Kyleena™ 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 or reference the benefit verification results to determine if additional documentation is required for each claim.

### Tips for completing the CMS-1500 form

1. **Include supplemental information for Kyleena** to help the payer identify the therapy, including the product name, dosage, and NDC: Kyleena (levonorgestrel-releasing intrauterine system), 19.5mg, NDC 50419042401.

2. **Include the appropriate ICD-10-CM diagnosis code(s) based on the patient’s condition.**

3. **Include the prior authorization number provided by the payer, if required.**

4. **Include the appropriate CPT and HCPCS codes.**

5. **Include the number of units. Typically, this will be 1.** Check with the payer or WHC Support Center for more information.

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For more information about accessing Kyleena, contact the WHC Support Center:

- **CALL 1-866-647-3646**
- **VISIT www.WHCSupport.com**

Please see important safety information on next page. For important information about Kyleena, please see the [full prescribing information.](#)
Indication and Important Safety Information

INDICATION FOR KYLEENA

Kyleena™ (levonorgestrel-releasing intrauterine system) 19.5 mg is indicated for the prevention of pregnancy for up to 5 years. Kyleena should be replaced after 5 years if continued use is desired.

IMPORTANT SAFETY INFORMATION ABOUT KYLEENA

Who is not appropriate for Kyleena

Use of Kyleena 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 neoplasia; 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.

Clinical considerations for use and removal of Kyleena

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

Pregnancy related risks with Kyleena

If pregnancy should occur with Kyleena in place, remove the intrauterine system because leaving it in place may increase the risk of spontaneous abortion and preterm labor. 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. 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 is 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 does 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.

Expect changes in bleeding patterns with Kyleena

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.

Because irregular bleeding/spotting is common during the first months of Kyleena use, exclude endometrial pathology (polyps or cancer) prior to the insertion of Kyleena in women with persistent or uncharacteristic bleeding. 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 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 Kyleena is essential in order to minimize serious infections, such as GAS.

Perforation (total or partial, including penetration/embedment of Kyleena in the uterine wall or cervix) may occur, most often during insertion, although the perforation may not be detected until sometime later. Perforation may reduce contraceptive efficacy. If perforation occurs, locate and remove Kyleena. Surgery may be required. Delayed detection or removal of Kyleena in case of perforation may result in migration outside the uterine cavity, adhesions, peritonitis, intestinal perforations, intestinal obstruction, abscesses, and erosion of adjacent viscera. The risk of perforation is higher if inserted in lactating women and may be higher if inserted in women who are postpartum or when the uterus is fixed retroverted.

Partial or complete expulsion of Kyleena may occur resulting in the loss of contraceptive protection. Delay insertion a minimum of six weeks or until uterine involution is complete following a delivery or second trimester abortion. Remove a partially expelled IUD. If expulsion has occurred, Kyleena may be replaced within 7 days after the onset of a menstrual period after pregnancy has been ruled out.

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

FOR IMPORTANT INFORMATION ABOUT KYLEENA, PLEASE SEE THE FULL PRESCRIBING INFORMATION.