SUBJECT: **Sleep Apnea Treatment, Positive Airway Pressure Devices**
INDEX TITLE: **Medical Management**
ORIGINAL DATE: **January 2013**

This policy applies to the following lines of business:

COMMERCIAL	[ ] HMO	[ ] PPO	[ ] Fully Insured	[ ] Individual Product	[ ] Marketplace (Exchange)	[X] All
GOVERNMENT PROGRAMS	[ ] MA HMO	[ ] MA PPO	[ ] MA C-SNP	[ ] MA D-SNP	[X] MA All	
	[ ] Medicaid					
OTHER	[X] Self-funded/ASO					

I. POLICY

It is the policy of MedStar Health, Inc. to provide payment for Sleep Apnea Treatment, Positive Airway Pressure (PAP) Devices when it is medically necessary (refer to CRM 015.MH- Medical Necessity policy) and covered by the member's specific benefit plan. Payment will be made for the rental of a PAP device for the first three months (rental period) from the original start date of therapy. If compliance criteria is met (refer to Indications, Continued Coverage Section), payment will made for an additional ten months* as part of the capped rental for the device. Refer to Variations Section for specific information for Medical Assistance.

II. DEFINITIONS

Apnea -- is defined as the cessation of airflow for at least ten seconds.

Apnea-Hypopnea Index (AHI) -- is equal to the average number of episodes of apnea and hypopnea per hour of sleep without the use of positive airway pressure device.

Note: The AHI or RDI is calculated on the average number of events per hour. If the AHI or RDI is calculated on less than two hours of continuous recorded sleep, the total number of recorded events to calculate the AHI or RDI during sleep testing is at least the number of events that would have been required in a two hour period.

Automated Positive Airway Pressure -- (aka: APAP**,** Auto PAP, Auto-Titrating, C-Flex) is a modification of conventional (fixed) CPAP technology. It is based on the observation that the effective positive-pressure level of CPAP for a given individual varies in relation to a number of factors. These factors include ingestion of alcohol and other sedative drugs, body positioning while sleeping, sleep stages, and even the course of CPAP itself. This observation implies that the positive-pressure level could change from night to night or even from hour to hour within a given night. Auto-CPAP continuously adapts the positive pressure level during the night, thus allowing a decrease in pressure level when apnea and hypopnea disappear and an increase in pressure level when they reappear. In addition to being used as a primary treatment, auto-CPAP can be used to determine an optimal fixed level of CPAP for long-term treatment with a conventional CPAP device.

BiLevel Positive Airway Pressure (BiPAP) -- refer to Respiratory Assist Device. BiPAP or bi-level positive airway pressure is a type of noninvasive ventilation that helps keep the upper airways of the lungs open by providing a flow of air delivered through a face mask. The air is pressurized by a machine, which delivers it to the face mask through long, plastic hosing.

Continuous Positive Airway Pressure (CPAP) -- is a non-invasive technique for providing single levels of air pressure from a flow generator, via a nose mask, through the nares. The purpose is to prevent the collapse of the oropharyngeal walls and the obstruction of airflow during sleep, which occurs in OSA.

Epworth Sleepiness Scale (ESS) -- a questionnaire used to measure daytime sleepiness. A score of 10 or more is considered sleepy and a score of 18 or more is considered very sleepy. This questionnaire is helpful in diagnosing sleep apnea.

Home Sleep Study Test (HST) -- is performed unattended in the member's home using a portable monitoring device.

Hypopnea -- is defined as an abnormal respiratory event lasting at least ten 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.

Obstructive Sleep Apnea (OSA) -- the most common form of apnea, is a sleep and breathing disorder characterized by the cessation of breathing for more than tenseconds at least five times per hour of sleep.

Mild- AHI index is 5-15 events per hour
Moderate- AHI index is 15-30 events per hour
Severe- AHI index or more than 30 events per hour.

Polysomnography (PSG) -- (facility based or home) is the continuous and simultaneous monitoring and recording of various physiological and pathophysiological parameters of sleep with physician review, interpretation, and report. It must include sleep staging, which is defined to include a 1-4 lead electroencephalogram (EEG), and electro-oculogram (EOG), and a submental electromyogram (EMG). It must also include at least the following additional parameters of sleep: airflow, respiratory effort, and oxygen saturation by oximetry. It may be performed as either a whole night study for diagnosis only or as a split night study to diagnose and initially evaluate treatment.

Respiratory Assist Device (RAD), also known as BiPAP -- is the administration of positive air pressure, using a nasal and/or oral mask interface which creates a seal, avoiding the use of more invasive airway access (e.g., tracheostomy). It may be applied to assist insufficient respiratory efforts in the treatment of conditions that may involve sleep-associated hypoventilation. It is to be distinguished from the invasive ventilation administered via a securely intubated airway, in a patient for whom interruption or failure of ventilatory support would lead to imminent demise of the patient.

Respiratory Cycle -- is defined as an inspiration, followed by expiration.

Respiratory Disturbance Index (RDI) -- is equal to the average number of respiratory disturbances per hour of continuous monitoring.

Note: The AHI or RDI is calculated on the average number of events per hour. If the AHI or RDI is calculated on less than 2 hours of sleep or recording time, the total number of recorded events used to calculate the AHI or RDI must be at least the number of events that would have been required in a two hour period (i.e.,. must reach ≥ 30 events without symptoms or ≥ ten events with symptoms.

Sleep Study/Test (aka: Polysomnography).

I. PURPOSE

The purpose of this policy is to define the indications for medical necessity for Sleep Apnea Treatment, Positive Airway Pressure (PAP) Devices.

II. SCOPE

This policy applies to various departments as indicated by the Benefit and Reimbursement Committee. These include but are not limited to Medical Management, Benefit Configuration and Claims departments.

III. PROCEDURE

A. Medical Background

Obstructive sleep apnea (OSA) is a sleep and breathing disorder characterized by the cessation of breathing for more than ten seconds at least five times per hour of sleep. Hypopnea is a related event that is characterized by a reduction in airflow and a decrease in oxygen saturation. During these episodes, the body reacts by waking just enough for breathing to resume, a pattern that can occur hundreds of times each night. This condition leads to sleep deprivation and places an excess strain on the cardiovascular system. As a result, patients may suffer from extreme daytime sleepiness, and experience greater cardiovascular morbidity and mortality.

Treatment options for OSA include conservative measures like weight loss and sleep position training, medications, BiPAP/CPAP, oral appliances, and surgery.

CPAP is a therapy for OSA that requires patients to wear a mask or nasal prongs over the nose (or nose and mouth) during sleep. The mask or nasal prongs are connected to an air pump that provides constant airflow. CPAP increases the pressure in the oropharyngeal airway, thereby maintaining airway patency. This approach does not represent a cure, as CPAP must be administered every night.

Obstructive sleep-disordered breathing is a common problem in children of all ages, severity ranging from primary or simple snoring, upper airway resistance syndrome, obstructive hypopnea syndrome and, in its most severe form, obstructive sleep apnea syndrome.

The American Academy of Pediatrics (AAP) defines OSA in children as "a disorder of breathing during sleep characterized by prolonged partial upper airway obstruction and/or intermittent complete obstruction (obstructive apnea) that disrupts normal ventilation during sleep and normal sleep patterns". The outstanding feature of the disorder is habitual and loud snoring. Adenotonsillar hypertrophy is the most common cause of obstructive sleep-disordered breathing. When left untreated, obstructive sleep-disordered breathing may lead to problems related to sleep disruption such as inattention, poor learning, behavioral problems, and attention-deficit/hyperactivity disorder or may cause more serious morbidity, including growth failure and pulmonary hypertension. The diagnosis of obstructive sleep-disordered breathing in most children is made through a thorough sleep-based history and physical examination. Adenoidectomy is the primary treatment for obstructed sleep-disordered breathing. CPAP, BiLevel PAP, and Auto PAP are used as a secondary treatment or as an adjunct therapy post tonsillectomy or adenoidectomy or as emergency treatment in

severe cases.

B. Indications

Continuous Positive Airway Pressure (CPAP) - Single Level

Initial Coverage

CPAP is covered for the treatment of obstructive sleep apnea (OSA) when **all** of the following indications are met:

1. A confirmed diagnosis of OSA for the coverage of CPAP was done through one of the following:

a) Attended Polysomnography (PSG) performed in a sleep laboratory (Type I)
b) Unattended home sleep study test (HST) with a Type I, II, III or IV home sleep monitoring device. (Refer to Home Sleep Study policy)

2. The member's sleep test indicates **any** of the following:

a) The AHI or RDI is greater than or equal to 15 events per hour with a minimum of 30 events
b) The AHI or RDI is greater than or equal to five and less than or equal to 14 events per hour with a minimum of 10 events AND documentation of **any** of the following:

- Excessive daytime sleepiness
- Impaired cognition
- Mood disorders
- Insomnia Hypertension, ischemic heart disease, or history of stroke

3. The member had a face-to-face clinical evaluation by the treating physician prior to the sleep test to assess the member for obstructive sleep apnea. The evaluation needs to include at least one of the following:

a) Sleep history and symptoms including: snoring, daytime sleepiness, observed apneas, choking or gasping during sleep, morning headaches
b) Duration of symptoms
c) Validation of sleep hygiene inventory such as the Epworth Sleepiness Scale
d) A physical examination that documents a focused cardiopulmonary and upper airway system evaluation, neck circumference and body mass index (BMI)

4. The member and/or their caregiver have received adequate instruction in the proper use and care of the equipment prior to its use

PAP Devices for Children

PAP devices are covered for children when **all** of the following indications are met:

1. The PAP device is approved by the Food and Drug Administration for the child's age
2. The child has been evaluated by an Ear, Nose and Throat (ENT) specialist prior to CPAP

3. **Any** of the following

a) Surgery is contraindicated
b) There is minimal adenotonsillar tissue
c) OSA is persistent after adenotonsillectomy
d) Member/parent(s) prefer non-surgical alternatives.

Automated Positive Airway Pressure (APAP, Auto-Titrating, Auto PAP, C-Flex)

Automated Positive Airway Pressure is considered medically necessary for the diagnosis of OSA for any one of the following indications:

1. When used during attended titration with Polysomnography to identify a single pressure for use with the standard CPAP for treatment of moderate to severe OSA
2. One of the following:

a) When used in the self-adjusting mode for unattended treatment of members with moderate to severe OSA without significant comorbidities (i.e., congestive heart failure (CHF), chronic obstructive pulmonary disease (COPD), central sleep apnea syndromes, or hypoventilation syndromes)
b) When used in an unattended way to determine a fixed CPAP treatment pressure for members with moderate to severe OSA without significant comorbidities (e.g., CHF, COPD, central sleep apnea or hypoventilation syndromes)

Note: Members being treated with fixed CPAP on the basis of APAP titration or being treated with APAP must have close clinical follow-up to determine treatment effectiveness and safety. This is especially important during the first few weeks of positive airway pressure (PAP) use.

3. A re-evaluation and, if necessary, a standard attended CPAP titration should be performed if symptoms do not resolve or if the APAP treatment otherwise appears to lack efficacy

Respiratory Assist Devices (RAD/BiPAP) Without Backup Rate

RAD/BiPAP without backup rate is covered for the first three months for the diagnosis of obstructive sleep apnea (OSA) when **both** of the following indications are met:

1. The member meets the above indications for CPAP
2. A single level CPAP device has been tried and proven ineffective based on a therapeutic trial conducted in either a facility or in a home setting.

- "Ineffective" is defined as documented failure to meet therapeutic goals using a CPAP 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).

Note: If RAD/BiPAP **without** backup rate is billed and criteria in #2 above is not met, payment will be based on the allowance for the least costly medically

appropriate alternative, CPAP single level.

Respiratory Assist Devices (RAD/BiPAP) With backup rate

(Refer to Limitations section)

New MedStar Health Members

The following indications for continued coverage apply to new MedStar Health members who own a CPAP/BiPAP machine:

- A baseline diagnostic sleep study needs to be on file and available when requested. If no baseline sleep study is available, a new sleep study must be done before continuation of coverage.

CONCURRENT USE OF OXYGEN WITH PAP THERAPY

Concurrent use of oxygen with PAP therapy is covered when the member meets **all** of the following indications:

1. The member must be in a "chronic stable state" (i.e. they are not experiencing an acute illness or an exacerbation of their underlying disease).
2. The member must have a severe lung disease, such as chronic obstructive pulmonary disease, diffuse interstitial lung disease, cystic fibrosis, bronchiectasis, widespread pulmonary neoplasm, or hypoxia-related symptoms or findings that might be expected to improve with oxygen therapy.
3. All co-existing diseases or conditions that can cause hypoxia must be treated.
4. The OSA must be sufficiently treated such that the underlying severe lung disease is unmasked. This must be demonstrated before oxygen saturation results obtained during Polysomnography are considered qualifying for oxygen therapy.
5. A qualifying oxygen saturation test may only occur during a titration polysomnographic study (either split-night or stand-alone) if **all** of the following criteria are met:
   a) The titration is conducted over a minimum of two hours
   b) During titration, one of the following:
      - The AHI/RDI is reduced to less than or equal to an average of ten events per hour
      - If the initial AHI/RDI was less than an average of ten events per hour, the titration demonstrates further reduction in the AHI/RDI
   c) Nocturnal oximetry conducted for the purpose for oxygen reimbursement qualification may only be performed after optimal PAP settings have been determined and the beneficiary is using the PAP device at those settings
   d) The nocturnal oximetry conducted during the PSG demonstrates an oxygen saturation
   ≤ 88% for five minutes total (which need not be continuous).

CONTINUED COVERAGE:

Continued coverage of a PAP or RAD/BIPAP device beyond the first three (3) months of therapy is covered for those members diagnosed with OSA whose OSA improves as a result of CPAP during the three month period as follows:

PAP Devices (Meets **all** indications)

1. The treating physician has conducted a clinical face to face re-evaluation and documents that the member's symptoms of obstructive sleep apnea are improved no sooner than the 61st day but no later than the 91st day after initiating therapy,
2. There is objective evidence of member adherence to therapy (use of the PAP device), reviewed by the treating physician.

Note: Adherence to therapy is defined as use of PAP ≥ four hours per night on 70% of nights during a consecutive 30 day period anytime during the first three months of initial usage.

RAD/BiPAP (Meets all indications)

1. If a CPAP device is tried and found ineffective during the initial three month home trial, substitution of a RAD does not require a new initial face-to-face clinical evaluation or a new sleep test.
2. If a CPAP device has been used for more than three months and the member is switched to a RAD, a new initial face-to-face clinical evaluation is required, but a new sleep test is not required. A new three month trial would begin for use of the RAD.

CHANGING from CPAP to RAD/BiPAP WITHOUT BACK UP RATE DUE TO INEFFECTIVE THERAPY WHILE ON CPAP (either during a facility-based titration or in the home setting)

The treating physician must document that the following issues were addressed prior to changing to a RAD without back device:

1. Interface fit and comfort. An appropriate interface has been properly fit and the beneficiary is using it without difficulty. This properly fit interface will be used with the RAD without back up rate device
2. CPAP pressure settings. The current pressure setting of the CPAP prevents the beneficiary from tolerating the therapy and lower pressure settings of the CPAP were tried but failed to help any of the following:
   a) Adequately control the symptoms of OSA
   b) Improve sleep quality
   c) Reduce the AHI/RDI to acceptable levels.

ACCESSORIES

1. Accessories used with a PAP device are covered when the coverage criteria for the PAP device are met.
2. For the usual maximum amount of accessories expected to be medically necessary, refer to the coding section of this policy.

C. Limitations/Exclusions

Limitations of PAP Therapy

1. Initial coverage of CPAP is limited to a 12 week period to identify members diagnosed with OSA who benefit from CPAP.
2. **Members who fail the initial 12 week trial** are eligible to re-qualify for a PAP device when they meet all of the following
   a) Have a repeat sleep test in a facility-based setting (Type I).
   b) Face-to face clinical re-evaluation by the treating physician to determine the cause of their failure to respond to PAP therapy
   Clinical Re-Evaluation
      - Re-evaluation must take place within the first three months of treatment.
      - Re-evaluation should document both member improvement in subjective symptoms of OSA and objective data related to member adherence to PAP therapy.
      - If the physician re-evaluation does not occur until after the 91st day but the evaluation demonstrates that the member is benefiting from PAP therapy, continued coverage of the PAP device will begin with the date of that re-evaluation.
   c) If a CPAP device is tried and found ineffective during the initial facility-based titration or home trial, substitution of a RAD without backup rate does not change the length of the trial unless there is less than 30 days remaining in the trial period.
   d) If less than 30 days remain in the trial period, the clinical re-evaluation (see above) and objective documentation of adherence must occur before the 120th day following the initiation of the CPAP.
   e) If more than 30 days remain in the trial period, the clinical re-evaluation would occur between the 31st and 91st days following the initiation of CPAP and objective documentation of adherence on the RAD without backup would need to occur prior to the 91st day following initiation of the CPAP.
   f) If a CPAP device has been used for more than 30 days and the member is switched to an RAD without back up rate,
      - A new initial face-to-face clinical evaluation is required, but a new sleep test is not required.
      - A new three month trial would begin for use of the RAD without back up rate.

- The clinical re-evaluation would occur between the 31st and 91st day following the initiation of the RAD. There would also need to be documentation of adherence to therapy during the three month trial with the RAD.

3. The PAP device must be FDA approved for the member's age.
4. **Discontinuation of Usage**- If there is discontinuation of usage of a PAP device at any time, the supplier is expected to confirm discontinuation and stop billing for the equipment and related accessories and supplies.
5. **Concurrent Use of Oxygen**
   - Documentation by the treating physician must clearly demonstrate that the indications for coverage and/or medical necessity above have been met.
   - Documentation by the treating physician should demonstrate that the indications for coverage of oxygen and oxygen equipment have been met.
6. **Auto-Titrating Continuous Positive Airway Pressure (APAP):**
   - Is not recommended for the diagnosis of obstructive sleep apnea (OSA).
   - Is not recommended for split-night titration.
   - APAP for continuous or long term use is considered not medically necessary.
   - Members with significant co-morbidities are not candidates for APAP titration or treatment. Co-morbidities include CHF, COPD, Central Sleep Apnea (Standard).

Exclusions

Respiratory Assist Devices (RAD) with backup rate:

- Is considered not medically necessary for the diagnosis of OSA and, therefore, **not covered** for this diagnosis.

D. Codes

The following codes for treatments and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Covered PAP Devices

E0601 Continuous Airway Pressure (CPAP) device

E0470 Respiratory assist device (RAD), bi-level pressure (BiPAP) capability, **without** backup rate feature, used with noninvasive interface, e.g., nasal or

facial mask (intermittent assist device with continuous positive airway pressure device)

Covered ICD-9 Diagnosis Codes for E0601 Only

327.20	Organic sleep apnea
327.21	Primary central sleep apnea
327.23	Obstructive sleep apnea
327.27	Central sleep apnea in conditions elsewhere classified
780.53	Hypersomnia with sleep apnea

Covered ICD-10 Diagnosis Codes

G47.30	Sleep apnea unspecified
G47.31	Primary central sleep apnea
G47.33	Obstructive sleep apnea
G47.37	Central sleep apnea in conditions elsewhere classified

Not Covered for the Diagnosis of OSA

E0471 Respiratory assist device (RAD), bi-level pressure (BiPAP) capability, **with** backup rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)

Covered PAP Accessories		**Maximum Number Allowed**
A4604	Tubing with integrated heating element for use with positive airway pressure device	1 per 3 months
A7027	Combination oral/nasal mask, used with continuous positive airway pressure device, each	1 per 3 months
A7028	Oral cushion for combination oral/nasal mask, replacement only, each	2 per 1 month
A7029	Nasal pillows for combination oral/nasal mask, replacement only, pair	2 per 1 month
A7030	Full face mask used with positive airway pressure device, each	1 per 3 months
A7031	Face mask interface, replacement for full face mask	1 per 1 month
A7032	Cushion for use on nasal mask interface,	2 per 1 month

	replacement only, each	
A7033	Pillow for use on nasal cannula type interface, replacement only, pair	2 per 1 month
A7034	Nasal interface (mask or cannula type) used with positive airway pressure device, with or without head strap	1 per 3 months
***** A7035	Headgear used with positive airway pressure device	1 per 6 months
***** A7036	Chinstrap used with positive airway pressure device	1 per 6 months
A7037	Tubing used with positive airway pressure device	1 per 3 months
A7038	Filter, disposable, used with positive airway pressure device	2 per 1 month
***** A7039	Filter, non-disposable, used with positive airway pressure device	1 per 6 months
A7044	Oral interface used with positive airway pressure device, each	No limitations
A7045	Exhalation port with or without swivel used with accessories for positive airway devices, replacement only	No limitations
A7046	Water chamber for humidifier, used with positive airway pressure device, replacement, each	1 per 6 months
E0561	Humidifier, non-heated, used with positive airway pressure device	No limitations
E0562	Humidifier, heated, used with positive airway pressure device	No limitations

*** These items are covered for Medical Assistance: 1 every 30 days**

E. Variations

Medical Assistance Product
Payment will be made for the rental of a PAP device for the first three months (rental period) from the original start date of therapy. If compliance criteria are met (refer to Indications, Continued Coverage Section), payment will be made for an additional seven months.

Medicare Product
CPAP based on clinical diagnosis alone or using diagnostic procedure other than PSG or Type II, Type III or a Type IV HST measuring at least three channels is covered only

when provided as a clinical study/trial and when that study meets clinical study/trial standards.
(Refer to Clinical Trial policy)

F. Quality Audit

Quality Audit monitors policy compliance and/or billing accuracy at the request of MedStar Health, Inc..

F. Records Retention

Records Retention for documents, regardless of medium is provided within the MedStar Health, Inc. Policy & Procedure Corp.028.MH Records Retention.

Unless otherwise mandated by Federal or State law, or unless required to be maintained for litigation purposes, any communications recorded pursuant to this Policy are maintained for a minimum of ten years from the date of recording

G. References

Medical Literature/Clinical Information:

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2. University of Maryland Medical Center. Sleep Disorders Center: Epsworth Sleepiness Scale. Last Updated: July 30, 2013. http://umm.edu/programs/sleep/health/quizzes/sleepiness
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Regulatory/Government Source:

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2. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD) No. L11504 - Respiratory Assist Devices. (Contractor: NHIC Corp). Revision Effective Date: 07/01/2013. http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=11504&ContrId=137&ver=52&ContrVer=1&DocType=All&bc=AgIAAAAAAAAAA%3d%3d&
3. NHIC Corp. DME MAC Jurisdiction A: PAP Documentation Requirement Revision - Ineffective Therapy on E0601., Posted 08/19/2010. http://www.medicarenhic.com/viewdoc.aspx?id=461
4. NHIC Corp. DME MAC Jurisdiction A : Positive Airway Pressure (PAP) Devices-Supplier Frequently Asked Questions, Revised: May 2012. Posted May 18, 2012. http://www.medicarenhic.com/viewdoc.aspx?id=837
5. Centers for Medicare and Medicaid Services (CMS). Medicare Learning Network (MLN). MLN Matters: # MM6048-Revised. Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA). Related CR Transmittal # R96NCD, Release date: 08/29/2008, Implementation date

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