A closer look at some of the key topics addressed by Watkins and colleagues[1] — perspective for multidiscipline teams that care for CIDP patients

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Important Safety Information

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 fac

For patients at r **on in patients before administ** **y.**

Hizentra is contr ponents of Hizentra (eg, po sensitivity. Because Hizentr

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Monitor patients atients at risk of acute renal failu for clinical signs of hemolysis or p

Hizentra is deriv Jakob disease (CJD) agent and

The most comm , fatigue, back pain, nausea, ext pain, fall, and nasopharyngitis.

The passive tran .

Indications

Hizentra®, Immu

Treatment of pri

Maintenance th sability and impairment.

Limitation of Us tudy. Continued maintenance beyond these periods should be individualized based on patient response and need for continued therapy.

For subcutaneous infusion only.

Please see full prescribing information for Hizentra including boxed warning.

X

X

Please note that the lead author has received honoraria as a CSL Behring advisory board member, and Dr. Dimachkie has received consultant fees and grants from CSL Behring. The other listed authors are employed by CSL Behring. Editorial support for the original article submission was funded by CSL Behring; however, the final article was peer-reviewed to meet the standards of the publishing journal.

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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.

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.

Indications

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

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

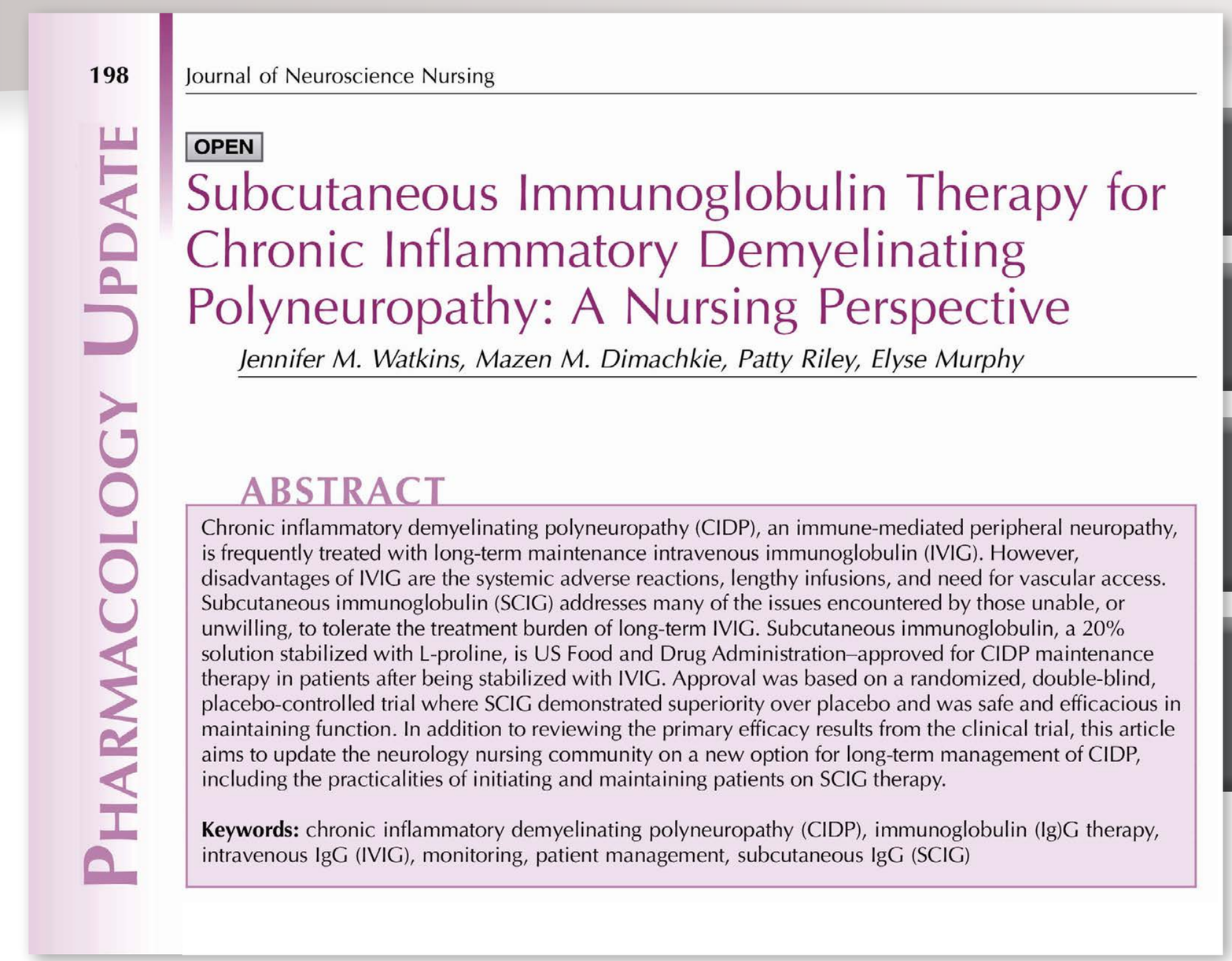
Maintenance therapy in adults with chronic inflammatory demyelinating polyneuropathy (CIDP) to prevent relapse of neuromuscular disability and impairment.

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.

Please see full prescribing information for Hizentra including boxed warning.

A closer look at some of the key topics addressed by Watkins and colleagues[1] — perspective for multidiscipline teams that care for CIDP patients



198 Journal of Neuroscience Nursing

PHARMACOLOGY UPDATE

OPEN

Subcutaneous Immunoglobulin Therapy for Chronic Inflammatory Demyelinating Polyneuropathy: A Nursing Perspective

Jennifer M. Watkins, Mazen M. Dimachkie, Patty Riley, Elyse Murphy

ABSTRACT

Chronic inflammatory demyelinating polyneuropathy (CIDP), an immune-mediated peripheral neuropathy, is frequently treated with long-term maintenance intravenous immunoglobulin (IVIG). However, disadvantages of IVIG are the systemic adverse reactions, lengthy infusions, and need for vascular access. Subcutaneous immunoglobulin (SCIG) addresses many of the issues encountered by those unable, or unwilling, to tolerate the treatment burden of long-term IVIG. Subcutaneous immunoglobulin, a 20% solution stabilized with L-proline, is US Food and Drug Administration–approved for CIDP maintenance therapy in patients after being stabilized with IVIG. Approval was based on a randomized, double-blind, placebo-controlled trial where SCIG demonstrated superiority over placebo and was safe and efficacious in maintaining function. In addition to reviewing the primary efficacy results from the clinical trial, this article aims to update the neurology nursing community on a new option for long-term management of CIDP, including the practicalities of initiating and maintaining patients on SCIG therapy.

Keywords: chronic inflammatory demyelinating polyneuropathy (CIDP), immunoglobulin (Ig)G therapy, intravenous IgG (IVIG), monitoring, patient management, subcutaneous IgG (SCIG)

CIDP and its current treatment options

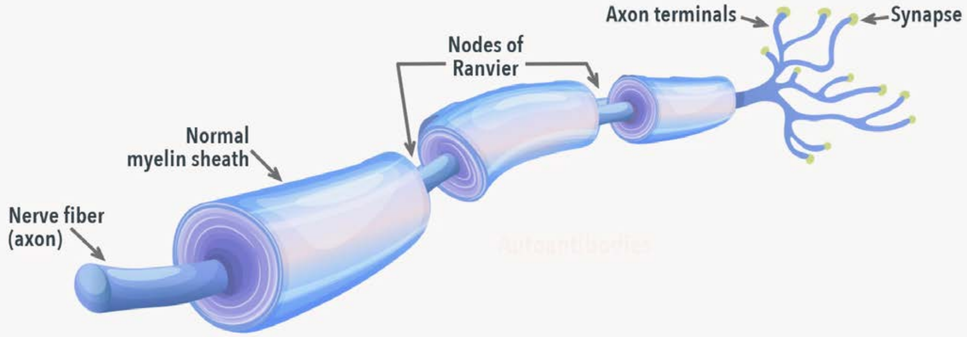
The clinical challenges of intravenous immunoglobulin therapy

The evolution of SCIG for CIDP, including the pivotal clinical trial and its long-term extension study

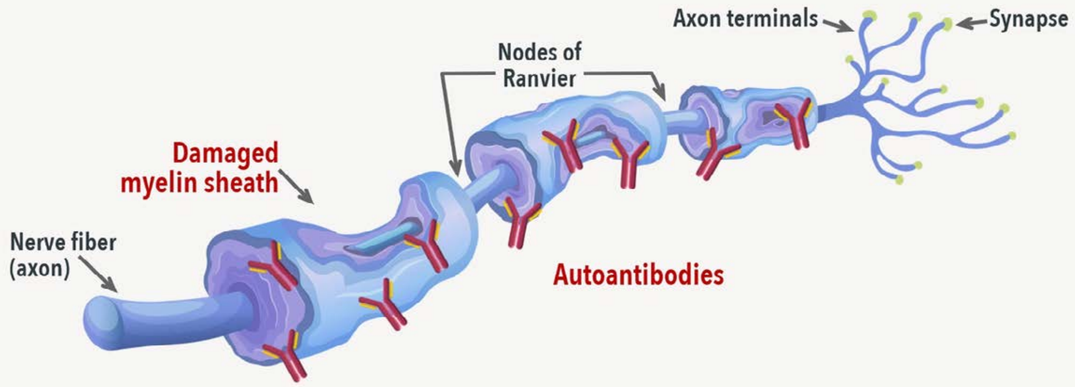
How nurses and pharmacists can help patients adapt to self-administration of SCIG

OTHER RESOURCES

Normal Sheath



Damaged Sheath



2. Köller, et al. 2005

Symptoms include...

- Loss of strength and sensation[3,4]
  - Usually symmetrical
  - Proximal and distal
- Areflexia[3]

CIDP is mediated by...

- Demyelination of peripheral sensory and motor nerves
  - which impairs conduction of electrical signals in nerve axons
- Demyelination is the result of an immune attack on myelin

The main treatments for CIDP are...

- For initial treatment[5]
  - immunoglobulin
  - corticosteroids
  - plasma exchange
- For maintenance
  - immunoglobulin (IG)
    - intravenous (IVIG)
    - subcutaneous (SCIG)
  - corticosteroids
  - plasma exchange

Immunosuppressants are sometimes used as add-on therapies

Intravenous administration typically requires...

- Infusions every 3 weeks
- Monitoring by a clinician
- ~3-5 hours infusion time and often 2 consecutive days
- IV access, which can lead to port placement in some patients

Systemic adverse reactions associated with IVIG[6]...

such as
- headache
- myalgia
- nausea, and
- flu-like symptoms

may occur because of
- the rate of infusion and
- the requirement for high infusion volumes.

Serious adverse reactions associated with IVIG include...

- Thromboembolic events

LEARN MORE

- Other serious events:
  - hemolysis
  - aseptic meningitis
  - renal dysfunction

These adverse reactions are also associated with subcutaneous immunoglubulin therapy.

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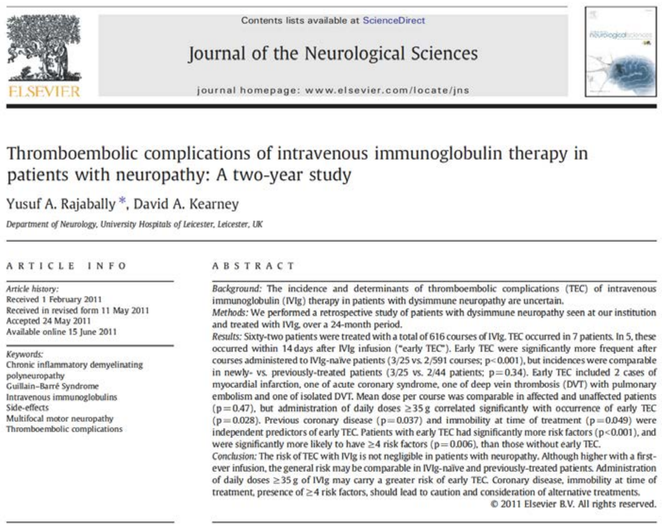
X

In three retrospective studies of patients receiving IVIG therapy for inflammatory neurologic conditions, including CIDP...

- Thromboembolic events (TE) were reported in 10.2% – 11.3% of patients during treatment periods of 24-36 months[7-9]

One study identified risk factors for TE in patients receiving IVIG[7]...



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Thromboembolic complications of intravenous immunoglobulin therapy in patients with neuropathy: A two-year study

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Side-effects
Multifocal motor neuropathy
Thromboembolic complications

ABSTRACT

Background: The incidence and determinants of thromboembolic complications (TEC) of intravenous immunoglobulin (IVIg) therapy in patients with dysimmune neuropathy are uncertain.
Methods: We performed a retrospective study of patients with dysimmune neuropathy seen at our institution and treated with IVIg, over a 24-month period.
Results: Sixty-two patients were treated with a total of 616 courses of IVIg. TEC occurred in 7 patients. In 5, these occurred within 14 days after IVIg infusion ("early TEC"). Early TEC were significantly more frequent after courses administered to IVIg-naïve patients (3/25 vs. 2/591 courses; $p<0.001$), but incidences were comparable in newly- vs. previously-treated patients (3/25 vs. 2/44 patients; $p=0.34$). Early TEC included 2 cases of myocardial infarction, one of acute coronary syndrome, one of deep vein thrombosis (DVT) with pulmonary embolism and one of isolated DVT. Mean dose per course was comparable in affected and unaffected patients ($p=0.47$), but administration of daily doses ≥35 g correlated significantly with occurrence of early TEC ($p=0.028$). Previous coronary disease ($p=0.037$) and immobility at time of treatment ($p=0.049$) were independent predictors of early TEC. Patients with early TEC had significantly more risk factors ($p<0.001$), and were significantly more likely to have ≥4 risk factors ($p=0.006$), than those without early TEC.
Conclusion: The risk of TEC with IVIg is not negligible in patients with neuropathy. Although higher with a first-ever infusion, the general risk may be comparable in IVIg-naïve and previously-treated patients. Administration of daily doses ≥35 g of IVIg may carry a greater risk of early TEC. Coronary disease, immobility at time of treatment, presence of ≥4 risk factors, should lead to caution and consideration of alternative treatments.

- Coronary artery disease
- Being unable to walk unaided at the time of infusion

and

- Any combination of at least 4 from this list:
  - Male gender
  - Age >60
  - Diabetes
  - Dyslipidemia
  - Hypertension
  - Immobility
  - Coronary artery disease
  - Family history of early TE
  - Atrial fibrillation

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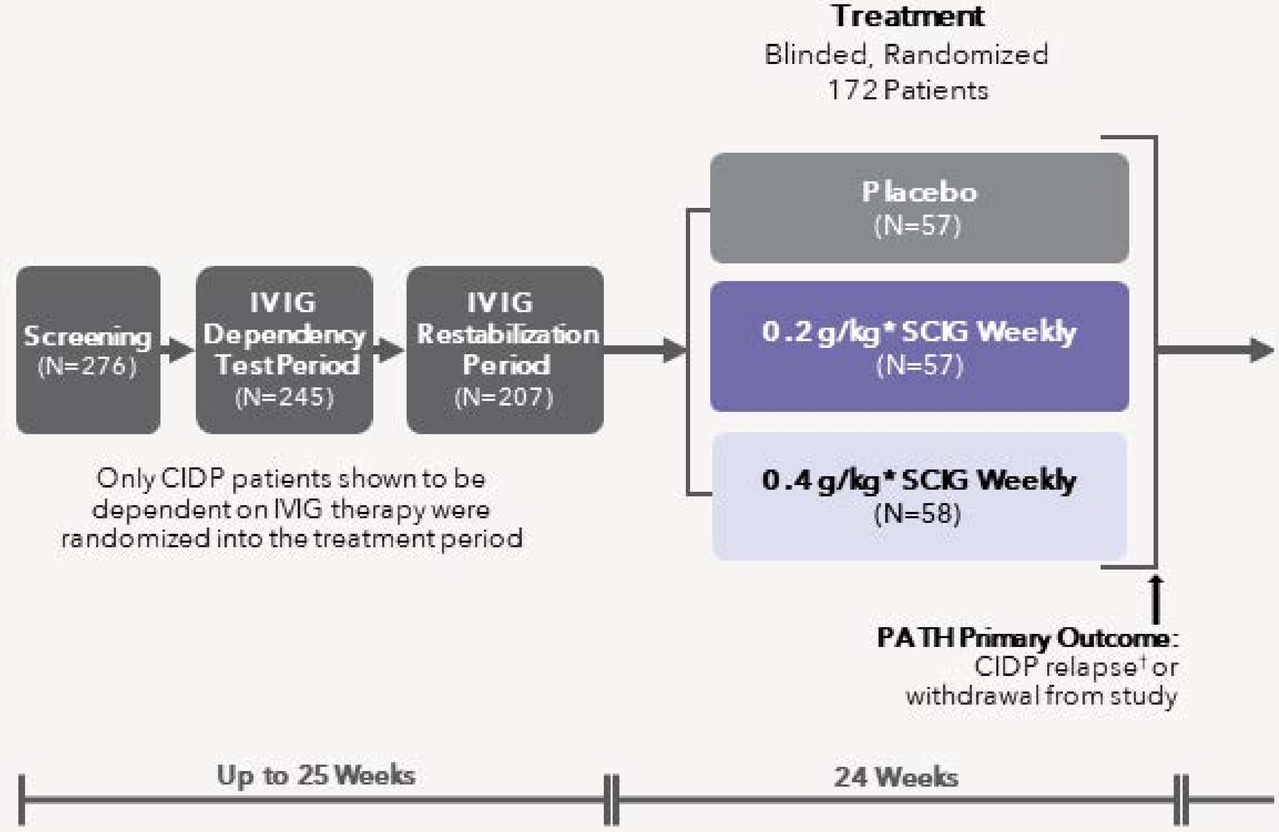
PATH STUDY

PATH STUDY OVERVIEW

NEXT >



* body weight; SCIG administered as a 20% solution
†CIDP relapse defined as: 1 point or more increase in adjusted INCAT (Inflammatory Neuropathy Cause and Treatment) score [0=healthy; 10=unable to make any purposeful movements with arms or legs]

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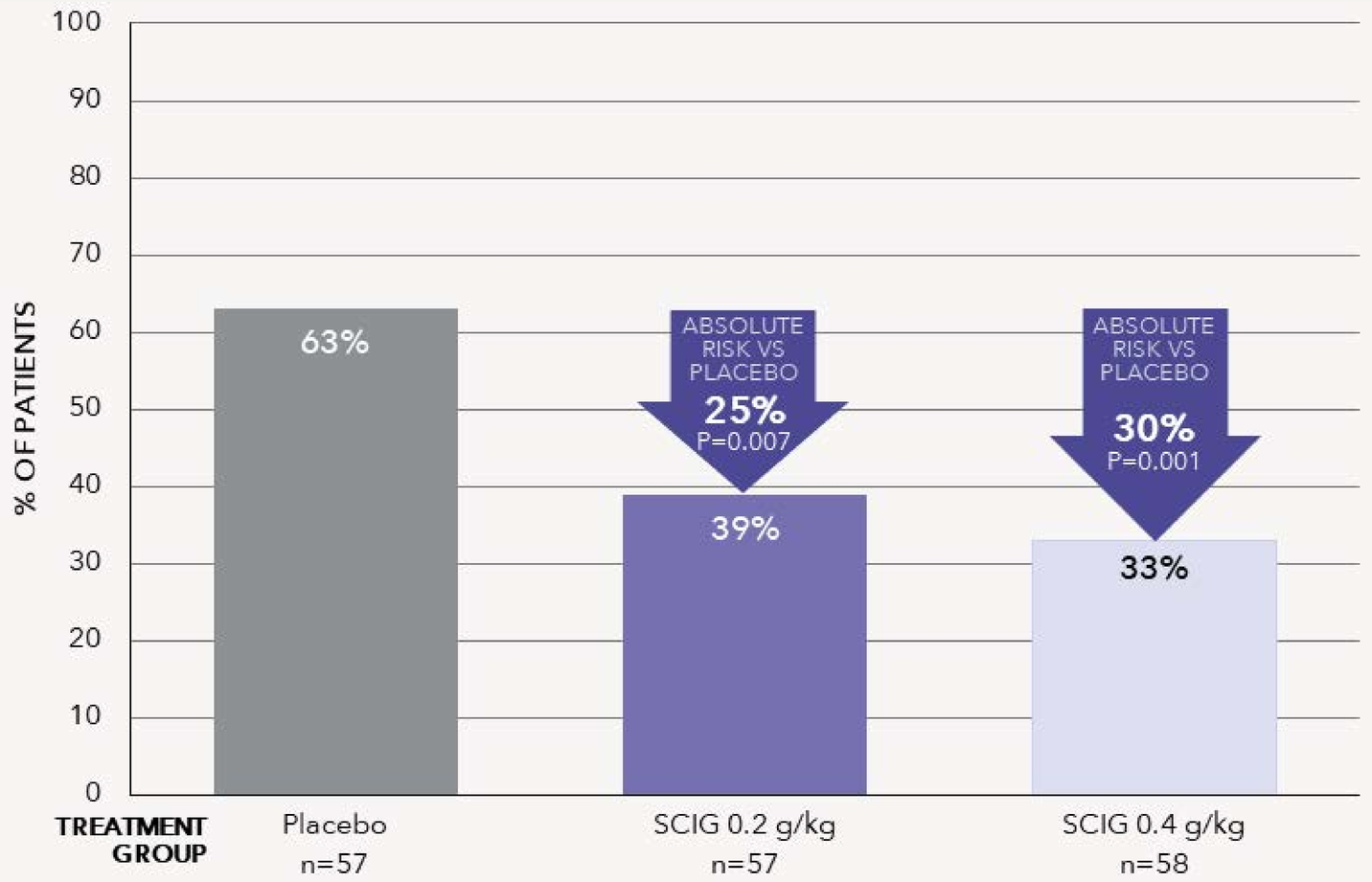
PATH STUDY
PRIMARY OUTCOME

NEXT >

PRIMARY OUTCOME[12]:
Patients Relapsing or Withdrawing by Week 24

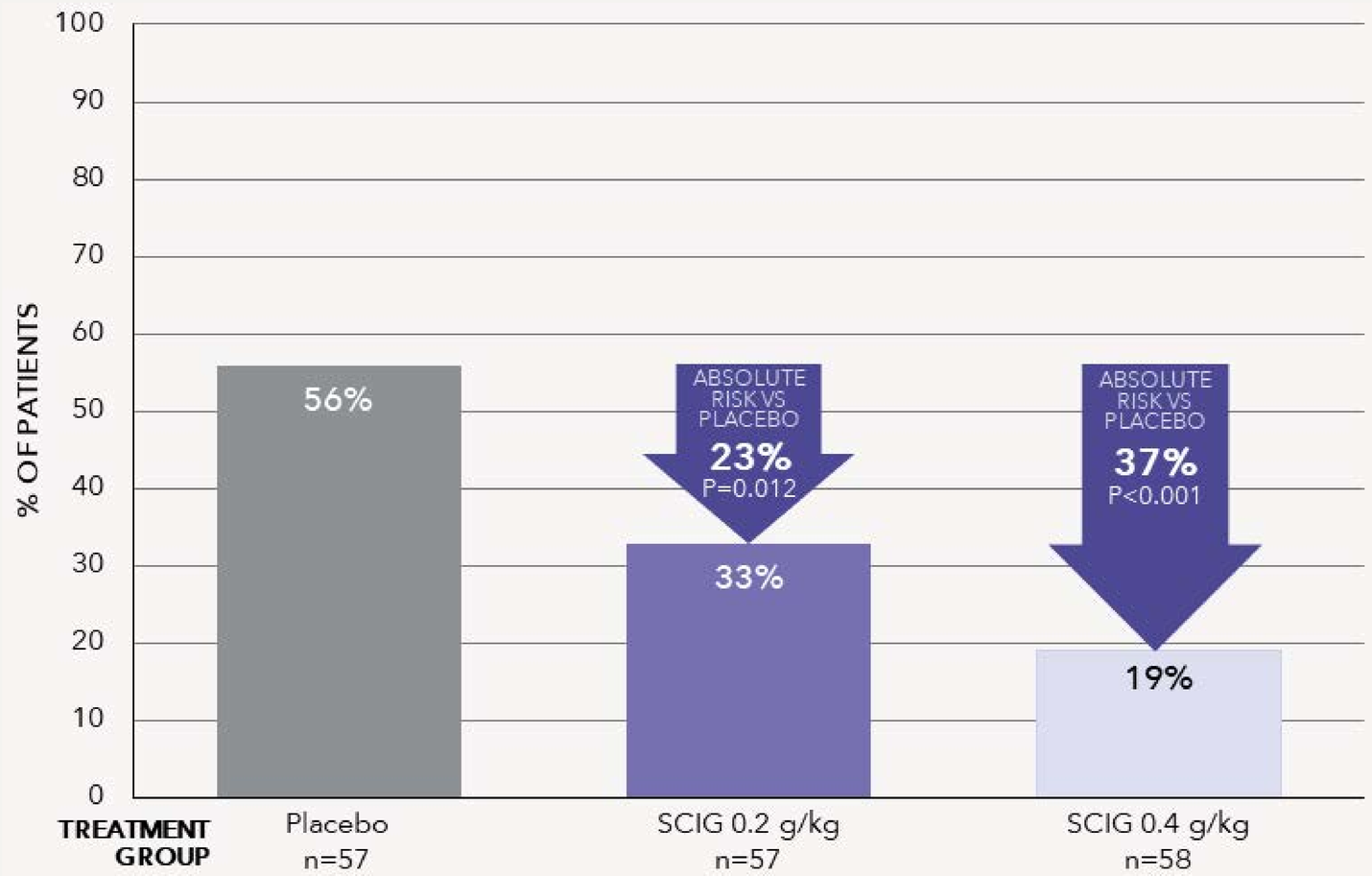


The difference between the 0.2 g/kg and the 0.4 g/kg doses of SCIg were not significantly different

PATH STUDY RELAPSES

RELAPSES (SENSITIVITY ANALYSIS):
Patients relapsing by week 24

NEXT >



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PATH STUDY SAFETY AND ARs

NEXT >

SAFETY AND ADVERSE REACTIONS (ARs)[12]

In the placebo group, 37% of patients experienced a treatment emergent adverse reaction at a rate of 1 per 29 infusions. In the Hizentra group, 58% of patients in the 0.2 g/kg group experienced a treatment emergent adverse reaction at a rate of 1 per 13 infusions, and 52% of patients in the 0.4 g/kg group experienced a treatment emergent adverse reaction at a rate of 1 per 20 infusions.

	Placebo (n=57) Patients with an event n (%)	0.2 g/kg (n=57) Patients with an event n (%)	0.4 g/kg (n=58) Patients with an event n (%)
Local Site Reactions	4 (7%)	11 (19%)	17 (29%)
Erythema	0	5 (9%)	10 (17%)
Swelling	2 (4%)	5 (9%)	6 (10%)
Induration	1 (2%)	2 (4%)	3 (5%)
Warmth	0	0	3 (5%)
Pain	2 (4%)	3 (5%)	2 (3%)
Headache	2 (4%)	4 (7%)	4 (7%)
Fatigue	1 (2%)	5 (9%)	0
Arthralgia	1 (2%)	3 (5%)	1 (2%)

All local site reactions that occurred in ≥5% of patients.

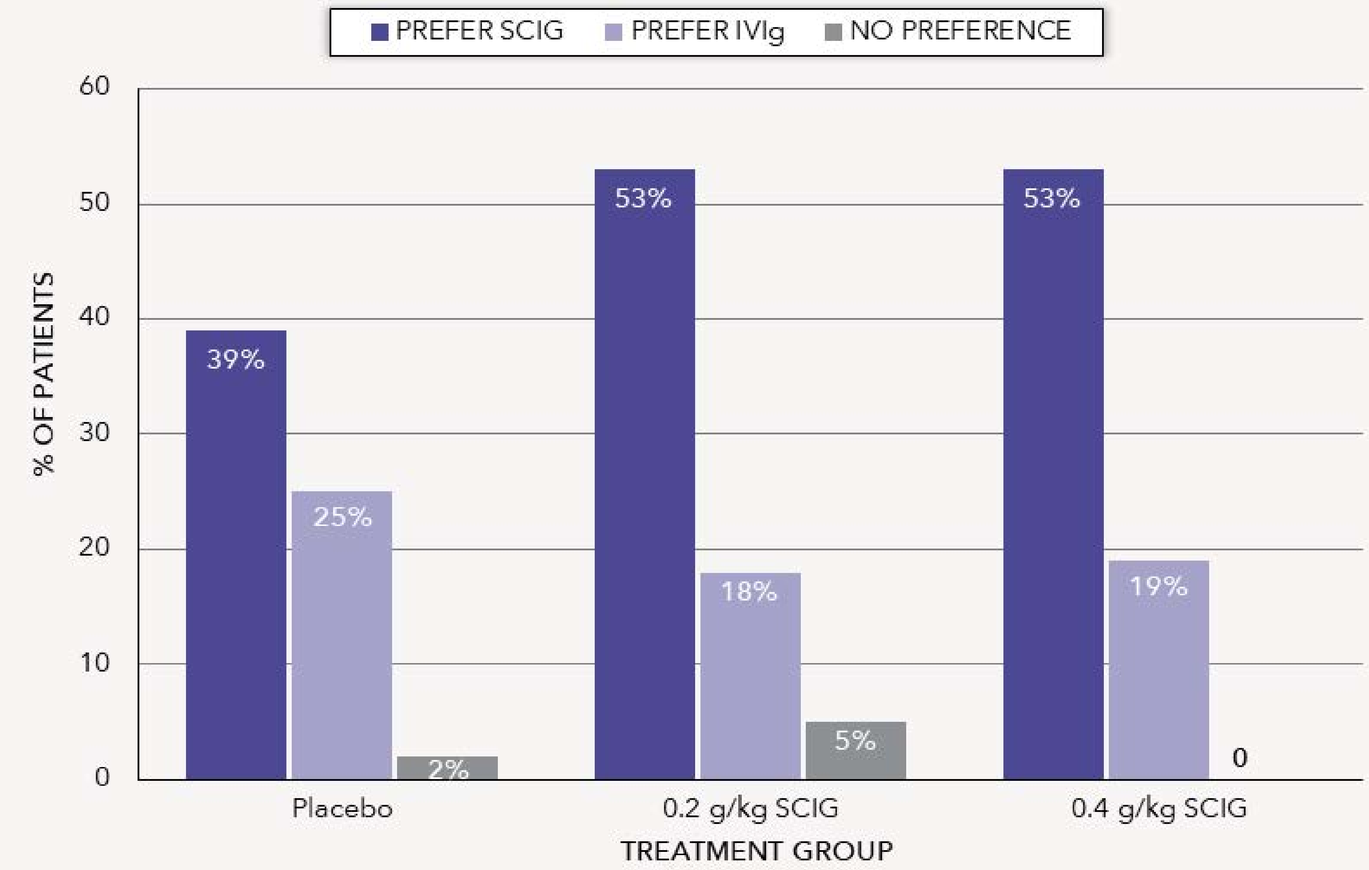
All local reactions were either mild (94.5%) or moderate (5.5%) in intensity. The frequency of local reactions tended to decrease over time.

After local site reactions the most common side effects in the clinical trials for SCIG were headache; chest, joint or back pain; diarrhea; tiredness; cough; rash; itching; fever, nausea, and vomiting. One serious adverse reaction was reported: allergic dermatitis. One patient withdrew due to a non-serious adverse reaction of fatigue

PATH STUDY
PATIENT EXPERIENCE

PATIENT EXPERIENCE:
Preference for SCIG vs. IVIG

PATH EXTENSION >



Primary reason for SCIG preference over IVIG: “Greater independence”

PATH EXTENSION

NEXT >

Extension[13]

Unblinded (open-label)

82 Patients
(Initial dosages)

PATH Participants
- Completed study
- Withdrew
- Had CIDP relapse

0.2 g/kg* SCIG weekly (N=20)

0.4 g/kg* SCIG weekly (N=62)

DOSAGE ADJUSTMENTS (learn more)

Primary outcome:
Long-term safety

Secondary outcome:
Long-term efficacy

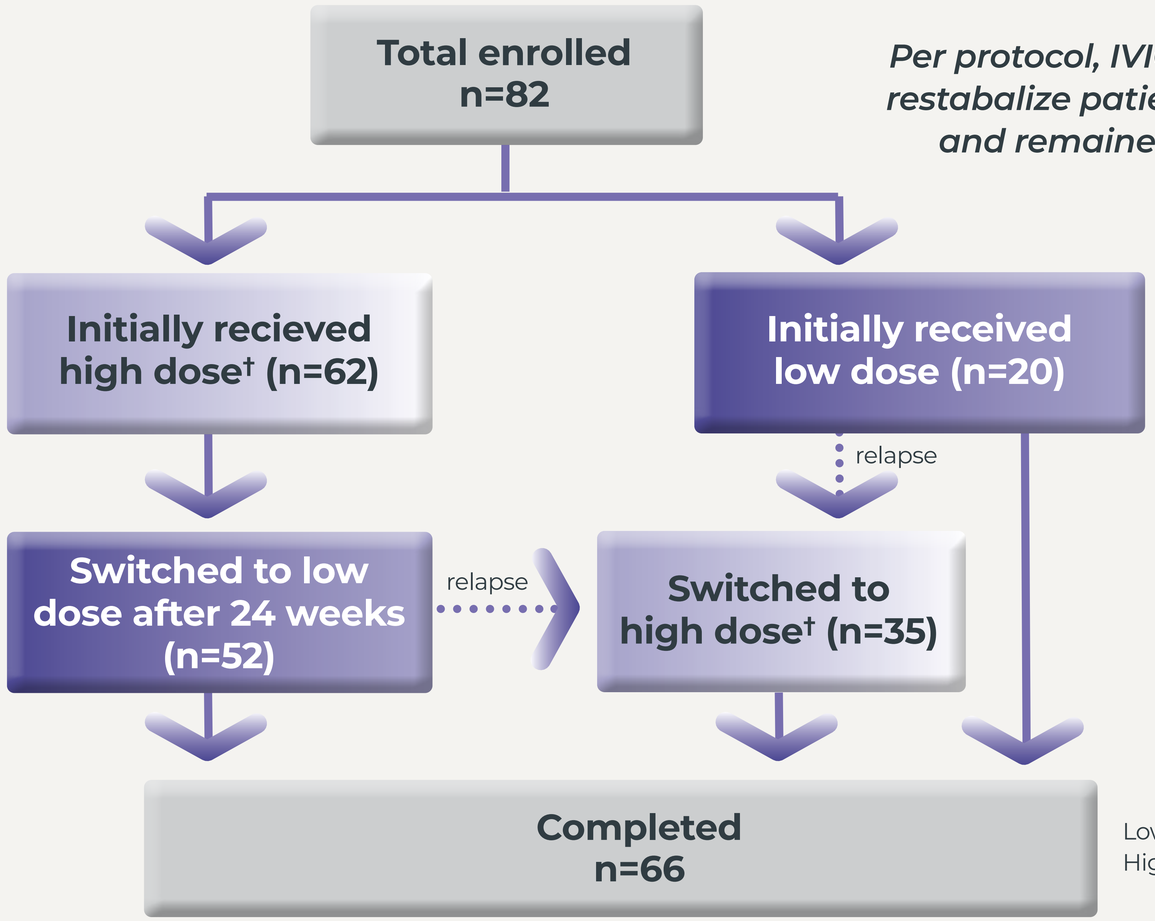
Patients could switch dosages according to prespecified criteria based on CIDP relapses and patient and investigator judgment

During the 48-week study
- 73 patients received the low dose
- 72 patients received the high dose

* body weight; SCIG administered as a 20% solution
†CIDP relapse defined as: 1 point or more increase in adjusted INCAT (Inflammatory Neuropathy Cause and Treatment) score [0=healthy; 10=unable to make any purposeful movements with arms or legs]

PATH EXTENSION

DOSAGE ADJUSTMENTS DURING PATH EXTENSION[13]



Per protocol, IVIG was not used to restabalize patients who relapsed and remained on the study.

Low dose = 0.2 g/kg/wk
High dose = 0.4 g/kg/wk

† Patients with a relapse on high dose could remain on high dose or discontinue.

PATH EXTENSION

EXTENSION STUDY:
Safety and Adverse Reactions (ARs)[13]

NEXT >

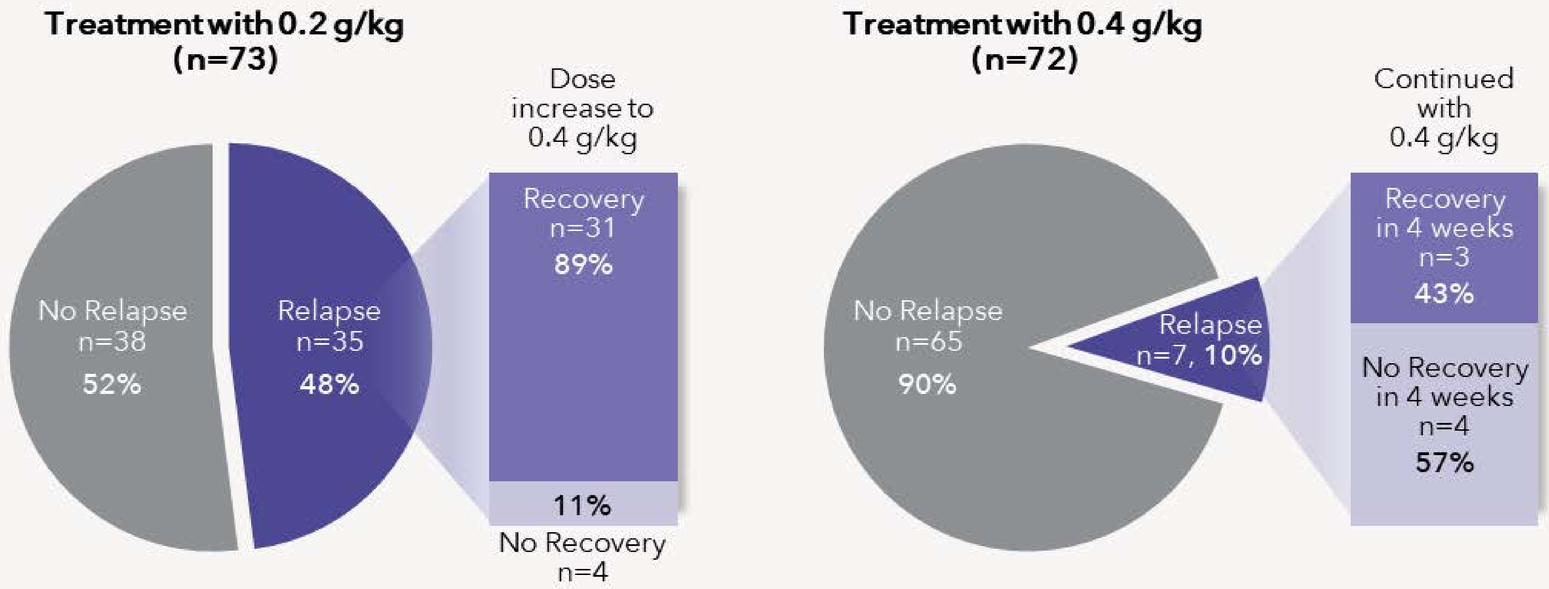
	0.2 g/kg (n=57) (No. (%) of subjects with an event)	0.4 g/kg (n=58) (No. (%) of subjects with an event)	Overall (No. (%) of subjects with an event)
Local Site Reactions occurring in ≥5% of patients	7 (9.6%)	13 (18.1%)	18 (22.0%)
Erythema	4 (5.5%)	4 (5.6%)	7 (8.5%)
Swelling	3 (4.1%)	6 (8.3%)	9 (11.0%)
Headache	0	4 (5.6%)	4 (4.9%)
Fatigue	1 (1.4%)	3 (4.2%)	4 (4.9%)
Nasopharyngitis	6 (8.2%)	6 (8.3%)	11 (13.4%)

In the Hizentra groups, treatment-emergent adverse reactions were experienced by 45% of patients in the 0.2 g/kg group at a rate of 1 per 18 infusions, and 64% of patients in the 0.4 g/kg group at a rate of 1 per 40 infusions. Local site reactions were experienced by 9.6% of patients in the 0.2 g/kg group at a rate of 1 per 59 infusions, and 18.1% in the 0.4 g/kg group at a rate of 1 per 250 infusions.

A total of 3 patients discontinued the study due to ARs; 2 patients on low dose, and 1 patient on high dose.

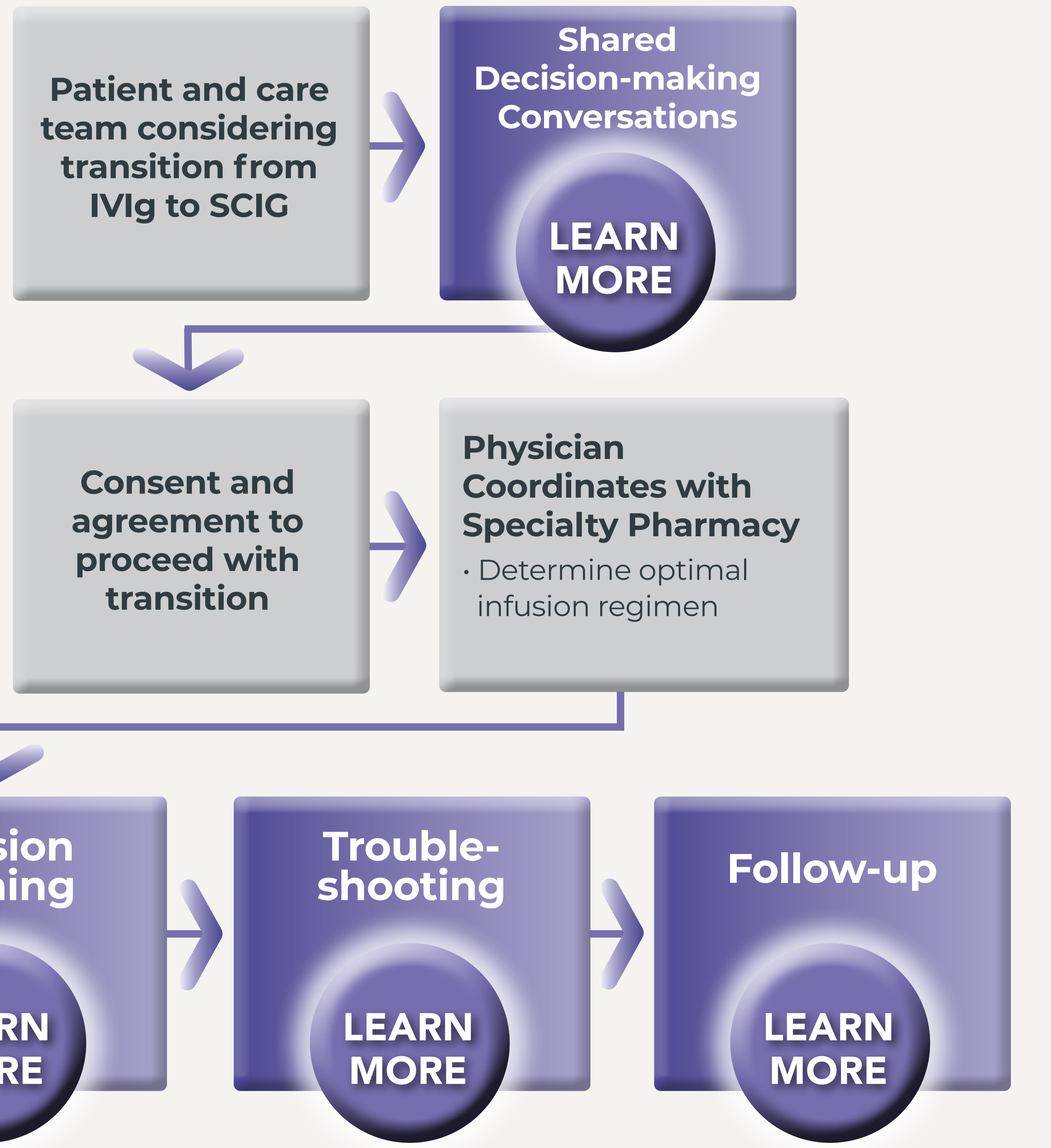
PATH EXTENSION

RELAPSE AND RECOVERY RATES[13]



- In the PATH Extension study, the 0.4 g/kg dose was more likely to prevent relapse than the 0.2 g/kg dose.
- 33 patients completed the study on low-dose SCIG and 33 on high-dose.
- At the end of the study, 82% of patients preferred their current therapy (SCIG) over previous IVIG therapy.

THE TRANSITION TO SCIG:
Roles of Nurses and Pharmacists



THE TRANSITION TO SCIG:
Roles of Nurses and Pharmacists

Patient and care

Shared Decision-making Conversations

X

IN-DEPTH, UP-FRONT SHARED DECISION-MAKING CONVERSATIONS ARE VITAL FOR FAVORABLE PATIENT EXPERIENCE ON SCIG

Initial Patient Assessment — LEARN MORE

Patient Education and Setting Expectations — LEARN MORE

LEARN MORE LEARN MORE LEARN MORE

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X

INITIAL PATIENT ASSESSMENT

Successful transition to SCIG depends on several patient-specific factors

Assessing these factors can help identify which patients are most likely to be successful

- Motivation (seeking autonomy), self-efficacy
- Ability to learn self-infusion
- Compliance
- Manual dexterity and other physical limitations
- Availability of caregiver to provide assistance
- Needle anxiety

LEARN MORE

UNDERSTANDING THE PATIENT'S PREFERENCES, VALUES, AND GOALS

Each patient's preferences, values, and goals should be discussed during the shared decision-making process. Some sample topics are shown below.

What expectations do you have about your treatment for CIDP?

- Patients may want to know:
  - What are all my treatment choices?
  - Is one treatment better than others?
  - Will treatment cure me?
  - Will treatment control my symptoms?
  - Will treatment have side effects?
  - How long will I need to be treated?

How important is convenience to you, and what aspects are most important?

- Examples may include:
  - Frequency of administration
  - Increased independence and autonomy with ability to self-administer
  - In-clinic vs home-based self-administration
  - Flexible place and time of administration (eg, travel, work)

What aspects of clinical support are important to you?

- Are you comfortable having less face-to-face contact with the clinical team?
- Would you welcome training and support for learning home-based infusion?

PATIENT COUNSELING:
assessment and setting expectations

X

What is a subcutaneous infusion and how does it work?
What are the advantages and disadvantages of SCIG and IVIG?
What are the local side effects at the infusion site?
How will I learn how to do subcutaneous infusions?
How often will I need to give myself infusions? And how long does it take?
What supplies or equipment do I need?
How will I get my supplies and medication?
What happens if I have problems or side effects?
How will I know how much medication to infuse?
How will I know if it is working or if I need to change dose?

Choose a question for information and resources.

PATIENT COUNSELING:
assessment and setting expectations

- **What is a subcutaneous infusion and how does it work?**
- What are the advantages and disadvantages of SCIG and IVIG?
- What are the local side effects at the infusion site?
- How will I learn how to do subcutaneous infusions?
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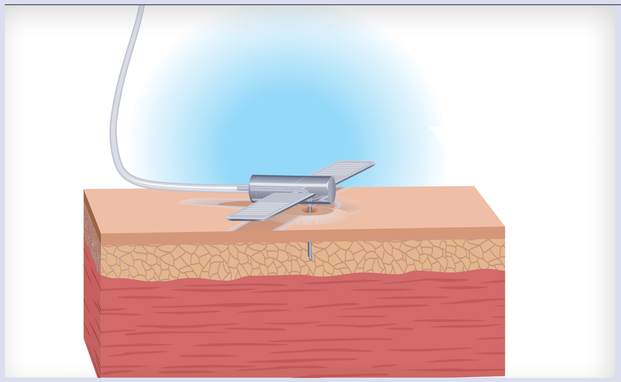
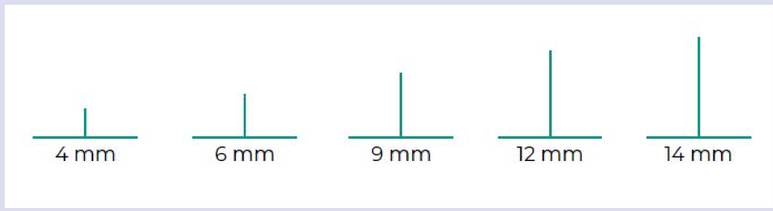
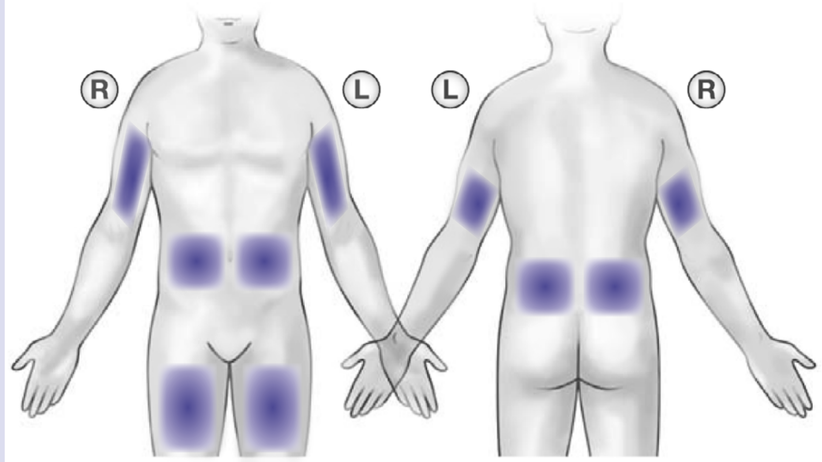


Subcutaneous immunoglobulin (SCIG) is infused subcutaneously into the tissue just below the skin's first layer. SCIG should never be infused into a vein.



SCIG needles are relatively small. Depending on patient's size and weight, clinicians should recommend a needle as short as 4 mm or as long as 14 mm. Most common SCIG needle lengths used are 9 mm and 12 mm.



Recommended infusion sites include the abdomen, inner or outer thighs, upper arms, or sides of upper legs/hips, as marked in dark gray

Up to 8 infusion sites may be used simultaneously; or up to 12 infusion sites consecutively per infusion.

In the PATH clinical trial, most patients used 4 infusion sites during single sessions

Infusion sites should be at least 2 inches apart; new sites should be at least 1 inch from a recently used site

Never infuse into areas where the skin is tender, bruised, red, or hard. Avoid infusing into scars or stretch marks

Important Safety Informatio

WARNING: Thrombosis may
coagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling vascular catheters, hyperviscosity, and cardiovascular risk factors.

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PATIENT COUNSELING:
assessment and setting expectations

- What is a subcutaneous infusion and how does it work?
- **What are the advantages and disadvantages of SCIG and IVIG?**
- What are the local side effects at the infusion site?
- How will I learn how to do subcutaneous infusions?
- How often will I need to give myself infusions? And how long does it take?
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- How will I get my supplies and medication?
- What happens if I have problems or side effects?
- How will I know how much medication to infuse?
- How will I know if it is working or if I need to change dose?

	IVIG	SCIG
ADVANTAGES[16]	• Less frequent dosing, typically every 3 weeks • Frequent contact with healthcare professionals during administration can mean better clinical monitoring and early identification of problems	• Self-administration feasible for patients with cognitive and fine motor ability • Smaller infusion volumes allow gradual absorption • No venous access needed • Fewer systemic side effects • Patient can choose when and where to infuse • Infusion usually takes about 1 hour
DISADVANTAGES[16]	• Requires venous access • Requires 3 or more hours per infusion • Skilled personnel typically needed for administration • Peaks and troughs of PK profile may affect efficacy and safety • More systemic AEs	• Requires more frequent infusions and multiple SC infusion sites and needlesticks • Lack of direct patient monitoring when self-administered to evaluate technique • Patient adherence may decrease • Localized site reactions

AE, adverse effect; IgG, immunoglobulin G; IVIG, intravenous immunoglobulin; PK, pharmacokinetics; SC, subcutaneous; SCIG, subcutaneous immunoglobulin

PATIENT COUNSELING:
assessment and setting expectations

What is a subcutaneous infusion and how does it work?	
What are the advantages and disadvantages of SCIG and IVIG?	**In the PATH trial, reports of local site reactions tended to decrease (or diminish) over time.**
What are the local side effects at the infusion site?	In the PATH clinical trial of adults with CIDP: • The most common side effects were redness, swelling, itching, and/or bruising at the infusion site • About 20-30% of patients experienced a local site reaction at some time during the study. • Local site reactions were reported in about 1 of every 35-45 infusions In the PATH study, the systemic adverse reaction rate per infusion for SCIG was 3.6-fold lower than the corresponding rate for IVIG. Other (systemic) side effects included headache; chest, joint or back pain; diarrhea; tiredness; cough; rash; itching; fever, nausea, and vomiting. One treatment-related serious side effect was also reported: allergic dermatitis. **There are risks common to all Ig therapies.** All Ig treatments, including Hizentra, come with inherent risks, the most serious being thrombosis (blood clotting).
How will I learn how to do subcutaneous infusions?	
How often will I need to give myself infusions? And how long does it take?	
What supplies or equipment do I need?	
How will I get my supplies and medication?	
What happens if I have problems or side effects?	
How will I know how much medication to infuse?	
How will I know if it is working or if I need to change dose?	

PATIENT COUNSELING:
assessment and setting expectations

What is a subcutaneous infusion and how does it work?	
What are the advantages and disadvantages of SCIG and IVIG?	A specially trained nurse from the specialty pharmacy will teach you how to self administer SCIG. Most people who choose SCIG will receive 3-5 training sessions. In the PATH clinical trial: • 88% of CIDP patients thought self-infusion was easy to learn • All 172 patients were able to learn self-infusion with 4 training sessions Your clinic nurse and/or your specialty pharmacy nurse and pharmacist will continue to be available for questions, concerns, or problems after you are trained. Specific online videos and printed step-by-step instructions can also be good reminders of how to do self-infusion. ***View prescribing information for step-by-step instructions for SCIG self-infusions***
What are the local side effects at the infusion site?	
How will I learn how to do subcutaneous infusions?	
How often will I need to give myself infusions? And how long does it take?	
What supplies or equipment do I need?	
How will I get my supplies and medication?	
What happens if I have problems or side effects?	
How will I know how much medication to infuse?	
How will I know if it is working or if I need to change dose?	

PATIENT COUNSELING:
assessment and setting expectations

X

What is a subcutaneous infusion and how does it work?	
What are the advantages and disadvantages of SCIG and IVIG?	
What are the local side effects at the infusion site?	
How will I learn how to do subcutaneous infusions?	
How often will I need to give myself infusions? And how long does it take?	In the PATH clinical trial, all CIDP patients using SCIG infused their medication weekly in one or two sessions, as shown in the diagram below. • The two sessions each week were done on the same day or on consecutive days. • Each infusion session lasted approximately 1 hour. The rate of infusion, number of infusion sites, and volume of infusion will be adjusted as tolerated in order to meet the needs of the patients.
What supplies or equipment do I need?	
How will I get my supplies and medication?	
What happens if I have problems or side effects?	
How will I know how much medication to infuse?	
How will I know if it is working or if I need to change dose?	

PATIENT COUNSELING:
assessment and setting expectations

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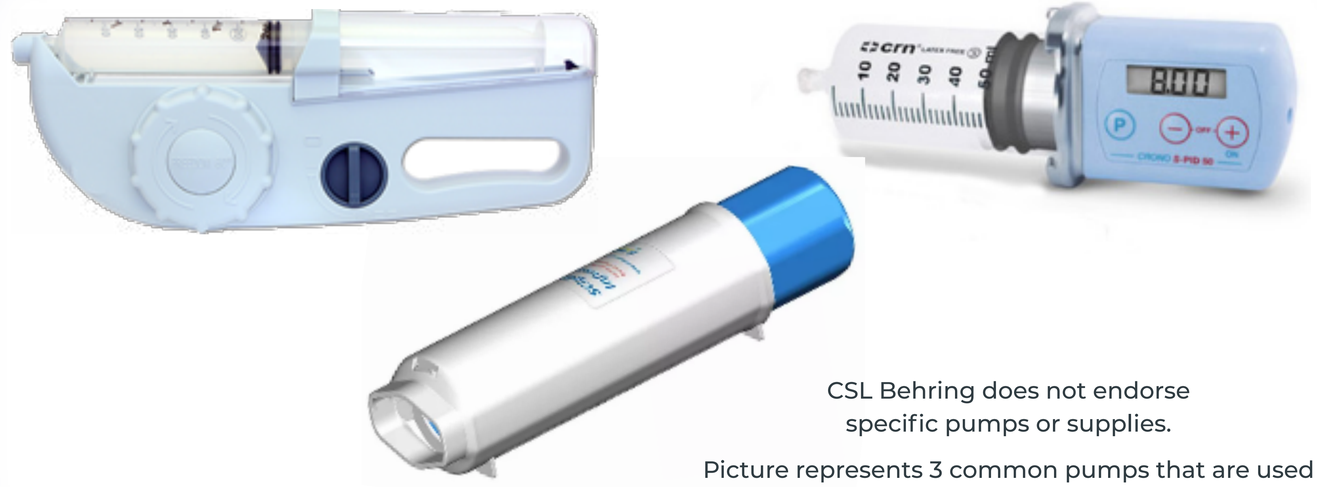
ITEMS	COMMENTS[14]
SCIG medication	Available in vials or in pre-filled syringes
Antiseptic wipes or alcohol swabs	Used to sterilize the preparation surface and medication vials
Mini-spike dispensing pin or 18-gauge needle	Needed for extracting medication from vials (not needed if using pre-filled syringes)
Syringe to Syringe transfer device	Needed for transferring medication from pre-filled syringe to pump syringe (not needed if using vials)
Subcutaneous needle sets	Available in different lengths for different patient types, different gauges (diameter) which can affect flow, and configuration to accommodate dosing
Pump Syringe	Contains the medication during the infusion process
Flow rate tubing	Connects the syringe containing medication to the needle and regulates the infusion rate when using a constant-pressure pump
Infusion pump	Several models are available
Logbook or app	Used to record infusions, medication lot numbers, and side effects
Gloves	If recommended by your doctor or nurse
Tapes and dressings	Used to secure needles in place during infusion
Sharps container	A waste disposal system provided by the specialty pharmacy

PATIENT COUNSELING:
assessment and setting expectations

What is a subcutaneous infusion and how does it work?	
What are the advantages and disadvantages of SCIG and IVIG?	
What are the local side effects at the infusion site?	Your nurse or specialty pharmacy will provide the necessary equipment to infuse SCIG. Supplies include but are not limited to: infusion administration tubing, subcutaneous needle sets, syringes, transfer device or needle(s), tape or transparent dressing, infusion pump, sharps container, and alcohol wipes.
How will I learn how to do subcutaneous infusions?	
How often will I need to give myself infusions? And how long does it take?	
What supplies or equipment do I need?	
How will I get my supplies and medication?	
What happens if I have problems or side effects?	
How will I know how much medication to infuse?	
How will I know if it is working or if I need to change dose?	



CSL Behring does not endorse specific pumps or supplies.

Picture represents 3 common pumps that are used with SCIG but there are several options available.

Important Safetyinformatio

WARNING: Thrombosis may coagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling vascular catheters, hyperviscosity, and cardiovascular risk factors.

CLICK FOR FULL IMPORTANT SAFETY INFORMATION

PATIENT COUNSELING:
assessment and setting expectations

What is a subcutaneous infusion and how does it work?	
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What supplies or equipment do I need?	
How will I get my supplies and medication?	
What happens if I have problems or side effects?	You and your healthcare team will manage your CIDP together. Your clinic nurse and/or your specialty pharmacy nurse and pharmacist will continue to be available for questions, concerns, or problems after you are trained. In some situations, a nurse may come to your home to re-assess self-infusion supplies (such as needle sizes) and to help you refine your self-infusion procedure. Inform patients that mild to moderate local infusion-site reactions (e.g., swelling and redness) are a common side effect of subcutaneous therapy, but to contact their healthcare professional if a local reaction increases in severity or persists for more than a few days.
How will I know how much medication to infuse?	
How will I know if it is working or if I need to change dose?	

PATIENT COUNSELING:
assessment and setting expectations

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What supplies or equipment do I need?	
How will I get my supplies and medication?	
What happens if I have problems or side effects?	
How will I know how much medication to infuse?	Your health care team (your doctor, nurses, and pharmacists) will work with you to determine: ✔ Your initial medication dose ✔ Your infusion regimen – The **initial** number of sites and volume per site – The **optimal** number of sites and volume per site ✔ The initial infusion rate and the optimal infusion rate ✔ Any changes in dose that may be needed to control your CIDP Your health care team can also work with you to change infusion supplies to help reduce or eliminate infusion-site reactions.
How will I know if it is working or if I need to change dose?	

PATIENT COUNSELING:
assessment and setting expectations

What is a subcutaneous infusion and how does it work?	
What are the advantages and disadvantages of SCIG and IVIG?	
What are the local side effects at the infusion site?	With your help, your health care team will continue to monitor how CIDP is affecting you, and how well you are tolerating the SCIG infusions. You are a part of your own health care team, so if you have concerns about the treatment or side effects, discuss them with other members of the team, such as your nurses, doctor, or pharmacist. People who take an active role in their own healthcare, and participate with their doctors and nurses to make shared decisions, often have better treatment outcomes and higher satisfaction with their treatment.[17]
How will I learn how to do subcutaneous infusions?	
How often will I need to give myself infusions? And how long does it take?	
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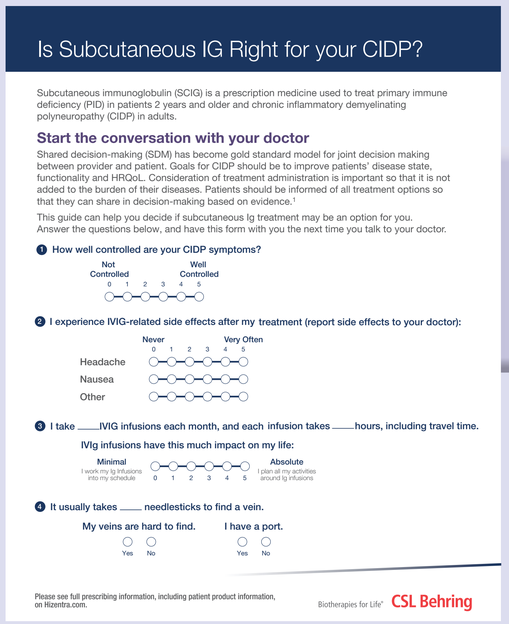


Is Subcutaneous IG Right for your CIDP?

Subcutaneous immunoglobulin (SCIG) is a prescription medicine used to treat primary immune deficiency (PID) in patients 2 years and older and chronic inflammatory demyelinating polyneuropathy (CIDP) in adults.

Start the conversation with your doctor

Shared decision-making (SDM) has become gold standard model for joint decision making between provider and patient. Goals for CIDP should be to improve patients' disease state, functionality and HRQoL. Consideration of treatment administration is important so that it is not added to the burden of their diseases. Patients should be informed of all treatment options so that they can share in decision-making based on evidence.[1]

This guide can help you decide if subcutaneous Ig treatment may be an option for you. Answer the questions below, and have this form with you the next time you talk to your doctor.

1. How well controlled are your CIDP symptoms?
   Not Controlled 0 1 2 3 4 5 Well Controlled
2. I experience IVIG-related side effects after my treatment (report side effects to your doctor):
   Never 0 1 2 3 4 5 Very Often
   Headache
   Nausea
   Other
3. I take ____IVIG infusions each month, and each infusion takes ____hours, including travel time.
   IVIg infusions have this much impact on my life:
   Minimal (I work my Ig infusions into my schedule) 0 1 2 3 4 5 Absolute (I plan all my activities around Ig infusions)
4. It usually takes ____ needlesticks to find a vein.
   My veins are hard to find. Yes No
   I have a port. Yes No

Please see full prescribing information, including patient product information, on Hizentra.com.

Biotherapies for Life® CSL Behring

A discussion guide is available that can help you keep track of your questions and talk about them with your health care team

Important Safety Informatio

WARNING: Thrombosis may coagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling vascular catheters, hyperviscosity, and cardiovascular risk factors.

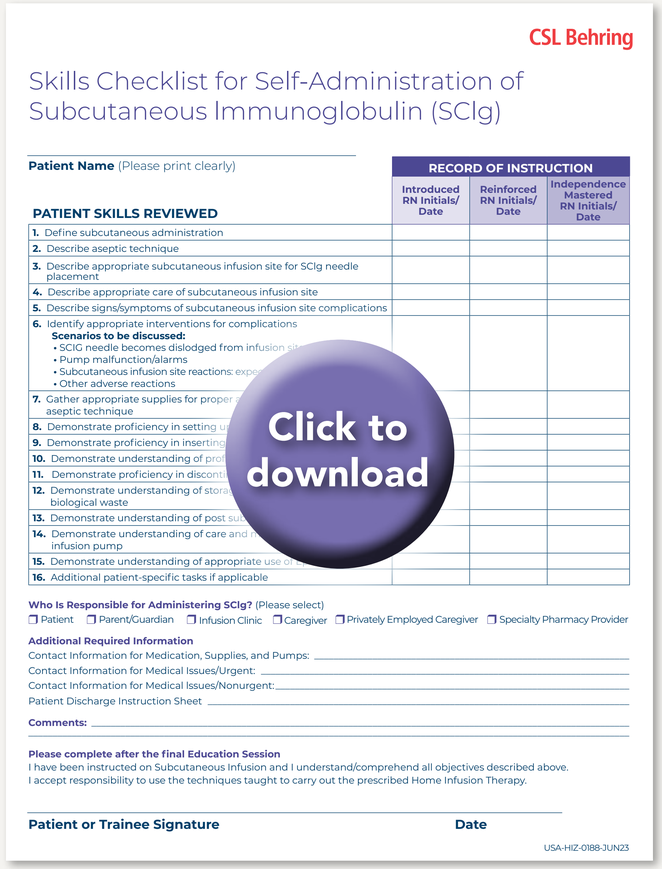
CLICK FOR FULL IMPORTANT SAFETY INFORMATION

INFUSION TRAINING

X

Specially trained nurses from the specialty pharmacy will provide in-home training to patients who choose to adopt SCIG therapy.

A check list is available as an overview of the topics and skills necessary for self-infusion training



CSL Behring

Skills Checklist for Self-Administration of Subcutaneous Immunoglobulin (SCIg)

Patient Name (Please print clearly)

PATIENT SKILLS REVIEWED	RECORD OF INSTRUCTION: Introduced RN Initials/ Date	Reinforced RN Initials/ Date	Independence Mastered RN Initials/ Date
1. Define subcutaneous administration			
2. Describe aseptic technique			
3. Describe appropriate subcutaneous infusion site for SCIg needle placement			
4. Describe appropriate care of subcutaneous infusion site			
5. Describe signs/symptoms of subcutaneous infusion site complications			
6. Identify appropriate interventions for complications **Scenarios to be discussed:** • SCIG needle becomes dislodged from infusion si… • Pump malfunction/alarms • Subcutaneous infusion site reactions: expe… • Other adverse reactions			
7. Gather appropriate supplies for proper a… aseptic technique			
8. Demonstrate proficiency in setting u…			
9. Demonstrate proficiency in insertin…			
10. Demonstrate understanding of prof…			
11. Demonstrate proficiency in disconti…			
12. Demonstrate understanding of stora… biological waste			
13. Demonstrate understanding of post su…			
14. Demonstrate understanding of care and … infusion pump			
15. Demonstrate understanding of appropriate use of …			
16. Additional patient-specific tasks if applicable			

Click to download

Who Is Responsible for Administering SCIg? (Please select)
❒ Patient ❒ Parent/Guardian ❒ Infusion Clinic ❒ Caregiver ❒ Privately Employed Caregiver ❒ Specialty Pharmacy Provider

Additional Required Information
Contact Information for Medication, Supplies, and Pumps: _____
Contact Information for Medical Issues/Urgent: _____
Contact Information for Medical Issues/Nonurgent: _____
Patient Discharge Instruction Sheet _____

Comments: _____

Please complete after the final Education Session
I have been instructed on Subcutaneous Infusion and I understand/comprehend all objectives described above.
I accept responsibility to use the techniques taught to carry out the prescribed Home Infusion Therapy.

Patient or Trainee Signature **Date**

USA-HIZ-0188-JUN23

In addition to in-home training for SCIG infusion, patients can access online videos and a printed step-by-step guide to reinforce their training

View the prescribing information for SCIG self-infusions

Important Safety Information

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.

CLICK FOR FULL IMPORTANT SAFETY INFORMATION

INJECTION-SITE REACTIONS: How to prevent them and how to manage them

INFUSION-SITE CONDITIONS	POSSIBLE CAUSES	MANAGEMENT
Redness	Some redness is expected, and usually resolves within 24 hours. • Incorrect needle placement • Needle too short • Potential sensitivity to tape	If redness causes discomfort: • A cold pack (wrapped in cloth) for a short period may help • Nurse/specialist should check needle placement technique and needle length • Consider slowing the infusion rate • Consider alternative tapes or dressings
Itching or burning	• Incorrect needle placement • Incorrect needle length • Irritation from tape, dressing, or cleaning alcohol • Ig at needle tip causing skin irritation	• Do not scratch or rub • Nurse/specialist may need to check needle placement and length • Consider alternative tapes or dressings • A cold pack (wrapped in cloth) for a short period may help • Nurse specialist may consider discussing dry priming
Blanching/whiteness	Normal tightening of tissue that can occur as SCIG infuses into the fatty tissue under the skin	No action needed; usually decreases as drug is absorbed • A warm compress may be considered for short periods
Rash	• Irritation from tape, dressing, or cleaning alcohol • Ig at needle tip causing skin irritation • Potential sensitivity to tape	• Consider possibility of allergy to drug or sensitivity to tapes • Ensure future infusion sites are at least 2 inches away until condition is resolved • Consider over-the-counter topical antihistamine • Contact physician or pharmacist if concerned about drug allergy or if condition persists or worsens
Swelling	**Some swelling is expected and should resolve within 24-72 hours** Painful or intolerable swelling may require adjustments to needle placement or length, or to infusion volumes or rate	If swelling causes discomfort: • A warm pack (wrapped in cloth) for short periods may help drug absorption • A cold pack (wrapped in cloth) may reduce discomfort but may delay drug absorption • Take a walk to help with absorption • Gentle massage at infusion site • Nurse/specialist may check needle placement and length • Consider whether there is a need to change the volume of infusion per site, or the rate of infusion
Development of nodules at the infusion site	**Unknown**	• Ensure future infusion sites are atleast 2 inches away until condition is resolved • Ensure infusion sites are rotated • A warm compress may help • Gentle massage at infusion site may help
Pain during infusion	• Incorrect needle placement (possibly in muscle) • Incorrect needle length • Infusion rate too fast	• Nurse/specialist should check needle placement and length • A cold pack (wrapped in cloth) for a short period may help • Consider slowing the infusion rate • Check tape placement for pulling on hair or skin
Bruising	• Needle may have disrupted a capillary	• Nurse/specialist may need to reassess needle insertion technique • Ensure future infusion sites are at least 2 inches away until condition is resolved
Leaking from the injection site	• Incorrect needle length • Incorrect needle insertion • Movement during infusion • Infusion volume per site is too high	• Nurse/specialist should check needle length and needle insertion technique • Ensure needle is securely taped during infusion • Consider reducing infusion volume per site or infusion rate

For comprehensive information about infusion practices, please refer to the Infusion Nurses Society Infusion Therapy Standards of Practice, 8th Edition. *J Infus Nurs*. 2021;44 (1S Suppl 1): S1-S224

FOLLOW-UP

After training is completed, patients may benefit from frequent follow-up, either in person or by phone. Follow-up visits should be used to:

- Assess treatment efficacy to determine if dosing should be adjusted
- Identify and resolve treatment barriers and problems
- Monitor compliance to infusion schedule and satisfaction with therapy

Being available to answer questions, resolve problems, and provide additional training can help increase the patient's confidence and competence with self-administration.

- Patients should be given contact information for their CIDP clinic, specialty pharmacy, training nurse and other members of their care team

At least during the first few months, the specialty pharmacy should closely monitor:

- Dosage and dosage changes
- Volume of infusion per site
- Infusion rate per site
- Tolerability

The specialty pharmacy and clinic should maintain close communication regarding:

- Changes in a patient's infusion routine
- Adverse reactions
- Technical issues
- Compliance

Patients will achieve varying levels of independence, and some will need more follow up than others.

Individualization is essential.

RESOURCES

DESCRIPTION	
PEER-REVIEWED ARTICLES	
DOWNLOAD	Download the full paper by Watkins and colleagues
Results of the PATH trial	
INFUSION TRAINING AND TIPS	
Tips for helping patients overcome needle anxiety, from *IG Living*	
DOWNLOAD	View prescribing information for step-by-step guide for SCIG self-infusion
DOWNLOAD	Self-infusion skills checklist
IgNS Standards of Practice V3.1	
OTHER RESOURCES	
DOWNLOAD	Patient-doctor discussion guide
References	

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