Liletta® (levonorgestrel-releasing intrauterine system) – New indication

- On June 29, 2023, the FDA approved AbbVie's Liletta (levonorgestrel-releasing intrauterine system), for the treatment of heavy menstrual bleeding for up to 5 years in patients who choose to use intrauterine contraception as their method of contraception.
    - Liletta should be replaced after the end of the fifth year if continued treatment of heavy menstrual bleeding is needed.
- Liletta is also approved for prevention of pregnancy for up to 8 years.
- The approval of Liletta for the new indication was based on a noncomparative, open-label clinical study conducted in 105 generally healthy participants 18 to 50 years of age with confirmed heavy menstrual bleeding. The primary efficacy endpoint was the proportion of women with successful treatment, defined as (1) an end-of-study menstrual blood loss (MBL) volume < 80 mL and (2) ≥ 50% reduction in MBL from baseline to end-of-study.
    - The proportion of participants meeting both criteria defining successful treatment was 80% (95% CI: 71, 88) at the end of the study.
    - The median MBL percent reduction from baseline to mid-study was 91% and to end-of-study was 96%.
- Liletta contains 52 mg of levonorgestrel (LNG). Initially, LNG is released *in vivo* at a rate of approximately 20 mcg/day. This rate decreases progressively to approximately 6.5 mcg/day after 8 years. The average *in vivo* release rate of LNG is approximately 13.5 mcg/day over a period of 8 years.
    - Liletta is inserted into the uterine cavity with the provided inserter by a trained healthcare professional using strict aseptic technique.
    - Refer to the Liletta drug label for complete dosing and administration recommendations.