

Prior Authorization DRUG Guidelines

CLOMID (CLOMIPHENE)

Effective Date: 7/28/05

Date Developed: 7/14/05 by C. Wilhelmy MD

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Clomid is an Ovulation Stimulator. It induces ovulation by stimulating the release of pituitary gonadotropins. It is a racemic mixture consisting of zucloimiphene and enclomiphene and inhibits estrogen feedback at the level of the hypothalamus. This results in GnRH secretion and subsequent pituitary release of FSH and LH, causing growth of ovarian follicles.

Pre-Authorization Criteria:

-Treatment of ovulatory failure in patients desiring pregnancy.

DOSING: ADULTS

Infertility (in males): Oral: 25 mg/day for 25 days with 5 days rest, or 100 mg every Monday, Wednesday, Friday

Ovulatory failure (females): Oral: 50 mg/day for 5 days (first course); start the regimen on or about the fifth day of cycle. The dose should be increased only in those patients who do not ovulate in response to cyclic 50 mg Clomid®. A low dosage or duration of treatment course is particularly recommended if unusual sensitivity to pituitary gonadotropin is suspected, such as in patients with polycystic ovary syndrome.

Repeat dosing: If ovulation does not appear to occur after the first course of therapy, a second course of 100 mg/day (two 50 mg tablets given as a single daily dose) for 5 days should be given. This course may be started as early as 30 days after the previous one after precautions are taken to exclude the presence of pregnancy. Increasing the dosage or duration of therapy beyond 100 mg/day for 5 days is not recommended. If ovulation does not occur after 3 courses of therapy, further treatment is not recommended, and the patient should be re-evaluated. If 3 ovulatory responses occur, but pregnancy has not been achieved, further treatment is not recommended. If menses does not occur after an ovulatory response, the patient should be re-evaluated. Long-term cyclic therapy is not recommended beyond a total of about 6 cycles.

NOTE: VCHCP requires that:

- Doses in excess of 150mg daily for 5 days be prescribed by a fertility specialist.
- Doses up to 150mg daily for 5 days **may** be prescribed by a family practitioner who has experience treating infertility

DOSING: ELDERLY - Refer to adult dosing.

DOSAGE FORMS - Tablet, as citrate: 50 mg

CONTRAINDICATIONS - Hypersensitivity to clomiphene citrate or any of its components; liver disease; abnormal uterine bleeding; enlargement or development of ovarian cyst; uncontrolled thyroid or adrenal dysfunction in the presence of an organic intracranial lesion such as pituitary tumor; pregnancy

PREGNANCY-Use is contraindicated in females who are already pregnant.

LACTATION - Clomiphene may decrease lactation. It is not known if clomiphene is present in breast milk.

PRECAUTIONS - Use with caution in patients unusually sensitive to pituitary gonadotropins (eg, PCOS); a lower dose may be necessary. Prolonged use may increase the risk of borderline or invasive ovarian cancer. Women with, or a family history of, hyperlipidemia may be at increased risk of hypertriglyceridemia. Pancreatitis has been reported. Ovarian hyperstimulation syndrome (OHSS), a rare exaggerated response to ovulation induction therapy manifest by severe abdominal pain, nausea/vomiting (intractable).

REFERENCES

1. Purvin, VA. Visual Disturbance Secondary to Clomiphene Citrate. Arch Ophthalmol 1995; 113:482.
2. Sokol, RZ. Prevention and Management of Complications Occurring During Treatment With Clomiphene. Drug Saf 1990; 5:313.
3. Walker, AB, Eldridge, PR, MacFarlane, IA. Clomiphene-Induced Pituitary Apoplexy in a Patient With Acromegaly. J Endocrinol 1995; 144:29.
4. UpToDate: Clomiphene

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