curative

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1. PURPOSE

To define steps and information needed to consistently review requests related to the diagnosis and medical management of sleep apnea, including requests for sleep studies.

2. SCOPE

The criterion standard diagnostic test for sleep apnea is considered a polysomnogram performed in a sleep laboratory. Polysomnography consists of monitoring and recording physiologic data during sleep. A standard polysomnogram, supervised by a sleep lab technician, typically includes:

- EEG [electroencephalography] (to stage sleep, detect arousal)
- Submental electromyogram
- Electro-oculogram (to detect arousal, rapid eye movement [REM] sleep)

Additional parameters of sleep that may be measured include:

- Respiratory airflow and effort (to detect apnea)
- Oxygen desaturation
- Electrocardiography
- Sleep position
- Leg movement
- Chest and abdominal excursions
- Continuous blood pressure monitoring
- Snoring

The first 3 elements listed here (EEG, submental electromyogram, and electro-oculogram) are required for sleep staging. By definition, a polysomnogram always includes sleep staging, while a cardiorespiratory "sleep study" does not. The actual components of the study will be dictated by the clinical situation. Supervision of the test may be considered important to ensure that the monitors are attached appropriately to the individual and do not become dislodged during the night. In addition, an attendant can identify severe OSA so that the effective level of continuous positive airway pressure (CPAP) therapy can be determined. These studies are known as "split night" studies, in which the diagnosis of OSA is established during the first half of the night and CPAP titration is conducted during the second half of the night. If successful, this strategy can eliminate the need for an additional polysomnogram for CPAP titration.

Typically, the evaluation of obstructive sleep apnea includes sleep staging to assess arousals from sleep, and determination of the frequency of apneas and hypopneas from channels measuring oxygen desaturation, respiratory airflow, and respiratory effort. An obstructive apnea is defined as at least a 10- second cessation of respiration associated with ongoing ventilatory effort. Obstructive hypopnea is a reduction, but not a cessation of air exchange, with an

associated fall in oxygen saturation (at least 3%– 4%) or arousal. The apnea/ hypopnea index (AHI) may also be referred to as the respiratory disturbance index (RDI). The AHI is defined as the total number of events per hour of sleep. When sleep onset and offset are unknown, the RDI may be calculated based on the total recording time. A diagnosis of OSA syndrome is accepted when an adult has an AHI >5 and symptoms of excessive daytime sleepiness or unexplained hypertension. An AHI greater than or equal to 15 is typically considered moderate OSA, while an AHI greater than 30 is considered severe OSA. Although there is poor correlation between AHI and OSA symptoms, an increase in mortality is associated with an AHI of greater than 15. Mortality has not been shown to be increased in individuals with an AHI between 5 (considered normal) and 15. Diagnosis of UARS rests on polysomnographic documentation of >10 EEG arousals per hour of sleep correlated with episodes of reduced intrathoracic pressure. Sources of measurement error with polysomnography include data loss, artifact, event recognition errors, measurement errors, use of different types of leads, and night-to-night variability.

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 individuals who have clinically significant and treatable disease. In light of the limited capacity of sleep laboratories, a variety of devices have been developed specifically to evaluate OSA at home. These 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 the majority of portable monitors do not record EEG. It has been proposed that unattended studies with portable monitoring devices may improve the diagnosis and treatment of individuals with OSA, although the limited number of channels in comparison with full polysomnographic recording may decrease the capability for differential diagnosis or detection of comorbid conditions.

Medical management of OSA includes lifestyle modification (weight loss, avoidance of alcohol, sedatives and caffeine consumption, especially before bedtime, allowing adequate sleep time, maintenance of appropriate body position during sleep [side versus back]), oral appliances and positive airway pressure devices (CPAP [continuous positive airway pressure], BiPAP [bilevel positive airway pressure], and APAP [automatic positive airway pressure]). (see policy titled Noninvasive Respiratory Assist Devices.) On average, a 10% weight loss produces an improvement of 50% in the apneahypopnea index. Oral appliances act by holding the mandible and tongue forward during sleep. The use of atrial overdrive pacing is also being evaluated in the treatment of OSA. This approach is being tried because of the bradycardia that generally occurs during episodes of apnea.

Nasal expiratory positive airway pressure (EPAP) can also be used to describe a device used to treat sleep apnea called Provent® (Ventus Medical). According to the manufacturer, Provent® uses a oneway valve that is placed over the nostrils at nighttime. The valve opens with inhalation, but partially closes during exhalation, creating positive pressure in the airway.

The Winx™ Sleep Therapy System (ApniCure™, Redwood City, CA) is a single pressure, oral airway device that operates without a mask or forced nasal air. Oral pressure therapy (OPT) provides light, negative pressure to the oral cavity by using a flexible mouthpiece connected to a bedside console that delivers negative pressure. This device is proposed to increase the size of the retropalatal airway by pulling the soft palate forward and stabilizing the base of the tongue.

Oral appliances can be broadly categorized as mandibular advancing/positioning devices or tongue retaining devices. Oral appliances can either be “off the shelf” or custom made for the

individual by a dental laboratory or similar provider. A number of oral appliances have received marketing clearance through the 510(k) pathway for the treatment of snoring and mild to moderate sleep apnea, including the Narval CC™, Lamberg SleepWell-Smarttrusion, 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.

The Daytime Nighttime Appliance (DNA Appliance, Biomodeling Solutions) and the mandibular Repositioning Nighttime Appliance (mRNA Appliance, Biomodeling Solutions) are customized palate and mandible expanding devices. In addition to the upper-jaw device that is common to both the DNA Appliance and the rRNA Appliance (worn both during the day and night), the mRNA Appliance moves the mandible forward and is worn during sleep. The DNA Appliance and mRNA Appliance systems use 3-dimensional axial springs which are proposed to expand the upper and lower jaw and airway gradually to treat and eliminate mild-to-moderate OSA eventually.

In 2017, SleepImage System (MyCardio) was cleared for marketing by the FDA through the 510(k) process to aid in the evaluation of sleep disorders (K163696). The SleepImage System is considered software as a medical device that provides automated analysis of sleep data from a single photoplethysmogram sensor.

3. DEFINITIONS

N/A

4. RESPONSIBILITIES

N/A

5. POLICY

Diagnosis and Medical/Surgical Management of Sleep Apnea

5.1 Diagnosis of Sleep Apnea

Curative considers the following tests medically necessary for diagnosing obstructive sleep apnea (OSA) in adults aged 18 years and older when criteria are met:

Attended Full-Channel Nocturnal Polysomnography (NPSG)

Attended full-channel nocturnal polysomnography (NPSG) (Type I device) performed in a healthcare facility is considered medically necessary for diagnosis in members with symptoms suggestive of obstructive sleep apnea when attended NPSG is used as part of a comprehensive sleep evaluation with adequate follow up, and member has one or more of the following indications for attended NPSG:

- Supervised polysomnography performed in a sleep laboratory may be considered medically necessary as a diagnostic test in individuals with a moderate or high pretest probability of OSA in the following situations:
    - Pediatric patients (i.e., < 18 years of age); OR
    - When individuals do not meet criteria for an unattended home sleep apnea test as described below, OR
    - A previous home sleep apnea test failed to establish the diagnosis of OSA in an

individual with a high pretest probability of OSA; OR

- A previous home sleep apnea test was technically inadequate, OR
- Failure of resolution of symptoms or recurrence of symptoms during treatment; OR
- When testing is done to rule out other sleep disorders such as central sleep apnea, injurious or potentially injurious parasomnias, or narcolepsy, OR
- Presence of a comorbidity that might alter ventilation or decrease the accuracy of a home sleep apnea test, including, but not limited to heart failure, neuromuscular disease, chronic pulmonary disease, or obesity hypoventilation syndrome.

- A repeated, supervised polysomnogram performed in a sleep laboratory may be considered medically necessary in individuals who meet the criteria above for an in-laboratory polysomnogram under the following circumstances:
- To initiate and titrate CPAP in adults who have:
  - An AHI or RDI of at least 15 events per hour, OR
  - An AHI or RDI of at least 5 events per hour in an individual with one or more signs
  - or symptoms associated with OSA (e.g., excessive daytime sleepiness, hypertension,
  - cardiovascular heart disease, or stroke.
- To initiate and titrate CPAP in children:
  - In pediatric patients, an AHI or RDI of ≥ 5; OR
  - An AHI or RDI ≥ 1.5 in an individual with excessive daytime sleepiness, behavioral problems, or hyperactivity.
- To assess the efficacy of surgery (including adenotonsillectomy) or oral appliances/devices.
- A supervised polysomnogram must include, at a minimum, measurement of all of the following:
  - Electroencephalography (EEG),
  - Electro-oculography (EOG),
  - Submental (or chin) electromyography (EMG),
  - Extremity muscle activity,
  - Respiratory effort,
  - Airflow,
  - Arterial oxygen saturation,
  - Electrocardiography (ECG) or heart rate.
- Member has *at least one* of the following comorbid medical conditions that degrade the accuracy of portable monitoring:
  - moderate to severe pulmonary disease (for example, COPD or asthma) (with nocturnal oxygen use or daytime hypercapnia with documented arterial blood gasses showing pO_2 less than 60 or pCO_2 greater than 45),

- neuromuscular disease (e.g., Parkinson's disease, spina bifida, myotonic dystrophy, amyotrophic lateral sclerosis),
- stroke with residual respiratory effects,
- epilepsy,
- congestive heart failure (NYHA class III or IV or LVEF less than 45%),
- pulmonary hypertension (mean pulmonary artery pressure > 25 mm Hg),
- chronic opioid medication use,
- super obesity (BMI greater than 45, or pulmonary function studies show obesity hypoventilation syndrome (BMI greater than 35 plus arterial blood gas with PCO2 greater than 45, or BMI greater than 35 plus inability to lie flat in bed)); *or*

- Member has *one or more* of the following comorbid sleep disorders:
  - periodic limb movement disorder (involuntary, jerking movements of the legs during sleep causing excessive daytime sleepiness (EDS) due to sleep fragmentation),
  - parasomnias that are unusual or atypical because of the individual's age at onset, the time, duration, or frequency of occurrence of the behavior including, but not limited to: nocturnal seizures, psychogenic dissociative states, REM sleep behavior disorder, sleep talking and/or confusional arousals,
  - severe insomnia,
  - narcolepsy,
  - central sleep apnea or complex sleep apnea; or
- Member has negative or technically inadequate portable monitoring results; *or*
- Member has low pretest probability of obstructive sleep apnea (normal BMI (less than 30), normal airway (Mallampati score 1 or 2), no snoring, and normal neck circumference (less than 17 inches in men, and less than 16 inches in women)); *or*
- Member lacks the mobility or dexterity to use portable monitoring equipment safely at home.

  Curative considers attended full-channel NPSG (Type I device) performed in a healthcare facility medically necessary for members who meet criteria for implantation of the Inspire System.

  Note: Where attended NPSG is indicated, a split-night study NPSG is considered medically necessary, in which the final portion of the NPSG is used to titrate continuous positive airway pressure (CPAP), if the Apnea Hypopnea Index (AHI) is greater than 15 in first 2 hours of a diagnostic sleep study. An additional full-night CPAP titration NPSG is considered medically necessary only if the AHI is less than or equal to 15 during the first 2 hours of a diagnostic sleep study, or if the split-night study did not allow for the abolishment of the vast majority of obstructive respiratory events (see section I.B. below).

Unattended (Home) Sleep Studies

Unattended (home) sleep studies using *any* of the following diagnostic techniques are considered medically necessary for members with symptoms suggestive of OSA when the home sleep study is used as part of a comprehensive sleep evaluation:

- Sleep monitoring using a Type II device; *or*
- Sleep monitoring using a Type III device, *or*
- Sleep monitoring using a Type IV(A) device, measuring airflow and at least 2 other channels and providing measurement of apnea-hypopnea index (AHI); *or*
- Sleep monitoring using a device that measures 3 or more channels that include pulse oximetry, actigraphy, and peripheral arterial tone (e.g., Watch-PAT device).
- A single unattended (unsupervised) home sleep apnea test with a minimum of three recording channels with the following sensors: nasal pressure, chest and abdominal respiratory inductance plethysmography, and oximetry; or alternatively peripheral arterial tone (PAT), oximetry and actigraphy (e.g., WatchPat®, Itamar Medical) may be considered medically necessary in adult individuals who are at moderate or high risk for obstructive sleep apnea (OSA) as described in the Policy Guidelines and have no evidence by history or physical examination of a health condition that might alter ventilation or require alternative treatment, including the following:
    - Central sleep apnea
    - Congestive heart failure
    - Chronic pulmonary disease
    - Obesity hypoventilation syndrome
    - Neuromuscular disorders with sleep-related symptoms
    - Narcolepsy
    - Injurious or potentially injurious parasomnias
- A single unattended (unsupervised) home sleep apnea test with a minimum of recording channels (as described above) may be considered medically necessary as a screening tool in individuals who are scheduled for bariatric surgery and have no evidence by history or physical examination of a health condition that might alter ventilation or require alternative treatment.
- Repeat unattended (unsupervised) home sleep apnea testing with a minimum of three recording channels with the following sensors: nasal pressure, chest and abdominal respiratory inductance plethysmography, and oximetry; or alternatively peripheral arterial tone (PAT), oximetry and actigraphy may be considered medically necessary in adult individuals 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 CPAP, e.g., if there is a significant change in weight or change in symptoms suggesting that CPAP should be retitrated or possibly discontinued.

Note: Sleep studies using devices that do not provide a measurement of apnea-hypopnea index (AHI) and oxygen saturation are considered not medically necessary because they do not provide sufficient information to prescribe treatment. Examples include the Biancamed SleepMinder, SNAP testing with fewer than three channels, and the SleepImage Sleep Quality Screener. Note that the ApneaLink does not meet criteria as a covered type IV

device because it does not measure airflow; however, the ApneaLink Plus records 5 channels, including airflow, and meets criteria for a covered sleep study device.

Note: Repeat home sleep testing on multiple consecutive nights has no proven value.

5.2 Physician Interpretation

Criteria required of the physician who interprets and bills the unattended sleep apnea testing (HST Type II, III, or IV) must include at least one of the following verified by documentation submitted:

- Current certification in Sleep Medicine by the American Board of Sleep Medicine (ABSM), OR
- Current subspecialty certification in Sleep Medicine by a member board of the American Board of Medical Specialties (ABMS), OR
- Completed residency or fellowship training by an ABMS member board and has completed all the requirements for subspecialty certification in sleep medicine except the examination itself and only until the time of reporting of the first examination for which the physician is eligible, OR
- Active staff membership of a sleep center or laboratory accredited by the American Academy of Sleep Medicine (AASM) or The Joint Commission (Formerly the Joint Commission on Accreditation of Healthcare).

Note: A split-night study, in which moderate-to-severe OSA is documented during the first portion of the study using PSG, followed by CPAP during the second portion of the study, can eliminate the need for a second study to titrate CPAP

5.3 Other Testing Indications

Attended full-channel nocturnal polysomnography (NPSG) (Type I device) performed in a healthcare facility is considered medically necessary for persons diagnosed with obstructive sleep apnea who have *any* of the following indications for attended NPSG:

- To titrate CPAP in persons diagnosed with clinically significant OSA for whom in-laboratory NPSG was medically necessary, but who were unable to undergo a split-night study because they had an insufficient AHI (less than 15) during the first two hours of an attended NPSG; *or*
- To titrate CPAP in persons with clinically significant OSA for whom in-laboratory NPSG was medically necessary, and who underwent a split-night study that did not abolish the vast majority of obstructive respiratory events; or
- To monitor results from CPAP in persons with OSA who have persistent significant symptoms (disturbed sleep with significant arousals) despite documented AHI less than 5 on CPAP and documented compliance with CPAP (CPAP used for 70 percent of nights for four or more hours per night, for two or more months); or
- To confirm diagnosis of obstructive sleep apnea prior to surgical modifications of the upper airway.

- Video-EEG-NPSG (NPSG with video monitoring of body positions and extended EEG channels) is considered medically necessary to assist with the diagnosis of paroxysmal arousals or other sleep disruptions that are thought to be seizure related when the initial clinical evaluation and results of a standard EEG are inconclusive.
- SNAP testing using 3 or more channels is considered a medically necessary method of home sleep testing; SNAP testing using less than 3 channels is considered experimental and investigational.

5.4 Repeat Sleep Study Indications

It may be necessary to perform repeat sleep studies up to twice a year for *any* of the following indications.

Note: Where repeat testing is indicated, attended full-channel nocturnal polysomnography (NPSG) (Type I device) performed in a healthcare facility is considered medically necessary for persons who meet criteria for attended NPSG in section I.A. above; in all other cases, unattended (home) sleep studies are considered medically necessary:

- To determine whether positive airway pressure treatment (i.e., CPAP, bilevel positive airway pressure (BiPAP), demand positive airway pressure (DPAP), variable positive airway pressure (VPAP), or auto-titrating positive airway pressure (AutoPAP)) continues to be effective in persons with new or persistent symptoms, after interrogation of current positive airway pressure device; *or*
- To determine whether positive airway pressure treatment settings need to be changed in persons with new or persistent symptoms, after interrogation of current positive airway pressure device. (**Note**: This criterion does not apply to AutoPAP devices, as these devices are automatically titrated and do not require manual adjustment of treatment settings.); *or*
- For persons with substantial weight loss (loss of 10 percent or more body weight) or some other change in their medical condition that would affect the need for continued positive airway pressure treatment (e.g., heart attack, stroke, heart failure), to determine whether continued treatment with positive airway pressure treatment is necessary; *or*
- To assess treatment response after upper airway surgical procedures and after initial treatment with oral appliances.

Note: A home sleep study is performed over multiple nights with a single interpretation is considered a single sleep study for purposes of reimbursement.

Note: Repeat sleep testing (home or attended sleep studies) for persons getting replacement CPAP equipment is considered not medically necessary unless the member also has one of the indications for repeat testing listed above.

5.5 Treatment

Treatment of snoring alone, without significant OSA, is *not* considered medically necessary.

Continuous Positive Airway Pressure (CPAP)

It is expected that members receive lifestyle advice where applicable (i.e., helping people to lose weight, stop smoking and/or decrease alcohol consumption).

- Curative considers CPAP, CPAP with pressure relief technology (e.g., C-Flex, C-Flex +) autoPAP (APAP), and APAP with pressure relief technology (e.g., A-Flex) medically necessary DME for members with a positive facility-based NPSG, or with a positive home sleep test including Type II, III, IV(A) or Watch-PAT devices, as defined by *either* of the following criteria:
    - Member's apnea-hypopnea index (AHI) or respiratory disturbance index (RDI) is greater than or equal to 15 events/hour with a minimum of 30 events: *or*
    - AHI or RDI greater than or equal to 5 and less than 15 events/hour with a minimum of 10 events and at least one of the following is met:
        - Documented history of stroke; *or*
        - Documented hypertension (systolic blood pressure greater than 140 mm Hg and/or diastolic blood pressure greater than 90 mm Hg); *or*
        - Documented ischemic heart disease; *or*
        - Documented symptoms of impaired cognition, mood disorders, or insomnia; *or*
        - Excessive daytime sleepiness (documented by either Epworth greater than 10 (see Appendix)); *or*
        - Greater than 20 episodes of oxygen desaturation (i.e., oxygen saturation of less than 85 %) during a full night sleep study, or any one episode of oxygen desaturation (i.e., oxygen saturation of less than 70 %).

The sleep study is based on a minimum of 2 hours of continuous recorded sleep or shorter periods of continuous recorded sleep if the total number of recorded events during that shorter period is at least the number of events that would have been required in a 2-hour period. If the AHI or RDI is calculated based on less than 2 hours of sleep or recording time, the total number of recorded events used to calculate the AHI or RDI (respectively) must be at least the number of events that would have been required in a 2-hour period (i.e., must reach more than 30 events without symptoms or more than 10 events with symptoms). Projections of AHI or RDI based upon shorter testing times and/or fewer events are not acceptable for use in determining whether the member meets medical necessity criteria. In addition, estimates of AHI or RDI should include all stages of sleep. Estimates of AHI or RDI that only count events during periods of REM sleep (and exclude periods of non-REM sleep from the calculation) are not acceptable for use in determining whether the member meets medical necessity criteria.

Notes: For purposes of this policy, apnea is defined as a cessation of airflow for at least 10 seconds. Hypopnea is defined as an abnormal respiratory event lasting at least 10 seconds with at least a 30 % reduction in thoraco-abdominal movement or airflow as compared to baseline, and with at least a 4 % oxygen desaturation.

The apnea-hypopnea index (AHI) is equal to the average number of episodes of apnea and hypopnea per hour of sleep without the use of a positive airway pressure device. Sleep time can only be measured in a Type I (facility-based polysomnogram) or Type II sleep study. Thus the AHI is reported only in Type I or Type II sleep studies.

The respiratory disturbance index (RDI) is equal to the episodes of apnea and hypopnea per hour of recording without the use of a positive airway pressure device. The RDI is reported in Type III, Type IV, and other home sleep studies.

Leg movement, snoring, respiratory effort related arousals (RERAs), and other sleep disturbances that may be included by some polysomnographic facilities are not considered to meet the AHI and/or RDI definition in this policy. Although AHI and RDI have been used interchangeably, some facilities use the term RDI to describe a calculation that includes these other sleep disturbances. Requests for positive airway pressure devices will be considered not medically necessary if based upon an index that does not score apneas and hypopneas separately from other sleep disturbance events. Only persons with an AHI and/or RDI, as defined in this policy, that meets medical necessity criteria may qualify for a positive airway pressure device.

- BiPAP without a backup rate feature, BiPAP with pressure relief technology (Bi-Flex), DPAP, VPAP are considered medically necessary DME for members who are intolerant to CPAP or AutoPAP, or for whom CPAP or AutoPAP is ineffective. Ineffective is defined as documented failure to meet therapeutic goals using CPAP or AutoPAP during the titration portion of a facility-based study or during home use despite optimal therapy (i.e., proper mask selection and fitting and appropriate pressure settings). The records must document that both of the following medical necessity criteria are met:
    - An appropriate interface for the CPAP and AutoPAP has been properly fit and the member is using it without difficulty; *and*
    - The current pressure setting of the CPAP or AutoPAP prevents the member from tolerating the therapy and lower pressure settings of the CPAP or AutoPAP were tried but failed to:
        - Adequately control the symptoms of OSA; *or*
        - Improve sleep quality; *or*
        - Reduce the AHI/RDI to acceptable levels.

These alternatives to CPAP may also be considered medically necessary for OSA members with concomitant breathing disorders, which include restrictive thoracic disorders, COPD, and nocturnal hypoventilation. An oral pressure appliance (OPAP) is considered medically necessary DME only on an exception basis for members who are unable to tolerate a standard nasal/face mask due to facial discomfort, sinus pain, or claustrophobia from masks.

Replacement of positive airway pressure devices is considered medically necessary at the end of their 5-year reasonable useful lifetime (RUL). Replacement of these items is considered medically necessary prior to the end of the 5-year RUL due to a change in the member's condition. Replacement needed due to misuse or abuse is not covered.

5.6 Continued Medical Necessity of Positive Airway Pressure Devices Beyond Initial Authorization Period

Continued use of a positive airway pressure device beyond the initial authorization period is considered medically necessary if the treating physician documents that the member is benefiting from positive airway pressure therapy. Documentation of clinical benefit is demonstrated by:

- Face-to-face clinical reevaluation by the treating physician with documentation that symptoms of obstructive sleep apnea are improved; *and*
- Objective evidence of adherence to use of the positive airway pressure device, reviewed by the treating physician. Adherence to therapy is defined as use of positive airway pressure four (4) or more hours per night on at least 70% of nights during a consecutive thirty (30) day period anytime during the initial period of usage.

5.7 Medical Management of Sleep Apnea:

- Medical therapy, when appropriate to the clinical situation, includes weight loss, avoidance of alcohol, sedatives, and caffeine consumption, especially before bedtime, allowing adequate sleep time, maintenance of appropriate body position during sleep (side versus back), oral appliances, positive airway pressure devices and a medically supervised smoking cessation program.
- Removable intraoral appliances (mandibular advancing/positioning devices, tongue-retaining devices) may be indicated for use in individuals with clinically significant OSA under the following conditions:
- Mild to moderate OSA, defined in adults by:
    - AHI, RDI, or REI of at least 15 events per hour; OR
    - AHI, RDI, or REI of at least 5 events per hour with any of the following associated symptoms which are documented by medical records:
        - Excessive daytime sleepiness (as evidenced by a pre-treatment Epworth
        - Score of greater than 10); or
        - Impaired cognition; or
        - Mood disorders; or
        - Insomnia; or
        - Hypertension; or
        - Ischemic heart disease; or
        - History of stroke; AND
    - One or more of the following
        - Individual is not a candidate for CPAP therapy
        - CPAP therapy has not been effective despite a 45-day trial and participation in a
        - CPAP compliance program
        - Individual has tried CPAP but has not been compliant despite a 45-day trial and participation in a CPAP compliance program
        - Individual prefers to use an oral appliance rather than CPAP as the initial therapy
- Diagnosis of OSA, whether by attended or unattended testing, meets the testing and provider qualification criteria under “When Diagnosis and Medical Management of Sleep Apnea is covered”, AND

- Documentation confirming the device is prescribed by a treating physician, AND
- Documentation confirming the device is fabricated and custom-fitted by qualified dental personnel, AND
- There is absence of temporomandibular dysfunction or periodontal disease.

- CPAP may be considered medically necessary in individuals with clinically significant OSA documented by supervised polysomnography or unattended (unsupervised) home sleep testing with a minimum of three recording channels (as described above) and defined as those individuals who meet 1 or 2 below. Prior to initiation of CPAP, conservative medical therapy as indicated above must be considered and applied as appropriate to the clinical situation.
  - An AHI, RDI, or REI > 15; OR
  - An AHI, RDI, or REI greater than or equal to 5 with any of the following associated symptoms which must be documented by medical records:
    - Excessive daytime sleepiness (as evidence by a pre-testing Epworth score of greater than 10); or
    - Impaired cognition; or
    - Mood disorders; or
    - Insomnia; or
    - Documented hypertension; or
    - Ischemic heart disease; or
    - History of stroke.

  The presence of the conditions above must be documented in the medical record and must be of clinical significance.
- Clinically significant OSA in pediatric patients is:
  - An AHI or RDI greater than or equal to 5 OR
  - An AHI or RDI greater than or equal to 1.5 in an individual with excessive daytime sleepiness, behavioral problems, or hyperactivity.
- Auto-adjusting positive airway pressure (APAP) may be considered medically necessary during a 2-week trial to initiate and titrate CPAP in adult individuals with clinically significant obstructive sleep apnea, or in those who have a significant change in weight or change in symptoms suggesting that CPAP should be retitrated or possibly discontinued.
- CPAP may be considered medically necessary in individuals with central sleep apnea documented by supervised polysomnography.
- CPAP may be considered medically necessary in individuals with complex sleep apnea documented by supervised polysomnography.

Note: A split-night study, in which sleep apnea is documented during the first portion of the polysomnogram followed by CPAP titration during the second portion, may eliminate the need for a second study to titrate CPAP. The Plan expects a split-night study to be

performed when the AHI is greater than 20 after the first 2-3 hours. On occasion, an additional full-night CPAP titration may be necessary if the split-night study did not allow for the abolishment of the vast majority of respiratory events or prescribed CPAP treatment does not control clinical symptoms.

- Adherence to and failure of CPAP Treatment: A good faith effort at CPAP compliance must be documented in the medical record and includes the following:
    - CPAP must be prescribed based on a CPAP titration to obtain the most effective pressure compatible with patient comfort.
    - The CPAP DME supplier and the sleep specialist must undertake appropriate measures to maximize the chance of success with CPAP. Measures to acclimate members to therapy may include, but are not limited to, one or more of the following:
        - Emotional support to overcome initial reluctance where appropriate, with specific attention to addressing mask intolerance due to anxiety. Mask intolerance must be addressed by the sleep specialist prior to being accepted as a reason for failure of CPAP.
        - Alternate mask fitting for effect and comfort.
        - Nasal pillows.
        - Ramping (which allows for a gradual increase in pressure).
        - Humidification.

In individuals who are unable to complete a satisfactory CPAP titration because of mask intolerance due to anxiety, unfamiliarity, or other non-physical reasons, a separate, dedicated, in-lab titration may be successful if the initial titration was time-limited due to its being part of a split-night study. If one or more titration efforts are unsuccessful, a one-month trial of home acclimation with autotitrating CPAP including gradual, daytime, non-sleeping exposure to the use of the system with documented follow-up and results must be provided.

Acclimation efforts, when necessary, should be attempted for a minimum of two months, and must be supported by proper documentation and compliance chip information before CPAP therapy will be considered a failure. Multiple visits to the sleep specialist during the acclimation period are expected, with documentation of all above efforts as applicable. Documentation must include ongoing management by the sleep specialist of two months or more.

Prior to coverage of alternative noninvasive respiratory assist devices or surgery, adequate adherence to CPAP, defined as an average of 4.5 hours of CPAP use per night on a routine basis, must be demonstrated unless the above efforts at acclimation have been documented as adequately tried and failed.

5.8 Medically Necessary Accessories and Supplies

The following accessories and supplies are considered medically necessary for members who meet criteria for positive airway pressure (PAP) devices:

- Chinstrap
- Disposable or non-disposable filters
- Full face mask with positive airway pressure device

- Headgear
- Heated or non-heated humidifier
- Nasal interface (mask or cannula type) for positive airway pressure device
- Oral interface for positive airway pressure device
- Replacement cushions and pillows for nasal application device
- Replacement interface for full face mask
- Tubing for heated or non-heated humidifier.

A nasal interface (mask or cannula type) may be used with a positive airway pressure device, with or without a head strap as an alternative to a full-face mask. However, upgraded face mask is considered medically necessary only if there is documentation that the member needs a different mask because he/she cannot maintain CPAP pressures or that in order to get the pressure the mask needs to be so tight as to generate pressure sores.

The following positive airway pressure supplies are considered not medically necessary convenience items:

- Positive airway pressure bed pillows
- Batteries for positive airway pressure devices
- DC adapters for positive airway pressure devices.

Note: Curative follows Medicare DME MAC rules with respect to the usual medically necessary quantity of supplies for positive airway pressure devices.

Upon individual review, positive airway pressure devices are considered a medically necessary form of non-invasive ventilation for members with lung disease without OSA. Requests for these devices for non-invasive ventilation of members with lung disease are subject to medical review.

Oral Appliances

Mandibular advancement oral appliances to reduce upper airway collapsibility or tongue retaining devices are considered medically necessary for members who have sleep test results that meets *one* of the following criteria:

- The AHI or RDI is greater than or equal to 15 events per hour with a minimum of 30 events: *or*
- The AHI or RDI is greater than or equal to 5 and less than 15 events per hour with a minimum of 10 events and documentation of:
    - Documented history of stroke; *or*
    - Documented hypertension (systolic blood pressure greater than 140 mm Hg and/or diastolic blood pressure greater than 90 mm Hg); *or*
    - Documented ischemic heart disease; *or*
    - Documented symptoms of impaired cognition, mood disorders, or insomnia; *or*

- Excessive daytime sleepiness (documented by either Epworth greater than 10 or MSLT less than 6); *or*
- Greater than 20 episodes of oxygen desaturation (i.e., oxygen saturation of less than 85 %) during a full night sleep study, or any 1 episode of oxygen desaturation (i.e., oxygen saturation of less than 70 %); *or*

- If the AHI is greater than 30 or the RDI is greater than 30 and meets *either* of the following:
  - The member is not able to tolerate a positive airway pressure (PAP) device; *or*
  - The use of a PAP device is contraindicated.
- Replacement of oral appliances is considered medically necessary at the end of their 5-year RUL. Replacement of these items is considered medically necessary prior to the end of the 5-year RUL due to a change in the member's condition. Replacement needed due to misuse or abuse is not covered.
- Oral appliances for snoring (e.g., Slow Wave DS8, and Snore Guard) are considered not medically necessary treatment of disease, as snoring is not considered a disease.
- Compliance monitors for oral appliances have no proven value.

Note: The Oasys Oral Airway System, and the Silent Partner OSA appliance are considered equally effective to standard oral appliances. All follow-up care, including fitting, adjustments, modifications, professional services (not all-inclusive) required during the first 90 days after provision of the oral appliance are considered to be included in the payment for device.

Note: Dental rehabilitation services (dentures, bridgework, etc.) as treatment for OSA, even if medically necessary, are not available benefits under standard Curative health insurance plans. Members should review their dental benefits plan, if any.

Note: The AM Aligner (an adjustable positioning dental device) is not covered because it is inclusive to the sleep appliance for the treatment of OSA

5.9 Medically Necessary Surgeries and Procedures

Medically necessary procedures for the treatment of OSA in adults include:

- **Adult Lingual or Pharyngeal Tonsillectomy and Adenoidectomy**

  Curative considers pharyngeal and lingual tonsillectomy medically necessary with UPPP or as an isolated procedure in adult OSA where hypertrophied tonsils compromise the airway space. An adenoidectomy is considered medically necessary for significant nasopharyngeal obstruction due to adenoid hyperplasia.

- **Drug-Induced Sleep Endoscopy (DISE)**

  Curative considers the use of DISE medically necessary to evaluate appropriateness of FDA-approved hypoglossal nerve stimulation if multiple levels of obstruction are suspected, and when all of the criteria for hypoglossal nerve stimulation are met. Curative considers DISE experimental and investigational for all other indications because of insufficient evidence in the peer-reviewed published medical literature of its safety and effectiveness.

- **Hypoglossal Nerve Neurostimulation**

  Curative considers Food and Drug Administration (FDA)-approved hypoglossal nerve neurostimulation (e.g., Inspire II System, Inspire 3028 system for Upper Airway Stimulation (UAS) Therapy) medically necessary for the treatment of moderate to severe obstructive sleep apnea when *all* of the following criteria are met:

  - Member is 18 years of age or older; *and*
  - Body mass index (BMI) is less than 40 kg/m2; *and*
  - A polysomnography (PSG) is performed within 24 months of first consultation for Inspire implant; *and*
  - Member has predominantly obstructive events (defined as central and mixed apneas less than 25% of the total AHI); *and*
  - Apnea hypopnea index (AHI) is 15 to 100 events per hour; *and*
  - Member has a minimum of one month of CPAP monitoring documentation that demonstrates CPAP failure (defined as AHI greater than 15 despite CPAP usage) or CPAP intolerance (defined as less than 4 hours per night, 5 nights per week); *and*
  - Absence of complete concentric collapse at the soft palate level as seen on a drug-induced sleep endoscopy (DISE) procedure; *and*
  - No other anatomical findings that would compromise performance of device (e.g., tonsil size 3 or 4 per tonsillar hypertrophy grading scale.

  Curative considers hypoglossal nerve neurostimulation experimental and investigational for all other indications.

  Curative considers non-FDA-approved hypoglossal nerve neurostimulation (e.g., the Apnex Hypoglossal Nerve Stimulation (HGNS™) System, the aura6000™ Neurostimulation System, ImThera's Targeted Hypoglossal Neurostimulation Therapy, and WellStar upper airway neurostimulation implant) experimental and investigational for the treatment of adult obstructive sleep apnea.

- **Jaw Realignment Surgery**

  (i.e., hyoid myotomy and suspension, mandibular osteotomy, genioglossal advancement)

  Curative considers jaw realignment surgery medically necessary for persons who fail other treatment approaches for OSA.

  Although jaw realignment surgery may be considered medically necessary on an individual case basis, because of the extent of surgery, these cases may be subject to review by Curative's Oral and Maxillofacial Surgery Unit to assess medical necessity.

  Note: According to the medical literature, persons undergoing jaw realignment surgery must usually also undergo orthodontic therapy to correct changes in occlusion associated with the surgery. Orthodontic therapy (i.e., the placement of orthodontic brackets and wires) is excluded from coverage under standard Curative medical plans regardless of medical necessity. Please check benefit plan descriptions for details. Benefits for orthodontic therapy may be available under the member's dental plan, if any.

- **Nasal Surgery**

  Curative considers nasal valve surgery, polypectomy, septoplasty, and turbinectomy medically necessary for adults with nasal obstruction and CPAP intolerance related to nasal issues and high-pressure requirements. Curative considers a turbinectomy medically necessary for severe nasal obstruction due to hypertrophied inferior nasal turbinates. Curative considers a polypectomy medically necessary for severe nasal obstruction due to nasal polyps.

  Note: Nasal valve surgery requires photos clearly documenting internal or external valve collapse contributing to nasal obstruction.

- **Palatopharyngoplasty**

  Palatopharyngoplasty (uvulopalatopharyngoplasty (UPPP), uvulopharyngoplasty, uvulopalatal flap, expansion pharyngoplasty, lateral pharyngoplasty, transpalatal advancement pharyngoplasty, relocation pharyngoplasty) is used to treat OSA by enlarging the oropharynx; it is considered medically necessary for OSA members who meet the criteria for CPAP or AutoPAP (see above), but who have had an inadequate response or are intolerant to CPAP or AutoPAP, despite adjustments to pressure and mask, as appropriate. (Intolerance includes claustrophobia, difficulty tolerating pressure, inability to sleep with CPAP device, intolerance of nasal or mouth interface, nasal irritation, or repeated removal of CPAP unintentionally during sleep.) The medical records must document that the member has attempted CPAP or AutoPAP before considering surgery.

  Curative considers palatopharyngoplasty experimental and investigational for persons with non-obstructive sleep apnea, upper airway resistance syndrome (UARS), and for all other indications.

- **The Zzoma Positional Device**

  Curative considers the Zzoma positional device not medically necessary because it has not been proven to be superior to other interventions to keep a person in a non-supine position.

- **Tongue Base Reduction Surgery**

  Curative considers tongue reduction procedures (midline glossectomy and lingualplasty) medically necessary for OSA to relieve obstruction in the lower pharyngeal airway.

- **Tonsillectomy**

  Curative considers tonsillectomy medically necessary with UPPP in members who meet medical necessity criteria for UPPP (see above for criteria for CPAP or AutoPAP).

- **Tracheostomy**

  Curative considers tracheostomy medically necessary for those members with the most severe OSA not manageable by other interventions. Requests for tracheostomy for OSA are subject to medical review. **Note**: Curative follows Medicare DME MAC rules for the medically necessary quantity of tracheostomy supplies for OSA and other indications.

5.10 Guidelines

The medical professional who is requesting, performing, and evaluating a polysomnogram or home sleep study should have training in sleep medicine, and should have performed a face-to-face evaluation of the patient. In addition, the treatment of patients diagnosed with OSA should be initiated and monitored by a professional with training in sleep medicine. Although not an exclusive list, patients with at least one of the following symptoms are considered to be at moderate risk for OSA:

- Habitual snoring.
- Observed apneas.
- Excessive daytime sleepiness.
- A body mass index greater than 35 kg/m2

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, unexplained hypertension) may be considered. Objective clinical prediction rules are being developed, however, at the present time risk assessment is based on clinical judgment.

The American Academy of Sleep Medicine (AASM) published clinical practice guidelines on diagnostic testing for adult OSA. The AASM considers a technically adequate home sleep apnea test (HSAT) device to incorporate "a minimum of the following sensors:

- nasal pressure,
- chest and abdominal respiratory inductance
- plethysmography, and
- oximetry; or else peripheral arterial tone (PAT) with oximetry and actigraphy.

The AASM recommended that patients who are obese, retrognathic, hypertensive, or who complain of snoring or daytime sleepiness should be assessed for presence or absence as well as the severity of OSA using the following methods (standard):

- Sleep history assessment includes witnessed apneas, gasping/choking at night, excessive sleepiness, total sleep amount, nocturia, morning headaches, and decreased concentration and memory.
- Physical assessment includes evaluation of respiratory, cardiovascular, and neurologic systems and signs of upper respiratory narrowing.
- Objective testing, under an AASM-accredited program, and attended by trained technical personnel. The diagnosis of OSA is confirmed if the number of obstructive events (apneas, hypopneas plus respiratory event related to arousals) is greater than 15 events/hour or greater than 5 events/hour in a patient reporting any of the following:
    - unintentional sleep episodes during wakefulness.
    - daytime sleepiness,
    - unrefreshing sleep.
    - fatigue.

    - insomnia.
    - waking up breath holding, gasping, or choking; or
    - a bed partner describing loud snoring, breathing interruptions, or both.
- In laboratory polysomnography (standard) records electroencephalogram, electrooculogram, chin electromyogram, airflow, oxygen saturation, respiratory effort, and heart rate.
- Home testing with portable monitors should at minimum, record airflow, respiratory effort, and blood oxygenation.

5.11 Not Medically Necessary

Diagnosis of Sleep Apnea:

- Diagnostic sleep testing for the following conditions is not medically necessary. They can be diagnosed through more appropriate means.
    - Bruxism
    - Drug dependency
    - Enuresis
    - Insomnia
    - Night terrors or dream anxiety attacks
    - Nocturnal myoclonus
    - Restless leg syndrome
    - Shift work and schedule disturbances
    - Somnambulism
    - Migraine Headaches
    - Snoring without other signs/symptoms of OSA
- Unattended (unsupervised) sleep studies are considered investigational in individuals who are considered at low risk for OSA.
- Unattended sleep studies for the diagnosis of complex sleep apnea are considered investigational.
- Unattended home sleep studies are considered investigational in children (younger than 18 years of age)
- Electrosleep therapy, which uses the passage of weak electric currents to the brain to induce sleep, is considered investigational.
- Topographic electroencephalogram (EEG) mapping is considered investigational in the diagnosis and/ or medical management of obstructive sleep apnea syndrome.
- Multiple sleep latency testing (MSLT) is considered not medically necessary in the diagnosis of obstructive sleep apnea syndrome.
- Video recording during polysomnography for the diagnosis of OSA in children or adults is

considered part of the standard polysomnography test and is not separately reimbursable.

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

Medical Management of Sleep Apnea:

- Over the counter bite guards are not covered.
- CPAP is not covered when the above medical criteria and guidelines are not met.
- Treatment of snoring without significant OSA is considered not medically necessary.
- Atrial pacing is considered investigational in the treatment of OSA.
- A nasal expiratory positive airway pressure (EPAP) device is considered investigational in the treatment of OSA.
- Single pressure, oral airway devices without forced nasal air are not considered CPAP and are considered investigational in the treatment of OSA.
- Palate and mandible expansion devices are considered investigational for the treatment of OSA.
- The use of an abbreviated daytime sleep session for acclimation to CPAP (PAP-NAP) is considered investigational.
- The use of a sleep positioning trainer with vibration is considered investigational for the treatment of positional OSA.
- The use of daytime electrical stimulation of the tongue is considered investigational for the treatment of OSA.

5.12 Experimental and Investigational - Medical

Diagnostic Procedures, Techniques, and Testing

The following diagnostic procedures, techniques, and testing are considered **experimental and investigational** in members with symptoms suggestive of OSA because their effectiveness for this indication has not been established:

- Acoustic pharyngometry.
- Actigraphy testing when used alone. Actigraphy, which consists of a small portable device that senses physical motion and stores the resulting information, has been used in research studies for the evaluation of rest-activity cycles. This technique, when used alone (single channel study), has not been validated as a method of diagnosing OSA. See CPB 0710 - Actigraphy and Accelerometry; *or*
- Cephalographic X-rays for diagnosis of OSA. A single panoramic x-ray of the jaws and a lateral cephalometric x-ray are considered medically necessary for the evaluation for an oral appliance for OSA. A second lateral cephalometric x-ray with the bite registration or oral appliance in place is considered medically necessary to visualize the mandibular repositioning and the changes in the airway space. Additional x-rays are considered medically necessary when surgical intervention for OSA is being considered; *or*

- Daytime nap polysomnography; *or*
- Diagnostic audio recording, with or without pulse oximetry to diagnose sleep apnea; *or*
- Dynamic sleep magnetic resonance imaging (MRI) for the diagnosis of OSA; *or*
- Genetic association studies (e.g., tumor necrosis factor-alpha (TNFA) 308 A/G polymorphism, angiotensin-converting enzyme (ACE) gene insertion/deletion, apolipoprotein E (ApoE) polymorphism) for the diagnosis of obstructive sleep apnea; or
- Laryngeal function studies; *or*
- Maintenance of wakefulness test; *or*
- Measurement of blood levels (serum and plasma) of C-reactive protein as a biomarker for the development of OSA; *or*
- Measurement of blood levels (serum and plasma) of interleukin-8 as a biomarker for the development of OSA syndrome (OSAS); *or*
- Measurement of blood levels (serum and plasma) of leptin as a biomarker for the development of OSAS; *or*
- Measurement of central corneal thickness, intraocular pressure, and retinal nerve fiber layer thickness for grading severities of obstructive sleep apnea syndrome (OSAS); *or*
- Measurement of circulating malondialdehyde concentrations as a biomarker for OSA; *or*
- Measurement of Fas-positive lymphocytes for evaluation of systemic inflammation in OSAS; *or*
- Measurement of plasma and serum interleukin-6 levels; *or*
- Measurement of plasma and serum tumor necrosis factor-alpha; *or*
- Measurement of serum/plasma brain-derived neurotrophic factor (BDNF) levels as a biomarker for OSA; *or*
- Measurement of serum/plasma insulin-like growth factor 1 (IGF-1) levels for diagnosis of OSA hypopnea syndrome; *or*
- Measurement of serum/plasma monocyte chemoattractant protein-1 (MCP-1) levels for diagnosis of OSA; *or*
- Multiple sleep latency test (see CPB 0330 - Multiple Sleep Latency Testing (MSLT) and Maintenance of Wakefulness Test (MWT)); *or*
- Natural sleep endoscopy for evaluation of OSA; *or*
- Screening for asymptomatic OSA; *or*
- SleepStrip; *or*
- Sonography; *or*
- The static charge sensitive bed; *or*
- Tomographic X-ray; *or*
- Upper gastro-intestinal endoscopy for diagnosing OSAS; *or*

- Use of serum level of advanced glycation end-products as a biomarker of obstructive sleep apnea-hypopnea syndrome; *or*
- Voxel-based brain morphometry (VBM) studies for evaluation of OSA; *or*
- X-rays of the temporomandibular joint or sella turcica.

Treatment

The following are considered experimental and investigational for the treatment of obstructive sleep apnea (OSA) in adults because the effectiveness of these approaches has not been established:

- A BiPAP device with a backup rate feature (e.g., adaptive servoventilation, VPAP Adapt SV) (see CPB 0452 - Noninvasive Positive Pressure Ventilation),
- Daytime neuromuscular stimulation of the tongue (e.g., eXciteOSA),
- Oral appliances for treatment of upper airway resistance syndrome (UARS),
- Oral appliances to reduce upper airway collapsibility for indications other than OSA (see section III.A.); for policy on oral occlusal appliances used to treat temporomandibular joint (TMJ) disorders, see CPB 0028 - Temporomandibular Disorders;
- Positive Airway pressure (PAP) for the treatment of persons with upper airway resistance syndrome (UARS) or for the improvement of seizure control in persons with epilepsy.

5.13 Experimental & Investigational - Surgical

The following surgeries and procedures are considered <u>experimental and investigational</u> for the treatment of OSA because its effectiveness has not been established:

- Apnea-triggered muscle stimulation,
- Cardiac (atrial) pacing,
- Cautery-assisted palatal stiffening operation (CAPSO),
- Contraction of the sternothyroid muscle with ansa cervicalis stimulation,
- Devices for positional therapy (e.g., the Lunoa System),
- Endoscopically assisted surgical expansion (EASE),
- Epiglottidectomy / partial epiglottidectomy,
- Genioplasty and genial tubercle advancement,
- Injection snoreplasty, injection of a sclerosing agent into the soft palate,
- Mandibular distraction osteogenesis,
- Nasal dilators,
- Nasal expiratory positive airway pressure (EPAP) (e.g., the Provent Sleep Apnea Therapy, and the ULTepap System),
- NighLase laser therapy for the treatment of snoring or OSA,
- Pillar™ Palatal Implant System (Restore Medical, Inc.),
- Rapid maxillary expansion,

- Remotely controlled mandibular positioner as a predictive screening tool for oral appliances that protrude the mandible,
- Respiratory muscle therapy (i.e., breathing exercises, oropharyngeal exercises, and wind musical instruments),
- Somnoplasty and coblation (radiofrequency ablation of the tongue base, uvula or soft palate [Somnoplasty] or of the nasal passages and soft palate [Coblation] (see CPB 0592 - Radiofrequency Ablation of Hypertrophied Nasal Turbinates),
- Surgical palatal expansion,
- The Advance System (an adjustable tongue-advancement device),
- The Repose (AIRvance Tongue Suspension) System and the Encore Tongue Base Suspension,

Curative considers the AIRvance Tongue Suspension (formerly Repose) System, a minimally invasive technique involving tongue base suspension, and the Encore tongue base suspension, experimental and investigational. These procedures, also referred to as tongue stabilization, tongue stitch or tongue fixation, have been used for treating sleep disordered breathing (SDB) caused by tongue base collapse. No specific criteria exist regarding the diagnosis of tongue base collapse in SDB. Preliminary short-term studies of surgery targeted to alleviate tongue base collapse in SDB have shown subjective improvements in snoring and statistically significant decreases in mean RDI. However, the reported rates of success have been inconsistent among studies, and larger controlled studies with long-term follow-up are necessary to determine whether these lingual suspension procedures are safe and effective.

- The Winx Therapy System / oral pressure therapy,
- Transcutaneous electrical nerve stimulation (TENS),
- Uvulectomy and Laser Assisted Uvuloplasty (LAUP),

Cold knife uvulectomy and laser assisted uvuloplasty (LAUP, laser uvulectomy) are considered experimental and investigational for OSA because they have not been shown to be as effective as UPPP for this indication. However, Curative may consider these procedures medically necessary, upon individual case review, for members with severe OSA who have other medical conditions that make them unable to undergo UPPP and have failed a trial of CPAP or AutoPAP or the use of an oral appliance or device.

Note: Uvulectomy is considered medically necessary for uvular neoplasm and as an emergent treatment for acute edema of the uvula causing acute respiratory distress. Uvulectomy is considered experimental and investigational as a treatment for recurrent throat infections and for all other indications.

5.14 CPAP claim management:

- CPAP equipment will be rented with rental fees applied to purchase price for a minimum trial period of three months to document patient compliance, patient tolerance, and clinical benefits prior to purchase.
- Payment for CPAP includes payments for the provision of all necessary accessories, i.e., mask, tubing, or cannula. Separate charges for replacement of masks, tubing, cannula

or for respiratory equipment maintenance services are not covered since they are included in the rental payment for CPAP.

6. PROCEDURE

N/A

7. TRAINING REQUIREMENT

- All Curative Medical UM associates are responsible for reading and comprehending this procedure. Employees are also responsible for contacting management or Privacy and Compliance with any questions or concerns regarding the information contained within this procedure.

8. ENFORCEMENT

Violations of this controlled document will cause the imposition of sanctions in accordance with the Curative sanctions-controlled document. This may include verbal/written warning, suspension, up to termination of employment or volunteer, intern, contractor status with Curative. Additional civil, criminal, and equitable remedies may apply.

9. DOCUMENTATION

N/A

10. REFERENCE DOCUMENTS AND MATERIALS

N/A

11. COLLABORATING DEPARTMENTS

- Medical and Pharmacy UM Departments

12. DOCUMENT CONTROL

APPROVED BY:		
(Printed Name)	**(Date)**	**(Signature)**

REVISION HISTORY			
Date	**Author**	**Version**	**Comments**
			Initial Version

APPENDICES

Any applicable attachments, resources or other materials should be included as appendices in this section. Label each appendix as follows:

Appendix A: