HelloHYQVIA

Free Trial Request Form

Fax Page 1 to 1-866-861-1752 | 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)

☐ 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:** _____

☐ **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 2 for calculation of ramp-up dosage.

☐ **Patient naive to subcutaneous immune globulin (human) (SCIG) treatment or switching from 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 2 for calculation of ramp-up dosage.

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

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

☐ Prescriber additional instruction: _____

_____

_____

Please see Page 2 for HYQVIA Ramp-Up Schedule and Recombinant Human Hyaluronidase Infusion Parameters.

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

Infusion Site(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.

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, 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.

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.

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.

5 Patient Authorization and Program Terms Confirmation

By signing this Authorization, I authorize my healthcare providers and pharmacy to disclose my protected health information, including, but not limited to, personal information related to my medical condition, treatment, and care management, as well as all information provided on this form including contact and any prescription information ("Personal Health Information"), to Takeda Pharmaceutical Company Limited, its affiliates, and their representatives, agents and contractors ("Company") in connection with the Company's provision of product, supplies, and/or services under the free trial program. I understand that the Company may communicate with me by mail, email, or telephone about my medical condition, treatment, and care management. I understand I may be contacted to participate in a follow-up survey about my experience in this free trial program. I understand that once disclosed to the Company, my Personal Health Information disclosed under this Authorization may no longer be protected by federal privacy law, including HIPAA. This Authorization will expire within five (5) years from today's date, unless a shorter period is provided for by state law; however, I understand that I may revoke this Authorization at any time by sending written notice of revocation to Takeda Patient Support, 300 Shire Way, Lexington, MA 02421, except to the extent that action already has been taken in reliance on this 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 2.**

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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)

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 1-866-861-1752 (or the digital, editable PDF version of the Request Form page 1 can be completed and faxed to 1-866-861-1752)

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) with three (3) ramp-up infusions 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 with one (1) in-office ramp-up dose of HYQVIA (product only), followed by two (2) ramp-up doses 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 with three (3) ramp-up doses 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; 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 Pharmaceuticals, Inc. 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

Initial Treatment interval and ramp-up schedule[1]

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.

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	Total grams

No infusions at 3, 5, and 6 weeks.

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

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

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
Intervals (minutes)	**Rate per site (mL/hour)**	**Rate per site (mL/hour)**	**Rate per site (mL/hour)**	**Rate per 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

INDICATION AND LIMITATION OF USE

HYQVIA is indicated for the treatment of primary immunodeficiency (PI) in adults and pediatric patients two years of age and older. HYQVIA is for subcutaneous use only. Safety and efficacy of chronic use of Recombinant Human Hyaluronidase in HYQVIA have not been established in conditions other than PI.

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 See Full Prescribing Information for Warnings and Precautions for: Hypersensitivity, Thrombosis, Immunogenicity of Recombinant Human Hyaluronidase (rHuPH20), Aseptic Meningitis Syndrome, Hemolysis, Renal Dysfunction/ Failure, Spread of Localized Infection, Transfusion-Related Acute Lung Injury, Transmittable Infectious Agents, and Interference with Lab Tests.

Adverse Reactions

The most common adverse reactions observed in >5% of patients in the clinical trials were: local adverse reactions (pain, erythema, edema, and pruritus) and systemic adverse reactions (headache, antibody formation against rHuPH20, fatigue, nausea, pyrexia, and vomiting).

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