C5.3 – ETONOGESTREL SUBDERMAL CONTRACEPTIVE IMPLANT

Policy

The etonogestrel 68mg subdermal implant (Nexplanon®) is an implantable form of birth control that is completely reversible. It is a single flexible, radiopaque, soft, thin plastic rod that is placed under the skin of the client's upper arm (ideally, non-dominant arm). Per FDA requirements, all Clinical Services Providers performing insertions and/or removals of the contraceptive subdermal implant should receive instructions, training and certification by the manufacturer prior to inserting or removing the implant. Clinical Services Providers should see Warnings and Precautions on current Prescribing Information follow manufacturer information for removing the implant. Counsel clients about back-up contraception as appropriate. Recent data on duration of action, show that the etonogestrel subdermal implant is efficacious for up to the end of the 4th year (see *Citations below in Resources), however it is FDA approved for up to 3 years of use. Please engage in discussion with the patient about the difference in FDA approval versus evidence-based efficacy as well as access to removal. It is vital that patients understand how to access removal of a LARC device prior to insertion.

Clients should be given information about the risks of implant insertion as part of the informed consent process. It is also very important to discuss the changes that can result in menstrual bleeding as a result of implant placement.

Procedure

Mode of Action

Etonogestrel 68mg sub-dermal implant has two main mechanisms of action:

1. Primarily, it effectively inhibits ovulation.
2. It increases the viscosity of cervical mucus making it more difficult for sperm to enter the uterus.

Effectiveness

The pregnancy rate is less than 1 per 200 women, which translates to an effectiveness of >99%.

Contraindications

Absolute Contraindications

- Pregnancy.
- Current breast cancer.
- Known hypersensitivity to any components of Nexplanon®-plastic (Ethylene Vinylacetate copolymer) rod, core of Ethylene Vinyl Acetate and Etonogesterol.

Strong Relative Contraindications

Exercise caution when providing/monitor for side effects:

- Undiagnosed vaginal bleeding.
- Malignant and benign liver tumors or hepatocellular adenoma.
- Current and/or history of ischemic heart disease.

- Past history of breast cancer with no evidence of disease for 5 years.
- Use of certain anticonvulsants that can decrease the efficacy of Nexplanon®:
- Phenytoin, carbamazepine, barbiturates, primidon topiramate, and oxcarbazepine.
- Cirrhosis – severe.
- Systemic lupus erythematosus **with** positive (or unknown) antiphospholipid antibodies.
- History of stroke

Other Considerations

The advantages of using the subdermal progestin implant generally outweigh the theoretical or proven risk. Please review the CDC medical eligibility criteria summary chart.

Advantages

- No action is required for contraception after insertion.
- It is always there when needed and is effective up to the end of the 4th year of use for contraception.
- Progestin is considered to be estrogen–friendly, therefore no impact on bone density.
- Can be inserted at any time if it is reasonably certain that the client is not pregnant.
- Has no impact on lactation and milk production, even when placed immediately after delivery.
- Overall reduction in menstrual bleeding.

Disadvantages

- Must be changed every 4-5 years (see citations below).
- Unpredictable bleeding patterns after placement that can range from infrequent to prolonged
- Requires Clinical Services Provider to insert and remove.
- Does not protect from STIs

Side Effects possible related to the implant

- Irregular and unpredictable bleeding ranging from infrequent to prolonged.
- Headache.
- Acne.
- Emotional lability
- Breast tenderness
- Weight gain is not associated with the implant. Average gain is 2.8 pounds at 1 year and 3.7 pounds at 2 years, which is not significantly dissimilar from non-users

Warning Signs

- Any subjective symptoms of pregnancy.
- Any sign of a blood clot, including sharp chest pain, sudden shortness of breath, persistent calf pain, crushing chest pain, heaviness in the chest, sudden severe headache, vomiting, dizziness or fainting with visual problems.
- Sudden partial or complete blindness.
- Complications with insertion or removal of device
- Yellowing of skin and whites of the eyes.
- Severe pain, swelling or tenderness in the abdomen.
- Breast lumps.
- Signs of severe depression.
- Heavy vaginal bleeding

Potential Complications Associated with the subdermal contraceptive implant

- Pain, irritation, swelling, hematoma or bruising at insertion site.
- Scarring, including a thick scar called a keloid.
- Infection.
- Implant breaks make removal difficult.
- Rarely expulsion of implant.
- Rarely need for surgery to remove an implant.
- Migration of the implant into surrounding or farther structures
- Ectopic pregnancy risk is not increased with the implant, but in the unlikely event that a pregnancy occurs while the implant is in situ, it must be ruled out.
- Interactions with other medicines (see website).
- Headache.
- Acne

Interactions with Other Medications

Certain drugs to treat cystic fibrosis (e.g., lumacaftor) might reduce effectiveness of hormonal contraceptives, including oral, injectable, transdermal and implantable contraceptives. Antiretroviral medications (such as efavirenz and fosampenavir) may impact etonogestrel levels but are not felt to be contraindications to implant use. Anti-epileptic medications can also interact with systemic hormonal contraceptives, such as the subdermal contraceptive implant. Please review all client medications thoroughly prior to insertion.

Instructions to the Client

The only maintenance of the subdermal contraceptive implant involves:

- Client aware of danger signs.
- Annual exam to assess problems and check position of Nexplanon® as well as provide other reproductive health cares.
- Client aware of when it should be replaced and how to access removal services.
- Call the clinic with any problems related to the method

Fertility Return

Clients should be aware of the variable lengths of time for fertility return after discontinuing any contraceptive, however, vast majority of women have rapid return to fertility after subdermal implant removal with average ovulation being 3 weeks after removal. 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.

Hormone Contraception and HIV

The CDC has affirmed the safe use of hormone contraception in women who are HIV positive.

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 & *Citations	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) *Thaxton L and Lavelanet A. Systematic review of efficacy with extended contraceptive implant duration. International Journal of Gynecology and Obstetrics. 21 October 2018. https://doi.org/10.1002/ijgo.12696 *McNicholas C, Maddipati R, Zhao Q, Swor E, Peipert JF, Use of etonogestrel implant and levonorgestrel iontrauterine device beyond the US FDA-approved duration. Obstetrics and Gynecolog. 125(3):599. 2015 *Ali M, Akin A, Bahomondes L, Brache V, Habib N, Landouylsi S, Hubacher D, WHO study group on subdermal implants for women. Extended use up to 5 years of the etonogestrel-releasing subdermal contraceptive implant: comparison to levonogestrel implant. Human Reproduction. 31(11):2491. 2016