Octagam 10%® (immune globulin intravenous [human]) – New indication

- On July 15, 2021, the FDA approved Octapharma's Octagam 10% (immune globulin intravenous [human]), for the treatment of dermatomyositis in adults.

- Octagam 10% is also approved for the treatment of chronic immune thrombocytopenic purpura (ITP) to rapidly raise platelet counts to control or prevent bleeding in adults.

- The approval of Octagam 10% for the new indication was based on a double-blinded, randomized, placebo-controlled study in 95 adults with dermatomyositis. The primary endpoint was the proportion of responders at week 16. A responder was defined as a subject with a minimal improvement of ≥ 20 points on the Total Improvement Score (TIS).

    — Response was achieved in 78.7% of patients treated with Octagam 10% vs. 43.8% with placebo (difference of 35.0, 95% CI: 16.7, 53.2; p = 0.0008).

- Octagam 10% has boxed warnings for thrombosis, renal dysfunction, and acute renal failure.

- The most common adverse reactions (> 5%) with Octagam 10% use for dermatomyositis were headache, fever, nausea, vomiting, increased blood pressure, chills, musculoskeletal pain, increased heart rate, dyspnea, and infusions site reactions.

- The recommended dose of Octagam 10% for the treatment of dermatomyositis is 2 g/kg divided in equal doses given over 2-5 consecutive days every 4 weeks

    — Refer to the Octagam 10% drug label for dosing for chronic ITP.