STEADY CARE THROUGH UNSTEADY TIMES

Supporting patient care by facilitating in-person office visits for intrauterine devices (IUDs)

INDICATION FOR KYLEENA

Kyleena® (levonorgestrel-releasing intrauterine system) 19.5 mg 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® (levonorgestrel-releasing intrauterine system) 52 mg 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.

IMPORTANT SAFETY INFORMATION ABOUT KYLEENA AND MIRENA

Who is not appropriate for Kyleena and Mirena

Use of Kyleena or Mirena 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 or Mirena.

Kyleena® (levonorgestrel-releasing intrauterine system) 19.5 mg

Mirena® (levonorgestrel-releasing intrauterine system) 52 mg

Please see Important Safety Information throughout and click to see full Prescribing Information for Kyleena and Mirena.

BAYER

ESTABLISH SINGLE OFFICE VISITS (SOVs) AND SAME-DAY INSERTION (SDI) FOR APPROPRIATE PATIENTS IN YOUR OFFICE

Clinical

- Educate your medical staff so they are comfortable counseling patients on all contraceptive options and knowledgeable on who may be appropriate for SOV and SDI with Kyleena® or Mirena®[1,2]

Operational

- Identify a physician, nurse, or other frontline staff member at your office as the office champion who can help streamline the process and make SDI more feasible[3]

Access

- Provide your office staff the coverage, coding, and billing education they need to help support your patients and practice[3]

> The American College of Obstetricians and Gynecologists (ACOG) recommends SDI for long-acting reversible contraception (LARC), such as IUDs as a best practice and should be offered routinely as a safe and effective contraceptive option[3]

IMPORTANT SAFETY INFORMATION ABOUT KYLEENA AND MIRENA (continued)

Clinical considerations for use and removal of Kyleena and Mirena

Use Kyleena or Mirena 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 or Mirena is displaced (e.g., expelled or perforated the uterus), remove it. Kyleena can be safely scanned with MRI only under specific conditions.

IDENTIFY YOUR APPROPRIATE PATIENTS FOR KYLEENA OR MIRENA

Counsel your patients on all contraceptive options

1. Discuss family planning needs and counsel patients on birth control options that match their goals and preferences[3]
2. If appropriate, gauge patient interest in LARC, including IUDs[3]
3. Determine and confirm with the patient that an IUD is the appropriate LARC option for them[3]

Set up counseling co-ops to train your staff on appropriate patient engagement practices for birth control counseling sessions.

Determine if your patient is a candidate for SDI with Kyleena or Mirena

SDI may be possible with Kyleena or Mirena[1,2]

- In appropriate patients, Kyleena or Mirena can be inserted any time you are reasonably certain your patient is not pregnant
- Prior to insertion, obtain a complete medical and social history to rule out any factors that may indicate a higher risk of infection. If indicated, perform a physical exam and appropriate tests for any forms of genital or other sexually transmitted infections

For more information on when SDI with Kyleena or Mirena may be appropriate for your patients, please see the table on the next page for insertion timing.

IMPORTANT SAFETY INFORMATION ABOUT KYLEENA AND MIRENA (continued)

Pregnancy related risks with Kyleena and Mirena

If pregnancy should occur with Kyleena or Mirena 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 or Mirena. 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.

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KNOW WHEN SDI WITH KYLEENA® OR MIRENA® IS APPROPRIATE FOR YOUR PATIENTS

Depending on your patient's circumstance, SDI may be considered if you are reasonably certain she is not pregnant[1,2]

Intrauterine system (IUS) insertion timing		Backup contraception?	
Women not currently using hormonal or intrauterine contraception	• Any time the provider can be reasonably certain the woman is not pregnant • Consider the possibility of ovulation and conception prior to initiation	YES	if not inserted during the first 7 days of the menstrual cycle, a barrier method should be used or patient should abstain from vaginal intercourse for 7 days
		NO	if inserted during the first 7 days of the menstrual cycle or immediately after first-trimester abortion
Switching from:			
Pills, transdermal patch, or vaginal ring	• Any time, including the hormone-free interval of the previous method	YES	if inserted during active use of previous method, continue previous method for 7 days after insertion or until the end of the current treatment cycle
		YES	if inserted during use of continuous hormonal contraception, continue method for 7 days after insertion
Injectable progestin contraceptive	• Any time	YES	if inserted >3 months (13 weeks) after the last injection, backup contraception (such as condoms or spermicide) should also be used for 7 days
		NO	if inserted <3 months after last injection
Implant or IUS	• Any time during the menstrual cycle • Insert Bayer IUD on the same day as removal of the implant or IUS	NO	there is no need for backup contraception
Inserting after abortion, miscarriage or delivery			
After first-trimester abortion or miscarriage	• Can be inserted immediately, unless it's a septic abortion	NO	there is no need for backup contraception
Immediate insertion after childbirth, or second-trimester abortion or miscarriage	• Insert after removal of placenta	NO	there is no need for backup contraception
Interval insertion following complete involution of the uterus	• Wait a minimum of 6 weeks, or until uterus is fully involuted before insertion. Insert any time there is reasonable certainty that the woman is not pregnant	YES	if not inserted during the first 7 days of the menstrual cycle, a backup method should be used or the patient should abstain from vaginal intercourse for 7 days
		NO	if inserted during the first 7 days of the menstrual cycle

IMPORTANT SAFETY INFORMATION ABOUT KYLEENA AND MIRENA (continued)

Educate her about PID

Kyleena and Mirena 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 and Mirena 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.

Expect changes in bleeding patterns with Kyleena and Mirena

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 and Mirena 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.

Perforation (total or partial, including penetration/embedment of Kyleena or Mirena 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 or Mirena 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 or Mirena 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.

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PREPARE YOUR OFFICE AND STAFF TO MEET THE NEEDS OF PATIENTS WHO ARE APPROPRIATE FOR SDI

Order, stock, and prepare Kyleena® and Mirena® IUDs for SDI

Your office can prepare ahead of time for SDI by[3]:

- ☑ Anticipating patient demand for SDI
- ☑ Stocking IUDs so they are readily available for SDI
- ☑ Equipping examination rooms with insertion kits

SDI may be possible if your examination rooms are equipped with insertion kits that contain the needed checklists and supplies.

If eligible, you can order Bayer IUDs like Kyleena and Mirena for your office using Bayer's **discount pricing programs**. Contact your Bayer Sales Consultant to learn more.

Educate staff on proper insertion and removal

A team of trained clinicians will help your practice effectively serve appropriate patients for SDI.[3]

You can educate your medical staff on the insertion and removal instructions for Kyleena and Mirena using the **insertion videos** on www.kyleenahcp.com and www.mirenahcp.com, or by requesting in-person or **virtual insertion training** from your Bayer Sales Consultant.

IMPORTANT SAFETY INFORMATION ABOUT KYLEENA AND MIRENA (continued)

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

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.

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

PROVIDE YOUR STAFF WITH THE SUPPORT RESOURCES THEY NEED TO MAKE SURE YOU AND YOUR PATIENTS ARE COVERED FOR SDI

Managing patient coverage

Help your office staff find coverage information for plans you accept. The Affordable Care Act generally requires health plans to cover FDA-approved contraceptive methods, including implants and IUDs, as a preventative service at a low cost or no cost to the patient. To help your staff verify patient coverage information for SDI in a timely and accurate manner, you can[3]:

- ☑ Inform your staff that 95% of patients had coverage for a Bayer IUD with low or no out-of-pocket costs based on benefit investigation submissions to Bayer in 2017 (other products costs may apply; N=291,664)[4]

The Bayer **Confidence in Coverage Program** and **Co-pay Savings Program for Kyleena and Mirena** are designed to support you and your eligible patients with the costs of IUDs. For more information, visit **www.WHCsupport.com/forms**.

Your staff can use the **Benefits Verification Worksheet** while checking the office visit co-pay and procedure coverage so they only have to check coverage once.

- ☑ Develop a patient coverage quick reference guide with coverage details and authorization requirements[3]
- ☑ Appoint a billing team staff member to oversee all benefit coverage procedures for SDI[3]

Ensure proper billing and coding with modifiers

- ☑ Check that your office staff has the latest billing and coding information, such as modifiers, required to receive separate reimbursement for SDI[3]

Find the billing and coding information your staff needs, including modifiers for SDI, for Kyleena and Mirena in the **SDI/SOV Billing and Coding Guide** or **Compass Guide** found at **www.WHCsupport.com/forms**.

For important information about Kyleena, please see the accompanying Full Prescribing Information.

For important information about Mirena, please see the accompanying Full Prescribing Information.

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AS YOUR PARTNER IN WOMEN'S CARE, BAYER IS HERE TO SUPPORT YOU AND YOUR PATIENTS

Contact your Bayer Sales Consultant to request support resources that can help you and your staff implement SDI at your practice

Clinical

Operational

Access

References: 1. Kyleena [prescribing information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals; 2021. **2.** Mirena [prescribing information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals; 2022. **3.** American College of Obstetricians and Gynecologists. Same-day insertion for long-acting reversible contraception: best practice checklist. https://www.acog.org/-/media/project/acog/acogorg/files/pdfs/brochures-flyers/dii-larc-same-day-insertion-checklist.pdf. Published November 2019. Accessed August 31, 2022. **4.** Data on file. Benefit verification–service removal plan overview; 2018.

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