COMPASS GUIDE
Your Resource for Ordering, Billing, and Reimbursement for Kyleena®, Mirena® and Skyla®

Kyleena has a permanent J code: J7296
See page 19 for details.

Please see Important Safety Information on pages 2-5, and click here 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
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 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 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. 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 neoplasia; liver disease, including tumors; untreated acute 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.

Please see Important Safety Information continued on next page, and click here to see the Full Prescribing Information for Kyleena®, Mirena® and Skyla®.
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.

Please see Important Safety Information continued on next page, and click here to see the Full Prescribing Information for Kyleena®, Mirena® and Skyla®.
IMPORTANT SAFETY INFORMATION ABOUT MIRENA® AND SKYLA® (continued)

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.

Please see Important Safety Information continued on next page, and click here to see the Full Prescribing Information for Kyleena®, Mirena® and Skyla®.
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, 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%).

- 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.

Please see Important Safety Information on pages 2-5, and click here to see the Full Prescribing Information for Kyleena®, Mirena® and Skyla®.
Introduction
Welcome to the COMPASS Guide

This informational guide is designed to support healthcare providers (HCPs) and office managers with questions regarding ordering, billing, and reimbursement for Kyleena®, Mirena® and Skyla®. This guide also provides general coverage, coding, and reimbursement resources related to Kyleena, Mirena and Skyla, as well as helpful information about the process to appeal denied claims.

While the information provided in this guide may support the claims filing process, its use does not guarantee payment. It is important to research specific health plan coverage and payment policies for each patient since this information will vary. You are responsible for submitting accurate, complete, and appropriate claims to payers, and for compliance with any obligations you may have as required by law, contract, or otherwise.

The COMPASS Guide for Kyleena, Mirena and Skyla Covers:

• WHC Support Center
• Ordering Information
• General Claim and Coding Information
• Health Insurance Coverage
• Frequently Asked Questions (FAQs)

Please see Important Safety Information on pages 2-5, and click here to see the Full Prescribing Information for Kyleena®, Mirena® and Skyla®.
Two Ways to Order Kyleena, Mirena and Skyla

**How to Order**

**WHC Support Center ("Buy & Bill")**

- Order Kyleena, Mirena and Skyla online, by phone, or by fax through the WHC Support Center
- Features a secure website for tasks such as placing an order, verifying the patient's insurance benefits for Kyleena, Mirena and Skyla, or checking your account status
- A toll-free support line provides HCPs, office managers and patients access to trained Customer Service Representatives, who can support reimbursement inquiries and general questions

**Specialty Pharmacy Program**

- Fill out the Specialty Pharmacy Prescription Request Form and select from one of the offered Specialty Pharmacies indicated in the Pharmacy check box
- Fax the completed Prescription Request Form, including the signed Patient Authorization section, to the appropriate Specialty Pharmacy
- The Specialty Pharmacy verifies patient coverage and bills the medical insurance company directly for the unit. The pharmacy collects patient's out-of-pocket costs, if applicable
- No need to collect co-pays for Kyleena, Mirena and Skyla. Submit only your fees for clinical services related to insertion of Kyleena, Mirena and Skyla
- The Specialty Pharmacy helps eliminate out-of-pocket expenses related to keeping an inventory of Kyleena, Mirena and Skyla
- Simple ordering process uses one form for all payers
- Please note: not all plans cover Kyleena/Mirena/Skyla through the Specialty Pharmacy channel. Coverage is patient specific

Kyleena® (levonorgestrel-releasing intrauterine system) 19.5 mg
Mirena® (levonorgestrel-releasing intrauterine system) 52 mg
Skyla® (levonorgestrel-releasing intrauterine system) 13.5 mg
The Women’s HealthCare (WHC) Support Center

- Access to the Provider Portal at WHCsupport.com
- Overview of the WHC Support Center Resources

Please see Important Safety Information on pages 2-5, and click here to see the Full Prescribing Information for Kyleena®, Mirena® and Skyla®.
Total Support

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

The WHC Support Center provides healthcare providers and office managers with a secure website, as well as a toll-free phone number staffed by trained specialists. Whether online or by phone, the WHC Support Center can provide information you need to access Kyleena, Mirena and Skyla (Bayer IUS Products).

To access the WHC Support Center online, visit www.WHCsupport.com. The provider portal provides access to these resources:

- Patient-specific benefits verification requests
- Ordering information for Bayer IUS products
- Account information, including how to make a payment and your account status

How to Register for Access

1. Log on to www.WHCsupport.com and register
   - Your registration information will be used to create a master file that will allow you to access the resources available from the online WHC Support Center
   - You will only need to submit this information once

2. Create a username and password
   - Once your registration information has been verified (this may take up to 48 hours for security purposes), you will then be able to navigate through a secure and confidential web environment

Kyleena® (levonorgestrel-releasing intrauterine system) 19.5 mg

Mirena® (levonorgestrel-releasing intrauterine system) 52 mg

Skyla® (levonorgestrel-releasing intrauterine system) 13.5 mg
Get a Range of Support
From the WHC Support Team

For patients, healthcare providers, and office managers, the WHC Support Center provides:

- Ordering information for Bayer IUS products
- Patient-specific benefits verification and prior authorization support
- Procedure and product coding
- Payer-specific coverage policy knowledge
- Health insurance claims and tracking support
- Information on appealing claim denials and underpayment

Please see Important Safety Information on pages 2-5, and click here to see the Full Prescribing Information for Kyleena®, Mirena® and Skyla®.

The information in this guide is for informational purposes and does not guarantee payment or coverage. Offices should research coding, coverage, and payment for individual patients prior to initiating treatment since policies and guidelines vary by payer and health plan. Offices are responsible for submitting accurate, complete, and appropriate claims to payers and for compliance with any obligations required by law, contract, or otherwise.
How to Contact the WHC Support Center

The WHC Support Center team is available Monday through Friday from 8 AM to 8 PM ET. You can reach the team by calling toll free 1-866-647-3646.

The support team can also be reached by sending an e-mail using the form provided on the provider portal. Simply fill in the form and submit your message. The team will receive the request during normal business hours and contact you as soon as possible.
The Specialty Pharmacy Program

• What Is the Specialty Pharmacy Program (SPP)?
• Simple Steps to Order
• FAQs

Please see Important Safety Information on pages 2-5, and click here to see the Full Prescribing Information for Kyleena®, Mirena® and Skyla®.
What Is the Specialty Pharmacy Program (SPP)?

If your patient’s health insurance plan requires, or your office chooses, Kyleena, Mirena and Skyla may be ordered via a specialty pharmacy. When using a specialty pharmacy:

•  Your office is not responsible for the upfront costs of purchasing Kyleena, Mirena and Skyla
•  You need to bill for the insertion procedure only
•  The specialty pharmacy verifies patient coverage and collects the patient’s out-of-pocket costs, if applicable

Submit a Specialty Pharmacy Prescription Request Form

The Specialty Pharmacy can dispense Kyleena, Mirena and Skyla, ship the unit directly to your office, and bill the medical insurer directly for the unit. The program will be administered entirely through the Specialty Pharmacy. The Specialty Pharmacy Prescription Request Form can be accessed online at www.WHCsupport.com.

Specialty Pharmacy Can:

•  Eliminate out-of-pocket expenses related to maintaining an inventory of Kyleena, Mirena and Skyla
•  Minimize uncertainty associated with insurance reimbursement for Kyleena, Mirena and Skyla
•  Submit only fees for clinical services, such as insertion, to insurance companies. No need to collect patient co-pays for Kyleena, Mirena and Skyla
•  Spend less time on benefit verification. Your office only needs to verify insurance coverage for the insertion procedure, not for Kyleena, Mirena and Skyla
•  Simplify the ordering process by using only one Specialty Pharmacy Prescription Request Form for all payers

Kyleena®
(levonorgestrel-releasing intrauterine system) 19.5 mg

Mirena®
(levonorgestrel-releasing intrauterine system) 52 mg

Skyla®
(levonorgestrel-releasing intrauterine system) 13.5 mg
Simple Steps to Order Through Specialty Pharmacy

1. Enter the following information on the Prescription Request Form:
   • Select a Specialty Pharmacy offered through the SPP
   • Patient demographic information
   • Both patient pharmacy benefit and medical insurance information (please ensure that this information is complete and include a copy of the patient’s benefit/insurance cards)
   • For patients who do not have insurance and/or do not want their insurance billed, a self-pay option is available
   • Prescriber information (this information can be entered once and the form photocopied to streamline future requests)

2. Complete the prescription:
   • Indicate appropriate diagnosis code
   • Indicate scheduled insertion date, if known (this will help ensure that you receive Kyleena/Mirena/Skyla when you need it)
   • Sign the prescription
3. **Patient Authorization:**
   - The patient must read and sign the Patient Authorization section of the form

   Both the Prescription Information and the Patient Authorization pages of the Specialty Pharmacy Prescription Request Form must be signed and faxed.

4. Provide your patient with an appointment reminder card

5. Fax the completed Specialty Pharmacy Prescription Request Form, **including the signed Patient Authorization section**, to the appropriate Specialty Pharmacy indicated in the Pharmacy check box. For questions, call the WHC Support Center at (866)-647-3646

6. Bill the patient’s insurance for the insertion procedure and your customary professional service charges only

   Kyleena, Mirena and Skyla can still be ordered through the Buy and Bill process if you choose not to receive them through Specialty Pharmacy.
Frequently Asked Questions (FAQs)

FAQs About Ordering Through Specialty Pharmacy

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

A: Complete all requested information before you fax the Specialty Pharmacy Prescription Request Form, **including the signed Patient Authorization section**. Your office should receive a return fax within 24 hours to confirm receipt. If the prescription is successfully processed, Kyleena, Mirena or Skyla will be shipped, and your office should expect to receive it—labeled with the patient’s name—within 5 to 7 business days. If the process takes longer than 7 business days, your office will receive an update by fax every 48 hours until there’s a resolution. If necessary, the patient can also contact the pharmacy on her own behalf to inquire about the status of her prescription.

Q: How do I know if my patient’s insurance covers Kyleena, Mirena and Skyla through Specialty Pharmacy?

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

Please see Important Safety Information on pages 2-5, and click here to see the Full Prescribing Information for Kyleena®, Mirena® and Skyla®.
Q: Why do I want both medical benefit and pharmacy benefit information?

A: Specialty Pharmacy researches both medical and pharmacy coverage benefits available to the patient based on their insurance coverage. Depending on the insurer, Kyleena, Mirena and Skyla may be available through Specialty Pharmacy as a medical benefit or as a pharmacy benefit. In either case, Specialty Pharmacy will bill the insurer directly.

Q: Where can I get information on whether a specialty pharmacy is available for use for a specific patient?

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

To find out more about Specialty Pharmacy or to request the Specialty Pharmacy Prescription Request Form, contact your Bayer Sales Consultant or visit our website at www.WHCsupport.com.
General Claim and Coding Information

• Coding
  – Healthcare Common Procedure Coding System (HCPCS) Codes
  – ICD-10-CM Diagnosis Codes
  – Local Codes
  – National Drug Codes
• Information on Appealing Denied Claims
• Reimbursement Resolution Checklist

Please see Important Safety Information on pages 2-5, and click here to see the Full Prescribing Information for Kyleena®, Mirena® and Skyla®.
Coding

Accurate diagnosis, procedure, and product coding are essential to ensure prompt claim processing and reimbursement.

Using the correct and specific codes is critical. Most payers, public and private, utilize coding systems developed by the Centers for Medicare & Medicaid Services (CMS).

Healthcare providers are responsible for selecting the appropriate codes used in filing a claim. Codes should be based on the patient’s diagnosis and the items and services furnished by the provider.

Healthcare Common Procedure Coding System (HCPCS) Codes

Level II HCPCS codes are published and updated annually by CMS. These alphanumeric codes are used to report drugs, supplies, and services. HCPCS codes starting with the letter “J” are used for products, supplies and services administered by the provider.

The HCPCS codes used to report Kyleena, Mirena and Skyla are:

<table>
<thead>
<tr>
<th>Product/Service</th>
<th>HCPCS Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kyleena</td>
<td>J7298</td>
<td>Levonorgestrel-releasing intrauterine contraceptive system (Kyleena), 19.5 mg</td>
</tr>
<tr>
<td>Mirena</td>
<td>J7298</td>
<td>Levonorgestrel-releasing intrauterine contraceptive system (Mirena), 52 mg</td>
</tr>
<tr>
<td>Skyla</td>
<td>J7301</td>
<td>Levonorgestrel-releasing intrauterine contraceptive system (Skyla), 13.5 mg</td>
</tr>
</tbody>
</table>

CPT-4 is a listing of descriptive terms and codes for reporting services and procedures performed by healthcare providers.

Note that health insurance companies may not cover all of the procedures listed here. Always check coverage prior to scheduling any procedure.

The following are the codes that may be used to report procedures associated with Kyleena, Mirena and Skyla.

<table>
<thead>
<tr>
<th>Product/Service</th>
<th>CPT Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insertion</td>
<td>58300</td>
<td>Insertion of intrauterine system</td>
</tr>
<tr>
<td>Postinsertion follow-up</td>
<td>76857</td>
<td>Ultrasound, pelvic (nonobstetric), real time with image documentation; limited or follow-up</td>
</tr>
<tr>
<td>Postinsertion follow-up</td>
<td>76830</td>
<td>Ultrasound: transvaginal</td>
</tr>
<tr>
<td>Removal</td>
<td>58301</td>
<td>Removal of intrauterine device</td>
</tr>
</tbody>
</table>

*CPT codes, descriptions, and other data only are copyright 2017 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association.

Please see Important Safety Information on pages 2-5, and click here to see the Full Prescribing Information for Kyleena®, Mirena® and Skyla®.
In some cases, adding a modifier to the code may be necessary. For example, if a discontinued placement of Kyleena, Mirena or Skyla occurs, add a modifier (52 or 53) to the CPT procedure code (58300) when billing Kyleena, Mirena or Skyla.

<table>
<thead>
<tr>
<th>CPT Code (with modifier)</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>58300-52</td>
<td>Reduced services: Under certain circumstances, a service or procedure is partially reduced or eliminated at the physician's discretion. Under these circumstances, the service provided can be identified by its usual procedure number and the addition of the modifier “52,” signifying that the service is reduced. This provides a means of reporting reduced services without disturbing the identification of the basic service.</td>
</tr>
<tr>
<td>58300-53</td>
<td>Discontinued the procedure: Under certain circumstances, the physician may elect to terminate a surgical or diagnostic procedure. Due to extenuating circumstances or those that threaten the well-being of the patient, it may be necessary to indicate that a surgical or diagnostic procedure was started but discontinued.</td>
</tr>
</tbody>
</table>
# ICD-10-CM Diagnosis Codes

International Classification of Diseases, 10th revision, Clinical Modification (ICD-10-CM) codes are used to classify diagnoses and conditions, and support medical necessity for specific procedures and services. They are used to indicate the reason for performing a given procedure and may be used by payers to determine coverage.

The following ICD-10-CM codes may be applicable to women who receive Kyleena, Mirena or Skyla.

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

<table>
<thead>
<tr>
<th>ICD-10-CM Codes</th>
<th>ICD-10-CM Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Z30.014</td>
<td>Encounter for initial prescription of IUD</td>
</tr>
<tr>
<td>Z30.430</td>
<td>Encounter for insertion of intrauterine contraceptive device</td>
</tr>
<tr>
<td>Z30.432</td>
<td>Encounter for removal of intrauterine contraceptive device</td>
</tr>
<tr>
<td>Z30.433</td>
<td>Encounter for removal and reinsertion of intrauterine contraceptive device</td>
</tr>
<tr>
<td>Z30.431</td>
<td>Encounter for routine checking of intrauterine contraceptive device</td>
</tr>
<tr>
<td>Z97.5</td>
<td>Presence of intrauterine contraceptive device</td>
</tr>
</tbody>
</table>

## Mirena-Specific Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>N92.0</td>
<td>Excessive or frequent menstruation with regular cycle</td>
</tr>
<tr>
<td>N92.1</td>
<td>Excessive or frequent menstruation with irregular cycle</td>
</tr>
<tr>
<td>N92.4</td>
<td>Excessive bleeding in the premenopausal period</td>
</tr>
</tbody>
</table>

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Additional Coding Considerations

If a payer does not recognize the CPT modifier 52 or 53 for the reduced service or discontinued procedure, a mechanical complication diagnosis code may be appropriate

• On the claims form, use Z30.430 as the primary ICD-10-CM code (indicating an IUD was inserted)

• Use one of the following codes as the secondary ICD-10-CM code to explain/justify why 2 units are being billed (indicating a complication took place with the IUD insertion)
  – T83.39XA  Other Mechanical Complication of an IUD
    Most commonly used code
  – T83.31XA  Breakdown (mechanical) of an IUD
  – T83.32XA  Displacement of an IUD-Malposition

• Always check with payer to determine the appropriate codes to use

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.

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

National Drug Codes (NDC) 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. Confirm NDC billing instructions with each payer, as requirements may vary.

Please see Important Safety Information on pages 2-5, and click here to see the Full Prescribing Information for Kyleena®, Mirena® and Skyla®.
The information in this guide is for informational purposes and does not guarantee payment or coverage. Offices should research coding, coverage, and payment for individual patients prior to initiating treatment since policies and guidelines vary by payer and health plan. Offices are responsible for submitting accurate, complete, and appropriate claims to payers and for compliance with any obligations required by law, contract, or otherwise.

NDC for Kyleena

- **NDC**: 50419-424-01
- The NDC for Kyleena is: 50419-424-01. However, for billing purposes, the 11-digit format is used: 50419042401.

NDC for Mirena

- **NDC**: 50419-423-01
- The NDC for Mirena is 50419-423-01. However, for billing purposes, the 11-digit format is used: 50419042301.
The NDC for Skyla is: 50419-422-01. However, for billing purposes, the 11-digit format is used: 50419042201.

Please see Important Safety Information on pages 2-5, and click here to see the Full Prescribing Information for Kyleena®, Mirena® and Skyla®.
CMS-1500 Form Instructions

Box 19: Remarks/Comments Field
- Include supplemental information for the specific Bayer IUD, to help the payer identify the therapy
- List the brand and generic name, NDC, and total units
- Example: Kyleena (levonorgestrel intrauterine system), 19.5 mg, NDC 50419042401

Box 21: Diagnosis Code(s)
- List the appropriate ICD-10-CM diagnosis code(s) based on the patient’s condition

Shaded Area above Box 24A: NDC and Qualifier
- List the 11-digit NDC
- Check if the payer requires a specific qualifier. Contact the payer or the WHC Support Center for more information.

Box 23: Prior Authorization Number
- Include the prior authorization number provided by the payer, if required

Box 24A: Date(s) of Service
- List the date(s) when service(s) occurred

Box 24B: Place of Service
- Enter “11” for services provided in the office

Box 24D: Procedures, Services or Supplies
- Enter the appropriate HCPCS code on line 1 and the appropriate CPT code for the procedure on line 2
- List any modifiers, if needed in the appropriate modifier section

Box 24E: Diagnosis Pointer
- Enter the letter from Box 21 corresponding to the primary diagnosis of each HCPCS or CPT code listed in Box 24D

Box 24F: Charges
- Enter the total charge assigned to each service or procedure listed in 24D

Box 24G: Days or Units
- Enter the number of units of service for each code listed in 24D. Typically, this will be 1. Check with the payer or the WHC Support Center for more information.

Kyleena®
(levonorgestrel-releasing intrauterine system) 19.5 mg

Mirena®
(levonorgestrel-releasing intrauterine system) 52 mg

Skyla®
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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. It is important that the claim is clearly marked “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.

Generally, the following documentation should be included when appealing a denied claim:
• Letter of Medical Necessity, if not previously submitted
• Letter of Appeal
• Copy of the original claim
• Copy of the denial notification from the payer
• Kyleena, Mirena or Skyla Prescribing Information

In the event of a denied claim, the WHC Support Center can:
• Try to determine the reason for denial
• Educate your office staff about the appeals process
• Track the status of the appeal
• Provide your office with a Sample Letter of Medical Necessity or Sample Letter of Appeal

The information in this guide is for informational purposes and does not guarantee payment or coverage. Offices should research coding, coverage, and payment for individual patients prior to initiating treatment since policies and guidelines vary by payer and health plan. Offices are responsible for submitting accurate, complete, and appropriate claims to payers and for compliance with any obligations required by law, contract, or otherwise.
Reimbursement Checklist

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

• Did your office personnel contact the health insurance plan’s claims department? If yes, what was the outcome?
• Do your office personnel 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 the patient financially responsible for a portion of the underpayment (eg, co-payment, deductible, coinsurance, etc)?
• Did your office personnel contact the payer’s provider relations representative or team? If so, what was the outcome?
• Did you follow the current electronic claims submission process as required by the patient’s health insurance plan?

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

Some health insurance plans may direct office personnel to the claims office where the claim was processed. This information is listed on the back of a member’s card or on the patient’s Explanation of Benefits (EOB).
Coverage

- Commercial Insurance
- Medicaid

Please see Important Safety Information on pages 2-5, and click here to see the Full Prescribing Information for Kyleena®, Mirena® and Skyla®.
Commercial Insurance

How to Verify Insurance Coverage

Many health insurance plans cover Kyleena, Mirena and Skyla as well as medical services associated with the insertion procedure. Kyleena, Mirena and Skyla are most frequently covered as a medical benefit because they are administered in the provider’s office, although in some cases they may be covered as a pharmacy benefit. Coverage can vary by payer, plan, and employer group.

It is important to verify each patient’s benefits to determine coverage and billing requirements prior to scheduling a Kyleena, Mirena or Skyla insertion procedure appointment. The WHC Support Center can provide support with patient-specific benefits investigations. Refer to the WHC Support Center section of this guide for more details about this resource.

Office personnel may also verify the patient’s health plan coverage for Kyleena, Mirena or Skyla by contacting the patient’s health insurance provider directly. The phone number can usually be found on the member’s insurance card.

Be sure to verify coverage and payment levels for both the intrauterine contraceptive and the insertion procedure. Relevant billing codes can be found in the coding section on pages 18 to 25.
Questions You Can Ask When Verifying Benefits

• Ask the health plan to check coverage for Kyleena, Mirena and Skyla under both medical and pharmacy benefits

• Are Kyleena, Mirena and Skyla covered as preventive services by the patient’s health insurance company?

• What is the patient’s financial responsibility, including co-pay, coinsurance, and/or deductible? If patient has a high deductible, how much has been met and does the cost of Kyleena, Mirena or Skyla apply to the deductible?

• Be sure to ask about coverage and payment levels for all codes that will be billed, including the insertion procedure

Employer Benefit Selection Process

When selecting their benefit plans, employers may choose to cover only certain contraceptive products. Some plans will have limited options available, and Kyleena, Mirena and Skyla may not necessarily be a covered benefit.

To determine coverage for Kyleena, Mirena and Skyla, it is important to verify each patient’s coverage, as it will vary by payer, plan, region, and employer.

Please see Important Safety Information on pages 2-5, and click here to see the Full Prescribing Information for Kyleena®, Mirena® and Skyla®.
Medicaid

State Medicaid programs offer coverage for contraceptives. However, state Medicaid program eligibility guidelines may vary and could restrict access to Kyleena, Mirena and Skyla for some women. As with private payers, offices should verify coverage prior to treatment. Among women enrolled in Medicaid managed care organizations (Medicaid MCOs), coverage will be based on the specific Medicaid MCOs’ policies for Kyleena, Mirena and Skyla.
Frequently Asked Questions

• General Coverage and Reimbursement

Please see Important Safety Information on pages 2-5, and click here to see the Full Prescribing Information for Kyleena®, Mirena® and Skyla®.
General Coverage and Reimbursement

Q: How are reimbursement rates determined for Kyleena, Mirena and Skyla and associated services?

A: Insurance plans determine payment for products and services through a variety of methods. Reimbursement for Kyleena, Mirena and Skyla is based on any contractual agreement that the health insurance plan has with the healthcare provider.

Q: What should I do if I am being under-reimbursed for Mirena and Skyla?

A: If you are not recovering your acquisition cost for Kyleena, Mirena and Skyla, you should call your provider relations representative to make sure your contract is up to date with the current fee schedule for that payer. If necessary, you may need to request an amendment to your contract to update your allowable reimbursement rate for Kyleena, Mirena and Skyla.
Frequently Asked Questions (continued)

Q: What should I do if a claim is denied?
A: You should follow the appropriate steps for the appeal process. Be sure to submit all necessary documentation to the payer when filing an appeal. The WHC Support Center can provide information to support this process.

Q: What additional resources are available to support the reimbursement process for Mirena and Skyla?
A: Additional reimbursement resources are available through the WHC Support Center at 1-866-647-3646 or www.WHCsupport.com. Bayer also offers reimbursement support through our dedicated Field Reimbursement Management team. These individuals function in a non-sales role to offer reimbursement support and information as needed. Your sales consultant can provide more details about this resource.

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