COMPASS GUIDE

A comprehensive resource for bringing **Kyleena®**, **Mirena®** and **Skyla®** into your practice

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STOP

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Please see Important Safety Information on pages 2-4, and click to see the Full Prescribing Information for Kyleena, Mirena and Skyla.

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

INDICATIONS 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. Replace the system after 5 years if continued use is desired.

INDICATIONS FOR MIRENA

Mirena® (levonorgestrel-releasing intrauterine system) 52 mg is indicated for prevention of pregnancy for up to 7 years; replace after the end of the seventh year. Mirena is indicated for the treatment of heavy menstrual bleeding for up to 5 years in women who choose to use intrauterine contraception as their method of contraception; replace after the end of the fifth year if continued treatment of heavy menstrual bleeding is needed.

INDICATION FOR SKYLA

Skyla® (levonorgestrel-releasing intrauterine system) 13.5 mg is indicated for the prevention of pregnancy for up to 3 years. Replace the system 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 malignancy; 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. Advise her of isolated reports of virilization of the female fetus following local exposure to LNG during pregnancy with an LNG IUS in place. 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.

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INDICATIONS AND IMPORTANT SAFETY INFORMATION (CONTINUED)

IMPORTANT SAFETY INFORMATION ABOUT KYLEENA, MIRENA AND SKYLA (continued)

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.

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.

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INDICATIONS AND IMPORTANT SAFETY INFORMATION (CONTINUED)

IMPORTANT SAFETY INFORMATION ABOUT KYLEENA, MIRENA AND SKYLA (continued)

Be aware of other serious complications and most common adverse reactions (continued)

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. The risk of uterine perforation is increased in women who have recently given birth, and in women who are breastfeeding at the time of insertion. In a large US retrospective, postmarketing safety study of IUDs, the risk of uterine perforation was highest when insertion occurred within ≤6 weeks postpartum, and also higher with breastfeeding at the time of insertion. The risk of perforation may be increased if inserted when the uterus is fixed, retroverted or not completely involuted. 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. In addition, perforation may reduce contraceptive efficacy and result in pregnancy.

Partial or complete expulsion of Kyleena, Mirena or Skyla may occur resulting in the loss of contraceptive protection. The risk of expulsion is increased with insertions immediately after delivery and appears to be increased with insertion after second-trimester abortion based on limited data. In the same postmarketing study, the risk of expulsion was lower with breastfeeding status. Remove a partially expelled IUD. If expulsion has occurred, a new Kyleena, Mirena or Skyla 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 (≥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%).
  - A separate study with 362 women who have used Mirena for more than 5 years showed a consistent adverse reaction profile in Years 6 and 7. By the end of Year 7 of use, amenorrhea and infrequent bleeding are experienced by 28% and 26% of users, respectively; irregular bleeding occurs in 12%, frequent bleeding in 8%, and prolonged bleeding in 2% of users. In this study, 6% of women reported the adverse event of weight gain, it is unknown if the weight gain was caused by Mirena.
- 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.

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COMPASS GUIDE: OVERVIEW

This Compass Guide will help you navigate the ordering and billing process of Kyleena, Mirena and Skyla.

In addition, we've included information on account resources that may help your patients and your practice.

The Compass Guide also includes:

- General coverage, coding, and reimbursement resources
- Helpful guidance for appealing denied claims

While this content supports the filing of claims, it does not guarantee payment. Patient information varies, so it is important to research specific coverage and payment policies. Make sure to submit accurate claims and comply with obligations required by law, contract, or otherwise.

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HEALTH INSURANCE COVERAGE

Commercial Insurance

Medicaid

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HEALTH INSURANCE COVERAGE:
COMMERCIAL INSURANCE

Kyleena, Mirena, Skyla, and insertion-related medical services are covered by many plans:

- Most frequently covered as a medical benefit since administration occurs in the healthcare provider's office but may be covered as a pharmacy benefit in some cases
- Product and service coverage may vary by the payer, the plan, and the employer group

Steps to Verifying Your Patient's Coverage

STEP 1

Verify your patient's benefits to determine coverage and billing requirements before scheduling an insertion.

Employer Benefit Selection Process

STEP 2

Have your office directly contact the patient's health insurance provider with the number on their insurance card.

- Ask to check Kyleena, Mirena and/or Skyla coverage under **both** medical and pharmacy benefits
- Ask if the products are covered **as preventative services** under the patient's plan
- Request confirmation on the patient's financial responsibility, including **co-pay, coinsurance, and/or deductible**
- For high-deductible plans, confirm the amount of deductible already met and if the **products' costs can apply**

Get All Billing Codes

STEP 3

Confirm coverage and payment levels for all codes that will be billed, including the insertion procedure**.**

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HEALTH INSURANCE COVERAGE:
MEDICAID

State Medicaid programs offer coverage for contraceptives, but eligibility guidelines may vary. As a result, some women will experience restricted access to Kyleena, Mirena and Skyla.

That is why your office should verify coverage for Medicaid patients prior to treatment like you would with private payers.

Among women enrolled in Medicaid managed care organizations (MCOs), coverage for Kyleena, Mirena and Skyla will be based on the specific policies of that Medicaid MCO.

Get All Billing Codes

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TWO WAYS TO ORDER

Option 1: Buy and Bill

Option 2: Specialty Pharmacy (SP)

TWO WAYS TO ORDER

OPTION 1: BUY AND BILL

OPTION 1: "Buy and Bill" through WHC Support Center

Order Kyleena, Mirena and Skyla after confirming your distributor

- AmerisourceBergen Specialty Distributor (ASD)
- Bayer Direct

Visit the secure website for:

Ordering Kyleena, Mirena and Skyla

Check your account status—more info here

Complete order by your choice:

Online (ASD only)

Phone

Fax

Email

Talk to trained Customer Service Representatives toll free

For your patients

For your practice

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TWO WAYS TO ORDER

OPTION 2: SPECIALTY PHARMACY (SP)

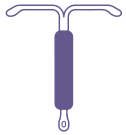
OPTION 2: Specialty Pharmacy (SP) Program

Fill out **SP Prescription Request Form** and select one of the SPs indicated in the Pharmacy check box

Fax completed Form and signed Patient Authorization to the right SP—be sure to include patient insurance information

SP verifies coverage, bills the insurance company, and collects any applicable out-of-pocket costs

No need to collect Kyleena, Mirena and Skyla co-pays—submit only clinical service fees related to intrauterine device insertion



SP helps eliminate out-of-pocket expenses related to Kyleena, Mirena and Skyla inventory maintenance

This option features one form for all payers for a simple ordering process

Coverage is patient-specific—not all plans cover Kyleena, Mirena and Skyla through the SP channel.

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ORDERING THROUGH BUY AND BILL

AmerisourceBergen Specialty Distributor (ASD) Accounts

Bayer Direct

FAQ

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ORDERING THROUGH BUY AND BILL:

ASD ACCOUNTS

PRODUCT ORDERING AVAILABLE THROUGH 4 DIFFERENT OPTIONS

1 TO ORDER BY PHONE,
call 1-866-647-3646

2 TO ORDER BY EMAIL,
click asd.customerservice@asdhealthcare.com

3 TO ORDER ONLINE,
visit www.whcsupport.com to sign into ASD's ordering portal

4 TO ORDER BY FAX,
dial 1-888-281-8199

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ORDERING THROUGH BUY AND BILL:

ASD ACCOUNTS (CONTINUED)

6 STEPS TO CREATING YOUR ASD ACCOUNT

Setting up an account will let you place your orders online for Kyleena, Mirena and Skyla and access other important site features.

STEP 1: Go to **asdhealthcare.com***

STEP 2: Click "**Log In**" and then click on "**Create a website log in here**"

STEP 3: Enter your ASD Account Number(s) and validate account

STEP 4: Create a username and select "**Validate User**"

STEP 5: Complete the short questionnaire

STEP 6: Agree to Terms & Conditions and submit

All submitted requests must be reviewed by and approved by the ASD Web Administrator and are processed within 24 business hours.

Once your request is approved, you will be sent a confirmation e-mail with a log-in reminder. You will not be able to log on or reset your password until you receive this e-mail message.

For new customers or inquiries about your account, e-mail whsales@asdhealthcare.com. **To place your orders,** e-mail Asd.customerservice@asdhealthcare.com

If you need to confirm your distributor, please contact your Bayer Sales Representative.

*Bayer is not responsible for the content presented by any independent website, including any advertising claims, special offers, illustrations, names or endorsements.

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ORDERING THROUGH BUY AND BILL:
BAYER DIRECT

HOW TO PLACE AN ORDER

Have a Bayer intrauterine device contract? Order in 2 simple steps.

STEP 1:

Place your order 3 easy ways:	Orders confirmed the way they get placed:
Phone: (844) 229-3799	Verbal confirmation via phone call
E-mail: bayerclscwhc@bayer.com	Confirmation e-mail will be sent
Fax: (412) 767-1240	Verbal or e-mail confirmation based on information provided

STEP 2: Provide your information when you order:

- Bayer Shipping Account #
- Expected Contracted Price/Unit (refer to contract for price/unit)
- Shipping Address
- Total Cost of Order
- Billing Address
- Customer Name
- Purchase Order #
- Customer Phone #
- Product Name
- Customer E-mail Address
- Quantity (refer to contract for requirements)

If you need to confirm your distributor, please contact your Bayer Sales Representative.

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ORDERING THROUGH BUY AND BILL:
BAYER DIRECT (CONTINUED)

HOURS OF OPERATION: 8 AM-5 PM EST

Orders submitted and processed before 3 PM (EST) ship the same day. Orders ship the next business day if placed after 3 PM (EST). Give 2 business days for units to arrive. Free standard shipping.

Questions? Do not hesitate to contact us.

For ordering, tracking, or shortage/damage questions, e-mail Bayer Customer Service at bayerclscwhc@bayer.com or call 844-229-3799.

For Bayer invoice questions, for account balance, or to make a payment, e-mail BHC_Credit_Services_EDL@bayer.com or call (800) 877-1161.

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ORDERING THROUGH BUY AND BILL:
FAQ

REIMBURSEMENT FAQ

Q: How are reimbursement rates determined for Kyleena, Mirena and Skyla and associated services?
A: Insurance plans use several methods to determine payment for products and services. Reimbursement is based on the contractual agreement the health insurance plan has with the healthcare provider.

Q: What should I do if I am being under-reimbursed for Kyleena, Mirena and Skyla?
A: If you are not recovering your acquisition cost, contact your provider relations rep to confirm your contract is updated with the payer's fee schedule. A contract amendment may be needed to make your allowable reimbursement rate current.

Q: What additional resources are available to support the reimbursement process for Kyleena, Mirena and Skyla?
A: Bayer offers reimbursement support through our dedicated Field Reimbursement Management team members who function in a non-sales role to offer reimbursement support and info. Your sales consultant can provide you more details.

There are other resources available to you:

Benefits Verification Worksheet >

Patient Benefit Investigation Guide >

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ORDERING THROUGH SPECIALTY PHARMACIES (SP)

Program Overview

Ordering

Referral Form Guidance

Fulfillment Process

Abandoned Unit Program

FAQ

ORDERING THROUGH SPECIALTY PHARMACIES (SP):
PROGRAM OVERVIEW

OUR SPECIALTY PHARMACY (SP) PROGRAM OVERVIEW

Based on your patient's health insurance plan requirements or your office preference, Kyleena, Mirena and Skyla can be ordered via an SP.

Submit an SP Prescription Request Form and see your order handled.

SPs can dispense product, ship it to your office, and directly bill the medical insurer. Access the SP Prescription Request Form here or WHCsupport.com.

How the SP benefits your office

- Your office is not responsible for the up-front costs of Kyleena, Mirena and Skyla
- The only clinical service you need to bill for is the insertion procedure
- The SP verifies patient coverage and collects any applicable out-of-pocket costs
- Ordering is simplified—only one SP Prescription Request Form for all payers

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ORDERING THROUGH SPECIALTY PHARMACIES (SP):
ORDERING

OUR SPECIALTY PHARMACY (SP) PROGRAM OVERVIEW

STEP 1: COMPLETE SP PRESCRIPTION REQUEST FORM

- **Select an SP associated with your patient's plan**
- **Provide patient's demographic info, and submit a copy of their pharmacy and medical benefit insurance information** with the SP Prescription Request Form—self-pay is available if patient does not have insurance or want their insurance billed
- Enter the incorrect information? Rest assured, the SP will run a benefits investigation and locate the prescription
- **Provide prescriber information**—enter only once with the photocopied form to make future requests easier

STEP 2: COMPLETE THE PRESCRIPTION

- **Indicate diagnosis code and "Need By" date**—the SP needs at least 10 business days from the date of form submission
- **Make sure to sign the prescription**

STEP 3: PATIENT AUTHORIZATION

- **Patient must read and sign** the Patient Authorization section of the SP Prescription Request Form
- The prescription Information and Patient Authorization **must be signed and faxed**

STEP 4: GIVE SP PATIENT REMINDER FORM TO PATIENT

- Instruct patient to call SP **within 48 hours** of the office visit to verbally confirm shipment or check delivery status
- A proactive approach may help decrease delays and limit frustration for your office

STEP 5: FAX SP PRESCRIPTION REQUEST

- Make sure signed Patient Authorization section **applies to the same SP marked in the Pharmacy check box**

STEP 6: BILL PATIENT'S INSURANCE

- This bill is only for patient's **insertion procedure** and your **professional service charges**

You can order Kyleena, Mirena and Skyla through Buy and Bill if you choose not to utilize an SP.

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ORDERING THROUGH SPECIALTY PHARMACIES (SP):
REFERRAL FORM GUIDANCE

TO ENSURE TIMELY SHIPMENT TO CLINIC FROM SP, ADVISE YOUR CUSTOMER TO COMPLETE THE FOLLOWING:

List Allergies: Ensure customer includes all patient allergies or lists “N/A” or “None”

Requested Date of Delivery: Recommended to be a minimum of 10 business days from referral date

Scheduled Insertion Date: Recommended to be a minimum of 14 business days from referral date

Shipping Address If Different From Clinic Address or Provider Address: Required if the signer’s address is different from that of the HCP. This is where it will be shipped.

Find your form here

Patient information, including their signature, must be completed with a copy of insurance attached

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Please see Important Safety Information on pages 2-4, and click to see the Full Prescribing Information for Kyleena, Mirena and Skyla.

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

ORDERING THROUGH SPECIALTY PHARMACIES (SP):

FULFILLMENT PROCESS

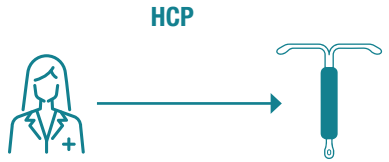
1 HCP Faxes Enrollment Form to SP

- —Ensure Form is properly filled out (refer to front page)
- —Ensure Form is sent to the correct SP—determine by contacting the patient's health insurance to check benefits
- —Remind your patient the SP will contact her to verify shipment
- —Your office will receive a confirmation fax when the SP receives the Form
- —Contact your FRM with questions about a medical benefit compared to a pharmacy benefit

2 SP Verifies Benefits

- —SP that received prescription may contact your office to verify information
- —SP will conduct a benefits investigation for the patient
- —After the benefits investigation, SP will attempt to contact patient 3 times for permission to ship IUD
- —If patient or HCP contact information is incorrect, there may be shipment delays while information is being confirmed
- —If your office receives a notice that the delivery is late, contact the SP with the number from the referral form

3 HCP Receives IUD



- —A signature is required upon delivery. If your information or shipping address is incorrect, the office will not receive the unit

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ORDERING THROUGH SPECIALTY PHARMACIES (SP):
FULFILLMENT PROCESS (CONTINUED)

The importance of the SP Prescription Request Form

Ensure that your office has the most up-to-date **SP Prescription Request Form** in hand.

Other procedures to remember:

- Only one unit can be returned with each SP Prescription Request Form
- A new SP Prescription Request Form must be completed with each unit
- If a unit is abandoned but the box is opened, the unit cannot be used and the unit may still be eligible for return

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ORDERING THROUGH SPECIALTY PHARMACIES (SP):

ABANDONED UNIT PROGRAM

What you need to know about Bayer Abandoned Units

An "Abandoned Unit" is an unused and unopened Kyleena, Mirena or Skyla shipped by the SP under the SP Program with a prescription label that includes an individual patient's name. In order to be returnable, the Kyleena, Mirena or Skyla should be in its original packaging. The original box must be sealed and must be abandoned for at least 60 days (2 months) from date of dispense but not greater than 210 days (7 months) from date of dispense.

Returning an Abandoned Unit in 6 steps

STEP 1: Complete the Bayer Abandoned Unit Program Return Form

STEP 2: Fax the form to the SP for verification

STEP 3: Wait for an email containing the authorization number and return mailing label from Qualanex, a third-party processor

STEP 4: Confirm that the SP identification number matches the ID number that is listed on the Qualanex return authorization form

STEP 5: Package the unit in one of the cardboard boxes that the Kyleena, Mirena or Skyla was initially shipped in or a large envelope

STEP 6: Mail the unit

To review Bayer Abandoned Unit Program frequently asked questions, click here

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ORDERING THROUGH SPECIALTY PHARMACIES (SP):
FAQ

Q: What happens after I fax the SP Prescription Request Form?

A: Complete all requested information before faxing the SP Prescription Request Form, including the signed Patient Authorization section. Your office will receive a return fax within 24 hours to confirm receipt. After successful processing, Kyleena, Mirena or Skyla will be shipped and your office should expect it by the date indicated on the Form, labeled with the patient's name.

If shipment goes past the date on the Form, please contact your Clinical Sales Specialist. The patient can also contact the pharmacy to check on the prescription.

Q: How do I know if my patient's insurance covers Kyleena, Mirena and Skyla through the SP?

A: Each SP Provider verifies insurance coverage by investigating both medical and pharmacy benefits for your patient. The SP Provider will contact your office if there are any delays in the benefit verification process.

Q: Why do I want both medical benefit and pharmacy benefit information?

A: The SP researches both coverage benefits based on the insurance coverage. Kyleena, Mirena and Skyla may be available through the SP as a medical or pharmacy benefit depending on the insurer. The SP will bill the insurer directly.

Q: Where can I get information on whether an SP is available for a specific patient?

A: Please review the patient's explanation of benefits (EOB) for additional information on SP services. In addition, contact the provider relations representative for the specific payer to determine whether Kyleena, Mirena and Skyla are available through the SP.

To find out more about SP or to request the SP Prescription Request Form, contact your Bayer Sales Consultant or visit our website at WHCsupport.com.

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ACCOUNT RESOURCES OFFERED

Co-pay Savings Program

Confidence in Coverage

Bayer Women's HealthCare Support Center

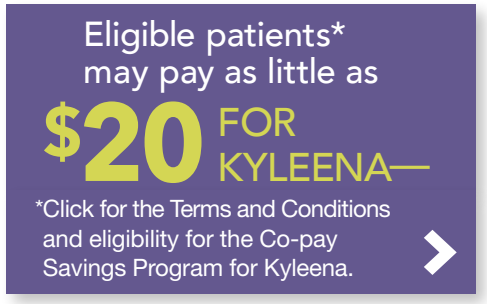
Purchasing and Reimbursement

ACCOUNT RESOURCES OFFERED:

CO-PAY SAVINGS PROGRAM

SUPPORT FOR YOUR PATIENTS IS OUR PRIORITY

Bayer is committed to helping more women lower their out-of-pocket (OOP) costs through the Co-pay Savings Program for Kyleena®.



STEP 1:

Go to **CopayforKyleena.com** and enroll as a healthcare provider on behalf of your patient

STEP 2:

Complete the patient eligibility questions and click "**Submit**" to advance to the next page

STEP 3:

If your patient is eligible, enter the patient's insurance information and click "**Enroll**"

Confirming Enrollment:

The final page will have a "**Congratulations**" message with both your patient's Co-pay Savings Program for Kyleena information and instructions for use. A welcome e-mail will automatically be sent to your patient.

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ACCOUNT RESOURCES OFFERED:
CONFIDENCE IN COVERAGE

ABOUT THE BAYER CONFIDENCE IN COVERAGE PROGRAM

If your eligible patient is denied coverage† by her plan after insertion, Bayer will replace the intrauterine device (IUD) at no cost.

If you discover a Bayer IUD you purchased is not covered by your patient's plan after insertion, simply:

1 **CONTACT**
your Bayer sales specialist. They can provide you with the Confidence in Coverage Program application form

2 **COMPLETE**
the form and submit it to Bayer with the de-identified explanation of benefits (EOB) showing denial of coverage

3 **RECEIVE**
an IUD at no cost, following approval

†Does not apply for patients who have a co-pay, insertion and removal costs, or any other costs.

Download the Confidence in Coverage program form at whcsupport.com

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ACCOUNT RESOURCES OFFERED:

BAYER WOMEN'S HEALTHCARE SUPPORT CENTER

TAKE ADVANTAGE OF THE WHC SUPPORT CENTER

The WHC Support Center is available to provide resources to support your practice with ordering information for Kyleena, Mirena and Skyla.

AmerisourceBergen Specialty Distributor (ASD) Customers

Order products, manage open orders, pay and review invoices.

Click here‡ to view a helpful video

Sign in to your ASD account

Bayer Direct Customers

Order products, manage open orders, pay and review invoices.

View contact information

Access Forms

Click below for additional information on ordering and reimbursement forms for Kyleena, Mirena and Skyla.

WHC Support Center Forms

Request a Representative

If you need to contact a sales representative, you can do so at any time.

Request a Rep

‡Bayer is not responsible for the content presented by any independent website, including any advertising claims, special offers, illustrations, names or endorsements.

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ACCOUNT RESOURCES OFFERED:

PURCHASING AND REIMBURSEMENT

When making purchasing decisions, in addition to considering the safety and efficacy of the product for your appropriate patients, it's important to understand the impact of costs and reimbursement rates. The information below will help you when making your purchasing decisions.

1

REVIEW your office expenses by each product

Consider the total cost of each product your practice prescribes. It may help to break down costs by type:

Acquisition Cost: Cost to purchase the product
Average Cost of Disposable Supplies: Cost for supplies related to the product
Average Staff Cost With Procedure: Cost of staff time needed for procedure of product
Average of Other Costs Associated With Procedure: Any other costs incurred for procedures or use of the product

2

IDENTIFY your office reimbursement for the top-contracted payers and products

For each product, add the total reimbursements received from each payer. The items listed below represent fees that are typically reimbursed. Add any additional fees as needed.[1]

- Product Fee
- Procedure Fee
- Supplies
- Office Visit(s) Fee
- Counseling Fee

3

COMPLETE your analysis

Total your expenses by product for each payer, then total your reimbursement rates using the information you gathered above. The analysis will allow you to understand the financial impact for each product across various payers

Payer 1: Reimbursement Amount Expenses
Payer 2: Reimbursement Amount Expenses
Payer 3: Reimbursement Amount Expenses

To place your order for Bayer IUDs, go to WHCSupport.com or call 1-866-647-3646

Reference: 1. Armstrong E, Gandal-Powers M, Levin S, et al. *Intrauterine devices and implants: a guide to reimbursement*. UCSF Bixby Center for Global Reproductive Health; 2016. Accessed June 16, 2021. https://larcprogram.ucsf.edu/.

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CLAIM AND CODING INFORMATION

Know Your Product Codes

Codes and Descriptions

National Drug Codes (NDCs) for BAYER IUDs

The CMS-1500 Form

The UB-04 Form

Appealing Denied Claims

Reimbursement Checklist

CLAIM AND CODING INFORMATION:
KNOW YOUR PRODUCT CODES

Accurate diagnosis, procedure, and product coding are essential to prompt claim processing and reimbursement. Most payers utilize coding systems developed by the Centers for Medicare & Medicaid Services (CMS).

Healthcare Common Procedure Coding System (HCPCS) Codes

Level II HCPCS codes, published and updated annually by CMS, are used to report drugs, supplies, and services. Codes that start with "J" are for products, supplies, and services administered by the healthcare provider.

Current Procedural Terminology (CPT®), Fourth Edition Codes§

A list of descriptive terms and codes for reporting services and procedures performed by healthcare providers. Health insurance companies may not cover all procedures listed, so confirm coverage prior to scheduling procedures.

International Classification of Diseases, 10th revision, Clinical Modification (ICD-10-CM) codes

Used to classify diagnoses and conditions, as well as support medical necessity for specific procedures and services. ICD-10-CM codes are also used to indicate the reason for a procedure and may be used by payers to determine coverage.

Local Codes

Some state Medicaid programs may require the use of local coding for Kyleena, Mirena and Skyla and the associated procedures. Providers should research Medicaid coding guidelines on a state-specific basis.

National Drug Codes (NDCs)

NDCs are universal product identifiers assigned to drugs upon FDA approval. Note that some payers, including Tricare and Medicaid, require the 11-digit NDC format when billing for Mirena and Skyla. Requirements may vary, so confirm NDC billing instructions with each payer.

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CLAIM AND CODING INFORMATION:
CODES AND DESCRIPTIONS

Basic IUD Codes

ICD-10 Codes - IUDs		CPT Procedure Code	HCPCSII/J Code
Z30.014	Encounter for initial prescription of IUD (Used when an IUD insertion kit must be ordered before placement. Not coded on the day of the actual insertion)		
Z30.430	Encounter for insertion of IUD	58300	Kyleena = J7296 Mirena = J7298 Skyla = J7301
Z30.431	Follow-up for patient with IUD or Routine checking for IUD		
Z30.432	Encounter for removal of IUD	58301	
Z30.433	Encounter for removal + reinsertion of IUD	58300 **AND** 58301-51* **OR** 58301-59* *(Check with payer for expected modifier.) Append modifier -51 or -59 to the lesser paying service. Reimbursement for IUD insertion is always higher than IUD removal, so 58300 should go first*	Kyleena = J7296 Mirena = J7298 Skyla = J7301

You are encouraged to report negative side effects or quality complaints of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088

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CLAIM AND CODING INFORMATION:
CODES AND DESCRIPTIONS (CONTINUED)

Basic IUD Codes

ICD-10 Codes - IUDs		CPT Procedure Code	HCPCSII/J Code
Z32.02	Pregnancy test/exam – negative	81025 (Urine pregnancy test)	Don't forget to bill for the point-of-care office pregnancy test (when conducted)

Clinical scenario	ICD-10 Codes		CPT Procedure Code	HCPCSII/J Code
Failed insertion/ discontinued procedure	Z30.430 **AND** <Co-occurring complication which caused failed/ discontinued procedure>	Encounter for insertion of IUD *Document reason for failed/stopped procedure with appropriate ICD-10 codes.	**58300-52* or -53*** ***NOTE:** Use modifier **-52 (Failed Procedure)** to denote that you attempted insertion, but the procedure was incomplete due to anatomical factors (e.g., Stenosis) or **-53 (Discontinued Procedure)** to indicate that you had to stop because of concerns for patient well-being (e.g., vaso-vagal, severe pain).	Kyleena = J7296 Mirena = J7298 Skyla = J7301
Perforation (during insertion procedure)	Z30.430 T83.39XA T83.39XD T83.39XS	Encounter for insertion of IUD Other mechanical complication of IUD, initial encounter Subsequent encounter Sequela	**58300-53** *Use modifier **-53** if procedure was discontinued due to perforation.	Kyleena = J7296 Mirena = J7298 Skyla = J7301

Some payers may also require the use of modifier 33 to identify a code as a preventative service.

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CLAIM AND CODING INFORMATION:
CODES AND DESCRIPTIONS (CONTINUED)

Clinical scenario	ICD-10 Codes		CPT Procedure Code	HCPCSII/J Code
Difficult insertion with ultrasound guidance	Z30.430 **AND** <Co-occurring complication justifying ultrasound>	Encounter for insertion of IUD	**58300-22** *Document the reason for additional work. **76998** (Ultrasonic guidance, intraoperative) *Document the justification for ultrasonic guidance (e.g. patient in severe pain).	Kyleena = J7296 Mirena = J7298 Skyla = J7301
Difficult insertion with ultrasound used to confirm the location of the IUD	Z30.430 <Co-occurring complication justifying ultrasound>	Encounter for insertion of IUD *Document complication with appropriate ICD-10 codes.	**58300-22** *Document the reason for additional work. **76857** Ultrasound, pelvic [nonobstetric], real time with image documentation; limited or follow-up -or - **76830** Ultrasound, transvaginal ***NOTE:** It is not routine practice to use ultrasound to confirm placement. You must document justification for ultrasonography (e.g. Uterine perforation, severe pain).	Kyleena = J7296 Mirena = J7298 Skyla = J7301
Missing strings, with ultrasound to locate	T83.32XA **AND** either Z30.431 **OR** Z30.432	Displacement of IUD - initial encounter	**76857** Ultrasound, pelvic, limited or follow-up **- OR - 76830** Ultrasound, transvaginal **NOTE:** The term "missing strings" is not a part of the ICD-10 description of T83.32XA.	
	Z30.431	Follow-up for patient with IUD *(if patient wants to keep IUD)*		
	Z30.432	Encounter for IUD removal *(if patient desires removal)*	**58301** or **58301-22*** ***NOTE:** You may append modifier **-22** if the removal was complicated. Supporting documentation may be requested by a payer. If the string is easily located in the canal, **-22** modifier should *not* be added. It should be appended only if it is a very difficult extraction and is separately documented with the claim.	

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CLAIM AND CODING INFORMATION:
CODES AND DESCRIPTIONS (CONTINUED)

Clinical scenario	ICD-10 Codes		CPT Procedure Code	HCPCSII/J Code
Failed removal	Z30.432 AND T83.32XA OR <Co-occurring complication which caused failed/discontinued procedure>	Encounter for insertion of IUD Displacement of IUD, initial encounter *Document reason for failed/stopped procedure with appropriate ICD-10 codes.	**58301-52 or -53*** ***NOTE:** Use modifier **-52** to denote that you attempted removal, but the removal procedure was incomplete (unable to remove/locate IUD) or modifier **-53** to indicate that you had to stop because of concerns for patient well-being. You must document reason for failed or incomplete procedure	

Mirena-Specific Codes

ICD-10-CM Code	Code Description
N92.0	Excessive or frequent menstruation with regular cycle
N92.1	Excessive or frequent menstruation with irregular cycle
N92.4	Excessive bleeding in the premenopausal period

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CLAIM AND CODING INFORMATION:
CODES AND DESCRIPTIONS (CONTINUED)

Modifier	Definition	Possible Clinical Scenarios	Documentation in Medical Record or on the Claim
-22	Increased procedural services	• Complex or difficult insertion • Unsuccessful insertion, followed by successful insertion during the same surgical session	In the medical record and in the claim, document: • Total time of the procedure as compared with typical duration • Reason for the additional work required • Include diagnoses with appropriate ICD-10 codes or simple descriptive diagnoses that explain the reasons for the added difficulty
-25	**Significant, separately identifiable E/M service**	**• The patient is seen for contraceptive counseling, a well woman visit, an STD check, a pregnancy test, or another reason. She chooses an IUD or implant, which is placed at that visit.**	**• Select an E/M code based on face-to-face time spent with the patient, but excluding the time needed for the IUD or implant placement • Document in the patient's medical record that at least 50% of the non-procedure time was spent in counseling • The -25 modifier is appended to the E/M code, NOT the CPT code**
-51*	Multiple procedures performed on the same day, during the same session	• Removal of IUD and insertion of new IUD on the same day • Removal of implant and insertion of IUD on the same day • Removal of IUD and insertion of implant on the same day	• The claim should support the reasons for removal and reinsertion on the same day (e.g. IUD expired, desired to continue with same method) • Append modifier -51 to the lesser paying service.
-52	Failed procedure	• Provider couldn't complete procedure for anatomic reasons (e.g. stenosis)	• In medical record and on the claim, document reasons for procedure failure (e.g. **N88.2** Stricture/stenosis of cervix)

Use modifier -25 with reimbursement for Same Day Insertions

If a payer does not recognize the CPT modifier 52 or 53, a failed insertion code may be appropriate.

CLICK HERE for more information

ADDITIONAL TELEHEALTH CODING INFORMATION

CPT codes 99201 to 99215 are the codes commonly used for an office or other outpatient visit. By using the modifier 95* or GT*, these codes can be used for telemedicine visits as well.

*Reimbursement and codes are subject to change.

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CLAIM AND CODING INFORMATION:
CODES AND DESCRIPTIONS (CONTINUED)

Modifier	Definition	Possible Clinical Scenarios	Documentation in Medical Record or on the Claim
-53	Discontinued procedure	• Provider couldn't complete procedure due to concerns for patient well-being • Severe pain • Vasovagal • Patient changed mind during procedure	In the medical record and on the claim, document: • Which work was actually performed • The reason the procedure was terminated (e.g. **R55** Syncope/vasovagal)
-59*	Distinct procedural service	• Removal of IUD and insertion of new IUD on the same day • Removal of implant and insertion of IUD on the same day	• The claim should support the reasons for removal and reinsertion on the same day (e.g. IUD expired, desired to continue with same method) • Append modifier -59 to the lesser paying service.
-76 -77	Repeat procedure -Same provider -Another provider	• Successful insertion but the IUD is expelled, followed by repeat insertion	• Document reason for repeat procedure (e.g. IUD was expelled)

*When choosing between modifiers -51 and -59, payer policy may be the determining factor. Some payers will not pay for multiple procedures using modifier -51. ***Check with payer.***

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CLAIM AND CODING INFORMATION:

NATIONAL DRUG CODES (NDCS) FOR BAYER IUDS

KYLEENA NDC: 50419-424-01

For billing purposes, use the 11-digit format: 50419042401.

Kyleena® (levonorgestrel-releasing intrauterine system) 19.5 mg

MIRENA NDC: 50419-423-01

Note that Mirena has 2 NDC numbers. Please refer to the NDC number located on the top left corner of the packaging, as well as the full Prescribing Information for Mirena.

The NDC for the Mirena product with the Bayer Inserter is 50419-423-01. However, for billing purposes, the 11-digit format is used: 50419042301.

Mirena® (levonorgestrel-releasing intrauterine system) 52 mg

SKYLA NDC: 50419-422-01

For billing purposes, use the 11-digit format: 50419042201.

Skyla® (levonorgestrel-releasing intrauterine system) 13.5 mg

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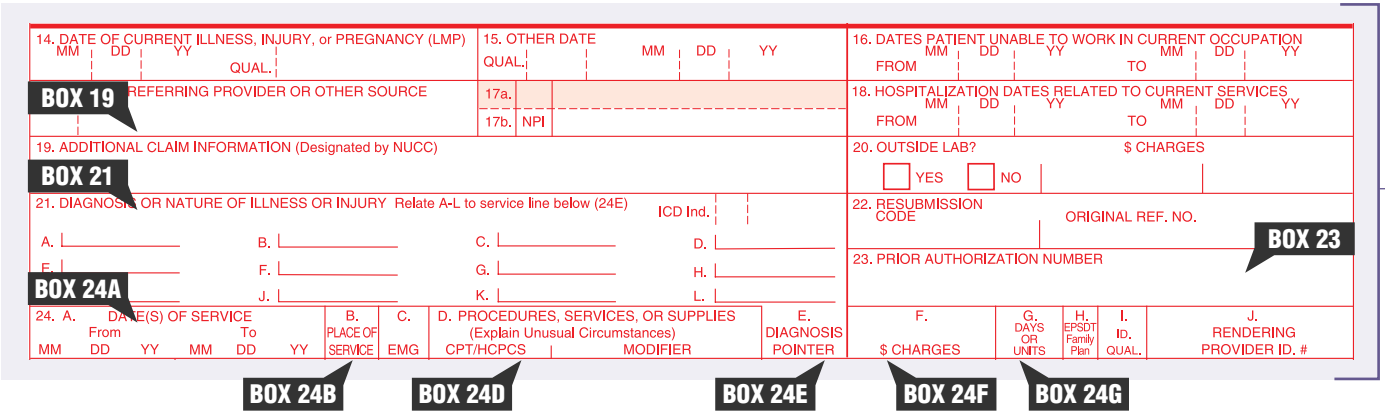
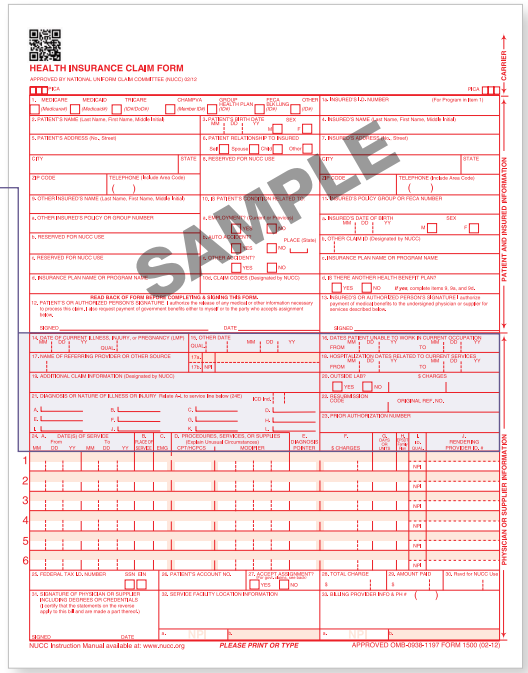
CLAIM AND CODING INFORMATION:
THE CMS-1500 FORM

Find your way around the CMS-1500 Form

There are important things to know about specific sections of this form—tap the BOX call outs below to learn more





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

CLAIM AND CODING INFORMATION:
THE UB-04 FORM

Find your way around the Universal Billing (UB-04) Form

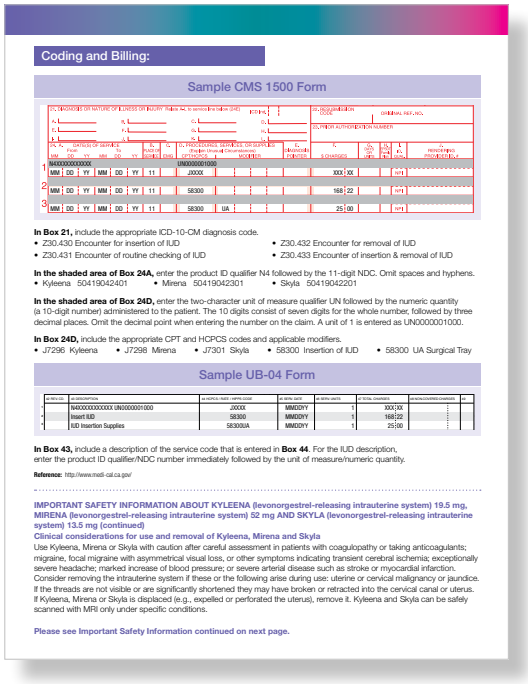
There are important things to know about specific sections of this form—tap the BOX call outs below to learn more

Sample UB-04 Form

	42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49
1		N4XXXXXXXXXX UN0000001000	JXXXX	MMDDYY	1	XXX XX		
2		Insert IUD	58300	MMDDYY	1	168 22		
3		IUD Insertion Supplies	58300UA	MMDDYY	1	25 00		

BOX 43

BOX 44



Coding and Billing:

Sample CMS 1500 Form

In Box 21, include the appropriate ICD-10-CM diagnosis code.
- Z30.430 Encounter for insertion of IUD
- Z30.431 Encounter of routine checking of IUD
- Z30.432 Encounter for removal of IUD
- Z30.433 Encounter of insertion & removal of IUD

In the shaded area of Box 24A, enter the product ID qualifier N4 followed by the 11-digit NDC. Omit spaces and hyphens.
- Kyleena 50419042401
- Mirena 50419042301
- Skyla 50419042201

In the shaded area of Box 24D, enter the two-character unit of measure qualifier UN followed by the numeric quantity (a 10-digit number) administered to the patient. The 10 digits consist of seven digits for the whole number, followed by three decimal places. Omit the decimal point when entering the number on the claim. A unit of 1 is entered as UN0000001000.

In Box 24D, include the appropriate CPT and HCPCS codes and applicable modifiers.
- J7296 Kyleena
- J7298 Mirena
- J7301 Skyla
- 58300 Insertion of IUD
- 58300 UA Surgical Tray

Sample UB-04 Form

In Box 43, include a description of the service code that is entered in **Box 44**. For the IUD description, enter the product ID qualifier/NDC number immediately followed by the unit of measure/numeric quantity.

Reference: http://www.medi-cal.ca.gov/

IMPORTANT SAFETY INFORMATION ABOUT KYLEENA (levonorgestrel-releasing intrauterine system) 19.5 mg, MIRENA (levonorgestrel-releasing intrauterine system) 52 mg AND SKYLA (levonorgestrel-releasing intrauterine system) 13.5 mg (continued)

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 MR only under specific conditions.

Please see Important Safety Information continued on next page.

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CLAIM AND CODING INFORMATION:
APPEALING DENIED CLAIMS

A claim denial can happen for a variety of reasons, including:

- Inaccurate or incomplete information
- Health insurance plan error
- Specific restriction in a patient's policy

Denied claims may be corrected and resubmitted for payment, but following the appropriate steps in the appeal process is crucial. And it is very important to submit all necessary documentation to the payer when filing an appeal:

- Letter of Medical Necessity, if not previously submitted
  -A sample Letter of Medical Necessity can be found **here**.
- Letter of Appeals
  -A sample Letter of Appeals can be found **here**.
- Copy of the original claim
- Copy of the denial notification from the payer
- Kyleena, Mirena or Skyla Prescribing Information

Make sure to clearly mark the claim "resubmission" so that the health insurance plan will not consider it a duplicate bill for the same service. Contact the health insurance plan for additional information on how to resubmit a claim.

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CLAIM AND CODING INFORMATION:
REIMBURSEMENT CHECKLIST

Below is a list of issues you may want to ensure your office has addressed.

- ☐ Did your office contact the health insurance plan's claims department? If yes, what was the outcome?
- ☐ Does your office know why the claim was reimbursed incorrectly?
- ☐ Was there a coding error? If so, have the office personnel rectified the error and resubmitted the claim?
- ☐ Is your patient financially responsible for a portion of the underpayment (co-payment, deductible, coinsurance)?
- ☐ Did your office contact the payer's provider relations representative or team? If so, what was the outcome?
- ☐ Did you follow the electronic claims submission process as required by your patient's health insurance plan?

Some health insurance plans have provider relations representatives who can assist with claims and reimbursement-related questions.

Some health insurance plans may direct you to the office where the claim was processed.
This info is listed on the back of your patient's member card or on his/her Explanation of Benefits (EOB).

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Kyleena®
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