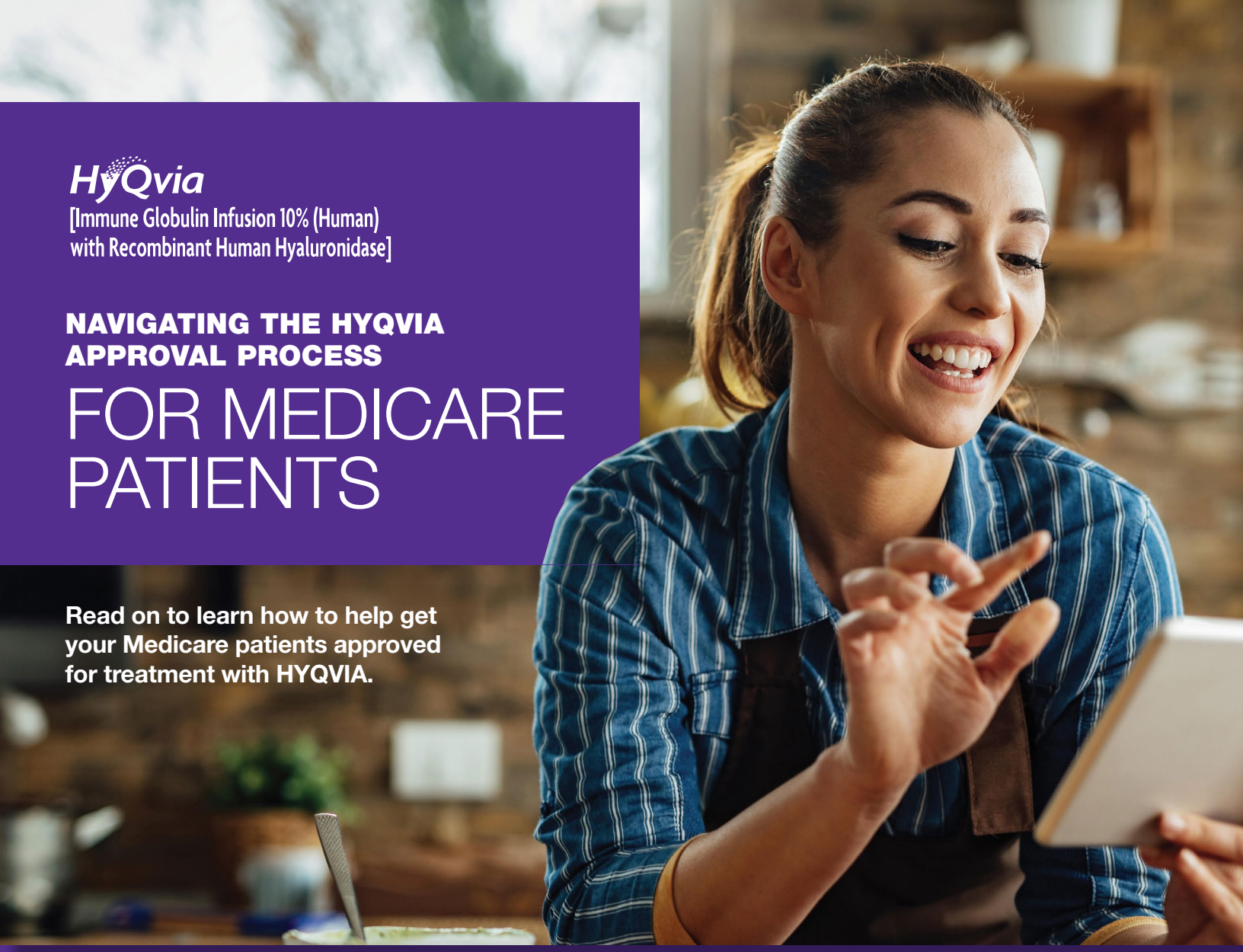

HyQvia
[Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase]

NAVIGATING THE HYQVIA APPROVAL PROCESS

FOR MEDICARE PATIENTS

Read on to learn how to help get your Medicare patients approved for treatment with HYQVIA.

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.

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

INTRODUCTION

This guide includes information about HYQVIA Medicare basics, ways that HYQVIA can be covered for your Medicare patients, site of care considerations, as well as a few tips that may help you obtain access and reimbursement for your patients who need HYQVIA.

What is HYQVIA?

HYQVIA is a subcutaneous immunoglobulin (SCIG) therapy that comes in a dual vial unit— 1 vial of Immune Globulin Infusion 10% (Human) Solution (IG) 10% and 1 vial of Recombinant Human Hyaluronidase to treat primary immunodeficiency in patients aged 2 years or older and for the treatment of chronic inflammatory demyelinating polyneuropathy (CIDP) as maintenance therapy to prevent relapse of neuromuscular disability and impairment in adults.[1]

The HYQVIA dose is primarily determined by the IG 10% component, which provides the therapeutic effect. This dispersion and absorption of IG 10% are made possible by the Recombinant Human Hyaluronidase.[1]

For CIDP, the monthly dosing for HYQVIA, which can be administered 2, 3, or 4 weeks after ramp-up, based on the individual clinical response.[1]

HYQVIA offers flexible administration options[1]

Your office can collaborate with patients to decide on several aspects of the treatment.

- Whether to use 1, 2, or 3 sites*
- The location of the infusion†
- Dosing frequency
- Ability to choose where to administer therapy

*Based on tolerability and total volume.
†In either the abdomen or the thighs.

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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MEDICARE'S FRAMEWORK CAN BE COMPLEX

Here is a reminder of the basics to help you understand your patients' coverage.

As you may already know, Medicare is a federal health insurance program for[2]:

- People aged 65 years or older
- Certain younger people with disabilities
- People of any age with end-stage renal disease

Medicare includes different parts

Original Medicare

Part A
Hospital insurance

Covers inpatient hospital stays, nursing facility care, hospice care, and home healthcare.[2]

Part B
Medical insurance

Covers services from physicians and other healthcare professionals, outpatient care, preventive services, durable medical equipment (DME), and some home-based services.[2]

- HYQVIA is 80% covered by Medicare Part B[3]

Medigap
Supplementary insurance

Supplementary insurance covering costs not addressed by Original Medicare[3]

- May cover some or all of the remaining 20% not covered for HYQVIA[3]

Medicare Advantage

Part C
Hospital and medical insurance

An alternative way to receive your Medicare benefits, includes Parts A, B, and usually D.[2]

- Covers at least 80% of HYQVIA and has a cap on out-of-pocket costs[3]
- Prior authorization (PA) may be required

Part D
Drug coverage

Available to everyone with Medicare, this is an optional benefit that helps cover the cost of prescription medications and some recommended vaccines. Plans that offer Medicare drug coverage are run by private insurance companies that follow Medicare rules.[2]

→ **Tip:** Keep in mind that, even though Medicare Advantage plans must cover at least what traditional Medicare covers, no 2 plans are the same.

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

SITE OF CARE COVERAGE

CONSIDERATIONS

As mentioned, HYQVIA is typically covered under Medicare Part B, with broad coverage in hospital, physicians offices, and in-home administration.[3,4] Below are some considerations to keep in mind when securing coverage for HYQVIA for your Medicare patients for various sites of care.

Places where infusions are completed

Home infusion | **Physician's office/ infusion clinic** | **Outpatient hospital settings** | **Inpatient hospital settings**

HOME INFUSION

Part B DME benefit: External infusion pumps and the supplies, like those used to administer HYQVIA, are categorized as DME.[5]

- Part B covers infusion equipment and supplies when used in the home[6]
- HYQVIA is covered under this benefit, when it is administered in the home via an external infusion pump to a patient with a covered diagnosis[3]

Home infusion therapy (HIT) services benefit: Covers home infusion therapy-associated professional services for certain drugs and biologics administered intravenously, or subcutaneously through a pump that is an item of DME.[5]*

- Patients needing professional services like nursing and remote monitoring at home[7]
- HYQVIA patients are eligible for HIT services[5]
- Professional services under the HIT services benefit include teaching and training. This may include education related to vascular access device maintenance, medication education and disease management, medication storage and patient safety, and self-monitoring[8]

*__Note:__ The DME (infusion pump and supplies) and HYQVIA are always covered under the DME benefit. Services covered under DME are not covered under HIT.

PHYSICIAN'S OFFICE/INFUSION CLINIC

- Medicare covers IG infusions in these settings, as long as the physician or healthcare professional is contracted with Medicare[3]
- Reimbursements typically come from Part B or a Medicare Advantage plan's medical portion[3]

OUTPATIENT HOSPITAL SETTINGS

- Medicare offers coverage under Part B for outpatient hospital settings, as long as the hospital is a contracted Medicare provider[3]
- This coverage includes all essential services and supplies for infusion[3]

Ramp-up dosing

- A dose ramp-up is recommended for HYQVIA, beginning with a partial dose and increasing to the maintenance dose[1,4]
- Ramp-up dosing is only covered when performed in a physician office, infusion clinic, or hospital outpatient setting[4]
- Ramp-up doses are never covered under the DME benefit, because Medicare requires ramp-up to be performed under medical supervision[9]
- After reaching maintenance dose, Medicare Part B covers doses for home infusion[4]

INPATIENT HOSPITAL SETTINGS

Not covered by Medicare Part B, costs are bundled into Medicare's overall hospital payment for the patient's stay (Part A).

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HELPFUL TIPS

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

Billing your patients for HYQVIA? Here's some guidance:

NATIONAL DRUG CODE

For HYQVIA billing, Medicare and some commercial payers may require a National Drug Code (NDC).[10] Refer to the Billing and Coding Guide for HYQVIA at **HYQVIAhcp.com**.

CODE ESSENTIALS

- Ensure that your patient's diagnosis/condition reflects an approved International Classification of Diseases, Tenth Revision (ICD-10) code
- When documenting HYQVIA, use the Healthcare Common Procedure Coding System (HCPCS) code J1575[11]
- The **"JB" Modifier** indicates subcutaneous route of administration[11]
- For HYQVIA, always pair the E0781 infusion pump code with J1575[12]

HIT PROFESSIONAL SERVICES BILLING TIPS[13]

- Use G codes for HYQVIA administration: G0089 (initial visit), G0069 (subsequent visit)[14]
- Report visit length in 15-minute units: 1 unit = 15 minutes
- G code fees are daily rates; do not multiply units by rate
- Ensure HYQVIA is billed with the visit or within 30 days prior
- Only billable when a professional (nurse) is at the patient's home

Reminder: Equipment, supplies and HYQVIA are billed separately from home infusion therapy professional services and are covered under the DME benefit.

HIT PROFESSIONAL SERVICES DOCUMENTATION REQUIREMENTS[13]

- A physician-signed Plan of Care is mandatory for billing HIT services
  - This plan is distinct from the Detailed Written Order

Reminder: home infusion therapy service codes (G codes) should not be included on the DME Information Form.

MODIFIER UPDATES (PRODUCT WASTAGE)

- Use **"JW" Modifier** for billing unused portions of single-dose drugs/biologicals supplied[11,15]
- Use **"JZ" Modifier** for drugs/biologicals from single-dose containers supplied without wastage[15]

NAVIGATING PAYER POLICIES

Medicare Advantage plans may have distinct billing and coverage rules.

- Medicare Advantage policies may require preauthorization before proceeding with the therapy[16]

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HyQvia
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RESOURCES AND SUPPORT

Your local Takeda representative is ready to support you

Get your questions answered about HYQVIA

Please visit **HYQVIAhcp.com/contact-rep** to get in touch with your dedicated Takeda representative. Or call **1-877-TAKEDA-7 (877-825-3327)** to speak with customer service.

Takeda Patient Support

When a patient is prescribed HYQVIA, Takeda Patient Support is here for them.
We'll work with their specialty pharmacy to help them get their Takeda treatment, review financial assistance options, and direct them to educational resources. Our support specialists are also here to help with:

- Benefits investigation to help determine your patient's insurance benefits and eligibility for certain services
- Prior authorization, reauthorization, and appeals information in coordination with your patient's insurance company to determine any requirements
- Specialty pharmacy (or site of care) triage and coordination
- Digital resources, such as a Takeda Patient Support enrollment portal and a co-pay submission portal
- Education about your patient's prescribed Takeda treatment and condition from nursing professionals
- Directing your patient to community support resources
- Information about financial assistance options for your patient, if they're eligible. In addition, our support specialists can assist with Co-Pay Assistance Program enrollment,* as well as provide information about other programs they may be eligible for

*To be eligible, your patient must be enrolled in Takeda Patient Support and have commercial insurance. Other terms and conditions apply. Call us for more details.

NEED ASSISTANCE?
Our support specialists are never more than a tap or a call away—**1-866-861-1750**, Monday through Friday, 8 AM to 8 PM ET.

Need to enroll your patient? Visit our convenient online enrollment portal at TakedaPatientSupport.com/HCP. You can also enroll your patient by faxing the completed Start Form to **1-866-861-1752**.
If English is not your patient's preferred language, we may be able to assist them in a language of their choosing.

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HyQvia
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IMPORTANT SAFETY INFORMATION

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.

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:

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.

HyQvia
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