Contraceptive Counseling

Guidance from the Centers for Disease Control (CDC) and Office of Population Affairs (OPA)

Patient Counseling Information for Bayer's Intrauterine Devices: Kyleena®, Mirena®, and Skyla®

INDICATION FOR KYLEENA: Kyleena® is indicated for the prevention of pregnancy for up to 5 years. Replace the system after 5 years if continued use is desired.
INDICATIONS FOR MIRENA: Mirena® is indicated for prevention of pregnancy for up to 8 years; replace after the end of the eighth year. Mirena is indicated 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.
INDICATION FOR SKYLA: Skyla® is indicated for the prevention of pregnancy for up to 3 years. Replace the system after 3 years if continued use is desired

IMPORTANT SAFETY INFORMATION ABOUT KYLEENA, MIRENA, AND SKYLA
Who is not appropriate for Kyleena, Mirena and Skyla. Use of Kyleena, Mirena or Skyla is contraindicated in women with: known or suspected pregnancy and cannot be used for post-coital contraception; congenital or acquired uterine anomaly, including fibroids if they distort the uterine cavity; known or suspected breast cancer or other progestin-sensitive cancer, now or in the past; known or suspected uterine or cervical malignancy; liver disease, including tumors; untreated acute cervicitis or vaginitis, including lower genital tract infections (eg, bacterial vaginosis) until infection is controlled; postpartum endometritis or infected abortion in the past 3 months; unexplained uterine bleeding; current IUD; acute pelvic inflammatory disease (PID) or history of PID (except with later intrauterine pregnancy); conditions increasing susceptibility to pelvic infection; or hypersensitivity to any component of Kyleena, Mirena or Skyla.

Kyleena® (levonorgestrel-releasing intrauterine system) 19.5 mg | Mirena® (levonorgestrel-releasing intrauterine system) 52 mg | Skyla® (levonorgestrel-releasing intrauterine system) 13.5 mg

Please see additional Important Safety Information on pages 4-5. Please click to see full Prescribing Information for Kyleena, Mirena, and Skyla

CDC & OPA: Steps to Quality Contraceptive Counseling

1. Establish and maintain rapport with the patient
2. Assess their needs and personalize discussions accordingly
3. Work interactively to establish a plan
4. Provide educational materials that can be understood and retained
5. Confirm patient understanding ("teach-back")

Establish and maintain rapport with the patient

- Use open-ended questions
- Demonstrate expertise, trustworthiness, and accessibility
- Ensure privacy and confidentiality
- Explain how personal information will be used
- Encourage them to ask questions and share information
- Listen to and observe them
- Be encouraging and demonstrate empathy and acceptance

Assess the patient's needs and personalize discussions accordingly

Reproductive Life Plan:

- Do you have any children now?
- Do you want to have (more) children?
- How many (more) children would you like to have and when?

Contraceptive Experiences and Preferences:

- What methods are you currently using, if any?
- What methods have you used in the past?
- Have you previously used emergency contraception?
- Did you use contraception at last sex?
- What difficulties did you experience with prior methods if any (eg, side effects or noncompliance)?
- Do you have a specific method in mind?
- Have you discussed method options with your partner, and does your partner have a preference for what method you use?

Work with the patient interactively to establish a plan

- Providers are encouraged to present information on potential reversible methods using a tiered approach (presenting most effective methods first)
- It is not appropriate to omit information on a method solely because the method is not available at the service site
- Providers should ensure patient understanding of: method efficacy; correct use of method; non-contraceptive benefits; side effects; protection from sexually transmitted infections (STIs), including human immunodeficiency virus (HIV)
- Providers should encourage patients to consider barriers to using the method(s) under consideration

Provide educational materials that *can be understood and retained*

Confirm patient understanding ("teach-back")

- Patient restates the most important messages in their own words
- Can increase likelihood of patient and provider reaching a shared understanding
- Has improved compliance with a treatment plan and health outcomes
- Helps ensure patient has opportunity to understand their options and make informed choices

Patient Counseling Information for

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Sexually Transmitted Infections: Advise the patient that this product does not protect against HIV infection (AIDS) and other sexually transmitted infections (STIs).

Risk of Ectopic Pregnancy: Advise the patient about the risks of ectopic pregnancy, including the loss of fertility. Teach them to recognize and report to her healthcare provider promptly any symptoms of ectopic pregnancy.

Risks of Intrauterine Pregnancy: Advise the patient to contact their healthcare provider if they think they might be pregnant. Inform the patient about the risks of intrauterine pregnancy while using the Bayer IUS, including the risks of leaving it in place and the risks of removing it or probing of the uterus. If the Bayer IUS cannot be removed in a pregnant patient, advise them to report immediately any symptom that suggests complications of the pregnancy. Advise them of isolated reports of virilization of the female fetus following local exposure to LNG during pregnancy with an LNG IUS in place.

Sepsis: Advise the patient that severe infection or sepsis, including Group A streptococcal sepsis (GAS), can occur within the first few days after the Bayer IUS is inserted. Instruct them to contact a healthcare provider immediately if they develop severe pain or fever shortly after the Bayer IUS is inserted.

Pelvic Infection: Advise the patient about the possibility of pelvic infections, including PID, and that these infections can cause tubal damage leading to ectopic pregnancy or infertility, or infrequently can necessitate hysterectomy, or cause death. Teach patients to recognize and report to their healthcare provider promptly any symptoms of pelvic infection. These symptoms include development of menstrual disorders (prolonged or heavy bleeding), unusual vaginal discharge, abdominal or pelvic pain or tenderness, dyspareunia, chills, and fever.

Perforation and Expulsion: Advise the patient that the IUS may be expelled from or perforate the uterus and instruct them on how they can check that the threads still protrude from the cervix. Inform them that excessive pain or vaginal bleeding during Bayer IUS placement, worsening pain or bleeding after placement, or the inability to feel the Bayer IUS strings may occur with Bayer IUS perforation and expulsion. Caution them not to pull on the threads and displace the Bayer IUS. Inform them that there is no contraceptive protection if the Bayer IUS is displaced or expelled. Instruct the patient to contact their healthcare provider if they cannot feel the threads and to avoid intercourse or use a non-hormonal back-up birth control (such as condoms or spermicide) until the location of the Bayer IUS has been confirmed. Advise them that if perforation occurs, the Bayer IUS will have to be located and removed; surgery may be required.

Ovarian Cysts: Advise the patient regarding the risk of ovarian cysts and that cysts can cause clinical symptoms including pelvic pain, abdominal pain or dyspareunia. Advise the patient to contact their healthcare provider if they experience these symptoms.

Bleeding Pattern Alterations: Advise the patient that irregular or prolonged bleeding and spotting, and/or cramps may occur during the first few weeks after insertion. Inform the patient that, during the first 6 months of use, the number of bleeding and spotting days may be higher and bleeding patterns may be irregular. If symptoms continue or are severe, they should report them to their physician or healthcare provider

Clinical Considerations for Use and Removal: Advise the patient to contact their physician or healthcare provider if they experience any of the following:

- stroke or heart attack,
- very severe or migraine headaches,
- unexplained fever
- yellowing or the skin or whites of the eyes
- pregnancy or suspected pregnancy,
- pelvic or abdominal pain or pain during sex
- HIV positive seroconversion (herself or partner)
- possible exposure to STIs,
- unusual vaginal discharge or genital sores,
- severe bleeding or bleeding that lasts a long time, or if they miss a period,
- Inability to feel the IUS threads

Magnetic Resonance Imaging (MRI) Safety Information: Inform the patient that Kyleena and Skyla can be safely scanned with MRI only under specific conditions. Instruct patients who will have an MRI to tell their doctor that they have Kyleena or Skyla.

Advise the patient to read the FDA-approved patient labeling

Please see Important Safety Information on pages 1, 4-5. Please click to see full Prescribing Information for Kyleena, Mirena, and Skyla

Clinical considerations for use and removal of Kyleena, Mirena and Skyla. Use Kyleena, Mirena or Skyla with caution after careful assessment in patients with coagulopathy or taking anticoagulants; migraine, focal migraine with asymmetrical visual loss, or other symptoms indicating transient cerebral ischemia; exceptionally severe headache; marked increase of blood pressure; or severe arterial disease such as stroke or myocardial infarction. Consider removing the intrauterine system if these or the following arise during use: uterine or cervical malignancy or jaundice. If the threads are not visible or are significantly shortened they may have broken or retracted into the cervical canal or uterus. If Kyleena, Mirena or Skyla is displaced (e.g., expelled or perforated the uterus), remove it. Kyleena and Skyla can be safely scanned with MRI only under specific conditions.

Pregnancy related risks with Kyleena, Mirena and Skyla

If pregnancy should occur with Kyleena, Mirena or Skyla in place, remove the intrauterine system because leaving it in place may increase the risk of spontaneous abortion and preterm labor. Advise her of isolated reports of virilization of the female fetus following local exposure to LNG during pregnancy with an LNG-IUS in place. Removal or manipulation may result in pregnancy loss. Evaluate women for ectopic pregnancy because the likelihood of a pregnancy being ectopic is increased with Kyleena, Mirena or Skyla. Also consider the possibility of ectopic pregnancy in the case of lower abdominal pain, especially in association with missed menses or if an amenorrheic woman starts bleeding. Tell women about the signs of ectopic pregnancy and associated risks, including loss of fertility. Women with a history of ectopic pregnancy, tubal surgery, or pelvic infection carry a higher risk of ectopic pregnancy.

Educate her about PID

Kyleena, Mirena and Skyla are contraindicated in the presence of known or suspected PID or in women with a history of PID unless there has been a subsequent intrauterine pregnancy. IUDs have been associated with an increased risk of PID, most likely due to organisms being introduced into the uterus during insertion. Promptly examine users with complaints of lower abdominal pain or pelvic pain, odorous discharge, unexplained bleeding, fever, genital lesions or sores. Inform women about the possibility of PID and that PID can cause tubal damage leading to ectopic pregnancy or infertility, or infrequently can necessitate hysterectomy, or cause death. PID is often associated with sexually transmitted infections (STIs); Kyleena, Mirena and Skyla do not protect against STIs, including HIV. PID may be asymptomatic but still result in tubal damage and its sequelae.

In clinical trials with:

- Kyleena – PID occurred more frequently within the first year and most often within the first month after insertion.
- Mirena – upper genital infections, including PID, occurred more frequently within the first year. In a clinical trial with other IUDs and a clinical trial with an IUD similar to Mirena, the highest rate occurred within the first month after insertion.
- Skyla – PID occurred more frequently within the first year and most often within the first month after insertion.

Expect changes in bleeding patterns with Kyleena, Mirena and Skyla

Spotting and irregular or heavy bleeding may occur during the first 3 to 6 months. Periods may become shorter and/or lighter thereafter. Cycles may remain irregular, become infrequent, or even cease. Consider pregnancy if menstruation does not occur within 6 weeks of the onset of previous menstruation.

If a significant change in bleeding develops during prolonged use, take appropriate diagnostic measures to rule out endometrial pathology

Be aware of other serious complications and most common adverse reactions

Some serious complications with IUDs like Kyleena, Mirena and Skyla are sepsis, perforation and expulsion. Severe infection, or sepsis, including Group A streptococcal sepsis (GAS) have been reported following insertion of a LNG-releasing IUS. Aseptic technique during insertion of the IUD is essential in order to minimize serious infections, such as GAS.

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Important Safety Information (cont.) About

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Be aware of other serious complications and most common adverse reactions (cont.)

Perforation (total or partial, including penetration/embedment of Kyleena, Mirena or Skyla in the uterine wall or cervix) may occur, most often during insertion, although the perforation may not be detected until sometime later. The risk of uterine perforation is increased in women who have recently given birth, and in women who are breastfeeding at the time of insertion. In a large US retrospective, postmarketing safety study of IUDs, the risk of uterine perforation was highest when insertion occurred within ≤6 weeks postpartum, and also higher with breastfeeding at the time of insertion. The risk of perforation may be increased if inserted when the uterus is fixed, retroverted or not completely involuted. If perforation occurs, locate and remove the intrauterine system. Surgery may be required. Delayed detection or removal of the intrauterine system in case of perforation may result in migration outside the uterine cavity, adhesions, peritonitis, intestinal perforations, intestinal obstruction, abscesses, and erosion of adjacent viscera. In addition, perforation may reduce contraceptive efficacy and result in pregnancy.

Partial or complete expulsion of Kyleena, Mirena or Skyla may occur resulting in the loss of contraceptive protection. The risk of expulsion is increased with insertions immediately after delivery and appears to be increased with insertion after second-trimester abortion based on limited data. In the same postmarketing study, the risk of expulsion was lower with breastfeeding status. Remove a partially expelled IUD. If expulsion has occurred, a new Kyleena, Mirena or Skyla can be inserted any time the provider can be reasonably certain the woman is not pregnant.

Ovarian cysts may occur and are generally asymptomatic, but may be accompanied by pelvic pain or dyspareunia. Evaluate persistent enlarged ovarian cysts.

In clinical trials with:

- Kyleena – the most common adverse reactions (≥5%) were vulvovaginitis (24%), ovarian cyst (22%), abdominal/pelvic pain (21%), headache/migraine (15%), acne/seborrhea (15%), dysmenorrhea/uterine spasm (10%), breast pain/breast discomfort (10%), and increased bleeding (8%).
- Mirena

  Adverse reactions reported in ≥5% users are alterations of menstrual bleeding patterns [including unscheduled uterine bleeding (31.9%), decreased uterine bleeding (23.4%), increased scheduled uterine bleeding (11.9%), and female genital tract bleeding (3.5%)], abdominal/pelvic pain (22.6%), amenorrhea (18.4%), headache/migraine (16.3%), genital discharge (14.9%), vulvovaginitis (10.5%), breast pain (8.5%), back pain (7.9%), benign ovarian cyst and associated complications (7.5%), acne (6.8%), depression/depressive mood (6.4%) and dysmenorrhea (6.4%).

  A separate study with 362 women who have used Mirena for more than 5 years showed a consistent adverse reaction profile in Years 6 through 8. By the end of Year 8 of use, amenorrhea and infrequent bleeding are experienced by 34% and 26% of users, respectively; irregular bleeding occurs in 10%, frequent bleeding in 3%, and prolonged bleeding in 3% of users. In this study, 9% of women reported the adverse event of weight gain, it is unknown if the weight gain was caused by Mirena.

- Skyla – the most common adverse reactions (≥5% users) were vulvovaginitis (20.2%), abdominal/pelvic pain (18.9%), acne/seborrhea (15.0%), ovarian cyst (13.2%), headache (12.4%), dysmenorrhea (8.6%), breast pain/discomfort (8.6%), increased bleeding (7.8%), and nausea (5.5%).

Teach patients to recognize and immediately report signs or symptoms of the aforementioned conditions. Evaluate patients 4 to 6 weeks after insertion of Kyleena, Mirena or Skyla and then yearly or more often if clinically indicated

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