



Medicare Part C Medical Coverage Policy

Respiratory Assist Devices for Obstructive Sleep Apnea and Breathing Related Sleep Disorders

Origination: June 26, 2000
Review Date: January 16, 2019
Next Review January, 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. Central Sleep Apnea is defined as central apnea or hypopneas that occur without airway obstruction

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.

Upper Airway Resistance Syndrome (UARS) is characterized by partial collapse of the airway resulting in increase resistance to airflow, leading to brief arousals and sleep fragmentation resulting in daytime sleepiness.

In Central Sleep Apnea, the message from the brain to the chest muscles does not always occur during sleep. (May be present in heart, stroke and brain injured patients.) There are several types of Central Apnea, including high altitude-induced periodic breathing, idiopathic CSA, narcotic-induced central apnea, obesity hypoventilation syndrome and Cheyne-Stokes breathing.

Complex sleep apnea (CompSA) is the emergence of central events on treatment with pressure (CPAP or BIPAP) in a patient with obstructive sleep apnea on diagnostic testing. This phenomenon is not well-understood these members may also have obstructive and/or mixed apneas.

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 decisions;
- General coverage guidelines included in original Medicare manuals unless superseded by operational policy letters or regulations; and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:

Respiratory Assist Devices (RAD's) - (E0470) and (E0471) Requests:

Preauthorization by the Plan for the 1st three months of therapy is required for all RAD requests.

For a RAD to be covered, the treating physician must fully document in the member's medical record symptoms characteristic of sleep-associated hypoventilation, such as daytime hypersomnolence, excessive fatigue, morning headache, cognitive dysfunction, dyspnea, etc.

A RAD is covered for those members with clinical disorder groups characterized as:

- (I) Restrictive thoracic disorders (i.e., neuromuscular diseases or severe thoracic cage abnormalities);
- (II) Severe chronic obstructive pulmonary disease (COPD);
- (III) Central sleep apnea (CSA) or complex sleep apnea (Comp SA); or
- (IV) Hypoventilation syndrome.

All must meet the specific criteria associated with the condition given below:

I. Restrictive Thoracic Disorders: A device is covered when criteria A – C are met.

- A. There is documentation in the member's medical record of a neuromuscular disease (for example, amyotrophic lateral sclerosis - ALS) or a severe thoracic cage abnormality (for example, post-thoracoplasty for TB), **and**
- B. One of the following:
 - a. An arterial blood gas PaCO₂, done while awake and breathing the member's prescribed FIO₂, is greater than or equal to 45mmHg, **or**

- b. Sleep oximetry demonstrates oxygen saturation $\leq 88\%$, ≥ 5 minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing the member's prescribed FIO₂, **or**
- c. For a neuromuscular disease (only), either i or ii,
 - i. Maximal inspiratory pressure $< 60\text{cm H}_2\text{O}$ **or**
 - ii. Forced vital capacity is $< 50\%$ predicted, **and**
- C. Chronic obstructive pulmonary disease does not contribute significantly to the member's pulmonary limitation.

If all of the above criteria are met, the RAD will be authorized for coverage for the first three months of therapy.

If all of the above criteria are not met, the RAD may be denied as not medically necessary.

II. Severe COPD:

An E0470 device is covered if criteria A-C are met.

- A. An arterial blood gas PaCO₂, done while awake and breathing the member's prescribed FIO₂, $\geq 52\text{mmHg}$, **and**
- B. Sleep oximetry demonstrates oxygen saturation $\leq 88\%$ for ≥ 5 minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing oxygen at 2LPM or the member's prescribed FIO₂ (whichever is higher), **and**
- C. Prior to initiating therapy, sleep apnea and treatment with a continuous positive airway pressure (CPAP) device has been considered and ruled out. (Formal sleep testing is not required if there is sufficient information to demonstrate the member does not suffer from some form of sleep apnea (Obstructive Sleep Apnea (OSA), CSA and/or Comp SA) as predominate cause of awake hypercapnea or nocturnal arterial oxygen desaturation).

If all of the above criteria are met, the device will be covered for the first three months of therapy.

If all of the above criteria are not met, E0470 will be denied as not medically necessary.

An E0471 (back up rate feature) device will be covered for a member with COPD in either of the two situations below, depending on the testing performed to demonstrate the need.

Situation 1: For Group II members (COPD) who qualified for an E0470 device, an E0471, started any time after a period of initial use of an E0470 device is covered if both criteria A **and** B are met.

- A. An arterial blood gas PaCO₂, done while awake and breathing the member's prescribed FIO₂, shows that the member's PaCO₂ worsens ≥ 7 mm HG compared to the original result from criterion A, (above), **and**

- B. A facility-based PSG demonstrates oxygen saturation $\leq 88\%$ for ≥ 5 minutes of nocturnal recording time (minimum recording time of 2 hours) while using an E0470 device that is not caused by obstructive upper airway events – i.e., $AHI < 5$.

Situation 2: For Group II members (COPD) who qualified for an E0470 device, an E0471 device will be covered if, at a time no sooner than 61 days after initial issue of the E0470 device, both of the following criteria **A and B** are met:

- A. An arterial blood gas PaCO₂ done while awake and breathing the member's prescribed FIO₂, still remains ≥ 52 mm Hg, **and**
- B. Sleep oximetry while breathing with the E0470 device, demonstrates oxygen saturation $\leq 88\%$ for ≥ 5 minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing oxygen at 2 LPM or the member's prescribed FIO₂, whichever is higher.

If the criteria described in either situation 1 of 2 are not met, E0471 will be denied as not medically necessary.

III. Central Sleep Apnea or Complex Sleep Apnea:

A RAD (E0470 or E0471) is covered when, prior to initiating therapy, a complete facility-based, attended PSG is performed documenting the following (A and B):

- A. The diagnosis of central sleep apnea (CSA) or complex sleep apnea (CompSA), **and**
- B. Significant improvement of the sleep-associated hypoventilation with the use of an E0470 or E0471 device on the settings that will be prescribed for initial use at home, while breathing the member's prescribed FIO₂.

If all of the above criteria are met, either device will be covered for members with documented CSA or CompSA for the first three months of therapy.

If all of the above criteria are not met, then E0470 or E0471 will be denied as not medically necessary.

IV. Hypoventilation Syndrome:

An E0470 device is covered if criteria 1, 2, **and either 3 or 4** are met:

- 1) An initial arterial blood gas PaCO₂, done while awake and breathing the member's prescribed FIO₂, ≥ 45 mm Hg

AND

2) Spirometry shows an FEV1/FVC \geq 70%. (Refer to II. SEVERE COPD (above) for information about device coverage for members with FEV1/FVC $<$ 70%.)

AND

3) An arterial blood gas PaCO₂, done during sleep or immediately upon awakening, and breathing the member's prescribed FIO₂, and shows worsening PaCO₂ of \geq 7mm Hg compared to the original result in criterion 1

OR

4) A facility-based PSG or HST demonstrates oxygen saturation \leq 88% for \geq 5 minutes of nocturnal recording time (minimum recording time of 2 hours) that is not caused by obstructive upper airway events, i.e., AHI $<$ 5.

If the above criteria are not met, E0470 will be denied as not medically necessary.

An E0471 device is covered for a member with hypoventilation syndrome if criteria A, B, **and either C or D** is met:

A. Covered E0470 device is being used,

AND

B. Spirometry shows an FEV1/FVC \geq 70%. (Refer to II. SEVERE COPD (above) for information about device coverage for members with FEV1/FVC $<$ 70%),

AND

C. An arterial blood gas PaCO₂, done while awake and breathing the member's prescribed FIO₂, shows that the PaCO₂ worsens \geq 7 mm Hg compared to the ABG result performed to qualify the member for the E0470 device,

OR

D. A facility-based PSG or HST demonstrated oxygen saturation \leq 88% for \geq 5 minutes of nocturnal recording time (minimum recording time of 2 hours) that is not caused by obstructive upper airway events – i.e., AHI $<$ 5 while using an E0470 device.

If the above criteria are not met, E0470 will be denied as not medically necessary.

CONTINUED COVERAGE CRITERIA FOR RAD DEVICES BEYOND THE 1ST THREE MONTHS OF THERAPY.

There must be documentation in the patient's medical record about the progress of relevant symptoms and patient usage of the device up to that time.

Failure of the patient to be consistently using the RAD device for an average of 4 hours per 24 hour period (compliance chip) by the time of the re-evaluation (on or after 61 days after initiation of therapy) would represent non-compliant utilization for the intended purposes and expectations of benefit of this therapy. This would constitute reason for continued coverage to be denied as not medically necessary.

WHEN COVERAGE WILL NOT BE APPROVED:

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

SPECIAL NOTES FOR RAD:

1. The polysomnogram when required must be performed in a facility-based laboratory (Type I study) or an inpatient hospital-based or home based sleep test (HST) and must comply with all applicable state regulatory requirements.
2. The treating physician must fully document any of the member's symptoms characteristic of sleep-associated hypoventilation, such as daytime hypersomnolence, excessive fatigue, morning headache, cognitive dysfunction, or dyspnea.
3. Either a non-heated or heated humidifier is covered when ordered by the treating physician for use with a covered PAP device.
4. CPAP, BiPAP or RAD should be prescribed pursuant to a CPAP titration to obtain the most effective pressure compatible with patient comfort. The Plan expects that the CPAP vendor and the prescribing sleep medicine physician will undertake appropriate measures to maximize the chance of success of the CPAP/BIPAP effort. These measures to acclimate members to therapy include education, emotional support to overcome initial reluctance where appropriate, alternate mask fitting for effect and comfort, nasal pillows, ramping.
5. 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.

6. Coverage with Evidence Development: Members may receive coverage of CPAP during participation in a clinical study to address targeted conditions as specified in the NCD.
 - a. In Medicare-aged subjects with clinically identified risk factors for OSA, how does the diagnostic accuracy of a clinical trial of CPAP compare with PSG and Type II, III & IV HST in identifying subject with OSA who will respond to CPAP?
 - b. In Medicare-aged subjects with clinically identified risk factors for OSA who have not undergone confirmatory testing with PSG or Type II, III & IV HST, does CPAP cause clinically meaningful harm?

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: E0470, E0471, E0561, E0562, A4604, A7027, A7028, A7029, A7030, A7031, A7032, A7033, A7034, A7035, A7036, A7037, A7038, A7039, A7046, 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 Respiratory Assist Devices – CGS Administrator (L33800); Effective date: 10/01/2015. Accessed via www.cms.gov 01/16/19.
2. BCBSNC Corporate Medical Policy “Diagnosis and Medical Management” effective March 2013; Accessed online at BCBSNC.com on 01/16/2019.
3. Decision Memo for Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA) (CAG-00093R2). Accessed via <https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=204&fromdb=true> on January 9, 2019.
4. Medicare National Coverage Determination for Continuous Positive Airway Pressure Therapy for OSA 240.4. Accessed via https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part4.pdf . Viewed on 1/9/19.

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 area re: continued coverage for CPAP, BiPAP and RAD after three months.

Revision Dates: 3/2011, 4/2011: Separated policy from the PAP Therapy and Surgical Treatment for Obstructive Sleep Apnea policies and removed all coverage criteria language; Indications For Coverage: added RAD clinical disorder groups I-IV.

Language updated for section I: Restrictive Thoracic Disorders A-C.; Continued Coverage language added for sections II-IV.

Added Section: Continued Coverage Criteria For RAD Devices Beyond the 1st Three Months of Therapy - to be consistent with CMS guidelines; Coding section: updated per Senior Coding Analyst; Reference section updated to reflect current CMS policies. GLOSSARY section: Updated to reflect RAD policy and added Group II member definition.

Revision Date: 02/19/2014; Minor edits to mirror LCD and updated Codes.

Revision Date: 1/21/15; Minor edits to reflect current LCD and updated clinical definitions provided by physician consult. October 29, 2015 updated LCD due to ICD-10 update only.

Revision Date: 1/18/17 Minor revisions only. Updated references to include Decision Memo for CPAP Therapy for OSA.

Revision Date: 1/16/19 Annual Review; No CMS updates. Minor Revisions Only.

Approval Dates:

Medical Coverage Policy Committee: January 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.

Central sleep apnea (CSA) – the message that is normally sent from the brain to the chest muscles to initiate breathing does not reliably occur during sleep. Member with CSA shows no signs of attempts to breathe despite an open airway. This type of sleep apnea is usually associated with serious illness, especially an illness in which the lower brainstem -- which controls breathing -- is affected.

Complex sleep apnea- a combination of obstructive and central apnea specifically identified by the emergence of central apneas or hypopneas upon exposure to a CPAP or RAD device.

Continuous Positive Airway Pressure (CPAP) – is a single-level continuous positive airway pressure device that delivers a constant level of positive air pressure (within a single respiratory cycle) from a flow generator, via a nasal, oral, or facial mask. The purpose is to assist spontaneous respiratory efforts and supplement the volume of inspired air into the lungs.

Epworth Scale- A semi-quantitative tool to measure the intensity of daytime sleepiness based on the patient's response to a series of eight questions about how likely they might be to fall asleep in various daytime situations. Highest possible score is 24; scores over 10 are suggestive of excessive daytime sleepiness. Because it is subjective it is best done early in the evaluation and before the sleep study (see *attached Epworth Sleepiness Scale for example*).

Excessive Daytime Sleepiness (EDS) - 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

Group II members - criteria include the presence of

(a) an arterial PO₂ of 56-59 mm Hg or an arterial blood oxygen saturation of 89 percent at rest (awake), during sleep for at least 5 minutes, or during exercise and any of the following:

- Dependent edema suggesting congestive heart failure, or
- Pulmonary hypertension or
- Cor pulmonale, determined by measurement of pulmonary artery pressure, gated blood pool scan, echocardiogram, or "P" pulmonale on EKG (P wave greater than 3 mm in standard leads II, III, or AVF), or
- Erythrocythemia with a hematocrit greater than 56 percent.

(b) Initial coverage for patients meeting Group II criteria is limited to 3 months or the physician specified length of need, whichever is shorter.

Hypopnea- an abnormal respiratory event lasting at least 10 seconds with a reduction in air flow by 30% or more accompanied by at least a 4% reduction in O₂ saturation.

Hypersomnolence- see Excessive Daytime Sleepiness (EDS)

Obstructive Sleep Apnea (OSA) - the most common 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 >20 to <40; LSAT <65%

Obstructive apnea- refers to a period of complete obstruction and absent airflow for a minimum of 10 seconds.

Oral Appliances- splints to move the mandible (and thus the tongue). These are effective in some patients.

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

Respiratory assist device (RAD) - 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.

- A respiratory assist device (RAD) without backup rate (E0470) delivers adjustable, variable levels (within a single respiratory cycle) of positive air pressure by way of tubing and a noninvasive interface (such as a nasal, oral, or facial mask) to assist spontaneous respiratory efforts and supplement the volume of inspired air into the lungs. A respiratory cycle is defined as an inspiration, followed by expiration.
- A respiratory assist device (RAD) with backup rate (E0471) delivers adjustable, variable levels (within a single respiratory cycle) of positive air pressure by way of tubing and a noninvasive interface (such as a nasal or oral facial mask) to assist spontaneous respiratory efforts and supplement the volume of inspired air into the lungs. In addition, it has a timed backup feature to deliver this air pressure whenever sufficient spontaneous inspiratory efforts fail to occur.

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.

RERAs (Respiratory Event Related Arousals) – are related to respiratory slowing that does not reach the level of a score-able apnea or hypopnea. RERAs are what

define UARS. **(For the purpose of this policy, RERAs are not included in the calculation of the RDI).**

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.

Upper Airway Resistance Syndrome (UARS) - EDS with arousals during sleep that are not associated with apneas and hypopneas but are associated with negative intrathoracic pressure from increased airway resistance. (Esophageal pressure can be measured for the diagnosis; UARS may also be inferred from repetitive episodes of progressive (crescendo) snoring culminating in an arousal, possibly with desaturation.) Upper airway resistance syndrome is a variant of OSA and is characterized by a partial collapse of the airway resulting in increased resistance to airflow. This causes many short episodes of breathing difficulties to occur each night, leading to brief arousals and sleep fragmentation. The patient does not actually stop breathing during sleep. The disruption in sleep can cause excessive daytime sleepiness. It is a disorder more common in women.