NHS
Cambridgeshire & Peterborough

Clinical Threshold Policy

Assisted Conception

This policy covers

The entitlement and service that will be provided by NHS Cambridgeshire and Peterborough (ICB) for
In Vitro Fertilisation (IVF) and Intracytoplasmic Sperm Injection (ICSI).

Specialist Fertility Treatments within the scope of this policy are:

- In-vitro fertilisation (IVF) and Intra-cytoplasmic sperm injection (ICSI).
- Donor Insemination (DI).
- Intrauterine Insemination (IUI) unstimulated.
- Sperm, embryo and male gonadal tissue cryostorage and replacement techniques.
- Egg donation where no other treatment is available.
- Egg and sperm storage for patients undergoing cancer treatment.
- Surrogacy.

Treatments excluded from this policy:

- Pre-implantation Genetic Diagnosis and associated IVF/ICSI. This service is commissioned by NHS England.
- Specialist Fertility Services for members of the Armed Forces are commissioned separately by NHS England.
- Surgical sperm retrieval methods are the commissioning responsibility of NHS England.

Policy

Referring and treating clinicians should ensure compliance with this policy. Referral proforma MUST be attached to the patient notes as evidence of compliance.

Couples who do not meet the criteria and consider they have exceptional clinical circumstances, which suggests that they are likely to gain significantly more benefit than might generally be expected, can be referred to NHS C&P (ICB)'s Exceptional Cases Panel using the **funding request form**.

Couples will be eligible to receive IVF/ICSI where they meet the specified referral criteria detailed below:

Criterion	Description
Maternal age:	Women aged 23 to less than 43 years at the start of treatment. For women >40 years, there must be a discussion of the additional implications of IVF and pregnancy at this stage.
Paternal age:	Age 23 years up to and including 55 years of age.
Number of cycles	One full/abandoned cycle.

Criterion	Description
Abandoned cycles:	There should be shared decision making between patients and providers to agree the funding for this cycle. If the choice is made to count the abandoned cycle as NHS funded, no further cycles will be NHS funded.
Number of transfers:	A maximum of three transfers of embryos (one fresh plus two frozen).
Number of embryos per transfer:	Embryo transfers should be as per HFEA guidance and generally this would be: • Women aged 23 to 39 years – ONE embryo may be transferred per procedure. • Women aged between 40 to less than 43 years – TWO embryos may be considered for transfer per procedure.
Duration of sub-fertility:	Couples should be referred from primary care after 12 months of unexplained infertility. Couples with unexplained infertility must have infertility of at least three years (two years for women 36+ yrs) 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 to be eligible for NHS funded IVF. If the woman has a miscarriage, the couple will wait for a further 3 years (two years for women 36+ yrs) of unexplained infertility from the date of the miscarriage to be eligible for NHS funded IVF. 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 (see note 1).
Previous Fertility treatment:	NHS funding is not available (whether self-funded or NHS funded) if couples have received 3 or more cycles and the woman is <40 years. If the woman is >40 and they have received 1 cycle then NHS funding is not available.
Previous sterilisation:	Couples are ineligible if previous sterilisation has taken place (either partner), even if it has been reversed.
Minimum/ Maximum BMI:	Women must have a BMI of 19 to ≤30kg/m^2 and the male partner must have a BMI <35kg/m^2. Patients outside of this range will not be added to the waiting list and should be referred back to their referring clinician and/or general practitioner for weight management advice and support if required. In female same sex couples, BMI criteria should only apply to the partner undergoing fertility treatment.
Smoking Status:	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. They should be provided with information about the impact of smoking on their ability to conceive naturally, the adverse health impacts of passive smoking on any children and smoking cessation support should be provided as necessary. Both partners must be non-smoking at the time of referral from secondary care to specialist IVF services and maintained during treatment. This applies equally for same-sex couples as passive smoking may affect the fertility of the partner undergoing fertility treatment. Smoking status should be ascertained by carbon monoxide testing in secondary care and specialist IVF services.

Criterion	Description
Parental Status:	Couples are ineligible for treatment if there are any living children from the current or any previous relationships, regardless of whether the child resides with them. This includes any adopted child within their current or previous relationships.
Child Welfare:	Providers must meet the statutory requirements to ensure the welfare of the child. This includes HFEA's Code of Practice which considers the 'welfare of the child which may be born' and takes into account the importance of a stable and supportive environment for children as well as the pre-existing health status of the parents.
Residential Status:	Both partners must be registered with a GP Practice within the CCG and be eligible for NHS care for at least 12 months prior to referral from primary care to secondary care.
Test for ovarian reserve:	To be eligible, the patient should have an Anti-Mullerian Hormone level of more than 5.4pmol/l or Antral Follicle Count of ≥ 4 measured in the last 3 months of referral from secondary care to the specialist IVF provider. If both tests are done, both criteria must be met.
The minimum investigations required prior to referral to the Tertiary centre:	**Female**: Laparoscopy and/or hysteroscopy and/or hysterosalpingogram or ultrasound scan where appropriate. Rubella antibodies. Must be immune (unless non-responder after 2 vaccinations). Chlamydia screening. Hepatitis B including core antibodies, Hepatitis C and HIV status, within the 3 months before treatment and repeated every 2 years. **Male**: Preliminary Semen Analysis and appropriate investigations where abnormal (including genetics). Hepatitis B including core antibodies, Hepatitis C and HIV status, within the 3 months before treatment and repeated every 2 years.
Medical Conditions:	Treatment may be denied on other medical grounds not explicitly covered in this document.
IUI (Unstimulated):	Due to poor clinical evidence, IUI will only be offered under exceptional circumstances. A maximum of 3 cycles of intrauterine insemination (IUI) will only be offered if prior approval for funding is obtained from the CCG.
Same sex couples:	Same-sex couples are entitled to treatment (see reference 2) on the NHS following at least 12 cycles of unsuccessful artificial insemination over 3 years (this is self-funded or 3 IUI may be NHS funded if they have gained Exceptional Case Panel approval – see reference 3).
Egg donation:	Available to women who have undergone premature ovarian insufficiency (amenorrhoea >6 months and a raised FSH >25 on 2 occasions >1 month apart) 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 meet the other eligibility criteria (see reference 4).
Surgical sperm retrieval for azoospermia:	This is funded by NHS England for patients who meet certain criteria: https://www.england.nhs.uk/wp-content/uploads/2018/07/Surgical-sperm-retrieval-for-male-infertility.pdf. Where NHSE funding for sperm retrieval is available, the NHS will fund further treatment with IVF.

Criterion	Description
Egg, sperm and oocyte storage:	Available for adolescent/adult men and women preparing for cancer treatment (see reference 5) or other conditions known to cause premature infertility. Following cancer treatment, couples seeking fertility treatment must meet the defined eligibility criteria.
Private treatment/part funding:	Patients meeting NHS criteria, but taking up private treatment, will not be able to retrospectively apply for treatment costs. Patients will not be able to pay for any 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.
Surrogacy:	Surrogacy is not commissioned. This includes part funding during a surrogacy cycle.

Notes

1. There is no wait for couples with a diagnosed cause of infertility – see below:
   a. Tubal damage, which includes:
   moderate or severe distortion not amenable to tubal surgery.
   b. Premature Menopause (defined as amenorrhoea for a period more than 6 months together with a raised FSH >25 and occurring before age 40 years).
   c. Male factor infertility. Results of semen analysis conducted as part of an initial assessment should be compared with the following World Health Organisation reference values as follows:
      - semen volume: 1.5 ml or more
      - pH: 7.2 or more
      - sperm concentration: 15 million spermatozoa per ml or more
      - total sperm number: 39 million spermatozoa per ejaculate or more
      - total motility (percentage of progressive motility and non-progressive
      - motility): 40% or more motile or 32% or more with progressive motility
      - vitality: 58% or more live spermatozoa
      - sperm morphology (percentage of normal forms): 4% or more.
   d. Endometriosis where specialist opinion is that IVF is the correct treatment.
   e. Cancer treatment causing infertility necessitating IVF/ICSI (eligibility criteria still apply).
2. Couples must meet eligibility criteria as for heterosexual couples. However, BMI eligibility criteria only apply to the female partner undergoing fertility treatment. As for heterosexual couples, couples with a diagnosed cause of absolute infertility will have immediate access to services.
3 Donor semen is used for same sex couples as part of IVF/ICSI treatment.
4 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.
5 Offer sperm cryopreservation to men and adolescent boys who are preparing for medical treatment for cancer that is likely to make them infertile. Offer oocyte or embryo cryopreservation as appropriate to women of reproductive age (including adolescent girls) who are preparing for medical treatment for cancer that is likely to make them infertile if:
   - they are well enough to undergo ovarian stimulation and egg collection; and
   - this will not worsen their condition; and
   - enough time is available before the start of their cancer treatment.

For new patients, cryopreserved material may be stored for an initial period of 10 years. However, for current patients, due to COVID restrictions, this period has been extended to 12 years.

Glossary

Abandoned/cancelled cycle of IVF:	an abandoned or cancelled cycle is defined as one where an egg collection procedure is not undertaken. If an egg collection procedure is undertaken, it is considered to be a full cycle.
Artificial insemination:	the insertion of sperm directly into the vagina or uterus.
Frozen embryo transfer:	where an excess of embryos is available following a fresh cycle, these embryos may be frozen for future use. Once thawed, these embryos are transferred to the patient as a frozen cycle.
Full cycle of IVF/ICSI:	"One full cycle" of IVF/ICSI treatment comprises: ovulation induction, egg retrieval, fertilisation and the transfer of resultant fresh or frozen embryos. It also includes appropriate diagnostic tests, scans and pharmacological therapy.
In vitro fertilisation (IVF):	is a process by which an egg is fertilised with a sperm outside the body (in vitro). The fertilised egg (embryo) is then transferred to the woman's uterus.
Intracytoplasmic sperm injection (ICSI):	involves injecting a single sperm directly into an egg in order to fertilise it. The fertilised egg (embryo) is then transferred to the woman's uterus.
Intrauterine insemination (IUI):	the insertion of sperm directly into the uterus.

Evidence and references to support this policy are based on National Institute for Health and Care Excellence Clinical Guidance CG156: Fertility problems: assessment and treatment. Published 20 February 2014. Updated 6 September 2017

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