Fibryga® (fibrinogen [human]) – New indication

- On July 31, 2024, the FDA approved Octapharma's Fibryga (fibrinogen [human]), for fibrinogen supplementation in bleeding patients with acquired fibrinogen deficiency.
- Fibryga is also approved for the treatment of acute bleeding episodes in patients with congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia.
- The approval of Fibryga for the new indication was based on a randomized, controlled, single-blinded study in adult cardiac surgical patients for whom fibrinogen supplementation was ordered in accordance with accepted clinical standards. Patients were randomly assigned to receive either Fibryga or cryoprecipitate.
    - Fibryga was demonstrated to be non-inferior to cryoprecipitate based on the total number of units of allogeneic blood products administered during the first 24 hours after termination of cardiopulmonary bypass.
- The most common adverse reactions (> 5%) with Fibryga use for acquired fibrinogen deficiency were abnormal hepatic function, acute kidney injury, anemia, atrial fibrillation, delirium and renal failure.
- The recommended intravenous dose of Fibryga for the treatment of acquired fibrinogen deficiency is as follows:
    - For adults: 4 g
    - For adolescents age ≥ 12 years: 50 mg/kg body weight
    - For children age < 12 years: 70 mg/kg body weight
    - Additional doses can be administered as needed to bleeding patients when plasma fibrinogen level is ≤ 200 mg/dL or thromboelastometry FIBTEM A10 is ≤ 10 mm (or equivalent values generated by other viscoelastic testing methods). Dosing may be adjusted depending on plasma fibrinogen levels or viscoelastic testing, severity of bleeding, body weight, or patient's clinical condition.
- Refer to the Fibryga drug label for dosing for congenital fibrinogen deficiency.