

THRESHOLD POLICY T39 FERTILITY

Policy author:	Ipswich and East Suffolk CCG & West Suffolk CCG, with support from Public Health Suffolk
Policy start date:	April 2014
Subsequent reviews	June 2017
Next review date:	August 2020

1. Policy Summary

- 1.1 This policy sets out the entitlement and service that will be provided by Ipswich and East and West Suffolk CCGs for NHS funded specialist fertility services for the population of both CCGs. This specifically includes In Vitro Fertilisation (IVF) and Intracytoplasmic Sperm Injection (ICSI).
- 1.2 Couples will be eligible to receive IVF/ICSI where they meet the specified referral criteria.
- 1.3 All couples must undergo the fertility investigations in primary and secondary care as per the existing CCG policy appropriate to them before eligibility for NHS-funded assisted reproduction services is considered.

IVF

An IVF procedure includes the stimulation of the women's ovaries to produce eggs which are then placed in a special environment to be fertilised. The fertilised eggs are then transferred to the woman's uterus.

An embryo transfer is from egg retrieval to transfer to the uterus. The fresh embryo transfer would constitute one such transfer and each subsequent transfer to the uterus of frozen embryos would constitute another transfer.

Previous IVF

Having received non-NHS funded/ self-funded IVF previously does not preclude women aged less than 40 from accessing NHS funded IVF however the number of cycles received previously will determine eligibility for further NHS funded cycles. Evidence shows a decrease in success after three cycles and therefore no women will receive more than a total of three cycles (including non NHS funded cycles). If they have self-funded ONE cycle previously, they are eligible for up to TWO fresh cycles. If they have self-funded TWO cycles previously, they are eligible for only ONE fresh cycle. If they have self-funded THREE cycles, they are not eligible for any further treatment. Women between age 40 to less than 42 years should not have had any IVF cycle (self or NHS funded) to be eligible for NHS funding.

Couples will not be allowed to pay for any additional interventions as part of the treatment within a cycle of NHS fertility treatment. This includes, but is not limited to, any drugs (including drugs prescribed by the couple's GP), recommended treatment that is outside the scope of the service specification agreed with the Secondary or Tertiary Provider or experimental treatments.

Where a patient meets the CCG eligibility criteria, but agrees to commence treatment on a privately funded basis, they may not retrospectively apply for any associated payment relating to the private treatment.

Embryo storage

The CCG will fund storage of the embryos for one year only. Patients must be counselled by the clinician and infertility counsellor to this effect. Any costs relating to the continued storage of the embryos beyond the first calendar year of the retrieval date is the responsibility of the couple. If any fertility treatment results in a live birth, then the couple will no longer be considered childless and will not be eligible for further NHS funded fertility treatments, including the implantation of any stored embryos.

Egg and sperm storage for patients undergoing cancer treatments

This is covered under separate arrangements.

Egg donation where no other treatment is available

This will be available to women who have undergone premature ovarian failure (longer than six months amenorrhoea and FSH greater than 25IU/L) due to an identifiable pathological or iatrogenic cause, before the age of 40 years, or to avoid transmission of inherited disorders to a child where the couple meets the other eligibility criteria. The patient may be able to provide an egg donor; alternatively, the patient can be placed on the waiting list, until an altruistic donor becomes available. If either of the couple exceeds the age criteria prior to a donor egg becoming available, they will no longer be eligible for treatment.

Donor insemination

Donor insemination may be indicated where:

- the male partner is likely to pass on an inheritable genetic condition;
- severe rhesus incompatibility has been a problem because of the male partner's homozygous status;
- the male partner does not produce suitable sperms (quantity or quality) and, therefore, ICSI is not possible

Anovulatory women can have ovulation induction prior to donor insemination. A maximum of six cycles of donor insemination will be funded followed by IVF with donor sperm if all other eligibility criteria are met.

The need to prevent transmission of sexually transmitted diseases (including HIV) by donor insemination has led to the mandatory quarantine of donor sperm for six months by cryopreservation prior to its use in the UK.

Intra uterine insemination (IUI)

Due to poor clinical evidence, IUI will only be offered under exceptional circumstances.

Chronic viral infections

Interventions to prevent the transmission of blood borne viruses in fertile serodiscordant couples (for example, where one partner has HIV or Hepatitis C) where all other criteria are met is commissioned from specialist centres.

Sperm washing will not be offered for men with Hepatitis B.

Surrogacy

Surrogacy is not commissioned as part of this policy. This includes part funding during a surrogacy cycle.

Exceptional Circumstances

Couples who do not meet the criteria and consider they have exceptional clinical circumstances, which suggest that they are likely to gain significantly more benefit than might generally be expected, can be referred to CCG's Individual Funding Request panel.

Not included in Policy

Gamete storage, preimplantation genetic diagnosis and intrauterine insemination are not part of this policy. These will be dealt with under existing Clinical Commissioning Group (CCG) arrangements including the prior approvals process.

Individual Prior Approvals

The CCG is likely to operate an individual prior approvals process to support the implementation of parts of this policy.

2. Eligibility Criteria

1. Age of woman and number of cycles

- a. Woman aged 23 to less than 40 years – two fresh cycles. If the woman reaches age of 40 years during treatment, the current cycle will be completed, but no further cycles will be offered.
- b. Woman aged 40 to less than 42 years – one fresh cycle providing all the following criteria are met:
 - i. Never previously had IVF treatment
 - ii. There is no evidence of low ovarian reserve (FSH less than 8.9IU/L)
 - iii. There has been a discussion of the additional implications of IVF and pregnancy at this age

2. Embryo transfers

- a. Women aged 23 to less than 40 years – one embryo will be transferred during each cycle to reduce the risk of multiple pregnancies. A maximum of four embryo transfers (fresh plus frozen) will be funded. All frozen embryos should be used before a fresh cycle is funded. Where couples have previously self-funded a cycle then the couples must utilise the previously frozen embryos, rather than undergo ovarian stimulation, egg retrieval and fertilisation again.
- b. Women aged 40 to less than 42 years – up to two embryos may be transferred during each cycle. A maximum of two embryo transfers (fresh plus frozen) will be funded.

3. Age of male partner

Less than 55 years - Male fertility has been shown to decrease with age, with evidence of greater incidence of disability, poor sperm function and DNA degradation.

4. Duration of infertility/waiting time

- a. Couples with unexplained fertility must have infertility of at least three years of ovulatory cycles, despite regular unprotected vaginal sexual intercourse with the partner seeking treatment or 12 cycles of artificial insemination over a period of three years.
- b. If the woman has a miscarriage, the couple will wait for a further 3 years of unexplained infertility from the date of the miscarriage to be eligible for NHS funded IVF. Couples with unexplained infertility should be referred from primary care after 12 months expectant management.
- c. Couples with a diagnosed cause of absolute infertility which precludes any possibility of natural conception, and who meet other eligibility criteria, will have immediate access to NHS funded assisted reproduction services.
- d. For same sex couples, see point 16.

5. Minimum Investigations

- a. The minimum investigations required prior to referral to the Tertiary centre are:

Female:

- Laparoscopy and/or hysteroscopy and/or hysterosalpingogram or ultrasound scan where appropriate
- Rubella anti bodies
- Day 2 FSH
- Chlamydia screening
- Hepatitis B including core antibodies and Hepatitis C and HIV status and core, within the last 3 months of treatment and repeated every 2 years.

Male:

- Preliminary Semen Analysis and appropriate investigations where abnormal (including genetics)
- Hepatitis B including core antibodies and Hepatitis C, within the last 3 months and repeated after 2 years.
- HIV status

6. Follicle Stimulating Hormone

- a. FSH less than 8.9 IU/L on day two of any menstrual cycle within three months of referral from secondary care to the specialist IVF provider.

7. Residency

- a. Both partners must be registered with a GP practice in Ipswich and East Suffolk or West Suffolk Clinical Commissioning Groups for at least 12 months prior to referral from primary care to secondary care and be eligible for NHS care.

8. Parental Status

- a. There should be no living child from the couple's current or any previous relationships, regardless of whether the child resides with them. This includes any adopted child within their current or previous relationships; this will apply to adoptions either in or out of the current or previous relationship.

9. Smoking

- a. Couples who smoke will not be eligible for NHS funded specialist assisted reproduction assessment or treatment, and should be informed of this criterion at the earliest possible opportunity in their progress through infertility investigations in primary care and secondary care. Couples presenting with fertility problems in primary care should be provided with information about the impact of smoking on their ability to conceive naturally, the adverse health impacts of maternal and passive smoking on the foetus, and the adverse health impacts of passive smoking on any children; and smoking cessation support should be provided as necessary.
- b. Both partners must be non-smoking at the time of referral from secondary care to specialist IVF services and maintained during treatment. Smoking status should be ascertained by carbon monoxide testing in secondary care and specialist IVF services.

10. BMI

- a. Women must have a BMI of between 19-30 kg/m² and men a BMI of 19-35 kg/m² at time of referral for specialist assisted reproduction assessment and at the time of any specialist treatment.
- b. Couples presenting with fertility problems in primary care should be provided with information about the impact of BMI on their ability to conceive naturally. Where appropriate, couples should be offered advice and support to achieve weight loss, and should be informed of the weight criterion in relation to NHS funded assisted reproduction services at the earliest appropriate opportunity in their progress through infertility investigations in primary care and secondary care.

11. Child Welfare

- a. The welfare of any resulting children is paramount. In order to take into account the welfare of the child, consideration will be given to factors which are likely to cause serious physical, psychological or medical harm, to the child to be born. This is a requirement of the licensing body, Human Fertilisation and Embryology Authority. Couples must conform to the statutory "Welfare of the Child" requirements.

12. Previous Sterilisation

- a. Couples are ineligible if previous sterilization has taken place (either partner even if it has been reversed)

13. Rubella Status

- a. The woman must be rubella immune.

14. Medical Condition

- a. Treatment may be denied on other medical ground not explicitly covered in this document.

15. Legal Responsibility

- a. Both members of the couple must accept joint legal responsibility for any child produced through fertility treatment.

16. Same Sex Couples (female)

- a. Same sex couples will be required to demonstrate infertility prior to commencing any investigations in line with the policy for heterosexual couples.
- b. Same sex couples must have undergone a minimum of 6 verified and documented cycles of artificial insemination within 12 months before being eligible to access NHS funded fertility assessment and treatment.
- c. Couples are encouraged to maximise opportunities within these 6 cycles by exploring the option of both partners undergoing artificial insemination.
- d. In line with the policy for heterosexual couples, same sex couples with unexplained infertility must wait a total of three years before becoming eligible for IVF treatment. Couples are encouraged to continue to try and conceive during this waiting period by safe methods.
- e. Couples with a diagnosed cause of absolute infertility which precludes any possibility of a natural conception, and who meet other eligibility criteria, will have immediate access to NHS funded assisted reproduction services.
- f. CCGs will not routinely fund donor sperm, but will fund the associated IVF/ICSI treatment in line with the eligibility criteria within this policy, providing the sperm meets the criteria set out by the treating provider unit.
- g. The partner of a prospective mother who has undertaken NHS funded fertility treatment, whether successful or not, will be deemed to have received their entitlement to NHS funded fertility treatment upon completion of this cycle, in line with the criteria for heterosexual couples, and will not be eligible for additional cycles with their partner or any future partners.
- h. Same sex fertile couples will not be funded for assisted conception methods under this policy.
- i. Couples will be required to fit all other criteria within this policy in line with heterosexual couples.

17. Same sex couples (male)

- a. Same sex male couples will not be able to access fertility treatment within their relationship but will be eligible for appropriate investigation where there is evidence of subfertility.

3. Background to the Condition

- 3.1 It is estimated that infertility affects one in seven heterosexual couples in the UK and there has been a small increase in the prevalence of fertility problems, and a greater proportion of people now seeking help for such problems (NICE CG 156).

The main causes of infertility in the UK are:

- unexplained infertility (no identified male or female cause) (25%);
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- ovulatory disorders (25%);
- tubal damage (20%);
- factors in the male causing infertility (30%)

- 3.2 IVF (In Vitro Fertilisation) is a fertility treatment whereby an egg is fertilised by sperm outside of the body. A woman's ovaries are stimulated to produce eggs which are then fertilised in a special environment outside the body. The fertilised egg is then transferred to a woman's uterus with the intention of establishing a successful pregnancy. ICSI (Intracytoplasmic Sperm Injection) is a type of IVF procedure whereby a single sperm is injected directly into an egg.

4. Rationale to the Decision

- 4.1 This policy is designed to ensure that limited healthcare resources are put to best possible use, benefitting patients with the best likelihood of success (live singleton birth).

A new clinical guidance on Fertility was published by NICE in February 2013 (CG156) and this policy has considered the evidence presented by NICE in recommending changes and the views of stakeholders through an established consultation process.

The decision to include access for women aged 40-42 who meet specific criteria was based on high to low quality evidence presented by NICE but recognizes the improved success rates of IVF since the publication of the previous policy.

The decision to maintain waiting times as per the previous policy for women with unexplained fertility was made based upon moderate to low quality of evidence presented by NICE and the difficulties in justifying additional spend in constrained NHS resources.

The decision to reduce the number of cycles from 3 to 2 was made to partially mitigate the extra resource needed to increase the age limit.

In order to be fair and try to standardise the access to IVF for patients across the region, this policy has tried to be in line with other East of England Clinical Commissioning Groups.

Further information on the evidence that informed this policy is available in the accompanying evidence brief.

5. References

1. NICE Fertility CG156 (2013). Available at:
<http://guidance.nice.org.uk/CG156/NICEGuidance/pdf/English>
2. Kidd SA, Eskenazi B, Wyrobek AJ "Effects of male age on semen quality and fertility: a review of the literature" *Fertil Steril* (2001); 75(2): 237
3. De La Rochebrochard E, de Mouzon J, Thepot f, Thonneau P "Fathers over 40 and increased failure to conceive: the lessons of invitro fertilisation in France" (2006); 85(5):1420