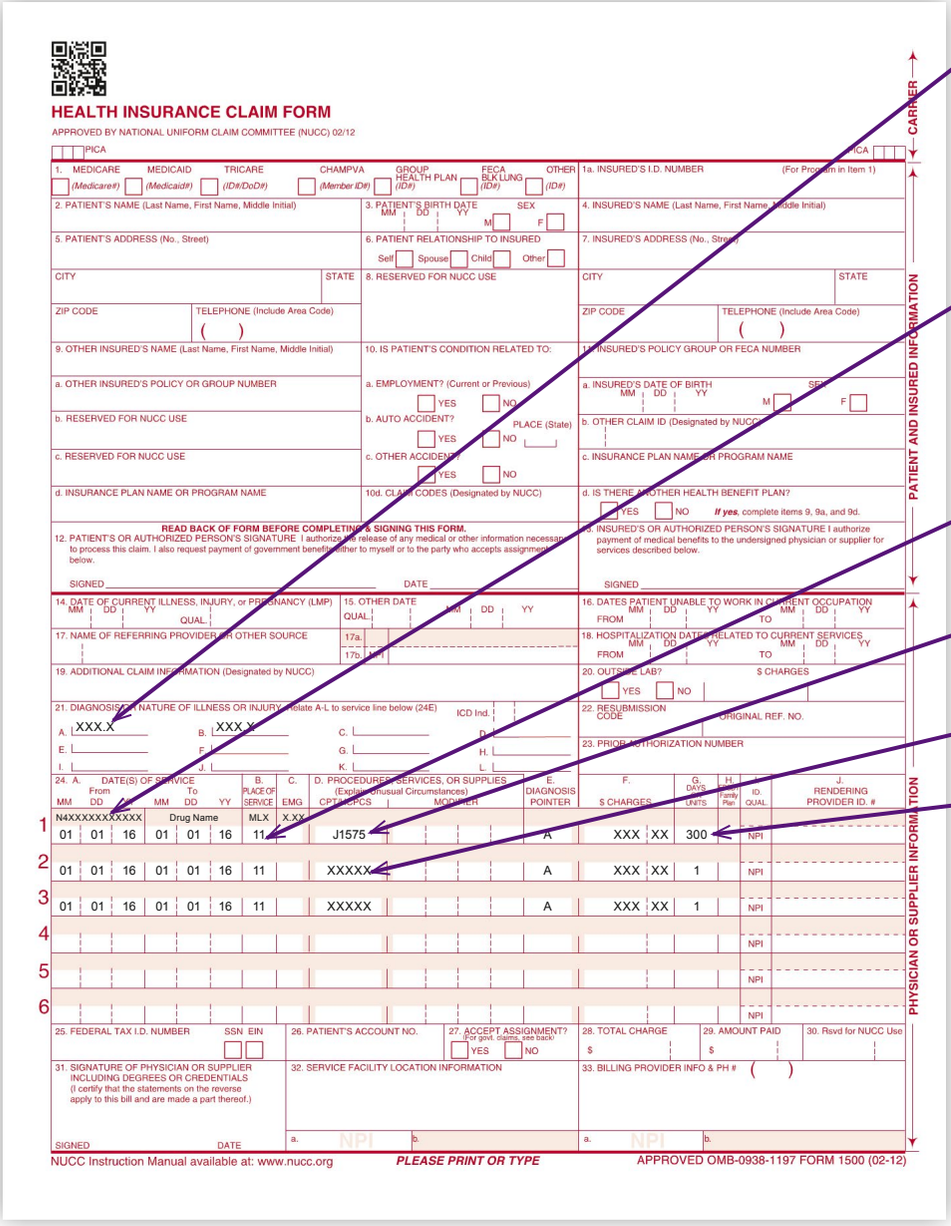
# Sample CMS-1500 Claim Form for HYQVIA

## Physical Office Setting

HyQvia

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



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

1. MEDICARE (Medicare#) MEDICAID (Medicaid#) TRICARE (ID#/DoD#) CHAMPVA (Member ID#) GROUP HEALTH PLAN (ID#) FECA BLK LUNG (ID#) OTHER (ID#)

1a. INSURED'S I.D. NUMBER (For Program in Item 1)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)

3. PATIENT'S BIRTH DATE MM DD YY SEX M F

4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. PATIENT'S ADDRESS (No., Street)

6. PATIENT RELATIONSHIP TO INSURED Self Spouse Child Other

7. INSURED'S ADDRESS (No., Street)

CITY STATE

8. RESERVED FOR NUCC USE

CITY STATE

ZIP CODE TELEPHONE (Include Area Code) ( )

ZIP CODE TELEPHONE (Include Area Code) ( )

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) YES NO

a. INSURED'S DATE OF BIRTH MM DD YY SEX M F

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? YES NO PLACE (State)

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? YES NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME

10d. CLAIM CODES (Designated by NUCC)

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO If yes, complete items 9, 9a, and 9d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.

SIGNED DATE

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

SIGNED

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.

15. OTHER DATE QUAL. MM DD YY

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM TO MM DD YY

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a.

17b. NPI

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM TO MM DD YY

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB? YES NO $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY (Relate A-L to service line below (24E)) ICD Ind.

A. XXX.X B. XXX.X C. D. E. F. G. H. I. J. K. L.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

| 24. A. DATE(S) OF SERVICE From MM DD YY | To MM DD YY | B. PLACE OF SERVICE | C. EMG | D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS | MODIFIER | E. DIAGNOSIS POINTER | F. $ CHARGES | G. DAYS OR UNITS | H. Family Plan | I. ID. QUAL. | J. RENDERING PROVIDER ID. # |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 N4XXXXXXXXXXX Drug Name | | MLX | X.XX | | | | | | | | NPI |
| 01 01 16 | 01 01 16 | 11 | | J1575 | | A | XXX | XX 300 | | | NPI |
| 2 01 01 16 | 01 01 16 | 11 | | XXXXX | | A | XXX | XX 1 | | | NPI |
| 3 01 01 16 | 01 01 16 | 11 | | XXXXX | | A | XXX | XX 1 | | | NPI |
| 4 | | | | | | | | | | | NPI |
| 5 | | | | | | | | | | | NPI |
| 6 | | | | | | | | | | | NPI |

25. FEDERAL TAX I.D. NUMBER SSN EIN

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES NO

28. TOTAL CHARGE $

29. AMOUNT PAID $

30. Rsvd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)

SIGNED DATE

32. SERVICE FACILITY LOCATION INFORMATION

a. NPI b.

33. BILLING PROVIDER INFO & PH # ( )

a. NPI b.

NUCC Instruction Manual available at: www.nucc.org

PLEASE PRINT OR TYPE

APPROVED OMB-0938-1197 FORM 1500 (02-12)

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

**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.[1]

**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).[1]

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).[1]

**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).[1]

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

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

**Box 24G Line 1:** Enter the number of **J1575** billing units[1,2]

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

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.

## 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.**



Takeda

## HYQVIA NDC Numbers[4]

| NDC Number | Grams Protein [Immune Globulin Infusion 10% (Human)] | J1575-Billing Units[a] [Injection, immune globulin/ hyaluronidase, (HYQVIA), 100 mg/mL immune globulin][2] |
|---|---|---|
| 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 |

[a]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]

## CPT® Codes[3]

| 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) |

## 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: 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.**


**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. Takeda Pharmaceuticals U.S.A., Inc.; 2024.



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