BIPAP is non-invasive, pressure-controlled ventilation, which allows unobstructed spontaneous breathing throughout the respiratory cycle. BIPAP provides airway support by blowing air into the airway, through a mask covering the nose. The pressure increases when the patient inhales and decreases when they exhale, making it easier for patients who have difficulty breathing impulsively at their own rate. Bi-level ventilation is used to treat sleep apnea in children. Based on the precise requirements of the patient, bi-level may be favored over continuous ventilation.

CLINICALLY SIGNIFICANT OBSTRUCTIVE SLEEP APNEA SYNDROME (OSA) (ADULT PATIENTS) is defined as those patients who meet any of the following criteria:

- An apnea-hypopnea index (AHI) or respiratory disturbance index (RDI) greater than or equal to fifteen (≥ 15) events per hour **OR**

- The AHI or RDI is greater than or equal to five (≥5) and less than or equal to fourteen (≤ 14) events per hour with documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or documented hypertension, ischemic heart disease or history of stroke.

CLINICALLY SIGNIFICANT OBSTRUCTIVE SLEEP APNEA SYNDROME (OSA) (PEDIATRIC PATIENTS) IS defined as those pediatric patients who meet any of the following criteria

- AHI or RDI of at least 5 per hour, **OR**
- AHI or RDI of at least 1.5 per hour in a patient with excessive daytime sleepiness, behavioral problems or hyperactivity.

CPAP - Positive airway pressure (PAP) may be continuous (CPAP) or auto-adjusting (APAP) or bi-level (bi-PAP). CPAP is a more familiar abbreviation and will refer to the 3 types of devices for delivery of positive airway pressure.

CPAP FAILURE – Usually defined as an AHI >20 events per hour while using CPAP

CPAP INTOLERANCE - CPAP use for <4 hours per night for ≥5 nights per week, or refusal to use CPAP. CPAP intolerance may be observed in patients with mild, moderate, or severe OSA

ELECTROENCEPHALOGRAM (EEG) is the tracing of the electrical activity of the brain by an electroencephalograph.

EPWORTH SLEEPINESS SCALE is a self-administered questionnaire that asks patients their likelihood of falling asleep in eight situations ranked from zero (never doze) to three (high chance of dozing). The numbers are then added together to score between zero and twenty-four. The eight situations are as follows:

1. Sitting and reading;
2. Watching TV;
3. Sitting inactive in a public place, i.e., theater;
4. As a passenger in a car for one hour without a break;
5. Lying down to rest in the afternoon when circumstances permit;
6. Sitting and talking to someone;
7. Sitting quietly after a lunch without alcohol; and
8. In a car, while stopped for a few minutes in traffic.

HYPOPNEA in adults is scored when the peak airflow drops by at least 30% of pre-event baseline for at least 10 seconds in association with either at least 4% arterial oxygen desaturation or an arousal. Hypopneas in children are scored by a 50% or greater drop in nasal pressure and either a 3% or more decrease in oxygen saturation or an associated arousal.

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INTRA-ORAL APPLIANCE is a device placed in the mouth to correct or alleviate malocclusion.

MILD ASTHMA is a condition limited to episodes of wheezing and mild symptoms (mild attack) which can be controlled primarily by the use of bronchodilators as needed.

MILD OSA - In adults: AHI or RDI of 5 to <15. In children: AHI ≥1.5 is abnormal

MODERATE ASTHMA is a condition which includes a wide range of clinical findings between mild and severe asthma. Patients with moderate asthma show chronic mild to moderate symptoms which frequently interfere with daily activities and sleep and require the use of managers and anti-inflammatory agents. **MODERATE OSA –** Adults: AHI or RDI ≥30. Children: AHI of ≥1

MULTIPLE SLEEP LATENCY TESTS (MSLT) involve repeated measurement of sleep latency, which is the time to the onset of sleep. The test is performed in the daytime under standardized conditions following quantified nocturnal sleep. Usually two to six tests are performed, one testing every two hours, to measure daytime sleep tendency.

ORAL PRESSURE THERAPY (OPT) is comprised of three major components: an oral interface (mouthpiece), a pump, and tubing. The negative pressure generated by the pump and conveyed via tubing through the mouthpiece into the oral cavity creates a pressure gradient to draw the soft palate anteriorly into stable contact with the tongue to permit improved airflow during sleep.

OSA - Obstructive sleep apnea is repetitive episodes of upper airway obstruction due to the collapse and obstruction of the upper airway during sleep

POLYSOMNOGRAPHY refers to the continuous and simultaneous monitoring and recording of various physiological and pathophysiological parameters of sleep for six or more hours with physician review, interpretation and report. In addition, polysomnography has sleep staging, which includes an electroencephalogram (EEG), electro-oculogram (EOG), and submental electromyogram (EMG).

RDI - The respiratory disturbance index is the number of apneas, hypopneas, or respiratory event-related arousals per hour of sleep time. RDI is often used synonymously with the AHI.

REI -The respiratory event index is the number of events per hour of monitoring time. Used as an alternative to AHI or RDI in home sleep studies when actual sleep time from EEG is not available.

RERA - Respiratory event-related arousal is defined as an event lasting at least 10 seconds associated with flattening of the nasal pressure waveform and/or evidence of increasing respiratory effort, terminating in an arousal but not otherwise meeting criteria for apnea or hypopnea

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SEVERE ASTHMA is a condition in which daily activities are severely restricted by frequent episodes of moderate to severe asthma symptoms (moderate to severe attack) controlled only by the regular use of high doses of inhaled corticosteroids with the regular addition of oral corticosteroids in some cases

SEVERE OSA - Adults: AHI or RDI ≥30. Children: AHI of ≥10

UARS - Upper airway resistance syndrome is characterized by a partial collapse of the airway and results in increased resistance to airflow. The increased respiratory effort is associated with multiple sleep fragmentations, as measured by very short alpha EEG arousals.

UPPER AIRWAY RESISTANCE SYNDROME (UARS) is a variant of OSA that is characterized by a partial collapse of the airway, resulting in increased resistance to airflow. It is defined by greater than ten alpha EEG arousals per hour. The presence of abnormally negative intrathoracic pressures (i.e., more negative than –10 cm) in conjunction with the EEG arousals supports the diagnosis. The measurement of intrathoracic pressures requires the use of an esophageal manometer as an adjunct to a polysomnogram.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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POLICY TITLE	DIAGNOSIS AND MEDICAL MANAGEMENT OF OBSTRUCTIVE SLEEP APNEA
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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational; therefore not covered:

HCPCS								
94799	95805							

HCPCS Codes	Description
E1399	Durable medical equipment, miscellaneous ***(when used as palate and mandible expansion devices for the treatment of obstructive sleep apnea)***
E1399	Durable medical equipment, miscellaneous ***(when used for nasal expiratory positive pressure)***

Covered when medically necessary, unattended (unsupervised) home sleep studies:

CPT Codes®								
95800	95801	95806						

HCPCS Codes	Description
G0398	Home sleep study test (HST) with type II portable monitor, unattended; minimum of 7 channels: EEG, EOG, EMG, ECG/heart rate, airflow, respiratory effort and oxygen saturation
G0399	Home sleep test (HST) with type III portable monitor, unattended; minimum of 4 channels: 2 respiratory movement/airflow, 1 ECG/heart rate and 1 oxygen saturation
G0400	Home sleep test (HST) with type IV portable monitor, unattended; minimum of 3 channels

ICD-10-CM Diagnosis Codes	Description
G47.10	Hypersomnia, unspecified
G47.11	Idiopathic hypersomnia with long sleep time
G47.12	Idiopathic hypersomnia without long sleep time
G47.13	Recurrent hypersomnia
G47.19	Other hypersomnia
G47.30	Sleep apnea, unspecified
G47.32	High altitude periodic breathing
G47.33	Obstructive sleep apnea (adult) (pediatric) – for repeat testing only
G47.34	Idiopathic sleep related non-obstructive alveolar hypoventilation
G47.39	Other sleep apnea

POLICY TITLE	DIAGNOSIS AND MEDICAL MANAGEMENT OF OBSTRUCTIVE SLEEP APNEA
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ICD-10-CM Diagnosis Codes	Description
I10	Essential (primary) hypertension
R06.83	Snoring
R40.0	Somnolence
Z13.89	Encounter for screening for other disorder
Z68.35	Body mass index (BMI) 35.0-35.9, adult
Z68.36	Body mass index (BMI) 36.0-36.9, adult
Z68.37	Body mass index (BMI) 37.0-37.9, adult
Z68.38	Body mass index (BMI) 38.0-38.9, adult
Z68.39	Body mass index (BMI) 39.0-39.9, adult
Z68.41	Body mass index (BMI) 40.0-44.9, adult
Z68.42	Body mass index (BMI) 45.0-49.9, adult
Z68.43	Body mass index (BMI) 50-59.9 , adult
Z68.44	Body mass index (BMI) 60.0-69.9, adult
Z68.45	Body mass index (BMI) 70 or greater, adult

Covered when medically necessary; supervised polysomnography performed in a sleep laboratory:

CPT Codes®								
95782	95783	95807	95808	95810	95811			

ICD-10-CM Diagnosis Codes	Description
E66.2	Morbid (severe) obesity with alveolar hypoventilation
F51.01	Primary insomnia
F51.02	Adjustment insomnia
F51.09	Other insomnia not due to a substance or known physiological conditions
F51.11	Primary hypersomnia
F51.12	Insufficient sleep syndrome
F51.19	Other hypersomnia not due to a substance or known physiological condition
F51.8	Other sleep disorders not due to a substance or known physiological condition
F51.9	Sleep disorder not due to a substance or known physiological condition, unspecified
G25.81	Restless legs syndrome
G47.00	Insomnia, unspecified
G47.10	Hypersomnia, unspecified
G47.11	Idiopathic hypersomnia with long sleep time
G47.12	Idiopathic hypersomnia without long sleep time

POLICY TITLE	DIAGNOSIS AND MEDICAL MANAGEMENT OF OBSTRUCTIVE SLEEP APNEA
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ICD-10-CM Diagnosis Codes	Description
G47.13	Recurrent hypersomnia
G47.14	Hypersomnia due to medical condition
G47.19	Other hypersomnia
G47.30	Sleep apnea, unspecified
G47.31	Primary central sleep apnea
G47.32	High altitude periodic breathing
G47.33	Obstructive sleep apnea (adult) (pediatric) – for repeat testing only
G47.34	Idiopathic sleep related non-obstructive alveolar hypoventilation
G47.35	Congenital central alveolar hypoventilation syndrome
G47.36	Sleep related hypoventilation in conditions classified elsewhere
G47.37	Central sleep apnea in conditions classified elsewhere
G47.39	Other sleep apnea
G47.61	Periodic limb movement disorder
G47.69	Other sleep related movement disorders
I10	Essential (primary) hypertension
R06.83	Snoring
Z68.35	Body mass index (BMI) 35.0-35.9, adult
Z68.36	Body mass index (BMI) 35.0-35.9, adult
Z68.37	Body mass index (BMI) 37.0-37.9, adult
Z68.38	Body mass index (BMI) 38.0-38.9, adult
Z68.39	Body mass index (BMI) 39.0-39.9, adult
Z68.41	Body mass index (BMI) 40.0-44.9, adult
Z68.42	Body mass index (BMI) 45.0-49.9, adult
Z68.43	Body mass index (BMI) 50-59.9 , adult
Z68.44	Body mass index (BMI) 60.0-69.9, adult
Z68.45	Body mass index (BMI) 70 or greater, adult

Covered when medically necessary; Continuous Positive Airway Pressure (CPAP), Bi-level Positive Airway Pressure (BiPAP), Auto-adjusting Positive Airway Pressure (APAP), and supplies:

CPT Codes®								
94660								

HCPCS Codes	Description
A4604	Tubing with integrated heating element for use with positive airway pressure device

POLICY TITLE	DIAGNOSIS AND MEDICAL MANAGEMENT OF OBSTRUCTIVE SLEEP APNEA
POLICY NUMBER	MP-2.045

HCPCS Codes	Description
A7027	Combination oral/nasal mask, used with continuous positive airway pressure device, each
A7028	Oral cushion for combination oral/nasal mask, replacement only, each
A7029	Nasal pillows for combination oral/nasal mask, replacement only, pair
A7030	Full face mask used with positive airway pressure device, each
A7031	Face mask interface, replacement for full face mask, each
A7032	Cushion for use on nasal mask interface, replacement only, each
A7033	Pillow for use on nasal cannula type interface, replacement only, pair
A7034	Nasal interface (mask or cannula type) used with positive airway pressure device, with or without head strap
A7035	Headgear used with positive airway pressure device
A7036	Chinstrap used with positive airway pressure device
A7037	Tubing used with positive airway pressure device
A7038	Filter, disposable, used with positive airway pressure device
A7039	Filter, non-disposable, used with positive airway pressure device
A7044	Oral interface used with positive airway pressure device, each
A7045	Exhalation port with or without swivel used with accessories for positive airway devices, replacement only
A7046	Water chamber for humidifier, used with positive airway pressure device, replacement, each
E0470	Respiratory assist device, bi-level pressure capability, without backup rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)
E0471	Respiratory assist device, bi-level pressure capability, with back-up rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)
E0472	Respiratory assist device, bi-level pressure capability, with backup rate feature, used with invasive interface, e.g., tracheostomy tube (intermittent assist device with continuous positive airway pressure device)
E0561	Humidifier, non-heated, used with positive airway pressure device
E0562	Humidifier, heated, used with positive airway pressure device
E0601	Continuous positive airway pressure (CPAP) device

ICD-10-CM Diagnosis Codes	Description
G47.33	Obstructive sleep apnea (adult) (pediatric)
G47.8	Other sleep disorders

POLICY TITLE	DIAGNOSIS AND MEDICAL MANAGEMENT OF OBSTRUCTIVE SLEEP APNEA
POLICY NUMBER	MP-2.045

Covered when medically necessary; Intraoral Appliances:

HCPS Codes	Description
E0485	Oral device/appliance used to reduce upper airway collapsibility, adjustable or nonadjustable, prefabricated, includes fitting and adjustment
E0486	Oral device/appliance used to reduce upper airway collapsibility, adjustable or nonadjustable, custom fabricated, includes fitting and adjustment

ICD-10-CM Diagnosis Codes	Description
G47.33	Obstructive sleep apnea (adult) (pediatric)

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IX. POLICY HISTORY

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MP 2.045	**CAC 4/29/03**
	CAC 10/26/04
	CAC 9/13/05
	CAC 11/29/05
	CAC 11/28/06
	CAC 1/30/07 – Milliman Criteria
	CAC 1/29/08
	CAC 7/29/08
	J12 MAC 12/12/08
	CAC 3/31/09
	CAC 5-25-10 Minor Revision. Placed policy in grid format. Added the following diagnosis ischemic heart disease, insomnia and history of stroke under medical necessity of CPAP. Added the following investigational indications: 1) Portable monitoring (with any device) in children, i.e., those younger than 18 years of age; 2) Radiofrequency volumetric tissue reduction of the tongue, with or without radiofrequency reduction of the palatal tissues for upper airway resistance syndrome or OSA and 3) Laser-assisted palatoplasty (LAUP) as a treatment for upper airway resistance or OSA. References updated.
	CAC 9-28-10 Added medically necessary indications for unattended (unsupervised) home sleep studies and also criteria for repeat unattended home sleep studies. Removed atrial pacing from investigational list as it does not belong in this policy. Revised definition of clinically significant obstructive sleep apnea.
	CAC 7/26/11 Minor Revision: Revised criteria for unattended (unsupervised) home sleep studies and supervised polysomnography (sleep study) performed in a sleep laboratory. Patient to have an unattended study unless contraindicated. Deleted requirement for a CPAP trial prior to receiving approval for APAP or BiPAP. Revised criteria for ongoing therapy. Deleted the requirement for a face-to-face evaluation for ongoing use of PAP therapy and documentation of adherence to prescribed treatment of use of PAP therapy at least 3-4 hours per night. Added criteria for pediatric patients for use of PAP therapy. Added statement describing qualifications for medical professionals who interpret a polysomnogram or home sleep study. Slight change to definition of clinically significant OSA. Extracted information regarding Actigraphy and Surgical treatment of OSA or upper airway resistance – separate policies developed for each of them. No changes to criteria for use of oral appliance for sleep apnea.
	2/1/12 Admin change. Changed statement to indicate moderate to severe asthma is included with chronic pulmonary disease. Added definitions for mild, moderate and severe asthma. Changed criteria for CPAP titration or retitration - this is now an indication for facility based PSG. FEP variation changed to reference FEP policy MP-2.01.18.
	CAC 10/30/12 Minor revision. Information related to oral appliances available was added to the background. Policy criteria related to oral appliances revised. Intraoral appliances are now considered medically necessary for clinically

	severe OSA that meets specific policy criteria which includes a trial with CPAP which has failed, contraindicated, or refused. Previously, these devices were indicated for mild OSA. The use of a nasal expiratory positive airway pressure (EPAP) device was added as investigational...References were updated. Codes reviewed 9/24/12
	CAC 7/30/13 Minor revision. o Added oral pressure therapy (such as Winx™) as a medically necessary along with CPAP, BiPAP, APAP. o Clarification provided that a single night is covered for a home sleep study; o Added the following statement, "Multiple consecutive nights of supervised or unattended (unsupervised) sleep studies that do not meet the above criteria for repeat studies are not medically necessary". o Added "The use of abbreviated daytime sleep study (PAP-NAP) as a supplement to standard sleep studies is considered investigational" o Added policy guidelines section to match BCBSA o Deleted note regarding preauth requirement.
	12/19/2013- New 2014 Code updates made.
	CAC 5/20/14 Consensus. No change to policy statements. References updated. Rationale section added. Codes reviewed.
	CAC 1/27/15 Minor. Statement added that screening of bariatric surgery patients may be medically necessary. Revised criteria for home sleep studies and in laboratory polysomnography. Revised Policy guidelines, Background/Description, Rationale and references. Coding reviewed.
	11/2/15 Administrative change. LCD numbers changed from L27530, L11528, L28603, L11504 to L35050, L33718, L33611, L33800 due to Novitas update to ICD-10.
	CAC 1/26/16 Minor. Removed statement "periodic limb movements of sleep or restless limb syndrome" from criteria for unattended and supervised sleep studies. Added "injurious or potentially injurious" to specify type of parasomnias for supervised and unattended sleep studies. Added note indicating a humidifier (either heated or non-heated) and tubing is medically necessary along with PAP therapy. For intraoral appliance requests and patient with an AHI of at least 5 events per hour, deleted "unexplained" from hypertension and added additional symptoms to include mood disorders, impaired cognition, ischemic heart disease, history of stroke and insomnia along with excessive daytime sleepiness. Rationale and references updated. Coding reviewed and updated. 2/18/16 added 95807 as covered service for supervised polysomnography performed in a sleep laboratory.
	7/8/16 Administrative posting. Change Medicare DME carrier from NHIC to Noridian.
	CAC 7/26/16 Minor review for the following changes

	• Clinical need for sleep study – changed from needing to meet one or more to needing 2 or more criteria o Removed statement "excessive daytime sleepiness because the next bullet is repetitive o Added "gasping/choking episodes associated with awakenings" • For the statement "No evidence by history or Physical Exam of health conditions that might alter ventilation or require alternative treatment o Deleted "congestive" and added NYHA Class III or IV to update language o Added "established diagnosis" to obesity ventilation syndrome o Removed narcolepsy, injurious or potentially injurious parasomnias – added note to refer to MP 2.335 Polysomnography for Non-Respiratory Sleep Disorders for these conditions o Added description of neuromuscular disorders o Added "within preceding 30 days" for stroke/ischemic attack o Deleted coronary artery disease (also not in BCBSA policy) These conditions now match for the attended and unattended sleep studies. • For attended facility sleep studies: Added the following statement. o To reevaluate the diagnosis of OSA and need for continued use of an oral appliance for a patient that does not meet the criteria for an unattended home sleep study described above. (e.g., if there is a significant change in weight or change in symptoms suggesting an adjustment is required or the use of the appliance can be discontinued • In the attended facility sleep studies section – removed injurious or potentially injurious parasomnias or narcolepsy since this is now addressed in MP 2.335. Now states "When testing is done to rule out central sleep apnea. Central sleep apnea is not addressed in MP 2.335. Added a note to refer to 2.335 for the other conditions. Coding reviewed and updated**.** Variation section reformatted.
	Admin update 1/1/17: Product variation section updated with BlueJourney product name.
	CAC 7/25/17 Minor revision. New policy statements added that palate and mandible expansion devices are considered investigational for the treatment of OSA. The policy statements in the first and second paragraph were changed from "history or physical examination" to "history and physical examination". Background, rationale, and references updated. Coding reviewed and updated. Coding reviewed.
	1/1/18 Admin Update: Medicare variations removed from Commercial Policies.

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	2/8/2018 Coding Update: removed the coding section for oral pressure therapy. HCPC codes A7002, A7047, and E0600 are for a suction machine and not for OPT.
	3/12/18 Minor review. Deleted statements for Oral Pressure Therapy (OPT) (Winx™). Company is no longer doing business. Added statement that a prefabricated or off the shelf oral appliance is considered not medically necessary. Coding Reviewed.
	2/21/19 Consensus review. No change to policy statements. Background, rationale summary and references updated.

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