

# A Quality Improvement

A Quality Improvement Toolkit



Increasing Access to Immediate Postpartum Long-Acting Reversible Contraception



The Florida Access LARC toolkit is intended to provide guidance to hospitals and health care providers in the development of individualized policies and protocols related to increasing access to immediate postpartum long-acting reversible contraception. It is not to be construed as a standard of care; rather it is a collection of resources that may be adapted by local institutions in order to develop standardized protocols. **The toolkit will be updated as additional resources become available.** 

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## ACCESS LARC

#### INCREASING ACCESS TO IMMEDIATE POSTPARTUM LONG-ACTING REVERSIBLE CONTRACEPTION

#### **TOOLKIT INTRODUCTION**

Beyond preventing unplanned pregnancies, research indicates that effective contraception helps prevent poor birth spacing, thereby reducing the risk of lowbirthweight and/or premature birth (Conde-Agudelo, 2006). It is also beneficial for a woman's physical and emotional health to be able to follow a reproductive life plan. LARCs (Long Acting Reversible Contraceptives), including intrauterine devices (IUDs) and contraceptive implants, have been identified by the Centers for Disease Control and Prevention as among the most effective family planning methods.

LARCs are effective for between three and 10 years (depending on the method) and do not require any upkeep or user effort. Insertion of the IUD or implant after a delivery and prior to discharge has the additional benefit of eliminating access barriers, since the provider and patient are both available during the hospitalization and insurance has not lapsed. This is a time when it is known that the woman is not pregnant and may be highly motivated to avoid a short-interval repeat pregnancy.

Many organizations are working toward educating women about the full range of contraception options, from most effective to least effective. LARCs have Long-Acting Reversible Contraceptives are among the most effective family planning methods – insertion of the IUD or implant after a delivery and prior to discharge eliminates access barriers in a time where women are highly motivated to avoid a short-interval repeat pregnancy

been endorsed by the American Congress of Obstetricians and Gynecologists (ACOG), the American Academy of Pediatrics (AAP), the American Academy of Family Physicians (AAFP), and the Centers for Disease Control and Prevention (CDC) as among the most effective family planning methods. Florida's Healthy Start program includes LARCs in contraception choice counseling in their newlydeveloped interconception education curriculum. The March of Dimes has provided community funding for LARC education. Florida Medicaid and several managed care organizations have also committed resources to providing education and reducing barriers to immediate postpartum LARCs (see Chapter 2 of this Toolkit).



#### Access LARC Initiative

The Florida Perinatal Quality Collaborative (FPQC) works to advance perinatal health care quality and patient safety for all of Florida's mothers and infants through the collaboration of FPQC stakeholders in the development of joint quality improvement initiatives, the advancement of data-driven best practices and the promotion of education and training. With the support of professional organizations and a change in Medicaid policy allowing the unbundling of LARCs in the immediate postpartum period, the Florida Perinatal Quality Collaborative (FPQC), as guided by a multidisciplinary advisory panel, has established the Access LARC Initiative. The aim of Access LARC is to work with participating Florida hospitals to improve hospital policies, procedures, and collaboration to increase rates of postpartum LARC usage, and to work with Medicaid, and other payers and state partners, to facilitate their use.

The FPQC's Access LARC Advisory Group consists of representatives from the American College of Obstetricians and Gynecologists (ACOG) District XII, the Florida Chapter of the Association of Women's Health, Obstetric, and Neonatal Nurses (AWHONN), the Agency for Healthcare Administration (AHCA), the Florida Department of Health (DOH), United Healthcare and Aetna Medicaid Managed Care Organizations, representatives from provider practice groups, hospitalists, hospital nurses and administration, lactation consultants, and public health professionals.

Because this initiative is expected to take significant effort for hospital teams to get all the pieces in place for successful implementation, the initiative is divided into two phases: Pre-implementation and Implementation.

Our goal is for 80% of participating hospitals to provide immediate postpartum LARCs by the end of the 15-month initiative.





#### **Initiative Phases**

The Pre-Implementation Phase focuses on creating and modifying hospital systems to enable acquisition and availability of and reimbursement for immediate postpartum LARC placement. Initial decisions regarding which LARC method (IUD or implant) as well as which hospital sites (L&D, postpartum, outpatient clinic) will be included in the initiative will guide the implementation process. The pharmacy department will need to address formulary revisions, determine pharmacy costs (device, local anesthetic, stocking charge), inventory levels, stocking locations and order system revisions. Billing and collections departments may need to create new billing processes (device, facility, provider), initiate contract amendments with managed care organizations, customize the claims process, and test billing revisions to assure reimbursement. Collaborations will also need to occur across departments to facilitate the creation or revision of policies and procedures, as well as to establish guidelines and work flows for labor and delivery, obstetric operating rooms, and postpartum floors. Administration support and close collaboration with managed care organizations at the highest level will be critical during this phase to assure the various departments work together and that the initiative continues to make timely progress given other hospital priorities. See Appendix A for the Pre-Implementation Key Driver Diagram.

<u>The Implementation Phase</u> focuses on the delivery of this new service. It includes assuring that providers are trained in immediate postpartum LARC insertion and in contraception choice counseling that includes the option of postpartum LARCs. This is the phase during which providers will actually begin offering and providing immediate postpartum LARC.

Experiences reported from other states indicate that the planning and implementation process for instituting postpartum LARC services took about six months. The timeline will vary depending on how quickly different hospital departments can convene for planning, the amount of effort needed to adjust the billing processes to meet the policy requirements, the process to expand the formulary, order and stock the devices, to modify or create policies and procedures and IT revisions and the training needs for clinical staff.

#### The Access LARC Toolkit

Based on experiences in other states and input from the Access LARC advisory committee, this toolkit was developed and includes the guidance, tips and resources for:

Pre-Implementation	Implementation
<ul> <li>Building a successful initiative</li> <li>Key stakeholder education</li> <li>Hospital/Managed care organization collaboration</li> <li>Policies and procedures</li> </ul>	<ul> <li>Provider and staff education on procedures and device insertion</li> <li>Comprehensive choice counseling</li> </ul>

As with all of the FPQC toolkits, this document was developed as a general guide to assist hospitals with the steps expected to be necessary to provide immediate postpartum LARCs. Only the pre-implementation chapters have



been included for the kick – off meeting. The final chapters as well as additional guidance and tools will be developed as the project evolves.

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#### **CHAPTER ONE: BUILDING A SUCCESSFUL INITIATIVE**

#### **General Quality Improvement Tips**

It takes a multidisciplinary team to implement systematic change. Quality improvement (QI) work often involves multiple disciplines and hospital departments. Engaging key stakeholders at the very beginning of a proposed QI project is key to successful implementation. It is important to strategically identify who needs to be at the planning table. These projects may require input and cooperation from departments that you don't traditionally interact with in your institution. Understanding the aspect of the project that impacts them as well as how the project will benefit their department is important to address for their initial buy-in. After leaders are identified, it will be important to engage them in planning and implementing evidence-based practice changes.

For the Access LARC initiative, gaining top level administrative support is key to successful implementation. Because so many departments are involved, it is especially important to obtain initial buy-in as well as ongoing support of senior level administration. In addition, it will be critical to have hospital representatives or liaisons affiliated with the managed care organization(s) that will be providing payment for immediate post-partum LARCs. Identifying a physician champion and nursing leader within the hospital who can facilitate the administrative coordination, lead the clinical process development, and ensure that clinical staff receives sufficient training is critical for success. Lactation consultant leadership will also be helpful to build support. It will be especially Others (for example: C

Multi-disciplinary Implementation Team
Disciplines and Departments
Obstetric Providers
Nursing (L & D, OB, OR, Mother/Baby)
Lactation Consultants
Billing/Collections
Contracts/MCO Liaison
IT/EMR
Pharmacy
Others (for example: OI, social work)

important that the planning team members are consistent. One representative and an alternative for each department is recommended and further substitutions of team members is discouraged.

#### Creating and Maintaining Successful Teams

The Institute for Healthcare Improvement (IHI) recommends that every team include at least one member who has the following roles:

- Clinical leadership. This individual has the authority to test and implement a change and to problem solve ✓ issues that arise in this process. This individual understands how the changes will affect the clinical care process and the impact these changes may have on other parts of the organization.
- Technical expertise. This individual has deep knowledge of the process or area in question. A team may  $\checkmark$ need several forms of technical expertise, including technical expertise in QI processes, health information technology systems needed to support the proposed change, and specifics of the area of care affected. For example, a team implementing an intensive care management clinic for people with poorly controlled diabetes might need technical expertise in change management, the clinic's electronic health record, and the patient treatment protocols that will be used.
- Day-to-day leadership. This individual is the lead for the QI team and ensures completion of the team's  $\checkmark$ tasks, such as data collection, analysis, and change implementation. This person must work well and closely



with the other members of the team and understand the full impact of the team's activities on other parts of the organization as well as the area they are targeting.

✓ Project sponsorship. This individual has executive authority and serves as the link to the QI team and the organization's senior management. Although this individual does not participate on a daily basis with the team, he or she may join periodically and stays apprised of its progress. When needed, this member can assist the team in obtaining resources and overcoming barriers encountered when implementing improvements.

Creating Quality Improvement Teams and QI Plans (2013) Practice Facilitation Handbook; Agency for Healthcare Quality and Research, ahrq.gov

Once champions are identified and a team is assembled, the following tips can be used to guide team meetings:

- Because this will be a multidisciplinary effort, all members of the team must be respected and their needs identified and addressed
- Teams should establish and maintain a routine meeting schedule
- It is important to provide an open and safe environment that encourages:
  - o Listening
  - o Sharing
  - o Questioning
  - o Negotiating
  - o Respecting
  - o Participating
- ♦ A very important product of successful teams is that members are likely to begin to broaden their understanding to an expanded system rather than only their particular unit. Create a QI culture a team environment that emphasizes quality and patient safety
- As many team members as possible should participate in collaborative events each team member can learn from other hospitals
- Sharing important information, progress and successes with everyone keeps the work of the team in the spotlight
- Be creative and flexible

#### **Easy Wins Matter**

Demonstrating some early, straightforward successes builds confidence and enthusiasm for continued improvement. For the Access LARC initiative, an important early win is the establishment of an influential, effective and comprehensive quality team.



#### Goals and timelines are very useful

It is suggested that highly effective teams develop implementation plans with specific goals and timelines. By providing this degree of structure for their work as well as assigning responsibility for specific actions, the teams are given a sense of progress and momentum that is encouraging. The figure below is an example of a suggested timeline for implementing Access LARC, which has two phases (Pre-Implementation and Implementation) over 15 months.

Pre-Implementation						Implementation									
Activity	Mo 1	Mo 2	Mo 3	Mo 4	Mo 5	Mo 6	Mo 7	Mo 8	Mo 9	Mo 10	Mo 11	Mo 12	Mo 13	Mo 14	Mo 15
Recruit champions for multidisciplinary team															
Conduct scheduled monthly team meetings															
Add devices to formulary															
Assure timely access to devices					-										
Assure billing mechanism in place for pLARC															
Revise policies/procedures to provide pLARC															
Modify IT systems to assure accurate tracking, billing and documentation of pLARC											•				
Educate all appropriate staff on advantages and clinical recommendations of pLARC															, 
Train clinicians on pLARC insertion															
Educate providers and community partners about contraceptive															
choice counseling and informed consent															

#### Data matter

The old adage "what gets measured gets done" is true for all quality improvement initiatives. Data are needed to test changes, provide feedback, and answer the essential question, "How do we know the change was an improvement?" For the Access LARC initiative most of the data to be collected will be measuring hospital progress in completing structural measures that must be in place to assure successful immediate postpartum LARC insertion.

#### Small tests of change matter

A key principle of implementation science is to fit the scope of the intervention to context it is used in. The exact manner in which project elements are deployed in each hospital needs to be adapted to each unit. While all improvement requires change, not all change results in an improvement. It is important that the quality improvement team be willing to test multiple ideas while searching for the changes that result in improved care at the local level. In the IHI Model for Improvement, these multiple small tests of change are referred to as the PDSA, or Plan Do Study Act cycle. PDSA cycles should be run among smaller groups (for example, one nurse, one



physician, and during one shift to start) before gradually expanding to a larger population within the system or organization if the change is determined to be successful.

For the Access LARC initiative, an example of a PDSA cycle might be the testing of billing procedures developed to assure timely reimbursement for inpatient LARCs.

The PDSA cycle is an improvement tool which promotes improvement via the implementation of rapid-cycle tests among an increasingly larger population and a wider range of conditions. The "**Plan**" step in the cycle involves identifying and planning the change to be tested. Plans should be as specific as possible and include information about where the test will take place, who will participate, resources needed, and how the effectiveness of the change will be measured. The "**Do**" portion of the cycle is the actual act of carrying



out the test. Initial tests should be small and local. For example, an initial test of a new form could be performed with one nurse and one patient on one nursing unit. If the test proves successful, the new form can be tested with several nurses and several patients in several different units. The "**Study**" phase of the PDSA cycle involves rapid data collection that is done during testing through a "huddle" or "debrief" with the staff or patients involved in the newly designed process. The results of testing will be analyzed and will help to determine whether a change process will be abandoned, adapted, or adopted. Testing periods should not last more than a month and can usually be completed within a few days, allowing for multiple testing cycles if needed. Finally, the "**Act**" portion of the cycle occurs when the decision to Adapt, Abandon or Adopt is made, based on the analysis of rapidly-collected information. If revisions and changes are indicated, the process is revised or "adapted," and a new testing cycle is instituted. If the trials have been unsuccessful, the change idea may be "abandoned." The decision to "adopt" a new process occurs after it has been tested broadly under various circumstances and settings.

Implementation Guide for the Toolkit to Support Vaginal Birth and Reduce Primary Cesareans (2016) California Maternal Quality Care Collaborative

#### Administrative support matters

Successful quality improvement project implementation may require staff time and budgetary resources for equipment/supplies, education/training, and data collection. Administrative support may be needed in identifying departmental champions for the QI team. For the Access LARC initiative, implementation teams may need administrative support in identifying organizational stakeholders and resources, purchasing supplies, moving order sets and policies through committees, and obtaining integration of best practices. Facilities also need to provide resources and staff support for entering and analyzing data collection. This will often involve working collaboratively with information technology and quality departments. Staff need release time or additional support to complete these activities successfully.

#### It takes time and persistence to get systems running smoothly

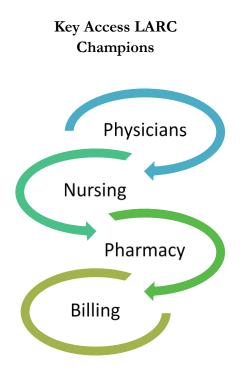
In most quality improvement initiatives, overall success often takes time and persistence; this is especially true for the Access LARC initiative. With the need to revise multiple systems (pharmacy, billing, labor and delivery, etc.)



persistence, follow-up and strong communication are critical to keeping the project on track. Other states have reported setbacks and failed PDSA cycles requiring one or more revisions. It is understood that refining systems is a work in progress. Sustainability requires steady effort and attention by committed leaders and front line staff.

#### Champions are essential

Formal leaders, opinion leaders, and early adopters are important to overall success since the changes can be uncomfortable and take a long time. Champions, however, are essential. Champions are individuals who actively associate with the project and dedicate themselves to incorporating best practices within the structure of each unit. For the Access LARC initiative, nursing, pharmacy, billing and physician champions are core components of successful implementation and especially with leading culture change. Nursing champions typically play a central role in testing, implementing, coordinating, and disseminating clinical practice refinement and changes. They also often provide counseling to the patient regarding contraception choices. Pharmacy champions are key to assuring that devices are obtained and stocked for timely insertion. While the pharmacy and billing champions work behind the scenes, their roles are crucial in establishing or modifying systems to ensure a successful implementation. Physicians and midwife champions are particularly important since they often provide contraception counseling to include this new choice for the patient and must be trained to insert the IUD or implant. They are often particularly visible stakeholders.



Champions are individuals who actively associate with the project and dedicate themselves to incorporating best practices within the structure of each unit

#### Sustainability

Successful sustainable efforts must reflect the foundation provided in the initial phases of the project. For the Access LARC initiative many systems changes, such as an expanded formulary, successfully revised billing procedure and contract amendments are easily sustainable. However, processes assuring that contraceptive choice counseling including immediate postpartum LARC as an option continues to be discussed prenatally must be continuously monitored. Assuring that this option is offered and continues to be available to women prior to discharge will solidify the necessary cultural change within your institution. This can be facilitated by continuing to track and highlight the number of postpartum LARCs provided and assuring that staff and provider training remains required. Periodic review of managed care plan policies is also important to assure continued seamless provision of postpartum LARCs.



#### Why Join a Collaborative

Participation in a collaborative helps your hospital implement evidence-based quality improvement recommendations by bringing together institutions with similar goals and providing resources to advance those goals. It offers an environment to learn together with others on the best strategies, methods and tools to adapt and implement in your hospital. Hospitals that participate in multi-organization quality improvement collaboratives achieve more gains faster than those who do so alone. Past participants have found it useful to not have to "reinvent the wheel."

Identification of potential barriers to your project are important to consider and solve prior to sharing with staff. It is possible that additional challenges may occur during implementation, but it will be in your favor to remove as many barriers as possible prior to the start.

Potential Barrier Drivers	Strategies to Overcome					
<ul> <li>Clinician</li> <li>Resistance to change</li> <li>Don't see the need for change</li> <li>Lack of understanding and/or knowledge deficit</li> </ul>	<ul> <li>Build compelling story with respected peer to speak to the importance of initiating proposed changes</li> <li>Provide peer based education to all clinicians with education on the initiative and goals</li> <li>Provide peer-reviewed evidence to support change</li> <li>Share goals of the proposed QI project/change</li> <li>Provide opportunities to answer questions and/or concerns</li> </ul>					
<ul> <li>Upper management</li> <li>Lack of knowledge of Perinatal QI</li> <li>Lack of resource support</li> </ul>	<ul> <li>Share data on outcomes of facility in relation to like facilities</li> <li>Provide high quality peer-reviewed research and evidence to support change</li> <li>Instill the importance of resource (people, financial) support for project to ensure success</li> <li>Share plan for implementation and sustainability</li> </ul>					
Time limitations	<ul> <li>Utilize efforts of many staff members – consider use of nurse clinical ladder to support project</li> <li>Make sure meetings are organized and succinct to decrease the impact on available time</li> <li>Offer meetings at multiple times; consider web-based meetings for those who may be off site</li> <li>Utilize regularly scheduled department meetings to highlight project and results <ul> <li>Be succinct</li> <li>Be prepared to answer questions</li> </ul> </li> </ul>					
Resource limitations	Connect with other hospitals or QI leaders for potential solutions or sharing resources through collaborative work					



#### CHAPTER TWO: KEY STAKEHOLDER EDUCATION

#### **Overview**

During the pre-implementation phase, key healthcare providers and staff should be educated on the definition, components, and importance of postpartum long-acting reversible contraception in order to facilitate buy-in, foster champions, and ease adoption of new processes. It will ensure hospital awareness of the project to increase access to LARC prior to discharge, and standardize department knowledge in preparation for creation of a policy or protocol on this topic.



Key staff and specific reasons for LARC education include:

- Physicians and Midwives
  - **Delivering physicians/midwives:** Universal acceptance of this new contraceptive option is ideal, although not all health insurance plans reimburse for inpatient LARCs separate from the global delivery fee. All obstetric providers should be aware of the option and provide the same choice counseling to their patients.
  - Non-delivering community physicians/midwives Choice counseling is most effective when initiated prenatally, thus providing time for questions and careful consideration of all the contraception options prior to the woman's delivering. It is important to educate community OB providers about the full array of choices now available to women as well as informing prenatal care providers about Access LARC.

#### ✓ Nurses

Nurses in L&D as well as on the postpartum unit provide important support for reproductive life choices made by pregnant women and new mothers. Immediate postpartum LARC is a relatively new contraceptive choice, so it is important for nurses to be able to provide comprehensive information. Their input into process changes necessary for implementation will also be important. Identifying a champion in each area will be critical in the successful implementation of Access LARC.

#### ✓ Pharmacy

This innovation will require assistance from pharmacy to obtain approval to add IUDs and implants to inpatient formularies. It may also require new processes, since the trend is to bundle services together rather than separate them. Providing the benefits and the science behind this change can greatly enhance cooperation and success.

#### ✓ Lactation Consultants

Lactation consultants are an important part of a woman's postpartum hospital stay, assisting with establishing successful breastfeeding. Traditional teaching has often recommended against any immediate postpartum hormonal contraceptives in breastfeeding women due to concerns regarding delayed lactogenesis. Currently available literature does not show that the hormonal IUDs or implants impair



breastfeeding, and therefore educating Lactation Consultants on newer literature is imperative in gaining their support for patients desiring immediate postpartum LARC.

#### ✓ Administration

As with any new initiative, obtaining administrative support is crucial before attempting any of the other steps in providing immediate postpartum LARC.

This broad education is a pre-cursor to training related to how to counsel and educate patients and the more focused education that some providers will receive on placement and insertion of IUDs and implants, which will be provided in the implementation phase.

#### **Educational Topics**

#### **Unplanned Pregnancies**

Approximately 45% of all pregnancies and 75% of teen pregnancies in the U.S. are unintended (Finer, 2016). In Florida, the unintended pregnancy rate was 59% in 2010, and 71% of unplanned births were publicly funded (compared to 68% nationally) (Sonfield and Kost 2015). The total public costs for unintended pregnancies in 2010 was \$1.3 billion. This equates to \$371 per woman aged 15-44 in Florida, compared with \$201 per woman nationally (Sonfield and Kost 2015).

The consequences of unintended or closely spaced pregnancies include poor pregnancy outcomes (i.e., low birth weight, preterm birth, small for gestational age, neonatal and infant death), delayed initiation of prenatal care, lower breastfeeding rates, and higher risk of maternal depression and potential future child maltreatment (Guttmacher Institute 2017). Short interpregnancy intervals are also associated with worse perinatal outcomes: maternal bleeding, anemia, death, preterm birth, and low birth weight (Jackson et al 2011; Conde-Agudelo 2006).

The total public costs for unintended pregnancies in 2010 was \$1.3 billion.

#### Long-Acting Reversible Contraception

LARC has been endorsed by the American Congress of Obstetricians and Gynecologists (ACOG), the American Academy of Pediatrics (AAP), the American Academy of Family Physicians (AAFP), and the Centers for Disease Control and Prevention (CDC) as among the most effective family planning methods. Clinical practice guidelines from CDC and ACOG support immediate postpartum insertions for both IUDs and contraceptive implants, with few contraindications.

Studies indicate that fewer than 1 in 100 women will get pregnant using an IUD or implant. Typical use of the birth control pill results in 9 out of 100 women becoming pregnant within a year and the use of male condoms results in 18 out



of 100 women becoming pregnant. The number is higher if not used correctly and consistently. While LARC use is growing, only 7.2% of women aged 15-44 and less than 5% of teens use LARCs in the U.S (CDC 2015).

#### Terminology

- **Immediate Postpartum** refers to the placement of the IUD or implant within the delivery hospitalization period.
- Immediate Post-Placental refers to the placement of an IUD within 10 minutes of delivery of the placenta and is a subgroup of immediate postpartum.
- Late Postpartum refers to placement after 48 hours and before four weeks post-delivery.
- **Standard or Interval** refers to placement of a LARC four weeks or more postpartum, or unrelated to a pregnancy event.

In an effort to expand contraception choice, this initiative focuses on immediate postpartum and post placental LARC placement on an inpatient basis.

In 2015, the CDC convened national experts to review scientific evidence for the use of various contraceptive methods for men and women with specific characteristics or medical conditions and update the 2010 U.S. Medical Eligibility Criteria for Contraceptive Use (US MEC 2016). Results of that review were published in the US MEC, 2016. Immediate postpartum LARCs MECs are listed on the table below.

miniculate 1 ostpartum Extres							
Condition	Sub-Condition	Cu-IUD	LNG-	Implant			
			IUD				
Postpartum (in	a) <10 minutes after delivery of the						
breastfeeding or non-	placenta						
breastfeeding women,	i) Breastfeeding	1	2	2			
including cesarean	ii) Nonbreastfeeding	1	1	1			
delivery	b) 10 minutes after delivery of the	2	2	1*/2**			
	placenta to <4 weeks						
	$c) \ge 4$ weeks	1	1	1			
	d) Postpartum sepsis	4	4	1			
LNG=levonorgestrel; Cu=copper; IUD=intrauterine device. *Nonbreastfeeding women, **Breastfeeding women							

#### Immediate Postpartum LARCs

LNG=levonorgestrel; Cu=copper; IUD=intrauterine device. Categories:

1 = A condition for which there is no restriction for the use of the contraceptive method.

2 = A condition for which the advantages of using the method generally outweigh the theoretical or proven risks.

3 = A condition for which the theoretical or proven risks usually outweigh the advantages of using the method.

4 = A condition that represents an unacceptable health risk if the contraceptive method is used.

Adapted from Centers for Disease Control and Prevention Medical Eligibility Criteria Classifications for Postpartum Long-Acting Reversible Contraception (2016)



#### Intrauterine Devices (IUDs)

The copper IUD (ParaGard<sup>®</sup>) can be used for 12 years, and the levonorgestrel IUDs (Skyla<sup>®</sup>, Kykena<sup>®</sup>, Liletta<sup>®</sup>, and Mirena<sup>®</sup>) for three to five years, with failure rates similar to female sterilization. The ACOG Practice Bulletin on LARC (2017 update) provides guidance on patient counseling for complications and side effects.

For all IUDs, immediate postpartum insertions are considered safe and effective. When inserted within 10 minutes of placental delivery, the copper-containing IUD (ParaGard) has no restrictions on its use (medical eligibility criteria category 1). After this period and up to four weeks' postpartum, the advantages of insertion generally outweigh the theoretical or proven risks (medical eligibility criteria category 2). For the levonorgestrel IUDs, the advantages of immediate postpartum insertion generally outweigh the theoretical or proven risks (medical eligibility criteria category 2) in breastfeeding women, and there are no restrictions on its use in nonbreastfeeding women (category 1).

Contraindications for immediate postpartum IUD insertion include peripartum chorioamnionitis, endometritis, and puerperal sepsis.

#### Contraceptive Implant (Hormonal)

The contraceptive implant (Nexplanon®) can be used for up to four years, and is a highly effective method of reversible contraception. The advantages of using this method in the immediate postpartum period generally outweigh the theoretical or proven risks (medical eligibility criteria category 2). Suggested counseling about the devices, advantages, contraindications, etc., including a shared decision-making model, are covered in detail in Chapter 6 of this toolkit.

#### Immediate Postpartum LARC

Between 40 and 57% of women resume sexual activity before their postpartum check-up (Brito 2009, Connolly 2005). These women may not recognize their risk for unintended pregnancy so soon after delivery. Postpartum women may be highly motivated to obtain contraception and delay another pregnancy.

Immediate and early postpartum is an ideal time to initiate contraception because women are currently accessing the healthcare system. Up to 40% of women do not return for their 6-week postpartum visit (Gurtcheff 2011) and 40-75% of women who plan to use an IUD postpartum do not obtain one (Simmons 2013). According to an August 2016 ACOG Committee Opinion, expulsion rates for immediate postpartum IUD insertions are higher than for interval insertions, vary by study, and may be as high as 10–27%. Despite the higher expulsion rates, a 2015 Cochrane Review (Lopez et al 2015) found that IUD placement immediately postpartum was associated with higher use of LARC at six months compared to standard insertion. Copper IUD:

**ParaGard**®

Levonorgestrel IUDs:

Skyla®, Kyleena®, Liletta®, Mirena®

> Contraceptive Implant:

Nexplanon®

Up to 40% of women do not return for their 6week postpartum visit.

40-75% of women who plan to use an IUD postpartum do not obtain one.



Although the initial cost of LARCs is greater than other forms of contraception, it is more effective in preventing pregnancies, since as many as 57% of women have resumed intercourse prior to their postpartum visit. When taking into account the cost of an avoided pregnancy, immediate postpartum implant insertion is expected to save \$1,263 per patient. (Gariepy, Duffy, Xu 2015). South Carolina's initial efforts to cover LARCs through Medicaid resulted in a first year cost for oral contraceptives (including the cost of expected unintended pregnancies) almost double that of immediate postpartum LARCs.

While there is limited research on this subject, unintended pregnancy is significantly more prevalent in women using opiods. In a study aimed to estimate the prevalence of unintended pregnancy among opiate-abusing women, researchers found that almost 9 of every 10 pregnancies were unintended (86%), with comparable percentages mistimed (34%), unwanted (27%), and ambivalent (26%). (Heil, 2011). Unfortunately, women undergoing treatment for opiate addiction demonstrate low contraceptive knowledge and use, and therefore may certainly benefit from the availability of immediate postpartum LARC.

#### IPP LARC Coverage Movement

Insertion of LARCs immediately postpartum has been proven to be safe, effective and is supported by clinical guidelines. As noted in the US Medical Eligibility Criteria for Contraceptive Use, the IUD and the contraceptive implant may be inserted prior to hospital discharge after vaginal or cesarean delivery in both breastfeeding and non-breastfeeding women.

However, reimbursement policies have traditionally posed a barrier to inpatient LARC placement. Medicaid and private insurers bundle labor and delivery related care into one global fee. The high cost of IUDs and implants, which would be included in that global fee, discouraged implementation of immediate postpartum LARCs. In 2012, South Carolina became the first state to "unbundle" LARCs, thus allowing separate payment for the device and associated costs by Medicaid. Since that time other state Medicaid agencies have followed suit and provided various funding methodologies. Currently, over half the states in the US have implemented or are exploring ways to implement such policies.

In 2014, the Association of State and Territorial Health Officers (ASTHO) and CDC created a LARC Immediately Postpartum Learning Community with an initial cohort of six states and an addition of seven states in cohort 2 (2015). In 2016, the scope and size of the learning community was expanded to include 22 states addressing increasing access to contraception.

Florida joined the Increasing Access to Contraception Learning Community in October 2016 as part of Cohort 3. As a member of Cohort 3, Florida's aim has been to implement system-wide changes to eliminate barriers of access to reproductive health care while addressing health disparities. Florida will focus on all women of reproductive age with a special emphasis on the under-insured and Medicaid populations. Florida will accomplish these activities through two goals:

1. Implementing statewide policy change to provide immediate postpartum LARC in an inpatient hospital setting.



2. Removing barriers to same day access to highly effective, reversible methods of contraception in clinic settings.

In addition to the ASTHO Learning Community, other national and statewide efforts to encourage the use of the most effective forms of contraception include:

- ✓ National objectives included in Healthy People 2020
- ✓ HEDIS measures reported by health plans
- ✓ Clinical opinions/guidelines endorsed by ACOG, AAP, AAFP, and CDC
- ✓ US Medical Eligibility Guidelines for Contraceptive Use
- ✓ Education and training for Title X providers
- ✓ Medicaid family planning waiver
- ✓ Healthy Start program emphasis
- ✓ March of Dimes emphasis

#### **Provider FAQs**

#### 1. How soon after delivery can a LARC be placed?

- Implants can be placed anytime immediately after delivery
- IUDs can be placed within 10 minutes of placental delivery in both vaginal and cesarean deliveries.

#### 2. What is the rate of expulsion for an IUD placed soon after delivery?

- For an IUD placed at the time of delivery there is an increased risk of expulsion reported to range from 10 27%. However, women who had an IUD placed immediately after delivery were more likely to continue with the method compared with women who had an interval placement. This is especially important in women who are not likely to follow up postpartum.
- A recent study showed that levonorgestrel IUDs placed 2 weeks after delivery have an expulsion rate of 4%, which is similar to that of interval placement.

#### 3. What are the advantages of LARC placement immediately postpartum?

- Confirmation that a women is not pregnant at the time of insertion
- The woman and the clinician are at the same place at the same time, eliminating access barriers to insertion
- Women are highly motivated to avoid unintended pregnancy following delivery, therefore there may be higher rates of adherence.
- LARC use requires only one motivated act, while other contraceptive options require continuous user motivation, dependence, and adherence.

#### 4. What are contraindications to immediate postpartum LARC placement?

- There are no additional contraindications to etonogestrel implant placement during the postpartum period compared to interval insertion.
- Immediate postpartum IUD placement is contraindicated with women with an intrauterine infection at the time of delivery, postpartum hemorrhage, or puerperal sepsis.



#### 5. What is the effect on breastfeeding?

Although there is a theoretical risk of decreased lactogenesis associated with administration of progesterone, several studies have shown that there is no difference in lactogenesis in women who underwent postpartum LARC placement. In addition, there was also no difference in the length of time women reported breastfeeding. In women who remain very concerned about this despite the evidence, placement of a copper IUD may be appropriate.

For non-breastfeeding women, the implant has no restrictions on immediate postpartum use (medical eligibility criteria category 1. Limited data on hormonal methods' effects on breastfeeding indicate no negative effects on breastfeeding outcomes. Because of theoretical concerns related to hormonal effects on milk production and infant growth and development, the advantages of insertion generally outweigh the theoretical or proven risks (medical eligibility criteria category 2).

- Progestin-based contraceptives are safe for breastfeeding moms and babies. A systematic review of
   43 studies showed no evidence of adverse effects (Kapp, Curtis & Nanda, 2010)
- A recent noninferiority study showed time to lactogenesis and breastfeeding at eight weeks were both noninferior in women receiving an immediate postpartum LNG IUD compared to those receiving a delayed device (Turok DK 2017)
- One randomized control trial (RCT) of immediate LNG IUD suggested possible impact on breastfeeding performance. Two RCTs of early implant insertion found no impact. (Phillips, et al. 2015, Chen 2011, Dahlke 2011, Elsedeek 2012)

## 6. Is backup contraception (i.e. barrier method) needed when a LARC is placed immediately postpartum?

No backup method of contraception is needed when a LARC is placed immediately after childbirth.

#### 7. Why not wait until the postpartum visit to insert LARCs?

- Up to 40% of women do not return for their 6-week postpartum visit (Gurtcheff 2011) and 40-75% of women who plan to use an IUD postpartum do not obtain it (Simmons 2013).
- Between 40 and 57% of women resume sexual activity before their postpartum check-up (Brito 2009, Connolly 2005).

#### 8. What if a woman wants to have the LARC removed?

Long acting reversible contraceptive devices can be removed at any time by a trained practitioner in the provider's office and a woman's fertility is reestablished. If the woman no longer has a provider, county health department family planning clinics can remove the IUD or implant.

#### 9. Why is prenatal choice counseling important?

Ideally, choice counseling and reproductive life planning options should be discussed, at a minimum, during the third trimester of pregnancy. This enables women to make an informed decision in advance of their



delivery date. Health care providers should inform their patients about all the reproductive planning options during the prenatal visits and ensure that the individual's priorities, needs and preferences guide her decision

#### List of Staff Education Resources

FPQC Education slide deck (21017) ACOG Immediate Postpartum LARC (2016) ACOG Practice Bulletin on LARC devices (2017) Academy of Breastfeeding Medicine Contraception statement (2015) CMS info bulletin on State Medicaid approaches to improve access (2016)

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#### CHAPTER THREE: HOSPITAL/MANAGED CARE ORGANIZATION COLLABORATION

#### **Overview**

Implementing immediate postpartum LARC insertion requires a variety of changes, both on the hospital side and on the managed care reimbursement side. It is critical to have the hospital managed care liaison on the planning team. At a minimum, billing and pharmacy benefits must be addressed and contract amendments may be necessary. Each Medicaid managed care plan may have a different and complex set of coverage rules and requirements. Billing methodologies may include billing for the device and services separately or might involve using a specific billing code which denotes LARC insertion associated with delivery to increase the global delivery fee. Therefore, it is important for provider



hospitals to understand the details of each managed care plan and not assume all reimbursement policies, coding and billing steps are the same among the plans.

#### Medicaid Managed Care Organizations (MCOs)

The managed care plan's role is pivotal in the successful implementation of the Access LARC quality initiative in clarifying and collaborating on policy, billing, and reimbursement barriers at the hospital level. There are several steps that health plans must implement to begin reimbursing for this inpatient service which include:

- ✓ Determining the adequacy of payment
- Engaging internal stakeholders/champions (administration, medical director, contracting and billing experts, quality representation)
- ✓ Promoting provider and member education and awareness of the program
- ✓ Assessing baseline utilization and improvement
- Negotiating contracts with hospitals
- Establishing/implementing internal systems to support billing methodologies of contracted hospitals
- ✓ Addressing programmatic edits that would impede reinsertion or removal of device

#### **Contract Amendments**

Plans may have multiple contracts given their flexibility to negotiate with various hospitals and given their individual policies, procedures, and framework. Content to be addressed in contract negotiations includes:

- Formulary Drug/Device for Reimbursement in the hospital
- Hospital Billing & Reimbursement Process and Agreement for Drug/Device



- Physician Billing & Reimbursement Process and Agreement for Service Rendered
- Enhancement of the communication and follow-up process between the health plan and physician to the hospital labor and delivery department to convey consent for immediate postpartum LARC insertion.

Refer to the Medicaid Health Plan LARC Access Guide for additional information

#### Billing & Reimbursement Methodology

Claims submitted for inpatient LARCs must include the exact billing codes specified by each MCO's policy, involving varying levels of customization to claims processes depending on the hospital's system. Hospitals also should identify a mechanism to reconcile the Medicaid reimbursements with patient accounts and monitor and resolve denials.

There may be a need to create order sets or add to billing forms for physicians to use when inserting a LARC to ensure that the supplies, device, and procedure are appropriately billed. Order sets should include the contraceptive device, local anesthetic, and steps for printing the consent form, garnering final consent, and performing the procedure before discharge.

#### LESSONS LEARNED FROM OTHER STATES IMPLEMENTING POSTPARTUM LARC

- Determine whether the billing system is adaptable to allow for line items outside the DRG and when possible altering the program to streamline billing for LARCs.
- Submit all required information exactly according to the policy to avoid claims being denied.
- Identify a mechanism to reconcile reimbursements with patient accounts and monitor and resolve denials.
- Test all elements of the claims process and resolve any system glitches prior to implementation.

#### **Billing and Reimbursement**

In the fee for service (FFS) delivery system, Florida Medicaid reimburses for immediate postpartum placement of long acting reversible contraceptives separate from the inpatient hospital labor and delivery Diagnosis Related (DRG) payments. This system change was implemented to support the Agency for Healthcare Administration's goal of improving birth outcomes.

Providers rendering services through the fee-for-service delivery system can seek reimbursement for LARC by utilizing the codes listed in the tables below.



#### **Device Insertion and Removal Procedure Codes**

CPT CODE	DESCRIPTION
11981	Insertion, non-biodegradable drug delivery implants
11982	Removal, non-biodegradable drug delivery implants
11983	Removal with reinsertion, non-biodegradable drug delivery implant
58300	Insertion of IUD
58301	Removal of IUD

#### LARC Device Codes

HCPCS CODE	DESCRIPTION	NDC		
J7297	LEVONORGESTREL-RELEASING INTRAUTERINE CONTRACEPTIVE SYSTEM (LILETTA), 52 MG	52544003554; 00023585801		
J7298	LEVONORGESTREL-RELEASING INTRAUTERINE CONTRACEPTIVE SYSTEM (MIRENA), 52 MG	50419042101; 50419042301; 50419042308		
J7300	INTRAUTERINE COPPER CONTRACEPTIVE (Paragard)	51285020401		
J7301	LEVONORGESTREL-RELEASING INTRAUTERINE CONTRACEPTIVE SYSTEM (SKYLA), 13.5 MG	50419042201		
*Q9984	LEVONORGESTREL-RELEASING INTRAUTERINE CONTRACEPTIVE (KyleEna), 19.5 MG	50419042401		
J7307 ETONOGESTREL (CONTRACEPTIVE) IMPLANT SYSTEM, INCLUDING IMPLANT AND SUPPLIES (Nexplanon) 00052433001				
* systems are currently being updated to include this temporary code <b>Note:</b> National Drug Codes (NDC) should be included. The only limit on these products is 1 unit per claim, up to 3 claims per year.				

The complete Florida Medicaid Health Alert clarifying immediate postpartum LARC payment can be found in Appendix B. This alert outlined Medicaid's fee-for-service billing and reimbursement methodology. Each plan can follow this example or use other payment methods.

Hospitals may want to review different payment methodologies used by other states in the following documents:

- Alabama Medicaid (March 2014) <u>published a provider alert</u> to their hospitals and physicians. Please note that ICD-9 codes are used given the timing of when they issued their alert.
- Connecticut Medical Assistance Program (April 2016): issued a policy transmittal (PT) to providers and managed care plans.



• Illinois Department of Healthcare and Family Services (June 2015): <u>published a hospital and</u> <u>reimbursement provider notice</u> to enrolled hospitals, physicians, advanced nurse practitioners, Federally Qualified Centers, and Rural Health Clinics.

#### Pharmacy

The hospital pharmacy's role in providing postpartum LARCs involves changing institutional procedures to support practitioners providing immediate postpartum LARCs. Hospital pharmacies should make sure the devices are included in their order system then determine initial inventory levels. Because IUDs must be inserted within ten minutes after delivery of the placenta, it is critical to stock the devices near the delivery site (labor and delivery or obstetric operating room) rather than in the central pharmacy to avoid potential delays.

Hospital pharmacies should make sure the devices are included in their order system then determine initial inventory levels.

Because it can take six months or longer to add a medication or device to the hospital formulary, it is helpful to inventory what data will be needed to pass the formulary committee and present the answers in advance. Typically, a physician submits the request to the formulary committee. Information often requested in the application, and suggested responses, are included below.

1. Delineate the clinical ADVANTAGES and DISADVANTAGES of the requested product compared to existing formulary product(s). Please be thorough and specific.

Sample Response:

Beyond preventing unplanned pregnancies, research indicates that effective contraception helps prevent poor birth spacing, thereby reducing the risk of low-birthweight and/or premature birth. It is also beneficial for a woman's physical and emotional health to be able to follow a reproductive life plan. LARCs (Long Acting Reversible Contraceptives), including intrauterine devices (IUD) and contraceptive implants, are safe and highly effective in preventing unintended pregnancies. LARCs have been endorsed by the American Congress of Obstetricians and Gynecologists (ACOG), the American Academy of Pediatrics (AAP), the American Academy of Family Physicians (AAFP), and the Centers for Disease Control and Prevention (CDC) as among the most effective family planning methods.

LARC methods are effective for between three and 12 years (depending on the method) and do not require any upkeep or user effort. Immediate postpartum LARC placement, insertion of the IUD or implant after a delivery and prior to discharge, has the additional benefit of eliminating access barriers, since the provider and patient are both available during the hospitalization and insurance has not lapsed. This is a time when it is known that the woman is not pregnant and may be highly motivated to avoid short-interval pregnancy. Offering women the option to choose a contraceptive method and providing LARC methods directly reimbursed by their health care coverage before hospital discharge is critical for increasing contraceptive access and reducing the number of repeat, unintended pregnancies.



2. Provide published literature which demonstrates in controlled, comparative studies a superior therapeutic advantage of this product versus comparable products currently on the formulary. If such studies are unavailable, please furnish the literature which has convinced you to prescribe this product and request it for addition to the formulary.

Sample Response:

LARCs are clearly the most effective form of reversible contraception. Fewer than 1 in 100 women using a LARC will get pregnant within one year. Compared to typical use of birth control pills and male condoms, 9 out of 100 and 18 out of 100 women will get pregnant within one year, respectively. The number is higher if not used correctly and consistently (Guttmacher Institute, 2016).

The American College of Obstetricians and Gynecologists endorses immediate postpartum LARCs as noted in Committee Opinion Number 670 (2016). ACOG's general endorsement of LARCs is described in ACOG Practice Bulletin #186 - Long Acting Reversible Contraception: Implants and Intrauterine Devices.

The Intrauterine Devices and Implants: A Guide to Reimbursement (2015) describes public and commercial coverage of LARCs and provides resources for stocking, reimbursement, and other issues related to LARC. The Guide was developed by the American College of Obstetricians and Gynecologists, the National Family Planning & Reproductive Health Association, the National Health Law Program, the National Women's Law Center, and the University of California, San Francisco Bixby Center for Global Reproductive Health.

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US Department of Health and Human Services/Centers for Disease Control and Prevention's 2010 Medical Eligibility Criteria Classifications for Postpartum Long-Acting Reversible Contraception MMWR Recomm Rep 2016;65



#### **CHAPTER FOUR: POLICIES AND PROCEDURES**

#### **Overview**

This procedure outline is a pre-cursor to detailed procedures related to how to insert IUDs and implants during the immediate postpartum period. In the implementation phase, some providers will receive more focused education on insertion and placement.

#### Postpartum LARC Approval Process

Prior to offering an immediate postpartum LARC device, it is important that individual hospitals seek administrative approval. Individual hospitals may have their own processes for approving the use of immediate postpartum LARCs. It

is important to work with hospital administration and individual labor and delivery units to ensure support. Please refer to Chapter One – Building a Successful Initiative for details on how to effectively gain support within your hospital. Throughout the pre-implementation as well as the implementation phases, it will be important to have regular communication channels and processes, and to ensure that all necessary departments remain represented.

#### Develop an Infrastructure Designed to Succeed

Once hospital approval has been obtained, the multidisciplinary team developed in Chapter One can get to work. The process of obtaining the necessary LARC devices on a hospital formulary can take up to six months, and should be started early in the pre-implementation phase. Each hospital has its own procedure for formulary revisions but general steps are outlined in Chapter Three.

#### IT Modifications and Documentation Data Tracking

Members of the Access LARC team will need to work closely with their IT department as well as billers to ensure not only that the appropriate billing codes are set up in their electronic health record (EHR), but that the codes have been tested and reimbursement is timely. Details on working with your hospital's EHR and billing are also described in Chapter Three – Hospital/Managed Care Organization Collaboration.

Tracking data obtained from this initiative will be important in ensuring success. In addition, FPQC will be requesting specific data related to planning and systems development, as well as the actual service provision. The FPQC suggests several process, structural, and outcome measures that facilities track, although individual facilities may choose to track additional data as well.

#### **Unit-Specific Policies and Procedures**

Each unit a woman interacts with during her prenatal, intrapartum, and postpartum care will need to have unitspecific policies and procedures. The following section provides information about establishing policies in each of





these units. In addition to the following units, pharmacy will need their own postpartum LARC-specific procedures, as will hospital billing. These are each addressed in Chapter Three, Hospital/Managed Care Organization Collaboration.

#### **Prenatal Procedures**

Effective implementation of immediate postpartum LARC begins with counseling during the prenatal period. Women who receive contraceptive counseling during prenatal care are more likely to use contraception, and specifically more effective contraception, than those who do not receive counseling during their prenatal care (Zapata, Murtaza, Whiteman et al, 2015). **Please refer to Chapter 6: Comprehensive Choice Counseling** for more information on how to appropriately and effectively counsel patients on their contraceptive choices during the antenatal course.

<u>Prenatal</u> Clinic Health Department Private Office

In addition to being appropriately counseled about the expected and possible side effects of IUD and implant use, women should be counseled about the following risks of IUD placement at the time of delivery:

- **Risk of Expulsion:** the best data estimates that the risk of IUD expulsion following placement at the time of cesarean delivery is approximately 10% and the risk of IUD expulsion following placement at the time of vaginal delivery is approximately 25-30% (Chen, Reeves, Hayes, Hohmann, Perriera, and Creinin, 2010; Celen, Möröy, Sucak, Aktulay, and Danişman, 2004)). The risk of expulsion decreases with provider training and experience. Women should be counseled regarding the symptoms of expulsion and told to seek care immediately if they suspect they have had an IUD expulsion. If they do not have a source of care, women can contact the family planning program in their county health department for an appointment.
- No visible strings: Women should be counseled that IUD placement at the time of cesarean delivery increases the risk that the IUD strings will not be visible. If IUD strings are not visible, IUD location will therefore have to be confirmed by ultrasound, and, if necessary removal may be more difficult.
- Impact on breastfeeding: the majority of evidence does not show any impact of IUDs or contraceptive implants on breastfeeding success (Chen, Reeves, Creinin, and Schwarz, 2011; Phillips, Tepper, Kapp, Nanda, Temmerman, and Curtis, 2016; Gurtcheff, Turok, Stoddard, Murphy, Gibson, and Jones, 2011; Turok, Leeman, Sanders et al, 2017).

#### Consent

Women expressing interest in using an immediate postpartum IUD or implant should sign a consent form during their prenatal care. This form should be included in the prenatal record transferred to the hospital prior to delivery. When women present to labor and delivery, their intention to receive an IUD or implant should be verified, and a new consent should be signed at that time per hospital-specific policies.

#### Insurance Verification

Not all insurance providers pay for immediate postpartum IUDs and implants or pay separately from a global delivery fee, even if the plan covers an interval insertion. Providers may consider maintaining an ongoing list of what insurers pay for insertion during the immediate postpartum period. Women should be counseled that should their insurance change between the time they sign a consent and the time of delivery, the device may no longer be



covered, and they may need to return during the postpartum period for insertion. While attempting to verify coverage during the antenatal course, consider working with your surgical scheduler, who should be familiar with the process of obtaining insurance verification. For women without any insurance coverage for LARCs, consider investigating other resources, such as grants or devices from the ARCH, a patient-assistance program that provides no-cost IUDs for women meeting program eligibility requirements.

#### Intrapartum Procedures

Please refer to Chapter 6: Comprehensive Choice Counseling for more information on how to appropriately and effectively counsel patients on their contraceptive choices during intrapartum. Intrapartum Labor and Delivery

#### Consent

Upon presentation to labor and delivery, confirm with a woman that she still desires a postpartum LARC, and have her sign the appropriate consent. If she is presenting for a scheduled cesarean delivery, insertion of an IUD should be included in the procedure consent. Women first presenting to care in triage, or those who have not been previously counseled on the availability of immediate postpartum LARC, should receive LARC counseling at the initial time of presentation.

In addition to the hospital-specific consent form, women must sign the FDA consent included in the package of the IUD or implant. This consent states that the woman has received and reviewed the package insert, and is required prior to placing a LARC device. See Chapter 6 on Patient Counseling for more informed on how to counsel and obtain informed consent.

#### Insurance Verification

Even if a woman's insurance was verified during her prenatal care, her insurance should be again verified to ensure it is current, and that immediate postpartum LARC is covered separate from the global delivery fee to ensure reimbursement for the device.

#### Review Contraindications

Guidance from the CDC Medical Eligibility Criteria for Contraceptive Use should be used to determine eligibility for postpartum LARCs. Table 1 shows a chart of the conditions relevant to immediate postpartum LARC.

Additional considerations are as follows:

- Chorioamnionitis
- Hemorrhage not adequately controlled with medication
- Prolonged rupture of membranes >24 hours should be considered, but is not an absolute contraindication to IUD placement in the absence of chorioamnionitis



If a woman who previously desired an IUD is no longer a candidate due to infection or hemorrhage, counsel her on an implant placement as an alternative LARC device.

Condition	Sub-Condition	Cu-IUD	LNG-	Implant		
			IUD			
Postpartum (in	a) <10 minutes after delivery of the					
breastfeeding or non-	placenta					
breastfeeding women, including cesarean delivery	i) Breastfeeding	1	2	2		
	ii) Nonbreastfeeding	1	1	1		
	b) 10 minutes after delivery of the placenta to <4 weeks	2	2	1*/2**		
	$c) \ge 4$ weeks	1	1	1		
	d) Postpartum sepsis	4	4	1		
LNG=levonorgestrel; Cu=copper; IUD=intrauterine device. *Nonbreastfeeding women, **Breastfeeding women Categories:						

#### Immediate Postpartum LARCs

 $1 = \Lambda$  condition for which there is no restriction for the use of the contraceptive method.

2 = A condition for which the advantages of using the method generally outweigh the theoretical or proven risks.

3 = A condition for which the theoretical or proven risks usually outweigh the advantages of using the method.

 $4 = \Lambda$  condition that represents an unacceptable health risk if the contraceptive method is used.

Adapted from Centers for Disease Control and Prevention Medical Eligibility Criteria Classifications for Postpartum Long-Acting Reversible Contraception (2016)

#### Detailed IUD and Implant Insertion Procedures

Please see Chapter 5 on Provider and Staff Education related to LARC Insertion for detailed instructions on immediate postpartum insertion of both the IUD and implant.

#### Supply Availability on Labor and Delivery

In order to ensure IUDs are available to be placed within ten minutes of placenta delivery, the devices should be stocked in or near Labor and Delivery and surgical areas where cesareans are performed, ideally within a Pyxis system on the unit. This will help avoid unpredictable delays that may occur if IUDs are stocked elsewhere, such as a centralized inpatient pharmacy. Labor and Delivery units and surgical areas will need to work with their pharmacy and hospital supply chain staff to ensure devices are readily available at the appropriate time.

Implants do not need to be inserted within ten minutes of placenta delivery, and individual hospitals may choose whether to stock these on Labor and Delivery, Postpartum unit, and/or a centralized inpatient pharmacy.

Additional supplies for IUD insertion should also be stocked on Labor and Delivery. For a full checklist on what supplies are needed, please see Chapter Five on Provider and Staff Education on Insertion Procedures in the "Implementation" section of this toolkit.



#### **Postpartum Procedures**

#### IUD

Women receiving an IUD during a cesarean delivery or immediately following a vaginal delivery should have routine postpartum care, including fundal checks and fundal massage as needed. If a woman has significant pelvic pain, feels a portion of the IUD in the vagina, or sees the IUD has fallen out, the physician should be notified. If any of these problems occur after hospital discharge, the woman should follow up with the provider who placed

Postpartum Recovery Mother/Baby

her LARC device, or can contact their local Department of Health family planning clinic if they are unable to see that provider for any reason.

Additional Considerations:

- Women diagnosed with postpartum endometritis with an IUD in situ should be treated with antibiotics. There are *no data* as to whether the IUD needs to be removed in this setting. However, data from women with pelvic inflammatory diseases who have an IUD in situ suggests uterine infection can be effectively treated with IV antibiotics without IUD removal (Tepper, Steenland, Gaffield, Marchbanks, and Curtis, 2013). If there is no response to antibiotics within 24-48 hours, it is reasonable to consider IUD removal.
- Women should receive information at the time of discharge regarding when and where to follow up for an IUD check. This includes a phone number to call regarding any concerns for the IUD or implant. See Chapter 5 on Insertion Training for more information.

#### Subdermal Contraceptive Implant (Nexplanon)

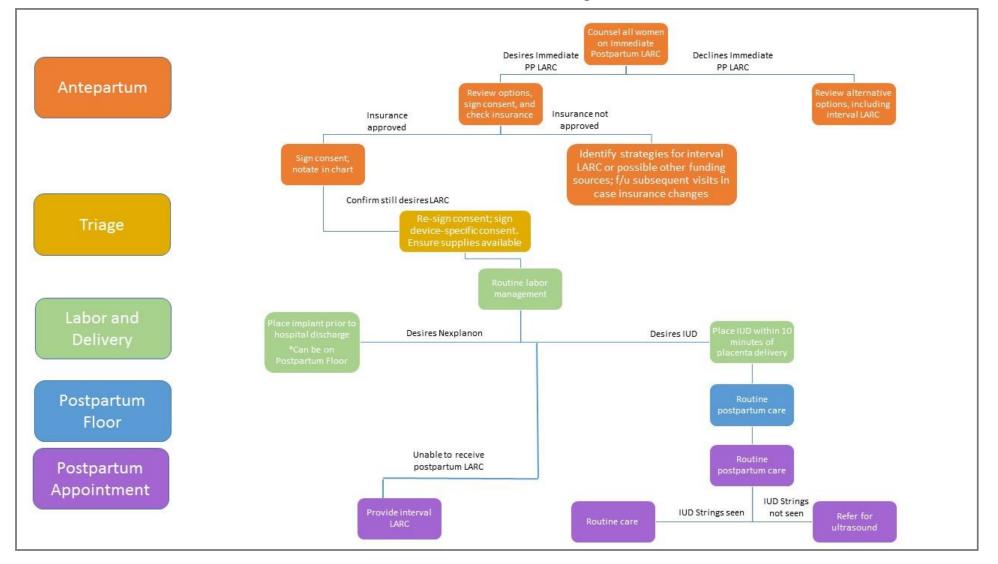
The subdermal contraceptive implant can be safely placed during the immediate postpartum period. The implant can be placed at any time following delivery and before discharge from the hospital. The process of placing the implant during the postpartum period is identical to the standard procedure used for interval placement. The FDA requires that any provider who is placing the contraceptive implant receive appropriate training and certification from Merck<sup>©</sup>. Hospital staff and providers should develop plans and procedures on the best time(s) and place(s) for performing insertions.

If the patient experiences severe pain, swelling or redness at the insertion site, the patient's provider should be notified. The mother should also be provided a phone number to call if these problems develop soon after discharge.

An overview of all of the unit-specific policies and procedures is summarized on the Modified Workflow Diagram below. This diagram outlines the course a woman will take starting with her prenatal care and following her through to the postpartum appointment to ensure she receives her LARC device.



#### Model Modified Workflow Diagram



#### CHAPTER FOUR



#### **Create Consent Documentation Process**

The EHR should be modified to facilitate informed consent through automatic creation of a consent form to be signed in-house, even if a consent was signed during the prenatal period. Sample consent forms for immediate postpartum IUDs and implants can be found in Chapter Six and can be modified by individual hospitals to best suit their needs.

#### Checklists

The following checklist has been developed to ensure all necessary steps are taken during the pre-implementation phase to allow for not only progression to the implementation phase, but also to capture all data necessary to for the FPQC Access LARC initiative.

#### PRE-IMPLEMENTATION CHECKLIST

- □ Identify key champions in all pertinent departments
- □ Establish and test billing codes; test processes for timely reimbursement
- □ Add LARC devices to formulary and identify appropriate storage location
- Educate clinicians, nurses, pharmacy, and lactation consultants about postpartum LARC
- □ Modify IT systems to document acquisition, stocking, ordering, placement, counseling, consent, billing, and reimbursement for postpartum LARCs.

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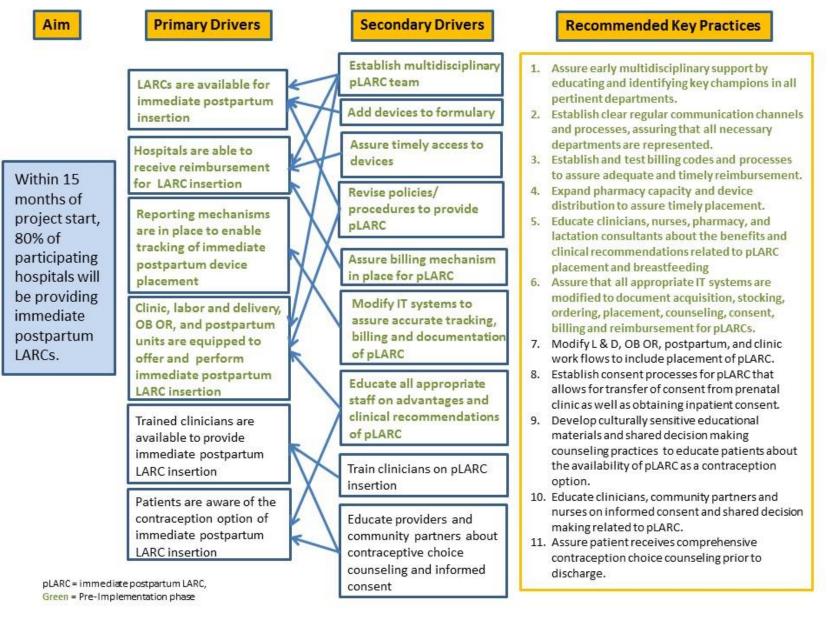
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#### APPENDIX A









GOVERNOR

JUSTIN M. SENIOR SECRETARY

## FLORIDA MEDICAID

### Florida Medicaid Health Care Alert

## August 15, 2017

Provider Type(s): 01, 25, 26, 29, 30, 32, 34, 66, 68, 69, 70, 77, 78

#### (Clarification) Long-Acting Reversible Contraceptive Inpatient Reimbursement (Fee-for-Service Delivery System)

In the fee-for-service delivery system, Florida Medicaid reimburses for immediate postpartum placement of long-acting reversible contraceptives (LARCs) separate from the inpatient hospital labor and delivery Diagnosis Related Group (DRG) payments. Medicaid health plans have the flexibility to negotiate mutually agreed upon reimbursement arrangements with their network providers. For more information on reimbursement of LARC devices immediate postpartum for health plan enrollees, please contact each health plan directly.

Providers rendering services through the fee-for-service delivery system can seek reimbursement for LARCs by utilizing the codes listed below. This reimbursement policy change became effective October 1, 2016 and was communicated to Medicaid providers via the updated <u>Inpatient Hospital</u> <u>Services</u> coverage policy, effective July 11, 2016. This system change was implemented to support the Agency's goal of improving birth outcomes. Research shows that LARCs are effective in reducing unintended pregnancies, premature and low birth weight births, and prenatal drug exposure.

#### **Device Insertion and Removal Procedure Codes**

CPT CODE	DESCRIPTION
11981	Insertion, non-biodegradable drug delivery implants
11982	Removal, non-biodegradable d rug delivery implants
11983	Removal with reinsertion, non-biodegradable drug delivery implant
58300	Insertion of IUD
58301	Removal of IUD



#### LARC Device:

HCPCS CODE	DESCRIPTION	NDC
J7297	LEVONORGESTREL-RELEASING INTRAUTERINE CONTRACEPTIVE SYSTEM (LILETTA), 52 MG	52544003554; 00023585801
J7298	LEVONORGESTREL-RELEASING INTRAUTERINE CONTRACEPTIVE SYSTEM (MIRENA), 52 MG	50419042101; 50419042301; 50419042308
J7300	INTRAUTERINE COPPER CONTRACEPTIVE (Paragard)	51285020401
J7301	LEVONORGESTREL-RELEASING INTRAUTERINE CONTRACEPTIVE SYSTEM (SKYLA), 13.5 MG	50419042201
*Q9984	LEVONORGESTREL-RELEASING INTRAUTERINE CONTRACEPTIVE (KyleEna), 19.5 MG	50419042401
J7307	ETONOGESTREL (CONTRACEPTIVE) IMPLANT SYSTEM, INCLUDING IMPLANT AND SUPPLIES (Nexplanon)	00052433001

\* systems are currently being updated to include this temporary code

**Note:** National Drug Codes (NDC) should be included. The only limit on these products is 1 unit per claim, up to 3 claims per year.

The Agency's effort to facilitate access to LARCs immediately postpartum is in collaboration with community partners, Medicaid health plans and other state partners, which include the Florida Perinatal Quality Collaborative (FPQC). The FPQC has established the "Access LARC" Initiative to provide training and resources in efforts to help Florida hospitals set up delivery and billing systems needed for immediate postpartum placement of LARC implementation. If a hospital is interested in participating in this initiative, then visit the <u>Access LARC website</u> for more information.

Send an email to the Florida Perinatal Quality Collaborative at <u>FPQC@health.usf.edu</u> to obtain a list of recruited hospital contacts participating in this initiative.

If you need assistance, please contact a Medicaid representative at <u>1-877-254-1055</u>.

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