

Drug Coverage Policy

Effective Date.......8/15/2024
Coverage Policy Number...... IP0036
Policy Title......Contraceptives

Contraceptives

- Balcoltra[™] (ethinyl estradiol 20 µg 21 days, levonorgestrel 0.1 mg 21 days Avion)
- Beyaz® (ethinyl estradiol 20 μg 24 days, drospirenone 3 mg 24 days Bayer)
- Depo-Provera[™] (medroxyprogesterone acetate intramuscular injection Pfizer, generics)
- Generess[™] FE (ethinyl estradiol 25 µg 24 days, norethindrone acetate 0.8 mg 24 days Allergan)
- Layolis™ FE (ethinyl estradiol 25 µg 24 days, norethindrone acetate 0.8 mg 24 days Actavis)
- Loestrin® 1/20 (ethinyl estradiol 20 μg 21 days, norethindrone acetate 1 mg 21 days
 Teva Women's Health)
- Loestrin® FE 1/20 (ethinyl estradiol 20 μg 21 days, norethindrone acetate 1 mg 21 days Teva Women's Health)
- Minastrin[™] 24 FE (ethinyl estradiol 20 µg 24 days, norethindrone acetate 1 mg 24 days Allergan)
- Mircette $^{\circ}$ (ethinyl estradiol 20 µg 21 days, ethinyl estradiol 10 µg 5 days, desogestrel 150 µg 21 days Teva Women's Health)
- 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)
- Nextstellis® (Estetrol 14.2 mg 24 days, drospirenone 3 mg 24 days Mayne)
- NuvaRing[®] (ethinyl estradiol 15 μg/day 21 days, etonogestrel 120 μg/day 21 days Organon)
- Phexxi[™] (lactic acid, citric acid, and potassium bitartrate vaginal gel Evofem)
- 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)
- Safyral™ (ethinyl estradiol 30 µg 21 days, drospirenone 3 mg 21 days Bayer)
- Seasonique® (ethinyl estradiol 30 μg 84 days, ethinyl estradiol 10 μg 7 days, levonorgestrel 150 μg – 84 days - Teva Women's Health)
- Slynd™ (drospirenone 4 mg 24 days Exeltis)
- Taytulla™ (norethindrone/ethinyl estradiol/ferrous fumarate Allergan)
- Twirla® patch (ethinyl estradiol 30 μ g 21 days, levonorgestrel 120 μ g 21 days Agile)
- Yasmin[®] (ethinyl estradiol 30 μg 21 days, drospirenone 3 mg 21 days Bayer)
- Yaz[®] (ethinyl estradiol 20 μg 24 days, drospirenone 3 mg 24 days Bayer)

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 quidance 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. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. 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 quidelines may be used to support medical necessity and other coverage determinations.

Cigna Healthcare Coverage Policy

OVERVIEW

Preventive care services are covered as required by the Affordable Care Act (ACA). The ACA designated resources that identify preventive services required for coverage are:

- United States Preventive Services Task Force (USPSTF) grade A or B recommendations
- Advisory Committee on Immunization Practices (ACIP) recommendations adopted by the Director of the Center for Disease Control and Prevention (CDC)
- Health Resources and Services Administration (HRSA)

The ACA states reasonable medical management techniques may be used to determine coverage limitations if a recommendation or guideline does not specify the frequency, method, treatment, or setting for the provision of a recommended preventive service. Reasonable medical management techniques may include precertification, concurrent review, claim review, or similar practices to determine coverage limitations under the plan. These established reasonable medical management techniques and practices may be utilized to determine frequency, method, treatment or setting for the provision of a recommended preventive service. 3

Some clients have made the decision not to cover medications used for the prevention of pregnancy (contraception). However, oral contraceptives have been used to treat a variety of medical conditions in addition to their use for contraception. Estrogen and progestin contraceptives have been used for the management of acne vulgaris, amenorrhea, dysmenorrhea, dysfunctional uterine bleeding, endometriosis or endometriosis-associated pain, hirsutism, menorrhagia, irregular menses, prevention of menstrual migraine or headache, polycystic ovarian syndrome, ovarian cysts, and premenstrual dysphoric disorder.1-4 Other dosage forms of

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estrogen and/or progestin would be expected to be useful for these other medical conditions as well.

Medical Necessity Criteria

Cigna covers Contraceptives per the Patient Protection and Affordable Care Act (PPACA), Health Resources and Services Administration (HRSA) Guidelines, and Public Health Service (PHS) Act section 2713.

Coverage criteria are listed for products in below table(s):

All products are approved for a duration of 12 months unless otherwise noted.

Employer Plans:	Employer Plans:			
Product	Criteria			
Balcoltra (ethinyl estradiol/ levonorgestrel)	Value/Advantage/Cigna Total Savings Drug List Plans: Approve if according to the prescribing physician, other formulary contraceptives would not be as medically appropriate for the patient as the requested non-formulary drug.* *Criterion developed in accordance with the Affordable Care Act, HRSA Guidelines, and PHS Act section 2713.			
Beyaz (ethinyl estradiol/ drospirenone/ levomefolate)	Cigna Total Savings Drug List Plans: Approve if according to the prescribing physician, other formulary contraceptives would not be as medically appropriate for the patient as the requested non-formulary drug.*			
Depo-Provera (medroxyprogesterone)	*Criterion developed in accordance with the Affordable Care Act, HRSA Guidelines, and PHS Act section 2713.			
Generess FE (ethinyl estradiol/ norethindrone)				
Layolis FE (ethinyl estradiol/ norethindrone)				
Loestrin (ethinyl estradiol/ norethindrone)				
Loestrin FE (ethinyl estradiol/ norethindrone)				
Minastrin 24 FE				

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Product	Criteria		
(ethinyl estradiol/ norethindrone)			
Mircette 28 Day (ethinyl estradiol/ desogestrel)			
Natazia	Value/Advantage/Cigna Total Savings Drug List Plans:		
(estradiol/ dienogest) Nextstellis (drospirenone/ estetrol)	Approve if according to the prescribing physician, other formulary contraceptives would not be as medically appropriate for the patient as the requested non-formulary drug.*		
	*Criterion developed in accordance with the Affordable Care Act, HRSA Guidelines, and PHS Act section 2713.		
Nuvaring	Cigna Total Savings Drug List Plans:		
(ethinyl estradiol/ etonogestrel)	Approve if according to the prescribing physician, other formulary contraceptives would not be as medically appropriate for the patient as the requested non-formulary drug.*		
	*Criterion developed in accordance with the Affordable Care Act, HRSA Guidelines, and PHS Act section 2713.		
Phexxi (lactic acid, citric	Standard/Performance/Value/Advantage/Cigna Total Savings/Legacy Drug List Plans:		
acid, potassium bitartrate)	Approve if according to the prescribing physician, other formulary contraceptives would not be as medically appropriate for the patient as the requested non-formulary drug.*		
	*Criterion developed in accordance with the Affordable Care Act, HRSA Guidelines, and PHS Act section 2713.		
Quartette	Cigna Total Savings Drug List Plans:		
(ethinyl estradiol/ levonorgestrel)	Approve if according to the prescribing physician, other formulary contraceptives would not be as medically appropriate for the patient as		
Safyral (ethinyl estradiol/ drospirenone/ levomefolate)	the requested non-formulary drug.* *Criterion developed in accordance with the Affordable Care Act, HRSA Guidelines, and PHS Act section 2713.		
Seasonique (ethinyl estradiol/ levonorgestrel)			
Slynd (drospirenone)	Value/Advantage/Cigna Total Savings Drug List Plans:		

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Product	Criteria	
Taytulla (ethinyl estradiol/ norethindrone)	Approve if according to the prescribing physician, other formulary contraceptives would not be as medically appropriate for the patient as the requested non-formulary drug.*	
Twirla (levonorgestrel and ethinyl estradiol)	*Criterion developed in accordance with the Affordable Care Act, HRS Guidelines, and PHS Act section 2713.	
Yasmin 28 <u>Cigna Total Savings Drug List Plans:</u>		
(ethinyl estradiol/ drospirenone)	Approve if according to the prescribing physician, other formulary contraceptives would not be as medically appropriate for the patient as	
Yaz	the requested non-formulary drug.*	
(ethinyl estradiol/ drospirenone	*Criterion developed in accordance with the Affordable Care Act, HRSA Guidelines, and PHS Act section 2713.	

Individual and Family Plans:

Product	Criteria			
Balcoltra (ethinyl estradiol/ levonorgestrel)	Approve if according to the prescribing physician, other formulary contraceptives would not be as medically appropriate for the patient as the requested non-formulary drug.*			
Beyaz (ethinyl estradiol/ drospirenone/ levomefolate)	*Criterion developed in accordance with the Affordable Care Act, HRSA Guidelines, and PHS Act section 2713.			
Depo-Provera (medroxyprogesterone)				
Generess FE (ethinyl estradiol/ norethindrone)				
Layolis FE (ethinyl estradiol/ norethindrone)				
Loestrin (ethinyl estradiol/ norethindrone)				
Loestrin FE (ethinyl estradiol/ norethindrone)				
Minastrin 24 FE				

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Product	Criteria
(ethinyl estradiol/	Criteria
norethindrone)	
nored initial one)	
Mircette 28 Day	
(ethinyl estradiol/	
desogestrel)	
desogestiei)	
Natazia	
(estradiol/ dienogest)	
(estradioly dieflogest)	
Nextstellis	
(drospirenone/estetrol)	
(drospirenone/ estetioi)	
Nuncaring	
Nuvaring	
(ethinyl estradiol/	
etonogestrel)	
Dhawi	
Phexxi	
(lactic acid, citric acid,	
potassium bitartrate)	
Ougut att a	
Quartette	
(ethinyl estradiol/	
levonorgestrel)	
Safyral	
(ethinyl estradiol/	
drospirenone/	
levomefolate)	
Seasonique	
(ethinyl estradiol/	
levonorgestrel)	
Slynd	
(drospirenone)	
Taytulla	
(ethinyl estradiol/	
norethindrone)	
Twirla	
(levonorgestrel and	
ethinyl estradiol)	
Yasmin 28	
(ethinyl estradiol/	
drospirenone)	
Yaz	

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Product	Criteria
(ethinyl estradiol/	
drospirenone	

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Conditions Not Covered

Any other use is considered not medically necessary (criteria will be updated as new published data are available).

References

- 1. Clinical Pharmacology [database online]. Elsevier 2023. Available at: Clinical Pharmacology Home (clinicalkey.com). Accessed on May 10, 2023. Search term: oral contraceptive, combinations.
- American College of Obstetricians and Gynecologists. ACOG Committee Opinion. Number 760, December 2018. Dysmenorrhea and Endometriosis in the Adolescent. Available at: https://www.acog.org/. Accessed on May 10, 2023.
- 3. American College of Obstetricians and Gynecologists. ACOG Practice Bulletin No. 194, June 2018. Polycystic ovary syndrome. Available at: https://www.acog.org/. Accessed on May 10, 2023.
- 4. American College of Obstetrics and Gynecology Practice Bulletin. Management of endometriosis. Number 114. July 2010. Reaffirmed 2018. Available at: https://www.acog.org/. Accessed on May 10, 2023.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	Removed Estrostep FE, LoSeasonique, and Ortho Micronor from coverage policy; no longer marketed. Added IFP box table; coverage policy supports Employer Group and IFP benefit plans.	8/15/2024

The policy effective date is in force until updated or retired.

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