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1 INTRODUCTION

- 1.1 In Vitro Fertilisation (IVF) is commissioned as a tertiary service within an overall infertility pathway. A standard infertility pathway is attached for information. This policy describes circumstances in which Stockport 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 Stockport CCG have their treatment (local NHS hospitals, tertiary care centres or independent sector providers). A Stockport CCG patient is defined as someone registered with a GP practice within the Stockport CCG boundary.
- 1.4 This policy has drawn on guidance issued by the Department of Health, Infertility Network UK and the revised NICE guidance (CG 156) published in February 2013

http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_101068.pdf

<http://www.infertilitynetworkuk.com/uploadedFiles/Standardising%20Access%20Criteria%20to%20NHS%20Fertility%20Treatment%2009%2006%2009.doc>

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

<http://www.nice.org.uk/nicemedia/live/14078/62770/62770.pdf> (full guidance)

2. GENERAL PRINCIPLES

- 2.1 Stockport CCG will fund investigations and treatment for subfertility as set out in the National Institute for Health and Clinical Excellence (NICE) clinical guideline (link above).
- 2.2 The eligibility criteria set out below do not apply to clinical investigations for subfertility, which are available to anyone with a fertility problem.
- 2.3 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 (see

section 20) or to preserve fertility, for example for patients about to undergo chemotherapy, radiotherapy or other invasive treatments.

- 2.4 Stockport 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 AND 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 30% 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 12 months should be taken as an indication for further assessment and possible treatment. 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.
- 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).
- 3.4 If, as a result of investigations, a cause for the infertility is found, the individual should be referred for appropriate treatment without further delay.
- 3.5 Stockport CCG will offer access to intra-uterine insemination (IUI) or donor insemination (DI) services where appropriate after subfertility of at least 12 months duration.
- 3.6 This policy adopts the NICE guidance that access to high level treatments including IVF should be offered to women up to the age of 42. First treatment cycles must be commenced before the woman's 43rd birthday. Second treatment cycles must be commenced before the woman's 40th birthday.
- 3.7 Women will be offered treatment provided their hormonal profile is satisfactory.

4. DEFINITION OF CHILDLESSNESS

- 4.1 Funding will be made available to patients who do not have a living child from their current relationship and where either of the partners does not have a living child from a previous relationship (i.e. one of the partners may have a child, the other must not).
- 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 treatment they will no longer be eligible for treatment (i.e. additional cycles – see section 12) if a pregnancy leading to a live birth occurs or the patient adopts a child.

5. SAME SEX COUPLES AND SINGLE WOMEN

- 5.1 This policy is intended, as per NICE guidance, for people who have a possible pathological problem (physical or psychological) to explain their infertility. Stockport CCG will fund treatment for same sex couples and single women provided there is evidence of 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 Stockport 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 Stockport 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. For this reason NHS IVF is not available to male couples except when a pregnancy does not occur through surrogacy after an appropriate period of time (equivalent to the 12 months with vaginal intercourse or 6 cycles of AI for other people). In those circumstances the man whose sperm is being used and the surrogate partner would be eligible to be referred for further clinical assessment and possible treatment of any underlying condition.

7. REVERSAL OF STERILISATION AND TREATMENT FOLLOWING REVERSAL

- 7.1 Subfertility treatment will not 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 be funded.
- 7.3 Where sub fertility remains after a reversal of sterilization treatment will not be funded.

8. FEMALE BODY MASS INDEX (BMI)

- 8.1 Women will be required to achieve a BMI of 19-30 before treatment begins. Women outside this range can still undergo investigations and be added to the 'watchful-waiting' list but treatment will not commence until their BMI is within this range. (Exceptionally a woman with a BMI above 29 may be able to demonstrate that they are not clinically obese through use of other acceptable measures).

9. SMOKING

- 9.1 Patients must be non-smoking in order to access any fertility 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 will result either in cessation of treatment or treatment costs being applied.

10. DRUGS AND 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.

11. INTRA-UTERINE INSEMINATION (IUI) / DONOR INSEMINATION (DI)

- 11.1 Unstimulated intrauterine insemination is offered as a treatment option in the following groups as an alternative to vaginal sexual intercourse;
- patients 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
 - patients with conditions that require specific consideration in relation to methods of conception (for example, after sperm washing where the man is HIV positive)
 - women in same-sex relationships or single women who have no live birth following self-funded artificial insemination (AI) of up to 6 cycles (as described in 5.1) or proven by clinical investigation as per NICE guidance.
- 11.2 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.
- 11.3 Patients who fail to achieve a pregnancy using IUI/DI will be considered for IVF.

12. IVF DEFINITION AND 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 under 40, Stockport CCG offers funding for 2 full cycles.
- 12.3 For women aged 40-42 Stockport CCG offers 1 full cycle provided:
- a) They have never previously had IVF (including privately)
 - b) There is no evidence of low ovarian reserve
 - c) There has been a discussion about the implications of IVF at this age
- 12.4 Access to additional cycles is not an automatic right – the outcome of any previous cycle will be taken into account.
- 12.5 The number of IVF cycles commissioned is unrelated to the number of IUI/DI cycles commissioned.
- 12.6 IVF success rates decline significantly after 3 cycles. In addition, NICE recommends that we take into account the outcome of previous IVF treatment when assessing the likely effectiveness and safety of any further IVF treatment. Stockport CCG will take into account the number of cycles received privately.

12.6.1 If patients have funded 3 or more IVF cycles privately they will not be entitled to any NHS funded cycles.

12.6.2 If patients have funded 2 cycles privately they will be entitled to 1 NHS cycle

12.6.3 If patients have funded 1 cycle privately they will be entitled to 2 NHS cycles

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 Stockport 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 AND ABANDONED CYCLES

14.1 A cancelled cycle is defined by NICE as 'egg collection not undertaken'. Where IVF is charged by providers as an 'all-in' price a cancelled cycle should not be charged.

14.2 An abandoned cycle is not defined by NICE but is defined by this policy as including treatment leading to a failed embryo transfer. Where IVF is charged by

providers as an 'all-in' price abandoned cycles will be charged at two-thirds of the local tariff price and will be counted against the number of commissioned 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 Other than exceptional cases, couples will have to self-fund sperm retrieval (for the treatment of male related fertility problems) for a privately funded cycle.
- 16.2 Other than exceptional cases 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 NHS funding will be available for women with premature menopause, defined as amenorrhoea of at least 12 months duration with a hormonal profile in the menopausal range, under the age of 42. 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 AND SPERM DONATION

- 18.1 NHS funding will be available for women requiring donated eggs/sperm. Due to a reduction in the availability of donated eggs and sperm this may result in couples having to wait. Due consideration will be given to those couples who would consequently be at risk of falling outside the age criteria.
- 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 AND SPERM STORAGE

- 19.1 Embryo and sperm storage will be funded for patients who are undergoing NHS fertility treatment. Storage will be funded for a maximum of 3 years or until 6 months post successful live birth, whichever is the shorter.
- 19.2 Stockport CCG will not separately fund access to and the use of frozen embryos remaining after a live birth. Couples may be charged separately for the use of these embryos by different service providers.

20. PRE – IMPLANTATION GENETIC DIAGNOSIS

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

21. ANTI – VIRAL TRANSMISSION (e.g. HIV and HepC)

- 21.1 This is subject to separate guidance issued by the Greater Manchester Sexual Health Network

22. CRYO – PRESERVATION

- 22.1 Early-menopausal women under the age of 42, and 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). The eligibility criteria set out in this policy do not apply to cryo-preservation but do apply to the use of the stored material

23. GENERIC INFERTILITY PATHWAY

