

Exploring the latest developments in hormonal and nonhormonal contraceptive options

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Continuing education approval: This activity has been evaluated and approved by the Continuing Education Approval Program of the National Association of Nurse Practitioners in Women's Health (NPWH) for 1.0 continuing education contact hour including 1.0 contact hour of pharmacology content now through February 28, 2026.

Educational objectives: At the conclusion of this educational activity, participants should be able to:

1. Describe mechanism of action, efficacy, use instructions, side effects, and contraindications for new progestin-only contraceptives.
2. Describe mechanism of action, efficacy, use instructions, side effects, and contraindications for new combination hormone contraceptives.
3. Discuss updated duration of use approvals for various intrauterine devices.
4. Discuss mechanism of action for currently available emergency contraception pills.

The authors have no actual or potential conflicts of interest in relation to the contents of this article.

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Women’s healthcare providers frequently find themselves navigating the complexities of family planning options with patients. The overwhelming variety of options available on the market today can leave patients feeling confused when determining the best course for their individual needs. This article explores the latest updates on traditional and modern approaches to contraceptive options, comparing efficacy, side effects, and user satisfaction.

KEY WORDS: hormonal contraception, nonhormonal contraception, intrauterine device, emergency contraception

Womens Healthcare. 2024;12(1):4-10. doi: 10.51256/WHC022404

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When having discussions for shared decision making about the best contraceptive for a patient, several factors should be considered. These include patient preference, product effectiveness, patient’s adherence ability, product accessibility (availability and cost), age, medical history, concomitant medications, side effects, frequency of sexual intercourse, need for prevention of sexually transmitted infections, and return to fertility rate (*Table 1*). The Centers for Disease Control and Prevention Medical Eligibility Criteria (MEC) for Contraceptive Use also may help to determine best products for patient use with their rating system of 1 to 4 (1: no restriction for use; 2: condition where advantages of using the contraceptive outweigh the risk; 3: condition where theoretical or proven risk usually outweighs the advantages of the contraceptive; and 4: condition represents an unacceptable health risk if the contraceptive method is used).¹

There are a variety of contraceptive products available whether over the counter (OTC), prescription, hormonal, or nonhormonal. In recent years, a few new products have been introduced to the market (*Table 2*). This article focuses on these newer contraceptive drug products available since 2018.

Progestin-only contraceptives

Two progestin-only products are newly approved: norgestrel 0.075 mg and drospirenone 4 mg. Norgestrel is the first oral contraceptive approved for OTC use. In July 2023, the US Food and Drug Administration (FDA) approved it for OTC use by any person of any age who has started menstruating, with the manufacturer determining the timeline for availability and price.² Even though norgestrel has recently been approved, it is not a new medication. It was previously marketed as

prescription only by FDA approval in 1973.² The company voluntarily discontinued the product in 2005 for marketing reasons.²

It was in 2022 that the new manufacturer of norgestrel applied to the FDA to switch the product to nonprescription status. The change in status required that patients safely and effectively use the product through instructions in package labeling without assistance from a healthcare provider. The Adherence to Continuous-Dose Oral Contraceptive: Evaluation of Self-Selection and Use Study (ACCESS) was a 24-week, multicenter study that included females age 11 years and older to assess if norgestrel met criteria for nonprescription status. Endpoints included safety, efficacy, adherence, and participants able to select the correct product and use product appropriately. Participants completed diaries every 4 days for adherence, timing of medication adherence, and sexual activity.^{3,4} The threshold of adherence rates was 85% (taking the tablet daily) and 80% for timing of medication adherence (taking the tablet within 27 hours of previous dose). Limitations of the study included recall bias with e-diary entries and improbable dosing (reported number of tablets taken exceeding number of tablets provided). Once these factors were accounted for, the ACCESS study results met the FDA threshold for adherence. Some literacy limitations included participants’ understanding of when to use a backup method of contraception due to missed pills and in distinguishing differences between emergency contraception and norgestrel.⁴ Therefore, it is important to highlight when a backup contraceptive method is recommended and discuss that norgestrel is not an emergency contraceptive.

Norgestrel is highly effective in preventing pregnancy and works by

Table 1. Factors affecting contraceptive selection

Product specific

- Cost
- Availability
- Accessibility
- Side-effect profile
- Effectiveness

Patient specific

- Patient product preference
- Age
- Medical history
- Concomitant medications
- Ability to adhere to method use
- Risk for sexually transmitted infection
- Desired time for return to fertility
- Frequency of sexual intercourse
- Desire for product discretion

Table 2. Newer products on market^{2,5,6,13,14,17,18}

Generic	Formulation	Administration	Comments
Norgestrel 0.075 mg	Oral tablet	Take one tablet by mouth daily	Approved for OTC use, no placebo pills
Drospirenone 4 mg	Oral tablet	Take one tablet by mouth daily (24 days active tablets, 4 days placebo)	Longer window for missed dose (24 hr vs 3 hr in other progestin-only pills)
Drospirenone 3 mg/estretrol 14.2 mg	Oral tablet	Take one tablet by mouth daily	Minimal impact on coagulation, liver function, triglyceride levels, and breast health
Segesterone acetate 150 µg/ethinyl estradiol 13 µg	Vaginal ring	Remains in vagina for 21 days and removed for 1 week	One ring provides 1 year of contraception as compared with previous ring on market
Levonorgestrel 120 µg/ethinyl estradiol 30 µg	Hormonal patch	Applied to recommended areas for 3 weeks, then removed for 1 week	Offers lower levels of estrogen than previous patches on market
Lactic acid, citric acid, and potassium bitartrate	Spermicidal gel packaged in individual 5 g applicators	Applied within 1 hr before intercourse	Efficacy based on user proficiency

OTC, over the counter.

thickening cervical mucus helping to block sperm travel to the ovum and suppressing ovulation in some cycles.⁵ The reported perfect-use efficacy of norgestrel is 98% but more likely closer to 93% if considering real-world use.⁴ Data regarding reduced effectiveness with norgestrel in patients with obesity or overweight are not clear at this time, and caution of use may be warranted in this population.²

Norgestrel tablets are taken every day at the same time with no placebo pills in the cycle. A missed dose is considered 3 hours from the set administration time. If a dose is missed, the missed dose should be taken as soon as possible and a backup nonhormonal contraceptive method should be used for 48 hours. Therefore, consideration of use in patients who have issues with adherence is prudent.

Reported side effects include irregular menses, acne, headache, dizziness, vaginal discharge, nausea, fatigue, increased appetite, breast tenderness, bloating, dysmenorrhea, nervousness, and libido changes.⁴

Those who have current or a history of breast cancer, any cancer that is progestin-sensitive, known or suspected pregnancy, using another hormonal contraceptive concurrently, unexplained abnormal vaginal bleeding, hypersensitivity to FD&C Yellow No. 5 (tartrazine), or benign or malignant liver tumors should not use norgestrel.⁴ Drug interactions with norgestrel are similar to other progestin-only products.

Drospirenone 4 mg also is a progestin-only product that was FDA approved for pregnancy prevention in 2019. It is the first progestin-only contraceptive to only contain drospirenone and has a reported Pearl Index of 4.0 (4 out of 100 women may become pregnant over 1 year of use) for efficacy.⁶ Its mechanism of action in preventing pregnancy is by suppressing ovulation. Other prescription progestin-only tablets contain norethindrone 0.35 mg. Per the manufacturer, females with a body mass index (BMI) baseline of greater than or equal to 30 kg/m² (35%) and 35 kg/m² (18%) were

included in their studies but the data were insufficient to analyze by BMI subgroups.⁶ Other studies have concluded that drospirenone shows effectiveness in females with a BMI of greater than 30 kg/m².⁷

Drospirenone is a fourth-generation progestin derived from the aldosterone receptor antagonist spironolactone. Due to its similarity with spironolactone, drospirenone has some unique properties such as antiandrogenic and antiminerocorticoid effects, which may help decrease acne and water retention. Caution should be used in patients with a history of hyperkalemia, in patients taking concomitant medications that increase potassium levels, or in patients taking strong inhibitors of CYP3A4 (eg, ketoconazole, itraconazole, voriconazole, indinavir, boceprevir, and clarithromycin) long term.⁶

Drospirenone tablets are taken once daily for 24 days followed by 4 days of placebo tablets. A missed dose of drospirenone 4 mg is one not taken 24 hours from the set

administration time offering a wider window of administration compared to other progestin-only pills. If a drospirenone dose is missed, the missed dose should be taken as soon as possible with the rest of the tablets taken daily as directed. If two or more of the active tablets are missed, patients should continue taking one tablet daily until the end of the pack and use a backup contraceptive method until 7 consecutive days of active tablets have been taken.⁶

Side effects of drospirenone may include acne, headache, metrorrhagia, dysmenorrhea, vaginal bleeding, irregular menses, breast tenderness, decreased libido, and weight gain. In April 2012, the FDA announced required changes to product labeling of combined oral contraceptives that contain drospirenone to include information about the increased risk of thromboembolism.^{6,8,9} It is unclear if there is a higher risk of thromboembolism with drospirenone alone, but it is listed as a precaution in the package labeling.⁶ The American College of Obstetricians and Gynecologists considers the risk of thromboembolism in pregnancy higher than the potential risk of drospirenone use.¹⁰ The product should be discontinued if a patient experiences a thromboembolic event. It is unclear if drospirenone may affect bone mineral density loss, as its use may decrease estradiol levels. It has been reported that drospirenone 4 mg does not decrease estradiol (E2) levels to less than 30 pg/mL, which is considered the point at which low estradiol levels could cause bone loss.¹¹ Patients with renal impairment, adrenal insufficiency, benign or malignant liver tumors, liver impairment, or unexplained vaginal bleeding should not use drospirenone.⁶

Overall, drospirenone products may have less acne side effects, which may be a benefit for some patients.

Case 1

DE is 28 years old and seeking contraception. This patient developed a deep venous thrombosis (DVT) and subsequent pulmonary embolus (PE) 4 months ago while taking desogestrel 150 µg/ethinyl estradiol 30 µg. Subsequently, DE was found to be factor 5 Leiden positive. DE is 5'2", 115 pounds, and has no other health conditions. Which of the following contraceptive method options would be appropriate?

- A. Copper IUD
- B. Drospirenone 4 mg pill
- C. Levonorgestrel 120 µg/ethinyl estradiol 30 µg/patch
- D. Norgestrel 0.075 mg pill
- E. Segesterone 150 µg/ethinyl estradiol 13 µg/vaginal ring

Considering the patient's medical history, it is advisable to avoid estrogen and therefore options C and E are not recommended. All contraceptive methods containing estrogen are contraindicated with this patient's history. Option B raises concerns because it is unclear if there is a higher risk of thromboembolism and thromboembolism is listed as a precaution in the package labeling. Product A is the only one of these options that is category 1 rating for use when there is a history of DVT or PE according to the CDC MEC recommendations. Product D is category 2 in this situation and also might be considered.

Drospirenone has not been found in high amounts in breastmilk. Adverse effects on breastmilk production or health, growth, and development in breastfed infants of mothers using drospirenone is not anticipated.⁶ Therefore, this may be another progestin-only contraceptive option for nursing mothers.

Combined hormonal contraceptives

The combination of drospirenone 3 mg and estetrol 14.2 mg was approved by the FDA for use in 2021, becoming the first product to contain a new estrogen since the conception of oral contraceptive pills over 60 years ago.¹² Produced by the fetal liver at 9 weeks' gestation, estetrol exhibits minimal impact on coagulation, liver function, triglycerides, and breast health.¹³ Additional research may suggest its potential safety for individuals with relevant contraindications. At present, the listed contraindications on product labeling are the same as those for other combined oral contraceptives. The pill has high bioavailability and

a long half-life, with a significantly lower potency than that of estrogen, so it is dosed in milligrams versus micrograms. The North American efficacy study showcased effectiveness, favorable cycle control, safety, tolerability among participants, and a rapid return to fertility once discontinued.¹² Additionally, there was no significant difference in efficacy for those participants with a BMI greater than 30 kg/m², but more research is needed in this area. Side effects reported included irregular bleeding, headache, mood disturbance, weight gain, decreased libido, and mood swings, with the highest number of participants discontinuing the medication due to irregular bleeding.¹² This combination contraceptive prevents pregnancy primarily by suppressing ovulation. Patients should be advised to use a backup method of contraception for at least 7 days after initiation unless the first pill is taken on the first day of menses. Individuals missing two or more pills also should use a backup method for at least 7 days.¹⁴

The FDA granted approval to the

Table 3. Intrauterine devices^{13,15}

Generic	Length of use	Comments
Copper IUD	10 years	Nonhormonal
Levonorgestrel 52 mg	8 years	Only IUD FDA approved for treatment of heavy menstrual bleeding
Levonorgestrel 19.5 mg	5 years	—
Levonorgestrel 13.5 mg	3 years	Smallest of the IUDs, may be helpful for placement in adolescent or nulliparous patients

IUD, intrauterine device.

combination segesterone 150 µg/ethinyl estradiol 13 µg vaginal ring in 2018, providing a year-long contraceptive solution in contrast to the monthly duration of previous rings on the market.¹⁵ The ring contains a lower dose of ethinyl estradiol and a progesterone derivative that lacks evidence of androgenic impact. Unlike the vaginal systems before it, segesterone/ethinyl estradiol is larger in diameter, increasing risk for expulsion.¹⁵ It should be kept in the vagina for 21 days, then removed, washed with a mild soap, and placed in the container provided for 7 days. If left out for more than 2 hours during the 21-day scheduled days, a backup method of contraception should be used until the vaginal system has been in place for 7 continuous days. Segesterone/ethinyl estradiol lowers the risk of pregnancy by suppressing ovulation. Although reported to be 97.5% effective, further research is required for women with a BMI of 29 kg/m² or greater.¹⁵ The most common side effects noted in phase 3 trials included headache, abnormal bleeding, nausea and vomiting, vulvovaginal infection, abdominal pain, and expulsion.¹⁶ Patients should be advised that for best pregnancy prevention,

the ring should be left in place during intercourse. If the ring is taken out, patients should be advised not to leave it out more than 2 hours, as exceeding this time frame would require treating it as a missed dose.

Individuals who prefer hormonal patches now have an additional option that received FDA approval in 2020. Levonorgestrel 120 µg/ethinyl estradiol 30 µg offers lower levels of estrogen and stronger adhesive properties.¹⁶ The lower levels of hormone also help to improve side effects that are very similar to those of other combined hormonal methods, with the most common being issues related to administration site such as acne, rash, or irritation.¹⁷ This combination patch should be applied to the abdomen, buttocks, or upper back once weekly for 3 weeks. Patch adherence should be checked regularly, and patches that have become partially or completely detached should be replaced.¹⁷ Backup methods of contraception should be considered if the patch has been removed for more than 24 hours.¹⁷ Very specific directions are included in the package insert to help providers educate patients on the proper use of the product. Levonorgestrel/ethinyl estradiol prevents pregnancy

by suppressing ovulation. There is some concern for efficacy for patients with a BMI greater than 30 kg/m² and it is therefore contraindicated in this population.¹⁷

Nonhormonal contraceptives

Although significant progress has been achieved in the field of hormonal contraception, some individuals prefer a nonhormonal method. The vaginal gel containing a combination of lactic acid, citric acid, and potassium bitartrate received FDA approval in 2020. Enclosed in individual applicators, it is recommended to be inserted in the vagina promptly or within 1 hour before each instance of vaginal intercourse.¹⁸ This nonhormonal birth-control barrier method is not dependent on partner reliability. It works by preserving vaginal pH, which inhibits sperm motility while the gel acts as a barrier, preventing sperm from reaching the cervix.¹³ Early FDA investigations revealed the product to exhibit 93% effectiveness under ideal conditions, while the AMPOWER phase 3 study demonstrated an 86.3% effectiveness rate with typical usage.¹³ Because of this, it has been suggested that it could be a preferable contraceptive choice for individuals entering the late perimenopausal phase when the likelihood of pregnancy is diminished.¹² It is an excellent choice for individuals who desire a nonhormonal method of birth control but have allergies that prevent them from using other types of barrier methods. As expected, vaginal irritation is the most common side effect.

Intrauterine device update

The utilization of intrauterine devices (IUDs) for contraception is steadily increasing among individuals across all reproductive age groups, now

ranking as the third most prevalent option after tubal ligation and oral contraceptive pills (Table 3). IUDs containing levonorgestrel vary in potency, ranging from 13.5 mg to 52 mg, which represents the highest strength available in the current market. Regardless of the strength, levonorgestrel IUDs have demonstrated effectiveness in individuals with a BMI greater than 30 kg/m². The 52-mg levonorgestrel IUDs obtained FDA approval in 2022 for an extended usage period of 8 years that was supported by studies demonstrating efficacy beyond the initially established 5-year duration.¹³ More research is needed on the lower-dose IUDs to study their effectiveness beyond their currently approved duration of use ranging from 3 to 5 years. The 5-year duration approval for the 52-mg levonorgestrel IUD as a treatment for heavy menstrual bleeding remains the same as research is lacking to support efficacy beyond this time. Studies suggest that the only non-hormonal IUD currently available exhibits effectiveness for a duration of up to 12 years.¹³ Nevertheless, there has been no FDA approval for a label change at present. Hormonal IUDs function by altering sperm motility, thickening cervical mucus, and thinning the lining of the uterus, thereby making the uterine environment unfavorable for pregnancy. The copper IUD works in much the same way, although it does not affect cervical mucus. Common side effects include irregular bleeding, cramping, and ovarian cysts.

Emergency contraception update

Individuals seek emergency contraception for a variety of reasons including unprotected intercourse, missed dose of birth control pills, or even due to fear that their chosen

Case 2

JB is 42 years old and wants to consider contraceptive method options. This patient has a history of high cholesterol and is currently taking a statin. Recent cholesterol lab tests reveal elevated low-density lipoprotein and slightly reduced high-density lipoprotein. JB reports an extensive family history of cardiovascular disease and is concerned about potential risks associated with hormonal contraceptive methods. The patient has a body mass index of 29 kg/m². JB does note menstrual cycles that have always been regular but have become heavier in the past 3 months. Which of the following options would be appropriate for JB?

- A. Drospirenone 3 mg/estetrol 14.2 mg tablet
- B. Levonorgestrel 52 mg IUD
- C. Levonorgestrel 120 µg/ethinyl estradiol 30 µg patch
- D. Norgestrel 0.075 mg tablet
- E. Segesterone 150 µg/ethinyl estradiol 13 µg vaginal ring

Concerns have been raised regarding estrogen and its impact on cardiovascular health with reports of estrogen affecting blood pressure, cholesterol levels, and clotting risk. However, options A, C, and E are not contraindicated based on cardiovascular concerns. Product A contains estetrol, which has demonstrated no impact on cholesterol and potential decreased risk for clotting. Product B may have an added benefit of reducing heavy menstrual bleeding. In this scenario, the choice among the provided options is dependent on a discussion of benefits and risks along with patient preference.

method of contraception may not be effective. Currently, two pills have been approved by the FDA for emergency contraception and both have been available for about 15 years.¹⁹ These are levonorgestrel 1.5 mg, available OTC, and ulipristal acetate 30 mg, which is available by prescription only. Both work by suppressing ovulation and carry the same side effects such as headache, nausea, dysmenorrhea, and breast tenderness.¹⁹ Levonorgestrel 1.5 mg must be ingested within 72 hours of unprotected intercourse, whereas ulipristal acetate 30 mg can be taken for up to 5 days after unprotected intercourse. Neither product includes an official weight limit on their packaging; however, their efficacy may potentially decrease with increasing BMI. Nevertheless, both products are recommended for emergency contraception in all women, irrespective of BMI.²⁰ In light of recent debates

surrounding emergency contraception and abortion, levonorgestrel 1.5 mg underwent a labeling revision in December 2022. The revised language in the labeling reflects evidence that levonorgestrel 1.5 mg works by inhibiting or delaying ovulation and the mid-cycle hormonal changes, and that there is no direct effect on postovulatory processes such as fertilization or implantation.²¹

Clinicians have been utilizing the copper T 380A IUD for more than two decades as a method of emergency contraception, although it does not hold FDA approval for this purpose. It has demonstrated high efficacy with pregnancy rates ranging from 0% to 5%.¹⁹ Current research shows that the 52-mg levonorgestrel IUD is as effective as the latter for emergency contraception. At this time, the FDA has not received applications for approval for

either of these IUDs for the purpose of emergency contraception.

Conclusion

As we navigate contraceptive options, it becomes evident that individuals now have a broader array of choices tailored to their unique needs and preferences. The updates provided offer a glimpse into the ongoing efforts to enhance efficacy and provide more accessible options for individuals seeking reliable contraception. ■

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