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Clinical Commissioning Group

East Midlands CCGs

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

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East Midlands CCGs

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

April 2014

(*This Policy was developed in line with NICE Guidance (GC156) and will be reviewed annually by Lincolnshire CCG or sooner if new guidance is issued)*

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Version Control Sheet

Draft	Section/Para /Appendix	Version/Description of Amendments	Date	Author/Amended by
1		1st Draft	13.08.13	IH
2		Comments received from • Andy Roylance • Nicky Bird • Andy Rix • Lola Banjoko • Dave Giffard	19.09.13	IH
3		Comments received from • Clare Lewis-Jones (Infertility Network) • Nicky Bird • Sue Sims • Heather Stringer (NURTURE). • Dr Robert Wilson • Julia Mehigan (Derbyshire Lesbian, Gay,Bisexual and Transgender Group • Judith Smith (CARE Nottingham)-	16.10.13	IH
4		Feedback from review meeting on 25/10/13	29.10.13	IH
5		Review of policy by Dr H Ewart	29.10.13	IH/HE
6		Final Policy approved by CCGs	31.03.14	LC
7		Due Regard Screening	01.04.14	LC
8.		Final Version issued	01.04.14	LC
9.		Policy issued for NHS Lincolnshire CCG	01.04.20	

Equality Act 2010
Equality Commitment Statement In carrying out their functions, the East Midlands Clinical Commissioning Groups and the Greater East Midlands Commissioning Support Unit (GEM CSU) are committed to having due regard to the Public Sector Equality Duty. This applies to all the activities for which the CCG's and GEM CSU are responsible, including policy development and review. The IVF/ICSI 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. The aim is to design and implement policy documents that meet the diverse needs of the populations to be served and the NHS workforce, ensuring that none are placed at a disadvantage over others. It takes into account current UK legislative requirements, including the Equality Act 2010 and the Human Rights Act 1998, and promotes equality of opportunity for all. This document has been designed to ensure that no-one receives less favourable treatment owing to their personal circumstances, in this instance their protected characteristics of their age, disability, sex (gender), gender reassignment, sexual orientation, marriage and civil partnership, race, religion or belief, pregnancy and maternity.

INTRODUCTION

1 In vitro Fertilisation (IVF) is commissioned as a tertiary service within an overall infertility pathway. This policy describes circumstances in which the East Midlands Clinical Commissioning Groups (CCGs) will fund treatment for IVF including Intra-cytoplasmic Sperm Injection (ICSI).

1.1 This policy applies to any patient who is registered with a GP practice within the East Midlands CCGs who have adopted this policy. The eligibility criteria set out in this policy apply irrespective of where patients have their treatment (local NHS hospitals, tertiary care centres or independent sector providers).

1.2 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 polices 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) 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 East Midlands CCGs 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 or one of the other measures recommended in NICE CG156 (section 1.3.3.2 – Ovarian reserve testing).

4. DEFINITION OF CHILDLESSNESS

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**.**

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 couple 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.

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 should be undertaken in a licensed clinical setting with an initial clinical assessment and appropriate investigations.

5.2 Please refer to local CCG policy for details of eligibility criteria for NHS funding for AI.

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 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 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.

.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 East Midlands CCGs offer funding for 1 full cycle of IVF treatment (+/- ICSI).

10.3 For women aged 40-42 years the East Midlands CCGs offer 1 full cycle provided:

a) They have never previously had IVF/ICSI.

b) There is no evidence of low ovarian reserve (NICE CG156 section 1.3.3.2 Ovarian reserve testing).
c) 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 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.

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 11.3 and 11.4 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'. Where IVF is charged by providers as an inclusive price, a cancelled cycle should not be charged. 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. 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
- 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 The East Midlands 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.

18. CRYO – PRESERVATION

18.1 Please refer to the individual CCG policy for embryo, oocyte and sperm storage for patients undergoing treatment likely to impair fertility.

19. POLICY REVIEW

19.1 This policy will be reviewed should there be any material changes to the guidelines issued by NICE or as agreed by all participating CCGs.

20. 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)
Invitro 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. (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 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.

21. **Schedule of Eligibility Criteria**

Eligibility Criteria		Yes/No
Women's Age	For women up to 40 years the East Midlands CCGs offer funding for 1 full cycle of IVF treatment (+/-ICSI) Couples who have self-funded will be entitled to 1 NHS cycle provided they have not received more than 2 cycles	
	For women aged between 40-42 years the East Midlands CCGs offer 1 full cycle provided: d) They have never previously had IVF. e) There is no evidence of low ovarian reserve f) 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 43rd birthday	
Women's BMI	BMI 19-30	
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. This is a requirement of the licensing body, Human Fertilization and Embryology Authority.	
Family Structure	Funding for IVF +/-ICSI will be available to couples who 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.	
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	
Sterilisation	Neither partner has been previously sterilised or had sterilisation reversed	

References

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

EMSCG P006v2 Commissioning Policy for Invitro Fertilisation (IVF) / Intracytoplasmic Sperm Injection (ICSI) within Tertiary Infertility Services (1st December 2010 v2)