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

- On August 3, 2017, the FDA approved Allergan/Medicines360's Liletta (levonorgestrel-releasing intrauterine system) for prevention of pregnancy for up to 4 years. The system should be replaced after 4 years if continued use is desired.
    - Previously, Liletta was approved for use for up to 3 years.
- Liletta's expanded indication is based on data from a clinical study which demonstrated a pregnancy rate of 0.13% (95% CI: 0.00, 0.74) during year 4 of Liletta use.
- Liletta is an intrauterine system containing 52 mg of levonorgestrel. It must be inserted by a trained healthcare provider using strict aseptic technique. Liletta can be removed at any time but must be removed by the end of the fourth year.
- Other currently available levonorgestrel-releasing intrauterine systems used for pregnancy prevention include Kyleena®, Mirena®, and Skyla®.
    - Kyleena and Mirena are approved for use for up to 5 years. Sklya is approved for use for up to 3 years.
    - Mirena is also indicated for the treatment of heavy menstrual bleeding in women who choose to use intrauterine contraception as their method of contraception.