

The Texas LARC Toolkit

A resource for implementing the Texas Medicaid policy
on providing long-acting reversible contraceptive (LARC) services

A collaboration of District XI (Texas) of the American Congress of
Obstetricians and Gynecologists,
the Texas Health and Human Services Commission (HHSC),
and the Texas Department of State Health Services (DSHS)

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Introduction

Since 2013, the Texas Health and Human Services Commission (HHSC) and the Texas Department of State Health Services (DSHS) have worked collaboratively to improve birth outcomes. This coordinated effort builds on previous efforts, including Healthy Texas Babies and the Maternal Mortality and Morbidity Task Force. One component of this effort is aimed at providing opportunities to reduce unintended pregnancies and allow Texans to determine for themselves the best way and time to grow their families.

Long-Acting Reversible Contraceptive (LARC) devices (ie, the intrauterine device [IUD] and subdermal contraceptive device) offer a reversible method of contraception with very high real-world effectiveness, ease of use, and high rates of user satisfaction and method continuation. Texas has made improving access to LARCs a priority. This toolkit is aimed at helping providers to increase the availability of LARCs to all Texas women.

The Texas LARC Toolkit offers suggestions and resources to support implementation of a policy to make LARCs available to women throughout the reproductive life cycle, including prior to the first pregnancy, during the postpartum period (both during the hospital stay and at the postpartum visit), and whenever family planning services are received.

Successful implementation of a LARC program requires planning and coordination by all individuals and service groups who will play a role in the program. Development of a LARC program requires all of the following at a minimum:

- Patient counseling and education
- Planning for program initiation
- Logistical planning
- Training of clinical and support staff
- Patient protocols and procedural aspects
- Billing and reimbursement

For specific information on Medicaid eligibility and billing, go to the Texas Medicaid website at www.hhsc.state.tx.us/medicaid/ or the Healthy Texas Women website www.healthytexaswomen.org or call 512-776-7111.

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Patient Counseling and Education

General considerations:

Prior to initiating any contraceptive method, patients should receive patient-centered education in their preferred language, and using terms and phrasing they understand and are comfortable with, in order to make informed decisions about family planning. Each patient should receive method-specific counseling on all methods suitable for that patient, as well as information on preventing sexually transmitted diseases/infections (STD/STIs) and HIV. Patients should be counseled on the relative real-world effectiveness of methods, the risks and side effects of different methods, how to manage side effects, and how to recognize and address possible complications. They should demonstrate understanding of the information received and satisfaction that all of their questions have been completely answered.

Timing of patient counseling:

Whenever counseling is given, patients should be informed of their opportunity to change their decision at any time prior to insertion of a contraceptive device without fear or possibility of reprisal.

Patient counseling during/before insertion in hospital – For immediate postpartum LARC insertion prior to hospital discharge, patient education should ideally begin in the prenatal clinic. If this is not possible, patient counseling should be done soon after admission to the hospital for delivery. This will allow the patient to receive counseling in an unhurried fashion, ensuring that she has an opportunity to fully understand all her contraceptive options and to make a fully informed decision.

Patient counseling for insertion in outpatient clinic – Patients should receive counseling prior to insertion of the contraceptive device, which can occur on the day of insertion or earlier.

Counseling topics:

Relative method effectiveness (range of effectiveness [actual effectiveness depends on correctness and consistency of use])¹:

- Extremely effective (~99%):
 - Total sexual abstinence
 - Lactational amenorrhea (< 6 months postpartum, amenorrheic, and providing 85-100% of infant feedings as breast feedings)
 - Contraceptive implant
 - Intrauterine device
 - Male or female sterilization

¹ Centers for Disease Control and Prevention. Selected practice recommendations for contraceptive use 2013. *MMWR* 62(No.RR-5). Available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6205a1.htm?s_cid=rr6205a1_w (web) <http://www.cdc.gov/mmwr/pdf/rr/rr6205.pdf> (PDF)

Association of Reproductive Health Professionals. Method Match. Online decision support tool to help patients compare and select from different methods of contraception; includes information on relative effectiveness of methods. Available at <http://www.arhp.org/methodmatch/>

American Congress of Obstetricians and Gynecologists. Long-acting reversible contraception program web page. Provides information, clinical guidance, and educational materials on Long-acting reversible contraceptives [LARCs]. Available at https://www.acog.org/About_ACOG/ACOG_Departments/Long_Acting_Reversible_Contraception

- Very effective (~91-99%):
 - Hormonal contraceptive pills
 - Hormonal contraceptive patch
 - Progestin injection (i.e., Depo-Provera)
 - Vaginal ring
- Effective (~80-99%)
 - Diaphragm
 - Female condom
 - Male condom
 - Withdrawal (“pulling out”)
- Moderately effective (see individual method effectiveness below if listed)
 - Cervical cap
 - Fertility awareness (“rhythm”) (~76-99%)
 - Spermicide (~72-82%)
 - Sponge

General patient counseling topics about LARCs:

- LARCs (the intrauterine device [IUD] and contraceptive implant) are highly effective for preventing pregnancy, are easy to use, and last for several years. Depending on the type, they last from 3 to 10 years.
- LARCs offer reversible contraception, and can be removed at any time.
- LARCs are the most effective reversible method of contraception available. Fewer than 1 in 100 women will become pregnant while using a LARC.
- LARCs do not protect against sexually transmitted infections (STI) or HIV infection. Persons at increased risk of STI or HIV infection should also use condoms with intercourse to reduce this risk.

IUD-specific counseling:

- The IUD is a small device that is inserted into the uterus and remains there until it is removed.
- There are 2 types of IUDs:
 - The hormonal IUD releases a hormone called progestin.
 - The copper IUD does not contain any hormones.
- How IUDs prevent pregnancy
 - All IUDs work by preventing fertilization.
 - The hormonal IUD thickens the cervical mucous to prevent sperm from reaching the egg, and thins the uterine lining to prevent a fertilized egg from implanting in the wall of the uterus.
- IUD insertion procedure:
 - A pelvic examination is performed by the health care provider.
 - With the speculum in the vagina, the IUD is introduced into the uterus with a slender tube.

- The tube is removed and the IUD remains inside the uterus.
 - Insertion may cause some discomfort; taking over the counter pain medicine before the procedure may help.
 - A fine string protrudes from the cervix into the vagina while the IUD is in place. The string does not extend outside the vagina and should not cause any discomfort.
 - If the patient wishes to confirm that the IUD is in place, she can feel for the string, but this is not required.
- Benefits of the IUD:
 - Most women are able to use them, including women of any age and parity, including nulliparous women.
 - Once it is placed, nothing else needs to be done to prevent pregnancy.
 - It can be removed at any time.
 - It can be inserted immediately after a pregnancy, or while breastfeeding.
 - No one else is aware it is there.
 - It does not interfere with sex and will not come out with sex or tampon use.
 - The hormonal IUD may decrease heavy periods and pain with periods.
- Risks of the IUD:
 - The IUD may come out by itself (be expelled spontaneously). This occurs in about 10-25% of women who have it inserted immediately after childbirth and in about 5% of women who have it inserted at another time.
 - Rarely, the IUD can perforate the uterine wall during insertion. This occurs about 1 time in 1,000 insertions.
 - There is a slight increase in the risk of pelvic inflammatory disease (PID) in the first 20 days after insertion, occurring in < 1% of women. PID can cause scarring of the reproductive organs and infertility.
 - Rarely, pregnancy can occur while an IUD is in place. If this happens, there is a higher chance of an ectopic pregnancy.
- Side effects of the IUD:
 - Women using the copper IUD may experience increased cramping and bleeding with periods, and bleeding between periods, both of which are more common in the first few months and usually decrease after the first year.
 - Women using the hormonal IUD may have spotting and irregular periods during the first 3 to 6 months, but periods will usually become shorter and lighter after longer use, and menstrual pain will usually decrease.
 - The hormonal IUD may cause some side effects due to the hormone, including breast tenderness, headaches, depression, and nausea.
- Dispel myths associated with the IUD:
 - Although the IUD does not increase the risk of infection or pelvic inflammatory disease after the first month, it does not protect against STI/STDs. All patients should be advised to use condoms to reduce the risk of STI/STDs.

- The IUD does not cause infertility.
- The IUD does not cause abortion.

Implant-specific counseling:

- The contraceptive implant is a small flexible rod placed just under the skin on the inside of the upper arm, providing contraception for up to 3 years.
- How the contraceptive implant prevents pregnancy:
 - The implant works by releasing a small amount of progestin (a hormone) into the blood.
 - The hormone has 3 effects:
 - It prevents ovulation.
 - It thickens the cervical mucous to reduce sperm penetration, so if ovulation occurs, it is less likely the egg will be fertilized.
 - It thins the uterine lining so a fertilized egg is less likely to implant in the uterus.
- The implant insertion/removal procedure:
 - A local anesthetic is applied to the skin on the inside of the upper arm.
 - The implant is then inserted just under the skin using a special inserter.
 - No incision is made in the skin and the procedure takes only a few minutes.
 - The woman should be able to feel the implant under the skin but it is not visible or noticeable to others.
 - When the woman is ready to have it removed, local anesthetic is applied to the skin, a small incision is made, and the implant is removed.
- Benefits of the contraceptive implant:
 - Most women are able to use it, including women of any age and parity, including nulliparous women.
 - Once it is placed, nothing else needs to be done to prevent pregnancy.
 - It can be removed at any time.
 - It can be inserted immediately after a pregnancy, or while breastfeeding.
 - No one else is aware it is there.
- Risks of the contraceptive implant:
 - A small percent of women (< 2%) will have a problem with insertion or removal of the implant.
 - Although pregnancy is very rare with a contraceptive implant, if a woman becomes pregnant while using the implant, there is a slightly higher risk of an ectopic pregnancy.
- Side effects of the contraceptive implant:
 - The most common side effect is irregular bleeding, which may improve with time.
 - Some women stop having periods on the implant.
 - Other possible side effects include headaches, mood changes, depression, acne, and weight gain.

Resources for patients and educators:

Association of Reproductive Health Professionals. Method Match. Online decision support tool to help patients compare and select from different methods of contraception; includes information on relative effectiveness of methods. Available at <http://www.arhp.org/methodmatch/>

Association of Reproductive Health Professionals. The facts about intrauterine contraception. Available at <http://www.arhp.org/Publications-and-Resources/Clinical-Fact-Sheets/The-Facts-About-Intrauterine-Contraception->

The American Congress of Obstetricians and Gynecologists. Long-acting reversible contraception (LARC): IUD and implant: Frequently Asked Questions. Available at <http://www.acog.org/Patients/FAQs/Long-Acting-Reversible-Contraception-LARC-IUD-and-Implant>

The Reproductive Health Access Project website contains helpful fact sheets and information for patients and providers on a broad range of contraceptive topics, including LARCs:

- Contraception home page: <http://www.reproductiveaccess.org/key-areas/contraception/>
- Your birth control choices fact sheet: <http://www.reproductiveaccess.org/resource/birth-control-choices-fact-sheet/>
- IUD
 - IUD fact sheet: <http://www.reproductiveaccess.org/resource/iud-facts/>
 - IUD consent form: <http://www.reproductiveaccess.org/resource/iud-consent-form/>
 - IUD aftercare instructions: <http://www.reproductiveaccess.org/resource/iud-aftercare-instructions/>
- Contraceptive implant:
 - Progestin implant fact sheet: <http://www.reproductiveaccess.org/resource/progestin-implant/>
 - Progestin implant consent form: <http://www.reproductiveaccess.org/resource/progestin-implant-consent-form/>
 - Progestin implant aftercare instructions: <http://www.reproductiveaccess.org/resource/progestin-implant-aftercare-instructions/>

Planning for Program Initiation

In the clinic:

Planning a program for LARC insertion at an outpatient clinic requires developing all of the following elements:

- Training of clinical and support staff
- Method of device availability
- Protocol for providing client education and obtaining informed consent
- Procedural protocol for LARC insertion
- Billing protocol for provider services and device reimbursement (as appropriate for the method used to acquire the device)

In the hospital:

Because pregnancy and the postpartum period are a time when women typically access health care services and often have a heightened interest in contraception, the postpartum period offers a convenient opportunity for initiation of LARC methods. In January 2016, Texas Medicaid revised its reimbursement policies to enable hospitals and providers to receive full reimbursement (outside the global fee for delivery) for the LARC device and the provider insertion procedure fee when women receive a LARC postpartum, prior to being discharged from the hospital. Managed care organizations (MCOs) that contract with Medicaid in Texas have adopted similar reimbursement policies. This policy revision is expected to remove a substantial barrier to providing LARC services to women in the immediate postpartum period, enabling new mothers to choose and initiate highly effective methods of contraception in a timely manner.

Immediate postpartum LARC insertion refers to the insertion of an IUD in the delivery room immediately after delivery of the placenta, or insertion of an IUD or subdermal contraceptive implant prior to hospital discharge. Planning for this requires developing all of the following elements:

- Administrative support and logistical infrastructure
- Process for credentialing of providers who will place the devices. Because of the special considerations with immediate postpartum IUD insertion, hospitals may require more specialized training and demonstration of competency.
- Pharmacy or supply chain process to acquire the devices and ensure availability at the time and place of insertion
- Training of support staff
- Protocol for patient education and informed consent
- Pharmacy, Labor and Delivery, Operating Room, and postpartum protocols to make the devices available immediately after delivery with trained clinical and support staff prepared to perform the procedure and care for the patient after insertion.
 - For postpartum IUD insertion immediately after delivery of the placenta, a protocol must be developed to ensure the devices and trained personnel are readily available in the Labor and Delivery suite or Operating Room.

- For IUD or subdermal implant insertion prior to hospital discharge, a protocol must ensure availability of the devices and trained personnel as well as a policy for where and how the procedure will be performed.
- Billing processes to capture hospital costs and provider services appropriately

Logistical Planning

Outpatient clinic planning:

Logistical requirements for clinic LARC insertion include the following considerations:

- Implement protocols for patient education about the range of contraceptive options, including LARCs.
- For patients who elect to use a LARC, ensure that they have given informed consent for the insertion of an IUD or implantable contraceptive device. Ensure also that patients are given an opportunity to withdraw their consent at any time without fear of reprisal.
- Develop a protocol for insertion that allows for proper technique and patient safety and comfort.
- Ensure that providers and support staff are appropriately trained.
- Ensure device availability at the appropriate time:
 - Clinics may use the “buy and bill” method by which providers purchase a stock of the device in advance from a pharmaceutical vendor and then pull from stock at the time of insertion, or the pharmacy option by which the device is obtained from a participating pharmacy for the individual patient.
 - Details on how to acquire the product for each option are available from the product manufacturer.
- Develop a protocol for billing to address product cost reimbursement and provider service fees. For details on billing and reimbursement options, see the “Billing and Reimbursement” section of this manual.
- Develop a protocol for patient education about the chosen method and appropriate follow up.

Hospital planning:

Logistical requirements for immediate postpartum LARC insertion in the hospital prior to discharge include the following considerations:

- Implement a protocol to ensure that patients have been educated about the range of postpartum contraceptive options and that their questions have been answered to their satisfaction. Ensure that patients have given informed consent for the insertion of an IUD or contraceptive implant and that they are given an opportunity to withdraw their consent at any time prior to LARC insertion without fear of reprisal.
 - Ideally, the hospital delivery team and prenatal care providers will cooperate to incorporate patient education on postpartum contraceptive options, including LARCs, into the course of prenatal care.
 - Any counseling provided in the hospital setting should be given at the time of admission when patient and educator have more freedom to devote the necessary time to ensure a fully informed decision on the part of the patient.
- For IUD insertion immediately after delivery of the placenta:
 - Develop a protocol that fits into the normal work flow in the Labor and Delivery suite for patients having a vaginal delivery and the Obstetrical Operating Room for those having a cesarean

- delivery. The process should not obstruct or unnecessarily delay the delivery or surgical procedure, or interfere with early mother-infant bonding, breastfeeding, or other patient care.
- Ensure that all equipment (including the IUD to be used), as well as trained and properly credentialed staff are readily available at the appropriate time, immediately after delivery of the placenta.
- For IUD or contraceptive implant insertion after delivery but before hospital discharge:
 - Develop a protocol that fits into the normal work flow on the postpartum ward, and does not unduly interfere with mother-infant bonding, breastfeeding, or mother and infant care.
 - Determine where the procedure will be performed. If this is not to be in the patient room, develop a protocol to ensure that the location to be used will be available and ready for use at the desired time, so as to limit the time the mother is away from her infant and to minimize disruption of both individual patient care and normal postpartum ward activities.
 - Ensure that all necessary equipment (including the contraceptive device to be used), as well as trained and properly credentialed staff are readily available at the appropriate time.
 - Coordinate with appropriate hospital departments and personnel (eg, Pharmacy staff, supply chain staff) to ensure that the device is readily available at the appropriate time in the Labor and Delivery suite or on the postpartum ward, to avoid delays in placement that may result in cancelation of the procedure or interfere with mother-infant bonding and patient care.
 - Care should be taken to ensure that a misstep in the process (eg, unavailability of the equipment or trained personnel, delay in patient education and informed consent, unavailability of the procedure room, etc.) does not become a bottleneck that interrupts the normal flow of work or patient care in the hospital.
 - Implement a protocol to assure continuity of care for women after discharge from the hospital:
 - Provide post-procedural patient education about the LARC method being used and how to arrange appropriate follow up visits.
 - Texas women receiving maternity care under Medicaid for Pregnant Women have Medicaid coverage for two months after the date of delivery. After that time, eligible women will be automatically enrolled in the Healthy Texas Women program (HTW).
 - The HTW auto-enrollment process goes into effect July 1, 2016.
 - Auto-enrollment is limited to women 18-44 years of age who are not covered by any other Medicaid program, CHIP, or private health insurance plan.
 - Women 15-17 years of age may apply for HTW by the traditional application process.
 - Women who reside in Texas and receive prenatal care under the CHIP Perinatal program are eligible for 2 postpartum visits as part of the CHIP Perinatal care package. Eligible women may receive continued family planning services under the Family Planning Program.
 - Patients can find information about their program eligibility and locate a healthcare provider at the Healthy Texas Women website, located at <https://www.healthytexaswomen.org/>

Training of Clinical and Support Staff

General considerations:

In general, LARC methods of contraception provide a very high real-world rate of contraceptive efficacy and high rates of patient satisfaction and continuation. Both the IUD and contraceptive implant are appropriate for most women, including nulliparous and adolescent women, and may be inserted any time in the menstrual cycle as long as the provider may be reasonably certain the woman is not pregnant (see “Timing of Insertion” in the “Patient Protocols and Procedural Aspects” section of this manual). Because pregnancy and the postpartum period are a time when women typically access health care services and often have a heightened interest in contraception, the postpartum period offers a convenient opportunity for initiation of LARC methods.

The copper IUD contains no hormone and has been proven effective for 10 years. Of the levonorgestrel-containing IUDs, Mirena has been proven effective for 5 years, Skyla and Liletta for 3 years. These IUDs contain low-dose progestin and no estrogen.

The contraceptive implant, Nexplanon, contains etonorgestrel in a single radiopaque rod inserted under the skin of the medial forearm. It is approved for 3 years of continuous use.

Patient medical eligibility:

IUD – The Centers for Disease Control and Prevention provides the following medical eligibility criteria for IUD ([CDC, 2010](#)) as a contraceptive method:

- Age:
 - Category 2 eligibility classification (the advantages generally outweigh the theoretical or proven risks) for women from menarche to < 20 years of age due to a concern over the risk of expulsion in a nulliparous woman and risk of sexually transmitted infection in a sexually active adolescent
 - Category 1 eligibility classification (no restriction) for women 20 years of age and older
- Parity:
 - Category 2 eligibility classification (the advantages generally outweigh the theoretical or proven risks) for nulliparous women due to conflicting evidence regarding an association with infertility; well-designed studies suggest no increase in the risk of infertility
 - Category 1 eligibility classification (no restriction) for parous women
- Postpartum (breastfeeding or not breastfeeding):
 - Either the copper IUD or the levonorgestrel-containing IUD may be used by breastfeeding women and may be used after vaginal or cesarean delivery; however, there is limited evidence regarding the possible effect of the IUD on breastfeeding (Lopez et al, 2015).
 - One randomized study found lower breastfeeding rates at 75 days after insertion and no significant difference in mean total days of breastfeeding for a levonorgestrel-containing IUD as compared with a copper-containing nonhormonal IUD.

- One randomized study found no significant difference in the rate of full breastfeeding, mean infant length, or mean infant weight at 6 and 12 months with a levonorgestrel-containing IUD as compared with a copper-containing nonhormonal IUD.
 - A woman who remains amenorrheic and breastfeeds exclusively or almost exclusively (ie, 85-100% of infant feeds are from the breast) will experience a pregnancy risk of approximately 2% per year until the infant is 6 months of age, making the lactational amenorrhea method of contraception an alternative some women may choose in the first 6 months postpartum.
 - Providers are encouraged to counsel patients who are breastfeeding or wish to breastfeed on the available evidence and the limitations of the evidence to allow them to make the most informed decision possible about contraception while breastfeeding.
 - The copper IUD is category 1 (no restriction) if inserted < 10 minutes after delivery of the placenta, and category 2 (the advantages generally outweigh the theoretical or proven risks) if inserted from 10 minutes after placental delivery until < 4 weeks postpartum, due to a lower expulsion rate with insertion in the first 10 minutes.
 - The levonorgestrel-containing IUD is category 2 (the advantages generally outweigh the theoretical or proven risks) for insertion at any time after placental delivery until < 4 weeks postpartum due to the absence of evidence evaluating the effect of timing of insertion.
 - Both the copper IUD and levonorgestrel-containing IUD are category 1 (no restriction) for insertion 4 weeks or more after delivery.
 - Both the copper IUD and levonorgestrel are contraindicated (ie, category 4 [unacceptable health risk]) in postpartum patients with puerperal sepsis.
- Other recent pregnancy:
 - Both the copper IUD and levonorgestrel-containing IUD are category 1 (no restriction) for insertion after a first trimester abortion (spontaneous or induced).
 - Both the copper IUD and levonorgestrel-containing IUD are category 2 (the advantages generally outweigh the theoretical or proven risks) for insertion after a second trimester abortion (spontaneous or induced) due to an increased risk of expulsion.
 - Both the copper IUD and levonorgestrel are contraindicated (ie, category 4 [unacceptable health risk]) immediately following a septic abortion.
 - Both the copper IUD and levonorgestrel-containing IUD are category 1 (no restriction) for insertion in patients with a prior ectopic pregnancy.
 - Note that the risk of a subsequent ectopic pregnancy is substantially reduced due to the very low risk of pregnancy with an IUD in place.
 - However, if a pregnancy occurs with an IUD in place, the risk of ectopic is greatly increased.

Implant – The Centers for Disease Control and Prevention provides the following medical eligibility criteria for the etonorgestrel-containing contraceptive implant:

- Age and parity:

- Category 1 eligibility classification (no restriction) for women of all ages from menarche and above, and for both nulliparous and parous women.
- Breastfeeding women:
 - Category 2 eligibility classification (the advantages generally outweigh the theoretical or proven risks) for breastfeeding women in the first 4 weeks postpartum due to a theoretical risk of diminished milk production and animal studies that suggest a potential for impact on neonatal brain development, although direct human evidence is lacking for either issue.
 - Category 1 eligibility classification (no restriction) for breastfeeding women any time after 1 month postpartum.
 - There is limited evidence regarding the possible effect of the progestin-containing implant (ie, etonorgestrel-releasing) on breastfeeding (Lopez et al, 2015).
 - One randomized study of women with a body mass index < 30 kg/m² found an increase in mean infant weight at 6 weeks of age, and no significant difference in the rate of full breastfeeding at 6 or 12 weeks postpartum, with the etonorgestrel implant placed at 24 to 48 hours postpartum as compared with no contraceptive method for the first 6 weeks followed by initiation of depot medroxyprogesterone acetate by injection.
 - One randomized study found no significant difference in the incidence of lactation failure, mean time to lactogenesis, full breastfeeding, or any breastfeeding with insertion of the etonorgestrel-releasing contraceptive implant at 1 to 3 days postpartum as compared with 4 to 8 weeks postpartum.
 - A woman who remains amenorrheic and breastfeeds exclusively or almost exclusively (ie, 85-100% of infant feeds are from the breast) will experience a pregnancy risk of approximately 2% per year until the infant is 6 months of age, making the lactational amenorrhea method of contraception an alternative some women may choose in the first 6 months postpartum.
 - Providers are encouraged to counsel patients who are breastfeeding or wish to breastfeed on the available evidence and the limitations of the evidence to allow them to make the most informed decision possible about contraception while breastfeeding.
- Postpartum (not breastfeeding) or other recent pregnancy:
 - Category 1 eligibility classification (no restriction) for postpartum women who are not breastfeeding at any time after delivery.
 - Category 1 eligibility classification (no restriction) after abortion in the first or second trimester (spontaneous or induced), including septic abortion
 - Category 1 eligibility classification (no restriction) after ectopic pregnancy

More information on medical eligibility – For more information on the medical eligibility criteria for LARCs according to a variety of patient medical risk factors and considerations, see the [*U.S. Medical Eligibility Criteria for Contraceptive Use, 2010: Adapted from the World Health Organization Medical Eligibility Criteria for Contraceptive Use, 4th edition*](#) from the Centers for Disease Control and Prevention (2010).

Clinical and support staff training for outpatient clinic insertion:

Clinical and support staff training for LARC insertion in the outpatient clinic include the following considerations:

- Clinical staff should be fully trained in patient counseling on contraceptive options, including relative effectiveness, method of use, risks, side effects, and patient follow-up.
- Clinic staff must be trained in the process to be used in the clinic to acquire the device to be used, either buy and bill or pharmacy option, to ensure the device is available for use at the time it is required.
- If assistance is to be provided to the clinician placing the LARC, clinic staff must be trained in setting up and assisting with LARC insertion, with proper attention to sterile technique, as well as care for the patient before, during, and after insertion. If no assistant will be provided, the clinician placing the LARC must be trained to do this.
- Providers must be trained in insertion of the chosen LARC product, including proper use of sterile technique, and in identifying and treating any difficulties or complications that arise. Providers must also be trained in IUD and contraceptive implant removal to ensure that the patient may have the device removed when desired.
- Billing staff for the clinic must be properly trained in the correct billing procedures to ensure full reimbursement.

Clinical and support staff training for hospital insertion:

Clinical and support staff training for immediate postpartum IUD insertion in the delivery room or Obstetrical Operating Room include the following considerations:

- Clinical staff in both the prenatal care realm and the hospital obstetrical service (ie, Labor and Delivery suite and/or postpartum ward) should be fully trained in patient counseling on contraceptive options, including relative effectiveness, method of use, risks and side effects, and patient follow-up (see “Patient Counseling and Education” section of this manual).
- Appropriate hospital staff must be trained in ordering and acquisition of the LARC devices according to the protocol established for the hospital, to ensure that the desired unit is readily available at the patient bedside when needed.
- Staff in the Labor and Delivery suite must be trained in setting up and assisting with IUD and subdermal contraceptive implant insertion, with proper attention to sterile technique, as well as care for the patient before, during, and after insertion.
- Providers must be trained in insertion of the chosen LARC product in the postpartum patient, and in identifying and treating any difficulties or complications that arise. Clinic providers must also be trained in LARC removal to ensure that the patient may have the device removed when desired.
- Billing staff for the hospital and the provider must be properly trained in the correct billing procedures to ensure full reimbursement.

Resources for clinic staff, clinicians, and patient educators:

Resources for providers are available at the LARC Program web page of the American Congress of Obstetricians and Gynecologists. The website provides information on clinical education and training, coding and reimbursement, clinical guidance, and educational materials on LARCs. Available at https://www.acog.org/About_ACOG/ACOG_Departments/Long_Acting_Reversible_Contraception

Information on LARC clinical training opportunities is available at the LARC Clinical Education and Training web page of the American Congress of Obstetricians and Gynecologists, providing a regularly updated list of web sites and conferences that offer clinical training on all methods of LARC insertion and removal. Available at <http://www.acog.org/About-ACOG/ACOG-Departments/Long-Acting-Reversible-Contraception/LARC-Clinician-Education-and-Training>

Centers for Disease Control and Prevention. Selected practice recommendations for contraceptive use 2013. *MMWR* 62(No.RR-5). See pp. 7-17 for information on IUD and contraceptive implants. Available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6205a1.htm?s_cid=rr6205a1_w (web)
<http://www.cdc.gov/mmwr/pdf/rr/rr6205.pdf> (PDF)

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<http://www.cdc.gov/mmwr/pdf/rr/rr5904.pdf> (PDF)

Lopez LM, Grey TW, Stuebe AM, Chen M, Truitt ST, Gallo MF. Combined hormonal versus nonhormonal versus progestin-only contraception in lactation. *Cochrane Database Syst Rev.* (2015). 20;3:CD003988.

Patient Protocols and Procedural Aspects

Timing of insertion:

In the patient who is not postpartum – Provided that the possibility of a current pregnancy may be reasonably excluded, the IUD or contraceptive implant may be inserted at any time during the menstrual cycle. A provider may be reasonably certain that a woman is not currently pregnant if she has no signs or symptoms of pregnancy (either intrauterine or ectopic) and meets at least one of the following criteria:

- < 7 days since the start of a normal menses
- No sexual intercourse since the beginning of the last normal menses
- Has been using a reliable method of contraception correctly and consistently
- < 7 days since a spontaneous or induced abortion
- < 4 weeks postpartum
- < 6 months postpartum, amenorrheic since delivery, and exclusively or almost exclusively breast feeding (at least 85% of infant feedings are breast feedings)

In the immediate postpartum patient – Because pregnancy and the postpartum period are a time when women typically access health care services and often have a heightened interest in contraception, the postpartum period offers a convenient opportunity for initiation of LARC methods.

For patient eligibility and clinical considerations related to the timing of IUD or contraceptive implant insertion, see “Patient medical eligibility” in the section on “Training of Clinical and Support Staff” in this manual.

Screening and testing for STI prior to IUD insertion:

Current evidence does not support routine screening for STIs in low-risk women prior to IUD insertion. For asymptomatic women with increased risk of STI (eg, 25 years of age or less, history of multiple sexual partners), the American College of Obstetricians and Gynecologists recommends screening for STI according to current [CDC guidelines](#), and insertion of the IUD on the same day or when the screening results return. If the result is positive, appropriate treatment should be administered. It is not necessary to remove the IUD in an asymptomatic woman with a positive test for chlamydia or gonorrhea.

CDC medical eligibility criteria for the use of IUD, based on the presence or risk of STI:

- Initiation or continuation of any IUD carries a category 2 (the advantages generally outweigh the theoretical or proven risk) eligibility classification in all of the following cases:
 - Current STI (other than HIV or hepatitis), provided there is no evidence of purulent cervicitis
 - Current vaginitis, including bacterial vaginosis and Trichomonas
 - Women who belong to a group generally considered to have increased risk of STI (eg, 25 years of age or less, history of multiple sexual partners), except when the woman has a very high individual likelihood of exposure to chlamydia or gonorrhea
- Continuation of an IUD carries a category 2 (the advantages generally outweigh the theoretical or proven risk) eligibility classification in the presence of purulent cervicitis. If the woman wishes to continue the method, it is usually not necessary to remove it. Appropriate antibiotics should be administered.
- The IUD should generally not be initiated in the following scenarios:

- Any woman with a very high individual likelihood of exposure to chlamydia or gonorrhea (category 3 [theoretical or proven risks usually outweigh the advantages] eligibility classification)
- A woman with current purulent cervicitis or infection with chlamydia or gonorrhea (category 4 [unacceptable health risk] eligibility classification)

For more information on the medical eligibility criteria for LARCs according to a variety of patient medical risk factors and considerations, see the [U.S. Medical Eligibility Criteria for Contraceptive Use, 2010: Adapted from the World Health Organization Medical Eligibility Criteria for Contraceptive Use, 4th edition](#) from the Centers for Disease Control and Prevention (2010).

Antibiotic prophylaxis:

Routine antibiotic prophylaxis has not been shown to reduce the risk of pelvic inflammatory disease and is not recommended prior to IUD insertion. The risk of pelvic infection is increased in the first 20 days after insertion, possibly due to bacterial contamination related to the process of insertion.

References:

American College of Obstetricians and Gynecologists (2011). Practice Bulletin No. 121: Long-acting reversible contraception: Implants and intrauterine devices. *Obstet Gynecol* 118: 184-196.

Centers for Disease Control and Prevention. Selected practice recommendations for contraceptive use 2013. *MMWR* 62(No.RR-5). Available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6205a1.htm?s_cid=rr6205a1_w (web) <http://www.cdc.gov/mmwr/pdf/rr/rr6205.pdf> (PDF)

Centers for Disease Control and Prevention. Sexually transmitted diseases: Treatment. Available at <http://www.cdc.gov/std/treatment/default.htm>

Billing and Reimbursement

In the clinic:

There are two main ways that providers can bill for LARC devices - The buy and bill method or the pharmacy method.

Texas Medicaid and Healthy Texas Women providers can use either method. Family Planning Program providers can only use the buy and bill method.

How to use the buy and bill method:

1. Provider orders the LARC device directly from the manufacturer or through a third party distributor or pharmacy. The product website will provide information on how to order and pay for the device.
2. Provider keeps the LARC device on-site in their general stock. When a patient requests a LARC method, the provider pulls from their on-site stock and can provide the service on the same day.

*If a device is damaged, opened, or expired, the provider should contact the manufacturer for possible replacement options.
3. Provider bills Texas Medicaid, Healthy Texas Women, or the Family Planning Program for both the LARC device and the insertion. For patients enrolled in Medicaid Managed Care, the provider should contact the patient's Managed Care Organization (MCO) for specific billing instructions.

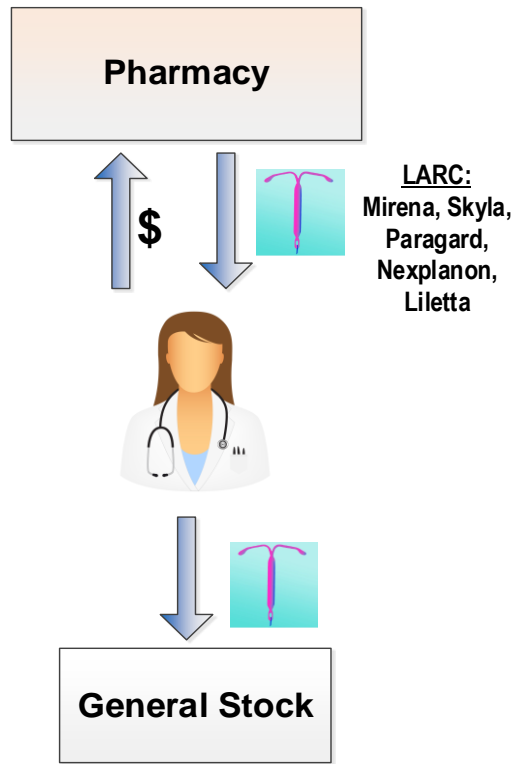
LARC Billing Codes

Code	Description
J7297	Liletta®
J7298	Mirena®
J7300	Paragard®
J7301	Skyla®
J7307	Nexplanon®
58300	IUD insertion
11981	Implant insertion

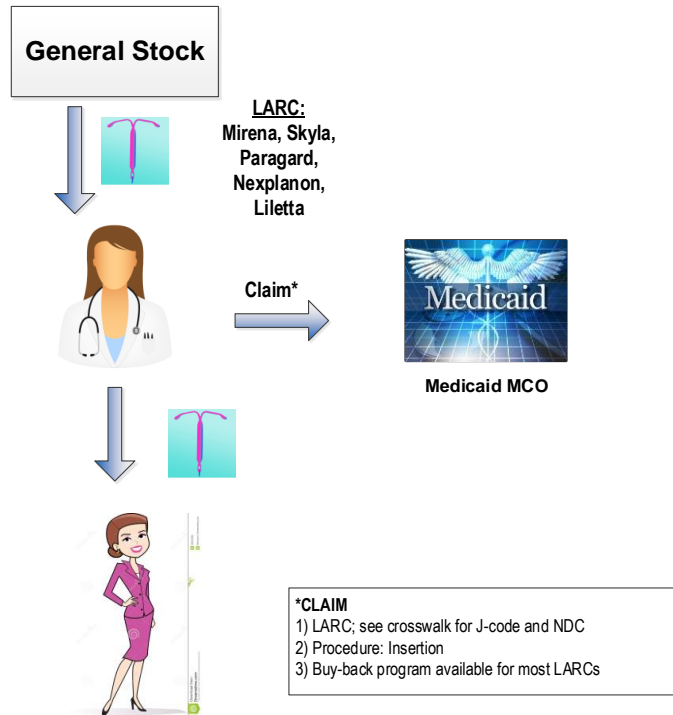
Providers do not have to bill procedure codes J7297, J7298, J7300, and J7301 with procedure code 58300 (insert intrauterine device) on the same day by the same provider to receive reimbursement for an IUD or for the insertion of the LARC product.

Buy and Bill Graphic Summary:

Before Appointment



During Appointment



How to use the pharmacy method:

Any provider that is currently enrolled in Texas Medicaid or Healthy Texas Women can prescribe LARC products listed on the Medicaid drug formulary and obtain them from certain specialty pharmacies for women that receive Medicaid or Healthy Texas Women services. Providers do not need to enroll with specialty pharmacies to obtain LARC products from them.

1. Patient requests a LARC method.
2. Provider submits a completed and signed prescription request form to the specialty pharmacy for the individual patient. See the [Texas Vendor Drug Program](#) website for instructions on completing each specialty pharmacy's prescription request form.
3. The specialty pharmacy dispenses the LARC product (shipped to the practice address, care of the patient) and bills Medicaid or Healthy Texas Women. The provider does not need to bill Medicaid or Healthy Texas Women for the LARC device.

Providers who prescribe and obtain LARC products through a specialty pharmacy are encouraged to return unused and unopened LARC products to the manufacturer's third-party processor. Prescribers should refer to the manufacturer for specific instructions on their buy-back program. The provider will not have to submit any additional claims, as this will be taken care of by the pharmacy.

4. Provider provides services to patient using the patient-specific LARC device obtained from the specialty pharmacy.
5. Provider bills Texas Medicaid or Healthy Texas Women for the insertion of the LARC product. For patients enrolled in Medicaid Managed Care, the provider should contact the patient's MCO for specific billing instructions.

LARC Billing Codes

Code	Description
58300	IUD insertion
11981	Implant insertion

Products currently available through the pharmacy method include:

Drug Name	National Drug Code (NDC)	Participating Specialty Pharmacy
Mirena®	50419042101 50419402301	Walgreens Specialty Pharmacy CVS Caremark Specialty Pharmacy
Skyla®	50419042201	Walgreens Specialty Pharmacy CVS Caremark Specialty Pharmacy
Nexplanon ®	00052433001	CVS Caremark Specialty Pharmacy Accredo Specialty Pharmacy
Paragard®	51285020401 51285020402	Biologics, Inc. Specialty Pharmacy

Walgreens Specialty Pharmacy
Frisco, TX
(800) 424-9002
NPI 1851463087

Accredo Specialty Pharmacy
Irving, TX
(972) 929-6800
NPI 1073569034

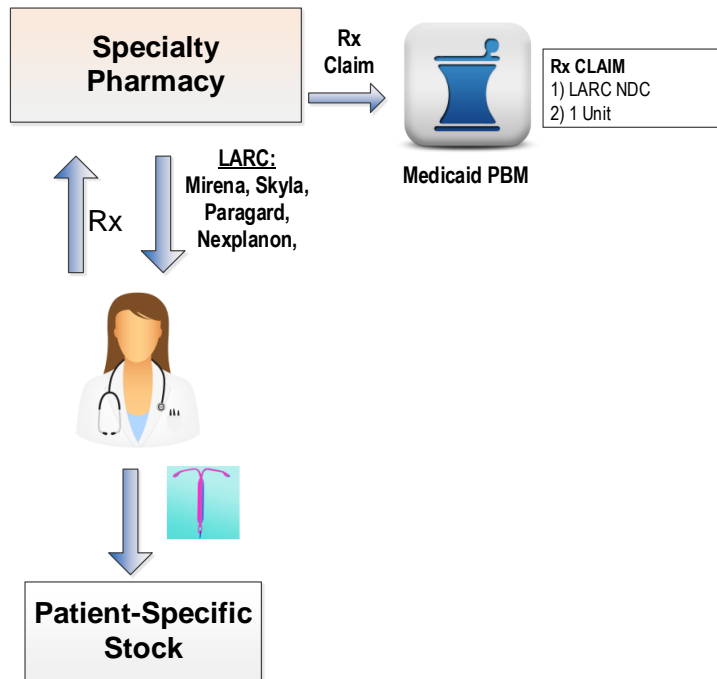
CVS Caremark Specialty Pharmacy
Fort Worth, TX
(817) 336-7281
NPI 1366551848

Biologics, Inc. Specialty Pharmacy
C/O TWH Access Solutions
(888) 275-8596
Cary, NC 27513
NPI 1487640314

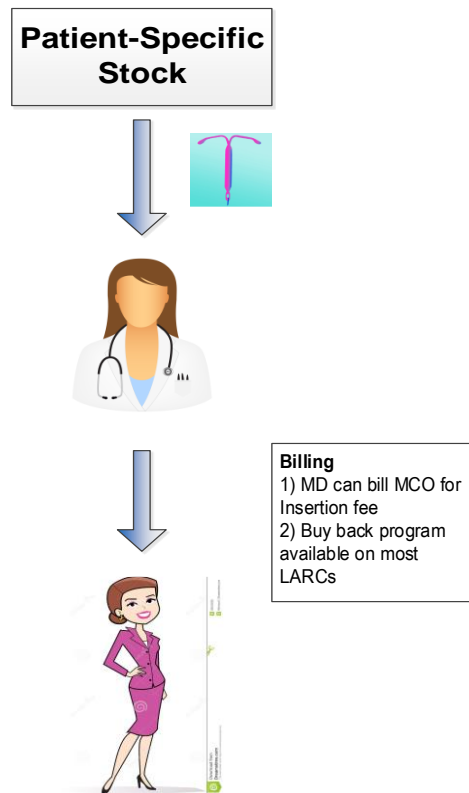
*For more information, please refer to the [Texas Vendor Drug Program](#) website.

Pharmacy Graphic Summary:

Before Appointment



During Appointment



FQHCs

How to order:

FQHCs must use the buy and bill method to get reimbursed for LARC.

How to bill:

Texas Medicaid and Healthy Texas Women - Under Texas Medicaid and Healthy Texas Women, FQHCs are reimbursed under a Prospective Payment System (PPS) methodology. Regardless of the services provided at the time of the visit, FQHCs are paid an encounter rate when treating Medicaid or Healthy Texas Women clients. FQHCs may be reimbursed for three family planning encounters per year, per client, regardless of the reason for the encounter.

Procedure codes specific to a LARC device (J7297, J7298, J7300, J7301 and J7307) may be reimbursed in addition to the FQHC encounter payment. When seeking reimbursement for a LARC device, providers must submit the procedure code for the contraceptive device along with the procedure code for the encounter on the same claim. Procedure codes for the insertion (11981 and 58300) will be processed as informational only.

Family Planning Program - Family Planning Program providers are reimbursed on a fee-for-service basis. For an FQHC to get reimbursed for LARC services provided to a Family Planning Program client, they need to follow the buy and bill method.

340B Drug Pricing Program

How to order:

All eligible organizations and covered entities that are enrolled in the federal 340B Drug Pricing Program to purchase 340B discounted drugs need to order LARC devices directly from individual wholesalers or the manufacturer. The covered organization must inform the wholesaler or manufacturer of their 340B enrollment in order to receive the 340B discounted rate.

How to bill:

Organizations enrolled in the 340B Program should bill for LARCs using the buy and bill method and must use modifier U8 when submitting claims for 340B LARC devices in order to receive reimbursement at 340B rates.

*For more information, please refer to the [Health Resources and Services Administration](#) website.

In the hospital:

Hospital Reimbursement for Immediate Postpartum LARC

Hospitals may receive reimbursement for the following procedure codes for LARC devices in addition to the hospital diagnosis related group (DRG) payment when a LARC device is inserted immediately postpartum for a Medicaid client:

Procedure codes				
J7297	J7298	J7300	J7301	J7307

Immediate postpartum insertion refers to insertion of a LARC (ie, either IUD or contraceptive implant) after delivery but before discharge from the hospital. When seeking reimbursement for an IUD or implantable contraceptive capsule inserted immediately postpartum, hospital/facility providers must submit an outpatient claim with the appropriate procedure code for the contraceptive device in addition to the inpatient claim for the delivery services. The provider performing the service may also bill for the insertion separately in order to receive reimbursement for the service provided.

This reimbursement method cannot be used for Emergency Medicaid clients. Emergency Medicaid clients can receive immediate postpartum LARC through the Family Planning Program. See the "Family Planning Program Reimbursement" section below for more information. For patients enrolled in Medicaid Managed Care, the provider should contact the patient's MCO to verify whether prior authorization is required for LARC services.

For more information, please refer to [Reimbursement Methodology to Change for Long-Acting Reversible Contraception \(LARC\) Devices Effective January 1, 2016](#).

Family Planning Program Reimbursement

Medicaid and Emergency Medicaid clients may receive LARC immediately postpartum as long as the client has already had eligibility determined for the Family Planning Program at the time of delivery.

To receive reimbursement for LARC services for Medicaid and Emergency Medicaid clients, Family Planning Program contractors must file a separate Family Planning Program claim for the device and the insertion.

LARC Billing Codes

Code	Description
J7297	Liletta®
J7298	Mirena®
J7300	Paragard®
J7301	Skyla®
J7307	Nexplanon®

58300	IUD insertion
11981	Implant insertion

LARC Removal

Providers should use the below codes to receive reimbursement for the removal of a LARC device.

Code	Description
58301	Remove IUD
11982	Remove Implant
11983	Remove/Insert Implant