Drug Reimbursement Coding and Pricing Advisory™

April 2026

YIMMUGO® (Immune Globulin Intravenous, Human-dira, 10% Liquid)

by Kedrion Biopharma Inc.

Important Information: New HCPCS J-code for YIMMUGO

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

All claims with a date of service on or after 4/1/2026 should indicate:

J1553 Injection, immune globulin (yimmugo), 100 mg

Please Note: New HCPCS code J1553 is billed as 100 mg per unit.

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

For claims with dates of service prior to 4/1/2026, HCPCS code J1599 may be utilized. If using previous code J1599 the claim should be submitted as 500 mg per unit.

For information on ordering YIMMUGO, please visit:
https://www.yimmugo.us/hcp/dosing-and-administration#ordering.

INDICATIONS AND USAGE

YIMMUGO® (immune globulin intravenous, human – dira) is a 10% immune globulin (Ig) liquid indicated for the treatment of primary humoral immunodeficiency in patients 2 years of age and older.

IMPORTANT SAFETY INFORMATION

WARNING: THROMBOSIS, RENAL DYSFUNCTION, and ACUTE RENAL FAILURE

- **Thrombosis may occur with Ig intravenous (IGIV) products, including YIMMUGO.**
- **Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur with the administration of IGIV products in predisposed patients. Renal dysfunction and failure occur more commonly in patients receiving IGIV products containing sucrose. YIMMUGO does not contain sucrose.**
- **For patients at risk of thrombosis, renal dysfunction, or renal failure, administer YIMMUGO 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 for hyperviscosity.**

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IMPORTANT SAFETY INFORMATION (cont'd)

CONTRAINDICATIONS

YIMMUGO is contraindicated in patients who have had an anaphylactic or severe systemic reaction to the administration of human Ig and in patients with immunoglobulin A (IgA) deficiency who have antibodies against IgA and a history of hypersensitivity.

WARNINGS AND PRECAUTIONS

Severe hypersensitivity reactions, including anaphylaxis, have been reported after administration. In case of hypersensitivity, discontinue infusion immediately and institute appropriate treatment. YIMMUGO contains ≤300 mcg/mL of IgA. Patients with known antibodies to IgA may be at greater risk.

Hemolysis that is either intravascular or due to enhanced red blood cell sequestration can develop subsequent to IGIV treatment. Risk factors for hemolysis include high doses and non-O blood group. Monitor patients for hemolysis.

Renal failure: Monitor renal function, including blood urea nitrogen (BUN) and serum creatinine, and urine output in patients at risk of developing acute renal failure.

Hyperproteinemia, increased serum viscosity, and hyponatremia may occur in patients receiving IGIV treatment, including YIMMUGO.

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

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

Transmissible infectious agents: YIMMUGO is made from human plasma and may contain infectious agents, eg, viruses and, theoretically, the Creutzfeldt-Jakob disease agent.

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

ADVERSE REACTIONS

The most common adverse reactions occurring in ≥5% of patients were headache, upper respiratory tract infections, fatigue, nausea, and increased blood pressure.

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

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HOW TO BILL FOR YIMMUGO® (Immune Globulin Intravenous, Human-dira, 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 YIMMUGO 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 YIMMUGO:

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)

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

D82 IMMUNODEFICIENCY ASSOCIATED WITH OTHER MAJOR DEFECTS
- D82.0 Wiskott-Aldrich syndrome

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 April 1, 2026**, Item 24D** of the CMS-1500 form or **FL 44** of the CMS-1450 (UB-04) claim form should indicate:

J1553 – Injection, immune globulin (yimmugo), 100 mg

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Item 24D or FL 44 – Administration Code

Since YIMMUGO 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 YIMMUGO:

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., **YIMMUGO 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 9/29/2025
83372-**0**605-01	YIMMUGO 5-gram single-dose vial	$1,186.15
83372-**0**605-11	YIMMUGO 10-gram single-dose vial	$2,372.30
83372-**0**605-21	YIMMUGO 20-gram single-dose vial	$4,744.60

*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

20g vial = 20,000mg / 100mg UOM = 200 billing units

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

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