Ixinity® (coagulation factor IX [recombinant]) – Expanded indication

- On March 26, 2024, Medexus Pharma announced the FDA approval of Ixinity (coagulation factor IX [recombinant]), in adults and children with hemophilia B for:
    - On-demand treatment and control of bleeding episodes
    - Perioperative management
    - Routine prophylaxis to reduce the frequency of bleeding episodes.
- Ixinity was previously approved for these indications in adults and children ≥ 12 years of age. This approval expands the label to include pediatric patients < 12 years of age.
- The approval of Ixinity for the expanded indication was based on a study of 21 previously treated patients (PTPs) (10 patients < 6 years of age and 11 patients 6 to < 12 years of age). PTP were defined as patients who were exposed to a factor IX containing product for 50 exposure days. Patients received Ixinity prophylaxis once to twice weekly.
    - The mean total annualized bleeding rate for PTPs < 12 years of age was 2.34 (standard deviation ± 4.23).
    - There were 52 bleeding episodes; nine did not require treatment and resolved with Ixinity routine prophylaxis once or twice-weekly treatment. In 45 of 52 (86.5%) of the episodes, hemostasis was achieved with zero to two infusions. For four bleeding episodes (7.7%) three infusions were required, two episodes (3.8%) four infusions were required, and one episode (1.9%) required five infusions for resolution.
- Ixinity is administered via intravenous infusion. Refer to the Ixinity drug label for complete dosing and administration recommendations.