Final

Jurisdictions B, C and D Councils Combined A-Team Questions
July 2014

Enteral/Parenteral/IV Therapy

1. If an initial DIF has been submitted for a patient receiving enteral therapy via gravity or syringe and the patient is subsequently switched to a pump & the **calories increase**, should the supplier complete a new initial DIF for the pump only and a revised DIF for the enteral nutrition? In other words, are two "active" DIF's required under these circumstances?

   Response:
   JB: National Government Services is researching to determine proper DIF submission in this situation.
   JC: The supplier may complete a single Revised DIF that includes both the increase in calories and the change to the method of administration (i.e., going from gravity or syringe to the pump).
   JD: Noridian does require a new initial for the pump (so we can keep track of the number of rentals) and a revision for the nutrition indicating the increase in calories and the change in the method of administration to a pump.

2. If an initial DIF has been submitted for a patient receiving enteral therapy via gravity or syringe and the patient is subsequently switched to a pump & the **calories remain the same**, should the supplier complete a new initial DIF for the pump only and a revised DIF for the enteral nutrition? In other words, are two "active" DIF's required under these circumstances?

   Response:
   JB: National Government Services is researching to determine proper DIF submission in this situation.
   JC: If a revised DIF is submitted notating a change in administration we can use this DIF to also set up the pump.
   JD: Yes, a revised DIF for the method of administration (pump) for the nutrition and a new initial DIF for the pump.

Education

3. Is there any way for a DME Provider to check in PECOS or NPPES or any other system or report to see if a physician is eligible to prescribe/order DMEPOS? The CMS listing of Practitioners enrolled in PECOS does not provide any additional information such as start or stop dates. The separate list of Practitioners eligible to prescribe PMDs is helpful, if accurate.

Response: The CMS has provided the Medicare Ordering and Referring Files for this purpose. Only physicians and non-physician practitioners who are eligible to order/refer will be listed on the Medicare Ordering and Referring File. If the ordering/referring physician and non-physician practitioner name appears on the file at the time of claim submission, the supplier's claim will pass the PECOS ordering/referring edit – regardless of when the practitioner enrolled. If the ordering/referring physician is not listed on the PECOS file, the supplier's claim will be not pass the PECOS ordering/referring edits.

A separate file titled, Medicare Ordering and Referring PMD File is also available identifying those physicians and non-physician practitioners that are eligible to order and refer PMD and have a current enrollment record in Medicare. If supplying a PMD, the supplier should ensure that the ordering/referring physician is of the type eligible to order/refer based upon that file. Both files are located at http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/MedicareOrderingandReferring.html.

In addition, the supplier must also ensure that the ordering/referring physician meets the requirements outlined in the Power Mobility Devices LCD and related Policy Article. Specifically, the requirement that podiatrist are prohibited from ordering power mobility devices.

Oxygen

4. According to the LCD for Oxygen and Oxygen Equipment section on Testing and Visit Requirements, the "blood gas study must be the most recent study within 30 days prior to the **Initial Date**" and the "beneficiary must be seen and evaluated by the treating physician within 30 days prior to the "date of **Initial Certification**." (emphasis added) The LCD says the "Initial Date" refers to the date reported in Section A of the CMN, while the instructions for Form CMS-484 (09/05), the Home Oxygen Certificate of Medical Need, state that the date to be placed in the Initial Date in Section A is the date oxygen is "needed initially."

   The LCD section on Policy Specific Documentation Requirements appears to have a different requirement because it states the testing and visitation requirements as "qualifying test results done within 30 days before the initial date of service" and "an in-person visit with a treating physician within 30 days before the initial date of service."

   a. What is the difference between the terms "Initial Date," "date of Initial Certification," and "initial date of service" as used in the LCD?

      Response: The "Initial Date," "date of Initial Certification," and "initial date of service" are referring to the date reported in Section A of the CMN as the Initial Date; the date the oxygen is "needed initially." Per PIM 100-08, chapter 5, section 5.3.1, The "Initial Date" found in Section A of the CMN, should be either the specific

date that the physician gives as the start of the medical necessity or, if the physician does not give a specific start date, the "Initial Date" would be the date of the order.

b. Does the blood gas study and the in-person visit need to be completed within 30 days prior to the date of delivery of the oxygen equipment?

Response: No. They must be completed within 30 days prior to the Initial Date in Section A on the CMN. Per PIM 100-08, Chapter 5, Section 5.3.1, The "Delivery Date/Date of Service" on the claim must not precede the "Initial Date" on the CMN or DIF or the start date on the written order. To ensure that an item is still medically necessary, the delivery date/date of service must be within 3 months from the "Initial Date" of the CMN or DIF or 3 months from the date of the physician's signature. The actual delivery of the oxygen may occur at any time but may not be billed before the Initial date and may only be billed after the oxygen and equipment have been delivered.

If the answer to b. is yes, when did the DMAC or CMS first announce this change to the supplier industry? (Please provide the name of the instruction document and the date)

5. For oxygen conserving devices, physicians often write the settings on the order for the device in terms of liter flow. Is this acceptable?

Response: Yes, this is acceptable. As a reminder, detailed written orders require:
• Beneficiary's name
• Physician's name
• Date of the order and the start date, if start date is different from the date of the order
• Detailed description of the item(s) (see below for specific requirements for selected items)
• Physician signature and signature date

For items provided on a periodic basis, including drugs, the written order must include:
• Item(s) to be dispensed
• **Dosage or concentration, if applicable [For oxygen, this would be liter flow]**
• Route of Administration
• Frequency of use
• Duration of infusion, if applicable
• Quantity to be dispensed
• Number of refills, if applicable

Also, an order is necessary only for separately billed items. An oxygen conserving device, should a supplier choose to use this technology, is included in the bundled

payment for the oxygen therapy; therefore, an order that specifically includes an oxygen conserving device is not necessary.

6. Now that stationary Oxygen contents require a F2F and WOPD, we are unsure exactly what documentation we need before we start billing for stationary contents separately in the 37th month. We have never been required to get a separate order for contents at setup. Because it is a therapy CMNs for contents were based on the billed portable or stationary unit being liquid or gas. The bigger question is do we need a new order at 36/37 months for contents along with a new FTF, or if we add it at setup does that allow us to transition without a new order/FTF?

   Response: It has been a long-standing Medicare requirement that there must be an order for all separately-billable items; therefore, this is not a "new" requirement to obtain an order for the billing of contents. Consequently, a WOPD must include a detailed description of all items that will be separately billed to Medicare – including any separately payable oxygen contents expected to be billed during months 37-60. This means that:

   - If the initial written order for oxygen and oxygen equipment included oxygen contents and assuming the original written order did not include a time-limited length of need, a new WOPD for oxygen contents will not be required when the supplier begins billing for oxygen contents for months 37-60.
   - If the initial written order for oxygen equipment did not specify oxygen contents, a new WOPD for oxygen contents will be required when the supplier begins billing for the contents during months 37-60. The new written order must meet all applicable policy requirements, including requirements tied to the Affordable Care Act (e.g., an in-person, face-to-face examination documenting the need for the item sometime during the six months prior to the order for, and delivery of, the item).

PAP/Other Respiratory Care Equipment

7. When a patient has a sleep study that is ten plus years old which qualified for PAP therapy at the time of the initial order but a signature on the sleep study was not required, patient compliance is appropriate and all documentation from current face to face visits with MD supports continued use, does the patient need to have a repeat sleep study because the sleep study interpretation was not signed? Can the original sleep study interpretation be signed at present date and if the original physician is no longer in that practice, can a physician within that practice sign it? (Does the fact that the sleep study is older than 7 years matter due to the fact that the study is eligible for archive? What evidence does the supplier have to produce when the study is archived?)

   Response: In this response, the DME MACs assume that the question refers to a sleep study and initiation of PAP therapy that was conducted prior to Medicare eligibility.

According to CMS signature requirements, to be valid for medical necessity purposes, there must be a signature on the sleep study interpretation. Without a signature, there is no valid sleep study. Unless the supplier can obtain a signature attestation from the original physician, the test may not be used.

8. If a sleep study is conducted in a sleep lab located in a hospital which is accredited by the Joint Commission, does the physician reading for the in-patient hospital need to be board certified or eligible in sleep medicine? The LCD for PAP therapy is very specific but the LCD (L32711) for outpatient sleep studies lists in one area that the facility-based clinic must be under the direction and control of physicians that are board certified or eligible in sleep medicine and in another section states the requirement is that the facility must have a medical director with a valid license in the state of the center and be accredited by AASM, The Joint Commission or ACHC.

   Response: While there may be differences between the PART A or B LCDs and the DME MAC LCDs for PAP, the DME MAC coverage, coding, and payment rules take precedence. The sleep test interpretation credentials in the DME MAC LCD must be met in order for PAP and supplies to be covered.

9. PAPs are on the F2F list and require a WOPD, but the accessories/supplies do not. At the time the physician is ordering the PAP, he/she may not know exactly which type of mask the patient will use. Would it be acceptable for the PAP WOPD to list a generic description for the mask, as long as a valid DWO for the actual supplies was obtained prior to billing?

   Response: Yes.

10. Are there any recommendations for enabling claims for a second, medically necessary, ventilator to be paid without having to go through appeal? When it is not a backup ventilator but a ventilator that is placed on the back of a wheelchair for the patient to be able to get up and out of bed. Is there a modifier or any narrative that would help in this situation?

    Response: As noted in the April 2014 publication entitled "Correct Coding and Coverage of Ventilators":

    COVERAGE OF SECOND VENTILATOR

    Medicare does not cover spare or back-up equipment. Claims for backup equipment will be denied as not reasonable and necessary - same/similar equipment.

Backup equipment must be distinguished from multiple medically necessary items which are defined as, identical or similar devices each of which meets a different medical need for the beneficiary. Although Medicare does not pay separately for backup equipment, Medicare will make a separate payment for a second piece of equipment if it is required to serve a different purpose that is determined by the beneficiary's medical needs.

The following are examples of situations in which a beneficiary would qualify for both a primary ventilator and a secondary ventilator:

- A beneficiary requires one type of ventilator (e.g. a negative pressure ventilator with a chest shell) for part of the day and needs a different type of ventilator (e.g. positive pressure ventilator with a nasal mask) during the rest of the day.
- A beneficiary who is confined to a wheelchair requires a ventilator mounted on the wheelchair for use during the day and needs another ventilator of the same type for use while in bed. Without two pieces of equipment, the beneficiary may be prone to certain medical complications, may not be able to achieve certain appropriate medical outcomes, or may not be able to use the medical equipment effectively

When the claim for a primary and secondary ventilator is billed correctly, it will process through the system. Suppliers billing a second ventilator should follow these instructions:

- Submit both ventilator codes on the same claim but on different claim lines. This is true even when the supplier is providing two of the same HCPCS code.
- Enter the reason for medical necessity of the secondary ventilator in the NTE segment of the electronic claim, or for paper claim submitters, in Item 19 on the CMS-1500 form. For example, the claim would include a statement explaining that the beneficiary is ventilator-dependent and why the patient needs two different ventilators (e.g., requires one on a wheelchair and the other at the bedside).

Prosthetics/Orthotics

11. O & P in a SNF: A SNF patient that is in need of an orthopedic product: their physician writes an order for him/her to be evaluated by PT/OT for a specific reason (i.e. foot drop) and the therapist evaluates patient and recommends that they would benefit from an AFO (and includes all of the coverage criteria set forth by Medicare). Then the physician would write that he/she concurs with the therapist's evaluation and writes an order for an AFO. Is this appropriate?

    Response: This is acceptable; however, there is no requirement that the physician write "I concur" on the PT/OT evaluation. Medical record documentation should support

payment of the item ordered. If the item is provided to a beneficiary in a Part A covered stay, payment for the item will be bundled into the SNF Part A payment. The supplier must make arrangements with the SNF to obtain their payment and may not submit a separate claim to Medicare.

12. O & P at home: A PCP evaluates a patient for drop foot. Notates in his/her chart notes that patient should be evaluated by an Orthotist to determine the most appropriate AFO for patient. Patient is seen by an Orthotist and he/she makes the recommendation for the AFO and sends to the referring PCP for review. Then the PCP writes that he/she concurs with the evaluation and writes the order for the recommended AFO. Is this appropriate?

    Response: The PCP examination and documentation in the medical record must support that the specific AFO ordered by the PCP is reasonable and necessary. For example, the AFO LCD stipulates that for custom fabricated items, there must be detailed documentation in the treating physician's records to support the medical necessity of custom fabricated rather than a prefabricated orthosis. This information will be corroborated by the functional evaluation in the orthotist or prosthetist's records.

    The role of the orthotist is to determine the appropriate brand or model of AFO, fit the orthosis and schedule the proper follow-up routine. While it is a good practice for the orthotist to provide their records to the PCP, there is no requirement to do so or for the physician to indicate agreement with the orthotist's recommendation.

Rehab Equipment

13. Providers are continuing to have problems with claims for certain WC options/accessories paying incorrectly when submitted with the KY modifier for use on complex rehab bases for beneficiaries who live in Round 2 CBAs. Has there been any progress in fixing the initial processing for these claims? If there is no update, can providers continue to request re-openings to have claims paid correctly? This is happening in all 4 jurisdictions.

    Response: We have not yet received an update from CMS. Suppliers may continue to request reopenings to have claims paid correctly.

14. A beneficiary needs a replacement seat upholstery code E0981. This beneficiary owns their own manual wheelchair; this wheelchair was funded by Medicare. The beneficiary reports that they are using the wheelchair daily as it had been ordered originally. The seat upholstery ripped from the frame and the chair is not safe or useable, and the beneficiary cannot use their equipment to get to the doctor until the seat upholstery is replaced. E0981 is listed as a HCPCS code requiring a face to face examination.

a. Does this repair need to comply with the new WOPD/F2F requirements?

   Response: We have requested input from the Centers for Medicare & Medicaid Services.

b. If so, this appears to be contrary to the PIM language that indicates no order is needed for a repair

   Response: We have requested input from the Centers for Medicare & Medicaid Services.

c. If the beneficiary wishes to pay out-of pocket to get the replacement seat upholstery immediately, may an ABN be obtained to advise the beneficiary that Medicare will not pay for the repair because it requires the F2F and WOPD?

   Response: We have requested input from the Centers for Medicare & Medicaid Services.

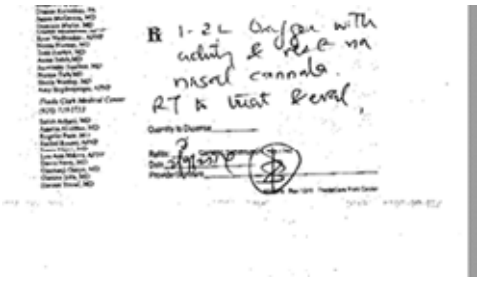
Ostomy/Urological/Medical Supplies

15. Suppliers have received claim denials for transplant medications provided to beneficiaries when it is identified that the transplant did not occur in a "Medicare approved facility". Is there a tool available for a provider to verify if Medicare paid for an organ transplant? How can we be assured that the hospital that did the transplant was "Medicare approved"? Is there a list of "approved" facilities we can review?

    Response: CMS has an approved transplant facilities listing that is located at the following link:
    http://www.cms.gov/Medicare/Provider-Enrollment-and-certification/CertificationandComplianc/Transplant.html

Documentation/Regulatory/Miscellaneous/Other

16. Oxygen Portable gas (E0431) is on the list of items subject to F2F and a written order prior to dispensing (WOPD). Oxygen Therapy also requires a CMN/CMS-484 which can be used as the detailed written order (DWO) if all the elements required are present. It is obtained after discharge but prior to billing. Does the following RX meet the requirements of a WOPD for oxygen portability (E0431 RR) ordered for discharge from a hospital? (Note: patient name, physician name and NPI were not copied but are at the top of the order).



Transcription: 1-2 L oxygen with activity & rest via nasal cannula. RT to treat & eval.

Response: The DME MACs do not review, approve or otherwise comment on the adequacy of any form, note, template or other document used to demonstrate compliance with Medicare rules and regulations. For WOPD, applicable DME MAC LCDs include information about the required contents of the WOPD. As stated in the Oxygen LCD, the WOPD must include all of the elements indicated below. The CMN CMS-484 may serve as the WOPD if it is sufficiently detailed (includes all the elements indicated below) and is obtained by the supplier prior to delivery.

- Beneficiary's name,
- Physician's Name
- Date of the order and the start date, if start date is different from the date of the order
- Detailed description of the item(s)
- The prescribing practitioner's National Provider Identifier (NPI),
- The signature of the ordering practitioner
- Signature date

For any of the specified items provided on a periodic basis, including drugs, the written order must include, in addition to the above:

- Item(s) to be dispensed
- Dosage or concentration, if applicable
- Route of Administration, if applicable
- Frequency of use
- Duration of infusion, if applicable
- Quantity to be dispensed
- Number of refills, if applicable

17. For nebulizer medication claims, the physicians are being educated to list the medication in the medical records. Sometimes we find that the medication will be listed, but the frequency prescribed on the order does not match the frequency listed in the medical record. For instance, a physician prescribes Albuterol 3 times per day, but the medical record says Albuterol QID. Will Medicare accept the medical record as support

of continuing medical need or initial justification of need even if the frequency in the medical record does not match the frequency on the prescription?

Response: The supplier should dispense the medications based upon the information on the order; however, the information on the order must be consistent with the documentation in the beneficiary's medical record. In the event of an audit, discrepancies between the billed amount and the amount described in the medical record will likely result in a claim denial.

18. An oxygen claim is submitted with a GA modifier indicating a valid ABN is on file. The claim is denied but returns a CO denial when the provider was expecting a PR denial. What would cause a CO denial if a valid ABN was on file? When contacting NGS customer service, we have been advised the claim would be reprocessed but we're concerned about the need for additional processing.

    Response: A CO denial may be received in several situations. For example, if the claim was subject to review and the ABN was found to be invalid, the supplier would be assigned liability. If the claim was incorrectly completed or a required CMN or DIF was not submitted the supplier may receive the CO denial. Suppliers should contact the Provider Contact Center of the Jurisdiction that processed the claim to determine the specific reason for denial and liability assignment.

19. Removed from combined questions JB specific

20. Removed from combined questions JD specific

21. We would like clarity and consistency on desk pad prescriptions. The most common format has a space for a date at the top of the prescription pad, and a space for the physician signature at the bottom of the prescription pad. In most cases the date at the top is the only date written on the Rx. When this format of prescription is used as a WOPD, is the date written in on the date line acceptable as both the date of initial need and the physician's signature date?

    Response: The Program Integrity Manual (PIM), Chapter 5, Section 5.2.3 requires that a DWO/WOPD contain Beneficiary identification information, a start date, a listing of all separately billable items, and a prescriber's signature in addition to information about utilization (as applicable) for the prescribed items. This PIM section describes two scenarios:

    1. If the prescriber creates a complete and compliant DWO/WOPD, only a single date - the "start date" - is required. This start date may be the date that the prescriber signs the document (either wet signature or electronic signature)

2. If someone other than the prescriber (e.g., DME supplier) creates the DWO/WOPD then the prescription must be reviewed and, "…personally signed and dated…" by the prescriber. In this scenario two (2) dates are required: a "start date" (for the items use by the physician) and a prescriber-entered "signature date".

22. Is length of need a required element on detailed written orders for all rental equipment? It is included on CMNs and on 7-element TXs for PMDs, but does not seem to be required on other DWOS or DIFs.

    Response: No. Suppliers should refer to the LCD for the specific item they are providing for the order requirements for that item.

23. If a physician orders a capped rental item with a lifetime need; in order to bill the 13th and final month rental, will the supplier need proof of continued medical necessity in their files? If the beneficiary has not had a visit with their physician in the previous 12 months that documented an on-going need for the rental item, would a new prescription/DWO need to be obtained in order to bill the 13th month?
    Response: Yes, they would need proof of continued medical need. As noted in the applicable LCDs, any of the following may serve as documentation justifying continued medical need:

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

    Timely documentation is defined as a record in the preceding 12 months unless otherwise specified elsewhere in the policy. If the requirements above are not met, in the event of an audit, the claim will be denied as not reasonable and necessary.

24. In a joint DME MAC publication, it stated:
    A face-to-face examination is required each time a new prescription for one of the specified items is ordered. A new prescription is required by Medicare for all claims for purchases or initial rentals.
    It goes on to state, "… claims for purchases or initial rentals, includes all claims for payment of purchases and initial rentals for items not originally covered (reimbursed) by Medicare Part B. Claims for items obtained outside of Medicare Part B, e.g. from another payer prior to Medicare participation (including Medicare Advantage plans), are considered to be new initial claims for Medicare payment purposes. This means that all

Medicare payment requirements must be met, the same as any other item initially covered by Medicare."

a. If the patient was evaluated on 12/01/2013 for a wheelchair subject to FTF, and received that equipment while covered under a Medicare HMO, if that patient switches to Medicare FFS a month later on January 1, 2014, would the 12/01/2013 office visit be accepted to comply with the FTF because it is dated within 6 months and there is no indication of a change in medical necessity?

   Response: Yes -- as long as the face-to-face visit met all other requirements (medical condition that required the DME item was discussed during the meeting, the visit was conducted by a MD, DO or other qualified practitioner, etc).

b. Would a new visit be required only in the event that the originating FTF is greater than 6 months at the time of change in insurance?

   Response: Yes -- as long as the face-to-face visit met all other requirements (medical condition that required the DME item was discussed during the meeting, the visit was conducted by a MD, DO or other qualified practitioner, etc).

c. Please confirm that under both scenarios, if it's expected that a new order and proof of delivery would still be required as a result of the change in insurance regardless of FTF applicability?

   Response: A new prescription is needed when:
   • There is a change of supplier
   • There is a change in the item(s), frequency of use, or amount prescribed
   • There is a change in the length of need or a previously established length of need expires
   • State law requires a prescription renewal

   When one of the above requirements triggers a new order on or after July 1, 2013, all ACA requirements must be met.

   Also note that there is no waiver of any Medicare requirements when a beneficiary transitions into Medicare. Items ordered after becoming Medicare-eligible are considered new initial claims and all Medicare documentation requirements must be met.