



**Health Evidence Review
Commission's
Evidence-based Guideline
Subcommittee**

**September 1, 2016
1:30 PM - 4:00 PM**

**Clackamas Community College
Wilsonville Training Center, Room 111-112
29373 SW Town Center Loop E, Wilsonville, Oregon,
97070**

Section 1.0

Call to Order

AGENDA

EVIDENCE-BASED GUIDELINES SUBCOMMITTEE (EbGS)

September 1, 2016

1:30pm - 4:00pm

Clackamas Community College
Wilsonville Training Center, Rooms 111-112
29353 SW Town Center Loop E
Wilsonville, Oregon 97070

Public comment will be taken on each topic per HERC policy at the time at which that topic is discussed. Please sign-in to testify.

#	Time	Item	Presenter
1	1:30 PM	Call to Order	Wiley Chan
2	1:35 PM	Review of June 2, 2016 minutes	Wiley Chan
3	1:40 PM	Staff update	Darren Coffman
4	1:50 PM	Review public comments Timing of Long-Acting Reversible Contraceptive (LARC) Placement	Moira Ray Cat Livingston
5	2:30 PM	Review draft scope statements for topic rescan on approved Coverage Guidances approved or rescanned in 2014 <ul style="list-style-type: none"> • Prenatal Genetic Testing (staff recommendation is to retire this coverage guidance) • Planned Cesarean Birth • Routine Ultrasound in Pregnancy • Chronic Otitis Media with Effusion in Children • Nonpharmacologic Interventions for Treatment Resistant Depression • Imaging for Low Back Pain • Low Back Pain: Pharmacological and Herbal Therapies • Low Back Pain: Non-Pharmacologic Non-Invasive Interventions • Low Back Pain: Minimally Invasive and Non-corticosteroid Percutaneous Interventions • Neuroimaging for Dementia 	Valerie King Cat Livingston
6	3:45 PM	Confirmation of the next meeting, November 3, 2016	Wiley Chan
8	3:50 PM	Next Topics	Cat Livingston
9	4:00 PM	Adjournment	Wiley Chan

Note: All agenda items are subject to change and times listed are approximate

MINUTES

Evidence-based Guidelines Subcommittee

Clackamas Community College
Wilsonville Training Center, Rooms 111-112
29353 SW Town Center Loop E
Wilsonville, Oregon 97070
June 2, 2016
2:00-5:00pm

Members Present: Wiley Chan, MD, Chair; Beth Westbrook, PsyD; George Waldmann, MD; Alison Little, MD, MPH, Kim Tippens, ND, MSAOM, MPH.

Members Absent: Eric Stecker, MD, MPH, Vice-Chair

Staff Present: Darren Coffman; Cat Livingston, MD, MPH; Jason Gingerich; Daphne Peck.

Also Attending: Adam Obley, MD, Val King MD, MPH, and Craig Mosbaek (OHSU Center for Evidence-based Policy); Jamie Hewlett and Tricia Mulcahy (Osiris); John Garrettson (Lifenet Health); Valene Marmolejo and Shannon Laney (Novadaq); Maria Rodriguez, MD (OHSU); Barry Benson (Merck); Alejandro Perez, MD (Providence Health); Jessie Little (OHA), Kim Wentz MD, MPH (OHA).

1. CALL TO ORDER

Wiley Chan called the meeting of the Evidence-based Guidelines Subcommittee (EbGS) to order at 2:00 pm.

2. MINUTES REVIEW

No changes were made to the 4/7/2016 minutes.

Minutes approved 5-0

3. STAFF REPORT

Coffman reported the decision of the HERC to limit acceptance of additional information after the formal written comment period for a coverage guidance has ended. Only in unusual circumstances (“a game changer”) would additional studies be considered after the end of the formal public comment period. Waldmann asked who would make the decision whether a study met criteria for inclusion. According to the policy reviewed by HERC, staff would make this decision. Coffman said staff would keep the comment for the next 2-year review cycle. Chan asked whether staff could develop concrete criteria

to define a “game-changing” study. Gingerich reviewed the criteria proposed to HERC in May, acknowledging that it will be edited before being considered for adoption in August by HERC.

Livingston reviewed the topics of Coronary Artery Calcium Scoring and Coronary Computed Tomography Angiography. During the last rescan, HERC had requested that staff consider the need for revision based on a pending AHRQ report. The report has now been released and reviewed by staff. There is no need to update the topics based on the report, though they will undergo a full rescan later this year per the normal process.

Livingston also updated the subcommittee on HERC revisions to parts of the GRADE-informed framework. Changes include calculating both the number needed to treat (NNT) and absolute risk reduction (ARR) when possible. NNT would be reported only when there was a statistically significant effect. In addition, staff will use the word “confidence” in the effect column rather than “certainty.” There will also be a new row in the GRADE-informed framework making a statement about the balance of benefits and harms across outcomes.

4. Skin substitutes for chronic skin ulcers

Adam Obley reviewed the public comment disposition. There was no discussion of comments A1, B1, C1 or D1. For comment E1, there was discussion of whether to treat OASIS® Wound Matrix and OASIS® Ultra Tri-Layer Matrix as complete separate products, which could downgrade the evidence for diabetic foot ulcers (DFUs), as different products were used for each of the two trials. With only a single trial for each product, the evidence would be downgraded to very low quality, which could change the coverage recommendation. After brief discussion the subcommittee agreed to recommend both products for DFUs and retain its recommendation for OASIS® Wound Matrix for venous leg ulcers (VLUs). There was no discussion of comment G1-G6. On comment H, Chan asked about the reason for the low certainty. Obley explained that it was because of imprecision and only having 1 fair quality randomized controlled trial (RCT).

Livingston reviewed the changes in coverage recommendations as stated in the meeting materials, then invited public comment.

John Garretson and Valene Marmolejo from Lifenet Health gave testimony. Lifenet Health is a tissue bank that processes tissue for Dermacell. He said the company has randomized data that fulfills the requirements that staff identified. Specifically, they have a randomized controlled trial published in February 2016. He said it is a stringently done multicenter RCT. The endpoint was 100% epithelialization and no drainage. He also said it had a more realistic conventional care arm, including several other treatments. Marmolejo also presented, noting that this is intended to be a single application product and that 75 percent of patients only required a single application. Garretson said the lead investigator was the Veteran’s Administration. He said this product could help contain costs for wound care.

In response to a question from Little about why these comments hadn’t been submitted earlier, a member of the audience from Dermacell said they were just recently told by a physician that this was under consideration.

Alejandro Perez provided public comment. Perez is with Providence Health and the Columbia Wound Care Consortium, a nonprofit wound care organization. He expressed concern that one of his public comments did not get considered. Perez remarked on the Zelen 2015 article comparing Epifix vs. Apligraf vs. standard of care. He said this study met FDA criteria for a good quality study. Secondly he said that the adjudication in the Zelen study was actually blinded. In addition, the Zelen 2016 study has been updated and now has 100 patients with similar findings. He then referenced Appendix E and reported that the average number of applications used in the studies was significantly lower than the coverage limits shown in the appendix. Finally, he said Epifix and Grafix come in various sizes, while use of Apligraf results in waste as it comes in only one size. He said that some of the outcomes used for the coverage guidance including quality of life and bone infection were not the intent of these skin substitutes, and that the committee set some studies up for failure. He also said that most local wound care professionals were unaware of these discussions about the draft coverage guidance.

Staff promised to investigate the issue of Perez's comment, which was submitted outside the formal public comment period. During the meeting Gingerich stated that the comment had not been forwarded to the subcommittee as it should have. *(After the meeting, staff investigated further and found that it had been treated correctly according to policy; the comment was provided to subcommittee members, though it did not receive a response in the public comment disposition because it was submitted outside the public comment period.)* Coffman asked whether there were any comments in his email were not addressed in the public comment disposition. Perez said he believed his statement that Lavery was a randomized study had not been addressed. Obley explained that staff agreed the trial was an RCT but that it had inadequate allocation concealment and that the randomization method wasn't clear. He said that the clarification from the manufacturer addressed the concern about allocation concealment but not concern about the randomization method.

Jamie Hewlett and Tricia Mulcahy from Osiris Therapeutics provided testimony. Hewlett said there was an independent clinical effectiveness review published in January 2016 where they looked at the Lavery study stating that Grafix had positive health outcomes. She also said that NICE rated Grafix highly. She said the Lavery study was a 20-center study. She also clarified that it was an independent auditor's assessment of wound closure that was included in the study (not the treating physician's assessment). All the Medicare Administrative Contractors in the United States cover Grafix. Other payers also cover Grafix. Mulcahy also noted that Grafix comes in multiple sizes, which provides cost savings. She said that in a study of 300,000 wounds, including DFUs, VLU's and pressure ulcers, comparing the costs of Apligraf and Dermagraft to Grafix, the cost was much lower with Grafix. There is a lot of waste with Apligraf and Dermagraft. Hewlett said there is another study coming out soon and asked whether it would be acceptable.

Livingston responded that in order to delay this coverage guidance further there would need to be a "game-changing" study, as discussed earlier in the meeting. The topic will be reviewed in 2 years as a matter of regular policy. Chan requested staff look at how we notify stakeholders. Coffman said we have a process where we notify certain societies when we list a topic. We also appoint an ad hoc expert to serve as a conduit for the field. Little noted that Perez was not aware though he is with a wound society. Perez said he found out later in the process. Other subcommittee members suggested increasing staff outreach to specialty societies, while acknowledging staff has limited time for outreach.

Chan said that we may need to discuss how we evaluate small studies that are too small to clearly show an effect on continuous measures (based on lack of optimal information size). Chan asked for a summary of the criteria for recommendation for or against coverage. Obley said it came down to the

methodologic quality of the available trials and “low” versus “very low” confidence in the strength of the estimates. Tippins asked how the subcommittee could bring the issues of waste and number of applications into the discussion. Coffman said that cost is important but that would be an additional criterion after showing effectiveness.

Waldmann asked if there could be cost information provided. Little said the costs in Appendix E appeared to be for the application, not the product itself and asked Gingerich to clarify about the costs for the product. Gingerich said that costs vary by payer. The Medicare information in the appendix depends on the setting of care. Appendix E shows product and application costs for a single application of the smallest available amount of product. He said that the cost of treatment for a patient would depend on payer arrangements, wound size, how many applications would be required as well as the setting of care. He did acknowledge that a product which was effective with a single application would be attractive from a cost perspective.

Tippins expressed reservations about not recommending Graftax and Epifix after public testimony and because of the relatively small differential in number of studies between these products and those recommended for coverage. Other subcommittee members expressed understanding of her concern, but supported the lack of recommendation for products where the assessment shows only “very low” confidence in the estimates. Some expressed hope that better studies would be available at the next scheduled review in 2 years. They also discussed that the new evidence for Dermacell would not meet the criteria discussed at the May HERC meeting as a “game changer,” as there are effective alternatives for this condition. Garretson said that the product usually needs only a single application, making it different from the existing alternatives. Chan said we cannot delay the process as there are new studies coming out continually. Coffman said if the process were to be delayed it would be important to put the coverage guidance out for comment, and Livingston added that a new study might be published tomorrow for another product at that point in time. The subcommittee took a 5 minute break to allow Obley to evaluate the new Dermacell study. After the break, Livingston reported that staff evaluated the study and found it to be comparable to the other studies for this topic; it would likely receive a fair rating. However in the absence of other studies, the level of confidence in the estimate of effect would still be very low, similar to several other products not recommended for coverage. Livingston recommended moving the coverage guidance forward. After brief additional discussion, the subcommittee voted to refer the draft coverage guidance to HERC without modifications.

Motion approved 5-0.

DRAFT COVERAGE GUIDANCE

Skin substitutes for chronic venous leg ulcers and chronic diabetic foot ulcers are recommended for coverage (*weak recommendation*) when all of the following criteria are met:

1. Product is recommended for the type of ulcer being treated (see table below)
2. FDA indications and contraindications are followed, if applicable
3. Wound has adequate arterial flow (ABI > 0.7), no ongoing infection and a moist wound healing environment
4. For patients with diabetes, Hba1c level is < 12
5. Prior appropriate wound care therapy (including but not limited to appropriate offloading, multilayer compression dressings and smoking cessation counseling) has failed to result in

significant improvement (defined as at least a 50 percent reduction in ulcer surface area) of the wound over at least 30 days

6. Ulcer improves significantly over 6 weeks of treatment with skin substitutes, with continued significant improvement every 6 weeks required for coverage of ongoing applications
7. Patients is able to adhere to the treatment plan

The following products are recommended/not recommended for coverage as shown below. All recommendations are weak recommendations except as specified.

Product	Diabetic foot ulcers	Venous leg ulcers
Dermagraft®	Recommended	Not recommended
Apligraf®	Recommended	Recommended
OASIS® (Wound Matrix and Ultra Tri-Layer Matrix)	Recommended	Recommended (OASIS® Wound Matrix only)
EpiFix®	Not recommended	Not recommended
Grafix®	Not recommended	Not recommended
Graftjacket®	Not recommended	Not recommended
Omnigraft®	Not recommended	Not recommended
Talymed®	Not recommended	Not recommended
TheraSkin®	Not recommended	Not recommended
Other skin substitutes	Not recommended	Not recommended

The use of skin substitutes is not recommended for coverage of chronic skin ulcers other than venous leg ulcers and diabetic foot ulcers (e.g., pressure ulcers) (*weak recommendation*).

5. Tobacco Cessation During Pregnancy

Obley reviewed the changes to the GRADE table, including the new formatting and the new balance of benefit and harm columns. He also reviewed the single public comment regarding high feedback ultrasound. Coffman introduced Charles Bentz, who is serving as ad hoc expert for this topic.

The subcommittee discussed the lack of a recommendation for pharmacotherapy, given the fact that the evidence does not support a health benefit from this intervention, though there is evidence it increases tobacco abstinence during pregnancy if all studies (randomized and non-randomized) are included. Livingston clarified that usually remaining silent on a recommendation is not preferred. However, in this case, federal law supercedes a coverage recommendation.

Given the lack of recommendation, Chan suggested adding language describing the evidence to the box. Westbrook asked to qualify that the evidence is insufficient only in pregnant women. Bentz said there are other important outcomes which weren't selected by the HERC for this coverage guidance, including

environmental outcomes. He also noted that there is unlikely to be additional evidence in this population due to ethical concerns and that he believes that pharmacotherapy along with behavioral interventions would show a clear benefit. He also raised concerns that hospitals offering nicotine replacement therapy (NRT) in a laboring woman could be adversely impacted by a non recommendation.

The subcommittee reworded the paragraph on pharmacotherapy to clarify that the evidence of the effectiveness of pharmacotherapy for critical outcomes is insufficient. They also discussed alternate language proposed by Dr. Stecker prior to the meeting.

Bentz asked to clarify that NRT would continue to be covered despite the lack of recommendation. Gingerich confirmed that Federal Law requires this coverage for pregnant women on Medicaid.

After brief additional discussion, the subcommittee voted to refer the draft coverage guidance to HERC as revised.

Motion approved 5-0.

HERC DRAFT Coverage Guidance

For women who use tobacco during pregnancy, the following interventions to aid in tobacco cessation are recommended for coverage:

- Behavioral interventions (*strong recommendation*)
- Financial incentives (contingent) (*weak recommendation*)
- Prenatal ultrasound with high feedback around smoking impacts on the fetus (*weak recommendation*)

The following interventions are not recommended for coverage:

- Electronic nicotine delivery systems (*strong recommendation*)
- Counseling-based interventions to reduce secondhand smoke exposure (*weak recommendation*)
- Partner support for smoking cessation (*weak recommendation*)

Federal law requires coverage of tobacco cessation services, including FDA-approved pharmacotherapy, for pregnant women. There is insufficient evidence of effectiveness of pharmacotherapy on critical outcomes. Therefore, there is no coverage recommendation on pharmacotherapy for smoking cessation in pregnant women.

5. Timing of Long-Acting Reversible Contraceptive Placement

Coffman introduced Maria Rodriguez, appointed as ad hoc expert for this topic. King reviewed the changes to the draft coverage guidance made since the last meeting and the new ways of presenting the estimates of effect as discussed earlier.

The subcommittee discussed the issue of differential loss to followup in the trials. King said that there was a high loss to followup in these trials, and that it was higher in the group randomized to delayed insertion. With those women, one would not know whether they got pregnant or had complications. In the immediate group, those most likely to follow up would have been those who had expulsions or complications. In one study, 13 of 14 unintended pregnancies occurred in the delayed placement arm. Chan raised the issue that the bias could run in the opposite direction. There was an extensive methodological discussion as to whether this differential lost to followup would overestimate or underestimate the effectiveness of these methods. Rodriguez said the loss to followup is exactly what one is trying to prevent with immediate implant placement. King clarified it was not a classic as-treated analysis.

Livingston reviewed the cover letter staff drafted to accompany the coverage guidance as well as the new guidance from the Centers for Medicare and Medicaid Services (CMS) which were included in the meeting materials. The CMS guidance will be included as an appendix to the coverage guidance and the cover letter will be posted on the HERC website during the public comment period, but not as a part of what the public is invited to comment on.

Livingston asked whether anything was lacking from the bulleted list in the letter. Rodriguez said there also can be barriers within a hospital or health system which can create implementation issues. She said there is lack of awareness of availability, safety and effectiveness among patients, staff and physicians. After discussion the subcommittee added a new bullet "Lack of health system support for the uptake of policies and procedures supporting the immediate placement of LARC" to the list of barriers.

Waldmann suggested forming a workgroup to deal with the complexities of implementation. Coffman said he had heard discussion of a learning collaborative, perhaps when this coverage guidance is implemented in January. Rodriguez said OHSU is working on a packet to provide implementation information at the hospital level. King said that in South Carolina they did very extensive training in hospitals and in outpatient facilities.

The subcommittee voted to ask staff to post the draft coverage guidance for comment as revised, and to separately post the cover letter.

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*).

Motion approved 5-0.

6. ADJOURNMENT

Livingston discussed next topics. Digital Breast Tomosynthesis (3D Mammography) for Breast Cancer Screening in Average Risk Women was up next, but may go to HTAS as HTAS will be looking at Breast

Cancer Screening in Women at Above-Average Risk. If that happens, the next EbGS topic will be Genetic Tests for Selection of Antidepressant Therapy.

The meeting was adjourned at 5:00 pm. The next meeting is scheduled for 9/1/2016 from 2:00-5:00 pm at Clackamas Community College, Wilsonville Training Center, Rooms 111-112, 29353 SW Town Center Loop E, Wilsonville, Oregon 97070.

DRAFT

Section 2.0

Coverage Guidances

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

DRAFT for EbGS meeting materials 9/1/2016

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/ Confidence in Estimate
<p>Unintended Pregnancy (Critical outcome)</p>	<p><u>Postabortion IUD (intention to treat at 6 months):</u> 3/406 (0.74%) for immediate IUD vs. 11/472 (2.3%) for delayed IUD ARD 1.59% RR 0.37 (95% CI 0.12-1.14) ●●●○ (Moderate confidence, based on 3 RCTs, N=878 women)</p> <p><u>Postpartum IUD:</u> 0/85 for immediate IUD vs. 0/85 for delayed IUD The identified systematic review of RCTs did not provide aggregate data on unintended pregnancy. No repeat pregnancies were reported in the 2 included RCTs providing pregnancy outcome data. ●●○○ (Low confidence because no unintended pregnancies were observed, based on 2 RCTs, N=192170)</p> <p><u>Implants:</u> No systematic reviews or RCTs were identified addressing immediate postpartum or postabortion implant use and unintended pregnancy.</p>

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

<p>Need for alternate or replacement contraception (e.g., expulsion of IUD, elective, indicated removal of device) <i>(Important outcome)</i></p>	<p><u>Postabortion IUD Expulsion at 6 months:</u> 18/406 (4.4%) for immediate IUD vs. 8/472 (1.7%) for delayed insertion ARD=2.74% NNH=37: For 1000 patients treated, 27 more experience expulsion RR 2.64 (95% CI 1.16-6.0) ●●●○ <i>(Moderate confidence, based on 3 RCTs, N=878)</i></p> <p><u>Postabortion IUD Removal:</u> 20/362 (5.5%) for immediate IUD vs. 12/428 (2.8%) for delayed IUD ARD 2.72% RR 2.01 (95% CI 0.99-4.06) ●●●○ <i>(Moderate confidence, based on 2 RCTs, N=790)</i></p> <p><u>Postpartum IUD Expulsion by 6 months:</u> 19/113 (16.8%) for immediate IUD vs. 3/97 (3.1%) for delayed insertion ARD=13.7% NNH=8: For 1000 patients treated, 125 more experience expulsion OR 4.89 (95% CI 1.47-16.32) ●●●○ <i>(Moderate confidence, based on 4 RCTs, N=210)</i></p> <p><u>Postpartum IUD Replacement:</u> 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. ●○○○ <i>(Very low confidence, based on one fair quality RCT, N=112)</i></p> <p><u>Implants:</u> No systematic reviews or RCTs were identified addressing implants and need for alternate/replacement contraception.</p>
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Outcomes	Estimate of Effect for Outcome/ Confidence in Estimate
Harms (Important outcome)	<p><i>Important harms specific to IUD insertion include uterine perforations and infections.</i></p> <p><u>Postabortion IUD Perforation:</u> 0/258 for immediate IUD vs. 0/317 for delayed IUD.</p> <p>No uterine perforations were observed in women randomized to immediate or delayed IUD insertion following first trimester abortion. ●○○○ (Very low confidence, based on no observed perforations in 1 fair quality RCT, N=575)</p> <p><u>Postabortion IUD infection:</u> (Rates of upper genital tract infections). 5/406 (1.2%) for immediate IUD vs. 6/472 (1.3%) for delayed insertion ARD=0.04% OR 1.0 (95% CI 0.32-3.14) ●●●○ (Moderate confidence, based on 3 RCTs, N=878)</p> <p><u>Postpartum IUD infections:</u> Rates 2/120 (1.6%) for immediate IUD vs. 2/123 (1.6%) for delayed IUD. <u>Reports</u> of upper genital tract infections were rare in both groups (no statistical analysis provided). ●○○○ (Very low confidence, based on 2 case reports 4 cases reported in 4 RCTs, N=243)</p> <p><u>Implants:</u> No systematic reviews or RCTs were identified addressing implants and harms.</p>

Balance of benefits and harms:

Although there is insufficient data to show a reduced risk of unintended pregnancy from immediate placement, IUDs are among the most effective forms of contraception. 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 postabortion IUD placement may be a result of differential loss to follow-up among the immediate and delayed study arms and the small study sizes relative to the rare occurrence of selected outcomes. The only “harm” shown by this evidence is an 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, more than 70% select a LARC method, including teens. When women select their preferred contraceptive method, continuation rates across all methods are higher. Evidence about women’s preferences for timing of LARC placement is not available, but low dropout rates in the immediate placement arms of the trials examined here suggest it is an acceptable option for most women choosing an IUD. 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:

Missed opportunities for contraception are significant in the postpartum and postabortion periods: 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. [Uninsured women, including those who are no longer covered under the Citizen Alien Waived Emergent Medical \(CAWEM\) program, may have additional access and financial barriers to obtaining contraception at a future visit. Uninsured women may also struggle to obtain important follow-up care including continued contraceptive management and/or device removal.](#)

[Ensuring that women are able to make a free, uncoerced, and informed choice about contraception is important.](#)

Rationale: Although there is strong evidence that LARC use reduces unintended pregnancies and abortions, there is not direct randomized evidence [comparing the timing](#) 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.

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. Although 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 from 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, there is no RCT evidence about differences in pregnancy outcomes based on immediate versus delayed implant placement, but the CDC recommends the use of implants immediately postabortion and postpartum, and the disadvantages associated with an increased risk of an IUD expulsion do not exist for implants.

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

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 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. 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 to 34 opting for a LARC device (Branum & Jones, 2015). Increasing LARC use, even by as much as 10% for women aged 20 to 29, is estimated to save nearly \$288 million per year in the U.S. in total costs related to unintended pregnancy (Trussell et al., 2013).

[Providing immediate postpartum LARC may also address short interpregnancy intervals, commonly defined as a birth occurring eighteen or fewer months following a live birth. A short interpregnancy interval is common \(33% of births in the U.S.\) and is associated with preterm birth, premature rupture of membranes, low birth weight, and small for gestational age infants \(Bigelow & Bryant, 2015\).](#)

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 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 (75%) opted for LARC devices, 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 to 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 in a three-year period, with users of non-LARC methods three times more likely to discontinue their initial method in 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 a 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% 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 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 more than 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 a randomized controlled trial (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%) because 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 immediate provision, whereas 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, which is consistent 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 (52mg LNG-IUS) approved for five 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, and 80% of women were continuing use 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, currently it is approved for only three years of continuous use (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 three years. The device is smaller than the Mirena® (28x30mm vs. 32x32mm), comes with a smaller diameter device inserter (3.8mm vs. 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 in a 10 year-period. After the first year of use, 78% of women continue 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 10cm 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

LARC 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) publishes 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. LARC is suitable 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 in which any intrauterine system (copper or levonorgestrel) would pose an unacceptable health risk or the risk outweighs benefits (category 4 or 3 on the MEC, respectively) are rare. Appendix E provides links to the MEC with additional information.

Hormonal Implant

The MEC categorizes the implant as safe (category 1 or 2) for nearly all conditions. Theoretical or proven risks outweigh the many benefits (category 3) only in rare circumstances. Appendix E provides links to the MEC with additional and more specific information on 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	No. and Type of Included Studies	Population	Outcomes of Interest
Total N			
Okusanya et al. (2014) 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	<u>Principal</u> : accidental pregnancy, spontaneous expulsion, uterine perforation, upper genital tract infection Follow-up time: 6 months

Systematic Review Total N	No. and Type of Included Studies	Population	Outcomes of Interest
Lopez et al. (2015) N=263	4 RCTs	Postpartum women of any age	<u>Primary</u> : successful placement (insertion), subsequent expulsion, method use at study assessment <u>Secondary</u> : 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 more than 10 years earlier. A total of five trials investigated immediate versus delayed insertion of IUDs (at a separate visit); however, two were not included in the meta-analysis because one was a conference abstract and the other used an IUD no longer available and was published many years earlier. Trials limited participants’ IUD options.

[Nearly all women randomized to immediate placement received an IUD. Attendance at follow-up visits for the delayed arm ranged from 33% to 70%, with nearly all the women who did attend the visit](#)

[ultimately having an IUD placed. In the immediate arm, 61-75% of women attended follow-up visits. Both arms experienced follow-up rates higher than those observed in real-world settings.](#)

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 four offered the CuT380A IUD. Timing included post-vaginal birth (three studies), post-cesarean delivery (two studies), or both (two studies).

[Ultimately, four studies \(two post-vaginal, two post-cesarean\) were included in the meta-analysis. Nearly all women \(95-100%\) randomized to immediate placement received an IUD, and 53-93% in the delayed arm ultimately received an IUD. Follow-up rates for the included studies ranged from 85% to 100% in the immediate arm, 81% to 94% in the delayed arm. Observed follow-up rates in both groups were higher than current real-world reports.](#)

Levi (2015)

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

[In the immediate insertion arm, 94% received an IUD compared to 61% in the delayed arm. Follow-up rates were high in both groups \(96% in immediate arm, 89% in delayed arm\).](#)

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 to 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 six 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 more than 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 six months because the 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 six 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, and 71% of those randomized to delayed insertion received an IUD. This represented all of the women who returned for a delayed insertion visit. At six 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 versus delayed post-cesarean placement, of the 42 women who 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 a third of those randomized were 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 and 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 thus could not have had one removed. For example, in the largest trial (which accounts for more than 90% of the overall pooled estimate), for women who 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 participants' selection of an alternate contraceptive method. 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, and she did not opt for

replacement. No statistical analysis was provided. Five women subsequently had their IUDs 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 whose strings were not visualized at the six-week postpartum evaluation, although 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, in terms of total annual costs, LARC devices 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 women enrolled in 340b pharmacy programs (OHA, 2015), reduced rates for bulk purchases, and 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 at a rate lower than provider costs (or do not reimburse in an inpatient setting), there is a disincentive for providers to use LARC devices. Furthermore, the high initial cost of the devices creates a barrier to facilities having stock on hand, thus preventing same-day insertions when patients choose LARC devices. Same-day insertion is a best practice (see Address Device Costs section below).

Loss of Insurance Coverage

[The April 2016 Center for Medicaid and CHIP services bulletin, *State Medicaid Approaches to Improve Access to LARC*, acknowledges provider hesitation to insert LARC devices when women do not have continued coverage “in the event there is later need for removal.” This is particularly relevant for women with Citizen Alien Waived Emergent Medical \(CAWEM\) coverage who lose their insurance shortly after delivery, but also applies to women at risk for interruptions in insurance coverage.](#)

Provider Barriers

Providers may not understand current patient eligibility criteria for LARC devices, may 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 that they need to have previously delivered a child, be older, or have failed another contraceptive method to be eligible for LARC. Women may believe that 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 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 17 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) 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 upfront 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 providers who are unable to keep stock on hand. These contracts can 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 more than 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.

Provider training

[Placement and related care for IUDs and other LARC devices involves training on insertions, removals, and side-effect management. Providers seeking this skill-set need access to training resources.](#)

[Additional training for immediate postpartum or post-cesarean is also available. Online CME resources for immediate postpartum insertion include a University of Washington CME course \(available at <http://www.cardeaservices.org/resourcecenter/inserting-long-acting-reversible-contraception-larc-immediately-after-childbirth>\).](#)

[In October 2015, Health Share sponsored a LARC training event provided by the Bixby Center at the University of California, San Francisco. The all-day, no-cost training included didactics, counseling skills, and hands-on insertion practice, and provided continuing education credits for physicians, nurses, midwives, and social workers. The event was open to all providers, not just those serving Medicaid enrollees.](#)

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. [by expanding access. Champions for LARC focus on the education of providers to meet patient demand for LARC devices.](#) 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 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 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 can 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 that coding and billing systems capture the 90% enhanced federal Medicaid match for family planning services and 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.

Ensure Availability of Appropriate Aftercare for Uninsured Women

[LARC devices may remain in place for 3 to 10 years after insertion. During this time period, women may lose or change insurance providers, and it is important to consider the availability of appropriate aftercare, including treatment for complications and device removal, even if women using LARC devices later lose their insurance coverage. In the absence of public policy changes ensuring the coverage of LARC-related care for uninsured women, one solution is to equip safety-net providers and clinics with education on LARC, including insertion, side-effect management, and removal skills. This may increase access for uninsured women needing follow-up related to the LARC device. Providing information to women at risk of insurance loss \(e.g., CAWEM\) with resources for follow-up care may also be useful.](#)

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 in the first year in direct medical costs alone and \$810 in a five-year period. With the addition of public health insurance and social program costs, the savings increases to \$1956 in one year and \$4,296 in a five-year period. Providing immediate postabortion IUDs to 1,000 women will avoid

more than 400 pregnancies, 180 deliveries, and 160 abortions in a five-year period. In sensitivity models, planned follow-up placement was estimated to have greater savings only when expulsion rates reached greater than 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 in a 2-year period, 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. Although there is a higher expulsion rate after 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 more than \$10,000 for the intervention to no longer be cost-saving. Similar to estimates from Salcedo and colleagues, expulsion rates needed to reach more than 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-\$1,210.77) 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 six-weeks postpartum in the subsequent year. Although 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 one year limits the validity of cost-effectiveness estimates because 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 the 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 within 6, 12, 24, and 36 months of a theoretical, publicly funded immediate postpartum implant program provided to 1,000 women (compared to a hypothetical cohort of 1,000 women not receiving an implant). Although costs were greater at six 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). Although 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 (Bednarek 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 that for every 1,000 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 their ability to achieve 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, more than 70% will select a LARC method, including teens, and the majority of women continue 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 for 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, along with 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 (Ricketts 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 that 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.

[The Selected Practice Recommendations for Contraceptive Use recommends that providers ensure that women make a “voluntary, informed choice” for their preferred contraceptive method \(CDC, 2013\). Ensuring that women have a free, uncoerced decision is an essential component of contraceptive counseling.](#)

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:

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 describes efforts in Illinois, Louisiana, and South Carolina to expand LARC access, including efforts through managed care contracting and quality improvement work. The full bulletin is 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. States with a coverage policy often reported "clear cost savings" and a "common sense" approach to covering immediate postpartum insertion, whereas 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).

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

[The American Academy of Family Physicians \(AAFP\) supports the provision of LARC as a first-line contraceptive method and supports reimbursing for postpartum placement in hospitals, separate from the global delivery fee \(AAFP, 2016\).](#)

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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/outcome¹

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.

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

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 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.

DRAFT

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							
<i>Postabortal IUD</i>							
3	RCTs	Moderate	<u>Not</u> 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 ●●●○
<i>Presence of LARC at six months</i>							
<i>Postabortion IUD</i>							
3	RCTs	Moderate	Not serious	Not serious	Not serious	None	Moderate quality ●●●○
<i>Postpartum IUD</i>							
4	RCTs	Moderate	Not serious	Not serious	Not serious	None	Moderate quality ●●●○
Need for alternate/Replacement contraception							
<i>Postabortal IUD (based on removal or expulsion by 6 months)</i>							
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 quality ●●●○
Harms							
Postabortion IUD (based on upper genital tract infection only)							
3	RCTs	Moderate	Not serious	Serious	Not serious	None	Low quality ●●○○

DRAFT

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.

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 (<i>includes implantable subdermal contraception insertion, removal, and surveillance</i>)
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	<i>Levonorgestrel-releasing intrauterine contraceptive system, 52mg (discontinued 12/31/2015 replaced with J7297 or J7298 as appropriate)</i>
J7307	Etonogestrel (contraceptive) implant system, including implant and supplies (Nexplanon®)

Note: Inclusion on this list does not guarantee coverage

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.

<http://www.cardeaservices.org/resourcecenter/inserting-long-acting-reversible-contraception-larc-immediately-after-childbirth>

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

DRAFT

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.

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 Effective Date	Payment Strategy	Policy Description	Implementation
<p>Alabama April 2014</p>	<p>Reimbursement of LARC insertion immediately postpartum in the inpatient hospital setting or outpatient practice setting.</p>	<p>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.</p> <p>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.</p>	<p>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.</p> <p>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):</p> <ul style="list-style-type: none"> • 58300 Insertion of IUD • 11981-FP Insertion, non-biodegradable drug delivery implant • 11983-FP Removal with reinsertion <p>ICD-9 diagnosis codes:</p> <ul style="list-style-type: none"> • V255 Encounter for contraceptive management, insertion of implantable

State Effective Date	Payment Strategy	Policy Description	Implementation
			subdermal contraceptive <ul style="list-style-type: none"> • V2511 Insertion of intrauterine contraceptive device • V2502 Initiate contraceptive NEC • V251 Insertion of IUD Physician bill on CMS 1500 form using the same coding as above and also indicate Place of Service: <ul style="list-style-type: none"> • 21 Inpatient hospital setting • 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: <ul style="list-style-type: none"> • J7300 • J7301 • J7302 • 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: <ul style="list-style-type: none"> • 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. 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
	<p>Reimbursements for LARCs outside of the normal encounter (per visit) rate for Rural Health Centers (RHCs)</p>	<p>obstetric fee code.</p> <ul style="list-style-type: none"> • State will cover two LARC devices every five years. <p>RHCs may receive reimbursement for IUDs and implants used for contraceptive purposes in addition to their normal encounter rate reimbursements.</p> <p>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.</p>	<ul style="list-style-type: none"> • V25.11 – encounter for insertion of intrauterine contraceptive device; and/or • V25.13 – encounter for removal and reinsertion of intrauterine contraceptive device. <ol style="list-style-type: none"> 1. For devices purchased under the 340B Program, individual providers and RHCs must bill the actual acquisition cost for the device. 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. 3. Reimbursement is separate from any encounter payment the RHC may receive for implanting the device. 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
<p>Georgia April 2014 for practitioner reimbursement;</p> <p>Hospital reimbursement to begin in 2016</p>	<p>Reimbursement of LARC insertion immediately postpartum in the inpatient hospital setting.</p>	<ol style="list-style-type: none"> 1. Reimburses hospitals and practitioners the cost of the LARC device outside of the global obstetric fee for delivery. 2. Georgia policy, regardless of delivery system (FFS or Managed Care Organization (MCO)) defines “immediate postpartum” as within ten minutes of birth. 3. Devices should be available in the birthing suite to ensure timely insertion. 	<ol style="list-style-type: none"> 1. LARC insertion is considered an add-on benefit and is not included in the DRG reimbursement process. 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: <ul style="list-style-type: none"> • J7300 • J7301 • J7302 • J7307
<p><u>Illinois</u> October 2012</p> <p>July 2014</p>	<p>Contraceptive Devices in FQHCs and RHCs</p> <p>Dispensing Fee Incentive</p>	<p>FQHCs and RHCs may receive reimbursement for LARC devices (IUDs and single rod implantable devices) for contraceptive purposes.</p> <p>340B providers may receive a dispensing fee add-on when dispensing highly-effective contraceptives</p>	<ol style="list-style-type: none"> 1. For devices purchased under the 340B Program, the FQHC or RHC must bill the actual acquisition cost for the device. 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
<p>October 2014</p>	<p>Increased reimbursement for insertion and removal of LARC in the outpatient setting.</p> <p>Allowed reimbursement for office visit along with LARC insertion/removal procedure on the same day.</p> <p>Outpatient provider office stocking.</p>	<p>1. Increased reimbursement rate for insertion/removal procedures of LARC.</p> <p>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.</p> <p>3. Pilot program to ensure practitioners have sufficient devices stocked, with automatic re-supply as needed.</p>	<p>3. Reimbursement is separate from any encounter payment the FQHC or RHC may receive for implanting the device.</p> <p>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:</p> <ul style="list-style-type: none"> • Postpartum visit (CPT 59430) • Initial or annual preventive visit (CPT 99381-99397) <p>2. A practitioner must order the device and document the insertion procedure in both the hospital's and the practitioner's medical record:</p> <p>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.</p> <p>The hospital must use the appropriate family planning ICD-9-CM diagnosis code (or upon implementation, ICD-10-CM) on the claim.</p>
<p>July 1, 2015</p>	<p>Reimbursement of LARC insertion immediately postpartum in the inpatient setting.</p>	<p>Medicaid allows hospitals separate reimbursement for the LARC device provided immediately postpartum in the inpatient hospital setting.</p>	
<p>Iowa March 2014</p>	<p>Reimbursement of LARC insertion immediately</p>	<p>1. Medicaid allows the insertion of IUDs and other LARC devices</p>	<p>1. Practitioners may bill for the professional service associated with insertion of the</p>

State Effective Date	Payment Strategy	Policy Description	Implementation
	postpartum in the hospital setting.	<p>before the beneficiary leaves the hospital following delivery.</p> <p>2. Payment for these services is allowed for both practitioners and hospitals.</p>	<p>LARC with the appropriate CPT code.</p> <p>2. If a practitioner supplies the LARC, the practitioner may also bill for the device(s).</p> <p>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.</p>
<p><u>Louisiana</u> June 2014</p>	<p>Reimbursement of LARC insertion immediately postpartum in the inpatient hospital setting.</p>	<p>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.</p> <p>2. Reimbursement amount is determined by:</p> <ul style="list-style-type: none"> • LARC service provided (insertion or reinsertion) • IUD or non-biodegradable drug delivery implant • The beneficiary’s age (0 – 15 years or 16+ years) <p>3. Medical management, including prior authorization and step</p>	<p>1. In FFS: Hospitals use the appropriate LARC J-code on their hospital stay claim.</p> <ul style="list-style-type: none"> • On a paper claim (CMS 1500) “DME” must be written in bold, black print on the top of the form. • If the hospital bills electronically, the 837P must be used with the Durable Medical Equipment (DME) file extension. <p>2. Payment for the LARC is equal to the DME fee schedule, and added to the amount of the hospital’s per diem payment.</p> <p>3. If a LARC device is expelled after insertion, the state applies a pre-determined cost of reinsertion and replacement device to the standard DRG or professional services rates.</p> <p>4. MCO contracts with the state prohibit</p>

State Effective Date	Payment Strategy	Policy Description	Implementation
	<p>departments or family planning agencies.</p>	<p>into the hospital’s provider base rate calculation.</p> <p>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.</p> <p>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.</p>	<p>2. Family planning agencies that participate in MassHealth are reimbursed for the LARC device and insertion when billed with the appropriate code:</p> <p>11981 - Insertion, non-biodegradable drug delivery implant 11983 - Removal with reinsertion, nonbiodegradable drug delivery implant 58300 - Insertion of intrauterine device (IUD) J7301 Levonorgestrel-releasing intrauterine contraceptive system, 13.5 mg J7302 Levonorgestrel-releasing intrauterine contraceptive system, 52 mg S4989 Contraceptive intrauterine device, including implants and supplies</p> <p>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.</p> <p>4. Regular HCPCS updates to capture new device availability</p>
<p>Montana January 2015</p>	<p>Reimbursement of LARC insertion immediately postpartum in the inpatient hospital setting.</p>	<p>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.</p>	<p>These services can now be billed as an outpatient service on a 13X type of bill, and will be paid at the OPSS rates. The following HCPCS/CPT codes are allowed:</p> <ul style="list-style-type: none"> • J7300 • J7301 • J7302

State Effective Date	Payment Strategy	Policy Description	Implementation
			<ul style="list-style-type: none"> • J7307 • 11981 • 58300
<p>New Mexico 2014</p>	<p>Reimbursement of LARC insertion immediately postpartum in the inpatient hospital setting.</p>	<p>1. Practitioners receive reimbursement for insertion in the hospital and for the device if the practitioner supplied it.</p> <p>2. Hospitals are reimbursed for the device as a medical supply company.</p> <p>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.</p>	<p>1. Hospitals are reimbursed for the device if:</p> <ul style="list-style-type: none"> • The facility is enrolled in the New Mexico Medicaid program as a medical supplier (provider type 414); a separate NPI is not required. • Date of service is the same as the DRG date of service. • Hospital’s professional claim (837P electronic claim or CMS-1500 form) is submitted as a medical supply company. • Claim includes the appropriate HCPCS procedure code and NDC number for the device. • Place of service (POS) code is 21 (inpatient hospital). • The billing taxonomy number for a medical supplier appears on the claim (typically 332B00000X). <p>2. Practitioners are reimbursed for the device and insertion if:</p> <ul style="list-style-type: none"> • Billed on the same professional claim (837P electronic or CMS-1500 paper) as the delivery procedure. • Claim indicates the device HCPCS code and NDC number.

State Effective Date	Payment Strategy	Policy Description	Implementation
			<ul style="list-style-type: none"> • Claim indicates procedure CPT codes (most likely 58300 or 11981). • Claim indicates the POS as 21 (inpatient hospital).
<p>New York April 2014</p>	<p>Reimbursement of LARC insertion immediately postpartum in the inpatient hospital setting.</p>	<ol style="list-style-type: none"> 1. Reimbursement provided for the LARC device and insertion during postpartum inpatient hospital stay. 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. 	<ol style="list-style-type: none"> 1. Hospitals include the LARC invoice separately from the inpatient labor and delivery claim. 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
<p><u>South Carolina</u> March 2012</p>	<p>Reimbursement of LARC insertion immediately postpartum in the inpatient hospital setting.</p> <p>Outpatient procedure using specialty pharmacy.</p>	<p>1. Allows reimbursement to the practitioner and hospital for delivery and all costs associated with LARC.</p> <p>2. In the outpatient setting, practitioners may order a LARC device for delivery to the practitioner’s office by a specialty pharmacy.</p> <p>3. Increased LARC reimbursement rate to cover slightly more than the practitioner’s cost to purchase LARC devices to stock in their office.</p>	<p>1. Inpatient reimbursement guidelines for the cost of the LARC in addition to the DRG for labor and delivery:</p> <ul style="list-style-type: none"> • Using the HCPCS code. • Using device J-codes. • Using a family planning modifier on the physician claim when billing for insertion <p>2. Hospitals are reimbursed for the device by submitting:</p> <ul style="list-style-type: none"> • The ICD-9 Surgical Code • The ICD-9 Diagnosis Codes • A UB-04 or Institutional Claim so that a gross-level credit adjustment can be generated. <p>3. Payments to hospitals through FFS:</p> <ul style="list-style-type: none"> • DRG portion of the claim will be paid in the regular weekly claims payment cycle. • The LARC reimbursement will process as a gross level credit adjustment and will appear on a future remittance advice on a monthly quarterly basis. <p>4. Outpatient reimbursement guidelines for the cost of the device:</p> <ul style="list-style-type: none"> • Device can be shipped for a specific patient overnight from specialty

State Effective Date	Payment Strategy	Policy Description	Implementation
			<p>pharmacy.</p> <ul style="list-style-type: none"> • Device billed directly to Medicaid FFS or the MCO. • 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. <p>5. Reimbursement for LARC through MCO’s: 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. MCOs in the state individually contract with providers and negotiate their rates; claim filing procedures differ based on the MCO.</p>
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.	<p>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.</p> <p>2. Practitioners may continue to obtain LARC products, then bill for them when they are used under the medical benefit.</p>	<p>specialty pharmacies to deliver Mirena and Skyla to practitioners (Walgreens Specialty Pharmacy, LLC and CVS Caremark Specialty Pharmacy).</p> <p>2. Practitioners continue to bill for the insertion of the LARC product.</p> <p>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.</p>

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

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.

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.

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.

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

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).

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

³³ Health Management Associates (2013). Medicaid reimbursement for immediate post-partum LARC. Retrieved from <https://www.acog.org/~media/Departments/LARC/HMAPostpartumReimbursementResource.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.

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Discussion Table

IDs/#s	Summary of Issue	Subcommittee response

Commenters

Identification	Stakeholder
A	Rita Sharshiner, MD <i>[Submitted June 7, 2016]</i>
B	Jill M. Zurawski, MD <i>[Submitted June 8, 2016]</i>
C	Mary Knox, MD <i>[Submitted June 13, 2016]</i>
D	Olivia Kroening-Roche, CNM, WHNP-BC, MS <i>[Submitted June 14, 2016]</i>
E	Kimberly Suriano, MD <i>[Submitted June 15, 2016]</i>
F	Gary Burgoine, MD <i>[Submitted June 15, 2016]</i>
G	OHSU Section of Family Planning <i>[Submitted June 21, 2016]</i>
H	Ruth Dallas, RN <i>[Submitted June 23, 2016]</i>
I	Monica M. Arce, CNM <i>[Submitted June 23, 2016]</i>
J	Suniti Kumar, MD <i>[Submitted June 23, 2016]</i>

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K	Loly Aguilar [Submitted June 23, 2016]
L	Geoffrey Carden, MD [Submitted June 24, 2016]
M	Oregon Academy of Family Physicians [Submitted June 24, 2016]
N	Oregon Foundation for Reproductive Health [Submitted June 27, 2016]
O	Oregon Perinatal Collaborative [Submitted June 27, 2016]
P	Lyn Jacobs, MD [Submitted June 27, 2016]
Q	Laurel Yoder, RN, BSN [Submitted June 27, 2016]
R	Melissa Belli, MD [Submitted June 28, 2016]
S	Karlita Nabours-Palermo, MSN, FNP-CX [Submitted June 29, 2016]
T	Gilda Lorensen, MD [Submitted July 3, 2016]
U	Holly Pranaat, CNM [Submitted July 5, 2016]
V	Helen Bellanca, MD, MPH on behalf of Health Share of Oregon [Submitted July 5, 2016]
W	Rebecca L Taub, MD, on behalf of the OHSU residents in Obstetrics and Gynecology [Submitted July 6, 2016]
X	Planned Parenthood Advocates of Oregon [Submitted July 7, 2016]
Y	Legal Voice [Submitted July 8, 2016]

Public Comments

ID/#	Comment	Disposition
A1	I am writing in support of the measure to cover long-acting reversible contraceptive placement in the immediate postpartum period. There is substantial and consistent evidence that immediate postpartum placement is safe in appropriately selected candidates and reduces the rate of unintended pregnancies.	<i>Thank you for your comments.</i>
A2	As an obstetrician providing care to underserved populations in Oregon, I see first-hand the consequences of not providing this essential service to those who need it most. Unintended pregnancies can occur as early as 3-4 weeks postpartum, long before most women present for their postpartum clinic visit. These short-interval	<i>Thank you for your comments. Information on the risks of short interpregnancy intervals has been added to the Background section of the Coverage Guidance.</i>

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ID/#	Comment	Disposition
	<p>pregnancies have been associated with an increased risk of preterm birth and small for gestational age infants, as well as other important maternal and perinatal complications.</p> <p>Thank you for your consideration and I am encouraged that this important topic is at the top of the priority list.</p>	
B1	<p>I am writing in support of Medicaid payment and supply for immediate postpartum LARC (long acting reversible contraception). As an OB hospitalist who has practiced in 3 states over 20 years, this is one of the biggest ways I have seen that we can support busy women to have control over their reproductive lives and prevent unintended pregnancy. We have had great patient satisfaction providing this service at Kaiser Northwest via grant but making it available to all women at all institutions consistently can continue our lowering teen pregnancy and unintended pregnancy rates. Please do women the service they deserve and support this coverage</p>	<p><i>Thank you for your comments.</i></p>
C1	<p>I would like to add my name in support of covering LARC (Nexplanon, IUD's) for immediate postpartum insertion. This is an important and valuable tool for contraception for many women.</p>	<p><i>Thank you for your comments.</i></p>
D1	<p>I would like to offer my strong support for providing immediate postpartum contraception with LARCs in the hospital. I could provide countless examples of when this would have benefited my patients. Most recently I delivered a baby for a 17 year old woman, her second. She suffered severe anemia during her pregnancies and had the anticipated social and economic struggles associated with two teen pregnancies. She did not return to the clinic for a LARC following her first pregnancy as is so often the problem. Following her second delivery I walked her over to the clinic to place her Nexplanon following her discharge from the hospital. The reality is that many women</p>	<p><i>Thank you for your comments.</i></p>

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ID/#	Comment	Disposition
	<p>will intend to follow up to receive contraception but the barriers of time, money, transportation, childcare, etc. prohibit them from doing so.</p> <p>Of course from an economic standpoint it seems only to benefit Medicaid to cover this and save the cost of insuring an unintended pregnancy, both for the pregnancy mother and the child she will give birth too.</p> <p>In an issue that so clearly and directly effects the lives of women, their children, society and the cost of healthcare it is hard to imagine why this would not be enacted.</p>	
E1	I am a practicing OBGYN in Portland Oregon. Our practice philosophy is committed to providing women's services to all women. I strongly support the use of LARC in the immediate postpartum period in appropriate cases. I believe it is a valuable option to have available. I support your efforts to develop a work around to overcome the current financial barrier.	<i>Thank you for your comments.</i>
F1	Please approve Medicaid coverage of immediate postpartum placement of IUDs and Nexplanon's (LARC). While our organization is committed to ensuring access to timely and effective contraception for all of our patients, there are some patients who, because of their social determinants of health, fail to access contraception when access is confined to office based care. For a subset of patients, immediate postpartum LARC access is critical to their long term health and well being and to their newborn, by preventing early and unplanned pregnancies. Medicaid billing practices have not allowed hospitals to bill for the device outside of the global fee for a delivery, and the devices are very expensive. Eighteen states have figured out an admin work around with their Medicaid offices to allow for billing of the device outside of the global fee. I encourage Oregon to move toward this.	<i>Thank you for your comments.</i>
G1	Unintended pregnancy has direct and indirect costs for families and communities and occurs disproportionately in poor women with limited resources and minimal access to health care. ^{1,2} Altering Medicaid policy to allow for reimbursement of postpartum	<i>HERC agrees that extending immediate LARC coverage to the CAWEM population is an important point; however, it is beyond the scope of this coverage guidance. We have passed</i>

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ID/#	Comment	Disposition
	<p>intrauterine devices and implants (LARC) is an important strategy to improve the health and well-being of some of the most vulnerable residents of our state. The evidence on the safety and effectiveness of this strategy are clear: the OHSU Section of Family Planning strongly endorses the Health Evidence Review’s Commission recommendation to prioritize coverage of LARC devices immediately postpartum.</p> <p>We have been providing immediate postpartum LARC as an option for women at OHSU since 2008 through a small grant that covers the costs of the devices. Only women with incomes less than 300% of the federal poverty level and who have a high risk of loss to follow-up are eligible. This service is valued and appreciated by the women who qualify.</p> <p>As physicians and researchers specializing in family planning services, we want to bring the voices of the women we care for to this conversation, to underscore the critical importance of passing and implementing this policy change swiftly. There is a large body of evidence demonstrating that the choice of immediate postpartum LARC improves health and saves public dollars, however this evidence has not been sufficient to change policy to date. An administrative barrier, prohibiting reimbursement for LARC outside of the global fee for obstetrics has prevented thousands of women from accessing this service. Our failure to act has very real consequences and costs for women and their families.</p> <p>Many of our patients are new immigrants, fleeing violence and seeking a new life for their family. Some of them are battling drug addiction. We see women who are incarcerated and pregnant. Quite a few are embarking on motherhood while still children themselves. All of the women we see are struggling in difficult circumstances. The lack of access to immediate postpartum LARC has led to unintended pregnancies and contributed to perpetuating the cycle of poverty and disparity. We need to change this now.</p>	<p><i>along your comment to others in OHA who would best be able to analyze policy options for potential consideration by OHA leadership. As additional state funding may be needed to provide this coverage outside of current programs, even if the service is expected to be cost saving over time, legislative action could be required.</i></p>

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	<p>We fully support the HERC’s recommendation to prioritize Medicaid reimbursement of immediate postpartum LARC. We strongly recommend that this service be provided for women in both the Oregon Health Plan and the Citizen/Alien Waived Emergent Medical (CAWEM) care populations. Restricting this service to only the OHP population would be a mistake. Research shows that extending postpartum contraception to the CAWEM population would improve health and save state funds (nearly 3\$ for every dollar spent).^{3,4}</p> <p>We are available to help assist the state with training and implementation of this policy.</p>	
H1	<p>I hope you will approve coverage of long acting BC for patient’s after delivery. This is the best time to assure that a women can plan her next pregnancy and avoid an unplanned pregnancy or abortion. The cost certainly is minimal compared to the cost of the care for the next pregnancy and delivery.</p> <p>Of course funds are limited but if we spend \$200 and save \$3,000 it seems that long term this will not be an added expense but instead a bottom line savings. Not to mention the human cost of unplanned pregnancies in low income uninsured families.</p>	<p><i>Thank you for your comments.</i></p>
I1	<p>I am a nurse-midwife working at Virginia Garcia Memorial Health Center. As you know, we work throughout Washington and Yamhill Counties with a lot of women that are underserved and have multiple barriers. Many of these barriers make it impossible for women to have access to long acting reversible contraception (LARCs). LARCs are well studied for its safety and effectiveness. The women we serve have high incidence of unplanned pregnancies - and every unplanned pregnancy has an effect on their family’s future. Having available IUDs that we could place immediately postpartum for women that we know may not return for care after their delivery will end up saving the state money and provide these women some control over when they get pregnant. Many of our women do not qualify for any kind of coverage when</p>	<p><i>Thank you for your comments.</i></p>

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	they are not pregnant, so access to prescriptions and paying for appointments becomes a barrier and a choice between the groceries for their families vs their contraception. Please take into consideration the financial effects on the State of Oregon, who will not have to pay for the care of women undergoing a pregnancy that they never intended to carry, as well as the effect on the lives of these women and families that may have a better chance at getting ahead and more stability.	
J1	I wholeheartedly support any type of birth control for any women who desires it at any time (as long as it is not medically contraindicated). Please, please support everyone for any and all birth control.	<i>Thank you for your comments.</i>
K1	I believe it is a great idea that you guys are currently considering providing coverage for IUDs and Nexplanons in the immediate postpartum period and that it would include patients that only qualify for CAWEM. This is great there is a huge quantity of people that cannot afford to pay to have these services.	<i>See G1.</i>
L1	I am a family medicine physician with obstetrics. I would love to see IUD and Nexplanon available for my CAWEM patients. It would limit unexpected, unintended pregnancies.	<i>See G1.</i>
M1	The Oregon Academy of Family Physicians represents 1400 family physicians in Oregon. This is an important issue for women’s health and we strongly support the HERC recommended coverage guideline about the timing of LARC contraception. In addition to support from the OAFP, our national organization, the American Academy of Family Physicians recommends LARC as the first-line method of contraception and advises that it should be available postpartum, prior to hospital discharge. The AAFP policy can be found here, http://www.aafp.org/about/policies/all/family-planning.html .	<i>Thank you for your comments. The American Academy of Family Physicians recommendations on LARC have been added to the Guidelines section of the Coverage Guidance.</i>
N1	Unintended pregnancy has direct and indirect costs for families and communities and occurs disproportionately in poor women with limited resources and minimal access	<i>See G1.</i>

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	<p>to health care.^{1,2} Altering Medicaid policy to allow for reimbursement of postpartum intrauterine devices and implants (LARC) is an important strategy to improve the health and well-being of some of the most impacted residents of our state. The evidence on the safety and effectiveness of this strategy are clear: The Oregon Foundation for Reproductive Health supports the prioritization of coverage of LARC devices immediately postpartum.</p> <p>As advocates for increased access to preventive reproductive health services, we want to emphasize the importance of passing and implementing this policy change swiftly. There is an increasingly large body of evidence demonstrating that the choice of immediate postpartum LARC improves health for our communities and saves public dollars. An administrative barrier, prohibiting reimbursement for LARC outside of the global fee for obstetrics has prevented thousands of women from accessing this service. This is unacceptable when a solution is so apparent.</p> <p>We hear from providers and health care center staff across the state who are frustrated about this policy and feel they are not able to give the best care to their patients who are in-need because of the barrier it presents. When providers have to make health care decisions based on cost instead of what is in the best-interest for their patient, it is an injustice. We hear of missed opportunities because women are not able to make it back for a postpartum or post-abortion visit, risking an unwanted or mistimed pregnancy because of the lack of access to contraception coverage. Reducing barriers women face due to cost and access is a key step in expanding LARC uptake as an effective form of pregnancy prevention. Securing the ability for health care centers to provide LARC's in the immediate postpartum or post-abortion time period can expand access and prevent loss to follow -up.</p> <p>We fully support the HERC's recommendation to prioritize Medicaid reimbursement of immediate postpartum LARC. The solutions outlined in the guidance document regarding addressing not only administrative barriers to payment but also the cost of</p>	

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	<p>the devices for health center are critical. We strongly recommend that this service be provided for women in both the Oregon Health Plan and the Citizen/Alien Waived Emergent Medical (CAWEM) care populations. Restricting this service to only the OHP population would be a mistake and would only add to the inequalities in our state. Research shows that extending postpartum contraception to the CAWEM population would improve health and save state funds.^{3,4} Any other decision is irresponsible to the health of our communities and costly to taxpayers.</p>	
O1	<p>As leaders of the Oregon Perinatal Collaborative, we are committed to improving maternal and neonatal outcomes for women through adoption of evidence based practices. Offering women the choice of highly effective, reversible contraception prior to hospital discharge is an important strategy to optimize health outcomes for women and their families. We strongly endorse the recommendation made by the Health Evidence Review Commission for Medicaid coverage of long acting reversible contraception (LARC) regardless of timing of placement.</p> <p>As reflected in the HERC’s evidence summary, excellent clinical data supports the safety, efficacy and acceptability of this practice. We would also like to note that postpartum contraception has been shown to be an effective strategy in reducing preterm birth, an intractable public health problem with long term consequences and costs.¹</p> <p>There are few public health interventions that have the opportunity to improve health outcomes, reduce social inequities, and save public funds. Offering women the choice of postpartum LARC prior to discharge has this potential, and we would support its swift and state wide implementation. We would advocate for inclusion of this benefit for all women in Oregon’s Medicaid program, regardless of citizenship status. Previous research has demonstrated the health benefits and cost savings for the state of expanding access to postpartum contraception for women in both CAWEM (Citizen/Alien Waived Emergent Medical) and Standard Medicaid (Oregon Health</p>	See G1.

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	<p>Plan).^{2,3} A 2010 study demonstrated that the state of Oregon would save \$2.94 for every dollar spent on a postpartum LARC program.³</p> <p>As leaders in women’s health, we recognize the importance of this proposed coverage change for improving the health of Oregon women and their families. We are available to support the state in implementing the practice as needed.</p>	
P1	As a career clinician with over 17 years of experience in caring for the underserved, I fully support coverage for long acting birth control in the postpartum period.	<i>Thank you for your comments.</i>
Q1	<p>I am writing to comment upon the Timing of Long-Acting Reversible Contraceptive Placement Draft Coverage Guidance, posted for public comment until 7/8/2016.</p> <p>I strongly support this measure. As has been reviewed in the Guidance document, provision of long-acting reversible contraception to patients provides substantial cost savings to the system over the long run, and substantial benefits to women's health in planning when and if to have children. I agree with the analyses and conclusions under Balance of benefits and harms, Resource Allocation, Values and Preferences, Other Considerations, and Rationale. Provision of access to immediate postpartum and post-abortion LARC's across a broad swath of patient populations, including those patients utilizing CAWEM, will hugely benefit the healthcare system and improve population health.</p> <p>I am a Registered Nurse, and a recent graduate of Oregon Health & Sciences University with my Master of Nursing in Nurse-Midwifery. I am employed as an RN at Virginia Garcia Memorial Health Center in Hillsboro, Oregon; and additionally am a member of the professional organization American College of Nurse-Midwives (ACNM). Please do not hesitate to contact me with any questions regarding this Comment email.</p>	<i>See G1.</i>
R1	I fully support this effort to provide LARC in the postpartum period.	<i>Thank you for your comments.</i>

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S1	<p>I am writing with regard to the Timing of Long-Acting Reversible Contraceptive (LARC) Placement Draft Coverage Guidance. I wholly support any motion to make LARC more available to communities with barriers. Unwanted pregnancy among women in these communities has enormous consequences for the public system. Moreover, the economic and social consequences on these women, their families, and their prospects for better lives are disproportionately huge. As a family nurse practitioner working daily with immigrant and other impoverished families in Yamhill and Washington Counties, I hope that we can make Nexplanon and intrauterine devices more widely available to all, for the benefit of all.</p>	<p><i>Thank you for your comments.</i></p>
T1	<p>I understand that immediate postpartum LARC use is under discussion. As a practicing OBGYN for nearly 30 years I very strongly support this practice.</p> <p>Many women and men contracept successfully. But, many do not, and contraceptives do fail. Nothing is more heartbreaking and difficult than facing the choices surrounding unintended pregnancy. Relationships, educational plans, career plans and more fall victim to these events. The efficacy and safety of immediate postpartum contraception are well understood. This practice can literally save lives as well as futures. The ultimate victims here are the children born not fully wanted, or aborted -- but this can be prevented.</p> <p>Cost effectiveness is another virtue of this practice. The resources spent on unintended pregnancy are enormous, whereas effective contraceptive use including immediate postpartum LARC is relatively inexpensive.</p> <p>Please support this practice financially for our patients.</p>	<p><i>Thank you for your comments.</i></p>
U1	<p>I am writing to comment in support of "Timing of Long-Acting Reversible Contraceptive Placement Draft Coverage Guidance." I am a Certified Nurse-Midwife at a practice affiliated with Providence St. Vincent Medical Center. I care for many patients who are pregnant and receive services through CAWEM, and have seen</p>	<p><i>See G1.</i></p>

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	<p>firsthand the difficulty they often face in obtaining contraception postpartum due to lack of coverage. LARCs are extremely effective and safe methods of contraception, including in the immediate postpartum period, and are methods that women report being very satisfied with. The OHP population, but especially the CAWEM population, is already underserved and faces many challenges. Many of the CAWEM patients that I serve are recent immigrants who are fleeing violence and seeking a better life for their families. Family planning is a vital aspect of this as women strive to provide for their children and work out of poverty. Extending contraception to the CAWEM population, in addition to the OHP population, would improve health and outcomes for women and their families, and would save state funds.</p>	
V1	<p>Health Share of Oregon is writing in support of the Health Evidence Review Commission’s June 16, 2016 draft coverage guidance for Timing of Long-Acting Reversible Contraceptive Placement.</p> <p>Health Share is the state’s largest coordinated care organization (CCO), providing Oregon Health Plan (OHP) coverage to approximately 240,000 Oregonians in Clackamas, Multnomah, and Washington counties. I am trained as a physician with a specialty in Family Medicine and serve as Associate Medical Director for Health Share. I have a deep background in maternal and child health (details below).</p> <p>Health Share supports this coverage guidance for three reasons:</p> <ol style="list-style-type: none"> 1. Immediate postpartum placement of LARCs is an evidence-based practice to improve rates of effective contraception use among women who do not desire pregnancy 2. Immediate postpartum placement of LARCs would help OHP members access the most effective forms of contraception in a way that is convenient to them, without the barriers that many women face in the postpartum period (e.g., difficulty with transportation and child care; difficulty scheduling and keeping appointments) 	<p><i>Thank you for your comments.</i></p>

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	<p>3. Immediate postpartum placement of LARCs will contribute to reducing unintended pregnancies, which take a significant toll on the lives and health of our members</p> <p>We have a number of clinicians in our service area who are eager to offer this service to their patients, and many members are interested in availing themselves of this opportunity. Ensuring OHP coverage for immediate postpartum placement of LARCs will facilitate our efforts to get the right care to the right people at the right time. We feel confident that this policy change will contribute in a positive way to the health and wellbeing of our population, and we appreciate the efforts that the Oregon Health Authority has made to bring this issue to light.</p>	
W1	<p>As the residents of Oregon’s only training program in Obstetrics and Gynecology, we are often first line providers for obstetric safety-net patients across the state. We provide prenatal, intrapartum, and postpartum care to underserved women at several hospitals across the Portland metropolitan area. We see firsthand the difficulties women have with unplanned pregnancies and encounter many patients for whom another pregnancy would be medically, psychologically, or economically disastrous. We, the Obstetrics and Gynecology residents at Oregon Health & Science University, strongly endorse the recommendation made by the Health Evidence Review Commission for Medicaid coverage of long-acting reversible contraception (LARC) regardless of timing of placement.</p> <p>Unintended pregnancy comes with costs to both families and communities, and disproportionately affects poor women with limited resources and access to medical care.^{1,2} These women are also those who are least likely to be able to afford the time away from work or family, childcare expenses, and transportation to make it to a postpartum or family planning visit to receive highly effective contraception. At OHSU we are able to provide immediate postpartum LARC through a small grant. However, current insurance reimbursement policies prohibit this practice at other hospitals in</p>	See G1.

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	<p>our state. The immediate postpartum period is the ideal opportunity to facilitate contraceptive access for women.</p> <p>We have all seen what a difference it can make in a woman’s life to have the peace of mind of knowing that she has a long-acting contraceptive method prior to leaving the hospital, and to know that she can focus on her new baby and current family without worrying about the possibility of another pregnancy before she is ready. Many of the patients in our resident clinic community are battling substance abuse or severe mental health issues, and the ability to prevent future pregnancy is paramount in ensuring their ability to take care of themselves and continue to parent their current children. This coverage is also of utmost importance to our immigrant and refugee populations who are often struggling to get a foothold in this country, and for this reason we advocate that this coverage be extended not only to our Oregon Health Plan population but to the Citizen/Alien Waived Emergent Medical (CAWEM) population as well.</p> <p>As reflected in the HERC’s evidence summary, there is excellent clinical data to support the safety, efficacy, and acceptability of immediate postpartum LARC. Research has also demonstrated this policy to be cost effective to the state.^{3,4} Prioritizing Medicaid reimbursement of immediate postpartum LARC is sound fiscal policy, appropriate medical care, and the ethical thing to do for the women and families of Oregon.</p> <p>As current trainees and future Obstetricians and Gynecologists to the women of Oregon, we are proud to live in a state with an excellent track record on women’s health, and we hope that this legacy continues with the implementation of this policy.</p>	
X1	<p>All Oregonians, regardless of economic status, have the right to determine if and when they wish to become pregnant. Because an unintended pregnancy can have dramatic financial consequences for a woman, her family, and her community, and</p>	<p><i>See G1 regarding ensuring access to women covered under the CAWEM program.</i></p>

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	<p>because LARC methods are the most medically- and cost-effective contraceptive methods on the market,¹ it makes basic economic sense for all women and families to have ready and affordable access to LARC. However, to ensure all Oregonians are able to exercise complete reproductive autonomy, it is additionally imperative that all individuals using LARC methods have coverage for the cost of LARC removal. Planned Parenthood Advocates of Oregon (PPAO) therefore urges HERC to:</p> <ul style="list-style-type: none"> • Recommend coverage for immediate postpartum and postabortion placement of LARC (subdermal implant or intrauterine device) for all persons, including those covered by the Oregon Health Plan, Citizen/Alien Waived Emergent Medical, other publically funded plans, and commercial plans • Define LARC coverage to include device removal at any time for any reason, and to specify that public plan eligibility at time of insertion determine coverage for removal <p>As illustrated in the coverage guidance, a growing body of research makes evident the benefits, safety, and efficacy of postpartum and postabortion LARC use. Women offered immediate postpartum/postabortion LARC insertions are significantly more likely to receive and continue using the device than those who must schedule an additional visit for the procedure.² Conversely, women not offered immediate postpartum/postabortion insertions often fail to return for their LARC visit, especially when transportation, work schedules, and/or childcare present obstacles to doing so. Others become pregnant in the interim. HERC’s guidance to Medicaid plans to reimburse providers for postpartum and postabortion LARC insertion remedies this barrier for some of Oregon’s most vulnerable populations, including young women, poor women, women of color, and immigrant women. In that vein, we strongly recommend that these services be provided to women covered by the Oregon Health Plan as well as those with Citizen/Alien Waived Emergent Medical (CAWEM) coverage. Securing coverage for those covered by CAWEM would improve the health of</p>	<p><i>Discussion of coverage for LARC removal has been added to the Contextual Questions Section (under Barriers and Solutions) in the Coverage Guidance. HERC recognizes that coverage of LARC removal for women who are uninsured or have limited benefits that don’t include this service is an important issue. Your comment has been passed along to others in OHA who would best be able to analyze policy options for potential consideration by OHA leadership. As additional state funding may be needed to provide this coverage outside of current programs, even if the service is expected to be cost saving over time, legislative action could be required.</i></p>

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	<p>Oregonians and save state dollars, while omitting coverage would perpetuate systemic inequity in our state.</p> <p>PPAO additionally calls upon HERC to include coverage of LARC removal in its guidance. In a nationally representative study of women who had ever used a LARC, 28% of respondents reported discontinuation due to dissatisfaction.³ Others request removal in order to become pregnant. We cannot overlook the health needs of those women who request removal for a host of reasons, including pain, irregular bleeding, and mood changes,⁴ nor should we establish systematic barriers that inhibit a woman from planning her pregnancy. Covering insertion but not removal would undeniably inhibit the reproductive autonomy of women who are eligible for publically funded pregnancy-related healthcare, but subsequently lose coverage following delivery or abortion.</p>	
X2	<p>Given our country’s painful history of reproductive coercion, it is exceptionally important to consider the potential repercussions of a publically funded policy which covers insertion of LARC but omits a requirement to cover removal of the device.⁵ While women of lower socioeconomic status exhibit similar levels of LARC discontinuation due to dissatisfaction as their counterparts, more data is needed to determine the nuanced trends in LARC discontinuation across populations.³ Researchers at the Guttmacher institute have cautioned policymakers to question the motivation behind continued LARC use, arguing that, while many women continue using LARC because they are satisfied with the method, others may experience “pressure from, or barriers within, the medical establishment to avoid removal, including the denial of removal coverage under state Medicaid law.”³ It is therefore imperative that all women receive comprehensive, unbiased contraceptive counseling on the full range of contraceptive methods at initiation, and that a woman’s reason for requesting LARC removal plays no factor in the care or coverage she receives.</p>	<p><i>A statement regarding the importance of free and informed decisions about contraception has been added to the Other Considerations section of the GRADE-Informed Framework.</i></p>

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	<p>PPAO makes these recommendations because we are committed to ensuring that every woman has the right to the reproductive healthcare that she chooses—a mission in line with Oregon health policy as enacted by the legislature and as verified by the electorate. To ensure that all women have unfettered reproductive autonomy to utilize the contraceptive method of their choice, PPAO urges HERC to prioritize postpartum and postabortion coverage for the full cycle of contraceptive use, which includes comprehensive contraceptive counseling, contraceptive dispensing or insertion, and contraceptive method removal when applicable. Doing so will improve individual health outcomes, reduce mid- and long-term healthcare costs, and advance public health.</p>	
Y1	<p>We are pleased to offer the following comments in response to the Health Evidence Review Commission’s (HERC) coverage guidance for timing of long-acting reversible contraceptive (LARC) placement on behalf of Legal Voice. Legal Voice is a regional non-profit public interest law organization that works to advance the legal rights of all women through policy advocacy, legislative advocacy, and legal rights education. Since its founding in 1978 as the Northwest Women’s Law Center, Legal Voice has been a leading regional expert on gender justice in healthcare access.</p> <p>Legal Voice supports the HERC’s recommendation that the Oregon Health Plan (OHP) extend coverage for LARC placement. Pregnancy prevention is an important element in ensuring the physical and emotional health of women and families. Low-income women and those with limited access to health care in particular are disproportionately affected by lack of access to reproductive health care.¹ Providing coverage for immediate post-birth and post-abortion LARC placement will help close this gap and enhance low income women’s reproductive freedom.</p>	<p><i>Thank you for your comments.</i></p>
Y2	<p>In order to ensure that LARC coverage is complete, and that LARCs are placed only with authentic informed consent, Legal Voice offers the following recommendations.</p>	<p><i>The HERC agrees with the commenter that informed consent should be required before placement of LARC (see comment X2). Discussions regarding the type and timing of postpartum</i></p>

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	<p><i>Coverage for Immediate Placement of LARCs Requires Meaningful and Informed Consent</i></p> <p>Informed consent, as described by the American College of Obstetricians and Gynecologists (ACOG), is an ongoing, collaborative process between patients and healthcare providers in order to best meet the patients’ needs and goals.² Particularly because of increased patient vulnerability at the time of a birth or abortion, it is essential that women are provided information about the range of contraceptive options available to them, that patients are able to communicate their own goals for contraceptive use, and that health care staff provide information about options that are aligned with these goals.</p> <p>While medical professionals often assume that pregnancy prevention efficacy is the most important feature for patients when they are selecting a method of contraception, an individual patient is likely to have a unique variety of goals and factors used to determine the best contraceptive option for herself.³ As one researcher has noted, “The field has witnessed a distinct shift from options-based counseling, in which a wide array of contraceptive methods are presented to potential contraceptives users, to directive and/or first-line counseling, in which one or two LARC methods are recommended over all others.”³ Thus, ensuring that patients are aware of all contraceptive options, benefits, and risks will result in patients who are more able to provide authentic and informed consent for any contraceptive choice they make.</p> <p>Of particular concern to Legal Voice is that all patients are provided with information about all contraceptive options and access to the method that they decide is best for their particular situation and values. There is an unfortunate history in this country of eugenicist and racist use of birth control and sterilization, including most recently, aggressive marketing of Norplant to low-income women and girls of color.³ For this reason, Legal Voice supports the HERC’s recommendation that providers discuss all</p>	<p><i>contraception should occur prior to labor, particularly for LARC. Informed consent should be obtained and documented regardless of the type of contraception, and documentation about any decision to decline postpartum contraception should also be entered into the medical record.</i></p>

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	<p>options with their patients and applauds the enhanced convenience of consolidated appointments, but suggests that providers take extra care to ensure that patients have sufficient knowledge and time to make an informed decision regarding which contraceptive method they will use.⁴ Protection of patients’ ability to make decisions can be used in tandem with consolidated appointments to ensure that patients are able to exercise control over their reproductive health in a way that honors individual autonomy as much as is possible.</p> <p>Further, because of the importance of ensuring that patients have access to information about all family planning and pregnancy prevention options, with respect to the HERC’s recommendation to develop “LARC Champions,” or professionals trained to provide advocacy and support specifically for LARC usage, while Legal Voice supports patients and providers having access to information about LARC usage, advocacy for a particular form of contraceptive technology can sometimes erode patients’ ability to make the most informed choices for their needs. Developing stakeholders who can share knowledge and support about the variety of contraceptive choices, rather than LARCs exclusively, will improve providers’ and patients’ ability to choose and access and use the best contraceptive for patients’ individual circumstances. Ideally, not only healthcare professionals, but also community-based health advocacy groups made up of those who will utilize the services will be included in communications and training development around LARCs and other contraceptive options. A more inclusive and community-based approach will help to center patients’ needs and decision making in the contraception selection process.</p>	

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Y3	<p><i>Ensuring coverage of LARC removal</i></p> <p>The draft Coverage Guidance focuses on coverage of immediate postpartum and postabortion placement of insertion of LARCs, but does not address another important, related service for coverage: removal of LARCs.</p> <p>It is well-established that device removal is an important aspect of appropriate care associated with LARCs. The federal Affordable Care Act specifies that no-cost contraceptive care includes “clinical services, including patient education and counseling, needed for provision of the contraceptive method,” and “[s]ervices related to follow-up and management of side effects, counseling for continued adherence, and device removal.”⁵ Patients should be free to discontinue use, with or without a medical reason for doing so.⁶</p> <p>While patients may have access to LARC removal through other Oregon Health Plan programs or other insurance, such as CCare, it is not clear that if a patient accesses LARC insertion services immediately postpartum or postabortion, as this guidance suggests, that the same patient would still be covered for removal. We recommend that HERC consider and examine any potential barriers to LARC removal due to this type of coverage gap. If a woman is unable access LARC removal services, then in effect, her control over a full range of contraceptive options is limited.</p>	<p><i>See response to comment X1 regarding ensuring access to LARC removal.</i></p>

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HERC Coverage Guidance – Timing Of Long-Acting Reversible Contraceptive (LARC) Placement Disposition of Public Comments

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HERC Coverage Guidance – Timing Of Long-Acting Reversible Contraceptive (LARC) Placement Disposition of Public Comments

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DRAFT





August 25, 2016

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Dear Medical Directors:

In developing our Coverage Guidance on Timing of Long-Acting Reversible Contraceptive (LARC) Placement, we have become aware that administrative issues, rather than coverage policy per se are discouraging the use of highly effective LARC devices (intrauterine devices and subdermal implants). While placement of LARC devices is already covered for most plans, administrative issues are preventing patients from receiving these devices at the point when they are most likely to achieve the objective of preventing unintended pregnancy. The LARC devices are safe and effective, and are more cost-effective than any other contraceptive method. For example, one cost-effectiveness analysis found that over 2 years, placement of a postpartum IUD was associated with a savings of \$282,540 per 1,000 women. They cannot be effective or cost-saving, however, unless they are placed.

In order for placement to occur, an appropriate device must be offered and placed at a time convenient to the woman desiring contraception, preferably when she is already receiving care for another condition. Best practices for timing of insertion include placement immediately following birth or abortion, as well as same-day placement in the outpatient setting. Currently, due to administrative barriers, women are often required to return for one or more visits in order to receive a LARC device. Many women do not return for follow up visits, including postpartum visits. Others may become pregnant before such a visit can occur. In order to offer immediate placement, providers must be confident that they and the facilities in which they work will be appropriately compensated for the devices and related care. We have heard reports of major hospital systems halting placement of these devices in the postpartum setting due to reimbursement issues and are aware of others that simply do not offer postpartum LARC placement unless funded through a grant for a very limited population.

As you implement the changes related to this coverage guidance, we urge you to address the following administrative barriers, if they are present in your plans and provider networks.

- Lack of reimbursement for the cost of these devices when provided after an in-hospital birth due to global DRG-based payment for delivery services
- Lack of reimbursement to professionals and facilities for the service of placing these devices in the inpatient setting
- Inadequate inventory of these devices to allow for their placement on a timely basis in all settings of care
- Lack of health system support for the uptake of policies and procedures supporting the immediate placement of LARC.
- Reimbursement rates to providers which are lower than the provider's cost of the devices
- Lack of providers able to perform postpartum placement of IUDs

- For devices provided through a pharmacy benefit, lack of a mechanism for providers to recoup the cost of the device if a device assigned to a particular woman is not placed
- Lack of provider reimbursement when LARC removal, replacement or re-insertion is required
- Any prior authorization requirements, which can delay or block placement of these devices
- Payer refusal to pay for two distinct services on the same day (e.g., a birth or the termination of pregnancy followed by LARC placement)

We have attached an Informational Bulletin from the Center for Medicaid and CHIP Services which outlines these issues as well as options other states have implemented to resolve them. Appendix E of our coverage guidance contains some helpful resources for plans and providers wishing to remove barriers to LARC for their population.

We hope that this information will help you as you work with your plan and contracted providers to ensure effective access to these important devices.

Sincerely,

<Signature>

Somnath Saha, MD, Chair, Health Evidence Review Commission

<Signature>

Wiley Chan, MD, Chair, Evidence-based Guidelines Subcommittee

Section 3.0
Coverage Guidance Rescan
2016

SCOPE STATEMENT FOR HERC COVERAGE GUIDANCE

PLANNED CESAREAN BIRTH

Population description	Pregnant women with or without medical/obstetric/fetal indications for cesarean birth <i>Population scoping notes: None</i>
Intervention(s)	Planned cesarean birth <i>Intervention exclusions: None</i>
Comparator(s)	Planned vaginal birth
Outcome(s) (up to five)	Critical: Perinatal morbidity, maternal morbidity (including unplanned cesarean birth), NICU admissions Important: Procedural harms, subsequent pregnancy outcomes <i>Considered but not selected for GRADE Table: Length of stay, maternal incontinence, satisfaction with birth experience, time to next pregnancy, infant feeding</i>
Key questions	<ol style="list-style-type: none">1. What is the comparative effectiveness of planned cesarean birth?2. Does the comparative effectiveness of planned cesarean birth vary by:<ol style="list-style-type: none">a. Medical, obstetrical or fetal indicationsb. Gestational agec. Multifetal pregnancyd. Maternal agee. Maternal body mass indexf. Complications in prior pregnancies3. What are the harms of planned cesarean birth?

CHANGE LOG

Date	Change	Rationale
8/17/2016	Changed comparator to "Planned vaginal birth". Added "unplanned cesarean birth" as a component of maternal morbidity in the outcomes section.	Unplanned cesarean section is not an appropriate comparator. The ultimate mode of delivery is not known at the time of choosing whether to plan a cesarean section. Unplanned cesarean birth is one important form of maternal morbidity.

SCOPE STATEMENT FOR HERC COVERAGE GUIDANCE

ROUTINE ULTRASOUND IN PREGNANCY

Population description	Pregnant women of average risk <i>Population scoping notes: None</i>
Intervention(s)	Transvaginal ultrasound and/or transabdominal ultrasound(s) on any schedule <i>Intervention exclusions: None</i>
Comparator(s)	Usual prenatal care with ultrasound(s) on any other schedule, no ultrasound
Outcome(s) (up to five)	Critical: Values-congruent reproductive outcomes, delivery planning, perinatal morbidity Important: Harms, subsequent interventions <i>Considered but not selected for GRADE Table: Perinatal mortality, maternal reassurance</i>
Key questions	<ol style="list-style-type: none">1. What is the comparative effectiveness of routine ultrasound in pregnancy?2. Does the comparative effectiveness of routine ultrasound vary by:<ol style="list-style-type: none">a. Pregnancy risk levelb. Maternal agec. Gestational age (or uncertainty thereof)d. History of preterm labore. Fetal presentationf. Ultrasound schedule3. What are the harms of routine ultrasound in pregnancy?

SCOPE STATEMENT FOR HERC COVERAGE GUIDANCE

CHRONIC OTITIS MEDIA WITH EFFUSION IN CHILDREN

Population description	Children with chronic otitis media with effusion with or without hearing loss <i>Population scoping notes: None</i>
Intervention(s)	Antibiotics, other medications (including antihistamines, decongestants, and oral/nasal steroids), tympanostomy, pressure equalization tubes, adenoidectomy with or without tonsillectomy, eustachian tube autoinflation, hearing aids <i>Intervention exclusions: None</i>
Comparator(s)	No treatment, usual care (including monitoring with regular audiometry or tympanometry), other listed interventions
Outcome(s) (up to five)	Critical: Language or speech delays Important: Harms, missed school and work (for parents), persistent clinically significant hearing loss <i>Considered but not selected for GRADE Table: Quality of life, academic performance</i>
Key questions	<ol style="list-style-type: none">1. What is the comparative effectiveness of the treatments for chronic otitis media with effusion in children?2. Does the effectiveness of treatments for chronic otitis media with effusion in children vary based on:<ol style="list-style-type: none">a. Ageb. Duration of the effusionc. Presence and degree of clinically significant hearing loss at diagnosisd. Presence of predisposing conditions (e.g., craniofacial anomalies)e. Previous treatment (e.g., conservative management, medications)3. What are the harms of treatments for chronic otitis media with effusion in children?

CHANGE LOG

Date	Change	Rationale
7/21/2016	<p>Move audiometry and tympanometry from interventions to a part of usual care in the comparator, clarify that population includes patients with or without hearing loss.</p> <p>Clarify that the outcome of hearing loss should only measure persistent clinically-significant hearing loss.</p> <p>Changed outcome from other developmental delays to speech delays</p> <p>Changed key question 2 subpoint so that presence of hearing loss is an important factor in addition to severity.</p>	<p>Audiometry and tympanometry are not interventions</p> <p>Provide more specific language</p> <p>Speech delays are more directly related to this condition</p> <p>Clearer</p>
8/5/2016	<p>Added hearing aids as comparator. Clarified that adenoidectomy could be considered as an intervention with or without tonsillectomy.</p>	<p>Ensure appropriate interventions are captured.</p>
8/11/2016	<p>Added academic performance as an outcome considered but not selected.</p>	<p>This outcome is more distal than others which were selected.</p>

SCOPE STATEMENT FOR HERC COVERAGE GUIDANCE

NON-PHARMACOLOGIC INTERVENTIONS FOR TREATMENT-RESISTANT DEPRESSION

Population description	Adults and children with treatment-resistant major depression <i>Population scoping notes: None</i>
Intervention(s)	Electroconvulsive therapy (ECT), repetitive transcranial magnetic stimulation (rTMS), vagal nerve stimulation (VNS), deep brain stimulation (DBS), psychotherapy <i>Intervention exclusions: None</i>
Comparator(s)	Usual care, adjunctive pharmacologic treatments (e.g., lithium, anticonvulsants, antipsychotics, ketamine), other listed interventions
Outcome(s) (up to five)	Critical: Mortality, remission of major depression, improvement in depression symptom scores including functional measures Important: Quality of life, adverse effects/harms <i>Considered but not selected for GRADE Table:</i> Time to remission of major depression
Key questions	<ol style="list-style-type: none"> 1. What is the comparative effectiveness of non-pharmacologic interventions for treatment-resistant depression? 2. Does the comparative effectiveness of non-pharmacologic interventions for treatment-resistant depression vary by: <ol style="list-style-type: none"> a. Age b. Gender c. Duration of symptoms d. Number, type and duration of previous treatment attempts e. Co-morbid conditions f. Ability to adhere to initial treatment plan 3. What are the harms of non-pharmacologic interventions for treatment-resistant depression?

SCOPE STATEMENT FOR HERC COVERAGE GUIDANCE

IMAGING FOR LOW BACK PAIN

Population description	Adults with acute low back pain or acute exacerbations of chronic low back pain <i>Population scoping notes: None</i>
Intervention(s)	MRI, CT, plain x-rays, myelography, thermography <i>Intervention exclusions: None</i>
Comparator(s)	Usual care without imaging, other listed interventions
Outcome(s) (up to five)	Critical: Short-term function, long-term function, long-term risk of undergoing surgery Important: Quality of life, adverse events (including incidental findings) <i>Considered but not selected for GRADE Table: Pain, reassurance</i>
Key questions	<ol style="list-style-type: none"> 1. What is the comparative effectiveness of advanced imaging for patients with non-specific low back pain? 2. Does the comparative effectiveness of advanced imaging for patients with non-specific low back pain vary by: <ol style="list-style-type: none"> a. Age b. Co-morbid conditions c. Duration of symptoms d. Presence of red-flag features e. Presence of radiculopathic pain f. Presence of abnormal neurologic signs or symptoms g. Candidacy for invasive interventions (e.g., surgery or percutaneous procedures) 3. What are the harms of advanced imaging for patients with non-specific low back pain?
Contextual questions	<ol style="list-style-type: none"> 1. Does the use of imaging in patients with low back pain affect the initial treatment strategy?

SCOPE STATEMENT FOR HERC COVERAGE GUIDANCE

LOW BACK PAIN: PHARMACOLOGICAL AND HERBAL THERAPIES

Population description	Adults with acute, subacute, or chronic low back pain with or without radiculopathy <i>Population scoping notes: None</i>
Intervention(s)	Pharmacological interventions, including acetaminophen, non-steroidal anti-inflammatory medications (NSAIDs), skeletal muscle relaxants, antidepressants, antiepileptics, benzodiazepines, opioids, topical therapies (e.g., NSAIDs, capsaicin, lidocaine, methyl salicylate), herbal therapies (e.g., devil's claw, willow bark, capsaicin), combinations of the above <i>Intervention exclusions: None</i>
Comparator(s)	Other interventions for low back pain (including others listed above, alone or in combination), no treatment
Outcome(s) (up to five)	Critical: Short-term function, long-term function, long-term risk of undergoing surgery Important: Adverse events, change in utilization of comparators <i>Considered but not selected for GRADE Table: Short-term pain, long-term pain</i>
Key questions	<ol style="list-style-type: none"> 1. What is the comparative effectiveness of pharmacological and herbal interventions for low back pain? 2. Does the comparative effectiveness of the interventions vary by: <ol style="list-style-type: none"> a. Duration of back pain b. Etiology of back or radicular pain (e.g., stenosis, disc herniation) c. Presence or absence of neurologic deficit d. Dose and frequency of the medication e. Previous back surgery f. Response to previous medication trials g. Risk level for poor functional prognosis h. Comorbidities (physical or behavioral) 3. What are the harms of pharmacological interventions for low back pain?
Contextual questions	<ol style="list-style-type: none"> 1. Does the use of pharmacological therapies affect the subsequent use of health care resources? 2. Does the effectiveness of pharmacological and herbal therapies depend on prior treatments the patient has received?

CHANGE LOG

Date	Change	Rationale
7/21/2016	<ul style="list-style-type: none">• Clarified that comparators could be provided in combination as well as individually• Added presence or absence of neurologic deficit	Ensure search returns information relevant for coverage policy.

SCOPE STATEMENT FOR HERC COVERAGE GUIDANCE

LOW BACK PAIN: NON-PHARMACOLOGIC NON-INVASIVE INTERVENTIONS

Population description	Adults with acute, subacute, or chronic low back pain with or without radiculopathy <i>Population scoping notes: None</i>
Intervention(s)	Physical therapy, exercise therapy, home exercise programs, intensive interdisciplinary rehabilitation, massage therapy, progressive relaxation, yoga, cognitive-behavioral therapy, other behavioral health interventions, acupuncture (with or without electrical stimulation), spinal manipulation, continuous or intermittent traction, transcutaneous electrical nerve stimulation, interdisciplinary pain treatment programs, advice to remain active, combinations of the above <i>Intervention exclusions: None</i>
Comparator(s)	Other interventions for low back pain (including others listed above, alone or in combination), no treatment
Outcome(s) (up to five)	Critical: Short-term function, long-term function, long-term risk of undergoing surgery Important: Adverse events, change in utilization of comparators <i>Considered but not selected for GRADE Table: Short-term pain, long-term pain</i>
Key questions	<ol style="list-style-type: none"> 1. What is the comparative effectiveness of non-pharmacological/non-invasive interventions for low back pain? 2. Does the comparative effectiveness of the interventions vary by: <ol style="list-style-type: none"> a. Duration of back pain b. Etiology of back or radicular pain (e.g., stenosis, disc herniation) c. Presence or absence of neurologic deficit d. Intensity and frequency of the intervention e. Previous back surgery f. Response to previous trials of non-pharmacological/non-invasive interventions g. Risk level for poor functional prognosis h. Comorbidities (physical or behavioral) 3. What are the harms of non-pharmacological/non-invasive interventions for low back pain? 4. Which therapies or combinations of therapies are most cost-effective?

Contextual questions	<ol style="list-style-type: none"> 1. Does the use of non-pharmacological/non-invasive interventions affect the subsequent use of health care resources? 2. Does the effectiveness of non-pharmacological/non-invasive interventions depend on prior treatments the patient has received?
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CHANGE LOG

Date	Change	Rationale
7/21/2016	<ul style="list-style-type: none"> • Clarified that comparators could be provided in combination as well as individually • Added presence or absence of neurologic deficit 	Ensure search returns information relevant for coverage policy.

SCOPE STATEMENT FOR HERC COVERAGE GUIDANCE

LOW BACK PAIN: MINIMALLY INVASIVE AND NON-CORTICOSTEROID PERCUTANEOUS INTERVENTIONS

Population description	<p>Adults with acute, subacute, or chronic low back pain with or without radiculopathy</p> <p><i>Population scoping notes: None</i></p>
Intervention(s)	<p>Local injections (including trigger point injections), botulinum toxin injection, coblation nucleoplasty, radiofrequency denervation, prolotherapy, intradiscal electrothermal therapy (IDET), medial branch block, percutaneous intradiscal radiofrequency thermocoagulation, lumbar radiofrequency neurotomy, spinal cord (dorsal column) stimulators, sacroiliac joint injections</p> <p><i>Intervention exclusions: Corticosteroid injections are considered separately; these interventions, when used for diagnostic purposes, are beyond the scope of this review</i></p>
Comparator(s)	<p>Other interventions for low back pain (including others listed above, alone or in combination), no treatment</p>
Outcome(s) (up to five)	<p>Critical: Short-term function, long-term function, long-term risk of undergoing surgery</p> <p>Important: Adverse events, change in utilization of comparators</p> <p><i>Considered but not selected for GRADE Table: Short-term pain, long-term pain</i></p>
Key questions	<ol style="list-style-type: none"> 1. What is the comparative effectiveness of non-corticosteroid percutaneous or minimally invasive interventions for low back pain? 2. Does the comparative effectiveness of the interventions vary by: <ol style="list-style-type: none"> a. Duration of back pain b. Etiology of back or radicular pain (e.g., stenosis, disc herniation) c. Frequency of the intervention d. Presence or absence of neurologic deficit e. Anatomic approach f. Use of imaging guidance g. Previous back surgery h. Response to previous percutaneous interventions (diagnostic or therapeutic) i. Risk level for poor functional prognosis j. Comorbidities (physical or behavioral) 3. What are the harms of non-corticosteroid percutaneous or minimally invasive

	interventions for low back pain?
Contextual questions	<ol style="list-style-type: none"> 1. Does the use of these therapies affect subsequent use of health care resources? 2. How would availability of these therapies affect the need for advanced imaging to determine appropriate candidates for these interventions? 3. Does the effectiveness of these interventions depend on prior treatments the patient has received?

CHANGE LOG

Date	Change	Rationale
7/21/2016	<ul style="list-style-type: none"> • Clarified that comparators could be provided in combination as well as individually • Added presence or absence of neurologic deficit 	Ensure search returns information relevant for coverage policy.
8/5/2016	Clarify that interventions are only treatment interventions (review will not include diagnostic interventions). Corresponding changes to Key Question 2.	Clarify scope (in response to public comment)

SCOPE STATEMENT FOR HERC COVERAGE GUIDANCE

NEUROIMAGING FOR DEMENTIA

Population description	Adults with mild cognitive impairment or dementia <i>Population scoping notes: Considered screening for asymptomatic adults but didn't include this population.</i>
Intervention(s)	Neuroimaging for dementia including MRI, fMRI, CT, PET, SPECT; with or without tau ligands <i>Intervention exclusions: None</i>
Comparator(s)	Usual care without neuroimaging, other listed interventions
Outcome(s) (up to five)	Critical: Identification of reversible causes of dementia, progression of cognitive impairment/dementia symptoms, progression of functional limitation Important: Quality of life, adverse effects <i>Considered but not selected for GRADE Table: None</i>
Key questions	<ol style="list-style-type: none">1. What is the comparative effectiveness of neuroimaging for:<ol style="list-style-type: none">a. Identifying reversible causes of dementiab. Patients with mild cognitive impairmentc. Patients with established diagnoses of dementia 2. Does the comparative effectiveness of neuroimaging vary by:<ol style="list-style-type: none">a. Type, severity, or durationb. Response to previous treatmentsc. Type of imaging 3. What are the harms of neuroimaging?
Contextual questions	<ol style="list-style-type: none">1. Does information obtained from neuroimaging for dementia predict prognosis?