C5.4 – LEVONORGESTREL-RELEASING INTRAUTERINE DEVICE

Policy

There are multiple levonorgestrel-releasing Intrauterine Devices (LNG IUD) available in the United States. The prescribing information is similar for all the LNG IUDs, but Clinical Services Providers are expected to know the specific indications and prescribing information for each method. The policy below is generalized. The LNG IUDs are T-shaped polyethylene frame compounded with barium sulfate and with a drug reservoir around the vertical stem. The reservoir contains the LNG and allows for sustained release over the duration of action. The barium sulfate allows the IUD to be visible on x-ray imaging. The typical dose LNG IUD contains 52mg of levonogestrel (Liletta® and Mirena®) that is released initially at a rate of 20mcg per day. This rate decreases progressively to approximately 6.5mcg per day at 8 years. Thus, the average release rates over 8 years are approximately 13.5 mcg per day.

Misoprostol is **not** recommended for routine use before LNG IUD insertion. Misoprostol at the time of insertion might be helpful in select circumstances (e.g., in women with a recent failed insertion). Paracervical block with lidocaine might reduce patient pain during LNG IUD insertion in nulliparous clients. Insertion should not be delayed to allow for patients to be on their menses, unless pregnancy cannot be reliably excluded. Insertion during menses does not improve pain with insertion or decrease risk of failed insertion. Clients should be given information about insertion risks, expected bleeding changes, and other risks/benefits of the LNG IUD as part of the informed consent process. It is vital that patients understand how to access removal of a LARC device prior to insertion.

Procedure

Mode of Action

It is not known exactly how the LNG IUD works; the following are hypotheses:

- The most likely way that the IUD prevents pregnancy is by thickening cervical mucus, which interferes with sperm motility and function.
- A weak local foreign body inflammatory response is noted with the IUD, but is less pronounced than with copper IUDs.
- Prevents endometrial proliferation-full suppression noted after about 3 months with substantial (70-100%) decrease in menstrual flow with the 52mg LNG IUD (Liletta® and Mirena®). The amount of menstrual bleeding reduction is less with the lower dose LNG IUD (19.5mgLNG IUD/Kyleena®).

Effectiveness

Theoretical and actual effectiveness rate are 99.9%.

Contraindications

Absolute Contraindications

Unacceptable Health Risk (method should not be used):

- Known or suspected pregnancy.

- Acute, active pelvic infections/STI, current pelvic inflammatory disease, including immediate postpartum uterine infection/sepsis.
- Gestational Trophoblastic Disease with persistently elevated beta HCG levels or malignant disease **with** evidence or suspicion of intrauterine disease.
- Uterine abnormalities, including a distorted uterine cavity such as bicornuate uterus, other Mullerian anomalies, or fibroid(s) distorting the cavity.
- Cervical cancer, awaiting treatment.
- Immediately post-septic abortion.
- Pelvic tuberculosis.
- Unexplained vaginal bleeding.
- Current pregnancy (unless being used as EC) or inability to rule out pregnancy.
- Breast cancer, current.

Strong Relative Contraindications

Theoretical or proven risks usually outweigh the advantages:

- Complicated solid organ transplantation.
- Breast cancer in the past with no evidence of disease for the past 5 years.
- Malignant Hepatoma, hepatocellular adenoma or severally decompensated cirrhosis/liver failure.
- Systemic lupus erythematosus with unknown or positive anti-phospholipid antibodies.

Other Considerations

The advantages of using the IUD generally outweigh the theoretical or proven risk.
Refer to the Appendix for the CDC Medical Eligibility Criteria Summary Chart

Advantages

- No action is required for contraception
- The LNG IUD should not be noticeable during intercourse.
- It is always there when needed.
- Reduction in menstrual bleeding and related anemias.
- Reduction in dysmenorrhea.
- Reduction in ectopic pregnancies through an overall reduction in pregnancies.
- Can be inserted at any time if it is reasonably certain the client is not pregnant.
- Rapid return of fertility when removed.
- Does not alter breast milk production.

Disadvantages

- Must be changed periodically as indicated by the manufacturer
- May be expelled without the client's knowledge.
- Does not protect against STIs.
- Require cervical inspection and bimanual exam before insertion.

Side Effects possible related to the implant

- Irregular periods for 3 to 6 months post-insertion. Discuss the immediate return of fertility following discontinuation. Immediate use of alternative contraception after removal of IUD is recommended if the client is not desiring pregnancy.
- Amenorrhea in 1/5 of women.
- Possible hormonal side effects (mood changes, acne, headache, breast tenderness, nausea, hirsutism) however, these are typically temporary.

Warning Signs

- A late or missed period is seldom related to pregnancy unless accompanied by other signs and symptoms of pregnancy, but should be evaluated if new onset.
- Abdominal pain or pelvic pain or pain with intercourse (suggests perforation, partial expulsion, or infection).
- Fever/Chills (suggests infection) accompanied by pelvic pain.
- Foul vaginal discharge (suggests infection).
- Missing or change in length of LNG IUD strings (suggests expulsion or displacement).
- Severe or prolonged vaginal bleeding or spotting.
- Yellowing of skin or eyes.

Potential Complications Associated with Levonorgestrel IUD

- Uterine perforation, although this is very rare.
- Vaso-vagal response with insertion/removal (hypotension, pallor, brachycardia, feeling faint etc).
- Intra-uterine infection risk is increased in the first 3 weeks after IUD placement, but then returns to baseline. Risk of STI's is not increased with LNG IUD placement and STI can be treated with IUD in place.
- Rejection/expulsion of device (rate of expulsion may be increased with nulliparous women).
- Pregnancy.
- Risk of possible spontaneous abortion if conception occurs (chances are 25% risk if IUD removed, and 50% if LNG IUD left in place).
- The FDA approved lifespan for each LNG IUD is variable. See prescribing information. Use of any IUD beyond the approved lifespan is considered off-label use.
- LNG IUD are very effective in preventing pregnancy, so there is an overall decreased risk of pregnancy. Increased risk of ectopic pregnancy in the unlikely event a pregnancy occurs; women should be encouraged to seek immediate care with known or suspected pregnancy.

STI Testing

If a client has not been screened for STIs according to CDC STI screening guidelines, screening must be performed at the time of insertion. STI can be treated with an IUD in place.

Instructions to the Client

The only maintenance of the LNG IUD involves:

- Client checking devise string monthly if the client finds these reassuring, but it is not necessary.
- Client aware of danger signs including those of infection, expulsion and bleeding/cramping expectations after LNG IUD insertion.

- Annual exam for preventative care, also able to assess problems and check position of the IUD.
- Clients should be aware of type of IUD and duration of action to ensure timely removal and replacement. Please ensure that the client knows how to access removal services.
- Counsel about the need for back-up contraception as appropriate.
- Call the clinic with any problems related to method.

Fertility Return

Return to fertility after removal is typically rapid. Immediate use of an alternative contraceptive is recommended after removal if the client is not seeking pregnancy. Encourage prenatal vitamin initiation at time of removal if not switching to a different highly or moderately effective contraceptive method.

Interactions with Other Medications

Not applicable.

Date Revised	**September 2023**
References	Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html)
Additional Resources	Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use, 2020 (https://www.cdc.gov/reproductivehealth/contraception/pdf/summary-chart-us-medical-eligibility-criteria_508tagged.pdf)