Drug Coverage Policy

Effective Date.....7/15/2026
Coverage Policy Number.....BEO002
Policy Title.....Clomiphene Benefit Exclusion Overrides Policy

Clomiphene Benefit Exclusion Overrides Policy

- Clomid® (clomiphene tablets – Cosette)
- Clomiphene citrate tablets (generic – multiple manufacturers)
- Milophene® (clomiphene citrate tablets – brand)

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. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. 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
Clomiphene citrate (Clomid) is a selective estrogen receptor modulator (SERM) indicated for the treatment of ovulatory dysfunction in women who desire pregnancy. It stimulates the release of gonadotropins, promoting follicular development and ovulation. Extended cyclic therapy generally should not exceed approximately six total cycles.[1]

Guidelines
The **American Society for Reproductive Medicine (ASRM) committee opinion (2020)** states that gonadotropin therapy carries more risks compared to oral ovulation induction agents and should only be used by clinicians with appropriate training. Most women respond to oral medications such as clomiphene or letrozole; gonadotropins are generally reserved for those who fail oral therapy or lifestyle modifications.[2] In men, the **American Society for Reproductive Medicine (ASRM)** recognizes clomiphene's off-label use as a therapeutic option for those with low testosterone and infertility who wish to preserve fertility.[3]

The **2023 international evidence-based guideline for PCOS** recommends letrozole as the first-line pharmacologic treatment for women with PCOS and anovulatory infertility without other infertility factors. Clomiphene and metformin may also be considered in this population. Gonadotropins can be used as second-line therapy for women who fail oral ovulation induction or are clomiphene-resistant. These guidelines also state there is no significant difference in clinical efficacy among gonadotropin preparations.[4]

Coverage Policy

This Benefit Exclusion Overrides policy has been developed to authorize coverage of the targeted drug for all medical conditions, except treatment for infertility. **This Benefit Exclusion Overrides policy is not applicable if clients have infertility as a covered benefit.** All approvals are provided for the duration noted below.

Infertility treatment services may be excluded under many benefit plans. Please refer to the applicable benefit plan document to determine benefit availability and the terms and conditions of coverage (0089 Infertility Services).

Clomiphene citrate tablets are considered medically necessary when the following is met:

1. **Treatment of Hypogonadotropic Hypogonadism (hypogonadism secondary to a pituitary deficiency) in males.** Approve for 1 year.

Conditions Not Covered
Coverage of clomiphene citrate tablets for the treatment of infertility is not medically necessary:

1. **Treatment of Infertility.** The purpose of this Benefit Exclusion Overrides policy is to exclude use of the targeted agents when used for the treatment of infertility.

References

1. Cosette Pharmaceuticals, Inc., Clomiphene Citrate Tablets [prescribing information]. South Plainfield, NJ: Par Formulations Private Limited; January 2025.

2. American Society for Reproductive Medicine (ASRM), Use of exogenous gonadotropins for ovulation induction in anovulatory women: A committee opinion. ASRM, Birmingham, AL: 2020.
3. Schlegel PN, Sigman M, Collura B, De Jonge CJ, Eisenberg ML, Lamb DJ, Mulhall JP, Niederberger C, Sandlow JI, Sokol RZ, Spandorfer SD, Tanrikut C, Treadwell JR, Oristaglio JT, Zini A. Diagnosis and treatment of infertility in men: AUA/ASRM guideline part II. Fertil Steril. 2021;115(1):62–69. ©2020 by American Urological Association Education and Research, Inc. and American Society for Reproductive Medicine.
4. International PCOS Guideline Development Group, International evidence-based guideline for the assessment and management of polycystic ovary syndrome. ASRM and collaborating organizations: 2023.

Revision Details

Summary of Changes	Review Date	Effective Date
New policy.	5/14/2026	7/15/2026

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