POSITION STATEMENT

Home Infusion Reimbursement Must Reflect Essential Specialized Pharmacy Professional Services

NHIA
National Home Infusion Association

BACKGROUND

For more than 30 years, home infusion providers have been safely and effectively coordinating and delivering intravenous and subcutaneous infused medications in patients' homes.

A primary benefit of home infusion therapy is that it allows 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 is an extension of the health care continuum and serves as a safe, convenient, cost-effective alternative for patients to receive infused medications when other settings are unnecessary, impractical or unavailable; when transport outside the home is a burden to the patient or family; or when home administration can improve quality of life. The federal government generally has been supportive of home infusion therapy. In a 2010 report to Congress, the Government Accountability Office (GAO) concluded that "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."[1]

Commercial health plans, Medicare Advantage plans, and government programs (e.g. TRICARE, Veteran's Administration) have long recognized the value of home infusion therapy, and have reimbursed for home infusion services using a model that a pays each day a drug is infused to cover equipment, supplies and pharmacy professional services. Unfortunately, the Medicare program historically did not offer home infusion coverage. Medicare reimbursed the cost of some infusion drugs and supplies under the Durable Medical Equipment (DME) benefit but never covered professional services provided by a pharmacist and nurse.

21st CENTURY CURES ACT

Medicare coverage of home infusion changed in 2016 when Congress enacted the 21st Century Cures Act. At that time, Congress reformed payment for drugs, moving from average wholesale price (AWP) methodology to the lower payments using average sales price (ASP). Congress recognized that this reduction in drug reimbursement would prohibit home infusion access for Medicare beneficiaries. To close this gap, Congress created a new home infusion professional services benefit associated with Part B DME infusion drugs. This benefit was intended to cover both pharmacy and nursing professional services and specified that providers would be reimbursed for each "infusion drug administration calendar day." Congress intended for this new benefit to be billed with the existing equipment and supply kit codes and drugs for each day a drug was infused in the home.

Unfortunately, the Centers for Medicare and Medicaid Services (CMS) issued an unduly restrictive rule that incorrectly defines the "infusion drug administration calendar day," limiting reimbursement only to days when a home infusion professional (i.e. nurse) is physically present in the patient's home. Unlike the practice in virtually all other home infusion, CMS refused to reimburse for pharmacy and other professional services through a payment for each day the drug is infused. As such, the minimal payment proposed by CMS for in-person services (approximately $138/once a week for continuous infusions such as milrinone and dobutamine) must cover all home infusion services. This reimbursement level is inadequate, unsustainable and will undoubtedly inhibit Medicare beneficiary access to home infusion services. Ultimately, NHIA believes Medicare patients will not be able to access home infusion services and will have to seek care in other, more expensive, settings.

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Inadequate Reimbursement

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NHIA'S RESPONSE

On February 14, 2019, the National Home Infusion Association (NHIA) filed a complaint in U.S. District Court against the Department of Health and Human Services Secretary Alex Azar, challenging the Agency's interpretation of "infusion drug administration calendar day," which limits payment to only those days in which a "skilled professional is in the patient's home." Representing home infusion providers and professionals, NHIA believes that CMS overreached its authority and will cause undue harm to home infusion patients and providers, and to the Medicare program itself. Furthermore, NHIA is working with Members of Congress on legislation that would clarify the definition of home infusion professional services to ensure future rules reimburse for the whole array of professional services already identified by Congress that are necessary for the safe and effective delivery of home infusion therapy.

HOME INFUSION PHARMACY ROLES AND RESPONSIBILITIES

Home infusion therapy requires coordination among a diverse and multidisciplinary team of providers. Primarily, these services are offered by pharmacists, nurses, dietitians, and pharmacy technicians, in consultation with the patient's physician and other health care providers.

Coordination between the home infusion pharmacy staff and nursing provider is essential to obtaining optimal outcomes. While CMS has narrowly interpreted the definition of home infusion professional services to reflect only those services delivered in the home by the nurse, NHIA has recommended a broader definition – one that reflects the following pharmacy-based services.

Initial and Ongoing Infusion Therapy Assessment

Infusion professional services begin the day the patient is referred for home infusion services. The original order for home infusion is often a simple prescription containing the basic parameters related to the infused drug. The pharmacist works in conjunction with the patient and their caregiver(s), nursing agency, physician, and referring agency (e.g. hospital, skilled facility, clinic, physician) to develop and coordinate the initiation of home infusion. This involves a thorough review of the patient's past medical history, history of present illness, complete medication list, laboratory reports, home environment, ambulatory status or other physical limitations, vascular access, infusion medication order, and more. Once this assessment is complete, the pharmacy's home infusion team will determine whether the patient and the prescribed therapy are appropriate for home infusion.

Infusion Plan of Care Development and Implementation

The home infusion pharmacist works with the patient/caregiver and nurse to develop a comprehensive plan of care delineating all aspects of home infusion therapy. The home infusion plan of care articulates the goals of therapy, states the medication to be infused, provides specific instructions for administration (i.e., whether a pump will be used), assures access device care, sets a schedule for lab orders, nursing visit frequency, and monitoring, and identifies other special orders such as pre-medications to be administered and standing orders for treatment of acute infusion reactions. The plan of care is evaluated each time home infusion drugs are furnished. These are critically important services that require the professional expertise and knowledge that is unique to home infusion pharmacists, but done in cooperation with the prescribing physician, nurse, and patient.

Infusion Therapy Care Coordination

Under the final rule, CMS reimburses only for care coordination services that are performed by a "skilled professional" as part of a visit that takes place by that professional in the patient's home. However, all aspects of the home infusion plan of care must be communicated and coordinated to avoid medication errors, missed or delayed doses, or unplanned hospitalizations. The pharmacy care team provides comprehensive case management of the infusion therapy and ensures that all members are informed of changes to the plan of care, changes in patient clinical status, adverse events, changes in supply needs, or schedule changes. Communication for the purposes of coordinating care takes place continuously during treatment. Communication with the patient and/or caregiver often occurs several times a week to assess for therapy effectiveness, adverse events, proper use of equipment and supplies, and to plan deliveries.

Drug Preparation and Compounding

Most home infusion drugs require some level of aseptic preparation prior to administration. Home infusion pharmacies have responded to increasingly robust regulations for ensuring the safety and quality of compounded sterile products (CSPs). The cost for maintaining the facility, environmental monitoring, employee testing, and certification associated with recognized standards (United States Pharmacopeia and the Food and Drug Administration) enforced by state Boards of Pharmacy and accreditation programs ensures home infusion CSPs are safe and free of contamination.

Nursing

To safely provide home infusion services, a home infusion nurse must be uniquely equipped with expertise beyond the scope of traditional nursing practice. Home infusion nursing services are fundamentally different than home health nursing services, skilled nursing facility nursing services, or other nursing services covered under other Medicare program benefits. Infusion nurses have specialized training and unique knowledge of, and experience in, vascular access devices (catheters) and maintenance; safe administration of sterile medications; prevention of catheter infection and occlusion; patient education regarding the access device and infusion therapy; and the maintenance of a safe infusion environment in the home.

PATIENT SATISFACTION WITH HOME INFUSION

As discussed, coordination of the home infusion process is complex and requires a diverse staff with specific skill sets. To ensure that the home infusion patient is satisfied with each component of the service, they are requested to complete a satisfaction survey either at the conclusion of therapy, or at defined intervals during treatment. The National Home Infusion Foundation (NHIF) published a validated Home Infusion Patient Satisfaction Survey[2] tool to facilitate comparisons among different home infusion providers. To date, surveys from more than 600 patients have been collected and compared in a pilot study. Analysis of the pilot study survey data which is submitted through a third-party administrator to NHIF, provides evidence of the value and appreciation that patients have for home infusion. For example, 98% of patients "Highly Agreed" or "Agreed" they were satisfied with the quality of the home infusion services provided under the current model. Home infusion pharmacies also score high marks in all areas of instruction, from how to store the medications to proper hand washing. Data from the Home Infusion Patient Satisfaction Survey[2] pilot study concludes that 98% of the patients understood the specific home infusion instructions. This data shows patients are satisfied with their care and are highly confident with the home infusion process consisting of pharmacy-based case management and weekly nursing visits once the patient demonstrates competency with self-administration.

QUALITY AND SAFETY

Several peer-reviewed studies using a variety of research methods document the quality and safety of home infusion therapy. For example, a systematic review of studies compared the home setting with a medical setting for infusion therapy and found that home infusion patients were no more likely to experience adverse drug events (ADE) or side effects (all $p < .05$) than those in a medical setting.[3] Another study with similar results but focusing on two groups of Medicare patients (60 and older and younger than 60) concluded that home infusion antimicrobial therapy is a viable and safe option for older patients. Similar to the systematic review of studies, it was noted that ADE's related to the catheter were no different between the two age groups in this study.[4]

Another retrospective study conducted over a two-year period, demonstrated a low overall ADE rate of 4.2% among 291 patients receiving infliximab. Additionally, there were no life-threatening serious adverse events (SAEs) associated with the 1,866 infusions analyzed in the study.[5] A similar study reported in 2019 involving a larger patient population (n=796) with a total 5,581 infusions also showed a low rate of infusion reactions. Specifically, there was a total of 109 infusion reactions (2.0% of all infusions) with a majority being acute and mild in severity. Furthermore, the author of this study concluded that these numbers were lower than what is reported in community-based and academic gastroenterology practices.[6]

An additional study focusing on Medicare patients utilizing home infusion antibiotic therapy demonstrated that treatment at home is cost effective and provides substantial savings while continuing to provide good clinical outcomes for patients with serious infections. Moreover, the patients in this study had no unplanned hospitalizations from antibiotic therapy failure or from line complications.[7] Finally, a randomized trial of home versus hospital intravenous antibiotic therapy in adults with infectious diseases showed that home IV therapy is well tolerated, is less costly, does not disadvantage quality of life or clinical outcomes compared to hospital therapy.[8]

As evident from the data in these studies, home infusion is safe and effective. Many of the reported studies conclude that these outcomes are due to the coordinated efforts of home infusion clinicians who monitor patients between infusions and work closely with prescribers to report side effects or changes in condition that might interfere with treatment efficacy or increase the risk for adverse events. As a result, the incidence of adverse events is very low and serious or life-threatening reactions negligible. These studies conclude that home infusion services can provide safe, clinically effective care, improve patients' quality of life, and reduce health care costs. Moreover, home infusion therapy is safe with low ADEs and SAEs and allows the patient to stay in the safety and comfort of their home, increase their independence and quality of life, and decrease their risk for hospital-acquired infections.

Home Infusion Accreditation

The home infusion industry has a well-established private sector driven accreditation structure. Several companies currently offer full-service accreditation programs that evaluate and credential all aspects of the home infusion pharmacy and nursing programs including, but not limited to:

- Sterile compounding in compliance with state, federal and industry standards (e.g. United States Pharmacopeia Chapters <797> and <800>)
- Clinical competencies for pharmacists and nurses who care for home infusion patients
- Equipment safety and maintenance procedures
- Assessments, care planning, and care coordination requirements
- Patient education and safety requirements
- Quality assessment and improvement program requirements

Commercial payers rely on the accreditation programs to validate that a home infusion provider meets or exceeds expected industry standards and complies with state and federal laws.

NHIA POSITION

Home infusion requires a wide range of professional support which varies depending on the therapy being administered. In all cases, patients receive professional services from pharmacists and nurses who coordinate and communicate continuously throughout the patient's time on service. Most often, the pharmacy is the entity contracted with the third-party payer, and assumes the responsibility for case managing the home infusion therapy (i.e. maintaining the official patient record, obtaining physician orders, designing the care plan, etc.).

Unfortunately, CMS' incorrect decision to define home infusion exclusively as a nursing service, and reimburse only for in-person nursing visits has caused confusion for many stakeholders, including accreditation organizations who are tasked with designing standards for this new Medicare program. NHIA strongly believes that CMS' interpretation and subsequent reduction in reimbursement will shift more patients to costlier settings like hospitals and skilled nursing facilities, put patients at risk for hospital-acquired infections, and decrease home infusion quality by fragmenting services.

Commercial payers seeking to mimic CMS' methodology might believe that "if it's good enough for Medicare, it's good enough for us" and explore using a similar payment methodology. Unfortunately, this philosophy would quickly undermine home infusion access and shortchange the important and necessary specialized pharmacy-related professional services, making home infusion unsustainable. If properly defined, we agree that exploring a coding system that more clearly delineates the home infusion professional services (particularly those provided by pharmacists) from the commodity items may have merit, but CMS's approach is far from viable.

NHIA and its member companies urge stakeholders to reject CMS' deeply flawed interpretation of the home infusion services and reimbursement methodology.

Instead, we encourage payers, accreditors, and regulators to maintain the existing, cost-effective model for how home infusion services are commonly provided, which reimburses home infusion pharmacies for the full range of professional services, equipment, and supplies necessary to safely provide infused drugs in the home setting. NHIA feels strongly that the current structure, which relies on an efficient and effective collaboration between pharmacists and nurses to achieve optimal outcomes, has a proven track record of delivering high-quality, effective patient care.

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About NHIA

NHIA represents companies that provide infusion therapy to home based patients as well as companies that manufacture and supply infusion and specialty pharmacy products. For additional information about this statement contact Connie.Sullivan@nhia.org. For more information about NHIA visit www.nhia.org.

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