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Clinical Guideline

Oscar Clinical Guideline: clomiphene (Clomid) (PG104, Ver. 4)

clomiphene (Clomid)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Infertility is a multifactorial issue affecting both men and women, characterized by the inability to conceive after 12 months or more of regular unprotected intercourse or therapeutic donor insemination. Early evaluation and treatment are warranted after 6 months for women over age 35 years. The cause can be identified through physical examinations, detailed medical and sexual history, and relevant laboratory investigations. Depending on the cause, various treatment options are available, which may include medications, surgery, assisted reproductive technologies, or a combination of these. If infertility management exceeds the expertise of a healthcare provider, the patient should be referred to a specialist with experience in diagnosing and treating infertility, such as a reproductive endocrinologist.

Clomiphene (Clomid) is a nonsteroidal fertility agent approved by the FDA to induce ovulation in women who ovulate infrequently or who are anovulatory, including patients with polycystic ovary syndrome (PCOS). Clomiphene is effective in stimulating ovulation in patients with a functioning hypothalamic-pituitary-ovarian axis and ovaries capable of normal functioning. In addition to its role in inducing ovulation, clomiphene is also used to evaluate ovarian reserve and to regulate ovulation timing in patients receiving donor insemination. While not

an FDA-approved use, clomiphene has been utilized to increase sperm counts in men with infertility due to idiopathic oligospermia (low sperm count or inadequate sperm functionality). Clomiphene is available as an oral tablet.

NOTE: Coverage for infertility treatments may vary based on an individual's benefit policy.

- Please refer to the specific benefit plan document to determine the extent and terms of coverage.
- This Clinical Guideline is applicable only to members whose plans cover infertility treatments.
- For medical coverage criteria regarding infertility diagnostic and treatment services, please refer to Oscar's Medical Clinical Guideline Number CG016 - Diagnosis and Treatment of Infertility.

Definitions

"Compendia" are summaries of drug information and medical evidence to support decision-making about the appropriate use of drugs and medical procedures.

"FDA" refers to the Food and Drug Administration.

"Infertility" is defined by the failure to achieve a successful pregnancy after 12 months or more of appropriate, timed unprotected intercourse or therapeutic donor insemination. Earlier evaluation and treatment may be justified based on medical history and physical findings and is warranted after 6 months for women over age 35 years.

Medical Necessity Criteria for Authorization

The Plan considers **clomiphene (Clomid)** medically necessary when **ALL** of the following criteria are met:

1. The requested medication is prescribed by or in consultation with a clinician experienced in management of gynecologic and endocrine disorders***; AND***
2. The member is 18 years of age and older***; AND***
3. The member has a diagnosis of female infertility***; AND***
4. The medication is not being used for induction of ovulation associated with in vitro fertilization programs***; AND***
5. Clinical chart documentation is submitted showing **ALL** of the following:
    a. complete gynecologic and endocrinologic evaluation and diagnosis of cause of infertility***; and***
    b. the member has demonstrated ovulatory dysfunction***; and***
    c. the member is currently not pregnant, confirmed by a negative pregnancy test***; and***
    d. the member has normal liver function***; and***
    e. complete pelvic examination and endometrial biopsy have been performed, and neoplastic lesions have been ruled out***; and***

f. Medical conditions that could prevent pregnancy have been excluded or adequately treated (medical conditions preventing pregnancy may include blocked fallopian tubes, hyperprolactinemia, thyroid, or adrenal disorders)***; and***
g. the fertility status of the male partner has been evaluated***; and***
h. The member does not have **ANY** of the following:
    i. ovarian cysts or ovarian enlargement, unless enlargement is due to PCOS***; or***
    ii. primary pituitary or ovarian failure***; or***
    iii. unexplained vaginal bleeding.

If the above prior authorization criteria are met, clomiphene (Clomid) will be approved for 6 months.

Experimental or Investigational / Not Medically Necessary

The use of clomiphene (Clomid) for any indication that is not FDA approved or compendia supported is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven.

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Clinical Guideline Revision / History Information

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