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

- On August 11, 2021, the FDA approved Bayer's Mirena (levonorgestrel-releasing intrauterine system), for prevention of pregnancy for up to 7 years; replace after the end of the seventh year.
    - Previously, Mirena was approved for prevention of pregnancy for up to 6 years.
- Mirena is also approved for the treatment of heavy menstrual bleeding for up to 5 years in women who choose to use intrauterine contraception as their method of contraception; replace after the end of the fifth year if continued treatment of heavy menstrual bleeding is needed.
- The approval of Mirena for the expanded indication was based on the Mirena Extension Trial, an open-label, uncontrolled study enrolling 362 women. The pregnancy rate calculated as the Pearl Index (PI) was the primary efficacy endpoint used to assess contraceptive efficacy. The PI was based on 28-day equivalent exposure cycles; evaluable cycles excluded those in which back-up contraception was used unless a pregnancy occurred in that cycle. The cumulative 2-year pregnancy rate for Years 6 and 7 was estimated by the Kaplan-Meier method.
    - Based on 2 pregnancies (1 in Year 6 and 1 in Year 7) and 7,269 exposure cycles, the cumulative pregnancy rate at the end of the 2 year period of extended use (Years 6 and 7) was 0.71% with a 95% upper confidence limit of 2.84%.
- For contraception, Mirena should be removed by the end of the seventh year and replaced 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 8 mcg/day after 7 years.
    - Mirena should be inserted by a trained healthcare provider.
    - Refer to Mirena's drug label for dosing for treatment of heavy menstrual bleeding.