

November 2008

Positive Airway Pressure (PAP) Device
Lunch and Learn Q & A

- Q1. For a patient on respiratory assist device (RAD) with backup (E0471) what is the backup feature?
- A1. **The backup feature allows the RAD to provide a breath for the patient at certain intervals.**
- Q2. If a patient received a sleep study in 2000 and now are on Medicare but due to equipment failure require a new machine. Will the patient need to obtain a new sleep study in order to meet coverage criteria?
- A2. **As long as the sleep study provided in 2000 documents that the coverage criteria in effect at the time of replacement have been met, then a new sleep study is not required.**
- Q3. In regards to the new order requirements, is a new order required if a machine or humidifier is being replaced? What about supplies?
- A3. **Yes. The Program Integrity Manual, Chapter 5, Section 5.2.4 states that a new order is required when there is a change in the order for the accessory, supply, drug, etc., on a regular basis if specified in the documentation section by a medical policy, when an item is replaced, and when there is a change in the supplier.**
- Q4. In regards to the documentation for continued coverage beyond the 91st day, we are currently sending a compliance letter to our physicians along with a statistical summary that is downloaded from the machine and having the physician review and sign whether or not the patient is being compliant. Is this going to fulfill the objective evidence of adherence to use of the device as required for DOS 11/1/08?
- A4. **If the statistical summary report clearly indicates that the patient was using the device for 4 or more hours on 70% of the nights during a 30 consecutive day period, that would meet the requirement.**

- Q5. For continued coverage criteria the policy states “For PAP devices with initial dates of service on or after November 1, 2008, documentation of clinical benefit is demonstrated by a face-to-face clinical re-evaluation by the treating physician with documentation that symptoms of obstructive sleep apnea are improved. Does this have to be completed by the treating physician or can our Respiratory Therapist (RT) complete this?
- A5. No, the face-to-face clinical re-evaluation for continued coverage criteria must be completed by the treating physician.**
- Q6. If the patient must see their treating physician for the face-to-face clinical re-evaluation, this would require the patient to have a whole additional visit. Is this covered by Medicare?
- A6. Yes, the patient would be expected to have another visit with their treating physician for the face-to-face clinical re-evaluation. The visit would not be covered under the DME benefit but would be covered under Part B.**
- Q7. Can an Advance Beneficiary Notice of Noncoverage (ABN) be issued upon set-up of the device stating that if the patient does not see their treating physician within the 31st to 91st day period the patient would be responsible for the bill until they obtain a follow up visit with the treating physician?
- A7. No, this would be considered as providing a blanket ABN. An ABN can be issue if at the time for continued coverage the patient refuses to return to their treating physician for the follow up visit as required per policy. This would then be a business decision on behalf of the supplier as to whether they want to continue providing the equipment or pick up the equipment. The patient should be provided the ABN once it has been established they will not meet medical necessity and the patient should sign and date the ABN prior to the month being billed with the GA modifier.**
- Q8. Slide 18 indicates that the apnea-hypopnea index (AHI) under criteria 2 should be greater than 5, is this correct?
- A8. No, the slide should indicate that the AHI should be greater than or equal to 5.**
- Q9. If a patient has been on CPAP therapy but against medical advice discontinues using the equipment and six months later the treating physician wants them to restart therapy. A new face-to-face has been completed. Is a new sleep study

required in this situation?

A9. Yes, according to the LCD, a repeat sleep test in a facility-based setting would be required.

Q10. Are stamp dates acceptable on the detailed written order?

A10. No, we will not accept stamp signatures or dates.

Q11. Can a hospital be affiliated with the Home Sleep Testing (HST) and still provide the PAP device?

A11. Yes, there is a provision for a hospital certified to perform such tests as noted in the local coverage determination “No aspect of an HST, including but not limited to delivery and/or pickup of the device, may be performed by a DME supplier. This prohibition does not extend to the results of studies conducted by hospitals certified to do such tests.”

Q12. A patient was on CPAP in 2005 with a different supplier for about four or five months and then returned the equipment. He/she recently went to their treating physician regarding CPAP therapy. Would the patient now need a new sleep study to qualify for CPAP because the treating physician is against another sleep study indicating they do not want to waste government money?

A12. Yes, the patient would need a new face-to-face evaluation and a facility-based polysomnogram with documentation indicating why the treatment failed the first time and supporting the medical necessity at this time.

Q13. During a recent industry held teleconference it was mentioned that for the face-to-face examination all the following elements; sleep history, duration of symptoms, signs and symptoms, and physical examination such as BMI, neck circumference, and focused cardiopulmonary and upper airway system evaluation must be included and that the Epworth Sleepiness Scale is recommended but not required. Is this correct?

A13. All of the documentation is highly recommended to support the medical necessity for the patient needing the PAP device, although it may not be necessary for every aspect to be addressed in every patient’s situation. The documentation should be based on each individual patient addressing their specific condition and needs.

Q14. According to the local coverage determination the face-to-face evaluation must be completed prior to the sleep study. Is it expected that the patient obtain another

sleep study if it is found during review of the documentation that the face-to-face was not completed prior to the original sleep study?

A14. The policy indicates that the face-to-face evaluation should occur prior to ordering the test. If not, the KX modifier may not be used on the claim. Individual consideration of exceptions could be handled through the appeals process.

Q15. Upon delivery of the PAP device and a mask, can a replacement cushion/pillow or second mask be provided due to the monthly maximum allowance?

A15. It is not recommended that two masks be provided at that time. The patient may have difficulty finding the correct interface for them individually and they may need to try a few before finding the correct one.

Q16. How is the physician community being educated regarding the new Positive Airway Pressure (PAP) device policy?

A16. The medical directors have published an article that can be used to help educate physicians about the elements of the policy that affect them. It can be found on the NGS web site, Education and Support tab, Tools and Materials page.

Q17. If a patient is in their first month and needs to try two different interfaces, will Medicare pay for the trial of two different masks?

A17. Both interfaces should be covered, but this would be different dates of service due to the trial of one and then the other. Both or several interfaces should not be given at once just in case one does not work. One should be tried prior to providing a new interface. The second interface may deny based on our system parameters but with documentation regarding the problems and trial with the first interface an appeal may be made.

Q18. On slide 6, the definitions for the Apnea-Hypopnea Index (AHI) and Respiratory Disturbance Index (RDI) are very similar with the differences being sleep time and recording time. The American Academy of Sleep Medicine recognizes Respiratory Effort Related Arousals (RERAs) in their definition of the RDI. May RERAs be included in the calculation of the RDI?

A18. No. For the purpose of the PAP policy the RDI does not include RERAs, therefore if they are calculated into the RDI for the purpose of coverage criteria the RDI will not meet coverage criteria. The RDI as defined by the local coverage determination policy only includes apneas plus hypopneas divided by total recording time. During a review the clinician will check to ensure the RDI and AHI are being calculated correctly.

- Q19. Can the detailed written order indicate CPAP supplies or must it include each supply provided? Does this also include dictating whether the humidifier is a heated or cool humidifier on the order?
- A19. The detailed written order must list each supply that will be separately billed. For a humidifier, it must specify a heated or non-heated humidifier. For more information regarding orders please refer to the Program Integrity Manual, IOM 100-08, Chapter 5.**
- Q20. Is there an expiration date for a sleep study?
- A20. If a sleep study is performed and is positive, it is expected that the PAP therapy would be initiated fairly soon after that. If PAP therapy was not initiated for months or years, a new study would be required.**
- Q21. Can the detailed written order contain check boxes for the physician to choose the type and amount of supplies to provide?
- A21. Yes, but the amount provided should reflect the need. For instance if the physician orders up to two oral cushions per month but the patient only requires one then only one should be provided.**
- Q22. Is it the supplier's responsibility to obtain documentation from the treating physician that the face-to-face clinical re-evaluation occurred?
- A22. Yes, the supplier must obtain documentation from the treating physician regarding the face-to-face clinical re-evaluation taking place between the 31st and 91st day after initiating therapy.**
- Q23. Is a Medicare beneficiary statement required for continued coverage under the PAP policy?
- A23. No, the Medicare beneficiary statement is not required for continued coverage under the PAP policy but is required under the Respiratory Assist Device (RAD) policy.**
- Q24. For continued coverage, the documentation needed is the face-to-face clinical re-evaluation, the patient's download, and ensure the patient is continuing to adhere to PAP therapy?
- A24. Correct, the documentation should include the re-evaluation occurring between the 31st and 91st day after initial therapy, the patient's objective adherence to therapy, and you should always ensure the patient is continuing to use the device.**

- Q25. For initial coverage, the documentation needed would be the initial face-to-face evaluation, the sleep study, and that the patient has been instructed on the use of the equipment and accessories?
- A25. Yes, the supplier would want documentation regarding the initial face-to-face in detailed narrative form from the treating physician, a qualifying sleep study, and documentation that the patient has been instructed on the proper use and care of the equipment and accessories.**
- Q26. Who is responsible for providing the patient with the instruction on the proper use and care of the equipment and accessories?
- A26. The supplier is responsible for documenting the instruction that has been provided to the patient. This can be completed on a supplier created form due to this process being their responsibility to perform.**
- Q27. How would the supplier ascertain the objective adherence to therapy through a phone call with the patient?
- A27. The patient would read the values on the digital display screen of the PAP device. The supplier would document this in a written report noting the patient's name, the name of the person who provided the information (patient or caregiver), the usage values, the date of the call, and the name of the supplier staff person recording the data. The report should be forwarded to the physician. For coverage of continued use beyond 3 months, the values recorded must document the adherence criterion that is specified in the policy – i.e., patient use of the PAP device for 4 or more hours per night on at least 70% of the nights in a 30 consecutive day period. It should be noted that very few PAP devices can provide this information through a visual display. Usually this data must be obtained through direct download or via telephone modem or wireless transmission.**
- Q28. Will the use of lifetime or 99 fulfill the requirement for length of need on the detailed written order?
- A28. Yes, lifetime or 99 are acceptable for length of need.**
- Q29. How many months of PAP supplies can be dispensed at one time?
- A29. Three months of supplies can be dispensed at one time. However, the supplier should be checking with the patient to ensure that they are only providing the amount of supplies needed by the patient and not just the maximum usual allowance. As referenced in the Program Integrity Manual, Chapter 4.26.1, "Contact with the beneficiary or designee regarding refills should take place no sooner than approximately 7 days prior to the delivery/shipping date. For**

subsequent deliveries of refills, the supplier should deliver the DMEPOS product no sooner than approximately 5 days prior to the end of usage for the current product.”

Q30. If the general physician completes the initial evaluation and the sleep study physician completes the re-evaluation is this acceptable? Can two different physicians complete the evaluations for initial and continued coverage criteria?

A30. Yes, since both physicians are treating the patient for the obstructive sleep apnea the evaluation may be completed by two different physicians.

Q31. Is it acceptable for the patient to go to their general physician for the initial face-to-face examination and the orders for the sleep study and then once the sleep study is completed the care is taken over by the sleep study physician who orders the equipment?

A31. Yes, this is acceptable.

Q32. In this case a nursing home physician orders the sleep test and the patient is sent to a sleep lab for the polysomnogram. Then the patient is discharged from the nursing home to home with orders from the nursing home physician for PAP therapy. Would their general physician once they have been discharged home be their new treating physician?

A32. Yes, in this case the nursing home physician would be the physician completing the initial face-to-face examination and their general physician once discharged home would become the treating physician for the re-evaluation.

Q33. Can the supplier’s respiratory therapist go to the patients home to obtain the data from the PAP device regarding the visual inspection of the usage data onto a form created by the supplier for documentation purposes?

A33. Yes, as long as the information is being obtained from the PAP device. The physician must be provided with the information but is not required to sign a form created by the supplier.

Q34. Is Medicare going to mandate that the sleep study be a Home Sleep Test (HST)?

A34. No, at this time the patient may have either a facility-based sleep study or one of the three covered home sleep tests.

Q35. For the information needed for adherence to therapy requiring greater than or equal to four hours per night, how do you obtain this information by visual inspection without a download from a compliance card?

A35. Most PAP devices cannot provide this data by visual inspection of the visual display screen. Reporting total hours of use over a 30 day span is not sufficient. For devices that are capable of reporting “sessions” and number of days used, if the session is set up to measure use ≥ 4 hours, one could use the number of sessions in conjunction with total days of use over a 30 day period and determine whether or not the patient met the adherence requirement.

Q36. Can the general physician treating the patient for sleep apnea perform the initial face-to-face evaluation and the re-evaluation?

A36. Yes, the evaluation can be completed by the general physician if they are treating the patient for the sleep apnea.

Q37. Since the physician needs to review the objective evidence of compliance, does that information have to be sent to them prior to the patient’s re-evaluation or does it have to be performed simultaneously?

A37. The documentation of compliance can be obtained either before, at the time of, or after the physician re-evaluation visit as long as it occurs prior to the 91st day and the report is sent to the physician.

Q38. If at the 91st day the patient is not compliant with either the re-evaluation or therapy, does the supplier have to pick up the machine and re-deliver it with an ABN stating the patient has not met compliance or can they explain at that time that due to being non-compliant an ABN is being issued?

A38. It is not expected that the supplier pick up the machine and re-deliver but can at that time issue the ABN being very specific to why the patient does not meet medical necessity at that time. If the patient refuses to sign the ABN it becomes part of the supplier’s business decision as whether they will continue to provide the equipment or pick it up.

Q39. If the supplier provided the treating physician with a form containing the objective evidence of adherence to use of the PAP device and the physician makes this document a part of the patient’s medical records is this acceptable?

A39. Yes, this can be acceptable.

Q40. For snow birds, if they reside in Indiana and have the initial face-to-face by their general physician and then go to Florida during the re-evaluation period, is it expected that they obtain a physician in Florida to perform the re-evaluation treating them for the sleep apnea?

A40. Yes, it is expected that the patient would obtain a physician to complete the re-evaluation.

Q41. If the patient completes the re-evaluation after the 91st day, would the next bill date be the date of the re-evaluation?

A41. Yes, if the physician re-evaluation does not occur until after the 91st day but the evaluation demonstrates that the patient is benefiting from the PAP therapy, continued coverage of the PAP device will commence with the date of the re-evaluation.

TEST ANSWERS

1. The face to face clinical evaluation may be completed by the patient's regular physician or sleep study physician, whichever is treating them for the OSA.

True

2. The Respiratory Disturbance Index (RDI) for purposes of this policy is equal to the average number of respiratory disturbances per hour.

False

3. A Home Sleep Test (HST) must be interpreted by a specified credentialed physician for claims with initial dates of service on or after.

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4. A DME supplier may deliver the HST as long as they have a licensed Respiratory Therapist on staff.

False

5. A supplier can submit a written or telephone reopening if the KX modifier is accidentally omitted and the criteria are met.

True