IEHP UM Subcommittee Approved Authorization Guideline

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COVERAGE POLICY
IEHP considers the treatment of obstructive sleep apnea (OSA) medically necessary according to the criteria outlined below:

I. **PAP (positive airway pressure):**
   Determination of medically necessary PAP therapy is as follows:
   A. CPAP (continuous positive airway pressure) (Medi-Cal, 2014):
      1. Presence of OSA and a complete Polysomnogram (PSG) has been performed within the previous year.
      2. Respiratory disturbance index (RDI) and apnea hypopnea index must be equal to or greater than 15; and,
         a. The obstructive sleep apnea improves with the application of CPAP; or
         b. RDI or AHI is equal to or greater than 5 and less than or equal to 14 with at least one of the following associated documented symptoms:
            1. Excessive daytime sleepiness
            2. Impaired cognition
            3. Mood disorders
            4. Insomnia
            5. Hypertension
            6. Ischemic Heart Disease
            7. History of stroke
   B. BiPAP (Bi-level positive airway pressure devices) (Aetna, 2018):
      BiPAP devices are considered medically necessary durable medical equipment (DME) for Members who are intolerant to CPAP or for whom CPAP is ineffective. BiPAP may also be considered medically necessary for OSA Members with concomitant breathing disorders, including restrictive thoracic disorders, Chronic Obstructive Pulmonary Disease (COPD), and nocturnal hypoventilation. If high inspiratory pressure (>15 cm H20), is necessary then BiPAP should be tried.

II. **Oral Appliances (Unicare, 2017; Ramar, 2015; Sherr, 2015):**
   A. Oral appliances are custom fitted devices that are prescribed for individuals who cannot tolerate or decline PAP therapy.
   B. The two general types of oral devices are:
      1. Jaw repositioning device
         a. Titratable
         b. Non-titratable
2. Devices that hold the tongue forward
3. Over the counter devices are available, but only a custom fitted device can assure the most effective intervention.

C. Oral appliances are covered by any of the following indications:
   1. Members with mild to moderate OSA.
   2. Patients with severe OSA who do not respond to or are unable or unwilling to tolerate PAP therapies.
   3. Oral appliances can also serve as an adjunct to PAP therapy and/or other treatment modalities for the management of OSA.

III. Surgical Interventions:
A. Uvulopalatopharyngoplasty (UPPP) (Amerigroup, 2017; Cigna, 2017; Atena, 2018); is considered medically necessary if all of the following are present:
   1. Documented obstructive sleep apnea with one of the following (a-d) requested:
      a. If UPPP is sole procedure: with AHI greater than 15 and less than 40, or
      b. If UPPP as sole procedure with AHI between 10-15 with one or more of the conditions listed below:
         i. Hypertension
         ii. Cardiac arrhythmias predominately during sleep
         iii. Pulmonary hypertension
         iv. Documented ischemic heart disease
         v. Impaired cognition or mood disorders
         vi. History of stroke
         vii. Excessive daytime sleepiness, as documented by either a score of greater than 10 on the Epworth Sleepiness Scale or inappropriate daytime napping, (e.g., during driving, conversation or eating) or sleepiness that interferes with daily activities.
      c. If UPPP is requested as part of a planned staged or combined surgery aimed at also relieving retrolingual obstruction, (e.g., genioglossal advancement, hyoid myotomy and suspension) with AHI greater than 15, or
      d. UPP as part of a planned staged or combined surgery aimed at also relieving retrolingual obstruction, with AHI between 10-15 with one or more of the conditions listed below:
         i. Hypertension
         ii. Cardiac arrhythmias predominately during sleep
         iii. Pulmonary hypertension
         iv. Documented ischemic heart disease
         v. Impaired cognition or mood disorders
         vi. History of stroke
         vii. Excessive daytime sleepiness, as documented by either a score of greater than 10 on the Epworth Sleepiness Scale or inappropriate daytime napping, (e.g., during driving, conversation or eating) or sleepiness that interferes with daily activities.
   2. CPAP (continuous positive airway pressure) has been tried with well-supported follow-up and clearly failed or is not tolerated
   3. Fiberoptic endoscopy suggests retro-palatal narrowing is the primary or a contributing source of airway obstruction if UPPP is part of a planned sole procedure or part of a staged or a combined surgery aimed at relieving retrolingual obstruction.
4. The individual is 18 years of age or older.

B. Soft Tissue Reconstruction (Amerigroup, 2017):
Hyoid myotomy and suspension, with or without mandibular osteotomy with
genioglossus (tongue) advancement, for the treatment of OSA is considered medically
necessary when ALL of the following criteria (1-4) are met:
1. The treatment of OSA in the individual is medically necessary based on AHI:
   a. AHI greater than or equal to 15, or
   b. AHI greater than or equal to 5, and less than 15 with documentation
demonstrating any of the following symptoms:
      i. Hypertension
      ii. Cardiac arrhythmias
      iii. Pulmonary hypertension
      iv. Documented ischemic heart disease
      v. Impaired cognition or mood disorders
      vi. History of stroke
      vii. Excessive daytime sleepiness, as documented by either a score of greater
           than 10 on the Epworth Sleepiness Scale or inappropriate daytime napping,
           (e.g., during driving, conversation or eating) or sleepiness that interferes with
daily activities.
2. CPAP (continuous positive airway pressure) has been tried with well-supported
   follow-up and clearly failed or is not tolerated
3. There is significant soft tissue and/or tongue base abnormalities with airway collapse
   (objective evidence of hypopharyngeal obstruction may be documented by either
   fiberoptic endoscopy or cephalometric radiographs.), and
4. The individual is 18 years of age or older

Jaw realignment surgery (that is, maxillomandibular advancement) is considered
medically necessary when ALL of the following criteria (1-4) are met:
1. OSA based on either a or b below:
   a. AHI greater than or equal to 15, or
   b. AHI greater than or equal to 5, and less than 15 with documentation
demonstrating any of the following symptoms:
      i. Hypertension
      ii. Cardiac arrhythmias
      iii. Pulmonary hypertension
      iv. Documented ischemic heart disease
      v. Impaired cognition or mood disorders
      vi. History of stroke
      vii. Excessive daytime sleepiness, as documented by either a score of greater
           than 10 on the Epworth Sleepiness Scale or inappropriate daytime napping,
           (e.g., during driving, conversation or eating) or sleepiness that interferes with
daily activities
2. CPAP (continuous positive airway pressure) has been tried with well-supported
   follow-up and clearly failed or is not tolerated
3. The individual has failed surgical intervention with either UPPP or genioglossus advancement and/or hyoid myotomy with suspension or both of these surgical procedures, and
4. The individual is 18 years of age or older
5. Jaw realignment surgery is also **medically necessary** for individuals with a documented severe jaw/facial bony abnormality that contributes to OSA, including, but not limited to, craniofacial abnormalities, micrognathia, retrognathia, or small retro-positioned jaw with associated overbite and small mouth.

D. **Tracheostomy** (Cigna, 2017; Unicare, 2017):
Tracheostomy is considered **medically necessary** for those Members with the most severe OSA when other medical and surgical options do not exist, have failed or are refused, or when deemed necessary by clinical urgency.

E. **Uvelectomy and Laser Assisted Uvuloplasty (LAUP)** (Unicare, 2017):
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, IEHP 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 the use of an oral appliance or device.

F. **Pediatric OSA: Tonsillectomy with or without Adenoidectomy** (Unicare, 2017):
Tonsillectomy with or without adenoidectomy is **medically necessary** for the treatment of obstructive sleep apnea in children since the available medical literature suggests that the majority of cases are amenable to and will benefit from these surgeries. The criteria is as follows:
1. Diagnosis of OSA with documentation of ALL of the following:
   a. Tonsillar hypertrophy; and
   b. PSG with an AHI greater than 1.0

**COVERAGE LIMITATIONS AND EXCLUSIONS**

Surgical Interventions deemed not medically necessary, experimental or investigational:
1. UPPP or LAUP for socially disruptive snoring alone
2. Routine thyroid screening tests
3. Oral appliances that are not individually fitted and prescribed by a dentist.
4. Radiofrequency Volumetric Tissue Reduction (RFVTR) (Apollo, 2018)
5. Unattended sleep studies (CMS NCD 4-08)

**ADDITIONAL INFORMATION**

Obstructive sleep apnea (OSA) is characterized by an interruption of breathing during sleep most commonly due to extra or loose tissue in the upper airway that collapses into the air passage with the effort of inhalation.

Obstructive sleep apnea occurs when the patency of the nasopharyngeal airway becomes insufficient during sleep. Anatomic risk factors include nuchal obesity, deviated septum, nasal polyps, enlarged uvula and soft palate, small chin with deep overbite, enlarged tonsils, and hypertrophy of the lateral pharyngeal musculature. Patients with OSA also appear to be unable
to maintain oropharyngeal muscle dilator activity during sleep sufficient to prevent airway collapse during the negative pressure of inspiration. Apneas and hypopneas are common during REM sleep, when muscles completely relax resulting in occlusion of the airway. The apneic event is terminated by a brief arousal to wakefulness or a lighter stage of sleep, which is accompanied by activation of the upper airway dilator and abductor muscles and restoration of airway patency.

Snoring is highly prevalent in adults and children, and it is also the most common symptom of OSA. Snoring that is not accompanied by an AHI greater than or equal to 5 in adults and not associated with reports of excessive daytime sleepiness is referred to as primary snoring and is considered a benign condition. Snoring that is associated with OSA, however, is generally loud and intermittent, and is accompanied by awakening with gasping or choking, sleep fragmentation, restlessness, impaired concentration, and daytime sleepiness. Daytime sleepiness is thought to be related to sleep disruption and may also be related to recurrent hypoxemia.

A. PSG demonstrates:
   1. AHI greater than or equal to 5

B. PSG demonstrates:
   1. AHI equal to or greater than 15

**CLINICAL/REGULATORY RESOURCE**

**CMS-NCD 240.41**

**DEFINITION OF TERMS**

A. AHI the average number of episodes of apnea and hypopnea per hour
B. RDI the average number of respiratory disturbances per hour
C. Apnea is defined as a cessation of airflow for at least 10 seconds
D. Hypopnea is defined as an abnormal respiratory event lasting at least 10 seconds with at least a 30% reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4% oxygen desaturation and an event that meets at least one of the following characteristics:
   1. Decrease in airflow of >50%
   2. An EEG arousal as defined by The American Sleep Disorders Association scoring criteria OR
   3. O2 desaturation of >3%

**REFERENCES**

5. Aetna: Obstructive Sleep Apnea in Adults, Number 0004, 1/19/2018
6. Unicare Clinical UM Guideline: Tonsillectomy for Children with or without Adenoidectomy, Number CG-SURG-30, 6/28/2017
10. Apollo Medical Review Criteria Guidelines, 2018. ENT 112: Obstructive Sleep Apnea (OSA)-Evaluation, Therapy

**DISCLAIMER**

IEHP Clinical Authorization Guidelines (CAG) are developed to assist in administering plan benefits, they do not constitute a description of plan benefits. The Clinical Authorization Guidelines (CAG) express IEHP’s determination of whether certain services or supplies are medically necessary, experimental and investigational, or cosmetic. IEHP has reached these conclusions based upon a review of currently available clinical information (including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). IEHP makes no representations and accepts no liability with respect to the content of any external information cited or relied upon in the Clinical Authorization Guidelines (CAG). IEHP expressly and solely reserves the right to revise the Clinical Authorization Guidelines (CAG), as clinical information changes.