



National Home Infusion Association
1600 Duke St. Suite 410
Alexandria VA 22314

January 30, 2021

Delivered via e-mail: EIPRecon@noridian.com

Smitha M. Ballyamanda, MD, CAQSM
Medical Director, DME MAC Jurisdiction A
Noridian Healthcare Solutions, LLC

Stacey V. Brennan, MD, FAAFP
Medical Director, DME MAC Jurisdiction B
CGS Administrators, LLC

Robert D. Hoover, Jr., MD, MPH, FACP
Medical Director, DME MAC Jurisdiction C
CGS Administrators, LLC

Peter J. Gurk, MD, CPE, CHCQM
Medical Director, DME MAC, Jurisdiction D
Noridian Healthcare Solutions, LLC

RE: External Infusion Pump LCD (DL33794) – Modify criteria for Hizentra® to consider coverage for chronic inflammatory demyelinating polyneuropathy (CIDP).

Dear DME MAC Medical Directors:

The National Home Infusion Association (NHIA) appreciates the opportunity to submit comments on the proposed change of the External Infusion Pump LCD, adding coverage for chronic inflammatory demyelinating polyneuropathy (CIDP) as an approved indication for Hizentra®. NHIA is a trade association that represents home infusion therapy providers, as well as companies that manufacture and supply infusion and specialty pharmacy products. As the leading voice for the home and specialty infusion community, we write to share our feedback on

expanding coverage to patients that require subcutaneous immune globulin infusions for treatment of CIDP.

NHIA generally believes that CMS should modernize the home infusion benefit rather than expand coverage using the DMEPOS EIP LCD reconsideration process. Rather than shift coverage for drugs from Part D to Part B, which is costly to beneficiaries and taxpayers, NHIA recommends that CMS create a modern benefit modeled after the commercial sector. For this reason, NHIA prefers not to expand the Part B DMEPOS program by adding coverage for CIDP.

Limit to CIDP

If the proposed policy is to move forward, then NHIA recommends coverage be limit to diagnosis G61.81- Chronic inflammatory demyelinating polyneuritis. Additional “unspecified” or “other” diagnosis codes should not be added to the proposed EIP LCD language.

Beneficiary Out of Pocket Concerns

Shifting coverage from Part D to Part B can greatly affect the beneficiary’s out of pocket cost and accessibility to infused drug therapies. By the time this coverage change becomes effective beneficiaries that have been receiving Hizentra® for CIDP under the Part D Prescription Drug Program will have already paid significant out of pocket cost, putting them in the catastrophic phase of the benefit for any remaining doses needed for 2021. The co-pay in the Part D catastrophic benefit is limited to 5%. If their access shifts from Part D to Part B DME, then the patient co-pay responsibility will be 20%. The result of this shift will create a significant hardship that has the very real potential to negatively impact access and adherence, especially for the 19% of Medicare beneficiaries without some type of supplemental coverage.¹ If the proposed changes to the external infusion pump policy are to move forward, then the change should take place on January 1, 2022 to allow beneficiaries to select coverage options that work best for them under a new paradigm and also to coincide with patient OOP deductible and co-pay resets at the start of a benefit period.

Retroactive Coverage Concerns

The proposed policy indicates coverage will be retroactive back to March 15, 2018. This has the very real potential of causing significant administrative burden and issues with timely filing for claims that have been previously settled prior to the new coverage policy being implemented. If coverage is made retroactive, then we ask that you provide guidance that previously paid claims are not subject to subrogation, which could prompt a credit and rebill at different payment rates - including increasing the beneficiary’s out of pocket costs. At a minimum, NHIA believes strongly that in no circumstances should coverage be retroactive beyond filing limits, which for Medicare is 365 days.

¹ Cubanski J, Damico A, Neuman T, and Jacobson G. Sources of Supplemental Coverage Among Medicare Beneficiaries in 2016. Kaiser Family Foundation. November 28, 2018. Available at: <https://www.kff.org/medicare/issue-brief/sources-of-supplemental-coverage-among-medicare-beneficiaries-in-2016/> (accessed 01/29/2021).

Home Infusion Therapy Services

Hizentra® was identified as a Category 2 Home Infusion Therapy (HIT) Service applicable drug in the transitional HIT benefit, G0069. Please confirm that if the policy is implemented with retroactive coverage, then the applicable HIT services related to Hizentra® for CIDP will also be eligible for coverage.

NHIA appreciates the opportunity to provide comments on these important issues and we welcome the opportunity to continue working with CMS and the DME MACs to improve access to Medicare home infusion drugs for Medicare beneficiaries. For questions or additional information, please contact me at bill.noyes@nhia.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Bill Noyes".

Bill Noyes, Sr. Vice President Reimbursement Policy

National Home Infusion Association