

## 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 – MONOPHASIC

Trade Name	Estrogen (Dose/Duration)	Progestin (Dose/Duration)	Manufacturer
NuvaRing®	ethinyl estradiol 15 µg/day – 21 days	etonogestrel 120 µg/day – 21 days	Organon
Annovera®	ethinyl estradiol 13 µg/day – 21 days	Segesterone acetate 0.15 mg /day – 21 days	TherapeuticsMD
Loestrin® 1/20	ethinyl estradiol 20 µg – 21 days	norethindrone acetate 1 mg – 21 days	Teva Women's Health
Loestrin® FE 1/20			Teva Women's Health
Minastrin™ 24 FE	ethinyl estradiol 20 µg – 24 days	norethindrone acetate 1 mg – 24 days	Allergan
Yaz®	ethinyl estradiol 20 µg – 24 days	drospirenone 3 mg – 24 days	Allergan
Beyaz®			Bayer
Balcoltra™			levonorgestrel 0.1 mg – 21 days
Generess™ FE	ethinyl estradiol 25 µg – 24 days	norethindrone acetate 0.8 mg – 24 days	Watson
Desogen® (discontinued)	ethinyl estradiol 30 µg – 21 days	desogestrel 150 µg – 21 days	Organon
Ortho-Cept®			Janssen
Loestrin® 1.5/30	ethinyl estradiol 30 µg – 21 days	norethindrone acetate 1.5 mg – 21 days	Teva Women's Health
Loestrin® FE 1.5/30			Teva Women's Health
Yasmin®	ethinyl estradiol 30 µg – 21 days	drospirenone 3 mg – 21 days	Bayer
Safyral™			Bayer
Twirla® patch	ethinyl estradiol 30 µg – 21 days	levonorgestrel 120 µg – 21 days	Agile Therapeutics
Femcon® FE (discontinued)	ethinyl estradiol 35 µg – 21 days	norethindrone 0.4 mg – 21 days	Allergan
Ovcon®-35 (discontinued)	ethinyl estradiol 35 µg – 21 days	norethindrone 0.4 mg – 21 days	Allergan
Norinyl® 1 + 35 (discontinued)	ethinyl estradiol 35 µg – 21 days	norethindrone 1 mg – 21 days	Watson
Ortho-Novum® 1/35			Janssen
Ortho-Cyclen®	ethinyl estradiol 35 µg – 21 days	norgestimate 0.25 mg – 21 days	Janssen
Norinyl® 1 + 50 (discontinued)	mestranol 50 µg – 21 days	norethindrone 1 mg – 21 days	Allergan
Nextstellis®	Estetrol 14.2 mg – 24 days	drospirenone 3 mg – 24 days	Mayne Pharma

### BRAND COMBINATION HORMONAL CONTRACEPTIVES – BIPHASIC

Trade Name	Estrogen (Dose/Duration)	Progestin (Dose/Duration)	Manufacturer
Lo Loestrin FE	ethinyl estradiol 10 µg – 24 days	norethindrone acetate 1 mg – 24 days	Allergan
Lo Minastrin™ Fe	ethinyl estradiol 10 µg – 2 days		
LoSeasonique®	ethinyl estradiol 20 µg – 84 days ethinyl estradiol 10 µg – 7 days	levonorgestrel 100 µg – 84 days	Teva Women's Health
Mircette®	ethinyl estradiol 20 µg – 21 days ethinyl estradiol 10 µg – 5 days	desogestrel 150 µg – 21 days	Teva Women's Health
Seasonique®	ethinyl estradiol 30 µg – 84 days ethinyl estradiol 10 µg – 7 days	levonorgestrel 150 µg – 84 days	Teva Women's Health

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**BRAND COMBINATION HORMONAL CONTRACEPTIVES - TRIPHASIC**

Trade Name	Estrogen (Dose/Duration)	Progestin (Dose/Duration)	Manufacturer
Estrostep® FE	ethinyl estradiol 20 µg – 5 days ethinyl estradiol 30 µg – 7 days ethinyl estradiol 35 µg – 9 days	norethindrone acetate 1 mg – 21 days	Allergan
Cyclessa® (discontinued)	ethinyl estradiol 25 µg – 21 days	desogestrel 100 µg – 7 days desogestrel 125 µg – 7 days desogestrel 150 µg – 7 days	Organon
Ortho Tri-Cyclen® Lo	ethinyl estradiol 25 µg – 21 days	norgestimate 180 µg – 7 days norgestimate 215 µg – 7 days norgestimate 250 µg – 7 days	Janssen
Tri-Norinyl®	ethinyl estradiol 35 µg – 21 days	norethindrone 0.5 mg – 7 days norethindrone 1 mg – 9 days norethindrone 0.5 mg – 5 days	Mayne Pharma
Ortho Tri-Cyclen®	ethinyl estradiol 35 µg – 21 days	norgestimate 180 µg – 7 days norgestimate 215 µg – 7 days norgestimate 250 µg – 7 days	Janssen
Ortho-Novum® 7/7/7	ethinyl estradiol 35 µg – 21 days	norethindrone 0.5 mg – 7 days norethindrone 0.75 mg – 7 days norethindrone 1 mg – 7 days	Janssen

**BRAND COMBINATION HORMONAL CONTRACEPTIVES - FOUR-PHASIC**

Trade Name	Estrogen (Dose/Duration)	Progestin (Dose/Duration)	Manufacturer
Natazia™	estradiol valerate 3 mg – 2 days estradiol valerate 2 mg – 5 days estradiol valerate 2 mg – 17 days estradiol valerate 1 mg – 2 days	dienogest 2 mg – 5 days dienogest 3 mg – 17 days	Bayer
Quartette™	ethinyl estradiol 20 µg – 42 days ethinyl estradiol 25 µg – 21 days ethinyl estradiol 30 µg – 21 days ethinyl estradiol 10 µg – 7 days	levonorgestrel 150 µg – 84 days	Teva Women's Health

**GENERIC COMBINATION HORMONAL CONTRACEPTIVES – MONOPHASIC**

Trade Name	Estrogen (Dose/Duration)	Progestin (Dose/Duration)	Manufacturer		
Etonogestrel-ethinyl estradiol vaginal ring	ethinyl estradiol 15 µg/day – 21 days	etonogestrel 120 µg/day – 21 days	Teva		
Eluryng vaginal ring			Amneal		
Amethyst™	ethinyl estradiol 20 µg – 28 days	levonorgestrel 90 µg – 28 days	Allergan		
Aubra®	ethinyl estradiol 20 µg – 21 days	levonorgestrel 100 µg – 21 days	Afaxys		
Aviane®			Teva		
Delyla™			Ohm		
Falmina™			Northstar Rx		
Lessina®			Teva		
Lutera™			Mayne Pharma		
Orsythia®			Par		
Sronyx™			Mayne Pharma		
Junel™ 1/20			ethinyl estradiol 20 µg – 21 days	norethindrone acetate 1 mg – 21 days	Teva
Microgestin® 1/20					Mayne Pharma
Junel™ FE 1/20	Teva				
Microgestin® FE 1/20	Mayne Pharma				
Larin™ 1/20	Northstar Rx				
Larin™ FE 1/20	Northstar Rx				
Tarina® FE 1/20	Afaxys				

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

Trade Name	Estrogen (Dose/Duration)	Progestin (Dose/Duration)	Manufacturer
Junel® FE 24	ethinyl estradiol 20 µg – 24 days	norethindrone acetate 1 mg – 24 days	Teva

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Trade Name	Estrogen (Dose/Duration)	Progestin (Dose/Duration)	Manufacturer		
Larin™ 24 FE			Northstar Rx		
Gianvi™	ethinyl estradiol 20 µg – 24 days	drospirenone 3 mg – 24 days	Teva		
Loryna™			Xiromed		
Vestura™ (discontinued)			Actavis		
Lo-Zumandimine™			Aurobindo		
Nikki™			Lupin		
Rajani™			Actavis		
Layolis™ FE	ethinyl estradiol 25 µg – 24 days	norethindrone acetate 0.8 mg – 24 days	Actavis		
Norethindrone/ethinyl estradiol/ferrous fumarate			Mylan		
Apri®	ethinyl estradiol 30 µg – 21 days	desogestrel 150 µg – 21 days	Teva		
Emoquette™			Qualitest		
Reclipsen™			Teva		
Enskyce™			Lupin		
Syeda™	ethinyl estradiol 30 µg – 21 days	drospirenone 3 mg – 21 days	Xiromed		
Zarah™			Mayne Pharma		
Jolessa™	ethinyl estradiol 30 µg – 21 days	levonorgestrel 150 µg – 21 days	Teva		
Levora®			Mayne Pharma		
Chateal®			Afaxys		
Portia®			Teva		
Altavera™			Xiromed		
Kurvelo			Lupin		
Marlissa			Glenmark Pharma		
Quasense®			ethinyl estradiol 30 µg – 84 days	levonorgestrel 150 µg – 84 days	Actavis
Introvale™	Xiromed				
Junel™ 1.5/30	ethinyl estradiol 30 µg – 21 days	norethindrone acetate 1.5 mg – 21 days	Teva		
Microgestin® 1.5/30			Mayne Pharma		
Gildess® 1.5/30 (discontinued)			Qualitest		
Junel™ FE 1.5/30*			Teva		
Larin FE 1.5/30			Northstar Tx		
Gildess® FE 1.5/30 (discontinued)			Qualitest		
Microgestin® FE 1.5/30*			Mayne Pharma		
Cryselle®			ethinyl estradiol 30 µg – 21 days	norgestrel 0.3 mg – 21 days	Teva
Low-Ogestrel®	Mayne Pharma				
Elinest™	Northstar Rx				
Ocella™	ethinyl estradiol 30 µg – 21 days	drospirenone 3 mg – 21 days	Teva		
Zovia® 1/35	ethinyl estradiol 35 µg – 21 days	ethynodiol diacetate 1 mg – 21 days	Mayne Pharma		
Kelnor™ 1/35			Teva		
Balziva™	ethinyl estradiol 35 µg – 21 days	norethindrone 0.4 mg – 21 days	Teva		
Zenchant™ 0.4/35			Actavis		
Briellyn			Glenmark		
Philith™			Northstar Rx		
Vyfemla™			Lupin		
Wymzya™ FE			Lupin		
Necon® 0.5/35			ethinyl estradiol 35 µg – 21 days	norethindrone 0.5 mg – 21 days	Mayne Pharma
Nortrel® 0.5/35					Teva
Wera™	Northstar Rx				

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

Trade Name	Estrogen (Dose/Duration)	Progestin (Dose/Duration)	Manufacturer
Necon® 1/35	ethinyl estradiol 35 µg – 21 days	norethindrone 1 mg – 21 days	A-S Medication

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Trade Name	Estrogen (Dose/Duration)	Progestin (Dose/Duration)	Manufacturer
Nortrel® 1/35			Teva
Alyacen 1/35			Glenmark
Cyclafem™ 1/35			Par
Dasetta 1/35			Northstar Rx
Pirmella™ 1/35			Lupin
MonoNessa®	ethinyl estradiol 35 µg – 21 days	norgestimate 0.25 mg – 21 days	Actavis
Mono-Linyah™			Northstar Rx
Previfem™			Qualitest
Sprintec®			Teva
Estarylla™			Xiromed
Norgestimate and ethinyl estradiol			Lupin, Glenmark
Xulane patch	ethinyl estradiol 35 µg/day – 21 days	norelgestromin 150 µg/day – 21 days	Mylan
Zafemy patch			Amneal
Necon® 1/50 (discontinued)	mestranol 50 µg – 21 days	norethindrone 1 mg – 21 days	Actavis
Ogestrel® (discontinued)	ethinyl estradiol 50 µg – 21 days	norgestrel 0.5 mg – 21 days	Actavis
Kelnor 1/50	ethinyl estradiol 50 µg – 21 days	ethynodiol diacetate 1 mg – 21 days	Teva
Ethinodiol-ethinyl estradiol			Mylan

**GENERIC COMBINATION HORMONAL CONTRACEPTIVES – BIPHASIC**

Trade Name	Estrogen (Dose/Duration)	Progestin (Dose/Duration)	Manufacturer
Azurette™	ethinyl estradiol 20 µg – 21 days ethinyl estradiol 10 µg – 5 days	desogestrel 150 µg – 21 days	Mayne Pharma
Kariva®	ethinyl estradiol 20 µg – 21 days ethinyl estradiol 10 µg – 5 days	desogestrel 150 µg – 21 days	Teva
Pimtreea			Northstar Rx
Viorele			Glenmark
Amethia™ Lo	ethinyl estradiol 20 µg – 84 days ethinyl estradiol 10 µg – 7 days	Levonorgestrel 100 µg – 84 days	Mayne Pharma
Camrese™ Lo			Teva
Amethia™	ethinyl estradiol 30 µg – 84 days ethinyl estradiol 10 µg – 7 days	Levonorgestrel 150 µg – 84 days	Mayne Pharma
Camrese™			Teva
Daysee			Lupin
Ashlyna			Glenmark
Ethinyl estradiol/levonorgestrel			Mylan
Necon® 10/11 (discontinued)	ethinyl estradiol 35 µg – 21 days	norethindrone 0.5 mg – 10 days norethindrone 1 mg – 11 days	Actavis

**GENERIC COMBINATION HORMONAL CONTRACEPTIVES – TRIPHASIC**

Trade Name	Estrogen (Dose/Duration)	Progestin (Dose/Duration)	Manufacturer
Tilia™ FE	ethinyl estradiol 20 µg – 5 days	norethindrone acetate 1 mg – 21 days	Mayne Pharma
Tri-Legest FE®	ethinyl estradiol 30 µg – 7 days ethinyl estradiol 35 µg – 9 days		Teva
Velivet™	ethinyl estradiol 25 µg – 21 days	desogestrel 100 µg – 7 days	Teva
Caziant™		desogestrel 125 µg – 7 days desogestrel 150 µg – 7 days	Mayne Pharma
Tri Lo Sprintec	ethinyl estradiol 25 µg – 21 days	norgestimate 180 µg – 7 days	Teva
Tri Lo Estarylla		norgestimate 215 µg – 7 days	Xiromed
Norgestimate and ethinyl estradiol		norgestimate 250 215 µg – 7 days	Lupin, Glenmark
Enpresse®	ethinyl estradiol 30 µg – 6 days	levonorgestrel 50 µg – 6 days	Teva
Levonest™	ethinyl estradiol 40 µg – 5 days	levonorgestrel 75 µg – 5 days	Northstar Rx
Myzitra™	ethinyl estradiol 30 µg – 10 days	levonorgestrel 125 µg – 10 days	Qualitest
Trivora®			Mayne Pharma
Necon® 7/7/7 (discontinued)	ethinyl estradiol 35 µg – 21 days	norethindrone 0.5 mg – 7 days norethindrone 0.75 mg – 7 days	Actavis
Nortrel® 7/7/7		norethindrone 1 mg – 7 days	Teva
Alyacen 7/7/7			Glenmark
Dasetta 7/7/7			Northstar Rx
Pirmella™ 7/7/7			Lupin
Aranelle™	ethinyl estradiol 35 µg – 21 days	norethindrone 0.5 mg – 7 days norethindrone 1 mg – 9 days	Teva
Leena™		norethindrone 0.5 mg – 5 days	Mayne Pharma
TriNessa®	ethinyl estradiol 35 µg – 21 days	norgestimate 180 µg – 7 days	Actavis
Tri-Previfem™		norgestimate 215 µg – 7 days	Qualitest
Tri-Sprintec®		norgestimate 250 µg – 7 days	Teva
Tri-Estarylla™			Sandoz
Tri-Linyah™			Northstar Rx

**PROGESTIN-ONLY CONTRACEPTIVES**

Trade Name	Estrogen (Dose/Duration)	Progestin (Dose/Duration)	Manufacturer
<b>Brands</b> Slynd™	NA	drospirenone 4 mg – 24 days	Exeltis USA
<b>Brands</b> Jolivet® (discontinued)	NA	norethindrone 0.35 mg – 28 days	Actavis
Ortho Micronor®			Janssen
Nor-Q.D.® (discontinued)			Actavis
<b>Generics</b> Camila®	NA	norethindrone 0.35 mg – 28 days	Mayne Pharma
Deblitane™			Northstar Rx
Errin®			Mayne Pharma
Nora-BE®			Actavis
Norethindrone			Lupin, Glenmark
Heather®			Glenmark
Jencycla™			Lupin
Lyza®			Afaxys
Norlyroc™			Ohm
Sharobel™			Northstar Rx

**REVIEW DATE:** 07/27/2022

**OVERVIEW**

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Combined oral contraceptives are sometimes called “the pill” and are the most commonly used form of contraception.<sup>1</sup> 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.<sup>2</sup> 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.<sup>3</sup>

### **Combined Oral contraceptives (COCs)**

COCs are available in monophasic, biphasic, triphasic, or four-phasic combinations.<sup>2</sup> 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.<sup>4</sup> Most progesterone-only oral contraceptives contain norethindrone 0.35 mg. Slynd is a progesterone-only oral contraceptive containing drospirenone.<sup>6</sup> 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 generic, Xulane and Zafemy, are transdermal patches composed of ethinyl estradiol and norelgestromin (35 mcg ethinyl estradiol and 150 mcg norelgestromin released every 24 hours).<sup>5,8</sup> 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).<sup>7</sup> Both transdermal patches are contraindicated (Boxed Warning) for use in women with a body mass index (BMI)  $\geq 30$  kg/m<sup>2</sup>.<sup>5,7</sup> 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).<sup>5,8</sup> Twirla has a limitation of use to consider the reduced effectiveness in women with a BMI  $\geq 25$  to  $< 30$  kg/m<sup>2</sup>.<sup>7</sup> Generic Ortho Evra products also have additional warnings in the labeling regarding higher estrogen exposure compared with oral contraceptives containing ethinyl estradiol 35 mcg.<sup>5,8</sup>

### **Vaginal Rings**

NuvaRing and its generics, etonogestrel-ethinyl estradiol and Eluryng, are vaginal rings indicated to prevent pregnancy.<sup>9</sup> 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.<sup>10</sup> 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, HRSA Guidelines, and PHS 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

**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. InformedHealth.org [Internet]. Cologne, Germany: Institute for Quality and Efficiency in Health Care. Contraception: Hormonal contraceptives. Updated July 29, 2017. Available at <https://www.ncbi.nlm.nih.gov/books/NBK441576>. Accessed on July 19, 2022.
2. Shrader SP, Ragucci KR, Diaz VA. Contraception. In: DiPiro JT, Talbert RL, Yee GC, et al., (Eds). *Pharmacotherapy – A Pathophysiologic Approach*. 8<sup>th</sup> ed. New York, NY: McGraw-Hill. 2011;1377-1392.
3. Curtis KM, Jatlaoui TC, Tepper NK, et al. US Selected Practice Recommendations for Contraceptive Use, 2016. *MMWR Recomm Rep* 2016;65(No. RR-4)1-66. DOI: <http://dx.doi.org/10.15585/mmwr.rr6504a1>. Accessed on July 19, 2022.
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 tablet [prescribing information]. Florham Park, NJ: Exeltis; May 2019.
7. Twirla® (levonorgestrel and ethinyl estradiol) transdermal system [prescribing information]. Princeton, NJ: Agile Therapeutics; April 2022.
8. Zafemy patch [prescribing information]. Bridgewater, NJ: Amneal Pharmaceuticals; April 2022.
9. NuvaRing® [prescribing information]. Jersey City, NJ: Organon; March 2022.
10. Annovera® [prescribing information]. Boca Ration, FL: TherapeuticsMD; May 2022.

