

| Pharmacy Policy Bulletin: J-0012 Contraceptives – Commercial                                                                                                                                                              |                                                                                                      |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|
| <b>Number:</b> J-0012                                                                                                                                                                                                     | <b>Category:</b> Prior Authorization                                                                 |
| <b>Line(s) of Business:</b><br><input checked="" type="checkbox"/> Commercial<br><input type="checkbox"/> Healthcare Reform<br><input type="checkbox"/> Medicare                                                          | <b>Benefit(s):</b><br><b>Commercial (1.):</b><br>1. Contraceptives Oral = Yes w/ Prior Authorization |
| <b>Region(s):</b><br><input checked="" type="checkbox"/> All<br><input type="checkbox"/> Delaware<br><input type="checkbox"/> New York<br><input type="checkbox"/> Pennsylvania<br><input type="checkbox"/> West Virginia | <b>Additional Restriction(s):</b><br>None                                                            |
| <b>Version:</b> J-0012-023                                                                                                                                                                                                | <b>Original Date:</b> 06/01/2001                                                                     |
| <b>Effective Date:</b> 10/28/2024                                                                                                                                                                                         | <b>Review Date:</b> 10/02/2024                                                                       |

|                                    |                                                                                                                                       |
|------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------|
| <b>Drugs Product(s):</b>           | <ul style="list-style-type: none"> <li>Contraceptives</li> </ul>                                                                      |
| <b>FDA-Approved Indication(s):</b> | <ul style="list-style-type: none"> <li>Contraception (prevention of pregnancy)</li> <li>Acne vulgaris</li> <li>Menorrhagia</li> </ul> |

|                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|--------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Background:</b> | <ul style="list-style-type: none"> <li>This policy applies only to those members whose prescription drug benefits require prior authorization of contraceptive therapies (oral, topical, etc.). Prior authorization of contraceptives allows groups to provide coverage of contraceptives for medically necessary indications (non-contraceptive purposes) while excluding coverage for use in contraception.</li> <li>Contraceptive therapies represent a category of the sex hormones indicated for the prevention of pregnancy. Contraceptive therapies contain either a combination of estrogen and progestin or progestin alone. Estrogens suppress follicle-stimulating hormone (FSH) preventing the development of a dominant follicle and potentiate the action of the progestin component, thus suppressing the luteinizing hormone surge. Estrogens also stabilize the endometrial lining (bleeding cycle control). Progestins contribute to other contraceptive effects on cervical mucus (thickening/impermeability) and the endometrium (involution/atrophy). Progestins also inhibit ovulation.</li> <li>There are numerous small clinical trials evaluating the use of oral contraceptives for a variety of off-label uses including dysfunctional uterine bleeding, amenorrhea, dysmenorrhea, polycystic ovarian syndrome (PCOS), fibroid uterus, endometriosis, peri-menopause, menorrhagia, hirsutism, gastric antral vascular ectasia (GAVE), gastrointestinal vascular malformations, chronic anovulation, AV malformations, regulation of menses, and cycle control. In addition, there is limited data evaluating the use of oral contraceptives for the improvement of mid-cycle bleeding or spotting. Oral contraceptives have also been used to regulate menstrual cycles, manage heavy menses, and as a required adjunct agent in individuals of childbearing age when receiving therapy with a known teratogen.</li> </ul> |
|--------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

## Approval Criteria

### I. Approval Criteria

When a benefit, coverage of contraceptive therapies may be approved when all of the following criteria are met **(A. and B.)**:

- A.** The member has a diagnosis of one (1) of the following **(1. through 19.)**:
- 1.** Amenorrhea (ICD-10: N91.0, N91.1, or N91.2)
  - 2.** Polycystic ovary disease (ICD-10: E28.2)
  - 3.** Endometriosis (ICD-10: N80)
  - 4.** Hirsutism (ICD-10: L68.0)
  - 5.** GI AV Malformations (ICD-10: Q27.33)
  - 6.** Menorrhagia (with complications such as anemia) (ICD-10: N92.2 or N92.4)
  - 7.** Acne (ICD-10: L70)
  - 8.** Concomitant use of isotretinoin (oral) or another known teratogen (Pregnancy category X) (No ICD-10 Code)
  - 9.** Migraine prophylaxis (ICD-10: G43)
  - 10.** Reduce risk of ovarian cancer in women at risk (nulliparity, positive family history, or carrier of BRCA genes) (No ICD-10 Code)
  - 11.** Reduce the risk of endometrial cancer in women at high risk (infertility, obesity, and exogenous unopposed estrogen) (No ICD-10 Code)
  - 12.** Fibroid uterus (ICD-10: D25)
  - 13.** Dysmenorrhea (ICD-10: N94.4, N94.5, or N94.6)
  - 14.** Regulation of menses, cycle control, or irregular bleeding (ICD-10: N92.0, N92.1, N92.5, or N92.6)
  - 15.** Dysfunctional uterine bleeding (ICD-10: N93)
  - 16.** Peri-menopausal symptoms (ICD-10: N95.1, N95.8, or N95.9)
  - 17.** Premenstrual dysphoric disorder (PMDD) (ICD-10: F32.81)
  - 18.** Ovarian Cysts (ICD-10: N83.0, N83.1, or N83.2)
  - 19.** Turner's Syndrome (ICD-10: Q96)
- B.** Contraceptive therapies will not be approved if the member has a diagnosis of one (1) of the following **(1., 2., or 3.)**:
- 1.** Contraception
  - 2.** Emergency contraception
  - 3.** Any other diagnosis not previously mentioned as being approved in the section above.

- II.** An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

### Limitations of Coverage

- I.** For Commercial members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.
- II.** For members with the Affordable Care Act (ACA) provision as it relates to contraceptive therapies, coverage of a non-formulary contraceptive will be approved at zero dollar cost share if the prescribing physician indicates that the non-formulary drug is medically necessary or the member has tried and failed one (1) formulary alternative.
- III.** For members with a closed formulary that does not follow the provisions of the ACA, a non-formulary contraceptive will only be approved if two (2) formulary contraceptives have been tried and the member meets the other criteria outlined within this policy.

### Authorization Duration

- Commercial Plans: If approved, up to a 12 month authorization may be granted.

### References:

1. Update in Contraception: Health Benefits of Oral Contraceptives, *Obstetrics and Gynecology Clinics*, Vol. 27, No. 4 12/2000.
2. Helping Women Choose Appropriate Hormonal Contraception: Update on Risks, Benefits and Indications, *The American Journal of Medicine*, Vol. 122, No. 6 June 2009.
3. Nguyen AT , Curtis KM, Tepper NK, et al. U.S. Medical Eligibility Criteria for Contraceptive Use, 2024. *MMWR Recomm Rep* 2024;73(4):1-126.
4. Quigley CA, Wan x, Garg S, et al. Effects of low-dose estrogen replacement during childhood on pubertal development and gonadotropin concentrations in patients with Turner syndrome: results of a randomized, double-blind, placebo-controlled clinical trial. *J Clin Endocrinol Metab*. 2014;99(9):E1754.
5. Grimes DA, Jones LB, Lopez LM, Schulz KF. Oral contraceptives for functional ovarian cysts. *Cochrane Database Syst Rev*. 2006.

*Pharmacy policies do not constitute medical advice, nor are they intended to govern physicians' prescribing or the practice of medicine. They are intended to reflect the plan's coverage and reimbursement guidelines. Coverage may vary for individual members, based on the terms of the benefit contract.*

*The plan retains the right to review and update its pharmacy policy at its sole discretion. These guidelines are the proprietary information of the plan. Any sale, copying or dissemination of the pharmacy policies is prohibited; however, limited copying of pharmacy policies is permitted for individual use.*