

Home Administration of Infused Biologics

Position Statement

Introduction

Biologics have been administered safely in the home setting since the 1980's, starting with immune globulin treatments for primary immune disease.¹ When the first monoclonal antibody (mAB) was introduced in 1986, safety for administration at home was questionable. Consequently, a business model emerged where most patients receive their mAB infusions in a physician office or hospital clinic setting. Over the past three decades, as the number and type of infused mABs have increased, providers have become more experienced with administering these agents in alternate settings. As a result, more patients are choosing to receive infusions at home, particularly when access to an infusion clinic or office is limited; when traveling is burdensome; or when quality of life is improved. Payers are also examining the costs associated with the different sites of care where patients receive infused drug therapies, and are exploring ways to direct patients to the most appropriate site, and level, of care. As the body of evidence demonstrating safety, cost savings, and satisfaction associated with home infusion grows, adult and pediatric patients are more frequently being referred to the home for a wide array of biologic treatments. Site of care optimization programs that offer patients the choice of receiving infusions at home increase access to novel treatments without compromising safety. Ensuring that patients receive coordinated care from an accredited home infusion provider is requisite to achieving optimal outcomes when infused biologics are administered in the home.

Discussion

Home administration of IV therapies dates back to the 1980s, and the provider definition as stated in the National Provider Identifier Database (NPIdb) recognizes the fact that biologics are included in the range of services routinely offered by infusion providers.² Home infusion is an extension of the health care continuum and serves as a safe, convenient, cost-effective alternative for patients to receive intravenous treatments when other settings are 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. A 2010 report to Congress by the Government Accountability Office (GAO) studied utilization of home infusion by commercial payers and 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.”*³ The report specifically acknowledges that both acute and chronic therapies are safely administered at home.

HOME INFUSION MANAGEMENT OF ACUTE INFUSION REACTIONS

Home infusion pharmacists and nurses have decades of experience managing the provision of intravenous biologics, such as immune globulin and infliximab. Home infusion clinicians recognize that the prevention and management of acute infusion reactions (AIRs) is inherent to administering immune therapies. Standard operating procedures (SOPs) for patient screening, clinician training, and medication administration are employed to prevent and manage AIRs. An article published in *INFUSION* magazine last year outlined the recommended approach (adapted from the World Allergy Organization guidelines for assessing and managing anaphylaxis) for managing AIRs in the home setting.⁴

In 2017, NHIA conducted an unpublished review of SOPs for infliximab submitted by seven home infusion companies that included three small regional providers, two hospital-based providers, and two national companies. All providers had SOPs requiring pre-admission screening for risk factors indicating a patient was predisposed to serious adverse events (SAEs), and for verifying access to emergency services (i.e. located within a 911 service area). The potential for adverse events was a major factor in determining whether or not to accept a patient on to service. All providers incorporated the use of pre-treatment medications, required onsite nurse supervision during and after the infusion, and provided specific instructions regarding the management of infusion related reactions consistent with the product labeling. Additionally, SOPs required communicating with patients prior to each scheduled infusion to assess for changes in the patient’s health condition. Assessment findings were required to be documented in the patient electronic medical record and communicated to the prescribing physician if they were cause for concern.

SAFETY

NHIA recognizes that randomized controlled trials (RCTs) conducted in the home infusion setting are lacking; however, decades of experience with agents where AIRs are common has influenced modern best practices for preventing and managing reactions. Evidence suggests that SAEs associated with the administration of mABs in the home

are rare. A retrospective review of data from one home infusion provider conducted over a two-year period demonstrated an overall adverse drug event (ADE) rate of 4.2% among 291 patients receiving infliximab. Additionally, there were no life-threatening SAEs associated with the 1,866 infusions analyzed in the study.⁵ An earlier study, published in 2005 in the *Journal of Pediatric Gastroenterology and Nutrition*, examined the cost, safety, and satisfaction with pediatric home infusions of infliximab. The study, which examined 59 doses provided over a two-year period to 10 carefully selected patients, concluded that home administration was safe, cost effective, and resulted in less time away from school and work.⁶ Additionally, the average patient satisfaction score was recorded as a nine on a 10-point scale.⁶ Further prospective home-based research is needed to assess adverse event frequency, outcomes, costs, and satisfaction rates across multiple providers for a broader range of biologic agents.

COST EFFECTIVENESS

Due to the dramatic growth in health care spending associated with specialty drugs, insurers are exploring ways to manage costs and eliminate waste. With spending on specialty drugs, many of which are infused biologics, expected to reach \$400 billion by 2020⁷, payers are employing site of care optimization strategies as a means of eliminating waste and lowering costs. Nationally, spending for specialty drugs is split equally between the pharmacy benefit and the medical benefit, and the average cost can vary widely by setting of administration. Hospital outpatient clinics are considered the most costly site of care for infused specialty products.⁸ Transitioning patients to home infusion, ambulatory infusion centers, or physician offices has the potential to generate an annual savings of 12-34% depending on the drug.⁹ In addition to generating a cost savings, Blue Cross Blue Shield of Michigan found that patients benefit from improved adherence and report high satisfaction because home infusion interferes less with work, school, and family activities.¹⁰ Finally, the cost savings generated through site of care optimization is passed on to the patient in the form of lower copays, and reduced out-of-pocket costs.

COORDINATED SERVICES

Achieving optimal outcomes with home administration of infused biologics requires careful planning, specialized clinician training, and coordination among the prescriber, pharmacy, nurse, and patient. The Centers for Medicare & Medicaid (CMS) recognized the unique requirements for dispensing infused medications during the implementation of the *Medicare Modernization Act* in 2006. CMS issued the following statement to Medicare Part D Plan Administrators regarding the provision of infused drugs: *"Part D plans must have a sufficient number of pharmacies capable of providing the full range*

of home infusion Part D drugs to ensure enrollees have adequate access to medically necessary home infusion therapies when needed.¹¹ CMS recognized that while any pharmacy can dispense an injectable drug in its unfinished, raw form, home infusion pharmacies are the most appropriate entity for providing a comprehensive service. NHIA contends that this same standard and expectation applies to the dispensing of infused biologics in that the delivery of medications and ancillary supplies is coupled with specialized clinical services.

STERILE COMPOUNDING

Home infusion providers are experts in the practice of sterile compounding. With the heightened focus on the potential for patient harm from contaminated sterile medications, NHIA asserts that home infusion providers are uniquely qualified to oversee the handling, preparation of biologics administered in the home setting. Home infusion providers are vigorously regulated and inspected by the state Boards of Pharmacy, Food and Drug Administration (FDA) and accreditation organizations for aseptic practices. Since biologics often require sophisticated aseptic manipulations to prepare biologics as part of the administration process, home infusion pharmacies ensure nurses receive the proper instruction and supplies for performing aseptic manipulations accomplished in the home.

NHIA Position

NHIA believes the safety of home administration of intravenous biologics has been substantially established and documented. Home infusion providers minimize risks for serious adverse events and acute infusion reactions through patient pre-screening and assessment, and organizational SOPs. Home infusion clinicians 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 rarely occur. Site of care optimization protocols promote patient choice and the utilization of the most clinically appropriate and cost effective place of service. Home administration of infused biologic agents allows patients to benefit from reduced exposure to hospital pathogens, improved adherence, and a better quality of life. NHIA believes that home infusion providers are well positioned to provide the necessary clinical oversight and coordination to ensure optimal outcomes in a cost-effective manner for patients receiving infused biologic therapies.

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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.