Respiratory Assist Device

All DME MAC Jurisdictions
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Medicare DME MAC Consultants

• **Denise Winsock**
  – NHIC, Corp. – Jurisdiction A

• **Stacie McMichel**
  – National Government Services – Jurisdiction B

• **Mia Gott**
  – CGS Administrators – Jurisdiction C

• **Cindy White**
  – Noridian Healthcare Solutions – Jurisdiction D
Agenda

- Coding/Definitions
- Coverage Criteria
- Sleep Tests
- Documentation Requirements
- Resources
- Questions & Answers
CODING/DEFINITIONS
Coding

- **E0470** – Respiratory Assist Device, Bi-Level Pressure, Without Backup Rate Feature
  - Delivers adjustable, variable levels of positive air (during single respiratory cycle) and supplements volume of air into the lungs

- **E0471** – Respiratory Assist Device, Bi-Level Pressure, With Backup Rate Feature
  - Has the same features as E0470, with the addition of timed backup feature to deliver air when insufficient inspiratory efforts fail
Definitions

– **FIO2** is the fractional concentration of oxygen delivered to the beneficiary for inspiration. The beneficiary’s prescribed FIO2 refers to the oxygen concentration the beneficiary normally breathes when not undergoing testing to qualify for coverage of a Respiratory Assist Device (RAD). That is, if the beneficiary does not normally use supplemental oxygen, their prescribed FIO2 is that found in room air.

– **FEV1** is the forced expired volume in 1 second.

– **FVC** is the forced vital capacity.
Definitions

- **Apnea** is defined as the cessation of airflow for at least 10 seconds.

- **Hypopnea** is defined as an abnormal respiratory event lasting at least 10 seconds associated with at least a 30% reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4% decrease in oxygen saturation.

- **The 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 airway pressure device.
Definitions

- For diagnosis of CSA, the central apnea-central hypopnea index (CAHI) is defined as the average number of episodes of central apnea and central hypopnea per hour of sleep without the use of a positive airway pressure device.

- For CompSA, the CAHI is determined during the use of a positive airway pressure device after obstructive events have disappeared.

- If the AHI or CAHI is calculated based on less than 2 hours of continuous recorded sleep, the total number of recorded events used to calculate the AHI or CAHI must be at least the number of events that would have been required in a 2-hour period (i.e., greater than or equal to 10 events).
Central Sleep Apnea (CSA) is defined by all the following:

- An apnea-hypopnea index (AHI) greater than or equal to 5; and
- The sum total of central apneas plus central hypopneas is greater than 50% of the total apneas and hypopneas; and
- A central apnea-central hypopnea index (CAHI) is greater than or equal to 5 per hour; and
- 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
  - 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:

- 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).

- 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

- After resolution of the obstructive events, a central apnea-central hypopnea index (CAHI) greater than or equal to 5 per hour.
Accessories

- Covered when coverage criteria for the device are met
- Usual Maximum amounts listed in LCD
  - Quantities > Medicare usual maximum amounts will be denied as not medically necessary
- Separately payable during rental and for beneficiary-owned equipment
### Accessories

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COVERAGE CRITERIA
Initial Coverage Criteria

• RAD covered for beneficiaries with:
  – Restrictive Thoracic Disorders
  – Severe COPD, or
  – Central Sleep Apnea (CSA) or Complex Sleep Apnea (Comp SA)
  – Hypoventilation Syndrome
## Initial Coverage Criteria

### Restrictive Thoracic Disorders

<table>
<thead>
<tr>
<th>A</th>
<th>Documentation of progressive neuromuscular disease, or severe thoracic cage abnormality</th>
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| B | 1. Arterial blood gas (while awake) ≥ 45 mm Hg or  
2. O2 saturation ≤ 88% for at least 5 continuous minutes  
3. For progressive neuromuscular disease (only) maximal inspiratory pressure is < 60 cm H2O or Forced vital capacity is %50 predicted and |
| C | Chronic Obstructive pulmonary disease does not contribute significantly to beneficiary’s pulmonary limitations |

- If criteria A-C are met, either E0470 or E0471 will be covered for the first three months.
### Initial Coverage Criteria

- **Severe COPD**

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<td>Arterial blood gas while awake, ≥ 52 mm HG and</td>
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<td>B</td>
<td>Sleep oximetry demonstrates O₂ saturation ≤ 88% for at least 5 continuous minutes while breathing O₂ at 2 LPM or beneficiary’s usual FIO₂ and,</td>
</tr>
<tr>
<td>C</td>
<td>Prior to initiating therapy, sleep apnea and treatment with a continuous positive airway pressure device (CPAP) has been considered and ruled out.</td>
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Initial Coverage Criteria

• Severe COPD

- An E0471 device will be covered for a beneficiary with COPD in either of the two situations below:

  1. For Group II beneficiaries (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 A and B are met:

     A. Arterial blood gas PaC02, done while awake and breathing prescribed FiO2 shows that the beneficiary’s PaC02 worsens ≥ 7 mm HG compared to the original result from criteria A.

     B. A facility based PSG demonstrates oxygen saturation ≤ 88 % for ≥ 5 minutes of nocturnal recording time while using an E0470 device that is not caused by obstructive upper airway events.
Initial Coverage Criteria

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

   A. An arterial blood gas PaC02 is done while awake and breathing the prescribed FI02, still remains ≥ 52 mm Hg.

   B. Sleep oximetry while breathing with the E0470 device demonstrates oxygen saturation ≤ 88% for ≥ 5 minutes of nocturnal recording time done while breathing oxygen at 2 LPM or the prescribed FI02
Initial Coverage Criteria

• Central Sleep Apnea (CSA)

| A | A diagnosis of CSA or complex CSA |
| B | Significant improvement of the sleep-associated hypoventilation with the use of an E0470 or E0471 on the settings that will be prescribed for initial use at home, while breathing the prescribed FiO2 |

• If criteria A and B are met, either E0470 or E0471 will be covered for the first three months of therapy.
Initial Coverage Criteria

• Hypoventilation Syndrome
  – An E0470 device is covered if both criteria A and B, and either C or D are met.
    A. An initial arterial blood gas PaCO₂, done while awake and breathing the prescribed FIO₂, is ≥45 mm Hg.
    B. Spirometry shows an FEV₁/FVC ≥70%.(Refer to II. SEVERE COPD (above) for information about device coverage for beneficiaries with FEV₁/FVC <70%).
Initial Coverage Criteria

- **Hypoventilation Syndrome**
  
  C. An arterial blood gas PaCO2, done during sleep or immediately upon awakening, and breathing the prescribed FIO2, shows the beneficiary's PaCO2 worsened ≥7 mm HG compared to the original result in criterion A (previous slide).

  D. A facility-based PSG or HST 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)
Initial Coverage Criteria

• Hypoventilation Syndrome
  – An E0471 device is covered for a beneficiary with hypoventilation syndrome if criteria A, B, and either C or D are met:
    A. A covered E0470 device is being used.
    B. Spirometry shows an FEV1/FVC ≥70% (Refer to II. SEVERE COPD (above) for information about device coverage for beneficiaries with FEV1/FVC <70%).
• Hypoventilation Syndrome

C. An arterial blood gas PaCO2, done while awake, and breathing the prescribed FIO2, shows that the beneficiary’s PaCO2 worsens ≥7 mm HG compared to the ABG result performed to qualify the beneficiary for the E0470 device.

D. A facility-based PSG or HST 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 apnea.).
Continued Coverage

• **After the first 3 months:**
  – Beneficiaries must be re-evaluated to establish continued need
  – Re-evaluation must occur no sooner than 61 days after initiating therapy
  – Treating physician must conduct the re-evaluation
  – Documentation in the medical record:
    • Progress of relevant symptoms
    • Usage (Average of 4 hours per 24 hour period by the time of the re-evaluation.)
    • Signed and dated statement by the treating physician
Benefits Entering Medicare

- For beneficiaries who received an E0470 or E0471 device prior to enrollment in fee-for-service (FFS) Medicare and are seeking Medicare reimbursement for a rental, either to continue using the existing device or for a replacement device.

  • Qualification Testing – Use of testing performed prior to Medicare eligibility is allowed. There must be documentation that the beneficiary had the testing required by the applicable scenario i.e., oximetry, sleep testing, spirometry, etc., prior to FFS Medicare enrollment, that meets the current coverage criteria in effect at the time that the beneficiary seeks Medicare coverage of a replacement device and/or accessories; and
• Clinical Evaluation – Following enrollment in FFS Medicare, the beneficiary must have an in person or face-to-face evaluation by their treating physician who documents all of the following in the beneficiary’s medical record:
  – 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.
SLEEP TESTS
Sleep Tests

- Payment for a RAD device for the treatment of the conditions specified in the RAD policy may be contingent upon an evaluation for the diagnosis of sleep apnea.

- The diagnosis of sleep apnea is based upon a sleep test that meets the Medicare coverage criteria in effect for the date of service of the claim for the RAD device.

- Testing must be ordered by the treating physician and conducted by an entity that qualifies as a Medicare provider of sleep tests and is in compliance with all applicable state regulatory requirements.

- The sleep test must be either a:
  - PSG performed in a facility-based laboratory (Type I study), or
  - Inpatient hospital-based, or
  - Home based sleep test (HST) (Types II, III, IV, Other).
    - Not all types of HST are appropriate for the evaluation of CSA or Comp SA.
Home Sleep Study (HST)

- An unattended HST may be performed to measure the AHI and RDI for Medicare coverage consideration
  - The portable monitoring device must meet the criteria defined in the LCD (Type II, III, IV, or Other Device)
  - The entity conducting the HST may **not** be a DME supplier
  - Instruction must be provided to the beneficiary by the entity conducting the HST
    - Face-to-face demonstration
    - Video or telephonic instruction with 24 hour availability of qualified personnel to troubleshoot
Interpreting Sleep Tests

- All sleep tests must be interpreted by a physician who holds one of the following:

  • Current certification in Sleep Medicine by the ABSM; or,

  • Current subspecialty certification in Sleep Medicine by a member board of the ABMS; or,

  • Completed residency or fellowship training by ABMS with all requirements for subspecialty certification in sleep medicine, until next eligible exam is offered

  • Active staff membership of a sleep center or laboratory accredited by AASM, ACHC, or TJC (formerly known as JCAHO)
Board certification entities:

- American Board of Sleep Medicine (ABSM) (for those certified prior to 2007) - Certification by ABSM was not time-limited (i.e., lifetime certification) so ABSM still maintains a site with credentials verification information at http://www.absm.org/listing.aspx.

- American Board of Medical Specialties (ABMS) – ABMS member boards took over administration of the certifying examination in sleep medicine from ABSM in 2007. The ABMS site, https://www.certificationmatters.org/is-your-doctor-board-certified/search-now.aspx, also has a credentials verification look-up function.
### American Board of Sleep Medicine

2510 North Frontage Road, Darren, IL 60561
Telephone: (630) 737-9700 Fax: (630) 737-9790

**Results for 'B'**

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<td>Roanoke Rapids</td>
<td>NC</td>
<td>Pulmonology</td>
<td>4/30/2001</td>
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<td>Vance Daniel Bachelder, M.D.</td>
<td>Duluth</td>
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<td>Ross N. Bacon, M.D.</td>
<td>Sioux City</td>
<td>IA</td>
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<td>Tehmina A. Badar, M.D.</td>
<td>Houston</td>
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<td>Shadi Badin, M.D.</td>
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<td>Charles Joonghe Bae, M D</td>
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<td>Juan E. Bahamon, M.D.</td>
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<td>Imad J. Bahhady, M.D</td>
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<td>Christopher A. Bailey, M.D.</td>
<td>Texarkana</td>
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<td>Rebecca Sue Bailey, M.D.</td>
<td>Austintown</td>
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<td>Denis Roland Baillargeon, M.D.</td>
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Physician Certification- ABMS Member Board Sites

Each member board of ABMS that is involved in physician training in sleep medicine and administration of a specialty examination in sleep medicine has credentials verification.

Those specific ABMS member sites are:

- **American Board of Family Medicine**
  2228 Young Drive
  Lexington, KY 40505-4294
  Phone: 859-269-5626 or 888-995-5700
  Fax: 859-335-7501 or 859-335-7509
  Web site: [https://www.theabfm.org/diplomate/find.aspx](https://www.theabfm.org/diplomate/find.aspx)
Physician Certification - ABMS Member Board Sites (continued)

- **American Board of Internal Medicine**
  - Address: Suite 1700
    Philadelphia, PA 19106-3699
  - Phone: 1.215.446.3500 or 1.800.441.2246
  - Fax: 1.215.446.3633
  - Web site: [http://www.abim.org/default.aspx](http://www.abim.org/default.aspx)

- **American Board of Pediatrics**
  - Address: 111 Silver Cedar Court
    Chapel Hill, NC 27514
  - Phone: 1.919.929.0461
  - Fax: 1.919.929-9255
  - Website: [https://www.abp.org/MOCVerification/VerificationServlet](https://www.abp.org/MOCVerification/VerificationServlet)
American Board of Psychiatry and Neurology
- Address: 500 Lake Cook Road, Suite 335
  Deerfield, IL 60015
- Phone: 1.847.945.7900
- Fax: 1.847.945.1146
- Website: https://application.abpn.com/verifyncert/verifyncert.asp

American Board of Otolaryngology
- Address: 5615 Kirby Drive
  Suite 600
  Houston, Texas 77005
- Phone: 1.713.850.0399
- Fax: 1.713.850.1104
- Website: http://www.aboto.org/ABOInternet/VerifyPhysicianCertification
ABMS Member Site Example

![ABPN verifyCERT Certification and Status Verification System](https://application.abpa.com/verifystatus/verifystatus_cert_data_sub.asp?cert_id=1000001000100000000000)

- **Name:** Edwards, Doran M.D.
- **City:**
- **State:**

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Physician Certification

• For physicians affiliated with an accredited sleep lab:
  – American Academy of Sleep Medicine (AASM)-accredited sleep lab - [http://www.sleepeducation.com/find-a-center](http://www.sleepeducation.com/find-a-center)
Detailed Written Orders & Face-to-Face (F2F) Prior to Delivery

- Effective 7/1/2013, HCPCS codes E0470 and E0471 of the RAD LCD, require a written order prior to delivery.

- CMS has directed DME MACs to delay enforcement of the F2F
  - The F2F exam must be within 6 months prior to the date of the written order.
  - Must document the beneficiary was evaluated and/or treated for a condition that supports the need for the item(s) ordered

- The written order must be received from the physician before the specified equipment is delivered.
Detailed Written Order Prior to Delivery

- Detailed written order prior to delivery of the E0470 and E0471 must include all of the following:
  
  - Beneficiary’s name
  - Physician’s name
  - Date of the order and the start date (if start date is different from order date)
  - Detailed description of items to be dispensed
  - Prescribing practitioner’s National Provider Identifier (NPI)
  - Signature of ordering practitioner
  - Ordering practitioner’s signature date
  - Signature and date stamps are not acceptable!
New Order

- **New prescription is needed when:**
  - Change in supplier
  - Change in treating physician
  - Change in the item(s), frequency of use, or amount prescribed
  - Change in the length of need or a previously established length of need expires
  - State law requires (new F2F not required)
Dispensing order

- Must be obtained prior to dispensing an item to beneficiary
- May be a written, fax, or verbal order
- Must include:
  - Description of the item
  - Beneficiary’s name
  - Physician’s name
  - Date of the order
  - Physician signature (written) or supplier signature (verbal)
Documentation Requirements

– Detailed written order for accessories

• Order signed and dated by the treating physician

• Detailed order should include:
  – Description of the item
  – Physician’s signature and date
  – Beneficiary’s name
  – Physician’s name
  – Date of the order
  – Options or additional features
KX Modifier

- **KX modifier requirements**
  - Must be added to codes E0470 and E0471 and accessories
  - Should not be used until required documentation has been actually obtained and in supplier’s files
  - For months 1-3, KX should be added if all initial coverage criteria has been met
  - For claims, the fourth month and forward, the KX should be added if the continued coverage has been met and the following documentation is in the supplier’s files:
    - Signed and dated statement from the treating physician
Replacement

- If an E0470 or E0471 device is replaced during the 5 year reasonable useful lifetime (RUL) because of loss, theft, or irreparable damage due to a specific incident, there is no requirement for a new clinical evaluation or testing.

- If an E0470 or E0471 device is replaced following the 5 year RUL, there must be a face-to-face evaluation by their treating physician that documents that the beneficiary continues to use and benefit from the device.

  - There is no requirement for new testing.
  - A new prescription is required.
Ventilator with Noninvasive Interfaces

- The Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations Manual (Internet-Only Manual, Publ. 100-3) in Chapter 1, Part 4, Section 280.1 stipulates that ventilators (E0450, E0460-E0464) are covered for the following conditions:
  - “Neuromuscular diseases, thoracic restrictive diseases, and chronic respiratory failure consequent to chronic obstructive pulmonary disease.”

- Each of these disease categories are comprised of conditions that can vary from severe and life-threatening to less serious forms. These disease groups may appear to overlap conditions described in the Respiratory Assist Devices LCD but they are not overlapping.
Choice of an appropriate device i.e., a ventilator versus a bi-level PAP device is made based upon the severity of the condition.

CMS distinguished the use of respiratory product types in a National Coverage Analysis Decision Memo (CAG-00052N) in June 2001 saying that RAD is “distinguished from ventilation in a patient for whom interruption or failure of respiratory support leads to death.”

Claims for ventilators (E0450, E0460-E0464) used for the treatment of conditions described in the RAD LCD will be denied as not reasonable and necessary.
Accessories Refill Requirements

- The supplier should assess whether the supplies remain functional, providing replacement (a refill) only when the supply item(s) is no longer able to function.

- Document the functional condition of the item(s) being refilled in sufficient detail to demonstrate the cause of the dysfunction that necessitates replacement (refill).
## Refill Documentation Requirements

<table>
<thead>
<tr>
<th>Obtained In Person @ Retail Store</th>
<th>Written Request From Beneficiary</th>
<th>Telephone Contact Between Supplier and Beneficiary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signed delivery slip or copy of itemized sales receipt</td>
<td>Beneficiary name and/or authorized rep (indicate relationship)</td>
<td>Beneficiary name and/or authorized rep (indicate relationship)</td>
</tr>
<tr>
<td>Delivery slip/receipt should indicate items were picked</td>
<td>Statement the beneficiary is requesting a refill</td>
<td>Name of person contacting/receiving call from beneficiary</td>
</tr>
<tr>
<td>Description of each item requested</td>
<td>Description of each item requested</td>
<td></td>
</tr>
<tr>
<td>Signature of requestor</td>
<td>Description of each item requested</td>
<td></td>
</tr>
<tr>
<td>Date of request</td>
<td>Date of contact</td>
<td></td>
</tr>
<tr>
<td>Quantity/functional condition of each item still remaining</td>
<td>Quantity/functional condition of each item still remaining</td>
<td></td>
</tr>
<tr>
<td>Contact no sooner than 14 calendar days prior to delivery/shipping</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shipment/delivery occurred no sooner than 10 calendar days prior to current supply exhausting</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Revisions Effective 12/1/2014

- **Revised**: Definitions of Central Sleep Apnea and Complex Sleep Apnea to include a CAHI index and expands signs and symptoms that describe the conditions.

- **Revised**: Severe COPD to clarify that definitive testing is not necessary to exclude OSA when the clinical picture is sufficient.

- **Revised**: Severe COPD to clarify that nocturnal oximetry is a cumulative 5 minutes of testing

- **Revised**: Hypoventilation Syndromes to remove FEV1

- **Revised**: PSG testing to also include HST testing when used in the in-patient hospital setting to establish or rule out the diagnosis of OSA.

- **Added**: Ventilator section based upon NCD and April 2014 coding and coverage article

- **Added**: Sleep Test coverage and payment rules
RAD Resources

- **RAD Local Coverage Determination (LCD)**
  

- **Rad Policy Article (PA)**
  

- **National Coverage Analysis Decision Memo (CAG-00052N) June 2001**
  

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Interactive Voice Response (IVR) - 866-419-9458

Customer Service Representatives - 866-590-6731
  • Monday through Friday 8:00 a.m. until 5:00 p.m. EST

PSP Portal

LCDs and Policy Articles

Jurisdiction A Supplier Manual
  http://www.medicarenhic.com/dme/supmandownload.aspx
National Government Services – Jurisdiction B Resources

http://www.NGSMedicare.com

- Interactive Voice Response (IVR) - 877-299-7900
- Provider Contact Center - 866-590-6727
  - Monday–Friday: 8:30 a.m.–5:30 p.m. ET
  - Training Closure Time: Fridays 2:30–4:30 p.m. ET

- NGSConnex
  http://www.NGSConnex.com

- Medical Policy Center located in Quick Links
- Policy Education located under Education & Training
  http://www.MedicareUniversity.com
CGS Administrators, LLC – Jurisdiction C Resources

http://www.CGSMedicare.com

- Interactive Voice Response (IVR) - 866.238.9650
- Customer Service Representatives - 866.270.4909
  - M-F 7:00 am - 5:00 pm CST
- Telephone Re-openings - 866.813.7878
  - M-F 7:00 am – 5:00 pm CST
- myCGS Web Portal
  http://www.cgsmedicare.com/jc/mycgs/index.html
- LCDs and Policy Articles
  http://www.cgsmedicare.com/jc/coverage/LCDinfo.html
- Jurisdiction C Supplier Manual
Noridian Healthcare Solutions– Jurisdiction D Resources

https://www.noridianmedicare.com/dme/

- IVR, Supplier Contact Center, & Telephone Reopenings – 1-877-320-0390
  - IVR: 6:00 a.m. – 8:00 p.m. CT M-F
  - Supplier Contact Center: 8:00 a.m. – 6:00 p.m. CT M-F
  - Telephone Reopenings: 8:00 a.m. – 6:00 p.m. CT M-F

- Endeavor
  - https://www.noridianmedicare.com/dme/claims/endeavor.html

- LCDs and Policy Articles
  - https://www.noridianmedicare.com/dme/coverage/lcd.html
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Type questions here

Then click Send
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