**BIPAP Coverage Guidelines**

**BIPAP/E0470**  
**DX: Thoracic Disorder**  
There is documentation in the patient's medical record of a neuromuscular disease (for example, amyotrophic lateral sclerosis) or a severe thoracic cage abnormality (for example, post-thoracoplasty for TB).

**Yes** I have documentation that the patient suffers from a neuromuscular disease and /or a thoracic cage abnormality.

Has the treating physician fully documented in the patient’s medical record symptoms or characteristic of sleep-associated hypoventilation, such as daytime hypersomnolence, excessive fatigue, morning headache, cognitive dysfunction, dyspnea, etc?

**No** my patient does not have a progressive neuromuscular disease.

If your patient’s diagnosis does not match any of the qualifying diagnosis available in this guidebook then an ABN must be signed to prior to dispensing. ABN needs to state the patient’s diagnosis does not qualify them for the BIPAP.

**Yes** the symptoms or characteristics have been documented and are in patient’s chart.

Does your patient also have one of the following conditions?
1. Arterial Blood Gas, PaCO2, greater than or equal to 45mm Hg on patients usual FI02.
2. Sleep oximetry has an O2sat level less than or equal to 88% for 5 continuous minutes on room air.
3. For a progressive neuromuscular disease ONLY, the maximal inspiratory pressure is less than 60 cm H2O or forced vital capacity must be less than or equal to 50% predicted

**No** the physician has not documented in the patient’s medical record symptoms or characteristics of the sleep disorder
ABN needs to state no supporting documentation from physician regarding conditions affecting the sleep disorder.

**Yes** my patient has one of the above conditions as well as the neuromuscular disease.

Does the patient have a chronic obstructive pulmonary disease contributing significantly to the patient’s pulmonary limit?

**No** the patient’s chronic obstructive pulmonary disease does not contribute to the neuromuscular disease.

Does the patient have a detailed written order from the physician?

**Yes** the patient has a detailed written order.

If all of the above criteria for patients with a thoracic disorder are met, a BIPAP/E0470 device will be covered for the **first three months of therapy**.

**AFTER 3 months see page 13 for coverage criteria.**

REV 07/26/2011
BIPAP/E0470  
DX: COPD  

Does the patient have COPD?

Yes, the patient’s diagnosis is documented COPD.

Has the treating physician fully documented in the patient’s medical record symptoms or characteristic of sleep-associated hypoventilation, such as daytime hypersonolence, excessive fatigue, morning headache, cognitive dysfunction, dyspnea, etc?

No my patient does not have COPD

If your patient’s diagnoses do not match any of the qualifying diagnosis available in this guidebook then an ABN must be signed to prior to dispensing.

ABN needs to state the patient’s diagnosis does not qualify them for the BIPAP.

Yes the symptoms or characteristics have been documented and are in patient’s chart.

Does your patient’s medical record document one of the following conditions?

1. Arterial Blood Gas, PaC02, done while awake breathing the patient’s prescribed FIO2, is greater than or equal to 52mm Hg.

2. Sleep oximetry demonstrates oxygen saturation ≤ 88% for ≥ 5 minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing oxygen at 2 LPM or the patient’s prescribed FIO2 (whichever is higher).

3. Prior to initiating therapy, Obstructive Sleep Apnea (OSA) and treatment with a continuous positive airway pressure device (CPAP) has been considered and ruled out.

No the treating physician did not document any of the sleep related symptoms.

Patient will have to be re-evaluated before Medicare will cover.

If the patient wants to get the unit an ABN needs to state no medical documentation in chart.

No the patient does not have one of the conditions accompanying their COPD.

An ABN must be signed and would state no qualifying criteria accompanying the diagnosis of COPD in the patient’s medical record.

Yes my patient has one of the above conditions as well as the COPD.

If all of the above criteria for patients with COPD are met, a BIPAP/E0470 device will be covered for the first three months of therapy.

AFTER 3 months see page 13 for coverage criteria.
BIPAP/E0470
DX: Central Sleep Apnea
Has the treating physician fully documented in the patient’s medical record symptoms or characteristic of sleep-associated hypoventilation, such as daytime hyper somnolence, excessive fatigue, morning headache, cognitive dysfunction, dyspnea, etc?

Yes there is documentation regarding the characteristics or symptoms of the sleep disorder.

Has the patient had a facility based sleep study?

Yes my patient has had a facility based sleep study.

Does the patient have central sleep apnea? Central sleep apnea (CSA) is defined as
1. An apnea-hypopnea index (AHI) greater than or equal to 5; and
2. Central apneas/hypopneas greater than 50% of the total apneas/hypopneas; and
3. Central apneas or hypopneas ≥ 5 times per hour; and
4. Symptoms of either excessive sleepiness or disrupted sleep.

Yes my patient has CSA as defined above.

Is there significant improvement of the sleep-associated hypoventilation with the use of a BIPAP E0470 device on the settings that will be prescribed for initial use at home, while breathing the patient's prescribed FIO2?

Yes the BIPAP significantly improves the sleep-associated hypoventilation.

The BIPAP/E0470 device will be covered for the first three months of therapy.

AFTER 3 months see page 13 for coverage criteria

NO the treating physician did not document any of the sleep related symptoms. Patient will have to be re-evaluated before Medicare will cover. If the patient wants to get the unit an ABN needs to state no medical documentation.

NO my patient has not had a facility based sleep study preformed.

ABN needs to state no facility based sleep study preformed to be able to qualify the beneficiary for a BIPAP.

NO the patient does not have CSA as defined above.

An ABN must be signed to be dispensed. ABN needs to state no diagnosis of CSA has been documented.

NO the BIPAP does not significantly improve the patient’s sleep-associated disorder.

An ABN must be signed to be dispensed. ABN needs to state the BIPAP does not significantly improve the patient’s sleep-associated disorder.
BIPAP/E0470
DX: Hypoventilation

Has the treating physician fully documented in the patient’s medical record symptoms or characteristic of sleep-associated hypoventilation, such as daytime hyper somnolence, excessive fatigue, morning headache, cognitive dysfunction, dyspnea, etc?

**Yes** there is documentation regarding the characteristics or symptoms of the sleep disorder.

Has the patient had a facility based sleep study?

**Yes** my patient has had a facility based sleep study.

Does patient fall under criteria 1, 2, and either 3 or 4 are met.

1. An initial arterial blood gas PaCO2, done while awake and breathing the patient's prescribed FIO2, is ≥45 mm Hg.

2. Spirometry shows an FEV1/FVC ≥70% and an FEV1 ≥50% of predicted. (Refer to II. SEVERE COPD (above) for information about device coverage for patients with FEV1/FVC <70% and FEV1 <50% of predicted).

3. An arterial blood gas PaCO2, done during sleep or immediately upon awakening, and breathing the patient's prescribed FIO2, shows the beneficiary's PaCO2 worsened ≥7 mm Hg compared to the original result in criterion 1 (above).

4. A facility-based PSG demonstrates oxygen saturation ≤88% for ≥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. (Refer to the Positive Airway Pressure Devices LCD for information about E0470 coverage for obstructive sleep apnea)

**Yes** the patient falls under criteria 1, 2, and either 3 or 4.

Is there significant improvement of the sleep-associated hypoventilation with the use of a BIPAP E0470 device on the settings that will be prescribed for initial use at home, while breathing the patient's prescribed FIO2?

**Yes** the BIPAP significantly improves the sleep-associated hypoventilation.

The BIPAP/E0470 device will be covered for the first three months of therapy.

*After 3 months see page 13 for coverage criteria*
Did your patient have a face to face visit with the physician prior to having a sleep study that documented? Sleep History and symptoms and/or (2) Epworth Scale and/or (3) Physical Examination?

**YES**, the face to face prior to sleep study documents one of the above conditions.

Do you have a detailed written order for CPAP and supplies?

**Yes** I have a detailed written order.

Is your patient’s diagnosis obstructive sleep apnea (327.23)?

**Yes** the patient suffers from obstructive sleep apnea?

Has your patient had a complete sleep study?

**Yes** my patient has had a complete sleep study

Does your patient have an AHI greater than or equal to 15 episodes per hour?

**Yes** the patient’s AHI is greater than or equal to 15 episodes per hour.

Did the patient have a sleep time of at least 120 minutes?

**Yes** the patient did have a sleep time at least 120 minutes long.

Was the CPAP proven to be ineffective?

Yes my patient has tried a CPAP and it was proven to be ineffective.

The BIPAP/E0470 device will be covered for the first three months of therapy.

**AFTER 3 months see page 13 for coverage criteria**

**NO**, there is was no documentation of the above conditions prior to the sleep study.

ABN must be signed and the ABN needs to state there was no documentation regarding the sleep disorder in the patients initial face to face.

**NO** the patient did not have an AHI of 15 or greater.

DID the patient have an AHI of 5 to 14 events per hour and one of the following diagnoses?

* Excessive sleepiness, impaired cognition, mood disorders, insomnia, hypertension, ischemic heart disease, or history of stroke.

**NO** the patient did not have an AHI of 5 to 14 events with one of these conditions.

Was the CPAP proven to be ineffective?

Yes my patient has tried a CPAP and it was proven to be ineffective.

The BIPAP/E0470 device will be covered for the first three months of therapy.

**AFTER 3 months see page 12 for coverage criteria**

**NO** none of these diagnoses matches up with my patient’s condition.

ABN needs to state the patient’s diagnosis does not qualify for a CPAP and supplies under Medicare guidelines.

**NO** the AHI is less than 5. 

**YES**, they had an AHI of 5 to 14 events per one of these conditions.

Was the CPAP proven to be ineffective?

No the CPAP was not proven to be ineffective. Patient qualifies for CPAP until proven ineffective

**NO** the patient did not have a sleep time of 120 minutes. 

See Addendum on page 3

No, the patient does not suffer from Obstructive Sleep Apnea.

ABN must be signed that states that the patient does not suffer from Obstructive Sleep Apnea.

**NO** the patient did not undergo a complete sleep study.

ABN needs to state no sleep study was preformed.

Yes the patient suffers from Obstructive Sleep Apnea?

Has your patient had a complete sleep study?

**Yes** my patient has had a complete sleep study

Does your patient have an AHI greater than or equal to 15 episodes per hour?

**Yes** the patients AHI is greater than or equal to 15 episodes per hour.

**NO** the patient did not have a complete sleep study.

ABN must be signed and the ABN needs to state there was no documentation of the above conditions prior to the sleep study.

**NO** the patient did not suffer from Obstructive Sleep Apnea.

ABN must be signed that states that there is no written order available at the time of dispensing.

**NO** the patient did not have an AHI of 15 or greater.

**YES**, they had an AHI of 5 to 14 events per one of these conditions.

Was the CPAP proven to be ineffective?

No the CPAP was not proven to be ineffective. Patient qualifies for CPAP until proven ineffective

**NO** none of these diagnoses matches up with my patient’s condition.

ABN needs to state the patient’s diagnosis does not qualify for a CPAP and supplies under Medicare guidelines.

**NO** the AHI is less than 5.

See Addendum on page 3

Yes the patient suffers from Obstructive Sleep Apnea?

Has your patient had a complete sleep study?

**Yes** my patient has had a complete sleep study

Does your patient have an AHI greater than or equal to 15 episodes per hour?

**Yes** the patients AHI is greater than or equal to 15 episodes per hour.

**NO** the patient did not have a sleep time of 120 minutes. See Addendum on page 3

No, the patient did not have a sleep time of at least 120 minutes.

Was the CPAP proven to be ineffective?

Yes my patient has tried a CPAP and it was proven to be ineffective.

The BIPAP/E0470 device will be covered for the first three months of therapy.

**AFTER 3 months see page 13 for coverage criteria**

**NO** the AHI is less than 5. See Addendum on page 3

Yes my patient has tried a CPAP and it was proven to be ineffective.

The BIPAP/E0470 device will be covered for the first three months of therapy.

**AFTER 3 months see page 12 for coverage criteria**
BIPAP/E0470
DX: Complex Sleep Apnea

Has the treating physician fully documented in the patient’s medical record symptoms or characteristic of sleep-associated hypoventilation, such as daytime hyper somnolence, excessive fatigue, morning headache, cognitive dysfunction, dyspnea, etc?

**Yes**

- there is documentation regarding the characteristics or symptoms of the sleep disorder.

- Has the patient had a sleep study?

**Yes my patient has had a sleep study.**

- Does the patient have Complex Sleep Apnea?

Complex sleep apnea (CompSA) is a form of central apnea specifically identified by the persistence or emergence of central apneas or hypopneas upon exposure to CPAP or an E0470 device when obstructive events have disappeared. These patients have predominately obstructive or mixed apneas during the diagnostic sleep study occurring at ≥ 5 times per hour. With use of a CPAP or E0470, they show a pattern of apneas and hypopneas that meets the definition of CSA described above.

**Yes my patient has Comp SA as defined above.**

- Is there significant improvement of the sleep-associated hypoventilation with the use of an BIPAP E0470 device on the settings that will be prescribed for initial use at home, while breathing the patient's prescribed FIO2?

**Yes**

- the BIPAP significantly improves the sleep-associated hypoventilation.

- The BIPAP/E0470 device will be covered for the first three months of therapy.

- *AFTER 3 months see page 13 for coverage criteria*

**NO**

- the treating physician did not document any of the sleep related symptoms. Patient will have to be re-evaluated before Medicare will cover.

- If the patient wants to get the unit an ABN needs to state no medical documentation.

**NO**

- my patient has not had a facility based sleep study preformed.

- ABN needs to state no facility based sleep study preformed to be able to qualify the beneficiary for a BIPAP.

**NO**

- the patient does not have Comp SA as defined above.

- An ABN must be signed to be dispensed.

- ABN needs to state no diagnosis of Comp SA has been documented.

**NO**

- the BIPAP does not significantly improve the patients sleep-associated hypoventilation.

- An ABN must be signed to be dispensed.

- ABN needs to state the BIPAP does not significantly improve the patient’s sleep-associated disorder.
BIPAP/E0471
DX: Thoracic Disorder

There is documentation in the patient's medical record of a neuromuscular
disease (for example, amyotrophic lateral sclerosis) or a severe thoracic
cage abnormality (for example, post-thoracoplasty for TB).

Yes my patient suffers from a neuromuscular
disease and/or a thoracic cage abnormality.
Has the treating physician fully documented in the patient’s medical record symptoms or characteristic of sleep-associated hypoventilation, such as daytime hypersomnolence, excessive fatigue, morning headache, cognitive dysfunction, dyspnea, etc?

NO my patient does not have a progressive neuromuscular disease.
If your patient’s diagnosis does not match any of the qualifying diagnosis available in this guidebook then an ABN must be signed to prior to dispensing. ABN needs to state the patient’s diagnosis does not qualify them for the BIPAP.

Yes the symptoms or characteristics have been documented and are in patient’s chart.
Does your patient also have one of the following conditions?
1. Arterial Blood Gas, PaCO2, greater than or equal to 45mm Hg on patients usual FiO2.
2. Sleep oxideymetry has an O2sat level less than or equal to 88% for 5 continuous minutes on room air.
3. For a progressive neuromuscular disease ONLY, the maximal inspiratory pressure is less than 60 cm H2O or forced vital capacity must be less than or equal to 50% predicted

NO the physician has not documented in the patient’s medical record symptoms or characteristics of the sleep disorder. ABN needs to state no supporting documentation from physician regarding conditions affecting the sleep disorder.

Yes my patient has one of the above conditions as well as the neuromuscular disease.

Does the patient have a chronic obstructive pulmonary disease contributing significantly to the patient’s pulmonary limit?

NO the patient’s chronic obstructive pulmonary disease does not contribute to the neuromuscular disease.
Does the patient have a detailed written order from the physician?

Yes the patient has a detailed written order.
If all of the above criteria for patients with a thoracic disorder are met, a BIPAP/E0471 device will be covered for the first three months of therapy.

NO, the patient does not have a detailed order. A detailed order must be received prior to the patient receiving the equipment.

AFTER 3 months see page 13 for coverage criteria.
BIPAP/E0471
DX: COPD
Situation 1
Does the patient have COPD?

Yes, the patient's diagnosis is documented COPD.
Has the treating physician fully documented in the patient's medical record symptoms or characteristic of sleep-associated hypoventilation, such as daytime hypersomnolence, excessive fatigue, morning headache, cognitive dysfunction, dyspnea, etc?

No
my patient does not have COPD
If your patient's diagnosis does not match any of the qualifying diagnosis available in this guidebook then an ABN must be signed to prior to dispensing.
ABN needs to state the patient's diagnosis does not qualify them for the BIPAP.

Yes
the symptoms or characteristics have been documented and are in patient's chart.

Did your patient qualify for a BIPAP (E0471)?

Yes
the patient did qualify for a BIPAP (E0471).

Did the patient meet both A and B?
A. An arterial blood gas PaCO2, done while awake and breathing the patient's prescribed FIO2, shows that the beneficiary's PaCO2 worsens ≥7 mm Hg compared to the original result from criterion A,(above).
B. A facility-based PSG demonstrates oxygen saturation ≤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. (Refer to the Positive Airway Pressure Devices LCD for information about E0470 coverage for obstructive sleep apnea).

No
the patient does not meet the E0471 criteria for a BIPAP.

An ABN must be signed and would state no qualifying criteria for a RAD due to lack of medical documentation supporting need.

Yes
my patient has both of the above conditions as well as the COPD.
The patient qualifies under situation 1 for an E0471/RAD. The BIPAP/E0470 device will be covered for the first three months of therapy.

AFTER 3 months see page 13 for coverage criteria
### BIPAP/E0471
**DX: COPD**
**Situation 2**

**Does the patient have COPD?**

- **Yes**, the patient's diagnosis is documented COPD.
  - Has the treating physician fully documented in the patient's medical record symptoms or characteristic of sleep-associated hypoventilation, such as daytime hyper somnolence, excessive fatigue, morning headache, cognitive dysfunction, dyspnea, etc?

- **NO** my patient does not have COPD
  - If your patient's diagnosis does not match any of the qualifying diagnosis available in this guidebook then an ABN must be signed to prior to dispensing.
  - ABN needs to state the patient's diagnosis does not qualify them for the BIPAP.

- **Yes** the symptoms or characteristics have been documented and are in patient’s chart.
  - Did your patient qualify for a BIPAP (E0471)?

- **Yes** the patient did qualify for a BIPAP (E0471).
  - Did the patient use the BIPAP (E0471) for at least 60 days?

- **Yes** the patient used the BIPAP (E0471) for at least 60 days.
  - **Yes**, the patient has both of the above conditions as well as the COPD. The patient qualifies under situation 2 for an E0471/RAD The BIPAP/E0470 device will be covered for the first three months of therapy. AFTER 3 months see page 13 for coverage criteria

- **NO** the treating physician did not document any of the sleep related symptoms. Patient will have to be re-evaluated before Medicare will cover.
  - If the patient wants to get the unit an ABN needs to state no medical documentation in chart.

- **No** the patient does not meet the E0471 criteria for a BIPAP.
  - An ABN must be signed and would state no qualifying criteria for a RAD due to lack of medical documentation supporting need.

- **No** the patient has not used the BIPAP for at least 60 days.
  - Have the patient continue to use BIPAP for 60 days and then check coverage guideline again.

- **No** the patient does not meet criteria A and B.
  - Get an ABN stating the PaCo2 and sleep oximetry do not meet Medicare guidelines.

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**Yes** my patient has both of the above conditions as well as the COPD.

*The patient qualifies under situation 2 for an E0471/RAD The BIPAP/E0470 device will be covered for the first three months of therapy. AFTER 3 months see page 13 for coverage criteria*
BIPAP/E0471
DX: Central Sleep Apnea
Has the treating physician fully documented in the patient’s medical record symptoms or characteristic of sleep-associated hypoventilation, such as daytime hyper somnolence, excessive fatigue, morning headache, cognitive dysfunction, dyspnea, etc?

Yes
There is documentation regarding the characteristics or symptoms of the sleep disorder.
Has the patient had a facility based sleep study?

Yes
My patient has had a facility based sleep study.
Does the patient have central sleep apnea?
Central sleep apnea (CSA) is defined as
1. An apnea-hypopnea index (AHI) greater than or equal to 5; and
2. Central apneas/hypopneas greater than 50% of the total apneas/hypopneas; and
3. Central apneas or hypopneas ≥ 5 times per hour; and
4. Symptoms of either excessive sleepiness or disrupted sleep.

No
The treating physician did not document any of the sleep related symptoms. Patient will have to be re-evaluated before Medicare will cover. If the patient wants to get the unit an ABN needs to state no medical documentation.

My patient has CSA defined above.

Is there significant improvement of the sleep-associated hypoventilation with the use of the BIPAP E0470 device on the settings that will be prescribed for initial use at home, while breathing the patient's prescribed FIO2?

Yes
The BIPAP significantly improves the sleep-associated hypoventilation.
The BIPAP/E0471 device will be covered for the first three months of therapy.

AFTER 3 months see page 13 for coverage criteria.

No
The patient does not have CSA as defined above.
An ABN must be signed to be dispensed. ABN needs to state no diagnosis of CSA has been documented.

No
The BIPAP does not significantly improve the patients sleep-associated hypoventilation.
An ABN must be signed to be dispensed. ABN needs to state the BIPAP does not significantly improve the patient’s sleep-associated disorder.
BIPAP/E0471
DX: Complex Sleep Apnea (Comp SA)
Has the treating physician fully documented in the patient’s medical record symptoms or characteristic of sleep-associated hypoventilation, such as daytime hyper somnolence, excessive fatigue, morning headache, cognitive dysfunction, dyspnea, etc?

Yes there is documentation regarding the characteristics or symptoms of the sleep disorder.

Has the patient had a facility based sleep study?

Yes my patient has had a facility based sleep study.

Does the patient have complex sleep apnea?

Yes my patient has Complex Sleep Apnea.

Has the patient been on a CPAP/E0470 device and obstructive events have disappeared?

Yes my patient has been on CPAP and the obstructive events have disappeared.

Does the patient meet criteria 1-4?

1. The total number of central apneas and obstructive apneas/hyponeas must be greater than 50% of the total apneas/hyponeas.
2. The AHI must be greater than or equal to 5.
3. Central apneas or hyponeas must be greater than or equal to 5 times per hour.
4. If the total sleep time is less than 2 hours of continuous recorded sleep, the total number of recorded events must be greater than or equal to 10.

Yes the patient meets all the criteria described in #1-4.

Does the BIPAP significantly improve the sleep-associated hypoventilation on the initial settings that will be used in the home?

Yes the BIPAP significantly improves the sleep-associated hypoventilation.

The BIPAP/E0471 device will be covered for the first three months of therapy.

AFTER 3 months see page 13 for coverage criteria
**BIPAP/E0471**

**DX: Hypoventilation Syndrome**

Has the treating physician fully documented in the patient’s medical record symptoms or characteristic of sleep-associated hypoventilation, such as daytime hyper somnolence, excessive fatigue, morning headache, cognitive dysfunction, ...

**Yes** there is documentation regarding the characteristics or symptoms of the sleep disorder.

Has the patient had a facility based sleep study?

**Yes** my patient has had a facility based sleep study.

Does the patient meet both criteria **A and B**?

- **A.** A covered E0470 device is being used.
- **B.** Spirometry shows an FEV1/FVC ≥70% and an FEV1 ≥50% of predicted. (Refer to II. SEVERE COPD (above) for information about device coverage for patients with FEV1/FVC <70% and FEV1 <50% of predicted).

**Yes** the patient meets both A and B.

Does the patient meet **C or D**?

- **C.** An arterial blood gas PaCO2, done while awake and breathing the patient's prescribed FIO2, shows that the beneficiary's PaCO2 worsens ≥7 mm Hg compared to the ABG result performed to qualify the patient for the E0470 device.
- **D.** A facility-based PSG demonstrates oxygen saturation ≤88% for ≥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. (Refer to the Positive Airway Pressure Devices LCD for information about E0470 coverage for obstructive sleep annnea.).

**Yes** the patient meets wither C or D.

The BIPAP/E0471 device will be covered for the **first three months of therapy**.

**AFTER 3 months see page 13 for coverage criteria**
BIPAP Quick Facts

Switching from CPAP to BIPAP
For beneficiaries changing from an E0601 (CPAP) to E0470 (BIPAP) due to ineffective therapy while on E0601 (CPAP) (wither during a facility-based titration or in the home setting), the treating physician must document that both of the following issues were addressed prior to changing to an E0470 (BIPAP) device:
   a. 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 E0470(BIPAP) device; and,
   b. E0601 (CPAP) pressure settings. The current setting of the E0601(CPAP) prevents the beneficiary from tolerating the therapy and lower pressure settings of the E0601(CPAP) were tried but failed to:
      i. Adequately control the symptoms of OSA; or,
      ii. Improve sleep quality; or,
      iii. Reduce the AHI/RDI to acceptable levels

Continuation of Coverage after 3 months
Patients covered for the first three months of an E0470 or an E0471 device must be re-evaluated to establish the medical necessity of continued coverage by Medicare beyond the first three months. While the patient may certainly need to be evaluated at earlier intervals after this therapy is initiated, the re-evaluation upon which Medicare will base a decision to continue coverage beyond this time must occur no sooner than 61 days after initiating therapy by the treating physician. Medicare will not continue coverage for the fourth and succeeding months of therapy until this re-evaluation has been completed.

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 E0470 or E0471 device for an average of 4 hours per 24 hour period 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 Medicare to deny continued coverage as not reasonable and necessary.

A signed and dated statement completed by the treating physician no sooner than 61 days after initiating use of the device, declaring that the patient is compliantly using the device (an average of 4 hours per 24 hour period) and that the patient is benefiting from its use must be obtained by the supplier of the device for continued coverage beyond three months.

If the above criteria are not met, continued coverage of an E0470 or an E0471 device and related accessories will be denied as not reasonable and necessary.
If patient already owns a BIPAP

- Any person coming in with a BIPAP that was not purchased from our company needs to be able to provide:
  
  - Sleep Study
  - Make
  - Model
  - Serial #
  - Supplier of the BIPAP
  - Date it was supplied

- An ABN needs to be signed if any of the above information is missing.
- Get a written order for all specific supplies.

Overall

- The orders attached to the initial set-up and supplies are good for lifetime unless stated otherwise.
- Either a non-heated or heated humidifier is covered when used with the BIPAP, you must have an RX.

Supply Quantities Allowed

A4604- Tubing with integrated heating system- 1 per 3 months

A7030- Full Face Mask- 1 per 3 months

A7031- Integrated Face Mask, replacement for full face mask- 1 per 1 month

A7032- Nasal cushion for mask replacement- 2 per 1 month

A7033- Pillow for nasal cannula, replacement- 2 per 1 month

A7034- Nasal interface (mask or cannula), with or without chinstrap- 1 per 3 months

A7035- Headgear- 1 per 6 months

A7036- Chinstrap- 1 per 6 months

A7037- Tubing- 1 per 3 month

A7038- Disposable tubing- 2 per 1 month

A7039- Non-Disposable filter- 1 per 6 months

A7046- Water Chamber for humidifier- 1 per 6 months

E0561- Humidifier, non-heated

E0562- Humidifier, heated
**Medicaid**

- Please see page 20.

**BCBS/Anthem Missouri Plans**

Non-invasive positive pressure respiratory assist devices (BiPAP) are considered **medically necessary** for any one of the following disorders, (subject to specific criteria for each respective condition – see further information below):

Restrictive thoracic disorders, (e.g., progressive neuromuscular diseases or severe thoracic cage abnormalities); or
Severe chronic obstructive pulmonary disease (COPD); or
Central sleep apnea; or
Obstructive sleep apnea (OSA).

**For Restrictive Thoracic Disorders**

**Medically Necessary:**

The use of a non-invasive positive pressure respiratory assist device (BiPAP) for the treatment of restrictive thoracic disorders is considered **medically necessary** when ALL of the following criteria are met:

- The member has been diagnosed with a progressive neuromuscular disease, (e.g., amyotrophic lateral sclerosis [ALS] or a severe thoracic cage abnormality, [e.g., post-thoracoplasty for TB]); and

- COPD *does not contribute* significantly to the individual's pulmonary limitation; and

  ONE or more of the following criteria are met:

  - An arterial blood gas PaCO\textsubscript{2} level is greater than or equal to 45 mm Hg, done while awake and breathing the individual's usual FIO\textsubscript{2} (fractionated inspired oxygen concentration); or

  - Sleep oximetry demonstrates an oxygen saturation less than or equal to 88% for at least five continuous minutes, done while breathing the individual's usual FIO\textsubscript{2}; or

  - Maximal inspiratory pressure is less than 60 cm H2O or forced vital capacity is less than 50% of predicted (for those with a progressive neuromuscular disease only).

**Note:** When the above medical necessity criteria for individuals with the indication of a restrictive thoracic disorder are met, a non-invasive positive pressure bi-level respiratory assist device, either with or without the back-up rate feature, will be considered **medically necessary**.
Not Medically Necessary:
The use of a non-invasive positive pressure respiratory assist device (Bi-level either with or without the back-up rate feature) for the treatment of restrictive thoracic disorders is considered not medically necessary if ALL the above medical necessity criteria are not met.

For Severe Chronic Obstructive Pulmonary Disease (COPD)
Medically Necessary:
The use of non-invasive positive pressure respiratory assist devices (BiPAP) for the treatment of severe COPD is considered medically necessary when ALL of the following are met:

- An arterial blood gas PaCO$_2$, done while awake and breathing the individual's usual FIO$_2$, is greater than or equal to 52 mm Hg; and
- Sleep oximetry demonstrates oxygen saturation less than or equal to 88% for at least five continuous minutes, done while breathing oxygen at 2 L/min. or the individual's usual FIO$_2$ (whichever is higher); and
- Prior to initiating therapy, obstructive sleep apnea and treatment with CPAP has been considered and ruled out.

Note: When the above medical necessity criteria for individuals with the indication of severe COPD are met, a non-invasive positive pressure Bi-level respiratory assist device, without back-up rate feature, will be considered medically necessary.

Not Medically Necessary:
The use of a non-invasive positive pressure respiratory assist device (Bi-level without back-up rate feature) for the treatment of severe COPD is considered not medically necessary if ALL the criteria are not met.

The use of a non-invasive positive pressure respiratory assist device (Bi-level with the back-up rate feature) is considered not medically necessary during the first two (2) months of therapy for persons with severe COPD (because proper adjustments and user accommodation to the use of a Bi-level without back-up feature will produce the desired therapeutic effect).

For Central Sleep Apnea, (i.e., apnea not due to airway obstruction)
Medically Necessary:
The use of a non-invasive positive pressure respiratory assist device (BiPAP) for the treatment of central sleep apnea is considered medically necessary when, prior to initiating therapy, a complete, facility-based, attended polysomnography has been performed and the test results have revealed ALL of the following:

- The diagnosis of central sleep apnea (CSA) has been confirmed; and
The presence of obstructive sleep apnea (OSA) has been excluded, as the predominant cause of the sleep-associated hypoventilation; and

If OSA is a component of the sleep-associated hypoventilation, CPAP has been ruled out as an effective therapy; and

Oxygen saturation level is less than or equal to 88% for at least five continuous minutes, done while breathing the individual's usual \( \text{FIO}_2 \); and

Significant clinical improvement of the sleep-associated hypoventilation has been demonstrated with the use of a Bi-level positive pressure device, either with or without the back-up rate feature, adjusted to the settings that will be prescribed for initial home use, while breathing the individual's usual \( \text{FIO}_2 \).

**Note:** When the above medical necessity criteria for individuals with the indication of CSA are met, a non-invasive positive pressure bi-level device, either with or without the back-up rate feature, will be considered **medically necessary**.

**Not Medically Necessary:**

The use of a non-invasive positive pressure respiratory assist device (Bi-level with/without the back-up rate feature) for the treatment of CSA is considered **not medically necessary** if ALL the above criteria are not met.

**For Obstructive Sleep Apnea (OSA)**

**Medically Necessary:**

The use of a non-invasive Bi-level positive pressure respiratory assist device (BiPAP) for the treatment of OSA is considered **medically necessary** when ALL of the following criteria are met:

- *Prior to initiating therapy*, a complete, facility-based, attended polysomnography has been performed and the test results have confirmed the diagnosis of OSA; and

- CPAP has been tried and proven ineffective; and

- The medical necessity criteria for the use of Bi-level non-invasive positive pressure respiratory assist devices (BiPAP) for the treatment of OSA, contained within CG-DME-32 have been met. *(Please refer to *Continuous Positive Airway Pressure (CPAP) for the Treatment of Obstructive Sleep Apnea in Adults and Children, and Related Devices for the Treatment of Obstructive Sleep Apnea in Adults.)*

**Note:** When the above medical necessity criteria for individuals with the indication of OSA are met, a non-invasive positive pressure bi-level device, *without back-up rate feature*, will be considered **medically necessary**.

**Not Medically Necessary:**
The use of a non-invasive positive pressure respiratory assist device (Bi-level without back-up rate feature) for the treatment of OSA is considered not medically necessary if ALL the above criteria are not met.

The use of a non-invasive positive pressure respiratory assist device (Bi-level with the back-up rate feature) is considered not medically necessary for the treatment of OSA.

For COPD Requiring Use of the Bi-level device with the back-up rate feature

Medically Necessary:

The subsequent use of a Bi-level device with the back-up rate feature, for the treatment of severe COPD for individuals who have already met the medical necessity criteria and have used a Bi-level device without the back-up rate feature for the first two months of therapy, is considered medically necessary when ALL of the following criteria are met:

- An arterial PaCO\textsubscript{2} that remains greater than or equal to 52 mm Hg, (repeated not sooner than 61 days post-initiation of initial device use) and done while awake and breathing the individual's usual FIO\textsubscript{2}; and

- A sleep oximetry demonstrating oxygen saturation levels of less than or equal to 88% for at least five continuous minutes and tested while using the Bi-level device and breathing oxygen at 2 L/min. or the individual's usual FIO\textsubscript{2}, whichever is higher; (this repeat testing is to be done not sooner than 61 days post-initiation of the initial therapy regimen); and

- Clinical documentation from the treating physician to indicate user compliance with the initial device (Bi-level without back-up rate feature) and the lack of desired therapeutic effect from use of this device.

Not Medically Necessary:

Subsequent use of a Bi-level device with the back-up rate feature for the treatment of severe COPD is considered not medically necessary when the above criteria are not met.

Supplies are included in the set-up but can be billed separately after the initial set-up. One of each item the patient utilizes is allowed every 6 months.

UHC

- Detailed order prior to dispensing is required.
- It is recommended that a CPAP been ruled out as not effective.
- Positive airway pressure (CPAP or BiPAP) titration in patients with sleep related breathing disorders; proven options for titration include:
  - full night study in a laboratory based facility
– a split-night study (initial diagnostic polysomnography followed by CPAP titration during polysomnography on the same night) as an alternative to one full night of diagnostic polysomnography followed by a second night of titration when used in accordance with the AASM criteria (Kushida et al., 2005)
– auto-titrating continuous positive airway pressure (APAP) devices when used in the self-adjusting mode for unattended treatment or in an unattended way to determine a fixed CPAP treatment pressure for patients with moderate to severe obstructive sleep apnea without significant comorbidities (CHF, COPD, central sleep apnea syndromes, or hypoventilation syndromes)

**COX**

- Detailed order prior to dispensing is required.
- It is recommended that a CPAP be ruled out.
  - Sleep study is not required but is suggested to have on file.

**Medicaid**

**All Ages**

**Qualification for a BIPAP (E0470) or RAD (E0471)**

Based on diagnosis (see below) and the physician must have documented in patients medical record-symptoms characteristics of sleep-associated hypoventilation, such as daytime hyper somnolence, excessive fatigue, morning headaches, cognitive dysfunction, dyspnea, etc. in addition to sleep study.

1. **Diagnosis: Obstructive Sleep Apnea**
   - Sleep Study with an AHI of 15 events per hour or greater
     
     If AHI is less than 15 then one of the following diagnoses must apply to the patient
     
     Excessive daytime sleepiness, impaired cognition, mood disorders, insomnia, hypertension, ischemic heart disease or history of stroke

     - Written order for all supplies from physician
     - A CPAP device must have been tried proven ineffective

2. **Diagnosis: Restrictive Thoracic Disorders**
- Patient must have a progressive neuromuscular disease or a severe thoracic cage abnormality such as type II Sever COPD, type II Central Sleep Apnea, type II Central Sleep Apnea, type IV Obstructive sleep apnea (E0470 only).

- Must also have one of the following:
  - an arterial blood gas PaCO2, done while awake and breathing on room air, is greater than or equal to 45mmHg, or
  - sleep oximetry demonstrates saturation less than or equal to 88% for at least 5 continuous minutes on room air, or
  - For a progressive neuromuscular disease they have to have a maximal inspiratory pressure is less than 60cmH2O or forced vital capacity is less than 50% predicted

- Chronic Obstructive pulmonary disease can not contribute significantly to the patient’s pulmonary limitation.

3. Diagnosis: Severe COPD

- The patient must have one of the following:
  - An arterial blood gas PaCO2, done while awake on room air which is greater than or equal to 52mmHg
  - Sleep oximetry with an O2 saturation less than or equal to 88% for at least five continuous minutes on 2 LPM of O2 or patient’s usual FI102 (whichever is higher).

- The patient must have previously been treated with CPAP therapy and considered to be suffering from OSA.

4. Diagnosis: Central Sleep Apnea

- Exclusion must exist of OSA as the predominant cause for the sleep disorder.

- If OSA is a diagnosis included with the Central Sleep Apnea then a CPAP has to be ruled out as an effective possibility

- The O2 saturation must be less than or equal to 88% for at least five continuous minutes on room air.

- Must have significant improvement of the sleep disorder with use of the BIPAP/RAD while on room air.

- If all above criteria for patients with CSA are met, a RAD with a back-up rate feature (E0470) will be covered for the first three months.
Dispensing Requirements: the following information must be present at the initial date of service.

- Written order with the appropriate diagnosis and documentation according to the patient's specific condition. (See Above)
- Sleep Study.
- Must have CyberAccess Pre-Certification prior to dispensing

Quick Facts

- Titration study must be part of the sleep study performed.
- All CPAP/BIPAP are a rent to purchase item. Purchase date will be the 12th month after the date of approval.
- The initial authorization covers the first 3 months from the date of approval.

Coverage past three months

- To receive an approval past the initial 3 months verification not before the 61st day of usage needs to be verified as well as record about the progress of relevant symptoms & patients use of device up to that time.

IF Patient already owns their BIPAP

- If the patient already owns BIPAP then we still need to attempt to receive the following information:
  
  Sleep Study  
  Physician Order  
  Make, model, and serial #  
  Previous supplier  
  Insurance covering owned equipment  
  Date previously received

Supplies

- Supplies used with CPAP/BIPAP device are covered when the coverage for the device is met and it reaches the purchase price (12 month rental) then Medicaid allows supplies every 6 months.
- Supplies billed without approval for the device will be denied.
Allowable

A7030- Full face mask used w/BIPAP device (each): 1 per 180 days
A7031- Face mask interface replacement (each): 1 per 180 days
A7032- Replacement cushion for nasal application device (each): 1 per 180 days
A7033- Replacement pillows for nasal application device (pair): 1 pair per 60 days
A7034- Nasal interface (mask or cannula type) used with a BIPAP with or without head strap: 1 per 180 days
A7035- Headgear used with BIPAP device: 1 per 180 days
A7037- Tubing used with BIPAP device: 1 per 180 days
A7038- Filter, disposable used with BIPAP: 2 per 30 days
A7039- Filter, non disposable used with BIPAP: 1 per 180 days
E0561- Humidifier, non heated, used w/ BIPAP- Prior authorization
E0562- Humidifier, heated, used w/BIPAP- Prior authorization.