

Assisted Conception Policy

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Name of originator/author:	Birmingham, Black Country and Solihull Infertility Policy Working Group
Name of responsible organisations:	NHS Clinical Commissioning Group Governing Bodies: <ul style="list-style-type: none">- Birmingham Cross City- Birmingham South Central- Sandwell and West Birmingham (Deferred to 2016)- Solihull- Walsall- Wolverhampton
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1. Assisted Conception Policy Summary

- One cycle of infertility treatment (IVF or ICSI) will be made available to females/couples who meet the definition for infertility and eligibility criteria.
- Infertility is defined as:
 - A female of reproductive age, who has not conceived after 1 year of unprotected vaginal sexual intercourse, in the absence of any known cause of infertility, should be offered further clinical assessment and investigation along with her partner.
 - Following the first year and clinical investigation:
 - Where the cause of infertility is known, the couple should be offered NHS infertility treatment without further delay where all eligibility criteria are met.
 - In the absence of any known cause of infertility, the couple should be offered NHS infertility treatment where all eligibility criteria are met after a further 1 year of regular unprotected vaginal sexual intercourse.
 - In circumstances where the above definition cannot be applied, for example females in a same sex relationship, a single female, or a transgender male, infertility is identified where the female has not conceived after 6 cycles of self-funded donor or partner insemination, undertaken at a HFEA registered clinic, in the absence of any known medical cause of infertility, and therefore should be offered NHS infertility treatment where all eligibility criteria are met.
- Eligibility criteria is as follows to access NHS funded infertility treatment once infertility has been defined:
 - Childlessness – treatment will only be available where neither partner has living or adopted children
 - Sterilisation – treatment will not be available if either partner within the couple has received a sterilisation procedure
 - Previous Infertility Treatment - treatment will not be offered to people where either female/partner has already undertaken any previous fertility treatment for fertility problems, regardless of whether the treatment was funded by the NHS or privately funded
 - Age of Female Partner - the female partner at the time of treatment must be under 40 years of age. Referrals for NHS infertility treatment should be made on or before the females 39th birthday (i.e. at least 12 months before her 40th birthday) to ensure relevant investigations can be completed, and treatment must have commenced prior to the females 40th birthday.
 - Age of Male Partner - the male partner at the time of treatment must be under 55 years of age.
 - Body Mass Index – the female/couple must have a BMI <30 kg/m² at the time of referral and commencement of treatment.
 - Smoking Status - Only non-smoking females/couples will be eligible for fertility treatment; smoking must have ceased by both partners three months prior to referral for infertility treatment.

[This is intended as a summary only, please refer to the policy documentation for the full and complete policy]

2. Assisted Conception Policy Definitions

Item	Definition
Assisted Conception	The collective name for all techniques used artificially to assist conception and pregnancy, including In vitro fertilisation (IVF), Intracytoplasmic sperm injection (ICSI), Intrauterine insemination (IUI) and donor insemination (DI). These techniques are referred to as Infertility Treatment.
Female/Partner/ Couple	<p>Any reference to a female/partner/couple could relate to any of the following:</p> <ul style="list-style-type: none"> • Heterosexual couple; a male and a female in a relationship • Same sex female couple; two females in a relationship • A single female • Transgender male; biologically born as a female, gender reassigned to male, retention of female reproductive organs
Infertility	<p>A female of reproductive age, who has not conceived after 1 year of unprotected vaginal sexual intercourse, in the absence of any known cause of infertility, should be offered further clinical assessment and investigation along with her partner.</p> <p>Following the first year and clinical investigation:</p> <ul style="list-style-type: none"> - Where the cause of infertility is known, the couple should be offered NHS infertility treatment without further delay. - In the absence of any known cause of infertility, the couple should be offered NHS infertility treatment after a further 1 year of regular unprotected vaginal sexual intercourse <p>In circumstances where the above definition cannot be applied, for example females in a same sex relationship, a single female, or a transgender male, infertility is identified where the female has not conceived after 6 cycles of self-funded donor or partner insemination, undertaken at a Human Fertilisation and Embryology Authority (HFEA) registered clinic, in the absence of any known medical cause of infertility.</p>
One cycle of fertility treatment	A cycle will consist of ovulation induction, egg retrieval, fertilisation and embryo transfer to the uterus, including all appropriate diagnostic tests, scans and pharmacological therapy.
In Vitro Fertilisation (IVF)	A female's egg and a male's sperm are collected and mixed together in a laboratory to achieve fertilisation outside the body. The embryos produced may then be transferred into the female. A clinic may also use donor sperm or eggs, where clinically indicated.

Intra-Cytoplasmic sperm injection (ICSI)	In conjunction with IVF, where a single sperm is directly injected, by a recognised practitioner, into the egg. A clinic may also use donor sperm or eggs, where clinically indicated.
Intrauterine insemination (IUI)	Insemination of sperm into the uterus of a woman. <i>(HFEA)</i>
Donor Insemination (DI)	Uses sperm from a donor to help a woman become pregnant. <i>(HFEA)</i>
Azoospermia	An absence of viable sperm in the semen.
Oligospermia	A subnormal concentration of viable sperm in the ejaculated semen.
Body Mass Index (BMI)	BMI is the most widely used way to measure your weight and is calculated using your weight in kilograms divided by your height in metres squared. <i>(NHS Choices)</i>

3. Assisted Conception Policy Content

Providing that all eligibility criteria detailed in Appendix 1 are met, for females/couples in whom this is clinically indicated, the Commissioner will fund 1 cycle¹ of In Vitro Fertilisation (IVF) or Intra-Cytoplasmic Sperm Injection (ICSI).

The Commissioner will fund donor sperm procedures where the male partner has Azoospermia or Oligospermia.

The Commissioner will fund donor egg procedures where the woman has undergone premature ovarian failure.

The Commissioner will ensure that an appropriate Provider is commissioned to provide infertility treatment. The provider will conform to all statutory responsibilities including Care Quality Commission and Human Fertilisation and Embryology Authority (HFEA).

The Provider will be registered with and operate in adherence to HFEA Code of Practice including a child welfare assessment, and HFEA Policy particularly in relation to multiple births and single embryo transfer. NICE Guidance will be followed including the promotion of advice and guidance around alcohol and caffeine use to increase chances of conception, for example.

The Commissioner will fund the cryopreservation and storage of any suitable surplus embryos following a completed NHS funded cycle for a period of 12 months, in line with Human Fertilisation and Embryology Authority (HFEA) guidelines. Following this period, the women/couple may self-fund continued storage.

The Commissioner will not part-fund assisted conception/infertility treatment for individuals or couples that are ineligible for NHS-funded services under this policy.

Where previous NHS treatment is a causal factor of the sub/infertility, and cryopreserved gametes are available, this policy will allow the use of cryopreserved gametes for infertility treatment in line with specialist clinical input and assuming patients meet all other eligibility criteria.

For those patients undergoing treatments such as chemotherapy for cancer or radical surgery who may be made sterile by such treatments; or for patients on the transgender pathway who meet the funded cryopreservation criteria (Human Embryo and Fertility Act 1990) this element of care will be funded via the Gamete Retrieval and Cryopreservation Policy (*in development*).

The commissioner does not fund surrogacy arrangements or any associated treatments (including fertility treatments) related to those in surrogacy arrangements.

It is acknowledged that, rarely, a cycle could fail at any time after commencement due to a number of reasons. For example; ovulation induction failure, failure to retrieve an egg, failure to fertilise or a failure to transfer/implantation an embryo into the uterus. These are known risks of infertility treatment and will be fully explained to the patient along with the likelihood of success. Should any such issue arise, the cycle will have failed and the Commissioner will not fund further cycles of IVF or ICSI.

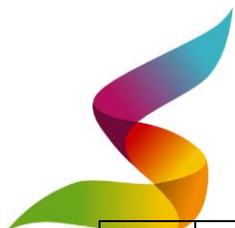
It is anticipated that, rarely, couples who would not be eligible for treatment because they do not fulfil the eligibility criteria may, by virtue of extenuating circumstances, be considered an exceptional case for NHS funding. If there is a case on the grounds of exceptional circumstances, the couples' GP or consultant should submit their request to the Commissioners Individual Funding Request Panel. The local IFR policy can be found here - <http://solihullccg.nhs.uk/publications/our-policies-and-procedures-1/generic-commissioning-policies-1/492-ifr-policy-version-1-5-1/file>

¹ Due consideration has been applied and the decision to fund one cycle of IVF therapy has been based on best clinical practice and financial modelling.

Where an individual/couple feels their circumstances falls outside of this policy, an initial request will enter the IFR process. Thereafter a decision will be made if this is exceptional or requires a service development.

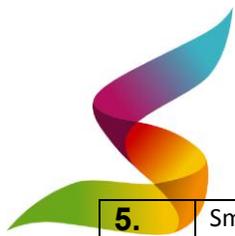
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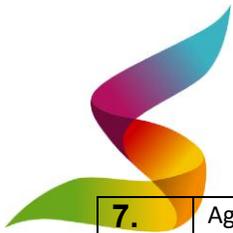
Appendix 1 – Eligibility Criteria Rationale

Ref	Feature	NICE Guideline	Proposed Criterion	Rationale
1.	Childlessness	n/a	NHS infertility treatment will be funded if neither partner has no living children of any age; this includes an adopted child or a child from either the present or a previous relationship. Once accepted for treatment, should a child be adopted or a pregnancy leading to a live birth occur, the couple will no longer be considered childless and will not be eligible for NHS funded treatment.	Resource Allocation: The priority of infertility treatment for childless couples.
2.	Sterilisation	n/a	NHS infertility treatment will not be available if female or either partner within the couple has received a sterilisation procedure or has undertaken a reversal of sterilisation procedure.	Sterilisation is offered within the NHS as an irreversible method of contraception. Protocols for sterilisation include counselling and advice that NHS funding will not be available for reversal of the procedure or any fertility treatment consequently to this.
3.	Previous Infertility Treatment	n/a	NHS infertility treatment will not be offered to people where either female/ couple has already undertaken any previous infertility treatment (IVF/ICSI) for fertility problems, regardless of whether the treatment was funded by the NHS or privately funded.	The ability of the commissioner to provide infertility treatment to the optimal number of couples.
4.	Body Mass Index	Females who have a body mass index (BMI) of 30 or over should be informed that they are likely to take longer to conceive. Men who have a BMI of 30 or over should be informed that they are likely to have reduced fertility. [CG 1.2.6]	Both partners must have a BMI <30 kg/m ² at the time of referral and commencement of treatment. Females/couples must be informed of this criterion at the earliest opportunity and offered the support of local NHS services to optimise their BMI.	Consistent with NICE Guideline.



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5.	Smoking Status	<p>Females who smoke should be informed that this is likely to reduce their fertility, should be offered referral to a smoking cessation programme to support their efforts in stopping smoking, and informed that passive smoking is likely to affect their chance of conceiving. Men who smoke should be informed that there is an association between smoking and reduced semen quality (although the impact of this on male fertility is uncertain), and that stopping smoking will improve their general health. [CG 1.2.4]</p>	<p>Only non-smoking females/couples will be eligible for fertility treatment; smoking must have ceased by both partners three months prior to referral for infertility treatment.</p>	<p>Maternal and paternal smoking can adversely affect the success infertility treatment and smoking during the antenatal period can lead to increased risk of adverse pregnancy outcomes. Females should be informed that passive smoking is likely to affect their chance of conceiving. There is an association between smoking and reduced semen quality.</p>
6.	Age of Female Partner	<p>In females aged under 40 years, offer NHS infertility treatment. If the woman reaches the age of 40 during treatment, complete the current full cycle but do not offer further full cycles.</p> <p>In females aged 40–42 years, offer NHS infertility treatment provided the following 3 criteria are fulfilled:</p> <ul style="list-style-type: none"> • they have 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. <p>[CG 1.11.1]</p>	<p>The age of the female partner at the time of treatment must be under 40 years of age.</p> <ul style="list-style-type: none"> - If infertility is clinically identified in a female from the age of 20 years old - NHS infertility treatment should be offered without delay. - Where the woman is aged between 36<39 years of age, the couple should be offered NHS infertility treatment without further delay <p>Referrals for NHS infertility treatment should be made on or before the females 39th birthday (i.e. at least 12 months before her 40th birthday) to ensure relevant investigations can be completed, and treatment must have commenced prior to the females 40th birthday.</p>	<p>Consistent with NICE Guideline. Fall off in treatment success with increasing maternal age. Increased maternal and child complication rate. Prevention of delays in treatment where appropriate</p> <p>Whilst NICE recommend an extension of the female age to 42 where specific criteria are met, the success rates for this cohort of patients is relatively low. For females aged under 34, success rates are 41%; in females aged 40-42, this drops down to 21%. [HFEA Trends and Figures 2011]</p>



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7.	Age of Male Partner	Both female fertility and (to a lesser extent) male fertility decline with age. [CG 1.2.1]	The age of the male partner at the time of treatment must be under 55 years of age.	<p>HFEA regulations enable men to donate sperm to assist infertile people and recommend that sperm donors should be aged under 41 years; the possible effect of a donor's age on assisted conception success is considered on a case by case basis.</p> <p>There is limited evidence that IVF success decreases in men over the age of the 40. Men aged over 40 are half as likely to conceive with IVF compared to 30 year old men when their female partner is aged 35-39 years (de La Rochebrochard et al, 2006). However, male age does not impact on the success of other infertility treatment such as ICSI (Spandorfer et al, 1998)</p> <p>In light of some evidence that male age does impact on infertility, and may have an impact on IVF outcomes, and keeping in line with other CCG areas which stipulate a male age restriction of 55 years, we have included this as a criterion for eligibility.</p>
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