

STEP THERAPY POLICY

POLICY: Contraceptives – Oral, Patch, and Vaginal Ring Products Step Therapy Policy

Note: This is not an all-inclusive list.

BRAND COMBINATION HORMONAL CONTRACEPTIVES – BIPHASIC

BRAND COMBINATION HORMONAL CONTRACEPTIVES - TRIPHASIC

08/21/2024

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Contraceptives – Oral, Patch, and Vaginal Ring Products Step Therapy Policy

BRAND COMBINATION HORMONAL CONTRACEPTIVES - FOUR-PHASIC

08/21/2024

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GENERIC COMBINATION HORMONAL CONTRACEPTIVES – MONOPHASIC (CONTINUED)
GENERIC COMBINATION HORMONAL CONTRACEPTIVES – MONOPHASIC (CONTINUED)

GENERIC COMBINATION HORMONAL CONTRACEPTIVES – TRIPHASIC (CONTINUED)

PROGESTIN-ONLY CONTRACEPTIVES

REVIEW DATE: 08/21/2024

OVERVIEW

Combined oral contraceptives are sometimes called “the pill” and are one of the most commonly used forms of contraception.¹ Along with the oral tablets, hormonal contraceptives are also available as transdermal patches and vaginal rings. Hormonal contraceptives contain a combination of estrogen and progestin or progestin alone.² The hormones prevent ovulation and can also prevent fertilized eggs from implanting in the womb. Estrogens suppress follicle-stimulating hormone (FSH) release from the pituitary, which may block the luteinizing hormone (LH) surge and prevent ovulation. Progestins provide most of the other contraceptive effects such as cervical mucus changes, which inhibit sperm penetration and motility. Progestins also induce endometrial atrophy, which helps to prevent pregnancy. Oral contraceptives are an effective method of reversible birth control.³

Combined Oral contraceptives (COCs)

COCs are available in monophasic, biphasic, triphasic, or four-phasic combinations.² The monophasic COCs maintain the same dose of estrogen and progestin throughout the cycle (21 days of active pills, 7 days of placebo). An extended cycle 84-day monophasic regimen is also available (e.g., Seasonale, generic). The estrogen and/or progestin doses are varied throughout the cycle for different time intervals in the bi-, tri-, and four-phasic COCs. All COCs have similar efficacy irrespective of monophasic or multiphasic regimens. The multiphasic regimens are generally used to minimize patient specific symptoms (e.g., nausea, breakthrough bleeding).

Progestin-Only Oral Contraceptives

Progesterone-only products provide an alternative for patients with contraindications to estrogen-containing hormonal contraceptives. Progestin-only contraceptives may be more favorable in women with certain medical conditions (e.g., venous thromboembolism) or women who are breastfeeding.⁴ Most progesterone-only oral contraceptives contain norethindrone 0.35 mg. Slynd™ is a progesterone-only oral contraceptive containing drospirenone.⁶ Drospirenone is also available as the progesterone component of numerous oral contraceptives containing ethinyl estradiol. Because drospirenone has antimineralocorticoid activity, drospirenone-containing products are contraindicated in patients with conditions which predispose them to hyperkalemia, including renal disease, hepatic dysfunction, and adrenal insufficiency.

Transdermal Patches

Ortho Evra® and its generics, Xulane® and Zafemy™, are transdermal patches composed of ethinyl estradiol and norelgestromin (35 mcg ethinyl estradiol and 150 mcg norelgestromin released every 24 hours).^{5,8} The brand, Ortho Evra, was discontinued in 2015 by the manufacturer, but the generics are still available. The only other transdermal contraceptive patch is Twirla®, composed of ethinyl estradiol and levonorgestrel (30 mcg ethinyl estradiol and 120 mcg levonorgestrel released every 24 hours).⁷ Both transdermal patches are contraindicated (Boxed Warning) for use in women with a body mass index (BMI) ≥ 30 kg/m².^{5,7} Generics for Ortho Evra have a limitation of use that it may be less effective in preventing pregnancy in women who weigh more than 198 pounds (90 kg).^{5,8} Twirla has a limitation of use to consider the reduced effectiveness in women with a BMI ≥ 25 to < 30 kg/m².⁷ Generic Ortho Evra products also have additional warnings in

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the labeling regarding higher estrogen exposure compared with oral contraceptives containing ethinyl estradiol 35 mcg.^{5,8}

Vaginal Rings

NuvaRing[®] and its generics, etonogestrel-ethinyl estradiol, EluRyng[™], EnilloRing[®], and Haloette[®], are vaginal rings indicated to prevent pregnancy.^{9,11,12} These products are disposable rings; one ring used continuously for 3 weeks, followed by a 1-week ring-free interval. Annovera[®] is a reusable ring with one ring providing contraception for 13 cycles.¹⁰ The cycles are 3 weeks with vaginal ring inserted and 1 week with the vaginal ring removed. Annovera contains ethinyl estradiol and segesterone acetate.

POLICY STATEMENT

This program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product. If the Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Step Therapy criteria below. All approvals are provided for 1 year in duration.

Note: When compliance with the Affordable Care Act, Health Resources and Services Administration Guidelines, and Public Health Services Act section 2713 is required and the conditions for coverage listed under the Criteria are not met, approval is granted when the requested drug is used primarily for the prevention of pregnancy and, according to the prescriber, the alternative Step 1 Products would not be as medically appropriate for the patient as the requested drug.

Automation: A patient with a of one Step 1 Product within the 130-day look-back period is excluded from Step Therapy.

Step 1: Generic oral contraceptives, transdermal Xulane, transdermal Zafemy, etonogestrel-ethinyl estradiol vaginal ring, Eluryng vaginal ring, EnilloRing vaginal ring, Haloette vaginal ring

Step 2: Brand oral contraceptives, transdermal Twirla, NuvaRing, Annovera

CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.
2. No other exceptions are recommended.

REFERENCES

1. Department of Health and Human Services. CDC. National Center for Health Services Data Brief. No. 327. December 2018. Current contraceptive status among women aged 15 to 49: US, 2015-2017. Available at: <https://www.cdc.gov/nchs/products/databriefs/db327.htm>. Accessed on August 19, 2024.
2. Shrader SP, Ragucci KR, Diaz VA. Contraception. In: DiPiro JT, Talbert RL, Yee GC, et al., (Eds). *Pharmacotherapy – A Pathophysiologic Approach*. 8th ed. New York, NY: McGraw-Hill. 2011;1377-1392.
3. Curtis KM, Nguyen, AT, Tepper NK, et al. US Selected Practice Recommendations for Contraceptive Use, 2024. *MMWR Recomm Rep* 2024;73(No. RR-3)1-80. Available at: [U.S. Selected Practice Recommendations for Contraceptive Use, 2024 \(cdc.gov\)](https://www.cdc.gov/mmwr/rr/rr202403a1.html). Accessed on August 19, 2024.
4. Use of hormonal contraception in women with coexisting medical conditions. *ACOG Practice Bulletin*. Clinical Management Guidelines for Obstetrician-Gynecologists. Number 206; January 2019:e128-e150.
5. Xulane[®] transdermal patch [prescribing information]. Morgantown, WV: Mylan; March 2022.
6. Slynd[™] [prescribing information]. Florham Park, NJ: Exeltis; July 2024.
7. Twirla[®] (levonorgestrel and ethinyl estradiol) transdermal patch [prescribing information]. Princeton, NJ: Agile Therapeutics; April 2022.
8. Zafemy[™] transdermal patch [prescribing information]. Bridgewater, NJ: Amneal; April 2022.

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9. NuvaRing® [prescribing information]. Jersey City, NJ: Organon; June 2024.
10. Annovera® [prescribing information]. Raleigh, NC: Mayne; January 2023.
11. EluRyng™ vaginal ring [prescribing information]. Bridgewater, NJ: Amneal; May 2022.
12. Haloette® vaginal ring [prescribing information]. Greenville, NC: Mayne; May 2022.
13. EnilloRing® vaginal ring [prescribing information]. Florham Park, NJ: Xiromed; June 2024.

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