Kyleena® (levonorgestrel-releasing intrauterine system) 19.5 mg

Mirena® (levonorgestrel-releasing intrauterine system) 52 mg

STEADY CARE THROUGH UNSTEADY TIMES

Supporting patient contraceptive care during and after COVID-19: Single office visits (SOVs) in practice

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.

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

COVID-19=coronavirus disease 2019.

BAYER

UTILIZE SOV FOR APPROPRIATE PATIENTS BY IMPLEMENTING TELEHEALTH AS PART OF YOUR CLINICAL PRACTICE

Clinical

- ☑ Maintain patient care using telehealth during and after COVID-19

Operational

- ☑ Set up telehealth in your office to help counsel patients about their family planning and contraceptive needs

Access

- ☑ Educate your office staff about the proper coding and billing practices for telehealth visits and for Kyleena® and Mirena®

The American College of Obstetricians and Gynecologists (ACOG) encourages the use of telehealth in your practice to continue providing optimal care for your patients[1]

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.

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.

CONTINUE TO PROVIDE CARE FOR YOUR PATIENTS BY USING TELEHEALTH IN YOUR PRACTICE

Implement telehealth to benefit you and your patients

Strategic use of telehealth can help:

- ☑ Solidify strong patient communication[2]
- ☑ Maintain patient-provider contraceptive counseling[3]
- ☑ Provide patient care while minimizing the number of in-office visits[3]

Telehealth can be an entry point to counsel patients on contraceptives, including long-acting reversible contraception (LARC) for appropriate patients

- ACOG recommends continuing to offer LARCs, including IUDs like Kyleena and Mirena when appropriate[1,4,5]

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.

You can also set up counseling co-ops to train your medical staff on appropriate patient engagement practices for birth control counseling.

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.

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

Kyleena® (levonorgestrel-releasing intrauterine system) 19.5 mg

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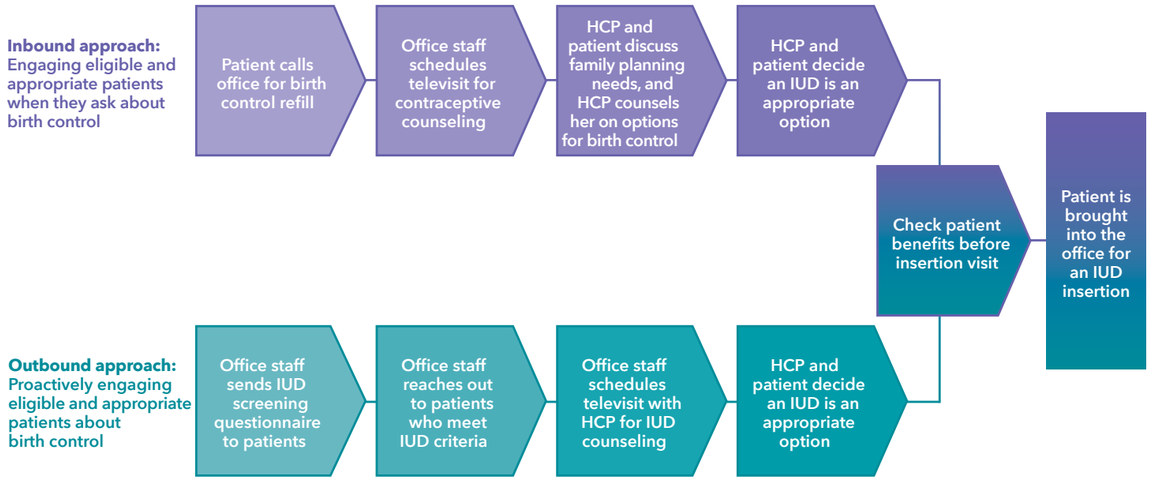
SET UP YOUR OFFICE STAFF WITH TELEHEALTH PRACTICES THAT CAN HELP THEM MEET THE NEEDS OF YOUR PATIENTS

Involve your team to help counsel and identify appropriate patients for SOV using telehealth

Most plans allow for telehealth discussions to be led by nurse practitioners and physician assistants as an alternative to supporting patient counseling needs.[6]*

Example telehealth workflow to help implement the SOV[7,8]



*Individual states and insurers may define healthcare professionals eligible for reimbursement of telehealth services differently.[6]

IMPORTANT SAFETY INFORMATION ABOUT KYLEENA AND MIRENA (continued)

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.

PREPARE YOUR OFFICE FOR SOV WITH KYLEENA® AND MIRENA®

Order, stock, and prepare Kyleena and Mirena IUDs for SOV

Your office staff can help ensure your office is ready for SOV by preparing ahead of time. Ask your staff to[9]:

- ☑ Anticipate patient demand for SOV
- ☑ Stock IUDs so they are readily available
- ☑ Equip examination rooms with insertion kits

You may be eligible to order Bayer IUDs like Kyleena and Mirena for your office using Bayer's **discount pricing programs**. Contact your Bayer Sales Consultant to learn more.

IMPORTANT SAFETY INFORMATION ABOUT KYLEENA AND MIRENA (continued)

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

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.

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%).

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

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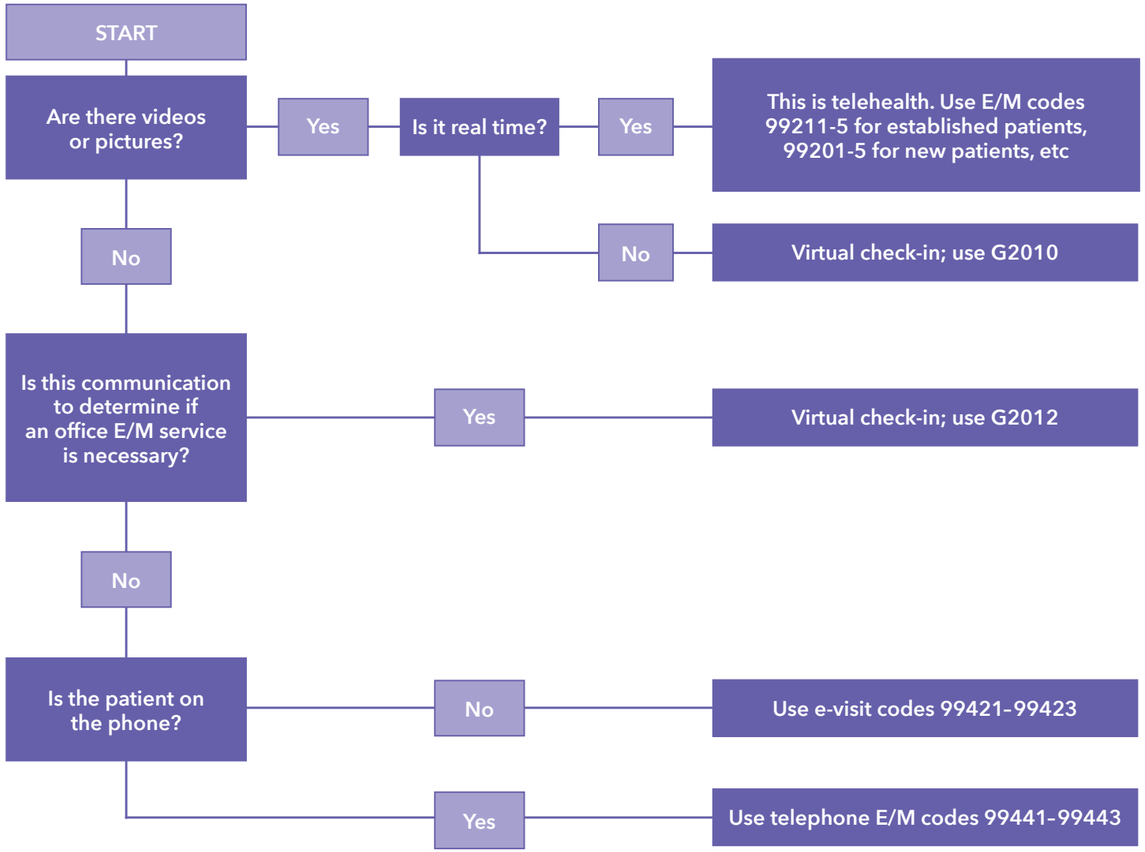
CODING FOR PATIENT COUNSELING WITH TELEHEALTH VISITS

Telehealth is a broad term that can take different forms. The mode of delivery will impact which codes are appropriate for use, so be sure you and your staff are clear on the methods being used when counseling patients.[10]

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

Telehealth coding[10*†]



Developed by James Dom Dera, MD, FAAFP. Source: Four algorithms that answer four key questions about COVID-19. *FPM*. May 18, 2020. Additional telehealth billing codes are available on the National Family Planning website. Accurate as of March 31, 2020 and does not guarantee reimbursement.

*Coding and billing for services provided via telehealth are how the service is provided to the patient, and not the service itself. Most services will be linked to **Z30.01-** (encounter for initial prescription of contraceptives) and **Z30.43-** (encounter for surveillance of intrauterine contraceptive device) series.[10,11]

†Individual states and insurers may define healthcare professionals eligible for reimbursement of telehealth services differently.[6]

E/M=evaluation and management.

LEVERAGE BAYER SUPPORT PROGRAMS FOR YOU AND YOUR PATIENTS

Managing patient coverage for the IUD insertion

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

Confidence in Coverage Program

If your eligible patient is denied coverage by her plan after IUD insertion, Bayer will replace the IUD at no cost.‡

Co-pay Savings Program for Bayer IUDs

Eligible commercially insured patients may pay as little as $20 for the Kyleena or Mirena IUD.§

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).[12]

‡Does not apply for patients who have a co-pay, insertion and removal costs, or any other costs.

§Eligible patients may pay as little as $20 for the cost of the Kyleena/Mirena IUD. Benefit limitations apply. For full terms and conditions please reference copayformirena.com/copayforkyleena.com. Patients who are enrolled in any type of government insurance or reimbursement programs are not eligible. As a condition precedent of the co-payment support provided under this program, e.g., co-pay refunds, participating patients and pharmacies are obligated to inform insurance companies and third-party payers of any benefits they receive and the value of this program, and may not participate if this program is prohibited by or conflicts with their private insurance policy, as required by contract or otherwise. Void where prohibited by law, taxed, or restricted. Patients enrolled in the Bayer US Patient Assistance Foundation are not eligible. Bayer may determine eligibility, monitor participation, equitably distribute product and modify or discontinue any aspect of the Co-pay Savings Program for Mirena/Kyleena at any time, including but not limited to this commercial co-pay assistance program.

IMPORTANT SAFETY INFORMATION ABOUT KYLEENA AND MIRENA (continued)

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

In clinical trials with (continued):

- 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.

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 telehealth and SOV at your practice

Clinical

Operational

Access

References: 1. American College of Obstetricians and Gynecologists. COVID-19 FAQs for obstetrician–gynecologists, gynecology. https://www.acog.org/clinical-information/physician-faqs/covid19-faqs-for-ob-gyns-gynecology. Accessed August 31, 2022. **2.** Implementing telehealth in practice: ACOG Committee opinion summary, number 798. *Obstet Gynecol*. 2020;135(2):493-494. doi:10.1097/AOG.0000000000003672. **3.** Upstream USA. Telehealth and contraceptive care. Updated June 1, 2020. **4.** Kyleena [prescribing information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals; 2021. **5.** Mirena [prescribing information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals; 2022. **6.** Women's Preventive Services Initiative. FAQ for telehealth services. https://www.womenspreventivehealth.org/faqs. Accessed August 31, 2022. **7.** Bokolo A. Use of telemedicine and virtual care for remote treatment in response to COVID-19 pandemic. *J Med Syst*. 2020;44(7):132. doi:10.1007/s10916-020-01596-5. **8.** Reproductive Health National Training Center. Prioritization of in-person and virtual visits during COVID-19: a decision-making guide for staff. https://rhntc.org/resources/prioritization-person-and-virtual-visits-during-covid-19-decision-making-guide-staff. Updated April 2020. Accessed August 31, 2022. **9.** 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. **10.** National Family Planning and Reproductive Health Association. Initiating telehealth in response to COVID-19: coding and billing for telehealth services. https://www.nationalfamilyplanning.org/file/COVID-Telehealth-Coding-11132020.pdf. Published November 2020. Accessed August 31, 2022. **11.** American College of Obstetricians and Gynecologists. LARC quick coding guide: coding for the contraceptive implant and IUDs. https://www.acog.org/-/media/project/acog/acogorg/files/pdfs/publications/larc-coding-guide.pdf. Accessed August 31, 2022. **12.** Data on file. Benefit verification–service removal plan overview; 2018.

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

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