HYQVIA Training Program

A positive patient experience begins with you

Baxter understands that many patients feel uneasy starting a new treatment. The first infusion sets the precedent and a skilled practitioner confident in the new administration method is essential.

Bringing the HYQVIA Training Program to your facility is a convenient, efficient way to train your nurses. Our IG Clinical Educators have more than 180 combined years of infusion therapy experience, and their expertise can help ensure a positive experience for both you and your patients.

- Live, face-to-face or remote webinar instruction provided by a skilled IG Clinical Educator
- One-hour program, with an optional additional 30 minutes of hands-on practice, held in your facility or other convenient location
- After participating in the training, you will receive resources to help train your patients, including the Step-by-Step Guide and Nurse Training Kit

Appropriate for healthcare professionals who directly administer HYQVIA, who train patients to administer HYQVIA, and/or healthcare professionals who serve as the primary trainer within their facility

The HYQVIA Training Program features:

- **HYQVIA Overview**
  Introduction to HYQVIA, administration considerations, managing the infusion

- **Live Administration Demonstration with Hands-on Practice**
  Using the administration method preferred by your facility

- **Helping Your Patients to Self-Administer HYQVIA**
  Training patients using the Step-by-Step Guide and available support resources

Ask your Baxter Representative about scheduling a training program

Please see Indication and Detailed Important Risk Information on the reverse side and accompanying full prescribing information including boxed warning.
Indication and Detailed Important Risk Information

INDICATION AND USAGE
HYQVIA is an immune globulin with a recombinant human hyaluronidase indicated for the treatment of Primary Immunodeficiency (PI) in adults. This includes, but is not limited to, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies

Limitation of Use: Safety and efficacy of chronic use of recombinant human hyaluronidase in HYQVIA have not been established in conditions other than PI.

BOXED WARNING: THROMBOSIS
Thrombosis may occur with immune globulin products, including HYQVIA [Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase]. 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
HYQVIA is contraindicated in patients who have a history of anaphylactic or severe systemic reactions to the administration of IgG, in IgA-deficient patients with antibodies to IgA and a history of hypersensitivity; and in patients with known systemic hypersensitivity to hyaluronidase or Recombinant Human Hyaluronidase of HYQVIA.

WARNINGS and PRECAUTIONS
Hypersensitivity: Severe hypersensitivity reactions may occur, even in patients who have tolerated previous treatment with IgG. Patients with antibodies to IgA and a history of hypersensitivity; and in patients with known systemic hypersensitivity to hyaluronidase or Recombinant Human Hyaluronidase of HYQVIA.

Thrombosis: Thrombosis may occur following treatment with immune globulin products, including HYQVIA. Risk factors may include advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling central vascular catheters, hyperviscosity, and cardiovascular risk factors. Thrombosis may occur in the absence of known risk factors. Consider baseline assessment of blood viscosity in patients at risk of hyperviscosity.

Immunogenicity of Recombinant Human Hyaluronidase (PH20):
Non-neutralizing antibodies to the recombinant human hyaluronidase component may develop. The potential exists for such antibodies to cross-react with endogenous PH20, which is known to be expressed in adult male testes, epididymis, and sperm. It is unknown whether these antibodies may interfere with fertilization in humans. The clinical significance of these antibodies is unknown.

Aseptic Meningitis Syndrome (AMS): AMS has been reported to occur with IgG products, including Immune Globulin Infusion 10% (Human) administered intravenously and subcutaneously. Discontinuation of IgG treatment has resulted in remission of AMS within several days without sequelae. The syndrome usually begins within several hours to two days following intravenously administered IgG, perhaps more frequently in association with high dose (2 g/kg) intravenously administered IgG. Conduct a thorough neurological examination on patients exhibiting symptoms and signs, including cerebrospinal fluid studies, to rule out other causes of meningitis.

Hemolysis: IgG products, including HYQVIA, contain blood group antibodies which may cause a positive direct antiglobulin reaction and hemolysis. Acute intravascular hemolysis has been reported following administration of IgG products, including Immune Globulin Infusion 10% (Human) administered intravenously, and delayed hemolytic anemia can develop due to enhanced RBC sequestration. Monitor patients for clinical signs and symptoms of hemolysis.

Renal dysfunction/Failure: Acute renal dysfunction/failure, acute tubular necrosis, proximal tubular nephropathy, osmotic nephrosis, and death may occur upon administration of IgG products administered intravenously, especially those containing sucrose. HYQVIA does not contain sucrose. Ensure that patients are not volume depleted prior to the initiation of infusion of HYQVIA. Monitor renal function and consider lower, more frequent dosing in patients who are at risk of developing renal dysfunction because of pre-existing renal insufficiency or predisposition to acute renal failure. Periodic monitoring of renal function and urine output is particularly important in patients judged to be at increased risk for developing acute renal failure.

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

Transfusion-Related Acute Lung Injury (TRALI): Non-cardiogenic pulmonary edema has been reported in patients following treatment with intravenously administered IgG products, including Immune Globulin Infusion 10% (Human). TRALI is characterized by severe respiratory distress, pulmonary edema, hypoxemia, normal left ventricular function, and fever. Monitor patients for pulmonary adverse reactions.

Transmittable Infectious Agents: Because the Immune Globulin Infusion 10% (Human) of HYQVIA is made from human plasma, it may carry a risk of transmitting infectious agents, e.g., viruses, the variant CJD (vCJD) agent, and theoretically, the Creutzfeldt-Jakob disease (CJD) agent. This also applies to unknown or emerging viruses and other pathogens. No cases of viral transmission or CJD have been associated with HYQVIA.

Interference with Laboratory Tests: False positive serological test results, with the potential for misleading interpretation, may result from the transitory rise of the various passively transferred antibodies in the patient’s blood after infusion of IgG. Passive transmission of antibodies to erythrocyte antigens (e.g., A, B, and D) may cause a positive direct antiglobulin reaction and hemolysis. Acute intravascular hemolysis has been reported following administration of IgG products. Hemolysis: IgG products, including HYQVIA. Hemolysis: IgG products, including HYQVIA.

ADVERSE REACTIONS
The most common adverse reactions observed in > 5% of patients in the clinical trials were: local adverse reactions (52%), headache (21%), antibody formation against recombinant human hyaluronidase (18%), fatigue (11%), nausea (7%), pyrexia (7%), and vomiting (7%). No serious adverse reactions occurred during the HYQVIA clinical trials.