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.

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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.

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.

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:

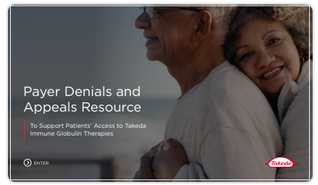
- Missing or inaccurate information
- Step-edit requirement
- Incorrect diagnosis code(s) submitted
- Billed to the wrong benefit (i.e., medical vs pharmacy)
- The site of care for infusion is not preferred/not covered
- Not covered on the formulary

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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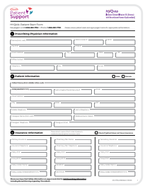
TAKEDA PATIENT SUPPORT* CO-PAY ASSISTANCE PROGRAM

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/s/. You can also enroll your patient by faxing the completed Start Form to 1-866-861-1752.

DOWNLOAD

*Must meet eligibility requirements.

†**IMPORTANT NOTICE:** Takeda's Co-pay Assistance Program ("the Program") provides financial support for commercially insured patients who qualify for the Program. Participation in the Program and provision of financial support is subject to all Program terms and conditions, including but not limited to eligibility requirements, the Program maximum benefit per claim and the annual calendar year Program maximum ("Annual Program Maximum"). The Annual Program Maximum for your prescribed Takeda product can be found by visiting: TakedaPatientSupport.com/s/copay.

By enrolling in the Program, you agree that the Program is intended solely for the benefit of you—not health plans and/or their partners. Further, you agree to comply with all applicable requirements of your health plan. The Program cannot be used if the patient is a beneficiary of, or any part of the prescription is covered by: 1) any federal, state, or government-funded healthcare program (Medicare, Medicare Advantage, Medicaid, TRICARE, etc.), including a state pharmaceutical assistance program (the Federal Employees Health Benefit (FEHB) Program is not a government-funded healthcare program for the purpose of this offer), 2) the Medicare Prescription Drug Program (Part D), or if the patient is currently in the coverage gap, or 3) insurance that is paying the entire cost of the prescription. 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.

Some health plans have established programs referred to as 'co-pay maximizer' programs. A co-pay maximizer program is one in which the amount of a patient's out-of-pocket costs is adjusted to reflect the availability of support offered by a manufacturer's co-pay assistance program. If you are enrolled in a co-pay maximizer program, your Annual Program Maximum may vary over time to ensure the program funds are used for your benefit (for the benefit of the patient). Takeda also reserves the right to reduce or eliminate the co-pay assistance available to patients enrolled in an insurance plan that utilizes a co-pay maximizer program.

If you learn your health plan has implemented a co-pay maximizer program, you agree to notify the Program immediately by calling 1-866-861-1750. It may be possible that you are unaware whether you are subject to a co-pay maximizer program when you enroll or re-enroll in the Program. Takeda will monitor program utilization data and reserves the right to discontinue assistance under the Program at any time if Takeda determines that you are subject to a co-pay maximizer, or similar program.

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 insurance provider. If your insurance situation changes you must notify the Program immediately by calling 1-866-861-1750. Coverage of certain administration charges will not apply for patients residing in states where it is prohibited by law.

This Program offer is not transferable and is limited to one offer per person and may not be combined with any other coupon, discount, prescription savings card, rebate, free trial, patient assistance, co-pay maximizer, alternative funding program, co-pay accumulator, or other offer, including those from third parties and companies that help insurers or health plan manage costs. Not valid if reproduced.

By utilizing the Program, you hereby accept and agree to abide by these terms and conditions. Any individual or entity who enrolls or assists in the enrollment of a patient in the Program represents that the patient meets the eligibility criteria and other requirements described herein. You must meet the Program eligibility requirements every time you use the Program. Takeda reserves the right to rescind, revoke, or amend the Program at any time without notice, and other terms and conditions may apply.

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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

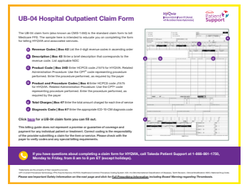
HYQVIA is covered by many insurers for the treatment of patients with primary immunodeficiency (PI) or chronic inflammatory demyelinating polyneuropathy (CIDP). This guide contains common administrative and diagnosis codes related to HYQVIA. The codes are provided for informational purposes and may not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

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.

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 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.