# HEALTH EVIDENCE REVIEW COMMISSION (HERC) COVERAGE GUIDANCE: TIMING OF LONG-ACTING REVERSIBLE CONTRACEPTIVE (LARC) PLACEMENT

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**HERC Coverage Guidance**

Immediate postpartum and postabortion placement of a long-acting reversible contraceptive (LARC) (implant or intrauterine device) is recommended for coverage *(strong recommendation*).

Note: Definitions for strength of recommendation are provided in Appendix A *GRADE Informed Framework Element Description*.

## RATIONALE FOR DEVELOPMENT OF COVERAGE GUIDANCES AND MULTISECTOR INTERVENTION REPORTS

Coverage guidances are developed to inform coverage recommendations for public and private health plans in Oregon as they seek to improve patient experience of care, population health and the cost-effectiveness of health care. In the era of the Affordable Care Act and health system transformation, reaching these goals may require a focus on population-based health interventions from a variety of sectors as well as individually-focused clinical care. Multisector intervention reports will be developed to address these population-based health interventions or other types of interventions that happen outside of the typical clinical setting.

HERC selects topics for its reports to guide public and private payers based on the following principles:

- Represents a significant burden of disease or health problem
- Represents important uncertainty with regard to effectiveness or harms
- Represents important variation or controversy in implementation or practice
- Represents high costs or significant economic impact
- Topic is of high public interest

Our reports are based on a review of the relevant research applicable to the intervention(s) in question. For coverage guidances, which focus on clinical interventions and modes of care, evidence is evaluated using an adaptation of the GRADE methodology. For more information on coverage guidance methodology, see Appendix A.

Multisector interventions can be effective ways to prevent, treat or manage disease at a population level. For some conditions, the HERC has reviewed evidence and identified effective interventions, but has not made coverage recommendations, as many of these policies are implemented in settings beyond traditional healthcare delivery systems.

## GRADE-INFORMED FRAMEWORK

The HERC develops recommendations by using the concepts of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system. GRADE is a transparent and structured process for developing and presenting evidence and for carrying out the steps involved in developing recommendations. There are several elements that determine the strength of a recommendation, as listed in the table below. The HERC reviews the evidence and makes an assessment of each element, which in turn is used to develop the recommendations presented in the coverage guidance box. Estimates of effect are derived from the evidence presented in this document. The level of confidence in the estimate is determined by the Commission based on assessment of two independent reviewers from the Center for Evidence-based Policy. Unless otherwise noted, estimated resource allocation, values and preferences, and other considerations are assessments of the Commission.

| **Outcomes** | **Estimate of Effect for Outcome/**<br>***Confidence in Estimate*** |
|---|---|
| **Unintended Pregnancy**<br>*(Critical outcome)* | Postabortion IUD (intention to treat at 6 months):<br>3/406 (0.74%) for immediate IUD vs.<br>11/472 (2.3%) for delayed IUD<br>ARD 1.59%<br>RR 0.37 (95% CI 0.12-1.14)<br>●●●○ *(Moderate confidence, based on 3 RCTs, N=878 women)*<br><br>Postpartum IUD:<br>The identified systematic review of RCTs did not provide aggregate data on unintended pregnancy. No repeat pregnancies were reported in the 2 included RCTs.<br>●●○○ *(Low confidence because no unintended pregnancies were observed, based on 2 RCTs, N=192)*<br><br>Implants: No systematic reviews or RCTs were identified addressing immediate postpartum or postabortion implant use and unintended pregnancy. |

| Outcomes | Estimate of Effect for Outcome/<br>*Confidence in Estimate* |
|---|---|
| **Abortion**<br>*(Critical outcome)* | IUDs:<br>None of the identified systematic reviews reported on abortion rates in the follow-up period.<br><br>Implants:<br>No systematic reviews or RCTs were identified addressing implants and abortion rates. |
| **Presence of LARC at one year**<br>*(Important outcome)* | None of the identified systematic reviews reported on LARC presence at one year but all reported on presence of an IUD at 6 months based on intention to treat analyses.<br><br>Postabortion IUD (Presence at six months, including women who experienced an expulsion followed by reinsertion):<br>260/406 (64.0%) for immediate IUD vs.<br>219/472 (46.4%) for delayed IUD<br>ARD=17.6%<br>NNT=6: For 1000 patients treated, 167 more have an IUD in place at 6 months<br>RR 1.4 (95% CI 1.24-1.58)<br>●●●○ *(Moderate confidence, based on 3 RCTs, N=878)*<br><br>Postpartum IUD (Presence at six months, including women who experienced an expulsion followed by reinsertion):<br>97/120 (80.8%) for immediate IUD vs.<br>83/123 (67.4%) for delayed insertion<br>ARD=13.3%<br>NNT=8: For 1000 patients treated, 125 more continue to have an IUD in place at 6 months<br>OR 2.04 (95% CI=1.01-4.09)<br>●●●○ *(Moderate confidence, based on 4 RCTs, N=243)* |

| Outcomes | Estimate of Effect for Outcome/<br>*Confidence in Estimate* |
|---|---|
| **Need for alternate or replacement contraception** (e.g., expulsion of IUD, elective, indicated removal of device) *(Important outcome)* | Postabortion IUD Expulsion at 6 months:<br>18/406 (4.4%) for immediate IUD vs.<br>8/472 (1.7%) for delayed insertion<br>ARD=2.74%<br>NNH=37: For 1000 patients treated, 27 more experience expulsion<br>RR 2.64 (95% CI 1.16-6.0)<br>●●●○ *(Moderate confidence, based on 3 RCTs, N=878)*<br><br>Postabortion IUD Removal:<br>20/362 (5.5%) for immediate IUD vs.<br>12/428 (2.8%) for delayed IUD<br>ARD 2.72%<br>RR 2.01 (95% CI 0.99-4.06)<br>●●●○ *(Moderate confidence, based on 2 RCTs, N=790)*<br><br>Postpartum IUD Expulsion by 6 months:<br>19/113 (16.8%) for immediate IUD vs.<br>3/97 (3.1%) for delayed insertion<br>ARD=13.7%<br>NNH=8: For 1000 patients treated, 125 more experience expulsion<br>OR 4.89 (95% CI 1.47-16.32)<br>●●●○ *(Moderate confidence, based on 4 RCTs, N=210)*<br><br>Postpartum IUD Replacement:<br>When expulsion occurred after post-cesarean placement, replacement was more common for those undergoing immediate IUD placement (3 out of 4 expulsions in immediate group vs. 0 out of 1 in the delayed group, statistical analysis not reported). No data are available about IUDs placed after vaginal delivery.<br>●○○○ *(Very low confidence, based on one fair quality RCT, N=112)*<br><br>Implants:<br>No systematic reviews or RCTs were identified addressing implants and need for alternate/replacement contraception. |

| Outcomes | Estimate of Effect for Outcome/<br>*Confidence in Estimate* |
|---|---|
| **Harms**<br>*(Important outcome)* | *Important harms specific to IUD insertion include uterine perforations and infections.*<br><br>Postabortion IUD Perforation:<br>No uterine perforations were observed in women randomized to immediate or delayed IUD insertion following first trimester abortion.<br>●○○○ *(Very low confidence, based on no observed perforations in 1 fair quality RCT, N=575)*<br><br>Postabortion IUD infection: (Rates of upper genital tract infections).<br>5/406 (1.2%) for immediate IUD vs.<br>6/472 (1.3%) for delayed insertion<br>ARD=0.04%<br>OR 1.0 (95% CI 0.32-3.14)<br>●●●○ *(Moderate confidence, based on 3 RCTs, N=878)*<br><br>Postpartum IUD infections:<br>Rates of upper genital tract infections were rare in both groups (no statistical analysis provided).<br>●○○○ *(Very low confidence, based on 2 case reports in 4 RCTs, N=243)*<br><br>Implants:<br>No systematic reviews or RCTs were identified addressing implants and harms. |

**Balance of benefits and harms:**
While the data from studies included in this review do not show a reduced risk of unintended pregnancy from immediate placement, IUDs are among the most effective forms of contraception and the unintended pregnancies in the included intention-to-treat studies of IUD placement timing occurred almost exclusively in women who failed to return for their follow-up appointments and thus never received an IUD. The lack of statistical significance of the findings on post-abortion IUD placement may be a result of differential loss to follow-up among the immediate and delayed study arms and small study sizes relative to the rare occurrence of selected outcomes. The only "harm" shown by this evidence is an

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| increased risk of IUD expulsion, which is easily remedied and usually without morbidity. Thus, the balance is in favor of immediate placement. Implants are also among the most effective forms of contraception and there is no evidence of differential harm based on timing of placement. |
| **Resource Allocation:** The costs of unintended pregnancy are significant. Effective contraception is cost-saving (not just cost-effective). Economic modeling predicts high levels of cost savings from immediate placement of LARC. |
| **Values and Preferences:** Evidence shows most women of reproductive age desire to control their fertility and time their pregnancies. When women who desire contraception are presented with all contraceptive options, over 70% select a LARC method, including teens. When women select their preferred contraceptive method, continuation rates across all methods are higher.<br>Evidence about women's preferences about timing of LARC placement is not available, but low drop-out rates in the immediate placement arms of the trials examined here suggest it is an acceptable option for most women choosing an IUD.<br>For IUDs, women would need to balance the higher expulsion rate for immediate insertion against the observed higher perforation rate for actively breastfeeding women with routine (delayed) placement, as well as the convenience and immediate effectiveness of IUDs compared to alternative forms of birth control. For implants there is no evidence about differential effectiveness or harms based on the timing of placement. Based on these factors, we expect low variability in values and preferences, with most women who have the option choosing immediate placement. |
| **Other Considerations:**<br>Missed opportunities for contraception are significant postpartum and postabortion, where 30-40% of insured women do not attend a postpartum visit and 40-75% do not attend a postabortion visit, thus increasing the risk of unplanned pregnancy, abortion, or unmet contraceptive needs. |
| **Rationale:** While there is strong evidence that LARC use reduces unintended pregnancies and abortions, there is not direct randomized evidence of LARC placement (immediate postpartum or postabortion vs delayed insertion) resulting in lowering rates of subsequent unintended pregnancy or abortion outcomes based on intention to treat analyses. However, 13 of the 14 unintended pregnancies in these studies occurred in the delayed placement arm to women without IUDs present.<br>In addition, there is direct evidence that immediate postpartum and postabortion IUD insertion results in higher LARC use rates at 6 months. Based on evidence of the effectiveness of LARC, this would lead to lower rates of unintended pregnancy and abortion. While there is an increased rate of IUD expulsion with immediate postpartum insertion, IUD use is still higher at 6 months and economic analyses show the cost savings from immediate insertion. There is also observational evidence based on a study of 61,000 women that a 6-fold risk of uterine perforation exists in actively breastfeeding women with delayed insertion compared to immediate insertion. Immediate postpartum LARC is a highly cost-saving strategy even considering IUD expulsion rates, and with the possibility of avoidance of uterine perforation. For implants, while |

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| there is no RCT evidence about the differences in pregnancy outcomes based on immediate versus delayed implant placement, use of implants is recommended by the CDC immediately postabortion and postpartum, and the disadvantages associated with an increased risk of an IUD expulsion do not exist for implants.<br><br>The strong recommendation for coverage for either type of LARC (IUD or implant) is based on existing evidence and guidelines on the benefits of LARC, lack of significant harms for immediate placement, high cost savings associated with immediate placement, and strong values and preferences. |
| **Recommendation:** Immediate postpartum and postabortion placement of LARC (implant or intrauterine device) is recommended for coverage *(strong recommendation*). |

*The Quality of Evidence rating was assigned by the primary evidence sources, except where indicated, not the HERC Subcommittee.

Note: GRADE framework elements are described in Appendix A. The GRADE Evidence Profile for these outcomes is provided in Appendix B.

# EVIDENCE OVERVIEW

## Clinical background

While women have many contraceptive options, intrauterine devices (IUDs) and contraceptive implants – otherwise known as long-acting reversible contraception (LARC) – are 20 times more effective at preventing pregnancy than pills, patches, or rings (Winner, et al., 2012). Because of their high effectiveness, LARC methods are associated with significant reductions in the numbers of unintended pregnancies and abortions (Peipert, et al., 2012; Winner, et al., 2012). The Medical Eligibility Criteria (MEC) published by the Centers for Disease Control and Prevention (CDC) lists LARC devices as safe for the majority of women, including those with common health conditions (e.g., hypertension, migraines, obesity, postabortion, postpartum, breastfeeding). These LARC options, which include both hormonal and non-hormonal devices, have few side effects and are suitable for teens, nulliparous and parous women (ACOG, 2015b; CDC 2010, 2012).

Despite LARC's superior effectiveness, LARC use is relatively low among women using contraception in the United States (U.S.). Rates of LARC use from the National Survey of Family Growth (NSFG) show continued growth in the use of LARC, largely driven by increasing IUD use. The most recent NSFG reports a five-fold increase in LARC use from 1.5% in 2002 to 7.2% in 2011-2013; with nearly 11.1% of women in the survey aged 25-34 opting for a LARC device (Branum & Jones, 2015). Increasing LARC use, even by as much as 10% for women 20-29, would be estimated to save nearly $288 million per year in the U.S. in total costs related to unintended pregnancy (Trussell, et al., 2013).

The CDC has identified preventing unintended pregnancy as a part of its 6|18 Initiative to address six common and costly health conditions by promoting 18 evidence-based interventions. The three proposed payer interventions for preventing unintended pregnancy are 1) reimbursing for the full range of contraceptive services including actual costs of LARC, 2) reimbursing for immediate postpartum LARC insertion by unbundling from obstetric global services, and 3) removing administrative and logistical barriers to LARC (CDC, 2015).

The body of literature on the effectiveness and safety of LARC contains many large observational studies on the impact of LARC provision on unintended pregnancy, abortion, and teen pregnancies. The Contraceptive CHOICE project offered no-cost contraception, including LARC devices, to 9,256 women aged 14 to 45 enrolled in a prospective cohort study investigating the population-based impact of eliminating contraception cost-barriers for women on unintended pregnancy, teen pregnancy, abortion, and rates of repeat abortion in St. Louis, compared to Missouri overall. Contraceptive options were presented to women in order of efficacy (i.e. LARC first), with all side effects mentioned, and women then selected their preferred method. When presented with this information the majority of enrollees opted for LARC devices (75%), including teens (70%).

Women opting for pills, patches or the ring were 20 times more likely to experience an unintended pregnancy (Winner, et al., 2012). The teen birth rate for those in the CHOICE cohort was 6.3 per 1000 compared to 34.3 per 1000 in the U.S. The abortion rate in St. Louis during the study period was half the state average for Missouri (Peipert, et al., 2012). A sub-analysis of teens (aged 15-19) found dramatically lower rates of pregnancy, birth, and abortion in the CHOICE cohort compared to national averages

despite the cohort consisting of women at higher risk of unintended pregnancy based on age and demographic factors (Secura, et al., 2014). The CHOICE cohort observed high continuation rates for LARC use over three years, with users of non-LARC methods three times more likely to discontinue their initial method over the following three years (Diedrich, et al., 2015).

The Colorado Family Planning Initiative, a five-year project funded by the Susan Thompson Buffett foundation expanded LARC access to Title X-funded agencies across the state by providing funds to put LARC stock on shelves, offer provider trainings, and offer no-cost contraception for Title X-funded clinics. Across participating counties, use of LARC increased from 5% to 19% among 15 to 24 year old women with a 29% decrease from expected fertility rates for 15 to 19 year-olds, and 14% decrease for 20 to 24 year olds. Abortion rates also decreased, 34% and 18% respectively, for these age groups (Ricketts, Klingler, & Schwalberg, 2014). Iowa also observed reductions in abortion rates (from 8.7 per 1000 to 6.7) after LARC use increased from 1% up to 15% through Medicaid expansion and the Susan Thompson Buffett initiative (Biggs, et al., 2015)

Reducing cost-barriers is a key step in expanding LARC access; however, many outpatient settings require multiple appointments and women desiring LARC may be lost to follow-up. Providing LARC in the immediate postpartum or postabortion time period can expand access and prevent loss to follow-up. Rates of attendance at postpartum visits are not optimal, with 2014 national estimates reporting that 76% of privately insured and 62% of publicly insured women attended their postpartum checks (National Committee for Quality Assurance, 2015). Additionally, immediate postpartum IUD insertion may be safer for women than waiting until the postpartum visit. In a large multinational observational study of over 61,000 women in Europe, actively breastfeeding at the time of insertion was associated with a six-fold increased risk of perforation (RR 6.1, 95% CI 3.9-9.6) (Heinemann, Reed, Moehner, & Minh, 2015).

Despite concerns for hormone-mediated myometrial changes in pregnancy, rates of perforation following elective termination are low. In an RCT of 575 women randomized to immediate or delayed IUD placement after first-trimester elective termination, Bednarek and colleagues reported no perforations during 6 months of follow up after insertion (Bednarek, et al., 2011).

National estimates of attendance at a postabortion follow-up visit are low (25-68%) as women travel long distances to receive abortion services, may be concerned about costs related to IUD insertion, or do not have time to return for a separate visit (Bednarek, et al., 2011; Stanek, et al., 2009).

In addition to follow-up barriers, reimbursement for immediate postabortion or postpartum LARC insertion varies by insurer and state. Coverage of LARC provision immediately following an abortion varies by insurance carrier, with Medicaid waivers and Title X programs covering provision, while private insurers require a separate visit. Increasing access to LARC by expanding coverage to include women immediately following an abortion or in the immediate postpartum period eliminates the need for return visits and potential loss to follow-up. Providing increased LARC access in the immediate postpartum or postabortion period may be safer and reduce unintended pregnancy rates, rapid repeat pregnancies, or repeat abortions in line with findings from outpatient insertion LARC trials (Peipert, et al., 2012; Winner, et al., 2012).

# Technology description

## Intrauterine Devices

Mirena® is a 52mg levonorgestrel-releasing intrauterine system (52 mg LNG-IUS) approved for 5 years of continuous use. The device is a 32x32mm plastic T-shape with monofilament polyethylene strings. The pregnancy rate for Mirena® is 0.2 in 100 women with 80% of women continuing at one year (Trussell, 2011).

Liletta®, approved by the (U.S. Food and Drug Administration (U.S. FDA) in 2015, is also a 52mg levonorgestrel-releasing system (LNG-IUS); however, it is approved for only 3 years of continuous use at the present time (U.S. FDA, 2015). The manufacturer, Actavis, continues to evaluate this device and is anticipating approval for a similar duration of effectiveness as Mirena®.

Skyla® is a 13.5mg levonorgestrel-releasing system (13.5mg LNG-IUS) approved by the U.S. FDA in 2013 (U.S. FDA, 2013). The duration of action is 3 years. The device is smaller than the Mirena® (28x30mm versus 32x32mm), comes with a smaller diameter device inserter (3.8mm versus 4.75mm for the Mirena®), and has been targeted to women who have a smaller uterus.

Paragard®, a copper (Cu) T380A IUD, has been on the U.S. market since approval in 1984. This hormone-free device is approved for 10 years of use in the U.S. Paragard® is as effective as permanent sterilization with a failure rate of 0.8 in 100 women for the first year and 1.9 per 100 women over 10 years. After the first year of use, an average of 78% of women continues with this method. Reasons for discontinuation include heavy menstrual bleeding and pain (ACOG, 2015b; U.S. FDA, 2014).

All IUDs and implants can be removed when fertility is desired, and at the end of their approved duration followed by immediate replacement with a new device.

## Hormonal Implant

Nexplanon® replaced Implanon® in 2011. Both are etonogestrel-releasing implants that are injected under the skin, typically in the inner arm about 10 cm above the elbow crease. Nexplanon® is radiopaque, a change from the Implanon® device, to assist in confirming location on imaging studies. The Nexplanon® insertion system was also improved over the older Implanon® system. Etonogestrel is highly effective at preventing pregnancy through changes in the hypothalamic-pituitary-ovarian axis that suppress ovulation; 0.05% of women with this device will become pregnant in the first year after insertion. Risks from insertion under the skin of the inner upper arm include bleeding, infection, and bruising or hematoma. After the first year, 84% of women continue with this method. Side effects prompting discontinuation include irregular bleeding, headache, and weight gain (U.S. FDA, 2014; ACOG, 2015b).

# Indications

Long-acting reversible contraception devices are indicated for women desiring to avoid pregnancy. Additionally, the Mirena®, a levonorgestrel releasing intrauterine system (LNG-IUS), is also FDA approved for the treatment of heavy menstrual bleeding (i.e. menorrhagia) (U.S. FDA, 2009).

The Centers for Disease Control and Prevention (CDC) publish two relevant documents on contraceptive use and practice. The Selected Practice Recommendations for Contraceptive use (SPR), published in 2013, and the Medical Eligibility Criteria (MEC), last updated in 2012. The SPR includes clinical guidance on initiation, follow-up, and side-effect management for all contraceptive methods (CDC, 2013). The MEC provides eligibility criteria for the initiation or continuance of all contraceptive methods, including LARC using four categories: no restriction (category 1), advantages generally outweigh theoretical or proven risk (category 2), theoretical or proven risk usually outweigh the advantages (category 3), or unacceptable health risk, method not to be used (category 4) (CDC, 2012).

The SPR and MEC state that LARC is appropriate for the vast majority of reproductive-aged women, including teens and nulliparous women. They are suitable contraceptive methods for patients with many common health conditions including obesity, controlled hypertension, and diabetes. The copper IUD is often the only option available for women desiring effective contraception without hormones or for whom hormonal contraception is contraindicated.

### Intrauterine Devices

The SPR and the MEC support immediate postpartum and postabortion IUD use. The MEC lists IUDs as safe for immediate use following first and second trimester abortions except in the setting of a septic abortion (category 4). Postpartum IUD insertion in the setting of puerperal sepsis also poses an unacceptable health risk for women (category 4).

Situations where any intrauterine system (copper or levonorgestrel) would pose an unacceptable health risk or where the risk outweighs benefits (category 4 or 3 on the MEC, respectively) are rare. Appendix E provides links to the MEC for those interested in additional information.

### Hormonal Implant

The MEC categorizes the implant as safe (category 1 or 2) across nearly all conditions. Theoretical or proven risks outweigh the many benefits (category 3) only in rare circumstances. Appendix E provides links to the MEC for those interested in additional and more specific information for particular conditions.

## Key Questions and Outcomes

The following key questions (KQ) guided the evidence search and review described below. For additional details about the review scope and methods please see Appendix C.

1. What is the comparative effectiveness of offering immediate postpartum or postabortion placement of a long-acting reversible contraceptive?
2. What are the harms of immediate postpartum or postabortion placement of a long-acting reversible contraceptive?

Critical outcomes selected for inclusion in the GRADE table are unintended pregnancies and abortions. Important outcomes selected for inclusion in the GRADE table are presence of LARC at one year, need for alternate/replacement contraception, and harms.

## Contextual Question

1. What payer and provider practices and policies promote effective use of LARC?

## Evidence review

### Intrauterine Devices

Two Cochrane systematic reviews (SR) (Lopez, et al., 2015; Okusanya, Oduwole, & Effa, 2014) identified in the core source search address the use of IUDs in the immediate postpartum or postabortion period.

A Cochrane SR protocol on immediate versus delayed postpartum insertion of a contraceptive implant was published in October 2015 and is still in process (Sothornwit, et al., 2015). Abstract review of the published reference list for the protocol did not reveal any RCTs. No other systematic reviews addressing the use of hormonal implants in the postpartum or postabortion period were identified through the search of core sources.

**Table 1. Summary of Included Systematic Reviews of IUD Insertion Timing**

| Systematic Review Total N | No. and Type of Included Studies | Population | Outcomes of Interest |
|---|---|---|---|
| Okusanya, et al. (2014)<br>N=878 | 3 RCTs | Women of any age or gravidity who received an IUD immediately after induced abortion or uterine evacuation for spontaneous incomplete abortion. | Principal: accidental pregnancy, spontaneous expulsion, uterine perforation, upper genital tract infection<br>Follow-up time: 6 months |
| Lopez, et al. (2015)<br>N=263 | 4 RCTs | Postpartum women of any age | Primary: successful placement (insertion), subsequent expulsion, method use at study assessment<br>Secondary: pregnancy, perforation, infection, other adverse events |

*Evidence from additional sources*

An additional RCT by Levi and colleagues was identified through an interval MEDLINE (Ovid) search performed to capture publications following the 2015 Cochrane review on postpartum insertion (Lopez, et al., 2015).

## Contraceptive Implants

The search of core sources did not identify any SRs or RCTs addressing contraceptive implants and any of the identified priority outcomes.

# EVIDENCE SUMMARY

## Intrauterine Devices

### *Okusanya [Cochrane] (2014)*

The Okusanya systematic review and meta-analysis (Okusanya, Oduwole, & Effa, 2014) included 12 trials investigating insertion of IUDs following elective termination or uterine evacuation for spontaneous pregnancy loss (i.e. miscarriage). Six trials were deemed at high risk of bias, the remaining six of unclear risk. Overall, this Cochrane SR stated that most of the 12 RCTs were at "moderate risk of bias" due to incomplete reporting on blinding (performance bias) and incomplete outcome data (attrition bias). Seven evaluated immediate insertion of different IUDs or modified IUDs. Nine of the included trials were published over 10 years earlier. A total of five trials investigated immediate versus delayed insertion of IUDs (at a separate visit); however, one was a conference abstract and not included in the analysis. Trials limited participants on IUD options.

### *Lopez [Cochrane] (2015)*

The Lopez systematic review and meta-analysis (Lopez, Bernholc, Hubacher, Stuart, & Van Vliet, 2015) included 15 trials investigating postpartum insertion of IUDs. Randomized controlled trials could include immediate post-placental (<10 minutes), early (within 48 hours of delivery), and standard (postpartum visit) insertion options. This update added seven trials published from 2010 to 2014 to the eight previously identified by an earlier 2001 Cochrane review. The newer studies included four full articles and three conference abstracts. Eight RCTs were deemed at high risk of bias; two were of low risk of bias, the remainder at unclear risk.

Five RCTs directly investigated immediate versus delayed insertion; however, one was a conference abstract whose data was reported separately. Two RCTs addressed immediate versus early insertion (<48 hours). The remaining trials, many from the 2001 review, investigated insertion of different devices or insertion techniques instead of timing of insertion, and included devices no longer in general use.

Trials limited participants to a single IUD option. In the seven recent trials on timing, three offered the 52mg-LNG-IUS and in four, the CuT380A IUD.

Timing included post-vaginal birth (three studies), post-cesarean delivery (two studies), or both (two studies).

### *Levi (2015)*

This RCT offered intra-cesarean or delayed insertion at 6 weeks or more postpartum to women 18-45 undergoing planned (70%) and unplanned cesarean deliveries. The primary outcome was IUD use at 6 months postpartum with relevant secondary outcomes including expulsion and discontinuation.

# Critical Outcome: Unintended Pregnancy

## Intrauterine Devices

### *Postabortion*

In their meta-analysis of three recent trials involving 878 patients comparing immediate postabortion to delayed IUD insertion, Okusanya and colleagues report a nearly three-fold increase in pregnancy for those randomized to delayed insertion (9 unintended pregnancies per 1000 compared 23 per 1000 in the delayed group), however the result was not statistically significant (RR 0.37, 95% CI 0.12-1.14, n=878, 3 studies). Among these three RCTs, attendance at follow-up visits for the delayed arm ranged from 33% to 70%, with nearly all the women who did attend the visit having an IUD placed. Only one woman in the immediate arms experienced a pregnancy (0.15%) and this was after an IUD expulsion. There were 13 pregnancies among 207 women in the delayed arms (6.3%) and all of these occurred in women who did not receive an IUD.

### *Postpartum*

In the four trials included in the 2015 Cochrane review comparing immediate postpartum to delayed IUD insertion, pregnancy in the first 6 months postpartum was rare. Two trials did not observe any subsequent pregnancies; two did not provide unintended pregnancy outcome data. No statistical analysis was provided.

In their single RCT, Levi and colleagues identified two pregnancies in the study group. One occurred in a woman randomized to interval placement who never received the insertion. The other occurred over a year after insertion in a woman with an IUD that had migrated into the abdominal cavity after being visualized on ultrasound in the uterus at 6 months as strings were not visualized on postpartum evaluation.

# Critical Outcome: Abortion

## Intrauterine Devices

Neither SR provided outcome data on the occurrence of abortion in the follow-up period.

# Important Outcome: Presence of LARC at one year

## Intrauterine Devices

Both systematic reviews provided aggregate outcome data on the presence of LARC at six months, rather than at the desired outcome interval of one year.

### *Postabortion*

Okusanya and colleagues report use of an IUD at 6 months was higher for those randomized to immediate postabortion placement compared to delayed insertion (65.0% vs. 46.4%, RR 1.40, 95% CI 1.24-1.58, n=878, 3 studies). In the largest RCT (575 women, accounting for 80% of the pooled estimate, with a participating site in Oregon ), all of the women randomized to the immediate arm received an IUD, while 71% of those randomized to delayed insertion received an IUD. This represented all of the

women who actually returned for a delayed insertion visit. At 6 months, 92.3% of women in the immediate group still had an IUD and 76.6% of the delayed group did (RR 1.20 [95% CI 1.11-1.31]) for this single RCT.

### *Postpartum*

Lopez and colleagues reported continuation at six months was higher for women randomized to immediate postpartum insertion compared to delayed insertion at the postpartum visit (80.8% vs. 67.4%, OR 2.04, 95% CI 1.10-4.09, n=243, 4 studies).

In the additional single RCT investigating immediate vs. delayed post-cesarean placement, of the 42 women that provided data at one year continuation rates were not statistically different by timing of insertion (Levi, et al., 2015). However, this trial was halted early due to low enrollment, only enrolling half the number calculated as needed from the power estimates and with a third of those randomized lost to follow-up.

For both postabortion and postpartum insertion studies, differential and higher losses to follow-up in the delayed groups would bias the results against showing a benefit (e.g. reduced unintended pregnancy abortion, or greater presence of LARC at one year) because the women most likely to have the event were also the most likely not to contribute data at follow-up.

# Important Outcome: Need for alternate/replacement contraception

## Intrauterine Devices

### *Postabortion*

Removal rates of IUDs at six months were similar for women undergoing immediate postabortion placement and delayed insertion (56 per 1000 immediate vs. 28 per 1000 delayed, RR 2.01, 95% CI 0.99-4.06, n=790, 2 studies). Okusanya and colleagues do not report on replacement device rates or selection of an alternate contraceptive method by participants. However, the RR in this SR may be somewhat misleading because many women in the delayed group never received an IUD and so could not have had one removed. For example, in the largest trial (which accounts for over 90% of the overall pooled estimate), for women who actually received an IUD, 16 of 258 (6%) in the immediate group requested removal compared to 11 of 222 (5%) in the delayed group. The treatment received RR is 0.98 (95% CI 0.94-1.03). Again, this is an example of differential losses to follow-up resulting in an underestimation of benefits and an overestimation of harms.

### *Postpartum*

For women receiving an IUD in the postpartum period, rates of expulsion in the following six months were higher for those in the immediate placement arm (168 per 1000 women immediate vs. 31 per 1000 delayed, OR 4.89, 95% CI 1.47-16.32, n=210, 4 studies). Lopez and colleagues do not report on replacement device rates or selection of an alternate contraceptive method by participants. However, even with expulsions, women allocated to immediate insertion were more likely to have an effective LARC in place at six months.

Levi and colleagues report four expulsions in women allocated to intraoperative placement, all within the first three weeks postpartum. Three women had their IUD replaced following expulsion. In women

allocated to interval IUD placement, only one experienced an expulsion, she did not opt for replacement. No statistical analysis was provided. Five women subsequently had their IUD removed for bleeding, pelvic pain, or both. In the delayed group, two women had IUD removals during the study period, for bleeding and pelvic pain.

## Important Outcome: Harms

### Intrauterine Devices

*Postabortion*

Genital tract infections were similar across groups (OR 1, 95% CI 0.32-3.14, n=878, 3 studies).

*Uterine perforations were not reported as outcomes in either SR. Postpartum*

Genital tract infections were rare in trials investigating postpartum insertion of IUDs. Two studies reported no infections in either arm; two studies reported a single infection in both treatment arms.

In their RCT of IUD insertion for women undergoing cesarean delivery, Levi and colleagues report a single case of endometritis out of 42 enrollees occurring in the intraoperative placement group five days postpartum and the device was removed. As mentioned above, in their RCT, Levi and colleagues also reported on a single case of pregnancy among 42 enrollees, occurring in a woman subsequently found to have an intraabdominal copper IUD which, while the strings were not visualized at 6 week postpartum evaluation, the device was visualized by ultrasound as intrauterine at that time.

# Contextual Question:

# Payer and Provider Policies to Promote LARC

A 2014 Center for Evidence-based Policy Medicaid Evidence-based Decisions Project (MED) report on Medicaid policies and programs to encourage use of LARC identified several common barriers and best practices to LARC enhance uptake (Ray, Leof, & King, 2014).

## Barriers to LARC Uptake

### Administrative Barriers

Obstetric care is billed and coded using a global diagnosis related group (DRG); costs are reimbursed in a block payment accordingly. When a LARC device is provided during an inpatient obstetric stay, the additional costs of the device itself and the insertion procedure are not captured in the DRG and thus goes unpaid in the current system.

### Cost of LARC Devices

Many LARC devices have a high initial cost compared to shorter acting contraceptive methods (e.g., pills, patch, ring). However, comparing total annual costs, LARC devices actually have the lowest costs (Trussell, et al., 2009; 2013). In 2015, Liletta®, a 52mg-LNG IUS, was approved by the FDA. The distributor, Medicines360, is providing the device at very reduced rates ($50) for those enrolled in 340b

pharmacy programs (OHA, 2015), reduced rates for bulk purchases, and they also offer a reduced cost starter pack (see Address Device Costs section below).

Clinics and providers may express concerns about high upfront costs to stock LARC devices. If payers reimburse below provider costs (or do not reimburse in an inpatient setting), there is a disincentive for providers to use them. Furthermore, the high initial cost of the devices creates a barrier to facilities having stock-in-hand, thus preventing same day insertions when patients choose LARC devices. Same-day-insertion is a best practice (see Address Device Costs section below).

### Provider Barriers

Providers may not understand current patient eligibility criteria for LARC devices, lack sufficient training to insert LARC devices in the postabortion or postpartum period, or be unclear on appropriate billing and coding so that they are reimbursed for the device and procedure costs.

### Patient Barriers

Women may inappropriately believe they need to have previously delivered a child, be older, or have failed another contraceptive method to be eligible for LARC. Women may believe their insurer does not cover LARC options for contraception or that the device is too expensive. Patients often are required to return for a second visit to have devices inserted, a barrier that reduces LARC utilization.

### System Barriers

Patients receive family planning services in a variety of settings, including private practices (from family medicine, pediatric and obstetrics/gynecology clinicians, or certified nurse midwives), community health centers, Title X clinics, and federally qualified health clinics (FQHCs). Systems barriers in these various settings may include coding and billing, initial device cost, reimbursement, provider training, and outdated clinical policies. Solutions for each of the challenges described below may need to be modified depending on the setting.

## Solutions to Overcome LARC Barriers

### Address Administrative Barriers

Policies that facilitate payment for immediate postpartum LARC insertion may increase use of the devices. Hospitals are unlikely to bundle a LARC device into the global delivery fee given the cost of the devices. As of February 2016, Medicaid programs in seventeen states and the District of Columbia accept claims and provide reimbursement for devices, allowing physicians to bill for a LARC device and insertion immediately postpartum and the facility to be paid for the device outside of the bundled payment for delivery.

For example, in Washington State, reimbursement for providing an immediate postpartum LARC is billed separately from the global DRG for delivery and the facility delivery claim through the use of a separate outpatient claim. Reimbursement is offered through three different claims processes: 1) the facility's pharmacy point of sale system, 2) as a separate professional claim filed by the facility (when facility

supplies device), or 3) a separate professional claim by the provider (when provider supplies device). Washington does not reimburse for unbundling the delivery (Washington State Health Care Authority, 2015).

## Address Device Costs

Policies that increase reimbursement for LARC devices may increase LARC uptake.

Same-day insertions are a best practice for both providers and patients. Creating systems for providers to have LARC device stock on hand is necessary for same-day insertions and may require payers to develop funding options for providers who are unable to afford the up-front costs of stocking LARC devices (e.g., buying an initial starter kit, partnering with other funding sources).

Contracting with specialty pharmacies to deliver devices for patients within 24 hours can help those providers who are unable to keep stock on hand. These contracts can also include options to return unused devices. Specialty pharmacies can also bill insurers directly, relieving the office of the device billing burden.

Liletta® manufacturers, Actavis and Medicines360 offer the Liletta AccessConnect program with two purchasing options (Actavis Pharma, 2015). Each purchasing option is described in detail on their website, https://www.lilettahcp.com/access/purchasing.

1. ***Volume Discount Program:*** Liletta® can be purchased directly from Actavis with volume-based discounts starting at $599.38 per device for 1 to 5 units and decreasing to $537.50 when ordering over 100 units.

2. ***Specialty Pharmacy:*** Currently, Actavis is partnering with Accredo to act as their specialty pharmacy provider.

Additionally, Actavis offers a significantly discounted rate to participants of the 340B Drug Pricing Program. In their guide to Intrauterine Devices, the Bixby Center at the University of California, San Francisco reports that the device will cost $50.00 for sites participating in the 340B program. The Oregon Health Authority reproductive health newsletter also reported this price in April, 2015.

## Develop LARC Champions

Increased provider knowledge on eligibility, more advanced procedure skills, and building skills for appropriate billing and coding may increase uptake of LARC by providers and practices. Partnering with stakeholders such as the local affiliates of professional societies (e.g., American College of Obstetricians and Gynecologists [ACOG], American Academy of Family Physicians [AAFP], American Academy of Pediatrics [AAP], American College of Nurse-Midwives [ACNM]), FQHCs, Title X clinics, and hospital organizations to develop LARC champions that can assist in dissemination of knowledge and skills. Champions can advocate for LARC use in their communities, and provide procedure training, and billing and coding assistance to providers and staff.

## Dispel Patient and Provider Myths

Dispelling myths that inappropriately exclude teens and nulliparous women from LARC devices is an important strategy that can be targeted to both patients and providers. Payers and providers can use the medical eligibility criteria, published by the Centers for Disease Control and Prevention (CDC) to guide physician practices (CDC, 2012). Using patient information materials that emphasize the efficacy and safety of LARC options and correct misinformation on eligibility can increase uptake. Appendix E provides links to the MEC and efficacy-based contraceptive options tools.

## Coordinate with Stakeholders

Health systems and payers can work to reduce unintended pregnancy rates through improving inter-conception care and encouraging pregnancy intention screening for all patients to help connect women to the resources that fit their reproductive life plans. Pregnancy intention screening can be delivered outside of traditional medical settings including substance use treatment centers and social service agencies, connecting women to family planning services. These conversations can include information on the efficacy, safety, and cost-effectiveness of LARC methods and include referrals to providers or integrate family planning services into their services.

Since 2015, effective contraception use is a Coordinated Care Organization incentive metric in Oregon. Effective contraception includes sterilization, IUDs/IUSs, implants, injections, pills, patches, rings or diaphragms. Efforts to promote inter-conception care may address the state incentive metric on contraceptive use.

Payers can review claim systems to ensure coding and billing systems capture the 90% enhanced federal Medicaid match for family planning services and also to distinguish between devices acquired through 340b clinics and those devices eligible for Medicaid pharmacy rebates. Stakeholders may be unaware of the federal match for family planning services.

# Resource Allocation

## Cost-effectiveness Reports

### *Postabortion IUD Insertion*

A 2013 analysis by Salcedo, Sorensen, and Rodriguez estimated cost-effectiveness of immediate IUD provision compared to routine placement at a follow-up visit from the public payer perspective (Salcedo, Sorensen, & Rodriguez, 2013). Compared to planned insertion at follow up, the immediate insertion of an IUD (including copper or LNG-IUS options) following an elective termination is estimated to save $111 per woman over the first year in direct medical costs alone, and $810 over 5 years. With the addition of public health insurance and social program costs, the savings increases to $1956 over 1 year, and $4296 over 5 years. Providing immediate postabortion IUDs to 1000 women will avoid over 400 pregnancies, 180 deliveries and 160 abortions over 5 years. In sensitivity models, planned follow-up placement was estimated to have greater savings only when expulsion rates reached over 30% in the immediate insertion group or nearly 90% of women attended their postabortion follow-up visit.

### *Postpartum IUD Insertion*

Washington and colleagues designed a model comparing costs and health outcomes for immediate post-placental or delayed (6-8 weeks postpartum) IUD insertion. Per 1,000 women over 2 years, immediate postpartum IUD insertion is estimated to prevent an additional 88 unintended pregnancies and provide medical cost savings of $282,540. Models included an 18% expulsion rate following immediate postpartum insertion. While there is a higher expulsion rate following immediate postpartum insertion, the additional device costs are offset by reductions in unintended pregnancy (Washington, et al., 2015). In this analysis the cost of an IUD needed to be over $10,000 for the intervention to no longer be cost-saving. Similar to estimates from Salcedo and colleagues, expulsion rates needed to reach over 38% to favor delayed insertion (Washington, et al., 2015).

Both IUD economic analyses were performed before the Liletta® device entered the market in 2015. Liletta® was developed to decrease the cost of IUDs for lower-resource settings and Medicines360, the distributor, offers Liletta® to 340b pharmacy benefit participants at approximately $50 per device, and about $500 for other purchasers (Oregon Health Authority, 2015). In the prior analyses, the costs for an IUD in the two economic models described above were estimated at $650 in the postabortion model, and at $810.77 ($410.77-$1210.77) in the postpartum model. Actual savings may be greater with increasing use of Liletta®, particularly in settings with access to 340b pricing.

### *Postpartum Implant Insertion*

Gariepy and colleagues estimated the cost-effectiveness of immediate implant insertion compared to insertion at 6 weeks postpartum over the subsequent year. While cost-effectiveness estimates of the contraceptive implant insertion report higher costs than delayed insertion, the increased likelihood of receipt of the device immediately postpartum and reduction in unintended pregnancy (2.4% for delayed vs. 21.6% for immediate) is estimated to save $1,263 per patient (Gariepy, Duffy, & Xu. 2015). Limiting estimates to only 1 year limits the validity of cost-effectiveness estimates as the contraceptive implant maintains a low failure rate across the three years of approved use and therefore cost savings may increase over a longer time frame.

A Colorado-based prospective study of pregnant adolescents (13-22 years of age) offered immediate postpartum implant insertion found that continuation rates were high (97% at 6 months, 86% at 12 months) and pregnancy rates lower in the immediate insertion group compared to those not receiving a device in hospital and going on to either receive an implant, other contraceptive method, or no method (pregnancies in the implant group 2.6% vs 20.1% in comparison at 12 months, 17.7% vs. 83.7% at 36 months) (Han, Teal, Sheeder, & Tocce, 2014).

Using their observations, the authors then created an economic model to estimate costs over 6, 12, 24, and 36 months of a theoretical publicly funded immediate postpartum implant program provided to 1000 women (compared to hypothetical cohort of 1000 women not receiving an implant). While costs were greater at 6 months in the immediate implant group ($72,606 more, relating to device costs), by 12, 24, and 36 months the cost savings through averted pregnancies, even after including costs of device removal, was estimated to save Colorado Medicaid, $546,950, $2.46 million, and $4.53 million respectively.

Births, abortions, and miscarriages resulting from unintended pregnancies are estimated to have cost U.S. public payers $21.0 billion in 2010 (Sonfield & Kost, 2015). Effective contraception is cost-saving (not just cost-effective). Increasing LARC use, through immediate postpartum or postabortion placement of IUDs, results in higher LARC use at six months (Lopez et al., 2015; Okusanya, et al., 2014). While there is a higher expulsion rate associated with postpartum compared to delayed insertion of IUDs (17% vs 3%), economic models demonstrate cost-savings even up to an expulsion rate of 30% (Salcedo, et al., 2013; Washington, et al., 2015).

The expulsion rate for immediate postabortion IUD insertion is greater following immediate insertion, (4% vs. 1.7%) (Okusanya, et al., 2014). In the largest trial, by Bednarek and colleagues (which was conducted in Oregon), expulsion rates needed to differ by 8% or more for immediate placement to be inferior (Bendarek, et al., 2011). Economic models estimate cost savings for immediate postabortion insertion up to a 30% expulsion rate (Salcedo, Sorensen, & Rodriguez, 2013). Economic models on postabortion IUD insertion estimate for every 1000 women undergoing placement, 400 pregnancies, 180 deliveries, and 160 abortions will be averted (Salcedo, et al., 2013).

Contraceptive implants are effective, have high continuation rates in nonrandomized studies, and are not at risk of expulsion. Therefore significant cost savings would also be projected with these devices (Han, et al., 2014; Diedrich, et al., 2015).

## Values and preferences

For women who choose it, reproductive life planning enhances women's ability to achieve their life, family, and career goals. Clinicians are encouraged to discuss contraceptive options and pregnancy planning with women at every visit (ACOG, 2016a; Gavin, et al., 2014). Most women desire to control their fertility and time their pregnancies. When women desiring contraception are presented with all contraceptive options, over 70% will select a LARC method, including teens, and the majority continues to use a LARC method at 12 and 36 months (Rosenstock, et al., 2012; Peipert, et al., 2012). When women select their preferred contraceptive method, continuation rates across all methods are higher. Immediate insertion of LARC following a birth or abortion is generally acceptable to women and may be preferable. Consolidating gynecological interventions (delivery or abortion, and IUD placement) may improve convenience and lessen associated discomforts with these procedures (including if there is anesthesia or analgesia involved). Requiring multiple visits to obtain a LARC method decreases uptake of these, and indeed any form of contraception. The one potential deterrent to immediate versus delayed IUD insertion is the increase in the risk of expulsion, which is inconvenient for the woman and adds some short-term cost for the system. There are not additional harms associated with immediate IUD insertion, and no deterrents to immediate versus delayed insertion of implants. Many women would likely choose immediate insertion of a LARC in the postpartum or postabortion time frame.

## Other considerations

Information from non-randomized studies estimates that LARC devices are 20 times more effective at preventing unintended pregnancy than contraceptive pills, patches, rings, and injections. Continuation rates for LARC devices are also greater than pills, patches, rings, and injections (Winner, et al., 2012).

Evaluated efforts to expand LARC use (e.g., Colorado, Iowa, St. Louis) are associated with significant reductions in teen pregnancy and abortion (Rickets, et al., 2014; Biggs, et al., 2015; Peipert, et al., 2012).

The CDC's MEC recommends LARC devices as suitable for the vast majority of reproductive-aged women (CDC, 2012). Since 2010, the CDC has endorsed immediate postpartum and postabortion LARC use and supports LARC methods for breastfeeding women (CDC, 2010).

The National Committee on Quality Assurance (NCQA) reports 30-40% of insured women do not attend a postpartum visit and 40-75% do not attend a postabortion visit, thus increasing the risk of unplanned pregnancy, abortion, or unmet contraceptive needs.

# POLICY LANDSCAPE

## Quality measures

In Oregon, effective contraception use became a Coordinated Care Organization incentive metric in January 2015. Effective contraception includes sterilization, IUDs/IUSs, implants, injections, pills, patches, rings, or diaphragms.

No quality measures related to LARC were identified when searching the National Quality Measures Clearinghouse.

## Payer initiatives

In April 2016, the Center for Medicaid and CHIP Services released an informational bulletin highlighting state efforts to improve access to LARC for Medicaid enrollees (Centers for Medicare and Medicaid Services, 2016). The five strategies featured in the bulletin mirror those addressed above and include:

1. Provide timely, comprehensive contraception coverage
2. Raise payment rates for LARC and other devices
3. Reimburse for immediate postpartum LARC by unbundling payment from obstetric services
4. Remove logistical barriers to managing supply of LARC devices
5. Remove administrative barriers for LARC provision

The bulletin also mentions efforts in Illinois, Louisiana, and South Carolina to expand LARC access, including efforts through managed care contracting and quality improvement work. The full bulletin can be found in Appendix F.

In addition, federal law requires coverage of all methods of birth control for most commercial health insurance plans and Medicaid Alternative Benefit Plans (see http://www.dol.gov/ebsa/faqs/faq-aca26.html).

At this time, Oregon has no specific guidance about the use of LARC in the immediate postpartum period, and coverage does not consistently occur across payers and settings.

Washington's Family Planning Provider Guide outlines the reimbursement for immediate postpartum LARC insertion:

The agency reimburses professional services for immediate postpartum IUD or contraceptive implant insertion procedures if billed separately from the professional global obstetric procedure codes and the facility (including hospital inpatient) delivery claim. The agency does not pay separately for unbundled services billed by a hospital.

The agency reimburses for the IUD or contraceptive implant device in one of the following ways:

- Through the facility's pharmacy point of sale system;
- As a separate professional claim submitted by the facility when the facility supplies the device; or
- As part of the professional claim when the device is supplied by the provider performing the insertion (Washington State Health Care Authority, 2015).

In their interview with 40 Medicaid agencies, Moniz and colleagues developed common themes differing in states with a policy covering immediate postpartum insertion of LARC and those not considering coverage. These themes include differences on beliefs of the health benefits of LARC, budget impacts, and competing demands for Medicaid agencies. Those with a coverage policy often reported "clear cost savings" and "common sense" approach to covering immediate postpartum insertion while those without coverage expressed concern about upfront costs, need to maintain cost-neutrality, and concern that providing payment for inpatient procedures outside of global payments may set a precedent for other medical specialties desiring separate payment outside of the diagnosis-related group code or DRG (Moniz, et al., 2015).

No coverage policies for postpartum or postabortion insertion of LARC were found in a search of provider manuals for Aetna, Cigna, Moda, and Regence commercial plans.

The Oregon Health Plan and CCARE, Oregon's Medicaid family planning waiver, will cover the provision of an immediate postabortion LARC device.

## Professional society guidelines

The American College of Obstetricians and Gynecologists (ACOG) has several position statements and a clinical practice guideline on LARC (reaffirmed in 2015). The ACOG recommendations include offering LARC methods at the time of delivery, abortion, or dilation and curettage for miscarriage (ACOG, 2015a), and ACOG also recommends LARC for adolescents (ACOG, 2014).

In their 2014 policy statement, the American Academy of Pediatrics (AAP) encouraged pediatricians to counsel adolescents on contraception in order of efficacy, starting with the most effective methods (i.e. LARC) first (American Academy of Pediatrics, 2014). The AAP also recommends offering LARC to postpartum teens in the immediate postpartum period, including while still in the hospital, based on evidence from systematic reviews combined with ACOG and CDC recommendations (Ott & Sucato, 2014).

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Coverage guidance is prepared by the Health Evidence Review Commission (HERC), HERC staff, and subcommittee members. The evidence summary was prepared by the Center for Evidence-based Policy at Oregon Health & Science University (the Center). This document is intended to guide public and private purchasers in Oregon in making informed decisions about health care services.

The Center is not engaged in rendering any clinical, legal, business or other professional advice. The statements in this document do not represent official policy positions of the Center. Researchers involved in preparing this document have no affiliations or financial involvement that conflict with material presented in this document.

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# APPENDIX A. GRADE INFORMED FRAMEWORK – ELEMENT DESCRIPTIONS

| Element | Description |
|---|---|
| Balance of benefits and harms | The larger the difference between the desirable and undesirable effects, the higher the likelihood that a strong recommendation is warranted. An estimate that is not statistically significant or has a confidence interval crossing a predetermined clinical decision threshold will be downgraded. |
| Quality of evidence | The higher the quality of evidence, the higher the likelihood that a strong recommendation is warranted. |
| Resource allocation | The higher the costs of an intervention—that is, the greater the resources consumed in the absence of likely cost offsets—the lower the likelihood that a strong recommendation is warranted. |
| Values and preferences | The more values and preferences vary, or the greater the uncertainty in values and preferences, the higher the likelihood that a weak recommendation is warranted |
| Other considerations | Other considerations include issues about the implementation and operationalization of the technology or intervention in health systems and practices within Oregon. |

## Strong recommendation

***In Favor:*** The subcommittee concludes that the desirable effects of adherence to a recommendation outweigh the undesirable effects, considering the balance of benefits and harms, resource allocation, values and preferences, and other factors.

***Against:*** The subcommittee concludes that the undesirable effects of adherence to a recommendation outweigh the desirable effects, considering the balance of benefits and harms, resource allocation, values and preferences, and other factors.

## Weak recommendation

***In Favor:*** The subcommittee concludes that the desirable effects of adherence to a recommendation probably outweigh the undesirable effects, considering the balance of benefits and harms, resource allocation, values and preferences, and other factors., but further research or additional information could lead to a different conclusion.

***Against:*** The subcommittee concludes that the undesirable effects of adherence to a recommendation probably outweigh the desirable effects, considering the balance of benefits and harms, cost and resource allocation, values and preferences, and other factors, but further research or additional information could lead to a different conclusion.

## Confidence in estimate rating across studies for the intervention/outcome[1]

***High:*** The subcommittee is very confident that the true effect lies close to that of the estimate of the effect. Typical sets of studies are RCTs with few or no limitations and the estimate of effect is likely stable.

***Moderate:*** The subcommittee is moderately confident in the estimate of effect: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different. Typical sets of

[1] Includes risk of bias, precision, directness, consistency and publication bias

studies are RCTs with some limitations or well-performed nonrandomized studies with additional strengths that guard against potential bias and have large estimates of effects.

***Low*:** The subcommittee's confidence in the estimate of effect is limited: The true effect may be substantially different from the estimate of the effect. Typical sets of studies are RCTs with serious limitations or nonrandomized studies without special strengths.

***Very low*:** The subcommittee has very little confidence in the estimate of effect: The true effect is likely to be substantially different from the estimate of effect. Typical sets of studies are nonrandomized studies with serious limitations or inconsistent results across studies.

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# APPENDIX B. GRADE EVIDENCE PROFILE

| Quality Assessment (Confidence in Estimate of Effect) | | | | | | | |
|---|---|---|---|---|---|---|---|
| No. of Studies | Study Design(s) | Risk of Bias | Inconsistency | Indirectness | Imprecision | Other Factors | Quality |
| **Unintended Pregnancy** | | | | | | | |
| ***Postabortal IUD*** | | | | | | | |
| 3 | RCTs | Moderate | Serious | Not serious | Not serious | Differential loss to follow up likely underestimates the benefit of immediate insertion in the intention to treat analysis | Moderate quality ●●●○ |
| ***Presence of LARC at six months*** | | | | | | | |
| ***Postabortion IUD*** | | | | | | | |
| 3 | RCTs | Moderate | Not serious | Not serious | Not serious | None | Moderate quality ●●●○ |
| ***Postpartum IUD*** | | | | | | | |
| 4 | RCTs | Moderate | Not serious | Not serious | Not serious | None | Moderate quality ●●●○ |
| **Need for alternate/Replacement contraception** | | | | | | | |
| ***Postabortal IUD (based on removal or expulsion by 6 months)*** | | | | | | | |
| 3 | RCTs | Moderate | Serious | Not serious | Not serious | Differential loss to follow up likely underestimates the benefit of immediate insertion in the intention to treat analysis | Moderate quality ●●●○ |
| ***Postpartum IUD (based on expulsion by 6 months)*** | | | | | | | |
| 4 | RCTs | Moderate | Not serious | Not serious | Not serious | None | Moderate |

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| Quality Assessment (Confidence in Estimate of Effect) | | | | | | | |
|---|---|---|---|---|---|---|---|
| No. of Studies | Study Design(s) | Risk of Bias | Inconsistency | Indirectness | Imprecision | Other Factors | Quality |
| | | | | | | | quality ●●●○ |
| **Harms** | | | | | | | |
| ***Postabortion IUD (based on upper genital tract infection only)*** | | | | | | | |
| 3 | RCTs | Moderate | Not serious | Serious | Not serious | None | Low quality ●●○○ |

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# APPENDIX C. METHODS

## Scope Statement

### *Populations*

Women in the postpartum or postabortion period who desire contraception

Population scoping notes: *None*

### *Interventions*

Offering immediate postpartum or postabortion placement of a long-acting reversible contraceptive (LARC)

Intervention exclusions: *None*

### *Comparators*

Usual care: Offering immediate non-LARC forms of contraception, scheduling delayed LARC placement, delaying discussion of options until 6 weeks postpartum or postabortion

### *Outcomes*

Critical: Unintended pregnancies, abortions

Important**:** Presence of LARC at one year, need for alternate/replacement contraception, harms

*Considered but not selected for the GRADE table:* Device expulsion, discontinuation of contraception for any reason other than desire to conceive

### *Key Questions*

KQ1: What is the comparative effectiveness of offering immediate postpartum or postabortion placement of a long-acting reversible contraceptive?

KQ2: What are the harms of immediate postpartum or postabortion placement of a long-acting reversible contraceptive?

### *Contextual Questions*

1: What payer and provider practices and policies promote effective use of LARC?

## Search Strategy

A full search of the core sources was conducted to identify systematic reviews, meta-analyses, technology assessments, and clinical practice guidelines using the terms long-acting reversible contraception or LARC. In addition, a search was conducted using the MeSH term contraception and the words postpartum, postabortion, or postabortion. Searches of core sources were limited to citations published in the past five years.

The core sources searched included:

Agency for Healthcare Research and Quality (AHRQ)
Blue Cross/Blue Shield Health Technology Assessment (HTA) program
BMJ Clinical Evidence
Canadian Agency for Drugs and Technologies in Health (CADTH)

Cochrane Library (Wiley Interscience)
Hayes, Inc.
Institute for Clinical and Economic Review (ICER)
Medicaid Evidence-based Decisions Project (MED)
National Institute for Health and Care Excellence (NICE)
Tufts Cost-effectiveness Analysis Registry
Veterans Administration Evidence-based Synthesis Program (ESP)
Washington State Health Technology Assessment Program

A MEDLINE® (Ovid) search was then conducted to identify systematic reviews, meta-analyses, technology assessments and RCTs published in the past five years.

Searches for clinical practice guidelines were limited to those published since 2010. A search for relevant clinical practice guidelines was also conducted, using the following sources:

Australian Government National Health and Medical Research Council (NHMRC)
Centers for Disease Control and Prevention (CDC) – Community Preventive Services
Choosing Wisely
Institute for Clinical Systems Improvement (ICSI)
National Guidelines Clearinghouse
New Zealand Guidelines Group
NICE
Scottish Intercollegiate Guidelines Network (SIGN)
United States Preventive Services Task Force (USPSTF)
Veterans Administration/Department of Defense (VA/DOD)

### *Inclusion/Exclusion Criteria*

Studies were excluded if they were not published in English, did not address the scope statement, or were study designs other than systematic reviews, meta-analyses, technology assessments, RCTs, or clinical practice guidelines.

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# APPENDIX D. APPLICABLE CODES

| CODES | DESCRIPTION |
|---|---|
| **ICD-10 Diagnosis Codes** | |
| Z30.019 | Encounter for initial prescription of contraceptives, unspecified |
| Z30.49 | Encounter for surveillance of other contraceptives (*includes implantable subdermal contraception insertion, removal, and surveillance)* |
| Z30.430 | Encounter for insertion of intrauterine contraceptive device |
| Z30.432 | Encounter for removal of intrauterine contraceptive device |
| Z30.433 | Encounter for removal and reinsertion of intrauterine contraceptive device |
| Z30.431 | Encounter for routine checking of intrauterine device |
| **CPT Codes** | |
| 58300 | IUD insertion |
| 58301 | IUD removal |
| 11981 | Insertion, non-biodegradable drug delivery implant |
| 11982 | Removal, non-biodegradable drug delivery implant |
| 11983 | Removal with reinsertion, non-biodegradable drug delivery implant |
| **HCPCS Level II Codes** | |
| J7297 | Levonorgestrel-releasing intrauterine contraceptive system, 52mg, 3 year duration (Liletta®) |
| J7298 | Levonorgestrel-releasing IU contraceptive system, 52mg, 5 year duration (Mirena®) |
| J7300 | Intrauterine copper contraceptive (Paragard®) |
| J7301 | Levonorgestrel-releasing intrauterine contraceptive system, 13.5mg (Skyla®) |
| *J7302* | *Levonorgestrel-releasing intrauterine contraceptive system, 52mg (discontinued 12/31/2015 replaced with J7297 or J7298 as appropriate)* |
| J7307 | Etonogestrel (contraceptive) implant system, including implant and supplies (Nexplanon®) |

Note: Inclusion on this list does not guarantee coverage

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# APPENDIX E. RESOURCES

American College of Obstetricians and Gynecologists: Immediate Postpartum LARC Resources
http://www.acog.org/About-ACOG/ACOG-Departments/Long-Acting-Reversible-Contraception/Coding-and-Reimbursement-for-LARC/Reimbursement-Resources-for-Postpartum-LARC-Initiation

Center for Disease Control & Prevention Medical Eligibility Criteria
http://www.cdc.gov/reproductivehealth/unintendedpregnancy/usmec.htm

Center for Disease Control & Prevention Contraception Options
http://www.cdc.gov/reproductivehealth/unintendedpregnancy/contraception.htm

The Washington State Department of Health, Prevention and Community Health Division created a postpartum LARC online training course featuring Dr. Sarah Prager of the University of Washington. The course itself, offered by CARDEA Services, runs about 1.5 hours and is free, although continuing medical and nursing education credits are available for a nominal $15 fee.
created a training course,
http://www.cardeaservices.org/resourcecenter/inserting-long-acting-reversible-contraception-larc-immediately-after-childbirth

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# APPENDIX F. INFORMATIONAL BULLETIN FROM CENTER FOR MEDICAID AND CHIP SERVICES

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, MD 21244-1850

CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR MEDICAID & CHIP SERVICES

***CMCS Informational Bulletin***

**DATE:** April 08, 2016

**FROM:** Vikki Wachino, Director
Center for Medicaid and CHIP Services

**SUBJECT:** **State Medicaid Payment Approaches to Improve Access to Long-Acting Reversible Contraception**

In July 2014, the Center for Medicaid and CHIP Services (CMCS) launched the Maternal and Infant Health Initiative to improve maternal and infant health outcomes. The initiative has two primary goals: 1) increasing the rate and improving the content of postpartum visits; and 2) increasing access and use of effective methods of contraception. Medicaid provides coverage for more than 70 percent of family planning services for low-income Americans. Given this important role, CMCS sought to identify approaches to Medicaid reimbursement that promote the availability of effective contraception.[1] This Informational Bulletin describes emerging payment approaches several state Medicaid agencies have used to optimize access and use of long-acting reversible contraception (LARC).

## Background

Beyond preventing unplanned pregnancies, research indicates that effective contraception helps prevent poor birth spacing, thereby reducing the risk of low-weight and/or premature birth.[2] It can also be essential to a woman's long-term physical and emotional well-being. LARCs—intrauterine devices (IUDs) and contraceptive implants—are highly effective methods of birth control that last between 3 and 10 years (depending on the method) without requiring daily, weekly, or monthly user effort.[3] The Centers for Disease Control and Prevention has identified LARCs as among the most effective family planning methods with a pregnancy rate of less than 1 pregnancy per 100 women in the first year. For comparison, the contraceptive pill has a rate of 9 pregnancies per 100 women in the first year, while the male condom has rate of 18 pregnancies per 100 women in the first year.[4] While Medicaid agencies typically reimburse for multiple types of contraception, LARCs possess a number of advantages: they are cost-effective, have

[1] Sonfield A and Gold RB. (2012). Public Funding for Family Planning, Sterilization and Abortion Services, FY 1980–2010, New York: Guttmacher Institute, <http://www.guttmacher.org/pubs/Public-Funding-FP-2010.pdf>.
[2] Agustin Conde-Agudelo, MD, MPH; Anyeli Rosas-Bermúdez, MPH; Ana Cecilia Kafury-Goeta, MD (2006). Birth Spacing and Risk of Adverse Perinatal Outcomes: A Meta-analysis. *JAMA* 295 (15): 1809-1823.
[3] Trussell J. Contraceptive efficacy. In: Hatcher R, Trussell J, Nelson A, Cates W, Kowal D, Policar M, eds. Contraceptive Technology. 20th ed. New York, NY: Ardent Media; 2011:779–863.
[4] U.S. Centers for Disease Control. Effectiveness of Family Planning Methods. http://www.cdc.gov/reproductivehealth/unintendedpregnancy/pdf/contraceptive_methods_508.pdf. Accessed March 28, 2016.

high efficacy and continuation rates, require minimal maintenance, and are rated highest in patient satisfaction.[5]

Despite these known advantages, LARC utilization in the U.S. remains relatively low when compared to rates in other countries. As of 2009, LARC utilization rates among contraception users in the U.S. are higher for women covered by Medicaid (11.5 percent) than the national rate (8.5 percent).[6] But more can be done to increase the use of this form of contraception. Two reasons cited for the low utilization of LARCs in the U.S. are (1) administrative and reimbursement barriers that result in high upfront costs for devices and (2) payment policies that reduce (or do not provide) reimbursement for devices or placement.[7,8] States have flexibility in how they reimburse for LARC, and by promoting access to contraceptive methods of choice—and the support necessary to use chosen methods effectively—states can support not only the health of women and their children, but also reduce the number of unintended pregnancies.

**LARC Utilization and Medicaid Reimbursement**

Payment challenges related to LARC utilization exist in both fee-for-service (FFS) and managed care environments, as well as in inpatient and outpatient settings (primary, specialty, or other ambulatory care).

In the inpatient setting, for example, the use of a single prospective payment for labor and delivery services may not sufficiently address the additional costs associated with the provision of LARC. There are significant advantages to providing LARC immediately after delivery while the woman is still under hospital care.[9] But many states do not provide additional payment for the cost of LARC, and do not provide additional payment to either the hospital or the practitioner for placement or insertion services.

In outpatient settings, payment rates may be insufficient for LARC devices and/or for placement services. LARC placement may require significant up-front costs to providers, primarily costs to obtain devices prior to placement. For devices covered through a patient's pharmacy benefit, and in the absence of prior arrangements (or state policy), providers may not be able to return a dispensed device if it is not used for the specific patient for whom it was dispensed; these devices must then be discarded at a financial loss to the provider.

If states limit provider payment to an initial LARC placement, but do not provide payment for replacement or reinsertion when necessary, providers may face further disincentives.

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[5] Peipert JF, Zhao Q, Allsworth JE, Petrosky E, Madden T, Eisenberg D, Secura G.(2011) Continuation and satisfaction of reversible contraception. *Obstet Gynecol*. 117(5):1105-13.
[6] Finer LB, Jerman J, Kavanaugh ML. (2012). Changes in use of long-acting contraceptive methods in the United States, 2007-2009. Fertility and Sterility 98(4), 893-89
[7] Committee Opinion No. 615. American College of Obstetricians and Gynecologists. 2015. Access to contraception. Obstet Gynecol: 125: 250-5.
[8] Rodriguez, MI, Evans, M, Espey, E. (2014). Advocating for immediate postpartum LARC: increasing access, improving outcomes, and decreasing cost. *Contraception*. 90, 468-471.
[9] Long-acting reversible contraception: implants and intrauterine devices. Practice Bulletin No. 121. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2011; 118:184–96.

Additionally, providers may be hesitant to insert LARC devices for women when continued coverage for individuals is uncertain in the event there is later need for removal of the LARC.

Finally, some states or Managed Care Organizations (MCOs) require prior authorization and, as part of the prior authorization, may question medical necessity absent failure using another birth control method (sometimes called step therapy).

**State Medicaid Payment Strategies to Optimize LARC Utilization**

To assist states in optimizing the existing statutory flexibilities in this area, this Informational Bulletin identifies LARC reimbursement strategies implemented by states. Information on challenges and opportunities were obtained through several sources, including a September 2014 Technical Review Panel on Contraceptive Services in Medicaid and the Children's Health Insurance Program (CHIP) and a scan of state policies and interviews with several state Medicaid officials. Emerging approaches to mitigate challenges in fourteen states, identified as of March 2015, involve a combination of contractual, payment strategies, and policy guidance. Additional states may also use similar strategies which fall into five broad categories:

1. Provide timely, patient centered comprehensive coverage for the provision of contraceptive services (e.g., contraception counseling; insertion, removal, replacement, or reinsertion of LARC or other contraceptive devices) for women of child-bearing age.
2. Raising payment rates to providers for LARC or other contraceptive devices in order to ensure that providers offer the full range of contraceptive methods.
3. Reimbursing for immediate postpartum insertion of LARC by unbundling payment for LARC from other labor and delivery services.
4. Removing logistical barriers for supply management of LARC devices (e.g., addressing supply chain, acquisition, stocking cost and disposal cost issues).
5. Removing administrative barriers for provision of LARC (e.g., allowing for billing office visits and LARC procedures on the same day; removing preauthorization requirements).

The following table summarizes state efforts to optimize LARC utilization, followed by a detailed summary of the approaches three states use. CMS is available to provide technical assistance to states who are interested in reviewing options for modifying LARC policies. For additional information on this Informational Bulletin, please contact Karen Matsuoka at karen.matsuoka@cms.hhs.gov or 410-786-9726.

# Table 1. State Medicaid Payment Strategies to Optimize Long-Acting Reversible Contraception (LARC) Utilization in 14 States

A scan of state reimbursement policies on LARC was conducted in 2014, resulting in the identification of payment practices in 14 states. This table describes the payment strategies that these 14 states used to optimize LARC utilization. The payment strategy noted for each state is intended to be a short title, while the policy description provides an overview of the key components of the state Medicaid policy that supports the strategy. The implementation considerations are specific details about how the state implements the payment strategy while maintaining compliance with the state policy.

| State<br>Effective Date | Payment Strategy | Policy Description | Implementation |
|---|---|---|---|
| **Alabama**<br>**April 2014** | Reimbursement of LARC insertion immediately postpartum in the inpatient hospital setting or outpatient practice setting. | 1. Covers the cost of the LARC device/drug implant as part of the hospital's cost, and the insertion of the device/drug implant is billable to Medicaid when the insertion occurs immediately after a delivery before discharge from an inpatient setting.<br><br>2. Covers the cost of the LARC device/drug implant as part of the hospital's cost, and insertion is billable to Medicaid when the insertion is provided in an outpatient setting after delivery and immediately after discharge from an inpatient setting. | 1. Inpatient: the hospital must use an International Classification of Diseases (ICD-9) delivery diagnosis code within the range 630 – 67914 and must use the ICD-9 surgical code 69.7 (insertion contraceptive device) to document LARC services provided after the Delivery.<br><br>2. Postpartum LARC in the outpatient hospital setting immediately after discharge from inpatient settings, should be billed on a UB-04 claim form using one code from each of the following with family planning modifier (FP):<br>• 58300 Insertion of IUD<br>• 11981-FP Insertion, non-biodegradable drug delivery implant<br>• 11983-FP Removal with reinsertion ICD-9 diagnosis codes:<br>• V255 Encounter for contraceptive management, insertion of implantable |

| State Effective Date | Payment Strategy | Policy Description | Implementation |
|---|---|---|---|
| | | | subdermal contraceptive<br>• V2511 Insertion of intrauterine contraceptive device<br>• V2502 Initiate contraceptive NEC<br>• V251 Insertion of IUD<br><br>Physician bill on CMS 1500 form using the same coding as above and also indicate Place of Service:<br>• 21 Inpatient hospital setting<br>• 22 Outpatient hospital setting |
| **California July 1, 2015** | Reimbursement of LARC | General acute care hospitals may submit claims for the long-acting reversible contraceptive methods on an outpatient claim, even when treatment is provided on an inpatient basis | Hospital LARC claims should be billed using the following Healthcare Common Procedure Coding System (HCPCS) codes:<br>• J7300<br>• J7301<br>• J7302<br>• J7307 |
| **Colorado October 2013** | Temporary system work-around for reimbursement of LARC insertion immediately postpartum in the inpatient hospital setting. | Medicaid Management Information System (MMIS) was scheduled for an update to the APR DRG[1], in January 2014 to automatically report if a claim includes LARC insertion. For a temporary system work around:<br>• The insertion will be reimbursed and paid separately from the global | 1. To receive a LARC payment in addition to the APR DRG, the hospital must include the ICD-9 and Current Procedural Terminology (CPT) codes that are included in the Colorado Medical Assistance Program Revenue Codes UB04/institutional billing form on the same claim as the hospital stay.<br><br>2. The "trigger" for LARC payment will be the inclusion of these codes: |

[1] 3M™ All Patient Refined Diagnosis-Related Group (APR DRG) Classification System for adjusting data for severity of illness (SOI) and risk of mortality (ROM).

| State Effective Date | Payment Strategy | Policy Description | Implementation |
|---|---|---|---|
| | | obstetric fee code.<br>• State will cover two LARC devices every five years. | • V25.11 – encounter for insertion of intrauterine contraceptive device; and/or<br>• V25.13 – encounter for removal and reinsertion of intrauterine contraceptive device. |
| | Reimbursements for LARCs outside of the normal encounter (per visit) rate for Rural Health Centers (RHCs) | RHCs may receive reimbursement for IUDs and implants used for contraceptive purposes in addition to their normal encounter rate reimbursements.<br><br>Federally Qualified Health Centers (FQHC) do not receive an additional payment for LARCs since the FQHC encounter payment rates are based on "full-cost" reimbursement calculations. | 1. For devices purchased under the 340B Program, individual providers and RHCs must bill the actual acquisition cost for the device.<br><br>2. Reimbursement will be based on the actual 340B acquisition cost. For devices not purchased through the 340B program, reimbursements are the lower of the provider's charges or the rate on the Department's practitioner fee schedule, whichever is applicable.<br><br>3. Reimbursement is separate from any encounter payment the RHC may receive for implanting the device.<br><br>4. When a LARC is inserted, removed, or reinserted during a visit, the practitioner must use the appropriate diagnostic code, such as, V25.11 or V25.5, and use the family planning modifier (FP) on the claim form. |

| State Effective Date | Payment Strategy | Policy Description | Implementation |
|---|---|---|---|
| | | | |
| **Georgia April 2014 for practitioner reimbursement;**<br><br>**Hospital reimbursement to begin in 2016** | Reimbursement of LARC insertion immediately postpartum in the inpatient hospital setting. | 1. Reimburses hospitals and practitioners the cost of the LARC device outside of the global obstetric fee for delivery.<br><br>2. Georgia policy, regardless of delivery system (FFS or Managed Care Organization (MCO)) defines "immediate postpartum" as within ten minutes of birth.<br><br>3. Devices should be available in the birthing suite to ensure timely insertion. | 1. LARC insertion is considered an add-on benefit and is not included in the DRG reimbursement process.<br><br>2. Practitioners receive additional reimbursement when one of the following four devices, indicated by their respective J code, is inserted within ten minutes of birth:<br>• J7300<br>• J7301<br>• J7302<br>• J7307 |
| **Illinois**<br>**October 2012**<br><br><br><br><br>**July 2014** | Contraceptive Devices in FQHCs and RHCs<br><br><br><br><br>Dispensing Fee Incentive | FQHCs and RHCs may receive reimbursement for LARC devices (IUDs and single rod implantable devices) for contraceptive purposes.<br><br><br>340B providers may receive a dispensing fee add-on when dispensing highly-effective contraceptives | 1. For devices purchased under the 340B Program, the FQHC or RHC must bill the actual acquisition cost for the device.<br><br>2. Reimbursement will be based on the actual 340B acquisition costs and must include modifier "UD" in conjunction with the appropriate procedure code. For devices not purchased through the 340B program, reimbursements are the lower of the provider's charges or the rate on the Department's practitioner fee schedule, whichever is applicable. |

| State Effective Date | Payment Strategy | Policy Description | Implementation |
|---|---|---|---|
| | | | 3. Reimbursement is separate from any encounter payment the FQHC or RHC may receive for implanting the device. |
| **October 2014** | Increased reimbursement for insertion and removal of LARC in the outpatient setting.<br><br>Allowed reimbursement for office visit along with LARC insertion/removal procedure on the same day.<br><br>Outpatient provider office stocking. | 1. Increased reimbursement rate for insertion/removal procedures of LARC.<br><br>2. Provide reimbursement for evaluation/management (E/M) visits, where a practitioner and beneficiary discuss contraceptive options, in addition to same day LARC insertion or removal procedures.<br><br>3. Pilot program to ensure practitioners have sufficient devices stocked, with automatic re-supply as needed. | 1. When a LARC is inserted, removed, or reinserted during a visit, the practitioner uses a modifier V25 on the claim along with the type of visit:<br>• Postpartum visit (CPT 59430)<br>• Initial or annual preventive visit (CPT 99381-99397)<br><br>2. A practitioner must order the device and document the insertion procedure in both the hospital's and the practitioner's medical record: |
| **July 1, 2015** | Reimbursement of LARC insertion immediately postpartum in the inpatient setting. | Medicaid allows hospitals separate reimbursement for the LARC device provided immediately postpartum in the inpatient hospital setting. | 3. The hospital must use its fee-for-service National Provider Identifier (NPI) to bill the appropriate device or implant (by specific National Drug Code (NDC) on the claim.<br><br>The hospital must use the appropriate family planning ICD-9-CM diagnosis code (or upon implementation, ICD-10-CM) on the claim. |
| **Iowa**<br>**March 2014** | Reimbursement of LARC insertion immediately | 1. Medicaid allows the insertion of IUDs and other LARC devices | 1. Practitioners may bill for the professional service associated with insertion of the |

| State Effective Date | Payment Strategy | Policy Description | Implementation |
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| | postpartum in the hospital setting. | before the beneficiary leaves the hospital following delivery.<br><br>2. Payment for these services is allowed for both practitioners and hospitals. | LARC with the appropriate CPT code.<br><br>2. If a practitioner supplies the LARC, the practitioner may also bill for the device(s).<br><br>3. When hospitals provide the LARC services, the claim must be submitted as an outpatient claim, separate from the inpatient DRG claim for the delivery. The outpatient claim will be based on the fee schedule for the HCPCS Level II procedure code billed. |
| **Louisiana**<br>**June 2014** | Reimbursement of LARC insertion immediately postpartum in the inpatient hospital setting. | 1. Hospitals and practitioners are reimbursed for LARCs as an add-on service in addition to their daily per diem rate for the inpatient hospital stay (DRG rate) or professional services rate, respectively.<br><br>2. Reimbursement amount is determined by:<br>• LARC service provided (insertion or reinsertion)<br>• IUD or non-biodegradable drug delivery implant<br>• The beneficiary's age (0 – 15 years or 16+ years)<br><br>3. Medical management, including prior authorization and step | 1. In FFS: Hospitals use the appropriate LARC J-code on their hospital stay claim.<br>• On a paper claim (CMS 1500) "DME" must be written in bold, black print on the top of the form.<br>• If the hospital bills electronically, the 837P must be used with the Durable Medical Equipment (DME) file extension.<br>2. Payment for the LARC is equal to the DME fee schedule, and added to the amount of the hospital's per diem payment.<br><br>3. If a LARC device is expelled after insertion, the state applies a pre- determined cost of reinsertion and replacement device to the standard<br>DRG or professional services rates.<br><br>4. MCO contracts with the state prohibit |

| State Effective Date | Payment Strategy | Policy Description | Implementation |
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| | | therapy, are prohibited for LARC devices and procedures. | prior authorization for LARC devices or procedures. Further, MCO contracts require hospital and practitioner reimbursement for LARC devices and procedures at a minimum of the FFS fee schedules for the same DME or CPT codes, respectively. |
| **Maryland**<br>**July 2013**<br><br>**September 2014** | Contraceptive Devices in FQHCs<br><br>Reimbursement of LARC insertion immediately postpartum in the inpatient setting | FQHCs are reimbursed for an office visit and the acquisition cost for one (1) of the three (3) covered LARC ~~procedures~~ devices.<br><br>LARC devices and insertion procedures are reimbursable and are separate from the delivery fee (Maryland Medicaid does not reimburse physicians for "global" maternity care services; deliveries are billed separately from prenatal care). | Practitioners receive reimbursement for one of the three devices, as indicated by their respective J code:<br>• J7300<br>• J7302<br>• J7307<br><br>1. Maryland Medicaid reimburses for all LARCs, including those placed immediately postpartum without preauthorization.<br><br>2. Hospitals include the LARC invoice separately from the inpatient labor and delivery claim using the appropriate claims using the appropriate codes and modifiers. |
| **Massachusetts**<br>**October 2014** | Reimbursement of LARC insertion immediately postpartum in the inpatient hospital setting.<br><br>Comprehensive LARC coverage for outpatient practice settings such as hospital outpatient | 1. Hospitals are reimbursed for the provision of the LARC device. The insertion procedure is reimbursed directly through the claim payment, while the device is reimbursed indirectly as part of the hospital's base rate. The device is reported on the annual cost report as a supply, and those costs are incorporated | 1. MassHealth payment methodology recently adopted the APR DRG model by 3M Health Information Systems, which weights every service that is entered on the claim. The device is accounted for on the annual hospital cost report, and these costs are incorporated into the hospital's overall provider base rate. |

| State Effective Date | Payment Strategy | Policy Description | Implementation |
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| | departments or family planning agencies. | into the hospital's provider base rate calculation.<br><br>2. Hospital-based practitioners bill the professional claim for surgical procedure through the hospital. The professional claim for hospital-based providers does not include the device.<br><br>3. Community-based practitioners are reimbursed separately for the professional service of inserting the device as well as the device itself (if supplied by the physician) on the claim. | 2. Family planning agencies that participate in MassHealth are reimbursed for the LARC device and insertion when billed with the appropriate code:<br><br>11981 - Insertion, non-biodegradable drug delivery implant<br>11983 - Removal with reinsertion, nonbiodegradable drug delivery implant<br>58300 - Insertion of intrauterine device (IUD)<br>J7301 Levonorgestrel-releasing intrauterine contraceptive system, 13.5 mg<br>J7302 Levonorgestrel-releasing intrauterine contraceptive system, 52 mg<br>S4989 Contraceptive intrauterine device, including implants and supplies<br>3. The community based practitioner is reimbursed separately for the professional service of inserting the device as well as for the device itself if supplied by the physician. Billing is done on a professional claim and paid according to a fee schedule.<br><br>4. Regular HCPCS updates to capture new device availability |
| **Montana January 2015** | Reimbursement of LARC insertion immediately postpartum in the inpatient hospital setting. | LARCs inserted at the time of delivery are excluded from the PPS inpatient APR-DRG group. Montana Medicaid is allowing PPS hospitals to unbundle the LARC device and the insertion from the inpatient delivery claim. | These services can now be billed as an outpatient service on a 13X type of bill, and will be paid at the OPPS rates. The following HCPCS/CPT codes are allowed:<br>• J7300<br>• J7301<br>• J7302 |

| State Effective Date | Payment Strategy | Policy Description | Implementation |
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| | | | • J7307<br>• 11981<br>• 58300 |
| **New Mexico 2014** | Reimbursement of LARC insertion immediately postpartum in the inpatient hospital setting. | 1. Practitioners receive reimbursement for insertion in the hospital and for the device if the practitioner supplied it.<br><br>2. Hospitals are reimbursed for the device as a medical supply company.<br><br>3. Insertion within the same surgery as a Cesarean section is considered incidental to the surgery, and therefore not reimbursed. However, the practitioner will still be reimbursed for the device. | 1. Hospitals are reimbursed for the device if:<br>• The facility is enrolled in the New Mexico Medicaid program as a medical supplier (provider type 414); a separate NPI is not required.<br>• Date of service is the same as the DRG date of service.<br>• Hospital's professional claim (837P electronic claim or CMS-1500 form) is submitted as a medical supply company.<br>• Claim includes the appropriate HCPCS procedure code and NDC number for the device.<br>• Place of service (POS) code is 21 (inpatient hospital).<br>• The billing taxonomy number for a medical supplier appears on the claim (typically 332BOOOOOX).<br><br>2. Practitioners are reimbursed for the device and insertion if:<br>• Billed on the same professional claim (837P electronic or CMS-1500 paper) as the delivery procedure.<br>• Claim indicates the device HCPCS code and NDC number. |

| State Effective Date | Payment Strategy | Policy Description | Implementation |
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| | | | • Claim indicates procedure CPT codes (most likely 58300 or 11981).<br>• Claim indicates the POS as 21 (inpatient hospital). |
| **New York April 2014** | Reimbursement of LARC insertion immediately postpartum in the inpatient hospital setting. | 1. Reimbursement provided for the LARC device and insertion during postpartum inpatient hospital stay.<br><br>2. Medicaid will reimburse for the replacement of IUDs once every five years (Skyla every three years) per manufacturer recommendations. Reimbursement will be provided for an IUD sooner than five years if medically necessary. | 1. Hospitals include the LARC invoice separately from the inpatient labor and delivery claim.<br><br>2. Physicians, midwives, and nurse practitioners may submit a separate claim to FFS Medicaid for their professional services. |

| State Effective Date | Payment Strategy | Policy Description | Implementation |
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| **South Carolina**<br>**March 2012** | Reimbursement of LARC insertion immediately postpartum in the inpatient hospital setting.<br><br>Outpatient procedure using specialty pharmacy. | 1. Allows reimbursement to the practitioner and hospital for delivery and all costs associated with LARC.<br><br>2. In the outpatient setting, practitioners may order a LARC device for delivery to the practitioner's office by a specialty pharmacy.<br><br>3. Increased LARC reimbursement rate to cover slightly more than the practitioner's cost to purchase LARC devices to stock in their office. | 1. Inpatient reimbursement guidelines for the cost of the LARC in addition to the DRG for labor and delivery:<br>• Using the HCPCS code.<br>• Using device J-codes.<br>• Using a family planning modifier on the physician claim when billing for insertion<br><br>2. Hospitals are reimbursed for the device by submitting:<br>• The ICD-9 Surgical Code<br>• The ICD-9 Diagnosis Codes<br>• A UB-04 or Institutional Claim so that a gross-level credit adjustment can be generated.<br><br>3. Payments to hospitals through FFS:<br>• DRG portion of the claim will be paid in the regular weekly claims payment cycle.<br>• The LARC reimbursement will process as a gross level credit adjustment and will appear on a future remittance advice on a monthly quarterly basis.<br><br>4. Outpatient reimbursement guidelines for the cost of the device:<br>• Device can be shipped for a specific patient overnight from specialty |

| State Effective Date | Payment Strategy | Policy Description | Implementation |
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| | | | pharmacy.<br>• Device billed directly to Medicaid FFS or the MCO.<br>• The practitioner's office has 30 days to return the unopened device to the specialty pharmacy if the device is not used for the specific patient for which it was ordered. The cost of the device is then credited back to Medicaid FFS or the MCO.<br><br>5. Reimbursement for LARC through MCO's:<br>The LARC policy is a FFS benefit; however, provision of LARC is estimated and included in the MCO's per member per month (PMPM) rate. Reimbursement methodology may differ between FFS and MCO's. The state currently includes coverage for the provision of LARCs in both its contractual language and its rate setting methodology with the MCO's.<br>MCOs in the state individually contract with providers and negotiate their rates; claim filing procedures differ based on the MCO. |
| **Texas** | Pharmacy reimbursement | 1. Texas Health and Human | 1. State currently contracts with two |

| State Effective Date | Payment Strategy | Policy Description | Implementation |
|---|---|---|---|
| **August 2014** | for LARC devices. | Services (HHS) allows providers the option to prescribe and obtain a limited number of LARC products from specialty pharmacies and to return unused and unopened LARC products through a "abandoned unit return" program.<br><br>2. Practitioners may continue to obtain LARC products, then bill for them when they are used under the medical benefit. | specialty pharmacies to deliver Mirena and Skyla to practitioners (Walgreens Specialty Pharmacy, LLC and CVS Caremark Specialty Pharmacy).<br><br>2. Practitioners continue to bill for the insertion of the LARC product.<br><br>3. If the patient was eligible for Medicaid on the date of service when the LARC product was prescribed and ordered, but the patient is no longer eligible for Medicaid, when the LARC product is inserted, Medicaid will cover the device but will not reimburse for the insertion procedure claim. |

## Detailed Payment and Policy Approaches of Three Selected States

Below is a more detailed description of the strategies used by three states (Illinois, Louisiana and South Carolina) to optimize LARC utilization and illustrate the range of approaches they have employed within existing state authorities.

The states were selected based on the range of changes they have implemented and the length of experience they have had implementing these innovative approaches. For example, the state of South Carolina was the first state to implement an immediate postpartum payment for LARC separate from the labor and delivery Diagnosis-Related Group (DRG) payment. Since establishing the policy, the state has addressed implementation challenges and seen improvement in its rates. These more detailed state examples provide greater insight for states considering which options may be most viable to address payment barriers for their Medicaid enrollees.

# Illinois

## Long-Acting Reversible Contraception (LARC) Optimization Strategies

### SUMMARY

This document describes payment strategies the Illinois Department of Healthcare and Family Services (HFS) incorporated into its Family Planning Action Plan to increase access to safe and effective LARC.

### BACKGROUND

In 2014, HFS implemented the Family Planning Action Plan to increase access to family planning services for Medicaid beneficiaries by: 1) providing comprehensive and continuous coverage for family planning services; and 2) aligning policies and reimbursement to providers to promote provision of highly effective contraception.[1]

- In 2010, 52 percent of all pregnancies (128,000) in Illinois were unintended.[2]
- Its unintended birth rate was 57 per 1,000 women aged 15-44.
- This same year, the reported public expenditures for family planning client services in Illinois totaled $57 million, of which $40.7 million was paid by Medicaid.[3]
- Illinois has the 21st highest pregnancy rate in the nation among adolescents between ages 15 and 19.

To address the rate of unintended pregnancies, the state Medicaid agency implemented several payment strategies to increase access to safe and effective LARC, such as IUDs, in an effort to reduce the number of unintended pregnancies. These strategies are: 1) increased provider reimbursement for insertion and removal of LARC in the outpatient practice setting; 2) provide reimbursement for an evaluation/management (E/M) visit on the same day as LARC insertion or removal procedures; 3) provision for reimbursement of actual LARC acquisition costs under the 340B program to Federally Qualified Health Centers and Rural Health Centers; provision for hospital reimbursement of LARC in addition to the DRG reimbursement for labor and delivery; 5) increased providers' 340B federal drug pricing program dispensing fee to encourage providers to supply LARC and other highly effective methods; and 6) established statewide Medicaid policy for family planning and reproductive health services to improve access to LARC methods.

### ILLINOIS MEDICAID REIMBURSEMENT FOR LARC

Effective July 1, 2015, HFS implemented a policy to allow hospitals to receive separate reimbursement for LARC devices provided immediately postpartum in the inpatient setting, in

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[1] Illinois Department of Healthcare and Family Services (2014). Important family planning policy change and payment increases. Retrieved from http://hfs.illinois.gov/assets/101014n1.pdf.
[2] Guttmacher Institute (2014). State facts about unintended pregnancy: Illinois. Retrieved from http://www.guttmacher.org/statecenter/unintended-pregnancy/pdf/IL.pdf .
[3] Sonfield A and Gold RB, Public Funding for Family Planning Sterilization and Abortion Services, FY 1980–2010, New York: Guttmacher Institute, 2012, < https://www.guttmacher.org/pubs/Public-Funding-FP-2010.pdf >.

addition to the DRG reimbursement for labor and delivery. Providers not employed by the hospital may bill the respective Current Procedural Terminology (CPT) code for LARC insertion in addition to the labor and delivery fee.[4]

Illinois also implemented several other payment strategies that are intended to increase access to LARC placement in the outpatient practice setting.

***Reimbursement of LARC Procedures in the Outpatient Practice Setting***

In October 2014, HFS increased the reimbursement rate for the insertion, removal, and reinsertion of IUDs and implants in the outpatient practice setting.[5] HFS increased the reimbursement rate for implant insertions by 20 percent and doubled the reimbursement rate for IUD insertions. LARC insertion and removal procedures may be reimbursed on the same day as evaluation and management visits. Physicians can receive the increased reimbursement for LARC insertion by including the LARC insertion CPT code on their billing form. Physicians can also use the relevant CPT codes to bill for the removal and reinsertion of implants, and removal of IUDS.

***Federally Qualified Health Centers (FQHC) and Rural Health Center (RHC)***

Effective October 13, 2012, FQHCs and RHCs may elect to receive reimbursement for implantable contraceptive devices. To the extent that the implantable contraceptive device was purchased under the 340B Drug Pricing Program, the FQHC or RHC must bill the actual acquisition cost for the device. Reimbursement is made at the FQHC or RHC's actual 340B acquisition cost for implantable contraceptive devices purchased through the 340B program. For implantable contraceptive devices not purchased through the 340B program, reimbursement is based on the lower of the provider's charges or the rate on the Department's practitioner fee schedule, whichever is applicable. Reimbursement for the device is separate from encounter payment for related procedures.

***Additional Dispensing Fees to Providers***

Effective July 2014, HFS increased the dispensing fee add-on payment to $35 for providers who dispense highly-effective contraceptives through the 340B federal drug pricing program. In order to receive the additional fee, providers must identify 340B purchased drugs by reporting modifier "UD" in conjunction with the appropriate procedure code and actual acquisition cost for the birth control method on the claim form.

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[4] Illinois Department of Healthcare and Family Services (2015). Informational Notice: Hospital Billing and Reimbursement for Immediate Postpartum Long-Acting Reversible Contraceptives. Retrieved from http://www.hfs.illinois.gov/html/063015n.html .

[5] Illinois Department of Healthcare and Family Services (2014). Important family planning policy change and payment increases. Retrieved from http://hfs.illinois.gov/assets/101014n1.pdf.

### *Approaches for Managed Care Entities*

The state's actuarially sound rates include reimbursement for LARC devices and clinical insertion. The state's external quality review organization (EQRO) has developed a family planning readiness review tool and reviews the plans' family planning policies and procedures. Additionally, the MCO contract was revised to include language that provider policies/protocols shall not present barriers that delay or prevent access, such as prior authorizations or step-therapy failure requirements; and that clients should receive education and counseling on all FDA-approved birth control methods from most effective to least effective, and have the option to choose the preferred birth control method that is most appropriate for them.[6]

### *Pharmaceutical Pilot Programs in Outpatient Settings*

HFS is piloting a new program with Bayer HealthCare (Mirena and Skyla) and Teva Pharmaceuticals (Paragard) to make these products available in physician offices without upfront physician costs. This will allow for an inventory of these LARC devices so that they are available when a patient returns for a postpartum visit, or at their annual reproductive health visit. If the patient decides she wants to use this type of contraception, it can be inserted immediately and the patient will not have to return for a second visit. This will improve the efficiency of this program and should lead to increased use of these devices. If deemed successful, the pharmaceutical companies plan to scale the program to a national level.[7]

## OUTCOMES

While the impact of these payment strategies have not yet been assessed, Illinois expects that improved access to contraceptive care for low-income women will result in savings due to a decrease in unintended pregnancies and the associated costs.

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[6] Wheal, L. (2015). Interview with Illinois Medicaid.

[7] Illinois Department of Healthcare and Family Services (2014). Family Planning and Reproductive Health Services. Retrieved from http://www.hfs.illinois.gov/assets/062614n1.pdf .

# Louisiana

## Long-Acting Reversible Contraception (LARC) Optimization Strategies

### SUMMARY

This document describes a payment strategy the Louisiana Medicaid agency implemented to increase access to safe and effective LARC.

### BACKGROUND

Prior to June 2014, Louisiana covered LARC devices under the pharmacy benefit. In the clinical setting, the pharmacy reimbursement rate for LARC devices was approximately $300 less than what the LARC devices cost; hence, physicians who provided LARC devices in the hospital setting suffered financial loss.[8] Furthermore, physicians were not reimbursed for 30 percent of the LARC devices ordered at the time of consent in the hospital, due to the failure of the patients for whom the device was ordered to return for subsequent insertion in the office practice setting.[9]

- In 2010, 60 percent of all pregnancies (53,000) in Louisiana were unintended.
- That same year, the reported public expenditures for family planning client services in Louisiana totaled $39.3 million; this includes $34.5 million through Medicaid.[10]

To address the high rate of unintended pregnancies, Louisiana Medicaid initiated a process to increase LARC utilization that included: 1) LARC reimbursement for insertion immediately after delivery in the inpatient hospital setting; 2) provider education; 3) adjustments in its State Plan Amendment (SPA) to allow more flexibility in inpatient and outpatient LARC reimbursement; and 4) the inclusion of LARC reimbursement requirements in its MCO contracts.

### LOUISIANA MEDICAID REIMBURSEMENT FOR LARC

Effective June 2014, the Louisiana Department of Health and Hospitals implemented a LARC reimbursement policy as a central component to reducing the number of unintended pregnancies among low-income women. This policy increases access to LARC placement in the inpatient hospital setting immediately after delivery and before the patient is discharged from the facility by:

- Allowing hospitals to receive reimbursement for the full cost of five LARC devices (Skyla, ParaGard, Nexplanon, Merina, and Norplant) in addition to the DRG that is normally paid to hospital.[11] Manufacturer wholesale prices are re-evaluated and re-adjusted annually.

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[8] Gee, R. (2014). Interview with Louisiana Medicaid Medical Director.
[9] Gee, R. (2015). Interview with Louisiana Medicaid Medical Director.
[10] Guttmacher Institute (2014). State facts about unintended pregnancy: Louisiana. Retrieved from http://www.guttmacher.org/statecenter/unintended-pregnancy/pdf/LA.pdf.
[11] Louisiana Medicaid Management Information System (2015). Louisiana Medicaid professional services fee schedule. Retrieved from http://www.lamedicaid.com/provweb1/fee_schedules/FEESCHED.pdf.

- Allowing hospitals or physicians receive additional fees for LARC insertion.
- Eliminating the use of medical management activities, such as prior authorization or step therapy, for LARC devices or procedures.[12]

***Hospital Reimbursement of LARC Insertion Immediately Postpartum***

The recent changes in Louisiana Medicaid payment policies provide reimbursement to acute care hospitals for LARC devices inserted immediately postpartum and prior to discharge.[13,14] The state is separately reimbursing the hospital both for the cost of the LARC device as well as its insertion procedure in order to clearly demonstrate to hospitals that they are fully reimbursed for LARC costs according to the Louisiana Medicaid fee schedule for durable medical equipment (DME).[15]

Louisiana MCOs have also supported and willingly adopted coverage and the reimbursement policy for postpartum LARC insertion. The hospital and the provider must submit their claims to the MCO for payment. The reimbursement rates are established by the MCO.[16]

***Practitioner Reimbursement of LARC Insertion***

Practitioners who insert a LARC device immediately post-delivery receive separate reimbursement for this service as defined in the Professional Services Program.[17] In the event that a LARC device is expelled after insertion, Louisiana factors the cost of the expulsion into the reimbursement and also pays for reinsertion of a new LARC. Adding the LARC devices to the physician schedule rather than just the pharmacy schedule allows the physician to store the device in office and not have to provide it to a specific individual.[18]

***Capitated Managed Care Implementation***

Louisiana Medicaid is completing a three year transition from a FFS reimbursement model to mandatory managed care, which will account for 95 percent of all Medicaid enrollees by December 2015. Based on retrospective data, Louisiana Medicaid negotiates blended capitated

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[12] Gee, R. (2015). Interview with Louisiana Medicaid Medical Director.
[13] Hospitals record the appropriate LARC J-code on the paper CMS1500 claim form with "DME" written in bold, black print on the top of the form when submitting their claim to the Fiscal Intermediary (FI). When the hospital bills electronically, the 837P must be used with the DME file extension. The Louisiana Medicaid DME fee Schedule J codes are only intended for use on Inpatient Claims.
[14] Foubister, V. (2013). Case study: Louisiana's poor rankings make improving birth outcomes a state imperative. Quality Matters. Retrieved from http://www.commonwealthfund.org/publications/newsletters/quality-matters/2013/february-march/case-study.
[15] Louisiana Department of Health and Hospitals (2014). Long acting reversible contraceptives (LARCs) for inpatient hospitals. Retrieved from http://dhh.louisiana.gov/assets/docs/BayouHealth/HealthPlanAdvisories/2014/HPA14-9.pdf.
[16] Gee, R. (2014). Interview with Louisiana Medicaid Medical Director.
[17] Practitioners include the LARC insertion code with the family planning modifier on their billing form (CMS 1500 or electronic equivalent). The reimbursement is dependent on the LARC service provided and the patient's age. The global CPT codes include: 11981 - Insertion, non-biodegradable drug delivery implant; and 58300 - Insertion of intrauterine device (IUD).
[18] Gee, R. (2015). Interview with Louisiana Medicaid Medical Director.

per member per month (PMPM) fees to account for projected LARC insertions. MCO contracts require hospital and practitioner reimbursement for LARC devices and procedures at a minimum of the FFS fee schedules for the same DME or CPT codes, respectively. In addition, the MCOs are not permitted to require prior authorization for LARC devices or procedures.

All five Louisiana Medicaid MCOs voluntarily adopted the LARC reimbursement strategy. The MCO contracts contain a requirement for developing birth outcomes quality improvement programs that align with the state's goals, and a one percent withhold of MCO administrative fees to fund shared savings-based pay for performance (P4P) incentives. These provide clear boundaries and predictable revenues that allow MCOs maximum flexibility in their interactions with their network providers and the incentives they offer providers and/or patients.

The Louisiana Medicaid agency achieved the legal authority to require MCOs to fully participate in LARC quality improvement efforts in four phases:

1. Applied non-payment strategies such as provider and MCO education and outreach to establish expectations for MCO performance;
2. Presented a compelling case for the political support needed to establish birth outcomes as the state's highest health priority;
3. Submitted a SPA to include LARC utilization payment policies as a strategy to improve birth outcomes; and
4. Aligned MCO contractual requirements with state Medicaid FFS payment strategies to increase LARC utilization.[19]

## ANTICIPATED OUTCOMES

Changes to reimbursement of LARC devices and procedures in the hospital were initiated in 2014. The Louisiana Medicaid Medical Director reports that due to these payment policy changes, voluntary election of LARC insertions increased from nine percent (7,000) of all child-bearing aged enrollees in 2013 to 11 percent (10,000) in 2014.

[19] Gee, R. (2015). Interview with Louisiana Medicaid Medical Director.

# South Carolina

## Long-Acting Reversible Contraception (LARC) Optimization Strategies

### SUMMARY

The South Carolina Birth Outcomes Initiative (SCBOI) launched in July 2011 to improve maternal and infant health outcomes and to reduce Medicaid costs. The SCBOI has supported the development and implementation of a LARC payment policy, which is a central component of South Carolina's effort to reduce the number of unintended pregnancies among low-income women and at-risk adolescents.

### BACKGROUND

Low-income women of childbearing age who are sexually active with limited access to effective contraception and family planning services are likely to have unintended pregnancies and increase Medicaid spending.[30]

- In 2010, public expenditures for family planning services in South Carolina totaled $33.7 million, including $25 million paid by Medicaid.[31]
- In 2011, South Carolina ranked as the 12th highest state in teen pregnancy.[32]
- Only 50% of Medicaid-covered postpartum women in South Carolina attend the postpartum visit.

To address this problem, South Carolina Department of Health and Human Services (SCDHHS) leveraged their Birth Outcome Initiative (BOI), an active collaborative of hospitals, providers, and policymakers, to increase LARC placements through changes to existing payment policies. Payment policy changes included 1) increased reimbursement for LARC devices; 2) reimbursement of LARC insertion immediately postpartum; and 3) supply management through the pharmacy benefit.

### SOUTH CAROLINA MEDICAID REIMBURSEMENT FOR LARC

The selected payment strategies are intended to increase access to LARC placement in both the inpatient hospital setting as well as the outpatient practice setting. Key elements of the reimbursement strategy include:

- Funding the full costs of four LARC devices (Skyla, ParaGard, Nexplanon, and Mirena).

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[30] Guttmacher Institute (2014). State facts about unintended pregnancy: South Carolina. Retrieved from http://www.guttmacher.org/statecenter/unintended-pregnancy/SC.html.

[31] Sonfield A and Kost K, Public Costs from Unintended Pregnancies and the Role of Public Insurance Programs in Paying for Pregnancy-Related Care: National and State Estimates for 2010, New York: Guttmacher Institute, 2015, <http://www.guttmacher.org/pubs/public-costs-of-UP-2010.pdf>,

[32] U.S. Department of Health and Human Services Office of Adolescent Health (2014). South Carolina adolescent reproductive health facts. Retrieved from http://www.hhs.gov/ash/oah/adolescent-health-topics/reproductive-health/states/sc.html#.

- Providing additional fees for insertion, device, and removal (if medically necessary) in addition to the DRG fee that is paid to hospital.
- Eliminating prior-authorization or step therapy requirements for LARC procedures.

***Reimbursement of LARC Insertion Immediately Postpartum in the Hospital***

In March 2012, the South Carolina became the first state in the country to change its reimbursement policy in order to increase LARC placement immediately after delivery and prior to hospital discharge.[33] Prior to that time, hospitals were not incentivized to perform this procedure due to the lack of payment for this activity (beyond the existing DRG payment). South Carolina's Medicaid program now reimburses hospitals the cost of the LARC device as well as payment to the physician for its insertion immediately post-delivery. This LARC reimbursement is provided in addition to any other payments for maternity related services.

Hospitals receive this increased payment through a quarterly adjustment for prior month's claims (credit adjustment). To receive reimbursement for the LARC device itself, hospitals must include on each Uniform Billing (UB-04) claim for delivery services the Healthcare Common Procedure Coding System (HCPCS) code that represents the device. As well as the International Classification of Diseases (ICD-9) Surgical and Diagnosis Codes that best describe the service delivered.

Physicians may also receive reimbursement for immediate post-delivery LARC insertion by including on their billing form (CMS 1500 or electronic equivalent) the LARC insertion code with the family planning modifier.

After the first year of implementation, South Carolina Medicaid learned that hospitals were not receiving the additional LARC payments; further implementation guidance and system changes were needed. In the second year of implementation, all Medicaid providers received specific billing instructions identifying how to capture appropriate reimbursement for all fees covered by the payment policy. By the third year of implementation, providers were receiving appropriate reimbursement, including retrospective payments that previously had not been billed or processed accurately.[34]

These new payments reimburse all costs and clinical efforts associated with LARC placement and promote a highly cost-effective, preventive health practice. However, payment alone is not sufficient to ensure LARC placements. This strategy also requires continued collaboration with MCOs, hospitals, and physicians to ensure that all stakeholders understand the purpose of these increased payments and the impact LARC will have on reducing unintended pregnancies and Medicaid costs.

***Reimbursement of LARC Insertion in the Outpatient Practice Setting***

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[33] Health Management Associates (2013). Medicaid reimbursement for immediate post-partum LARC. Retrieved from https://www.acog.org/~/media/Departments/LARC/HMAPostpartumReimbursmentResource.pdf.
[34] Giese, M. (2015). Interview with SCDHHS Director of Birth Outcomes Initiative.

SCDHHS also addressed the initial costs to providers for stocking LARC devices in its SCBOI "specialty benefit" in the spring of 2014. The new payment policy allows a physician to order a LARC device for a specific Medicaid recipient which is shipped to the physician's office by a specialty pharmacy which is designated by either the state Medicaid agency's Pharmacy Benefit Manager or by the individual MCO's. The device can be shipped overnight and is billed directly to Medicaid FFS or the MCO so that the physician does not incur the initial cost of the device. The physician's office has 30 days to insert the LARC for the specific patient for which it was ordered and bill Medicaid the insertion fee only, or to return the unopened device to the specialty pharmacy if the device is not used. The cost of the device is then credited back to Medicaid or the MCO.

***Capitated Managed Care Implementation***

Managed care enrollment is mandatory in South Carolina. As a result, approximately 90 percent of all Medicaid births are covered by the six fully capitated MCOs. Although the Medicaid agency did not require its capitated MCOs to adopt this payment policy, all six of them did so voluntarily.

In the first year of implementation of the policy, South Carolina did not develop a payment mechanism specifically for the MCOs to provide this service. Instead, the additional fees associated with LARC payments were prospectively estimated and included in the actuarially sound MCO per member per month (PMPM) rate. The MCO then provides the additional payments to the clinicians in the MCO's network through their negotiated contractual rates. It is not possible to compare the differences in LARC utilization between the MCO and FFS populations (90 percent and 10 percent, respectively).

The MCOs use their regular claims processing cycles to pay for these LARC services and don't have a special process like FFS Medicaid, which was described earlier.

## OUTCOMES

As noted above, South Carolina initiated changes to the reimbursement of LARC devices and procedures in the hospital setting in March 2012 and issued a clarification bulletin for billing in 2013 which allowed for appropriate claims payment dating back to the inception of the policy. Although the impact of both of these policy changes has not yet been fully evaluated, South Carolina has documented that their rate of voluntary election of inpatient insertions has gone from approximately 0% to 16%. South Carolina also has seen a 110% increase in inpatient LARC utilization between FY2013 through FY 2015.