Jurisdictions B, C and D Councils Combined A-Team Questions
November 2019

Education/Documentation/Other:

1) Is an order from the ordering practitioner acceptable to meet the continued need (up to the 13 months) and continued use requirement for ongoing rentals; and repairs to bene owned equipment?

   DME MAC Response: Suppliers are reminded that continued medical need and continued use are two separate requirements. Additionally, a new CMN and/or treating physician/practitioner's order is not needed for repairs. Per the Standard Documentation Requirements article, for ongoing supplies and rented DME items, there must be information in the beneficiary's medical record to support that the item continues to remain reasonable and necessary. Documentation to support continued medical need must be timely and may be fulfilled by one of the following:

   - **A recent order by the treating physician for refills.**
   - **A recent change in prescription.**
   - A properly signed CMN or DIF with an appropriate length of need specified.
   - Timely documentation in the beneficiary's medical record showing usage of the item.

   With respect to continued use, suppliers are responsible for monitoring the utilization of supplies or rented items by the beneficiary. Therefore, the presence of an order from the ordering practitioner is not sufficient to meet the requirements for continued use. Any of the documents listed below may serve as documentation that an item submitted for reimbursement continues to be used by the beneficiary:

   - Timely documentation in the beneficiary's medical record showing usage of the item, related option/accessories and supplies.
   - Supplier records documenting the request for refill/replacement of supplies in compliance with REFILL DOCUMENTATION/REQUIREMENTS section. This is deemed sufficient to document continued use for the base item as well.
   - Supplier records documenting beneficiary confirmation of continued use of a rental item.

   For both continued medical need and continued use, timely documentation is defined as a record in the preceding 12 months unless otherwise specified. To view the documentation requirements for continued medical need, continued use and repairs in detail, please consult the Local Coverage Article: Standard Documentation Requirements for All Claims Submitted to DME MACs (A55426).

2) In the event of servicing a patient with an off- the-shelf brace (of any kind), is it required that our clinicians (meaning ABC Accredited Orthotist, CPed, or CFO-each would be properly certified with proven credentials) do their charting according to Medicare guidelines?

   DME MAC Response: The records of O&P practitioners are considered part of the medical record. Consequently, they must conform to the documentation guidance outlined in the CMS *Program Integrity Manual* (CMS Pub. 100-08), Chapter 3, §3.3.2 and any applicable LCD and LCD-related Policy Article.

   As a reminder, off-the-shelf items are defined as prefabricated items that require "minimal self-adjustment" (**see 42 CFR §414.402)** for fitting at the time of delivery for appropriate use and do not require expertise in trimming, bending, molding, assembling or customizing to fit an individual. For custom fitted items, there must be documentation in the beneficiary's medical record demonstrating that what was performed at the time of delivery

was more than minimal self-adjustment that could not have been accomplished by the beneficiary, caregiver or supplier.

Home Medical Equipment:

No questions

Enteral/Parenteral/IV Therapy:

3) Patients that have a primary place of service of an assisted living facility (13) or group home (14) at times leave the facility to visit family for a period of time (say a month).

   When a shipment of enteral nutrients and supplies, or infusion drugs and supplies, is made to the address of the family the beneficiary is visiting the shipping address and place of service changes. This is prompting a request from the DME MACs for a revised DWO and DIF showing that the patient is in a different place of service. This then prompts the need for an additional revision when the patient returns to the assisted living facility or group home. Is there a less paperwork intense process to deal with these common circumstances? After all it does not change the reimbursement in anyway nor does the dispensing pharmacy/supplier change.

   DME MAC Response: A new order is **not** required when the beneficiary temporarily travels from one location to another. However, since the DIF includes a POS field, a revised DIF should be submitted when the beneficiary changes POS. The Local Coverage Article: Standard Documentation Requirements for All Claims Submitted to DME MACs (A55426) advises that a new prescription (order) is required in the following circumstances:
   - For all claims for purchases or initial rentals
   - If there is a change in the order for the accessory, supply, drug, etc.
   - On a regular basis (even if there is no change in the order) only if it is so specified in the documentation section of a particular medical policy
   - When an item is replaced
   - Where there is a change in the supplier, and the new supplier is unable to obtain a copy of a valid order and documentation from the original supplier

4) Home infusion providers often receive orders from physicians to provide ramp-up doses for HYQVIA in the home environment. DME MAC instructions for the coverage for HYQVIA states that…

   Administration of HYQVIA requires a gradual increase in the infusion rate at the beginning of each infusion. This infusion rate ramp-up is patient-specific and must be determined under medical supervision over the course of several infusions of HYQVIA. Once the infusion rate ramp-up specification(s) have been determined, they can be programmed into an appropriate E0781 pump. There is no coverage under the Durable Medical Equipment Benefit for equipment, drugs and infusions supplies used during these initial doses as they are considered as incident to the required professional supervision. Claims to the DME MAC for the pump, drugs and supplies administered in this scenario will be rejected as wrong jurisdiction.
   (January 7, 2016 article HYQVIA (Immune Globulin Infusion (Human) 10%, with Recombinant Human Hyaluronidase) - Coverage and Correct Coding – Revised (Joint DME MAC Publication)

   Beginning January 1, 2019 DME MAC coverage began for home infusion professional services, which includes HCPCS G0069 - Professional services for the administration of subcutaneous immunotherapy for each infusion drug administration calendar day in the individual's home, each 15 minutes. Now that there is coverage for home infusion professional services, which includes nursing services, would it be possible to modify/update the

guidance to allow DME MAC coverage for ramp-up doses of HYQVIA provided in the home under the supervision of a register nurse?

DME MAC Response: No, the new Home Infusion Therapy benefit is separate and distinct from other benefits such as the DME benefit. First and foremost, the infused drug must meet the requirements of the DME benefit as described in the External Infusion Pump Local Coverage Determination (LCD). The statute creating the Home Infusion Therapy benefit reads such that home infusion therapy professional services are only permitted in instances where the pump (and therefore drug) is covered under the DME benefit. Only when HYQVIA® dosing has stabilized and no longer requires supervised, professional administration services is the drug eligible for coverage under the EIP LCD.

5) During a recent meeting with a DME MAC, it was noted that under the Standard Documentation Requirements and in the PIM, Chapter 5, the "number of refills" is NOT a requirement for a supply DWO…only for "Drugs used as a supply for a DME item" is it stated that the number of refills is a requirement.

   This brings several questions;
   (1) A supply kit is not considered as a drug, so does that mean none of the supply kits B4034 – B4035 (enteral), A4221, A4222, A4223 (EIP), B4220- B4224 (TPN) would require number of refills on the DWO? Additionally;

   (2) TPN and enteral would be considered as equipment and supplies (other than drugs), and more importantly;

   (3) technically, enteral and TPN are not under the DME benefit as supplies OR covered "drugs as supplies to DME", rather they are under the Prosthetic device benefit, therefore, TPN/Enteral DWO's would not require the number of refills as they are not considered as drugs. [ref Medicare Claims Processing Manual Chapter 20 - Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) sections 10.1 definitions]

   DME MAC Response: Enteral nutrition, TPN and supply allowances are not considered drugs used as a supply DME. Therefore, the number of refills would not be a required element on the detailed written order. Per the Standard Documentation Requirements, a detailed written order for enteral nutrition, TPN, and supply allowances, must include the following elements:
   - Beneficiary's name
   - Date of the order
   - Description of all items, options, accessories or additional features that are separately billed or require an upgraded code. The description can be a general description (e.g., wheelchair or hospital bed), a HCPCS code, a HCPCS code narrative, or a brand name/model number.
   - For supplies – **list all supplies that are separately billable, and for each include the frequency of use (if applicable), and the quantity dispensed**
   - Prescribing physician/practitioner's signature (and date if applicable - see above)

Prosthetics/Orthotics:

No questions.

Respiratory Care Equip/Oxygen:

6) For compliant CPAP users entering Medicare, if we are unable to obtain the proper documentation from the initial sleep testing (i.e.- sleep study not signed or not available), we are required to treat them as a new set up. Since these are current CPAP users the face to face exam may not contain all the signs and symptoms that the visit prior to treatment would address. In a medical review/audit situation, will consideration be taken with the fact that

the patient has been a compliant CPAP user and that the initial signs and symptoms may not be detailed as they were at the visit prior to treatment?

DME MAC Response: For beneficiaries who receive a PAP device prior to enrollment in fee for service 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:

    a. The beneficiary has a diagnosis of obstructive sleep apnea; and,

    b. 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. The supplier may hold claims, pending confirmation that the above requirements are met, and then submit claims with the KX modifier beginning with the date of the beneficiary's enrollment in the FFS Medicare.

7) The CPAP and Oxygen LCDs address concurrent use of oxygen with PAP therapy; however, the guidance is specific to patients with the diagnosis of OSA. Does the same guidance apply to patients diagnose with CSA? We have clinicians who believe the guidance makes sense for OSA patients but does not for CSA patients because of the inherent difference between CSAs and OSAs.

DME MAC Response: Although only the Positive Airway Pressure (PAP) Devices LCD addresses concurrent use of oxygen and PAP for OSA, the overarching requirement for any device with concurrent use of oxygen is testing in the chronic stable state. When nocturnal oxygen is ordered concurrently with any device used to treat any sleep disordered breathing condition for a Medicare beneficiary, a polysomnogram (PSG) titration conducted in a sleep laboratory must be done to assure chronic stable state after optimal RAD settings have been determined and the beneficiary is using the RAD device at those settings.

Rehab Equipment:

8) Is it acceptable for a supplier's employed ATP to act as a scribe for the LCMP during the specialty evaluation?

DME MAC Response: This is not an acceptable practice. For the LCDs with LCMP evaluation requirements (Power Mobility Devices, Manual Wheelchairs, Wheelchair Options/Accessories and Wheelchair Seating), each professional has a separate and distinct role in the process to document the medical necessity of the item to be ordered. Each LCD clearly states the role and function of each professional evaluating the beneficiary. The LCDs specifically indicate that the "licensed/certified medical professional, such as a PT or OT, or practitioner who has specific training and experience in rehabilitation wheelchair evaluations and that documents the need for the device in the beneficiary's home." In addition the LCDs indicate that there should be no financial relationship between the supplier and LCMP. The ATP is hired by the supplier. If the ATP is scribing for the physical therapist, there is an inherent conflict of interest. Moreover, by serving as the scribe, the ATP makes the therapist more "efficient" by saving time thus allowing them to see more patients, what is often described as "in kind" assistance. The requestor may wish to seek an advisory opinion from the Office of Inspector General (OIG) to confirm.

9) If a beneficiary weighing 515 lbs qualifies for a power wheelchair with tilt and recline per policy but the mobility limitation is not due to a neurological condition, skeletal deformity, or myopathy; will Medicare allow - during the prior authorization process - a group 3 VHD multiple power base code (K0863) since there is no group 2 VHD multiple power base category?

   DME MAC Response: The LCD for Power Mobility Devices requires the beneficiary to not only meet the weight requirements for the Group 3 PMD, but to also present with one of the qualifying diagnoses. Meeting the weight requirement alone is not an indication for affirmation. If the Group 3 is provided and the coverage criteria are not met, a non-affirmation decision will be issued. Suppliers may offer the beneficiary an ABN in anticipation of the claim denial and/or submit the claim for a denial and appeal.

10) How should suppliers document/submit a claim for repairs when we suspect the repair is needed due to beneficiary abuse/misuse of the equipment?

   DME MAC Response: If the supplier suspects abuse or misuse of DMEPOS items by the beneficiary, the supplier may render the service and request that the beneficiary sign an Advance Beneficiary Notice of Noncoverage (ABN). The supplier may then submit the claim to the Medicare and append the GA modifier on each affected claim line.

Medical Supplies:

No questions

CEDI:

No questions submitted