Yimmugo®
Immune Globulin Intravenous, Human-dira, 10% Liquid

DISCOVER THE YIMMUGO® DIFFERENCE

Specialty Pharmacy and Payer Access Guide

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.**

Please see full Important Safety Information and full Prescribing Information for complete prescribing details, including Boxed Warning.

Kedrion Biopharma

The YIMMUGO® difference

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YIMMUGO is a highly purified, 10% IVIG that delivers what patients with PI need the most[1]:

PROTECTION

Proven efficacy against serious **bacterial infections** and other infections[1]

HIGH TOLERABILITY

Demonstrated **safety and infusion tolerability** with a low rate of headache[1]

PRECISION

Patented manufacturing process designed to **preserve functional antibodies** and **remove specific impurities** believed to cause side effects[2]*

RECOMMENDED DOSAGE[1,3]

DOSE: 300-800 mg/kg (3-8 mL/kg) every 3 to 4 weeks

FIRST INFUSION	SUBSEQUENT INFUSIONS
0.5 mg/kg/min (0.005 mL/kg/min) for 30 minutes; gradually increase every 30 minutes up to 3.0 mg/kg/min (0.03 mL/kg/min)	0.5 mg/kg/min (0.005 mL/kg/min) for 30 minutes; gradually increase up to 13 mg/kg/min (0.13 mL/kg/min)

MAXIMUM INFUSION RATE: 8 mL/kg/h

A convenient dosing calculator is available for YIMMUGO.

Scan or visit YIMMUGO.us/HCP to use the YIMMUGO dosing calculator.

*There have been no head-to-head comparisons between YIMMUGO and other IVIG products. No comparisons between conventional mixing techniques and vibromixing have been conducted.[2]
IVIG, intravenous immune globulin; PI, primary immunodeficiency.

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.

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Storage, handling, and availability

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YIMMUGO® is available in 3 vial sizes for dosing flexibility[1]

		Package NDC	Container NDC
	**5 g in 50 mL**	83372-605-01	83372-605-02
	**10 g in 100 mL**	83372-605-11	83372-605-12
	**20 g in 200 mL**	83372-605-21	83372-605-22

- YIMMUGO is **glycine stabilized** and **does not contain any sugars or preservatives**[1]
- Refrigerate between 2 °C to 8 °C (36 °F to 46 °F)[1]
- YIMMUGO has a **shelf life of 30 months** when stored at 5 °C/41 °F ± 3 °C/37.4 °F. Do not use after expiration date[1,4]
- Within the expiration date, **YIMMUGO may be stored at room temperature** (more than 8 °C and up to 25 °C/more than 46 °F and up to 77 °F) for a single period not exceeding 6 months[1]
- **Do not freeze.** Do not use any solutions that have been frozen[1]
- The components used in the packaging for YIMMUGO are not made with natural rubber latex[1]
- Keep YIMMUGO in its original carton to **protect it from light**[1]

NDC, national drug code.

IMPORTANT SAFETY INFORMATION (cont'd)

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.

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Get started with a Letter of Medical Necessity

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Tips for drafting a Letter of Medical Necessity or Medical Exception

To help avoid denials, **familiarize yourself with the payer's specific guidelines** before submitting your request.

Know and meet all deadlines for submitting any required forms or documents to the payer.

If your request is approved, **check with the payer to determine length of the approval**.

It is helpful to **keep complete records**, including copies of the materials you send, and a log of telephone calls made to the payer.

Be detailed and thorough. Recommended information for a Letter of Medical Necessity includes:

1. Patient information, including insurance information
2. Indication for the medication being prescribed
3. A summary of the patient's diagnosis including:
   - Diagnosis code(s)
   - Severity of the patient's condition
   - Prior treatment(s), including the duration and patient response to each treatment
4. The clinical rationale for treatment including clinical trial data supporting FDA approval of the drug, and administration and dosing information
5. A summary of your recommendation
6. Additional enclosures, which may include, where applicable:
   - YIMMUGO® Prescribing Information
   - Relevant peer-reviewed articles
   - Clinical practice guidelines
   - Clinical notes/medical records
   - Diagnostic test results
   - FDA approval letter

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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.

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Submitting a Letter of Medical Necessity

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The sample letter below is provided for your guidance only. It includes examples of information you may wish to include when a patient's insurance company/payer requests a Letter of Medical Necessity or Letter of Medical Exception.

Use of the information in this sample letter does not guarantee reimbursement or coverage and is not intended to be a substitute for, or to influence your independent medical judgment as a physician. You may modify this sample content or write your own letter. The payer sometimes may require that you complete payer-specific form(s).

[Insert Your Practice/Physician Letterhead]
[Insert Date]

ATTN: [Insert Medical Director/Payer Contact Name]
[Insert Medical Director/Payer Contact Title]
[Insert Payer Company Name]
[Insert Payer Street Address]
[Insert Payer City, State ZIP Code]

RE: Letter of Medical Necessity/Exception for YIMMUGO® [Immune Globulin Intravenous Human-dira, 10% Liquid]

Insured Patient:
Date of Birth:
Subscriber ID Number:
Subscriber Group Number:
Case ID Number:

Dear [Insert Contact Name]:

I am the treating physician for [Insert Patient Name], who has been diagnosed with [Insert Diagnosis], ICD-10-CM [Insert Code]. I am writing to request [approval/a step therapy override/a medical exception] for YIMMUGO as the prescribed treatment for my patient's condition.

I believe YIMMUGO is medically necessary for this patient based on my practice experience, the patient's clinical history as described below, and the drug's clinical and safety profile. In a Phase III clinical study, YIMMUGO resulted in fewer than one serious bacterial infection (SBI—defined as bacterial pneumonia, bacteremia/septicemia, osteomyelitis/septic arthritis, visceral abscesses, or bacterial meningitis) per person-year over a 12-month period (Section 14 of Prescribing Information). YIMMUGO demonstrated a low rate of discontinuation due to adverse events (2/67 patients or 3%) and only 2% of infusions (22/923) were associated with a headache (Section 6.1 of Prescribing Information). To increase the safety margin, the YIMMUGO manufacturing process includes a unique combination of steps designed to inactivate adventitious viruses, remove specific proteins such as IgA, FXIa and other thrombogenic factors, and remove properdin which is an activator of the complement system and can lead to unwanted side effects (Section 11 of Prescribing Information and Duellberg C, et al. *Drugs in R&D*. 2023. https://doi.org/10.1007/s40268-023-00430-w). For these reasons, I recommend YIMMUGO for my patient over the preferred brands.

Summary of patient's medical history

- [Patient's diagnosis, date of diagnosis, relevant symptom information, condition/severity, and history]
- [Past history of diabetes, hypertension, cardiovascular disease, or other conditions that increase risk for thrombosis]
- [Past history of IVIG infusion-related reactions such as headache and fever]
- [Previous therapies used for this condition with treatment duration and treatment response/lack of response]

Rationale for treatment

- [Summary of your professional opinion of the patient's prognosis and need for YIMMUGO]
- [Rationale for YIMMUGO based on product properties and the patient's medical history]
- [Relevant clinical trial data supporting approval of YIMMUGO]

Additional supportive information (enclosed)

- YIMMUGO Prescribing Information at https://www.yimmugo.us/download/YIMMUGO-PI.pdf
- YIMMUGO Efficacy, Safety, and Pharmacokinetics Clinical Trial at https://onlinelibrary.wiley.com/doi/epdf/10.1111/vox.13337
- [Relevant supportive clinical documentation such as history and physical, progress notes, treatment history, outcomes]
- [Supportive peer-reviewed journal articles or clinical guidelines]

In summary, based on the patient's medical scenario, I believe YIMMUGO is medically necessary for this patient as described above, and I request coverage for their treatment. Please call my office at [Insert primary phone number] if I can be of further assistance or if you require additional information. Thank you for your consideration and I look forward to receiving timely approval of this request on behalf of my patient.

Sincerely,

[Insert Physician Name, Title, and Participating Provider Number]
[Signature]

Provide relevant medical information and/or supporting documents for payers to review.

Contact the payer to identify any additional documentation that may be required for submission.

Connect with a local Kedrion representative for more information.

Download a sample letter and get started.

To avoid delay, it may be helpful to submit a Letter of Medical Necessity, even if it isn't explicitly requested.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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.

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Get started with a Referral Form

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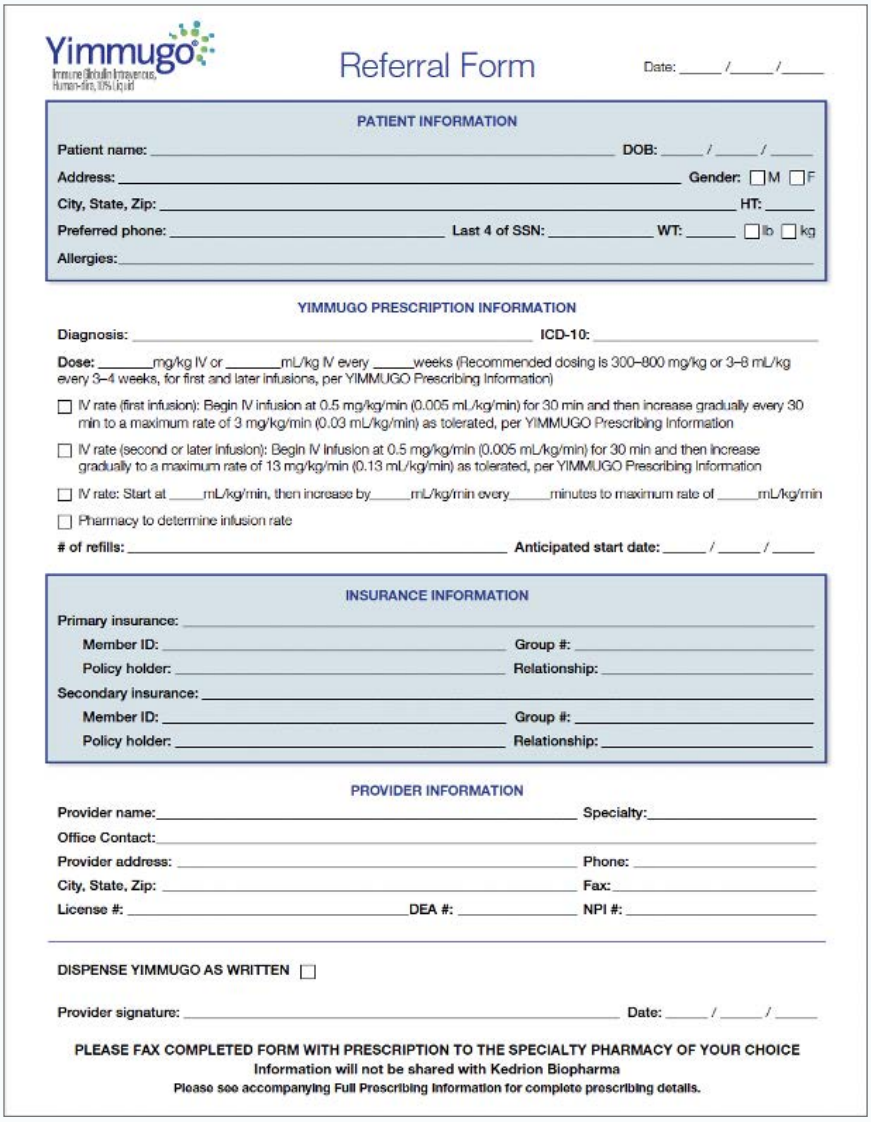
For use by physicians and office staff in the referral of patients to specialty pharmacies.



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Referral Form

Date: ____ / ____ / ____

PATIENT INFORMATION

Patient name: _____ DOB: ____ / ____ / ____
Address: _____ Gender: ☐M ☐F
City, State, Zip: _____ HT: _____
Preferred phone: _____ Last 4 of SSN: _____ WT: _____ ☐lb ☐kg
Allergies: _____

YIMMUGO PRESCRIPTION INFORMATION

Diagnosis: _____ ICD-10: _____

Dose: _____mg/kg IV or _____mL/kg IV every _____weeks (Recommended dosing is 300–800 mg/kg or 3–8 mL/kg every 3–4 weeks, for first and later infusions, per YIMMUGO Prescribing Information)

☐ IV rate (first infusion): Begin IV infusion at 0.5 mg/kg/min (0.005 mL/kg/min) for 30 min and then increase gradually every 30 min to a maximum rate of 3 mg/kg/min (0.03 mL/kg/min) as tolerated, per YIMMUGO Prescribing Information

☐ IV rate (second or later infusion): Begin IV infusion at 0.5 mg/kg/min (0.005 mL/kg/min) for 30 min and then increase gradually to a maximum rate of 13 mg/kg/min (0.13 mL/kg/min) as tolerated, per YIMMUGO Prescribing Information

☐ IV rate: Start at _____mL/kg/min, then increase by _____mL/kg/min every _____minutes to maximum rate of _____mL/kg/min

☐ Pharmacy to determine infusion rate

# of refills: _____ Anticipated start date: ____ / ____ / ____

INSURANCE INFORMATION

Primary insurance: _____
Member ID: _____ Group #: _____
Policy holder: _____ Relationship: _____
Secondary insurance: _____
Member ID: _____ Group #: _____
Policy holder: _____ Relationship: _____

PROVIDER INFORMATION

Provider name: _____ Specialty: _____
Office Contact: _____
Provider address: _____ Phone: _____
City, State, Zip: _____ Fax: _____
License #: _____ DEA #: _____ NPI #: _____

DISPENSE YIMMUGO AS WRITTEN ☐

Provider signature: _____ Date: ____ / ____ / ____

PLEASE FAX COMPLETED FORM WITH PRESCRIPTION TO THE SPECIALTY PHARMACY OF YOUR CHOICE
Information will not be shared with Kedrion Biopharma
Please see accompanying Full Prescribing Information for complete prescribing details.

Complete and sign Referral Form

Fax completed form along with prescription to the specialty pharmacy of your choice.

Call 888-262-8040 if you have any questions about completing this form.

Download a Referral Form and get started.

Connect with your local Kedrion Biopharma representative to request materials or more information.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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

Please see full Important Safety Information and full Prescribing Information for complete prescribing details, including Boxed Warning.

Copay and reimbursement support is available

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A dedicated team of reimbursement specialists are ready to provide support for YIMMUGO®

THIS SUPPORT INCLUDES:

- Patient-specific benefit verifications
- Payer coverage and coding research
- Assistance with claims questions
- Appeal support for denied prior authorization or claims
- Copay assistance

ELIGIBILITY RULES:

- Patients must be commercially insured
- Patients must express a financial need
- Patients' health plan permits members to participate in copay assistance programs
- Patients must be prescribed YIMMUGO by a licensed prescriber

COPAY BENEFIT:

- $8000 per patient per year
- Electronic processing; no patient cards necessary

For medical benefit claims and **full terms and conditions**, please visit:

https://yimmugo.medmonk.com

For pharmacy benefit claims, use:

BIN: 016664
PCN: MEDMONK
Cardholder ID: MEDMONK

TO CONNECT WITH A REIMBURSEMENT SPECIALIST:

888-262-8040

reimbursementsupport@medmonk.com

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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

Please see full Important Safety Information and full Prescribing Information for complete prescribing details, including Boxed Warning.

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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.

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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.

REFERENCES: 1. YIMMUGO [prescribing information]. Kedrion Biopharma Inc.; 2024. **2.** Duellberg C, Hannappel A, Kistner S, Maneg O. Biochemical characterization of a new 10% IVIG preparation [IgG Next Generation (BT595)/Yimmugo®] obtained from a manufacturing process preserving IgA/IgM potential of human plasma. *Drugs R D*. 2023;23(3):245-255. **3.** Kriván G, Borte M, Harris JB, et al. Efficacy, safety and pharmacokinetics of a new 10% normal human immunoglobulin for intravenous infusion, BT595, in children and adults with primary immunodeficiency disease. *Vox Sang*. 2022;117(10):1153-1162. **4.** Data on file. Kedrion Biopharma Inc.; 2025.

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