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1. INTRODUCTION

1.1 This policy describes circumstances in which Halton 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 centers or independent sector providers). A Halton[CCG] patient is defined as someone registered with a GP practice within the CCG boundary.

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


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


2. GENERAL PRINCIPLES

2.1 The 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 in-vitro fertilisation (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 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 can not 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 Halton 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 however, must be commenced before the woman’s 42nd birthday (see 12.3). Second and third treatment cycles must be commenced before the woman’s 40th birthday. If the woman reaches the age of 40 during treatment, the current full cycle should be completed but no further cycles offered.

3.7 Women will be offered treatment provided their hormonal profile is satisfactory.
4. **DEFINITION OF CHILDLESSNESS**

4.1 The definition of childlessness, with regards to this policy, is where a couple or individual has no living children from a current or any previous relationship.

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 In very exceptional circumstances patients who do not meet the criteria may receive NHS funding. Applications must be made to the CCG.

4.4 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. The 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 should 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 (ie 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 treatment 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 subfertility remains after a reversal of sterilisation, treatment will not be funded.

7.4 The CCG will consider exceptional circumstances to all 3 of the positions stated above. This may for example be related to the death of a child (or children) or evidence that a sterilisation was carried out within an abusive relationship.

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 30 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 Patients with unexplained subfertility, mild male factor fertility problems or minimal to mild endometriosis will not be routinely offered IUI other than in exceptional circumstances, for example, when people have social, cultural
or religious objections to IVF or 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, or same sex couples and single women who have met the criteria set out in 5.1.

11.2 Donor insemination (with IUI) will be funded where clinically indicated.

11.3 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 semenalysis, should be offered a further 6 cycles of unstimulated intrauterine insemination before IVF is considered.

11.4 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 23-39 the CCG offers 3 full cycles.

12.3 *Where deemed clinically necessary*; patients under the age of 38 at the time of 1st hospital appointment and requiring more than 1 full cycle will have to wait 6 months between the end of one cycle (date of last negative test) and commencement of another. Patients over the age of 38 will have to wait 6 months from the commencement of a cycle and the commencement of another.

For women aged 40-42 the 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.

12.6 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 as to whether they were funded by the NHS or privately.
12.4.1 If patients have funded 3 or more IVF cycles privately they will not be entitled to any NHS funded cycles.
12.4.2 If patients have funded 2 cycles privately they will be entitled to 1 NHS cycle.
12.4.3 If patients have funded 1 cycle privately they will be entitled to 2 NHS cycles.

12.8 A person will normally be entitled to a maximum of 3 cycles irrespective of the number of the relationships they have tried to conceive within. However, a person may be eligible for a new entitlement to treatment within a new relationship even if they have had IVF previously providing the nature of previous subfertility is clearly linked to their previous partner and there are no concerns with regard to the welfare of the child.

13. **NUMBER OF TRANSFERRED EMBRYOS**

13.1 In keeping with the Human Fertilisation and Embryology Authority’s (HFEA) multiple birth reduction strategy people 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](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](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 but the CCG will consider any financial issues for the couple this may give rise to. The CCG will rely on clinical advice from the provider.

16. SPERM RETREIVAL

16.1 Sperm retrieval for the treatment of male related fertility problems is a separate clinical procedure and will be charged at Payment by Results rates to the CCG.

16.2 Funding will be provided for men who, with their partner, will be eligible for NHS funded treatment.

16.3 Funding could be provided if appropriate for those exceptional cases where vasectomised men and their partners have IVF funding approved.

16.4 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 amenenorrhea of at least 12 months duration with an 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 The CCG will not separately fund access to and the use of frozen embryos remaining after a live birth. Couples may be charged separately by providers for the use of these embryos

20. **PRE – IMPLANTATION GENETIC DIAGNOSIS**

19.1 This is subject to a separate CCG policy.

19.2 All applications must be made to the 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)**

20.1 This is subject to separate guidance issued by the Greater Manchester Sexual Health Network
22.  CRYO – PRESERVATION

21.1 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.