

## CLINICAL POLICY ADVISORY GROUP (CPAG)

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

#### Statement

Derby and Derbyshire ICB, in line with its principles for procedures of limited clinical value has deemed that **IVF and ICSI should not routinely be commissioned** unless the criteria within this policy are met.

These commissioning intentions will be reviewed periodically. This is to ensure affordability against other services commissioned by the ICB.

#### \*Statement of Intent

The IVF ICSI within Tertiary Infertility Services policy is currently being reviewed at a regional and national level.

## 1. Background

Fertility problems are common in the United Kingdom (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.

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, as a result of investigations, a cause for the infertility is found, the individual should be referred for appropriate treatment.

In vitro fertilisation (IVF) is one of the main methods used to help people conceive. Treatment begins with stimulation of the ovaries and includes collecting eggs and sperm, fertilising the eggs outside the woman's body, and placing 1 or 2 of the embryos into the womb.

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.

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.

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 ICB policy), this should be taken as an indication for consideration of IVF.

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

As such this policy should be read in conjunction with the following DDICB Fertility Policies:

- [Intrauterine Insemination Policy](#)
- [Surrogacy Involving Assisted Conception Policy](#)
- [Gamete Storage Policy](#)

## 2. Recommendation

Derby and Derbyshire ICB, in line with its principles for procedures of limited clinical value has deemed that IVF and ICSI should not routinely be commissioned unless the criteria within this policy are met.

The ICB will fund IVF treatment (+/- ICSI) for the following groups if all of the criteria below are

met:

- Heterosexual couples
- Same sex couples
- People with a physical disability
- Single women who can evidence infertility or with a condition leading to infertility

Eligibility Criteria	
Number of Cycles	A maximum of a completed cycle of IVF (+/-ICSI). Couples/single women who have previously self-funded IVF treatment will be entitled to 1 NHS funded cycles provided they have not received more than 2 completed cycles of privately funded IVF (refer to Exclusion criteria below)
Women's Age	For women up to 40 years the ICB will offer funding for 1 full cycle of IVF treatment (+/-ICSI).  For women aged between 40-42 years the ICB offer 1 full cycle provided: 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 Ovarian stimulation should have been completed before the woman's 43 <sup>rd</sup> birthday.
FSH Levels	Women will be offered treatment provided their predicted ovarian response to gonadotrophin stimulation is satisfactory, as indicated by a Follicle Stimulation Hormone (FSH) of $\leq 8.9$ IU/l.
Women's BMI	BMI 19-30kg/m <sup>2</sup> (Refer to Rationale Below).
Welfare of the Child	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. N.B This is a requirement of the licensing body, HFEA.
Family Structure	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.  A child adopted by the couple or adopted in a previous relationship is considered to have the same status as a biological child.  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.
Smoking	Couples must be non-smoking for 28 days in order to access any fertility treatment and must continue to be non-smoking throughout treatment.  Sole use of e-cigarettes, without the concurrent use of tobacco, is classified as non-smoking for the purposes of this policy.
Sterilisation	Neither partner has been previously sterilised or had sterilisation reversed.

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

The eligibility criteria do not apply to the use of assisted conception techniques for reasons other than subfertility, e.g., 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.

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.

## **Inclusion Criteria**

### BMI

- 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.
- 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.
- Patients with a BMI of less than 19 should be advised that increasing their body weight is likely to improve their chance of conception.

### Oocyte Donation

- Oocyte donation may be commissioned as part of IVF/ICSI policy when clinically appropriate. Examples include:
  - Primary Ovarian Insufficiency (POI) also known as premature ovarian failure, premature menopause or early menopause is a condition characterized by amenorrhoea, 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 30 UI/l or greater then would 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
- NHS funding would not normally be available for women outside these groups who do not respond to follicular stimulation.

## **Exclusion Criteria**

- A couple, or single woman, who is accepted for treatment will cease to be eligible for treatment (i.e., additional cycles) if a pregnancy occurs naturally leading to a live birth or if the couple adopts a child.
- 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.

## **3. Rationale for Recommendation**

In vitro Fertilisation (IVF) is commissioned as a Tertiary Service within an overall infertility pathway. This policy describes circumstances in which the ICB 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 ICB. The eligibility criteria set out in this policy will apply irrespective of where

patients have their treatment (local NHS hospitals, tertiary care centres or independent sector providers).

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). 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.

#### 4. Useful Resources

- Human Fertilisation & Embryology Authority. In vitro fertilisation (IVF). <https://www.hfea.gov.uk/treatments/explore-all-treatments/in-vitro-fertilisation-ivf/>
- Human Fertilisation & Embryology Authority. Intracytoplasmic Sperm Injection. (ICSI) <https://www.hfea.gov.uk/treatments/explore-all-treatments/intracytoplasmic-sperm-injection-icsi/>
- NHS Website. Infertility Overview. <https://www.nhs.uk/conditions/infertility/>
- NHS Website. IVF. <https://www.nhs.uk/conditions/ivf/availability/>
- HM Government. Fertility Treatment. A guide to your consumer rights. [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/992534/Patient\\_guide\\_fertility\\_.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/992534/Patient_guide_fertility_.pdf)

#### 5. References

- East Midlands Clinical Commissioning Groups (2014) Commissioning Policy for In Vitro Fertilisation (IVF)/Intracytoplasmic Sperm Injection (ICSI) within tertiary Infertility Services. Nottingham: East Midlands Clinical Commissioning Groups
- Human Fertilisation & Embryology Authority. In vitro fertilisation (IVF). <https://www.hfea.gov.uk/treatments/explore-all-treatments/in-vitro-fertilisation-ivf/>
- Human Fertilisation & Embryology Authority. Intracytoplasmic Sperm Injection. (ICSI) <https://www.hfea.gov.uk/treatments/explore-all-treatments/intracytoplasmic-sperm-injection-icsi/>
- National Institute for Health and Clinical Excellence (2013) Fertility Problems: Assessment and Treatment. NICE Guideline (CG156) <https://www.nice.org.uk/guidance/cg156>
- HM Government. Overseas NHS Visitors: Implementing the Charging Regulations [Accessed May 2022] <https://www.gov.uk/government/publications/overseas-nhs-visitors-implementing-the-charging-regulations>
- NHS England (2016). Clinical Commissioning Policy: Surgical sperm retrieval for male infertility. <https://www.england.nhs.uk/wp-content/uploads/2018/07/Surgical-sperm-retrieval-for-male-infertility.pdf>
- NICE. Menopause. How should I diagnose Premature Ovarian Insufficiency? <https://cks.nice.org.uk/topics/menopause/diagnosis/diagnosis-of-premature-ovarian-insufficiency/>

## 6. Appendices

### Appendix 1 – Consultation

All relevant providers/stakeholders will be consulted via a named link consultant/specialist. Views expressed should be representative of the provider/stakeholder organisation. CPAG will consider all views to inform a consensus decision, noting that sometimes individual views and opinions will differ.

Consultee	Date
Consultant Obstetrics and Gynaecology, UHDBFT	April 2022
Consultant Obstetrics and Gynaecology, CRHFT	April 2022
Public Health Derby City Council	April 2022
Public Health Derbyshire County Council	April 2022
East Midlands Affiliated Commissioning Committee	May 2022
Clinical Policy Advisory Group (CPAG)	June 2022
Population Health and Strategic Commissioning Committee (PHSCC)	July 2022
Joint and Community Commissioning Development Manager	January 2023
Clinical Policy Advisory Group (CPAG)	March 2023
Clinical Policy Advisory Group (CPAG)	July 2023

### Appendix 2 - Document Update

Document Update	Date Updated
<p><u>Version 10.0</u> Policy has been re-worded and reformatted to reflect the DDICB clinical policies format. This includes the addition of background information, useful resources, references and consultation.</p> <p>Appendix 3. Reference to pre-2017 surcharging to non-EEA citizens removed. This has been amended to state "<b>IVF IS EXCLUDED</b> from the list of NHS treatments overseas visitors access, even if a surcharge is paid".</p> <p>A criterion to define Premature Ovarian Failure has been lowered from FSH of &gt;40 UI/L to an FSH of &gt;30 UI/L in line with NICE Guidance.</p>	June 2022
<p><u>Version 10.1</u> Recommendation section reworded to include funding of IVF for Heterosexual couples</p>	March 2023
<p><u>Version 10.2</u> Separate box for "Number of Cycles" added to "Eligibility criteria" table. All other references to "number of cycles" within the recommendation section have been removed.</p>	July 2023

## Appendix 3 - 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 categories that may lead to health problems.
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 patient
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 frozen cycle.
Gonadotrophins	Hormones that stimulate the function of the organs in which reproductive cells are produced (Lawrence, 2000; 254).
Human Fertilisation and Embryology Authority (HFEA).	UK's independent regulator overseeing the use of gametes and embryos in fertility treatment and research. (HFEA, 2009).
Invitro Fertilisation (IVF)	This is a process whereby eggs are removed from the ovaries and fertilised with sperm in the laboratory.
IVF Cycle	A full cycle of IVF treatment covers ovarian stimulation and egg recovery, insemination, and embryo replacement. A cycle is deemed to be complete when all viable fresh and frozen embryos resulting from that stimulation have been transferred.
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.
Low Ovarian Reserve	Low Ovarian Reserve is the loss of normal reproductive potential in the ovaries due to a lower count or quality of the remaining eggs.
National Institute for Health & Clinical Excellence (NICE)	NICE is an independent organisation responsible for providing national guidance on promoting good health and preventing and treating ill health.
Oocyte	A not yet fully developed egg cell.
Ovarian Stimulation	The process of stimulating one or more follicles to grow by the administration of gonadotrophins.
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 the genes of embryos created through IVF for this genetic condition.

## Appendix 4 - Operational Issues

### Number of Transferred Embryos

- 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).
- 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.
- For women aged between 37-39 years double embryo transfer can be considered if no top-quality embryo is available.
- For women aged between 40-42 years, double embryo transfer maybe considered.

### Cancelled Cycles

- 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.

### Handling of Existing Frozen Embryos from Previous Cycles

- All stored and viable embryos should 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.

### Surgical Sperm Retrieval

- 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.
- Funding will be provided for men who, with their partner, would be eligible for NHS funded IVF/ICSI treatment.
- Funding will not be provided for sperm retrieval in men who have undergone vasectomy whether or not the female partner also required infertility treatment.

### Egg Sharing/Donation and Sperm Donation

- NHS funding will be available for women who fulfil the eligibility criteria and require donated eggs/sperm.
- Egg and sperm donations will be sourced by providers.

### Embryo And Sperm Storage

- 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.
- NHS Derby & Derbyshire ICB 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.



## Appendix 5 - Overseas Visitors and Eligibility for NHS-Funded IVF Treatment

Current Guidance on Overseas Visitors and Eligibility can be found at <https://www.gov.uk/government/publications/overseas-nhs-visitors-implementing-the-charging-regulations>

- An individual ordinarily resident in the UK is eligible for NHS funded fertility treatment.
- Overseas visitors coming to, or remaining in, the UK for six months or more are usually required to pay the immigration health charge (referred to as the health surcharge, or IHS) unless an exemption from paying the surcharge applies or the charge is waived.
- **IVF IS EXCLUDED** from the list of NHS treatments overseas visitors can access, even if the above surcharge is paid.
- Where a non-resident wishes to access IVF, they should be charged 150% of the National NHS tariff (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 ICB can enter a risk share scheme and split 50% of the costs each.