

INTRAUTERINE CONTRACEPTIVES (IUCS)

Family PACT makes available two Food and Drug Administration (FDA)-approved IUCs: the copper T380A (ParaGard®) and the levonorgestrel releasing intrauterine system (LNG-IUS; Mirena®). Both IUCs are as effective as tubal sterilization, provide continuous contraceptive protection over long time intervals, allow for rapid return of fertility after removal, and have a high rate of client satisfaction. When compared with other methods over a five-year period, the IUC is the most cost effective method of contraception available. This *Clinical Practice Alert* (CPA) updates the October 2006 "Intrauterine Contraceptives" CPA.

KEY POINTS

- IUCs are ideally suited for women who desire long-term contraception (for at least two years), including young women, those who have not been pregnant, and women who are unable or unwilling to use a combined hormonal method of contraception.
- An IUC user has no greater risk of pelvic inflammatory disease (PID) or tubal infertility than a woman who uses no method of contraception, other than a transient increased risk of infection in the first few weeks after placement.
- Providers must include complete documentation in a client's medical record to support services claimed for reimbursement and keep a written log or electronic record of all IUCs placed for at least three years from the placement date. The log must include the client's name, medical record and Health Access Programs (HAP) card number, date of placement, type of IUC, and the lot number of the IUC. Providers must maintain invoices of IUCs billed to Family PACT for at least three years.

QUESTIONS AND ANSWERS

How do IUCs prevent pregnancy?

The mechanism of action of both IUCs is to interfere with fertilization and not to affect implantation of a pre-embryo. The LNG-IUS works mainly by thickening cervical mucus while the copper IUC impairs sperm function. IUCs are not abortifacients.

Can women with multiple sexual partners use an IUC...don't they have a greater risk of PID?

An IUC user has no greater risk of PID or tubal infertility than a woman who uses no method of contraception, other than a transient increased risk of infection in the first few weeks after placement. Owing to its effect on cervical mucus, the LNG-IUS may reduce the risk of PID. Women who are at a "very high individual risk of exposure to gonorrhea (GC) or chlamydia (Ct)" are considered to be U.S. Eligibility Criteria for Contraceptive Use (US-MEC) Category 3,* while women with current GC or Ct, purulent cervicitis, or acute PID are US-MEC Category 4.* A prior history of PID is no longer considered to be a reason to avoid IUC use.

Can an adolescent or a woman who has never been pregnant choose to use an IUC?

Yes. Recent studies support this practice^{1,2} and these groups are classified as US-MEC Category 2.* Placement may be more difficult in adolescents and women who have never been pregnant and expulsion rates are slightly higher, in the range of five to seven percent, in comparison to a baseline expulsion rate of three to four percent.

What are the main differences between the two available IUCs?

The copper IUC is FDA-approved for 10 years of use, while the LNG-IUS is approved for five years. The advantages of the copper IUC are the absence of hormonal side effects and a longer duration of efficacy. The advantages of the LNG-IUS are a reduction in dysmenorrhea, and after the first three months, shorter and lighter menstrual periods that may progress to amenorrhea.

When should an IUC be placed?

A copper IUC can be placed any time that there is reasonable assurance that the client is not pregnant, while LNG-IUS product labeling recommends placement within seven days of the onset of menstruation. IUCs also can be placed immediately after a delivery or pregnancy termination, but there is a slightly higher likelihood of expulsion after delivery or second trimester abortion.

What interventions need to be performed prior to IUC placement?

There are *no* routine screening tests necessary before IUC placement. Pregnancy, Ct, and GC tests should be performed only as clinically indicated. Cervical cytology frequency is not affected by IUC use, and a pre-placement cytology, done in addition to routine cervical cytology, is unnecessary. Prophylactic antibiotics have no effect on infection rates.

Should a routine post-IUC placement visit be scheduled?

Practices are inconsistent in the U.S., but the World Health Organization (WHO),³ and the package labeling for both IUCs, recommend a follow-up visit in three to six weeks or after the first menstrual period following placement. If a follow-up visit is not routinely scheduled, the client should be advised to schedule a visit if she cannot feel her IUC string after her menstrual period.

How should an IUC user be managed if diagnosed with cervical Ct or GC, or with PID?

- Treat cervical Ct and GC with a Centers for Disease Control and Prevention (CDC)-recommended antibiotic regimen and leave the IUC in place.
- Treat PID with one of the CDC-recommended treatments and leave the IUC in place if she wishes to continue its use. If she does not want to keep the IUC, remove it after antibiotic treatment has been started. If the infection does not improve, generally the IUC is removed and antibiotics continued.
- Provide comprehensive management for sexually transmitted infections, including counseling about condom use.

Can the LNG-IUS cause systemic side effects?

Small amounts of levonorgestrel are absorbed, and in a few users, systemic side effects such as breast tenderness and headaches may occur. The mean plasma concentration of levonorgestrel reached is only five percent of an oral contraceptive containing levonorgestrel 150 mcg.

* Refer to CDC. **U.S Medical Eligibility Criteria for Contraceptive Use, 2010** MMWR 2010;59 RR-4.

Why should I use a uterine sound before the IUC insertion?

- Always use a tenaculum and a sound before IUC placement to determine uterine depth and angulation. Once the depth is found to be six to ten centimeters (cm) for the LNG-IUS or six to nine cm for the copper IUC, the IUC kit can be opened and the IUC placed.
- Avoid using the IUC inserter as a sound. Doing so may lead to the discovery of a uterine cavity that is too large or small to accommodate the IUC, and consequently, the contamination and wastage of the placement kit.

What can be done to manage cervical stenosis at the time of placement, especially with nulliparous women?

- Gently use greater outward traction on the tenaculum to minimize canal-to-cavity angulation.
- Place a para-cervical *or* an intra-cervical block to relax cervical smooth muscle and reduce pain.⁴
- Use an "Os-Finder" device, if available, or dilate the internal Os with dilators.
- The use of misoprostol before IUC placement has been evaluated in two small studies. In both studies, patient pain scores were the same in the treatment and control groups. One study showed a marginal improvement in ease of insertion,⁵ but the other did not.⁶ Consequently, current evidence does not support this practice, nor is the medication a Family PACT benefit.

What should be done when the IUC string cannot be visualized?

When an IUC string cannot be visualized, the possibility of expulsion, pregnancy, embedment, and translocation into the abdominal cavity must be considered. Ask the client whether she desires removal or retention of the IUC. Use the following step-wise approach.⁷

- Use a cytology brush to sweep the string from the cervical canal. If unsuccessful, recommend a back-up contraceptive method until IUC location is confirmed.
- Do a pregnancy test. If positive, perform or obtain a pelvic ultrasound to determine the location of the pregnancy and the IUC.
- If she is not pregnant and wishes to maintain the IUC, perform or obtain an abdominal pelvic ultrasound to assess the IUC location. If correct IUC placement is not confirmed, proceed to a vaginal pelvic ultrasound. If an appropriately located IUC is confirmed, no further follow-up is required until the IUC is to be removed. If absent from the uterus, a kidneys, ureters, and bladder (KUB) X-ray should be ordered to determine if the IUC has been expelled (IUC absent) or translocated into the abdominal cavity (IUC present).
- In non-pregnant patients who desire IUC removal, explore the endocervix with a Kelly, Patterson alligator or Spencer Wells forceps. If exploration is not successful, office extraction may be attempted by a clinician experienced in intrauterine instrumentation.
- If the IUC is felt but office extraction is unsuccessful, hysteroscopy is used to remove an embedded IUC.

APPLICATION OF FAMILY PACT POLICY

Who can insert IUCs in Family PACT?

Physicians, nurse practitioners, certified nurse midwives, and physician assistants who are operating within their scope of practice can perform IUC placements and removals in the Family PACT Program.

Will Family PACT cover the LNG-IUS if it is being used mainly to treat heavy menstrual bleeding?

The LNG-IUS reduces menstrual bleeding and can be an effective treatment for heavy or painful periods. Contraceptive methods provided in the Family PACT Program are intended to be used for family planning and not for treatment of unrelated medical conditions. As long as the primary purpose of the LNG-IUS is contraceptive, it may be used in women with heavy menses.

Does Family PACT cover IUC placements immediately after an abortion?

Yes, Family PACT benefits include the professional fee for IUC placement (Current Procedural Terminology [CPT] Code 58300), the placement kit (X1522: ParaGard;® X1532: Mirena® IUS) and placement supplies. Post abortion IUC placement is considered to be US-MEC Category 2,* owing to the slightly increased expulsion after abortion.

Which IUC-related complications are covered by Family PACT?

- Family PACT covers three imaging procedures in clients with a missing IUC string: ultrasound, pelvic (non-obstetric), real time with image documentation; limited or follow-up (CPT 76857); transvaginal ultrasound, (CPT 76830); and radiologic examination, abdomen; single anteroposterior (KUB; CPT 74000). These codes must be billed with primary diagnosis code S402 (IUC, maintain adherence and surveillance) and secondary diagnosis code V45.51 (presence of IUC). A Treatment Authorization Request (TAR) is not required
- Procedures to manage an embedded or translocated IUC include hysteroscopy, dilation and curettage, laparoscopy, or laparotomy. These services must be authorized by the use of a TAR.

Why do I need to track lot numbers of the IUCs placed in my practice?

- To facilitate client contact in the case of a product recall, providers must keep a written log or electronic record of all IUCs placed for at least three years from the placement date. Include the client's name, record number, date of placement, type of IUC, and lot number.
- All IUCs placed through the Family PACT Program must be FDA-approved devices, labeled for use in the U.S., and obtained from an appropriately registered, permitted, or licensed manufacturer, wholesaler, or distributor. Providers must maintain invoices for IUCs billed to Family PACT for at least three years in accordance with Title 22, California Code of Regulations, Code 51476 (a).

Providers should refer to the Family PACT Policies, Procedures, and Billing Instructions manual for the complete text of the Family PACT standards, official administrative practices, and billing information.

References

1. Deans EI, Grimes DA. Intrauterine devices for adolescents: a systematic review. *Contraception*. 2009 Jun;79(6):418-23.
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3. WHO Selected Practice Recommendations For Contraceptive Use 2004. Accessed at <http://whqlibdoc.who.int/publications/2004/9241562846.pdf>.
4. Allen RH. Interventions for pain with intrauterine device placement *Cochrane Database Syst Rev*. 2009; 8(3):CD007373.
5. Saav I., et.al. [Cervical priming with sublingual misoprostol prior to placement of an intrauterine device in nulliparous women: a randomized controlled trial](#). *Human Reproduction*. 2007 Oct.; 22(10):2647-52.
6. Dijkhuizen K, Dekkers OM, et. al. Vaginal misoprostol prior to insertion of an intrauterine device: an RCT. *Hum Reproduction*. 2011; 26(2):323-9.
7. Prabhakaran S, Chuang A. In-office retrieval of intrauterine contraceptive devices with missing strings. *Contraception* 2011; 83(2)102-6.