

## Yimmugo® (immune globulin intravenous, human - dira) – New drug approval

- On June 17, 2024, [Grifols announced](#) the FDA approval of [Yimmugo \(immune globulin intravenous, human - dira\)](#), for the treatment of primary humoral immunodeficiency (PI) including but not limited to the humoral immune defect in congenital agammaglobulinemia, common variable immunodeficiency (CVID), X-linked agammaglobulinemia (XLA), Wiskott-Aldrich syndrome, and severe combined immunodeficiencies (SCID) in patients 2 years of age and older.
- The efficacy of Yimmugo was established in an open-label study in 67 patients with PI. The patients were to receive Yimmugo at either 3-week or 4-week intervals for a period of 12 months. The primary outcome measure was the rate of serious bacterial infections (SBI), defined as bacterial pneumonia, bacteremia/septicemia, osteomyelitis/septic arthritis, visceral abscesses, or bacterial meningitis over a period of 12 months.
  - The annualized rate of acute SBIs 0.07 acute SBIs/person-year.
- Yimmugo carries a boxed warning for thrombosis, renal dysfunction, and acute renal failure.
- Yimmugo is contraindicated in patients:
  - Who have had an anaphylactic or severe systemic reaction to the administration of human immune globulin
  - With IgA-deficiency who have antibodies against IgA and a history of hypersensitivity.
- Additional warnings and precautions for Yimmugo include hypersensitivity; hemolysis; hyperproteinemia, increased serum viscosity and hyponatremia; aseptic meningitis syndrome; transfusion-related acute lung injury; transmissible infectious agents; and monitoring laboratory tests; and interference with laboratory tests.
- The most common adverse reactions (≥ 5%) with Yimmugo use were headache, upper respiratory tract infections, fatigue, nausea, and increased blood pressure.
- The recommended intravenous dosing of Yimmugo is provided in the table below.

Dose	Infusion number	Initial infusion rate	Maintenance infusion rate (if tolerated)
300 to 800 mg/kg (3 to 8 mL/kg) every 3 to 4 weeks	For the 1 <sup>st</sup> infusion	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)
300 to 800 mg/kg (3 to 8 mL/kg) every 3 to 4 weeks	From the 2 <sup>nd</sup> infusion	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)

- Grifols' launch plans for Yimmugo are pending. Yimmugo will be available as a solution containing 10% IgG (100 mg/mL): 5 g in 50 mL, 10 g in 100 mL, 20 g in 200 mL.