Transcript Details
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From IVIg to SCIg: Rethinking Long-Term CIDP Therapy

Announcer:
Welcome to ReachMD. This medical industry feature, titled “From IVIg to SCIg: Rethinking Long-Term CIDP Therapy” is sponsored by CSL Behring. And now, here’s your host, Dr. Jennifer Caudle.

Dr. Caudle:
This is ReachMD, and I’m your host Dr. Jennifer Caudle. Joining me today to discuss initiation of Hizentra® Immune Globulin Subcutaneous (Human), 20 percent liquid in patients with chronic inflammatory demyelinating polyneuropathy, or CIDP, is Dr. Todd Levine. Dr. Levine is the Director of the ALS Clinic at Honor Health in Phoenix, Arizona. Dr. Levine, welcome to the program.

Dr. Levine:
Thanks for having me.

Dr. Host:
And before we get started, let’s take a quick moment to review some Important Safety Information for Hizentra.

Announcer:
Important Safety Information

Indications and Usage

Hizentra®, Immune Globulin Subcutaneous (Human), 20% Liquid, is indicated for:

• Treatment of primary immunodeficiency (PI) in adults and pediatric patients 2 years and older.

• Maintenance therapy in adults with chronic inflammatory demyelinating polyneuropathy (CIDP) to prevent relapse of neuromuscular disability and impairment.

– Limitation of Use: Maintenance therapy in CIDP has been systematically studied for 6 months and for a further 12 months in a follow-up study. Continued maintenance beyond these periods should be individualized based on patient response and need for continued therapy.

For subcutaneous infusion only.

WARNING: Thrombosis may occur with immune globulin products, including Hizentra. 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. For patients at risk of thrombosis, administer Hizentra 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.

Please stay tuned to hear more Important Safety Information in this program.

Please see full prescribing information for Hizentra including boxed warning at Hizentra.com/HCP

Dr. Caudle:
And now that we’ve reviewed some of the Important Safety Information, let’s dive into our discussion. Dr. Levine, what challenges do patients with CIDP typically face during treatment, and how might starting subcutaneous immunoglobulin therapy earlier be right for

patients previously stabilized on IVIg?

Dr. Levine:
Well, CIDP is a rare, autoimmune-mediated neuropathy where chronic inflammation causes damage to the protective myelin sheath around peripheral nerves.[1-3]

So when we treat CIDP, our primary goals are to calm that inflammation, prevent further nerve damage, and preserve neuromuscular function.[2,4,5] The challenge is that the inflammation in CIDP doesn't come from just one pathway—it involves multiple mechanisms.[1,2,6] That complexity can make the treatment approach tricky, but it also highlights the value of broad-spectrum immunomodulator therapies that can act across several fronts.[1,5,7]

So immunoglobulin, or Ig, is a recommended treatment option for CIDP, per the EAN and PNS guideline*, alongside corticosteroids and plasma exchange. As a broad-spectrum immunomodulator, Ig helps suppress multiple inflammatory mechanisms that drive CIDP pathology.[2,5,6,8-11]

Ig is *initially* administered intravenously—also called IVIg—to help patients regain function and stabilize their symptoms.[2,4,12] However, IVIg can be challenging as a maintenance therapy. Over time, issues like systemic side effects, venous access difficulties, and fluctuating Ig levels can make it less sustainable for ongoing management.[5,13-17]

That's where Hizentra comes in. As a subcutaneous form of immunoglobulin, or SubQ Ig, Hizentra offers a way to maintain disease control while addressing some of the common limitations of IVIg. Its at-home self-administration helps patients avoid the time, logistical burden, and possibly systemic side effects often associated with IV infusions.[5,14]

So when we're considering switching to Hizentra as soon as patients are stabilized, I look for patients who are recently diagnosed and already showing good response to IVIg, or those whose lifestyle or treatment goals would clearly benefit from a more convenient and possibly more tolerable long-term option. If we can identify those individuals early—based on both clinical presentation and personal priorities—we have a chance to not only improve their day-to-day experience, but also optimize long-term outcomes.

Dr. Caudle:
And what clinical signs or individual factors help you decide whether Hizentra is right for a patient?

Dr. Levine:
Well, when determining if Hizentra is an appropriate choice, it's important to consider both clinical and individual patient factors. In terms of clinical factors, weekly dosing of Hizentra provides week to week CIDP relapse-control and steady Ig levels, so patients experience less of a peak and trough between treatments and fewer systemic side effects.[18,19] In fact, a 3.6-fold lower rate of systemic adverse reactions has been shown after transitioning from IVIg to Hizentra.* And because the Hizentra dose can be adjusted based on how a patient is responding, it's easy to personalize the therapy to meet their unique needs.[5]

*This difference should be interpreted with caution as there was no parallel group of subjects receiving placebo in the IVIg restabilization phase of the phase III Polyneuropathy and Treatment with Hizentra (PATH) study.

Beyond the clinical side, we also have to consider practical barriers. For some patients, traveling to an infusion center multiple times a month isn't realistic, especially if they live in remote areas, have mobility challenges, or busy schedules. Others may have issues with venous access which makes administration of IVIg difficult.[14] But, once trained by a healthcare provider, patients can self-administer Hizentra in the comfort of their own home at a time that is convenient for them. In fact, Hizentra is the first and only SubQ Ig available in prefilled syringes, and prefilled syringes may simplify the self-infusion process for patients. That's why early identification is key—we need to recognize patients who could benefit from a switch to a more convenient option that provides consistent Ig levels, like Hizentra.

Dr. Caudle:
That makes sense, so could you explain how Hizentra can help maintain consistent functional outcomes in patients with CIDP?

Dr. Levine:
Absolutely. Drastic fluctuations in serum Ig levels can directly impact symptom control, so let's discuss how Hizentra achieves consistent Ig levels in the management of CIDP.[14,19]

Hizentra offers a smoother pharmacokinetic profile because of the subcutaneous administration route and schedule.[19] With smaller, more frequent doses, it maintains stable Ig levels over time compared to the sharp peaks and troughs seen with IVIg.[18,20] Patients treated with IVIg might feel well right after their infusion, but in my experience, some patients don't feel well for multiple days. With IVIg, there is an increased rate of systemic adverse reactions soon after infusion, and as Ig levels decline over the next few weeks, symptoms like weakness, fatigue, or sensory changes can creep back in.[18,20-22]

Dr. Caudle:
For those just tuning in, you're listening to ReachMD. I'm Dr. Jennifer Caudle, and today I'm speaking with Dr. Todd Levine about early

*EAN, European Academy of Neurology; PNS, Peripheral Nerve Society

initiation of Hizentra SubQ Ig in CIDP maintenance treatment. Now, I'd like to shift gears and discuss the logistics of changing a patient's treatment. Dr. Levine, what are some best practices for transitioning IVIg-stabilized patients to Hizentra?

Dr. Levine:
Well, transitioning a patient from IVIg to Hizentra can be a smooth process when approached with the right strategy and support. One of the most important aspects is timing—we want to start a patient on Hizentra one week after their last IVIg infusion. This helps ensure that serum Ig levels remain steady during the transition, and it minimizes the risk of breakthrough symptoms.

And when it comes to dosing, Hizentra is available in two different dosing regimens, which allows for flexibility based on the patient's disease control needs. The recommended dose is 0.2 grams per kilogram per week, although a dose of 0.4 grams per kilogram per week is also safe and effective to prevent CIDP relapse.

Education and support are also key. Patients need to receive training on self-administration, so nurse-guided training—either in the clinic or through support programs like Hizentra Connect—can make a big difference. Training through Hizentra Connect also includes ongoing support with infusion technique, detailed reports sent to healthcare providers, and help with insurance navigation and reimbursement.

And finally, monitoring is critical. After the switch, providers should keep a close eye on how the patient is doing by checking for symptom stability and asking about their experience with self-infusion. Over the long term, dosing should be individualized and tailored to find the most appropriate dose for each patient.[5,23] Both the PATH and PATH Extension studies demonstrated that Hizentra 0.2 grams per kilogram or 0.4 grams per kilogram dose were effective in preventing CIDP relapse when administered weekly, with the Hizentra 0.4 gram per kilogram dose more likely to prevent relapse.[*5,23] But because this is a complex heterogenous disease with multiple mechanisms, it's important to look at each patient individually and tailor doses accordingly.

*In the PATH and PATH OLE clinical studies, there was no statistical difference between the two doses.

Dr. Caudle:
Now, when it comes to making treatment decisions alongside patients, what strategies can healthcare providers use to effectively communicate the available options?

Dr. Levine:
One of the most effective strategies is to meet patients where they are and really understand their daily challenges, goals, and concerns. Shared decision-making doesn't just involve a one-time conversation. It's a continual process where providers and patients work together to make treatment choices that reflect the patient's goals, preferences, and lifestyle.[24] Because therapies can always be changed if one thing isn't working.

Providers should regularly check in with their patients to review goals, answer questions, and ensure their concerns and priorities are heard. From there, it's about laying out all the treatment options, explaining the pros and cons of each option, and helping them understand how each one might fit into their life.[5] This approach empowers patients by giving them a sense of ownership over their care, which we know can lead to better engagement and adherence. Once a decision is made, outlining next steps and addressing potential challenges upfront helps patients feel prepared, supported, and confident in their care plan. [24]

Dr. Caudle:
And as we come to the end of our program, Dr. Levine, how should we approach conversations with patients about starting SubQ Ig treatments like Hizentra?

Dr. Levine:
When discussing Hizentra, it's helpful to start by focusing on efficacy and safety. So for patients who are stable on IVIg, I emphasize that Hizentra has been shown to effectively maintain CIDP relapse prevention while reducing the risk of systemic side effects and provides smoother, more consistent Ig levels.[5,19] And those benefits are why it makes sense for appropriate patients to transition from IVIg to SubQ Ig. The most common side effect of Hizentra is local infusion site reactions, such as redness, swelling, itching, and/or bruising. In the PATH study, all local reactions were either mild, at 94.5 percent, or moderate, at 5.5 percent, in intensity—and the frequency tended to decrease over time.[25]

It's also important to talk about convenience and lifestyle fit. Hizentra is a subcutaneous therapy that can be self-administered at home using prefilled syringes, giving patients more flexibility and independence. That means no more lengthy visits to infusion centers or waiting for a nurse to come to the house. For many patients, especially those balancing work or family responsibilities, that's a huge relief. So really, it's about framing Hizentra as not just another treatment, but as a lifestyle-friendly, patient-centered option that puts them in control.

Dr. Caudle:

That's a great way to round out our discussion. And I want to thank my guest, Dr. Todd Levine for joining me to discuss early initiation of Hizentra SubQ Ig in patients with CIDP. Dr. Levine, it was great speaking with you today.

Dr. Levine:
Thanks for having me.

Dr. Caudle:
For ReachMD, I'm Dr. Jennifer Caudle. Please stay tuned to hear some Important Safety Information.

Announcer:
Hizentra is contraindicated in patients with a history of anaphylactic or severe systemic reaction to human immune globulin (Ig or components of Hizentra (eg, polysorbate 80, as well as in patients with immunoglobulin A deficiency with antibodies against IgA and a history of hypersensitivity. Because Hizentra contains L-proline as stabilizer, use in patients with hyperprolinemia is contraindicated. IgA-deficient patients with anti-IgA antibodies are at greater risk of severe hypersensitivity and anaphylactic reactions. Thrombosis may occur following treatment with Ig products, including Hizentra.

Monitor patients for aseptic meningitis syndrome (AMS, which may occur following treatment with Ig products, including Hizentra. In patients at risk of acute renal failure, monitor renal function, including blood urea nitrogen, serum creatinine and urine output. In addition, monitor patients for clinical signs of hemolysis or pulmonary adverse reactions (eg, transfusion-related acute lung injury [TRALI].

Hizentra is derived from human blood. 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.

The most common adverse reactions (observed in ≥5% of study subjects were local infusion-site reactions, as well as headache, diarrhea, fatigue, back pain, nausea, extremity pain, cough, upper respiratory tract infection, rash, pruritus, vomiting, upper abdominal pain, migraine, arthralgia, pain, fall, and nasopharyngitis.

The passive transfer of antibodies can interfere with response to live virus vaccines and lead to misinterpretation of serologic test results.

Please see full prescribing information for Hizentra [at HIZ.COM], including boxed warning.
To report SUSPECTED ADVERSE REACTIONS, contact the CSL Behring Pharmacovigilance Department at 1-866-915-6958 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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