

Contraceptive Agents

Executive Summary^{1-7,15,17}

- Nineteen new oral contraceptive (OCs) products and one new contraceptive transdermal patch are being marketed in the United States; all are generic entrants with no unique FDA indications.
- There is a wide variety of oral contraceptive products currently on the Uniform Formulary (UF) with differences in estrogen content, progestogen content, regimen, phasic formulation, non-contraceptive benefits, and route of administration.
- There are no differences in clinical efficacy between monophasic and multiphasic formulations.
- Comparisons between combination oral contraceptives and miscellaneous agents indicate comparable efficacy.
- The choice of a specific contraceptive product is determined by the individual patient's characteristics.

Background^{1-7,15,17}

The UF contains a wide variety of hormonal and non-hormonal contraceptives. This review primarily focuses on the following formulations: monophasic, extended cycle/continuous use regimen, multiphasic (biphasic, triphasic, quadriphasic), progestogen-only, and miscellaneous (transdermal patch, vaginal ring, and injection) contraceptives. Since 2013, chewable and extended cycle formulations have been introduced into the market; however, there do not appear to be any significant differences in efficacy among the contraceptives. Contraceptive method choice essentially depends on the safety, effectiveness, availability, and acceptability.

Refer to the accompanying 2016 Contraceptive Mega Table for:

- Contraceptive UF subclasses
- Cycle regimen
- Current formulary status

Summary of the Evidence¹⁻²⁰

- When taken properly, oral hormonal contraceptives are reversible and very effective forms of contraception.
- Miscellaneous contraceptive methods include transdermal patch (Xulane), vaginal ring (NuvaRing), and injection (depot medroxyprogesterone acetate and equivalent).
- All of these methods result in comparable overall failure rates of up to 9% with typical use, depending on the individual's consistency and correctness of use. With correct use, the overall contraceptive failure rate drops to less than 1%.
- While all contraceptive formulations are generally effective in prevention of pregnancy in women with obesity (BMI >35 kg/m²), the United States Medical Eligibility Criteria (US MEC) for Contraceptive Use recommends depot medroxyprogesterone acetate or the copper intrauterine device to reduce the risk of contraceptive failure.
- Risks and benefits of contraceptives depend on various factors, including dose and type of estrogen and progestin activity. Higher estrogen content is associated with higher risks of venous thromboembolism.
- Most, if not all, estrogen-progestin contraceptives offer non-contraceptive benefits, including menstrual cycle regularity, acne reduction, dysmenorrhea, decreased pelvic pain due to endometriosis, and decreased menstrual migraines, regardless of FDA labeling. Extended cycle or continuous use formulations offer treatment of premenstrual syndrome and premenstrual dysphoric disorder.
- Most commonly reported adverse effects of oral contraceptives include breast tenderness, headache, migraine, nausea, nervousness, vomiting, dizziness, weight gain, fluid retention, tiredness, decline of libido, and increased blood pressure.
- Certain drugs or herbal products may decrease effectiveness of combined contraceptives or increase breakthrough bleeding. Co-administration of drugs affecting the hepatic cytochrome P450 enzyme system may increase or decrease plasma levels of hormone contraceptives. These include barbiturates, carbamazepine, griseofulvin, oxcarbazepine, phenytoin, rifampin, topiramate, ketoconazole, itraconazole, and St John's wort. HIV drugs and antibiotics have also been shown to affect plasma concentration of contraceptives.

Affordable Care Act Implementation^{14-15,20}

Under the Affordable Care Act (ACA), FAQs Implementation Part XXVI, the Departments of Labor (DOL), Health and Human Services (HHS), and the Treasury identified health plan coverage requirements for preventive health care services for women. "These FAQs provide further guidance on the scope of coverage required for [18 of the FDA's methods of female] contraception and the extent to which plans and issuers may utilize reasonable medical management." Specifically, health plans must cover, without cost sharing, at least one form of birth control under each contraceptive method and may utilize reasonable medical management techniques to encourage a specific item within the chosen contraception method. While the Secretary of Defense is drafting legislation for "Expansion of TRICARE-covered Preventive Health Care Services," with provision to waive copayments for preventive services, the DoD is currently **not** required to be in parity with the ACA.

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Abbreviations and Acronyms

ACA	– Affordable Care Act
BMI	– body mass index
CDC	– Centers for Disease Control and Prevention
DoD	– United States Department of Defense
DOL	– United States Department of Labor
FAQ/FAQs	– Frequently Asked Question(s)
FDA	– U.S. Food and Drug Administration
HHS	– U.S. Department of Health and Human Services
HRSA	– Health Resources and Services Administration
OC	– oral contraceptive(s)
US MEC	– United States Medical Eligibility Criteria for Contraceptive Use
USPSTF	– United States Preventive Services Task Force