National Home Infusion Association

Providing solutions for the home and specialty infusion therapy community

August 12, 2019

The Honorable Seema Verma
Administration
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Verma,

The National Home Infusion Association (NHIA) applauds the Administration for its Patients over Paperwork Initiative and for your ongoing efforts to streamline regulations and reduce administrative burden for health care providers. On behalf of our more than 375 members, we thank you for the opportunity to comment on these important issues.

Home infusion therapy (HIT) is a comprehensive set of goods and services that allow patients with serious infections, congestive heart failure, immunologic diseases, gastroenterological diseases, cancer and other conditions to remain home, away from the risk of hospital acquired infections, where they can resume their personal and professional activities. Home infusion therapy providers routinely provide enteral and parenteral products as part of their service lines.

Home infusion and nutrition support therapies require several important components: the drug or nutrient; the equipment and supplies (durable and disposable) necessary to self-infuse; and a wide array of professional services to prepare and administer the therapy (e.g., case management, medication preparation and compounding, clinical monitoring for adverse events and efficacy, coordination with the patient's other health care HIT suppliers, 24/7 patient support, etc.). Professional services are typically delivered by a multi-disciplinary team, led by the HIT supplier, that includes a physician, home infusion pharmacist, dietitian, nurse, and the patient and his or her caregiver.

NHIA has identified several areas where CMS could make changes to put home infusion patients over unnecessary and duplicative paperwork. Areas for reform include the Detailed Written Order (DWO); the DME Information Form (DIF), Advanced Beneficiary Notice (ABN), Medicare Bill for Denial (BFD), Local Coverage Determinations (LCD), Medically Unusual Edits (MUE), and transitions of care. Below is a summary of the unique challenges HIT suppliers experience in these categories, and some specific recommendations for change.

Detail Written Order

A Durable Medical Equipment (DME) supplier must obtain from the prescribing physician a signed Detailed Written Order (DWO) that outlines the type of therapy, clinical services needed, and all

associated ancillary items. The DWO must be received by the DME supplier before claims can be submitted. The supplier must also obtain a DWO before submitting a claim for DME equipment and any associated options, accessories, and/or supplies that are separately billed. DME infused drugs are considered a supply.

Once the supplier has obtained the necessary documentation to support coverage criteria, the patient is started on the therapy. However, the DME supplier clinician frequently reviews the patient's labs, weight, and response to therapy and may adjust the initial order accordingly. The current documentation guidelines require that the supplier obtain a new signed DWO each and every time there are changes to the order, even for routine and minor adjustments to the therapy. This requirement is extremely cumbersome for suppliers and physicians alike and can delay therapy changes. For example:

> For covered therapy under the Enteral Nutrition benefit, there may be formula substitutions due to "out of stock/shortages" which remain in the same HCPCS code but result in a slight increase or decrease of calories, or due to monitoring weight and labs the order may increase or decrease calories slightly on a regular basis. The method and route of administration do not change, only the number of calorie units to be billed as the formula change remains in the same HCPCS code category (See table below for descriptions B4150 – B4155). A prescription for these changes is obtained either by signed RX or verbal order taken by clinician. There are no changes to the HCPCS codes being billed.
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> In this scenario, the underlying HCPCS codes do not change. But because of modifications to the dosage or formula, current rules require DME suppliers to obtain and submit a new DWO. This process takes time and could delay needed modifications to therapy.

B4150	ENTERAL FORMULA, NUTRITIONALLY COMPLETE WITH INTACT NUTRIENTS, INCLUDES PROTEINS, FATS, CARBOHYDRATES, VITAMINS AND MINERALS, MAY INCLUDE FIBER, ADMINISTERED THROUGH AN ENTERAL FEEDING TUBE, 100 CALORIES = 1 UNIT
B4152	ENTERAL FORMULA, NUTRITIONALLY COMPLETE, CALORICALLY DENSE (EQUAL TO OR GREATER THAN 1.5 KCAL/ML) WITH INTACT NUTRIENTS, INCLUDES PROTEINS, FATS, CARBOHYDRATES, VITAMINS AND MINERALS, MAY INCLUDE FIBER, ADMINISTERED THROUGH AN ENTERAL FEEDING TUBE, 100 CALORIES = 1 UNIT
B4153	ENTERAL FORMULA, NUTRITIONALLY COMPLETE, HYDROLYZED PROTEINS (AMINO ACIDS AND PEPTIDE CHAIN), INCLUDES FATS, CARBOHYDRATES, VITAMINS AND MINERALS, MAY INCLUDE FIBER, ADMINISTERED THROUGH AN ENTERAL FEEDING TUBE, 100 CALORIES = 1 UNIT
B4154	ENTERAL FORMULA, NUTRITIONALLY COMPLETE, FOR SPECIAL METABOLIC NEEDS, EXCLUDES INHERITED DISEASE OF METABOLISM, INCLUDES ALTERED COMPOSITION OF PROTEINS, FATS, CARBOHYDRATES, VITAMINS AND/OR MINERALS, MAY INCLUDE FIBER, ADMINISTERED THROUGH AN ENTERAL FEEDING TUBE, 100 CALORIES = 1 UNIT
B4155	ENTERAL FORMULA, NUTRITIONALLY INCOMPLETE/MODULAR NUTRIENTS, INCLUDES SPECIFIC NUTRIENTS, CARBOHYDRATES (E.G., GLUCOSE POLYMERS), PROTEINS/AMINO ACIDS (E.G., GLUTAMINE, ARGININE), FAT (E.G., MEDIUM CHAIN TRIGLYCERIDES) OR COMBINATION, ADMINISTERED THROUGH AN ENTERAL FEEDING TUBE, 100 CALORIES = 1 UNIT

> For covered therapy under the Parenteral Nutrition (PN) benefit, there are frequent changes to the patient's order for proper nutritional management of the patient. These changes may be volume (total quantity of solution) changes, dextrose changes, or changes in grams of protein (Amino Acids) that stay within the same HCPCS code range (example see code descriptions B4189 – B4199) and/or changes in the grams of lipids ordered. These may change on a weekly

or even daily basis depending on review of the patient labs. A prescription is received, and documentation for the change is supported by the patient's lab evaluations. With PN, there may be changes in the units billed for the lipid increase or decrease or the days per week, but there are no changes to the HCPCS codes being billed in this scenario. Again, with each adjustment to the patient's formula, a new DWO must be prepared and signed off by the physician and sent to the supplier.

B4185	PARENTERAL NUTRITION SOLUTION, PER 10 GRAMS LIPIDS
B4189	PARENTERAL NUTRITION SOLUTION; COMPOUNDED AMINO ACID AND CARBOHYDRATES WITH ELECTROLYTES, TRACE ELEMENTS, AND VITAMINS, INCLUDING PREPARATION, ANY STRENGTH, 10 TO 51 GRAMS OF PROTEIN - PREMIX
B4193	PARENTERAL NUTRITION SOLUTION; COMPOUNDED AMINO ACID AND CARBOHYDRATES WITH ELECTROLYTES, TRACE ELEMENTS, AND VITAMINS, INCLUDING PREPARATION, ANY STRENGTH, 52 TO 73 GRAMS OF PROTEIN - PREMIX
B4197	PARENTERAL NUTRITION SOLUTION; COMPOUNDED AMINO ACID AND CARBOHYDRATES WITH ELECTROLYTES, TRACE ELEMENTS AND VITAMINS, INCLUDING PREPARATION, ANY STRENGTH, 74 TO 100 GRAMS OF PROTEIN - PREMIX
B4199	PARENTERAL NUTRITION SOLUTION; COMPOUNDED AMINO ACID AND CARBOHYDRATES WITH ELECTROLYTES, TRACE ELEMENTS AND VITAMINS, INCLUDING PREPARATION, ANY STRENGTH, OVER 100 GRAMS OF PROTEIN - PREMIX

Recommendation:

For claims under both the enteral and parenteral nutritional benefit, we urge you to eliminate the requirement to obtain a signed and dated DWO and allow the prescription to stand for changes to the initial order when there are no changes in the HCPCS codes being billed. If an enteral formula change or PN grams of protein (Amino Acids) change resulted in a shift from one HCPSC code to a different range we maintain that the supplier should obtain a new DWO.

DME Information Form

DMEMAC Information Forms (DIFs) are required to be completed and signed as an attestation from the supplier that they have documentation for the equipment and therapy being ordered for the beneficiary, and that the therapy meets coverage criteria under Medicare. This documentation must be available from the supplier and be supported by a DWO from the physician. When the supplier completes and submits the initial DIF with the claim, they have the required documentation and orders to support the therapy ordered.

A revised DIF is required whenever there is a minor change to the patient's therapy. It is extremely cumbersome on the supplier to continue to revise DIFs when the HCPCS codes do not change and the only rationale for the revised DIF is to support the units that may increase or decrease for enteral or parenteral nutrition therapy.

The revised DIF must be submitted with the first claim that has changes and the DMEMAC's are constantly uploading the revisions. It is a significant burden to both supplier and the DMEMACs to manage all the paperwork revisions to keep up with during a course of therapy.

Recommendation:

Rather than requiring suppliers to obtain a new DIF each time there's an adjustment to a patient's enteral or parenteral nutrition therapy, we urge you to modify the policy so that a new DIF would be

required only if the change in the ordered therapy results in a change in the HCPCS code or route of administration.

Retroactive Advance Beneficiary Notice

Medicare policy requires DME suppliers to deliver an Advance Beneficiary Notice of Noncoverage (ABN) when items or services are not considered medically necessary under the Medicare policy in order for a beneficiary to make an informed decision when liability may be shifted to the patient, or secondary payer. In some situations, services are furnished to non-Medicare patients, that is patients with commercial insurance, Medicaid or some other type of coverage, who later receive notification of Medicare entitlement effective retroactively. In many cases patients meet their commercial plan coverage criteria, but not the Medicare coverage criteria. If a patient receives Medicare coverage retroactively, suppliers do not have the opportunity to properly obtain an ABN for lack of coverage for service, because services have already been rendered.

It is not feasible for suppliers to obtain ABNs prior to services rendered when active patients have not been part of the Medicare program, and later receive Medicare eligibility granted retroactively. The result is suppliers have to file claims with the appropriate modifier that indicates a valid ABN was not on file prior to dates of service and can't secure payment from other insurance plans or even the beneficiary. This is a risk over which suppliers have no control.

Recommendation:

In the case of Medicare retroactive enrollment, allow for an ABN exemption for claims from the date that Medicare eligibility is granted back to the retroactive Medicare eligibility date.. This would allow the claim to flow correctly through the Medicare system, assigning the appropriate PR (patient responsibility) remark code, and allow the claim to move to any other insurance plans or the beneficiary.

Medicare Billing for Denial

Medicare Part B DME's billing guidelines and coverage often differ significantly from commercial payors, which places a hardship on suppliers and patients when attempting to collect from a commercial payer secondary to Medicare. This challenge is even more pronounced in situations where Medicare will not cover an item or service, either because it is statutorily excluded or because the patient does not meet the coverage criteria. In such scenarios, a supplier must first submit a claim to Medicare according to its guidelines in order to secure a denial, and then must bill the next payor according to different guidelines, which could mean using different HCPCS codes and different Date of Service conventions. Moreover, since there is no distinction between billing Medicare for payment or billing Medicare for denial, other than use of modifiers, our understanding is that the Standard Documentation Policy Article applies and that suppliers are required to obtain the same documents when Medicare will not be paying the claim.

Recommendation:

Revise the policy to direct suppliers to bill Medicare with the appropriate modifier to indicate that services are not covered, but in accordance with the secondary payor's claims processing and documentation guidelines as a means to streamline the process of billing for denial and reducing the paperwork burden placed on suppliers.

Local Coverage Determination Reconsideration (LCD)

While the new Local Coverage Determination (LCD) Reconsideration Process is more transparent, it significantly delays changes to coverage, which can know take a year or more. The ICD-10 codes have moved from the LCDs to the Policy Articles in order to update rapidly as codes change, a recent example of this is the update to Primary Immune Deficiency Disease ICD-10 codes (CR11295).The HCPCS codes, including drug J HPCPS codes, remain in the DME MAC LCDs. In years past, when a newly approved drug fit into existing External infusion Pumps LCD coverage criteria, the DME MAC would develop and distribute a Joint Publication on coverage and coding (see Exhibit A), which provided suppliers the information necessary to let Physicians and Medicare beneficiaries know if and how the drug would be covered under the Part B DMEPOS benefit. Since the roll out of the new 21st Century Cures LCD process in January of 2019 the DME MAC s are no longer creating Joint Publication on coverage and/or coding for newly FDA approved drugs, stating they must go through the LCD reconsideration process. This creates a patient access issue, especially for Immunoglobulin (Ig) products that are in short supply. Given the cost of many of these drugs suppliers require very clear guidance on coverage prior to accepting beneficiaries on service.

Recommendations:

- Recreate a fast track LCD update process for newly approved drugs that meet existing coverage criteria, non-controversial LCD update.
- Require the DME MACs to publish coding guidance for newly approved drugs, explaining use of the not otherwise classified (NOC) HCPCS code.
- Require the DME MACs to move the J-codes HCPCS from the LCD to the Policy Article, as the A/B MACs have done to allow for more rapid coverage updates.

Medically Unlikely Edits

CMS developed Medically Unlikely Edits (MUEs) to reduce the paid claims error rate for Part B claims. An MUE for a HCPCS/CPT code is the maximum units of service that a provider would report under most circumstances for a single beneficiary on a single date of service. In some cases, units over and above the MUE maximum can be paid in the appeals process when clinical documentation is provided to support the need. This may be a one-time need or a need over a specified period of time. Currently each and every claim with units that deny for MUE units above the limit have to go through the appeals process, while these are often dealt with in the first two levels of appeals some reach the third level of appeal, the Administrative Law Judge (ALJ). The appeals process has been overwhelmed for years. The current wait time for the ALJ third level of appeals is over three and a half year. See table 1.

Average Processing Time By Fiscal Year

Fiscal Year	Number of Days
FY09	94.9
FY10	109.6
FY11	121.3
FY12	134.5
FY13	220.6
FY14	414.9
FY15	661.8
FY16	877.2
FY17	1,108.7
FY18	1,193.9
FY19	1,361.7
1st Quarter	1,302.9
2nd Quarter	1,321.1
3rd Quarter	1,361.7

Recommendation:

We request that CMS work with the DME MACs to develop policies to ease the administrative burden when there is clinical documentation to show patient specific need of units beyond the MUE limit. First, we would ask that that the DME MAC be required to process payment for all units up to the limit allowed (below the MUE limit). Secondly, when the supplier is successful in the appeals process by providing clinical documentation to support the need for units beyond the MUE limit, and that need is expected for a period of time, we request an approval process which links the clinical documentation to future claims for a period of time, so that each and every claim does not have to go through the appeals process.

Transitions of Care

The DMEPOS program allows for delivery of *equipment* to a hospital or skilled nursing facility two days prior to discharge, so that a patient can use a walker, cane, oxygen, etc. to travel home. Unfortunately, the DMEPOS program does not allow for the delivery of *supplies* prior to discharge, which is a significant challenge in home infusion as the drugs are considered a supply. Patients on continuous IV medication, pain management and inotropic drug therapies, need these drug therapies as they leave the institutional environment and travel home. Hospitals and SNFs typically do not allow their equipment to leave their facilities and often the equipment they use is not ambulatory/portable (e.g., may be pole-mounted or require an outlet to power).

Recommendation:

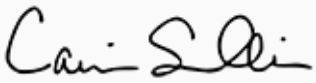
In order to allow for smooth transitions to the home environment we request that the policy be modified to allow for delivery of equipment *and supplies* to a facility two days prior to discharge to allow for a smooth transition home. We understand that the supplies are not to be used in the facility, but

rather at time of discharge in order to allow for a smooth transition home with the home infusion provider that has the specialized equipment, supplies and support services to safely manage the beneficiaries care outside of a healthcare facility.

Conclusion

In conclusion, we believe there are several opportunities where CMS could ease the regulatory burden on home infusion suppliers so that they can put patients over paperwork. We welcome the opportunity to work with you to advance some of these recommendations so that Medicare beneficiaries can receive these essential, lifesaving therapies. If you have questions or need additional information, please contact Bill Noyes at bill.noyes@nhia.org or myself at connie.sullivan@nhia.org.

Sincerely,



Connie Sullivan, B.S. Pharm
President and Chief Executive Officer