

Commissioning Policy for In Vitro Fertilisation (IVF)/Intracytoplasmic Sperm Injection (ICSI) within Tertiary Infertility

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Version:	V2.3
Ratified by:	Governing Bodies
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Name of originator/author:	Trish Allen, Consultant in Public Health Gina Gill, Commissioning Manager Jackie Newman, IFR Support Officer
Name of responsible committee/individual:	N/A
Date issued:	March 2019
Review date:	March 2020
Date of first issue	2013
Target audience:	All CCG employees, directors, lay members, managers, CCG practices and contractors

CONSULTATION SCHEDULE

Name and Title of Individual	Groups consulted	Date Consulted
Director of Quality & Safety	Internal	22/01/19
Equality and Inclusion Business Partner	CSU/Internal	24/01/19
Direct Privacy Impact Assessment	CSU/Internal	04/04/19

APPROVALS & RATIFICATION SCHEDULE

Name of Committee approving Policy	Date
Governing Bodies (in common)	

VERSION CONTROL

Version	Version/Description of amendments	Date	Author/amended by
1	New policy	2013	
2.1	<p>3.2.1 Couples are defined as two persons in a stable relationship of at least 1 years duration and are cohabiting, with each other. The referring clinician must ensure that couples are aware of the implications of IVF treatment and the commitments required before making a referral for assisted conception.</p> <p>5.6.1 A cycle is the process whereby one course of IVF (+/- ICSI) commences with ovarian stimulation and is deemed to be complete on conclusion of the transfer an embryo. The number of transferred embryos will be made in accordance with section</p> <p>5.7. Any additional transfers will be self-funded by the patient.</p>	October 2015	Barry Weaver, Commissioning Manager
2.2	<p>5.13.1 Cryopreservation of gametes will be available to all patients undergoing treatment for organic illness that may render them infertile. Any funding requests for cryopreservation other than in patients suffering from cancer will be subject to prior approval.</p>	October 2017	Barry Weaver, Commissioning Manager
2.3	<p>Surgical Sperm Retrieval</p> <p>Same sex couples</p> <p>Fertility preservation</p>	March 2019	Gina Gill, Commissioning Manager Jackie Newman, IFR Officer
2.4	<p>Changed text:</p> <p>5.1.2 Infertility is defined as the failure of a female of reproductive age to conceive after 1 year of regular unprotected vaginal intercourse, in the absence of any known medical cause of infertility. In circumstances where the above definition</p>	March 2019	Gina Gill, Commissioning Manager Jackie Newman, IFR Officer

	<p>cannot be applied (for example same sex female couple) infertility is defined as the failure to conceive after 6 cycles of self-funded donor insemination during the previous 12 months, undertaken at a Human Fertilisation and Embryology Authority (HFEA) licensed clinic, in the absence of any known reproductive pathology.</p> <p>5.13.1 Fertility Preservation Cryopreservation of gametes will be available to all patients undergoing medical treatment that may render them infertile. Any funding requests for cryopreservation will be subject to prior approval. There is no lower age for eligibility under these circumstances. The CCG will pay for storage for a maximum of 5 years. After this period, patients wishing to continue to store may self-fund in line with HEFA Guidance. Explicit that the method of freezing that must be used is Vitrification for oocytes.</p> <p>5.13.2 Patients wishing to use stored gametes must meet the eligibility criteria at the time of application for assisted conception in an NHS setting.</p> <p>5.10.1 Surgical sperm retrieval (SSR) is the funding responsibility of NHSE and therefore will not be funded by the CCG</p>		
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IMPACT ASSESSMENTS – available upon request

	Stage	Complete	Comments
Equality Impact Assessment	1	24/01/2019	Strengthened Equality statement, no stage 2 required
Quality Impact Assessment	1	22/01/2019	Strengthened Quality, positive move for patients incorporating Equality Act 2011 & closing the gaps around discrimination
Data Protection Impact Assessment (DPIA)	N/A	04/04/2019	N/A – As this purely a policy change. As there is no change in service and no personal data is being shared a DPIA does not need to be undertaken.

Contents

Section	Section title	Page number
1	Purpose and Introduction	5
2	Scope	4-5
3	Definitions	6-8
4	Roles & responsibilities	8
5	Commissioning Criteria for Assisted Conception	8-11
6	Training	11
7	References	11
8	Monitoring and evaluation	12
9	Review date	12

SUMMARY

In vitro Fertilisation (IVF) is commissioned as a tertiary service within an overall infertility pathway.

This policy originates from the 2010 South Staffordshire Primary Care Trust (PCT) Commissioning Policy and Referral Guidelines for Assisted Reproductive Treatments, and the main acceptance criteria remain the same.

<https://www.webarchive.org.uk/wayback/archive/20130329024359/http://www.southstaffordshirepct.nhs.uk/policies/Commissioning/Policy07AssistedConception.pdf>

Where a couple has a medical reason for being unable to conceive a child, couples (including same sex couples) who are able to demonstrate infertility and fulfil the policy criteria will be eligible for treatment under this policy.

The eligibility criteria set out below do not apply to clinical investigations for subfertility which are available to anyone with a fertility problem as advised by a relevant clinician and do not apply to the use of assisted conception techniques for reasons other than subfertility.

1. PURPOSE AND INTRODUCTION

1.1 Purpose of the policy

1.1.1 The attached policy for the commissioning of assisted reproduction services was originally prepared as a result of local consultation in response to revised NICE Clinical Guidance and developed with clinical direction.

1.2 Introduction

1.2.1 In vitro Fertilisation (IVF) is commissioned as a tertiary service within an overall infertility pathway. This policy describes circumstances in which the South Staffordshire Clinical Commissioning Groups (CCGs) will fund treatment for IVF/ (ICSI).

- 1.2.2 This policy has drawn on the GEM CSU policy, based on guidance issued by the Department of Health, Infertility Network UK and the revised NICE Clinical Guideline 'Fertility, assessment and treatment for people with fertility problems' (CG156 February 2013).
- 1.2.3 South Staffordshire CCGs respect the right of patients to be treated according to the obligations set out in the NHS Constitution.
- 1.2.4 This policy replaces all previous IVF/ICSI policies and is inclusive of all protected groups.

2. SCOPE

2.1 Included in the policy

- 2.1.1 IVF can be a legitimate medical intervention as part of NHS provision where a couple has a medical reason for being unable to conceive a child. Couples (including same sex couples) who are able to demonstrate this and fulfil the following criteria will be eligible for tertiary infertility treatments under this agreement.

2.2 Not included in the policy

- 2.2.1 The following are outside the scope of this policy:

- Intra-Uterine Insemination(IUI)/ Donor Insemination (DI)
- Surrogacy
- Pre-Implantation Genetic Diagnosis (PGD)
- Surgical Sperm Retrieval (SSR)

- 2.2.2 The eligibility criteria set out below do not apply to clinical investigations for subfertility which are available to anyone with a fertility problem as advised by a relevant clinician.

- 2.2.3 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 or to preserve fertility, for example for someone about to undergo chemotherapy, radiotherapy or other invasive treatments.

3. DEFINITIONS

3.1 Abbreviations

CCG	Clinical Commissioning Group
NICE CG	Nice Clinical Guidance
GEM CSU	Greater East Midlands Commissioning Support Unit
HFEA	Human Fertilisation and Embryology Authority – UK independent regulator overseeing the use of gametes and embryos in fertility treatment
ICSI	Intra Cytoplasmic Sperm Injection – a single sperm is injected into the egg

IVF	In Vitro Fertilisation – patient's eggs and her partners sperm are collected and fused in a laboratory setting to achieve fertilisation outside the body
NICE CG	National Institute of Clinical Excellence –organisation responsible for providing national guidance on promoting good health and preventing and treating ill health
BMI	Body Mass Index = weight in kilograms divided by the square of height in metres
IFR	Individual Funding Request – CCG process for applications for services/treatments not routinely commissioned. Patients must demonstrate exceptionality to secure funding.
SET	Single Embryo Transfer
PGD	Pre-Implantation Genetic Diagnosis
IUI	Intra-Uterine Insemination
DI	Donor Insemination

3.2 Definition of a couple

- 3.2.1 Couples are defined as two persons in a stable relationship of at least 1 year's duration and are cohabiting with each other. The referring clinician must ensure that couples are aware of the implications of IVF treatment and the commitments required before making a referral for assisted conception.

3.3 Definition of infertility, timing of access to treatment and age range

- 3.3.1 Fertility problems are common in the UK and it is estimated that they affect 1:7 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.
- 3.3.2 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 will be taken as an indication for further assessment and possible treatment.
- 3.3.3 Female partner must be aged 23 years, but less than 39 years, at Commencement of treatment (i.e. must not have reached 39th birthday). Commencement of treatment is regarded as completion of initial consultation, any treatment required to rectify clinical problems, and commencement of drug regime.
- 3.3.4 If the woman is aged 35 or over then such assessment will 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.
- 3.3.5 If, as a result of investigations, a cause for the infertility is found, the Individual will be referred for appropriate treatment without further delay.

- 3.3.6 Women aged 35 – 39 years will be offered treatment **provided** their predicted ovarian reserve is found to be satisfactory, since this provides useful information regarding likely response to treatment. Although there is continuing debate around the most effective test, AMH is the test of choice for many providers, since it has been found to be reliable and can be performed at any stage of the cycle. It is proposed that a threshold of AMH >3 will be applied to all women 35 years or over for access to IVF treatment. Cost is around £29, and will be included in the provider fees.

3.4 Definition of childlessness

- 3.4.1 Funding for IVF/ICSI will be available to couples who do not have a living child from their current relationship nor any previous relationships.
- 3.4.2 A child adopted by a couple is considered to have the same status as a biological child. This does not include foster children.
- 3.4.3 A couple accepted for treatment will cease to be eligible for treatment if a pregnancy occurs naturally leading to a live birth or if the couple adopts a child.

4. ROLES AND RESPONSIBILITIES

Not applicable to this clinical policy

5. COMMISSIONING CRITERIA FOR ASSISTED CONCEPTION

5.1 Treatment Options

- 5.1.1 This policy is intended, as per NICE Clinical Guidelines, for people able to have regular sexual intercourse who have failed to conceive due to a specific identified pathological problem or who have unexplained infertility.
- 5.1.2 CCGs will fund IVF treatment for

Same sex couples
People with a physical disability

Infertility is defined as the failure of a female of reproductive age to conceive after 1 year of regular unprotected vaginal sexual intercourse, in the absence of any known medical cause of infertility.

In circumstances where the above definition cannot be applied (for example a same sex female couple) infertility is defined as the failure to conceive after 6 cycles of self-funded donor insemination during the previous 12 months, undertaken at a Human Fertilisation and Embryology Authority (HFEA) licensed clinic, in the absence of any known reproductive pathology.

5.2 Surrogacy

- 5.2.1 Surrogacy will **not** be routinely funded by South Staffordshire CCGs. Cases will be considered via the CCGs' Individual Funding Request route and must demonstrate exceptionality.

5.3 Reversal of sterilisation and treatment following reversal

- 5.3.1 IVF/ICSI treatment will **not** be funded where either partner has been sterilised or where reversal of sterilisation has been undertaken.

5.4 Body mass index (BMI)

- 5.4.1 Couples will be advised that having a BMI of 30 or over (in either or both partners) is associated with reduction in fertility and chances of conceiving, which may be reversed with weight loss.
- 5.4.2 Women being considered for IVF **must** have a stable BMI below 30 at the commencement of IVF treatment. A BMI below 30 is a requirement as there is evidence to show that oocyte collection rates are significantly lower and early pregnancy loss rates are significantly higher, in women with BMI of 30 or more, compared with those with BMI less than 30.
- 5.4.3 Where there is a statement regarding BMI the criterion has not been arbitrarily applied and has been included on the grounds of evidence for clinical and safety reasons.

5.5 Smoking

- 5.5.1 Both partners **must** be non-smoking for at least 28 days before treatment commences, and must continue to be non-smoking throughout treatment. Providers will seek evidence through testing, and confirmation from each partner. Providers will also include this undertaking on the consent form, and ask each partner to acknowledge that smoking will result either in cessation of treatment or treatment costs being applied.

5.7 Definition and number of cycles

- 5.7.1 A cycle is the process whereby one course of IVF (+/- ICSI) commences with ovarian stimulation and is deemed to be complete on conclusion of the transfer an embryo. The number of transferred embryos will be made in accordance with section 5.7. Any additional transfers will be self-funded by the patient.
- 5.7.2 For women aged 23 - 39 years, where the couple meets the eligibility criteria, South Staffordshire CCGs offer funding for 1 completed cycle of IVF treatment (+/- ICSI), **provided** they have not previously undergone NHS funded IVF/ICSI.
- 5.7.3 Couples who have previously self-funded their IVF treatment will be entitled to 1 NHS funded cycle **provided** they have not received more than 2 complete cycles of privately funded treatment. Where couples have previously self-funded and frozen embryos exist, the couple **must** utilise any viable embryos rather than undergo ovarian stimulation, egg retrieval and fertilisation again. The use of these embryos in this circumstance will require self-funding. **This is not applicable where same-sex couples have self-funded donor insemination for the purpose of demonstrating**

infertility in line with section 5.1.2

5.8 Number of transferred embryos

- 5.8.1 In keeping with the Human Fertilisation and Embryology Authority's (HFEA) multiple birth reduction strategy, couples will be counselled about the risks associated with multiple pregnancies and advised that they will receive a **single embryo transfer** (whether fresh or frozen) in line with NICE guidance, unless there is a clear clinical justification for not doing so (e.g. a single, top quality embryo is not available, or for older women, see 11.3 below). In any event a maximum of 2 embryos will be transferred per procedure (either fresh or frozen).
- 5.8.2 Women with a good prognosis will be advised that a single embryo transfer (SET), for both the fresh and any subsequent frozen embryo transfers can almost remove the risk of a multiple pregnancy, while maintaining a live birth rate which is similar to that achieved by transferring 2 fresh or frozen embryos.
- 5.8.3 For women aged between 37-39 years double embryo transfer **may** be considered if no top quality embryo is available.

5.9 Cancelled cycles

- 5.9.1 A cancelled cycle is defined by NICE as 'egg collection not undertaken'. Where IVF is charged by providers as an inclusive price, a cancelled cycle will not be charged. Couples will be eligible for one cancelled cycle as part of their NHS treatment.

5.10 Handling of existing frozen embryos from previous cycles

- 5.10.1 All stored and viable embryos will be used before a new cycle commences. This includes embryos resulting from previously self-funded cycles. Embryos frozen as part of an NHS funded cycle will be stored for up to 3 years. After 3 years, couples will be required to self- fund storage of any embryos.

5.11 Surgical sperm retrieval

- 5.11.1 Surgical sperm retrieval (SSR) is the funding responsibility of NHSE and therefore will not be funded by the CCG. <https://www.england.nhs.uk/wp-content/uploads/2018/07/Surgical-sperm-retrieval-for-male-infertility.pdf>

5.12 Oocyte and sperm donation

- 5.12.1 Sperm donation is not normally funded.
- 5.12.2 Oocyte donation may be commissioned as part of IVF/ICSI policy in cases where it is clinically appropriate:
- 5.12.2.1 Premature ovarian failure
 - 5.12.2.2 Gonadal dysgenesis including Turner syndrome
 - 5.12.2.3 Bilateral oophorectomy
 - 5.12.2.4 Ovarian failure following chemotherapy or radiotherapy
- 5.12.3 NHS funding would not normally be available for women outside these groups who do not respond to follicular stimulation.

5.12.4 Egg donations will be sourced by providers.

5.13 Embryo and sperm storage during fertility treatment

5.13.1 Embryo and sperm (when required after surgical retrieval) storage will be funded for couples 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.

5.13.2 South Staffordshire CCGs 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.

5.14 Fertility Preservation

Cryopreservation of gametes will be available to all patients undergoing medical treatment that may render them infertile. Any funding requests for cryopreservation will be subject to prior approval. There is no lower age for eligibility under these circumstances. The CCG will pay for storage for a maximum of 5 years. After this period, patients wishing to continue to store may self-fund in line with HEFA Guidance.

5.14.1 **Freezing method** – Where oocytes are being preserved, the CCG will only fund freezing by vitrification. Other methods of freezing oocytes are not routinely funded.

5.14.2 Patients wishing to use stored gametes **must** meet the eligibility criteria at the time of application for assisted conception in an NHS setting.

5.15 TRAINING

None known

6.0 Internal and External References

6.1 Internal references

6.1.1 SSPCT Policy Statement No. 7 Commissioning Policy and Referral Guidelines for Assisted Reproductive Treatments.

<http://www.webarchive.org.uk/wayback/archive/20130329024359/http://www.southstaffordshirepct.nhs.uk/policies/Commissioning/Policy07AssistedConception.pdf>

6.1.2 External references

6.1.3 Nice Clinical Guidance:
CG156 Fertility <http://www.nice.org.uk/guidance/cg156>

6.1.4 GEM CSU IVF Policy:
http://www.northderbyshireccg.nhs.uk/assets/Clinical_Guidelines/_IVF/Paper_1_-_IVF_Policy_and_eligibility_criteria_17_04_14_FINAL.doc

6.1.5 Infertility Network UK:
<http://www.infertilitynetworkuk.com/>

7 MONITORING AND EVALUATION

The adherence of this policy will be monitored by Midlands and Lancashire CSU through the contract management route.