HelloHYQVIA

Free Trial Request Form

Fax Page 1 to 1-866-861-1617 I Phone: 1-866-861-1750

Do not submit to Takeda any documentation of labs, clinical history, or other documents supporting the prior authorization process.

HyQvia

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

1 Prescribing Physician

Name (First, Last): _____ NPI #: _____ Tax ID #: _____

Street Address: _____ City: _____ State: _____ ZIP: _____

Office Contact: _____ Telephone: _____ Fax: _____ Email: _____

2 Patient Information

Patient Name (First, Middle Initial, Last): _____ ☐ Male ☐ Female

DOB (MM/DD/YYYY): _____ Email: _____

Street Address: _____ City: _____ State: _____ ZIP: _____

Mobile Telephone (M): _____ Work Telephone (W): _____ Home Telephone (H): _____ Preferred #: ☐ M ☐ W ☐ H

Caregiver Name (First, Last): _____ Relationship to Patient: _____

Caregiver Telephone: _____ Specialty Pharmacy/Site of Care (i.e., Infusion Center): _____

3 Infusion Location(s)

Infusion Center/Office Name: _____ Infusion Center/Office Telephone: _____

☐ All Infusions In-Home* ☐ First Infusion In-Office; Subsequent In-Home* ☐ All Infusions In-Office

For In-Office (first or recurring) Choose One: ☐ Drug ☐ Drug, Ancillaries, and Pump ☐ Drug, Ancillaries, Pump, and Administration

*All in-home infusions will be provided with drug, ancillaries, pump, and administration support.

4 HYQVIA Prescription and Prescribing Physician Signature

Prescription: HYQVIA® [Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase] Solution **ICD-10:** _____

☐ **For Primary Immunodeficiency (PI)**

☐ Patient switching from intravenous immune globulin (human) (IVIG) treatment: Administer HYQVIA at the same dose and frequency as the previous intravenous treatment, after the initial dose ramp-up.[1] See ramp-up schedule table on page 3 for calculation of ramp-up dosage.

☐ Patient switching from subcutaneous immune globulin (human) (SCIG): Administer HYQVIA at 300 to 600 mg/kg at 3-week or 4-week intervals, after the initial ramp-up.[1] See ramp-up schedule table on page 3 for calculation of ramp-up dosage.

Patient Weight (kg): _____ x Ordered Dose: _____ mg/kg ÷ 1,000 = Total Grams*: _____ Every _____ Weeks

☐ **For Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)**

☐ If switching from IVIG (human) treatment, administer HYQVIA at the same dose and frequency as the previous IV treatment, after the initial dose ramp-up.[1] See ramp-up schedule table on page 3 for calculation of ramp-up dosage.

Last IVIG (g): _____ Dosed Every _____ Weeks
Patient Weight (kg): _____
Desired HYQVIA Dose (g): _____ Every _____ Weeks

☐ Pharmacy to calculate ramp-up dose per the ramp-up schedule in the package insert.

☐ Prescriber additional instruction: _____

_____

_____

Please see ramp-up schedule tables on page 3 to calculate ramp-up dosage.

☐ I acknowledge that by signing this document, I have discussed with my eligible patient about HYQVIA. I have informed my patient that Takeda will contact them via phone or text to coordinate and start a free trial for HYQVIA.

Number of Infusion Site(s): ☐ One (1) infusion Site ☐ One (1) or Two (2) Infusion Site(s) ☐ One (1), Two (2), or Three (3) Infusion Site(s)

Infusion Sites(s)†: ☐ Middle to Upper Abdomen ☐ Thigh(s)

Pump: ☐ Peristaltic ☐ Syringe Driver

High-Flow 24G Needle Length: ☐ 6 mm ☐ 9 mm ☐ 12 mm ☐ 14 mm

*To calculate total infusion volume in mL, multiply total grams by 10.

†If 2 infusion sites are used, the infusion sites should be on opposite sides of the body. Avoid bony prominences or areas that are scarred, inflamed, or infected.

Confirmation of Epinephrine Prescription

☐ I certify that my patient has a) confirmed having either a separate prescription for epinephrine injection that they are required to fill prior to their initial HYQVIA infusion or b) I have given my patient a separate prescription for epinephrine injection and have instructed my patient to fill the prescription at their cost prior to their initial HYQVIA infusion.

Allergies

☐ No known drug allergies

☐ Patient allergies (drug and non-drug): _____ ☐ Special instructions: _____

By signing this document, I certify that the patient is capable of self-infusing in the home, where applicable, the patient meets the eligibility requirements, and I have read and agree to the Program Terms. I understand that this program is intended for the evaluation of HYQVIA with my eligible patient to determine whether HYQVIA is right for them. I authorize the agents of Takeda to use the above information to provide the HelloHYQVIA Free Trial Program to my patient. I understand that the agents of Takeda will keep this information confidential and will use it only for the HelloHYQVIA program. This usage may include a follow-up survey about my patient's and/or my experiences with the HelloHYQVIA program and HYQVIA. Neither I nor my agents will submit any portion of the free trial HYQVIA, supplies, pump, or administration services for reimbursement to any third-party payer, including Medicare or Medicaid, either directly or indirectly. I understand Takeda may confirm with a third-party infusion provider that it will not submit any portion of the free trial HYQVIA, supplies, pump, or administration services for reimbursement to any third-party payer, including Medicare or Medicaid, either directly or indirectly. Provider verifies that they will not bill for products/services, particularly if the first infusion is in office and subsequent infusions are in home.

I acknowledge that by signing this document, I have discussed with my eligible patient about HYQVIA. I have informed my patient that Takeda will contact them via phone or text to coordinate and start a free trial for HYQVIA.

Prescriber Signature (Required): _____ Date: _____

Stamps not acceptable DISPENSE AS WRITTEN

The prescriber is required to comply with his/her state-specific prescription requirements such as e-prescribing, state-specific prescription form, fax language, etc. Non-compliance with state-specific requirements could result in delay.

5 Patient Authorization and Program Terms Confirmation

By agreeing to these Takeda Patient Support ("Program") text message terms and conditions, you agree to receive text messages on your mobile device subject to the Terms & Conditions described below. You also consent to receive autodialed and/or prerecorded calls and/or text messages from or on behalf of the Program at the telephone number provided above. You understand that this consent is not a condition of purchase or use of the Program or of any Takeda product or service. Such messages may be nonmarketing messages related to the Patient Support Program. There is no fee payable to Takeda to receive text messages; however, your carrier's message and data rates may apply.

You represent that you are the account holder for the mobile telephone number(s) that you provide to opt in to the Program. You are responsible for notifying Takeda immediately if you change your mobile telephone number. You may notify Takeda of a number change by calling 1-866-861-1750. Data obtained from you in connection with your registration for, and use of, this SMS service may include your phone number and/or email address, related carrier information, and elements of pharmacy claim information and will be used to administer this Program and to provide Program benefits such as information about your prescription, refill reminders, and Program updates and alerts. Takeda will not be liable for any delays in the receipt of any SMS messages, as delivery is subject to effective transmission from your network operator. This Program is valid with most major US cellular providers. Takeda may be required to contact the user if an adverse event is reported. You agree to indemnify Takeda and any third parties texting on its behalf in full for all claims, expenses, and damages related to or caused, in whole or in part, by your failure to immediately notify us if you change your telephone number, including but not limited to all claims, expenses, and damages related to or arising under the Telephone Consumer Protection Act.

Takeda reserves the right to rescind, revoke, or amend the Program without notice at any time.

You can unsubscribe from this Program by texting back STOP to any message or by calling 1-866-861-1750.

Consent for Marketing Information: By signing below, I authorize the use of my Information for Takeda marketing activities and consent to receiving marketing, market research opportunities, and promotional communications from Takeda. I hereby give consent to Takeda, its affiliates, and their agents and representatives to send communications and information to me via the contact information I have provided above. I understand that this consent will be in effect until I cancel such authorization.

_____ Patient/Legal Representative Signature

_____ Date

_____ Patient Name

_____ Legal Representative Name and Relationship

☐ **I have read, reviewed, and agree to the Program Terms on page 3.**

Please see additional Important Safety Information on page 3 and click for Full Prescribing Information including Boxed Warning regarding Thrombosis.

6 Patient HIPAA Authorization

Patient Name (First, Middle Initial, Last): _____ DOB (MM/DD/YYYY): _____

By signing the Patient Authorization section on the second page of this Takeda Patient Support Ig Enrollment Form, I authorize my physician, health insurance, and pharmacy providers (including any specialty pharmacy that receives my prescription) to disclose my protected health information, including, but not limited to, information relating to my medical condition, treatment, care management, and health insurance, as well as all information provided on this form ("Protected Health Information"), to Takeda Pharmaceuticals U.S.A., Inc. and its present or future affiliates, including the affiliates and service providers that work on Takeda's behalf in connection with the Takeda Patient Support, Ig Patient Support Program (the "Companies"). The Companies will use my Protected Health Information for the purpose of facilitating the provision of the Takeda Patient Support, Ig Patient Support Program products, supplies, or services as selected by me or my physician and may include (but not be limited to) verification of insurance benefits and drug coverage, prior authorization education, financial assistance with co-pays, patient assistance programs, and other related programs. Specifically, I authorize the Companies to 1) receive, use, and disclose my Protected Health Information in order to enroll me in Takeda Patient Support, Ig and contact me, and/or the person legally authorized to sign on my behalf, about Takeda Patient Support, Ig; 2) provide me, and/or the person legally authorized to sign on my behalf, with educational materials, information, and services related to Takeda Patient Support, Ig; 3) verify, investigate, and provide information about my coverage for HYQVIA, including but not limited to communicating with my insurer, specialty pharmacies, and others involved in processing my pharmacy claims to verify my coverage; 4) coordinate prescription fulfillment; and 5) use my information to conduct internal analyses. I understand that employees of the Companies only use my Protected Health Information for the purposes described herein, to administer the Takeda Patient Support, Ig Patient Support Program or as otherwise required or allowed under the law, unless information that specifically identifies me is removed. Further, I understand that my physician, health insurance, and pharmacy providers may receive financial remuneration from the Companies for providing Protected Health Information, which may be used for marketing purposes. I understand that Protected Health Information disclosed under this Authorization may no longer be protected by federal privacy law. I understand that I am entitled to a copy of this Authorization. I understand that I may revoke this Authorization and that instructions for doing so are contained in Takeda's Website Privacy Notice available at www.takeda.com/privacy-notice/ or I may revoke this Authorization at any time by sending written notice of revocation to Takeda Patient Services 610 Crescent Executive Court, Suite 200 Lake Mary, FL 32746. I understand that such revocation will not apply to any information already used or disclosed through this Authorization. This Authorization will expire within five (5) years from the date it is signed and provided on the first page of this enrollment form, unless a shorter period is provided for by state law. I understand that I may refuse to sign this Authorization and that refusing to sign this Authorization will not change the way my physician, health insurance, and pharmacy providers treat me. I also understand that if I do not sign this Authorization, I will not be able to receive Takeda Patient Support, Ig Patient Support Program products, supplies, or services.

Signature of Patient (Required): _____ Date: _____

*Legal Representative Signature: _____ Date: _____

*Legal Representative Name: _____

*Relationship to Patient: _____

*Required only if applicable.

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

Instructions for Completion of Form

Step 1: Page 1, sections 1-4 and the epinephrine prescription box, must be completed by the prescribing physician on behalf of the patient with primary immunodeficiency (PI) and chronic inflammatory demyelinating polyneuropathy (CIDP)
Step 2: Page 1, section 5 *can be completed only by* the patient or their legal representative; the patient signature is required to allow personal health information to be shared by third parties to Takeda to facilitate access to HYQVIA (fulfilling and coordinating delivery of medication, etc.)
Step 3: Once the prescribing physician and the patient or patient's legal representative have completed and signed page 1, the Request Form page 1 will be faxed to 1-866-861-1617 (or the digital, editable PDF version of the Request Form page 1 can be completed and faxed to 1-866-861-1617)
If you have any questions, please call 1-866-861-1750.

Program Terms

- **For In-Home Administration:** The HelloHYQVIA Free Trial Program provides, at no cost, patients two years and older with primary immunodeficiency (PI) or adults with chronic inflammatory demyelinating polyneuropathy (CIDP) with three (3) ramp-up infusions for PI and four (4) ramp-up infusions for CIDP of HYQVIA, ancillary supplies, pump, and administration (in-home infusion nursing services) by a Takeda contractor.
- **For First Infusion In-Office/Remaining Infusions at Home:** The HelloHYQVIA program provides patients two years and older with PI or adults with CIDP with one (1) in-office ramp-up dose of HYQVIA (product only), followed by two (2) ramp-up doses for PI and three (3) ramp-up doses for CIDP of HYQVIA, ancillary supplies, pump, and administration (in-home infusion nursing services) by a Takeda contractor, at no cost.
  - Where ancillaries are requested, office will be provided ancillary supplies and pump.
  - Where administration services are requested, infusion nursing services provided by a Takeda contractor will be provided.
- **For In-Office Administration:** The HelloHYQVIA program provides, at no cost, patients two years and older with PI or adult patients with CIDP with three (3) ramp-up doses for PI and four (4) ramp-up doses for CIDP of HYQVIA (product only).
  - Where ancillaries, pump, and administration are requested, infusion services will be provided by a Takeda contractor.
- This free trial offer is solely intended to allow new patients to try HYQVIA and to determine with their healthcare provider whether HYQVIA is right for them. There is no obligation to continue use of HYQVIA after the free trial has been completed.
- This free trial prescription is valid for one time only with no refills. For any future use, the patient must obtain a new prescription for HYQVIA.
- To be eligible: 1) patient must be two years and older with an ICD-10 code verifying diagnosis of PI or an adult patient with CIDP; 2) be a new patient not currently using HYQVIA and who has not previously enrolled in the HelloHYQVIA program; and 3) for in-home administration, physician has determined patient is capable of administering free trial HYQVIA.
- Free trial HYQVIA cannot be exported or transferred in exchange for money, other property, and services.
- No portion of the free trial HYQVIA, supplies, pump, or administration services may be submitted for reimbursement to any third-party payer, including Medicare or Medicaid, either directly or indirectly.
- This program is only valid for residents of the United States, excluding Puerto Rico and other US territories.
- Takeda Pharmaceutical Company Limited reserves the right to change or discontinue this program at any time without notice.
- This is not a financial assistance nor cost savings program.

HYQVIA Ramp-Up Schedule and Recombinant Human Hyaluronidase Infusion Parameters

Check box on page 1 to confirm patient has an active epinephrine prescription. As a safety measure, the patient needs to have epinephrine for the first free trial HYQVIA infusion.

Infusion Parameters for Recombinant Human Hyaluronidase (Hy) and Immune Globulin Infusion 10% (Ig)[1]

Rate of Administration for Hy: 1-2 mL/min/site(s), and increase as tolerated up to 300 mL/hour if using a pump method

Rate of Administration for Ig:	Patients <40 kg (<88 lb)		Patients ≥40 kg (≥88 lb)	
	First 2 Infusions	Subsequent 2 or 3 Infusions	First 2 Infusions	Subsequent 2 or 3 Infusions
Interval (Minutes)	Rate/site (mL/hour)	Rate/site (mL/hour)	Rate/site (mL/hour)	Rate/site (mL/hour)
5-15	5	10	10	10
5-15	10	20	30	30
5-15	20	40	60	120
5-15	40	80	120	240
Remainder of Infusion	80	160	240	300

Initial Treatment Interval and Ramp-Up Schedule for PI[1]

For patients previously on another IgG treatment, the first dose should be given approximately 1 week after the last infusion of their previous treatment.

PI: Ramp-up schedule if switching from IVIG[1]

Week	Dose Interval	Dose
	Switch from IVIG	
1	1st dose	Total grams x 0.25
2	2nd dose	Total grams x 0.50
3	No Infusion	
4	3rd dose	Total grams x 0.75
5	No Infusion	
6	No Infusion	
7	4th dose	Total grams

Total grams=total monthly equivalent dose in grams.

Ramp-up schedule if switching from SCIG

Treatment Interval		4 Weeks	3 Weeks
1st Infusion	1st week	Total grams x 0.25	Total grams x 0.33
2nd Infusion	2nd week	Total grams x 0.50	Total grams x 0.67
3rd Infusion	4th week	Total grams x 0.75	Total grams
4th Infusion*	7th week	Total grams	

No infusions at 3, 5, and 6 weeks.

*The 4th infusion is not part of the HelloHYQVIA program.

Initial Treatment Interval and Ramp-Up Schedule for CIDP[1]

- Doses less than or equal to 0.4 g/kg can be administered without ramp-up
- Patients must be on stable doses of IVIG for 12 weeks before switching to HYQVIA

Ramp-up schedule if switching from IVIG[1]

Week	Dose Interval	Dose
	Switch from IVIG	
1	No Infusion	
2	1st dose	Total grams x 0.25
3	2nd dose	Total grams x 0.25
4	3rd dose	Total grams x 0.50
6	4th dose	Total grams x 0.75
9	5th dose	Total grams

Total grams=total monthly equivalent dose in grams. No infusions at 1, 5, 7, and 8 weeks. The 5th infusion is not part of the HelloHYQVIA program.

INDICATIONS

HYQVIA is indicated for the treatment of primary immunodeficiency (PI) in adults and pediatric patients two years of age and older and for 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.**

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 >5% of patients in the clinical trials were:

Primary Immunodeficiency (PI): local adverse reactions including pain, erythema, edema, and pruritus, and systemic adverse reactions including, headache, antibody formation against Recombinant Human Hyaluronidase (rHuPH20), fatigue, nausea, pyrexia, and vomiting.

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP): 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.

Reference: 1. HYQVIA [prescribing information]. Lexington, MA: Baxalta US Inc.

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Takeda