Department:	Medical Management	**Original Approval:**	12/03/2008
Policy #:	MM135	**Last Approval:**	09/26/2018
Title:	Positive Airway Pressure Devices, including Continuous Positive Airway Pressure (CPAP) and Bi-level Respiratory Assist Device (Bi-level RAD)		
Approved By:	UM Committee		

REQUIRED DOCUMENTATION

For initial records:

- Clinical documentation including history exam, assessment and plan
- Epworth sleepiness scale results
- Results of sleep study

For continued rental or purchase:

Documentation of follow up visit with sleep clinic

- Documentation of benefit of the device to the member
- Results of adherence testing, in particular the number of days with at least 4 hours of use in a time period

DEFINITIONS

Codes used for CPAP and BiPAP authorizations

• **E0601:** single-level continuous positive airway pressure device

• **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:** A bi-level respiratory assist device with backup rate

BACKGROUND

ADULTS: Sleep disorders are some of the most common medical problems in the United States and have a significant impact on quality of life, productivity, and health. There are many different types of sleep-related disorders including sleep apnea; upper airway resistance syndrome; insomnia; narcolepsy; nocturnal movement disorders, such as Restless Leg Syndrome (RLS) and Periodic Limb Movement Disorder (PLMD); unexplained excessive daytime sleepiness; and arousal disorders (parasomnias). Most, if not all, of these sleep-related disorders are treatable if diagnosed properly. Sleep apnea is characterized by an interruption of breathing during sleep, due to extra or loose tissue in the upper airway that collapses into the air passage with the effort of inhalation. This is often linked to obesity and decreased muscle tone due to aging. When the airway becomes blocked, a drop in blood oxygen content can occur which is detected by the brain, causing the patient to wake just enough to tighten the airway muscles and allow breathing to then resume. This may occur several hundred times in one night.

Obstructive sleep apnea can cause many symptoms, such as depression, irritability, sexual dysfunction, learning and memory difficulties, and falling asleep while at work or driving. Sleep apnea treatment is intended to alleviate or eliminate the occurrence of sleep apnea. This in turn should allow the patient to achieve healthy sleep patterns and mitigate or eliminate the symptoms of OSA.

Continuous Positive Airway Pressure (CPAP) is the most common treatment for sleep apnea in adults. Variations of the CPAP device, including auto-CPAP and BiPAP®, adjust the airflow to the needs of the patient.

INDICATIONS/CRITERIA

Medicaid Members	***Continue to criteria for approval below.*** ***Adults and adolescents:*** *CMS LCD,* ***Children under 13 years:*** American Academy of Pediatrics Current Clinical Practice Guideline: Diagnosis and Management of Childhood Obstructive Sleep Apnea Syndrome http://pediatrics.aappublications.org/content/130/3/576.
Medicare Members	***CMS LCD***

INITIATION OF POSITIVE AIRWAY PRESSURE (PAP) DEVICE FOR OBSTRUCTIVE SLEEP APNEA

INITIAL COVERAGE:
PAP (positive airway pressure) device will refer to both a single-level continuous positive airway pressure device (E0601) and a bi-level respiratory assist device without back-up rate (E0470) when it is used in the treatment of obstructive sleep apnea.

I. E0601 device is covered for the treatment of obstructive sleep apnea (OSA) if criteria A – C are met:

A. The member has a face-to-face clinical evaluation by the treating practitioner prior to the sleep test to assess the member for obstructive sleep apnea.

B. The member has a sleep that meets either of the following criteria (1 or 2):

1. The apnea-hypopnea index (AHI) or Respiratory Disturbance Index (RDI) is greater than or equal to 15 events per hour with a minimum of 30 events; or,

2. The AHI or RDI is greater than or equal to 5 and less than or equal to 14 events per hour with a minimum of 10 events and documentation of:

a. Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia; or,

b. Hypertension, ischemic heart disease, or history of stroke.

C. The member and/or their caregiver have received instruction from the supplier of the device in the proper use and care of the equipment.

II. E0470 device is covered for members with OSA who meet criteria A-C above, in addition to criterion D:

D. E0601 has been tried and proven ineffective based on a therapeutic trial conducted in either a facility or in a home setting.

If an E0601 device is tried and found ineffective during the initial facility-based titration or home trial, substitution of an E0470 does not require a new initial face-to-face clinical evaluation or a new sleep test.

If an E0601 device has been used for more than 3 months and the beneficiary is switched to an E0470, a new initial face-to-face clinical evaluation is required, but a new sleep test is not required. A new 3 month trial would begin for use of the E0470.

A bi-level positive airway pressure device with back-up rate (E0471) is not considered reasonable and necessary for a primary diagnosis of OSA.

For Treatment of OSA in Children:

Please consult the American Academy of Pediatrics Current Clinical Practice Guideline: Diagnosis and Management of Childhood Obstructive Sleep Apnea Syndrome
http://pediatrics.aappublications.org/content/130/3/576.
In children younger than 13 years old, both the clinical presentation and criteria for the diagnosis of OSA differ from those in adults.
The criteria for diagnosis of OSA in children under 13 years are:

- Mild sleep apnea: AHI 1-5
- Moderate to severe sleep apnea: AHI >5

For preschool children, OSA occurs most commonly due to relatively large size of tonsils and adenoids compared to the airway size. For this reason, adenotonsillectomy (AT) is generally recognized as the most appropriate first-line treatment of choice for preschool aged children with OSA. (Marcus, 2002; Hoban, 2007; Benninger, 2007; Darrow, 2007).
CPAP may be appropriate for young children with OSA in the following settings:

- Adenotonsillectomy has been unsuccessful in relieving OSA; OR
- Adenotonsillar tissue is minimal; OR
- Adenotonsillectomy is inappropriate based on OSA being attributable to another underlying cause (e.g., craniofacial anomaly) or adenotonsillectomy is contraindicated

For children younger than 13 years of age criteria for CPAP include the following:

- A diagnosis of moderate to severe obstructive sleep apnea, defined as an apnea-hypopnea index (AHI) greater than 5 particularly if the AHI remains elevated following adenotonsillectomy; OR
- A diagnosis of mild obstructive sleep apnea, defined as an apnea-hypopnea index from 1 to 5 and one of the following:
    - Behavioral problems

- Cardiovascular disease (including elevated blood pressure, pulmonary hypertension)
- Craniofacial abnormalities
- Down syndrome
- Excessive daytime sleepiness
- Impaired cognition
- Inattention or hyperactivity
- Congenital anomalies
- Neuromuscular disorders

Respiratory Assist Devices for Diagnoses Other Than Obstructive Sleep Apnea

CHPW uses: CMS Noridian Local Coverage Determination (LCD): Respiratory Assist Devices (L33800) to determine medical necessity for Respiratory Assist Devices - bi-level RAD without the back-up rate (E0470) and bi-level RAD with back-up rate (E0471) for patients with conditions that include the following:

- Restrictive Thoracic Disorders (i.e., neuromuscular diseases or severe thoracic cage abnormalities)
- Severe Chronic Obstructive Pulmonary Disease (COPD)
- Complex Sleep Apnea including Central Sleep Apnea
- Hypoventilation Syndrome

CONTINUATION OF THERAPY FOR OBSTRUCTIVE SLEEP APNEA

After the initial 3 months of trial period, the provider must submit a request for continuation of CPAP/BiPAP therapy with the following documentation:

- A face-to-face clinical re-evaluation of the patient by the ordering provider, between 31 and 91 days after initiating therapy, which documents that the patient's symptoms of the OSA have improved.
- A review of objective evidence by the ordering provider of the patient's adherence to use of the PAP device. Adherence is defined as use of the PAP device > 4 hours per night on 70% of nights during a consecutive 30-day period anytime during the 3 months of initial usage.
- If a patient fails the initial trial of CPAP and is switched to BiPAP without back up rate (E0470), the face-to-face clinical re-evaluation of the patient by the ordering provider still must be done in 31-91 days from initiation of the first treatment with CPAP unless the initial trial of CPAP lasted more than 61 days so that there would not be at least 30 days trial of BiPAP. In this case, the follow up re-evaluation can be extended to within 120 days of the initiation of the first treatment with CPAP. The start date of treatment is always the date that CPAP was started.

Members who failed the initial 12 week trial of PAP are eligible to re-qualify for a PAP device but must have:

- Face-to-face clinical re-evaluation by the treating practitioner to determine the etiology of the failure to respond to PAP therapy; and,
- Repeat sleep test in a facility-based setting (Type 1 study) if indicated. This may be a repeat diagnostic, titration or split-night study

For members with a diagnosis other than OSA

The requirements for continuation of therapy with CPAP or BiPAP are detailed in:
In summary, after the initial 3 months of rental, the provider will submit a request for continuation of BiPAP (with or without back up) rental with the following documentation:

- Medical records that indicate that member was re-evaluated on/after the 61st day of therapy and
- Signed and dated physician statement completed no sooner than 61 days after initiating use of the device declaring:
    - Member is consistently using device an average of 4 hours per 24 hour period; and
    - Member is benefiting from its use.

For Apple Health Members:

If the patient is determined to be adherent, then CPAP (E0601) or BiPAP without back up (E0470) is purchased after the initial 3 month rental period.
A bi-level positive airway pressure device (BiPAP) with back-up rate (E0471) is assessed for adherence and then has continued rental for a total of 13 months at which time it is considered purchased.

REPLACEMENT
CHPW follows Medicare Guidelines as appropriate
For CPAP/BiPAP:
CMS Noridian Local Coverage Determination Local Coverage Determination (LCD): Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea (L33718)

If a PAP device is replaced during the 5 year reasonable useful lifetime (RUL) because of loss, theft, or irreparable damage due to a specific incident, there is no requirement for a new clinical evaluation, sleep test, or trial period.

If a PAP device is replaced following the 5 year RUL, there must be a face-to-face evaluation by their treating practitioner that documents that the beneficiary continues to use and benefit from the PAP device. There is no requirement for a new sleep test or trial period.

For Respiratory Assist Devices:
Noridian Local Coverage Determination (LCD): RESPIRATORY ASSIST DEVICES (L33800).

SPECIAL CONSIDERATIONS

Enter all special considerations here.

LIMITATIONS/EXCLUSIONS

Please refer to a product line's certificate of coverage for benefit limitations and exclusions for these services:

PRODUCT LINE	LINK TO CERTIFICATE OF COVERAGE
MEDICARE ADVANTAGE	http://healthfirst.chpw.org/for-members/resource-library/handbooks-and-guides
WASHINGTON APPLE HEALTH	http://chpw.org/our-plans/apple-health/
INTEGRATED MANAGED CARE	http://chpw.org/our-plans/apple-health/

Citations & References

CFR		
WAC		
RCW		
CMS	Noridian Local Coverage Determination (LCD): RESPIRATORY ASSIST DEVICES (L33800). Noridian Local Coverage Determination (LCD): Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea (L33718):	
Contract Citation	☒ WAH	1.55 Durable Medical Equipment
	☒ IMC	
	☒ MA	
CHPW Clinical Practice Guidelines	American Academy of Pediatrics current Clinical Practice Guideline: Diagnosis and Management of Childhood Obstructive Sleep Apnea Syndrome	
Other Requirements		
NCQA Elements		

Revision History

Revision Date	Revision Description	Revision Made By
12/03/2008	Approval	MMLT
12/08/2010	Approval	MMLT

04/15/2011	Clarify age definition for Adults and Children	Lucy Sutphen, MD, FACP
12/12/2011	Switch to CMS coverage criteria for adults; name change to reflect expanded devices (from UM003_CCC-CPAP-and_BiPAP to UM003_CCC_Positive Pressure Airway Devices)	Lucy Sutphen, MD, FACP
12/14/2011	Approval	MMLT
11/28/2012	Approval	MMLT
04/08/2014	Criteria and references updated.	MMLT
05/15/2015	Clarification of "gap" coverage added; links verified	Revisions by Kate Brostoff MD
05/26/2015	Approval	MMLT
10/23/2015	Updated change in rental convert to purchase process to align with HCA's Respiratory Care Provider guide (October 1, 2015)	Kelly Force, Kate Brostoff, MD
11/11/2015	Approval	MMLT
01/07/2016	Updated to align with HCA's Respiratory Care Provider Guide (January 1, 2016): added specific rental and convert to purchase information for Bi- level Respiratory Assist Device (RAD)	Kelly Force, Kate Brostoff, MD
02/02/2016	Approval	MMLT
02/10/2017	Minor editing changes; links updated	Cyndi Stilson, RN for Dr. LuAnn Chen
02/13/2017	Approval	MMLT
10/10/2017	Change's to E0471 criteria to remove OSA	Sheila Ranganathan, RN
10/11/2017	Approved	Cyndi Stilson, RN
10/16/2017	Approval	MMLT
03/26/2018	Changed from UM003 to MM135	Cindy Bush
04/23/2018	Transferred to new template	Cindy Bush
08/24/2018	Removed reference to prior authorization. Added required documentation. Clarified criteria for continued use. Removed rental vs purchase section. Clarified requirements if a patient has failed the initial 3 month trial. Links corrected. Clarified that for a failed initial trial, a second sleep study only needs to be done if indicated. Added reference to CHPW Clinical Practice Guidelines. Clarified criteria for CPAP in	LuAnn Chen, MD

	pediatric population. Clarified reevaluation requirements.	
09/20/2018	Approval	UM Medical Subcommittee Committee
09/26/2018	Approved	UM Committee