Jurisdictions B, C, and D All Council Combined Questions

August 2022

Documentation/Education/Home Medical Equipment/CEDI

1. Accreditation must match your products on your CMS855/PECOS per MLN Fact Sheet MLN905710:

   Which product categories currently have edits to deny vs. informational edits?

   DME MAC response: Currently an informational message is included on the remittance advice if the supplier is not properly accredited by a CMS-approved AO. There are other edits that apply to OR01 Orthoses: Custom Fabricated and OR02 Orthoses: Prefabricated (Custom Fitted) when there are specific state requirements for the use of a licensed/certified orthotist or prosthetist. Those edits were addressed in the November 2021 council questions.

Enteral/Parenteral/IV Therapy

2. Is there information that a provider can provide on a claim (perhaps in the narrative) that would enable the MACs to pay the full amount billed when the prescribed drug exceeds the MUE?

   DME MAC response: The purpose of a medically unlikely edit (MUE) is to allow review of clinical documentation in the appeals process when an item exceeds the normal usage. A narrative would not accomplish that review.

3. Can the DME Macs all agree to pay up to the MUE limit on the initial processing of a claim and then allow suppliers to appeal those over the MUE?

   DME MAC response: MUE editing is only one factor in claims processing. During a TPE review, the reviewer may determine the number of units allowed based on information in the medical record. However, suppliers should utilize the appeals process to provide additional documentation to support medical necessity in the case of a denial due to exceeding the number of services allowed.

4. Noted that CGS will deny the entire claim when units are prescribed beyond the MUE and will only pay up to the MUE upon redetermination. To receive payment from CGS beyond the MUE, our claims must be taken to reconsideration. Noridian does not process their appeals this way. Can CGS reexamine its position on approving units billed beyond the MUE in redetermination?

DME MAC response: CGS is currently processing redeterminations in the same manner as Noridian. Questions for a specific contractor should be addressed with that contractor.

5. Do medically unlikely edits (MUEs) apply to lipids that are prescribed within the limits described in the current Parenteral Nutrition LCD?

"The treating practitioner must document the medical necessity for protein orders outside of the range of 0.8-2.0 gm/kg/day (B4168, B4172, B4176, B4178), dextrose concentration less than 10% (B4164, B4180), or lipid use per month in excess of the product-specific, FDA-approved dosing recommendations (B4185, B4187)."

B4185 is used for all FDA approved lipids, with the exception of Omegavan (B4187), and each product has specific dosing that can vary for example:

Prescribed dosing range for:

Intralipid	1.0 gm/kg body weight /day
Smoflipid (4 oil)	1-2 gm/kg body weight /day
Clinolipid (2 oil)	1-1.5 gm/kg body weight/day

TABLE 1. ADULT ILE DAILY DOSING RECOMMENDATIONS[2-7]

ILE	SO-ILE	SO,MCT,OO,FO-ILE	OO,SO-ILE
Oil Source	100% soybean oil	30% soybean oil, 30% MCT oil, 25% olive oil, 15% fish oil	80% olive oil, 20% soybean oil
Recommended Dose	Critically ill: <1g/kg/d Stable: 1 g/kg/d	1-2 g/kg/d	1-1.5 g/kg/d
Maximum Dose	2.5 g/kg/d	2.5 g/kg/d	2.5 g/kg/d
Maximum Infusion Rate	0.11 g/kg/h	0.11 g/kg/h	0.11 g/kg/h

Abbreviations: ILE, lipid injectable emulsion; OO,SO-ILE, olive oil, soybean oil ILE—Clinolipid® (Baxter Healthcare Corporation); SO,MCT,OO,FO-ILE, soybean oil, medium-chain triglycerides, olive oil, fish oil ILE—SMOFLipid® (Fresenius Kabi); SO-ILE, soybean oil ILE—Intralipid® (Baxter Healthcare Corporation), Nutrilipid® (B. Braun Medical, Inc).

PN Dosing 1-Sheet-Nov 2020-FINAL.pdf (nutritioncare.org)

DME MAC response: Not all editing is made public. Suppliers are reminded that there is CMS publication of some MUE editing that can be found on the Medically Unlikely Edits | CMS portion of the CMS website. In the event a claim is denied, suppliers may appeal with the medical documentation supporting the items provided and billed. The beneficiary's medical record must adequately document the specific condition and the necessity for the special nutrient as well as the amount necessary.

Medical Supplies/Ostomy/Urological/Diabetic Supplies

6. Current CMS policy does not cover collection pouches for beneficiaries with spontaneous fistulas.

   Despite available products, Medicare/Medicaid, home care, and/or long-term care coverage for fistulas is limited to only fistulas that are caused or treated by a surgical procedure. Products for spontaneous fistulas are not covered.

   Many products currently utilized for ostomy management could be effective for the management of spontaneous fistulas however the Ostomy Supplies policy article (A52487) clearly indicates that ostomy products are covered for "beneficiary with a surgically created opening (stoma) to divert urine, or fecal contents outside the body. Ostomy supplies are appropriately used for colostomies, ileostomies, or urinary ostomies. Use for other conditions will be denied as "noncovered." Likewise, HCPCS A6154 (wound pouch) under the Surgical Dressing article (A54563) could be effective in managing fistula drainage but the policy article states that it is not covered for "drainage from a cutaneous fistula which has not been caused by or treated by a surgical procedure". These limitations deny coverage to beneficiaries who need effective products for treatment.

   We ask that the DMD's please provide clarification as to why spontaneous fistulas are currently non covered by Medicare? and what treatment options (if any) are recommended for proper drainage management of spontaneous fistulas? We understand this may require an LCD Reconsideration but wanted to get the Med. Directors thoughts on it?

   DME MAC response: This is a benefit category issue. Ostomy supplies are covered under the Prosthetic benefit per Social Security Act, section 1861(s)(8) prosthetic devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care). An ostomy is a surgically created artificial opening which is not equivalent to a spontaneous fistula; therefore, spontaneous fistulas do not meet Medicare benefit category requirements. With respect to the question of an LCD reconsideration, this avenue is not available since this is not a "reasonable and necessary" determination by the DME MACs.

Prosthetics/Orthotics

7. Status of the PCC first model. The Primary Care First Model was introduced, and at this time we are not aware of a pathway to allow enrollment on an annual basis, so physicians are unable to enroll. Have you received communication from CMS on this process?

   DME MAC response: The DME MACs have not received any additional communication on this demonstration model. For questions about the model or solicitation process, please email PrimaryCareApply@telligen.com or call 1-833-226-7278 or refer to this website link: Primary Care First Model Options | CMS Innovation Center.

8. Verifying the order of signing the attestation, when "incident to" has allowed NP/PA to sign, the MD/DO needs to co-sign notes. Does the date the MD/DO signs matter or is it just prior to dispensing?

DME MAC response: The supervising physician should sign and date the document, and the beneficiary's medical record should reflect that the "incident to" requirements have been met. Please refer to Benefit Policy Manual, publication 100-02, Chapter 15, Section 60.1, cited in Question 9 below.

9. Regarding the "incident to" requirement, is there actually a time frame in which the patient needs to have seen the supervising physician who "has been and continues to provide follow-up care" under the "NP/PA incident to" provision?

DME MAC response: The Medicare *Benefit Policy Manual* (CMS Pub. 100-02), Chapter 15, Section 60.1 notes the following:

> *Where a physician supervises auxiliary personnel to assist him/her in rendering services to patients and includes the charges for their services in his/her own bills, the services of such personnel are considered incident to the physician's service if there is a physician's service rendered to which the services of such personnel are an incidental part and there is direct supervision by the physician. This does not mean, however, that to be considered incident to, each occasion of service by auxiliary personnel (or the furnishing of a supply) need also always be the occasion of the actual rendition of a personal professional service by the physician.* ***Such a service or supply could be considered to be "incident to" when furnished during a course of treatment where the physician performs an initial service and subsequent services of a frequency which reflects his/her active participation in and management of the course of treatment****.* [Emphasis Added]

Rehab Equipment

10. Situation: A Hospital-owned DME supplier uses the services of OTs/PTs who are employed by that same facility to do specialty evals for complex power and manual wheelchairs. In the PMD policy article there is an exception noted as part of the Face-to-Face exam. "Exception: if the supplier is owned by a hospital, the PT or OT working in the inpatient or outpatient hospital setting may perform part of the face-to-face encounter." This exception is not included in the manual WC LCD-maybe because there is no requirement for a F2F, even though complex chairs K0005 and E1161 require the same specialty exam. Recently there have been several ADMC denials for the financial relationship between the supplier and therapist in this scenario. Is this exception only applicable to PMD's or was this an oversight in the manual wheelchair policy?

DME MAC response: The exception is specific to the power mobility device policy article; however, we appreciate the comment and will consider adding this exception to the manual wheelchair policy article.

11. Suppliers would like some clarification on when a wheelchair option or accessory is eligible for repair or replacement (due to wear and tear or damage) once it is out of warranty, vs which options and accessories are subject to the 5-year RUL (considered the same as the base equipment). Recently, CGS included code E0958 (one-arm drive attachment) as an example in a presentation as being billable with the RB modifier, as well as CGS' Advanced Modifier Engine showing the RB modifier as an option for that component. Q: is there any rule that would help identify when an option or accessory is subject to the 5-year RUL? Examples: K0195 or E0990 elevating leg rests; E0958 one arm drive, E0986 power assist device, E0973 adj detachable arm assemblies. Also, if the part is billable as a repair with the RB modifier, is it appropriate to bill for the actual labor (K0739) associated with that repair/replacement?

    DME MAC response: Unless otherwise specified in the policy, all DME is subject to the five-year reasonable useful lifetime (RUL). In addition, if the part is billable as a repair with the RB modifier, it would be appropriate to bill for the labor associated with the repair/replacement.

12. Suppliers are having difficulty with claims processing when billing multiple units of E1028 as capped rentals. Denials are happening after about 6 months instead of each E1028 paying the full 13 months. It appears that processing systems may be maxing at a total of 13 units vs 13 claims for each item coded as E1028. Currently these denials are being sent thru redeterminations for correction. Are the MACs aware of this and is anything being done to correct this? CCNs can be provided.

    DME MAC response: This issue was identified in 2019 and the DME MACs have processes in place to identify and correct claims impacted. If we were unable to identify this circumstance on a claim and it resulted in denial, redetermination would be the appropriate action. Examples would be needed for evaluation and should be addressed with the specific contractor.

    As a suggestion from the DME MACs, the wheelchair industry may wish to obtain data and approach the CMS HCPCS Workgroup with a coding proposal to create new codes for the most common items currently classified under HCPCS code E1028.

Respiratory Care Equipment/Oxygen/PAP/Other

13. There are several providers utilizing home sleep testing for diagnostic qualification for OSA and PAP Therapy. The AASM (American Academy of Sleep Medicine) references the following:

    Home sleep test kits are being more frequently used to diagnose sleep apnea. Most of the available home sleep apnea testing devices do not directly measure sleep as they don't have EEG electrodes to monitor brain waves or neural activity. At the advent of home sleep testing, home sleep tests provided only the ‘recording time’, relying on the assumption that people are sleeping while using the device (and thus overestimating AHI). Almost all newer home sleep testing devices today estimate the actual sleeping time by discarding segments that the patient is not estimated to be asleep. Since these devices still do not measure ‘sleep’ directly, some experts in the field still argue that "AHI" is not the best term to use on a home sleep study report because we don't actually measure the denominator. Thus, the AASM created a new term

specific to home sleep apnea tests that do not directly measure ‘sleep’: the "respiratory event index" or REI. The denominator of the REI is based on Total Monitoring Time: REI = (total apneas + total hypopneas)/ Total Monitoring Time in hours. In addition to having created REI as a surrogate AHI for airflow based HSAT, the AASM also created the term ‘pAHI’ to refer to an REI measurement for an HSAT based on peripheral arterial tone (PAT).

Some of our providers include the following information in the interpretation of the home sleep test results:

The sleep event scoring was based on the AASM Manual for the Scoring of Sleep and Associated Events: Rules, Terminology and Technical Specifications, Version 2.6. www.aasmnet.org, Darien, Illinois: American Academy of Sleep Medicine, 2020. Apneas are defined as a drop in the peak thermal sensor excursion by > 90% of baseline for at least 10 seconds. Hypopneas were scored using the 4% oxygen desaturation rule and a decrease in the nasal pressure excursions by > 30% of baseline for at least 10 seconds. A respiratory event index (REI) in the setting of unattended home sleep apnea testing is defined as the combination of apneas and hypopneas divided by the total recording time minus any artifact time and the time that the patient was estimated to be awake and is expressed as events per hour. REI is frequently used interchangeably with the Medicare apnea-hypopnea index (AHI) and Medicare respiratory disturbance index (RDI

There is conflicting information between both DMACs. Noridian has indicated over numerous educational events, REI is not acceptable. CGS has indicated that REI calculations is acceptable. In addition, A and B MAC sleep study policies cover peripheral arterial tone when used to aid in the diagnosis of OSA in beneficiaries who have signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility. HSAT devices with pAHI have been accepted by both DME MACs despite it being an REI based on Monitoring Time.

Is the REI calculation (including the ‘pAHI’ as a surrogate for REI) acceptable to use for the initial coverage requirements because the PAP LCD guidelines only indicate AHI and RDI are acceptable methods for scoring sleep studies?

DME MAC response: Going forward both Noridian and CGS will be accepting respiratory event index (REI). Please note that this acceptance assumes that the calculation excludes respiratory event related arousals (RERAs). RERAs are not recognized by CMS or the DME MACs.