Xembify® (immune globulin subcutaneous, human - klhw) – New drug approval

- On July 4, 2019, Grifols announced the FDA approval of Xembify (immune globulin subcutaneous, human – klhw), for the treatment of primary humoral immunodeficiency (PI) in patients 2 years of age and older.
    - This includes, but is not limited to, congenital agammaglobulinemia, common variable immunodeficiency, X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.
- Subcutaneous immune globulin 20% is also available as Cuvitru® and Hizentra®.
    - Cuvitru and Hizentra carry the same indication as Xembify.
    - In addition, Hizentra is also indicated for the treatment of adult patients with chronic inflammatory demyelinating polyneuropathy as maintenance therapy to prevent relapse of neuromuscular disability and impairment.
- Xembify carries a boxed warning for thrombosis.
- Xembify is contraindicated in patients with anaphylactic or severe systemic reactions to human immunoglobulin or inactive ingredients of Xembify such as polysorbate 80, and in IgA deficient patients with antibodies against IgA and a history of hypersensitivity.
- Additional warnings and precautions of Xembify include aseptic meningitis syndrome, renal dysfunction/failure, hemolysis, transfusion-related acute lung injury, transmissible infectious agents, and interference with laboratory tests.
- The most common adverse reactions (≥ 5%) with Xembify use were infusion site erythema, infusion site pain, infusion site swelling, infusion site bruising, infusion site nodule, infusion site pruritus, infusion site induration, infusion site scab, infusion site edema, and systemic reactions including cough and diarrhea.
- The recommended dose of Xembify is given subcutaneously once weekly (or more frequently during the week) based on body weight and serum trough IgG levels.
    - The patient's clinical response should be the primary consideration in dose adjustment.
    - Doses divided over the course of a week or once weekly achieve similar exposure when administered regularly at steady-state.
    - Consult the Xembify drug label for additional dosing recommendations.
- Grifols plans to launch Xembify in the fourth quarter of 2019. Xembify will be available as a solution containing 20% IgG (200 mg/ml; 0.2 g/ml).