Skyla® (levonorgestrel-releasing intrauterine system) 13.5 mg

Bayer® Women's HealthCare Support
Specialty Pharmacy Prescription Request Form

Mirena® (levonorgestrel-releasing intrauterine system) 20 mcg per day

Specialty Pharmacies

Specialty Pharmacy	Fax	Phone	Hours of Operation
❑ CVS Caremark (In the Continental US)	(866)-216-1681	(866)-638-8312	8:30 AM - 8:30 PM ET
❑ CVS Caremark (In Hawaii-Neighbor Islands)	(877)-232-5455	(800)-896-1464	8:30 AM - 8:30 PM HT
❑ CVS Caremark (In Hawaii-Oahu)	(808)-254-4445	(808)-254-2727	8:30 AM - 8:30 PM HT
❑ Prime Therapeutics	(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

Patient Information

Last Name: _____ First Name: _____ MI: _____ Primary Language: _____

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

Phone: _____ Alternate Phone: _____ DOB: _____ 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 Skyla®

Skyla ICD-9: ❑ V25.11

Other (List ICD-9): _____

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 a Skyla Educational Kit ❑ Yes

I would like to receive a Skyla Educational Kit ❑ Yes

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

_____

❑ Rx Mirena®

Mirena ICD-9: ❑ V25.11 ❑ 626.2 ❑ 627.0

Other (List ICD-9): _____

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 a Mirena Educational Kit ❑ Yes

I would like to receive a Mirena Educational Kit ❑ Yes

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.

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 ❑

Prescription Insurance: _____

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 3.

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

www.WHCSupport.com

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The Specialty Pharmacy Program prescription process

To order Skyla® or Mirena®, 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 Skyla or Mirena 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 Skyla or Mirena insertion.
   a. Fax the completed Prescription Form, including the Patient Authorization section, to either CVS Caremark (Continental US 1-866-216-1681; Hawaii -Neighbor Islands 1-877-232-5455; Hawaii-Oahu 1-808-254-4445), Walgreens (1-800-830-5292), or Prime Therapeutics (1-877-684-8854). For questions call 1-866-638-8312 for CVS Caremark in the Continental US, 1-800-896-1464 in Hawaii-Neighbor Islands, and 1-808-254-2727 in Hawaii-Oahu; 1-877-686-4633 for Walgreens; and 1-855-457-0170 for Prime Therapeutics.
   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.

Indication for Skyla

Skyla 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

Know who is not appropriate for Skyla

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 Skyla.

Clinical considerations for use and removal

Use Skyla with caution after careful assessment in patients with coagulopathy or who are 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 Skyla if these or the following arise during use: uterine or cervical malignancy or jaundice. If Skyla is displaced (eg, expelled or perforated the uterus), remove it. Skyla can be safely scanned with MRI only under specific conditions.

Pregnancy related risks with Skyla

If pregnancy should occur with Skyla in place, remove Skyla 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 Skyla. 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

IUDs have been associated with an increased risk of PID, most likely due to organisms being introduced into the uterus during insertion. 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); Skyla does not protect against STIs, including HIV. In Skyla clinical trials, PID occurred more frequently within the first year and most often within the first month after insertion.

Expect changes in bleeding patterns

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.

Be aware of other serious complications and most common adverse reactions

Some serious complications with IUDs like Skyla are expulsion, sepsis, and perforation. Perforation may reduce contraceptive efficacy. 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.

Ovarian cysts may occur and are generally asymptomatic but may be accompanied by pelvic pain or dyspareunia. Evaluate persistent enlarged ovarian cysts.

The most common adverse reactions (≥5%) 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 and then yearly or more often if clinically indicated.

Indication for Mirena

Mirena 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.

Important Safety Information

Know who is not appropriate for Mirena

Mirena is contraindicated in women with known or suspected: pregnancy; congenital or acquired uterine anomaly including fibroids if they distort the uterine cavity; breast carcinoma; uterine or cervical neoplasia; unresolved, abnormal Pap smear; liver disease including tumors; untreated acute cervicitis or vaginitis, including lower genital tract infections (e.g., bacterial vaginosis) until infection is controlled; postpartum endometritis or infected abortion in past 3 months; unexplained vaginal bleeding; current IUD; acute pelvic inflammatory disease (PID) or history of PID (except with later intrauterine pregnancy); or conditions increasing susceptibility to pelvic infections.

Use with caution in patients with certain conditions

In patients with certain types of valvular or congenital heart disease and surgically constructed systemic-pulmonary shunts, Mirena increases risk of infective endocarditis and may be a source of septic emboli. Give appropriate antibiotics at insertion and removal to patients with known congenital heart disease who may have higher risk. Monitor for infections any patient on chronic corticosteroid therapy or insulin for diabetes.

Use Mirena with caution 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.

In the event of pregnancy

If pregnancy should occur with Mirena in place, Mirena should be removed. Removal or manipulation may result in pregnancy loss. Up to half the pregnancies that occur with Mirena in place are ectopic. Tell women about the risks of ectopic pregnancy 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

Prior to insertion, 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 diseases (STDs); Mirena does not protect against STDs, including HIV. The highest risk of PID occurs shortly after insertion (usually within the first 20 days).

Expect changes in bleeding patterns

Expect spotting and irregular/heavy bleeding for 3-6 months, then shorter, lighter periods. Cycles may remain irregular and become infrequent and may cease. Consider pregnancy if menstruation does not occur within 6 weeks of the onset of previous menstruation.

Be aware of other serious complications and most common adverse reactions

Some serious complications with IUDs like Mirena are expulsion, sepsis, myometrial embedment and uterine or cervical perforation. 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.

Ovarian cysts may occur and are generally asymptomatic but may be accompanied by pelvic pain or dyspareunia. Evaluate persistent enlarged ovarian follicles.

The most common adverse reactions (>10%) are uterine/vaginal bleeding alterations (51.9%), amenorrhea (23.9%), intermenstrual bleeding and spotting (23.4%), abdominal/pelvic pain (12.8%) and ovarian cysts (12%).

Teach patients to recognize and immediately report signs or symptoms of the aforementioned conditions. Evaluate patients 4-12 weeks after insertion and then yearly or more often if clinically indicated.

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See accompanying full Prescribing Information for Skyla and Mirena.
http://labeling.bayerhealthcare.com/html/products/pi/Skyla_PI.pdf
http://labeling.bayerhealthcare.com/html/products/pi/Mirena_PI.pdf

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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 Skyla and Mirena and a company that provides quality control and checks the accuracy of reports on sales of Skyla and Mirena (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 Skyla or Mirena; 2) provide information on coverage and reimbursement of Skyla or Mirena to me and my healthcare providers; 3) facilitate returns of Skyla or Mirena; 4) for sales purposes, including to evaluate healthcare provider prescribing patterns; and 5) comply with applicable law.

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 (i.e., take back) this authorization earlier by writing to Bayer Healthcare Pharmaceuticals, Attn: Medical Communications, 100 Bayer Boulevard, Whippany, NJ 07981, 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.

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 both pages of this 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.

_____

Printed name of Individual or Individual's representative — Date

_____

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 (e.g., parent, guardian, etc.)

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

Please see Important Safety Information for Skyla and Mirena on second page and accompanying full Prescribing Information for Skyla and Mirena.
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