Product Overview

HyQvia
[Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase]

Say Hy

to **the unique combination of IG + Hy. HyQvia can meet patients where they are***

*HyQvia can be administered across multiple sites of care, including hospitals, infusion centers, offices, or at home (HCP supported, or administered by the patient or their care partner, after appropriate training).

HyQvia is indicated for the treatment of chronic inflammatory demyelinating polyneuropathy (CIDP) as maintenance therapy to prevent relapse of neuromuscular disability and impairment in adults. HyQvia is for subcutaneous use only.

IMPORTANT SAFETY INFORMATION

WARNING: THROMBOSIS

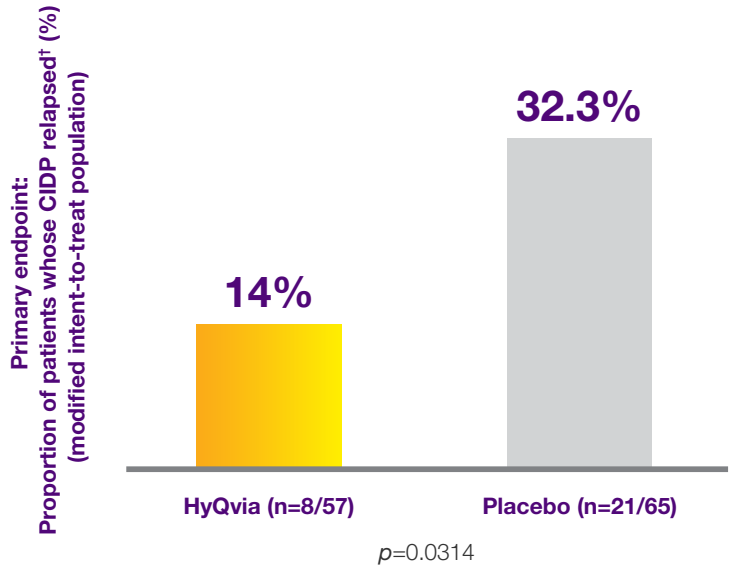
- **Thrombosis may occur with immune globulin (IG) products, including HyQvia. Risk factors may include advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling vascular catheters, hyperviscosity, and cardiovascular risk factors. Thrombosis may occur in the absence of known risk factors.**
- **For patients at risk of thrombosis, administer HyQvia 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 of hyperviscosity.**

Please see additional Important Safety Information throughout, and on last page, and click for Full Prescribing Information.

Proven relapse prevention[1,2]

In ADVANCE-1, 122 subjects underwent efficacy evaluation and the relapse rate during the 6-month treatment period **(primary endpoint)** with HyQvia was 14.0% (n=8/57) vs 32.3% with placebo (n=21/65); *p*=0.0314. There was a treatment difference of -18.3% (A two-sided 95% CI: -32.1%, -3%).*†

A statistically significant difference between the relapse rates of the HyQvia group and the placebo group was observed at 6 months.[1*†]



- Treatment difference -18.3% (A two-sided 95% CI: -32.1%,-3%)

*ADVANCE-1 (Study 1) was a 6-month, multicenter, randomized, placebo-controlled phase 3 study of 132 adults with CIDP on a stable dose of IVIG for ≥12 weeks before screening who received either HyQvia (N=62) or placebo (N=70). The mean duration of exposure was 5.2 months in the HyQvia group and 4.7 months in the placebo group.[1]

†Relapse was defined as an increase of ≥1 point relative to the pre-subcutaneous treatment baseline score in 2 consecutive adjusted INCAT disability scores obtained <7 days apart.[1] Primary efficacy analyses were conducted in the modified intention-to-treat set (all randomized patients who received any double-blind medication), and compared relapse rates using a continuity-corrected X^2 test conducted at the 5% level of statistical significance.

IMPORTANT SAFETY INFORMATION (continued)

Contraindications

- History of anaphylactic or severe systemic hypersensitivity reactions to human IG
- IgA-deficient patients with antibodies to IgA and a history of hypersensitivity to human IG
- Known systemic hypersensitivity to hyaluronidase including Recombinant Human Hyaluronidase of HyQvia
- Known systemic hypersensitivity to human albumin (in the hyaluronidase solution)

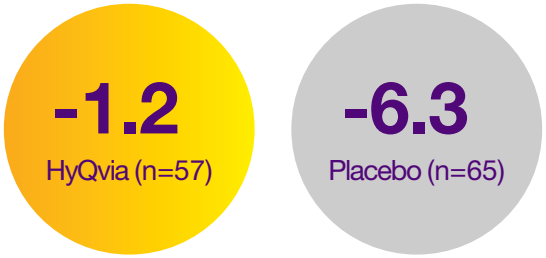
Please see additional Important Safety Information throughout, and on last page, and click for Full Prescribing Information including Boxed Warning regarding Thrombosis.

INCAT=Inflammatory Neuropathy Cause and Treatment; IVIG=intravenous immune globulin.

Secondary endpoint: Activities of daily living

In ADVANCE-1,* the effect of HyQvia on activities of daily living was measured by the R-ODS centile score.[1†]

Least squares (LS) mean change[1†]

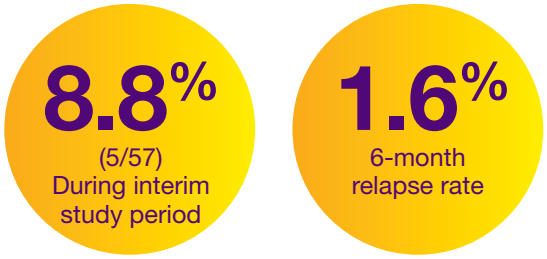


ADVANCE-1 was not designed to control for multiplicity; therefore, no definitive conclusions may be drawn from this information.

*ADVANCE-1 (Study 1) was a 6-month, multicenter, randomized, placebo-controlled phase 3 study of 132 adults with CIDP on a stable dose of IVIG for ≥12 weeks before screening who received either HyQvia (N=62) or placebo (N=70). The mean duration of exposure was 5.2 months in the HyQvia group and 4.7 months in the placebo group. The analysis of the primary endpoint demonstrated a statistically significant difference between the relapse rates in the HyQvia group (N=57, 14.0%) compared to the placebo group (N=65, 32.3%) (p=0.314)[1]

†The Rasch-built Overall Disability Scale (R-ODS) centile score, used to assess activities of daily living, was a centile metric score with lower scores reflecting more severe limitations. Change from pre-SC treatment baseline in R-ODS centile metric scores at the end of the study visit using ANCOVA.[2]

ADVANCE-3: A phase 3b open-label extension study of patients who completed ADVANCE-1 without CIDP worsening or relapse[1‡]



‡ADVANCE-3 (Study 2) was a single-arm, open-label, multicenter extension study that included 79 patients, 2590 infusions, and a follow-up of 0 to 5.1 years. Interim analysis data freeze February 2022.

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions

Hypersensitivity: Severe hypersensitivity reactions may occur, even in patients who have tolerated previous treatment with human IG. If a hypersensitivity reaction occurs, discontinue infusion immediately and institute appropriate treatment. IgA-deficient patients with antibodies to IgA are at greater risk of developing potentially severe hypersensitivity reactions, including anaphylaxis.

Please see additional Important Safety Information throughout, and on last page, and click for Full Prescribing Information including Boxed Warning regarding Thrombosis.

ANCOVA=analysis of covariance; LS=least squares; SE=standard error.

HyQvia has an established safety profile[1]

Adverse Reactions (ARs)[a] in Greater Than 5% of Subjects Associated With Infusions of HyQvia in the Pivotal ADVANCE-1 Trial

Adverse Reactions[b]	HyQvia Number of Subjects (%) N=62	HyQvia Number of ARs per Infusion (Rate[c]) N=598	Placebo Number of Subjects (%) N=70	Placebo Number of ARs per Infusion (Rate[c]) N=644
Local ARs	17 (27.4)	103 (0.17)	5 (7.1)	13 (0.02)
Systemic ARs	18 (29.0)	44 (0.07)	7 (10.0)	14 (0.02)
Nausea	7 (11.3)	8 (0.01)	0	0
Fatigue	5 (8.1)	7 (0.01)	1 (1.4)	1 (<0.01)
Pruritus	5 (8.1)	14 (0.02)	1 (1.4)	1 (<0.01)
Headache	4 (6.5)	9 (0.02)	5 (7.1)	12 (0.02)
Pyrexia	4 (6.5)	6 (0.01)	0	0

[a]Causally related adverse events and/or temporally associated adverse events occurring within 72 hours.

[b]Excluding infections

[c]Rate = total number of events divided by total number of infusions.

- A total of 62 subjects received HyQvia and a total of 598 infusions of HyQvia were administered[1]
- Blood pressure elevation was reported in 4 subjects (6.5%) treated with HyQvia in this study, including 2 subjects with a history of hypertension on antihypertensive medications. Three of the 4 subjects had events which were causally related and/or temporally associated (occurring within 72 hours)[1]
- A total of 4 subjects (3.0%) experienced AEs that led to discontinuation from the study; 3 subjects in the HyQvia group and one in the placebo group. The AEs leading to discontinuation in the 3 HyQvia subjects included: a cerebrovascular accident in 1 subject (who had coexisting cardiovascular risk factors), infusion site edema and infusion site pain in another subject, and nausea and chills in the third subject[1]

ADVANCE-1 (Study 1) was a 6-month, multicenter, randomized, placebo-controlled phase 3 study of 132 adults with CIDP on a stable dose of IVIG for ≥12 weeks before screening who received either HyQvia (N=62) or placebo (N=70). The mean duration of exposure was 5.2 months in the HyQvia group and 4.7 months in the placebo group.[1]

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

Thrombosis: Has been reported to occur following treatment with IG products, including HyQvia and in the absence of known risk factors. In patients at risk, administer at the minimum dose and infusion rate practicable. Ensure adequate hydration before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.

Please see additional Important Safety Information throughout, and on last page, and click for Full Prescribing Information including Boxed Warning regarding Thrombosis.

AE=adverse event.

Most Frequent Local ARs Reported in >1% of Infusions During Treatment With HyQvia (ADVANCE-1: all safety subjects)[1]

Infusion Site Reaction	HyQvia Number of ARs per Infusion (%) N=598	Placebo Number of ARs per Infusion (%) N=644
Discomfort/pain	39 (6.5%)	12 (1.9%)
Swelling/edema	38 (6.4%)	6 (0.9%)
Erythema	36 (6.0%)	0
Pruritus	15 (2.5%)	0

- All HyQvia local reactions (100%) were either mild (88.41%) or moderate (11.59%) in severity[1]

ADVANCE-1 (Study 1) was a 6-month, multicenter, randomized, placebo-controlled phase 3 study of 132 adults with CIDP on a stable dose of IVIG for ≥12 weeks before screening who received either HyQvia (N=62) or placebo (N=70). The mean duration of exposure was 5.2 months in the HyQvia group and 4.7 months in the placebo group.[1]

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

Immunogenicity of Recombinant Human Hyaluronidase (rHuPH20): Non-neutralizing antibodies to the Recombinant Human Hyaluronidase component can develop. The clinical significance of these antibodies or whether they interfere with fertilization in humans is unknown.

Aseptic Meningitis Syndrome: Has been reported with use of IG, including HyQvia and may occur more frequently in females. The syndrome usually begins within several hours to two days following IG treatment.

Conduct a thorough neurological exam on patients exhibiting signs and symptoms, to rule out other causes of meningitis. Discontinuing IG treatment has resulted in remission within several days without sequelae.

Please see additional Important Safety Information throughout, and on last page, and click for Full Prescribing Information including Boxed Warning regarding Thrombosis.

ARs[a] in >5% of Subjects Associated With Infusions of HyQvia in the ADVANCE-3 Trial[1]

ARs[b]	Number of Subjects (%) N=79	Number of ARs per Infusion (Rate[c]) N=2590
Local ARs	19 (24.1)	251 (0.10)
Systemic ARs	32 (40.5)	249 (0.10)
Headache	16 (20.3)	71 (0.03)
Pyrexia	12 (15.2)	58 (0.02)
Nausea	7 (8.9)	9 (<0.01)
Erythema	6 (7.6)	75 (0.03)
Fatigue	6 (7.6)	9 (<0.01)
Abdominal pain	5 (6.3)	8 (<0.01)
Back pain	4 (5.1)	4 (<0.01)
Lipase increased	4 (5.1)	4 (<0.01)
Pain in extremity	4 (5.1)	11 (<0.01)

[a]Causally related adverse events and/or temporally associated adverse events occurring within 72 hours.
[b]Excluding infections
[c]Rate = total number of events divided by total number of infusions

- At the time of the interim analysis, 79 subjects received HyQvia and a total of 2590 infusions of HyQvia were administered[1]
- Blood pressure elevation was reported in 5 subjects (6.3%) in this study, including 1 subject with a history of hypertension on antihypertensive medications. One (1) of the 5 subjects had an event which was causally related and/or temporally associated (occurring within 72 hours)[1]
- A total of 3 subjects (3.8%) experienced AEs that led to discontinuation from the study and 1 subject (1.3%) died prior to the time of the interim analysis. The AEs leading to discontinuation in the 3 subjects included mantle cell lymphoma in 1 subject, muscular weakness and worsening of CIDP in another subject, and abdominal pain in the third subject. The cause of death in the 1 subject was cholangiocarcinoma[1]

Most Frequent Local ARs Reported in >1% of Infusions During Treatment with HyQvia (ADVANCE-3: all safety subjects)[1]

Infusion Site Reaction	Number of ARs per Infusion (%) N=2590
Erythema	225 (8.7%)
Swelling/edema	58 (2.2%)

- Most of the local reactions (95%) were either mild (85.44%) or moderate (9.34%) in severity[1]

ADVANCE-3 (Study 2) was a single-arm, open-label, multicenter extension study that included 79 patients, 2590 infusions, and a follow-up of 0 to 5.1 years.

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

Hemolysis: HyQvia contains blood group antibodies which may cause a positive direct antiglobulin reaction and hemolysis. Monitor patients for signs and symptoms of hemolysis and delayed hemolytic anemia and, if present, perform appropriate confirmatory lab testing.

Please see additional Important Safety Information throughout, and on last page, and click for Full Prescribing Information including Boxed Warning regarding Thrombosis.

Development of antibodies to rHuPH20: Binding antibody positivity rate comparable to rates reported in other development programs[1]

- A total of 15 subjects (15%) who were treated with HyQvia in ADVANCE-1 and ADVANCE-3 developed high-binding anti-rHuPH20 antibody titers (≥1:160)
- A total of 7 subjects (11.3%) who were treated with HyQvia in ADVANCE-1 and a total of 14 subjects (17.7%) in ADVANCE-3 developed high-binding anti-rHuPH20 antibodies (≥1:160)
- Of the 7 subjects in ADVANCE-1, 6 continued to have high-binding antibodies in ADVANCE-3, and 1 subject did not enter ADVANCE-3
- Eight of the 14 subjects developed high-binding antibodies during ADVANCE-3
- The occurrence of high-binding antibodies was not associated with an increased rate of TEAEs
- One subject had a transient positivity of neutralizing antibodies which were not associated with any TEAE consistent with decreased rHuPH20 effect (in ADVANCE-3)

ADVANCE-1 (Study 1) was a 6-month, multicenter, randomized, placebo-controlled phase 3 study of 132 adults with CIDP on a stable dose of IVIG for ≥12 weeks before screening who received either HyQvia (N=62) or placebo (N=70). The mean duration of exposure was 5.2 months in the HyQvia group and 4.7 months in the placebo group.[1]

ADVANCE-3 (Study 2) was a single-arm, open-label, multicenter extension study that included 79 patients, 2590 infusions, and a follow-up of 0 to 5.1 years.

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

Renal Dysfunction/Failure: Acute renal dysfunction/failure, acute tubular necrosis, proximal tubular nephropathy, osmotic nephrosis, and death may occur with intravenous (IV) use of IG products, especially those containing sucrose. Ensure patients are not volume depleted prior to infusion. In patients at risk due to pre-existing renal insufficiency or predisposition to acute renal failure, assess renal function before initiation and throughout treatment, and consider lower, more frequent dosing. If renal function deteriorates, consider discontinuation.

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rHuPH20=Recombinant Human Hyaluronidase; TEAE=treatment-emergent adverse event.

Bob

Would like a CIDP maintenance therapy that can be administered subcutaneously

55 years old **8** years since CIDP diagnosis

Not actual patient.

School counselor and single dad with 3 teenagers

Definite diagnosis of CIDP per the European Federation of Neurological Societies/Peripheral Nerve Society (EFNS/PNS). Bob did not have focal atypical or pure sensory atypical CIDP. Bob has an adjusted INCAT score of 4.

Treatment history

- Has received a stable dose of IVIG 1.2 g/kg every 4 weeks at an infusion center for the past several years and has well-controlled symptoms
- His doctor recommended a subcutaneous option or a port following his most recent medical evaluation
- He and his doctor decided to move forward with HyQvia, which would give him the opportunity to switch his site of care to home

Transitioning Bob to HyQvia may allow him to:

- Start HyQvia every 4 weeks* at the same frequency and dose as his previous IVIG therapy
- Self-administer at home after receiving appropriate training, which may provide site-of-care convenience
- Receive his CIDP maintenance therapy subcutaneously instead of intravenously

*The first HyQvia dose was administered 2 weeks after the last IVIG dose and was ramped up to the full dose.

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

Spread of Localized Infection: Do not infuse HyQvia into or around an infected area due to potential risk of spreading a localized infection.

Transfusion-Related Acute Lung Injury: Non-cardiogenic pulmonary edema may occur with IV administered IG. Monitor patients for pulmonary adverse reactions. If suspected, perform appropriate tests for presence of anti-neutrophil and anti-HLA antibodies in both product and patient serum. May be managed using oxygen therapy with adequate ventilatory support.

Please see additional Important Safety Information throughout, and on last page, and click for Full Prescribing Information including Boxed Warning regarding Thrombosis.

Steve

Wants to explore CIDP treatment options with his doctor

60 years old **3** years since CIDP diagnosis

Not actual patient.

Accountant who lives in a rural area and works from home

Definite diagnosis of CIDP per the European Federation of Neurological Societies/Peripheral Nerve Society (EFNS/PNS). Steve did not have focal atypical or pure sensory atypical CIDP. Steve has an adjusted INCAT score of 4.

Treatment history

- Receives a stable dose of IVIG 1.1 g/kg every 3 weeks at an infusion center for his maintenance therapy with his symptoms well controlled
- Prefers the infusion center because dexterity issues limit his ability to self-administer treatment

Transitioning Steve to HyQvia may allow him to:

- Start HyQvia every 3 weeks* at same frequency and dose of his previous IVIG
- Receive a CIDP maintenance therapy that was preferred by a majority of patients in a clinical trial
- Continue his treatment at an infusion center where he is supported by a healthcare provider

*The first HyQvia dose was administered 2 weeks after the last IVIG dose and was ramped up to the full dose.

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

Transmittable Infectious Agents: Because HyQvia is made from human plasma, it may carry a risk of transmitting infectious agents (e.g. viruses, other pathogens). No cases of transmission of viral diseases or variant Creutzfeldt-Jakob disease (vCJD) have been associated with HyQvia.

Interference with Lab Tests: False positive serological test results and certain assay readings, with the potential for misleading interpretation, may occur as the result of passively transferred antibodies.

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Dosing

HyQvia [Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase] Solution is a dual vial unit containing 1 vial of Immune Globulin Infusion 10% (Human) [IG 10%] and 1 vial of rHuPH20.[1]

The dose of HyQvia is based on the immune globulin component, which provides the therapeutic effect. The vial of rHuPH20 contains the appropriate amount of enzyme to facilitate the administration of the contents of the vial of IG 10%.[1]

Dosing guidelines for HyQvia for CIDP[1]

Dose and dosing frequency can be adjusted based on the individual patient's clinical response

- Before initiating therapy with HyQvia, calculate the weekly equivalent dose to plan for the ramp-up schedule. Dose and dosing frequency can be adjusted based on the individual clinical response
- A dose ramp-up schedule is recommended by gradually increasing the subcutaneous (SC) infusion volume until the full dose is reached
- Depending on the treating physician's discretion, in patients who tolerate the first two infusions well, subsequent infusions may be administered by gradually increasing doses and decreasing dose intervals, considering the volume and total infusion time
- Doses less than or equal to 0.4 g/kg may be administered without a ramp-up provided acceptable patient tolerance

IMPORTANT SAFETY INFORMATION (continued)

Adverse Reactions

The most common adverse reactions observed in clinical trials in >5% of patients were: local reactions, headache, pyrexia, nausea, fatigue, erythema, pruritus, increased lipase, abdominal pain, back pain, and pain in extremity.

Drug Interactions

Passive transfer of antibodies may transiently interfere with the immune responses to live attenuated virus vaccines (e.g., measles, mumps, rubella, and varicella).

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Dosing (continued)

Ramp-up for patients transitioning from IVIG treatment[1]

- Patients transitioning from intravenous administration of immune globulin must be on stable* doses of IVIG
- Before initiating therapy with HyQvia, calculate the weekly equivalent dose by dividing the last IVIG dose by the IVIG dose interval in weeks
- For patients with IVIG dosing less than or equal to 4 weeks, starting dose and dosing frequency of HyQvia is the same as the patient's previous IVIG treatment. The typical dosing interval range in the clinical trial for HyQvia was 4 weeks. For patients with less frequent IVIG dosing (greater than 4 weeks), the dosing interval can be converted to 3 or 4 weeks while maintaining the same monthly equivalent IG dose
- Administer the calculated one-week dose (1st infusion) **two weeks after the last IVIG infusion** as directed in section 2.3 of the Full Prescribing Information. One week after the first HyQvia dose, administer another weekly equivalent dose (2nd infusion)
- A ramp-up period can take 4-9 weeks, depending on the dosing interval and tolerability

IVIG to HyQvia Infusion Dose Ramp-up Schedule in ADVANCE-1 Study

Week†	Infusion Number	Dose Interval	Example for 100 g every 4 weeks
1	No infusion	Not Applicable (NA)	NA
2	1st infusion	1-week dose	25 g
3	2nd infusion	1-week dose	25 g
4	3rd infusion	2-week dose	50 g
5	No infusion	NA	NA
6	4th infusion	3-week dose	75 g
7	No infusion	NA	NA
8	No infusion	NA	NA
9	5th infusion	4-week dose	100 g (Full dose reached)

Depending on the treating physician's discretion, in patients who tolerate the first two infusions well, subsequent infusions may be administered by gradually increasing doses and decreasing dose intervals, considering the volume and total infusion time

*Variations in the dosing interval of up to ±7 days or monthly equivalent dose amount of up to ±20% between the subject's IgG infusions are considered a stable dose.
†Clock starts one week after the last IVIG dose is administered. Week 1 is the week that starts one week after the last IVIG dose.

IMPORTANT SAFETY INFORMATION (continued)

Use in Specific Populations

Pregnancy: Limited human data are available on the use of HyQvia during pregnancy. The effects of antibodies to the Recombinant Human Hyaluronidase on the human embryo or fetal development are unknown. It is not known whether HyQvia can cause fetal harm when administered to a pregnant woman or if it can affect reproductive capacity. HyQvia should be given to a pregnant woman only if clearly needed.

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Dosing (continued)

Transitioning from IVIG: Ramp-up period can take 4-9 weeks depending on dosing interval and tolerability[1]

When to start HyQvia

HyQvia Dosing Schedule	Q4 weeks[1]	Q3 weeks	Q2 weeks
Example Monthly IVIG Dose	1.6 g/kg		
Example Target Full Dose	1.6 g/kg	1.2 g/kg	0.8 g/kg
Week 1	No infusion		
Week 2	◔	◔	◑
Week 3	◔	◔	◑
Week 4	◑	◕	●
Week 5			
Week 6	◕	●	
Week 7			
Week 8			
Week 9	●		
Week 10			
Week 11			
Week 12			
6 months			

Full dose Q4 weeks

Full dose Q3 weeks

Full dose Q2 weeks

The first HyQvia infusion can be administered 2 weeks after the last IVIG infusion

2-week infusion (previous IVIG dose given Q2 weeks)	◑ 1/2 Q2W dose	● Full Q2W dose		
3-week infusion (previous IVIG dose given Q3 weeks)	◔ 1/3 Q3W dose	◕ 2/3 Q3W dose	● Full Q3W dose	
4-week infusion (previous IVIG dose given Q4 weeks)	◔ 1/4 Q4W dose	◑ 1/2 Q4W dose	◕ 3/4 Q4W dose	● Full Q4W dose

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Dosing (continued)

Initial infusion rates[1]

The full dose of rHuPH20 (Hy) solution is infused at a rate of 1 to 2 mL per minute (60 mL to 120 mL/hr) per infusion site or as tolerated. IG 10% can be administered through the same subcutaneous needle set within approximately 10 minutes after the rHuPH20 infusion is completed.

Patients with body weight of 40 kg or above[1]

The IG 10% should be infused at an initial rate of 10 mL per hour per infusion site. If tolerated, the rate of the administration may be increased at intervals of 5-15 minutes and to a maximum infusion rate of 240 mL per hour per infusion site for the initial one or two infusions. For subsequent infusions the rate can be adjusted to a maximum of 300 mL per hour per infusion site.

Patients with body weight under 40 kg[1]

The IG 10% should be infused at an initial rate of 5 mL per hour per infusion site. If well tolerated, the rate of the administration may be increased at intervals of 5-15 minutes and to a maximum of 80 mL per hour per infusion site for the initial one or two infusions. For subsequent infusions the rate can be adjusted to a maximum of 160 mL per hour per infusion site.

The dose can be administered at 1, 2, or 3 infusion sites with a maximum infusion volume of 600 mL per site (or as tolerated). If using three sites, the maximum is 400 mL per site.

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Welcome to Takeda Patient Support

When your patient enrolls, we're here to help them gain access to their prescribed Takeda medication. Our dedicated specialists provide several services, including:

- **Benefits investigation** to help determine your patient's insurance benefits
- **Prior authorization (PA)**, reauthorization, and appeals information in coordination with your patient's insurance company to determine any requirements
- **Financial assistance options** including the Takeda Patient Support Co-Pay Assistance Program. The program may cover up to 100% of your patient's out-of-pocket co-pay costs, if they're eligible*†
- **Education and training** about their prescribed Takeda treatment or condition from nursing professionals. Our nurses cannot provide medical advice
- **Specialty pharmacy triage**, coordination, and more‡

Need Assistance?

Our support specialists are never more than a tap or call away — **1-866-861-1750**, Monday through Friday, 8 AM to 8 PM ET.

Need to Enroll Your Patient?

Visit our convenient online enrollment portal at **TakedaPatientSupport.com/hcp**. You can also enroll your patient by faxing the completed Start Form to **1-855-268-1826**.

If English is not your patient's preferred language, we can assist them in a language of their choosing.

*Must meet eligibility requirements.

†**IMPORTANT NOTICE:** The Takeda Patient Support Co-Pay Assistance Program (the Program) is not valid for prescriptions eligible to be reimbursed, in whole or in part, by Medicaid, Medicare (including Medicare Part D), Tricare, Medigap, VA, DoD, or other federal or state programs (including any medical or state prescription drug assistance programs). No claim for reimbursement of the out-of-pocket expense amount covered by the Program shall be submitted to any third party payer, whether public or private. The Program cannot be combined with any other rebate/coupon, free trial, or similar offer. Copayment assistance under the Program is not transferable. The Program only applies in the United States, including Puerto Rico and other U.S. territories, and does not apply where prohibited by law, taxed, or restricted. This does not constitute health insurance. Void where use is prohibited by your patient's insurance provider. If your patient's insurance situation changes, they must notify the Program immediately at 1-866-861-1750. Coverage of certain administration charges will not apply for patients residing in states where it is prohibited by law. Takeda reserves the right to rescind, revoke, or amend the Program at any time without notice.

‡If your patients' medication is dispensed by specialty pharmacy.

Say **Hy** to maintenance therapy with **proven efficacy**, **established safety profile**, and **choices**

HyQvia
[Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase]

Control

- In the pivotal ADVANCE-1 trial,* during the 6-month treatment period, analysis of the primary endpoint demonstrated a statistically significant difference between the relapse rates† in the HyQvia group (N=57, 14.0%) compared to the placebo group (N=65, 32.3%) (p=0.0314)[1]
- The treatment difference of -18.3% (two-sided 95% CI: -32.1%, -3.1%) indicated that HyQvia demonstrated superiority over placebo in preventing relapse of CIDP[1]

Choice

- HyQvia offers choices for you and your patients: reimbursed across multiple sites of care, to give your patients the option of infusing in-center or at home (HCP supported, or administered by the patient or their care partner, after appropriate training)[1‡]

Time

- HyQvia allows for up to 28 days between infusions based on clinical response, which can give your patients time for the things they enjoy[1]
- HyQvia can be administered every 2, 3, or 4 weeks[1]
- Average infusion time was approximately 2 hours in a clinical trial[1]

Safety Profile

Please see Important Safety Information throughout brochure including Boxed Warning regarding Thrombosis

- The most common adverse reactions observed in >5% of patients in clinical studies (ADVANCE-1: study 1 and ADVANCE-3: study 2) of HyQvia for CIDP were local reactions, headache, pyrexia, nausea, fatigue, erythema, pruritus, increased lipase, abdominal pain, back pain, and pain in extremity.[1§]
- In study 1, a total of 4 subjects (3.0%) experienced AEs that led to discontinuation from the study; 3 subjects in the HyQvia group and 1 in the placebo group. The AEs leading to discontinuation in the 3 HyQvia subjects included: a cerebrovascular accident in 1 subject (who had coexisting cardiovascular risk factors), infusion site edema and infusion site pain in another subject, and nausea and chills in the third subject.[1]
- In study 2, a total of 3 subjects (3.8%) experienced AEs that led to discontinuation from the study and 1 subject (1.3%) died prior to the time of the interim analysis. The AEs leading to discontinuation in the 3 subjects included mantle cell lymphoma in 1 subject, muscular weakness and worsening of CIDP in another subject, and abdominal pain in the third subject. The cause of death in the 1 subject was cholangiocarcinoma[1]
- In study 1, all HyQvia local reactions (100%) were either mild (88.41%) or moderate (11.59%) in severity[1]
- In study 2, most of the local reactions (95%) were either mild (85.44%) or moderate (9.34%) in severity[1]

*ADVANCE-1 (Study 1) was a 6-month, multicenter, randomized, placebo-controlled phase 3 study of 132 adults with CIDP on a stable dose of IVIG for ≥12 weeks before screening who received either HyQvia (N=62) or placebo (N=70). The mean duration of exposure was 5.2 months in the HyQvia group and 4.7 months in the placebo group.[1]

†Relapse was defined as an increase of ≥1 point relative to the pre-subcutaneous treatment baseline score in 2 consecutive adjusted INCAT disability scores obtained <7 days apart.[1]

‡Patients can receive HyQvia treatment at an infusion center, in hospital, or at home. It can be given by an HCP, self-administered after training, or given by a trained caregiver. A choice of home administration must be a joint decision between HCP and patient; patients cannot make this decision themselves.[1]

§Causally related ARs and/or temporally associated ARs occurring within 72 hours.[1]

Scan the code or click here to learn more about HyQvia.

Please see additional Important Safety Information throughout, and click for Full Prescribing Information including Boxed Warning regarding Thrombosis.

INDICATION

HyQvia is indicated for the treatment of chronic inflammatory demyelinating polyneuropathy (CIDP) as maintenance therapy to prevent relapse of neuromuscular disability and impairment in adults. HyQvia is for subcutaneous use only.

HyQvia
[Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase]

IMPORTANT SAFETY INFORMATION

WARNING: THROMBOSIS

- **Thrombosis may occur with immune globulin (IG) products, including HyQvia. 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. Thrombosis may occur in the absence of known risk factors.**
- **For patients at risk of thrombosis, administer HyQvia 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 of hyperviscosity.**

Contraindications

- History of anaphylactic or severe systemic hypersensitivity reactions to human IG
- IgA-deficient patients with antibodies to IgA and a history of hypersensitivity to human IG
- Known systemic hypersensitivity to hyaluronidase including Recombinant Human Hyaluronidase of HyQvia
- Known systemic hypersensitivity to human albumin (in the hyaluronidase solution)

Warnings and Precautions

Hypersensitivity: Severe hypersensitivity reactions may occur, even in patients who have tolerated previous treatment with human IG. If a hypersensitivity reaction occurs, discontinue infusion immediately and institute appropriate treatment. IgA-deficient patients with antibodies to IgA are at greater risk of developing potentially severe hypersensitivity reactions, including anaphylaxis.

Thrombosis: Has been reported to occur following treatment with IG products, including HyQvia and in the absence of known risk factors. In patients at risk, administer at the minimum dose and infusion rate practicable. Ensure adequate hydration before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.

Immunogenicity of Recombinant Human Hyaluronidase (rHuPH20): Non-neutralizing antibodies to the Recombinant Human Hyaluronidase component can develop. The clinical significance of these antibodies or whether they interfere with fertilization in humans is unknown.

Aseptic Meningitis Syndrome: Has been reported with use of IG, including HyQvia and may occur more frequently in females. The syndrome usually begins within several hours to two days following IG treatment.

Conduct a thorough neurological exam on patients exhibiting signs and symptoms, to rule out other causes of meningitis. Discontinuing IG treatment has resulted in remission within several days without sequelae.

Hemolysis: HyQvia contains blood group antibodies which may cause a positive direct antiglobulin reaction and hemolysis. Monitor patients for signs and symptoms of hemolysis and delayed hemolytic anemia and, if present, perform appropriate confirmatory lab testing.

Renal Dysfunction/Failure: Acute renal dysfunction/failure, acute tubular necrosis, proximal tubular nephropathy, osmotic nephrosis, and death may occur with intravenous (IV) use of IG products, especially those containing sucrose. Ensure patients are not volume depleted prior to infusion. In patients at risk due to pre-existing renal insufficiency or predisposition to acute renal failure, assess renal function before initiation and throughout treatment, and consider lower, more frequent dosing. If renal function deteriorates, consider discontinuation.

Spread of Localized Infection: Do not infuse HyQvia into or around an infected area due to potential risk of spreading a localized infection.

Transfusion-Related Acute Lung Injury: Non-cardiogenic pulmonary edema may occur with IV administered IG. Monitor patients for pulmonary adverse reactions. If suspected, perform appropriate tests for presence of anti-neutrophil and anti-HLA antibodies in both product and patient serum. May be managed using oxygen therapy with adequate ventilatory support.

Transmittable Infectious Agents: Because HyQvia is made from human plasma, it may carry a risk of transmitting infectious agents (e.g. viruses, other pathogens). No cases of transmission of viral diseases or variant Creutzfeldt-Jakob disease (vCJD) have been associated with HyQvia.

Interference with Lab Tests: False positive serological test results and certain assay readings, with the potential for misleading interpretation, may occur as the result of passively transferred antibodies.

Adverse Reactions

The most common adverse reactions observed in clinical trials in >5% of patients were: local reactions, headache, pyrexia, nausea, fatigue, erythema, pruritus, increased lipase, abdominal pain, back pain, and pain in extremity.

Drug Interactions

Passive transfer of antibodies may transiently interfere with the immune responses to live attenuated virus vaccines (e.g., measles, mumps, rubella, and varicella).

Use In Specific Populations

Pregnancy: Limited human data are available on the use of HyQvia during pregnancy. The effects of antibodies to the Recombinant Human Hyaluronidase on the human embryo or fetal development are unknown. It is not known whether HyQvia can cause fetal harm when administered to a pregnant woman or if it can affect reproductive capacity. HyQvia should be given to a pregnant woman only if clearly needed.

Please click for Full Prescribing Information.

References: 1. HyQvia. Prescribing information. Takeda Pharmaceuticals U.S.A., Inc.; 2024. **2.** Bril V, Hadden RDM, Brannagan TH, et al. Hyaluronidase-facilitated subcutaneous immunoglobulin 10% as maintenance therapy for chronic inflammatory demyelinating polyradiculoneuropathy: The ADVANCE-CIDP 1 randomized controlled trial. *J Peripher Nerv Syst*. 2023;10.1111/jns.12573. doi:10.1111/jns.12573 [Epub ahead of print].

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