



National Home Infusion Association
1600 Duke St. Suite 410
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December 22, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1738-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare Program; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Policy Issues and Level II of the Healthcare Common Procedure Coding System (HCPCS) (CMS-1738-P)

Dear Administrator Verma:

The National Home Infusion Association (NHIA) appreciates the opportunity to submit comments on the proposed rule: Medicare Program; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Policy Issues and Level II of the Healthcare Common Procedure Coding System (HCPCS) (the “Proposed Rule”) published by the Centers for Medicare & Medicaid Services (CMS) in the Federal Register on November 4, 2020.¹ 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 the changes CMS is proposing to make to its interpretation regarding the definition of durable medical equipment (DME).

For more than 40 years, home infusion pharmacies have been safely and effectively providing professional services to administer intravenous and subcutaneous medications to patients in their homes, where they can resume their personal and professional lives and are less exposed to the risk of hospital-acquired infections. Home infusion is a safe and effective alternative to

¹ 85 Fed. Reg. 70358 (Nov. 4, 2020).

institutional care for treatment of many disease states.² Patients overwhelmingly prefer to receive their treatments at home rather than in an institutional setting. In fact, research shows that up to 95 percent of patients prefer receiving their infusions at home, and nearly 98 percent of patients surveyed last year indicated they are highly satisfied with their home infusion services.³

NHIA appreciates the extraordinary efforts CMS has made to respond to the needs of Medicare beneficiaries during this unprecedented public health emergency. At no time has it been more critical to provide individuals with the option for receiving care at home than it has been throughout the COVID-19 pandemic. Granting Medicare beneficiaries the ability to choose home infusion for treatment of infection, congestive heart failure, immune diseases, cancer, and a variety of other conditions frees up capacity, allowing hospitals to focus on serving COVID-19 patients. Increasing access to home infusion also provides seniors at higher risk of contracting COVID-19 an alternative to visiting the hospital or clinic to receive infusions necessary for managing chronic conditions and further protects providers from additional potential exposure to the virus. Despite these advantages, millions of beneficiaries lack access to home infusion due to the absence of a comprehensive Medicare benefit.

In addition to being safe, effective, and preferred by patients, home infusion therapy is a very efficient and cost-effective site of care – something that the commercial market has long recognized. As a report from the Government Accountability Office (GAO) on the utilization of home infusion in the commercial market concluded, “providing infusion therapy at home generally costs less than treatment in other settings... and the benefit is largely free from inappropriate utilization and problems in quality of care.”⁴ Additionally, the cost savings generated through site of care optimization are passed on to the patient in the form of lower copays and reduced out-of-pocket costs.

Under the Proposed Rule, CMS states that this would “expand the scope of the Medicare Part B benefit for DME” by making changes to its interpretation of the requirement that DME be “appropriate for use in the home.”⁵ NHIA notes that within the DMEPOS program, home infusion has focused on medications that require the use of an infusion device/pump that could be used independent of a healthcare professional (HCP). This Proposed Rule would be a major shift from that practice and NHIA appreciates the consideration the agency has given to including other categories of drugs that require an HCP to perform the administration.

The Use of Ambulatory Pumps in Home Infusion

The use of an infusion pump in the home setting is driven by a number of factors related to the drug properties such as solution viscosity and volume, medication dosing frequency, access

² Polinski, J. M., Kowal, M. K., Gagnon, M., Brennan, T. A., & Shrank, W. H. (2017). Home infusion: Safe, clinically effective, patient preferred, and cost saving. *Healthcare*, 5(1-2), 68-80. doi:10.1016/j.hjdsi.2016.04.004

³ Assessment of Home Infusion Patient Satisfaction. (2019). National Home Infusion Foundation

⁴ Home infusion therapy: Differences between Medicare and private insurers’ coverage. (2010, June). United States Government Accountability Office Report to Congressional Requesters. Accessed December 18, 2019: <https://www.gao.gov/assets/310/305261.pdf>.

⁵ 85 Fed. Reg. 70358 (Nov. 4, 2020).

device type, and patient and caregiver ability to perform infusion independently. We note that an infusion pump is a method – not a route of administration – for intravenous (IV) or subcutaneous therapies, and the decision about whether to use an infusion pump should always be based on clinical judgment after performing a complete patient and therapy assessment. This assessment is typically done by the home infusion clinical team at the time of referral. Examples of typical criteria for the use of a home infusion pump often include one or more of the following:

- Dosing frequency of every eight hours or more, or when continuous infusion is required
- Variable rate infusions (e.g., immune globulin, parenteral nutrition)
- Infusions lasting longer than 90 minutes
- Infusion volumes of less than 50ml or greater than 250ml
- High viscosity solutions (e.g., nafcillin)
- Small bore IV access devices

Using an infusion pump in the home setting can introduce complexity for patients, opportunity for error due to program modifications or equipment malfunction, and contamination. For these reasons, in-home infusion pumps are typically reserved for situations where another, less complex method of administration is not an option. In addition, the one-to-one nurse-to-patient ratio that is present for medications that require an HCP for administration reduces the need to use a pump in the home as the nurse is able to carefully monitor the infusion rate using non-mechanical means.

NHIA questions the logic for basing eligibility for coverage under Medicare Part B on language that could require home infusion providers to use the less optimal method of administration of a pump when clinical conditions do not warrant its use. NHIA is concerned that CMS's proposal will have the unintended consequence of taking what should be a clinical decision about whether to use a pump out of the hands of clinicians and mandating it for payment purposes.

NHIA Recommendation #1:

CMS should reconsider the strategy of expanding access to home infusion for HCP-administered drugs through the DMEPOS program. NHIA believes pumps should be available and reimbursed under the DMEPOS benefit when clinically justified, however the use of a pump should not be the primary criterion for determining coverage for home infusion (see NHIA recommendation #2). NHIA strongly encourages CMS to consider adding language to the rule to clarify that if a pump is not clinically warranted in a particular situation (and therefore not eligible for coverage under Medicare Part B), then the drug will remain eligible for coverage under Medicare Part D in the event the patient is willing to pay privately for the non-covered expenses associated with home infusion. In addition, NHIA suggests that CMS explore ways to minimize the out-of-pocket burden for patients when drugs are billed under the Part D benefit rather than continue with the current outdated home infusion therapy drug policy that limits access by requiring the use of a pump.

Modernizing the Home Infusion Therapy Services Benefit

CMS asks for comment on whether its proposal would be adequate to expand access to home infusion drugs administered through external infusion pumps and home infusion therapy furnished by qualified home infusion therapy suppliers. The current proposal will expand access for only a handful of drugs, mostly for rare conditions. While NHIA is pleased to see CMS considering expanding access for these important therapies, the vast majority of Medicare beneficiaries needing home infusion will not benefit from this proposal. Rather than retrofitting the home infusion therapy benefit into the construct of the DMEPOS benefit, CMS should implement a modern home infusion therapy benefit. For over forty years, home infusion has helped millions of patients covered by commercial insurance, Medicaid, and other government payers (e.g., Tricare) shorten hospital stays and avoid long-term care facilities.

Home infusion is predicated on patients and caregivers becoming independent with administering the infusion therapy, usually without the use of an item of DME. Patients are supported remotely by pharmacists who oversee the process and monitor the patient's response to therapy and presence of adverse events. This model has been overwhelmingly effective in the private sector at lowering costs by shortening hospital stays and avoiding long-term care admissions. The payment model involves home infusion providers receiving a bundled supplies and services payment for each day a patient administers the drug, regardless of whether a nurse visits the home. This system could be easily replicated by CMS in a demonstration project for infusion medications currently covered under the Part D benefit. This broadened approach allows clinicians to choose the best and most appropriate method of administration for the patient and therapy.

The safety and benefits to patients of the commercial home infusion model has been validated in many studies.² Additionally, in 2019 the National Home Infusion Foundation (NHIF) conducted a study using a third-party consultant for data collection and analysis, of patient satisfaction in more than 32,000 home infusion patients. Patients were overwhelmingly satisfied with the overall services (97.5 percent).³ Additionally, NHIF has recently begun collecting outcomes data associated with home infusion. Patients served by 12 unique home infusion providers evaluated the reason for discharge from service between July and September 2020. The data shows that over 90 percent of patients (n=1444) receiving anti-infectives, chemotherapy, and other agents successfully complete therapy without experiencing hospitalization, adverse drug reactions (ADRs), or death. Across all therapy categories, rates of unplanned hospitalization as a reason for discharge was four percent, and ADR as a reason for discharge was 0.4 percent.

NHIA believes that CMS should consider implementing a modern home infusion therapy services benefit in order to increase access. A modern benefit would provide for an alternate coverage path for drugs that do not require either an infusion pump. NHIA strongly believes that CMS should not mandate that a pump be used in order for a drug to be covered. As discussed above, a pump is not always necessary and can introduce the opportunity for error or contamination. NHIA recommends that CMS allow for coverage of drugs under Medicare Part D for drugs used in the home infusion therapy setting, while the home infusion therapy services and disposable supplies would be covered under Medicare Part B.

NHIA Recommendation #2:

NHIA requests that CMS create a demonstration project to study expanding home infusion access to any Part D covered drug that is administered intravenously or subcutaneously for an administration period of 15 minutes or more.⁶ Under the demonstration, drugs used in the home infusion therapy setting would be billed to Medicare Part D, while there would be a bundled payment billed through the A/B MACs for home infusion therapy services, and disposable equipment and supplies.

Home Infusion Therapy Services

NHIA is concerned that the current approach to reimbursement for home infusion therapy services will limit access to Part B covered drugs for which there is a short (i.e., \leq one hour) infusion time. NHIA believes that the policy articulated in the Proposed Rule is unlikely to generate access for drugs that require more than one-two hours of total nursing time to perform home assessments and administration. The home infusion therapy services rate that was established under the Medicare program is not sufficient to support long administration times, which occur in addition to the intensive pharmacist and nursing services that happen remotely and in advance of the actual visit to administer the medication. In addition, the average sales price (ASP) likely will be driven down due to the recently announced “Most Favored Nations” (MFN) policy, which will place most home infused drugs out of reach for HIT pharmacies that purchase at the top of the ASP fee schedule. For these reasons, NHIA is concerned that HIT service fees will be insufficient to make most HCP-administered drugs accessible at home. NHIA asserts that applying a fee schedule used for patient-administered therapies (i.e., continuous infusions where the HCP is not required to be present) will not translate to drugs that require the HCP to stay with the patient for several hours. Also, the lack of sufficient payment for the remote pharmacist services will remain a significant barrier for all Medicare beneficiaries seeking home infusion. NHIA believes that a pharmacist working under the physician home infusion plan of care should be able to bill for professional services through the home infusion therapy provider. Therefore, NHIA recommends that CMS allow pharmacists, as well as nurses, to bill for infusion-related assessments, education, and monitoring provided remotely for home infusion patients.

NHIA Recommendation #3:

NHIA continues to recommend that CMS implement sufficient reimbursement for home infusion therapy services in order to promote access to home infusion therapy drugs. NHIA urges CMS to allow home infusion providers to bill services codes G0068, G0069, and G0070 for professional services, including nursing services, provided remotely in accordance with the plan of care authorized by the physician.

⁶ See Section 5012(a)(3)(C) of the 21st Century Cures Act (Pub.L. 144-255)

“Appropriate for Use in the Home” Requirement

The Proposed Rule would interpret the “appropriate for use in the home” requirement for an external infusion pump to include that the labeling required by the Food and Drug Administration (FDA) requires the home infusion drug to be “prepared immediately prior to administration” or be administered by a HCP, or both. NHIA believes requiring the drug to be “prepared prior to administration” is unnecessary and does not add value to the “appropriate for use in the home” requirement. Since most drugs also provide storage information allowing some ability to use the product after mixing, this criterion may result in unnecessary waste and less use of ISO 5 (cleanroom) environments to prepare drugs when available and storage conditions permit.

CMS also would require that a qualified home infusion therapy services supplier administer the drug or biological in a safe and effective manner in the patient’s home. NHIA agrees with this requirement for coverage eligibility, to help ensure safety and quality.

Finally, CMS would require that the FDA-required labeling specify that infusion via an external pump is a possible route (method) of administration, at least once per month, for the drug. NHIA agrees with the requirement that drug infusion occur at least once per month, and we ask CMS to clarify that there is no minimum dose requirement and that a product infused one time (e.g., COVID monoclonal antibodies) would be eligible for coverage. In addition, NHIA suggests that the use of an external infusion pump should be driven by clinical reasons related to administration variables rather than FDA language. NHIA believes that CMS must understand that the decision regarding whether to use an external infusion pump currently is not based on the kind of FDA language that CMS proposes, and this would be a significant change to the FDA’s role. NHIA is concerned about shifting medical decisions for selecting the most appropriate method of administration and site of care to the FDA as it is not feasible to re-create the wide range of circumstances encountered in the home setting in clinical trials. Decisions about treatment site of care should be left to the physician and the patient.

NHIA also asks CMS to consider that including a statement that an infusion pump is a “possible” method of administration will not guarantee access under the Medicare Part B benefit, as pumps may not be appropriate in all cases, such as for treatment of COVID-19, short infusion time periods, and for a standard volume of solution.

NHIA Recommendation #4:

NHIA requests that CMS remove the requirement that drugs be “prepared immediately prior to administration” in order to be eligible for coverage. NHIA requests that CMS retain the requirement that a qualified home infusion therapy services supplier administer the drug or biological in a safe and effective manner in the patient’s home. NHIA agrees with the requirement that drug infusion occur at least once per month and asks CMS to clarify that there is no minimum dose requirement.

Alternative Coverage Pathway

If CMS will not create the modern benefit recommended above, NHIA believes that the main criteria (of those proposed by CMS) for a new coverage pathway for the existing DMEPOS benefit are the need for an HCP and a pump. In addition, CMS should add a new criterion, which is limiting the benefit to FDA-approved label indications for eligible drugs. NHIA believes that these criteria should drive coverage under Medicare Part B for certain drugs.

NHIA Recommendation #5:

If CMS does not move forward with modernizing the home infusion therapy benefit as recommended, NHIA requests that CMS base coverage for home infusion therapy drugs on the need for a pump and health care professional and limit the benefit to FDA-approved label indications.

LCD Process

CMS proposes that if its proposed changes to coverage of home infusion drugs are finalized, the local coverage determinations (LCDs) for external infusion pumps would need to be updated by the DME MACs, “consistent with long-standing practice.” CMS notes that its staff would not take on the responsibility for evaluating requests and making determinations regarding which drugs or biologicals would satisfy the “appropriate for use in the home” criteria.

NHIA Recommendation #6:

If CMS moves forward with the changes to coverage of home infusion drugs discussed in the Proposed Rule, NHIA agrees with using the LCD determination process for eligibility. This process should be limited to FDA-approved label indications. NHIA requests that home infusion therapy services providers have the ability to comment on any proposal to add a new drug to the Part B benefit.

Coverage of Existing Drugs

CMS is silent in the Proposed Rule regarding the treatment of drugs currently covered under the DMEPOS benefit, most of which do not meet this new criterion. NHIA requests that CMS confirm that the proposed policy is not intended to apply to existing drugs currently covered under the DMEPOS benefit.

NHIA Recommendation #7:

NHIA requests that CMS clarify that in revising its interpretation of the “appropriate for use in the home” requirement, it is not revising the policy for drugs currently covered under the DMEPOS benefit. If CMS does intend for the revised interpretation to apply to drugs currently covered under the DMEPOS benefit, NHIA requests that CMS explicitly state this and provide for an additional comment period to give stakeholders an opportunity for comment prior to implementing any changes to the drugs currently covered under the existing DMEPOS benefit.

Summary

NHIA appreciates and agrees with CMS that more Medicare beneficiaries should have access to home infusion. Home infusion creates value for beneficiaries by improving their quality of life, reducing exposure to infectious diseases, and promoting feelings of control over healthcare choices.⁷ NHIA encourages the administration to explore ways to improve home infusion access for all beneficiaries that rely on intravenous and subcutaneous infusion medications, and not limit the expansion to the small number of drugs and biologics that will meet the criteria in the proposed rule. NHIA urges CMS to reconsider its proposal to expand Medicare coverage by requiring the use of a home infusion pump and instead create a demonstration project to study a modern approach, as described earlier in this letter. NHIA contends that expanding home infusion access to drugs and biologics covered under Part D, along with a bundled payment under Medicare Part B paid for each day of administration for the associated professional services (pharmacy and nursing) and disposable equipment and supplies, is the most impactful approach to improving access to home infusion for all Medicare beneficiaries.

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

Sincerely,

A handwritten signature in black ink, appearing to read 'Connie Sullivan', with a stylized flourish at the end.

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

⁷ Polinski, J. M., Kowal, M. K., Gagnon, M., Brennan, T. A., & Shrank, W. H. (2017). Home infusion: Safe, clinically effective, patient preferred, and cost saving. *Healthcare*, 5(1-2), 68-80. doi:10.1016/j.hjdsi.2016.04.004