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The Treatment of Rare Chronic Medical Conditions with Home Infusion: A Focus on CIDP

BY BRIAN TONKOVIC, PHARMD

It is well documented that the clinical and economic costs associated with chronic medical conditions like heart disease, cancer, and diabetes are significant. Patients with serious chronic conditions make up approximately 1 percent of the U.S. population, but account for 20 percent of our country’s healthcare spend. In addition, chronic conditions negatively impact the quality of life for nearly one out 10 Americans – approximately 25 million people. Given the growing numbers of adults with one or more chronic disease diagnoses, the current focus on prevention of chronic diseases, as well as appropriate utilization of related healthcare resources, is both intense and urgent. One key focus in support of responsible, effective resource utilization is appropriate site of care, which impacts both economic and quality-of-life issues.

Site of care is an especially important consideration for less frequently diagnosed chronic diseases. These conditions typically require specialty infusion medications, which demand unique monitoring and management strategies. One site-of-care option – home infusion – is particularly well-suited to addressing these concerns, as well as cost and quality-of-life issues. By highlighting the use of home infusion of the specialty medication intravenous immune globulin (IVIg) for the treatment of chronic inflammatory demyelinating polyneuropathy (CIDP), this article will illustrate the benefits of using home infusion therapy in the treatment of rare chronic diseases.

BACKGROUND

Specialty Infusion Medications. A significant proportion of insurance claims for patients with rare diseases are for specialty pharmacy medications. These medications, many of which are manufactured through biologic processes, have been proven effective in a rapidly growing list of chronic diseases. The annual yearly cost trend for these medications is expected to grow to 22 percent by 2014 and to surpass traditional (nonspecialty) drug spend by 2018, the financial impact of which will be significant to patients and payers. Specialty medications require unique monitoring and management strategies, including appropriate site of care, to ensure effective utilization and avoid waste. In fact, a recent specialty drug trend report identified a 16 percent decline in physician office administration of specialty drugs, with a corresponding 15 percent increase in the use of outpatient facilities, over a five-year period.

Intravenous Immune Globulin (IVIg). IVIg is approved by the Food and Drug Administration (FDA) for treatment of a few select diagnoses. However, given extensive trials and the resulting positive outcomes for multiple disease states, significantly increased use of this drug is anticipated. In the field of neurology alone, immunoglobulin therapy utilization is predicted to grow 70 percent between 2012 and 2015. Importantly, there are over 160 published medical conditions for which IVIg has been used as treatment; however, only about 50 percent of these indications have been reviewed by organizations with expert consensus, leaving the review burden on health plans.

Immunoglobulin therapy is the focus of specialty drug management strategies; this is because it is expensive, subject to clinical guidelines for use, and often administered in costly settings. Increased utilization demands stewardship for this drug, which can cost over $450,000 per year when administered in an outpatient infusion center.

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP). CIDP is an autoimmune disorder that affects the nervous system with a very heterogeneous presentation of symptoms, severity and course.

The exact pathologic mechanism remains unclear, although it appears to involve an autoimmune process whereby the myelin sheath that covers and protects peripheral nerves is attacked. As the myelin around the nerves is damaged, the ability of the nerves to conduct electricity, and therefore to contract muscles, worsens. Patients present with numbness and tingling, weakness, loss of reflexes, and pain, all which can be debilitating and can negatively impact the patient’s ability to perform basic activities of daily living (ADLs).

The course of CIDP varies widely among individuals. Some may have a bout of CIDP followed by spontaneous recovery, while others may have many bouts with partial recovery in between. Others may present with a chronic progressive course of disease, while still others may not respond to treatment. The disease is a typically treatable cause of inflammatory neuropathy, and initiation of early treatment to prevent loss of nerve cells is important. Even with treatment, however, some individuals may experience residual numbness or weakness.

HOME IVIG THERAPY FOR CIPD

IVIg was recently approved by the FDA for the first time to treat a neurologic condition – CIDP. IVIg doses for CIDP are generally higher per treatment cycle than those required for most other disease states that it is used to treat. The impact of higher dosing – in addition to increased cost – is longer infusion times. These times range from five to eight hours or more, depending on total dose and patient tolerance. For some patients, the dose is divided over two or more days. The dosing schedule, especially when provided in an outpatient center, results in significant disruption to a patient’s life.

IVIg dosing is diagnosis- and weight-based. While treatment of a patient with CIDP involves some margin for dosing changes depending on patient response to therapy, dosing is a significantly dependent variable. However, site of care is an important independent variable. Currently, more than 61 percent of patients treated with IVIg receive their infusions in a hospital outpatient center, with an associated cost that is two to four times that associated with home infusion.
Indeed, home infusion offers a lower-cost, as well as a safe and convenient, option for IVIg infusion. The transition of clinically appropriate patients to home positively impacts not only cost of care but also patient quality of life and satisfaction. Factors such as time missed from work or school, travel expenses, and nosocomial exposure risk can be positively addressed by home care.

Importantly, most patients tolerate IVIg without any adverse reactions. Approximately 5 percent to 20 percent will experience mild reactions such as headaches, nausea, malaise, fevers, and changes in blood pressure, typically infusion rate-related.8,9,10 Severe reactions such as anaphylaxis are exceptionally rare.

The safety of IVIg infusions in the home setting is well documented.11-14 This safety record is supported by robust infusion protocols, policies, and patient-specific assessment forms that guide nurses and pharmacists to customize the therapy to each individual patient.

**CASE STUDY**

In 2011, in collaboration with five health plans, a program was implemented to promote and provide access to home infusion services – rather than hospital outpatient infusion center services – for IVIg patients identified by the payers as high-users. The goals were to transition existing members receiving infusions in outpatient centers to home infusion care, and then to implement effective strategies to redirect newly approved members to home infusion at the time of prior authorization. One such patient, who had CIDP, had been traveling to a downtown Boston area hospital for his monthly infusions. Each clinic visit required the patient to take a day off from work, a burden that affected his work productivity.

In consultation with the patient’s prescribing physician, a protocol was implemented comprised of divided multiday infusion regimens using pre-medications, and well-defined, established home infusion procedures and assessments. The specialty pharmacy patient transition team discussed potential administration options and barriers with the patient, and provided him with an estimate of his out-of-pocket expenses. The pharmacist addressed the patient’s concerns regarding adverse reactions and IVIg brand selection. In addition, the transition team worked with the infusion clinic, assessing the patient’s history of IVIg brand use and determining his specific infusion parameters. In recognition of the potential for infusion reaction with a change in the administration regimen, brand and pre-med protocols were kept the same. The patient, working with his pharmacist and physician, decided to divide his dose into infusions given on two consecutive days. He was able to arrange with his infusion nurse to have these infusions performed after work.

As a result of this program, the patient's transition to home infusion was seamless, his new infusion schedule was significantly less disruptive to his lifestyle, and he did not experience any new adverse reactions at home. In addition, in 2012, the patient received a total of 1,260 grams of IVIg in the home, saving his insurance provider $175,147 in avoided outpatient claims.

**CONCLUSION**

To improve stewardship of limited and costly healthcare resources, it is a responsibility within the healthcare system to incorporate best practices that consider clinical outcome, cost and patient quality of life. This includes best practices for uncommon but significantly expensive chronic diseases such as CIDP. Recognizing that hospital outpatient infusions represent 61 percent of IVIg administrations, much must be done to accommodate site-of-care considerations.4 As illustrated in the above case study, home infusion management should be a key option, as it meets the goals of positive clinical outcomes, cost savings and improved patient quality of life.

It is important to note that patient outreach programs have revealed many patients who were unaware that IVIg could be administered at home.7 Interestingly, many physician agents, including advanced practice nurses, seem to be similarly unaware.7 This suggests an immediate opportunity to lower healthcare costs and improve patient outcomes through the consideration of home infusion as a site-of-care option for IVIg patients, including those with CIDP.

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lot of decline in that rate to mimic the decline in 30-day rehospitalization, which makes it a challenge to change the rate of rehospitalization/hospitalization. Understanding this is important to those who are charged with measuring improvement in readmission rates.

As a direct result of this work, several major national initiatives have been launched, such as the Partnership for Patients, the Community-based Care Transitions Program, and a QIO-wide endeavor in every state and jurisdiction, aimed at improving transitions of care. Physicians are now paid by Medicare for certain services to ensure safe transitions, while hospitals face penalties if their patients are rehospitalized often.

WHAT CAN YOU DO?
Readers who want to learn more about the efforts of the nation’s QIOs, each QIO is tasked with working with its communities to improve care transitions. To learn more about what your QIO is doing, visit your state’s website, and contact the person who is leading the Integrating Care for Populations and Communities effort. The National Coordinating Center at CFMC (www.cfmc.org) can provide contact information as well.

QIOs can provide hospitals with their own data as analyzed from claims data analyzed by CMS, and community data that reflects the readmissions/admissions experience of a group of fee-for-service beneficiaries as defined by location of residence. They cannot, however, provide hospitals with data about other hospitals or provider types.


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materials are available in multiple languages.

The focus on quality medical care provides both an imperative – and an opportunity – to work with patients, payers and providers to meet their evolving needs, and to bring forward holistic, innovative, valued solutions that help to improve healthcare. Regardless of shifts in our healthcare system or the delivery of care, there will always be a need for resources that help patients to play an active role in managing their own health. GSK has made a commitment to invest in resources that focus on an integrative and holistic approach, and to working together with our customers to address significant healthcare concerns in order to improve patient health. We have a vested interest in achieving these objectives; however, we cannot do it alone. Together we have a better chance of making a difference.

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