



NATIONAL ASSOCIATION OF
SPECIALTY PHARMACY

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January 4, 2021

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

BY ELECTRONIC DELIVERY

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 Association of Specialty Pharmacy (NASP) is pleased to provide comments in response to 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)*. We offer feedback on the regulatory adjustments CMS proposes regarding the “appropriate for use in the home” requirement in the definition of durable medical equipment (DME) as it applies to certain external infusion pumps and on the agency’s implementation of home infusion therapy services.

NASP’s members are committed to the practice of specialty pharmacy, including specialty pharmacies that provide home infusion services and to serving specialty patients to ensure better clinical outcomes and reduced overall healthcare costs.

NASP defines a specialty pharmacy as:

- Multi-state licensed and registered pharmacies that are accredited as a specialty pharmacy by an independent, third-party accreditor AND
- Solely or largely provide medications and patient medication management services to patients with serious health conditions requiring treatment with complex medication therapies.

NASP represents the entire spectrum of the specialty pharmacy industry, including the nation’s leading independent specialty pharmacies and practicing pharmacists; small and mid-size pharmacy benefit managers (PBMs); pharmaceutical and biotechnology manufacturers of specialty drugs; group purchasing organizations; wholesalers and distributors; integrated delivery systems and health plans; and technology and data management companies. NASP is the unified voice of specialty pharmacy in the United States.

Many specialty pharmacies provide home infusion medications and services to support patient access to medications needed to manage their complex health conditions. In fact, many specialty pharmacies today began as home infusion pharmacies. Home infusion is often a less costly and needed option for those patients with geographic challenges to accessing therapy in another care setting. For vulnerable patients with chronic and life-threatening health conditions, home infusion can be a far safer alternative to receiving treatment in a hospital or physician office setting, particularly during the COVID-19 pandemic. Home infusion as an option for patients also safely frees up capacity within a hospital setting at a time when hospitals are otherwise occupied in addressing patients with the coronavirus. NASP appreciates CMS' efforts to establish flexibilities throughout the COVID public health emergency to support patient access to home infusion and home health care services.

Expanded Classification of External Infusion Pumps as DME

“Appropriate for Use in the Home”

The proposed rule would expand the scope of the Medicare Part B benefit for DME by revising the regulatory interpretation of the “appropriate for use in the home” requirement in the definition of DME at 42 CFR 414.202 for certain drugs or biologicals that are infused in the home and require use of an external infusion pump. A three-part “test” is proposed by CMS to meet the “appropriate for use in the home” requirement, as follows:

1. The Food and Drug Administration (FDA)-required labeling requires the associated home infusion drug to be prepared immediately prior to administration or administered by a health care professional or both;
2. a qualified home infusion therapy supplier (as defined at § 486.505) administers the drug or biological in a safe and effective manner in the patient's home (as defined at § 486.505); and
3. the FDA-required labeling specifies infusion via an external infusion pump as a possible route of administration, at least once per month, for the drug.

NASP has concerns with the criteria and approach CMS is proposing and urges the agency to reconsider its approach. The following outlines our recommendations for each of the criteria.

(1) Immediate Preparation Prior to Administration or Administration by a Health Care Professional

NASP believes that a stated requirement that the drug to be prepared prior to administration is extremely unclear and confusing and even potentially life threatening. There is no standard in regulation or statute defining “immediate to administration.” Many drugs include storage criteria that permit use of the product after it has been created. It is unclear what impact CMS' criteria would have on the coverage or use of stored products. The FDA has spent considerable time and effort, particularly over the last several years ensuring that products are prepared in sterile environments to meet safety standards. It seems CMS' criteria may falsely suggest or even require that products that are otherwise created offsite in a sterile environment have to instead be prepared on-site in a patient's home setting in order to qualify under the proposed regulatory requirements. Safety, sterility and quality of infused drugs is paramount, and NASP is concerned about CMS' proposed unclear standard and the risk it creates to patient health and safety. We urge CMS to remove the requirement that drugs be “prepared immediately prior to administration.”

NASP agrees that a qualified home infusion therapy professional should administer an infused drug or biological in a patient's home. Specialized training is provided for nurses who are typically responsible for administering infused drugs, and this expertise is relied on to support the use of these drug/biological products.

(2) A Qualified Supplier Administers Drugs/Biologicals

NASP agrees with the proposed coverage requirement to have a qualified supplier administer drugs/biologicals to ensure safety and efficacy of the product and to support patient safety.

(3) FDA-required Labeling Specifies Infusion At Least Once Per Month for the Drug

NASP is concerned that the requirement that the drug infusion occur at least one time per month is too limiting a factor that could disrupt a patient's infusion coverage if the patient's treating medical professional adjusts a patient's drug therapy or its timing. Often times, specialty infused drugs or biologicals are titrated based on a patient's response to treatment. The treating medical professional also will sometimes make a decision that such a drug/biological can be effectively administered at less frequent intervals (e.g., skipping a month's therapy). Such a requirement, as proposed by CMS, provides no flexibility to adjust for a treating medical professional's decision making.

NASP is also concerned about the impact such a proposed requirement would have on a product that is infused one time rather than on a monthly basis, including COVID-related monoclonal antibody treatments when they are to be administered via an external pump or otherwise. At a minimum, clarity is needed as to when this standard would be adjusted to support the appropriate use of the drug being infused or a treating health care professional's clinical decision making.

It is important that the CMS understand that the decision to utilize an external pump for the administration of drugs or biologicals and the frequency of such infusions is a decision to be made by a patient's treating professional based on clinical needs, and prescriber decisions should not be influenced by coverage. The FDA approves pumps for use with drugs but does not determine dosage levels or other medical decisions in relation to use of the drugs/biologicals. Any decisions about treatment via home infusion are outside of the FDA's role and authority and must be made by the treating provider in consultation with the patient.

NASP urges CMS to adjust or otherwise remove the proposed requirement.

Expanding Access to Home Infusion Drugs and Home Infusion Therapy Services

In the proposed rule, CMS asks for comment on whether its proposal is adequate to expand access to medically appropriate home infusion drugs that are administered through external infusion pumps and home infusion therapy services by qualified suppliers. NASP is pleased that the current proposal, when adjusted as we recommend, will expand access to some drugs and biologicals to support critically important access for some patients, particularly those with rare diseases and conditions.

However, we feel the proposal continues to too narrowly define home infusion coverage. NASP believes that any medication that requires professional administration, especially via intravenous or similar routes should be covered in similar fashion independent of the equipment (e.g. infusion pump) necessary for the medication's administration. In the proposed rule, as outlined, there are other drugs/biologicals that will not otherwise be covered, limiting access for other patients who would otherwise benefit from home infusion and related home infusion therapy services, and otherwise limiting the savings to Medicare that comes from home-based infusions. This limitation is primarily due to CMS' decision to establish an expanded home infusion benefit through the current Medicare DMEPOS benefit rather than to construct a new benefit as envisioned through the 2016 *Cures Act*. NASP does not believe that coverage for home infusion drugs/biologicals under a home infusion benefit should be limited to only those drugs/biologicals that are administered through an external infusion pump.

There are two key issues that NASP recommends CMS work with the specialty pharmacy and broader home infusion pharmacy provider community to address: 1) How to ensure coverage and access to home infusion drugs/biologicals that are not dependent on the use of an external pump as DME or when a treating provider determines it is not in the patient's best interest to have the drug/biological provided through the use of an external pump; and 2) How to ensure appropriate coverage of pharmacy-related services that support the monitoring of patients and engagement with a patient's treating provider to address adverse events and clinical factors to optimize the use of home infused drugs/biologicals.

NASP appreciates the opportunity to comment on the proposed rule. For additional information, please contact me at sarquette@naspnet.org, (703) 842-0122 or NASP's Washington Representative Julie Allen at julie.allen@powerslaw.com, 202-494-4115.

Respectfully submitted,



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