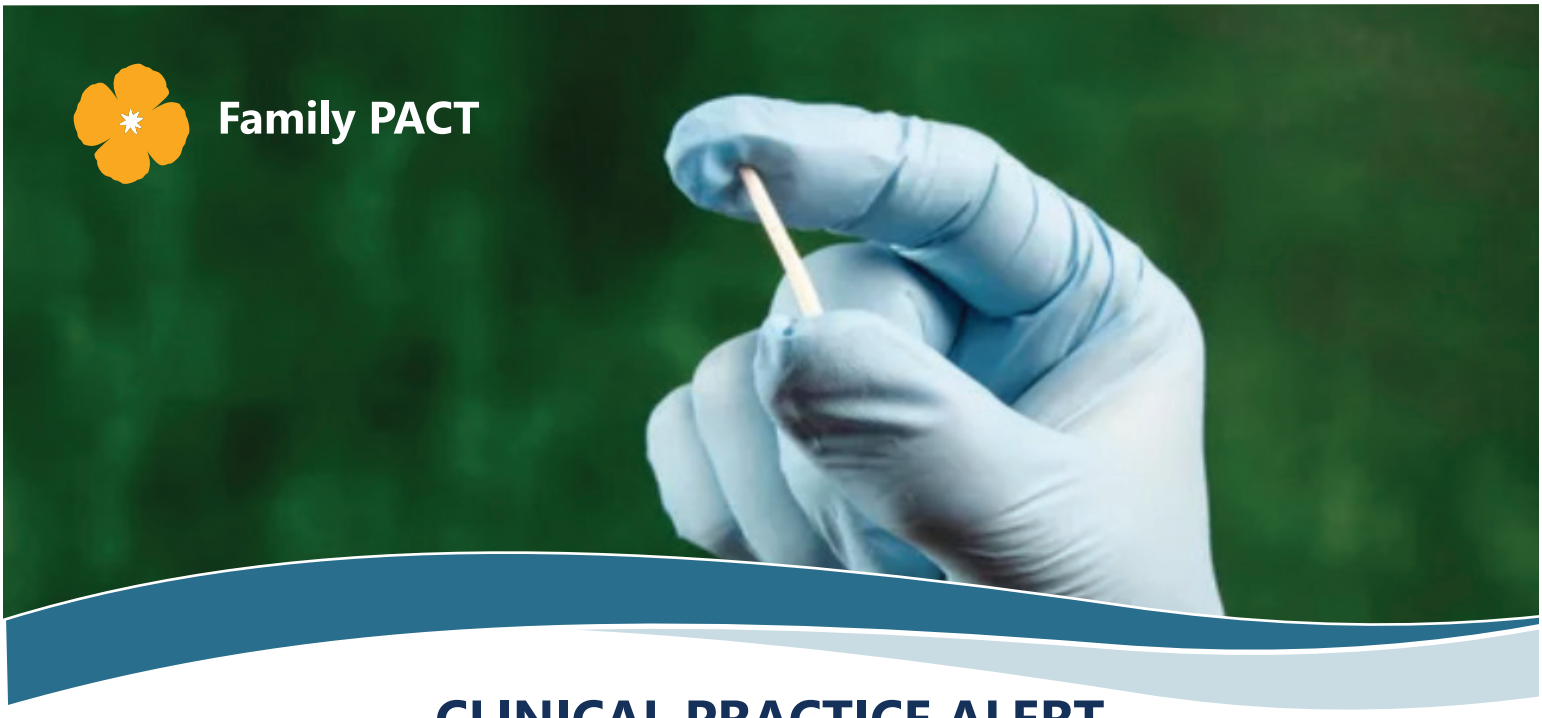

CLINICAL PRACTICE ALERT
CONTRACEPTIVE IMPLANTS

Introduction

The contraceptive implant (Nexplanon®) is a single rod-shaped implant containing the hormone progestin etonogestrel. It is inserted under the skin, at the inner side of the upper arm 3 centimeters below the sulcus between the biceps and triceps muscles. It is approved by the U.S. Food and Drug Administration (FDA) for use up to 3 years. When compared to its predecessor, Implanon®, Nexplanon® has a radiopaque rod-shaped implant and an improved one-hand applicator that was developed to decrease the risk of deep placement.

Notes:

- The term Nexplanon® is used when specific information regarding the product is provided. Otherwise, the generic name (contraceptive implant or implant) is used.
- In this document, the term "individuals" is used to refer to *individuals with a uterus*. When a guideline is quoted directly, the original terms of "woman" or "female" are used.

Key Recommendations:

- The benefits of contraceptive implants include high efficacy, rapid reversibility, steady hormone release, and a discreet placement site.
- Implant use will cause changes in menstrual bleeding patterns such that predictable monthly periods will cease, and bleeding may be unscheduled. Potential implant users must be counseled regarding characteristic bleeding patterns and be willing to accept these changes before implant placement is performed.
- Nexplanon® must be inserted and removed only by clinicians who have completed a company-sponsored training program.
- Family PACT providers must purchase Nexplanon® from a designated supplier and labeled for use in the United States. Providers must maintain invoices for Nexplanon® billed to Family PACT for at least 3 years in accordance with California Code of Regulations, title 22, section 51476, subdivision (a).

Questions and Answers

How effective are contraceptive implants?

The contraceptive implant is one of the most effective contraceptive methods available. Eleven international studies showed a failure rate of 0.38 failures per 100 individuals per year. In later studies in the United States, the typical failure rate was 0.1 failures per 100 individuals per year. No ectopic pregnancies were reported in either study. The CHOICE study[1] showed that efficacy, safety, and continuation rates were the same in users of all ages and all body mass indexes (BMIs).

What is the mechanism of action of contraceptive implants?

The main mechanism of action is by the inhibition of ovulation. A large clinical trial showed that no women ovulated in the first 30 months of use and 6% ovulated in the last 6 months of use, although no pregnancies resulted. In addition, etonogestrel causes thickening of cervical mucus, which contributes to contraceptive efficacy.

Are there any contraindications to implant placement?

As a progestin-only method, implants have few contraindications. According to the Centers for Disease Control and Prevention (CDC) *U.S. Medical Eligibility Criteria for Contraceptive Use, 2016 (U.S. MEC)*[2], current breast cancer is the only **U.S. MEC-4** (an unacceptable health risk if the contraceptive is used) condition. **U.S. MEC-3** conditions include past breast cancer (5 or more years ago and no recurrence), severe (decompensated) liver cirrhosis, a history of a benign or malignant liver tumor, lupus with positive (or unknown) antiphospholipid antibodies, unexplained vaginal bleeding (before evaluation and suspicious for a serious condition), and continuation of the implant after a heart attack or stroke.

What should the individual expect regarding menstrual patterns?

The menstrual bleeding pattern of individuals who use contraceptive implants is unpredictable and bleeding may be unscheduled. Studies show that there are no predictable trends in bleeding patterns over time. Counsel individuals that they will have fewer bleeding episodes and the same or fewer bleeding days, but that the bleeding days and episodes will be unpredictable and there may be more spotting days than before implant insertion.

How can this bleeding pattern be managed?

Pre-insertion counseling regarding the nature of the expected bleeding pattern is an important step in improving method acceptability. When unpredictable bleeding occurs after implant insertion, reassure the individual that this is an expected consequence of the method.

The *U.S. Selected Practice Recommendations for Contraception Use, 2016 (U.S. SPR)*[3] states that the following treatment options during days of bleeding can be considered:

- Estradiol 1-2 mg orally once a day for 10-14 days (a Family PACT benefit).
- Oral contraceptives, given for two or three cycles (oral contraceptives solely as a treatment to control abnormal vaginal bleeding is not a Family PACT benefit).
- Ibuprofen 800 mg three times a day for 7 days.

Since continuous progestin prevents endometrial hyperplasia; endometrial biopsy rarely is necessary.

Is the contraceptive implant a good method for adolescents?

While contraceptive implants are as safe and efficacious in adolescents as in older women, some adolescents will not be able to tolerate the unpredictable bleeding pattern induced by the method. Clear and direct post-placement counseling that is easily accessible to the individual will improve continuation rates.

Are there any drug-drug interactions with contraceptive implants?

- The U.S. MEC[2] lists a number of anti-retroviral drug regimens for human immunodeficiency virus (HIV) as **MEC-2**, but a few are considered to be **MEC-1**. Some anti-seizure drugs also are listed as **MEC-2**.
- Although there are no published studies on drug interactions with contraceptive implants, efficacy may be reduced for individuals who require chronic use of cytochrome P-450 enzyme-inducing drugs. Examples of these medications include rifampin, phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine, and St. John's wort.
- A back-up method should be used by individuals using short-term rifampin for methicillin-resistant Staphylococcus aureus (MRSA) skin infections.

When is the recommended time to place a contraceptive implant?

Nexplanon® package labeling includes the following guidelines. If placed as recommended, back-up contraception is not necessary.

- Standard start-up: insert within 5 days of initiation of menses.
- Switching from combined hormonal methods: insert within 7 days of last active dose.
- Switching from progestin-only method: insert any day when progestin-only pills are used or before the due date of the next depot medroxyprogesterone acetate (DMPA) injection.
- If an "off-cycle" insertion is performed, pregnancy should be excluded, and the individual should use a non-hormonal method of birth control during the first 7 days after the insertion. In addition, emergency contraception (EC) should be offered if there has been unprotected sexual intercourse during the 5 days before the insertion.

The U.S. MEC[2] gives the following recommendations for contraceptive implant placement after pregnancy.

- **MEC-2**: <30 days postpartum and breastfeeding.
- **MEC-1**: Postpartum and not breastfeeding and after first or second-trimester abortion.

Can a contraceptive implant be placed after using ulipristal acetate (UPA-EC: Ella®) for emergency contraception?

Individuals should be advised to wait 5 days after taking UPA-EC before insertion of the implant. They should be made aware that they must use condoms reliably or abstain from sexual intercourse during the 5 days after taking UPA-EC and then for 7 days after implant insertion. Insertion of the implant at the time of UPA-EC use may be considered. The risk that the implant might decrease the effectiveness of UPA-EC must be weighed against the risk of not starting a regular hormonal method.

Applications of Family PACT Policies

Is my practice required to make implant placements and removals available to all our clients?

Family PACT Standards state that contraceptive implant services shall be available onsite. However, in some cases, clients can be referred to another provider, based on established arrangements with other Family PACT and Medi-Cal provider(s) for contraceptive implant procedures that are outside the technical skill of the Family PACT provider or when there is insufficient volume to ensure and maintain a high skill level of the Family PACT provider.

Referrals to Family PACT or Medi-Cal providers for contraceptive implant services shall be documented in the client's medical record and include information on the referral provider and a scheduled appointment for the client (Program Standards section of the *Family PACT Policies, Procedures and Billing Instructions (PPBI)* manual).

How can clinicians be trained in Nexplanon® placement and removal?

Only providers that have completed the company-sponsored training course will be permitted to purchase Nexplanon®. See the additional resources section below to request training. Physicians and non-physician medical practitioners (nurse practitioners, certified nurse midwives, and physician assistants) can perform Nexplanon® insertions and removals.

How often will Family PACT cover a contraceptive implant for an individual?

Family PACT benefit policies cover implant placement once every 3 years. It is limited to one per client, for any provider, every 34 months. While the duration of action of Nexplanon® is 36 months (with evidence indicating it is reliable contraception for up to 5 years), the 34-month limit will permit early removal and insertion of a new implant if necessary for scheduling purposes.

In some circumstances, an earlier replacement will be covered. Providers must document the medical necessity for billing repeat implant placement within the device's duration of use in the Remarks field (Box 80)/Additional Claim Information field (Box 19) of the claim. More information can be found in the Benefits: Family Planning section of the PPBI manual.

What recordkeeping policies does Family PACT require?

- The individual must sign a written consent for Nexplanon® insertion and removal. The consent form provided by the Nexplanon® manufacturer with the insertion kit is recommended but another with equivalent content may be used.
- To facilitate individual contact in the case of a product recall, providers must keep a written log or electronic record of all Nexplanon® inserted for at least 3 years from the insertion date. The log must include the client's name, record number, Health Access Programs (HAP) ID number, date of insertion, and the lot number of the Nexplanon® used.
- A confidential contact address should be obtained from the individual so that they can be notified in the event of a product recall or other Nexplanon®-related safety considerations.

- All Nexplanon® inserted through the Family PACT Program must be FDA-approved, labeled for use in the United States, and obtained from the approved distributors (CuraScript SD or TheraCom). The contraceptive implant is available through Apexus and 340B federal pricing.
- Providers must maintain invoices for insertion kits billed to Family PACT for at least 3 years from the date of the invoice.

Which contraceptive implant complications does Family PACT cover?

- The management of certain contraceptive implant complications is a benefit of Family PACT, as specified in the PPBI manual. Examples include implant-site cellulitis or abscess, hematoma, and heavy vaginal bleeding. These services must be authorized using a Treatment Authorization Request (TAR) found in the Benefits: Family Planning section of the PPBI manual.
- To evaluate the location of a *non-palpable* radiopaque implant, Family PACT benefits include an x-ray of the upper arm (radiologic examination; humerus, minimum two views) and an upper arm ultrasound scanning study with a high-frequency linear array transducer (15-18 MHz or greater), which is helpful to measure the depth of the implant (ultrasound, limited, joint or other nonvascular extremity structure(s), real-time with image documentation). A TAR is not necessary.
- When upper extremity x-ray or ultrasound results are indeterminate and further imaging is necessary for surgical management, upper extremity magnetic resonance imaging (MRI) and fluoroscopy are benefits with an approved TAR. If at any time these imaging methods fail to locate the implant, etonogestrel blood level determination can be used for verification of the presence of the implant. For details on etonogestrel blood level determination and further instructions, contact Organon at 1-844-674-3200.
- Removal of non-palpable implants should be performed only by a health care professional experienced in removing deeply placed implants and familiar with localizing the implant and the anatomy of the arm. If imaging shows the implant to be too deep for clinic removal or in a vulnerable area (close to vascular structures or nerves), the individual can be referred (via TAR) for an implant removal procedure in an office or surgicenter. Conscious sedation and real-time ultrasound imaging during the removal are Family PACT benefits.
- When referring for expert management, the use of an Organon Center of Experience is strongly encouraged. Call the Organon Service Center at 1-844-674-3200.

References

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Additional Resources

1. Nexplanon consumer website: http://www.Nexplanon.com/.
2. Nexplanon provider website: https://organonpro.com/en-us/product/nexplanon/overview/.
3. Menon K. Insertion and removal of Nexplanon. *BMJ Sex Reprod Health*. 2021 Jan;47(1):70. https://srh.bmj.com/content/47/1/70.long.
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