

Drug Policy

Policy: CC	Contraceptives – Oral, Patch, and Vaginal Ring Products Preferred Step Therapy Policy	Annual Review Date: 04/18/2024 Last Revised Date: 04/18/2024
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OVERVIEW

Combined oral contraceptives (COCs) are the most popular reversible birth control method used in the US. Hormonal contraceptives contain a combination of estrogen and progestin or progestin alone. Apart from COCs, the contraceptive options have expanded to include transdermal patches (Ortho Evra®, and its generic equivalent Xulane™), a vaginal contraceptive ring (NuvaRing®), a long-acting injectable (e.g., Depo-Provera®, generics), implantables (e.g., Nexplanon®), and intrauterine devices (e.g., Mirena®). 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. OCs are one of the most effective methods of reversible birth control with an unintended pregnancy incidence of < 1% with perfect use; however, incidence rates with typical use are up to 8%.

POLICY STATEMENT

A step therapy program has been developed to encourage the use of a generic Step 1 product prior to the use of a Step 2 product. If the step therapy rule is not met for a Step 2 agent 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: Patients with a history of one Step 1 drug within the 130-day look-back period are excluded from step therapy.

Preferred Products

- Generic oral contraceptives
- Generic vaginal ring contraceptives
- EluRyng vaginal ring
- Xulane patch
- Zafemy patch

Non-preferred Products

- Brand oral contraceptives
- Annovera
- Nextstellis kit
- NuvaRing
- Twirla patch

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CRITERIA

1. If the patient has tried one preferred product, authorization for a non-preferred product may be given
2. If according to the prescriber, the preferred products would not be as medically appropriate for the patient as the requested non-preferred product, authorization for the non-preferred product may be given.

NOTE: Members with plans subject to healthcare reform may obtain coverage at zero cost if determined medically necessary

Initial Approval/ Extended Approval.

A) *Initial Approval:* 1 year (365 days)

B) *Extended Approval:* 1 year (365 days)

Step Therapy Exception Criteria

In certain situations, the patient is not required to trial preferred agents. Approve for 1 year if the patient meets the following (A, B, or C):

- A. The patient has an atypical diagnosis and/or unique patient characteristics which prevent use of all preferred agents. If so, please list diagnosis and/or patient characteristics **[documentation required]; OR**
- B. The patient has a contraindication to all preferred agents. If so, please list the contraindications to each preferred agent **[documentation required]; OR**
- C. The patient is continuing therapy with the requested non-preferred agent after being stable for at least 90 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required] AND meets ONE of the following:
 1. The patient has at least 130 days of prescription claims history on file and claims history supports that the patient has received the requested non-preferred agent for 90 days within a 130-day look-back period AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product); OR
 2. When 130 days of the patient's prescription claims history file is unavailable for verification, the prescriber must verify that the patient has been receiving the requested non-preferred agent for 90 days AND that the patient has been receiving the requested non-preferred agent via paid claims (i.e. the patient has NOT been receiving samples or coupons or other types of waivers in order to obtain access to the requested non-preferred agent) AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product).

Documentation Required: When documentation is required, the prescriber must provide written documentation supporting the trials of these other agents, noted in the criteria as **[documentation required]**. Documentation should include chart notes, prescription claims records, and/or prescription receipts.

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Approval Duration: All approvals for continuation of therapy are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. American College of Obstetricians and Gynecologists. ACOG Committee Opinion. Number 375. August 2007. Brand versus generic oral contraceptives. *Obstet Gynecol.* 2007;110(2 Pt 1):447-448.
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. Ortho Evra transdermal patch [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals Inc.; June 2013.
4. 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 October 2, 2021.
5. 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.
6. Xulane transdermal patch [prescribing information]. Morgantown, WV: Mylan Pharmaceuticals, Inc.; February 2021.
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; February 2020.
9. Zafemy patch [prescribing information]. Bridgewater, NJ: Amneal Pharmaceuticals; February 2021.
10. NuvaRing® [prescribing information]. Whitehouse Station, NJ: Organon, a subsidiary of Merck; January 2020.

DRUGS AFFECTED: Products include the following, but 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™	ethinyl estradiol 20 µg – 21 days	Levonorgestrel 0.1 mg – 21 days	Avion Pharms
Generess™ FE ^y	ethinyl estradiol 25 µg – 24 days	norethindrone acetate 0.8 mg – 24 days	Watson
Desogen®	ethinyl estradiol 30 µg – 21 days	desogestrel 150 µg – 21 days	Organon

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(discontinued)			
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
	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

Brand Combination Hormonal Contraceptives - Triphasic

Trade Name	Estrogen (Dose/Duration)	Progestin (Dose/Duration)	Manufacturer
Eurostep® 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	Janssen

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Trade Name	Estrogen (Dose/Duration)	Progestin (Dose/Duration)	Manufacturer
		norethindrone 0.75 mg – 7 days norethindrone 1 mg – 7 days	

Brand Combination Hormonal Contraceptives - Four-Phase

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				
Junel® FE 24	ethinyl estradiol 20 µg – 24 days	norethindrone acetate 1 mg – 24 days			Teva
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

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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
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
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
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

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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
Estarilla™			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
Pimtra			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 ethinyl estradiol 30 µg – 7 days ethinyl estradiol 35 µg – 9 days	norethindrone acetate 1 mg – 21 days	Mayne Pharma
Tri-Legest FE®*			Teva
Velivet™	ethinyl estradiol 25 µg – 21 days	desogestrel 100 µg – 7 days	Teva
Caziant™		desogestrel 125 µg – 7 days	Mayne Pharma
		desogestrel 150 µg – 7 days	
Tri Lo Sprintec	ethinyl estradiol 25 µg – 21 days	norgestimate 180 µg – 7 days	Teva
Tri Lo Estarilla		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
Levonest™	ethinyl estradiol 40 µg – 5 days	levonorgestrel 75 µg – 5 days	Northstar Rx

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Myzila™	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 norethindrone 1 mg – 7 days	Actavis
Nortrel® 7/7/7			Teva
Alyacen 7/7/7			Glenmark
Dasetta 7/7/7			Northstar Rx
Pirmella™ 7/7/7			Lupin
Aranelle™			Leena™
TriNessa®	ethinyl estradiol 35 µg – 21 days	norgestimate 180 µg – 7 days norgestimate 215 µg – 7 days norgestimate 250 µg – 7 days	Actavis
Tri-Previfem™			Qualitest
Tri-Sprintec®			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 Jolivette® (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

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