

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

HELP PATIENTS

ENROLL

IN HELLOHYQVIA

HelloHYQVIA
Free Trial Program

The HelloHYQVIA Free Trial Program is designed with your patients in mind.

With nurse-supported infusions at home or in-office infusions, eligible patients can try HYQVIA [Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase] Solution and decide, along with their doctor, if it's right for them.*

*To be eligible, patients must have an ICD-10–verified diagnosis, be new patients not currently using HYQVIA, and have not been previously enrolled in the HelloHYQVIA program. ICD-10=International Statistical Classification of Diseases, Tenth Revision.



Highlights of the HelloHYQVIA Free Trial Program

- ✓ HYQVIA can be administered by a nurse at home, a physician's office, or an infusion center. Supplies will be shipped directly to your patient's home, if applicable.
- ✓ A nurse will guide patients through the infusion process, either in person or virtually, to help optimize HYQVIA infusion parameters.
- ✓ The entire cost of the first 3 HYQVIA infusions for PI and first 4 HYQVIA infusions for CIDP during the ramp-up period is free, including the pump, supplies, and initial infusion training.

CIDP=chronic inflammatory demyelinating polyneuropathy; PI=primary immunodeficiency.

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.

Please see additional Important Safety Information on page 4 and click for [Full Prescribing Information](#).

01

Patient enrollment

Once you and your patient decide to take part in the HelloHYQVIA program, you will begin the enrollment process.

What you need to do

- Verify that your patient is eligible for the program before you complete the HelloHYQVIA Free Trial Form
- Fax the finished form to 1-866-861-1617
- If your patient is receiving therapy administered by a program nurse at home or in a chosen site of care, epinephrine is required and a prescription will be needed from you



HelloHYQVIA Free Trial Form

You can access the HelloHYQVIA Free Trial Form on the Access and Support page on the HYQVIA HCP website at HYQVIAhcp.com/access-support.

02

Welcome call

Before your patient's first infusion, **they will receive a welcome call from a HelloHYQVIA Case Manager** who will help with:



Completing the HelloHYQVIA Free Trial Form, if needed



Connecting your patient with the specialty pharmacy that will coordinate medication shipment



Connecting your patient with a nurse who will help schedule their in-home administration training

HCP=healthcare professional.

Please see Important Safety Information on pages 1 and 4 and click for [Full Prescribing Information](#) including Boxed Warning regarding Thrombosis.

03

Begin treatment

A nurse will go to the patient's home to administer the HYQVIA infusions and provide initial administration training, if applicable.

This will include



Directions on how to set up the supplies for the infusion of HYQVIA



Detailed instructions for administration



An Infusion Report that will be completed by the nurse



HelloHYQVIA Infusion Report

This report will be used by the nurse to help monitor your patient's infusions and any reactions during the Free Trial Program. It will be shared with you and, if applicable, the specialty pharmacy after the free trial to help with the therapy onboarding process.

After the HelloHYQVIA program

As your patient progresses through the Free Trial Program, the HelloHYQVIA program nurses will send notes around each visit. You will get notes about how the infusions went, review any questions about administration, and be able to see if there are any reactions or issues. As you and your office receive these notes, it will be helpful to guide the conversation around if HYQVIA is right for your patient. The insurance process may be lengthy, so planning next steps may need to happen sooner than the last infusion. This may help to ensure there are no treatment gaps during the transition.

For additional information or to learn how to enroll your patients in the HelloHYQVIA Free Trial Program, visit HYQVIAhcp.com/access-support or call 1-866-861-1750.

Please see Important Safety Information on pages 1 and 4 and click for [Full Prescribing Information](#) including Boxed Warning regarding Thrombosis.

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)

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 see additional Important Safety Information on page 1 and click for [Full Prescribing Information](#) including Boxed Warning regarding Thrombosis.