CODES AND DESCRIPTIONS FOR BAYER IUD PRODUCTS

Billing code details for IUD processes, including use of **Kyleena®**, **Mirena®** and **Skyla®**

Basic IUD Codes

ICD-10 Codes - IUDs		CPT Procedure Code
Z30.014	Encounter for initial prescription of IUD (Used when an IUD insertion kit must be ordered before placement. Not coded on the day of the actual insertion)	
Z30.430	Encounter for insertion of IUD	58300
Z30.431	Follow-up for patient with IUD or Routine checking for IUD	
Z30.432	Encounter for removal of IUD	58301
Z30.433	Encounter for removal + reinsertion of IUD	*58300* ***AND*** *58301-51** ***OR*** *58301-59** *(Check with payer for expected modifier.) Append modifier -51 or -59 to the lesser paying service.*
Z32.02	Pregnancy test/exam - negative	81025 (Urine pregnancy test) Don't forget to bill for the point-of-care office pregnancy test (when conducted)

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STOP The information in this guide is for informational purposes and does not guarantee payment or coverage. Offices should research coding, coverage, and payment for individual patients prior to initiating treatment since policies and guidelines vary by payer and health plan. Offices are responsible for submitting accurate, complete, and appropriate claims to payers and for compliance with any obligations required by law, contract, or otherwise.

National Drug Codes (NDCs) for Bayer IUDs

KYLEENA NDC: 50419-424-01	MIRENA NDC: 50419-423-01*	SKYLA NDC: 50419-422-01

For billing purposes, use the following 11-digit formats:

50419042401	50419042301	50419042201
Kyleena® (levonorgestrel-releasing intrauterine system) 19.5 mg	Mirena® (levonorgestrel-releasing intrauterine system) 52 mg	Skyla® (levonorgestrel-releasing intrauterine system) 13.5 mg
KYLEENA HCPCSII/J CODE: J7296	**MIRENA HCPCSII/J CODE: J7298**	**SKYLA HCPCSII/J CODE: J7301**

*Note that Mirena has 2 NDC numbers. Please refer to the NDC number located on the top left corner of the packaging, as well as the Full Prescribing Information for Mirena.

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,

Please see Important Safety Information continued throughout and click to see Full Prescribing Information for Kyleena, Mirena and Skyla.

Clinical Scenario Codes and Descriptions

Modifier	Definition	Possible Clinical Scenarios	Documentation in Medical Record or on the Claim
-22	Increased procedural services	• Complex or difficult insertion • Unsuccessful insertion, followed by successful insertion during the same surgical session	In the medical record and on the claim, document: • Total time of the procedure as compared with typical duration • Reason for the additional work required • Include diagnoses with appropriate ICD-10 codes or simple descriptive diagnoses that explain the reasons for the added difficulty
-25	Significant, separately identifiable E/M service	• The patient is seen for contraceptive counseling, a well woman visit, an STD check, a pregnancy test, or another reason. She chooses an IUD or implant, which is placed at that visit.	• Select an E/M code based on face-to-face time spent with the patient, but excluding the time needed for the IUD or implant placement • Document in the patient's medical record that at least 50% of the non-procedure time was spent in counseling • The -25 modifier is appended to the E/M code, NOT the CPT code
-51*	Multiple procedures performed on the same day during the same session	• Removal of IUD and insertion of new IUD on the same day • Removal of implant and insertion of IUD on the same day • Removal of IUD and insertion of implant on the same day	• The claim should support the reasons for removal and reinsertion on the same day (e.g. IUD expired, desired to continue with same method) • Append modifier -51 to the lesser paying service.
-52	Failed procedure	• Provider couldn't complete procedure for anatomic reasons (e.g. stenosis)	• In the medical record and on the claim, document reasons for procedure failure (e.g. **N88.2** Stricture/stenosis of cervix)
-53	Discontinued procedure	• Provider couldn't complete procedure due to concerns for patient well-being • Severe pain • Vasovagal • Patient changed mind during procedure	In the medical record and on the claim, document: • Which work was actually performed • The reason the procedure was terminated (e.g. **R55** Syncope/vasovagal)
-59*	Distinct procedural service	• Removal of IUD and insertion of new IUD on the same day • Removal of implant and insertion of IUD on the same day	• The claim should support the reasons for removal and reinsertion on the same day (e.g. IUD expired, desired to continue with same method) • Append modifier -59 to the lesser paying service.
-76 -77	Repeat procedure -Same provider -Another provider	• Successful insertion but the IUD is expelled, followed by repeat insertion	• Document reason for repeat procedure (e.g. IUD was expelled)

*When choosing between modifiers -51 and -59, payer policy may be the determining factor. Some payers will not pay for multiple procedures using modifier -51. ***Check with payer.***

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.

INDICATION FOR SKYLA

Skyla® (levonorgestrel-releasing intrauterine system) 13.5 mg is indicated for the prevention of pregnancy for up to 3 years. Replace the system after 3 years if continued use is desired.

Please see Important Safety Information continued throughout and click to see Full Prescribing Information for Kyleena, Mirena and Skyla.

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.

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.

IMPORTANT SAFETY INFORMATION ABOUT KYLEENA, MIRENA AND SKYLA (Continued)

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.

You are encouraged to report negative side effects or quality complaints of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see Important Safety Information continued throughout and click to see Full Prescribing Information for Kyleena (levonorgestrel-releasing intrauterine system) 19.5 mg, Mirena (levonorgestrel-releasing intrauterine system) 52 mg and Skyla (levonorgestrel-releasing intrauterine system) 13.5 mg.

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