Mirena® (levonorgestrel-releasing intrauterine system) – Expanded indication

- On August 20, 2020, the FDA approved Bayer's Mirena (levonorgestrel-releasing intrauterine system), for the prevention of pregnancy for up to 6 years; replace after the end of the sixth year.
    - Previously, Mirena was approved for intrauterine contraception for up to 5 years.
- Mirena is also approved for the treatment of heavy menstrual bleeding for women who choose to use intrauterine contraception as their method of contraception for up to 5 years.
- The approval of Mirena for the expanded indication was demonstrated in the Mirena Extension Trial, an open-label, uncontrolled study enrolling 362 women. The primary efficacy endpoint was the pregnancy rate calculated as the Pearl Index (PI) in women ≤ 36 years of age at the end of year 6.
    - The PI for the 6th year of use based on the 1 pregnancy that occurred during year 6 and within 7 days after Mirena removal or expulsion was 0.35 with a 95% upper confidence limit of 1.95.
- For contraception, Mirena should be removed by the end of the sixth year and replace at the time of removal with a new Mirena if continued use is desired.
    - Mirena contains 52 mg of levonorgestrel (LNG). Initially, LNG is released at a rate of approximately 20 mcg/day. This rate decreases progressively to approximately 10 mcg/day after 5 years and 9 mcg/day after 6 years.
    - Mirena should be inserted by a trained healthcare provider.
    - Refer to Mirena's drug label for dosing for all its other indications.