



Indian Health Service  
National Pharmacy and Therapeutics Committee  
**Formulary Brief: Contraception**  
-August 2016-



**Background:**

The IHS National Pharmacy & Therapeutics Committee reviewed the medication class of Hormonal Contraception in August 2016, including long-acting reversible contraceptives (LARCs – Intrauterine Devices [IUD] and Implants), injectable contraception (medroxyprogesterone acetate), diverse combined oral contraceptive (COC) regimens, progesterone-only pills (POPs), transdermal and vaginal contraceptives (“the Patch” and “the Ring”), and emergency contraception (Plan B One-Step<sup>®</sup>, ulipristal acetate (Ella<sup>®</sup>) and the Copper IUD). IHS utilization and procurement data were also reviewed. Additionally, the U.S. Centers for Disease Control and Prevention (CDC) guidance on contraceptive best practices was highlighted.

As a result of the review, the NPTC:

- **ADDED an extended cycle combined oral contraceptive pill (any)**
- **ADDED the emergency contraceptive agent, ulipristal acetate**
- **REMOVED the branded designation for the contraceptive transdermal patch, vaginal ring, contraceptive implant, copper IUD, and progesterone IUD. (All items remain on the NCF without a branded identifier)**

**Discussion:**

Access to contraception affords a woman the opportunity to plan and space her pregnancies and to avoid undesired pregnancy. Use of contraception can be lifesaving for women for whom pregnancy is medically contraindicated. Use of contraception has contributed to marked declines in maternal and infant mortality. Coverage of 18 contraceptive methods without co-pay is mandated by the Affordable Care Act.<sup>1-3</sup>

Contraceptive Methods Reviewed<sup>4-6</sup>:

Method	Name	Use	Pregnancies expected (per 100 women in a year)	Comments
IUD-Copper	Paragard <sup>®</sup>	Up to 10 years	<1	Non-hormonal. May also be used for emergency contraception.
IUD-Levonorgestrel	Mirena <sup>®</sup>	Up to 5 years	<1	Favorable bleeding profile, may be useful in the management of menorrhagia. Liletta is a lower cost alternative.
	Skyla <sup>®</sup>	Up to 3 years	<1	
	Liletta <sup>®</sup>	Up to 3 years	<1	
Implant	Nexplanon <sup>®</sup>	Up to 3 years	<1	Overall well-tolerated, may have irregular bleeding. Often preferred by adolescents.
Injectable	Depo-Provera <sup>®</sup>	Injection every 12 weeks	6	Concern for weight gain may lead to discontinuation. Concern for bone loss not born out by available evidence. May be used for more than 2 years in adults and in adolescents when no acceptable alternative is available.
Combined oral contraceptive pills (COCs)	Many	Taken daily	9	Many regimens with fixed or varying doses of estrogen (mostly ethinyl estradiol) and progesterone (many) in mono-, bi-, tri-, and quadriphasic regimens. Similar efficacy and side effects for all formulations.
COC – extended regimen	Several	Taken daily	9	Extended regimens (typically 84 active pills and 7 inactive) offer less bleeding days (and bleeding associated side effects) but with more unscheduled bleeding.
Progesterone-only pills (POPs)	Several	Taken daily	9	For those with a contraindication or preference to avoid estrogen. To maintain efficacy, must be taken at the same time each day (within 3 hours). There are no inactive pills.
Patch	Xulane <sup>®</sup>	Placed weekly x 3 weeks, then one patch free week	9	Similar side effects and risk profile to COCs, possible modest increased risk VTE. May be less effective in women over 198 lbs.
Vaginal ring	NuvaRing <sup>®</sup>	Worn vaginally x 3 weeks, then one ring free week.	9	Similar side effects and risk profile to COCs.

### Intrauterine Contraception (Failure Rate < 1 per 100 women)

There are 4 IUDs available in the U.S. Three devices release levonorgestrel: Mirena® (20 mcg/day → 10 mcg/day over 5 years), Liletta® (18.6 mcg/day → 12.6mcg/day over 3 years), Skyla® (14 mcg/day → 5 mcg/day over 3 years) and Paragard® (copper-containing). The progesterone-containing IUDs have an especially favorable bleeding profile and may be useful in the management of menorrhagia. Skyla® has a slightly smaller frame which may facilitate placement in nulliparous women (although these women are eligible to use any IUD). The copper IUD may also be used for emergency contraception. The cost profile of Liletta® is especially favorable.

### Implants (Failure Rate < 1 per 100 women)

The contraceptive implant (Nexplanon®) is approved for use for 3 years. It is a single 4 cm capsule that releases 60–70 mcg/day → 25–30 mcg/day etonogestrel over 3 years of use. Placement of IUDs and implants require an appropriately skilled and credentialed provider. LARCs are recommended for first-line use in adolescents by the AAP and ACOG.

### Injections (Failure Rate 6 per 100)

Medroxyprogesterone acetate (Depo-Provera®) is available in both IM and SQ formulations. Concern for weight gain is cited as a frequent reason for patients discontinuing this method. Although a black box warning has been issued about bone loss with prolonged use, national and international experts endorse the safety of this method for long-term use in adults when no acceptable alternative exists.

### Pills, Patches and Rings (Failure Rate 9 per 100)

There are many formulations of combined hormonal contraceptive pills, most with ethinyl estradiol and a variety of progestins, originally in regimens of 21 days of active pills and 7 days of placebo pills. Many regimens have been developed, including extended cycle pills which have up to 84 days of active pills and are designed to minimize symptoms associated with withdrawal bleeds. Progestin-only pills are designed for those with a contraindication to estrogen use and are sometimes preferred by breastfeeding women. To preserve efficacy, POPs must be taken within 3 hours of the same time each day. Transdermal patches and vaginal contraceptive rings are offer alternative delivery methods and less frequent administration.

### Emergency Contraception (EC)

EC provides an opportunity to avoid unintended pregnancy when a primary method of contraception has failed, was not used, or when a woman has been sexually assaulted. It is the policy of the Indian Health Service that EC be made available to all female patients who request it without barriers or delay. There are 3 dedicated methods of EC currently available in the U.S.:

- Plan B One-Step® (levonorgestrel) - Less effective at weight >165 lbs and >3 days of exposure
- Ella® (ulipristal acetate) - effective up to 5 days after exposure. May be less effective over 195 lbs
- The Copper IUD - if inserted within 5 days of unprotected intercourse is nearly 100% effective

Sites are encouraged to expedite access to ulipristal acetate and copper IUD insertion without posing barriers or delays in Plan B One-Step® access.

### Efficacy:

The Choice study, a prospective trial of contraceptive efficacy that enrolled nearly 10,000 women in St. Louis, provided free contraception for 3 years and followed women to ascertain contraceptive failure rates and satisfaction. Those who selected LARC methods (IUDs and Implants) were significantly more likely to continue their methods and to be satisfied with their choice. **The LARC methods were 20 times more effective than Pills, Patches, and Rings.** Notably the abortion rate in the study population was 3 times lower than the local population and 4 times lower than the national rate.<sup>7-8</sup>

### Method Selection and Contraceptive Best Practices:

In 2010, the CDC adapted the World Health Organization Medical Eligibility Criteria for Contraceptive Use (MEC) for the U.S. In 2013, the U.S. Selected Practice Recommendations for Contraceptive Use (SPR) were issued. The CDC updated the MEC and SPR in July 2016. The MEC provides guidance on the appropriateness of each method for given personal characteristics and medical conditions. A review of the MEC table, [available here](#), reveals the relative safety of most methods for most conditions and serves as a handy reference tool. More information is available on the website and via phone application (“app”). The SPR includes best practices for contraceptive prescribing, including how to be “reasonably certain that a woman is not pregnant”, and which screening tests (if any) are recommended prior to the initiation of various methods.<sup>5-6</sup>

The American Congress of Obstetricians and Gynecology and the American Academy of Pediatrics recommend LARC methods as first line for adolescents. Adolescent confidentiality in contraceptive access should be assured in accordance with federal, state, tribal, and local legislation. Attention to the billing and insurance claim process is necessary to assure that adolescent confidentiality is not unintentionally violated.<sup>9-11</sup>

**\*\*Resources:\*\***

**For clinicians:** There's an app for that!

CDC MEC & SPR app: <http://www.cdc.gov/reproductivehealth/contraception/usmec.htm>

Free posters and handouts: [www.bixbycenter.ucsf.edu/orderform](http://www.bixbycenter.ucsf.edu/orderform)

**For patients:** Here's some engaging and accurate contraception information for patients:

[www.bedsider.org](http://www.bedsider.org)

<http://www.arhp.org/methodmatch/>

Be sure your patients can find you for their birth control needs. Please [register](#) your clinic with Bedsider's Clinic Finder Program; it's easy and free. The IHS and Bedsider are working together to offer better access to birth control.

**Findings:**

In compliance with the provisions of the Affordable Care Act, all prescription contraception methods are included on the IHS NCF. Clinicians are encouraged to consult the MEC and SPR for guidance on contraceptive best practices. Barriers to contraceptive access should be identified and eliminated.

**Conclusions:**

1. LARCs are the most effective contraceptive methods and should be widely available. Training in insertion and removal for appropriate staff should be accorded a high priority to assure access.
2. The MEC and SPR are important tools to guide contraceptive selection and contraceptive practice.
3. Plan B One-Step<sup>®</sup> is available for direct dispensing at all IHS pharmacies. Ulipristal acetate and Copper IUD placement are more effective emergency contraceptive options that require a prescription (and, for the IUD, a trained inserter). Patients should be informed of the availability of these prescription-based methods without creating any barriers to on-demand access for Plan B One-Step<sup>®</sup>.

*If you have any questions regarding this document, please contact the NPTC at [IHSNPTC1@ihs.gov](mailto:IHSNPTC1@ihs.gov). For more information about the NPTC, please visit the [NPTC website](#).*

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