

# IVF

**NHS North West London Integrated Care Board**

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

**Adopted by NWL CCGs to be effective from October 2016**

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## 1. INTRODUCTION

- 1.1 In vitro Fertilisation (IVF) is commissioned as a tertiary service within an overall infertility pathway. This policy describes the circumstances in which North West London (NWL) Clinical Commissioning Group, will fund treatment for IVF including Intra-cytoplasmic Sperm Injection (ICSI).
- 1.2 This policy applies to any patient who is registered with a GP practice within any the North West London ICB or if not registered with a GP, resides in a NWL borough. The eligibility criteria set out in this policy apply irrespective of where the treatment occurs (local NHS hospitals, tertiary care centres or independent sector providers).
- 1.3 This policy has drawn on guidance issued by the Department of Health, feedback from local clinicians and the revised NICE Clinical Guideline 'Fertility, assessment and treatment for people with fertility problems (CG156 February 2013).
- 1.4 The items below are outside of the scope of this policy therefore not funded by NWL ICB:
  - Donor Sperm
  - Natural IVF
  - Pre-Implantation Genetic Diagnosis (PGD) (this is the commissioning responsibility of NHS England)
- 1.5 This policy has been reviewed in relation to having due regard to the Public Sector Equality Duty (PSED) of the Equality Act 2010 to: eliminate discrimination, harassment, victimisation; advance equality of opportunity; and foster good relations.  
Where there is a statement on access criteria, such as age and BMI, these have not been applied arbitrarily, but have been included on the grounds of evidence for clinical and safety reasons. This can be evidenced in Section 3, 5, 6, 7, 8, 9 and 10 of the policy.

## 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. Couples (including same sex couples) should be able to demonstrate this and fulfill the following criteria in order to be eligible for the tertiary fertility treatments outlined in this policy.
- 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 IVF will not be funded if the criteria outlined in this policy are not met. Funding may be considered in exceptional clinical circumstances via the submission of an Individual Funding Request (IFR).
- 2.4 NWL ICB respect the right of patients to be treated according to the obligations set out in the NHS Constitution. In particular, patients “have the right to expect local decisions on funding of other drugs and treatments to be made rationally following a proper consideration of the evidence. If the local NHS decides not to fund a drug or treatment [...] they will explain that decision”. (NHS Constitution 2012).

### **3. DEFINITION OF INFERTILITY, TIMING OF ACCESS TO TREATMENT AND AGE RANGE**

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- 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 of unprotected intercourse. Of those who do not conceive in the first year, about half will do so in the second year, with a cumulative pregnancy rate of 90% (NICE CG156, p.6). In 25% of infertility cases the cause cannot be identified (NICE Fertility Quality Standards, p.6).
- 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 In women under the age of 40 without a known cause of infertility, IVF will be funded after 2 years of regular unprotected intercourse where criteria, such as BMI, and smoking status outlined in this document is met. Patients who have a known cause of infertility which cannot be treated (otherwise than by IVF) will have access to treatment are not subject to 2 year threshold.  
If, as a result of investigations, a cause for the infertility is found, the individual should be referred for appropriate treatment without further delay.
- 3.4 In line with local commissioning priorities, NWL ICB have decided that IVF should be made available to women up to the age of 40. Ovarian stimulation should therefore have been completed before the woman's 40<sup>th</sup> birthday and any resultant embryos be transferred within the following 12 months.

### **4. DEFINITION OF CHILDLINESS**

- 4.1 IVF+/-ICSI will be funded for couples who do not have any living biological or adopted children from their current relationship or from any previous relationships.
- 4.2 A couple will no longer be eligible for treatment if a pregnancy occurs naturally leading to a live birth or if the couple adopts a child. This is irrespective of the fact that the stage of the fertility pathway the couple is in.

## **5. SAME SEX COUPLES OR A WOMAN NOT IN A PARTNERSHIP**

- 5.1 The criteria and requirements, as per NICE Clinical Guidelines, are intended for people able to have regular sexual intercourse and have failed to conceive due to a specific identified pathological problem or who have unexplained infertility.
- 5.2 IVF will be funded for same-sex couples, or a woman not in a partnership if they have an identified pathological problem or unexplained infertility has been established; provided that evidence is available to demonstrate that at least 12 cycles of self-funded donor sperm and artificial insemination (AI) have been undertaken by a licensed provider (where at least 6 are by IUI), and appropriate clinical assessments and investigations have been carried out.
- 5.3 *NHS funding is not available for insemination facilities (IUI with donor sperm) where there is not an established clinical need*
- 5.4 Clinical criteria outlined in this document such as BMI and smoking status must also be met

## **6. SURROGACY**

- 6.1 NHS NWL ICB do not fund surrogacy.

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

- 7.1 Reversal of sterilisation will not be funded. Patients who have had reversal of sterilisation are not eligible for NHS IVF funding.

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

- 8.1 As outlined by NICE (CG156, 2016 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 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 (see NICE CG156).
- 8.3 Women who have a BMI of less than 19 and who have irregular menstruation should be advised that increasing body weight is likely to improve their chance of conception.
- 8.4 Where there is a statement on eligibility criteria for BMI, any requirements have not been applied arbitrarily, but have been included on the grounds of evidence for clinical and safety reasons.

## 9. **SMOKING**

- 9.1 The couple's health and social circumstances should pose no significant risk to conception, pregnancy or the health of the resultant child(-ren). Smoking reduces fertility and increases risks to mother and baby during and after the pregnancy. NWL ICB encourage all households, especially those with young children, to be smoke free.
- 9.2 Both partners must be non-smokers for at least 6 months before commencement of the treatment and must continue to do so for the whole duration of the 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.

## 10. **DEFINITION AND NUMBER OF CYCLES**

10.1 An IVF cycle (+/- ICSI) is defined as ovarian stimulation and transfer of all resulting viable fresh and frozen embryos. NWL ICB definition of a cycle is the transfer of one fresh and one frozen embryo. If the fresh transfer does not result in a viable pregnancy, then the transfer of the frozen embryo is funded. Storage is funded for one year; therefore the transfer of the frozen embryo must take place within 1 year.

10.2 NWL ICB provide 1 cycle of IVF treatment (+/- ICSI) for eligible women aged up to 40 years, who:

- a) Have not had any previous cycles of IVF funded by the NHS or alternatively, no more than 2 self-funded cycles.
- b) Have no evidence of low ovarian reserve (NICE CG156, Recommendation 1.3.3.2 Ovarian reserve testing).
- c) Have been advised on risks and implications of the treatment.
- d) Do not have any living biological or adopted children from their current relationship or from any previous relationships.

10.3 Where a fresh embryo transfer has been unsuccessful couples must utilise their frozen embryo transfer. If there are no fresh embryos, then only **one** frozen transfer is permitted. Additional frozen transfers will be self-funded by the patient.

10.4 Sperm storage, when required after surgical retrieval, will be funded for couples who are undergoing NHS fertility treatment. Embryo and sperm storage will be funded for a maximum of 1 year or until a successful live birth is achieved, whichever is the shorter.

10.5 NWL ICB will not separately fund storage and use of frozen embryos remaining after a live birth. Couples may self-fund the use of these embryos.

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

11.1 In line with the Human Fertilisation and Embryology Authority's (HFEA) multiple birth reduction strategy, couples should be advised about the risks associated with multiple pregnancies and receive a single embryo transfer (whether fresh or frozen) as specified by the 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 12.6 below). In any event a maximum of 2 embryos should be transferred per procedure (either fresh or frozen).

11.2 For women aged between 37-39 years, a double embryo transfer can be considered if no high quality embryo has been obtained.

## **12. ABANDONED CYCLES/ CANCELLED CYCLES**

- 12.1 An abandoned cycle is defined by NICE as a cycle where, for a variety of reasons, 'egg collection [is] not undertaken' (CG 156).
- 12.2 Where IVF is charged by providers as an inclusive price, a cancelled or abandoned cycle should not be charged. Couples will be eligible for one cancelled cycle as part of their NHS treatment.
- 12.3 An abandoned cycle where ovarian hyper stimulation syndrome (OHSS) occurs are not counted as a full treatment cycle and patients are eligible for another attempt.
- 12.4 If a cycle is cancelled for poor response the couple would not be eligible for further stimulation.
- 12.5 If failed fertilization occurs, where an egg/sperm does not fertilise, couples would be eligible for an attempt with ICSI.

## **13. THE USE OF EMBRYOS FROM PREVIOUS SELF-FUNDED CYCLES**

- 13.1 All embryos resulting from a self-funded cycle should be used before commencing a new NHS-funded cycle.

## **14. Cryopreservation of Gametes (Oocytes, embryos and Sperm for patients at risk of permanent infertility)**

- 14.1 Cryopreservation of gametes (oocytes, embryos, and sperm) for the purpose of storage for patients undergoing treatment that may render permanent infertility– see separate policy\*

## **15. SURGICAL SPERM RETRIEVAL**

- 15.1 In the eventuality of male factor infertility, surgical sperm retrieval is a separate clinical procedure which is commissioned where clinically appropriate. This includes cases of obstructive azoospermia or ejaculatory failure where this cannot be corrected by other means.
- 15.2 Funding will not be provided for sperm retrieval in men who have undergone vasectomy (male sterilisation) whether or not the female partner also requires infertility treatment.

## **16. OOCYTE (“EGG”) and SPERM DONATION**

- 16.1 NHS NWL ICB do not fund oocyte or sperm donation
- 16.2 NHS NWL ICB may fund the fertilisation and transfer of donor eggs from UK clinics licensed by the HFEA for women with premature ovarian failure due to a pathological or iatrogenic cause, or to avoid the transmission of inherited disorders to a child where the couple meets the relevant eligibility criteria.
- 16.3 The use of eggs sourced through other channels, including overseas clinics, will not be funded.

## **17. SPERM WASHING**

- 17.1 For couples where the man is HIV positive, any decision about fertility management should be the result of discussions between the couple, a fertility specialist and an HIV specialist (NICE CG 156). NHS NWL ICB will only fund sperm washing for IVF in infertile couples where the male partner is HIV positive and either he is not compliant with Highly Active Anti-Retroviral Therapy (HAART) or his plasma viral load is 50 copies/ml or greater. Sperm washing in other conditions will not further reduce the risk of infection, but is likely to reduce the chances of conception. It should also be pointed out that sperm washing reduces, but does not eliminate the risk of infection.
- 17.2 Where the above criteria are met, NHS NWL ICB will fund sperm washing and up to 6 cycles of IUI or 1 IVF in line with the rest of the policy, subject to other IVF clinical criteria being met, in order to prevent the transmission of HIV to an unborn child.

## **18. POLICY REVIEW**

### **1. POLICY REVIEW**

- 1.1 This policy will be reviewed every two years, and on an exceptional basis, should there be any material changes to the evidence and guidelines issued by NICE, other professional organisations or when agreed by all participating ICB.

## Appendix 1: 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, c, 2009)
In vitro Fertilisation (IVF)	This is a process whereby eggs are removed from the ovaries and fertilised with sperm in the laboratory.
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. (HFEA, 2015).
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 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 with the use of follicle stimulating hormone

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.
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Latest version of the policy is available at:  
<http://www.hounslowccg.nhs.uk/what-we-do/individual-funding-requests.aspx>  
Version 6 (January 2020)

## Appendix 2: Mandatory Investigations for completion before referral

		Insert Response
Is age of female partner less than 40 years? (Please be aware that the stimulation phase of IVF must start before the patient turns 40)		
Menstrual history	LMP	
	Cycle	
	Menorrhagia	
Social history of both couples	Female Smoking status	
	Female Alcohol intake	
	Male Smoking Status	
	Male Alcohol intake	
Sexual history	Frequency	
	Duration of trying	
	Dyspareunia	
Predisposing factors	PCOS	
	PID/STIs	
	Tubal Surgery	
	Erectile Dysfunction	
	History of scrotal lumps/surgery	
BMI of female patient ( ≥ 30 will exclude from treatment)		
Preconception investigations done in primary care	Smear result	
	Rubella Status	
	Chlamydia screening	
	Mid luteal Progesterone	
	Day 2-5 LH/FSH in irregular cycle	
	FBC	
	TFT	
	Prolactin	
	Semen Analysis	
Previous Hospital Investigations (Please supply where appropriate)	HSG or hysteroscopy findings	
	Vaginal US	
	Laparoscopy	

### **Appendix 3: References**

1. NICE Clinical Guideline 156, Assessment and treatment for people with fertility problems (2014)
2. EMSCG P006v2 Commissioning Policy for Invitro Fertilisation (IVF) / Intracytoplasmic Sperm Injection (ICSI) within Tertiary Infertility Services (1<sup>st</sup> December 2013) The NHS Nottingham North & East Clinical Commissioning Group 2013.