Blue Cross Blue Shield of Michigan

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Blue Cross Blue Shield of Michigan Medical Policy

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Enterprise:	Blue Cross Blue Shield of Michigan
Department	Medical Affairs
Effective Date:	8/1/2015
Next Review Date	4th Quarter 2023

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

Procedure code: E0601

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.

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 minimum use prescribed is 4 or more hours per night for at least 70% of nights within a 30 day period, which is required to demonstrate adherence to therapy.
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, use of supplies, and the importance and requirements of compliance. The DME provider must assess compliance with use of the machine and identify problems with use.
CPAP software allows for the downloading of information to determine the actual level of the patient's use of the machine.

Codes:

A4604	A7027	A7028	A7029	A7030	A7031
A7032	A7033	A7034	A7035	A7036	A7037
A7038	A7039	A7046	E0561	E0562	E0601

Medical Policy Statement:

The initial 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.

Rationale:

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

Scope:

- This policy applies to all underwritten contracts and self funded contracts subject to customer approval. Customer specific benefit variations supersede this medical policy.
- 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.

Implementation:

During the initial three months of CPAP use, clinical response and patient compliance must be assessed by the treating physician. Further approval of CPAP will not be allowed until this assessment occurs. 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** CPAP 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.

INITIAL COVERAGE: An 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 physician prior to the sleep test to assess the member for obstructive sleep apnea.
B. The member has a sleep test (reference the policies *Sleep Disorders, Diagnosis, and Medical Management,* and *Continuous Positive Pressure Airway Devices* for coverage requirements) 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.

If a claim for an E0601 is submitted and all of the criteria above have not been met, it will be denied as not reasonable and necessary.

CONTINUED COVERAGE BEYOND THE FIRST THREE MONTHS OF THERAPY:

Continued coverage of a CPAP device 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, the treating physician must conduct a clinical re-evaluation and document that the member is benefiting from PAP therapy.

For PAP devices with initial dates of service on or after October 1, 2011, documentation of clinical benefit is demonstrated by:

1. Clinical re-evaluation by the treating physician (for dates of service on or after January 1, 2016, a face-to-face meeting must be conducted); with documentation that symptoms of obstructive sleep apnea are improved; and,
2. Objective evidence of adherence to use of the CPAP device, reviewed by the treating physician.

Adherence to therapy is defined as use of CPAP ≥4 hours per night on 70% of nights 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 CPAP device and related accessories will not be considered reasonable and necessary, and claims will not be paid.

If the physician re-evaluation does not occur until after the 91st day but the evaluation demonstrates that the member is benefiting from CPAP therapy as defined in criteria 1 and 2 above, continued coverage of the PAP device will commence with the date of that re-evaluation.

Members who fail the initial 12 week trial are eligible to re-qualify for a CPAP device but must have a face-to face clinical re-evaluation by the treating physician to determine the etiology of the failure to respond to CPAP therapy. If the treating physician determines it is necessary, a follow-up sleep study, either home or facility-based, may be required. This may be a repeat diagnostic, titration, or split-night study.

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

ACCESSORIES:

Accessories used with a CPAP device are covered when the coverage criteria for the device are met. If the coverage criteria are not met, the accessories will be considered not reasonable and necessary, and claims will not be paid.

The following table represents the usual maximum number of accessories expected to be reasonable and necessary:

HCPCS	DESCRIPTION
A4604	1 per months
A7027	1 per 3 months
A7028	2 per 1 month
A7029	2 per 1 month
A7030	1 per 3 months
A7031	1 per 1 month
A7032	2 per 1 month
A7033	2 per 1 month
A7034	1 per 1 months

A7035	1 per 6 months
A7036	1 per 6 months
A7037	1 per 3 months
A7038	2 per 1 month
A7039	1 per 6 months
A7046	1 per 6 months

Quantities of supplies greater than those described in the policy as the usual maximum amounts will not be covered.

REFILLS REQUIREMENTS

For DMEPOS items and supplies provided on a recurring basis, billing must be based on prospective, not retrospective use. For DMEPOS products (A4604, A7027-A7046) that are supplied as refills to the original order, suppliers must contact the member prior to dispensing the refill and not automatically ship on a pre-determined basis, even if authorized by the member. This shall be done to ensure that the refilled item remains reasonable and necessary, existing supplies are approaching exhaustion, and to confirm any changes or modifications to the order. Contact with the member or designee regarding refills must take place no sooner than 14 calendar days prior to the delivery/shipping date. For delivery of refills, the supplier must deliver the DMEPOS product no sooner than 10 calendar days prior to the end of usage for the current product. This is regardless of which delivery method is utilized. (CMS' Program Integrity Manual, Internet-Only Manual, CMS Pub. 100-8, Chapter 5, Section 5.2.6).

For all DMEPOS items that are provided on a recurring basis, suppliers are required to have contact with the member or caregiver/designee prior to dispensing a new supply of items. Suppliers must not deliver refills without a refill request from a member. Items delivered without a valid, documented refill request will be denied as not reasonable and necessary.

Suppliers must not dispense a quantity of supplies exceeding a member's expected utilization. Suppliers must stay attuned to changed or atypical utilization patterns on the part of their clients. Suppliers must verify with the ordering physicians that any changed or atypical utilization is warranted. Regardless of utilization, a supplier must not dispense more than a three (3)-month quantity at a time.

Either a non-heated (E0561) or heated (E0562) humidifier is covered when ordered by the treating physician for use with a covered PAP (E0601) device.

Recurring supplies for the CPAP device require a prescription from a treating physician.

Replacement and Repairs:

Replacement refers to the provision of an identical or nearly identical item. Equipment which the member owns or is a capped rental item may be replaced in cases of loss or irreparable damage. Irreparable damage refers to a specific accident or to a natural disaster (e.g., fire, flood, etc.).

Irreparable wear refers to deterioration sustained from day-to-day usage over time, and a specific event cannot be identified. Replacement of equipment due to irreparable wear takes into consideration the reasonable, useful lifetime of the equipment, which is **5** years. If the equipment has been in continuous use by the member for the equipment's useful lifetime and the warranty has expired, then the member may elect to obtain a new piece of equipment.

Computation of the useful lifetime is based on when the equipment is delivered to the member, not the age of the equipment. Replacement due to wear is not covered during the reasonable, useful lifetime of the equipment.

We pay for repair or replacement under these conditions:

- Repair or replacement is needed due to normal wear and tear or changes in the member's condition or size
- Repair or replacement of the item is for use of the medically necessary DME

Charges necessary to restore purchased DME must not exceed the cost of a new item. If the repair is estimated to exceed 75% of the amount allowed for purchase of new DME, then new equipment should be purchased (capped rental would begin again).

Replacement of a PAP device requires a prescription from a treating physician. There is no requirement for a new clinical evaluation, sleep test, or trial period.

References:

Blue Cross Blue Shield Association, "Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome," *Medical Policy Reference Manual*, Policy # 2.01.08, original policy date, Nov 1996, last reviewed July 2021

"Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea," LCD L33718 CGS Administrators, LLC., Local Coverage Determination
Contractor Number 18003, Effective October 2015, revision effective for service on or after 8/8/2021

Policy Effective Date	BCBSM Signature Date	Comments
10/1/11	Unknown- not on PDF	BCBSM policy established
6/01/13	not signed	Routine maintenance, CMS updates
8/1/15	10/23/15	Routine maintenance; language updates and addenda added
8/1/15	11/30/15	Routine maintenance, added LCD from CGS (formerly NGS) and device replacement clarifications
8/1/15	11/30/2016	Routine maintenance, added LCD from CGS (formerly NGS) and device replacement clarifications
8/1/15	9/27/2017	Routine maintenance, updated references
8/1/2015	11/20/2018	Routine maintenance
8/1/2015	6/5/2019	Updated RUL per SBP #18146 and added replacement/repairs information
8/1/2015	11/5/2020	Routine maintenance
8/1/2015	11/11/2021	Routine maintenance- references updated
8/1/2015	11/10/2022	Routine maintenance

Addenda:

DESCRIPTION OF SERVICE:

- 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.
- 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 minimum use prescribed is 4 or more hours per night for at least 70% of nights within a 30 day period, which is required to demonstrate adherence to therapy.
- 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.
- The initial CPAP benefit for the treatment of OSA is limited to twelve weeks.
- During the initial twelve weeks of CPAP use, clinical response and patient compliance must be assessed by the treating physician. Further approval of CPAP will not be allowed until this assessment occurs.

Documentation of clinical benefit is demonstrated by:

- Effective January 1, 2016, a face-to-face clinical re-evaluation by the treating physician with documentation that symptoms of obstructive sleep apnea are improved; and,
- Objective evidence of adherence to use of the CPAP device, reviewed by the treating physician. Adherence to therapy is defined as use of CPAP ≥4 hours per night on 70% of nights during a consecutive thirty (30) day period anytime during the first three (3) months of initial use.
- If the clinical benefit criteria are not met, continued coverage of a CPAP device and related accessories will not be considered reasonable and necessary, and claims will not be paid.
- Members who fail the initial 12 week trial are eligible to re-qualify for a CPAP device but must have a face-to-face clinical re-evaluation by the treating physician to determine the etiology of the failure to respond to CPAP therapy. If the treating physician determines it is necessary, a follow-up sleep study may be required.

  Members who fail the second 12-week trial period must have a face-to-face clinical re-evaluation by the treating physician to determine the next course of therapy. Members

must return the device to the supplier or will have to pay for the rental on their own. Accessories and supplies will not be covered.

ACCESSORIES, SUPPLIES AND REPLACEMENT:

- Accessories used with a CPAP device are covered when the coverage criteria for the device are met. If the coverage criteria are not met, the accessories will be considered not reasonable and necessary, and claims will not be paid.
- Recurring supplies for the CPAP device require a prescription from a treating physician.
- Replacement: A CPAP device is considered to have a 5-year reasonable useful lifetime period. If a device needs to be replaced because of loss, theft, or irreparable damage due to a specific incident, there will be no requirement for a new clinical evaluation, sleep test, or trial period.

PAYABLE PROCEDURE CODES:

A4604	A7032	A7038
A7027	A7033	A7039
A7028	A7034	A7046
A7029	A7035	E0561
A7030	A7036	E0562
A7031	A7037	E0601

REQUIRED BILLING DOCUMENTATION SUBMISSION

- Report the KX modifier with CPAP devices and the supplies and accessories that are used with them indicating you have appropriate documentation within the patient file.

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Dear Valued Member:

Blue Cross Blue Shield of Michigan is partnering with your CPAP equipment supplier and physician to make sure that you receive the maximum benefit from your CPAP treatment.

Your CPAP supplier will work with you to provide equipment and accessories that are appropriate, comfortable, and easy to use.

After your first three months of use, you must have a follow up visit/evaluation with your treating physician AND provide information about your use of the CPAP device to your CPAP supplier.

Note: You must have used your CPAP device four hours or more per night on 70 percent of nights during a consecutive 30 day period anytime during the first three months of use. There are several ways you may verify your use of the CPAP equipment and supply the information:

DME supplier can document your compliance
The removable memory card can be brought to the CPAP supplier who will assess the information for verification of appropriate use.

CPAP manufacturer
Some new CPAP devices have technology that allows suppliers and physicians to remotely monitor on-going compliance. Your supplier can let you know if your CPAP has this capability.

When you have a follow-up meeting with your physician between the 31st day but no later than the 91st day after initial CPAP use:
Your physician will assess your progress and treatment compliance, and can provide documentation for the CPAP supplier. The removable memory card in your CPAP device can be brought to the physician's office for the data to be downloaded (if the physician has the equipment for read-out). This will indicate how much the CPAP machine is being used.

If your physician does not have read-out equipment, your CPAP supplier probably will probably educate you about the use of the function.

With the proper use of the device, your benefit coverage for this treatment will continue.

If the supplies are not used appropriately, you must see your physician to determine the next course of treatment, which may include continued use of the CPAP device.
If you cannot verify treatment compliance, or if the CPAP device is no longer prescribed, you must return the device to the supplier or you may be responsible for any balance on the device.

I have read and understand my responsibilities to follow the above treatment compliance terms associated with my CPAP device. I also understand that if I do not meet or verify treatment compliance and if I do not return the device to the supplier when instructed, I may be financially responsible for any applicable costs for the device.

Signature_____

Date_____

Member's name_____

Members' enrollee ID_____