# THE TEXAS Long-Acting Reversible Contraception TOOLKIT

Volume 2

A resource for Texas health care providers to support access to long-acting reversible contraception (LARC)

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# Introduction

Long-acting reversible contraceptives (LARCs) provide the highest level of effectiveness of any reversible method of contraception (American College of Obstetricians and Gynecologists [ACOG], 2017). Requiring no action on the part of the user after the device is in place, LARCs have high rates of user satisfaction and method continuation. Texas has made improving access to LARC a priority.

The Texas LARC Toolkit offers information and resources to help women's health care providers increase LARC availability to Texas women throughout their reproductive life cycle, including prior to the first pregnancy, during the postpartum period, and whenever family planning services are received.

Successful implementation of a LARC program, whether in a clinic or hospital setting, requires planning and coordination by all individuals and service groups involved. Health care organizations interested in developing a LARC program should consider the following items discussed in this toolkit:

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

### Reference

American College of Obstetricians and Gynecologists (2017). Practice Bulletin No. 186: Long-acting reversible contraception: Implants and intrauterine Devices. **Obstet Gynecol**, **130**(5), e251-e269.

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# **Planning for Program Initiation**

### In the Clinic

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

- Training of clinical and support staff;
- Method to ensure device availability, which may involve maintaining an anticipatory device stock or arranging for specialty pharmacy delivery on individual patient request;
- Protocols for providing client education and obtaining informed consent
- Procedural protocols for LARC insertion and removal; and
- Billing protocols for provider services and device reimbursement, which will vary according to the method selected to make the device available and based on the individual patient's health care payment coverage.

### 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 immediate postpartum period offers a convenient opportunity for initiation of LARC methods (ACOG, 2016).

Immediate postpartum LARC insertion refers to the insertion of an IUD in the delivery or operating room immediately after delivery of the placenta (Whitaker & Chen, 2018), or insertion of a subdermal contraceptive implant prior to hospital discharge (ACOG, 2016). Planning for this requires developing all of the following elements:

- Administrative support and logistical infrastructure
- Pharmacy or supply chain process to acquire the devices and ensure availability at the time and place of insertion
- Process for training and privileging of providers who will place the devices
- Training of support staff
- Protocols for patient education and informed consent

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- 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 to the labor and delivery suite or operating room
  - For contraceptive implant insertion prior to hospital discharge, a protocol must be developed to ensure availability of the devices and trained personnel as well as a plan for where the procedure will be performed
- Billing processes to capture hospital costs and provider services appropriately, particularly device reimbursement

A survey of 10 Georgia hospitals that set out to develop programs for immediate postpartum LARC delivery reveals important considerations for other hospitals contemplating such an undertaking (Hofler et al., 2017). Several common themes that emerged from hospitals with successful implementation included the importance of identifying a team with representation from all relevant departments, involvement of hospital administration, and regular communication among key participants. Three broad stages of the process were identified:

- 1. Exploration: Identify team members and champions, including individuals with clinical, pharmacy (or medical device supply), finance, information technology, and administrative input. Inform stakeholders to ensure participation. Verify willingness of third-party payers to provide reimbursement. Create and maintain good communication within and among teams throughout the process.
- 2. Installation: Set in place the process for offering postpartum LARC. Clinician team members create policies, protocols, and consent forms. Clinician team members develop clinical training for physician and nursing staff. Pharmacy (or medical supply) and clinical team members establish the procedure for stocking the devices. The information technology team supports medical record documentation, order entry, and inventory control. Finance and billing teams determine proper coding information and mechanisms to ensure charge capture, as well as identify correct billing procedures for third-party payers. Several hospitals agreed on the importance of preparing for common billing challenges.
- 3. Implementation and sustainability: Make postpartum LARC available to patients. Start pilot implementation. Improve and streamline program with

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feedback and adjustment. For example, at one hospital, nurses were trained on an ad hoc basis during the installation phase. However, training became a regular part of orientation for new nurses following implementation.

### References

American College of Obstetricians and Gynecologists (2016). Committee Opinion No. 670: Immediate postpartum long-acting reversible contraception. *Obstet Gynecol*, *128*(2), e32-e37. Available at <a href="https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Obstetric-Practice/Immediate-Postpartum-Long-Acting-Reversible-Contraception">https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Obstetric-Practice/Immediate-Postpartum-Long-Acting-Reversible-Contraception.

Hofler, L. G., Cordes, S., Cwiak, C. A., Goedken, P., Jamieson, D. J., Kottke, M. (2017). Implementing immediate postpartum long-acting reversible contraception programs. *Obstet Gynecol*, *129*(1), 3-9.

Whitaker, A.K., & Chen, B.A. (2018). Society of Family Planning Guidelines: Postplacental insertion of intrauterine devices. *Contraception, 97*(1), 2-13. Available at <a href="https://www.contraceptionjournal.org/article/S0010-7824(17)30473-0/fulltext">https://www.contraceptionjournal.org/article/S0010-7824(17)30473-0/fulltext</a>.

### **Resources for providers**

American College of Obstetricians and Gynecologists. Long-acting reversible contraception program website. Available at <a href="https://www.acog.org/About-ACOG/ACOG-Departments/Long-Acting-Reversible-Contraception.">https://www.acog.org/About-ACOG/ACOG-Departments/Long-Acting-Reversible-Contraception.</a>

- ACOG Immediate postpartum LARC website at https://www.acog.org/LARCImmediatePostpartum.
- ACOG LARC clinical education and training website at https://www.acog.org/About-ACOG/ACOG-Departments/Long-Acting-Reversible-Contraception/LARC-Clinician-Education-and-Training.
- ACOG LARC video series at <a href="https://www.acog.org/LARCvideos">https://www.acog.org/LARCvideos</a>.

Hofler, L. G., Cordes, S., Cwiak, C. A., Goedken, P., Jamieson, D. J., Kottke, M. (2017). Immediate postpartum long-acting reversible contraception (LARC): Program implementation guide. Appendices 1-3 to Hofler et al. (2017), *Obstet Gynecol*, *129*. Available at <a href="http://links.lww.com/AOG/A900.">http://links.lww.com/AOG/A900.</a>

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# **Training of Clinical and Support Staff**

# **Determining patient medical eligibility**

Providers must determine whether a patient is a candidate for LARC before offering it as a contraceptive method. The Centers for Disease Control and Prevention (CDC) publishes eligibility recommendations on the safe use of contraceptive methods for women with specified characteristics or medical conditions (CDC, 2016). The CDC provides 4 categories of eligibility based on evidence for the balance of risk and benefit of a given contraceptive method for the population under consideration. The 4 categories are defined as follows:

Category 1 – No restrictions

Category 2 – The advantages generally outweigh theoretical or proven risks

Category 3 – Theoretical or proven risks generally outweigh the advantages

Category 4 – Use of the method presents an unacceptable health risk

Providers may use this information to help identify contraceptive methods appropriate for a particular woman and to aid her in choosing her preferred method. While the CDC provides medical eligibility information for all methods of contraception under a variety of clinical circumstances, this toolkit addresses medical eligibility designations only for LARC methods in common clinical settings.

#### **IUD**

The CDC provides the following medical eligibility criteria for the IUD as a contraceptive method (CDC, 2016; in the tables below, "Cu" means "copper" and "LNG" means "levonorgestrel"):

### Age and parity

Age	Cu-containing IUD	LNG-containing IUD	Comments
Menarche to < 20 years	Category 2	Category 2	Concern exists over risk of STI in sexually active adolescent
> 20 years	Category 1	Category 1	-
Parity	CU-containing	LNG-containing	Comments
	IUD	IUD	
Nulliparous	IUD  Category 2	IUD  Category 2	Concern exists over the risk of expulsion

### Postpartum placement (following vaginal or cesarean delivery)

Timing of placement	Cu- containing IUD	LNG- containing IUD	Comments
< 10 minutes postplacental, breastfeeding	Category 1	Category 2	Conflicting evidence on breastfeeding outcomes with LNG-IUD
< 10 minutes postplacental, not breastfeeding	Category 1	Category 2	-
4 weeks or more postpartum, breastfeeding or not breastfeeding	Category 1	Category 1	-

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Timing of placement	Cu- containing IUD	LNG- containing IUD	Comments
Postpartum sepsis	Category 4	Category 4	-

Note: Spontaneous expulsion of the IUD is more common with immediate postplacental insertion as compared with late postpartum (6-8 weeks after delivery) or interval (outside the postpartum period) insertion (CDC, 2016; Whitaker & Chen, 2018). Uterine perforation, though rare, is more common among breastfeeding women and women who are 36 weeks or less postpartum as compared with other women (CDC, 2016).

#### Following other recent pregnancy

Pregnancy outcome	Cu-containing IUD	LNG-containing IUD	Comments
1st trimester abortion	Category 1	Category 1	-
2nd trimester abortion	Category 4	Category 2	Increased risk of expulsion
Septic abortion	Category 2	Category 4	Contraindicated in a woman with sepsis
Prior ectopic pregnancy	Category 1	Category 1	-

Note: All references to abortion include both spontaneous and induced.

### **Contraceptive implant**

The CDC provides the following medical eligibility categories for the etonorgestrelcontaining contraceptive implant (CDC, 2016):

#### Age and parity

Patient characteristic	Etonorgestrel-containing implant
All ages, beginning with menarche	Category 1
Nulliparous	Category 1
Parous	Category 1

#### Following pregnancy

Timing of placement	Etonorgestrel-containing implant	Comments
< 30 days postpartum, breastfeeding	Category 2	Theoretical risk of problems with lactation; evidence of poor quality suggests no effect
30 days or more postpartum, breastfeeding	Category 1	-
Postpartum, not breastfeeding, any time	Category 1	-
Following abortion (spontaneous or induced), any trimester, including septic abortion	Category 1	-
Prior ectopic pregnancy	Category 1	-

For more information on the medical eligibility criteria for LARC and other contraceptive methods according to a variety of patient medical risk factors and

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considerations, see the "Medical eligibility criteria for contraceptive use, 2016" from the CDC (2016).

# Clinical and support staff training for outpatient clinic insertion

Training for LARC insertion and removal in the outpatient clinic includes the following considerations:

- Patient counseling on contraceptive options, including relative method effectiveness, method of use, risks, side effects, and patient follow-up (see the Patient Counseling and Education section of this toolkit for more information).
- The process to be used in the clinic to acquire the devices to be provided.
   Outpatient clinic providers of LARC have the choice of using the buy and bill
   method or the pharmacy option (see Obtaining LARC devices for the clinic
   setting in the Billing and Reimbursement section of this toolkit for more
   information).
- The protocol for setting up the room and caring for the patient before, during, and after the procedure.
- Provider training for insertion of the LARC devices, including identifying and addressing any difficulties or challenges that may arise.
- Provider training for IUD and contraceptive implant removal to ensure that patients may have the devices removed when desired.
- Correct billing procedures to ensure optimal reimbursement (see the Billing and Reimbursement section of this toolkit for more information).

Provider and support staff training for outpatient LARC delivery is available from a variety of sources, including nonprofit advocacy groups, professional organizations, and LARC device manufacturers. Providers who wish to order or purchase the Nexplanon contraceptive implant device must first complete Nexplanon insertion training provided by the manufacturer. For more information on training resources for LARC, see Resources for providers, support staff, and patient educators at the end of this section.

# Clinical and support staff training for hospital insertion

Training for immediate postpartum LARC should include the following considerations:

- Counseling patients on contraceptive options, including relative effectiveness, method of use, risks and side effects, and patient follow-up. Clinicians and patient educators in both the prenatal clinic setting and the hospital delivery setting should be trained in this. Patient counseling should ideally begin in the prenatal clinic (American Academy of Pediatrics [AAP] & ACOG, 2012; Whitaker & Chen, 2018). See the Patient Counseling and Education section of this toolkit for more information.
- 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. Timing constraints on providing LARC to
  the patient hospitalized for delivery will likely require hospitals to maintain a
  supply of devices on hand in order to meet the need.
- Establishing protocols for setting up and assisting with IUD and subdermal contraceptive implant insertion, as well as caring for the patient and newborn before, during, and after insertion. IUD insertion done immediately following placental delivery must take place in the delivery room or the operating room.
- Training providers on insertion of LARC devices in postpartum patients, including identifying and addressing difficulties or challenges that may arise.
- Ensuring correct billing procedures for optimal reimbursement (see the Billing and Reimbursement section of this toolkit for more information).

Immediate postpartum IUD insertion requires a different technique from that used for interval IUD placement. Hands-on didactic training is strongly recommended before a provider begins to perform this procedure in the hospital setting. However, the following is a brief description of the procedure as provided by ACOG (2016):

The IUD should be introduced into the vagina within 10 minutes of delivery of the placenta, following a vaginal or cesarean delivery. Immediate postpartum IUD

<sup>&</sup>lt;sup>1</sup> The Texas Medicaid Provider Procedures Manual defines immediately postpartum as insertion within 10-15 minutes of placental delivery for IUDs.

placement is contraindicated in women with sepsis, endometritis, or chorioamnionitis.

Following a vaginal delivery, the IUD may be inserted manually or using a Kelly or ringed forceps. The IUD should be removed from the inserter and the string cut to a length of approximately 10 cm. The IUD is grasped at the wing portion with the forceps and passed through the cervix to the fundus of the uterus. Ultrasound may be used for guidance, if needed.

Following cesarean delivery, hemostasis is confirmed and the IUD is placed through the uterine incision into the fundus before closure of the uterine incision is complete. This can be done using the inserter provided by the manufacturer, a ringed forceps, or manually. The string is then placed carefully into the cervical canal manually or with the ringed forceps.

Contraceptive implant insertion can be performed any time after delivery before discharge from the hospital (ACOG, 2016). The technique is the same as that for insertion in the clinic, and there are no contraindications specific to the woman who has just experienced childbirth except for a theoretical effect on breastfeeding (see Effects on breastfeeding in the Patient Counseling and Education section of this toolkit for more information).

### Clinician training for LARC removal

To ensure patient autonomy and a woman's satisfaction with her chosen contraceptive method, it is important for providers to be able to offer removal of a LARC device when a woman requests it or when removal is indicated. Device manufacturers provide training resources for removal of their respective devices, and some of the LARC trainings provided by professional organizations and advocacy groups cover removal. Providers should ensure that women who receive a LARC device are able to have it removed when desired. For more information on training resources for LARC removal, see Resources for providers, support staff, and patient educators at the end of this topic section.

### References

American Academy of Pediatrics & the American College of Obstetricians and Gynecologists (2012). Postpartum contraception. In *Guidelines for perinatal care, 7th Ed.* (pp. 202-203) Elk Grove Village IL, Washington DC.

American College of Obstetricians and Gynecologists (2016). Committee Opinion No. 670: Immediate postpartum long-acting reversible contraception. *Obstet Gynecol, 128*(2), e32-e37. Available at <a href="https://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Obstetric-Practice/Immediate-Postpartum-Long-Acting-Reversible-Contraception">https://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Obstetric-Practice/Immediate-Postpartum-Long-Acting-Reversible-Contraception</a>

Centers for Disease Control and Prevention (2016). U.S. Medical eligibility criteria for contraceptive use, 2016. MMWR, 65 (No.3) Available at <a href="https://www.cdc.gov/mmwr/volumes/65/rr/rr6503a1.htm">https://www.cdc.gov/mmwr/volumes/65/rr/rr6503a1.htm</a>

Whitaker, A.K., & Chen, B.A. (2018). Society of Family Planning Guidelines: Postplacental insertion of intrauterine devices. *Contraception, 97*(1), 2-13. Available at <a href="http://www.contraceptionjournal.org/article/S0010-7824(17)30473-0/fulltext">http://www.contraceptionjournal.org/article/S0010-7824(17)30473-0/fulltext</a>

# Resources for providers, support staff, and patient educators

ACOG LARC Program has resources for training of providers and support staff for LARC delivery in the clinic available on the <u>Clinical Education and Training</u> page of their website, including a link to a PDF document with information about free training opportunities on all methods of LARC. These include links to device manufacturer-sponsored training, as well as training provided by professional and advocacy groups, some of which provide continuing education credits. Many of these resources also offer training for LARC removal.

The <u>Immediate Postpartum</u> page of the ACOG LARC Program website offers links to the full text of ACOG Committee Opinions and Practice Bulletins on LARC topics and resources for training on immediate postpartum LARC, as well as other resources on LARC, freely accessible. A link is also provided to an educational video on immediate postplacental LARC insertion, available to ACOG members only.

The <u>LARC Video</u> series web page on the ACOG LARC Program website contains links to available videos related to LARC services, including clinical preparation, patient counseling, and insertion techniques for IUD devices available in the U.S.

The <u>Immediate Postpartum Intrauterine Device Insertion Training Workshop</u> page on the Bixby Center for Global Reproductive Health website provides instructions for constructing a training model for immediate postpartum IUD insertion, training instructional materials, and training videos.

The <u>Medical Eligibility Criteria for Initiating Contraception</u> page from the Reproductive Health Access Project offers a quick reference guide for contraceptive method eligibility criteria.

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## **Patient Counseling and Education**

#### General considerations

Prior to initiating any contraceptive method, women should receive patient-centered education in their preferred language, using terms and phrasing they understand and are comfortable with, in order to make informed decisions about family planning. Each woman should receive method-specific counseling on all methods suitable for her, including LARCs, abstinence and natural family planning, as well as information on preventing sexually transmitted diseases/infections (STD/STIs) and human immunodeficiency virus (HIV) (CDC, 2014). Counseling should cover the method of use and real-world effectiveness of each method, risks and side effects, how to manage side effects, and how to recognize and address possible complications. Counselors should ensure that women demonstrate understanding of the information received and satisfaction that all of their questions have been thoroughly answered.

Perhaps more than any other factor, patient counseling can influence a woman's trust in her provider, her sense of autonomy, and in the setting of a family planning visit, satisfaction with her contraceptive choice. Women have many different views and impressions about reproductive health care in general and LARC in particular. It is incumbent on providers to understand an individual's concerns and beliefs, in order to provide information that will enable her to select the contraceptive method with which she will be most satisfied.

Providers should be mindful that their own assumptions and motivations may not mirror patients' assumptions about providers' motivations. Because unintended pregnancy and adverse pregnancy outcomes are more common among younger women, less educated women, women of low income, and women of color, increased access to LARC has been suggested as a means to reduce health care disparities among these populations (Parks & Peipert, 2016). However, when women 18 to 29 years of age were interviewed about their impressions related to LARC usage (Higgins, 2016), many expressed the opinion that racial minorities, poor women, and less educated women are more often pressured to use LARC. This was perceived by some as an attempt to take contraceptive decision-making away from these women or to reduce their population numbers.

Evidence suggests that women in racial and ethnic minority groups are more likely to receive counseling on contraception than white women, but not more likely to obtain a contraceptive method, suggesting the difference in counseling rate is not due to increased counseling requests by minority patients, but perhaps due to bias on the part of the health care community (Gomez, Fuentes, & Allina, 2014). A randomized study of health care providers viewing video simulations of patient encounters found that providers were more likely to recommend intrauterine contraception to minority women and women of low socioeconomic status than to white women or women of higher socioeconomic status (Dehlendorf, et al., 2010).

A study of the attitudes of women 18 to 29 years of age found that most were either unsure about or not interested in future IUD use. These attitudes were strongly influenced by their beliefs about the IUD and the importance they placed on different aspects of its use (Gomez & Freihart, 2017). Women who expressed interest in future IUD use cited the ease of use as a primary motivator, while those who were not interested emphasized "horror stories" they had heard and fears of injury or infertility. Unsure women were inclined to weigh the advantages against disadvantages and expressed a need for more information.

These findings reinforce the notion that the provider must first come to know the individual and her beliefs and preferences, and then assist her to make her own informed reproductive health choice. Providers should be prepared to dispel myths and provide adequate and correct information in a way that supports patient autonomy and enables the woman to advocate effectively for herself.

### Timing of patient counseling

Whenever counseling is given, the patient should be informed of her freedom to change her decision at any time prior to placement of a LARC device, and to request LARC removal at any time, without fear or possibility of reprisal.

# Patient counseling for LARC in the outpatient clinic

Every woman who requests contraceptive services should receive counseling on all methods appropriate for her and be allowed to choose the method she prefers. If a LARC method is chosen, and the provider can be reasonably certain the woman is not pregnant, the LARC should be provided on the same day, whenever possible (ACOG, 2015). For a list of criteria to be reasonably certain a woman is not

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pregnant, see Timing of insertion under the Patient Protocols and Procedural Aspects section of this toolkit. If the patient will return for the LARC at a later date, she should receive another method of contraception to use until she returns for LARC placement. If a woman has expressed a desire for LARC for postpartum contraception and immediate postpartum LARC was not provided, the LARC should be available at the time of the postpartum clinic visit (ACOG, 2016a).

# Patient counseling for immediate postpartum LARC

Most women wish to delay childbirth for at least several months and often for several years after childbirth (AAP & ACOG, 2012). Adolescents who had recently experienced childbirth reported that contraception was important to them and most desired to delay another pregnancy for at least 6 years (Sober, et al 2017). They viewed physicians and the prenatal clinic as the most accurate source of contraceptive information, and reported feeling comfortable discussing contraception with their providers. The majority preferred face-to-face counseling by a physician over written materials, believed postpartum contraceptive counseling should begin during prenatal care, and wished to begin their chosen method before leaving the hospital.

Counseling for postpartum contraception should be a routine component of prenatal care (AAP & ACOG, 2012; ACOG, 2016a). Fertility may return very soon after childbirth, especially for women who do not breastfeed exclusively. Every woman in prenatal care should receive counseling on all methods of postpartum contraception appropriate for her, including LARC.

If a woman has not received contraceptive counseling prior to admission for delivery, it should be discussed before the onset of active labor if an IUD is offered for placement during the hospital admission since the device must be placed immediately after delivery of the placenta. Counseling for an immediate postpartum contraceptive implant may take place before the onset of labor or after delivery, since the implant can be placed any time after delivery before hospital discharge.

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### **Counseling topics**

### Relative method effectiveness<sup>2</sup>

Whatever the setting, every woman should receive counseling on all methods of contraception appropriate for her, including a discussion of the relative effectiveness of each method. In the following list, the range of effectiveness for women using each method for 1 year is included in parentheses; actual effectiveness for a given woman depends on correctness and consistency of use.

- Extremely effective (> 99% effective):
  - Total sexual abstinence
  - Contraceptive implant
  - Intrauterine device
  - Male or female sterilization
- Less effective (ranges of effectiveness are shown where the source used provides a range or multiple sources provide differing rates or ranges):
  - ▶ Lactational amenorrhea (98-99%; must be < 6 months postpartum, amenorrheic, and providing 85-100% of infant feedings as breast feedings)
  - ▶ Progestin injection (Depo-Provera, 94-97%)
  - ► Hormonal contraceptive pills (91-92%)
  - ▶ Hormonal contraceptive patch (91-92%)
  - Vaginal ring (91-92%)
  - ▶ Diaphragm (82-88%)
  - ▶ Male condom (82-85%)
  - ▶ Female condom (79%)
  - Withdrawal ("pulling out," 78-82%)
  - ▶ Cervical cap (71-86%)
  - Fertility awareness ("rhythm," 75-76%)

<sup>&</sup>lt;sup>2</sup> (ACOG, 2015; CDC, 2016)

- ▶ Spermicide (71-72%)
- ▶ Sponge (68-88%, more effective in parous women)

### General patient counseling topics<sup>3</sup>

Counseling topics should include advantages, risks, contraindications, and alternatives to LARC. The following are several general points. Providers should use their judgement to cover additional points.

- LARC methods have the highest level of effectiveness, user satisfaction, and rate of continuation of all reversible contraceptive methods.
- LARC methods are safe and appropriate for most women, including nulliparous and adolescent women.
- The high level of effectiveness (> 99%) is not affected by coital practices or frequency, and does not require any action by the user after the LARC device is in place.
- There is no need for return visits to the clinic or pharmacy for resupply.
- LARC methods are highly cost-effective, and there are few contraindications to their use.
- LARC effectiveness is comparable to that of permanent sterilization, but the contraceptive effect is reversible, and the return to fertility after device removal is rapid.
- LARC methods do not protect against STIs or HIV infection. Using male latex condoms correctly with every sexual encounter will reduce the risk of STIs, including HIV.

# **IUD-specific counseling**

The IUD is a small device inserted into the uterus, remaining there until it is removed. All IUDs available in the U.S. are roughly T-shaped.

There are two general types of IUDs, hormonal and copper-containing (ACOG, 2017):

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<sup>&</sup>lt;sup>3</sup> (ACOG, 2015; ACOG, 2016a; CDC, 2016b)

- The hormonal IUD releases levonorgestrel (LNG), a progestin, in a slow continuous manner after the IUD is placed.
- The copper IUD is a polyethylene structure wrapped with copper wire which does not contain any hormone.

There are currently 5 IUDs available in the U.S., 4 LNG-containing and 1 copper-containing (ACOG, 2017; Lohr et al, 2017):

- Two LNG IUDs, Mirena and Liletta, measure 32 mm by 32 mm and contain 52 mg of LNG. Mirena is approved for up to 5 years of use, and Liletta for up to four years.
- Kyleena measures 30 mm by 28 mm, contains 19.5 mg of LNG, and is approved for up to 5 years of use. It has a smaller diameter insertion tube than Mirena and Liletta.
- Skyla also measures 30 mm by 28 mm, contains 13.5 mg of LNG, and is approved for up to 3 years of use. It also has a smaller diameter insertion tube than Mirena and Liletta.
- Paragard, the copper-containing Copper T 380A, measures 36 mm by 32 mm and is approved for up to 10 years of use.

How IUDs prevent pregnancy (ACOG, 2017):

- All IUDs work by preventing fertilization.
- The copper IUD appears to prevent fertilization by reducing the motility and viability of sperm.
- The LNG-containing IUD prevents fertilization by altering the amount and viscosity of cervical mucous rendering it impenetrable to sperm. The available evidence indicates that no IUD available in the U.S. disrupts pregnancy or acts as an abortifacient.

Who is a candidate to initiate IUD use (ACOG, 2017; CDC, 2016a; Lohr et al, 2017):

- Most women who desire reversible contraception, including adolescents and nulliparous women, may use the IUD.
- Postpartum and breastfeeding women without evidence of uterine infection may use the IUD. It can be placed immediately after delivery of the placenta or at a postpartum visit.

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- Women with a history of pelvic inflammatory disease (PID) may use the IUD.
- Women with cardiovascular disease, controlled hypertension, obesity, a history of bariatric surgery, and certain other chronic conditions may use the IUD.
- Women with active uterine infection following delivery, or current PID should not initiate IUD use.
- Women with unexplained abnormal vaginal bleeding should not initiate IUD use. The underlying cause of the bleeding should first be evaluated and then the patient's eligibility for an IUD should be reevaluated.
- Women with known or suspected pregnancy should not initiate IUD use. For criteria to be reasonably certain a woman is not pregnant, see Timing of insertion under the Patient Protocols and Procedural Aspects section in this toolkit.
- For more condition-specific eligibility recommendations for IUD initiation and continuation, see the <u>CDC U.S. Medical Eligibility Criteria</u> for <u>Contraceptive</u> Use, 2016.

#### Risks of the IUD:

- The IUD may expel spontaneously, although the risk varies widely in published studies. This occurs in about 2-10% of women in the first year of use (ACOG, 2017), but increases to 10-27% for women receiving the IUD immediately postpartum (ACOG, 2016a).
- Rarely, the IUD may perforate the uterine wall during insertion. This occurs at a rate of slightly more than 1 in 1,000 insertions (ACOG, 2016b, ACOG, 2017).
- The risk of PID among women using the IUD is approximately 1%. It is more common in women with increased risk of STI and in the first 20 days after IUD insertion (ACOG, 2016b). STI testing should follow standard guidelines, and may be performed for women who are due for screening on the same day the IUD is placed. A woman with current evidence of chlamydial, gonorrheal, or purulent cervicitis should not undergo IUD insertion (CDC, 2016b).
- Rarely, pregnancy can occur while an IUD is in place. Over 10 years of IUD use, approximately 2% of women will experience a pregnancy. If a pregnancy occurs, there is a higher chance of an ectopic pregnancy (ACOG,

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2016b). For recommendations on patient management when pregnancy occurs with an IUD in place, see <u>ACOG Committee Opinion No. 672: Clinical challenges of long-acting reversible contraceptive methods</u> (ACOG, 2016b).

Side effects of the IUD (ACOG, 2017):

- 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.
- Most women using the LNG-containing IUD will experience decreased menstrual bleeding; some will become amennorheic.
- Some women experience weight gain, which is similar for those using the LNG-containing IUD and those using the copper-containing IUD.
- The LNG-containing IUD may cause some effects related to the hormone, including breast tenderness, headaches, depression, and nausea.

### **Implant-specific counseling**

The contraceptive implant is a flexible rod 4 cm in length and 2 mm in diameter, containing 68 mg of etonorgestrel (ACOG, 2017). It is placed just under the skin, usually on the inside of the upper arm, and allows controlled hormone release to provide highly effective contraception for up to 3 years.

How the contraceptive implant prevents pregnancy (ACOG, 2017):

- The implant works primarily by suppressing ovulation.
- Additional contraceptive effect may result from thickening of the cervical mucous and altering the endometrial lining.

Benefits of the contraceptive implant (ACOG, 2017; CDC, 2016b):

- The implant is the most effective form of reversible contraception; pregnancy occurs in much less than 1% of women using the method for a year.
- Most women are able to use it, including women of any age and parity, and nulliparous women.
- Once it is placed, nothing else needs to be done to prevent pregnancy.
- It can be removed at any time with rapid return of fertility.
- It can be inserted immediately after a pregnancy, or while breastfeeding.

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Risks of the contraceptive implant (ACOG, 2016b; ACOG, 2017):

- Approximately 1-2% of women will have a complication related to insertion or removal of the implant.
  - Problems with insertion may include pain, bleeding, or hematoma formation at the site; unrecognized failure to insert the implant; and incorrect or deep insertion.
  - Complications related to removal may include the inability to locate the implant by palpation due to deep location, and breakage of the device. If necessary, the implant can be located with a radiologic procedure.
- Although pregnancy is very rare with a contraceptive implant, if a woman becomes pregnant while using the implant, there may be a slightly higher risk of ectopic pregnancy.

Side effects of the contraceptive implant (ACOG, 2017; CDC, 2016b):

- The most common side effect is a change in the menstrual pattern. This may include amenorrhea, infrequent bleeding, or frequent or prolonged bleeding. These symptoms may improve with time.
- Other possible side effects include intestinal symptoms, headaches, breast pain, mood changes, and acne.
- Weight gain occurs in about 12% of women, and is similar to that for women using the copper-containing IUD.

### **Effects on breastfeeding**

There are theoretical concerns that exogenous progestins, such as those contained in the contraceptive implant or hormonal IUD, may interfere with the initiation or continuation of lactation, but available evidence suggests there is no effect on breastfeeding outcomes for women using a LARC method (ACOG, 2016a).

Regarding the progestin-containing implant (ie. etonorgestrel-releasing), there is limited evidence related to the possible effect 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

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- 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 when the etonorgestrel-releasing contraceptive implant was placed one to three days postpartum, as compared with 4 to 8 weeks postpartum.

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, with 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 (i.e., 85-100% of infant feeds are from the breast) will experience a pregnancy risk of approximately 0.5-1.5% until the infant is six months of age, making the lactational amenorrhea method of contraception an alternative some women may choose in the first 6 months postpartum (Sridhar & Salcedo, 2017). However, real-world effectiveness may be lower due to variations in breastfeeding exclusivity and earlier return of menstruation.

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.

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# Addressing myths and misconceptions associated with LARC

Many patients have misunderstandings related to LARC. However, it is important for providers to recognize that not all misconceptions are on the part of the patient. In fact, some studies suggest that many ideas widely perceived as myths by the health care community are actually viewed by some patients as misconceptions on the part of providers. For example, a common patient perception described in the literature on LARC myths is that providers often understate the side effects of LARC and offer false reassurance that they will resolve over time. In a focus group of women 18 to 29 years of age (Higgins, 2016), many respondents reported that their providers had inaccurately minimized potential side effects, particularly those related to bleeding and pain, often resisting or refusing patient requests for removal of the device. Patients reported that such misleading counseling and failure to honor their request to remove the LARC device undermined the trust they placed in their providers and their own sense of autonomy in contraceptive choice.

The following addresses some other common myths and misconceptions related to LARC:

- The risk of PID is higher in the first 20 days after insertion. After the first 20 days, the risk of PID in women with an IUD is similar to that for women without an IUD, approximately 1.6 cases per 1,000 woman-years of use (Russo, Miller, & Gold, 2013).
- The IUD and contraceptive implant do not protect against STI/STDs. All
  patients should be advised to use condoms to reduce the risk of STI/STDs
  (CDC, 2016b).
- The IUD does not cause infertility (Russo, Miller, & Gold, 2013).
- The IUD does not cause abortion (ACOG, 2017). It prevents pregnancy by preventing fertilization.
- LARC use does not increase the risk of ectopic pregnancy. It actually reduces
  the risk of ectopic pregnancy by lowering the overall risk of pregnancy.
  However, a pregnancy that occurs with an IUD in place is more likely to be
  ectopic than one that occurs when no IUD is present. If pregnancy occurs
  with a contraceptive implant in place, it may be more likely to be ectopic,
  although the evidence is less clear on this (ACOG, 2016b; Russo, Miller, &

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- Gold, 2013). Ultrasound should be performed to rule out ectopic pregnancy, any time a pregnancy occurs with a LARC device in situ.
- IUD insertion may cause pain or discomfort, which is generally greater for nulliparous women than for parous women, although both groups reported low pain scores in one study (Russo, Miller, & Gold, 2013). No intervention has been shown reliably to reduce pain with insertion (ACOG, 2016b; Russo, Miller, & Gold, 2013). For more information on management of pain with IUD insertion, see Management of pain with IUD insertion in the Patient Protocols and Procedural Aspects section of this toolkit.

### References

American Academy of Pediatrics & the American College of Obstetricians and Gynecologists (2012). Postpartum contraception. In *Guidelines for perinatal care, 7th Ed.* (pp. 202-203) Elk Grove Village IL, Washington DC.

American College of Obstetricians and Gynecologists (2016a). Committee Opinion No. 670: Immediate postpartum long-acting reversible contraception. *Obstet Gynecol,* 128(2), e32-e37. Available at <a href="https://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Obstetric-Practice/Immediate-Postpartum-Long-Acting-Reversible-Contraception">https://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Obstetric-Practice/Immediate-Postpartum-Long-Acting-Reversible-Contraception</a>

American College of Obstetricians and Gynecologists (2016b). Committee Opinion No. 672: Clinical challenges of long-acting reversible contraceptive methods. **Obstet Gynecol, 128**(3), e69-e77. Available at <a href="https://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Gynecologic-Practice/Clinical-Challenges-of-Long-Acting-Reversible-Contraceptive-Methods">https://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Gynecologic-Practice/Clinical-Challenges-of-Long-Acting-Reversible-Contraceptive-Methods</a>

American College of Obstetricians and Gynecologists (2015). Committee Opinion No. 642: Increasing access to contraceptive implants and intrauterine devices to reduce unintended pregnancy. *Obstet Gynecol,* 126(4), e44-e48. Available at <a href="https://www.acog.org/Resources-And-Publications/Committee-Opinions/Commi

American College of Obstetricians and Gynecologists (2017). Practice Bulletin No. 186: Long-acting reversible contraception: Implants and intrauterine devices. **Obstet Gynecol, 130**(5), e251-e269.

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Centers for Disease Control and Prevention (2014). Providing quality family planning services. *MMWR*, *63*(No. 4) Available at https://www.cdc.gov/reproductivehealth/contraception/qfp.htm

Centers for Disease Control and Prevention (2016a). U.S. Medical eligibility criteria for contraceptive use, 2016. *MMWR*, *65*(No.3) Available at <a href="https://www.cdc.gov/mmwr/volumes/65/rr/rr6503a1.htm">https://www.cdc.gov/mmwr/volumes/65/rr/rr6503a1.htm</a>

Centers for Disease Control and Prevention (2016b). U.S. Selected practice recommendations for contraceptive use, 2016. *MMWR*, *65* (No.4) Available at <a href="https://www.cdc.gov/reproductivehealth/contraception/mmwr/spr/summary.html">https://www.cdc.gov/reproductivehealth/contraception/mmwr/spr/summary.html</a> (web) <a href="https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6504.pdf">https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6504.pdf</a> (PDF)

Dehlendorf, C., Ruskin, R., Grumbach, K., Vittinghoff, E., Bibbins-Domingo, K., Schillinger, D., & Steinauer, J. (2010). Recommendations for intrauterine contraception: A randomized trial of the effects of patients' race/ethnicity and socioeconomic status. *Am J Obstet Gynecol*, *203*(4), 319.e1-319.e8. Available at <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3012124/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3012124/</a>

Gomez, A.M., Fuentes, L., Allina, A. (2014). Women or LARC first? Reproductive autonomy and the promotion of long-acting reversible contraceptive methods. **Perspect Sex Reprod Health, 46**(3), 171-175.

Higgins, J. A., Kramer, R. D., & Ryder, K. M. (2016). Provider bias in long-acting reversible contraception (LARC) promotion and removal: Perceptions of young adult women. *Am J Public Health, 106*(11), 1932-1937. Available at <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5055778/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5055778/</a>

Hoopes, A.J., Gilmore, K., Cady, J., Akers, A.Y., Ahrens, K.R. (2016). A qualitative study of factors that influence contraceptive choice among adolescent school-based health center patients. *J Pediatr Adolesc Gynecol*, 29(3), 259-64.

Lohr, P. A., Lyus, R., & Prager, S. (2017). Use of intrauterine devices in nulliparous women. *Contraception, 95*, 529-539. Available at <a href="https://www.societyfp.org/Resources/Clinical-guidelines.aspx">https://www.societyfp.org/Resources/Clinical-guidelines.aspx</a>

Lopez, L.M., Grey, T.W., Stuebe, A.M., Chen, M., Truitt, S.T., Gallo, M.F. (2015). Combined hormonal versus nonhormonal versus progestin-only contraception in lactation. *Cochrane Database Syst Rev.* 20;3:CD003988.

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Parks, C., & Peipert, J. F. (2016). Eliminating health disparities in unintended pregnancy with long-acting reversible contraception (LARC.) *American Journal of Obstetrics & Gynecology, 214*(6), 681-688. Available at <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4884485/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4884485/</a>

Russo, J. A., Miller, E., & Gold, M. A. (2013). Myths and misconceptions about long-acting reversible contraception (LARC). *J Adolesc Health, 52*, S14-S21.

Sober, S., Shea, J.A., Shaer, A.G., Whittaker, P.G., & Schreiber, C.A. (2017). Postpartum adolescents' contraceptive counselling preferences [Abstract]. *Eur J Contracept Reprod Health Care, 22*(2), 83-87.

Sridhar, A., & Salcedo, J. (2017). Optimizing maternal and neonatal outcomes with postpartum contraception: Impact on breastfeeding and birth spacing. *Maternal Health, Neonatology, and Perinatology, 3*, 1-10. Available at <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5237348/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5237348/</a> doi: 10.1186/s40748-016-0040-y

### **Resources for patients and educators**

Association of Reproductive Health Professionals. The facts about intrauterine contraception. Available at <a href="http://www.arhp.org/Publications-and-">http://www.arhp.org/Publications-and-</a>
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 <a href="https://www.acog.org/Patients/FAQs/Long-Acting-Reversible-Contraception-Intrauterine-Device-and-Implant">https://www.acog.org/Patients/FAQs/Long-Acting-Reversible-Contraception-Intrauterine-Device-and-Implant</a>.

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

- Medical eligibility criteria quick resource guide: <a href="https://www.reproductiveaccess.org/resource/medical-eligibility-initiating-contraception/">https://www.reproductiveaccess.org/resource/medical-eligibility-initiating-contraception/</a>
- Contraception home page: <a href="https://www.reproductiveaccess.org/key-areas/contraception/">https://www.reproductiveaccess.org/key-areas/contraception/</a>

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- Your birth control choices fact sheet: <a href="https://www.reproductiveaccess.org/resource/birth-control-choices-fact-sheet/">https://www.reproductiveaccess.org/resource/birth-control-choices-fact-sheet/</a>
- IUD fact sheet: <a href="https://www.reproductiveaccess.org/resource/iud-facts/">https://www.reproductiveaccess.org/resource/iud-facts/</a>
- Contraceptive implant fact sheet:
   <a href="https://www.reproductiveaccess.org/resource/progestin-implant/">https://www.reproductiveaccess.org/resource/progestin-implant/</a>

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# **Patient Protocols and Procedural Aspects**

### **Timing of insertion**

### In the clinic

If it is possible to be reasonably certain that a woman is not currently pregnant, the IUD or contraceptive implant may be inserted at any time during the menstrual cycle. It is not necessary to request that the woman return for insertion during the next menses, which may create a barrier to access (ACOG, 2017). 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 (CDC, 2016b):

- < 7 days since the start of a normal menses</li>
- 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</li>
- < 6 months postpartum, no menses since delivery, and exclusively or almost exclusively breast feeding (at least 85% of infant feedings are breast feedings)

If the provider can ascertain with reasonable certainty that a woman is not pregnant by the above criteria, no pregnancy test is needed, and the IUD or contraceptive implant may be placed that day.

If the criteria to be reasonably certain that she is not pregnant are not met, an IUD should not be placed on the same day due to a high risk of pelvic infection and septic spontaneous abortion if an IUD is placed during pregnancy. Rather, the woman should be asked to return when it is possible to be reasonably certain she is not pregnant (see criteria listed above), and she should receive another contraceptive method to use in the meantime (CDC, 2016a; CDC, 2016b).

If a woman is requesting a contraceptive implant, and she does not meet the criteria to be reasonably certain she is not pregnant, the benefit of reliable

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contraception likely outweighs the risk even if the provider cannot be certain she is not pregnant. Several studies have shown no increase in the risk of congenital anomalies or perinatal death in infants with in utero exposure to oral contraceptives or medroxyprogesterone acetate (injectable contraceptive). The provider may consider placing the contraceptive implant on the same day with instructions to return in two to four weeks for a pregnancy test (CDC, 2016b). The provider may want to confirm a negative pregnancy test on the day of implant insertion but should be mindful that a negative test does not rule out an early pregnancy. The woman should be counseled on the potential risk and offered the option of delaying the implant placement. If she chooses to delay implant placement, she should receive another contraceptive method for use in the meantime.

## In the immediate postpartum setting<sup>4</sup>

The immediate postpartum period while the patient is hospitalized for delivery offers an ideal opportunity for initiation of a LARC method because a woman is often highly motivated to initiate contraception at this time, she is certain not to be pregnant, and her presence in the hospital eliminates the need to schedule a separate appointment for LARC placement. Because 40% to 57% of women report having unprotected intercourse before the usual postpartum clinic visit, and women often begin to ovulate very soon after delivery, immediate postpartum LARC provides a reliable means of reducing unintended pregnancy in this population.

While the majority of available evidence seems to support no adverse effect on breastfeeding outcomes for women using a LARC method, women who intend to breastfeed should be counseled about a theoretical risk of reduced breastfeeding duration with a hormonal LARC method.

### **Immediate postplacental IUD insertion**

The IUD should be inserted within 10 minutes of delivery of the placenta. The risk of spontaneous expulsion with post-placental insertion is reported to be 10% to 27% in published studies (ACOG, 2017). This is somewhat higher than for clinic insertion, but is cost-effective when compared with insertion at the postpartum visit (Washington et al., 2015).

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<sup>&</sup>lt;sup>4</sup> (ACOG, 2017)

# Immediate postpartum contraceptive implant insertion

The contraceptive implant can be inserted any time after delivery before the patient is discharged home. Breastfeeding women should be counseled that there are theoretical concerns about milk production and infant growth and development with implant insertion in the first 30 days postpartum. However, the U.S. Medical Eligibility Criteria for Contraceptive Services classifies implant insertion in the first 30 days after childbirth in a breastfeeding woman as Category 2 (the advantages generally outweigh theoretical or proven risks; CDC, 2016a).

# Screening and testing for STI prior to IUD insertion

For asymptomatic women, screening for STI should follow CDC guidelines (CDC, 2015). If the woman is current with screening, it need not be repeated at the time of IUD insertion. If she is due for screening, this may be done at the time of IUD insertion. If that test is positive, she should receive treatment and the IUD may be left in place (ACOG, 2017).

A woman with current evidence of purulent cervicitis or cervical infection with chlamydia or gonorrhea should not have an IUD placed at the time. Instead, she should receive another contraceptive method while the infection is appropriately treated, and then be reassessed for IUD eligibility at a subsequent clinic visit (CDC, 2016a; CDC, 2016b). Testing should be repeated in 3 months due to a high risk of reinfection (ACOG, 2017; CDC, 2015).

### **Antibiotic prophylaxis for IUD insertion**

Routine antibiotic prophylaxis with IUD insertion has not been shown to reduce the risk of PID or to reduce the frequency of removal within 90 days (Grimes & Schulz, 2001), and is not recommended (ACOG, 2017). The risk of pelvic infection is increased in the first 20 days after insertion, but is low (approximately 1%) thereafter (ACOG, 2016).

Insertion of an IUD is contraindicated in a woman with suspected chlamydial infection or gonorrhea, purulent cervicitis, or symptoms of PID (CDC, 2016a; CDC, 2016b). In such a case, the infection should be treated appropriately according to CDC guidelines (CDC, 2015). IUD placement should be delayed until treatment is

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complete, symptoms have resolved, and the cervical and bimanual exam are normal. Testing should be repeated in 3 months due to a high risk of reinfection (ACOG, 2017; CDC, 2015).

If cervicitis or PID develops with an IUD in place, the IUD need not be removed while treatment is provided in accordance with CDC guidelines (CDC, 2015; CDC, 2016a). If symptoms do not improve after 48 to 72 hours of appropriate antibiotic treatment, treatment should continue and consideration should be given to removal of the IUD (ACOG, 2016).

### Management of pain with IUD insertion

Insertion of an IUD may cause pain, and patient anxiety about expected pain with insertion may pose a barrier to access.

Topical application of 2% lidocaine gel was not effective at reducing pain with tenaculum placement or device insertion. However, a 4% formulation reduced pain with insertion in nulliparous women, and a 10% spray formulation reduced pain with insertion in parous women (Lopez, et al., 2015). A meta-analysis showed that 1% lidocaine paracervical block reduced pain with tenaculum placement (ACOG, 2016; Lopez, et al., 2015).

Evidence for misoprostol given in conjunction with IUD placement is mixed. The majority of studies have shown that misoprostol use is actually associated with increased pain with insertion. However, in one study of nulliparous women, those who received misoprostol experienced a lower incidence of moderate to severe pain and reported a more favorable experience (Lopez, et al., 2015). ACOG (2016) recommends against routine misoprostol use prior to IUD insertion, but allows that it may be considered with a difficult insertion.

Other interventions, including nonsteroidal anti-inflammatory drugs and nitroprusside, have shown no benefit in reducing pain with IUD insertion (ACOG, 2016; Lopez, et al., 2015).

# **Need for backup contraception**

If a contraceptive implant or IUD is placed in the immediate postpartum period, no backup contraceptive method is necessary (CDC, 2016b).

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For patients undergoing interval initiation of a LARC method, backup contraception may be necessary. A LARC method should only be initiated if the provider can be reasonably certain that the woman is not currently pregnant.

Backup contraception after IUD placement (CDC, 2016b):

- With the copper IUD, no backup contraception is necessary after insertion. It is effective immediately.
- With the levonorgestrel-containing IUD, backup contraception depends on timing related to the onset of menses:
  - ▶ If inserted within the first 7 days since the onset of menstrual bleeding, no backup contraception is needed.
  - ▶ If inserted more than 7 days after the onset of menstrual bleeding, the woman should refrain from intercourse or use a backup method of contraception for the following 7 days.

Backup contraception after contraceptive implant placement (CDC, 2016b):

- If the implant is placed within 5 days after the onset of normal menses, no backup is needed.
- If the implant is placed more than 5 days after the onset of menses, the woman should abstain from sexual intercourse or use an additional contraceptive method for the first 7 days after insertion.

### References

American College of Obstetricians and Gynecologists (2017). Practice Bulletin No. 186: Long-acting reversible contraception: Implants and intrauterine devices. *Obstet Gynecol*, 130(5), e251-e269.

American College of Obstetricians and Gynecologists (2016). Committee Opinion No. 672; Clinical challenges of long-acting reversible contraceptive methods. *Obstet Gynecol*, *128*(3), e69-e77. Available at <a href="https://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Gynecologic-Practice/Clinical-Challenges-of-Long-Acting-Reversible-Contraceptive-Methods">https://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Gynecologic-Practice/Clinical-Challenges-of-Long-Acting-Reversible-Contraceptive-Methods</a>

Centers for Disease Control and Prevention (2015). Sexually transmitted diseases treatment guidelines, 2015. MMWR 64(No.3) Available at <a href="https://www.cdc.gov/std/treatment/default.htm">https://www.cdc.gov/std/treatment/default.htm</a>

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Centers for Disease Control and Prevention (2016a). U.S. Medical eligibility criteria for contraceptive use, 2016. MMWR 65(No.3) Available at https://www.cdc.gov/mmwr/volumes/65/rr/rr6503a1.htm

Centers for Disease Control and Prevention (2016b). U.S. selected practice recommendations for contraceptive use, 2016. *MMWR* 65(No. 4) Available at <a href="https://www.cdc.gov/reproductivehealth/contraception/mmwr/spr/summary.html">https://www.cdc.gov/reproductivehealth/contraception/mmwr/spr/summary.html</a>

Grimes, D. A. & Schulz, K. F. (2001). Antibiotic prophylaxis for intrauterine contraceptive device insertion [Abstract]. *Cochrane Database Syst Rev, 2001*(2), CD001327.

Lopez, L.M., Hernholc, A., Zeng, Y., Allen, R.H., Bartz, D., O'Brien, P.A., & Hubacher, D. (2015) Interventions for pain with intrauterine device insertion [Abstract]. *Cochrane Database Syst Rev, 2001*(7), CD007373.

Washington, C. I., Jamshidi, R., Thung, S. F., Nayeri, U. A., Caughey, A. B., & Werner, E. F. (2015) Timing of postpartum intrauterine device placement: A cost-effectiveness analysis. *Fertil Steril*, *103*(1), 131-137.

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# **Billing and Reimbursement**

## **Coding for LARC services**

Below is a listing of Healthcare Common Procedure Coding System (HCPCS) procedure and device codes commonly used when billing for LARC services (CMS, 2018a; CMS, 2018b).

Table 1. LARC device codes and related procedure codes

IUDs	J7296, J7297, J7300, J7301
Implant	J7307
Insertion and Removal	58300, 58301, 58562, 11981, 11982, 11983

# **Providing LARC in the clinic**

# **Coverage for uninsured Texas women**

#### **Children's Health Insurance Program (CHIP)**

CHIP does not cover contraceptive services in accordance with state law.

#### **Medicaid**

Women who receive prenatal care through Medicaid for Pregnant Women remain eligible for Medicaid benefits for up to two months after the pregnancy ends. During this time, Medicaid will cover LARC services provided in the clinic. Women who remain eligible for Medicaid when they are not pregnant may continue to receive LARC services through the Medicaid program.

# **Healthy Texas Women and Family Planning Program**

When coverage under Medicaid for Pregnant Women ends, a woman will automatically be enrolled into the Healthy Texas Women (HTW) program if she is at least 18 years of age and meets all other eligibility requirements. Women who are at least 15 years of age and less than 18 must apply for HTW coverage (with parental consent) when Medicaid for Pregnant Women coverage ends.

In addition, any Texas woman who is not pregnant and meets eligibility requirements may enroll directly in the HTW Program. Minors who are at least 15 years of age and less than 18 must have parental consent. The HTW Program covers LARC services for enrolled women.

The Family Planning Program covers LARC services for Texas women who meet income eligibility requirements and do not qualify for HTW or have other similar coverage.

To find out more about HTW and FPP, or to locate a provider, go to the Healthy Texas Women website at <a href="https://exaswomen.org">HealthyTexasWomen.org</a> or call 2-1-1.

For HTW or FPP billing inquiries, providers may contact TMHP at 1-800-925-9126.

## Obtaining LARC devices for the clinic setting

There are two ways to acquire and bill for LARC devices to be provided in the outpatient clinic, the buy and bill method and the pharmacy method. Most Texas Medicaid and Healthy Texas Women providers may use either method. Providers who are delivering services under a contract with FPP must use the buy and bill method. Providers who are designated Federally Qualified Health Centers (FQHC) must use the buy and bill method.

#### How to use the buy and bill method

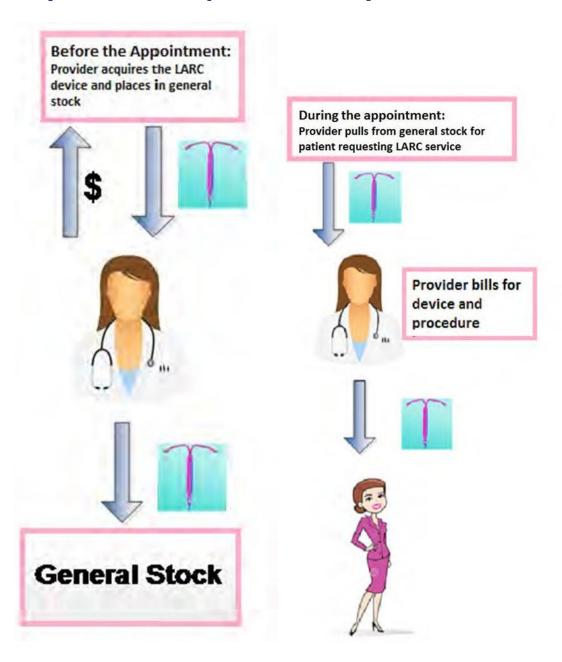
1. A provider orders the LARC device directly from the manufacturer or through a third-party distributor. The product manufacturer's website provides information on how to order and pay for the device. These are available in different size lots, and a discount may be available for purchasing multiple devices at a time.

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- 2. The provider keeps the LARC devices on-site in general stock. When a patient requests a LARC method, the provider pulls from the on-site stock and can provide the service on the same day.
- 3. The provider files a claim with Texas Medicaid, HTW, or FPP for both the LARC device and the appropriate insertion procedure. For patients enrolled in Medicaid managed care, the provider should contact the patient's managed care organization (MCO) for specific billing instructions.
- 4. If a purchased device is damaged, opened but not used, or expired, the provider should contact the manufacturer for possible replacement options.

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# **Buy and Bill Graphic Summary**



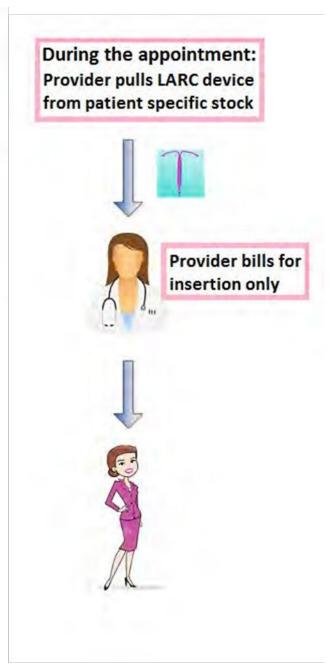
#### How to use the pharmacy method

Any provider currently enrolled in Texas Medicaid or HTW may use the pharmacy method to obtain any LARC product on the Texas Medicaid or HTW drug formulary for use by a woman enrolled in one of these programs.

- 1. A patient requests a LARC method from her provider.
- The provider submits a completed and signed prescription request form to a specialty pharmacy for the device to be provided to that particular patient.
   See the Texas Vendor Drug Program's <u>LARC Frequently Asked Questions</u> document for additional details on this process.
- 3. The specialty pharmacy dispenses the LARC product and bills Medicaid or Healthy Texas Women for the device. The device is shipped to the practice address, care of the patient, to be provided only to that patient. The provider does not bill for the LARC device.
- 4. The patient returns to the clinic and receives the LARC service using the patient-specific LARC device obtained from the specialty pharmacy.
- 5. The provider files a claim with Texas Medicaid or HTW using the appropriate LARC insertion procedure code.
- 6. Providers who obtain LARC devices using the pharmacy method are encouraged to return unused and unopened LARC products according to the manufacturer's abandoned unit return policy. Prescribers may obtain information and return forms at the <u>LARC Products Pharmacy Benefit</u> page on the Texas Vendor Drug Program website. The provider will not have to submit any additional claims, as this will be taken care of by the pharmacy. The provider should use the specialty pharmacy associated with the requested LARC device, as listed on the LARC Products Pharmacy Benefit Page.
- 7. For patients enrolled in Medicaid managed care, the provider should contact the patient's MCO for specific billing instructions. See Table 2 below (in the section entitled Providing LARC in the hospital) for contact information for each of the Medicaid MCOs operating in Texas.

# **Pharmacy Graphic Summary**





## **Billing by Federally Qualified Health Centers**

When providing LARC services to a patient with Texas Medicaid or Healthy Texas Women, an FQHC is reimbursed under a Prospective Payment System (PPS) methodology, whereby the FQHC receives an encounter rate for the patient clinic visit. FQHCs may receive payment for up to three family planning encounters per year, per client. When providing family planning services, the FQHC provider should bill the Evaluation and Management (E&M) code appropriate to the level of service provided. When LARC services are provided in the clinic, covered LARC devices may be reimbursed in addition to the FQHC encounter rate, as long as the device code and the appropriate E&M code are submitted on the same claim form. Procedure codes for individual services, such as the insertion procedure, will be processed as informational only and will not be paid separately. Because FQHCs are not eligible to use the Vendor Drug Program in Texas, they must use the buy and bill method for LARC device reimbursement.

When providing LARC services to a patient enrolled in the Family Planning Program, an FQHC is reimbursed on a fee-for-service basis, not by the PPS methodology applied to HTW and Texas Medicaid claims. When filing a claim under the Family Planning Program, the FQHC provider should follow the instructions for using the buy and bill method. The claim form should include the appropriate codes for both the LARC device and the insertion procedure, to reflect the services provided.

## **Billing by Rural Health Clinics**

Provider Type (PT) 71 – Rural health clinics (RHC) that are designated Family Planning Clinics (PT 71) may be reimbursed for family planning services using their RHC National Provider Identification (NPI) number and the FP3 benefit code. If the FP3 benefit code is not included, services listed on the claim will be treated as informational and will not be eligible for payment. Claims for family planning services should include the E&M code for the level of service provided and the appropriate family planning diagnosis code. If a LARC service is provided, the claim should include the appropriate LARC device code for reimbursement.

PT 78 and 79 – When providing LARC services, PT 78 (freestanding RHC) and PT 79 (hospital-based RHC) must use the procedure code T1015, as well as the appropriate LARC device code to receive both their encounter rate for the visit and reimbursement for the LARC device.

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## **Using the 340B Drug Pricing Program**

The federal 340B drug pricing program, administered by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services, enables eligible health care entities to provide outpatient drugs, including LARC devices, at reduced cost. All eligible organizations and covered entities that are enrolled in the federal 340B Drug Pricing Program should 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.

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

For more information on the HRSA 340B drug pricing program, please refer to the Health Resources and Services Administration website.

# Providing LARC in the hospital

Hospitals in Texas may be able to receive reimbursement for all LARC devices listed in Table 1 above when a LARC device is provided immediately postpartum to a woman eligible for Medicaid for the delivery. This would be in addition to the hospital diagnosis related group (DRG) payment for delivery. Emergency Medicaid only covers those services necessary to stabilize the emergency medical condition, and contraception, including LARC, is not covered. Immediate postpartum insertion refers to the delivery of a LARC service (i.e., either IUD or contraceptive implant) after delivery but before discharge from the hospital.

## Traditional, Fee-for-Service Medicaid

When seeking reimbursement for an IUD or implantable contraceptive device provided immediately postpartum to a patient whose delivery is covered by traditional Texas Medicaid for Pregnant Women, hospital/facility providers must submit a separate outpatient claim with the appropriate procedure code for the contraceptive device in addition to the inpatient claim for the delivery services for claims submitted to the Texas Medicaid and Healthcare Partnership (TMHP). The provider performing the LARC service in the hospital must also submit an outpatient claim separate from the inpatient delivery claim to TMHP to receive payment for the insertion procedure.

## **Medicaid managed care**

Texas Medicaid managed care organizations (MCO) must adopt claims processing procedures to reimburse the LARC device cost to hospitals and facilities, in addition to the contracted rate for inpatient labor and delivery, when a LARC service is provided immediately postpartum, before the patient is released from the facility. MCOs must educate hospital providers on claim submission requirements.

Administrative procedures, such as claims filing, may differ from traditional Medicaid (fee-for-service) and among MCOs. For claims submitted to a Texas Medicaid managed care organization (MCO), providers must follow the MCO's claim processing procedures for reimbursement of immediate postpartum LARC devices in addition to the rate for delivery services.

Providers should contact the client's specific MCO for details. Contact information for each of the state's Medicaid MCOs is included in Table 2.

#### **Medicaid MCO Contact Information**

Table 2. Contact information for Texas Medicaid Managed Care Organizations.

Health Plan	Provider Services Hotline	Health Plan Web Address
Aetna	1-800-248-7767 (Bexar STAR) 1-800-306-8612 (Tarrant STAR)	https://www.aetnabetterhealth.com/texas
Amerigroup	1-800-454-3730	https://www.myamerigroup.com/tx/pages/welcome.aspx
BCBS	1-877-560-8055 (STAR) 1-877-784-6802 (STAR Kids)	https://www.bcbstx.com/medicaid/

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Health Plan	Provider Services Hotline	Health Plan Web Address
Children's Medical	1-800-947-4969	https://www.childrensmedicalcenterhealthplan.com/home
Cigna	1-877-653-0331	https://www.cigna.com/starplus/
Community First	1-800 434-2347	http://www.cfhp.com/
Community Health Choice	1-888-760-2600	https://www.communityhealthchoice.org/
Cook Children's	1-800-964-2247	http://www.cookchp.org/English/Pages/default.aspx
Dell Children's <sup>5</sup>	1-888-821-1108	https://www.dellchildrens.net/health-plan/
Driscoll	1-877-324-3627 (Nueces STAR) 1-855-425- 3247(Hidalgo STAR)	http://driscollhealthplan.com/
El Paso Health	1-877-532-3778 ext. 1507	http://www.elpasohealth.com/

<sup>&</sup>lt;sup>5</sup> See the Texas Medicaid Provider Procedures Manual, Managed Care Handbook, Section on Family Planning Carve-Out Services, for information on claims processes for MCOs that are subject to a carve-out for certain family planning and contraceptive services.

Health Plan	Provider Services Hotline	Health Plan Web Address
FirstCare	1-800-431-7798 (First Care STAR - Lubbock and MRSA West)	https://www.firstcare.com/en/Home
Molina	1-855-322-4080	http://www.molinahealthcare.com/members/tx/en- US/Pages/home.aspx
Parkland	1-888-672-2277	https://www.parklandhmo.com/
Scott & White	1-855-897-4448	http://rightcare.swhp.org/en-us/
Superior	1-877-391-5921 (STAR, STAR+PLUS, MRSA, STAR Kids) 1-866-439-2042 (STAR Health)	https://www.superiorhealthplan.com/
Texas Children's	1-877-213-5508	http://www.texaschildrenshealthplan.org/
United Healthcare	1-888-887-9003	http://www.uhccommunityplan.com/tx.html

# **Emergency Medicaid**

Providers and hospitals are not eligible to receive reimbursement for LARC services through Emergency Medicaid for a woman whose delivery is covered by that program. Emergency Medicaid covers only those services needed to stabilize the emergency medical condition, including labor and delivery services. Women who

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are eligible for Emergency Medicaid at the time of delivery may be able to receive immediate postpartum LARC through the Family Planning Program (FPP).

Postpartum patients who have delivered under Emergency Medicaid coverage and meet eligibility requirements for FPP may receive immediate postpartum LARC services through a contracted FPP provider. The patient's eligibility should be assessed by a participating FPP contractor before the LARC service is provided. Ideally, she would be assessed for eligibility in the course of prenatal care.

The direct provider of the LARC service to the hospitalized postpartum woman may be either the FPP contractor or a provider acting under a memorandum of understanding (MOU) with the FPP contractor, as described in the <a href="HHSC Family Planning Program Provider Manual">HHSC Family Planning Program Provider Manual</a>. The direct provider of the postpartum LARC service performs the insertion procedure, using a device taken from hospital stock, in the usual way described previously in this toolkit.

The FPP contractor must then submit an outpatient claim to TMHP for the LARC device and insertion procedure on the Family Planning 2017 Claim Form, using provider type 46 or 71, as appropriate for that contractor. The FPP contractor will then reimburse the delivery hospital and clinician for the device and insertion procedure, according to the previously agreed on MOU.

#### References

Centers for Medicare & Medicaid Services (2018a). 2018 Alpha-numeric HCPCS file. Available at <a href="https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS.html">https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS.html</a>

Centers for Medicare & Medicaid Services (2018b). Physician fee schedule: HCPCS level file. Available at

https://www.cms.gov/apps/ama/license.asp?file=/Medicare/Medicare-Fee-for-Service-Payment/physicianfeesched/downloads/pe\_townhall\_hcpcs\_level.zip

Texas Medicaid & Healthcare Partnership (April, 2018). Texas Medicaid Provider Procedures Manual. Retrieved from

http://www.tmhp.com/Pages/Medicaid/Medicaid Publications Provider manual.asp x

For HTW or FPP billing inquiries, providers may contact TMHP at 1-800-925-9126.

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