

STEP THERAPY POLICY

POLICY: Contraceptives – Oral and Patch 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
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 [™]	ethinyl estradiol 20 µg – 21 days	Levonorgestrel 0.1 mg – 21 days	Avion Pharms
Generess [™] FE ⁷	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, Inc.
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
Modicon [®] (discontinued)	ethinyl estradiol 35 µg – 21 days	norethindrone 0.5 mg – 21 days	Janssen
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

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	levonorgestrel 100 µg – 84 days	Teva Women's Health
Mircette [®]	ethinyl estradiol 20 µg – 21 days	desogestrel 150 µg – 21 days	Teva Women's Health
	ethinyl estradiol 10 µg – 5 days		
Seasonique [®]	ethinyl estradiol 30 µg – 84 days	levonorgestrel 150 µg – 84 days	Teva Women's Health
	ethinyl estradiol 10 µg – 7 days		

BRAND COMBINATION HORMONAL CONTRACEPTIVES - TRIPHASIC

Trade Name	Estrogen (Dose/Duration)	Progestin (Dose/Duration)	Manufacturer
Estrostep [®] FE	ethinyl estradiol 20 µg – 5 days	norethindrone acetate 1 mg – 21 days	Allergan

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Trade Name	Estrogen (Dose/Duration)	Progestin (Dose/Duration)	Manufacturer
	ethinyl estradiol 30 µg – 7 days ethinyl estradiol 35 µg – 9 days		
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
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
Gildess® 1/20 (discontinued)			Qualitest
Microgestin® FE 1/20			Mayne Pharma
Gildess® FE 1/20 (discontinued)			Qualitest
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		
Brielyn			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)

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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
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
Estarlylla [™]			Xiromed
Norgestimate and ethinyl estradiol			Lupin, Glenmark
Xulane patch	ethinyl estradiol 35 µg/day – 21 days	norelgestromin 150 µg/day – 21 days	Mylan
Necon [®] 1/50 (discontinued)	mestranol 50 µg – 21 days	norethindrone 1 mg – 21 days	Actavis
Zovia [®] 1/50 (discontinued)	ethinyl estradiol 50 µg – 21 days	ethynodiol diacetate 1 mg – 21 days	Actavis
Ogestrel [®]	ethinyl estradiol 50 µg – 21 days	norgestrel 0.5 mg – 21 days	Actavis

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
Brands Slynd™	NA	drospirenone 4 mg – 24 days	Exeltis USA, Inc.
Brands Jolivet® (discontinued)	NA	norethindrone 0.35 mg – 28 days	Actavis
Ortho Micronor®			Janssen
Nor-Q.D.® (discontinued)			Actavis
Generics 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: 07/15/2020

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

POLICY STATEMENT

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.

Automation: A patients with a history of one Step 1 drug within the 130-day look-back period is excluded from step therapy.

Step 1: Generic oral contraceptives, transdermal Xulane

Step 2: Brand oral contraceptives, transdermal Twirla

CRITERIA

1. If the patient has tried one Step 1 product, authorization for a Step 2 product may be given.
2. No other exceptions are recommended.

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