

# Sample CMS-1500 Claim Form for HYQVIA Physician Office Setting

**HyQvia**

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

**Box 21:** Enter the patient's diagnosis/condition based on the International Classification of Diseases-10 (ICD-10) code. Use the ICD-10 code to the highest level of specificity for the date of service. Enter diagnoses/conditions in priority order if applicable.<sup>1</sup>

**Box 24:** Medicaid and some commercial payers may require the National Drug Code (NDC) number in the shaded portion of the line item in fields 24A-24G. If applicable, the following should be entered: the qualifier "N4" (left-justified), immediately followed by the NDC number. Providers typically need to report the NDC number in an 11-digit format (eg, 0944-2514-02 would be reported as N400944251402).<sup>1</sup>

Next, the NDC should be followed by: a space for separation, followed by the dispensing unit of measure qualifier (eg, ML [milliliter]), immediately followed by the quantity (number of units up to 3 decimal places).<sup>1</sup>

**Box 24B Line 1:** Code should specify the entity where service(s) were rendered. Check with individual payers for reimbursement policies regarding these codes (ie, 11 office, 12 home, 22 on campus-outpatient hospital).<sup>1</sup>

**Box 24D Line 1:** Unique HYQVIA Healthcare Common Procedure Coding System (HCPCS) code is **J1575** [Injection, immune globulin/hyaluronidase, (HYQVIA), 100 mg immune globulin].<sup>2</sup>

**Box 24D Line 2:** Appropriate Current Procedural Terminology (CPT) code to represent related administration procedure (refer to CPT codes listed on this page).<sup>3</sup>

**Box 24G Line 1:** Enter the number of **J1575** billing units.<sup>1,2</sup>

The information contained here is provided for informational purposes only and is not intended to provide billing or coding instruction for a specific claim. Every reasonable effort has been made to verify the accuracy of the information, which is current as of June 2018.

It is the responsibility of healthcare providers to submit true, accurate, and complete claims for products and services rendered. Healthcare providers 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.

## 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.**



HYQVIA NDC Numbers<sup>4</sup>

| NDC Number   | Grams Protein<br>[Immune Globulin<br>Infusion 10% (Human)] | J1575-Billing Units <sup>a</sup><br>[Injection, Immune globulin/<br>hyaluronidase,<br>(HYQVIA), 100 mg/mL<br>immune globulin] <sup>2</sup> |
|--------------|--|--|
| 0944-2510-02 | 2.5  | 25   |
| 0944-2511-02 | 5.0  | 50   |
| 0944-2512-02 | 10.0   | 100  |
| 0944-2513-02 | 20.0   | 200  |
| 0944-2514-02 | 30.0   | 300  |

<sup>a</sup>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.<sup>4</sup>

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.

References

1. Centers for Medicare & Medicaid Services. Transmittal 3083. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3083CP.pdf>. Accessed June 19, 2018.

2. Centers for Medicare & Medicaid Services. 2018 alpha-numeric index. HCPCS 2018 index. <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS-Items/2018-Alpha-Numeric-HCPCS-File-.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=descending>. Accessed June 18, 2018.

3. American Medical Association. CPT® code/relative value search. <https://apps.ama-assn.org/CptSearch/user/search/cptSearch.do>. Accessed June 18, 2018.

4. HYQVIA [Prescribing Information]. Westlake Village, CA: Baxalta US Inc.

CPT® Codes<sup>3</sup>

| CPT Codes | Description   |
|-----------|---|
| 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) |

**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: 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.

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](#) including Boxed Warning regarding Thrombosis.

