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Subject: Positive Airway Pressure Devices

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DESCRIPTION:

Obstructive sleep apnea (OSA) syndrome is associated with sleep-related breathing disorders such as snoring, upper airway resistance syndrome, and obesity-hypoventilation syndrome and is believed to affect approximately 2 – 4% of the US adult population. OSA syndrome is most common in middle-aged, obese, male smokers. Untreated, OSA can result in daytime somnolence, cognitive impairment, systemic hypertension, pulmonary hypertension, myocardial infarction, cardiac arrhythmias, and increased risk of accidents. Educational interventions at the initiation of PAP therapy is considered to be a best practice.

Diagnosis of OSA typically includes sleep study testing (see MCG Sleep Testing, 01-95828-01) performed during the patient's habitual sleep hours and ideally includes all stages and positions of sleep.

Treatment of OSA is primarily based on all of the following:

Apnea-hypopnea index (AHI) or respiratory disturbance index (RDI)

Severity of presenting symptoms

Existence and severity of comorbid conditions.

Sleep studies are scored according to how many times per hour a patient stops breathing (apnea), or almost stops breathing (hypopnea). The final score is called a Respiratory Disturbance Index (RDI), or Apnea-Hypopnea Index (AHI). Any score over 5 may mean that the patient has sleep apnea.

$$\text{RDI} = \frac{\text{\# of apnea episodes + \# of hypopnea episodes}}{\text{Total number of hours of sleep}}$$

Continuous Positive Airway Pressure (CPAP), the first line treatment of OSA, is a non-invasive means of delivering low levels of air pressure through a nasal mask and flow generator system, through the nostrils, to prevent collapse of the oropharyngeal walls during sleep. CPAP acts as a pneumatic splint of the upper airway and is considered the treatment of choice for OSA. In order to assure adequate treatment results, an optimal CPAP pressure is determined by conducting a titration study where the pressure is gradually increased until the sleep-related breathing events are eliminated in all stages and positions of sleep.

C-Flex (also known as pressure-relief CPAP) is a flexible positive airway pressure device (Respironics, Murrysville, PA), which is characterized by a pressure reduction at the beginning of expiration and return to a therapeutic pressure before inhalation. Flexible positive airway pressure devices are intended to improve patient satisfaction and adherence over standard CPAP.

CPAP with expiratory pressure relief (EPR) is an enhancement to CPAP, used to improve patient comfort and adherence over standard CPAP.

Bi-level positive airway pressure creates higher inspiratory and lower expiratory pressures and is primarily used in patients with concomitant hypoventilation syndromes, central sleep apnea or treatment-emergent central sleep apnea.

Bi-Flex is a type of or enhancement to a bi-level device, which "softens" airflow at inhalation and exhalation, making breathing more natural and comfortable for patients.

Adaptive servoventilation (ASV) is a type of bi-level device that has a backup rate feature. This type of positive airway pressure device automatically adjusts its settings according to the individual's breathing effort. Brand examples of ASV devices are VPAP Adapt and ResMed.

Bi-level PAP S/T (spontaneous timed) is a bi-level respiratory assist device which delivers alternating levels of positive airway pressure rather than the continuous pressure provided by a CPAP device. These devices have two pressure settings, a higher pressure for inhalation and a lower pressure for exhalation. However, some individual's require a backup timed response where a breath will be initiated if a breath is not taken within the set timed parameter.

Auto-titrating CPAP (APAP) has the ability to provide variable expiratory pressures based upon the patient's physiologic response to treatment (i.e.: flow, pressure, airway resistance). APAP devices can also provide a non-variable continuous positive airway pressure (CPAP). APAP is an effective treatment for OSA when a facility based titration has not been performed; to address possible pressure changes that may occur throughout the night due to body position or sleep stage; or to assist with patient comfort.

Nasal expiratory positive airway pressure (EPAP) devices (e.g., Provent® Professional Sleep Apnea Therapy) are nasal patches with microvents (valves) that are inserted into each nostril and worn during sleep. They are then disposed of and replaced with another pair each night. This appliance may also be referred to as a nasal dilator or a nasal valve device.

Oral pressure therapy (OPT) (e.g., ApniCure's Winx™ Sleep Therapy System) used for the treatment of OSA 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 (i.e., region behind the palate) by pulling the soft palate forward and stabilizing the base of the tongue.

Electrical therapy devices (NightBalance®, Night Shift™ Sleep Positioner) for positional obstructive sleep apnea are small devices that attach the neck or chest and prevent the patient from adopting a supine sleeping position achieved through a subtle vibration.

POSITION STATEMENT:

CPAP (including APAP, C-flex or CPAP with ERP)

CPAP devices **meet the definition of medical necessity** for the first three months of therapy when:

A diagnosis of OSA is based on a diagnostic sleep test **AND**

The diagnostic sleep test report confirms a diagnosis of symptomatic or asymptomatic OSA and includes an AHI and/or RDI as follows:

- Apnea/Hypopnea Index (AHI), Respiratory Disturbance Index (RDI), or Respiratory Event Index (REI) of 5 or more but less than 15 in adult members with symptomatic OSA (excessive daytime sleepiness, impaired cognitive ability, mood disorders, insomnia, hypertension, ischemic heart disease, or stroke) **OR**
- AHI, RDI, or REI of 15 or more in adult members with symptomatic or asymptomatic OSA. (CPAP is contraindicated in asymptomatic members without cardiovascular disease who demonstrate mild OSA on diagnostic NPSG.)

NOTE: In pediatric members, AHI, RDI, or REI greater than or equal to 1.5 is considered abnormal, and AHI, RDI, or REI of 15 or more is considered severe OSA.

CPAP (E0601) or auto-titrating PAP (APAP) (E0601) with or without a humidifier (E0561, E0562) for an initial 90 day period **meets the definition of medical necessity** for the treatment of OSA in a child when ALL of the following criteria are met:

- OSA diagnosis established by diagnostic sleep test
- child weighs 30 kilograms (66 pounds) or more
- adenotonsillectomy has been unsuccessful or is contraindicated, or when definitive surgery is indicated but must wait complete dental and facial development.

Bi-level Positive Airway Pressure (including Bi-Flex)

Bi-level positive airway pressure with a backup respiratory feature (E0471) **or Adaptive Servo-Ventilation* (E0472) meets the definition of medical necessity for the first three months of therapy** for members with clinical disorder groups characterized as one of the following (see specific criteria for each specific disorder):

1. Restrictive thoracic disorders (i.e., progressive neuromuscular diseases or thoracic cage abnormalities)
2. Severe chronic obstructive pulmonary disease (COPD)
3. Central sleep apnea (CSA) or treatment-emergent central sleep apnea.

***NOTE**: Adaptive Servo-Ventilation, auto SV/BiPAP and auto SV advanced devices should not be used in individuals with symptomatic chronic congestive heart failure (CHF) with reduced ejection fraction (LVEF less than or equal to 45%). ResMed Ltd ® identified a significant increase in the risk of cardiovascular

death in individuals with symptomatic, chronic heart failure (NYHA II – IV) with reduced ejection fraction (LVEF less than or equal to 45%) and moderate to severe predominant central sleep apnea (AHI greater than or equal to 15, CAHI/AHI greater than or equal to 50% and CAI greater than or equal to 10). Philips Respironics® issued the same warning for at-risk individuals using BiPAP autoSV/BiPAP auto SV Advanced devices.

In individuals with LVEF greater than 45% or mild CHF-related central sleep apnea, ASV may be used as an option for treatment, at the clinical discretion of the prescribing qualified healthcare. Professional.

Restrictive Thoracic Disorders:

All of the following criteria must be met:

1. There is documentation in the member's medical record of a progressive neuromuscular disease (for example, amyotrophic lateral sclerosis) or thoracic cage abnormality (for example, post-thoracoplasty for TB),
2. One of the following:
    a. An arterial blood gas PaCO2, done while awake and breathing the member's usual FIO2 is greater than or equal to 45 mm Hg;
    b. Sleep oximetry demonstrates oxygen saturation less than or equal to 88% for at least five continuous minutes, done while breathing the member's usual FIO2;
    c. For a progressive neuromuscular disease (only), maximal inspiratory pressure is less than 60 cm H20 or forced vital capacity (FVC) is less than 50% predicted;
3. There is documentation that chronic obstructive pulmonary disease does not contribute significantly to the member's pulmonary limitation.

Severe COPD:

All of the following criteria must be met:

1. An arterial blood gas PaCO2, done while awake and breathing the member's usual FIO2, is greater than or equal to 52 mm Hg;
2. Sleep oximetry demonstrates oxygen saturation less than or equal to 88% for at least five continuous minutes, done while breathing oxygen at 2 LPM or the member's usual FIO2 (whichever is higher);
3. Prior to initiating therapy, Obstructive Sleep Apnea (OSA) and treatment with a continuous positive airway pressure device (CPAP) has been considered and ruled out.

Central Sleep Apnea or Treatment-Emergent Central Sleep Apnea:

Prior to initiating therapy, a complete facility-based, attended polysomnogram must be performed documenting **ALL** of the following:

1. The diagnosis of central sleep apnea (CSA) or treatment-emergent central sleep apnea;
2. The ruling out of CPAP as effective therapy if either CSA or OSA is a component of the initially observed sleep-associated hypoventilation;
3. Significant improvement of the sleep-associated hypoventilation with the use of a bi-level therapy or APAP on the settings that will be prescribed for initial use at home, while breathing the member's usual FIO2.

Central sleep apnea (CSA) or treatment-emergent central sleep apnea is defined as:

- An apnea-hypopnea index (AHI) greater than or equal to 5, and
- Central apneas or hypopneas greater than 50% of the total apneas/hypopneas, and
- Central apneas or hypopneas greater than or equal to 5 times per hour, and
- Symptoms of either excessive sleepiness or disrupted sleep.

Treatment-emergent central sleep apnea is a form of central sleep apnea specifically identified by the persistence or emergence of central apneas and/or hypopneas upon exposure to CPAP, bi-level therapy, or APAP, when obstructive events have disappeared. These members have predominately obstructive or mixed apneas during the diagnostic sleep study occurring at greater than or equal to 5 times per hour. With use of a CPAP, bi-level therapy, or APAP, they show a pattern of central apneas and/or central hypopneas that meets the definition of CSA described above.

If a CPAP device is tried and found ineffective during the initial 3-month home trial, substitution of bi-level therapy or APAP does not require a new clinical evaluation **OR** a new sleep test if the above criteria is met.

If a CPAP device has been used for more than 3 months and is switched to bi-level therapy or APAP, a new initial face-to-face clinical evaluation is required and the criteria above must be met, but a new sleep test is not required. A new 3-month trial would begin for use of bi-level therapy or APAP.

NOTE: If the above criteria are not met, continued coverage of a PAP device and related accessories will be denied as **does not meet the definition of medical necessity.**

A member who fails (including member non-adherence) the initial 3-month PAP trial is eligible to re-qualify for a PAP device but must have **BOTH**:

1. Face-to-face clinical re-evaluation by the treating physician to determine the etiology of the failure to respond to PAP therapy; **AND**
2. Repeat sleep test in a facility-based setting (Type 1 study).

Bi-level therapy without a backup rate feature (E0470) meets the definition of medical necessity for the treatment of obstructive sleep apnea when CPAP has been tried and proven ineffective or is not tolerated.

Bi-level therapy with a backup rate feature (E0471) is considered **experimental or investigational** for the treatment of obstructive sleep apnea. The published clinical evidence does not support proven value for this indication.

Bi-level therapy S/T with a backup rate feature is considered **experimental or investigational** when used as a life-support ventilator. There is insufficient scientific peer-reviewed literature to support the application of Bi-level therapy S/T other than to augment the ventilation of a spontaneously breathing member.

Nasal expiratory positive airway pressure (EPAP) devices (e.g., Provent® Professional Sleep Apnea Therapy) and oral pressure therapy devices (e.g., ApniCure's Winx™ Sleep Therapy System) are considered **experimental or investigational.** There is insufficient clinical evidence published in the peer-reviewed literature to support the safety, efficacy, and long-term outcomes of the use of these types of devices in the treatment of OSA.

Electrical devices for positional obstructive sleep apnea (e.g. Night Shift™ Sleep Positioner, NightBalance®) **do not meet the definition of medical necessity.** There is insufficient clinical evidence in the peer reviewed literature to support long term outcomes in treating OSA.

CONTINUED COVERAGE BEYOND THE FIRST THREE MONTHS (90 days) OF THERAPY

Continued coverage of a PAP device (E0601, E0470/E0471) beyond the first three months of therapy requires that, no sooner than the 31st day but no later than the 91st day after initiating therapy, there must be documented objective evidence that the member is adhering to PAP therapy.

(Objective evidence of adherence to PAP therapy is defined as use of PAP > 4 hours per 24 hour period for 70% of use during a consecutive thirty (30) day period anytime during the first three (3) months of initial usage.)

If the above criteria are not met, continued coverage of a PAP device and related accessories will be denied as not meeting the definition of medical necessity.

Accessories:

Accessories used with a PAP device are covered when the coverage criteria for the PAP device are met.

If the coverage criteria are not met, the accessories **will be denied as not meeting the definition of medical necessity.**

Replacement

Mask replacement may be warranted due to the following supported by documentation:

- Proper mask fit to ensure comfort and adequate control of symptoms of OSA (especially during the first 3 months to 1 year)
- Malfunction of mask
- Verification of warranty expiration.

A replacement PAP/Bi-level device **meets the definition of medical necessity** to treat obstructive sleep apnea or essential sleep apnea with a prescription from a qualified health professional due to reasonable wear and tear to the device which renders the item:

- nonfunctioning and not repairable, **AND**
- the item is no longer under warranty.

Duplicate equipment is considered a convenience (e.g., travel PAP) and **does not meet the definition of medical necessity**.

PAP Cleaning Machines or devices are considered to be items of convenience and **do not meet the definition of medical necessity.**

The following table represents the **usual maximum amount** of accessories expected to be medically necessary:

Table:

A4604	4 in 12 months
A7027	4 in 12 months
A7028	24 in 12 months
A7029	24 in 12 months
A7030	4 in 12 months
A7031	12 in 12 months
A7032	24 in 12 months
A7033	24 in 12 months
A7034	4 in 12 months
A7035	2 in 12 months
A7036	2 in 12 months
A7037	4 in 12 months
A7038	24 in 12 months
A7039	2 in 12 months
A7046	2 in 12 months

Quantities of supplies greater than those described above, as the usual maximum amounts, will be subject to medical review of documentation supporting medical necessity, justifying a larger quantity in the individual case. The following information may be required documentation to support medical necessity, such as: attending physician history and physical, attending physician visit notes, other pertinent information such as nursing home records, home health agency records, and records from other healthcare professionals.

LOINC Codes:

DOCUMENTATION TABLE	LOINC CODES	LOINC TIME FRAME MODIFIER CODE	LOINC TIME FRAME MODIFIER CODES NARRATIVE
Physician history and physical	28626-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Attending physician visit note	18733-6	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Clinical notes and chart section (i.e., nursing home records, home health agency records, and other health care professional	28650-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.

Either a non-heated (E0561) or heated (E0562) humidifier is covered when ordered by the treating physician **for use with a covered PAP device**.

BILLING/CODING INFORMATION:

The following codes may be used to describe positive airway pressure devices and accessories:

HCPCS Coding:

A4604	Tubing with integrated heating element for use with positive airway pressure device
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 of 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, nondisposable, 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
A7047	Oral interface used with respiratory suction pump, each **(Investigational)**
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 backup rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device) [describes adaptive servo ventilation]
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	CPAP (continuous positive airway pressure) device (also used for reporting APAP)
K1001	Electronic positional obstructive sleep apnea treatment, with sensor, includes all components and accessories, any type (**Investigational**)
S8186	Swivel adapter

***NOTE:** Bi-level therapy devices with a backup rate feature (E0471) are considered **experimental or investigational** when billed with any of the below listed ICD-10 diagnosis codes for obstructive sleep apnea.

NOTE: There is no specific HCPCS code for reporting C-Flex, CPAP with ERP, or Bi-Flex devices.

NOTE: Oral pressure therapy devices (e.g., Winx Sleep Therapy System) are considered **experimental or investigational**, but may sometimes be reported using E0600 (respiratory suction pump, home model, portable or stationary, electric) and A7002 (tubing, used with suction pump, each).

ICD-10 Diagnosis Codes That Support Medical Necessity:

G47.30	Sleep apnea, unspecified
G47.33	Obstructive sleep apnea (adult) (pediatric)
G47.39	Other sleep apnea
R40.0	Somnolence

REIMBURSEMENT INFORMATION

Equipment and Accessories:

First three months of approved therapy: equipment rental will be paid for the approved 3 months of therapy only.

Continued coverage approved beyond three months: After 3 months, if compliance is confirmed, authorization will be provided to allow billing up to the purchase price, deducting previously authorized rental months from the purchase rate.

Equipment and accessories are limited to the most cost effective equipment and accessories that meet the member's needs as determined by BCBSF.

Reimbursement for maintenance of positive airway pressure devices is included in the monthly rental allowance for the device.

If there is discontinuation of usage of a PAP device at any time, the supplier is expected to ascertain this and stop billing for the equipment and related accessories and supplies.

Documentation Required:

The member's medical records should include the attending physician history and physical, attending physician visit notes including member symptoms, sleep study report (including AHI/RDI) that confirmed the OSA diagnosis, and other pertinent information (i.e., hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports). This documentation must be available upon request.

LOINC Codes:

DOCUMENTATION TABLE	LOINC CODES	LOINC TIME FRAME MODIFIER CODE	LOINC TIME FRAME MODIFIER CODES NARRATIVE
Physician history and physical	28626-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim
Physician initial assessment	18736-9	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Attending physician progress note	18741-9	18805-2	Include all data of the selected type that represents observations made

			six months or fewer before starting date of service for the claim.
Physician hospital discharge summary	11490-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Provider orders	46209-3	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Physician consulting initial assessment	18763-3	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Physician consulting progress notes	28569-2	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Clinical notes and chart section (i.e., nursing home records, home health agency records, and other health care professional	28650-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Pulmonary studies	27896-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Attending physician visit notes	18733-6	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Neuromuscular electro-physiology studies	27897-8	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Blood gas tests	18767-4	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.

An order for each item billed must be signed and dated by the treating physician, kept on file by the supplier, and made available upon request.

The re-evaluation must take place within the first 3 months of treatment; however, formal assessment of improvement cannot be documented before the 31st day. The re-evaluation must include documentation of both improvements in subjective symptoms of OSA and objective data related to adherence to PAP therapy.

Documentation of adherence to PAP therapy shall be accomplished through direct download from the device, Smart Card or other data card or visual inspection of usage data with documentation provided in a written report format to be reviewed by the treating physician and included in the member's medical record. This information must be available upon request.

Many suppliers have created forms that they send to physicians and ask them to complete. Even if the physician completes this type of form and puts it in his/her chart, this supplier-generated form is not a substitute for the medical record documentation noted above.

There is no specific HCPCS code for reporting C-flex, CPAP with ERP, or Bi-Flex devices. Therefore, these devices are typically reported as a standard CPAP or Bi-level device. These devices or enhancements would not be considered separately reimbursable from standard devices. Literature does not support an increased efficacy of these devices over standard CPAP and Bi-level therapy.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products:

The following National Coverage Determination (NCD) was reviewed on the last guideline reviewed date: Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA) (240.4) located at cms.gov.

The following Durable Medical Equipment Regional Carrier (DMERC) Local Coverage Determination (LCD) was reviewed on the last guideline reviewed date: Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea (L33718) and Respiratory Assist Devices (L33800) located at cgsmedicare.com.

DEFINITIONS:

Apnea: temporary cessation of breathing and, therefore, of the body's intake of oxygen and release of carbon dioxide; cessation of airflow for 10 seconds or more.

Apnea index (AI): the number of apneic episodes per hour of sleep.

Apnea-hypopnea index (AHI): The number of episodes of reduced or absent respiratory effort per hour; the total apneas plus hypopneas during total time asleep, divided by the number of hours asleep.

Bi-level PAP S/T (spontaneous/timed): a ventilatory support system.

Central sleep apnea: Absence of breathing during sleep that occurs when the respiratory center of the brainstem does not send normal periodic signals to the muscles of respiration. Observation of the patient reveals no respiratory effort, that is, no movement of the chest, and no breath sounds.

Data card: A small card resembling a credit card that stores information from CPAP, Bi-level therapy or AUTOPAP (APAP) machines. This data card is then placed into a data card reader, downloaded to a computer, and read with optional software. Depending on the model of the machine, the data card will hold compliance data, total hours that the machine has been used, and efficiency data (e.g., Smart Card).

Excessive daytime sleepiness: Score greater than or equal to 10 on the Epworth Sleepiness Scale.

Hypopnea: an abnormal respiratory event lasting 10 seconds or more with at least a 30% reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4% oxygen desaturation.

Obstructive sleep apnea (OSA): Absent or dysfunctional breathing that occurs when the upper airway is intermittently blocked during sleep. Observation of the patient reveals vigorous but ineffective respiratory efforts, often with loud snoring or snorting.

Respiratory disturbance index (RDI): The average number of episodes of apnea, hypopnea, and respiratory event-related arousal per hour of sleep.

Respiratory Event Index (REI): 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

Sleep apnea: The cessation of breathing during sleep. To be so classified, the apnea lasts for at least 10 sec and occurs 30 or more times during a 7-hr period of sleep. This strict definition may not apply to older persons in whom periods of sleep apnea are increased. The disorder is classified according to the mechanism involved. In obstructive apnea, respiratory effort is present but ineffective because of obstruction to the upper airway. Central sleep apnea is marked by absence of respiratory muscle activity. Mixed apnea begins with absence of respiratory effort followed by upper airway obstruction. Patients with obstructive sleep apnea are usually middle-aged, obese men with a history of excessive daytime sleepiness and night breathing marked by loud snorting, snoring, and gasping sounds. Patients with central sleep apnea may exhibit excessive daytime sleepiness, but the snorting and gasping sounds during sleep are absent.

Somnolence: sleepiness; drowsiness.

Treatment-Emergent Central Sleep Apnea: A form of central sleep apnea specifically identified by the persistence or emergence of central apneas and/or hypopneas upon exposure to CPAP, bi-level therapy, or APAP, when obstructive events have disappeared.

Type I sleep study devices – polysomnography: capable of recording all of the physiologic parameters and signals defined for polysomnography. The recording is furnished in a sleep laboratory facility in which a technologist is physically present to supervise the recording during sleep time and has the ability to intervene if needed. Minimal requirements include recording of EEG, EOG, chin EMG, anterior tibialis EMG, ECG, airflow, respiratory effort and oxygen saturation. Body position must be documented or objectively measured. A sleep technologist must be in constant attendance during the sleep study.

Type II sleep study devices: for sleep studies performed unattended in or out of a sleep lab facility or attended in a sleep lab facility. Type II devices are portable devices that may measure the same channels as Type I testing, except that a heart-rate monitor can replace the ECG. These devices have a minimum of 7 channels (e.g., EEG, EOG, EMG, ECG-heart rate, airflow, respiratory effort, and oxygen saturation and monitors sleep staging). A sleep technologist is not in constant attendance in Type II studies.

Type III sleep study devices: for sleep studies performed unattended in or out of a sleep lab facility or attended in a sleep lab facility. Type III devices monitor and record a minimum of 4 channels and must record ventilation or airflow, heart rate or ECG, and oxygen saturation. A sleep technologist is not in constant attendance in Type III studies.

Type IV sleep study devices: measures three or more channels. Type IV devices must include airflow as one of the required 3 channels. Other measurements may include oximetry and heart rate. A sleep technologist is not in constant attendance when Type IV devices are used.

RELATED GUIDELINES:

Medical & Surgical Management of Obstructive Sleep Apnea (OSA), Snoring, and Other Conditions of the Soft Palate and Nasal Passages, 02-40000-16
Oxygen, 09-E0400
Sleep Testing, 01-95828-01

OTHER:

None applicable.

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the BCBSF Medical Policy & Coverage Committee on 08/22/19.

GUIDELINE UPDATE INFORMATION:

02/15/01	Medical Coverage Guideline Reformatted.
01/01/02	HCPCS coding update.
02/28/02	Reviewed; reimbursement information added regarding supplies and accessories.
06/15/02	Revised AHI (i.e., RDI) requirement for patients with asymptomatic OSA; added Medicare & More program exception for reimbursement of accessories.
10/01/02	Local codes removed.
01/01/03	HCPCS coding update.
05/15/03	Reviewed; reimbursement limitation removed for accessories and supplies reported with positive airway pressure devices.
10/15/03	HCPCS code added (S8186).
01/01/04	Annual HCPCS coding update.
04/15/04	Scheduled review; added limitations for accessories, added cross-reference to the Oxygen MCG for oxygen used with CPAP; revised timeframe for physician follow-up to 90 days; revised coverage criteria to reflect AHI values of 5 – 14 and 15 or more.
06/15/04	Revised BiPAP coverage criteria; remove criteria regarding patient compliance.
01/15/05	Annual HCPCS coding update (A7045 added).
05/15/05	Scheduled review; add coverage criteria for APAP (DPAP); add A7046.
01/01/06	Annual HCPCS coding update: revise A7032 and A7033.
05/15/06	Scheduled review (consensus review); no change in coverage statement; references updated.
08/15/06	Revisions consisting of changes in coverage criteria for BiPAP and APAP/DPAP; added non-coverage statement and definition for BiPAP S/T.
07/01/07	HCPCS 3rd quarter coding update: added K0553, K0554, and K0555.
08/15/07	Reviewed; guideline reformatted; references updated.
01/01/08	Annual HCPCS coding update: added A7027, A7028, and A7029; removed K0553, K0554, and K0555.
02/15/08	Revised to expand ICD-9 diagnosis list for obstructive sleep apnea.
09/15/08	Scheduled review; added position statement regarding Smartcards; added limitation for A7027 and revised limitation for A7037; added Program Exception for Medicare Advantage products regarding Bi-PAP S/T and home sleep testing; updated references.

05/15/09	Revised to include coverage criteria for initial trial period for use of PAP devices and continuation beyond the initial trial period; added criteria for specific diagnoses/conditions; added criteria for determining compliance; added documentation requirements; reformatting revisions.
08/15/09	Revised position statement regarding data cards (e.g., Smart Card) for PAP devices; added position statement for C-Flex devices; updated references.
04/15/10	Scheduled review with revisions. MCG title changed. Added criteria regarding adaptive nasal ventilation (i.e., BiPAP with backup rate feature). Updated references.
08/15/10	Revision to Position Statement to include indicators for pediatric patients.
10/15/10	Revision; formatting changes; related ICD-10 codes added.
04/15/11	Scheduled review with revisions to address C-Flex, CPAP with ERP, and Bi-flex devices; references updated; formatting changes.
07/01/11	Revision; formatting changes.
11/15/11	Revision to add position statement regarding nasal expiratory positive airway pressure devices (EPAP).
11/15/12	Annual review; position statement unchanged; continuation of coverage criteria revised; references updated.
03/15/13	Reimbursement section revised; position statement unchanged.
12/15/13	Annual review; position statement unchanged; Program Exceptions section updated; references updated.
01/01/14	Annual HCPCS coding update: added A7047; updated Description section and Position Statement; formatting changes.
05/15/14	Revisions regarding APAP description; formatting changes.
05/15/15	Revision; position statements, description, and references updated; formatting changes.
11/01/15	Revision: ICD-9 Codes deleted.
08/15/16	Revision; position statement section and references updated; formatting changes.
10/01/16	Revision; formatting changes.
02/15/17	Revision; Update to position statement.
09/15/17	Review; Replacement and travel PAP position statements updated; references updated.
09/15/18	Review; Bi-level positive airway pressure statement updated to include Adaptive Servo-Ventilation; objective evidence of adherence to PAP therapy definition updated and references updated.
09/15/19	Review; Position statements for PAP therapy for pediatrics, PAP cleaning devices & positional OSA electric devices added; references updated.
01/01/20	Annual CPT/HCPCS coding update. Added code K1001.