

Specialist Fertility Services including Assisted Conception

Policy properties	Information relating to this policy
Policy name	Specialist Fertility Services including Assisted Conception
Policy type	Threshold
Included intervention(s)	Level 3 fertility services
Included indication/condition(s)	Infertility
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Replaces:	N/A
Ipswich & East Suffolk and West Suffolk CCG policy	T39: Fertility
NEE CCG policy	12: Assisted conception using IVF/ICS/IUI for infertility

Interventions covered by this policy

Three levels of fertility treatment services are provided:

- Level 1 services, primary care: initial assessment and investigation and referral to the next level if necessary.
- Level 2 services, secondary and specialist care: specialist investigations, drug treatment and monitoring, other interventions as indicated
- Level 3 services, tertiary specialist care: further specialist investigations and treatment including assisted conception

This policy covers **Level 3 fertility services**, the key procedures being:

In Vitro Fertilisation (IVF): ovarian stimulation, the collection of the resulting eggs and fertilisation with sperm in the lab. If fertilisation is successful, the embryo is allowed to develop for between two and six days and is then transferred back to the woman's womb. Any remaining good quality embryos can be frozen to use later on in a frozen embryo transfer if the first transfer is unsuccessful.

Intracytoplasmic sperm injection (ICSI): instead of mixing the sperm with the eggs, IVF with ICSI involves injecting a single sperm into each mature egg, which maximises the chance of fertilisation.

Conditions to be considered for treatment under this policy

Infertility is defined in this policy as failure to conceive after frequent unprotected intercourse for 3 years in couples of reproductive age in the absence of known reproductive pathology.

For a woman of reproductive age who is using artificial insemination (AI) to conceive (with either partner or donor sperm) infertility is defined as failure to conceive after 12 documented cycles of treatment over a 3-year period.

Eligibility criteria for provision of the intervention

Patients should **only** be referred for level 3 fertility services if they meet **all** of the following criteria at the time of referral (or **all applicable** criteria for same sex couples, also see below*). The number of cycles and number of embryos to be transferred depend on age and number of previous cycles of IVF (see below**).

- They meet the definition of infertility and its duration above appropriate to their situation
- Age of female partner: between 23 and 42 years inclusive
- Age of male partner: between 23 years and less than 55 years

- Women aged 23-39 should have self-funded no more than 2 cycles of IVF previously; women aged 40-42 inclusive should not have had any self-funded cycles of IVF previously (see below**).
- They met the criteria in the Policy 'Subfertility investigation and treatment in secondary care' and have completed further assessments and investigations indicated. As a minimum these should have included:

Female:

- Laparoscopy and/or hysteroscopy and/or hysterosalpingogram or ultrasound scan where appropriate
- Rubella antibodies; the woman must be rubella immune
- Chlamydia screening
- Hepatitis B including core antibodies, and Hepatitis C, within the last 3 months
- HIV status
- AMH (anti-Mullerian hormone), which should be >5.4 pmol - Women referred for IVF assessment shall be offered an ovarian reserve test as per NICE guidance to identify and exclude those with low chance of conception. GPs should ensure the patient meets all of the initial criteria within the referral form in the first instance prior to the AMH request being sent to the Fertility Unit. Ovarian reserve testing should only be conducted within the overall context of a fertility assessment carried out by a specialist centre.

Male:

- Preliminary Semen Analysis and appropriate investigations where abnormal (including genetic analysis if indicated)
 - Hepatitis B including core antibodies, and Hepatitis C, within the last 3 months
 - HIV status
- BMI of female partner is 19 or more and less than 30 kg/m² at referral and throughout treatment
 - BMI of male partner is less than 30 kg/m² at referral and throughout treatment
 - Both partners are non-smokers at the time of referral from secondary care to specialist fertility services and throughout treatment. Smoking status should be ascertained by carbon monoxide testing in secondary care and specialist IVF services.
 - Neither partner has undergone sterilisation in the past (irrespective of whether they have undergone subsequent reversal of sterilisation)
 - There are no concerns regarding the welfare of the unborn child in accordance with the Human Fertilisation and Embryology Authority (HFEA) guidance.
 - Both partners are registered with a SNEE ICB GP Practice (within Ipswich and East Suffolk, West Suffolk or North East Essex) and were eligible for NHS care for at least 12 months prior to the referral from primary to secondary care.
 - Neither couple has a living child 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.

**Same sex couples (female)*

- A woman who is using AI to conceive should meet the definition of infertility and its duration above. Fertile same sex couples will not be funded for assisted conception methods under this policy. Couples are encouraged to maximise opportunities within AI cycles by exploring the option of both partners undergoing AI.
- Same sex couples will be required to meet relevant eligibility criteria above.
- SNEE ICB 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.
- 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, in line with the criteria for heterosexual couples, and will not be eligible for additional cycles with their partner or any future partners.

Same sex couples (male)

- 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. Surrogacy is not commissioned as part of this policy.

***Female partner age, previous cycles of IVF, number of cycles⁴ and number of embryos transferred:*

Age 23 years or more and less than 40 years:

- will be eligible for TWO full cycles (for women who have self-funded no or one previous cycle of IVF); or ONE full cycle (for women who have self-funded two previous cycles of IVF). If the woman reaches the age of 40 years during treatment, the current cycle will be completed, but no further cycles will be offered.
- 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.

Age 40 years to 42 years inclusive:

- will be eligible for ONE full cycle providing all the following criteria are met:
 - Never previously had IVF treatment
 - There is no evidence of low ovarian reserve
 - There has been a discussion of the additional implications of IVF and pregnancy at this age
- Up to two embryos may be transferred during each cycle. A maximum of two embryo transfers (one fresh plus one frozen) will be funded.

Exclusions

This policy does not cover:

- Gamete storage, preimplantation genetic diagnosis and intrauterine insemination
- Couples with a known clinical 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
- Treatment may be denied on other medical ground not explicitly covered in this policy

Additional notes

- Read in conjunction with the subfertility investigation and treatment in secondary care.
- Read in conjunction with the cryopreservation of sperm, oocytes or embryos for patients about to undergo treatments which pose a risk to their fertility.

Referral may be made to the ECC Panel for patients who do not meet the policy criteria in whom there are considered to be exceptional circumstances supporting the need for referral for specialist fertility services.

It is expected that 84% of couples in the general population having regular unprotected

⁴ A full cycle comprises one round of ovarian stimulation and the transfer of resultant fresh embryo(s). Where an excess of embryos is available following a fresh cycle, these embryos may be frozen for future use, and subsequently thawed and transferred to the patient as a frozen cycle within the 'full cycle'.

intercourse will conceive within one year and 92% within two years. However, a minority will be unable to conceive and may benefit from fertility treatment (NCCWCH 2013).

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

- Unexplained infertility (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. It is estimated that infertility affects 1 in 7 heterosexual couples in the UK (NICE, 2017).

Criteria – additional information

Women with a **BMI** over 30 kg/m² take longer to conceive when compared with women with a lower BMI, adjusting for other factors such as menstrual irregularities. The RCOG advises that losing weight will increase the chances of conception. NICE CG156 also recommends that 'men who have a BMI of 30 or over should be informed that they are likely to have reduced fertility'. Couples who require it 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.

Women with a low BMI are also likely to have reduced fertility and NICE recommend that 'women who have a BMI of less than 19 and who have irregular menstruation or are not menstruating should be advised that increasing body weight is likely to improve their chance of conception'.

Criteria for minimum maternal and paternal **age** in this policy have been set with reference to the average age of conception and cohabiting. The average age of first time mothers in 2014 ONS data was 28.5 years and a 2012 ONS short report found that people aged between 25-34 are the most likely group to be cohabiting. There is some suggestive evidence that the optimum age for conception and complications being less likely is between the ages of 23 and 31. The upper age limit of 42 years for women accessing infertility services is recommended by NICE.

There is significant association between reduced fertility and **smoking** in both men and women, and there are also risks associated with smoking and passive smoking during pregnancy. 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, provided with information about the negative impacts of smoking, and offered support to stop.

NICE CG156 gives advice on initial **assessment and investigation** of patients with concerns regarding fertility. Prior to referral to level 2 or 3 services all patients should have been given advice about increasing the chances of conception (NICE CG 156 section 1.2) including with respect to the timing of sexual intercourse, lifestyle including smoking, alcohol and healthy weight, and offered initial assessment and investigations including semen analysis, review of menstrual cycle and maternal blood testing to determine ovulation.

Patients undergoing male or female **sterilisation** should have provided informed consent and been counselled that the procedures are regarded as permanent and irreversible.

The Human Fertilisation and Embryology (HFE) Act 1990 states that 'a woman shall not be provided with treatment services unless account has been taken of the **welfare of any child** who may be born as a result of the treatment (including the need of that child for supportive parenting), and of any other child who may be affected by the birth'.

Treatment components – additional information

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 SNEE ICB 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.

The SNEE ICB will fund **embryo storage** as part of assisted conception treatment 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, sperm and embryo storage for patients undergoing cancer treatments are covered under separate arrangements.

Egg donation where no other treatment is available will be available to women who have undergone premature ovarian failure (longer than six months amenorrhoea and AMH greater than 5.4 pmol 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 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.

Due to poor clinical evidence, **intra uterine insemination (IUI)** will only be offered in exceptional circumstances.

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 (including part funding) is not commissioned as part of this policy. As advised by the Department of Health 2018.

Compliance with NICE guidance

NICE CG 156 states that women aged under 40 years who have not conceived after 2 years of regular unprotected intercourse or 12 cycles of artificial insemination (where 6 or more are by intrauterine insemination), should be offered 3 full cycles of IVF, with or without ICSI.

The decision to maintain waiting times as per the previous policy (i.e. 3 years rather than 2) for women with unexplained fertility was made based upon moderate to low quality 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. 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. NICE CG156 also recommend that IUI can be used in some circumstances.

References

References included in original Suffolk / North East Essex policy / policies.

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- National institute for clinical and health excellence. Fertility: assessment and treatment for people with fertility problems. Clinical guideline 156. February 2013.
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Additional guidance referred to in production of ICS policy

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