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BLUE CROSS BLUE SHIELD of MI MEDICAL POLICY

Enterprise:	Blue Cross Blue Shield of MI
Department	BCBSM Medical Policy Administration
Effective Date:	October 1, 2011
Next Review Date	January 1, 2013

TOPIC: Continuing Coverage of CPAP Machines and Supplies for the Treatment of Obstructive Sleep Apnea

Background

Sleep Apnea

Sleep apnea occurs when an adult stops breathing or has slowed breathing during sleep. It can be mild, moderate, or severe, based on the number of times each hour that breathing stops (apnea) or slows (hypopnea).

The two main types of sleep apnea are:

- Obstructive sleep apnea (OSA), which is the result of blocked airflow during sleep, such as from narrowed airways. Other factors, such as obesity, often contribute to obstructive sleep apnea.
- Central sleep apnea, which results from a problem with how the brain signals the breathing muscles. This type of apnea can occur with conditions such as heart failure, brain tumors, brain infections, and stroke.

Continuous Positive Airway Pressure (CPAP) Therapy

Continuous positive airway pressure therapy (CPAP) uses a machine to help a person who has obstructive sleep apnea (OSA) breathe more easily during sleep. A CPAP machine increases air pressure in the throat so that the airway does not collapse while breathing in.

CPAP is the most effective nonsurgical treatment for obstructive sleep apnea.

After extensive discussions with providers and a review of recent data, problems associated with the payment of CPAP supplies have been identified. These include patient non-compliance and the associated costs of discarded devices and supplies, discontinued rentals and discontinued use of purchased items. The main source of the noncompliance is attributed to inadequate fitting of face masks and education regarding the use of the equipment. BCBSM is currently paying for purchased devices that are not being used. This wastage and non-compliance impacts the cost as well as the quality of care delivered to our subscribers with obstructive sleep apnea.

Once a patient has been diagnosed with obstructive sleep apnea, the use of a CPAP machine may be prescribed by the attending physician. The level of use is determined by the attending/ordering physician based on their judgment and the results of CPAP trials and sleep studies. The usual use prescribed is *4 or more hours per night for at least 70% of nights within a 30 day period.*

The extent to which the use of CPAP contributes to the effective management of OSA depends in large part on the level of compliance a patient exhibits. If the CPAP is not used correctly with the required frequency, a patient's symptoms will be inadequately managed and all of the attendant risks of unmanaged or poorly managed OSA: worsening pulmonary function, pulmonary hypertension, secondary cardiac disease, arrhythmia and death are unnecessarily increased.

Treatment Challenges and Patient Compliance

Several factors may contribute to CPAP treatment failure. These include inadequate education regarding use of the equipment, poor fitting of the mask involved and inadequate use due to patient non compliance. A clarification of the roles played by the physician and DME provider in the management of OSA patients should help in the reduction of costs associated with wasted materials as well as the overall quality of care these individuals receive.

It is expected that at the time the CPAP treatment is ordered, the ordering physician will impress upon the patient the reason for the treatment, the importance of the treatment, the medically necessary frequency of the treatment, the importance of compliance with the treatment plan and the need for on-going follow-up.

It is also expected that the DME provider will provide initial and ongoing education regarding the proper operation of the machine and use of supplies, assess compliance with use of the machine and identify problems with use.

Current CPAP machine "micro-chip" technology allows DME suppliers to review historical data to determine the actual level of the patient's use of the machine.

Codes

Codes	Codes (continued)
A4604	**A7035**
A7027	**A7036**
A7028	**A7037**
A7029	**A7038**
A7030	**A7039**
A7031	**A7046**
A7032	**E0561**
A7033	**E0562**
A7034	**E0601**

Medicare Information

Some national and local coverage policies indicate that specific information is required to be kept on file for specific supplies and/or services. The supporting documentation must be supplied if requested by the payer.

To initiate therapy, patient must have the following: A "face to face" evaluation with their treating physician and the evaluation should include: signs and symptoms of OSA (sleep history), Epworth Sleepiness Scale, BMI, neck circumference and evaluation of cardiopulmonary and upper airway system.

* Documentation of face to face evaluation needs to be contained in patient's chart notes and forwarded to DME company with referral.
* After patient is set up on PAP equipment, patient must have a "re evaluation" with the treating physician no sooner than the 31st day but no later than the 90th day on service.
* Re evaluation needs to include the following: documentation that the symptoms of OSA have improved and objective evidence of compliance to therapy (ie: download) which must be reviewed by the treating physician.
* Compliance is defined by Medicare for this policy as use of PAP device for at least 4 hours per night for 70% of the nights in a 30 consecutive day period during the first 90 days.
* If above criterion is not met, Medicare will not consider the PAP device "medically necessary" and will not cover the cost of the device.
* If patient does not meet criteria for coverage within the 90 day period, then in order for patient to "re-qualify" for PAP therapy, the patient must undergo another "face-to-face" clinical evaluation with the treating physician and attend another "facility-based" sleep test to assist in discerning the reasons for the initial failure.
* ICD-9 code 327.23 is now the only acceptable code for PAP devices for patients diagnosed with "obstructive sleep apnea.
* RDI…for purposes of this policy, RDI only includes apneas and hypopneas (RERA's

have not yet been defined and according to this new ruling may not be included in the extrapolation of the RDI.)

Policy Statement

The CPAP benefit for the treatment of OSA is limited to twelve weeks. On-going coverage of CPAP machines and supplies will require documentation of patient compliance and clinical benefit with the physician prescribed treatment plan. If patients are found to be consistently non compliant with the recommended plan of care, reimbursement for use of the CPAP machine and supplies will be discontinued. Reimbursement will be denied as “Not A Benefit”.

Rationale

These changes should support improvements in treatment compliance, improve the overall quality of CPAP related care and minimize equipment wastage.

Implementation

After the initial three months of CPAP use, clinical response and patient compliance must be assessed. Further approval of CPAP will not be allowed until this assessment occurs. The assessment may occur no sooner than the 31st day of treatment or after the 91st day of treatment. The DME provider must document compliance. This should be done through access and review of data taken from the CPAP machine. The DME provider should verify clinical response by documenting input from the physician in the clinical record. (See Appendix A for *Guidelines for Continued Coverage of CPAP)*

Patient compliance must be verified on all CPAP procedure codes (listed above). Use of the appropriate modifier represents the DME provider’s attestation that records are on file that support that the patient receiving the CPAP equipment has been compliant with their physician’s prescribed plan of care and that the ordering physician has agreed that therapy is providing a positive clinical benefit. If the appropriate modifier is not appended to CPAP claims, the coverage and payment for the CPAP device and supplies will be discontinued. Patient compliance documentation must be available after the third month of CPAP use. If the required documentation attested to by the appropriate Modifier is not available upon request or audit, any payments for those items reported with the Modifier will be subject to recovery.

When billing the medical supplies and accessories for **all** Positive Pressure Airway Devices in the treatment of obstructive apnea, the appropriate modifier will be required to ensure that the requirements specified in the Medical Policy have been met.

Procedure codes E0561, E0562, and E0601 are payable as rental only.

Scope

- This policy applies to all underwritten contracts and to all self-funded or ASC contracts, pending approval.
- This policy does not apply to use of BiPAP machines.
- This policy does not apply to ventilator patients.
- This policy applies to patients who are greater than the age of 18 years at the time CPAP use is ordered. It does not apply to pediatric patients.
- This policy applies to all underwritten contracts and self funded contracts subject to customer approval. Customer specific benefit variations supersede this medical policy.

Appendix A

Guidelines to Support CPAP Device for Treatment of Obstructive Sleep Apnea Policy

Guidelines for continued coverage after 12 weeks:

- **After 12 weeks, data review supports compliance. Patient reports symptoms improved:** Approve 12 months of continued coverage.
- **After 12 weeks, data review supports compliance, but patient claims no improvement or symptoms worse:** Face to face evaluation by ordering physician is required to assess symptoms and make necessary adjustments **OR** order facility based sleep study. Physician should make adjustments and re-order CPAP or pursue different treatment option.
- **After 12 weeks, data review does not support compliance:** regardless of patient's symptom report, face to face evaluation with ordering physician is required to assess symptoms and make necessary adjustments **OR** order facility based sleep study. Should make adjustments and re-order CPAP or pursue a different treatment option.

Guidelines for continued coverage after second 12 week trial period:

- **After second trial period, data review supports compliance. Patient reports symptoms improved:**
  Approve 12 months of continued coverage
- **After second trial period, data review supports compliance, but patient claims no improvement or symptoms worse:**
  Face to face evaluation by ordering physician is required to assess symptoms and make necessary adjustments **OR** order facility based sleep study. Physician should make adjustments and re-order CPAP or pursue different treatment option.
- **After second trial period, data review does not support compliance:**
  Regardless of patient's symptom report, face to face evaluation with ordering physician is required to assess symptoms and make necessary adjustments **OR** order facility based sleep study. Should make adjustments and re-order CPAP or pursue a different treatment option.

Guidelines for continued coverage after third 12 week trial period:

- **If patient compliant, and symptoms improved by patient report:**
  Continue coverage for 12 months.
- **If patient compliant, but symptoms not improved, face to face evaluation with ordering physician is required to assess symptoms:**
  Make adjustments and order facility based sleep study.

- **If patient not compliant, face to face evaluation with ordering physician is required. If symptoms are adequately addressed with lower usage than originally ordered, physician should re-order using lowered level of usage.**
  Approve for next 12 months of coverage.
- **If patient not compliant and symptoms not adequately addressed, CPAP is:**
  Not A Benefit: Subscriber and Physician must appeal to plan for individual consideration for further coverage.

If a patient receives adequate clinical benefit from CPAP use less than 4 or more hours per night and/or less than 70% of the nights in the most recent 30 day period, then the physician should document this and establish the acceptable level of use against which compliance can be measured for that patient.