DOCUMENTATION CHECKLIST

JURISDICTIONS B & C

RESPIRATORY ASSIST DEVICE – E0471

Bi-Level Pressure Capacity **WITH** Backup Rate

REQUIRED DOCUMENTATION

All Claims for E0471 – Initial Coverage (1st Three Months)

- ☐ **Standard Written Order (SWO)**
  - ○ The SWO contains all of the following elements:
    - ☐ Beneficiary's name or Medicare Beneficiary Identifier (MBI)
    - ☐ Order Date
    - ☐ General description of the item
      - ○ The description can be either a general description (e.g., wheelchair or hospital bed), a HCPCS code, a HCPCS code narrative, or a brand name/model number
      - ○ For equipment - In addition to the description of the base item, the SWO may include all concurrently ordered options, accessories or additional features that are separately billed or require an upgraded code (List each separately).
      - ○ For supplies – In addition to the description of the base item, the DMEPOS order/ prescription may include all concurrently ordered supplies that are separately billed (List each separately)
    - ☐ Quantity to be dispensed, if applicable
    - ☐ Treating Practitioner Name or NPI
    - ☐ Treating Practitioner's signature
  - ○ The practitioner's signature on the detailed written order meets **CMS Signature Requirements** https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM6698.pdf
  - ○ Any changes or corrections have been initialed/signed and dated by the ordering practitioner.
- ☐ **Delivery Documentation**

Direct Delivery	Shipped/Mail Order Tracking Slip	Shipped/Mail Order Return Post-Paid Delivery Invoice
☐ Beneficiary's name ☐ Delivery address ☐ Quantity delivered ☐ A description of the item(s) being delivered. The description can be either a narrative description (e.g., lightweight wheelchair base), a HCPCS code, the long description of a HCPCS code, or a brand name/model number. ☐ Delivery date ☐ Signature of person accepting delivery ☐ Relationship to beneficiary	☐ Shipping invoice ○ Beneficiary's name ○ Delivery address ○ A description of the item(s) being delivered. The description can be either a narrative description (e.g., lightweight wheelchair base), a HCPCS code, the long description of a HCPCS code, or a brand name/model number. ○ Quantity shipped ☐ Tracking slip ○ References each individual package ○ Delivery address ○ Package I.D. #number ○ Date shipped ○ Date delivered ☐ A common reference number (package ID #, PO #, etc.) links the invoice and tracking slip (may be handwritten on one or both forms by the supplier)	☐ Shipping invoice ○ Beneficiary's name ○ Delivery address ○ A description of the item(s) being delivered. The description can be either a narrative description (e.g., lightweight wheelchair base), a HCPCS code, the long description of a HCPCS code, or a brand name/model number. ○ Quantity shipped ○ Date shipped ○ Signature of person accepting delivery ○ Relationship to beneficiary ○ Delivery date

NOTE: If a supplier utilizes a shipping service or mail order, suppliers have two options for the DOS to use on the claim:

1. Suppliers may use the shipping date as the DOS. The shipping date is defined as the date the delivery/shipping service label is created or the date the item is retrieved by the shipping service for delivery. However, such dates should not demonstrate significant variation.
2. Suppliers may use the date of delivery as the DOS on the claim.

Medical Record Documentation

- ☐ The medical record fully documents symptoms characteristic of sleep-associated hypoventilation (daytime hypersomnolence, excessive fatigue, morning headache, cognitive dysfunction, dyspnea, etc.)
- ☐ Medical records support that the beneficiary has one of the following clinical disorders and meets all coverage criteria for that clinical disorder.
- ☐ **Restrictive Thoracic Disorder**
  - ○ The beneficiary's medical record documents a neuromuscular disease (for example, ALS) or a severe thoracic cage abnormality (for example, post-thoracoplasty for TB); **and**
  - ○ The medical record documents ONE of the following:
    - ☐ An arterial blood gas PaC02, done while the beneficiary is awake and breathing the prescribed FI02, is greater than or equal to 45 mm Hg; **or**
    - ☐ Sleep oximetry demonstrates oxygen saturation less than or equal to 88% for greater than or equal to 5 minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing the beneficiary's prescribed recommended FIO2; **or**
    - ☐ For neuromuscular disease only,
      - ○ The maximal inspiratory pressure is less than 60 cm H2O **or**
      - ○ Forced vital capacity is less than 50% predicted; **and**
  - ○ The medical record supports that COPD does not contribute significantly to the beneficiary's pulmonary limitation.
- ☐ **Severe COPD -** Covered in either of the two situations below, depending on the testing performed to demonstrate the need.
  - ○ **Situation 1 –** Beneficiary qualified for an E0470 device and, after any period of initial use of an E0470 device, both of the following criteria are met:
    - ☐ An arterial blood gas (ABG) PaCO2, done while awake and breathing the beneficiary's prescribed FIO2, shows that the beneficiary's PaCO2 worsens greater than or equal to 7 mm Hg compared to the ABG result performed to qualify the beneficiary for the E0470 device; and
    - ☐ A facility-based PSG demonstrates oxygen saturation less than or equal to 88% for greater than or equal to a cumulative 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 less than 5.
  - ○ **Situation 2 –** Beneficiary qualified for an E0470 device and, at a time no sooner than 61 days after initial issue of the E0470 device, both of the following criteria are met:
    - ☐ An arterial blood gas PaCO2 done while awake and breathing the beneficiary's prescribed FIO2, still remains greater than or equal to 52 mm Hg.
    - ☐ Sleep oximetry, while breathing with the E0470 device, demonstrates oxygen saturation less than or equal to 88% for greater than or equal to a cumulative 5 minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing oxygen at 2 LPM or the beneficiary's prescribed FIO2 [whichever is higher].
- ☐ **Central Sleep Apnea or Complex Sleep Apnea**
  - ○ Prior to initiating therapy, a complete facility-based, attended polysomnogram was performed.
  - ○ The polysomnogram documents **all** of the following.
    - ☐ A diagnosis of central sleep apnea (CSA) or complex sleep apnea (CompSA); **and**

☐ There was significant improvement of the sleep-associated hypoventilation with the use of the device on the settings prescribed for initial use at home, while breathing the beneficiary's prescribed FI02.

Central Sleep Apnea (CSA) is defined as:

1. An apnea-hypopnea index (AHI) greater than 5, and
2. The sum total of central apneas plus central hypopneas is greater than 50% of the total apneas and hypopneas, and
3. A central apnea-central hypopnea index (CAHI) is greater than or equal to 5 per hour, and
4. The presence of at least one of the following:
   - Sleepiness
   - Difficulty initiating or maintaining sleep, frequent awakenings, or nonrestorative sleep
   - Awakening short of breath
   - Snoring
   - Witnessed apneas
5. There is no evidence of daytime or nocturnal hypoventilation.

Complex Sleep Apnea (CompSA) is a form of central apnea specifically identified by all of the following:

1. With use of a positive airway pressure device without a backup rate (E0601 or E0470), the polysomnogram (PSG) shows a pattern of apneas and hypopneas that demonstrates the persistence or emergence of central apneas or central hypopneas upon exposure to CPAP (E0601) or a bi-level device without backup rate (E0470) device when titrated to the point where obstructive events have been effectively treated (obstructive AHI less than 5 per hour).
2. After resolution of the obstructive events, the sum total of central apneas plus central hypopneas is greater than 50% of the total apneas and hypopneas; and
3. After resolution of the obstructive events, a central apnea-central hypopnea index (CAHI) greater than or equal to 5 per hour.

☐ **Hypoventilation Syndrome**

- ○ A covered E0470 device is being used; **and**
- ○ Spirometry shows an FEV1/FVC greater than or equal to 70%. (Refer to Severe COPD section for information about device coverage for beneficiaries with FEV1/FVC less than 70%; **and**
- ○ One of the following criteria are met:
  - ☐ An arterial blood gas (ABG) PaCO2, done while awake, and breathing the beneficiary's prescribed FIO2, shows that the beneficiary's PaCO2 worsens greater than or equal to 7 mm Hg compared to the ABG result performed to qualify the beneficiary for the E0470 device; **or**
  - ☐ A facility-based PSG or HST demonstrates oxygen saturation less than or equal to 88% for greater than or equal to 5 minutes of nocturnal recording time (minimum recording time of 2 hours) that is not caused by obstructive upper airway events – i.e., AHI less than 5 while using an E0470 device. (Refer to the Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea LCD for information about E0470 coverage for obstructive sleep apnea).

All Claims for E0471 – Continued Coverage (Beyond the 1st Three Months of Therapy)

☐ The medical record contains a re-evaluation on or after the 61st day of therapy.

- ○ The re-evaluation records the progress of relevant symptoms; **and**
- ○ The re-evaluation documents beneficiary usage of the device up to that time.

☐ The supplier's file includes a signed and dated statement completed by the treating practitioner no sooner than 61 days after initiating use of the device.

- ○ The statement declares that the beneficiary is compliantly using the device (an average of 4 hours per 24 hour period); **and**
- ○ The statement confirms that the beneficiary is benefiting from its use.

Replacement E0471 During Reasonable Useful Lifetime Due to Loss, Theft, or Irreparable Damage

☐ Documentation that verifies the reason for the replacement (police report, insurance report, fire report, etc.)

Replacement E0471 Following 5 year RUL

- ☐ An in-person evaluation by the treating practitioner that documents the beneficiary continues to use and benefit from the device
- ☐ An SWO for the E0471

Beneficiaries Entering Medicare (Continued Use of Existing Device or Replacement Device)

- ☐ An SWO for the E0471
- ☐ Qualification testing shows that the beneficiary meets current coverage criteria for one of the 4 clinical disorder groups covered under the RAD policy. (Testing may either have been performed prior to Medicare eligibility or following enrollment in FFS Medicare.)
- ☐ The treating practitioner conducted a clinical evaluation following the beneficiary's enrollment in FFS Medicare that documents:
  - ○ The beneficiary has the qualifying medical condition for the applicable scenario; and
  - ○ The testing performed, date of the testing used for qualification and results; and
  - ○ The beneficiary continues to use the device; and,
  - ○ The beneficiary is benefiting from the treatment.

Refill Request for Non-Consumable Supplies

- ☐ Beneficiary's name or authorized representative if different from the beneficiary
- ☐ A description of each item that is being requested
- ☐ Date of the request
- ☐ Documentation that describes the functional condition of the item(s) being refilled in sufficient detail to demonstrate the cause of the dysfunction that necessitates the replacement
- ☐ Contact did not take place sooner than 14 days prior to the delivery/shipping date
- ☐ Delivery was no sooner than 10 calendar days prior to end of usage for the current product

Replacement of Accessories During the 13-month capped rental period for the RAD device:

- ☐ Medical record documentation that supports the initial coverage requirements for the RAD device (see clinical disorder groups with associated criteria located in the MEDICAL RECORD DOCUMENTATION section)

The following additional criteria must be met when replacing accessories during months 4-13 of the capped rental period for the RAD device:

- ☐ Documentation that supports the continued coverage requirements for the RAD device (see ALL CLAIMS FOR E0471 – CONTINUED COVERAGE (BEYOND THE 1ST THREE MONTHS OF THERAPY) section)

Replacement of Accessories for Medicare-Paid, Beneficiary-Owned RAD device:

- ☐ For claims for replacement accessories (e.g., interfaces, tubing, filters, humidifier chambers), if Medicare paid for the base RAD device initially (i.e., for 13 months of continuous use), the medical necessity for the beneficiary-owned base RAD device is assumed to have been established.
- ☐ Documentation that the base DME item continues to meet medical need
- ☐ The replacement of specific accessories or furnishing of new accessories remain medically necessary and are essential for the effective use of the base DME.

Continued Medical Need for the equipment/accessories/supplies is verified by either:

- ☐ A refill order from the treating practitioner dated within 12 months of the date of service under review; or
- ☐ A change in prescription dated within 12 months of the date of service under review; or
- ☐ A medical record, dated within 12 months of the date of service under review, that shows usage of the item.

REMINDERS

Items with no physician or other licensed health care provider order must be submitted with an "EY" modifier added to each affected HCPCS code.

- Where permitted, KX must be added to code E0471 and codes for the accessories.
- For initial coverage, the KX modifier must not be used on claims unless all RAD coverage criteria are met, and all required documentation has actually been obtained.
- For continued coverage, the KX modifier can only be used on claims if both the "Initial Coverage" criteria and "Continued Coverage" criteria have been met. See the RAD LCD for detailed information about use of the KX modifier.
- If all the coverage criteria have not been met, the GA or GZ modifier must be added to the code. When there is an expectation of a medical necessity denial, suppliers must enter GA on the claim line if they have obtained a properly executed Advance Beneficiary Notice (ABN) or GZ if they have not obtained a valid ABN.
- Claim lines billed without a KX, GA, or GZ modifier will be rejected as missing information.

ONLINE RESOURCES

- **DME MAC Supplier Manual**
  - **JB:** https://www.cgsmedicare.com/jb/pubs/supman/index.html
  - **JC:** https://www.cgsmedicare.com/jc/pubs/supman/index.html
- **Local Coverage Determinations (LCDs) and Policy Articles**
  - **JB:** https://www.cgsmedicare.com/jb/coverage/lcdinfo.html
  - **JC:** https://www.cgsmedicare.com/jc/coverage/LCDinfo.html

NOTE: It is expected that the beneficiary's medical records will reflect the need for the care provided. These records are not routinely submitted to the DMERC but must be available upon request. Therefore, while it is not a requirement, it is a recommendation that suppliers obtain and review the appropriate medical records and maintain a copy in the beneficiary's file.

DISCLAIMER

This document was prepared as an educational tool and is not intended to grant rights or impose obligations. This checklist may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either written law or regulations. Suppliers are encouraged to consult the *DME MAC Supplier Manual* and the Local Coverage Determination/Policy Article for full and accurate details concerning policies and regulations.