Bivigam® (immune globulin intravenous [human]) – Expanded indication

- On December 12, 2023, ADMA Biologics announced the FDA approval of Bivigam (immune globulin intravenous [human]), for the treatment of adults and pediatric patients 2 years of age and older with primary humoral immunodeficiency (PI).
    - Previously, the indication for Bivigam was restricted to patients aged 12 years and older.
    - This includes, but is not limited to, the humoral immune defect in common variable immunodeficiency, X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.
- The approval of Bivigam for the expanded indication was based on an open-label, single-arm study in 16 pediatric patients: 3 patients ≥ 2 to < 6, 5 patients ≥ 6 to < 12, and 8 patients ≥ 12 to ≤ 16 years. The efficacy analysis was based on the incidence of acute serious bacterial infections (SBIs). SBIs encompass bacteremia/sepsis, bacterial meningitis, osteomyelitis/septic arthritis, bacterial pneumonia, or visceral abscess.
    - No acute SBIs occurred during the mean observation period of 152 days, yielding a mean number of acute SBI episodes per person-year of 0.0. No other serious infections, or hospitalizations due to infections occurred, and no patients required intravenous antibiotics during the study.
- Bivigam carries a boxed warning for thrombosis, renal dysfunction, and acute renal failure.
- The recommended dose of Bivigam for replacement therapy in PI in adults and children 2 years of age and older, is 300 to 800 mg/kg body weight administered intravenously every 3 to 4 weeks. The dosage may be adjusted over time to achieve the desired trough levels and clinical response.
- Bivigam dose adjustments may be required in patients who fail to maintain trough total IgG concentrations of at least 500 mg/dL with a target of 600 mg/dL. Starting with the second infusion, the dose will be adjusted proportionally, targeting a trough of ≥ 600 mg/dL, based on the previous trough and the associated dose.