

# ALYGLO<sup>®</sup> may be covered under the Cigna Healthcare medical benefit for commercially insured patients who meet specific criteria\*

See back side for details.

\*GC Biopharma cannot guarantee payment of any claim. Coding, coverage, and reimbursement may vary significantly by payer, plan, patient, and setting of care. Actual coverage and reimbursement decisions are made by individual payers following the receipt of claims. For additional information, customers should consult with their payers for all relevant coding, reimbursement, and coverage requirements. It is the sole responsibility of the provider to select the proper code and ensure the accuracy of all claims used in seeking reimbursement. All services must be medically appropriate and properly supported in the patient medical record. Coverage data provided are current as of March 2026.<sup>1</sup>

## INDICATION

ALYGLO<sup>®</sup> is indicated for the treatment of primary humoral immunodeficiency (PI) in adults aged 17 years and older. This includes, but is not limited to, congenital agammaglobulinemia, common variable immunodeficiency (CVID), Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

## IMPORTANT SAFETY INFORMATION

### WARNING: THROMBOSIS, RENAL DYSFUNCTION and ACUTE RENAL FAILURE

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

If you have an inquiry related to drug safety, or to report adverse events, please contact GC Biopharma USA at 1-833-426-6426 or email [medicalinfo@gcbiopharmausa.com](mailto:medicalinfo@gcbiopharmausa.com). You can also visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

Please see additional Important Safety Information on back, and full Prescribing Information enclosed.

## When prescribing IVIG, check the box for ALYGLO<sup>®</sup> on the pre-authorization form.

According to Cigna policy, patient must meet BOTH of the following criteria (A and B):

- A. Patient demonstrates a medical necessity for IVIG (as defined by condition in the Cigna policy); AND
- B. Patient meets ONE of the following conditions (i or ii):
  - i. Patient has tried THREE of the following products: Bivigam<sup>®</sup>, Flebogamma DIF<sup>®</sup>, Gammaked<sup>™</sup>, Gammaplex<sup>®</sup>, Gamunex<sup>®</sup>-C, Octagam<sup>®</sup>, Panzyga<sup>®</sup>, Privigen<sup>®</sup>; OR
  - ii. According to the prescriber, a product with minimal FXIa is needed based on a comorbidity of the patient.

## Have questions about coverage?

Contact our Support Team at **(888) 501-8040**. We're here to help navigate and provide support where needed.

## IMPORTANT SAFETY INFORMATION (CONT.)

- **Contraindications:** ALYGLO is contraindicated in patients who have a history of anaphylactic or severe systemic reaction to the administration of human immune globulin and in IgA-deficient patients with antibodies to IgA and a history of hypersensitivity.
- **Hypersensitivity:** In case of hypersensitivity, discontinue infusion immediately and institute appropriate treatment. Epinephrine should be available for immediate treatment of severe acute hypersensitivity reactions.
- **Hyperproteinemia, Increased Serum Viscosity, and Hyponatremia:** Hyperproteinemia, increased serum viscosity, and hyponatremia may occur.
- **Aseptic Meningitis Syndrome (AMS):** Aseptic meningitis syndrome (AMS) may occur, especially with high doses or rapid infusion. AMS usually begins within several hours to 2 days following ALYGLO treatment. Discontinuation of treatment has resulted in remission of AMS within several days without sequelae.
- **Hemolysis:** Delayed hemolytic anemia due to enhanced red blood cell (RBC) sequestration and acute hemolysis consistent with intravascular hemolysis have been reported. Cases of severe hemolysis-related renal dysfunction/failure or disseminated intravascular coagulation have occurred following infusion of IGIV. Closely monitor patients for clinical signs and symptoms of hemolysis, particularly patients with risk factors.
- **Transfusion-Related Acute Lung Injury:** Noncardiogenic pulmonary edema (transfusion-related acute lung injury [TRALI]) may occur. TRALI is characterized by severe respiratory distress, pulmonary edema, hypoxemia, normal left ventricular function, and fever. Patients with TRALI may be managed using oxygen therapy with adequate ventilator support. Monitor patients for pulmonary adverse reactions.
- **Transmissible Infectious Agents:** Because ALYGLO is made from human blood, it 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 immunoglobulin, the transitory rise of the various passively transferred antibodies in the patient's blood may yield positive serological testing results, with the potential for a misleading interpretation.
- **Adverse reactions** (observed in ≥ 5% of study subjects) were headache, nausea/vomiting, fatigue, nasal/sinus congestion, rash, arthralgia, diarrhea, muscle pain/aches, infusion site pain/swelling, abdominal pain/discomfort, cough, and dizziness.
- It is recommended that ALYGLO be administered separately from other drugs or medications.

Please see additional Important Safety Information on front, and full Prescribing Information enclosed.

Reference: 1. Cigna Drug and Biologic Coverage Policy, [https://static.cigna.com/assets/chcp/pdf/coveragePolicies/pharmacy/ph\\_5026\\_coveragepositioncriteria\\_immune\\_globulin\\_intravenous\\_igiv.pdf](https://static.cigna.com/assets/chcp/pdf/coveragePolicies/pharmacy/ph_5026_coveragepositioncriteria_immune_globulin_intravenous_igiv.pdf), last accessed February 27, 2026.