CODING GUIDE

Diagnostic and Billing Codes for Subcutaneous Administration of HYQVIA

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

This guide contains the following information necessary to bill payers for HYQVIA [Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase] Solution:

- Healthcare Common Procedure Coding System (HCPCS) codes
- National Drug Code (NDC) numbers
- Current Procedural Terminology (CPT) codes

The provider is responsible for ensuring accurate and appropriate diagnostic coding to obtain reimbursement.

DME and Supply Codes[1]

HCPCS Code and Description	
E0779	Ambulatory infusion pump, mechanical, reusable, for infusion of 8 hours or greater
E0780	Ambulatory infusion pump, mechanical, reusable, for infusion less than 8 hours
E0781[a]	Ambulatory infusion pump, single or multiple channels, electric or battery operated, with administrative equipment, worn by patient
E0791	Parenteral infusion pump, stationary, single, or multichannel
A4221	Supplies for maintenance of non-insulin drug infusion catheter, per week (list drugs separately)
K0552	Supplies for external non-insulin drug infusion pump, syringe type cartridge, sterile, each

[a]HYQVIA is administered using a programmable variable infusion pump (HCPCS code E0781) that is capable of infusing a patient's therapeutic dose at infusion rates of up to 300 mL/hr/site. Medicare coverage is available for claims with dates of service on or after September 12, 2014 when all of the following requirements have been met: 1) the criteria for subcutaneous immune globulin as specified in the external infusion pump local coverage determination are met, and 2) HYQVIA is administered subcutaneously through an E0781 pump that is preprogrammed, and 3) the E0781 pump is delivered to the Medicare beneficiary in a "locked mode" (i.e., the patient is unable to self-adjust the infusion rate).[2]

HYQVIA HCPCS Code[1]

HCPCS Code and Description	
J1575	Injection, immune globulin/hyaluronidase, (HYQVIA), 100 mg immune globulin

Home Infusion Therapy[1]

HCPCS Code and Description	
S9338	Home infusion therapy, immunotherapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem

CPT® Codes[3]

Subcutaneous Administration	
96369	Subcutaneous infusion for therapy or prophylaxis (specify substance or drug); initial, up to 1 hour, including pump setup and establishment of subcutaneous infusion site(s)
96370	Subcutaneous infusion for therapy or prophylaxis (specify substance or drug); each additional hour (list separately in addition to code for primary procedure)
96371	Subcutaneous infusion for therapy or prophylaxis (specify substance or drug); additional pump setup with establishment of new subcutaneous infusion site(s) (list separately in addition to code for primary procedure)

HYQVIA NDC Numbers[4]

	Grams Protein [Immune Globulin Infusion 10% (Human)]	**J1575-Billing Units**[b] [Injection, immune globulin/ hyaluronidase, (HYQVIA), 100 mg/mL immune globulin]
0944-2510-02	2.5	25
0944-2511-02	5.0	50
0944-2512-02	10	100
0944-2513-02	20	200
0944-2514-02	30	300

[b]HYQVIA is supplied in a dual-vial unit of 2 single-use vials containing the labeled amount of functionally active Immune Globulin Infusion 10% (Human) and Recombinant Human Hyaluronidase.[4]

The information contained in this Coding Reference Guide is provided for informational purposes only. Every reasonable effort has been made to verify the accuracy of the information; however, this guide is not intended to provide specific guidance on how to utilize, code, bill, or charge for any product or service. Healthcare providers should make the ultimate determination as to when to use a specific product based on clinical appropriateness for a particular patient.

Third-party payment for medical products and services is affected by numerous factors, and Takeda cannot guarantee success in obtaining insurance payments. This Coding Reference Guide is current as of January 2024.

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 pages 2 and 3 and click for Full Prescribing Information.

ICD-10 Diagnosis Codes[1,5]

D80	Immunodeficiency With Predominantly Antibody Defects
D80.0	Hereditary hypogammaglobulinemia Autosomal recessive agammaglobulinemia (Swiss type) X-linked agammaglobulinemia [Bruton] (with growth hormone deficiency)
D80.1	Nonfamilial hypogammaglobulinemia Agammaglobulinemia with immunoglobulin-bearing B-lymphocytes Common variable agammaglobulinemia [CVAgamma] Hypogammaglobulinemia NOS
D80.3	Selective deficiency of immunoglobulin G [IgG] subclasses
D80.4	Selective deficiency of immunoglobulin M [IgM]
D80.5	Immunodeficiency with increased immunoglobulin M [IgM]
D80.6	Antibody deficiency with near-normal immunoglobulins or with hyperimmunoglobulinemia
D80.7	Transient hypogammaglobulinemia of infancy
D80.8	Other immunodeficiencies with predominantly antibody defects Kappa light chain deficiency
D80.9	Immunodeficiency with predominantly antibody defects, unspecified
D81	**Combined Immunodeficiencies**
D81.0	Severe combined immunodeficiency [SCID] with reticular dysgenesis
D81.1	Severe combined immunodeficiency [SCID] with low T- and B-cell numbers
D81.2	Severe combined immunodeficiency [SCID] with low or normal B-cell numbers
D81.4	Nezelof's syndrome
D81.6	Major histocompatibility complex class I deficiency Bare lymphocyte syndrome
D81.7	Major histocompatibility complex class II deficiency
D81.89	Other combined immunodeficiencies
D81.9	Combined immunodeficiency, unspecified Severe combined immunodeficiency disorder [SCID] NOS

D82	Immunodeficiency Associated With Other Major Defects
D82.0	Wiskott-Aldrich syndrome Immunodeficiency with thrombocytopenia and eczema
D82.1	DiGeorge's syndrome Pharyngeal pouch syndrome Thymic alymphoplasia Thymic aplasia or hypoplasia with immunodeficiency
D82.2	Immunodeficiency with short-limbed stature
D82.3	Immunodeficiency following hereditary defective response to Epstein-Barr virus X-linked lymphoproliferative disease
D82.4	Hyperimmunoglobulin E [IgE] syndrome
D82.8	Immunodeficiency associated with other specified major defects
D82.9	Immunodeficiency associated with major defect, unspecified
D83	**Common Variable Immunodeficiency**
D83.0	Common variable immunodeficiency with predominant abnormalities of B-cell numbers and function
D83.1	Common variable immunodeficiency with predominant immunoregulatory T-cell disorders
D83.2	Common variable immunodeficiency with autoantibodies to B- or T-cells
D83.8	Other common variable immunodeficiencies
D83.9	Common variable immunodeficiency, unspecified
G61	**Inflammatory Polyneuropathy**
G61.81	Chronic inflammatory demyelinating polyneuritis

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.

Please see additional Important Safety Information on pages 1 and 3 and click for Full Prescribing Information including Boxed Warning regarding Thrombosis.

IMPORTANT SAFETY INFORMATION (Continued)

Warnings and Precautions (Continued)

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 subjects 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 pages 1 and 2 and click for Full Prescribing Information including Boxed Warning regarding Thrombosis.

References

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