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

Education/Documentation/Other:

No Questions Submitted

Home Medical Equipment:

1.) On Capped Rental there should be 1 payment as KH and 2 payments as KI. If a KH and/or KI payment is taken back due to SNF, Hospitalization etc., can any subsequent date be billed as a KH or KI? Typically, KJ claims has already processed and paid when this happens.

DME MAC Response – Yes, the KH and/or KI payment may be billed on a subsequent claim when the original KH and/or KI payment is recouped due to an overlapping SNF stay.

Enteral/Parenteral/IV Therapy:

2.) With the MUE edit in place for the maximum quantity on the B4185 lipid code, currently each claim is appealed, due to the administrative burden for both the supplier and the DME MAC, is there a specific time frame that CMS is reviewing the data to turn off the edit?

a.) Secondly, is there opportunity to streamline subsequent claims once a favorable redetermination for the quantity over the limit has been approved? For example, can the DIF be set to approve and pay these quantities for future claims for the beneficiary or can the MUE edit be removed once it has been reviewed and approved at the redetermination level? If that's not possible, would a claim narrative specifying "favorable redetermination DCN# on B4185" help?

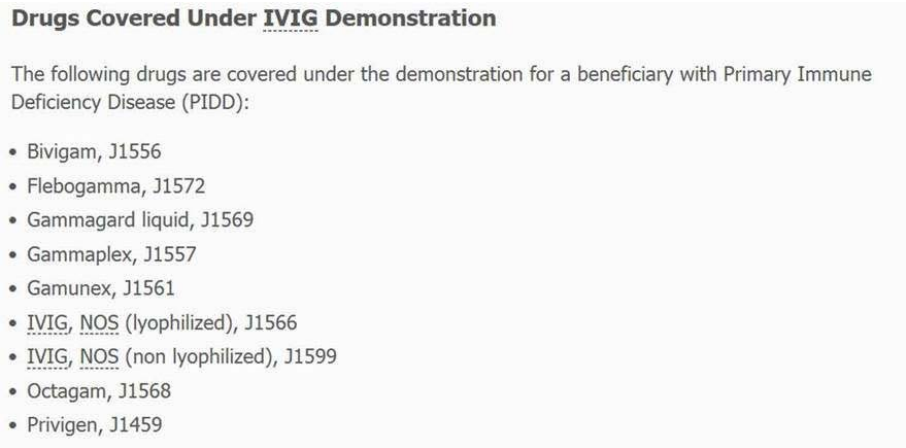
DME MAC Response – CMS posts changes to each of its National Correct Coding Initiative Procedure-to-Procedure (PTP) and Medically Unlikely Edit (MUE) on a quarterly basis. The DME MACs are not tasked to manage the related edits and do not have access to the time frames in which CMS reviews the data related to the edits. Additionally, quantities do change frequently, and as such these claims must be adjudicated as they are billed and justification for on-going need over the MUE limits must be provided.

3.) The IVIG demo provider/supplier information on the Noridian website includes a list of HCPCS and drugs that the demo applies to. The IVIG Demo website lists only Gamunex for J1561, but the IVIG LCD lists both Gamunex C and Gammaked for J1561.

a.) Could you confirm that both Gamunex and Gammaked are covered under the demo?

b.) Would it be possible to update this IVIG demo provider/supplier page to reflect that both are covered?

Screenshot of Demo Page (3/22/2019)



Drugs Covered Under IVIG Demonstration

The following drugs are covered under the demonstration for a beneficiary with Primary Immune Deficiency Disease (PIDD):

- Bivigam, J1556
- Flebogamma, J1572
- Gammagard liquid, J1569
- Gammaplex, J1557
- Gamunex, J1561
- IVIG, NOS (lyophilized), J1566
- IVIG, NOS (non lyophilized), J1599
- Octagam, J1568
- Privigen, J1459

DME MAC Response – Since this particular question surrounds the demonstration project only and is under the supervision of JA, it is not applicable to every DME MAC and should be removed.

4.) Request that the DME MAC's update their transitional home infusion services FAQ's and educational materials to reflect CMS FAQ's on the topic, specifically the intersection of home health and home infusion services. Per CMS FAQ #14 the home infusion service G-codes cannot be billed if there is an active home health episode in place, this conflicts with DME MAC FAQ #1.

Excerpt from CMS FAQs

14. During the two-year temporary transitional payment period (CYs 2019 and 2020), can an eligible home infusion supplier furnish home infusion therapy services, and bill for the temporary transitional payment, to the same patient that is under a home health plan of care, where the home health agency is furnishing care unrelated to the home infusion therapy, such as wound care and physical therapy? No. For the two-year temporary transitional payment period (CYs 2019-2020), home health services covered under the Medicare home health benefit include the in-home services covered under the new home infusion therapy benefit. Therefore, if a patient under a home health plan of care requires in-home skilled services needed for the safe and effective administration of a transitional home infusion drug and the home health agency determines it does not have the staff available to furnish those services as home health services under the home health benefit (and cannot provide such services under arrangement), then the home health agency cannot accept the patient on service or continue to provide other home health services under an existing plan of care. Home health agencies can only accept patients for treatment on the reasonable expectation that the home health agency can meet the patient's medical, nursing, rehabilitative, and social needs in his or her place of residence. Each patient must receive an individualized written plan of care identifying these needs, including any revisions or additions.

Excerpt from DME MAC FAQs

1. Contrary to the Final Rule I am being told by CMS that Home Health Agencies (HHA) can qualify beneficiaries for episodes of care based on their infusion needs. If an HHA is providing the home infusion nursing services under an Episode of Care, can the Home Infusion supplier bill for Home Infusion professional services (that includes pharmacy services)?

Response: Section 50401 of the Bipartisan Budget Act of 2018 (Pub. L 115-123) amended Section 1834(u) of the Social Security Act (the Act) by adding paragraph (7), which requires a temporary, transitional payment be made to **eligible home infusion suppliers** for home infusion therapy services furnished on or after January 1, 2019 until the implementation of the full home infusion therapy benefit, as required by section 5012(d) of the 21st Century Cures Act (Pub. L. 144-255).

Section 1842(u)(7)(F) of the Act requires eligible home infusion suppliers to be Medicare DME suppliers that are enrolled as pharmacies that supply external infusion pumps and supplies in order to receive the home infusion therapy services temporary transitional payment.
Not until the full implementation of the benefit in 2021 will home health agencies have the option of becoming home infusion therapy suppliers.

56406 Federal Register / Vol. 83, No. 219 / Tuesday, November 13, 2018 / Rules and Regulations, states: "The Medicare home infusion therapy benefit covers the professional services, including nursing **services furnished in accordance with the Plan of Care**, patient training and education (not otherwise covered under the durable medical equipment benefit), remote monitoring, and monitoring services for the provision of home infusion therapy and home infusion drugs furnished **by a qualified home infusion therapy supplier**." [Emphasis Added]

§ 486.520(a), requires that all patients must be under the care of an ‘‘applicable provider'' as defined at § 486.505. Section 486.520(b) requires that the qualified home infusion therapy supplier ensure that all patients must have a Plan of Care established by a physician that prescribes the type, amount, and duration of home infusion therapy services that are furnished. The Plan of Care would also include the specific medication, the prescribed dosage and frequency as well as the professional services to be utilized for treatment. In addition, the plan of care would specify the care and services necessary to meet the patient-specific needs.

Section 5012 of the 21st Century Cures Act added section 1861(iii)(3)(D)(i) to the Act that defines the term qualified home infusion therapy supplier as a ‘‘pharmacy, physician, **or other provider of services** or supplier licensed by the State in which the pharmacy, physician, or provider or services or supplier furnishes items or services and that . . . . ‘‘(III) is accredited by an organization designated by the Secretary pursuant to section 1834(u)(5) . . .'' [Emphasis Added]

Medicare *Claims Processing Manual* Chapter 20 - Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS), §180, defines "eligible home infusion suppliers" as: "***a licensed pharmacy*** *that provides external infusion pumps and external infusion pump supplies)."* [Emphasis Added]

It is important to emphasize that the home infusion therapy services temporary transitional payment is separate from the home health benefit. Home infusion therapy is excluded from the Medicare home health benefit, and separately payable, beginning January 1, 2019. As a result of the benefit restrictions, HHAs can neither "qualify" beneficiaries, nor render services and bill under this benefit, since they are not "eligible home infusion suppliers". CMS recognizes that currently home infusion suppliers may contract with HHAs to furnish the nursing services; however, it is incumbent upon the home infusion supplier to negotiate appropriate contract terms in order to only assume responsibility for services related to home infusion therapy.

Resources:
CMS FAQs: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Home-Infusion-Therapy/Downloads/Home-Infusion-Therapy-Services-Temp-Transitional-Payment-FAQs.pdf

DME MAC FAQs: https://med.noridianmedicare.com/web/jadme/policies/dmd-articles/2019/frequently-asked-questions-temporary-transitional-payment-for-home-infusion-therapy-services-for-cy-2019-and-2020-cr10836

DME MAC Response – The DME MAC home infusion services FAQs are correct and are not in conflict with the CMS FAQs.

Medical Supplies:

No Questions Submitted

Prosthetics/Orthotics:

No Questions Submitted

Respiratory Care Equip/Oxygen:

5.) Continuous Positive Airway Pressure Device (CPAP): In the scenario where the patient has failed compliance during the initial (90 day/3-month) trial period per the published LCD, the patient may "re-qualify" in the following manner: Beneficiaries who fail the initial 12 week trial are eligible to re-qualify for a PAP device but must have both: 1. Face-to-face clinical re-evaluation by the treating practitioner to determine the etiology of the failure to respond to PAP therapy; and, 2. Repeat sleep test in a facility-based setting (Type 1 study).This may be a repeat diagnostic, titration or split-night study. Does the term “requalifying” mean a patient requalifies once they have had a new clinical re-evaluation with the treating physician and a new sleep study? We have been trained by the DME MACs that “requalifying” is a second trial period to allow the beneficiary to become compliant with the PAP device. The first 3 months of PAP rental is considered the initial trial period and if we have to “requalify” the patient again, that we also be another trail period. We feel that the LCD is not clear in this regard. To continue coverage of a PAP device (E0470 or E0601) beyond the first three months, 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. This language is all reflective of the initial 90 day trial period.

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

Face-to-face clinical re-evaluation by the treating practitioner with documentation that symptoms of obstructive sleep apnea are improved; and,

Objective evidence of adherence to use of the PAP device, reviewed by the treating practitioner”

The LCD does not specify that the beneficiary must have a second trial period. It also doesn’t state that suppliers can’t bill with the KX modifier until the end of such a second trial period. The DME MACs appear to be asking suppliers to provide free service to patients while they attempt another trial period and many patients will never become compliant leaving the supplier without payment for the PAP device and supplies for months at a time.

Months 1-3 of the "restart" of the trial period are billed with the KX modifier and appropriate KH or KI modifiers, which is how we have been trained by the DME MACs.

If there has been a change to the PAP LCD, when did this change and where is the change documented? This is a big change in the interpretation of the policy and the industry would need time to implement going forward.

DME MAC Response –Our education since early 2018 has been that, in the event of a failed trial, the supplier should not resume billing the fourth month until the beneficiary becomes compliant. The DME MACs will be publishing a joint article clarifying the billing of the second trial.

6.) If a patient has an inpatient diagnosis of acute exacerbation of COPD, do you automatically deny oxygen ordered upon discharge due to the word acute or are you reviewing the records to see how the patient was managed and that they continue to require oxygen upon discharge to home and allow? Would this also apply to patients admitted due to pneumonia and discharged home with oral antibiotics?

DME MAC Response – The DME MACs do not "automatically" deny oxygen ordered upon discharge. During any review, all documentation provided is taken into consideration in determining coverage. The Oxygen and Oxygen Equipment LCD (L33797) is not diagnosis-driven. Any oxygen claim chosen for review by the DME MAC clinicians during a TPE audit must show how the five (5) coverage criteria have been met in order for Medicare to consider payment.

7.) We are seeing oxygen orders for patients with interstitial lung disease (ILD), which is considered a severe lung disease. However, often the medical records don't document alternative treatment. Based on feedback by the physician community, earlier drug treatment is often too expensive for patients to afford so oxygen appears to be the first viable line of treatment. If that is the case, can such a patient ever qualify for oxygen coverage if an alternative treatment was not tried prior to oxygen?

DME MAC Response –The National Coverage Determination's Manual, Section 240.2(B) Medical Documentation states in pertinent part:

> The treating physician's prescription or other medical documentation **must** indicate that other forms of treatment (e.g., medical and physical therapy directed at secretions, bronchospasm and infection) have been tried, have not been sufficiently successful, and oxygen therapy is still required. While there is no substitute for oxygen therapy, each patient must receive optimum therapy before long-term home oxygen therapy is ordered. [Emphasis added]

Therefore, the documentation submitted in support of medical necessity for the home oxygen therapy must address/indicate that alternative treatment is clinically ineffective or considered and ruled out.

Rehab Equipment:

8.) Condition of Payment Prior Authorization (PA) program: If the beneficiary is in a Skilled Nursing Facility (SNF), and we do not go through COP; if we bill with the valid SNF place of service - will the claim be denied with a PR denial code?

DME MAC Response – All codes subject to the Condition of Payment Prior Authorization (PA) Program must be submitted with a unique tracking number (UTN). If the UTN is not included on the claim for payment or is related to a non-affirmation decision, the DME MAC will deny the claim for failing to meet the prior authorization requirements as a condition of payment. Claims submitted without a UTN will deny with return/reject ANSI code 39 and ANSI remark codes N517 and N704.

CEDI:

No Questions Submitted