



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	Bayer
Beyaz®			Bayer
Balcoltra™	ethinyl estradiol 20 µg – 21 days	levonorgestrel 0.1 mg – 21 days	Avion
Generess™ FE	ethinyl estradiol 25 µg – 24 days	norethindrone acetate 0.8 mg – 24 days	Allergan
Desogen® (discontinued)	ethinyl estradiol 30 µg – 21 days	desogestrel 150 µg – 21 days	Organon
Ortho-Cept®			Ortho
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
Nextstellis®	Estetrol 14.2 mg – 24 days	drospirenone 3 mg – 24 days	Mayne

BRAND COMBINATION HORMONAL CONTRACEPTIVES – BIPHASIC

Trade Name	Estrogen (Dose/Duration)	Progestin (Dose/Duration)	Manufacturer
Lo Loestrin FE	ethinyl estradiol 10 µg – 24 days ethinyl estradiol 10 µg – 2 days	norethindrone acetate 1 mg – 24 days	Allergan
Lo Minastrin™ Fe			
LoSeasonique® (discontinued)	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

Trade Name	Estrogen (Dose/Duration)	Progestin (Dose/Duration)	Manufacturer
Seasonique®	ethinyl estradiol 30 µg – 84 days ethinyl estradiol 10 µg – 7 days	levonorgestrel 150 µg – 84 days	Teva Women's Health

BRAND COMBINATION HORMONAL CONTRACEPTIVES - TRIPHASIC

Trade Name	Estrogen (Dose/Duration)	Progestin (Dose/Duration)	Manufacturer
Estrostep® FE (discontinued)	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
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
Haloette® vaginal ring			Mayne
Amethyst™	ethinyl estradiol 20 µg – 28 days	levonorgestrel 90 µg – 28 days	Teva
Afirmelle™	ethinyl estradiol 20 µg – 21 days	levonorgestrel 100 µg – 21 days	Aurobindo
Aubra EQ®			Afaxys
Aviane®			Teva
Falmina™			Northstar Rx
Lessina®			Teva

Lutera™			Mayne		
Orsythia® (discontinued)			Par		
Sronyx™			Mayne		
Vienna®			Xiromed		
Aurovela® 1/20	ethinyl estradiol 20 µg – 21 days	norethindrone acetate 1 mg – 21 days	Aurobindo		
Blisovi™ FE 1/20			Lupin		
Hailey® FE 1/20			Glenmark		
Junel™ 1/20			Teva		
Microgestin® 1/20			Mayne		
Junel™ FE 1/20			Teva		
Microgestin® FE 1/20			Mayne		
Larin™ 1/20			Northstar Rx		
Larin™ FE 1/20			Northstar Rx		
Tarina® FE 1/20			Afaxys		
Aurovela® 24 FE			ethinyl estradiol 20 µg – 24 days	norethindrone acetate 1 mg – 24 days	Aurobindo
Blisovi™ 24 FE					Lupin
Hailey® 24 FE	Glenmark				
Junel® FE 24	Teva				
Larin™ 24 FE	Northstar Rx				
Tarina 24 FE	Afaxys				
Gianvi™ (discontinued)	ethinyl estradiol 20 µg – 24 days	drospirenone 3 mg – 24 days	Teva		
Jasmiel®			Afaxys		
Loryna™			Xiromed		
Vestura™			Teva		
Lo-Zumandimine™			Aurobindo		
Nikki™			Lupin		

GENERIC COMBINATION HORMONAL CONTRACEPTIVES – MONOPHASIC (CONTINUED)

Trade Name	Estrogen (Dose/Duration)	Progestin (Dose/Duration)	Manufacturer
Layolis™ FE	ethinyl estradiol 25 µg – 24 days	norethindrone acetate 0.8 mg – 24 days	Actavis
Norethindrone/ethinyl estradiol/ferrous fumarate			Mylan
Generess® FE			Allergan
Kaitlib™ FE			Lupin
Apri®	ethinyl estradiol 30 µg – 21 days	desogestrel 150 µg – 21 days	Teva
Kalliga™			Aurobindo
Juleber™			Northstar Rx
Cyred EQ®			Afaxys
Isibloom®			Xiromed
Emoquette™ (discontinued)			Qualitest
Reclipsen™			Teva
Enskyce™			Lupin
Syeda™			ethinyl estradiol 30 µg – 21 days
Zarah™	Mayne		
Zumandimine®	Aurobindo		
Ocella™	Teva		

Trade Name	Estrogen (Dose/Duration)	Progestin (Dose/Duration)	Manufacturer		
Levora®	ethinyl estradiol 30 µg – 21 days	levonorgestrel 150 µg – 21 days	Mayne		
Chateal EQ®			Afaxys		
Portia®			Teva		
Altavera™			Xiromed		
Ayuna®			Aurobindo		
Kurvelo			Lupin		
Marlissa			Glenmark		
Setlakin™	ethinyl estradiol 30 µg – 84 days	levonorgestrel 150 µg – 84 days	Northstar Rx		
Iclevia™			Aurobindo		
Jolessa®			Teva		
Aurovela® 1.5/30	ethinyl estradiol 30 µg – 21 days	norethindrone acetate 1.5 mg – 21 days	Auobindo		
Hailey™ 1.5/30			Glenmark		
Junel™ 1.5/30			Teva		
Microgestin® 1.5/30			Mayne		
Larin™ 1.5/30			Northstar Rx		
Cryselle®	ethinyl estradiol 30 µg – 21 days	norgestrel 0.3 mg – 21 days	Teva		
Low-Ogestrel®			Mayne		
Elinest™			Northstar Rx		
Zovia® 1/35	ethinyl estradiol 35 µg – 21 days	ethynodiol diacetate 1 mg – 21 days	Mayne		
Kelnor™ 1/35			Teva		
Balziva™	ethinyl estradiol 35 µg – 21 days	norethindrone 0.4 mg – 21 days	Teva		
Zenchant™ 0.4/35			Physicians TC		
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
Nortrel® 0.5/35					Teva
Wera™	Northstar Rx				
Nortrel® 1/35	ethinyl estradiol 35 µg – 21 days	norethindrone 1 mg – 21 days	Teva		
Nylia® 1/35			Aurobindo		
Alyacen 1/35			Glenmark		
Cyclafem™ 1/35 (discontinued)			Par		
Dasetta 1/35			Northstar Rx		

GENERIC COMBINATION HORMONAL CONTRACEPTIVES – MONOPHASIC (CONTINUED)

Trade Name	Estrogen (Dose/Duration)	Progestin (Dose/Duration)	Manufacturer
Pirmella™ 1/35 (discontinued)	ethinyl estradiol 35 µg – 21 days	norethindrone 1 mg – 21 days	Lupin
Mono-Linyah™	ethinyl estradiol 35 µg – 21 days	norgestimate 0.25 mg – 21 days	Northstar Rx
Milj®			Aurobindo
Nymyo™			Mayne
Previfem™ (discontinued)			Par
Sprintec®			Teva
Estarylla™			Xiromed
Norgestimate and ethinyl estradiol			Lupin, Glenmark

Trade Name	Estrogen (Dose/Duration)	Progestin (Dose/Duration)	Manufacturer
Vylibra®			Afaxys
Xulane® patch	ethinyl estradiol 35 µg/day - 21 days	norelgestromin 150 µg/day - 21 days	Mylan
Zafemy™ patch			Amneal
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	desogestrel 150 µg - 21 days	Mayne
Kariva®			Teva
Bekyree™			Lupin
Pimtrea™			Northstar Rx
Simliya™			Aurobindo
Viorele®			Glenmark
Volnea®			Xiromed
Amethia™ Lo (discontinued)	ethinyl estradiol 20 µg - 84 days	Levonorgestrel 100 µg - 84 days	Mayne
Camrese™ Lo			Teva
Lojaimiess™			Xiromed
Amethia™	ethinyl estradiol 30 µg - 84 days	Levonorgestrel 150 µg - 84 days	Mayne
Camrese™			Teva
Daysee™			Lupin
Ashlyna®			Glenmark
Simpesse®			Aurobindo
Ethinyl estradiol/levonorgestrel			Mylan

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
Tri-Ligest FE®			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
Tri Lo Sprintec®	ethinyl estradiol 25 µg - 21 days	norgestimate 180 µg - 7 days	Teva
Tri Lo Estarylla®		norgestimate 215 µg - 7 days	Xiromed
Tri Lo Mili®		norgestimate 250 215 µg - 7 days	Aurobindo
Tri Lo Marzia™			Lupin
Enpresse®	ethinyl estradiol 30 µg - 6 days	levonorgestrel 50 µg - 6 days	Teva
Levonest™		levonorgestrel 75 µg - 5 days levonorgestrel 125 µg - 10 days	Northstar Rx
	ethinyl estradiol 40 µg - 5 days		
	ethinyl estradiol 30 µg - 10 days		

GENERIC COMBINATION HORMONAL CONTRACEPTIVES – TRIPHASIC (CONTINUED)

Trade Name	Estrogen (Dose/Duration)	Progestin (Dose/Duration)	Manufacturer
Trivora®	ethinyl estradiol 30 µg – 6 days ethinyl estradiol 40 µg – 5 days ethinyl estradiol 30 µg – 10 days	levonorgestrel 50 µg – 6 days levonorgestrel 75 µg – 5 days levonorgestrel 125 µg – 10 days	Mayne
Nortrel® 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	Teva
Nylia® 7/7/7			Teva
Alyacen 7/7/7			Glenmark
Dasetta™ 7/7/7			Northstar Rx
Pirmella™ 7/7/7 (discontinued)			Lupin
Aranelle™	ethinyl estradiol 35 µg – 21 days	norethindrone 0.5 mg – 7 days norethindrone 1 mg – 9 days norethindrone 0.5 mg – 5 days	Teva
Leena™			Mayne
Tri-Previfem™ (discontinued)	ethinyl estradiol 35 µg – 21 days	norgestimate 180 µg – 7 days norgestimate 215 µg – 7 days norgestimate 250 µg – 7 days	Qualitest
Tri-Sprintec®			Teva
Tri-Estarylla™			Xiromed
Tri-Linyah™			Northstar Rx
Tri-Vylibra®			Afaxys
Tri-Nymyo™			Mayne
Tri-Mili®			Aurobindo

PROGESTIN-ONLY CONTRACEPTIVES

Trade Name	Estrogen (Dose/Duration)	Progestin (Dose/Duration)	Manufacturer
Brands Slynd™	NA	drospirenone 4 mg – 24 days	Exeltis
Generics Camila®	NA	norethindrone 0.35 mg – 28 days	Mayne
Deblitane™			Northstar Rx
Errin®			Mayne
Nora-BE®			Actavis
Norethindrone			Lupin, Glenmark
Heather®			Glenmark
Incassia®			Aurobindo
Jencycla™			Lupin
Lyleq®			Afaxys
Lyza®			Afaxys
Sharobel™			Northstar Rx
Tulana™			Afaxys

REVIEW DATE: 08/23/2023

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in

interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Cigna National Formulary Coverage:

OVERVIEW

Combined oral contraceptives are sometimes called “the pill” and are one of the most commonly used form 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 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, 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.

Contraceptives – Oral, Patch, and Vaginal Ring product(s) is(are) covered as medically necessary when the following step therapy criteria is(are) met. Any other exception is considered not medically necessary.

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

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 18, 2023.
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, 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 August 18, 2023.
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; April 2022.
9. NuvaRing® [prescribing information]. Jersey City, NJ: Organon; January 2023.
10. Annovera® [prescribing information]. Boca Ration, FL: TherapeuticsMD; April 2022.
11. Eluryng™ vaginal ring [prescribing information]. Bridgewater, NJ: Amneal; May 2022.
12. Haloette® vaginal ring [prescribing information]. Greenville, NC: Mayne; May 2022.

HISTORY

Type of Revision	Summary of Changes	Review Date
Early Annual Revision	Annovera was added as a Step 2 product.	07/27/2022
Annual Revision	Generic Haloette vaginal ring was added as a Step 1 product.	08/23/2023

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