Jurisdictions B, C and D Councils Combined A-Team Questions
November 2017

Enteral/Parenteral/IV Therapy

1. The Parenteral Nutrition Local Coverage Determination and Policy Article contain references to tests that are outdated and generally not available at many major medical facilities. Specifically, Situation E – Severe Malabsorption criteria which focuses on outdated fecal fat results.
   (a) Would using a qualitative spot check or a Sudan Stain be a more effective protocol to satisfy this criteria?
   (b) Do the DMDs have this LCD on their priority list for potential revision?
   (c) Will this type of revision require public meetings and notice and comment to make such a change?

   DME Response: An LCD Reconsideration is required for LCD coverage criteria changes. Information on how to request an LCD Reconsideration is available on each DME MAC web site. This proposed change would require compliance by the DME MACs with the 21st Century Cures Act requirements for LCD revisions.

2. Blincyto (Blinatumomab) now has FDA approval to treat patients who are Philadelphia chromosome positive with indications for multiple cycle treatment regimens (up to 9). We understand that a policy Reconsideration has been submitted for review by the DME MACs and retro-active approval is possible. Due to the high cost of the therapy, suppliers will likely be unable to service patients based on new FDA guidelines until official correspondence is received on determination of coverage. Can we expect the determination on coverage to be updated in the near future to avoid ambiguity of coverage and potential access issues for patients prescribed Blincyto for Philadelphia chromosome positive and or additional cycles?

   DME Response: The DME MAC medical directors received a valid reconsideration request and a final response regarding what actions the DME MACs will take is due to the requestor on 12/14/2017.

Home Medical Equipment

3. There has been some contradicting information in the industry regarding billing unassigned for competitive bid items by a non-contracted supplier. According to a joint publication released approximately a month ago, if a beneficiary resides in a CBA and elects to purchase a competitively bid item from a supplier that is NON contracted and NON participating with Medicare, the publication indicates the supplier is required to submit the claim as assigned. If the supplier sells an E0143 walker to this beneficiary, executes an ABN according to chapter 3 of the supplier manual and discloses their non-contracted status:

(a) Are they precluded from collecting their full charge amount up front?
(b) Are they precluded from collecting the full single payment amount up front?
(c) If the beneficiary utilizes the option to waive their right to file a claim, is the supplier still limited in the amounts they can charge?

DME Response: If the beneficiary resides in a competitive bidding area and the supplier is a non-bid winning supplier, any claim submitted for a competitively bid item must be processed as an assigned claim. If an unassigned claim is submitted, it will be rejected. The supplier may collect their charges from the beneficiary up front if they have a valid ABN and append the GA modifier. The supplier must indicate how much the beneficiary paid on the claim. If the claim is subsequently paid, the DME MAC will refund the beneficiary the appropriate amount. If the beneficiary chooses Option 2 on the ABN and waives their rights to file a claim to fee-for-service Medicare, then the amount charged to the beneficiary will be up to the supplier.

Reference: IOM 100-4, Claims Processing Manual, Chapter 30. 50.7.3 - Effects of Lack of Notification, Medicare Review and Claim Adjudication
(Rev. 2782, Issued: 09-06-13, Effective: 12-09-13, Implementation: 12-09-13)
A. Beneficiary Liability
A beneficiary who has been given a properly written and delivered ABN and agrees to pay may be held liable. The charge may be the supplier/provider's usual and customary fee for that item or service and is not limited to the Medicare fee schedule. If the beneficiary does not receive proper notice when required, s/he is relieved from liability.

Medical Supplies/Ostomy/Urological/Diabetic Supplies

4. Please clarify the difference between length of need and the number of refills as it pertains to detailed written orders when supplies are dispensed on a monthly basis. Are both elements required on a DWO?

DME Response: Length of need is not a requirement for a detailed written order. For items provided on a recurring basis, the number of refills is one of the required elements (Reference: Policy Article A55426 - Standard Documentation Requirements for All Claims Submitted to DME MACs.)

5. For supplies, if the dispensing order comes over with a specific quantity per month (ex: 150 per month), will this description satisfy both the frequency of use element and the quantity to be dispensed element on the DWO?

DME Response: Per Policy Article A55426 - Standard Documentation Requirements for All Claims Submitted to DME MACs, both the frequency of use and quantity to be dispensed are required elements; however, they are not the same. The frequency of use is the number of times per day (e.g., for an item used daily) while the quantity to be dispensed is the total quantity per

fill. Using the given example of 150 per month, the DME MACs would anticipate the detailed written order would also include the frequency of use such as "five per day." As a reminder, someone other than the ordering physician can create the detailed written order, which should alleviate any missing elements.

Prosthetics/Orthotics

No questions Submitted.

Rehab Equipment

No questions submitted.

Respiratory Care Equipment/Oxygen/PAP/Other

6. We have a physician that wants to use Telehealth for the CPAP 90 day follow up visit for continued coverage. Telehealth guidelines stipulate it is designed for rural area patients. Furthermore, the patient must travel to an approved location to participate in the Telehealth visit. Assuming the physician documents that the machine is being used compliantly and that the beneficiary's symptoms of OSA are improved, if the visit otherwise meets the Telehealth guidelines, can the Telehealth visit be used to satisfy Medicare's requirement for continued coverage via the Face-to-Face clinical re-evaluation?

   DME Response: From the PAP LCD:
   CONTINUED COVERAGE BEYOND THE FIRST THREE MONTHS OF THERAPY:

   Continued coverage of a PAP device (E0470 or E0601) beyond the first three months of therapy requires that, no sooner than the 31st day but no later than the 91st day after initiating therapy, the treating practitioner must conduct a clinical re-evaluation and document that the beneficiary is benefiting from PAP therapy.

   For PAP devices with initial dates of service on or after November 1, 2008, documentation of clinical benefit is demonstrated by:

   1. *Face-to-face clinical re-evaluation by the treating practitioner with documentation that symptoms of obstructive sleep apnea are improved; and,*
   2. *Objective evidence of adherence to use of the PAP device, reviewed by the treating practitioner.*

   Adherence to therapy is defined as use of PAP ≥4 hours per night on 70% of nights during a consecutive thirty (30) day period anytime during the first three (3) months of initial usage.

   If the above criteria are not met, continued coverage of a PAP device and related accessories will be denied as not reasonable and necessary.

Criterion #1 includes examinations conducted via the Centers for Medicare & Medicaid Services (CMS)-approved use of telehealth examinations (as described in Chapter 15 of the Medicare Benefit Policy Manual and Chapter 12 of the Medicare Claims Processing Manual - CMS Internet-Only Manuals, Publ. 100-02 and 100-04, respectively).

7. Is it possible that Medicare will consider coverage of home oxygen for an acute illness, such as pneumonia, acute bronchitis, or post-surgical hypoxia, for short-term usage upon discharge from the hospital?

   DME Response: The National Coverage Determination (IOM 100-3, Chapter 1, Part 4, Section 240.2) outlines several conditions where oxygen will considered for coverage (i.e., severe lung disease such as COPD). Although the question refers to hospital inpatient stays, note that any ABG or SAT test value is not valid if conducted "during a period of acute illness or an exacerbation of their underlying disease" during an outpatient setting (i.e., primary care physician's office, hospital emergency room or skilled nursing facility (SNF)). The conditions in the question are not severe lung diseases. While short-term oxygen therapy may help the beneficiary, oxygen would not be covered by Medicare. Suppliers may present a valid ABN to the beneficiary in these situations.

Documentation/Education/Regulatory/Miscellaneous/Other

8. We would like clarification of a Joint DME MAC Council Q&A from August 2017. Question 15 states that the upgrade process must be started at the time services are rendered and not during the appeals process. We believe the question merits more detail to better solicit guidance from the MACs as this scenario presents fairly commonly. In many cases, an "electric bed" is ordered per the 5EO, and the beneficiary often elects to upgrade to a fully electric bed (E0265). The provider initially reviews the medical record and believes they support a semi-electric bed (E0260). During a prepay audit the E0260 denies, and it is determined the beneficiary only qualifies for a lesser, variable height bed (E0255). The physician is unresponsive to requests for additional medical records to support the E0260, and the supplier acknowledges that the documentation in their possession will support the lesser E0255 bed. The ABN originally disclosed the upgrade fee between the E0260 and the E0265. The ABN did not disclose the medical necessity defect between the E0255 and the E0260, and the supplier concedes they do not have the authority or documentation to pass on the incremental fee between the E0255 and E0260. However the supplier believes it <u>is</u> reasonable for Medicare to pay for the bed at the E0255 level of service based on the medical records, and they also believe it is reasonable to maintain the original provision of the upgrade disclosure between the rates for the E0260 and E0265 based on the ABN document that is in their possession.
   (a) In this case the code can only be changed through redeterminations due to the discovery via claim development and unfavorable audit response. Can the provider change the code to the E0255 and send to redeterminations under the limitation that the beneficiary would only be charged the amount on the <u>original</u> ABN?

(b) Going forward, now that the medical necessity is known to the supplier, can it be disclosed to the beneficiary via a newly executed ABN for future services (resulting in a higher charge to the beneficiary)?
(c) The beneficiary will continue to use the same equipment as originally delivered. Would execution of an updated ABN and change of billing HCPCS in this scenario necessitate a new delivery ticket, new orders or new F2F (if the original delivery was in excess of 6 months from the original F2F)?

DME Response: Answer for (a): The supplier is not able to change the code at the Redeterminations level after a medical necessity denial via a pre-pay review. Answer for (b): Yes, this would be acceptable as the beneficiary would be aware based on the Redeterminations letter they receive. Answer to (c): A new delivery ticket would not be required (the beneficiary is still in possession of the E0265). A detailed written order or new face to face encounter would not be required per ACA 6407 guidelines.

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No questions submitted