Jurisdictions B, C and D Councils Combined A-Team Questions
October 2023

Enteral/Parenteral/IV Therapy

1. Background: On January 12, 2023, a Joint DME MAC Publication was issued on KX modifier use for External Infusion Pumps (EIP). Specifically, it stated that: “Claims for external infusion pumps, drugs, and supplies billed without a KX, GA, or GZ modifier, with a date of receipt on or after March 1, 2023 (and a "from" date of service on or after January 1, 2023), will be rejected for missing information”.

   Questions related to the submission of claims for drugs approved by the FDA after March 1, 2023 that require a pump to administer but are not specified in the EIP LCD.

   a. How can claims for new FDA approved drugs delivered with an External Infusion Pump be reviewed on a case-by-case basis to determine if the requested treatment is consistent with the FDA approved label and it meets reasonable and necessary criteria?

      i. In this scenario what modifier(s) should appended to the claim (KX, GA, GY, GZ)? It is our understanding that without one of these 4 modifiers the claim will be rejected.
      Response – If LCD guidelines are met for the class of drug and indication(s), the KX modifier should be appended. If not, the appropriate G modifier should be appended. Manufacturers are encouraged to request an LCD reconsideration to include newly FDA-approved drugs with a new indication that may be eligible for inclusion in the EIP LCD.

      ii. Are there additional modifiers that could be used to identify a drug with a miscellaneous J-code as newly approved to allow for a drop down to manual review for a case-by-case determination?
      Response – There is not a specific modifier or modifier set that would cause an FFS Medicare claim to stop for a manual review. The DME MAC Medical Review staff can stop claims for review by asking for documentation via an additional documentation request (ADR) letter.

      iii. What is the pathway process for Medicare Beneficiaries to access new FDA approved drugs delivered with an External Infusion Pump before the drug has been formally added to the Local Coverage Determination, and how can this be done without placing the Medicare Beneficiary in a situation where they potentially face undo financial burden?
      Response – See response i. above.

      iv. Can the DME MACs issue a Joint Advisory Article outlining coverage criteria for new approved drugs delivered with an External Infusion Pump during the LCD Reconsideration Process period?
      Response – CMS does not allow MACs to publish new coverage criteria in bulletin articles. If an article is necessary, it will be added to DME MAC websites after the LCD in question has been finalized and published.

2. Will the DME MACs be publishing the allowable for new HCPCS code B4148 that becomes effective October 2023? B4148 - “Enteral feeding supply kit; elastomeric control fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape.
   Response – When CMS notifies the DME MAC with the fee schedule for B4148, it will be added to the DME MAC websites.

3. In Quarter 2 (May 2023), the council posed the following question and received the following answer:
   1. “The place of service for DMEPOS claims is considered the location where a beneficiary will primarily use the DMEPOS item. The list of acceptable POS codes includes, among others, 04 – Homeless Shelter, 12 – Home, 13 – Assisted Living Facility, and 56 – Psychiatric Residential Treatment Center. "01 – Pharmacy is also listed as place of service where DMEPOS claims would be considered for coverage. Under what circumstances would DMEPOS items be covered when the place of service is 01 – Pharmacy?”

i. "DME MAC response: Any covered DMEPOS item will be considered in place of service 01 Pharmacy. Chapter 6 of the Supplier Manual provides a list of place of service codes that may be considered. DME MACs would expect that this would be an unusual occurrence. Please provide examples in which POS 01 place code has been used."
    1. Would it be appropriate to bill with POS 01 and have DMEPOS covered in any of the following examples?
    Response – Any of the following examples are acceptable for use of POS 01.
        a. A beneficiary asks to receive an infusion in an infusion suite attached to a pharmacy because the beneficiary is temporarily displaced from his/her home.
        b. A beneficiary asks to receive an infusion in an infusion suite attached to a pharmacy because the beneficiary has privacy concerns about having infusion drugs and supplies delivered to his/her home.
        c. A beneficiary asks to receive an infusion in an infusion suite attached to a pharmacy because a nurse cannot be scheduled to perform the infusion in the beneficiary's home on the date the beneficiary requests the infusion.
        d. A beneficiary prefers to have his/her infusions performed in an infusion suite attached to a pharmacy.

4. Starting July 1, 2023, Part B coinsurance for a month's supply of insulin (HCPCS J1817, J1811, J1813) used in an insulin pump covered under the DME benefit cannot exceed $35 (as required by Section 11407 of the Inflation Reduction Act). The following modifiers were added to the policy effective April 1, 2023:
    a. JK: 1-month supply or less of drug/biological
    b. JL: 3-month supply of drug/biological
        i. Since supplier may dispense up to a three-month supply of insulin, if supplier dispenses 45 days' supply or 60 days' supply, would it be appropriate to bill as following since only the JK and JL modifiers are available?
        Response – The DME supplier should append the JK modifier for any claims for 1-month supply of insulin or less and append JL only if the supplier is dispensing a 3-month supply. For example:
            1. Supplier dispenses 60 days' supply: Bills 1st claim JK and second claim JK, holding the second claim if future date.
            2. Supplier dispenses 45 days' supply: Bills 1st claim JK and second claim JK, holding the second claim if future date.

        DME MAC expectation is that either a 30-day or 90-day supply of insulin is provided and billed.

Medical Supplies/Ostomy/Urological/Diabetic Supplies

5. The Surgical Dressing LCD states “Use of more than one type of wound filler or more than one type of wound cover in a single wound is not reasonable and necessary.”
    a. We have scenarios where the medical records include multiple primary or secondary dressings in the plan of treatment. Knowing that this is not reasonable and necessary, we will only ship one of the dressing types. We are still receiving denials because more than one type of wound filler/cover is listed within the Medical Records. We are following coverage criteria and not sending supplies that will be denied as not reasonable and necessary, what course of action should be taken in this scenario? CGS Examples:
        i. 23003873209000
        ii. 23059831412000

6. The Surgical Dressing LCD states “Dressing size must be based on and appropriate to the size of the wound. For wound covers, the pad size is usually about 2 inches greater than the dimensions of the wound. For example, a 2 in. x 2 in. wound requires a 4 in. x 4 in. pad size.”
    a. HCPCS A6210 is listed as a Wound Cover. Description - FOAM DRESSING, WOUND COVER, STERILE, PAD SIZE MORE THAN 16 SQ. IN. BUT LESS THAN OR EQUAL TO 48 SQ. IN., WITHOUT ADHESIVE BORDER, EACH DRESSING
    b. “Foam dressings are covered when used on full thickness wounds (e.g., stage 3 or 4 ulcers) with moderate to heavy exudate. Dressing change for a foam wound cover used as a primary dressing is up to 3 times per week. When a foam wound cover is used as a secondary dressing for wounds with

very heavy exudate, dressing change is up to 3 times per week. Dressing change frequency for foam wound fillers is up to once per day."

i. We are receiving denials and being told when a foam dressing is primary, that it needs to be the approximate size of the wound. The LCD only mentions that a wound cover should be about 2 inches greater than the dimensions of the wound. The only section in the LCD that refers to a wound cover sheet needing to be the approximate size of the wound is under the Alginate or Other Fiber Dressings (A6196-A6199).

1. Why would a Primary Foam Dressing wound cover be denied due to dressing size if the dressing size that was shipped and billed was about 2 inches greater than the dimensions of the wound? CGS Examples:
    a. 23027828540000
    b. 23019830585000
    c. 23101801862000
    d. 23019800991000

Response – The DME MACs would like additional clarification on the issue. All of the claim examples were from ADR letters.

7. For A6196 & A6197, the policy article states the dressings may be used as either a primary AND/OR secondary, however we are now receiving 273 denials for a quantity over 30 when being used for primary AND secondary dressings. During prepayment reviews, we were told that without excessive amounts of exudate usage of the alginate as both a primary and secondary dressing would not be medically necessary, however the policy article states they can be used as a primary and secondary dressing without additional criteria, such as exudate.
    a. LCD section: Alginate or Other Fiber Gelling Dressings (A6196, A6197 and A6198) are absorbent dressings that manage moderately to highly exudative full thickness wounds (e.g., stage 3 or 4 ulcers), are composed of a multi-layer or multi-component structure with either alginate or gelling fiber as the predominant component. Codes A6196, A6197 and A6198 may be used as either a primary and/or secondary dressing, as determined by the treating practitioner.
    Response – Good wound care practice dictates that a secondary dressing may be appropriate when there is an expectation that exudate will strikethrough or exceed the capacity of the primary dressing to absorb the exudate. If a claim is denied, appeal rights are available and clinical review staff will review the documentation to make a reasonable and necessary determination.

Prosthetics/Orthotics

8. Regarding servicing existing AFOs attached to a shoe for repairs, replacements and add ons:
    a. When billing for a shoe transfer (L3620) for an AFO being moved from one shoe to another, that is a shoe that is patient owned and has no HCPCS, how should we format the narrative for the L3620?
    Response – Code L3620 describes the transfer of an orthosis from one shoe to another, solid stirrup, from an existing brace-shoe combination. There is no additional narrative necessary. When billing for a shoe replacement or shoe transfer that is an integral part of a leg brace, a KX modifier must be added to the code.

9. With the upcoming pause of competitively bid orthoses in January 2024, thus allowing any eligible supplier to participate in dispensing competitively bid products as long as pre-authorization is obtained. Will physicians continue to be exempt from the pre-authorization requirement in the upcoming rules or changes with the option to use the KV modifier? Additionally, will the modifiers ST and J5 still be in use under these new regulations? Who can and cannot use the modifiers if they are still applicable and are there other restrictions when they are being used?
    Response – There are no changes in the prior authorization process. When the current competitive bidding round concludes on December 31, 2023, every DMEPOS supplier that provides the affected HCPCS codes can provide them. They must follow the current prior authorization process. The DME MACs are researching the KV and J5 question.

Rehab Equipment

10. Please advise if the policy changed or if education is needed for claims processing and redetermination with regard to replacement parts as a repair submitted as a purchase (lump sum). There have been several recent denials along with redeterminations being upheld on parts with NURBKX with the following:

Rent purchase guidelines not met. The item is a capped rental and can only be purchased on K0835-K0864.

CR 9579 from April 2016 - The regulations at 414.210(e) also provide that payment for repair parts is made on a lump sum purchase basis. Therefore, effective October 1, 2016, all repair part claims billed with the RB modifier, whether within or outside a competitive bidding area, whether described by a HCPCS code that is a competitive bidding item or not, and whether described by a code for miscellaneous (not otherwise classified or specified) items or not, shall be paid on a lump sum purchase basis. There appears to be a recent pattern of claim denials (appeals being upheld) for capped rental repair parts when submitted as a purchase on non complex power wheelchair bases. The denials state rent purchase guidelines not met, however, per CR 9579 (effective Oct 1, 2016 ALL replacement parts as a repair are paid as a lump sum and actually should reject as unprocessable if submitted as a rental (RRRB).
Response – There have been no changes in the process. Please submit 3-5 claim examples to your council POE rep for further research.

11. When should the KE modifier be used on wheelchair accessories and for what date of service span. Cares Act (reference CR 11784 May 8, 2020)?
Proposed response – Please contact your individual DME MAC for guidance. For example, suppliers in Jurisdictions B and C may use the KE/KY Modifier Tool on the CGS website.

Respiratory Care Equipment/Oxygen/PAP/Other

12. If the sleep test does not specify how the test was scored (3% or 4%), are we safe to interpret it as being scored at 4%?
Response – The DME MAC review staff do not assume that the sleep test was scored according to Medicare criteria. Suppliers are encouraged to assure that sleep tests scoring criteria are specifically noted on the sleep test report. If omitted, an addendum may be requested from the interpreting physician and included in the medical record.

13. Are there any considerations or discussions within the DMEMACS and CMS about allowing the 3% desaturations to be considered?
Response – No.

14. If a sleep study does not denote the scoring methodology, but in calculating the number of obstructive apneas per hour of sleep time, the HME supplier can see that the "apnea index" is between 5 and 15 or greater than 15 (obstructive apneas/total sleep time)* 60 minutes, would the sleep study need to be "rescored" by the interpreting physician to document the methodology?
Response – See #12. The interpreting physician can rescore the sleep test or add an addendum that discusses the scoring methodology used to determine AHI.

15. In an effort to be able to educate sleep labs and physicians and provide clarity on the FAQ from March 2023, can the beneficiary qualify for nocturnal oxygen based on oxygen saturation recorded on a home sleep study, PSG, if it is determined that the patient's overall AHI is less than 5, and OSA has been ruled out?
Response - When referring to "overnight oximetry", the LCD is definitionally only referring to stand-alone oximetry continuously recorded overnight. This definition does not include oximetry that is part of other overnight testing, such as a home sleep test. The LCD also notes that oximetry performed as part of home sleep testing or as part of any other home testing is NOT considered to be eligible to be used for qualification for home oxygen and oxygen equipment. Oximetry obtained during a PSG in a lab is allowable (if OSA was ruled out during the diagnostic portion or the OSA is sufficiently treated during the titration portion).

Documentation/Education/ Home Medical Equipment/CEDI

16. CMS posted a list of approved telehealth CPT codes and the list includes several codes identified as audio only (https://www.cms.gov/files/zip/list-telehealth-services-calendar-year-2023.zip). For the purpose of ordering and supporting DMEPOS, do the DME MACs require all telehealth visits to have both visual and audio components? What, if any, restrictions apply to DMEPOS services that are supported by audio only visits?
Response – Evaluations conducted using CMS-approved methods of telehealth are acceptable for supporting that an item of DMEPOS is reasonable and necessary, as long as all of the coverage criteria are met and sufficiently documented via an audio-only encounter.

17. If a physician prescribes a walker and wheelchair on the same order, but the medical records support the Medicare requirements are met for the wheelchair and not the walker, will the mere presence of the walker on the same order be grounds for denial of the wheelchair? If yes, would the supplier have to submit proof that both items were not provided simultaneously, or if they were provided, must the supplier submit an ABN to confirm the patient has accepted financial liability for the walker?
    Response – The specific presence of a walker and a manual wheelchair on the same order does not cause an automatic denial of the either the walker or the manual wheelchair. Recall the Manual Wheelchair Bases LCD (L33788) coverage criteria states the "beneficiary's mobility limitation cannot be sufficiently resolved by the use of an appropriately fitted cane or walker." It would be in the best interest of the DME supplier to get an ABN for the walker since both the LCD and the NCD prohibit the medical necessity of more than one mobility device at a time.

18. If a non-clinician (e.g. a social worker or licensed social worker) documents support for a product or supply based on patient interactions and visits to the home, if the MD signs in agreement, will Medical Reviewers accept the augmented notes because of the physician's signature and affirmation? Are there any clinical professionals (e.g. RT, LPN, MA, discharge planners, etc.), that create notes in the patient file, whose narratives would be deemed unacceptable even if it is subsequently signed and supported by the physician?
    Response – CMS *Program Integrity Manual* Ch. 5, Section 5.9 -The patient's medical record is not limited to the physician's office records. It may include hospital, nursing home, or HHA records and records from other health care professionals. Medical review staff will use the totality of the beneficiary's medical record, authenticated by the treating practitioner, to make a reasonable and necessary determination. Suppliers are reminded of CMS *Program Integrity Manual* guidance regarding medical records: …*neither a physician's order… nor a supplier prepared statement nor a physician attestation by itself provides sufficient documentation of medical necessity, even though it is signed by the treating physician or supplier. There must be information in the patient's medical record that supports the medical necessity for the item…*