Digging Into CPAP Policy Requirements

Initial Coverage
12 week trial

All the following MUST be met:

A. FTF clinical evaluation by treating physician prior to a sleep test to assess patient for OSA -MUST-

B. Medicare covered sleep test that meets either one of the following criteria:
   1. AHI or RDI > 15 events per hour with a minimum of 30 events or
   2. AHI or RDI > 5 – 14 events per hour with a minimum of 10 events and documentation of:
      • Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia; OR
      • Hypertension, ischemic heart disease, or history of stroke

C. Patient or caregiver received instruction from the supplier in the proper use and care of CPAP (E0601)
Initial Evaluation – Prior to SS

- For the initial evaluation, the report would commonly document pertinent information about the following elements, but may include other details. Each element would not have to be addressed in every evaluation.

- Information that may be included:
  - History
    - Signs and symptoms of sleep disordered breathing including snoring, daytime sleepiness, observed apneas, choking or gasping during sleep, morning headaches
    - Duration of symptom
    - Validated sleep hygiene inventory such as Epworth Sleepiness Scale
  - Exam
    - Focused on cardiopulmonary and upper airway system evaluation
    - Neck Circumference
    - Body Mass Index (BMI)

- If physician visit doesn’t have enough information in note, check with sleep lab for additional documentation.

Sleep Tests

- The must be conducted by an entity that qualifies as a Medicare provider of sleep tests and is compliance with applicable state regulatory requirements.
- The sleep test must be a polysomnogram performed in a facility-based laboratory (type 1 study)
- Home Sleep Test (HST) (type 2, 3, or 4)
  - The beneficiary must have received instruction on how to properly apply portable sleep monitoring device. Must be provided by HST entity and NOT by the DME supplier
  - The instructions can be done via F2F demonstration, video, or telephone with 24 hour availability

**No aspect of a HST, including delivery and/or pick up of the device, may be performed by the DME supplier.**
Sleep Studies – Make sure to get signed sleep version!

• **Diagnostic:**
  - Indicates if sleep apnea is present, and
  - What type of sleep apnea, or

• **Split Night:**
  - Enough data collected to determine that sleep apnea is present
  - Meets guidelines over the minimum 2 ours of recording time,
  - Then goes from a diagnostic study to a titration study in one night

• **Titration Study:**
  - Not required for reimbursement purposes
  - Done once diagnosed with sleep apnea
  - Determines appropriate pressure to use on a device to eliminate or reduce apneas and hypopneas
  - Some sleep labs will work for appropriate mask fittings

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**AHI versus RDI**

**Apnea-hypopnea index (AHI) =**

• the average number of episodes of apnea and hypopnea per hour of sleep without the use of a positive airway pressure device
• Respiratory effort related arousals (RERAs) are not included in the calculation of the AHI
• Sleep time can only be measured in a Type I (facility based polysomnogram) or Type II sleep study

**Respiratory disturbance index (RDI) =**

• the average number of apneas plus hypopneas per hour of recording without the use of a positive airway pressure device
• Respiratory effort related arousals (RERAs) are not included in the calculation of the RDI
• RDI is reported in Type III, Type IV, and other home sleep studies
Polysomnography – Type I Sleep Test

- Continuous and simultaneous monitoring and recording of various physiological and pathophysiological parameters of sleep with physician review, interpretation and report
- Facility based and must include sleep staging
  - 1-4 lead electroencephalogram (EEG) and
  - Electro-oculogram (EOG) and
  - Submental electromyogram (EMG) and
  - Electrocardiogram (ECG)
- Must also include parameters of sleep
  - Airflow
  - Respiratory effort
  - Oxygen saturation by oximetry

Home Sleep Tests Type II and III

- Type II device – monitors and records a minimum of seven channels
  - EEG
  - EOG
  - EMG
  - ECG/heart rate
  - Respiratory movement/effort
  - Airflow
  - Oxygen saturation

- Type III device – monitors and records a minimum of four channels
  - Respiratory movement/effort
  - Airflow
  - ECG/heart rate
  - Oxygen saturation
Home Sleep Test Type IV

- Type IV device - monitors and records a minimum of three channels one of which is airflow
- Other devices may be considered on a device by device basis
  - Clinical evidence demonstrating results that accurately and reliably correspond to AHI or RDI

Definitions

- **Apnea:**
  - Cessation of airflow for at least 10 seconds
  - Breathing stops

- **Hypopnea:**
  - Abnormal respiratory event lasting at least 10 seconds associated with at least a 30% reduction in thoracoabdominal movement or air flow as compared to baseline and with at least a 4% decrease in oxygen saturation (updated 1/2006)
  - Low/slow breathing
  - Length of time when there is no chest or diaphragm movement
Physician Interpreting Sleep Test Holds

- Current certification in Sleep Medicine by the ABSM
- Current subspecialty certification in Sleep Medicine by a member board of the ABMS
- Completed residency or fellowship training by an ABMS member board and has completed all the requirements for subspecialty certification in Sleep Medicine except the examination and only until the time of reporting of the first examination for which the physician is eligible
- Active staff membership of a sleep center or laboratory accredited by the AASM, ACHC, or The Joint Commission (formerly JCAHO)

Implemented January 2010

Interpreting Sleep Studies

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](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](https://www.certificationmatters.org/is-your-doctor-board-certified/search-now.aspx), also has a credentials verification look-up function.
1. **For physicians affiliated with an accredited sleep lab**
   a. American Academy of Sleep Medicine (AASM) accredited sleep lab
      http://www.sleepeducation.com/findacenter
   b. The Joint Commission
      http://www.qualitycheck.org/consumer/searchQCR.aspx

2. **Board certification entities**
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      https://www.certificationmatters.org/isyourdoctorboardcertified/searchnow.aspx

   c. 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 listed below:

American Board of Family Medicine
2228 Young Drive
Lexington, KY 405054294
Phone: 8592695626 or 88889955700
Fax: 8593357501 or 8593357509
website:
https://www.theabfm.org/diplomate/find.aspx

American Board of Internal Medicine
510 Walnut Street Suite 1700
Philadelphia, PA 191063699
Phone: 2154463500 or 18004412246
Fax: 2154463633
website: http://www.abim.org/default.aspx

American Board of Pediatrics
111 Silver Cedar Court
Chapel Hill, NC 27514
Phone: 9199290461
Fax: 9199299255
website:
https://www.abp.org/MOCVerification/VerificationServlet
Those specific ABMS member sites are listed below:

American Board of Psychiatry and Neurology
500 Lake Cook Road, Suite 335
Deerfield, IL 60015
Phone: 8479457900
Fax: 8479451146
website:  
https://application.abpn.com/verifycert/verifycert.asp

American Board of Otolaryngology
5615 Kirby Drive Suite 600
Houston, Texas 77005
Phone: 7138500399
Fax: 7138501104
website:
http://www.aboto.org/AB0Internet/VerifyPhysicianCertification

Do sleep studies expire?

Sleep studies do not expire, except…….

For an initial study performed for the purposes of a diagnosis, it is preferred that the therapy be initiated within 3 months of the study, but in no case would longer than 12 months be considered!

This is for initial studies – new to CPAP therapy

Basically, the patient has 12 months from the date of the study to treat OSA with CPAP machine.

If over 12 months old, new F2F visit and new diagnostic (PSG) sleep study needs to be completed.
Hospital DME and HST

Neither a DME supplier, nor its affiliate, can have any connection to the HST. Assume that St. Mary’s Hospital owns a sleep lab. It does not matter if the lab is a “department” of the hospital (i.e., under the hospital’s Tax ID #) or if the lab is a separate legal entity (with its own Tax ID #) that is owned by the hospital.

- **Scenario 1** – St. Mary’s DME is a “department” of the hospital. Medicare patient tests positive for OSA from a HST conducted by the lab. St. Mary’s DME cannot provide a CPAP to the Medicare patient.

- **Scenario 2** – St. Mary’s DME is a separate legal entity (own Tax ID #) owned by the hospital. Medicare patient tests positive for OSA from a HST conducted by the lab. St. Mary’s DME cannot provide a CPAP to the Medicare patient.

The above restrictions apply to Medicare. Commercial insurers may be less restrictive.

Does the treating physician who does the initial face-to-face examination have to write the order for the PAP therapy or can it be ordered by the interpreting physician from the sleep lab?

**Answer:**
The treating physician that does the initial face to face exam does not have to be the same physician that orders the CPAP.
Coverage Beyond 3 Months

For PAP Policy E0601 and E0470:

- Adherence to therapy per criteria
  - Used > 4 hours per night 70% of nights during a consecutive thirty day period anytime during the first three months of initial usage
  - 21 nights within 30 consecutive days
- Documentation from treating physician at re-evaluation between 31st-91st day after initial therapy:
  - OSA symptom improvement
  - Adherence to therapy
  - Benefiting from therapy

**Add KX modifier for month which information is received**

Re-evaluations That Occur After 91st Day

- Physician documents benefiting from therapy and
- Objective evidence of adherence reviewed by treating physician
  - Used > 4 hours per night 70% of nights during a consecutive thirty day period anytime during the first three months of initial usage

**Continued coverage begins with the date of re-evaluation**
If a Beneficiary Fails a 12 Week Trial Period

- Must go back to physician for office visit to determine etiology of failure,
- Follows up with a new sleep study – can be diagnostic, split night, or titration
- New DWO

- Then- Month 4 with KJKX starts once patient becomes compliant!
- In the meantime, patient pays cash – with ABN – if option 1 chosen then GA, no KX

CPAP to RAD

- During initial three month trial
  - Does not change length of trial if more than 30 days remain
    - Re-evaluation between 31st and 91st day
    - Adherence to therapy on the E0470 prior to 91st day
  - Less than 30 days remain in trial
    - Re-evaluation must occur before the 120th day
    - Adherence to therapy on the E0470 before the 120th day
- After initial three month trial
  - New initial face-to-face evaluation
  - New three month trial with the E0470
    - Clinical re-evaluation between 31st and 91st day with E0470
    - Adherence to therapy with E0470
- Documentation by the treating physician prior to switching
  - Interface fit and comfort so it can be used with the E0470
  - E0601 pressure settings prevents tolerating therapy and other pressures have been tried but failed to control OSA symptoms, improve sleep, reduce AHI/RDI
RAD With Backup

RAD with backup (E0471) is not considered reasonable and necessary for the primary treatment of OSA

- Will get denied as not reasonable and necessary

Replacement PAP

- PAP initially provided and covered through Medicare

  - Inside of RUL due to loss, theft, or irreparable damage
  - No new clinical evaluation, sleep test or trial
  - Need to get police or fire report, and/or beneficiary letter
  - Use RA modifier on 1st month with narrative
    - Explain reason for replacement, why it cannot be repaired
    - Details about replacement – manufacturer and/or model #
  - After RUL requires a FTF evaluation
    - Beneficiary continues to use and benefit from device
    - No requirement for a new sleep study or trial period as long as the meets the current coverage criteria in effect
    - Use RA modifier on 1st month with narrative
      - Abbreviation – RUL – reasonable useful lifetime
      - Date received original equipment that is being replaced
      - Example: RUL E0601 Sept 2013
**BENEFICIARIES ENTERING MEDICARE:**
For beneficiaries who received a PAP device prior to enrollment in fee for service (FFS) Medicare and are seeking Medicare coverage of either rental of the device, a replacement PAP device and/or accessories, both of the following coverage requirements must be met:

1. **Sleep test** – There must be documentation that the beneficiary had a sleep test, prior to FFS Medicare enrollment, that meets the Medicare AHI/RDI coverage criteria in effect at the time that the beneficiary seeks Medicare coverage of a replacement PAP device and/or accessories; and,

2. **Clinical Evaluation** – Following enrollment in FFS Medicare, the beneficiary must have a face-to-face evaluation by their treating practitioner who documents in the beneficiary’s medical record that:
   1. The beneficiary has a diagnosis of obstructive sleep apnea; and,
   2. The beneficiary continues to use the PAP device.

If either criteria 1 or 2 above are not met, the claim will be denied as not reasonable and necessary.

If no sleep study available, a new sleep study is needed that will meet Medicare requirements, and follow a new 12 week trial period.

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**Medicare vs MAP**

**Medicare Advantage Plan to Medicare FFS:**
- Same benefits, rules, requirements, and coverage criteria as the FFS
- May continue to receive items and services if FFS coverage criteria and documentation requirements met

**Example:** Beneficiary received capped rental item (HB) through MAP, now must meet the FFS criteria for the new capped rental period would begin.

**Exception:** If beneficiary previously enrolled in FFS, received capped rental item, then enrolled in MAP, stayed with MAP for 60 or fewer days, then returned to FFS. Then pick up rental where left off. An end to medical necessity is enrollment in HME for 60 or more days.

**Exception:** Beneficiary begins taking O2 under MAP, you must obtain initial CMN and submit the claim at the time FFS coverage begins. Does not need a new blood gas, but must use the most recent one. Plus the all other oxygen coverage criteria must be met.
Use of O2 with PAP Therapy

- Testing must be done in Chronic Stable State
- Both oxygen LCD and PAP LCD must be followed
- OSA sufficiently treated and lung disease unmasked
- Overnight oximetry during home sleep test not eligible to be used for oxygen qualification.
- Testing may only occur during a Titration Study and
  1. Minimum 2 hours
  2. During titration specific reduction in AHI/RDI criteria met
  3. Only performed after optimal PAP settings determined
  4. Nocturnal oximetry conducted during PSG shows <88% for 5 minutes.

NO exceptions to this rule

<table>
<thead>
<tr>
<th>HCPCS</th>
<th>Narrative</th>
<th>Frequency</th>
</tr>
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<tbody>
<tr>
<td>A7028</td>
<td>Replacement Oral Cushion for combination oral/nasal mask</td>
<td>2 per 1 month</td>
</tr>
<tr>
<td>A7029</td>
<td>Replacement nasal pillows for combination oral/nasal mask</td>
<td>2 per 1 month</td>
</tr>
<tr>
<td>A7031</td>
<td>Replacement full face mask interface</td>
<td>1 per 1 month</td>
</tr>
<tr>
<td>A7032</td>
<td>Replacement nasal mask interface</td>
<td>2 per 1 month</td>
</tr>
<tr>
<td>A7033</td>
<td>Replacement pillow nasal cannula type interface</td>
<td>2 per 1 month</td>
</tr>
<tr>
<td>A7038</td>
<td>Disposable filter used with positive airway device</td>
<td>2 per 1 month</td>
</tr>
<tr>
<td>A7031</td>
<td>Replacement full face mask interface</td>
<td>1 per 1 month</td>
</tr>
<tr>
<td>A4694</td>
<td>Tubing with heated element</td>
<td>1 per 3 months</td>
</tr>
<tr>
<td>A7027</td>
<td>Combination oral/nasal mask</td>
<td>1 per 3 months</td>
</tr>
<tr>
<td>A7030</td>
<td>CPAP full face mask</td>
<td>1 per 3 months</td>
</tr>
<tr>
<td>A7034</td>
<td>Nasal interface (mask or cannula type)</td>
<td>1 per 3 months</td>
</tr>
<tr>
<td>A7037</td>
<td>Tubing used with positive airway device</td>
<td>1 per 3 months</td>
</tr>
<tr>
<td>A7035</td>
<td>Headgear used with positive airway device</td>
<td>1 per 6 months</td>
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<tr>
<td>A7036</td>
<td>Chinstrap used with positive airway device</td>
<td>1 per 6 months</td>
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<tr>
<td>A7039</td>
<td>Non-disposable filter used with positive airway device</td>
<td>1 per 6 months</td>
</tr>
<tr>
<td>A7040</td>
<td>Replacement water chamber for humidifier with positive airway device</td>
<td>1 per 6 months</td>
</tr>
</tbody>
</table>
Refill requests

- A4604 and A7027-A7046 require a refill request
- Contact must occur no sooner than 14 days prior to ship/delivery date
- Supplier must deliver no sooner than 10 calendar days prior to the end of usage of the current supplies

Request for Refill must include

- Beneficiary’s full name
- Description of each item being requested
- Date of refill request
  - **Consumables** (e.g. respiratory medication, urological, ostomy)
    - Quantity of each item the beneficiary still has remaining
  - **Non-consumables** (e.g. PAP supplies, mastectomy supplies)
    - Functional condition of each item being refilled to demonstrate the cause of it malfunctioning
      - For example: seal worn out, tubing has holes, filters discolored, etc.
    - Can be a form or in patient’s chart notes
    - **Watch delivery ticket address: was it delivered or picked up in store**
    - Can supply 3 months (90 days)—make sure to do a narrative with the claim indicating such
Are upgrades allowed on CPAP supplies when a beneficiary elects to have a more extensive mask than what would be allowed by Medicare?

No. Medicare covers the mask but does not consider it an upgrade if it is simply a more expensive type of mask. Medicare suppliers who enrolled as “non-participating” have the option of not accepting assignment on a claim-by-claim basis which would allow additional reimbursement options. A difference in price alone does not warrant an upgrade. The beneficiary needs a mask to use with their PAP device. If the quantities of masks that they wanted were above what Medicare allowed, which is one every three months, then that could potentially be an upgrade regarding the quantity of masks.

- Think about orders – getting brand specific – need to be generic such as full face mask
- Think about non-assigned. Let bene know which item insurance covers (assigned) and what is out of pocket with small reimbursement (non-assigned)

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If a patient is setup an A7034 nasal mask, and it does not work after 2-3 weeks, can a supplier dispense an A7030 full face mask and bill for it?

Medicare covers 1 mask every 3 months. If a second mask is billed within the 3 month period, it will deny due to same/similar/frequency edits.
When billing Positive Airway Pressure (PAP) devices, a supplier enters a narrative on the claim that the beneficiary needed new headgear to be compatible with the new mask. Would that be paid by Medicare? If not, what would be paid?

No, that would not be paid. There is a utilization allowance for the actual mask and if a supplier is exceeding that allowance then the claim will deny as not reasonable and necessary. The fitting and the type of mask that was ordered should all be taken into consideration, either during the sleep study or during their trial period. If the beneficiary does need new headgear, unfortunately, Medicare cannot allow more than one per the utilization guideline within the PAP LCD – medical policy.

*Headgear is 1/6 months
*Option: Bene can pay cash!

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**Initial Order**

Must have prior to dispensing equipment
May be verbal or written
Requirements:
- Beneficiary’s name
- Description of items
- Date of order
- Prescriber’s Printed Name
- Prescriber’s signature (if written) or Supplier signature (if verbal)
- Prescribing practitioners NPI (for base E0601 or E0470)

- If verbal order taken, need to know whom at the supplier took the order and who called the order in.
Detailed Written Order

Must be completed prior to submitting claim – recommend prior delivery
May be completed by someone other than physician
– physician must review, sign, and date

Requirements:

- Beneficiary’s name
- Date of Order
- Detailed description of item being ordered
  - All billable items listed separately
- Pressure settings
- Frequency of use / duration
- Quantity
- Refills
- Practitioner printed name
- Practitioner’s NPI
- Practitioner signature

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Blanket Order
For Supplies

Patient: John Doe
Order Date: 09/10/2018
Length of Need - Lifetime (99)

1 - CPAP machine
   set pressure at 10 cm H2O

1 - Heated Humidifier

- Comb Oral/Nasal Mask 1/3 Mo
- Full Face Mask 1/3 Mo
- Replacement Face Mask 1/3 Mo
- Nasal Application Device 1/3 Mo
- PAP Headgear 1/6 Mo
- PAP Chinstrap 1/6 Mo
- PAP Tubing 1/6 Mo
- PAP Non-disposable Filter 1/6 Mo
- Humidifier Chamber 1/6 Mo
- Oral Cushion 2/1 Mo
- ReplacementSed Nasal Pillow Comb Mask 2/1 Mo
- ReplacementSed Nasal Cushion 2/1 Mo
- ReplacementSed Nasal Pillows 2/1 Mo
- PAP Disposable Filter 2/1 Mo

Electronically signed by Charles Smith, MD on September 10, 2018
NPI: 1234567890
Valid Order

<table>
<thead>
<tr>
<th>Patient: John Doe</th>
<th>Order Date: 09/10/2018</th>
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<tbody>
<tr>
<td>Length of Need: Lifetime</td>
<td>(99)</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>1 - CPAP Device at 11cmH2O</td>
<td></td>
</tr>
<tr>
<td>1 - Heated Humidifier</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Item</th>
<th>Quantity</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mask - Nasal Pillow</td>
<td>1</td>
<td>1/3 Mo</td>
</tr>
<tr>
<td>Mask - Full Face</td>
<td>1</td>
<td>1/3 Mo</td>
</tr>
<tr>
<td>Oral Mask Interface</td>
<td>1</td>
<td>1/3 Mo</td>
</tr>
<tr>
<td>Nasal Mask cushion</td>
<td>2</td>
<td>2/1 Mo</td>
</tr>
<tr>
<td>Full Face Mask Cushion</td>
<td>1</td>
<td>2/1 Mo</td>
</tr>
<tr>
<td>Nasal Pilloes</td>
<td>2</td>
<td>2/1 Mo</td>
</tr>
<tr>
<td>Tubing</td>
<td>1</td>
<td>1/3 Mo</td>
</tr>
<tr>
<td>Chinstrap</td>
<td>1</td>
<td>1/6 Mo</td>
</tr>
<tr>
<td>Headgear</td>
<td>1</td>
<td>1/6 Mo</td>
</tr>
<tr>
<td>Filter, Disposable</td>
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<td>2/1 Mo</td>
</tr>
<tr>
<td>Filter, Non-Disposable</td>
<td>1</td>
<td>1/6 Mo</td>
</tr>
<tr>
<td>Humidifier Chamber</td>
<td>1</td>
<td>1/6 Mo</td>
</tr>
</tbody>
</table>

Other ____________________

Electronically signed by Charles Smith, MD on September 11, 2018
NPI: 1234567890

Proof of Delivery

Signed POD required to verify beneficiary received item

Requirements:

- Beneficiary’s name
- Delivery address
  - if beneficiary picks up at store, this is the delivery address
  - Detailed description to identify the item(s) being delivered
    - Brand name, serial #, narrative description
- Quantity delivered
- Date delivered
- Beneficiary signature
- Supplier signature

Can be signed by:

- Beneficiary
- Beneficiary’s designee – relationship to beneficiary must be noted on delivery slip

VGM Group | www.vgm.com
When is a new order required?

<table>
<thead>
<tr>
<th>Change in order</th>
<th>State Licensure or Regulation</th>
<th>When indicated in the Medical Policy</th>
<th>Replacement</th>
<th>Change in Supplier</th>
</tr>
</thead>
</table>

MLN MM9741
released August 19, 2016

- Change due to industry changes and patients struggling to find a supplier to get replacement accessories
- Implementation date of Nov. 2, 2016
- Only applies to CPAP and BiPAP patient owned equipment where Medicare FFS paid all 13 months rental
- New supplier only needs to obtain office visit to show benefiting and needs to continue use and needs to be within the preceding 12 months, and new DWO for supplies
- And make sure to follow refill request requirements
Team of expert consultants providing:

- Prescreen Reviews
- Forms and Documentation Reviews
- Proactive Claim Audits
- On-going compliance support packages
- “Any willing provider” prep kit (1 hr product-specific webinar for staff and 1 hr documentation/form review = $399 for VGM Members)
- TPE/RAC/UPIC Audit support and appeal preparation

(404) 343-1815   |   Info@vanHalemGroup.com   |   vanHalemGroup.com

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www.vgm.com/reimbursement

Nov 9th at 11am central
Is the Hospital Bed and Group Support Surface a Good Market to Expand into in 2019?
https://attendee.gotowebinar.com/register/4213146431610892034

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