

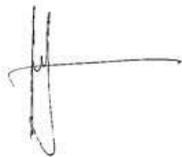
COMMISSIONING POLICY FOR IN VITRO FERTILISATION (IVF)/ INTRACYTOPLASMIC SPERM INJECTION (ICSI) WITHIN TERTIARY INFERTILITY SERVICES V2.3 2017

Agreed at Cannock Chase CCG



Signature:
Designation: Chair of Cannock Chase CCG
Date: 01 October 2015

Agreed at South East Staffordshire & Seisdon Peninsula CCG



Signature:
Designation: Chair of South East Staffordshire & Seisdon Peninsula CCG
Date: 12 October 2017

Agreed at Stafford and Surrounds CCG



Signature:
Designation: Chair of Stafford & Surrounds CCG
Date: 27 October 2015

COMMISSIONING POLICY FOR IN VITRO FERTILISATION (IVF)/ INTRACYTOPLASMIC SPERM INJECTION (ICSI) WITHIN TERTIARY INFERTILITY SERVICES

Version number	2.3
Responsible Executive Lead	Mark Seaton, Director of Commissioning
Author(s)	Trish Allen, Consultant Public Health
Date ratified by Governing Body	See front cover sheet
Date issued	May 2017
Review date	May 2018
Date approved by Equality Impact Assessment	Not required – no significant change from PCT policy
Target audience	GPs, Patients, providers

HISTORY OF CHANGES		
Old version number	Significant changes	New version number
SSPCT Policy Statement No. 7 Commissioning Policy and Referral Guidelines for Assisted Reproductive Treatments	<p>Single IVF cycle only for eligible couples. NICE 3 cycle recommendation is evidence based, but would increase costs considerably. Most CCGs currently offer 1 cycle only.</p> <p>Maintain current female age range 23-39 years.</p> <p>Decline with age in rates of conception is seen mostly after age 30 years and is more marked after age 35.</p> <p>Testing for ovarian reserve is recommended for women 35-39 years, using AMH as the test of choice, since it has been found to be reliable and can be performed at any stage of the cycle</p> <p>Surgical sperm retrieval will be funded in appropriately selected patients</p> <p>Sperm donation will not normally be available.</p> <p>Oocyte donation may be commissioned as part of IVF/ICSI policy when clinically appropriate:</p> <p>Cryopreservation of gametes for all patients undergoing treatment for organic illness</p> <p>IVF treatment is available for same sex couples and people with a physical disability, provided there is evidence of subfertility and where it is possible to do so within the eligibility criteria.</p>	V1
V2	Added text: 3.2.1 Couples are defined as two persons in a stable	V2

	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.	
V2	Changed text: 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 5.7. Any additional transfers will be self-funded by the patient.	V2
V2.1	Added text: 5.6.1 Any additional transfers will be self-funded by the patient.	V2.2
V2.2	Changed text: 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.	V2.3

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.

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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)

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 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.

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

provided there is evidence of subfertility, defined as no live birth following artificial insemination (AI) as per local CCG policy or proven by clinical investigation as per NICE guidelines. AI will be undertaken in a licensed clinical setting with an initial clinical assessment and appropriate investigations.

5.1.3 CCGs will **not** normally fund AI. Please refer to local CCG policy for details of eligibility criteria for NHS funding for AI.

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.

5.6 Definition and number of cycles

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 5.7. Any additional transfers will be self-funded by the patient.

- 5.6.2 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.
- 5.6.3 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.

5.7 Number of transferred embryos

- 5.7.1 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).
- 5.7.2 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.
- 5.7.3 For women aged between 37-39 years double embryo transfer **may** be considered if no top quality embryo is available.

5.8 Cancelled cycles

- 5.8.1 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.

5.9 Handling of existing frozen embryos from previous cycles

- 5.9.1 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.

5.10 Surgical sperm retrieval

- 5.10.1 Surgical sperm retrieval (SSR) will be funded in appropriately selected patients, providing that azoospermia is not the result of a sterilisation process, and will only be funded where the couple meet the eligibility criteria set out within this document. Men with obstructive azoospermia will be offered surgical correction of epididymal blockage to restore patency of the duct, unless it is following vasectomy which is not covered by this policy. Surgical correction will be considered as an alternative to surgical sperm recovery and IVF.

5.10.2 Funding will be provided for men who, with their partner, would be eligible for NHS funded IVF/ICSI treatment.

5.10.3 Funding will **not** be provided for sperm retrieval in men who have undergone vasectomy, whether or not the female partner also required infertility treatment.

5.11 Oocyte and sperm donation

5.11.1 Sperm donation is not normally funded.

5.11.2 Oocyte donation may be commissioned as part of IVF/ICSI policy in cases where it is clinically appropriate:

- Premature ovarian failure
- Gonadal dysgenesis including Turner syndrome
- Bilateral oophorectomy
- Ovarian failure following chemotherapy or radiotherapy

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

5.11.4 Egg donations will be sourced by providers.

5.12 Embryo and sperm storage during fertility treatment

5.12.1 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.

5.12.2 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.

5.13 Cryopreservation for organic illness

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. There is no lower age limit for eligibility under these circumstances. There will be an annual review to ensure that patients still meet the criteria and wish to continue to have their semen, oocytes or embryos stored. Patients who no longer fulfil the criteria will be offered the option to self-fund continued storage of their semen, oocytes or embryos in line with the HFEA guidance around maximum storage times. Longer terms may be requested, and will be individually reviewed depending on the case.

5.13.2 Normal eligibility criteria for IVF apply when using stored gametes for assisted conception in an NHS setting.

6. TRAINING

None known

7. INTERNAL AND EXTERNAL REFERENCES

7.1 Internal references

- 7.1.1 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>

7.2 External references

- 7.2.1 Nice Clinical Guidance:
CG156 Fertility <http://www.nice.org.uk/guidance/cg156>
- 7.2.2 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
- 7.2.3 Infertility Network UK:
<http://www.infertilitynetworkuk.com/>

8. MONITORING AND EVALUATION

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

9. REVIEW

This policy will be reviewed annually or, will there be any material changes to the guidelines issued by NICE. Next review due May 2018.