

September 5, 2025

DME MAC Medical Directors
26 Century Boulevard
Suite ST610
Nashville, TN 37214-3685

RE: Proposed Local Coverage Determination (LCD) External Infusion Pumps (DL33794)

Dear DME MAC Medical Directors:

The National Home Infusion Association (NHIA) appreciates the opportunity to submit comments on the proposed local coverage determination (LCD) for External Infusion Pumps (DL33794) posted by the Centers for Medicare & Medicaid Services (CMS) on July 24, 2025.¹ NHIA is a trade association representing providers of home and alternate site infusion therapies, as well as manufacturers and suppliers of infusion and specialty pharmacy products. As the leading voice for the home and alternate site infusion community, we write to share our feedback regarding certain changes proposed by CMS to the External Infusion Pumps (EIP) LCD.

I. Blinatumomab

The proposed LCD would expand coverage under Medicare Part B for blinatumomab for additional indications. NHIA notes that while blinatumomab may technically qualify for coverage according to the criteria for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS), we are concerned that the proposed LCD does not recognize the extensive pharmacy services that are required to ensure safe access to blinatumomab in the home setting, as discussed below.

No home infusion drug can be administered successfully at home without access to the necessary pharmacy and nursing services, and blinatumomab is no exception. Additionally, because blinatumomab must be treated as a hazardous drug, it requires investment in specialized facilities, staff expertise, and procedures that few home infusion pharmacies offer today due to the extraordinary expense for managing such facilities in compliance with the United States Pharmacopeia Chapter <800> Hazardous Drugs – Handling in Health Care Settings (USP <800>) standard.

¹ <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=40247&ver=8#>

Unfortunately, the Medicare Part B home infusion therapy (HIT) services benefit does not provide any payment for the extensive services provided by a DME pharmacy. These pharmacy services include time spent performing patient assessments, coordinating care and developing a plan of care, monitoring, 24/7 availability of a clinician, and drug preparation and compounding. NHIA believes that the DME MACs should consider whether these essential services are sufficient and accessible when evaluating new drugs for coverage under the DMEPOS benefit. Currently, NHIA believes participation by infusion pharmacies in DMEPOS and HIT services for Category 3 therapies is insufficient to support patients requiring blinatumomab infusion at home in a manner that minimizes the risk of a clinically relevant therapy interruption (>4 hours).

The proposed LCD would expand coverage for blinatumomab to adult and pediatric Medicare beneficiaries one month and older with DC19-positive Philadelphia chromosome-negative B-cell precursor acute lymphoblastic leukemia (ALL) in a specific phase of chemotherapy. NHIA generally supports this expanded indication and notes that Medicaid programs may follow updated Medicare guidelines in this area. This would be of benefit, since the highest incidence of diagnosis for the disease is in children aged one to four. NHIA remains very concerned, however, that decisions to add new drugs to the DMEPOS benefit are being made independent of considerations for patient access due to the fragmentation between the DME infused drug benefit and the HIT services benefit and the lack of sufficient coverage for pharmacy services under the Medicare Part B HIT services benefit mentioned above.

CMS' own published data reflects significant access issues for Medicare beneficiaries to DME infused drugs.² Specifically, the data shows:

- 407 suppliers dispensed Hizentra, the highest utilized subcutaneously infused Category 2 DME drug
- 283 suppliers dispensed milrinone, the highest utilized Category 1 drug
- 64 suppliers dispensed fluorouracil, the highest utilized chemotherapy/highly complex Category 3 drug
- 48 suppliers dispensed blinatumomab, a Category 3 drug

NHIA observes that the more complex and involved the pharmacy services are, the lower the number of dispensing pharmacies.

**2023 DME Public Utilization
Files**

HIT Services Category	Drug	Suppliers
Category 1	Injection, milrinone lactate, 5 mg	283

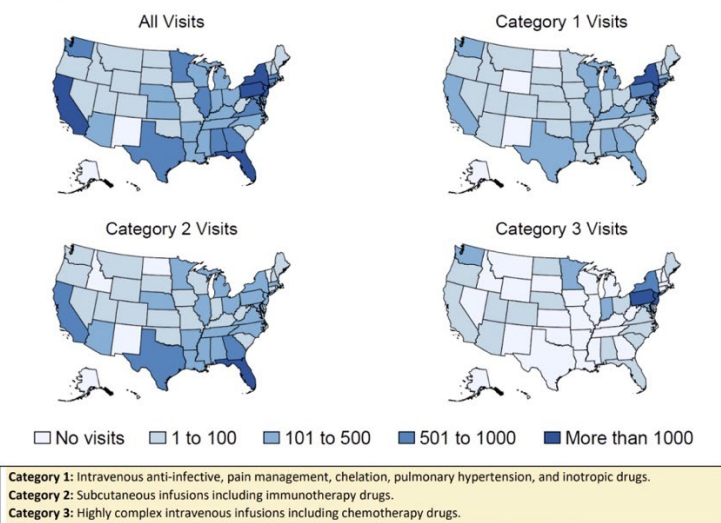
² <https://data.cms.gov/provider-summary-by-type-of-service/medicare-durable-medical-equipment-devices-supplies>

Category 2	Injection, immune globulin (hizentra), 100 mg	407
Category 3	Injection, blinatumomab, 1 microgram	48
Category 3	Injection, fluorouracil, 500 mg	64

Data in CMS’ most recent HIT Monitoring Report further highlights access issues with low supplier participation in the program and eroding patient access to many DME infused drugs that require significant pharmacy services, especially the Category 1 and Category 3 drugs.³ For example, the number of Category 1 HIT drug recipients decreased by 20% over the 27 month period Q12022 to Q2 2024, while the number of Category 1 HIT visits decreased by over 40%. Regarding Category 3 HIT drugs, recipients of those drugs, which includes blinatumomab, decreased by 33%, while the number of Category 3 HIT visits decreased by 25.5%.

CMS’ data also showed that the number of HIT Service providers billing for visits Q1 2022 – Q2 2024 was very low and declining, hovering around 60. **Only seven HIT supplier organizations provided 55% of all HIT visits**, with 35 organizations providing fewer than 100 visits. CMS’ 2025 HIT Monitory Report also revealed large geographic disparities for HIT Services, especially for Category 3, where services were concentrated in the Mid-Atlantic. The graphic below from the most recent CMS report illustrates the lack of access in many states to providers of HIT services for chemotherapy and complex biologics.

Exhibit 4. HIT ser Chart Title by state and payment category (Q3 2023 - Q2 2024)



³ <https://www.cms.gov/files/document/hitmonitoringreportfeb272025sxf508.pdf>

Pharmacy Professional Services for Blinatumomab

Blinatumomab requires home infusion clinicians (pharmacists and nurses) spend significant time over several days prior to initiating home infusion to prepare for the transition of the patient's care from the hospital to the home infusion team. This process involves many hours of communication to assess the patient, coordinate the plan, and ensure the availability of the drug based on the patient's status at the time of discharge. Drug preparation and handling must occur according to USP <800> as blinatumomab is considered a hazardous drug per NIOSH recommendations. Due to the complex nature of the infusion protocol for blinatumomab, the pharmacy supplies the patient with back up equipment and provides 24/7 on-call support from a pharmacist. There are significant clinical implications for patients if the infusion is interrupted for more than four hours, thus the home infusion team must have plans in place to respond quickly to issues that interrupt the infusion. It is apparent that the pharmacy investment far exceeds the reimbursement for drug, equipment, and supplies in DMEPOS. Without a sufficient benefit for pharmacy services, Medicare beneficiaries needing blinatumomab may find that home infusion pharmacy access is very limited.

DMEPOS Reimbursement

Home infusion pharmacies often pay more than Medicare reimburses for Part B drugs at ASP+6% less sequestration. Drug manufacturer discounts and rebates are typically not offered to home infusion pharmacies due to the class of trade system used by manufacturers to categorize purchasers. NHIA is concerned that payment for equipment and supplies is inadequate to support the physical and clinical infrastructure needed to offer home administration of blinatumomab. In addition, because the Medicare HIT services benefit only recognizes nursing services when a nurse or other professional is physically present in the patient's home, there is a substantial gap in the Medicare benefit in paying for the extensive pharmacy services required to offer blinatumomab to patients at home.

To ensure safety and equitable access to care, NHIA strongly believes the DME MACs must consider whether or not the specialized pharmacy and nursing services needed to support patients on drugs added to the EIP LCD are readily available. Since many private sector plans are likely to follow Medicare's new EIP policy, the implications of the proposed changes to the EIP LCD are likely to extend well beyond the Medicare program.

NHIA Recommendation:

NHIA asks the DME MACs and CMS to re-evaluate the home infusion benefit under the Medicare program and implement changes to ensure decisions to add drugs take into consideration the extensive pharmacy services required and whether the associated HIT services

are sufficiently available to patients as all DME infused drugs require pharmacy and nursing support in the home.

II. Foslevodopa/Foscarbidopa

The proposed LCD also would update coverage criteria for infusion-based therapy for the treatment of motor control symptoms associated with Parkinson's Disease that are inadequately controlled by non-infusion-based therapy.

Under current DME MAC billing and coding guidance⁴, VYALEV™ is administered via a proprietary external infusion pump, the VYAFUSER™. NHIA has concerns over the lack of an alternate infusion pump, should a VYAFUSER supply chain issue arise. If there is a supply chain issue that results in the VYAFUSER or any of the required supplies not being available, NHIA seeks information regarding whether a supplier may utilize a different E0781 external infusion pump to administer Vyalev? If not, how will CMS ensure beneficiaries continue to have access to Vyalev?

NHIA Recommendation:

NHIA asks for clarification regarding whether a supplier may utilize a different E0781 external infusion pump to administer Vyalev in the event of a supply chain issue.

NHIA appreciates the opportunity to provide comments on the proposed EIP LCD and stands ready to work with CMS on this important coverage policy. For questions or additional information, please contact me at connie.sullivan@nhia.org.

Sincerely,

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

⁴ <https://www.cgsmedicare.com/jb/pubs/news/2025/02/cope171778b.html>