

**CLINICAL POLICY ADVISORY GROUP (CPAG)**

**InVitro Fertilisation (IVF) Intracytoplasmic Sperm Injection (ICSI) within Tertiary Infertility Services Policy**

**Statement**

Derby and Derbyshire CCG, has agreed that IVF/ICSI should be commissioned when certain eligibility criteria are met.

This policy will be reviewed periodically. This is to review clinical effectiveness and ensure affordability against other services commissioned by the CCG.

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

## **1. INTRODUCTION**

- 1.1. In vitro Fertilisation (IVF) is commissioned as a tertiary service within an overall infertility pathway. This policy describes circumstances in which NHS Derby & Derbyshire Clinical Commissioning Group (DDCCG) will fund treatment for IVF including Intra- cytoplasmic Sperm Injection (ICSI)

This policy applies to any patient who is registered with a GP practice within Derby and Derbyshire CCG. The eligibility criteria set out in this policy will apply irrespective of where patients have their treatment (local NHS hospitals, tertiary care centers or independent sector providers).

- 1.3 This policy has drawn 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).
- 1.4 The following are outside the scope of this policy:
- Intra-Uterine Insemination(IUI)/ Donor Insemination (DI)
  - Surrogacy
  - Pre-Implantation Genetic Diagnosis (PGD)
  - Gamete and embryo cryopreservation for people undergoing treatment likely to impair their fertility
- 1.5 This policy replaces all previous IVF/ICSI policies and is inclusive of all protected groups.

## **2. GENERAL PRINCIPLES**

- 2.1 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, or single women who, are able to demonstrate this and fulfil the following criteria will be eligible for tertiary infertility treatments under this agreement.
- 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.

- 2.3 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.
- 2.4 The Derby and Derbyshire CCG respect the right of patients to be treated according to the obligations set out in the NHS Constitution.

### **3. DEFINITION OF INFERTILITY, 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.
- 3.3 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.
- 3.4 For women aged up to 42 years who have not conceived after 2 years of regular unprotected intercourse or a course of artificial insemination (in line with local CCG policy), this should be taken as an indication for consideration of IVF.
- 3.5 If, as a result of investigations, a cause for the infertility is found, the individual should be referred for appropriate treatment without further delay.
- 3.6 This policy reflects the NICE guidelines that access to high level treatments including IVF should be offered to women up to the age of 42. Ovarian stimulation should have been completed before the woman's 43rd birthday.

- 3.7 Women will be offered treatment provided their predicted ovarian response to gonadotrophin stimulation is satisfactory, as indicated by an Follicle Stimulation Hormone (FSH) of  $\leq 8.9$  IU/l.

#### **4. DEFINITION OF CHILDLessNESS**

- 4.1 Funding for IVF/ICSI will be available to couples, or single women who can demonstrate infertility, and do not have a living child from their current relationship nor any previous relationships.
- 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.
- 4.3 A child previously given up for adoption is the legal responsibility of the adoptive parents and as such is not considered to be a biological child of the birth parents.
- 4.4 A couple, or single woman, who is accepted for treatment will cease to be eligible for treatment (i.e. additional cycles – see section 12) if a pregnancy occurs naturally leading to a live birth or if the couple adopts a child.

#### **5. TREATMENT OPTIONS**

- 5.1 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.
- 5.2 The CCG will fund IVF treatment for:
- Same sex couples
  - People with a physical disability
  - Single women who can evidence infertility or with a condition leading to infertility

Provided there is evidence of subfertility, defined as no live birth following intrauterine insemination (IUI) as per our local policy or proven by clinical investigation as per NICE guidelines. IUI should be undertaken in a licensed clinical setting with an initial clinical assessment and appropriate investigations.

- 5.3 Please refer to local CCG policy for details of eligibility criteria for NHS funding for IUI
- 5.4 The option of IUI can be discussed as part of the assessment and treatment of an underlying fertility problem where the patient has cultural or religious objections to IVF. See the Intrauterine Insemination Policy.

## **6. SURROGACY**

- 6.1 Please refer to the individual CCG surrogacy policy.

## **7. REVERSAL OF STERILISATION AND TREATMENT FOLLOWING REVERSAL**

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

## **8. BODY MASS INDEX (BMI)**

- 8.1 Couples should 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.
- 8.2 Women being considered for IVF must have a stable BMI below 30 and more than 19 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 under 30.
- 8.3 Patients with a BMI of less than 19 should be advised that increasing their body weight is likely to improve their chance of conception
- 8.4 Where there is a statement on criteria for BMI the criteria has not been arbitrary applied and has been included on the grounds of evidence for clinical and safety reasons.

## 9. SMOKING

- 9.1 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 from referrers and confirmation from each partner. Providers should 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.
- 9.2 Sole use of e-cigarettes, without the concurrent use of tobacco, is classified as non- smoking for the purposes of this policy.

## 10. DEFINITION AND NUMBER OF CYCLES

- 10.1 A cycle is the process whereby one course of IVF (+/- ICSI) commences with ovarian stimulation and is deemed to be complete when all viable fresh and frozen embryos resulting from that stimulation have been transferred.
- 10.2 For women aged up to 40 years the NHS Derby & Derbyshire CCG offer funding for 1 full cycle of IVF treatment (+/- ICSI).
- 10.3 For women aged 40-42 years the NHS Derby & Derbyshire CCG offer 1 full cycle provided:
  - a) There is no evidence of low ovarian reserve (NICE CG156 section 1.3.3.2 Ovarian reserve testing).
  - b) The implications of IVF and pregnancy at this age have been discussed with the patient.
- 10.4 Couples meeting the eligibility criteria will be eligible to receive a maximum of 1 completed cycle of IVF treatment (+/- ICSI). In addition, couples who have previously self-funded their IVF treatment will be entitled to one NHS funded cycle provided they have not received more than two complete cycles of privately funded treatment.

Where couples have previously self-funded and frozen embryos exist, the couple must utilize 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.

Where a member of the couple has previously received NHS funded treatment as part of another couple they will not be barred from accessing NHS funded treatment under their current relationship where they meet all criteria.

## **11. NUMBER OF TRANSFERRED EMBRYOS**

- 11.1 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 in older women, see below). In any event a maximum of 2 embryos will be transferred per procedure (either fresh or frozen).
- 11.2 Women with a good prognosis should be advised that a single embryo transfer, 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.
- 11.3 For women aged between 37-39 years double embryo transfer can be considered if no top quality embryo is available.
- 11.4 For women aged between 40-42 years, double embryo transfer may be considered.

## **12. CANCELLED CYCLES**

- 12.1 A cancelled cycle is defined by NICE as 'egg collection not undertaken'. Couples will be eligible for one cancelled cycle as part of their NHS treatment.

## **13. HANDLING OF EXISTING FROZEN EMBRYOS FROM PREVIOUS CYCLES**

- 13.1 All stored and viable embryos should be used before a new cycle commences. This includes embryos resulting from previously self-funded cycles.
- 13.2 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.

## 14. SURGICAL SPERM RETRIEVAL

- 14.1 Surgical sperm retrieval for the treatment of male related fertility problems is a separate clinical procedure and will be commissioned where clinically appropriate by NHSE. This will include cases of obstructive azoospermia or ejaculatory failure where this has not been corrected by other means.
- 14.2 Funding will be provided for men who, with their partner, would be eligible for NHS funded IVF/ICSI treatment.
- 14.3 Funding will not be provided for sperm retrieval in men who have undergone vasectomy whether or not the female partner also required infertility treatment.

## 15. OOCYTE DONATION

- 15.1 Oocyte donation may be commissioned as part of IVF/ICSI policy when clinically appropriate;

- Premature ovarian failure:

### Definition

“Primary ovarian insufficiency (POI) also known as premature ovarian failure, premature menopause or early menopause is a condition characterized by amenorrhea, hypoestrogenism and elevated serum gonadotrophin levels in women younger than 40 years. If the woman is aged less than 40 (i.e up to 40<sup>th</sup> birthday) has amenorrhoea and an FSH of 40 U/l or greater then should clearly have premature ovarian failure and be a candidate for egg donation”

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

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

## 16. EGG SHARING/DONATION AND SPERM DONATION

16.1 NHS funding will be available for women who fulfil the eligibility criteria and require donated eggs/sperm.

16.2 Egg and sperm donations will be sourced by providers.

## **17. EMBRYO AND SPERM STORAGE**

17.1 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.

17.2 NHS Derby & Derbyshire 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.

## **18. CRYO – PRESERVATION**

18.1 Please refer to the NHS Derby & Derbyshire Gamete Storage Policy.

## **19. OVERSEAS VISITORS AND ELIGIBILITY FOR NHS-FUNDED IVF TREATMENT**

19.1 An individual ordinarily resident in the UK is eligible for NHS funded fertility treatment, including non-EEA citizens with ILR (Indefinite Leave to Remain)

Overseas visitors, who are not EEA passport holders, don't have ILR, or do not have UK citizenship may usually access NHS healthcare if they pay a health surcharge.

Until 21st August 2017, this would have included IVF.

From 21st August 2017, the Charging Regulations were amended, to exclude IVF from the list of NHS treatments overseas visitors could access, even if a surcharge was paid.

Where a non-EEA citizen wishes to access IVF they should be charged 150% of the or locally agreed price, where applicable). IVF treatment charges should be

made in advance of any treatment being given

If care is deemed an emergency by the Fertility Consultant, the provider and CCG can enter a risk share scheme, and split 50% of the costs each, as outlined below.

## 20. **POLICY REVIEW**

20.1 This policy will be reviewed as required.

## 21. GLOSSARY

Term	Meaning
Blastocyst	Any undifferentiated embryonic cell (Lawrence, 2000: 75)
Body Mass Index (BMI)	Body Mass Index (BMI) is a number calculated from a person's weight and height. BMI provides a reliable indicator of body fatness for most people and is used to screen for weight
Donor Insemination (DI)	The introduction of donor sperm into the vagina, the cervix or womb itself
Embryo	A fertilised egg.
Embryo transfer	The replacement of embryo(s) back into the female
Frozen Embryo Replacement (FER)	Where an excess of top quality embryos is available, these embryos may be cryogenically frozen for future use. Once thawed, these embryos are transferred to the patient as a
Gonadotrophins	Hormones that stimulate the function of the organs in which reproductive cells are produced (Lawrence,
Human Fertilisation and Embryology Authority (HFEA).	UK's independent regulator overseeing the use of gametes and embryos in fertility treatment and research. (HFEA, c, 2009)
Invitro Fertilisation (IVF)	This is a process whereby eggs are removed from the ovaries and fertilised with sperm in
Intra-cytoplasmic Sperm Injection (ICSI)	This is a technique that can be used in IVF whereby a sperm is injected into an egg to assist in fertilisation. (NHS Direct, 2009).
Intrauterine Insemination (IUI)	A procedure to separate fast moving sperm from more sluggish or non-moving sperm. The fast moving sperm are then placed into the woman's womb close to the time of ovulation when the egg is released from the ovary in the middle of the monthly cycle.
National Institute for Health & Clinical Excellence (NICE)	NICE is an independent organisation responsible for providing national guidance on promoting good
Oocyte	A not yet fully developed egg cell.
Ovarian Stimulation	The process of stimulating one or more follicles to

Pre-implantation genetic diagnosis (PGD)

This is a technique that enables people with a specific inherited condition in their family to avoid passing it on to their children. It involves checking

## 22. Schedule of Eligibility Criteria

Eligibility Criteria		Yes/No
Women's Age	<p>For women up to 40 years the East Midlands CCGs offer funding for 1 full cycle of IVF treatment (+/-ICSI)</p> <p>Couples who have self-funded will be entitled to 1 NHS cycle provided they have not received more than 2 cycles</p>	
	<p>For women aged between 40-42 years the East Midlands CCGs offer 1 full cycle provided:</p> <p>a) There is no evidence of low ovarian reserve b) There has been a discussion about the implications of IVF and pregnancy at this age</p> <p>Ovarian stimulation should have been completed before the woman's 43<sup>rd</sup> birthday</p>	
Women's BMI	BMI 19-30	
Welfare of the Child	<p>The welfare of any resulting children is paramount. In order to take into account the welfare of the child, the centre should consider factors which are likely to cause serious physical psychological or medical harm, either to the child to be born or to any existing children of the family. This is a requirement of the licensing body Human</p>	
Family Structure	<p>Funding for IVF +/-ICSI will be available to couples, or single women, who are able to demonstrate infertility, and do not have a living child from their current relationship nor any previous relationship.</p> <p>A child adopted by the couple or adopted in a previous relationship is considered to have the same status as a biological child.</p> <p>A child previously given up for adoption is the legal responsibility of the adoptive parents and as such is not</p>	
Smoking	<p>Couples must be non-smoking for 28 days in order to access any fertility treatment and must continue to be non-smoking throughout treatment</p> <p>Sole use of e-cigarettes, without the concurrent use of tobacco, is classified as non-</p>	
Sterilisation	Neither partner has been previously sterilised or had sterilisation reversed	

### 23. References

NICE Clinical Guideline 156, Assessment and treatment for people with fertility problems (2013)

EMSCG P006v2 Commissioning Policy for In vitro Fertilisation (IVF) / Intracytoplasmic Sperm Injection (ICSI) within Tertiary Infertility Services (1<sup>st</sup> December 2010 v2)

Department of Health (Overseas Visitor) Charging Regulations. Accessed online at [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/742251/guidance-on-implementing-the-overseas-visitor-charging-regulations-may-2018.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/742251/guidance-on-implementing-the-overseas-visitor-charging-regulations-may-2018.pdf)

Reference: e-Learning for Health/ HEE Overseas Visitors Cost Recovery Programme. Accessed online 23<sup>rd</sup> November 2018 at <https://www.e-lfh.org.uk/programmes/overseas-visitors-cost-recovery/>

## 24. Appendix

### Appendix 1- Consultation

<b>Consultee</b>	<b>Date</b>
Robyn Dewis - Public Health (Derbyshire County Council)	June 2019
Hind Omer – F2 Registrar	June 2019
Helen Moss – DDCCG	June 2019
Clinical Policy Advisory Group	June, August , December 2019, February 2020
Clinical and Lay Commissioning Committee	July, November, December 2019, March 2020

## Appendix 2- Document Update

<b>Document Update</b>	<b>Date Updated</b>
Policy updated – version 8	April 2014
Policy updated – version 9	June 2019
Policy updated – version 9.1	October 2019
Policy updated – version 9.2 (Addition of '5.4 The option of IUI can be discussed as part of the assessment and treatment of an underlying fertility problem where the patient has social, cultural or religious objections to IVF. See the Intrauterine Insemination Policy')	December 2019
Policy updated – version 9.2 (removal of social objections to IVF as a route for IUI as part of the assessment and treatment of an underlying fertility problem where the patient; addition of statement regarding NHSE surgical sperm retrieval )	February 2020