

**St Helens CCG
NHS Funded Treatment for
Subfertility
Policy
2015/16**

Standard Operating Procedure	St Helens CCG NHS Funded Treatment for Sub Fertility Policy
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1. Introduction

- 1.1 This policy describes circumstances in which the Clinical Commissioning Group (CCG) will fund treatment for subfertility as defined in section 3.
- 1.2 The objective of treatment for subfertility is to achieve a successful pregnancy quickly and safely with the least intervention required and the delivery of a healthy child.
- 1.3 The criteria set out in this policy apply irrespective of where the residents of the CCG have their treatment (local NHS hospitals, tertiary care centres or independent sector providers). A patient is defined as someone registered with a GP practice within the CCG boundary.

This policy has drawn on guidance issued by the Department of Health, Infertility Network UK and the NICE guidance (CG156) published in February 2013.

<http://www.infertilitynetworkuk.com/uploaded/Fact%20Sheets/Standardising%20Access%20Criteria%20to%20NHS%20Fertility%20Treatment%20FINAL.pdf>

<http://guidance.nice.org.uk/CG156> (summary guidance)

<http://www.nice.org.uk/guidance/cg156/resources/cg156-fertility-full-guideline3>

[Fertility problems | Guidance and guidelines | NICE](#)

2. General Principles

- 2.1 The CCG has had regard to the NICE guidance in the formulation of this policy.
- 2.2 The eligibility criteria set out below does not apply to clinical investigations for subfertility which are available to anyone with a fertility problem.
- 2.3 The eligibility criteria does not apply to the use of assisted conception techniques for reasons other than subfertility, for example in families with serious inherited diseases where in-vitro fertilization (IVF) is used to screen out embryos carrying the disease or to preserve fertility, for example for patients about to undergo chemotherapy, radiotherapy or other invasive treatments.
- 2.4 The CCG respects the right of patients to be treated according to the obligations set out in the NHS Constitution and the Human Rights Act specifically with regard to age and sex discrimination.

3. Definition of Subfertility, Timing of Access to Treatment & Age Range

- 3.1 Fertility problems are common in the UK and it is estimated that they affect one in seven couples. 84% of couples in the general population will conceive within one year if 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 92%). In 25% of infertility cases the cause cannot be identified.
- 3.2 Where a woman is of reproductive age and having regular unprotected vaginal intercourse two to three times per week, failure to conceive within twelve months should be taken as an indication for further assessment and possible treatment. In the following circumstances an earlier assessment should be considered:
 - If the woman is aged 36 or over then such assessment should be considered after 6 months of unprotected regular intercourse since her chances of successful conception are lower and the window of opportunity for intervention is less.

- If there is a known clinical cause of infertility or a history of predisposing factors for infertility.
- 3.3 Women should be offered access to investigations if they have subfertility of at least 1 year duration (6 months for women aged 36 and over) and offered IVF if they have subfertility of at least 2 years duration (12 months for women aged 36 and over). Additional criteria apply for IVF in women aged 40 – 42 (see paragraph 12.4).
- 3.4 If, as a result of investigations, a cause for the infertility is found, the patient should be referred for appropriate treatment without further delay.

The CCG will offer access to intra-uterine insemination (IUI) or donor insemination (DI) services where appropriate after subfertility of at least 12 months duration. See Section 11.

NICE guidance recommendations 117 – 119. P223

<http://www.nice.org.uk/guidance/cg156/resources/cg156-fertility-full-guideline3>

[Fertility | Guidance and guidelines | NICE](#) section 1.91 p31

This policy adopts the NICE guidance that access to high level treatments including IVF should be offered to women between the ages of 23 - 42. First treatment cycles must be commenced before the woman's 42nd birthday (See section 12.4 for further details).

Women will be offered treatment provided their hormonal profile is satisfactory i.e. in line with NICE CG156 section 6.3 guidance recommendations.

<http://www.nice.org.uk/guidance/cg156/resources/cg156-fertility-full-guideline3> p101

[Fertility | Guidance and guidelines | NICE](#) section 1.3.3.2 p20

Other Eligibility Criteria

4. Definition of Childlessness

- 4.1 Funding will be made available where a couple have no living children from a current or any previous relationship i.e. if previous living child from current or previous relationship then excluded from subfertility treatment.
- 4.2 A child adopted by a patient or adopted in a previous relationship is considered to have the same status as a biological child.
- 4.3 Once a patient is accepted for subfertility treatment they will no longer be eligible for further treatment if a pregnancy leading to a live birth occurs or the patient adopts a child.

5. Same Sex Couples & Single Women Eligibility Criteria

- 5.1 This policy is intended, as per NICE guidance, for people who have a possible pathological problem (physical or psychological) to explain their subfertility. The CCG will fund subfertility treatment for same sex couples and single women provided there is evidence of proven subfertility, defined as no live birth following artificial insemination (AI) of up to 6 cycles or proven by clinical investigation as per NICE guidance. AI must be undertaken in a clinical setting with an initial clinical assessment and appropriate investigations.
- 5.2 The CCG will not fund the AI cycles referred to in 5.1 but will fund access to a clinical consultation to discuss options for attempting conception, further assessment and appropriate treatment.

6. Surrogacy

- 6.1 The CCG will not commission any form of fertility treatment to those in surrogacy

arrangements (i.e. the use of a third party to bear a child for another couple). This is due to the numerous legal and ethical issues involved.

7. Reversal of Sterilisation & Treatment Following Reversal

- 7.1 Subfertility treatment will not normally be provided where this is the result of a sterilisation procedure in either partner.
- 7.2 The surgical reversal of either male or female sterilisation will not normally be funded.
- 7.3 Where subfertility remains after a reversal of sterilisation, treatment will not normally be funded.

8. Female Body Mass Index (BMI)

- 8.1 Women will be required to achieve a BMI of 19-29.9 before subfertility treatment begins. Women outside this range can still undergo investigations, but subfertility treatment will not commence until their BMI is within this range.

9. Smoking

- 9.1 Patients should be confirmed non-smokers in order to access any subfertility treatment and must continue to be non-smoking throughout treatment. Providers should seek evidence from referrers and confirmation from patients. Providers should also include this undertaking on the consent form and ask patients to acknowledge that smoking could result in cessation of treatment.

10. Drugs & Alcohol

- 10.1 Patients will be asked to give an assurance that their alcohol intake is within Department of Health guidelines and they are not using recreational drugs. Any evidence to the contrary will result in the cessation of treatment.

<https://www.gov.uk/government/policies/reducing-drugs-misuse-and-dependence>

<https://www.gov.uk/government/policies/reducing-harmful-drinking>

Treatment Options

11. Intra-uterine Insemination (IUI)/Donor Insemination (DI)

- 11.1 Consider unstimulated intrauterine insemination as a treatment option in the following groups as an alternative to vaginal sexual intercourse:
 - People who are unable to, or would find it very difficult to, have vaginal intercourse because of a clinically diagnosed physical disability or-psychosexual problem who are using partner or donor sperm;
 - People with conditions that require specific consideration in relation to methods of conception (for example, after sperm washing where the man is HIV positive);
 - People in same sex relationships.
- 11.2 For people with unexplained infertility, mild endometriosis or 'mild male factor infertility', who are having regular unprotected sexual intercourse, do not routinely offer intrauterine insemination, either with or without ovarian stimulation. Advise them to try to conceive for a total period of time as per section 3.3 before IVF will be considered.
- 11.3 Donor insemination (with IUI) will be funded where clinically indicated.
- 11.4 Stimulated IUI will be funded where clinically indicated, due concern must be given to the risk of multiple births in this situation and insemination abandoned if this is felt to be a possibility.

11.5 Patients who are receiving IUI who have not conceived after 6 cycles of donor or partner insemination, despite evidence of normal ovulation, tubal patency and semen analysis, should be offered a further 6 cycles of unstimulated intrauterine insemination before IVF is considered.

11.6 Patients who fail to achieve a pregnancy using IUI/DI will be considered for IVF.

12. IVF Definition & Number of Cycles

12.1 A cycle is the process whereby one course of IVF (or ICSI) commences with ovarian stimulation and is deemed to be complete when all viable fresh and frozen embryos resulting from that stimulation have been replaced.

12.2 For women aged 23-39 the CCG offers 2 cycles.

12.3 All cycles must commence prior to the woman's 40th birthday.

12.4 For women aged 40 and up to 42, they can apply for 1 cycle through an Individual Funding Request process (Appendix 1 and 2) provided:

- They have never previously had IVF (including private treatment).
- There is no evidence of low ovarian reserve (see section 3.4).
- There has been a discussion about the implications of IVF at this age.
- The cycle must commence prior to the woman's 42nd birthday.

12.5 Access to additional cycles is not an automatic right – the outcome of any previous cycle will be taken into account.

12.6 The number of IVF cycles commissioned is unrelated to the number of IUI/DI cycles commissioned.

12.7 As IVF success rates decline significantly after 3 cycles the CCG will take into account the number of cycles received irrespective of whether they were funded by the NHS or privately.

12.8 If patients have funded 2 or more IVF cycles privately they will not be entitled to any NHS funded cycles.

12.9 If patients have funded 1 cycle privately they will be entitled to 1 NHS funded cycle.

13. Number of Transferred Embryos

13.1 In keeping with the Human Fertilisation and Embryology Authority's (HFEA) multiple birth reduction strategy patients will be counselled about the risks associated with multiple pregnancies and advised that they will receive a single embryo transfer (whether fresh or frozen) unless there is a clear clinical justification for not doing so (e.g. a single top quality embryo is not available). In any event a maximum of 2 embryos will be transferred per procedure (either fresh or frozen).

13.2 Patients with a good prognosis should be advised that a single embryo transfer, involving fresh followed by frozen single embryo transfers, can virtually abolish the risk of a multiple pregnancy while maintaining a live birth rate which is the same as that achieved by transferring 2 fresh or frozen embryos.

13.3 The CCG will only contract with providers who make a public commitment to comply with the HFEA single embryo transfer policy and can demonstrate significant progress towards achieving the annual target set by the HFEA with performance that is not significantly above the target.

13.4 Further information is available via the HFEA's 'One at a Time' website – <http://www.oneatatime.org.uk>.

13.5 Provider multiple-pregnancy data is available via the HFEA's website – <http://www.hfea.gov.uk/6195.html>

14. Cancelled & Abandoned Cycles

- 14.1 A cancelled cycle is defined by NICE as 'egg collection not undertaken'. This would not count as a cycle when considering eligible number of cycles.
- 14.2 An abandoned cycle is not defined by NICE but is defined by this policy as including IVF treatment leading to a failed embryo transfer. This would count as a cycle when considering eligible number of cycles.

15. Handling of Existing Frozen Embryos from Previously Funded Cycles

- 15.1 All stored and viable embryos should be replaced before a new cycle commences. This includes embryos stored by private providers.

16. Sperm Retrieval

- 16.1 Sperm retrieval for the management of male related fertility problems is a separate clinical procedure and will be charged at payment by results rates to the CCG.
- 16.2 Sperm retrieval for the management of male related fertility problems will be provided for men who, with their partner, will be eligible for NHS funded IVF treatment.
- 16.3 Couples will have to self-fund sperm retrieval for vasectomised men even if the female partner also requires subfertility treatment.

17. Ovum/Embryo Donation

- 17.1 Ovum/Embryo donation and subfertility treatment will be available for women with the following conditions:

Premature ovarian failure, defined as amenorrhoea of at least 12 months duration with a hormonal profile in the menopausal range, under the age of 40. The cause may be spontaneous, or as a result of other morbidity, or congenital abnormality or iatrogenic.

- 17.2 NHS funding would not normally be available for women outside these groups who do not respond to follicular stimulation.

18. Egg Sharing/Donation & Sperm Donation

- 18.1 Egg sharing/donation and sperm donation will be available for couples requiring donated eggs/sperm.
- 18.2 Egg sharing/donation for any 'commercial' consideration (i.e. purchase of additional entitlements) will not be approved.
- 18.3 Egg and sperm donations will be sourced by providers and charged separately.

19. Embryo, Egg & Sperm Storage

- 19.1 Embryo, egg and sperm storage will be funded for patients who are undergoing NHS subfertility treatment in line with The Human Fertilisation and Embryology Authority guidance. The storage standard period for sperm, egg and embryo storage is normally ten years.

20. Pre-Implantation Genetic Diagnosis

- 20.1 This is subject to a separate NHS England policy.
- 20.2 All applications must be made to the NHS England for approval and must be for conditions listed by the Human Fertilisation and Embryology Authority.

21. Anti-Viral Transmission (e.g. HIV and Hep C)

21.1 This is subject to separate guidance issued by the Greater Manchester Sexual Health Network. The policy can be accessed at the following site;

http://www.sexualhealthnetwork.co.uk/media/documents/HIV%20Infertility%20guidelines%20DRAFT%2030%20REVISED_%2001.03.12-63581586c959cb88b9d756179645917b.pdf

22. Cryopreservation

22.1 Cryopreservation services in line with the relevant principals outlined in NICE IPG 156 Section 1.16 will be offered to:

Women with premature ovarian failure under the age of 40 (see previous definition - see section 17).

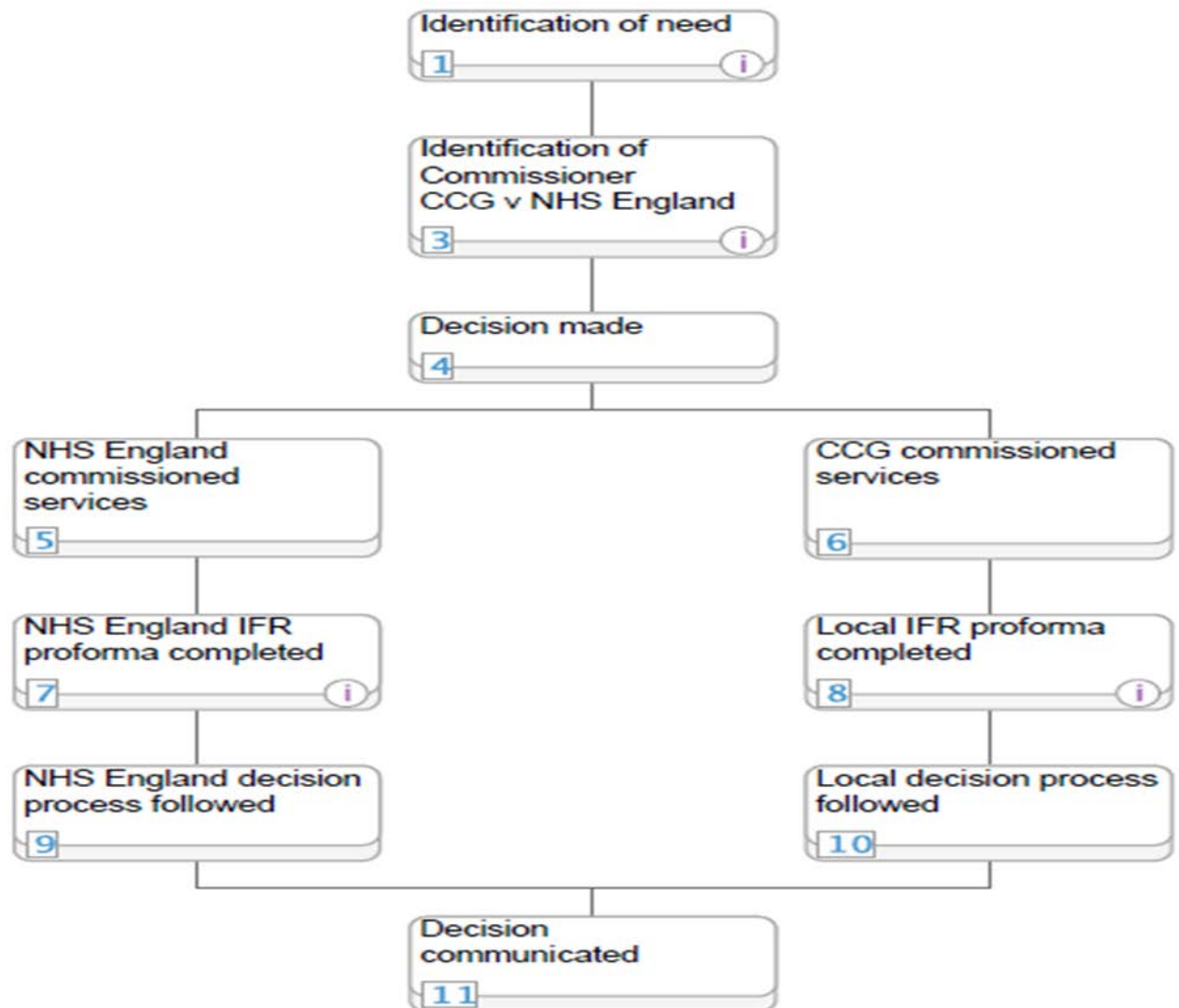
Men and women with cancer, or other illnesses which may impact on fertility, may access tertiary care services to discuss fertility preservation (egg, embryo or sperm storage). Other illnesses are not defined in this policy but will be considered on an individual basis via an Individual Funding Request.

Storage will be in-line with section 19.

22.2 The eligibility criteria set out in this policy do not apply to cryopreservation but do apply to the use of the stored material.

22.3 Storage of ovarian tissue will not be funded.

23. Appendix 1 IFR Process



24. Appendix 2 IFR Panel Contact Details

St Helens CCG
Telephone: 01244 650 305
Email: IFR.manager@nhs.net