HYQVIA: The Newly Approved Subcutaneous Immune Globulin Administered Every 3 to 4 Weeks in Adults With Primary Immunodeficiency

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

Tuesday, July 14, 2015

7:00PM-9:00PM

Program Description

HYQVIA [Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase], the newly approved immune globulin that can be administered subcutaneously every 3 to 4 weeks, is indicated for the treatment of primary immunodeficiency (PI) in adults. HYQVIA contains a recombinant human form of the naturally occurring enzyme hyaluronidase, which increases the dispersion and absorption of immune globulin in the subcutaneous tissue.[1]

Patients with PI are susceptible to increased frequency and severity of infections.[2] Intravenous immune globulin (IGIV) has been the mainstay of immune globulin replacement treatment in the U.S. since the 1980s. More recently, subcutaneous administration of immune globulin (IGSC) has become an efficacious alternative to IGIV for some patients with PI.[3] However, the main challenge with conventional IGSC is that the extracellular matrix component of the subcutaneous tissue limit the infusible volume per site, thus requiring multiple infusion sites weekly or every other week.[4] HYQVIA allows a full therapeutic dose of immune globulin to be administered subcutaneously via a single infusion site every 3 to 4 weeks.[1]

Location

Il Forks
17776 Dallas Parkway
Dallas, TX 75287

Speaker

Mark Ballow, MD
Professor of Pediatrics,
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& Rheumatology
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Please contact your Baxter Territory Business Manager, Janet Rivas, at 214-425-7410 if you would like to attend this program. Registration Link: https://baxalta.cvent.com/714HyQvia

Program Objectives

The purpose of this program is to

- Describe how HYQVIA [Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase] can meet recognized patient needs by allowing a full therapeutic dose of immune globulin to be administered subcutaneously once a month (every 3 to 4 weeks)
- Review the clinical efficacy, tolerability, and safety of HYQVIA
- Discuss how to identify adult patients with primary immunodeficiency and initiate treatment with HYQVIA

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.

Detailed Important Risk Information

BOXED WARNING: THROMBOSIS

Thrombosis may occur 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 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.

Please see the Detailed Important Risk Information continued on page 2 and the accompanying Full Prescribing Information, including boxed warning.

Detailed Important Risk Information (continued from page 1)

HyQvia
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WARNINGS and PRECAUTIONS

Hypersensitivity: Severe hypersensitivity reactions may occur, even in patients who have tolerated previous treatment with IgG. Patients with antibodies to IgA are potentially at greater risk of developing potentially severe hypersensitivity and anaphylactic reactions. In case of hypersensitivity, discontinue HYQVIA infusion immediately and institute appropriate treatment.

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 or indirect antiglobulin (Coombs') test.

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.

1. HYQVIA [Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase] solution for subcutaneous administration Prescribing Information. Westlake Village, CA: Baxter Healthcare Corporation; September 2014.
2. Bonilla FA, Bernstein IL, Khan DA, et al. Practice parameter for the diagnosis and management of primary immunodeficiency. *Ann Allergy Asthma Immunol.* 2005;94(5 Suppl 1):S1-S63.
3. Wasserman RL, Melamed I, Kobrynski L, et al. Efficacy, safety, and pharmacokinetics of a 10% liquid immune globulin preparation administered subcutaneously in subjects with primary immunodeficiency disease. *J Clin Immunol.* 2011;31(3):323-331.
4. Wasserman RL, Melamed I, Stein MR, et al. Recombinant human hyaluronidase-facilitated subcutaneous infusion of human immunoglobulins for primary immunodeficiency. *J Allergy Clin Immunol.* 2012;130(4):951-957.

Please see the accompanying Full Prescribing Information, including Boxed Warning.

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