



Medicare Part C Medical Coverage Policy

Positive Airway Pressure Therapy for Obstructive Sleep Apnea and Breathing Related Sleep Disorders

Origination: June 26, 2000
Review Date: October 16, 2019
Next Review October 2021

******This policy applies to all Blue Medicare HMO, Blue Medicare PPO, Blue Medicare Rx members, and members of any third-party Medicare plans supported by Blue Cross NC through administrative or operational services. ******

DESCRIPTION OF PROCEDURE OR SERVICE

Breathing related sleep disorders include Obstructive Sleep Apnea (OSA), Central Sleep Apnea, Hypopnea, and Upper Airway Resistance Syndrome (UARS). Of these disorders, OSA is the most common.

Sleep apnea is a disorder where breathing nearly or completely stops for periods of time during sleep. In obstructive sleep apnea, the brain sends the message to breathe, but there is a blockage to air flowing into the chest. It is a condition in which repetitive episodes of upper airway obstruction occur during sleep. The obstruction may be localized to one or two areas or may encompass the entire upper airway passages to include the nasal cavity (nose), oropharynx (palate, tonsils, tonsillar pillars) and hypopharynx (tongue base).

POLICY STATEMENT

Coverage will be provided for treatments for OSA when they are determined to be medically necessary and when the medical criteria and guidelines shown below are met.

BENEFIT APPLICATION

Please refer to the member's individual Evidence of Coverage (EOC) for benefit determination. Coverage will be approved according to the EOC limitations if the criteria are met.

Coverage decisions will be made in accordance with:

- The Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations (NCDs);
- General coverage guidelines included in Original Medicare manuals unless superseded by operational policy letters or regulations; and
- Written coverage decisions of local Medicare carriers and intermediaries with jurisdiction for claims in the geographic area in which services are covered.

Benefit payments are subject to contractual obligations of the Plan. If there is a conflict between the general policy guidelines contained in the Medical Coverage Policy Manual and the terms of the member's particular Evidence of Coverage (EOC), the EOC always governs the determination of benefits.

INDICATIONS FOR COVERAGE. CPAP (E0601) and BiPAP (E0470)

Requests for the Diagnosis of OSA:

I. Preauthorization by the Plan for the 1st three (3) months of therapy is required for all CPAP or BiPAP requests if:

1. Criteria A and B (1 or 2) and C the following are met:

- A. Member has a face-to-face clinical evaluation by the treating physician prior to the sleep test to assess for obstructive sleep apnea (Sleep Study must be interpreted by a physician who has a current certification in Sleep Medicine by the American Board of Sleep Medicine (ABSM); or, current subspecialty certification in Sleep Medicine by a member board of the American Board of Medical Specialties (ABMS) or American Osteopathic Association (AOA); or have completed residency or fellowship training by an ABMS or AOA member board and has completed all the requirements for subspecialty certification in sleep medicine except the examination itself and only until the time of reporting of the first examination for which the practitioner is eligible; or, is an active staff membership of a sleep center or laboratory accredited by the American Academy of Sleep Medicine (AASM), Accreditation Commission for Health Care (ACHC), or The Joint Commission (TJC, formerly the Joint Commission on Accreditation of Healthcare Organizations – JCAHO) **and**
- B. The member has a positive sleep test result that meets **one** of the following criteria (1 or 2):
 - 1. The Apnea Hypopnea Index (AHI) or Respiratory Disturbance Index (RDI) is greater than or equal to fifteen (15) events per hour; or
 - 2. The AHI or RDI is greater than or equal to 5 with less than or equal to 14 events per hour with a minimum of 10 events and documentation of:
 - Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia, **or**
 - Hypertension, ischemic heart disease, or history of stroke; **and**
- C. The member and/or the caregiver have received instruction from the supplier of the device in the proper use and care of the equipment.

2. A BiPAP device is covered if criteria I. 1. A-C above are met AND:

A CPAP device has been tried and proven ineffective based on a therapeutic trial/titration conducted in a facility or home setting.

NOTE: “Ineffective” as noted above, is defined as documented failure to meet therapeutic goals using an E0601 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).

II. Continued Coverage beyond 3 months for purchase:

1. At the Plan’s discretion, an **additional one (1) month rental** (to demonstrate compliance) may be granted if the member is demonstrating compliance and is near the seventy percent (70%) requirement, but due to extenuating circumstances has not reached the goal. This option cannot be repeated.
2. Once the trial is completed, purchase requires the following:
 - a. The member meets criteria I. B.1 and I.B.2 listed above;
 - b. The medical record demonstrates that the member has used the device at least four (4) hours, seventy percent (70%) of a thirty (30) day period. (This is 21 out of 30 days via a compliance chip or sleep record).

WHEN COVERAGE WILL NOT BE APPROVED:

If all of the criteria above have not been met for either a CPAP or BiPAP device, the request will be denied as not medically necessary.

SPECIAL NOTES FOR CPAP/BiPAP:

1. If a CPAP device is tried and found ineffective during the initial facility-based or home trial/titration, substitution of a BIPAP 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 (3) months and the member is switched to a BIPAP, a new initial face-to-face clinical evaluation is required, but a new sleep test is not required. A new three (3) month trial would begin for use of the BIPAP device.
3. The Plan expects that the initial face-to-face evaluation will be sent at the time the request is submitted for review. However, the Plan will review the request even without the documented face-to-face evaluation providing all other medical necessity criteria are provided, (The Plan expects documentation of a face-to-face evaluation be available in the event of an audit by either the Plan or CMS. Verbal attestation that a face to face evaluation was completed is sufficient to make a determination.

4. Either a non-heated or heated humidifier is covered when ordered by the treating physician for use with a covered PAP device.

BILLING/ CODING/PHYSICIAN DOCUMENTATION INFORMATION

This policy may apply to the following codes. Inclusion of a code in the section does not guarantee reimbursement.

Applicable codes:, A4604, A7027, A7028, A7029, A7030, A7031, A7032, A7033, A7034, A7035, A7036, A7037, A7038, A7039, A7044, A7046, A7047, E0470, E0601, E0485, E0486, E0561, E0562, 95800, 95801, 95805, 95806, 95807, 95808, 95810, 95811, G0398, G0399, G0400.

The Plan may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

References:

1. Medicare Local Coverage Determination for Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea – CGS Administrators (L33718); Effective date: 10/01/2015. Accessed via <https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx> 10/8/19.
2. Medicare National Coverage Determination for Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA) (ID #240.4); Effective date: 8/4/08. Accessed via Internet site www.cms.gov/mcd/viewwncd on 10/9/19.
3. Medicare Local Coverage Determination for Oral Appliances for Obstructive Sleep Apnea – CGS Administrators (L33611); Effective date: 10/01/2015. Accessed via <https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx> 10/9/19.

Policy Implementation/Update Information:

Revision Dates: February 14, 2002; June 11, 2002; August 24, 2005; May 16, 2007- Clarified compliance with using the device as prescribed can be obtained from the member, the treating physician and/or the compliance chip.

Revision Dates: June 17, 2009: New online policy format; clarified description of procedure; added respiratory assist device section; Clarified first section under Special Notes referencing continued coverage for CPAP, BiPAP and RAD after three months.

Revision Dates: 3/2011, 4/2011: Policy separated from Surgical Treatment and RAD for OSA policies. Coverage criteria pertaining to RAD and Surgical Treatment from policy was removed; Indications For Coverage: Reference coverage criteria for CPAP/BiPAP and added criteria for the 1st three months of therapy, added Criteria A-C along with criterion D for BiPAP. Added language pertaining to oral appliance as referenced in CMS guidelines. Removed language related to Sleep Tests due to not on the PA list; Special Notes section added 1-5; When Coverage Will Not Be Approved: Updated language per CMS referencing criteria not met for either CPAP or BiPAP device, request will be denied as not medically necessary; Coding: Updated per Senior Coding Analyst; Reference section updated per CMS guidance; Glossary section: Updated to reflect PAP policy.

Revision Date: 01/06/2013; Edited Criteria to mirror NCD and revised LCD under II - Continued Coverage. Codes also updated.

Revision Date: 04/16/2014; Mirrored NCD for Criteria 1.B (1 & 2); Edited Section II for staff clarification, updated codes; Added code A7047. October 29, 2015 updated LCD due to ICD-10 update only.

Revision Date: 03/16/2016: Indications For Coverage – added “NOTE” to item 2 for definition and clarification; Special Notes – added item #5 as referenced in L33718; Added codes to reflect policy and LCD; Updated reference section.

Revision Date: 12/20/2017: Staff Clarification; Removed Indications for Coverage.1. D. May be in a clinical trial for Coverage with Evidence Development if they do not meet the preceding criteria. (See Clinical Trial Policy). Other revisions were minor revisions only.

Revision Date: 10/16/19: Staff Clarification: Added Parentheses Note to Indications for Coverage 1. A. “(Sleep Study must be interpreted by a physician who has a current certification in Sleep Medicine by the American Board of Sleep Medicine (ABSM); or, current subspecialty certification in Sleep Medicine by a member board of the American Board of Medical Specialties (ABMS)

or American Osteopathic Association (AOA); or have completed residency or fellowship training by an ABMS or AOA member board and has completed all the requirements for subspecialty certification in sleep medicine except the examination itself and only until the time of reporting of the first examination for which the practitioner is eligible; or, **is an active** staff membership of a sleep center or laboratory accredited by the American Academy of Sleep Medicine (AASM), Accreditation Commission for Health Care (ACHC), or The Joint Commission (TJC, formerly the Joint Commission on Accreditation of Healthcare Organizations – JCAHO)”

Approval Dates:

Medical Coverage Policy Committee: October 16, 2019

Policy Owner: Carolyn Wisecarver, RN, BSN
Medical Policy Coordinator

GLOSSARY OF TERMS

I. Basic terms for diagnosis

Apnea- the cessation of airflow for a minimum of 10 seconds.

Apnea/ Hypopnea Index (AHI) - is defined as the average number of episodes of apnea and hypopnea per hour of sleep without the use of a positive pressure device.

BiPAP - Bilevel Positive Airway Pressure: Alternates blowing 2 set pressures, a higher pressure for inhalation and a lower pressure for expiration.

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 nares. The purpose is to prevent the collapse of the oropharyngeal walls and the obstruction of airflow during sleep, which occurs in obstructive sleep apnea (OSA).

Excessive Daytime Sleepiness (EDS)/Hypersomnolence - tendency to be unrefreshed from overnight sleep and to be prone to inappropriate episodes of sleep during the daytime. Hallmark symptom of obstructive sleep apnea. Found also in narcolepsy.

FI02 – the fractional concentration of oxygen delivered to the member for inspiration. This policy refers to the oxygen concentration the member normally breathes when not undergoing testing to qualify for coverage.

FEV1 – the forced expired volume in 1 second.

FVC – the forced vital capacity

Obstructive Sleep Apnea (OSA) - the most severe form of Sleep Disordered Breathing (SDB) characterized by repetitive episodes of upper airway obstruction that occur during sleep.

Medical management of OSA includes lifestyle modification (weight loss, avoidance of alcohol, sedatives and caffeine consumption, especially before bedtime, allowing adequate sleep time, body position during sleep [side versus back]), oral appliances and positive airway pressure devices (**CPAP** [continuous positive airway pressure], **BiPAP** [bilevel positive airway pressure], and **DPAP** [demand positive airway pressure]). On average, a 10% weight loss produces an improvement of 50% in the apnea-hypopnea index. Oral appliances act by holding the mandible and tongue forward during sleep. While these methods do not result in a cure, they can reduce the AHI; however, compliance is a problem with all of these methods.

Obstructive Sleep Apnea Intensity/Severity - (as suggested by sleep study findings; overall evaluation is on a case by case basis and includes Epworth score, number of arousals and desaturation nadirs, etc.)

Mild OSA: RDI or AHI >5 to >20; LSAT >85% to <95%

Moderate OSA: RDI or AHI >20 to <40; LSAT >65% to <85%

Severe OSA: RDI or AHI >40; LSAT <65%

Polysomnogram (PSG) - Simultaneous and continuous monitoring of relevant normal and abnormal physiologic activity during sleep.

Respiratory Disturbance Index (RDI) - is defined as the average number of apneas plus hypopneas per hour of recording without the use of a positive airway pressure device. Also see Apnea/ Hypopnea Index.

Sleep Hygiene - measures directed at improving or correcting the sleep apnea condition by non-surgical, non-CPAP means. Includes lifestyle changes such as weight loss where appropriate, avoidance of alcohol or other sedatives in the evening, ensuring an adequate sleep time opportunity, and avoidance of obstruction-provoking sleep positions.

Split Night Study - a polysomnogram in which the presence of significant obstructive events is demonstrated early enough in the night that a CPAP titration can be accomplished during the same lab episode.

Trial/Titration – either conducted in a sleep lab or at home with an auto-titrating machine.