Jivi® (antihemophilic factor [recombinant], PEGylated-aucl) – Expanded indication

- On May 19, 2025, Bayer announced the FDA approval of Jivi (antihemophilic factor [recombinant], PEGylated-aucl), for use in previously treated adults and **pediatric patients 7 years of age and older with hemophilia A** (congenital Factor VIII deficiency) for:
    - On-demand treatment and control of bleeding episodes
    - Perioperative management of bleeding
    - Routine prophylaxis to reduce the frequency of bleeding episodes.
- Jivi was previously approved for this indication in pediatric patients 12 years of age and older.
- The use of Jivi for the expanded indication was supported by evidence from three clinical studies, Study 2 (PROTECT VIII), Study 3 (PROTECT Kids) and Study 4 (Alfa-PROTECT), which included 108 pediatric patients 2 to < 12 years of age and 12 pediatric patients 12 to < 17 years of age.
- Refer to the Jivi drug label for complete dosing and administration recommendations.