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

- On August 12, 2022, the FDA approved Bayer Healthcare's Mirena (levonorgestrel-releasing intrauterine system), for prevention of pregnancy for up to 8 years; replace after the end of the eighth year.
    - Mirena was previously approved for prevention of pregnancy for up to 7 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 Mirena Extension Trial, an open-label, uncontrolled study in 362 women using Mirena. The pregnancy rate calculated as the Pearl Index (PI) was the primary efficacy endpoint used to assess contraceptive efficacy. The cumulative 3-year pregnancy rate for Years 6, 7 and 8 was estimated by the Kaplan-Meier method
    - The PI for the 8th year of use based on no pregnancies occurring during Year 8 and within 7 days after Mirena removal or expulsion and 2,534 evaluable cycles was 0.00 with a 95% upper confidence limit of 1.90.
    - Based on 2 pregnancies (1 in Year 6 and 1 in Year 7) and 10,216 exposure cycles, the cumulative pregnancy rate at the end of the 3-year period of extended use (Years 6, 7 and 8) was 0.68% with a 95% upper confidence limit of 2.71%.
- Mirena contains 52 mg of levonorgestrel (LNG) released *in vivo*, at a rate of approximately 21 mcg/day after 24 days. This rate decreases progressively to approximately 11 mcg/day after 5 years and 7 mcg/day after 8 years. For contraception, remove Mirena by the end of the eighth year and replace at the time of removal with a new Mirena if continued use is desired.
- Refer to the Mirena drug label for complete dosing and administration recommendations.