Bayer WHC Reimbursement Resource Sample CMS-1500 Claims Form and Instructions

Bayer WHC Reimbursement Resource

Sample CMS-1500 Claims Form

Bayer has developed this resource to provide healthcare professionals (HCPs) with coverage, coding, and reimbursement information for Kyleena®, Mirena®, and Skyla®.

Kyleena, Mirena and Skyla and associated procedures provided in the physician's office may be billed using the CMS-1500 claim form, which is available in both paper and electronic formats. The recommended codes can be used for both formats. Submitting claims electronically does not always allow for attaching additional documentation. Check with your payers to determine if additional documentation is required for each claim.

The information in this resource provides considerations for Kyleena, Mirena and Skyla and the submission of claims for the appropriate services. Providers should confirm the appropriate coverage, coding, and reimbursement with the applicable payer or claims processor before submitting claims for an item or service.

Providers must ensure that all claims submitted to payers are accurate, complete, and adequately supported by documentation in the medical record. The following content is for informational purposes only and does not guarantee that codes will be appropriate or that coverage and reimbursement will result. Final coding and billing decisions for any item or service must be made by the HCP after considering the medical necessity of the items and services, the policies and procedures of the payer, and the applicable local, state, or federal laws.

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.

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.

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.

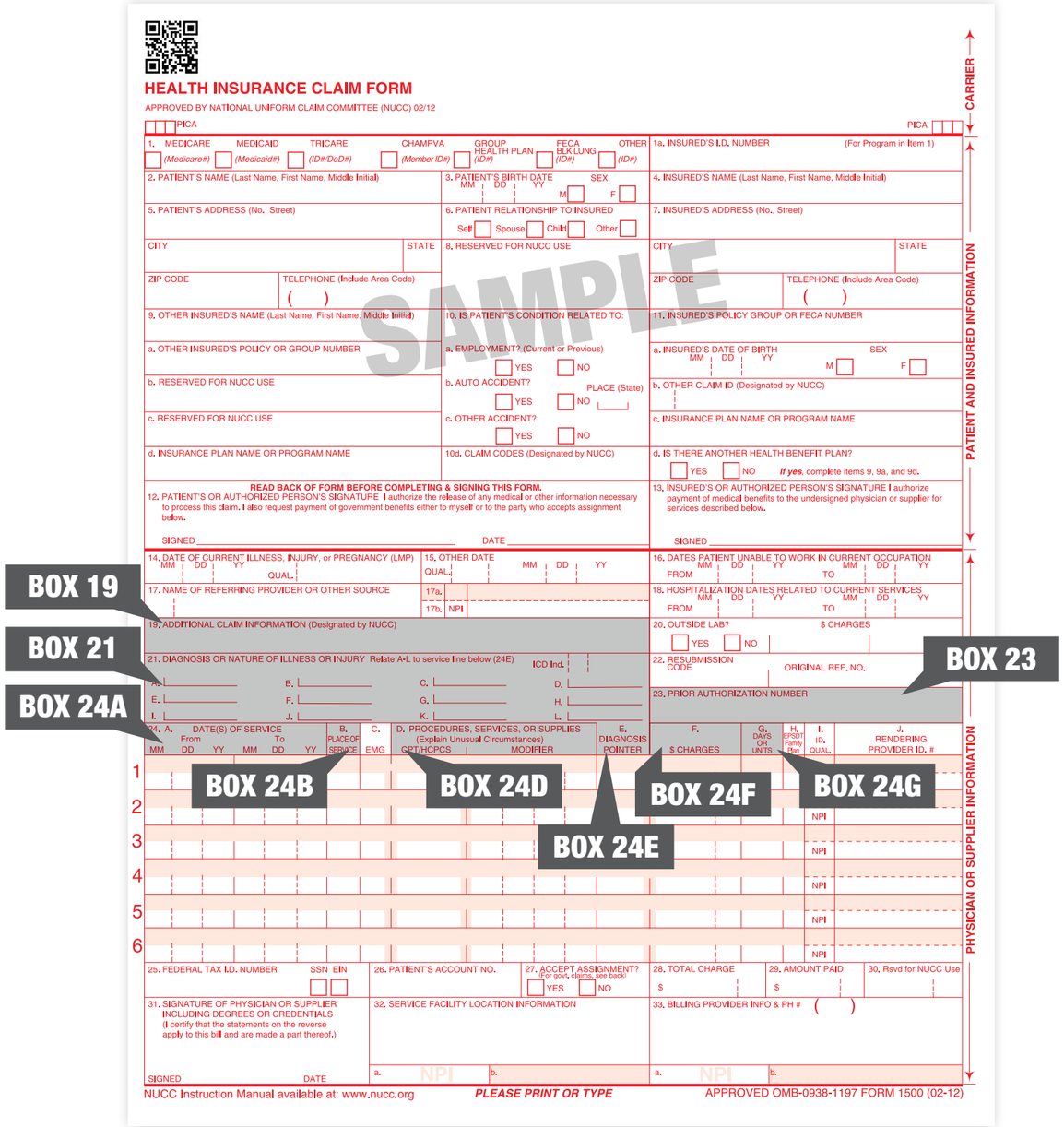
Pregnancy related risks with Kyleena, Mirena and Skyla

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.

Please see Important Safety Information on the next page, and click to see the Full Prescribing Information for **Kyleena®, Mirena®** and **Skyla®.**

Sample CMS-1500 Claims Form

This sample claims form is provided for your guidance only.



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

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

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.

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.

For important information about **Kyleena,** please **click here** to see the Full Prescribing Information

For important information about **Mirena,** please **click here** to see the Full Prescribing Information

For important information about **Skyla,** please **click here** to see the Prescribing Information

Sample CMS-1500 Form Instructions

Box 19: Remarks/Comments Field
- Include supplemental information for the specific Bayer IUD, to help the payer identify the therapy
- List the brand and generic name, NDC, and total units
- Example: *Kyleena (levonorgestrel intrauterine system), 19.5 mg, NDC 50419042401*

Box 21: Diagnosis Code(s)
- List the appropriate ICD-10-CM diagnosis code(s) based on the patient's condition
- Example: Use the ICD-10-CM code, **Z30.430** to report ***encounter for insertion of intrauterine device***
- Example: For certain uses of Mirena, use the following ICD-10-CM codes (note these codes do not apply to Kyleena or Skyla)
  - N92 – excessive or frequent menstruation with regular cycle
  - N92.1 – excessive or frequent menstruation with irregular cycle
  - N92.4 – excessive bleeding in the premenopausal period

Shaded Area above Box 24A: NDC and Qualifier
- List the 11-digit NDC number
  - To describe Kyleena, Mirena or Skyla, use the following 11-digit NDC numbers:
    - Kyleena: 50419042401
    - Mirena: 50419042301
    - Skyla: 50419042201
- Check if the payer requires a specific qualifier. Contact the payer for more information.

Box 23: Prior Authorization Number
- Include the prior authorization number provided by the payer, if required

Box 24A: Date(s) of Service
- List the date(s) when service(s) occurred

Box 24B: Place of Service
- Enter "11" for services provided in the office

Box 24D: Procedures, Services or Supplies
- Enter the appropriate HCPCS code on line 1 and the appropriate CPT code for the procedure on line 2
- Example: To describe Kyleena, Mirena or Skyla, use the following HCPCS codes:
  - Kyleena: **J7296**
  - Mirena: **J7298**
  - Skyla: **J7301**
- Example: For the procedure, use CPT code 58300 to report ***insertion of intrauterine system***
- List any modifiers, if needed in the appropriate modifier section
  - Some payers may also require the use of **modifier 33** to identify the CPT code as a preventive service. Check with payer for more information.

Box 24E: Diagnosis Pointer
- Enter the letter from Box 21 corresponding to the primary diagnosis of each HCPCS or CPT code listed in Box 24D

Box 24F: Charges
- Enter the total charge assigned to each service or procedure listed in 24D

Box 24G: Days or Units
- Enter the number of units of service for each code listed in 24D. Typically, this will be 1. Check with the payer for more information.

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