Skyla®
(levonorgestrel-releasing intrauterine system) 13.5 mg

Mirena®
(levonorgestrel-releasing intrauterine system) 52 mg

Bayer Women's HealthCare Support Benefit Investigation Request Form

Reimbursement Support Program Phone: (866) 647-3646, option 1 for Mirena® or option 2 for Skyla®; then option 1 for HCP; then option 2 for BI; Fax: (877) 946-1000

Physician Information

Licensed Physician Name: _____
Tax ID #: _____ DEA: _____
State License #: _____
State of License: _____
NPI #: _____
Medicaid ID #: _____
Payer-Specific Provider #: _____

Practice Information

Site Name: _____
Address: _____
City: _____ State: _____ ZIP: _____
Phone: _____ Fax: _____
Office Contact: _____
Best Time to Call: _____

Product Selection/Diagnosis Code

Check all that apply

❒ **Skyla**
❒ V25.11 (Z30.430) ❒ Other: _____

❒ **Mirena**
❒ V25.11 (Z30.430) ❒ 626.2 (N92.0) ❒ 627.0 (N92.4)

Other: _____ Insertion Date: _____

Patient Information

Name: _____
Date of Birth: _____
Address: _____
City: _____
State: _____ ZIP: _____
Phone: _____

Patient Insurance

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

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

Authorizations

Healthcare Provider (please check the appropriate box)

❒ I certify that Skyla therapy is medically necessary and that this information is accurate to the best of my knowledge. I authorize Lash Group, Inc. in its capacity on behalf of Bayer HealthCare Pharmaceuticals ("Lash Group") to be my designated agent and to act as my business associate (as defined in 45 CFR 160.103) to use and disclose any information in this form to the insurer of the above-named patient and to obtain any information about the patient, including any protected health information (as defined in 45 CFR 160.103), from the insurer, including eligibility and other benefit coverage information, for my payment and/or healthcare operation purposes. As my business associate, Lash Group is required to comply with, and by its signature hereto, agrees that it will comply with the applicable requirements of 45 CFR 164.504(e) regarding business associates, and that it will safeguard any protected health information that it obtains on my behalf, and will use and disclose this information only for the purposes specified herein or as otherwise permitted by law.

❒ I certify that Mirena therapy is medically necessary and that this information is accurate to the best of my knowledge. I authorize Lash Group, Inc. in its capacity on behalf of Bayer HealthCare Pharmaceuticals ("Lash Group") to be my designated agent and to act as my business associate (as defined in 45 CFR 160.103) to use and disclose any information in this form to the insurer of the above-named patient and to obtain any information about the patient, including any protected health information (as defined in 45 CFR 160.103), from the insurer, including eligibility and other benefit coverage information, for my payment and/or healthcare operation purposes. As my business associate, Lash Group is required to comply with, and by its signature hereto, agrees that it will comply with the applicable requirements of 45 CFR 164.504(e) regarding business associates, and that it will safeguard any protected health information that it obtains on my behalf, and will use and disclose this information only for the purposes specified herein or as otherwise permitted by law.

Healthcare Provider Signature: _____ Date: _____

Lash Group Signature: _____ Date: _____

Patient

I authorize the Skyla or Mirena Reimbursement Support Programs to obtain information from my healthcare provider, insurance company, and other sources as deemed necessary to ensure the accuracy and completeness of understanding my coverage for Skyla or Mirena.

Patient Signature: _____ Date: _____

www.WHCSupport.com

Please see Important Safety Information for Skyla and Mirena on page 2 and full Prescribing Information for Skyla and Mirena.

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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.

Indications 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. Mirena should be replaced after 5 years if continued use is desired.

IMPORTANT SAFETY INFORMATION ABOUT SKYLA AND MIRENA

Who is not appropriate for Skyla and Mirena

Use of Skyla or Mirena 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 or Mirena.

Clinical considerations for use and removal of Skyla and Mirena

Use Skyla or Mirena 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 Skyla or Mirena is displaced (e.g., expelled or perforated the uterus), remove it.

In addition, Skyla can be safely scanned with MRI only under specific conditions.

Pregnancy related risks with Skyla and Mirena

If pregnancy should occur with Skyla or Mirena 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 Skyla or Mirena. 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 and Mirena do not protect against STIs, including HIV.

In clinical trials with:

- Skyla – 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.

Expect changes in bleeding patterns with Skyla and Mirena

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 and Mirena 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.

In clinical trials with:

- 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%).
- Mirena – adverse reactions reported in ≥5% of users were alterations of menstrual bleeding patterns [including unscheduled uterine bleeding (31.9%), decreased uterine bleeding (23.4%), and increased uterine bleeding (11.9%)], 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%), dysmenorrhea (6.4%), and depression/depressive mood (6.4%).

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

www.WHCSupport.com

Please see full Prescribing Information for Skyla and Mirena.

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Using the Bayer Women's HealthCare Support Center Hotline

The Bayer Women's HealthCare Support Center Hotline can assist you in determining your patients' coverage for Skyla® and Mirena® as well as the insertion procedure. There are 3 options in using the Bayer Women's HealthCare Support Center Hotline:

Call toll-free 1-866-647-3646, option 1 for Mirena or option 2 for Skyla; then option 1 for HCP; then option 2 for BI, and speak to a representative between 8:00 AM and 8:00 PM ET, Monday through Friday

OR

Complete the Benefit Investigation Request Form and fax it (toll-free) to 1-877-946-1000

OR

Visit www.WHCSupport.com

1. Collect Patient and Healthcare Provider Information

In the space provided on the Benefit Investigation Request Form:

- Healthcare provider's name, address, phone, tax ID, DEA #, state license #, and NPI # (this can be entered once and the form photocopied to streamline future requests)
- Patient name, address, phone number, and scheduled insertion date (if known)
- Patient insurance information

2. Submit the Benefit Investigation Request Form via Fax: 1-877-946-1000

A reimbursement specialist will call your office to verify receipt of the form and will verify your patient's coverage and benefits. The Skyla and Mirena Support Center Hotline will fax your office a summary of the coverage and benefits as soon as it is completed, usually within a few days. The Summary of Benefits will indicate whether the patient has coverage for Skyla or Mirena through the pharmacy or medical benefit, coverage for the insertion procedure, and the codes that should be used to bill.

3. Select Option for Ordering Skyla or Mirena

Your ordering options may be determined by the specifics of your patient's insurance plan:

- If Skyla or Mirena is covered through the pharmacy benefit, the Skyla or Mirena Specialty Pharmacy Program can bill the insurer for Skyla or Mirena. The healthcare provider should bill for the insertion procedure using code CPT 58300. The Skyla or Mirena Specialty Pharmacy Program will request a prescription from the healthcare provider, collect any required co-payment from the patient, label the product for the patient, and ship to the prescriber's office
- If Skyla or Mirena is covered through the medical benefit, the healthcare provider should purchase Skyla or Mirena at the wholesale price and bill using codes J7301 for Skyla, J7298 for Mirena, and CPT 58300 for the insertion
- If the patient does not have coverage for Skyla or Mirena, she may still choose to purchase out-of-pocket at the retail price. The healthcare provider will need to provide a prescription to the Skyla or Mirena Specialty Pharmacy Program that will then collect payment from the patient for Skyla or Mirena and ship the product to the prescriber's office. The healthcare provider should bill for the insertion procedure using code CPT 58300

4. Underpaid or Denied Claims

Although rare, occasionally a claim for Skyla or Mirena is denied or underpaid. The Skyla and Mirena Support Center Hotline is available to help. Fax a copy of the insurer's Explanation of Benefits (EOB) and a copy of your original claim to the Skyla and Mirena Support Center Hotline at 1-877-946-1000 so that we can contact the insurer to inquire about the issue. In situations where the claim needs to be formally appealed, the Skyla and Mirena Support Center Hotline will provide the healthcare provider's office with a sample letter of appeal that can be printed on the healthcare provider's letterhead for submission to the insurer.

Please see Important Safety Information for Skyla and Mirena on page 2 and full Prescribing Information for Skyla and Mirena.