Gammagard Liquid® (immune globulin infusion [human] 10% solution) – New indication

- On January 22, 2024, Takeda announced the FDA approval of Gammagard Liquid (immune globulin infusion [human] 10% solution), as a therapy to improve neuromuscular disability and impairment in adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP).
    - Gammagard Liquid has not been studied in immunoglobulin-naïve patients with CIDP. Gammagard Liquid maintenance therapy in CIDP has not been studied for periods longer than 6 months. After responding during an initial treatment period, not all patients require indefinite maintenance therapy with Gammagard Liquid in order to remain free of CIDP symptoms. The duration of any treatment beyond 6 months should be individualized based upon the patient's response and demonstrated need for continued therapy.
- Gammagard Liquid is also approved as replacement therapy for primary humoral immunodeficiency in adult and pediatric patients two years of age or older and as a maintenance therapy to improve muscle strength and disability in adult patients with multifocal motor neuropathy.
- The approval of Gammagard Liquid for the new indication was based on an open-label, single-arm study in a total of 18 patients with CIDP. The primary endpoint was responder rate, where a responder was defined as a patient who demonstrated an improvement of functional disability, indicated by at least a 1-point decrease in the adjusted Inflammatory Neuropathy Cause and Treatment (INCAT) disability score at the completion of the intravenous (IV) treatment period (6 months) or the last study visit of the IV treatment period, relative to pre-IV treatment baseline.
    - The responder rate was 94.4% (95% CI: 74.2, 99.0).
- Gammagard Liquid carries a boxed warning for thrombosis, renal dysfunction, and acute renal failure.
- The most common adverse reactions (≥ 5%) with Gammagard Liquid use for CIDP were headache, pyrexia anemia, leukopenia, neutropenia, illness, blood creatinine increased, dizziness, migraine, somnolence, tremor, nasal dryness, abdominal pain upper, vomiting, chills, nasopharyngitis, and pain in extremity.
- The recommended induction dose of Gammagard Liquid for the treatment of CIDP is 2 g/kg via IV infusion in divided doses over 2 to 5 consecutive days, followed by maintenance infusions. The maintenance dose is 1 g/kg in divided doses over 1 to 4 consecutive days, every 3 weeks.
    - Refer to the Gammagard Liquid drug label for dosing for its other indications.