

Cigna National Preferred Formulary Coverage Policy



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Coverage Policy Number NPF047

Step Therapy Contraceptives – Oral and Patch Products

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Related Coverage Resources

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.

NPF Coverage Policy

Drugs Affected

Note: This is not an all-inclusive list.

BRAND COMBINATION HORMONAL CONTRACEPTIVES – MONOPHASIC

Trade Name	Estrogen (Dose/Duration)	Progestin (Dose/Duration)
Loestrin® 1/20	ethinyl estradiol 20 µg – 21 days	norethindrone acetate 1 mg – 21 days
Loestrin® FE 1/20		
Minastrin™ 24 FE	ethinyl estradiol 20 µg – 24 days	norethindrone acetate 1 mg – 24 days
Yaz®	ethinyl estradiol 20 µg – 24 days	drospirenone 3 mg – 24 days
Beyaz®		
Balcoltra™	ethinyl estradiol 20 µg – 21 days	Levonorgestrel 0.1 mg – 21 days
Generess™ FE ^y	ethinyl estradiol 25 µg – 24 days	norethindrone acetate 0.8 mg – 24 days
Desogen® (discontinued)	ethinyl estradiol 30 µg – 21 days	desogestrel 150 µg – 21 days

Trade Name	Estrogen (Dose/Duration)	Progestin (Dose/Duration)
Ortho-Cept®		
Loestrin® 1.5/30	ethinyl estradiol 30 µg – 21 days	norethindrone acetate 1.5 mg – 21 days
Loestrin® FE 1.5/30*		
Yasmin®	ethinyl estradiol 30 µg – 21 days	drospirenone 3 mg – 21 days
Safyral™		
Twirla® patch	ethinyl estradiol 30 µg – 21 days	levonorgestrel 120 µg – 21 days
Femcon® FE (discontinued)	ethinyl estradiol 35 µg – 21 days	norethindrone 0.4 mg – 21 days
Ovcon®-35 (discontinued)	ethinyl estradiol 35 µg – 21 days	norethindrone 0.4 mg – 21 days
Modicon® (discontinued)	ethinyl estradiol 35 µg – 21 days	norethindrone 0.5 mg – 21 days
Norinyl® 1 + 35 (discontinued)	ethinyl estradiol 35 µg – 21 days	norethindrone 1 mg – 21 days
Ortho-Novum® 1/35		
Ortho-Cyclen®	ethinyl estradiol 35 µg – 21 days	norgestimate 0.25 mg – 21 days
Norinyl® 1 + 50 (discontinued)	mestranol 50 µg – 21 days	norethindrone 1 mg – 21 days

BRAND COMBINATION HORMONAL CONTRACEPTIVES – BIPHASIC

Trade Name	Estrogen (Dose/Duration)	Progestin (Dose/Duration)
Lo Loestrin FE	ethinyl estradiol 10 µg – 24 days	norethindrone acetate 1 mg – 24 days
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
Mircette®	ethinyl estradiol 20 µg – 21 days ethinyl estradiol 10 µg – 5 days	desogestrel 150 µg – 21 days
Seasonique®	ethinyl estradiol 30 µg – 84 days ethinyl estradiol 10 µg – 7 days	levonorgestrel 150 µg – 84 days

BRAND COMBINATION HORMONAL CONTRACEPTIVES - TRIPHASIC

Trade Name	Estrogen (Dose/Duration)	Progestin (Dose/Duration)
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
Cyclessa® (discontinued)	ethinyl estradiol 25 µg – 21 days	desogestrel 100 µg – 7 days desogestrel 125 µg – 7 days desogestrel 150 µg – 7 days
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
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
Ortho Tri-Cyclen®	ethinyl estradiol 35 µg – 21 days	norgestimate 180 µg – 7 days norgestimate 215 µg – 7 days norgestimate 250 µg – 7 days
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

BRAND COMBINATION HORMONAL CONTRACEPTIVES - FOUR-PHASIC

Trade Name	Estrogen (Dose/Duration)	Progestin (Dose/Duration)
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
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

GENERIC COMBINATION HORMONAL CONTRACEPTIVES – MONOPHASIC

Trade Name	Estrogen (Dose/Duration)	Progestin (Dose/Duration)
Amethyst™	ethinyl estradiol 20 µg – 28 days	levonorgestrel 90 µg – 28 days
Aubra®	ethinyl estradiol 20 µg – 21 days	levonorgestrel 100 µg – 21 days
Aviane®		
Delyla™		
Falmina™		
Lessina®		
Lutera™		
Orsythia®		
Sronyx™		
Junel™ 1/20	ethinyl estradiol 20 µg – 21 days	norethindrone acetate 1 mg – 21 days
Microgestin® 1/20		
Junel™ FE 1/20		
Gildess® 1/20 (discontinued)		
Microgestin® FE 1/20		
Gildess® FE 1/20 (discontinued)		
Larin™ 1/20		
Larin™ FE 1/20		
Tarina® FE 1/20		
Junel® FE 24	ethinyl estradiol 20 µg – 24 days	norethindrone acetate 1 mg – 24 days
Larin™ 24 FE		
Gianvi™	ethinyl estradiol 20 µg – 24 days	drospirenone 3 mg – 24 days
Loryna™		
Vestura™ (discontinued)		
Lo-Zumandimine™		
Nikki™		
Rajani™		
Layolis™ FE	ethinyl estradiol 25 µg – 24 days	norethindrone acetate 0.8 mg – 24 days
Norethindrone/ethinyl estradiol/ferrous fumarate		
Apri®	ethinyl estradiol 30 µg – 21 days	desogestrel 150 µg – 21 days
Emoquette™		

Trade Name	Estrogen (Dose/Duration)	Progestin (Dose/Duration)
Reclipsen™	ethinyl estradiol 30 µg – 21 days	drospirenone 3 mg – 21 days
Enskyce™		
Syeda™		
Zarah™		
Jolessa™	ethinyl estradiol 30 µg – 21 days	levonorgestrel 150 µg – 21 days
Levora®		
Chateal®		
Portia®		
Altavera™		
Kurvelo		
Marlissa		
Quasense®		
Introvale™	ethinyl estradiol 30 µg – 84 days	levonorgestrel 150 µg – 84 days
Junel™ 1.5/30	ethinyl estradiol 30 µg – 21 days	norethindrone acetate 1.5 mg – 21 days
Microgestin® 1.5/30		
Gildess® 1.5/30 (discontinued)		
Junel™ FE 1.5/30*		
Larin FE 1.5/30		
Gildess® FE 1.5/30 (discontinued)		
Microgestin® FE 1.5/30*		
Cryselle®		
Low-Ogestrel®	ethinyl estradiol 30 µg – 21 days	norgestrel 0.3 mg – 21 days
Elinest™		
Ocella™		
Zovia® 1/35	ethinyl estradiol 35 µg – 21 days	ethynodiol diacetate 1 mg – 21 days
Kelnor™ 1/35		
Balziva™	ethinyl estradiol 35 µg – 21 days	norethindrone 0.4 mg – 21 days
Zenchent™ 0.4/35		
Briellyn		
Philith™		
Vyfemla™		
Wymzya™ FE		
Necon® 0.5/35		
Nortrel® 0.5/35	ethinyl estradiol 35 µg – 21 days	norethindrone 0.5 mg – 21 days
Wera™		
Necon® 1/35		
Nortrel® 1/35	ethinyl estradiol 35 µg – 21 days	norethindrone 1 mg – 21 days
Alyacen 1/35		
Cyclafem™ 1/35		
Dasetta 1/35		
Pirmella™ 1/35		
MonoNessa®		
Mono-Linyah™	ethinyl estradiol 35 µg – 21 days	norgestimate 0.25 mg – 21 days
Previfem™		
Sprintec®		

Trade Name	Estrogen (Dose/Duration)	Progestin (Dose/Duration)
Estarilla™		
Norgestimate and ethinyl estradiol		
Xulane patch	ethinyl estradiol 35 µg/day – 21 days	norelgestromin 150 µg/day – 21 days
Necon® 1/50 (discontinued)	mestranol 50 µg – 21 days	norethindrone 1 mg – 21 days
Zovia® 1/50 (discontinued)	ethinyl estradiol 50 µg – 21 days	ethynodiol diacetate 1 mg – 21 days
Ogestrel®	ethinyl estradiol 50 µg – 21 days	norgestrel 0.5 mg – 21 days

GENERIC COMBINATION HORMONAL CONTRACEPTIVES – BIPHASIC

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

GENERIC COMBINATION HORMONAL CONTRACEPTIVES – TRIPHASIC

Trade Name	Estrogen (Dose/Duration)	Progestin (Dose/Duration)
Tilia™ FE*	ethinyl estradiol 20 µg – 5 days	norethindrone acetate 1 mg – 21 days
Tri-Legest FE®*	ethinyl estradiol 30 µg – 7 days ethinyl estradiol 35 µg – 9 days	
Velivet™	ethinyl estradiol 25 µg – 21 days	desogestrel 100 µg – 7 days desogestrel 125 µg – 7 days desogestrel 150 µg – 7 days
Caziant™		
Tri Lo Sprintec	ethinyl estradiol 25 µg – 21 days	norgestimate 180 µg – 7 days norgestimate 215 µg – 7 days norgestimate 250 215 µg – 7 days
Tri Lo Estarilla		
Norgestimate and ethinyl estradiol		
Enpresse®	ethinyl estradiol 30 µg – 6 days	levonorgestrel 50 µg – 6 days
Levonest™	ethinyl estradiol 40 µg – 5 days	levonorgestrel 75 µg – 5 days
Myzila™	ethinyl estradiol 30 µg – 10 days	levonorgestrel 125 µg – 10 days
Trivora®		
Necon® 7/7/7 (discontinued)	ethinyl estradiol 35 µg – 21 days	norethindrone 0.5 mg – 7 days norethindrone 0.75 mg – 7 days norethindrone 1 mg – 7 days
Nortrel® 7/7/7		
Alyacen 7/7/7		
Dasetta 7/7/7		
Pirmella™ 7/7/7		

Trade Name	Estrogen (Dose/Duration)	Progestin (Dose/Duration)
Aranelle™	ethinyl estradiol 35 µg – 21 days	norethindrone 0.5 mg – 7 days
Leena™		norethindrone 1 mg – 9 days norethindrone 0.5 mg – 5 days
TriNessa®	ethinyl estradiol 35 µg – 21 days	norgestimate 180 µg – 7 days
Tri-Previfem™		norgestimate 215 µg – 7 days
Tri-Sprintec®		norgestimate 250 µg – 7 days
Tri-Estarylla™		
Tri-Linyah™		

PROGESTIN-ONLY CONTRACEPTIVES

Trade Name	Estrogen (Dose/Duration)	Progestin (Dose/Duration)
Brands Slynd™	NA	drospirenone 4 mg – 24 days
Brands Jolivet® (discontinued)	NA	norethindrone 0.35 mg – 28 days
Ortho Micronor®		
Nor-Q.D.® (discontinued)		
Generics Camila®	NA	norethindrone 0.35 mg – 28 days
Deblitane™		
Errin®		
Nora-BE®		
Norethindrone		
Heather®		
Jencycla™		
Lyza®		
Norlyroc™		
Sharobel™		

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

Step 1: Generic oral contraceptives, transdermal Xulane

Step 2: Brand oral contraceptives, transdermal Twirla

Cigna covers Step 2 agents as medically necessary when the following criteria are met:

1. If the individual has tried one Step 1 product, authorization for a Step 2 product may be given.
2. Approve if according to the prescribing physician, other formulary contraceptives would not be as medically appropriate for the individual as the requested non-formulary drug.*

*Criterion developed in accordance with the Affordable Care Act, HRSA Guidelines, and PHS Act section 2713.

Conditions Not Covered

Any other exception is considered not medically necessary.

Background

Overview

Combined oral contraceptives (COCs) are a popular reversible birth control method used in the US.¹ Hormonal contraceptives contain a combination of estrogen and progestin or progestin alone.² COCs work primarily before fertilization to prevent conception. 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, motility, and inducing endometrial atrophy. 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, generics). The bi-, tri-, and four-phasic COCs vary the estrogen and/or progestin doses throughout the cycle for different time intervals. 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.⁷ 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.⁷

Transdermal Patches

Ortho Evra and its generic, Xulane, are transdermal patches composed of ethinyl estradiol and norelgestromin (35 mcg ethinyl estradiol and 150 mcg norelgestromin released every 24 hours).^{5,6} The brand, Ortho Evra, was discontinued in 2015 by the manufacturer, but the generic Xulane is 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).⁸ Both transdermal patches may have reduced effectiveness in women with a greater body mass index (BMI). Xulane has a limitation of use that it may be less effective in preventing pregnancy in women who weigh more than 198 pounds (90 kg) and is additionally contraindicated for use in women with a BMI ≥ 30 kg/m².⁶ Twirla is indicated as a method of contraception for use in women of reproductive potential with a BMI < 30 kg/m² for whom a combined hormonal contraceptive is appropriate.⁸ It is also contraindicated in women with a BMI ≥ 30 kg/m². Twirla has a limitation of use to consider the reduced effectiveness in women with a BMI ≥ 25 to < 30 kg/m² before prescribing. Xulane has additional warnings in its labeling regarding higher estrogen exposure of Xulane compared to oral contraceptives containing ethinyl estradiol 35 mcg.⁶

References

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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>.
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5. Ortho Evra transdermal patch [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals Inc.; August 2017.
6. Xulane transdermal patch [prescribing information]. Morgantown, WV: Mylan Pharmaceuticals, Inc.; April 2020.
7. Slynd tablet [prescribing information]. Florham Park, NJ: Exeltis USA, Inc.: May 2019.
8. Twirla® (levonorgestrel and ethinyl estradiol) transdermal system [prescribing information]. Princeton, NJ: Agile Therapeutics, Inc.; February 2020.

Last Revision Details

Early annual revision	Added Twirla as a Step 2 product.	07/15/2020
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