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Newest Updates to the RAD Policy
Are you and the sleep facilities ready?

11/13/14

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Objectives

- Review the changes that are going into effect for the RAD medical policy effective 12/1/14.
- Discuss ways to educate referral sources including sleep facilities, practitioners, and even the patients.
- Explain a few basic guidelines to use for ventilator equipment coverage.

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Initial Coverage Criteria

- Patient's medical record fully documents symptoms characteristic of
  - Sleep-associated hypoventilation
    - Such as daytime hypersomnolence, excessive fatigue, morning headache, cognitive dysfunction, dyspnea, etc.

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 (CompSA)

IV. Hypoventilation syndrome

Use KX modifier if all coverage criteria is met to device & accessories

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Group I: Restrictive Thoracic Disorders

Beneficiary must meet A-C:

A. Neuromuscular disease or severe thoracic cage abnormality AND

B. One of the following

a. Arterial blood gas $PaCO_2$, while awake and breathing patient's prescribed FIO_2 is > 45 mm Hg, OR

b. Sleep oximetry demonstrates oxygen saturation < 88% for > 5 minutes nocturnal, while breathing prescribed FIO_2, OR

c. For neuromuscular disease (only)

i. maximal inspiratory pressure < 60 cm H_2O or

ii. Forced vital capacity < 50% predicted

C. Chronic obstructive pulmonary disease does not contribute significantly to patient's pulmonary limitation

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Central Sleep Apnea or Complex Sleep Apnea

Coverage for CSA or CompSA:

Prior to initiating therapy, a complete facility-based, attended polysomnogram must be performed documenting both A and B

A. Diagnosis of central sleep apnea (CSA) or complex sleep apnea (CompSA), **AND**

B. Significant improvement of the sleep-associated hypoventilation with the BiPAP with or without backup while breathing prescribed FIO2.

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CSA

Prior Definition

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 $\geq$ 5 times per hour, **and**
4. Symptoms of either excessive sleepiness or disrupted sleep.

New Definition

1. An apnea-hypopnea index (AHI) greater than or equal to five, **AND**
2. The sum total of central apneas plus central hypopneas is greater than 50% of the total apneas an hypopneas, **AND**
3. A central apnea-central hypopnea index (CAHI) is greater than or equal to 5 per hour, **AND**
4. 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

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CompSA

- 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 beneficiaries 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.

- 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.

CAHI

- 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).

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Severe COPD Coverage

- ABG $PaCO_2$, while awake and breathing patient's prescribed FiO_2 greater than 52 mm Hg; **AND**
- Sleep oximetry demonstrates oxygen saturation of less than or equal to 88 percent for at least 5 minutes nocturnal, done while breathing at 2 lpm or the patient's prescribed FiO_2 (whichever is higher); **AND**

Old Policy

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

New Policy

Prior to initiating therapy, sleep apnea and treatment with a continuous positive airway pressure device (CPAP) has been considered and ruled out. (Note: Formal sleep testing is not required if there is sufficient information in the medical record to demonstrate that the beneficiary does not suffer from some form of sleep apnea (Obstructive Sleep Apnea (OSA), CSA and/or Comp SA) as the predominant cause of awake hypercapnia or nocturnal arterial oxygen desaturation).

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Severe COPD (E0471)

E0471 covered for COPD in following 2 situations:

- Situation 1 – E0471 started anytime after a period of initial use of E0470 if both A and B are met
  - A. ABG PaCO2, while awake and breathing beneficiary's prescribed FIO2, shows that the beneficiary's PaCO2 worsens ≥ 7 mm Hg compared to original result criterion A
  - B. Facility-based PSG demonstrates oxygen saturation ≤ 88% for ≥ 5 minutes nocturnal (minimum recording 2 hours) while using E0470 that is not caused by obstructive upper airway event
- Situation 2 – E0471 no sooner than 61 days after initial issue of E0470 both A and B met:
  - A. ABG PaC02 done while awake and breathing beneficiary's prescribed FI02, still remains ≥ to 52 mm Hg AND
  - B. Sleep oximetry, while breathing with E0470, demonstrates oxygen saturation ≤ 88% for ≥ 5 minutes nocturnal, (minimum recording time of 2 hours) while breathing oxygen at 2 LPM or prescribed FI02, whichever is higher

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Hypoventilation Coverage

1. ABG $PaCO_2$, done while awake breathing prescribed FiO_2 is greater than or equal to 45 mm Hg.
2. Spirometry shows FEV1/FCV greater than or equal to 70 percent and FEV1 greater than 50 percent of predicted. **----REMOVED**
3. ABG $PaCO_2$, done during sleep or immediately upon awaking breathing prescribed FiO_2 shows the beneficiary's $PaCO_2$ worsened greater than or equal to 7mm Hg compared to result in criterion 1 above.
4. PSG demonstrates oxygen saturation less than or equal to 88 percent for at least 5 minutes nocturnal (minimum recording time of two hours) not caused by obstructive upper airway events.

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Hypoventilation Syndrome E0471

- E0471 covered if criteria 1, 2, **and** either 3 or 4
  1. E0470 is being used
  2. Spirometry shows FEV1/FVC ≥ 70% ~~and FEV1 ≥ 50% of predicted~~ **removed**
  3. ABG PaCO2 done awake breathing prescribed FIO2 shows the beneficiary's PaCO2 worsens ≥ 7 mm Hg compared to ABG performed to qualify for E0470
  4. PSG demonstrates oxygen saturation ≤ 88% for ≥ 5 minutes nocturnal (minimum recording time of 2 hours) that is not caused by obstructive upper airway events

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Detailed Written Order Requirements

- ✓ Beneficiary's name
- ✓ Date of order, and start date if different
- ✓ Detailed description of item(s) being ordered such as device, humidity, type of mask, headgear, filters or tubing, or brand name/model number
- ✓ Pressure settings
- ✓ Frequency of use or duration
- ✓ Treating practitioner's printed name and NPI
- ✓ Treating practitioner's signature and date
- ✓ Make sure to use a Date Stamp Received

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Continued coverage beyond the first three months:

Must be re-evaluated by treating practitioner no sooner than 61st day after initial therapy.

- Documenting that patient is compliant with the device. Compliance is using the machine for at least four hours per a 24-hour period.
- Documentation that patient is benefiting from use of the therapy.
- Make sure it's signed and dated by treating practitioner.

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Accessories: RAD

- Covered when coverage criteria met and ordered by treating physician
- Heated (E0562) or non-heated (E0561) humidifier
- Must monitor the amount of non-consumable supplies/accessories

~Make sure the supply on hand has nearly exhausted prior to dispensing any additional supplies

~Assess whether the supplies remain functional, provide replacement only when the supply item is no longer able to function

~Make sure to document the functional condition of the item being refilled in sufficient detail

~Contact no sooner than 7 days prior to delivery/shipping date and delivery no sooner than days prior to the end of usage of current product

<u>Need the following information documented:</u>

1. Patient name
2. Description of item being requested
3. Date of refill request
4. Non-consumables—functional condition of the item being refilled

   examples:the seal is worn out or discolored; filter is no longer cleanable, etc.

*Required for any type of delivery, recommend for in-store pick up as well.

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HCPCS	Narrative	Frequency
A7028	Replacement Oral Cushion for combination oral/nasal mask	2 per 1 month
A7029	Replacement nasal pillows for combination oral/nasal mask	2 per 1 month
A7032	Replacement nasal mask interface	2 per 1 month
A7033	Replacement pillow nasal cannula type interface	2 per 1 month
A7038	Disposable filter used with positive airway device	2 per 1 month
A7031	Replacement full face mask interface	1 per 1 month
A4604	Tubing with heated element	1 per 3 months
A7027	Combination oral/nasal mask	1 per 3 months
A7030	Full face mask	1 per 3 months
A7034	Nasal interface (mask or cannula type)	1 per 3 months
A7037	Tubing used with postive airway device	1 per 3 months
A7035	Headgear used with positive airway device	1 per 6 months
A7036	Chinstrap used with positve airway device	1 per 6 months
A7039	Nondisposable filter used with positive airway device	1 per 6 months
A7046	Replacement water chamber for humidifer with positive airway device	1 per 6 months

Example 1 **Unacceptable Blanket Order** Does not provide a detailed list of each separately billed item and the replacement instructions are non-specific	Example 2 **Unacceptable Blanket Order** Order form lists supplies and accessories in a way that does not allow the physician to pick and choose the specific items being ordered for this beneficiary	Example 3 **Acceptable order** Order form lists supplies and accessories in a way that the physician can pick and choose the specific items being ordered for this beneficiary. Note: NPI needs to be on order.
Patient: John Doe Start Date: 08/01/2011 Length of Need - Lifetime (99) CPAP Device at 10 cmH20 Heated Humidifier Bi-Pap Equipment (mask, accessories, disposable and reusable filters) - replace as needed Charles Smith August 15,2011 Charles Smith, M.D.	Patient: John Doe Start Date: 08/01/2011 Length of Need - Lifetime (99) Bi-Pap w/o BU - IPAP 12 cm H_20, EPAP 10 CM H_20 Heated Humidifier PAP Oral Interface Repl Exhalation Port for PAP Combi Oral/Nasal Mask 1/3 Mo Full Face Mask 1/3 Mo Replacement Face Mask 1/1 Mo Nasal Application Device 1/3 Mo PAP Headgear 1/6 Mo PAP Chinstrap 1/6 Mo PAP Tubing 1/3 Mo PAP Non-disposable Filter 1/6 Mo Humidifier Chamber 1/6 Mo Oral Cushion 2/1 Mo Repl Nasal Pillow Comb Mask 2/1 Mo Replacement Nasal Cushion 2/1 Mo Replacement Nasal Pillows 2/1 Mo PAP Disposable Filter 2/1 Mo Charles Smith August 15,2011 Charles Smith, M.D.	Patient: John Doe Start Date: 08/01/2011 Length of Need - Lifetime (99) CPAP Device at 11cmH20 Heated Humidifier ☒ Mask - Nasal Pillow 1/3 Mo ☐ Mask - Full Face 1/3 Mo ☐ Oral Mask Interface 1/3 Mo ☐ Nasal Mask cushion 2/1 Mo ☐ Full Face Mask Cushion 1/1 Mo ☐ Nasal Pillows 2/1 Mo ☒ Tubing 1/3 Mo ☐ Chinstrap 1/6 Mo ☒ Headgear 1/6 Mo ☒ Filter, Disposable 2/1 Mo ☒ Filter, Non-Disposable 1/6 Mo ☒ Humidifier Chamber 1/6 Mo ☐ Other _____ Charles Smith August 15,2011 Charles Smith, M.D. NPI: 1234567890

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VENTILATOR- NOINVASIVE vs RAD

The 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
  - Chronic respiratory failure consequent to COPD
- Each of these disease categories are comprised of conditions that vary from severe and life-threatening to less serious
- Disease groups may appear to overlap conditions described in the RAD LCD - not overlapping
- Choice of an appropriate device i.e., a ventilator versus a bi-level PAP device 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.”

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VENTILATOR- NOINVASIVE vs RAD Continued……

- The conditions described in the RAD LCD determination are not life-threatening conditions where interruption of respiratory support would quickly lead to serious harm or death.
- These policies describe clinical conditions that require intermittent and relatively short durations of respiratory support.
- Any type ventilator **would not** be eligible for reimbursement for any of the conditions described in the RAD LCD even though the ventilator equipment may have the capability of operating in a bi-level PAP (E0470, E0471) mode. Bi-level PAP devices (E0470, E0471) are considered as reasonable and necessary in those clinical scenarios.

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Basic coverage for Medicare

BASIC coverage determination for all audit entities:

- ✓ Must not bill Medicare more than you would any other entity
- ✓ Item must be Medically Necessary for use within the home
- ✓ Medicare will pay for least costly alternative
- ✓ Must provide the item prior to billing

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PIM 5.7- Documentation

"For any DMEPOS item to be covered by Medicare, the patient's medical record must contain sufficient documentation of the patient's medical condition to substantiate the necessity for the type & quantity of items ordered & for the frequency of use or replacement (if applicable). ----- However, neither a physician's order nor a CMN nor a DIF nor a physician attestation statement by itself provides sufficient documentation of medical necessity, even though it is signed by the treating physician or supplier. ----"

SAME WITH TEMPLATES –templates are tools for education of and not MEDICAL NECESSITY DOCUMENTATION ALONE

NOTE - this is now in policies / articles PIM {Program Integrity Manual} on line only

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Vents Posted 8-28-14

DME MAC Jurisdiction A

Widespread Prepayment Probe for HCPCS Code E0464 (PRESSURE SUPPORT VENTILATOR WITH VOLUME CONTROL MODE, MAY INCLUDE PRESSURE CONTROL MODE, USED WITH NON-INVASIVE INTERFACE (E.G. MASK))

Posted August 28, 2014 (SPE)

DME MAC JA will be initiating a widespread prepayment probe for claims submitted with HCPCS code E0464 (Pressure support ventilator with volume control mode, may include pressure control mode, used with non-invasive interface (e.g. mask).

This review is being initiated due to an increase in billing identified by data analysis.

Ventilators are classified in the Frequent and Substantial Servicing (FSS) payment category. The monthly rental payment for items in this pricing category is all-inclusive, meaning there is no separate payment by Medicare for any options, accessories or supplies used with a ventilator. In addition, all necessary maintenance, servicing, repairs and replacement are also included in the monthly rental. Claims for these items and/or services will be denied as unbundling. Medicare does not cover spare or back-up equipment. Claims for backup equipment will be denied as not reasonable and necessary.

The Centers for Medicare & Medicaid Services (CMS) *National Coverage Determinations Manual* Chapter 1, Part 4, and Section 280.1 stipulates "that ventilators are covered for treatment of neuromuscular diseases, thoracic restrictive diseases, and chronic respiratory failure consequent to chronic obstructive pulmonary disease. Includes both positive/negative pressure types."

Documentation must include the following:

1. Physician order for the item
2. Information from the medical record that demonstrates the reasonable and necessary coverage criteria for the item(s) are met.
3. Proof of delivery.
4. Any other pertinent information that would justify payment for the item(s) provided.
5. Advanced Beneficiary Notice (ABN) if one was obtained, this must be submitted with the above requested documentation.

To avoid unnecessary denials for missing or incomplete information, please ensure when submitting documentation requests that all requested information is included with your file and respond in a timely manner.

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Vents under Prepayment Review

Release on 8/28/14: Jur. A : E0464 (non-invasive) under prepayment review

Documentation must include the following:

1. Physician order for the item

2. Information from the medical record that demonstrates the reasonable and necessary coverage criteria for the item(s) are met.

3. Proof of delivery.

4. Any other pertinent information that would justify payment for the item(s) provided.

5. Advanced Beneficiary Notice (ABN) if one was obtained, this must be submitted with the above requested documentation.

Everyone Needs To Be prepared!

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Ventilators

- National Coverage Determination (280.1)
  - E0463/E0464
- Categorized as Frequent & Substantial Servicing
- Monthly rental includes payment for supplies and accessories
- Humidifiers are considered accessory; cannot be billed separately
- Monthly rental includes payment for repair and maintenance
- Supplier is required to have emergency plan, back up plan in the event primary ventilator breaks down

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Documentation

Generally Covered for Treatment of:

- Neuromuscular Disorders
- Thoracic Restrictive Diseases
- Chronic Respiratory Failure

Examples of diagnosis: ALS, MS, tracheostomy complication, COPD, etc.

Medical Record must state:

- Why the ventilator is medically necessary, and
- Why a CPAP/BiPAP is insufficient

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Documentation

- Repeated hospital admissions due to respiratory failure
- If a ventilator is used, follow-up visits are documented to show there was a decrease in admissions
- Remember Medicare pays for least costly alternative, which means a BiPAP or BiPAP S/T needs to be considered and/or ruled out
- Clinical documentation must be specific to the individual patient's needs
- Make sure the documentation is very clear and thorough as to why the patient needs a ventilator versus a respiratory assist device such as a BiPAP or BiPAP S/T
- Justifications might include the fact that the only other alternative would be a tracheostomy which would increase chances of infections and adds increased trauma to an already stressed patient and his/her family.

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Orders

Dispensing Order:

- Patient's name
- Prescribing Physician's name
- Date of order
- Description of the item
- Start date of the order, if different from date of the order
- Physician's signature (if written order) or supplier signature (if verbal order)

Detailed Written Order:

- Patient's name
- Treating physician's name (printed or typed)
- Start date of order – if start date is different than order date
- Order for ventilator with description/brand/model/ and settings
- Any other billable items
- Physician signature
- Physician signature date and NPI
- Length of need
- Frequency of use

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Continued Use and Continued Medical Need

Continued Use:

- Contact patient regularly to verify they are at home and continue use of the vent---this is a monthly billing, or
- Obtain progress notes documenting ventilator use

Continued Medical Need:

- A recent order by the treating physician, or
- A recent change in prescription, or
- Timely documentation in the medical record

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Documentation to support medical necessity includes:

- ✓ Valid Physicians order and DWO
- ✓ Good Diagnosis
- ✓ Documentation of medical necessity in medical record
- ✓ Ventilator settings
- ✓ Documentation of supplier's back up plan
- ✓ Proof of delivery

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What is happening?

Effective July 1, 2013

Medicare will require that specific items of DME will require:

1. Written Order Prior to Delivery (WOPD)

   aka: Detailed Written Order Prior to Delivery

2. Face to Face (F2F) encounter completed by ordering practitioner

Key phrase is "PRIOR TO DELIVERY"

The days of delivering on a dispensing/verbal order are gone! (under the F2F rules)

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Detailed Order

1. All Medicare items require an order
2. Must be signed and dated by ordering practitioner & include NPI
3. F2F items require the order be completed “PRIOR” to delivery (WOPD)
4. Description of item can be narrative or brand name –
5. Make sure you date stamp the order and medical records
6. Go by date of order, when start date is different than date of order, DME MACs go by date of order.

   Sometimes items require delivery prior to discharge so start date may be different, and date order received by supplier will be different, but Medicare will go by date of order. For example, ventilators.
7. Once the detailed order is signed by the ordering practitioner, it cannot be altered by the supplier. If a correction is needed, the ordering practitioner needs to make correction and then initial/date that correction or get a new order.

The Supplier can complete the detailed written order, then have the ordering practitioner review, sign, and date.

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Written Order Prior to Delivery

On August 7, 2014 a new update was released:

I. If errors in the WOPD are found prior to delivery, the supplier has two options:

A. The WOPD may be properly amended following the guidance in the Program Integrity Manual (Internet-Only Manual, Publ. 100-08), Chapter 3, Section 3.3.2.5; or,

B. A new WOPD may be created and sent to the physician for signature and date.

II. If errors in the WOPD are found after delivery of the item, the supplier has two options:

A. If the error is discovered **prior to claim submission**, the original supplier may recover the delivered item(s), obtain a compliant, complete WOPD and then may re-deliver the item(s) to the beneficiary; or,

B. If the error is discovered **after submitting a claim**, the original supplier can recover their items and a new supplier must complete the transaction after complying with all requirements.

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TEMPLATES

- Although CMS does not prohibit the use of templates or check lists we will caution all of our suppliers that these are frequently denied in review.
- Templates tend to not cover the true needs of the individual patient and are not thorough enough to sufficiently determine coverage.
- Use of the DMEMAC physician educational letters has been found to be useful to many suppliers.
- We are confident that the DME Medical Directors will assist us on this educational effort as they have in the past with many difficult LCDs.

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Education

- Make sure your entire staff revised medical policy
- Educate referral sources --
  - Sleep facilities
  - Pulmonologist
  - Cardiologist
  - Any of referrals that deal with these types of respiratory patients
- Remind referrals—documentation in medical records always required
- Use Documentation Checklist
- Intake/CSR reviews information upon receiving referral
- Review information prior to delivery AND before submitting the claim
- Use VGM/US Rehab Reimbursement Team
- Medicare Quick Reference Guide

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Thank you for your support!

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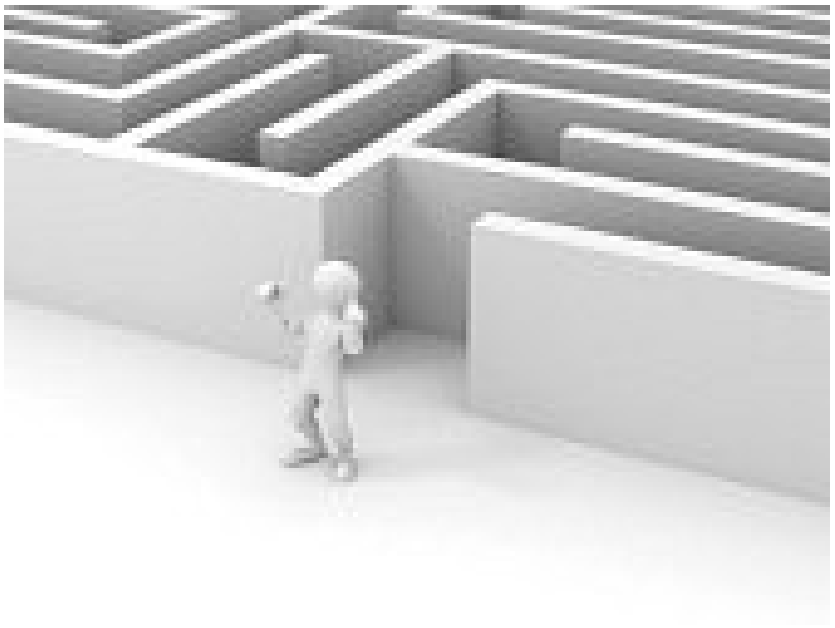

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