**HYQVIA [IMMUNE GLOBULIN INFUSION 10% (HUMAN) WITH RECOMBINANT HUMAN HYALURONIDASE] SOLUTION**

# ACCESS GUIDE

Resources to help you and your patients with primary immunodeficiency (PI) or chronic inflammatory demyelinating polyneuropathy (CIDP) along their insurance journey.

Navigating the process of getting a patient's prescription approved by a health plan can be complex and time-consuming. This access guide is invaluable for understanding and managing the various coverage scenarios you and your patients may encounter.

**Information and links to resources you will need along the way**

- ✔ Determining which benefit HYQVIA is covered under
- ✔ Prior authorization (PA) requirements
- ✔ Reimbursement guides
- ✔ Administrative and billing codes

## Contents



## 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 throughout and click for Full Prescribing Information.***

**ACCESS GUIDE**

# COVERAGE RESOURCES

HYQVIA is covered similarly to other treatments for PI and CIDP, but requirements may vary by plan. The first questions patients may have are whether their health insurance covers HYQVIA and how much it will cost.

## Benefits investigation

A benefits investigation can uncover these answers. Call the patient's health plan on their behalf to determine coverage and out-of-pocket costs. Be sure to have your patient's insurance information, including any secondary insurance, to get the process started.

HYQVIA may be covered under the medical benefit, the pharmacy benefit, and, in some plans, both. This dual benefit design can impact how HYQVIA is acquired and reimbursed.


**Dual Benefit Brochure**

Learn more about the medical and pharmacy benefit types and how they affect your patient's coverage.

DOWNLOAD


**HYQVIA Medicare Resource**

This HYQVIA Medicare Resource is an educational resource for Office Staff and healthcare professionals on the different facets of navigating medicare for their HYQVIA patients.

DOWNLOAD

**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.

***Please see additional Important Safety Information throughout and click for Full Prescribing Information including Boxed Warning regarding Thrombosis.***

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# PRIOR AUTHORIZATION RESOURCES

Depending on a patient's medical and prescription drug benefit, you may be required to submit a PA before your patient can receive treatment with HYQVIA. Each health plan has different requirements, so calling and confirming their policy is always good. Sometimes PAs do get denied. You and your patient can appeal the decision. It's also important to understand why it was denied in the first place. Some common reasons for denial:

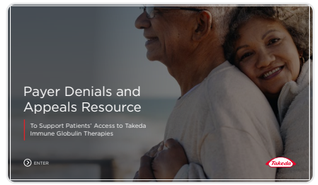
- Missing or inaccurate information
- Step-edit requirement
- Incorrect diagnosis code(s) submitted
- Billed to the wrong benefit (i.e., medical vs pharmacy)
- The site of care for infusion is not preferred/not covered
- Not covered on the formulary

## These resources are at your disposal to assist with the PA process for HYQVIA:


### PA Checklist

Be prepared for every PA submission.

DOWNLOAD




### Denials and Appeals Resource

Understand the appeals and denials process for both pharmacy and medical benefits.

DOWNLOAD


### Appeals Checklist

Appealing a denial requires organized paperwork and information.

DOWNLOAD

### Sample Letter of Medical Necessity

A Letter of Medical Necessity supports the PA process by explaining the clinical rationale for HYQVIA.

DOWNLOAD

### Sample Letter of Appeal

This letter can be used as a guide when the appeal needs to clearly answer the reason for denial and explain the healthcare professional's clinical rationale.

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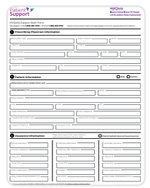
# TAKEDA PATIENT SUPPORT* CO-PAY ASSISTANCE PROGRAM

If a patient is prescribed HYQVIA and needs co-pay assistance, you can direct the patient to enroll in the Takeda Patient Support Co-Pay Assistance Program. The program can cover up to 100% of your patient's out-of-pocket co-pay costs if they're eligible.*† A support specialist can review your patient's coverage and determine eligibility.



**Takeda Patient Support Start Form**

Need to enroll your patient? Visit the convenient online enrollment portal at **TakedaPatientSupport.com/HCP/HYQVIA/Enroll_Your_Patient**. You can also enroll your patient by faxing the completed Start Form to 1-866-861-1752.

**DOWNLOAD**

*Must meet eligibility requirements.

[†**IMPORTANT NOTICE:** The Takeda Patient Support Co-Pay Assistance Program (the Program) is not valid for prescriptions eligible to be reimbursed, in whole or in part, by Medicaid, Medicare (including Medicare Part D), Tricare, Medigap, VA, DoD, or other federal or state programs (including any medical or state prescription drug assistance programs). No claim for reimbursement of the out-of-pocket expense amount covered by the Program shall be submitted to any third party payer, whether public or private. The Program cannot be combined with any other rebate/coupon, free trial, or similar offer. Copayment assistance under the Program is not transferable. The Program only applies in the United States, including Puerto Rico and other U.S. territories, and does not apply where prohibited by law, taxed, or restricted. This does not constitute health insurance. Void where use is prohibited by your patient's insurance provider. If your patient's insurance situation changes, they must notify the Program immediately at [1-855-268-1825]. Coverage of certain administration charges will not apply for patients residing in states where it is prohibited by law. Takeda reserves the right to rescind, revoke, or amend the Program at any time without notice.]

## IMPORTANT SAFETY INFORMATION (Continued)

**Warnings and Precautions (Continued)**

**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.

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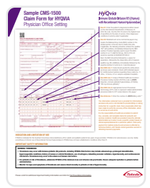
# REIMBURSEMENT

Correct codes are critical to reimbursement because health plan administrative processes rely heavily on using these codes. We have compiled a list of the most commonly used codes for your convenience. You can download these diagnostic code and claim form resources and additional information needed to process billing.

## HYQVIA Billing and Coding Guide

HYQVIA is covered by many insurers for the treatment of patients with primary immunodeficiency (PI) or chronic inflammatory demyelinating polyneuropathy (CIDP). This guide contains common administrative and diagnosis codes related to HYQVIA. The codes are provided for informational purposes and may not include all necessary codes.

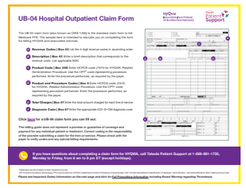
DOWNLOAD



## CMS-1500 Claim Form

The CMS-1500 claim form is the standard claim form used to bill many government and private insurers. This sample is intended to assist you with completing the form for billing HYQVIA and associated services.

DOWNLOAD



## HYQVIA UB-04 Hospital Outpatient Claim Sample

The HYQVIA UB-04 Hospital Outpatient Claim Sample is intended to educate offices on how to complete the UB-04 Hospital Outpatient Claim Form.

DOWNLOAD

## IMPORTANT SAFETY INFORMATION (Continued)

**Warnings and Precautions (Continued)**

**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.

## IMPORTANT SAFETY INFORMATION (Continued)

### Warnings and Precautions (Continued)

**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:

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 throughout and click for Full Prescribing Information including Boxed Warning regarding Thrombosis.***