

Commissioning Policy for In Vitro Fertilisation (IVF)/ Intracytoplasmic Sperm Injection (ICSI) within tertiary Infertility Services, in Telford and Wrekin

Owner(s)	Director of Commissioning, Telford and Wrekin CCG
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1 Introduction

In Vitro Fertilisation (IVF) is commissioned as a tertiary service within an overall infertility pathway. This policy describes circumstances in which Telford and Wrekin CCG will fund treatment for IVF including Intra-cytoplasmic Sperm Injection (ICSI).

This policy seeks to provide a safe, equitable and accessible fertility service to all couples where a couple has been unable to conceive, within the agreed eligibility criteria set out in this policy (section 4).

- I. **Couples will only be referred for fertility investigations/assisted conception if they meet the eligibility criteria for assisted conception and when all appropriate tests and investigations have been successfully completed in primary and secondary care in line with NICE clinical guidelines¹.**

If the couple meet the criteria and wish to proceed with treatment they will be placed on the waiting list with the agreed provider in the context of the resources available.

Telford and Wrekin CCG has reviewed their approach to assisted conception with regard to the guidelines published by the National Institute for Health & Care Excellence (NICE)¹. Full implementation of the NICE clinical guideline has not been possible on the grounds of affordability.

The eligibility criteria do not apply to the use of assisted conception techniques for reasons other than subfertility, for example:-

- in families with serious inherited diseases where IVF is used to screen out embryos carrying the disease or to preserve fertility
- for someone about to undergo chemotherapy, radiotherapy or other invasive treatments.

The CCG's position is to limit treatment to one cycle per couple. This allows for increased access to NHS treatment and ensures that couples are treated in a timely manner.

The initial assessment should be undertaken by the patient's GP. The couple should be provided with advice on each of the following areas:

- frequency and timing of sexual intercourse
- alcohol consumption
- smoking
- caffeinated beverages
- body weight
- occupation
- tight undergarments
- prescribed, over-the-counter and recreational drug use.

Couples who are accepted for NHS funded IVF/ICSI treatment will receive all their care at a provider approved by the CCG, including the prescribing and dispensing of their drugs. This ensures:

- Equity of access to treatment for all individuals who meet the eligibility criteria.
- Continuity of expert clinical care.
- Cost efficiency (large centres are likely to be able to negotiate discounts on the costs of the drugs)

2 Background

It is estimated that infertility affects 1 in 7 heterosexual couples in the UK. Since the original NICE guideline on fertility published in 2004 there has been a small increase in the prevalence of fertility problems, and a greater proportion of people now seeking help for such problems.

The main causes of infertility in the UK are (percent figures indicate approximate prevalence):

- unexplained infertility (i.e. no identified male or female cause) (25%)
- ovulatory disorders (25%)
- tubal damage (20%)
- factors in the male causing infertility (30%)
- uterine or peritoneal disorders (10%).

In about 40% of cases, disorders are found in both the man and the woman. Uterine or endometrial factors, gamete or embryo defects, and pelvic conditions such as endometriosis may also play a role.

Given the range of causes of fertility problems, the provision of appropriate investigations is critical. These investigations include semen analysis; assessment of ovulation, tubal damage and uterine abnormalities; and screening for infections such as *Chlamydia trachomatis* and susceptibility to rubella.

Once a diagnosis has been established, treatment falls into 3 main types:

- medical treatment to restore fertility (for example, the use of drugs for ovulation induction)
- surgical treatment to restore fertility (for example, laparoscopy for ablation of endometriosis)
- assisted reproduction techniques– any treatment that deals with means of conception other than vaginal intercourse. It frequently involves the handling of gametes or embryos.

3 Definition of Infertility

“Infertility can be defined as the failure to conceive after regular unprotected sexual intercourse for a period of 2 years in the absence of known reproductive pathology”.

Over 80% of couples in the general population will conceive within 1 year if: the woman is aged under 40 years **and** they do not use contraception and have regular sexual

intercourse. Of those who do not conceive in the first year, about half will do so in the second year (cumulative pregnancy rate over 90%).

4 Number of IVF Cycles

The CCG will fund 1 full cycle of IVF (with or without ICSI). NB: If a spontaneous conception leading to a live birth occurs, or if a child is adopted while on the waiting list, the couple would become ineligible for IVF treatment.

5 Patient eligibility criteria

This policy applies to any patient in circumstances where Telford and Wrekin CCG is the responsible commissioner for their NHS care.

Length of relationship

A couple is defined as two individuals in a relationship of at least two years duration, which involves them being married or cohabiting with one another.

Previous Treatment

Any couple who have previously received one or more cycles of treatment, including privately funded treatment (even if they meet the local criteria) will not be eligible for funding.

Age

Funding will be provided for women aged under 40 years at the time of treatment, i.e. up to their 40th birthday. Referrals into the service should be made in appropriate time to ensure that treatment can take place by the woman's 40th birthday.

An earlier referral for specialist consultation to discuss the options for attempting conception, further assessment and appropriate treatment should be made where:

- the woman is aged 36 years or over
- there is a known clinical cause of infertility or a history of predisposing factors for infertility

There is evidence that fertility rate decreases with age. Evidence is available from <http://publications.nice.org.uk/fertility-cq156/figures-and-tables-to-support-chances-of-conception-and-embryo-quality-recommendations#figure-2-ivf-success-in-terms-of-live-births-per-100-embryo-transfers>

Maternal Weight

Treatment will not be provided for any woman with a Body Mass Index <19 or any woman with a BMI>30.

Living Children

Funding will not be available to couples who have any living children by the present relationship or any previous relationship. This includes a child adopted by the parent/couple (excludes foster children). Once accepted for treatment, should a child be adopted or a pregnancy leading to a live birth occur, the parent/couple will no longer be eligible for NHS Funded Treatment.

Reversal of Sterilisation:

IVF treatment will not be available if the patient or either partner within a couple has received a sterilisation procedure or has undertaken a reversal of sterilisation procedure.

Welfare of the Child

Patients/couples who do not conform to the Human Fertilisation & Embryology Authority's (HFEA) Code of Practice, 8th edition, will be excluded from having access to NHS funded assisted fertility treatment. This includes consideration of the "welfare of the child which may be born". This will take account of a patient/couple's ability to provide a stable and supportive environment for a child and family medical histories. Treatment Centres will undertake this assessment.

Compliance with Treatment

Any couple who are considered unlikely to accept or comply with the demands of adhering to a treatment plan should, ideally, not be referred. Consideration should also be given to a woman's willingness to adopt healthier lifestyles during pregnancy.

Smoking

Couples accepted for treatment will be confirmed non-smokers. Previous smokers should stop smoking for at least 4 weeks prior to referral and continue to refrain from smoking throughout the treatment process. Smokers who wish to be referred for treatment should initially be referred to local smoking cessation services

Maternal and paternal smoking can adversely affect the success rates of assisted reproduction procedures, including in vitro fertilization treatment. Smoking during the antenatal period leads to increased risk of adverse pregnancy outcomes. Minimizing exposure to second hand smoke will ensure a healthy start to life to any child/children born as a result of assisted conception.

6 Same Sex Couples

Applications will be considered for sub-fertility treatment for same-sex couples provided there is proven sub-fertility, defined as no live birth following artificial insemination (AI) of at least 12 cycles or proven by clinical investigation as per NICE guidance. At least 6 cycles of AI should be undertaken in a clinical setting with an initial clinical assessment and appropriate investigations.

The CCG will not fund the AI cycles referred to above, but will fund access to a clinical consultation to discuss options for attempting conception, further assessment and appropriate treatment.

All couples will have to be in a stable relationship for at least 2 years before eligibility for NHS funded IVF or other assisted conception treatment.

In the case of same-sex couples in which only one partner is sub-fertile, clinicians should explore the possibility of the other partner becoming the biological parent before carrying out interventions involving the sub-fertile partner.

NHS Funding will not be available for access to insemination facilities for women who are not in a partnership or are part of a same-sex partnership. In circumstances in which those in a same-sex relationship are eligible for sub-fertility treatments, all other criteria for eligibility to sub-fertility treatments will apply as well.

7 Single Woman

NHS Funding will not be available for single women

8 Embryo Storage

Embryo freezing and storage will be funded for a maximum of 12 months for eligible women, or until the female partner's 40th birthday if this is sooner. Couples who do not use up their frozen embryos by 12 months will be responsible for subsequent annual storage charges. The CCG will not separately fund access to and the use of frozen embryos remaining after a live birth

9 Pre-Implantation Genetic Diagnosis

Refer to NHS England commissioning policy: <http://www.england.nhs.uk/wp-content/uploads/2013/04/e01-p-a.pdf>

10 Surrogacy

Please refer to the individual CCG surrogacy policy: <http://www.telfordccg.nhs.uk/clinical-commissioning-policies->

11 Donor Egg

This will only be funded for women who have undergone premature ovarian failure due to an identifiable pathological or iatrogenic cause or to avoid transmission of inherited disorders to a child where the couple meet the other eligibility criteria. Egg donation outside of these criteria will not be funded.

¹ National Institute for Health and Care Excellence. Fertility: Assessment and treatment for people with fertility problems. NICE Clinical Guideline 156. February 2013