



Effective Date.....10/15/2023
Next Review Date.....10/15/2024
Coverage Policy Number IP0036

Contraceptives

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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.

Overview

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.

This policy supports medical necessity review for selected brand contraceptives.

- **Balcoltra** (ethinyl estradiol/ levonorgestrel)
- **Beyaz** (ethinyl estradiol/ drospirenone/ levomefolate)
- **Depo-Provera** (medroxyprogester-one)
- **Estrostep FE** (ethinyl estradiol/ norethindrone)
- **Generess FE** (ethinyl estradiol/ norethindrone)
- **Layolis FE** (ethinyl estradiol/ norethindrone)
- **Loestrin** (ethinyl estradiol/ norethindrone)
- **Loestrin FE** (ethinyl estradiol/ norethindrone)
- **Loseasonique** (ethinyl estradiol/ levonorgestrel)
- **Minastrin 24 FE** (ethinyl estradiol/ norethindrone)

- **Mircette 28 Day** (ethinyl estradiol/ desogestrel)
- **Natazia** (estradiol/ dienogest)
- **Nextstellis** (drospirenone/ estetrol)
- **Nuvaring** (ethinyl estradiol/ etonogestrel)
- **Ortho Micronor** (norethindrone)
- **Phexxi** (lactic acid, citric acid, potassium bitartrate)
- **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** (ethinyl estradiol/ drospirenone)

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

Medical Necessity Criteria

Coverage varies across plans and requires the use of preferred products. Refer to the customer's benefit plan document for coverage details.

The brand contraceptive products in the table below are considered medically necessary when the following are met:

Employer Group Non-Covered Products and the Preferred Covered Alternatives:

Product	Criteria
Balcoltra (ethinyl estradiol/ levonorgestrel)	<u>Value/Advantage/Cigna Total Savings Drug List Plans:</u> 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)	<u>Cigna Total Savings Drug List Plans:</u> 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.
Depo-Provera (medroxyprogester- one)	
Estrostep FE (ethinyl estradiol/ norethindrone)	
Generess FE (ethinyl estradiol/ norethindrone)	
Layolis FE (ethinyl estradiol/ norethindrone)	
Loestrin	

Product	Criteria
(ethinyl estradiol/ norethindrone)	
Loestrin FE (ethinyl estradiol/ norethindrone)	
Loseasonique (ethinyl estradiol/ levonorgestrel)	
Minastrin 24 FE (ethinyl estradiol/ norethindrone)	
Mircette 28 Day (ethinyl estradiol/ desogestrel)	
Natazia (estradiol/ dienogest)	<p><u>Value/Advantage/Cigna Total Savings Drug List Plans:</u></p> <p>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.*</p> <p>*Criterion developed in accordance with the Affordable Care Act, HRSA Guidelines, and PHS Act section 2713.</p>
Nextstellis (drospirenone/ estetrol)	
Nuvaring (ethinyl estradiol/ etonogestrel)	<p><u>Cigna Total Savings Drug List Plans:</u></p> <p>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.*</p> <p>*Criterion developed in accordance with the Affordable Care Act, HRSA Guidelines, and PHS Act section 2713.</p>
Ortho Micronor (norethindrone)	
Phexxi (lactic acid, citric acid, potassium bitartrate)	<p><u>Standard/Performance/Value/Advantage/Cigna Total Savings/Legacy Drug List Plans:</u></p> <p>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.*</p> <p>*Criterion developed in accordance with the Affordable Care Act, HRSA Guidelines, and PHS Act section 2713.</p>
Quartette (ethinyl estradiol/ levonorgestrel)	<p><u>Cigna Total Savings Drug List Plans:</u></p> <p>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.*</p> <p>*Criterion developed in accordance with the Affordable Care Act, HRSA Guidelines, and PHS Act section 2713.</p>
Safyral (ethinyl estradiol/ drospirenone/ levomefolate)	
Seasonique (ethinyl estradiol/ levonorgestrel)	
Slynd (drospirenone)	<p><u>Value/Advantage/Cigna Total Savings Drug List Plans:</u></p> <p>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.*</p> <p>*Criterion developed in accordance with the Affordable Care Act, HRSA Guidelines, and PHS Act section 2713.</p>
Taytulla (ethinyl estradiol/ norethindrone)	
Twirla (levonorgestrel and ethinyl estradiol)	

Product	Criteria
Yasmin 28 (ethinyl estradiol/ drospirenone)	<u>Cigna Total Savings Drug List Plans:</u> 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.
Yaz (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 as applicable.

Reauthorization Criteria

Brand Contraceptives are considered medically necessary for continued use when initial criteria are met.

Authorization Duration

Initial approval duration: up to 12 months unless otherwise stated.

Reauthorization approval duration: up to 12 months unless otherwise stated.

Background

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: ¹

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

Additional Clinical Information

Progestin-only oral contraceptives are also available and indicated for the prevention of pregnancy.³ Like the combination estrogen/progestin oral contraceptives, progestin-only oral contraceptives also have medical literature which document use for other conditions.^{4, 6}

Both medroxyprogesterone acetate injectable suspension formulations (intramuscular [IM] and subcutaneous [SC] administration) are indicated for contraception.¹ Depo-subQ Provera 104 is also indicated for the management of endometriosis-associated pain, while the IM medroxyprogesterone acetate injectable formulation

has been studied for use in endometriosis. Injectable medroxyprogesterone acetate has also been used for a variety of other medical conditions.

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.
2. 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.

Supplemental References

5. Health and Human Services. Center for Consumer Information and Insurance Oversight. Affordable Care Act Implementation. FAQs-Set 12. Accessed August 8, 2022. Available at: https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs12.html
6. American College of Obstetricians and Gynecologists. ACOG Practice Bulletin No. 194, June 2018. Polycystic ovary syndrome.

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