MAY 2019

NHIA Conference WRAP-UP

Highlights From the 2019 NATIONAL HOME INFUSION ASSOCIATION ANNUAL CONFERENCE

A SUPPLEMENT TO NEUROLOGY REVIEWS | A Member of the MDedge Network

Ig therapy standards of practice: Updates and implementation

ORLANDO—Because of the complicated nature of immunoglobulin (Ig) therapy, and the fact that Ig therapy spans multiple disease states and practice settings, standards are essential to guiding clinical practice across the care continuum, said Stacey Ness, PharmD, at the 2019 National Home Infusion Association (NHIA) annual conference.

Ig are a variety of specific subclasses and isotypes of glycoprotein molecules that are produced in white blood cells to perform a critical piece of the body's immune response. Ig was first introduced in the 1950s as a treatment for primary immunodeficiency. It also is used to reduce risk of infection for patients who have poorly functioning immune systems from other causes such as from lymphocytic leukemia, as immune replacement therapy, and to improve immune system response. Ig also is a major therapeutic tool for management of chronic inflammatory demyelinating polyneuropathy (CIDP).

Peripheral neuropathy is a manifestation of neurologic infections for which Ig increasingly is used as a treatment. CIDP is a neurological disorder characterized by progressive weakness and impaired sensory function. In demyelinating neuropathy, the myelin sheath of neurons is damaged, impairing the conduction of signals in the affected nerves. This, in turn, causes deficiency in sensation, movement, cognition, or other functions. CIDP is treated both intravenously (IV) and subcutaneously.

IgNS advances standards

The Immunoglobulin National Society (IgNS), formed in 2012 to advance and sustain the practice of Ig therapy for different conditions in various settings and areas of practice, helped to drive the conversation about IVIg at the recent NHIA conference, emphasizing a comprehensive, multidisciplinary team approach to therapy. This team approach is a cornerstone of the second edition of its "Immunoglobulin Therapy Standards of Practice" (https://ig-ns.org/product/ig-therapy-standards-of-practice/), which was released in 2018.

"Ig care cannot exist in a vacuum," said Dr. Ness, who is director of specialty clinical services at Managed Health Care Associates in Eden Prairie, Minnesota, and current president of IgNS. "We're trying to advance the spirit of collaborative care by everybody who impacts the patient who is being treated with Ig, regardless of site of care or disease being treated."

IgNS's first standards, with a major emphasis on the nurse's role, were released in 2014. The second edition highlights other professional roles, including pharmacist, pharm tech, prescribing physician, and others. It emphasizes treatment planning, intravenous administration, patient care counseling, multidisciplinary practices, and data collection.

As Ig products and treatment approaches have become more complex, the standards of practice for administering

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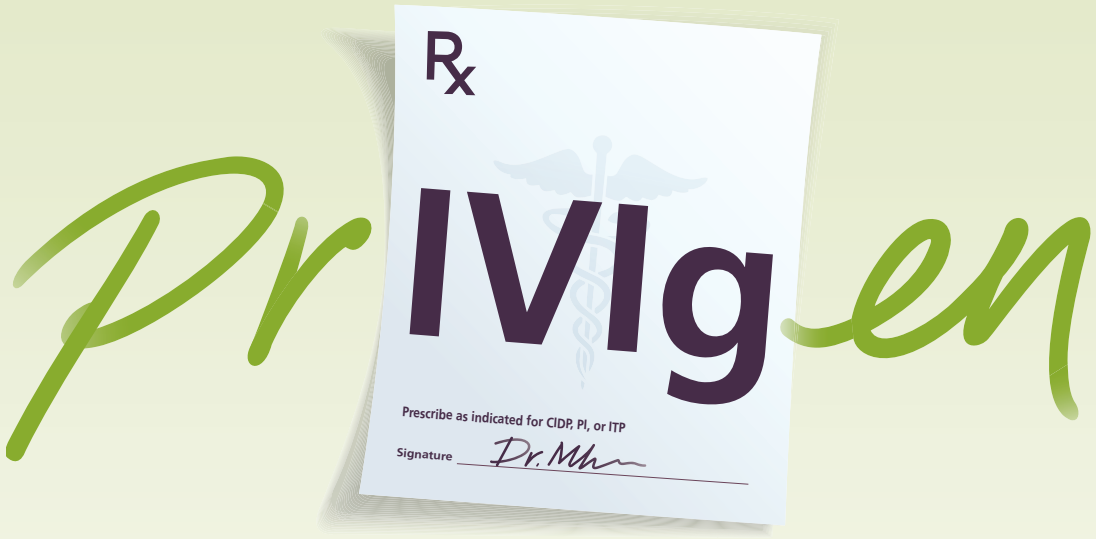

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Privigen is indicated for the treatment of:

- Primary humoral immunodeficiency (PI)
- Chronic immune thrombocytopenic purpura (ITP) in patients age 15 years and older
- Chronic inflammatory demyelinating polyneuropathy (CIDP) in adults
  —Limitation of use: maintenance therapy in CIDP has not been studied for periods longer than 6 months. Individualize duration of treatment beyond 6 months based on patient response.

Please see the brief summary of prescribing information on the following page.

Important Safety Information

WARNING: THROMBOSIS, RENAL DYSFUNCTION AND ACUTE RENAL FAILURE

- **Thrombosis may occur with immune globulin products, including Privigen. Risk factors may include advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling vascular catheters, hyperviscosity, and cardiovascular risk factors.**
- **Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur with immune globulin intravenous (IGIV) products in predisposed patients. Renal dysfunction and acute renal failure occur more commonly in patients receiving IGIV products that contain sucrose. Privigen does not contain sucrose.**
- **For patients at risk of thrombosis, renal dysfunction or renal failure, administer Privigen at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.**

See full prescribing information for complete boxed warning.

Please see Important Safety Information continued on next page.

Biotherapies for Life® CSL Behring

Reference: 1. Data on file. Available from CSL Behring as DOF PVG-002.

Privigen is contraindicated in patients with history of anaphylactic or severe systemic reaction to human immune globulin, in patients with hyperprolinemia, and in IgA-deficient patients with antibodies to IgA and a history of hypersensitivity.

In patients at risk of developing acute renal failure, monitor urine output and renal function, including blood urea nitrogen and serum creatinine.

Hyperproteinemia, increased serum viscosity, or hyponatremia can occur with Privigen. Infrequently, aseptic meningitis syndrome (AMS) may occur—especially with high doses or rapid infusion.

Hemolysis, either intravascular or due to enhanced red blood cell sequestration, may occur. Risk factors include non-O blood group and high doses. Closely monitor patients for hemolysis and hemolytic anemia.

During and shortly following Privigen infusion, elevations of systolic and diastolic blood pressure (including cases of hypertensive urgency) have been observed. These elevations resolved or significantly improved within hours with oral anti-hypertensive therapy or observation alone. Check patients for a history of hypertension and monitor blood pressure during this period.

Consider relative risks and benefits before prescribing high-dose regimen for chronic ITP and CIDP in patients at increased risk of thrombosis, hemolysis, acute kidney injury or volume overload. Monitor patients for pulmonary adverse reactions (transfusion-related acute lung injury [TRALI]).

Privigen is derived from human plasma. The risk of transmission of infectious agents, including viruses and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent and its variant (vCJD), cannot be completely eliminated.

In clinical studies of patients with PI, the most common adverse reactions to Privigen, observed in >5% of subjects, were headache, fatigue, nausea, chills, vomiting, back pain, pain, elevated body temperature, abdominal pain, diarrhea, cough, stomach discomfort, chest pain, joint swelling/effusion, influenza-like illness, pharyngolaryngeal pain, urticaria, and dizziness. Serious adverse reactions were hypersensitivity, chills, fatigue, dizziness, and increased body temperature.

In clinical studies of patients being treated for chronic ITP, the most common adverse reactions, seen in >5% of subjects, were laboratory findings consistent with hemolysis, headache, elevated body temperature, anemia, nausea, and vomiting. A serious adverse reaction was aseptic meningitis syndrome.

In clinical studies of patients being treated for CIDP, the most common reactions, observed in >5% of subjects, were headache, asthenia, hypertension, nausea, pain in extremity, hemolysis, influenza-like illness, leukopenia, and rash. Serious adverse reactions were hemolysis, exacerbation of CIDP, acute rash, increased diastolic blood pressure, hypersensitivity, pulmonary embolism, respiratory failure, and migraine.

Treatment with Privigen might interfere with a patient's response to live virus vaccines and could lead to misinterpretation of serologic testing. In patients over 65 and those at risk of renal insufficiency, do not exceed recommended dose and infuse at the minimum rate practicable.

Please see full prescribing information at Privigen.com.

BRIEF SUMMARY OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use Privigen safely and effectively. See full prescribing information for Privigen.
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Initial U.S. Approval: 2007

WARNING: THROMBOSIS, RENAL DYSFUNCTION AND ACUTE RENAL FAILURE

See full prescribing information for complete boxed warning.

- **Thrombosis may occur with immune globulin products, including Privigen. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling vascular catheters, hyperviscosity, and cardiovascular risk factors.**
- **Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur with immune globulin intravenous (IGIV) products in predisposed patients. Renal dysfunction and acute renal failure occur more commonly in patients receiving IGIV products containing sucrose. Privigen does not contain sucrose.**
- **For patients at risk of thrombosis, renal dysfunction or failure, administer Privigen at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.**

----------INDICATIONS AND USAGE----------

Privigen is an Immune Globulin Intravenous (Human), 10% Liquid indicated for the treatment of:

- Primary humoral immunodeficiency (PI)
- Chronic immune thrombocytopenic purpura (ITP) in patients age 15 years and older
- Chronic inflammatory demyelinating polyneuropathy (CIDP) in adults

Limitations of Use:
Privigen maintenance therapy in CIDP has not been studied beyond 6 months.

----------CONTRAINDICATIONS----------

- History of anaphylactic or severe systemic reaction to human immune globulin
- Hyperprolinemia (Privigen contains the stabilizer L-proline)
- IgA-deficient patients with antibodies to IgA and a history of hypersensitivity

----------WARNINGS AND PRECAUTIONS----------

- IgA-deficient patients with antibodies to IgA are at greater risk of developing severe hypersensitivity and anaphylactic reactions.
- Monitor renal function, including blood urea nitrogen and serum creatinine, and urine output in patients at risk of developing acute renal failure.
- Hyperproteinemia, increased serum viscosity, and hyponatremia may occur.
- Aseptic meningitis syndrome (AMS) may occur, especially with high doses or rapid infusion.
- Hemolysis that is either intravascular or due to enhanced red blood cell sequestration may occur. Risk factors include high doses and non-O blood group. Closely monitor patients for hemolysis and hemolytic anemia.
- Elevations of systolic and diastolic blood pressure (including cases of hypertensive urgency) have been observed during/shortly following Privigen infusion. These blood pressure elevations were resolved or significantly improved within hours with either observation alone or changes in oral anti-hypertensive therapy. Check patients for a history of hypertension and monitor blood pressure during and following Privigen infusion.
- Monitor patients for pulmonary adverse reactions (transfusion-related acute lung injury [TRALI]).
- Carefully consider the relative risks and benefits before prescribing the high dose regimen (for chronic ITP and CIDP) in patients at increased risk of thrombosis, hemolysis, acute kidney injury, or volume overload.
- Privigen is made from human blood and may contain infectious agents, e.g., viruses, the variant Creutzfeldt Jakob disease [vCJD] agent and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

----------ADVERSE REACTIONS----------

- **PI** – The most common adverse reactions, observed in >5% of study subjects, were headache, fatigue, nausea, chills, vomiting, back pain, pain, elevated body temperature, abdominal pain, diarrhea, cough, stomach discomfort, chest pain, joint swelling/effusion, influenza-like illness, pharyngolaryngeal pain, urticaria, and dizziness. Serious adverse reactions were hypersensitivity, chills, fatigue, dizziness, and increased body temperature.
- **Chronic ITP** – The most common adverse reactions, observed in >5% of study subjects, were laboratory findings consistent with hemolysis (hemoglobin and hematocrit decrease without blood loss in conjunction with positive direct antiglobulin test (DAT) and elevated blood lactate dehydrogenase (LDH) and/or indirect bilirubin), headache, elevated body temperature, anemia, nausea, and vomiting. A serious adverse reaction was aseptic meningitis.
- **CIDP –** The most common adverse reactions observed in >5% of study subjects were headache, asthenia, hypertension, nausea, pain in extremity, hemolysis, influenza like illness, leukopenia, and rash. Serious adverse reactions were hemolysis, exacerbation of CIDP, acute rash, blood pressure diastolic increased, hypersensitivity, pulmonary embolism, respiratory failure, and migraine.

To report SUSPECTED ADVERSE REACTIONS, contact CSL Behring Pharmacovigilance at 1-866-915-6958 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch.*

----------DRUG INTERACTIONS----------

The passive transfer of antibodies may:

- Lead to misinterpretation of the results of serological testing.
- Interfere with the response to live virus vaccines.

----------USE IN SPECIFIC POPULATIONS----------

- Geriatric: In patients over age 65 or in any patient at risk of developing renal insufficiency, do not exceed the recommended dose, and infuse Privigen at the minimum rate practicable.

See 17 for PATIENT COUNSELING INFORMATION.

Based on September 2017 revision

Ig therapy standards of practice: Updates and implementation

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these treatments have also evolved. Administration of Ig requires specialized expertise, skill, and knowledge by the provider. Choosing the most appropriate Ig product and dose is a highly individualized process, Dr. Ness said.

Among the recommendations in the new IgNS guidelines is the importance of addressing cultural considerations in treatment, she added. "As we utilize Ig more and more, we need to educate patients about what it is and what it is not." Providers are also concerned about the ability of patients and their caregivers to comprehend the treatment information being presented to them, and how to help motivate adherence to prescribed treatments.

Luba Sobolevsky, PharmD, executive director of IgNS, noted that Ig is used for nearly 100 medical conditions spanning diverse clinical areas and requires a large degree of individualization of care. Because patients often have multiple diagnoses, biologics and disease-modifying therapies are increasingly part of the clinical picture. This complexity of Ig therapy explains the need for a specialty professional society dedicated to Ig, and for the specialized standards, she said.

Risk factors in Ig treatment

According to the IgNS standards, relevant patient risk factors, which can guide the choice of Ig therapy, include diabetes mellitus, cardiac and pulmonary function, blood type, and obesity. Boxed warnings for the 14 IV and subcutaneous Ig products on the market also detail risks for renal dysfunction and failure and thrombosis.

Adverse drug reactions such as anaphylaxis, headache, fatigue, nausea, myalgia, rash, and pruritus can occur at any time during IVIg administration and for several days or more afterward. This underscores the importance of proper supervision by a clinician who is expert in recognizing and managing these adverse drug reactions.

Other key topics addressed in the standards include product availability, treatment planning, ongoing therapeutic monitoring, maintaining adequate hydration, follow-up assessments, and advocacy for the individual patient.

Dr. Ness encouraged all health care personnel involved in Ig therapy to review IgNS's evidence-based standards as a foundation for developing clinical practice policies, procedures, and best practices for Ig administration in their organizations, for orienting and training new staff, and for promoting patient safety.

For more information on IgNS and its standards, visit its website at www.ig-ns.org or email info@ig-ns.org.

—Larry Beresford

Managing chronic pain in the opioid abuse era

ORLANDO—In the current era of opioid abuse, it has become a challenge for many to strike the balance between safe medication use and effective pain management, said Tanya Uritsky, PharmD, at the 2019 National Home Infusion Association (NHIA) annual conference. "Understanding the risks of opioid medications, as well as the appropriate use of these analgesics to achieve effective pain control, is more important than ever," she said. Dr. Uritsky is a clinical pharmacy specialist in pain management and palliative care at the hospital of the University of Pennsylvania.

Dr. Uritsky defined pain as a subjective phenomenon experienced by the patient. In other words, "whatever the patient says it is." It is easy to lose sight of the emotional and other aspects of pain, which are essential to controlling it, she said. "Because there are no objective measures or markers of pain, the patient and clinician have to find a way to trust each other."

Dr. Uritsky drew distinctions between somatic, visceral, and neuropathic pain, which call for different treatment strategies. Neuropathic pain conditions can be quite diverse, and opioids generally are not considered a good choice for treating them. Methadone, on the other hand, has been shown to be effective in treating neuropathic pain, but it presents significant management challenges to the prescriber. Dr. Uritsky recommended leaving the prescribing of methadone to pain specialists.

The widely used pain scale that asks patients to rate their pain from 0 to 10 has generated a lot of recent controversy, in part because people do not agree on what the numbers correlate to in patient experience. Also, some believe it promotes more prescribing of opioids, with negative consequences.

One approach to pain assessment that patients and clinicians can endorse is focusing on maintaining function, Dr. Uritsky said. For many patients, their top goal is to be functional in their activities of daily life. Severe pain can block that goal. "Pain has

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Managing chronic pain in the opioid abuse era

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many layers, and unremitting pain can affect all aspects of quality of life. It becomes all-consuming for the patient."

Revised pain assessment and management standards issued by the Joint Commission in January 2018 emphasize a leadership team with responsibility for pain management and safe prescribing, the involvement of patients in developing their treatment plans, the need for realistic and reasonable goals for treatment, and assessment of risk for opioid misuse. There are number of tools that can be used for assessing such risk, Dr. Uritsky said. But it is important to ask patients if there is a history of substance abuse when prescribing opioidanalgesics.

Fear of addiction

Fear of addiction is widespread, given the media attention to the rising rate of opioid overdose deaths in recent years. "The addiction stigma is intense, but patients do not understand what addiction means," she said. Even health professionals often are unclear on distinctions between terms like addiction, dependence, tolerance, abuse, and withdrawal.

Clinicians can emphasize to their patients that pain is an important mechanism for self-protection, although when it becomes chronic it may not seem very helpful. Oftentimes, the goal is pain reduction, not the complete elimination of pain, she said.

An interdisciplinary team approach to care is important, and universal precautions, as practiced with infectious diseases, can provide a helpful framework for treating everyone the same regarding opioid risks. For chronic pain, try to maximize nonpharmaceutical interventions, Dr. Uritsky said. Consider cognitive-behavioral therapy focused on coping as well as massage or other complementary therapies.

Other options

In another session at the NHIA conference, Larry Good, MD, a gastroenterologist in Lynbrook, NewYork, outlined the promise and the inconsistent evidence base for cannabis-derived treatments for a number of medical conditions, including neuropathy. "Medical cannabis products hold great promise, but high-quality efficacy and safety data are sorely lacking," Dr. Good said.

While the evidence of efficacy has been slow to emerge, in part because of barriers to cannabis research erected by the federal government, the 2018 Farm Bill's transformation of hemp policy has limited the Drug Enforcement Administration's ability to restrict medical marijuana research. Some moderately strong evidence for its efficacy has come from studies of neuropathic pain, Dr. Good said. Other intravenous therapies for managing neuropathic pain include ketamine and lidocaine.

—Larry Beresford

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Mücke M, Phillips T, Radbruch L, et al. Cannabis-based medicines for chronic neuropathic pain in adults. *Cochrane Database Syst Rev*. 2018;3:CD012182.

The professional's role in teaching Ig self-infusion

ORLANDO—Intravenous (IV) immunoglobulin (Ig) is a first-line therapy in the treatment of chronic inflammatory demyelinating polyneuropathy (CIDP), among other neurologic infections and diseases. But subcutaneous (SC) injections of Ig therapy into a patient's fatty tissue—typically in the abdomen, thigh, or back of the arm for gradual absorption into the bloodstream—offers advantages over the more conventional IV administration, according to lecturers at a symposium held during the 2019 National Home Infusion Association (NHIA) annual conference.

These advantages include fewer adverse reactions such as headaches and flulike symptoms, which can be more common with IV administration, as well as prevention of treatment-related disease state fluctuations. Some patients present difficulties in obtaining venous access; others have lifestyle issues that may preclude being hooked up to an IV for several hours at a time.

For patients with CIDP, the SC option was approved by the FDA on March 16, 2018, when it approved for CIDP treatment Hizentra, a 20% Ig formulation manufactured by CSL Behring, King of Prussia, Pennsylvania. Hizentra has been well tolerated for ongoing maintenance of patients with primary immunodeficiency (PID) since 2010.

Evidence and support

The Behring-supported, multinational Polyneuropathy and Treatment with Hizentra (PATH) study was a randomized, double-blinded, placebo-controlled trial comparing relapse rates in patients with CIDP at 69 neuromuscular centers.

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The professional's role in teaching Ig self-infusion

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The researchers found that 63% of patients on placebo had a relapse or were withdrawn from the study, compared with 39% on low-dose and 33% on high-dose Ig, concluding that SC Ig was efficacious and tolerated well enough to be used as a maintenance treatment for CIDP.[1]

The proper administration and management of Hizentra, the first medication approved in the US for SC Ig treatment of CIDP, was explored in a Behring-sponsored breakfast presentation at the recent NHIA conference.

Presenters highlighted Behring's Starting Hizentra Administration with Resources and Education (SHARE) program, which educates nurses and other clinicians on the SC administration of Hizentra for PID and CIDP. The SHARE program provides information on best practices and techniques for teaching self-administration, along with interactive online courses and a professional certification exam in SC Ig administration.

Any human-derived product has a risk of disease transmitting, said Kristen Coleman, an infusion science specialist at CSL Behring. It also can cause thrombosis. Hizentra has been well tolerated in PID, and site reactions including redness, swelling, itching, and bruising at the injection site tend to go away with time.

Self-administration

Subcutaneous Ig is typically self-administered by patients in their own home, but there is an essential role for the home infusion nurse in preparing, teaching, and supporting the patient. The nurse typically goes to the patient's home for 2 to 3 in-person visits, and then follows up with monthly phone calls. Patients learn to use aseptic clean processes, select an injection site with sufficient fatty tissue, and properly dispose of needles. Patients give themselves up to 8 injections at a time at sites located at least 2 inches apart, typically on a weekly schedule. Injection is not usually painful unless the needle reaches muscle tissue.

Melody Bullock, BSN, BS, MS, a Behring infusion science specialist with PID, demonstrated the process by self-administering her regular Ig dose using a portable infusion pump while sharing her personal story from the podium. "I believe in the product and its benefits for patients and in the supportive programs offered to patients," she said. Those support programs include the following:

- A step-by-step instructional video
- "Voice2Voice," patient advocates sharing their experience with other patients and caregivers
- The Assurance Program, where patients are able to build up a reserve of Hizentra
- A copay relief and patient assistance program
- A Hizentra Therapy Journal or app for tracking their injection experience over time.

A poster presented at the NHIA conference by Achaia Taltoan, PharmD, of Coram CVS Specialty Infusion Services in Marietta, Georgia, and colleagues compared rates of systemic and local adverse events in home care patients with PID who received either IV or SC therapy. No significant differences were noted in rates of adverse events or symptoms—except that with SC administration, patients were less likely to report fatigue after infusion. Dr. Taltoan concluded that a lack of significant differences in the rates of adverse events between the two groups suggests similar patient comfort and safety for IV and SC Ig treatment.[2]

—Larry Beresford

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2. Taltoan A, Uche A. Comparison of rates of adverse events in intravenous immunoglobulin and subcutaneous immunoglobulin therapy in a home infusion patient population. Abstract presented at National Home Infusion Association conference, March 9-13, 2019, Orlando, Fla.

Home infusion trade group sues HHS over Medicare coverage rule

ORLANDO—On February 14, 2019, the National Home Infusion Association (NHIA) filed a lawsuit in U.S. District Court for the District of Columbia against the Department of Health and Human Services (HHS), challenging its published final rule for implementing Medicare coverage for home infusion professional services (http://www.nhia.org/documents/NHIA_Complaint_FILED.pdf).

"The Centers for Medicare and Medicaid Services (CMS) does not understand, value, or appreciate home infusion services or the pharmacist's essential role in it," said NHIA's lawyer, David Farber, at the 2019 National Home Infusion Association (NHIA) annual conference. Mr. Farber is a partner at King & Spalding in Washington, DC.

Home and alternate site infusion and specialty pharmacy services are not a single benefit, but a patchwork of categories and coverage for different types of therapies, Mr. Farber said. This includes medical equipment and licensed professionals trained in home health care. NHIA's lawsuit applies to certain Medicare Part B drugs delivered by an external infusion pump, but not intravenous immunoglobulin, antibiotics, insulin, or Part D medications, which are covered separately.

Multidisciplinary services

Home infusion delivery includes pharmacist-developed services such as compounding sterile products; nursing-related services; coordination with other providers of care, including the prescribing physician; and other clinical services required to treat patients in their homes. This also involves reviewing the patient's medical history and physical limitations, modifying ordered therapies to accommodate the home environment, and developing a plan of care that articulates goals for the treatment.

Prior to 2016, there was no specific coverage for these professional services under Medicare, in contrast to private payers. Reimbursement for the intravenous therapy drugs, typically paid with an Average Wholesale Price (AWP)-based methodology, largely helped to subsidize the professional services component of home infusion.

One aim of the 21st Century Cures Act, passed by Congress in 2016, was intended to link home infusion therapy payment to the Average Sales Price (ASP), which trends a quarter less for brand drugs and two-thirds less for generic drugs covered under Part B. To compensate for this effective reduction in payment, Congress created the home infusion professional services benefit.

As outlined in Medicare's external infusion pump local coverage determination policies, the home infusion benefit applies to 28 drugs in 3 categories: chemotherapies, subcutaneous immunoglobulin, and "other." Professional services for delivering these therapies are to be paid at daily rates ranging from $138.74 to $239.76, using "G" category billing codes.

The new benefit was not, however, intended to be introduced until 2021, giving CMS time to create appropriate implementing policies. Congress recognized that providers couldn't wait that long for the coverage, so the 2018 Bipartisan Budget Act contained a provision—effective from January 1, 2019, to December 31, 2020—for a transitional professional services benefit to be paid on the basis of an "infused drug administration calendar day."

When CMS issued its final implementing rule for "Home Infusion Therapy Requirements" (https://www.federalregister.gov/documents/2018/11/13/2018-24145/medicare-and-medicaid-programs-cy-2019-home-health-prospective-payment-system-rate-update-and-cy) on November 13, 2018, it stated that this payment would only be made on days when a "skilled professional" (i.e., the home infusion nurse) is present in the patient's home.

Challenging the ruling

NHIA's suit challenges this interpretation to limit the days when home infusion professionals' services could be covered as contrary to the intent of Congress. The CMS interpretation effectively eliminates reimbursement for the pharmacist and other professional services critical to home infusion therapy, including nursing, when they are provided remotely.

"This rule undercuts Congress's intent to ensure that Medicare beneficiaries can access these therapies in the safety and comfort of their own homes," said Varner Richards, PharmD. Dr. Richards is Chair of the NHIA Board of Directors and CEO of Intramed Plus in Columbia, South Carolina. "It simply doesn't reflect the reality of how home infusion services are currently delivered and reimbursed." Nowhere in the law does it say a nurse must be present in the home to qualify for covered professional services, Dr. Richards noted.

The decision to sue CMS was not taken lightly, added Sharon Scribner Pearce, NHIA's vice president of government affairs. The association has been working behind the

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scenes to promote policy changes that could ensure appropriate, sustainable reimbursement for home infusion professional services. "We tried to explain how home infusion therapy works as a team. We also shared with CMS current practice in how these services are paid by private insurers and other government programs such as Tricare and the Veterans Administration."

Congressional support

Members of Congress also made calls and sent letters on NHIA's behalf. The association's concern is not just about the transitional benefit, but also about how the permanent professional services benefit is likely to be implemented by CMS starting in 2021, Ms. Pearce said. The association plans to survey its members to clarify and quantify professional services components of their home infusion therapy. With briefs and counter-briefs expected to be filed in April and May, a possible judgment on NHIA's suit could be rendered by Judge Richard Leon in June or July, Mr. Farber said. "If we lose, we'll return to Congress to try to correct it legislatively."

—Larry Beresford