

**SAMPLE KYLEENA® (levonorgestrel-releasing intrauterine system) 19.5mg  
LETTER OF MEDICAL NECESSITY**

[Date]

[Contact name – usually the health plan’s medical or pharmacy director][Title]

[Name of Health Insurance Company]

[Address]

[City, State, ZIP Code]

Insured: [First and Last Name]

Patient (if different from insured): [First and Last Name]

Patient Date of Birth: [Insert MM/DD/YEAR]

Policy Number: [Insert Number]

Group Number: [Insert Number]

Dear [Insert Contact Name]:

The intent of this letter is to provide additional medical information to support coverage of Kyleena® (levonorgestrel-releasing intrauterine system) 19.5 mg for my patient, [Insert Patient Name]. Kyleena is indicated for the prevention of pregnancy for up to 5 years<sup>1</sup>. This letter serves to document the medical necessity to use Kyleena® for my patient and provides information about her medical history and treatment.

***Patient History and Diagnosis***

My patient, [Insert Patient Name], is a [age]-year-old female seeking contraception in my office on [MM/DD/YEAR].

Kyleena is a progestin-containing intrauterine system (IUS) indicated for prevention of pregnancy for up to 5 years.<sup>1</sup>

[Provide a brief discussion of the patient’s relevant medical history].

Below, you can find additional information about Kyleena.

**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.

**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.

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<sup>1</sup> Kyleena [packageinsert]. Bayer Healthcare Pharmaceuticals, Inc.; Whippany, NJ: 2018.

**Please see Important Safety Information for Kyleena included in this letter.  
For important information about Kyleena, please see the [Full Prescribing Information](#).**

**SAMPLE KYLEENA® (levonorgestrel-releasing intrauterine system) 19.5mg**  
**LETTER OF MEDICAL NECESSITY**

***Product Information***

Kyleena is a progestin-containing intrauterine system (IUS) indicated for prevention of pregnancy for up to 5 years.

Kyleena contains 19.5 mg of levonorgestrel (LNG) released *in vivo* at a rate of approximately 17.5 mcg/day after 24 days. This rate decreases progressively to 9.8 mcg/day after 1 year and to 7.4 mcg/day after 5 years. The average *in vivo* release rate of LNG is approximately 9 mcg/day over a period of 5 years.

Kyleena must be removed by the end of the fifth year and can be replaced at the time of removal with a new Kyleena if continued contraceptive protection is desired.

**IMPORTANT SAFETY INFORMATION (cont'd)**

**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 (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**

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.

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**Clinical Studies**

The contraceptive efficacy of Kyleena was evaluated in a clinical trial that enrolled generally healthy women aged 18–35, of whom 1,452 received Kyleena. Of these, 40% (574) were nulliparous women, 870 (60%) women completed 3 years of the study, 707 (49%) elected to enroll in an extension phase up to a total of 5 years, and 550 (38%) completed 5 years of use. The trial was a multicenter, multi-national, randomized, open-label study conducted in 11 countries in Europe, Latin America, the US and Canada. Women less than six weeks postpartum, with a history of ectopic pregnancy, with clinically significant ovarian cysts or with HIV or otherwise at high risk for sexually transmitted infections were excluded. A total of 563 (39%) were treated at US sites and 889 (61%) were at non-US sites. The racial demographics of enrolled women who received Kyleena was: Caucasian (80%), Black/African American (5.1%), Other (2.6%) and Asian (1.2%); 11% indicated Hispanic ethnicity. The clinical trial had no upper or lower weight or BMI limit. The weight range was 38 to 173 kg (mean weight: 68.7 kg) and mean BMI was 25.3 kg/m<sup>2</sup> (range 15.2 –57.6 kg/m<sup>2</sup>). Of Kyleena-treated women, 22% discontinued the study treatment due to an adverse reaction, 5.0% were lost to follow-up, 2.3% withdrew for unspecified reasons, 1.2% discontinued due to a protocol deviation, 0.9% discontinued due to pregnancy, and 20% discontinued due to other reasons.

The pregnancy rate calculated as the Pearl Index (PI) in women aged 18 –35 years was the primary efficacy endpoint used to assess contraceptive reliability. The PI was calculated based on 28 -day equivalent exposure cycles; evaluable cycles excluded those in which back-up contraception was used unless a pregnancy occurred in that cycle. The Year 1 PI was based on 2 pregnancies and the cumulative 5-year pregnancy rate was based on 13 pregnancies that occurred after the onset of treatment and within 7 days after Kyleena removal or expulsion.

**Pearl Indices by Year and 5-Year Cumulative Pregnancy Rate**

Kyleena Clinical Trial	Pearl Index					Cumulative 5-Year Kaplan Meier Rate
	Year 1	Year 2	Year 3	Year 4	Year 5	
Number of Evaluable 28-day Cycles of Exposure	16,207	13,853	11,610	8,556	7,087	57,313
Pregnancy Rate (95% Confidence Interval)	0.16 (0.02, 0.58)	0.38 (0.10, 0.96)	0.45 (0.12, 1.15)	0.15 (0.00, 0.85)	0.37 (0.04, 1.33)	1.45 (0.82, 2.53)

**IMPORTANT SAFETY INFORMATION (cont'd)**

**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.

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**IMPORTANT SAFETY INFORMATION (cont'd)**

**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 may be increased if inserted when the uterus is not completely involuted or fixed retroverted. A postmarketing safety study over a 1-year observational period reported that lactation at the time of insertion of an IUS/IUD was associated with an increased risk of perforation. In this study, for users of another LNG-releasing IUS, the incidence of uterine perforation was reported as 6.3 per 1,000 insertions for lactating women, compared to 1.0 per 1,000 insertions for non-lactating women.

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 a second trimester abortion. Remove a partially expelled IUD. If expulsion has occurred, a new Kyleena 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 ( $\geq 5\%$ ) 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.

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If you have any additional questions, please feel free to contact me at [Healthcare Practitioner's Phone Number, including area code] or [Healthcare Practitioner's Email Address] to discuss.

Thank you in advance for your immediate attention to this request.

Sincerely,

[Healthcare Practitioner's Name and Credentials]

[Healthcare Practice Name]

Attachments [Original claim form, copy of denial or explanation of benefits, FDA approval letter, Kyleena prescribing information, product invoice, additional supporting documents]