Kyleena™ (levonorgestrel-releasing intrauterine system) – New Drug Approval

- On September 19, 2016, Bayer announced the FDA approval of Kyleena (levonorgestrel-releasing intrauterine system) for the prevention of pregnancy for up to 5 years.
- Kyleena is a small, flexible plastic T-shaped intrauterine device (IUD) containing levonorgestrel (LNG).
- Other currently available LNG-releasing IUDs include Liletta™, Skyla™, and Mirena®.
    - Liletta and Skyla are indicated for pregnancy prevention for up to 3 years while Mirena can be used for up to 5 years. Mirena is recommended for women who have had ≥ 1 child.
    - Mirena is also indicated for the treatment of heavy menstrual bleeding in women who choose to use intrauterine contraception as their method of contraception.
- The safety and efficacy of Kyleena were demonstrated in an open-label clinical study of 1,452 women who received Kyleena. The pregnancy rate, calculated as the pearl index (PI), was the primary efficacy endpoint used to assess contraceptive reliability.
    - Year 1 PI was 0.16 (95% CI: 0.02, 0.58) and year 5 PI was 0.37 (95% CI: 0.04, 1.33). The cumulative 5-year pregnancy rate was 1.45 (95% CI: 0.82, 2.53).
- Similar to other LNG-containing IUDs, Kyleena is contraindicated in pregnancy or suspicion of pregnancy; use as post-coital contraception; congenital or acquired uterine anomaly, including fibroids, that distorts the uterine cavity; acute pelvic inflammatory disease (PID) or a history of PID unless there has been a subsequent intrauterine pregnancy; postpartum endometritis or infected abortion in the past 3 months; known or suspected uterine or cervical neoplasia; known or suspected breast cancer or other progestin-sensitive cancer, now or in the past; uterine bleeding of unknown etiology; untreated acute cervicitis or vaginitis, including bacterial vaginosis or other lower genital tract infections until infection is controlled; acute liver disease or liver tumor; conditions associated with increased susceptibility to pelvic infections; and a previously inserted IUD that has not been removed.
- Warnings and precautions of Kyleena include risk of ectopic pregnancy, risks with intrauterine pregnancy, sepsis, pelvic infection, perforation, expulsion, ovarian cysts, bleeding pattern alterations, breast cancer, clinical considerations for use and removal, and magnetic resonance imaging information.
- The most common adverse events (≥ 5%) with Kyleena use were vulvovaginitis, ovarian cysts, abdominal pain/pelvic pain, headache/migraine, acne/seborrhea, dysmenorrhea/uterine spasm, breast pain/breast discomfort, and increased bleeding.
- Kyleena is placed by a healthcare provider during an in-office visit. It contains 19.5 mg of LNG released *in vivo* at a rate of approximately 17.5 mcg/day after 24 days. This rate decreases progressively to 9.8 mcg/day after 1 year and to 7.4 mcg/day after 5 years. The average *in vivo* release rate of LNG is approximately 9 mcg/day over a period of 5 years.
    - Kyleena must be removed by the end of the 5th year and can be replaced at the time of removal with a new Kyleena if continued contraceptive protection is desired.
    - Kyleena may be removed by a healthcare provider at any time prior to 5 years of use.

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- Bayer plans to launch Kyleena in October 2016. Kyleena will be available as one sterile intrauterine system consisting of a T-shaped polyethylene frame with a steroid reservoir containing LNG, packaged within a sterile inserter.