LILETTA® CODING UPDATE

BEGINNING JANUARY 1, 2016, THE HCPCS* CODE (J-CODE) APPROPRIATE FOR LILETTA IS CHANGING FROM J7302 TO J7297

Code: J7297
Descriptor: Levonorgestrel iu 52mg 3 yr
Effective Date: January 1, 2016

While all coding decisions should be made by the physician based on an independent review of the patient's condition, you may find the information in this flyer helpful when billing LILETTA®.

Considerations before submitting claims

- Check with specific payers or contact LILETTA AccessConnectSM to confirm when to begin submitting claims using J7297
  - Private plans and Medicaid will vary; most should have the code uploaded in January but some might take longer
- Review your provider contracts for inclusion of J7297 for LILETTA, if appropriate
- Adjust your billing software, if necessary. Contact your software provider for more information
- Understand each payers’ individual requirements for claims submission for LILETTA
- Educate all appropriate staff (eg, billing staff) about using J7302 and J7297

Considerations after submitting claims

- Monitor your claims and remittances for the first 30 to 60 days following implementation of J7297 to confirm that you are reimbursed correctly
- If a payer issues an administrative denial for a claim using J7297:
  - Directly contact the payer’s provider-relations representative for assistance

Disclaimer: This flyer is presented for informational purposes only. It represents no statement, promise, or guarantee by Actavis concerning, coverage and/or levels of reimbursement, payment, or charge and is not intended to increase or maximize reimbursement by any payer. It is the responsibility of the healthcare provider to determine the appropriate code(s) for services provided to his or her patient. Laws, regulations, and policies concerning reimbursement are complex and are updated frequently. While we have made an effort to be current as of the issue date of this flyer, the information may not be current or comprehensive when you view it. Please consult the applicable payer organization with regard to local or actual coverage, reimbursement policies, and determination processes. Actavis does not endorse any individual plans. Formulary coverage does not imply efficacy or safety.

*Healthcare Common Procedure Coding System.
IMPORTANT SAFETY INFORMATION (Continued)

Clinical considerations for use and removal of LILETTA

Use LILETTA 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. Because irregular bleeding/spotting is common during the first months of LILETTA use, exclude endometrial pathologial (polyps or cancer) prior to the insertion of LILETTA in women with persistent or uncharacteristic bleeding. If the threads are not visible or are significantly shortened, they may have broken or retracted into the cervical canal or uterus. If LILETTA is displaced (eg, expelled or perforated the uterus), remove it.

Pregnancy related risks with LILETTA

If pregnancy should occur with LILETTA 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 LILETTA. 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

Insertion of LILETTA is contraindicated in the presence of known or suspected PID or endometritis or a history of PID unless there has been a subsequent intrauterine pregnancy. IUSs have been associated with an increased risk of PID, most likely due to organisms being introduced into the uterus during insertion. About 1/3 of women diagnosed with PID developed the infection within a week of LILETTA insertion, while the remainder were diagnosed more than six months after insertion. Counsel women who receive LILETTA to notify a healthcare provider if they have complaints of lower abdominal or pelvic pain, odorous discharge, unexplained bleeding, fever, or genital lesions or sores. PID is often associated with sexually transmitted infections (STIs); LILETTA does not protect against STIs, including HIV. PID or endometritis may be asymptomatic but still result in tubal damage and its sequelae. 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.

Expect changes in bleeding patterns with LILETTA

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 IUSs like LILETTA are sepsis, perforation, and expulsion. Severe infection or sepsis, including Group A streptococcal sepsis (GAS), have been reported following insertion of other LNG-releasing IUSs. Aseptic technique during insertion of LILETTA is essential in order to minimize serious infections such as GAS. Perforation (total or partial, including penetration/embedment of LILETTA 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 LILETTA. Surgery may be required. Delayed detection or removal of LILETTA 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 is higher if inserted in lactating women and may be higher if inserted in women who are postpartum or when the uterus is fixed retroverted. Partial or complete expulsion of LILETTA may occur, resulting in the loss of contraceptive protection. Delay LILETTA insertion a minimum of 6 weeks or until uterine involution is complete following a delivery or a second trimester abortion. Remove a partially expelled LILETTA. If expulsion has occurred, a new LILETTA may be inserted within 7 days after the onset of a menstrual period after pregnancy has been ruled out. Ovarian cysts may occur and are generally asymptomatic, but may be accompanied by pelvic pain or dyspareunia. Evaluate persistent ovarian cysts.

In the clinical trial of LILETTA the most common adverse reactions (≥5% users) were vaginal infections (13.6%), vulvovaginal infections (13.3%), acne (12.3%), headache or migraine (9.8%), nausea or vomiting (7.9%), dyspareunia (7.0%), abdominal pain or discomfort (6.8%), breast tenderness or pain (6.7%), pelvic discomfort or pain (6.1%), depression or depressed mood (5.4%), and mood changes (5.2%).

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

Please see Important Safety Information on reverse side and accompanying full Prescribing Information.
LILETTA (levonorgestrel-releasing intrauterine system)
Initial U.S. Approval: 2015

INDICATIONS AND USAGE
LILETTA is a sterile, levonorgestrel-releasing intrauterine system indicated for prevention of pregnancy for up to 3 years. (1)

DOSAGE AND ADMINISTRATION
- Release rate of levonorgestrel (LNG) is 18.6 mcg/day initially and declines progressively to approximately 16.0 mcg/day at 1 year, 14.3 mcg/day at 2 years, and 12.6 mcg/day at 3 years after insertion; LILETTA can be removed at any time but must be removed by the end of the third year. (2)
- To be inserted by a trained healthcare provider using strict aseptic technique. Follow insertion instructions exactly as described. (2.1)
- Patient should be re-examined and evaluated 4 to 6 weeks after insertion and once a year thereafter, or more frequently if clinically indicated. (2.3)

CONTRAINDICATIONS
- Pregnancy or suspected pregnancy;
- Use for post-coital contraception (emergency contraception) (4)
- Congenital or acquired uterine anomaly that distorts the uterine cavity (4)
- Acute pelvic inflammatory disease (PID) or a history of PID unless there has been a subsequent intrauterine pregnancy. (4)
- Postpartum endometritis or infected abortion in the past 3 months (4)
- Known or suspected uterine or cervical neoplasia (4)
- Known or suspected breast cancer or other progestin-sensitive cancer (4)
- Uterine bleeding of unknown etiology (4)
- Known or suspected liver tumor (benign or malignant) (4)
- Acute liver disease or liver tumor (benign or malignant) (4)
- Increased susceptibility to pelvic infections (4)
- A previously inserted IUS that has not been removed (4)
- Hypersensitivity to any component of LILETTA (4)

WARNINGS AND PRECAUTIONS
- Remove LILETTA if pregnancy occurs with LILETTA in place and LILETTA is in the uterus. If pregnancy occurs, there is increased risk of ectopic pregnancy including loss of fertility, pregnancy loss, septic abortion (including septicemia, shock and death) and premature labor and delivery. (5.1, 5.2)
- Group A streptococcal infection has been reported; strict aseptic technique is essential during insertion. (5.3)
- Before using LILETTA, consider the risks of PID. (5.4)
- Perforation may occur and reduce contraceptive effectiveness. Risk is increased if inserted in women with fixed retroverted uterus, during lactation, and postpartum. (5.5)
- Partial or complete expulsion may occur. (5.6)
- Evaluate persistent enlarged ovarian follicles. (5.7)
- Bleeding patterns become altered, may remain irregular and amenorrhea may ensue. (5.8)

ADVERSE REACTIONS
The most common adverse reactions reported in clinical trials (> 10% users) are, vaginal and vulvovaginal infections, and acne. (6)

DRUG INTERACTIONS

USE IN SPECIFIC POPULATIONS
- Pregnancy
- Lactation
- Pediatric Use
- Geriatric Use
- Hepatic Impairment
- Renal Impairment
- Obesity

DESCRIPTION
- LILETTA
- Insert

CLINICAL PHARMACOLOGY
- Mechanism of Action
- Pharmacodynamics
- Pharmacokinetics

NONCLINICAL TOXICOLOGY
- Carcinogenesis, Mutagenesis, Impairment of Fertility

CLINICAL STUDIES
- Clinical Trial on Contraception

REFERENCES

HOW SUPPLIED/STORAGE AND HANDLING

PATIENT COUNSELING INFORMATION
FULL PRESCRIBING INFORMATION

1  INDICATIONS AND USAGE
LILETTA™ is indicated for prevention of pregnancy for up to 3 years. The system should be replaced after 3 years if continued use is desired.

2  DOSAGE AND ADMINISTRATION
LILETTA contains 52 mg of levonorgestrel (LNG). Initially, LNG is released at a rate of 18.6 mcg/day. This rate decreases progressively to approximately 16.3 mcg/day at 1 year, 14.3 mcg/day at 2 years, and 12.6 mcg/day at 3 years after insertion. The average in vivo release rate of LNG is approximately 15.6 mcg/day over a period of 3 years.

LILETTA can be removed at any time but must be removed by the end of the third year. LILETTA can be replaced at the time of removal with a new LILETTA if continued contraceptive protection is desired.

2.1 Insertion Instructions
LILETTA (Figure 1) is provided in a sterile pouch [see Description (11)] and is inserted into the uterine cavity with the provided inserter (Figure 2) by carefully following the insertion instructions. Use strict aseptic techniques throughout the insertion procedure before opening it. Do not insert LILETTA after the expiration date on the box.

- Observe the expiration date on the pouch before opening it. Do not insert LILETTA after the expiration date.
- Obtain a complete medical and social history to determine conditions that might influence the selection of a levonorgestrel-releasing intrauterine system (LILETTA) for contraception. If indicated, perform a physical examination and appropriate tests for genital or sexually transmitted infections. [See Contraindications (4), Warnings and Precautions (5.4, 5.10).]
- Obtain a complete medical and social history to determine conditions that might influence the selection of a levonorgestrel-releasing intrauterine system (LILETTA) for contraception. If indicated, perform a physical examination and appropriate tests for genital or sexually transmitted infections. [See Contraindications (4), Warnings and Precautions (5.4, 5.10).]
- Check the expiration date on the box before opening it. Do not insert LILETTA after the expiration date.
- Visually inspect the packaging (sealed pouch) containing LILETTA to verify that the packaging has not been damaged (e.g., torn, punctured, etc.). If the packaging has any visual damage that could compromise sterility, do not use the unit for insertion. [see Warnings and Precautions (5.3)].
- Ensure that the patient understands the contents of the Patient Information Booklet and obtain consent. A sample consent form that includes the lot number is on the last page of the Patient Information Booklet.
- Complete the pelvic examination, speculum placement, tenaculum placement, and sounding of the uterus before opening the LILETTA pouch.
- Do not open the pouch to insert LILETTA if the cervix is unable to be properly visualized, if the uterus cannot be adequately instrumented (during sounding), or if the uterus sounds to less than 5.5 cm.

Timing of Insertion
Refer to Table 1 for instructions on when to start use of LILETTA.

Table 1: When to Insert LILETTA

Starting LILETTA in women not currently using hormonal or intrauterine contraception
- LILETTA can be inserted any time the provider can be reasonably certain the woman is not pregnant. Consider the possibility of ovulation and conception prior to initiation of this product.
- If LILETTA is not inserted during the first 7 days of the menstrual cycle, a barrier method of contraception (such as condoms and spermicide) should be used or the patient should abstain from vaginal intercourse for 7 days to prevent pregnancy.

Switching to LILETTA from an oral, transdermal or vaginal hormonal contraceptive
- LILETTA may be inserted at any time.
- May be inserted during the hormone-free interval of the previous method.
- If inserted during active use of the previous method, continue the previous method after LILETTA insertion for seven days or until the end of the current cycle.
- If using continuous hormonal contraception, discontinue the method seven days after LILETTA insertion.

Switching to LILETTA from an injectable progestin contraceptive
- LILETTA may be inserted at any time: a barier method of contraception (such as condoms and spermicide) should also be used for 7 days if LILETTA is inserted as instructed more than 3 months (13 weeks) after the last injection.

Switching to LILETTA from a contraceptive implant or another IUS
- Insert LILETTA on the same day the implant or IUS is removed.
- LILETTA may be inserted at any time during the menstrual cycle.

Inserting LILETTA after abortion or miscarriage
- First-trimester
  - LILETTA may be inserted immediately after a first-trimester abortion or miscarriage.
- Second-trimester
  - Do not insert LILETTA until a minimum of 6 weeks after second trimester abortion or miscarriage, or until the uterus is fully involuted. If involution is delayed, wait until involution is complete before insertion. [see Warnings and Precautions (5.5, 5.6)].
  - If the woman has not yet had a period, consider the possibility of ovulation and conception occurring prior to insertion of LILETTA. [See Contraindications (4), Warnings and Precautions (5.2), and FDA-Approved Patient Labeling.] LILETTA can be inserted any time the provider can be reasonably certain the woman is not pregnant.
  - If LILETTA is not inserted during the first 7 days of the menstrual cycle, a barrier method of contraception should be used or the patient should abstain from vaginal intercourse for 7 days to prevent pregnancy.

Inserting LILETTA after Childbirth
- Do not insert LILETTA until a minimum of 6 weeks after delivery, or until the uterus is fully involuted. If involution is delayed, wait until involution is complete before insertion. [see Warnings and Precautions (5.5, 5.6)].
- If the woman has not yet had a period, consider the possibility of ovulation and conception occurring prior to insertion of LILETTA. [See Contraindications (4), Warnings and Precautions (5.2), and FDA-Approved Patient Labeling.] LILETTA can be inserted any time the provider can be reasonably certain the woman is not pregnant.
- If LILETTA is not inserted during the first 7 days of the menstrual cycle, a barrier method of contraception should be used or the patient should abstain from vaginal intercourse for 7 days to prevent pregnancy.
- There appears to be an increased risk of perforation in lactating women. [see Warnings and Precautions (5.5)].

Planning for Insertion
- Ensure all needed items for LILETTA insertion are readily available:
  - Gloves
  - Speculum
  - Sterile uterine sound
  - Sterile tenaculum
  - Antiseptic solution
  - LILETTA with inserter in sealed pouch
  - Sterile, blunt-tipped scissors
  - Additional items that may be useful could include:
• Local anesthesia, needle, and syringe
• Do finder and/or cervical dilators
• Ultrasound with abdominal probe
• Exclude pregnancy and confirm that there are no other contraindications to the insertion and use of LILETTA.
• Follow the insertion instructions exactly as described in order to ensure proper insertion.
• If you encounter cervical stenosis at any time during uterine sounding or LILETTA insertion, use cervical dilators, not force, to overcome resistance. If necessary, dilation, sounding, and insertion may be performed with ultrasound guidance.
• Insertion may be associated with some pain and/or bleeding or vasovagal reactions (e.g., diaphoresis, syncope, bradycardia, or seizure), especially in patients with a predisposition to these conditions. Consider administering analgesics prior to insertion.

Use aseptic technique during the entire insertion procedure. Loading and inserting LILETTA does not require sterile gloves. If not using sterile gloves, complete all steps for loading the IUS (Steps 1-7) inside the pouch. Maintain sterility during LILETTA insertion; do not touch LILETTA or parts of any sterile instrument that will pierce tissue (e.g., a tenaculum on the cervix) or go into the uterine cavity.

Preparation for Insertion
• With the patient comfortably in lithotomy position, do a bimanual exam to establish the size, shape, and position of the uterus and to evaluate any signs of uterine infection.
• Gently insert a speculum to visualize the cervix.
• Thoroughly cleanse the cervix and vagina with antiseptic solution.
• Administer cervical anesthetic, if needed.
• Apply a tenaculum to the cervix and use gentle traction to align the cervical canal with the uterus. The uterus should sound to a depth of at least 5.5 cm. Insertion of LILETTA into a uterus that sounds to less than 5.5 cm may increase the incidence of expulsion, bleeding, pain, perforation, and possibly pregnancy. LILETTA should not be inserted if the uterus sounds to less than 5.5 cm.
• After ascertaining that the patient is appropriate for LILETTA, open the pouch containing LILETTA.

Insertion Procedure
Loading the IUS into the Inserter
Step 1
• Place the LILETTA pouch on a flat surface with the clear side of the pouch facing up (Figure 3).

Figure 3: Place the LILETTA pouch on a flat surface.
• Open the sterile LILETTA pouch from the bottom (end with the rod ring) approximately 1/3 of the way until the lower ends of the IUS threads, the rod, and the insertion tube are exposed (Figure 4). If using sterile gloves, you can open the pouch completely before putting on the sterile gloves.

Figure 4: Release the threads from the flange and insert the rod.

Step 2
• Pull back the blue threads to dislodge them from the flange.
• Be careful to not pull the IUS down at the same time (Figure 4).

Step 3
• Hold the exposed end of the insertion tube containing the IUS (Figure 4) while keeping the end of the insertion tube with the IUS inside the packaging.
• Remove the rod from the pouch.
• Do not touch the end of the rod that will go into the insertion tube.
• Place the rod into the insertion tube (alongside the IUS threads) to about the 5 cm marking (Figure 4).

Step 4
• While holding the insertion tube and the rod firmly between the fingers and thumb of one hand, pull downward on both blue threads with the other hand to draw the IUS into the insertion tube (Figure 5).
• The arms of the IUS should be kept in a horizontal plane, parallel to the flat side of the flange (refer to Figure 4).
• Do not pull the IUS all of the way through the insertion tube; only pull the threads until the IUS is loaded at the top of the insertion tube. Note: If you accidentally remove the IUS completely out of the insertion tube, do not use or attempt to re-load.

Figure 5: Pull on the threads to pull the IUS into the tube. Figure 6: Adjust the Flange.

Step 5
• Hold the insertion tube and the rod firmly with one hand.
• With the other hand, adjust the position of the flange (through the sterile packaging if not using sterile gloves) by moving the tube to correspond to the sound measurement (Figure 6).
• The top end of the flange should be at the measurement corresponding to the sounded depth of the uterus.

Step 6
• Final IUS positioning: position the IUS in the tube so that the knobs of the lateral arms are opposed to each other and protrude slightly above the tip of the insertion tube to form a hemispherical dome (Figure 7).
• Hold the tube at its proximal end firmly to maintain rod position.
• With the other hand, while pulling on the blue threads, slowly advance the rod forward to adjust the position of the IUS.
• When the IUS tips are in the correct position (slightly protruding), pinch and hold the proximal end of the tube firmly to maintain rod position.
• The proximal end of the insertion tube will be approximately at the top of the first indent on the rod (Figure 7).

Figure 7: Final IUS Positioning
ENSURE A HEMISPHERICAL DOME IS ACHIEVED. When the IUS is in the correct position, the lower end of the tube will be aligned approximately at the upper edge of the upper indent on the rod.

Step 7
Check to make sure the IUS is correctly loaded. You should note the following:
- The IUS is completely within the insertion tube with the knobs of the arms forming a hemispherical dome at the top of the tube.
- The top of the rod is touching the bottom of the IUS.
- The blue threads are hanging through the end of the insertion tube.
- The flange is marking the depth of the uterus based on pre-insertion sounding.

Step 8
Remove the loaded IUS insertion tube from the pouch while holding the lower end of the tube firmly between your fingers and thumb.

If not using sterile gloves, do not touch the flange and any part of the insertion tube above the flange during this step and through the IUS insertion procedure.

IUS Insertion into the Uterus

Step 1
- Apply gentle traction on the tenaculum to straighten the alignment of the cervical canal and uterine cavity.
- While still firmly pinching the proximal end of the insertion tube to maintain the IUS in the correct position (Hand A), slide the loaded IUS insertion tube through the cervical canal until the upper edge of the flange is approximately 1.5 – 2.0 cm from the cervix (Figure 8).
- DO NOT advance flange to the cervix at this step.
- DO NOT force the inserter. If necessary, dilate the cervical canal.

Step 2
- Release hold on the tenaculum.
- Hold the insertion tube with the fingers of one hand (Hand A) and the rod with the fingers of the other hand (Hand B).
- Hold the rod still (Hand B), relax the firmness of the pinch on the tube, and pull the insertion tube back with Hand A to the edge of the second indent of the rod (Figure 9).
- This will allow the IUS arms to open in the lower uterine segment.

Step 3
- Wait 10 – 15 seconds for the arms of the IUS to fully open.

Step 4
- Apply gentle traction with the tenaculum before advancing the IUS.
- With Hand A still holding the proximal end of the tube, advance both the insertion tube and rod simultaneously up to the uterine fundus (Figure 10). You will feel slight resistance when the IUS is at the fundus.
- The flange should be touching the cervix when the IUS reaches the uterine fundus.

Note: Fundal positioning is important to prevent expulsion.

Step 5
- Hold the rod still (Hand B) while pulling the insertion tube back with Hand A to the ring of the rod (Figure 11).

Step 6
- While holding the inserter tube with Hand A, withdraw the rod from the insertion tube all of the way out to prevent the rod from catching on the knot at the lower end of the IUS.

Note: Ensure the tube is held firmly in place until the rod is completely pulled outside of the tube as there will be some slight resistance while removing the rod from the tube.

Step 7
- Completely remove the insertion tube.

Step 8
- Use blunt-tipped sharp scissors to cut the IUS threads perpendicular to the thread length, leaving about 3 cm outside of the cervix (Figure 12). Note: Cutting threads at an angle may leave sharp ends.
- Do not apply tension or pull on the threads when cutting to prevent displacing the IUS.

Figure 10: After 10 – 15 seconds, advance to the fundus while holding both the rod and the tube.

Figure 12: Cut the threads about 3 cm from the cervix.
Insertion of LILETTA is now complete.

Important information to consider during or after insertion:
- If you suspect the IUS is not in the correct position:
  - Check insertion with an ultrasound or other appropriate radiologic test.
  - If incorrect insertion is suspected, remove LILETTA. A removed LILETTA must not be re-inserted.

Difficult insertion
- If insertion is difficult because the uterus cannot be appropriately instrumented, the following measures can be considered:
  - Use of cervical anesthesia to make sounding and manipulation more tolerable.
  - Use of dilators to dilate the cervix if needed to allow passage of the sound.
  - Abdominal ultrasound guidance during dilation and/or insertion.
- If there is clinical concern, exceptional pain, or bleeding during or after insertion, take appropriate steps, such as physical examination and ultrasound, immediately to exclude perforation.

2.2 Patient Counseling and Record-Keeping
- Keep a copy of the consent form and LILETTA lot number for your records.
- Counsel the patient on what to expect following LILETTA insertion. Give her the Patient Information Booklet, which includes the website address (www.LILETTA.com). Discuss expected bleeding patterns with LILETTA use. Review the signs and symptoms of LILETTA expulsion. [See Patient Counseling Information (17).]
- Prescribe analgesics, if indicated.

2.3 Patient Follow-Up
- Re-examine and evaluate patients 4 to 6 weeks after insertion and once a year thereafter, or more frequently if clinically indicated.

2.4 Removal of LILETTA

Timing of Removal
- If pregnancy is desired, LILETTA can be removed at any time.
- If pregnancy is not desired. LILETTA can be removed at any time; however, a contraception method should be started prior to removal of LILETTA (see Dosage and Administration (2.5)). Counsel your patient that if she has intercourse in the week prior to removal without use of a backup contraceptive method, she is at risk of pregnancy.
- LILETTA should be removed after 3 years. LILETTA can be replaced at the time of removal with a new LILETTA if continued contraceptive protection is desired.

Planning for Removal
- Ensure all needed items for LILETTA removal are readily available:
  - Gloves
  - Speculum
  - Sterile forceps
  - Additional items that may be required could include:
    - Local anesthetic, needle, and syringe
    - Os finder and/or cervical dilators
    - Ultrasound with abdominal probe
    - Sterile tenaculum
    - Antiseptic solution
  - Long, narrow forceps
  - Removal may be associated with some pain and/or bleeding or vasovagal reactions (e.g., syncope, bradycardia, or seizure), especially in patients with a predisposition to these conditions.
  - After removal of LILETTA, examine the system to ensure that it is intact.

Removal Instructions
- With the patient comfortably in lithotomy position, place a speculum and visualize the cervix.
  - When the threads of LILETTA are visible:
    - Remove the IUS by applying gentle traction on the threads with forceps (Figure 13).
    - The arms of the device will fold upward as it is withdrawn from the uterus.
    - If the IUS cannot be removed with traction on the threads, perform an ultrasound examination to confirm location of the IUS, including assessment for partial or total perforation. If the IUS is in the uterus, use a tenaculum, narrow forceps to grasp LILETTA. Consider use of a tenaculum, cervical anesthesia, cervical dilators, and/or ultrasound guidance as needed.
    - If the threads of LILETTA are not visible:
      - Determine location of the IUS by ultrasound examination.
      - If the IUS is in the uterine cavity, use a long, narrow forceps (e.g., Alligator forceps) to grasp LILETTA. Consider use of a tenaculum, cervical anesthesia, cervical dilators, and/or ultrasound guidance as needed. If LILETTA cannot be removed using the above techniques, consider hysteroscopic evaluation for removal.
      - If the IUS is not in the uterine cavity, consider an abdominal x-ray or CT scan to evaluate if the IUS is in the abdominal cavity. Consider laparoscopic evaluation for removal, as clinically indicated.

2.5 Continuation of Contraception After Removal
- If pregnancy is not desired and if a woman wishes to continue using LILETTA, a new system can be inserted immediately after removal any time during the cycle.
- If a patient with regular cycles wants to start a different birth control method, time the removal and initiation of a new method to ensure continuous contraception. Either remove LILETTA during the first 7 days of the menstrual cycle and start the new method or start the new method at least 7 days prior to removing LILETTA if removal is to occur at other times during the cycle.
- If a patient with irregular cycles or amenorrhea wants to start a different birth control method, start the new method at least 7 days before LILETTA removal.
- If LILETTA is removed but no other contraceptive method has already been started, the new contraceptive method can be started on the day LILETTA is removed. The patient should use a backup barrier method of contraception (e.g., condoms and spermicide) or abstain from vaginal intercourse for 7 days to prevent pregnancy.

3 DOSAGE FORMS AND STRENGTHS
LILETTA is a levonorgestrel-releasing intrauterine system consisting of a T-shaped polyethylene frame with a drug reservoir containing 52 mg levonorgestrel, packaged within a sterile inserter.

4 CONTRAINDICATIONS
The use of LILETTA is contraindicated when one or more of the following conditions exist:
- Pregnancy or suspected pregnancy
- For use as post-coital contraception (emergency contraception)
- Congenital or acquired uterine anomaly, including fibroids, that distorts the uterine cavity
- Acute pelvic inflammatory disease (PID) or a history of PID unless there has been a subsequent intrauterine pregnancy
- Postpartum endometritis or infected abortion in the past 3 months
- Known or suspected uterine or cervical neoplasia
- Known or suspected breast cancer or other progestin-sensitive cancer, now or in the past
- Uterine bleeding of unknown etiology
- Untreated acute cervicitis or vaginitis, including bacterial vaginosis, known chlamydial or gonococcal cervical infection, or other lower genital tract infections until infection is controlled
- Acute liver disease or liver tumor (benign or malignant)
- Conditions associated with increased susceptibility to pelvic infections [see Warnings and Precautions (5.4)]
- A previously inserted IUS that has not been removed
- Hypersensitivity to any component of LILETTA [see Adverse Reactions (6.2)]

5 WARNINGS AND PRECAUTIONS
5.1 Ectopic Pregnancy
Evaluate women for ectopic pregnancy if they become pregnant with LILETTA in place because the likelihood of a pregnancy being ectopic is increased with LILETTA. Approximately half of pregnancies that occur with LILETTA in place are likely to be ectopic. Also consider the possibility of ectopic pregnancy in the case of lower abdominal pain, especially in association with missed periods or if an amenorrheic woman starts bleeding. If an ectopic pregnancy is confirmed, LILETTA should be removed. The incidence of ectopic pregnancy in the clinical trial with LILETTA, which excluded women with a history of ectopic pregnancy and use LILETTA is unknown. Women with a previous history of ectopic pregnancy, tubal surgery or pelvic infection have a higher risk of ectopic pregnancy. Ectopic pregnancy may require surgery and may result in loss of fertility. Tell women who choose LILETTA about the risks of ectopic pregnancy, including the loss of fertility. Teach them to recognize and report to their healthcare provider promptly any signs of ectopic pregnancy.
5.2 Intrauterine Pregnancy

If pregnancy occurs while using LILETTA, determine if LILETTA is in the uterus. If LILETTA is in the uterus, attempt to remove LILETTA because leaving it in place may increase the risk of spontaneous abortion and preterm labor. Removal of LILETTA or probing of the uterus may also result in spontaneous abortion. In the event of an intrauterine pregnancy with LILETTA, consider the following:

Septic abortion

In patients becoming pregnant with an IUS in place, septic abortion— with sepsisemia, shock, and multiorgan failure—may occur. Septic abortion typically requires hospitalization and treatment with intravenous antibiotics. Septic abortion may result in spontaneous abortion or a medical indication for pregnancy termination. Should severe infection of the uterus occur, hysterectomy may be required, which will result in permanent infertility.

Continuation of pregnancy

If a woman becomes pregnant with LILETTA in place and if LILETTA cannot be removed or the woman chooses not to have it removed, warn her that failure to remove LILETTA increases the risk of spontaneous abortion, preterm birth, and prematurity delivery. Prenatal care should include counseling about these risks and that she should report immediately any flu-like symptoms, fever, chills, cramping, pain, bleeding, vaginal discharge or leakage of fluid, or any other symptom that suggests complications of the pregnancy.

5.3 Seepsis

Severe infection or sepsis, including Group A streptococcal sepsis (GAS), have been reported following insertion of other LNG-releasing IUSs. In some cases, severe pain occurred within hours of insertion followed by sepsis within days. Because death from GAS is more likely if treatment is delayed, it is important to be aware of these rare but serious infections. Aseptic technique during insertion of LILETTA is essential in order to minimize serious infections such as GAS.

5.4 Pelvic Inflammatory Disease or Endometritis

Insertion of LILETTA is contraindicated in the presence of known or suspected PID or endometritis or a history of PID, unless there has been a subsequent intrauterine pregnancy [see Contraindications (4)]. IUSs have been associated with an increased risk of PID, most likely due to organisms being introduced into the uterus during insertion.

In the clinical trial with LILETTA, pelvic infection was diagnosed in 0.6% of women. The infection was diagnosed as PID in 0.4% of women and as endometritis in 0.2% of women. About 1/3 of women diagnosed with PID developed the infection within a week of LILETTA insertion, while the remainder were diagnosed more than six months after insertion. The cases of endometritis had onset less than 40 days after LILETTA insertion.

Counsel women who receive LILETTA to notify a healthcare provider if they have complaints of lower abdominal or pelvic pain, odorous discharge, unexplained fever, or genital lesions or sores. In such circumstances, perform a pelvic examination promptly to evaluate for possible pelvic infection. Remove LILETTA in cases of recurrent PID or endometritis, or if an acute pelvic infection is severe or does not respond to treatment.

Women at increased risk for PID or endometritis

PID and endometritis are often associated with a sexually transmitted infection (STI), and LILETTA does not protect against STIs. The risk of PID or endometritis is greater for women who have multiple sexual partners, also for women whose sexual partner(s) have multiple sexual partner(s) have multiple sexual partners, and for women who use oral contraceptives. Women who have PID or endometritis are at increased risk for a recurrence or re-infection. In particular, ascertain whether the woman is at increased risk of infection (for example, leukemia, acquired immune deficiency syndrome [AIDS], IV drug abuse).

Asymptomatic PID or endometritis

PID or endometritis may be asymptomatic but still result in tubal damage and its sequelae. Treatment of PID or endometritis

Following a diagnosis of PID or endometritis, or suspected PID or endometritis, perform appropriate testing for sexually transmitted infection and initiate antibiotic therapy promptly. LILETTA does not protect against STIs. The risk of PID or endometritis may be reduced if the woman uses another method of contraception (1). In the LILETTA clinical trial, 7 of the 10 women who developed PID or endometritis were successfully treated without removal of LILETTA.

Assess the woman in 48-72 hours. If no clinical improvement occurs, continue antibiotics and consider removal of LILETTA. If the woman wants to discontinue use, remove LILETTA and provide education about bacterial vaginosis and asymptomatic PID or endometritis. If possible, instruct the woman to avoid sexual intercourse for a week to reduce the risk for a recurrence or re-infection. Evaluate persistent ovarian cysts. Surgical intervention is not usually required, but may be necessary in some cases. Discuss this risk with patients who choose to use LILETTA.

5.5 Perforation

Perforation (total or partial, including penetration/embedment of LILETTA 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 and result in pregnancy. The incidence of perforation during or following LILETTA insertion in the clinical trial, which excluded breastfeeding women, was 0.1%.

If perforation occurs, locate and remove LILETTA. Surgery may be required. Delayed detection or removal of LILETTA in case of perforation may result in migration outside the uterine cavity, adhesions, peritonitis, intestinal perforations, intestinal obstruction, abscesses, and erosion of adjacent viscera. A large post-marketing safety study with other IUSs demonstrated an increased risk of perforation in lactating women. The risk of perforation may be increased if LILETTA is inserted when the uterus is fixed retroverted or not completely involuted during the postpartum period. Delay LILETTA insertion a minimum of six weeks or until involution is complete following a delivery or a second trimester abortion.

5.6 Expulsion

Partial or complete expulsion of LILETTA may occur, resulting in the loss of contraceptive protection. In the clinical trial with LILETTA, an overall expulsion rate of 3.5% was reported, with a rate of 2.0% in nulliparous women and 5.6% in parous women. Expulsion may be associated with symptoms of bleeding or pain, or it may be asymptomatic and go unnoticed. LILETTA typically decreases menstrual bleeding over time; therefore, an increase in menstrual bleeding may be indicative of an expulsion.

The risk of expulsion may be increased when the uterus is not completely involuted at the time of insertion or LILETTA is inserted in less than 6 weeks until uterine involution is complete following a delivery or a second trimester abortion.

Remove a partially expelled LILETTA. If expulsion has occurred, a new LILETTA may be inserted within 7 days after the onset of a menstrual period after pregnancy has been ruled out.

5.7 Ovarian Cysts

Because the contraceptive effect of LILETTA is mainly due to its local effects within the uterine cavity, follicular rupture usually occurs in women of follicular phase utilizing LILETTA. Sometimes atresia of the follicle is delayed and the follicle may continue to grow. Most ovarian cysts that occur during use of LNG-releasing IUSs are asymptomatic and disappear spontaneously during two to three months of observation. Cysts that cause clinical symptoms can result in pelvic or abdominal pain or dyspareunia. Symptomatic ovarian cysts occurred in 3.4% of subjects using LILETTA, and 0.3% of subjects discontinued use of LILETTA because of an ovarian cyst.

Evaluate persistent ovarian cysts. Surgical intervention is not usually required, but may be necessary in some cases. Discuss this risk with patients who choose to use LILETTA.

5.8 Bleeding Pattern Alterations

LILETTA can alter the bleeding pattern and result in spotting, irregular bleeding, heavy bleeding, oligomenorrhea, and amenorrhea. During the first three to six months of LILETTA use, the number of bleeding and spotting days may be increased and bleeding patterns may return to normal within the first six months of LILETTA use. Spotting or bleeding days usually decreases but bleeding may remain irregular.

In the LILETTA clinical trial, amenorrhea developed in approximately 19% of LILETTA users by the end of the first year of use, in 26% by the end of the second year of use, and in approximately 38% of users by the end of year 3. In the trial, 1.5% of LILETTA subjects discontinued due to bleeding complaints. Table 2 shows the bleeding and spotting days based on 28-day cycle equivalents.

<table>
<thead>
<tr>
<th>28-day Cycle Equivalent</th>
<th>Cycle 1</th>
<th>Cycle 4</th>
<th>Cycle 7</th>
<th>Cycle 13</th>
<th>Cycle 26</th>
</tr>
</thead>
<tbody>
<tr>
<td>Days on treatment</td>
<td>1-28</td>
<td>85-112</td>
<td>169-196</td>
<td>337-364</td>
<td>674-728</td>
</tr>
<tr>
<td>Number of bleeding days</td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
</tr>
<tr>
<td>5.8</td>
<td>5.2</td>
<td>2.3</td>
<td>3.3</td>
<td>1.5</td>
<td>2.6</td>
</tr>
<tr>
<td>5.9</td>
<td>6.0</td>
<td>4.3</td>
<td>4.2</td>
<td>3.0</td>
<td>2.7</td>
</tr>
<tr>
<td>Number of spotting days</td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
</tr>
<tr>
<td>5.8</td>
<td>6.0</td>
<td>4.3</td>
<td>4.2</td>
<td>3.0</td>
<td>2.7</td>
</tr>
<tr>
<td>5.9</td>
<td>6.0</td>
<td>4.3</td>
<td>4.2</td>
<td>3.0</td>
<td>2.7</td>
</tr>
</tbody>
</table>

Note: Includes all LILETTA subjects.

In the LILETTA clinical trial, 248 of 255 (97.3%) of women evaluated experienced menses within 3 months after LILETTA removal.

If a significant change in bleeding develops during prolonged use, take appropriate diagnostic measures to rule out endometrial pathology. Consider the possibility of pregnancy. If pregnancy does not develop and there is no evidence of infection, consider the need for contraception. Once pregnancy has been excluded, repeated pregnancy tests are generally not necessary in amenorrheic women unless indicated, for example, by other signs of pregnancy or by pelvic pain.

5.9 Breast Cancer

Women who currently have or have had breast cancer, or have a suspicion of breast cancer, should not use hormonal contraception, including LILETTA, because some breast cancers are hormone sensitive [see Contraindications (4)]. Breast cancer risk is increased in women with persistent or uncharacteristic bleeding.

5.10 Clinical Considerations for Use and Removal

Obtain a complete medical and social history, including partner status, to determine conditions that might influence the selection of an IUS for contraception.

Because irregular bleeding/spotting is common during the first months of LILETTA use, exclude endometrial pathology (polyps or cancer) prior to the insertion of LILETTA in women with persistent or uncharacteristic bleeding.

Special attention must be given to ascertaining whether the woman is at increased risk of infection (for example, leukemia, acquired immune deficiency syndrome [AIDS], IV drug abuse), or has a history of PID unless there has been a subsequent intrauterine pregnancy. LILETTA does not protect against HIV/STI transmission. [See Warnings and Precautions (5.4)].

Use LILETTA with caution after careful assessment if any of the following conditions exist, and consider removal of the IUS if any of them arise during use:

- Coagulopathy or use of anticoagulants
- Migraine, focal migraine with asymmetrical visual loss or other symptoms indicating transient cerebral ischemia
- Exceptionally severe headache
- Marked increase of blood pressure
- Severe arterial disease such as stroke or myocardial infarction
5.11 Magnetic Resonance Imaging (MRI) Information

LILETTA is MR Safe.

6 ADVERSE REACTIONS

The following serious or otherwise important adverse reactions are discussed elsewhere in the labeling:

- Ectopic Pregnancy [see Warnings and Precautions (5.1)]
- Intracranial Pregnancy [see Warnings and Precautions (5.2)]
- Group A Streptococcal Sepsis (GAS) [see Warnings and Precautions (5.3)]
- Pelvic Inflammatory Disease or Endometritis [see Warnings and Precautions (5.4)]
- Perforation [see Warnings and Precautions (5.5)]
- Expulsion [see Warnings and Precautions (5.6)]
- Ovarian Cysts [see Warnings and Precautions (5.7)]
- Bleeding Pattern Alterations [see Warnings and Precautions (5.8)]

6.1 Clinical Trial Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The data described below reflect exposure of 1,751 generally healthy 16- to 45-year-old women to LILETTA in a large, multi-center contraceptive trial conducted in the US, including 1,412 exposed for 1 year and 383 subjects who completed 3 years of use; 58% were nulliparous (mean age 25.1 ± 4.3 years) and 42% were parous (mean age 30.3 ± 6.1 years).

Most women who received LILETTA were Caucasian (78.4%) or Black/African American (13.3%). 14.7% of women were of Hispanic ethnicity. The clinical trial had no upper or lower weight or BMI limit. Mean BMI of LILETTA subjects was 26.9 kg/m² (range 15.8 – 61.6 kg/m²); 25.1% had a BMI ≥ 30 kg/m², and 5.3% had a BMI ≥ 40 kg/m². The data cover more than 22,000 28-day cycles of LILETTA exposure. The frequencies of reported adverse drug reactions represent crude incidences.

The most common adverse reactions during the LILETTA clinical trial (occurring in ≥ 5% users) are shown in Table 3.

In the contraceptive trial, 12.3% of LILETTA users discontinued prematurely due to an adverse reaction. The most common adverse reaction leading to discontinuation was expulsion (3.5%), bleeding complaints (a total of 1.5%). The next most common adverse reactions causing discontinuation were acne (1.3%), mood swings (1.2%), dysmenorrhea (0.6%), and uterine spasm (0.6%). Two women discontinued the clinical study due to PID (0.6%), and uterine spasm (0.6%).

6.2 Postmarketing Experience

The following adverse reactions have been identified during post-approval use of other LNG-releasing IUSs. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure:

- Hypersensitivity including rash, urticaria, and angioedema
- Device Breakage

7 DRUG INTERACTIONS

No drug-drug interaction studies have been conducted with LILETTA. Contraceptive effect of LILETTA is mediated via the direct release of LNG into the uterine cavity and is unlikely to be affected by drug interactions via enzyme induction or inhibition.
12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action
The local mechanism by which continuously released LNG provides contraception has not been conclusively demonstrated. Studies of LNG-releasing IUSs suggest several mechanisms for pregnancy prevention: prevention of fertilization due to the thickening of the cervical mucus, which inhibits sperm passage through the cervix, and inhibition of sperm mobility and function (capacitation), and alteration of the endometrium.

12.2 Pharmacodynamics
LILETTA has mainly local progestogenic effects in the uterine cavity and cervix. High local concentrations of LNG lead to morphological changes including stromal pseudodecidualization, glandular atrophy, a leukocytic infiltration, and a decrease in glandular and stromal mitoses. Changes in the uterine endometrium may lead to alterations in the menstrual bleeding pattern [see Warnings and Precautions (5.8)]. In clinical trials with other LNG-releasing IUSs, ovulation was inhibited in some women but most cycles were ovulatory.

12.3 Pharmacokinetics
Absorption
Low doses of LNG are administered into the uterine cavity with the LILETTA intrauterine delivery system. The initial in vivo release rate is 18.6 μg/day and decreases to 16.3 μg/day at 1 year, 14.3 μg/day at 2 years, and 12.6 μg/day after 3 years.

In the phase 3 study, systemic LNG concentrations were assessed in a subset of subjects through Month 30 and in all subjects at Month 36. Plasma LNG concentrations following insertion of LILETTA are shown in Table 4.

Table 4: Plasma LNG Concentrations (mean ± SD, pg/mL) Following LILETTA Insertion

<table>
<thead>
<tr>
<th>Initial (7 days)</th>
<th>6 Months</th>
<th>12 Months</th>
<th>24 Months</th>
<th>30 Months</th>
<th>36 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>(N = 40)</td>
<td>(N = 36)</td>
<td>(N = 33)</td>
<td>(N = 29)</td>
<td>(N = 9)</td>
<td>(N=243)</td>
</tr>
<tr>
<td>252 ± 123</td>
<td>195 ± 69</td>
<td>170 ± 50</td>
<td>147 ± 46</td>
<td>133 ± 28</td>
<td>135 ± 51</td>
</tr>
</tbody>
</table>

Table 5: Cumulative Pregnancy Rates

<table>
<thead>
<tr>
<th>LILETTA Clinical Trial</th>
<th>Year 1 Pearl Index</th>
<th>Cumulative 3-Year Life Table</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of 28-day Cycles of Exposure</td>
<td>17,125</td>
<td>34,711</td>
</tr>
<tr>
<td>Pregnancy Rate (95% CI)</td>
<td>0.15 (0.02, 0.55)</td>
<td>0.55 (0.24, 1.23)</td>
</tr>
</tbody>
</table>

Of 68 women who desired pregnancy after study discontinuation, 71% conceived within 6 months following LILETTA removal, and 87% conceived within 12 months after removal of LILETTA.
• Review the signs and symptoms of LILETTA expulsion with the patient. Counsel the patient on how she can check that the threads still protrude from her cervix, and not to pull on them. Inform her that there is no contraceptive protection if LILETTA is displaced or expelled. [See Warnings and Precautions (5.6).]

• Counsel the patient regarding the risk of ovarian cysts and that cysts can cause clinical symptoms including pelvic pain, abdominal pain or dyspareunia and infrequently will need surgery. [See Warnings and Precautions (5.7).]

• Counsel the patient that irregular or prolonged bleeding and spotting, and/or cramps may occur during the first three to six months after insertion. If her symptoms continue or are severe, she should report them to her healthcare provider. [See Warnings and Precautions (5.8).]

• Inform the patient that LILETTA is MR Safe and that it is safe for her to have an MRI with LILETTA in place. [See Warnings and Precautions (5.11).]

• Instruct the patient to contact her healthcare provider if she experiences any of the following:
  « A stroke or heart attack
  « Very severe or migraine headaches
  « Unexplained fever
  « Yellowing of the skin or whites of the eyes, as these may be signs of serious liver problems
  « Pregnancy or suspected pregnancy
  « Pelvic pain or pain during sex
  « She or her partner becomes HIV positive
  « Possible exposure to sexually transmitted infections (STIs)
  « Unusual vaginal discharge or genital sores
  « Severe vaginal bleeding or bleeding that lasts a long time, or if she misses a menstrual period
  « Inability to feel LILETTA's threads

Complete the Follow-up Reminder Card and give it to the patient.

LILETTA™ is a trademark of Odyssea Pharma SPRL, an Actavis affiliate.

Manufactured by:
Odyssea Pharma, Belgium
An affiliated company of Actavis Pharma, Inc.

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Parsippany, NJ 07054 San Francisco, CA 94111

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LLT27591-P-02/15
Patient Information
LILETTA (lye-LET-uh)
(levonorgestrel-releasing intrauterine system)

LILETTA does not protect against HIV infection (AIDS) and other sexually transmitted infections (STIs).

Read this Patient Information carefully before you decide if LILETTA is right for you. This information does not take the place of talking with your gynecologist or other healthcare provider who specializes in women’s health. If you have any questions about LILETTA, ask your healthcare provider. You should also learn about other birth control methods to choose the one that is best for you.

What is LILETTA?
- LILETTA is a hormone-releasing system inserted in your uterus by your healthcare provider to prevent pregnancy for up to 3 years.
- LILETTA can be removed by your healthcare provider at any time.
- LILETTA can be used whether or not you have given birth to a child.

LILETTA is a small, flexible plastic T-shaped system that slowly releases a progestin hormone called levonorgestrel (LNG) that is often used in birth control pills. Because LILETTA releases LNG into your uterus, only small amounts of the hormone enter your blood. LILETTA does not contain estrogen.

Two thin threads are attached to the stem (lower end) of LILETTA. The threads are the only part of LILETTA you should feel when LILETTA is in your uterus; however, unlike a tampon string, the threads do not extend outside your body.

LILETTA is small and flexible

What if I need birth control for more than 3 years?
LILETTA must be removed after 3 years. Your healthcare provider can insert a new LILETTA during the same office visit if you choose to continue using LILETTA.

What if I want to stop using LILETTA?
LILETTA is intended for use up to 3 years, but you can stop using LILETTA at any time by asking your healthcare provider to remove it. You could become pregnant as soon as LILETTA is removed, so you should use another method of birth control if you do not want to become pregnant. Discuss your options with your healthcare provider, because certain methods should be started 7 days before LILETTA is removed to ensure continued birth control.

What if I change my mind about birth control and want to become pregnant in less than 3 years?
Your healthcare provider can remove LILETTA at any time. You could become pregnant as soon as LILETTA is removed. About 5 out of 6 women who want to become pregnant will become pregnant sometime in the first year after LILETTA is removed.

How does LILETTA work?
LILETTA may work in several ways including by thickening cervical mucus, inhibiting sperm movement, reducing sperm survival, and thinning the lining of your uterus. It is not known exactly how these actions work together to prevent pregnancy.

How well does LILETTA work for contraception?
The following chart shows the chance of getting pregnant for women who use different methods of birth control. Each box on the chart contains a list of birth control methods that are similar in effectiveness. The most effective methods are at the top of the chart. The box on the bottom of the chart shows the chance of getting pregnant for women who do not use birth control and are trying to get pregnant.

LILETTA, an intrauterine system (IUS), is in the box at the top of the chart.

Who might use LILETTA?
You might choose LILETTA if you:
- want birth control that provides a low chance of getting pregnant (less than 1 in 100)
- want birth control that works continuously for up to a maximum of 3 years
- want birth control that is reversible
- want a birth control method that you do not need to take daily
- are willing to use a birth control method that is inserted in the uterus
- want birth control that does not contain estrogen

Who should not use LILETTA?
Do not use LILETTA if you:
- are or might be pregnant; LILETTA cannot be used as an emergency contraceptive
have had a serious pelvic infection called pelvic inflammatory disease (PID) unless you have had a normal pregnancy after the infection went away
have an untreated pelvic infection now
have had a serious pelvic infection in the past 3 months after a pregnancy
can get infections easily. For example, if you:
  • have problems with your immune system
  • have multiple sexual partners or your partner has multiple sexual partners
  • use or abuse intravenous drugs
  • have or suspect you might have cancer of the uterus or cervix
  • have bleeding from the vagina that has not been explained
  • have liver disease or liver tumor
  • have breast cancer or any other cancer that is sensitive to progestin (a female hormone), now or in the past
  • have an intrauterine system in your uterus already
  • have a condition of the uterus that changes the shape of the uterine cavity, such as large fibroid tumors
  • are allergic to levonorgestrel, silicone, polyethylene, or barium sulfate

Before having LILETTA inserted, tell your healthcare provider if you:
  • have had a heart attack
  • have had a stroke
  • were born with heart disease or have problems with your heart valves
  • have problems with blood clotting or take medicine to reduce clotting
  • have high blood pressure
  • recently had a baby or if you are breastfeeding
  • have severe migraine headaches
  • are or might be pregnant
  • have acute pelvic inflammatory disease or a history of pelvic inflammatory disease
  • have AIDS, HIV, or any other sexually transmitted infection
  • have any other medical conditions

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How is LILETTA inserted?
LILETTA is inserted by your healthcare provider during an in-office visit. First, your healthcare provider will examine your pelvis to find the exact position of your uterus. Your healthcare provider will then clean your vagina and cervix with an antiseptic solution and slide a slim plastic tube containing LILETTA into your uterus. Your healthcare provider will then remove the plastic tube, and leave LILETTA in your uterus. Your healthcare provider will trim the threads to the right length. Insertion takes only a few minutes.

You may experience pain, bleeding, or dizziness during and after insertion. If your symptoms do not pass within 30 minutes after insertion, LILETTA may not have been inserted correctly. Your healthcare provider will examine you to see if LILETTA needs to be removed or replaced.

Should I check that LILETTA is in place?
Yes, you should check that LILETTA is in proper position by feeling the threads. It is a good habit to do this 1 time a month. Your healthcare provider should teach you how to check that LILETTA is in place. First, wash your hands with soap and water. You can check by reaching up to the top of your vagina with clean fingers to feel the threads. Do not pull on the threads.

If you feel more than just the threads or if you cannot feel the threads, LILETTA may not be in the right position and may not prevent pregnancy. Use non-hormonal back-up birth control (such as condoms and spermicide) and ask your healthcare provider to check that LILETTA is still in the right place.

If LILETTA is accidentally removed and you had vaginal intercourse within the preceding 24 hours, you may be at risk of pregnancy, and should talk to a healthcare provider.

How soon after insertion of LILETTA should I return to my healthcare provider?
Call your healthcare provider if you have any questions or concerns (see “When should I call my healthcare provider?”). Otherwise, you should return to your healthcare provider for a follow-up visit 4 to 6 weeks after LILETTA is inserted to make sure that LILETTA is in the right position.

Can I use tampons with LILETTA?
Tampons may be used with LILETTA.

What if I become pregnant while using LILETTA?
Call your healthcare provider right away if you think you are pregnant. If you get pregnant while using LILETTA, you may have an ectopic pregnancy. This means that the pregnancy is not in the uterus. Unusual vaginal bleeding or abdominal pain may be a sign of ectopic pregnancy.

Ectopic pregnancy is a medical emergency that often requires surgery. Ectopic pregnancy can cause internal bleeding, infertility, and even death.

There are also risks if you get pregnant while using LILETTA and the pregnancy is in the uterus. Severe infection, miscarriage, premature delivery, and even death can occur with pregnancies that continue with an intrauterine system (IUS). Because of this, your healthcare provider may try to remove LILETTA, even though removing it may cause a miscarriage. If LILETTA cannot be removed, talk with your healthcare provider about the benefits and risks of continuing the pregnancy.

If you continue your pregnancy, see your healthcare provider regularly. Call your healthcare provider right away if you get flu-like symptoms, fever, chills, cramping, pain, bleeding, vaginal discharge, or fluid leaking from your vagina. These may be signs of infection.

It is not known if LILETTA can cause long-term effects on the fetus if it stays in place during a pregnancy.

How will LILETTA change my periods?
For the first 3 to 6 months, your period may become irregular and the number of bleeding days may increase. You may also have frequent spotting or light bleeding. Some women have heavy bleeding during this time. After you have used LILETTA for a while, the number of bleeding and spotting days is likely to lessen. For some women, menstrual periods will stop altogether. When LILETTA is removed, your menstrual periods will likely return to their former pattern.

If you have any concerns that you may be pregnant while using LILETTA, do a urine pregnancy test or call your healthcare provider.

Is it safe to breastfeed while using LILETTA?
You may use LILETTA when you are breastfeeding if more than 6 weeks have passed since you had your baby. If you are breastfeeding, LILETTA is not likely to affect the quality or amount of your breast milk or the health of your nursing baby. However, isolated cases of decreased milk production have been reported among women using progestin-only birth control pills.

Will LILETTA interfere with sexual intercourse?
You and your partner should not feel LILETTA during intercourse. LILETTA is inserted in the uterus, not in the vagina. In some cases, your partner may feel the threads. If this occurs, or if you or your partner experience pain during sex, talk with your healthcare provider.

Can I have an MRI with Liletta in place?
LILETTA is MR Safe. It is safe to have an MRI following LILETTA insertion.

What are the possible side effects of LILETTA?
LILETTA can cause serious side effects, including:
  • ectopic pregnancy. If you get pregnant while using LILETTA, you might have an ectopic pregnancy. This means that the pregnancy is not in the uterus. Unusual vaginal bleeding or abdominal pain may be a sign of ectopic pregnancy. Ectopic pregnancy is a medical...
Some IUS users get a serious

• Pain, bleeding, or dizziness during and after insertion. If these symptoms
• mood changes
• depression
• breast pain
• abdominal pain
• pain during sex
• nausea/vomiting
• headache
• infection of the outer part of your vagina (vulvovaginal)

The most common side effects of LILETTA include:

• vaginal infection
• infection of the outer part of your vagina (vulvovaginal)
• acne
• headache
• nausea/vomiting
• pain during sex
• abdominal pain
• breast pain
• pelvic pain
• depression
• mood changes
• Pain, bleeding, or dizziness during and after insertion. If these symptoms
do not stop within 30 minutes after insertion, LILETTA may not have
been inserted correctly. Your healthcare provider will examine you to
see if LILETTA needs to be removed or replaced.
• Missed menstrual periods. About 1 out of 5 women stop having
periods after 1 year of LILETTA use. If you have any concerns that
you may be pregnant while using LILETTA, do a urine pregnancy test
or call your healthcare provider. When LILETTA is removed, your
menstrual periods will usually return to your previous pattern.

After LILETTA has been inserted, when should I call my healthcare
provider?
Call your healthcare provider if you have any concerns about LILETTA.
Be sure to call if you:
• think you are pregnant
• have pelvic pain or during sex
• have unusual vaginal discharge or genital sores
• have unexplained fever, flu-like symptoms or chills
• might be exposed to sexually transmitted infections (STIs)
• are concerned that the IUS may have been expelled (came out)
• cannot feel LILETTA’s threads
• develop very severe or migraine headaches
• have yellowing of the skin or whites of the eyes. These may be signs
of liver problems.
• have had a stroke or heart attack
• you or your partner becomes HIV positive
• have severe vaginal bleeding or bleeding that concerns you

General information about the safe and effective use of LILETTA.
Medicines are sometimes prescribed for purposes other than those
listed in a Patient Information leaflet.
This leaflet summarizes the most important information about LILETTA.
If you would like more information, talk to your healthcare provider. You
can ask your pharmacist or healthcare provider for information about
LILETTA that is written for health professionals.
For more information, go to www.LILETTA.com or call 1-855-LILETTA
(1-855-545-3882).
This Patient Information has been approved by the U.S. Food and Drug
Administration.
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