Clomifene
Shared Care Guideline

Introduction
Clomifene is an anti-oestrogen preparation which stimulates the production of pituitary gonadotrophic hormones, which in turn stimulates the maturation and endocrine activity of the ovarian follicle. This can be used as monotherapy or in combination with metformin*. Licensed indications:
Clomifene citrate is indicated for the treatment of ovulatory failure in women with normal ovarian reserve desiring pregnancy. It is indicated only for patients in whom ovulatory dysfunction is demonstrated. Other causes of infertility must be excluded or adequately treated.
NICE guidance states: use for women with WHO type 2 ovulation disorders (normo-gonadotrophic and normo-oestrogenic) desiring pregnancy.

Adult Dosage and Administration
Treatment should be initiated with 50mg daily for 5 days, starting within 5 days of the onset of menstruation. In patients with amenorrhoea, treatment should be started within the first 5 days of a progestogen-induced withdrawal bleed. When ovulation occurs at this dosage, there is no advantage to increasing the dose in subsequent cycles of treatment.
If ovulation appears not to have occurred after the first course of therapy, a second course of 100mg daily (two 50mg tablets given as a single daily dose) for 5 days should be given. If after two cycles at this dosage, ovulation does not occur, the dose may be increased on specialist recommendation. Doses greater than 100mg daily are unlicensed. If again, this fails to induce ovulation, clomifene treatment should be discontinued.
If ovulation is induced, treatment may be continued for 6 cycles. For women who are taking clomifene citrate, do not continue treatment for longer than 6 cycles.
Preparations available:
• Clomifene citrate (non-proprietary) 50mg tablets
• Clomifene citrate (Clomid®) 50mg tablets.

Hospital Specialist Responsibilities
• Assess patient is suitable for treatment. Baseline tests as per NICE Fertility problems: assessment and treatment *(www.nice.org.uk)
• Arrange shared care with the patient’s GP
• Advise GP on dose to be prescribed
• Provide the patient/carer with relevant (written) information on use, side effects in particular the risk of a multiple pregnancy and need for monitoring
• Offer ultrasound monitoring during at least the first cycle of treatment to ensure that they are taking a dose that minimises the risk of multiple pregnancy
• Continue to review the patient at agreed specified intervals, sending a written summary to the GP whenever the patient is reviewed
• Provide any other advice or information for the GP if required

GP Responsibilities
• Ensure that he/she has the information and knowledge to understand the therapeutic issues relating to the patient’s clinical condition
• Prescribe clomifene, continued prescribing is appropriate for patients attending regular review
• Report any adverse drug reactions to initiating specialist and the usual bodies (e.g.CHM, MHRA)
• Adjust the dose as advised by the specialist
• Regular monitoring will be undertaken by secondary care
Adverse Effects, Precautions and Contraindications

**Adverse effects** appear to be dose related, and are infrequent at the recommended dose. Multiple pregnancies, including simultaneous intrauterine and extrauterine pregnancies, have been reported. The more commonly reported side-effects are:

- hot flushes
- abdominal discomfort
- nausea and vomiting
- headache

Less common, but more serious side-effects are:

- visual disturbances: stop treatment
- ovarian hyperstimulation: refer back to initiating specialist

**Precautions:**
A history of:
- Ovarian Hyperstimulation Syndrome
- Multiple pregnancy
- Ectopic pregnancy
- Uterine fibroids
- Ovarian cancer

**Contraindications:**
- Pregnancy
- Liver disease
- Abnormal uterine bleeding
- Ovarian cyst

Common Drug Interactions

None stated

Communication

For any queries relating to this patient's treatment with clomifene, please contact the specialist named at the top of this document.

This information is not inclusive of all prescribing information and potential adverse effects. Please refer to full prescribing data in the SPC or the BNF

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