Drug Reimbursement Coding and Pricing Advisory™

July 2026

QIVIGY® (Immune Globulin Intravenous Human-kthm) 10% Liquid

by Kedrion Biopharma Inc.

Important Information: New HCPCS J-code for QIVIGY

As of July 1, 2026, the Centers for Medicare and Medicaid Services (CMS) has approved a new product-specific HCPCS J-code for QIVIGY.

All claims with a date of service on or after 7/1/2026 should indicate:

J1577 Injection, immune globulin (qivigy), 100 mg

Please Note: New HCPCS code J1577 is billed as 100 mg per unit.

Please ensure your systems are updated to include this new HCPCS code and billing strength for QIVIGY.

For claims with dates of service prior to 7/1/2026, HCPCS code J1599 may be utilized. If using previous code J1599 the claim should be submitted as 500 mg per unit.

INDICATIONS AND USAGE

QIVIGY® (immune globulin intravenous, human-kthm) is a 10% immune globulin (Ig) liquid indicated for the treatment of adults with primary humoral immunodeficiency.

IMPORTANT SAFETY INFORMATION

WARNING: THROMBOSIS, RENAL DYSFUNCTION, and ACUTE RENAL FAILURE

See full prescribing information for complete boxed warning.

- **Thrombosis may occur with immune globulin products, including QIVIGY.**
- **Renal dysfunction, acute renal failure, osmotic nephrosis may occur with immune globulin intravenous (IGIV) products in predisposed patients. Such events require immediate medical intervention, if not recognized or managed appropriately, may result in persistent or significant disability or incapacity or lead to fatal outcome.**
- **For patients at risk of thrombosis, renal dysfunction or failure, administer QIVIGY at the minimum dose available and the minimum 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 for hyperviscosity.**

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IMPORTANT SAFETY INFORMATION (cont'd)

CONTRAINDICATIONS

QIVIGY is contraindicated in patients who have had an anaphylactic or severe systemic reaction to the administration of human immune globulin and in IgA deficient patients with antibodies against IgA and history of hypersensitivity.

WARNINGS AND PRECAUTIONS

Severe hypersensitivity reactions, including anaphylaxis, may occur. In case of hypersensitivity, discontinue QIVIGY infusion and manage as appropriate.

Hyperproteinemia, hyperviscosity, and hyponatremia may occur in patients receiving IGIV treatment, including QIVIGY.

Aseptic meningitis syndrome may occur in patients receiving IGIV treatment, especially with high doses or rapid infusion.

Hemolysis can develop subsequent to IGIV treatment. Monitor patients for hemolysis.

Transfusion-related acute lung injury: Monitor patients for pulmonary adverse reactions.

Transmissible infectious agents: QIVIGY is made from human plasma and may carry a risk of transmitting infectious agents, eg, viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent, and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

Interference with laboratory tests: After infusion of Ig, transitory rise of passively transferred antibodies may yield positive serological results, with potential for misleading interpretation.

ADVERSE REACTIONS

The most common adverse reactions occurring in ≥5% of patients treated were headache, fatigue, infusion-related reaction, Coombs direct test positive, nausea, sinusitis, dizziness, and diarrhea.

To report SUSPECTED ADVERSE REACTIONS, contact Kedrion Biopharma Inc. at 1 855-3KDRION (1-855-353-7466) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see enclosed full Prescribing Information for complete prescribing details, including Boxed Warning.

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HOW TO BILL FOR QIVIGY® (Immune Globulin Intravenous, Human-kthm, 10% Liquid) USING THE CMS-1500 and CMS-1450 (UB-04) FORM

Item 21 or Form Locator (FL) 67 – Diagnosis Code

The appropriate ICD-10-CM code(s) should be entered for QIVIGY in **Item 21** of the CMS-1500 form or **FL 67** of the CMS-1450 (UB-04) claim form. Also, enter the ICD indicator **0** (zero) for ICD-10-CM code(s) in **Item 21.**

Possible ICD10-CM codes for QIVIGY:

D80 PREDOMINATELY ANTIBODY DEFICIENCIES
- D80.0 Hereditary hypogammaglobulinemia
- D80.1 Nonfamilial hypogammaglobulinemia
- D80.2 Selective deficiency of immunoglobulin A (IgA)
- D80.3 Selective deficiency of immunoglobulin G (IgG) subclasses
- D80.4 Selective deficiency of immunoglobulin M (IgM)
- D80.5 Immunodeficiency with increased immunoglobulin M (IgM)
- D80.6 Antibody deficiency with near-normal immunoglobulins or with hyperimmunoglobulinemia
- D80.8 Other immunodeficiencies predominantly antibody defects (eg, kappa light chain deficiency)
- D80.9 Immunodeficiency with predominantly antibody defects, unspecified (humoral immunodeficiency)

D81 COMBINED IMMUNODEFICIENCIES
- D81.0 Severe combined immunodeficiency (SCID) with reticular dysgenesis
- D81.1 Severe combined immunodeficiencies (SCID) with low T- and B-cell numbers
- D81.2 Severe combined immunodeficiency (SCID) with low or normal B-cell numbers
- D81.5 Purine nucleoside phosphorylase (PNP) deficiency
- D81.6 Major histocompatibility complex class I deficiency
- D81.7 Major histocompatibility complex class II deficiency
- D81.89 Other combined immunodeficiencies
- D81.9 Combined immunodeficiency, unspecified

D83 COMMON VARIABLE IMMUNODEFICIENCY (CVID) – B-CELL DYSFUNCTION
- D83.0 CVID with predominant abnormalities of B-cell numbers and function
- D83.1 CVID with predominant immunoregulatory T-cell disorders
- D83.2 CVID with autoantibodies to B- or T-cells
- D83.8 Other CVIDs
- D83.9 CVID unspecified

Item 24D or FL 44 – Medication Information

For claims with a date of service on or after July 1, 2026**, Item 24D** of the CMS-1500 form or **FL 44** of the CMS-1450 (UB-04) claim form should indicate:

J1577 – Injection, immune globulin (qivigy), 100 mg

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Item 24D or FL 44 – Administration Code

Since QIVIGY is administered as an intravenous infusion, an appropriate CPT® administration code should be entered on a separate line in **Item 24D** of the CMS-1500 claim form or **FL 44** of the CMS-1450 (UB-04) claim form.

Possible Administration Codes for QIVIGY:

96365 - Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour

96366 - Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (List separately in addition to code for primary procedure)

S9338 - Home infusion therapy, immunotherapy, administration services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem as maintained by CMS, fall under Home Infusion Therapy

Item 19 or 24A shaded area and FL 43 – Medication Information

In **Item 19** or **24A shaded area** of the CMS-1500 form or **FL 43** of the CMS-1450 (UB-04) form, the full name of the medication administered, including strength if applicable (e.g., **QIVIGY 10%)**, dosage, basis of measurement (mg, mL, etc.) as well as the NDC (National Drug Code) on the package used should be entered.

Please Note: Payer NDC requirements and placement may vary; check with payer.

Item 24F or FL 47 – Medication Charge

NDC*	NDC Description	WAC**Price Effective 2/23/2026
76179-**0**010-02	QIVIGY 5-gram single-dose vial	$1,436.15
76179-**0**010-04	QIVIGY 10-gram single-dose vial	$2,872.30

*Note that the product's NDC has been "zero-filled" to ensure creation of an 11-digit code that meets general billing standards. The zero-fill location is indicated in bold.
**WAC (Wholesale Acquisition Cost) is based on information listed in the National Drug Compendia.

Please Note: WAC pricing is only to be used to determine the cost of the drug and does not include the administration charge.

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Item 24G or FL 46 - Medication Quantity

The quantity of medication administered should be indicated in **Item 24G** of the CMS-1500 form or **FL 46** of the CMS-1450 (UB-04) claim form. The number of units administered should be entered, for example:

5g vial = 5,000mg / 100mg UOM = 50 billing units

10g vial = 10,000mg / 100mg UOM = 100 billing units

A convenient dosing calculator is available for QIVIGY. Visit QIVIGY® | Official HCP Website for more resources and to use the QIVIGY dosing calculator.

Please Note: Billing units may vary by payer; please check with payer for appropriate billable units to be used.