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

Bayer Women's HealthCare Support Specialty Pharmacy Prescription Request Form

Select Choice of Specialty Pharmacies

Specialty Pharmacy		Fax	Phone	Hours of Operation
❑ CVS Specialty (In the Continental US)	United Health Care & Aetna Insurance	(866) 216-1681	(866) 638-8312	8:30 AM - 8:30 PM ET
❑ CVS Specialty (In Hawaii-Neighbor Islands)		(877) 232-5455	(800) 896-1464	8:30 AM - 8:30 PM HT
❑ CVS Specialty (In Hawaii-Oahu)		(808) 254-4445	(808) 254-2727	8:30 AM - 8:30 PM HT
❑ Prime Therapeutics	Blue Cross Blue Shield Insurance	(877) 684-8854	(855) 457-0170	8:00 AM - 8:00 PM ET
❑ Walgreens		(800) 830-5292	(877) 686-4633	8:00 AM - 8:00 PM ET
❑ Cigna Specialty Pharmacy Services	Cigna Insurance	(800) 351-3616	(800) 351-3606	6:00 AM - 12:00 AM ET
❑ Humana Specialty Pharmacy	Humana	(877) 405-7940	(800) 486-2668	8:00 AM - 8:00 PM ET
❑ Magellan Rx		(866) 364-2673	(866) 554-2673	8:00 AM - 7:00 PM ET
❑ Skyemed Pharmacy & Infusion Services (Tricare)		(866) 398-2988	(866) 778-8255	7:00 AM - 7:00 PM ET

Patient Information

Last Name: Patient must complete this section First Name: _____ MI: _____ DOB: _____

Address: _____ City: _____ State: _____ ZIP Code: _____

Phone: _____ Alternate Phone: _____ Primary Language: _____ Gender: _____

Prescription Information

By submitting this prescription request form, prescriber and patient are aware that the Specialty Pharmacy will ship upon verification of benefits and collection of applicable co-pay. If there is a zero-dollar co-pay, patient may not be contacted. The Specialty Pharmacy will ship to prescriber's office, and will not contact prescriber before shipping.

■ Rx Kyleena™

Kyleena (ICD-10): ❑ Z30.430

Other (List ICD-10): _____

SIG: To be inserted one time by prescriber.

Route intrauterine

Quantity: 1

- Date of last menses: _____
- List Allergies: _____
- Requested Date of Delivery: _____
- Scheduled Insertion Date: _____
- Product Substitution Permitted (Signature) Date

_____

Dispense as Written (Signature) Date

_____

❑ I have previously received an IUS Educational Kit

❑ I would like to receive an IUS Educational Kit

- For ARNP, NP, and PA, collaborative physician agreement is with: _____

■ Rx Mirena®

Mirena (ICD-10): ❑ Z30.430 ❑ N92.0 ❑ N92.4

Other (List ICD-10): _____

SIG: To be inserted one time by prescriber.

Route intrauterine

Quantity: 1

- Date of last menses: _____
- List Allergies: _____
- Requested Date of Delivery: _____
- Scheduled Insertion Date: _____
- Product Substitution Permitted (Signature) Date

_____

Dispense as Written (Signature) Date

Dr. Signature

❑ I have previously received an IUS Educational Kit

❑ I would like to receive an IUS Educational Kit

- For ARNP, NP, and PA, collaborative physician agreement is with: _____

■ Rx Skyla®

Skyla (ICD-10): ❑ Z30.430

Other (List ICD-10): _____

SIG: To be inserted one time by prescriber.

Route intrauterine

Quantity: 1

- Date of last menses: _____
- List Allergies: _____
- Requested Date of Delivery: _____
- Scheduled Insertion Date: _____
- Product Substitution Permitted (Signature) Date

_____

Dispense as Written (Signature) Date

Dr. Signature

❑ I have previously received an IUS Educational Kit

❑ I would like to receive an IUS Educational Kit

- For ARNP, NP, and PA, collaborative physician agreement is with: _____

Prescriber Information

Prescriber Name (Last, First): _____ Title (please check one) ❑ MD ❑ DO ❑ NP ❑ PA

Office Contact: _____ Phone: _____ Fax: _____

Address: _____ City: _____ State: _____ ZIP Code: _____

Ship to address if different from above: _____ DEA #: _____

Group or Hospital: _____ Physician Medicaid #: _____ License #: _____ NPI #: _____

If covered through Buy and Bill, Physician ❑ will accept Buy and Bill coverage.

Please see Important Safety Information for Kyleena, Mirena and Skyla on third page and accompanying full Prescribing Information for Kyleena, Mirena and Skyla.

Patient Insurance Information

(Please copy and attach the front and back of medical and prescription insurance cards - Send with request)

Patient has no insurance and/or does not want insurance billed. Request self-pay option ❑

Also Attach Insurance Card

Prescription Insurance: Insurance Information Here
Phone: _____
Subscriber #: _____ Group #: _____
Policy Holder Information (if different from patient)
Name: _____ Employer: _____
Relation to Patient: _____

Medical Insurance: _____
Phone: _____
Subscriber #: _____ Group #: _____
Policy Holder Information (if different from patient)
Name: _____ Employer: _____
Relation to Patient: _____

PLEASE FAX THE PRESCRIPTION REQUEST FORM, INCLUDING THE SIGNED PATIENT AUTHORIZATION SECTION ON PAGE 4.

Please see Important Safety Information for Kyleena™, Mirena® and Skyla® on next page and accompanying full Prescribing Information for Kyleena, Mirena and Skyla.

The Specialty Pharmacy Program prescription process

To order Kyleena, Mirena or Skyla, complete the Specialty Pharmacy Prescription Request Form as follows:

1. Select Specialty Pharmacy.
2. Enter the patient and prescriber information in the space provided on the Specialty Pharmacy Prescription Request Form, including the patient's pharmacy drug benefit and medical insurance information.
   - Please ensure that all information is complete
   - Include copies of the patient's pharmacy benefit and medical insurance cards
   - Prescriber information (complete this information and then photocopy the form for future use)
3. Complete the prescription section.
   - Indicate if Kyleena, Mirena or Skyla will be administered
   - Indicate appropriate diagnosis code
   - Sign the prescription
   - For ARNP, NP, and PA, identify who your collaborative agreement is with if requested to write prescriptions in your state
4. Have the patient read and sign the Patient Authorization section of the form and fax it to the appropriate SP with the SP request form.
5. Finalize the prescription request and prepare for your patient's Kyleena, Mirena or Skyla insertion.
   a. Fax the completed Prescription Form, including the Patient Authorization section, to either CVS Specialty (Continental US 1-866-216-1681; Hawaii-Neighbor Islands 1-877-232-5455; Hawaii-Oahu 1-808-254-4445), Prime Therapeutics 1-877-684-8854, Walgreens 1-800-830-5292, Cigna 1-800-351-3616, Humana 1-877-405-7940, Magellan Rx 1-866-364-2673, or Skyemed 1-866-398-2988. For questions call 1-866-638-8312 for CVS Specialty in the Continental US, 1-800-896-1464 in Hawaii-Neighbor Islands, and 1-808-254-2727 in Hawaii-Oahu; 1-855-457-0170 for Prime Therapeutics; 1-877-686-4633 for Walgreens; 1-800-351-3606 for Cigna; 1-800-486-2668 for Humana; 1-866-554-2673 for Magellan Rx; and 1-866-778-8255 for Skyemed.
   b. Bill the patient's insurance for the procedure and your customary professional services charges only.

To find out more about the Specialty Pharmacy Program or to request prescription forms, contact your Bayer Sales Consultant or visit our website at www.whcsupport.com for more information.

Please see Important Safety Information for Kyleena, Mirena and Skyla on third page and accompanying full Prescribing Information for Kyleena, Mirena and Skyla.

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.

INDICATIONS FOR MIRENA

Mirena® (levonorgestrel-releasing intrauterine system) 52 mg is indicated for intrauterine contraception for up to 5 years. Mirena is also indicated to treat heavy menstrual bleeding in women who choose to use intrauterine contraception as their method of contraception. Mirena is recommended for women who have had a child. Mirena should be replaced after 5 years if continued use is desired.

INDICATION FOR SKYLA

Skyla® (levonorgestrel-releasing intrauterine system) 13.5 mg is indicated for the prevention of pregnancy for up to 3 years. Skyla should be replaced 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 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, 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. 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.

Because irregular bleeding/spotting is common during the first months of Kyleena, Mirena or Skyla use, exclude endometrial pathology (polyps or cancer) prior to the insertion of the IUD 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, 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. Perforation may reduce contraceptive efficacy. 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. 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 Mirena users, 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, Mirena or Skyla 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, Kyleena, Mirena or Skyla 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%).
- 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%).
- 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 see the accompanying Full Prescribing Information

For important information about Mirena, please see the accompanying Full Prescribing Information

For important information about Skyla, please see the accompanying Full Prescribing Information

Please see accompanying full Prescribing Information for Kyleena, Mirena and Skyla.

Patient Authorization

I authorize the use and/or disclosure of my private health information, described below, which may include "Protected Health Information" or "PHI" as defined by the Health Insurance Portability and Accountability Act of 1996 (as amended, "HIPAA"). In general terms, I understand that Protected Health Information is health information that identifies me or that could reasonably be used to identify me. I understand that this authorization is voluntary.

I authorize my healthcare providers, including my physicians, pharmacies, and my health plan insurers to share my name, address, and phone number along with my prescription, medical diagnosis, treatment, and insurance information with Bayer and its agents and contractors. These agents include a company that provides reports to Bayer on sales of Kyleena™, Mirena® and Skyla® and a company that provides quality control and checks the accuracy of reports on sales of Kyleena, Mirena or Skyla (collectively "Bayer").

I understand that certain healthcare providers, such as my pharmacies, may receive payment from Bayer in connection with the disclosure of my PHI as described in this authorization.

I allow the use of my PHI and the sharing of my PHI to: 1) communicate with me, my healthcare providers, and health plans about my medical care, including treatment with Kyleena, Mirena or Skyla; 2) provide information on coverage and reimbursement of Kyleena, Mirena or Skyla to me and my healthcare providers; 3) facilitate returns of Kyleena, Mirena or Skyla; 4) be used for sales purposes, including to evaluate healthcare provider prescribing patterns; and 5) comply with applicable law.

I understand that any personal information provided on this form will not be used for any purposes other than those described above unless I give written consent, or it is required or permitted under the law, and my name and all other identifying information is removed.

This authorization will remain in effect for 1 year after the date I sign it and will expire after 1 year unless I revoke it prior to this time. I can withdraw (ie, take back) this authorization earlier by sending a written request to Bayer Healthcare Pharmaceuticals, Attn: Medical Communications, 100 Bayer Boulevard, Whippany, NJ 07981 (Fax# 973-305-3560), except to the extent my healthcare provider or health plan has taken action in reliance on my authorization. I understand that if I revoke this authorization, it will not have any effect on any actions my healthcare providers or my health plan may have taken before receiving the revocation, and will not affect Bayer's ability to use and disclose any information it has already received.

I also understand that persons or entities that receive my PHI under this authorization may not be required by privacy laws (such as the HIPAA Privacy Rule) to protect the information and may share it with others without my permission, if permitted by laws applicable to them.

I may refuse to sign this form, and refusal will not affect my treatment, payment for treatment, enrollment in a health plan, or eligibility for benefits.

I have read this entire authorization and/or had its contents read to me. I have had an opportunity to ask questions about the uses and disclosures of PHI described above, and all of my questions have been answered to my satisfaction. I authorize the use and disclosure of my information as described in this form. I understand that I am entitled to receive a signed copy of this authorization.

Patient must always print name

Printed name of Individual or Individual's representative — Date

Patient must always sign here

Signature of Individual or Individual's representative — Date

If signed by the Individual's representative, a description of the representative's relationship to the Individual and such person's authority to act for the Individual (eg, parent, guardian, etc)

PLEASE FAX THE PRESCRIPTION REQUEST FORM, INCLUDING THE SIGNED PATIENT AUTHORIZATION SECTION ON THIS PAGE.

Please see Important Safety Information for Kyleena, Mirena or Skyla on third page and accompanying full Prescribing Information for Kyleena, Mirena and Skyla.