2010 Durable Medical Equipment Criteria

Noninvasive Airway Assist Devices: General (Custom) - UDOH[1, 2]

Created based on InterQual Subset: Noninvasive Airway Assist Devices: General
Version: InterQual® 2010

PATIENT	D.O.B.	ID#	GROUP#
Diagnosis/ICD9	Sex M F (circle one)	Height	Weight
PCP/SPECIALIST	ID#	Telephone#	
VENDOR:	Telephone#	Authorization: / / to / /	

EQUIPMENT/INDICATIONS (choose one and see below)

☐ 100 Continuous positive airway pressure (CPAP) device (*E0601*)
☐ 200 Bilevel positive airway pressure (BiPAP) device w/o backup rate (*E0470*)
☐ 300 Bilevel positive airway pressure (BiPAP) device with backup rate (*E0471, E0472*)
☐ Indication Not Listed (Provide clinical justification below)

☐ 100 Continuous positive airway pressure (CPAP) device (*E0601*) **[One]**[3]
- ☐ 110 Initial application **[One]**[4]
  - ☐ 111 Adult clinical presentation **[Both]**
    - ☐ -1 Obstructive sleep apnea Dx by polysomnogram[5, 6, 7]
    - ☐ -2 Apnea-hypopnea index (AHI)/respiratory disturbance index (RDI) **[One]**[8, 9]
      - ☐ A) AHI/RDI ≥ 15 based on ≥ 2 hrs of continuous recorded sleep or AHI/RDI ≥ 30 based on < 2 hrs continuous recorded sleep
      - ☐ B) AHI/RDI ≥ 5 and < 15 based on ≥ 2 hrs of continuous recorded sleep or AHI/RDI ≥ 10 based on < 2 hrs continuous recorded sleep **and [One or More]**
        - ☐ 1) HTN/Hx of CVA/ischemic heart disease
        - ☐ 2) Symptoms of daytime sleepiness/sleep-disordered breathing[10, 11]
  - ☐ 112 Pediatric clinical presentation **[Both]**[12, 13]
    - ☐ -1 Polysomnogram results **[One or More]**[6, 14]
      - ☐ A) AHI ≥ 1[15]
      - ☐ B) Peak end-tidal PCO_2 ≥ 53 mmHg
      - ☐ C) Oxygen saturation **[One or More]**
        - ☐ 1) O_2 sat < 92% and end-tidal PCO_2 ≥ 50 mmHg for ≥ 8% of total sleep time
        - ☐ 2) O_2 sat ≤ 90% at any time during study
    - ☐ -2 Sx/findings **[One or More]**
      - ☐ A) Snoring and difficulty breathing during sleep[16]
      - ☐ B) Failure to thrive[17]

- ☐ C) Pulmonary HTN
- ☐ D) Excessive daytime sleepiness[18]
- ☐ E) Documented behavioral problems[19]

☐ 200 Bilevel positive airway pressure (BiPAP) device w/o backup rate (*E0470*) **[One]**[20, 21]
- ☐ 210 Initial application **[Both]**[4]
  - ☐ 211 Daytime symptoms of sleep-disordered breathing[10, 11]
  - ☐ 212 Clinical presentation **[One]**
    - ☐ -1 Obstructive sleep apnea and failed CPAP[5, 22]
    - ☐ -2 Central/complex sleep apnea **[All]**[5, 23]
      - ☐ A) Dx by attended facility-based polysomnogram[6]
      - ☐ B) CPAP failed to improve daytime symptoms of sleep-disordered breathing[24]
      - ☐ C) AHI improved with use of NIPPV[8, 25]
    - ☐ -3 Progressive neuromuscular condition **[One]**[26]
      - ☐ A) PCO_2 ≥ 45 mmHg measured on room air/O_2 while awake[27]
      - ☐ B) FVC < 50% predicted[28]
      - ☐ C) Maximum inspiratory pressure < 60 cm H_2O
      - ☐ D) Nocturnal O_2 sat ≤ 88% measured on room air/O_2 for ≥ 5 mins[27, 29]
    - ☐ -4 COPD **[One]**[30]
      - ☐ A) PCO_2 ≥ 55 mmHg measured on room air/O_2 while awake[27]
      - ☐ B) PCO_2 50 to 54 mmHg **and** nocturnal desaturation **[Both]**
        - ☐ 1) Nocturnal O_2 sat ≤ 88%
        - ☐ 2) Measured on O_2 ≥ 2L/min for ≥ 5 mins[29]
      - ☐ C) PCO_2 50 to 54 mmHg and hospitalization ≥ 2x w/in 1 yr for respiratory failure
    - ☐ -5 Thoracic expansion limited **[One]**[31]
      - ☐ A) PCO_2 ≥ 45 mmHg measured on room air/O_2 while awake[27]
      - ☐ B) Nocturnal O_2 sat ≤ 88% measured on room air/O_2 for ≥ 5 mins[27, 29]

☐ 300 Bilevel positive airway pressure (BiPAP) device with backup rate (*E0471, E0472*) **[One]**[20, 21]
- ☐ 310 Initial application **[Both]**[32]
  - ☐ 311 Daytime symptoms of sleep-disordered breathing[10, 11]
  - ☐ 312 Clinical presentation **[One]**
    - ☐ -1 Central/complex sleep apnea **[All]**[5, 23]
      - ☐ A) Dx by attended facility-based polysomnogram[6]
      - ☐ B) CPAP failed to improve daytime symptoms of sleep-disordered breathing[24]
      - ☐ C) AHI improved with use of NIPPV[8, 25]
    - ☐ -2 Progressive neuromuscular condition **[One]**[26]
      - ☐ A) PCO_2 ≥ 45 mmHg measured on room air/O_2 while awake[27]
      - ☐ B) FVC < 50% predicted[28]

- ☐ C) Maximum inspiratory pressure < 60 cm H_2O
- ☐ D) Nocturnal O_2 sat ≤ 88% measured on room air/O_2 for ≥ 5 mins[27, 29]

☐ -3 COPD **[All]**[30]

- ☐ A) Bilevel device w/o back-up rate used ≥ 4 hrs/day ≥ 61 days
- ☐ B) PCO_2 ≥ 52 mmHg measured on room air/O_2 while awake[27]
- ☐ C) Nocturnal O_2 sat ≤ 88% measured for ≥ 5 mins on BiPAP w/o back-up rate with O_2 ≥ 2 L/min[29]

☐ -4 Thoracic expansion limited **[Both]**[31]

- ☐ A) PCO_2 ≥ 45 mmHg measured with use of bilevel device w/o back-up rate
- ☐ B) Measured on room air/O_2 while awake[27]

☐ 320 Ongoing application **[One]**[33]

- ☐ 321 Documented continued need for BiPap device

Notes

(1)
Alternate name(s) for this equipment include:
Bilevel Positive Airway Pressure (BiPAP)
Continuous Positive Airway Pressure (CPAP)
Noninvasive positive-pressure ventilation (NIPPV)

(2)
DME coverage and payment determinations are made by the individual health plan. The decision as to whether an item is rented or purchased may be based on vendor contracts, the expected duration of use, and the need for customization of the equipment.

(3)
CPAP is a noninvasive treatment used to assist patients with sleep apnea by delivering continuous air pressure via a mask or nasal device to maintain airway patency during sleep.

(4)-POL:
Utah Medicaid provides a capped rental for 12 months on initial application for CPAP/BiPAP devices (E0601 &E0470)

(5)
Sleep apnea is a condition in which a patient's breathing nearly or completely stops for periods of 10 seconds or more during sleep. It is estimated to affect 2% to 4% of adults 30 to 60 years of age (Norman and Loredo, Clin Geriatr Med 2008; 24(1): 151-165, ix; Patil et al., Chest 2007; 132(1): 325-337). There are several types of sleep apnea: **Obstructive** (upper respiratory airflow blockage during sleep), **Hypopnea** (decreased depth and rate of respiration during sleep), **Central** (no respiratory effort made during sleep in the absence of obstruction), **Mixed** (any combination of the above), and **Complex** (central apnea associated with CO_2 regulation and obstructive airway disease).

(6)
Polysomnogram (PSG) is a sleep study used to diagnose specific sleep disorders, primarily obstructive sleep apnea (OSA). The parameters typically monitored include brain wave activity, eye movements, REM sleep, limb movement, heart rate and rhythm, airflow through the nose and mouth, chest wall excursion, oxygen saturation, snoring loudness, and sleep position.

(7)
In addition to a facility-based PSG, portable monitoring devices are also being used in the home to diagnose OSA. Although results may be less accurate, a home study may be acceptable based on the patient's clinical presentation and the medical practitioner's judgment. A home study may be appropriate for patients with a high pretest probability of OSA or for patients that are unable to have the study performed in the sleep laboratory (e.g., severe obesity, nonambulatory). The home study may also be used to monitor a patient's response to non-CPAP treatments, such as oral appliances or upper airway surgery (Ahmed et al., Chest 2007; 132(5): 1672-1677; Collop et al., J Clin Sleep Med 2007; 3(7): 737-747; Kushida et al., Sleep 2005; 28(4): 499-521).

(8)

Apnea is defined as a cessation of airflow for at least 10 seconds. Hypopnea is an abnormal respiratory episode with a reduction in thoracoabdominal movement or airflow and a decrease in oxygen saturation. The apnea-hypopnea index (AHI) is determined by adding the total number of apnea and hypopnea episodes during the sleep time and dividing that number by the total hours of sleep. Respiratory disturbance index (RDI) has sometimes been used synonymously with AHI. In addition to the number of apnea and hypopnea episodes, the RDI includes the number of respiratory effort-related arousals (RERA). Obstructive sleep apnea (OSA) can be categorized into 3 levels of severity:

- Mild AHI/RDI ≥ 5 and ≤ 15
- Moderate AHI/RDI > 15 and ≤ 30
- Severe AHI/RDI > 30

Other factors analyzed during the polysomnogram that are used to determine the severity of the OSA include: fragmentation of sleep, oxygen desaturation, and the presence of arrhythmias (Kakkar and Hill, Otolaryngol Clin North Am 2007; 40(4): 713-743).

(9)

AHI/RDI values are calculated based on the average number of events per hour. When the AHI/RDI values are based on < 2 hours of continuous recorded sleep time, a minimum number of events are required for approval of the CPAP device. This value equals the minimum requirement of events in 2 hours of recorded sleep time.

(10)

Daytime symptoms of sleep-disordered breathing include morning headache, hypersomnolence (sleepiness), excessive fatigue, cognitive dysfunction, or dyspnea. Other conditions thought to be associated with sleep-disordered breathing include: HTN, CHF, CAD, and stroke. The relationship between cardiovascular diseases and OSA is recognized and continues to be studied (Chowdhuri, Otolaryngol Clin North Am 2007; 40(4): 807-827).

(11)

Daytime sleepiness may be measured by using the Epworth Sleepiness Scale. This questionnaire assists in quantifying a patient's sleepiness. There are 8 questions that describe situations where the subject may be prone to doze (e.g., watching television, reading, sitting and talking with another person). These situations are then rated for the probability of falling asleep. Scores 10-12 suggest excessive daytime sleepiness; a score > 12 confirms excessive daytime sleepiness (Kakkar and Hill, Otolaryngol Clin North Am 2007; 40(4): 713-743).

(12)

These pediatric criteria cover children between the ages of 1 and 18. Patients >18 are considered adults.

(13)

In a child, the diagnosis of sleep apnea can be difficult to establish because the presentation is often subtle. Symptoms of OSA in children include loud snoring, apneic episodes while sleeping, daytime somnolence (uncommon in young children), and behavioral problems (e.g., poor school performance, decreased attention span). CPAP is one treatment option for these children, which requires close parental monitoring for compliance and ongoing support by the clinical team (American Academy of Pediatrics, Pediatrics 2002; 109(4): 704-712). In addition, follow-up is needed when the child grows to ensure that the mask continues to fit and that the CPAP levels are appropriate.

(14)

Portable PSG done in the home has not been studied well enough to determine the accuracy of diagnosing OSA in children. Other diagnostic techniques such as videotaping, nocturnal pulse oximetry, and daytime nap PSG may be helpful when the results are positive, but have poor predictive value when the study is negative; patients will require a PSG performed in a sleep laboratory for a definitive diagnosis (American Academy of Pediatrics, Pediatrics 2002; 109(4): 704-712). Interpretation of a pediatric PSG must be performed by a specialist familiar with pediatric sleep disorders.

(15)

The AHI should be reported as the number of events per hour of total sleep time.

(16)

All children who snore do not have OSA; however, snoring is prevalent in children with confirmed sleep-disordered breathing. The definitive test to distinguish between primary snoring and sleep-disordered breathing is PSG.

(17)-DEF:

For the purpose of these criteria, failure to thrive would be a child whose weight falls under the 5th percentile.

(18)
This criterion is applicable to school-age children.

(19)
Behavioral or cognitive problems which interfere with a child's performance in school may be associated with mild to moderate sleep-disordered breathing. These problems may be manifested by attention-deficit-hyperactivity disorder or the inability to concentrate. Some evidence does suggest that there is an association between sleep-disordered breathing and neurobehavioral symptomatology but additional research is needed before any conclusions can be made about a cause and effect relationship (Chervin et al., Pediatrics 2006; 117(4): e769-778).

(20)
BiPAP is a noninvasive treatment used to assist patients with sleep apnea by delivering air pressure via a mask or nasal device. The device maintains airway patency during inspiration and reduces pressure during expiration to increase comfort for the patient.

(21)
BiPAP devices are available with or without a backup rate feature. The machines that have backup will provide the patient with a breath when a spontaneous inspiration is not initiated within a set period of time. *E0472* is used with an invasive interface (e.g., tracheostomy tube).

(22)
CPAP should be tried and ruled out as an effective therapy for OSA prior to the initiation of BiPAP.

(23)
Patients with mixed or complex apneas have a combination of both central and obstructive sleep apneas. Treatment for complex apnea is multipronged and may consist of CPAP or BiPAP, medications, and O_2 or CO_2 supplementation. All modalities of treatment need to be finely tuned in order for the patient to obtain optimal results (Gilmartin et al., Curr Opin Pulm Med 2005; 11(6): 485-493).

(24)
OSA may co-exist with other respiratory insufficiency diagnoses (e.g., COPD, central sleep apnea). When the diagnosis of OSA is made by PSG, CPAP should be tried as an initial therapy to relieve the patient's daytime symptoms of sleep-disordered breathing. In patients where CPAP has not been effective, BiPAP with or without backup rate is the treatment of choice.

(25)
Patients will have their CPAP or BiPAP settings titrated during polysomnographic recording subsequent to the initial diagnostic phase of the study to determine the pressure needed to maintain adequate oxygenation at home. This may be done on the same night (i.e., split night study) or on another night, to adjust the equipment and determine its effectiveness, as demonstrated by a decreased AHI. Over time, patients will see a resolution of their symptoms of daytime sleepiness, impaired cognition, mood disorders, or insomnia.

(26)
Progressive neuromuscular conditions affect nerve transmission to the respiratory muscles and impact the patient's ability to spontaneously breathe. Examples of these illnesses include: Aran-Duchenne muscular atrophy, progressive muscular dystrophy, and ALS.

(27)
If the patient uses oxygen, then the CO_2 level or O_2 sat should be measured while the patient is breathing his or her usual liter/minute of oxygen.

(28)
Forced vital capacity (FVC) is the total volume of air forcibly exhaled after a maximum inspiration.

(29)
The 5 minute timeframe should be continuous to assure an accurate measurement.

(30)
COPD is a chronic, progressive respiratory disorder characterized by nonreversible airflow limitation. The abnormal inflammatory response of the lungs is secondary to noxious particles or gases (e.g., tobacco smoke, air pollution). Emphysema and chronic bronchitis are the two main diseases causing COPD.

(31)

Limited thoracic cage expansion refers to diseases, injuries, or surgeries that prevent the lungs from fully expanding. Examples include the sequelae of polio, high spinal cord injury, burns with scarring, neuropathies, myopathies, dystrophies, ALS, chest wall deformities, and scleroderma.

(32)-POL:

Utah Medicaid provides a prior authorization for 12 months on initial application for BiPAP devices (E0471)

(33)

Ongoing application refers to requests to renew an authorization after completing a trial period. The duration of the trial and frequency of renewal is based on an organization's policy. An annual review of effectiveness of therapy is required for ongoing approval of BiPAP (E0471).