

NHS WEST ESSEX CLINICAL COMMISSIONING GROUP

Fertility Services Commissioning Policy
Policy No. WECCG89

Description	<p>This policy replaces all previous versions.</p> <p>This policy sets out the entitlement and service that will be provided by the CCG for In Vitro Fertilisation (IVF) and Intracytoplasmic Sperm Injection (ICSI).</p> <p>Where patients have been referred to tertiary care prior to this version becoming effective, they are subject to the eligibility criteria and scope of treatment set out in the relevant version.</p> <p>Previous versions of this policy:</p> <p>EoE Version 1 – Effective 15 August 2008 to 30 June 2010 Version 2 – Effective 1 July 2010 to 31 May 2011 EoE Version 3 – Effective 1 June 2011 to 1 December 2014 Version 4 – Effective 1 December 2014 to 31 December 2016 Version 5 – Effective January 2017 to January 2019 Version 6 – Effective January 2018 to January 2020 Version 7 – Effective September 2018 to January 2020</p>
Target Audience	CCGs, NHS Trusts, Tertiary Providers, Commissioners, GPs, Fertility Nurses, Service Users.

Version Number	7
Accountable Officer	Chief Officer
Responsible Officer	Chief Medical Officer
Date Approved	September 2018
Approved By	Chief Medical Officer
Date Summary presented to Board	25 th January 2018
Review Date	January 2020
Stakeholders engaged in development/review	Public consultation, GP clinical leadership groups, CCG policy review group and health and care commissioning committee.
Equality Impact Assessment	<p>The outcome of the Equality Impact Analysis is as follows:</p> <p>Age – This policy has age restrictions for offering IVF based on evidence around success rates.</p> <p>Sex – This policy applies to both women and men.</p> <p>Disability – No exclusions for disability.</p> <p>Gender reassignment – No exclusions for gender reassignment</p>

	<p>patients. Marriage or Civil Partnership, Race, Sexual Orientation and Pregnancy – Process makes no differential for social circumstances and no reason to suppose differential in need between these groups.</p>
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SUSTAINABILITY STATEMENT: We declare that NHS West Essex Clinical Commissioning Group will demonstrate commitment to promoting environmental and social sustainability through our actions as a corporate body and as a commissioner. We aim to reduce our carbon footprint by 28% from a 2013 baseline by 2020.

Amendment History

Version	Date	Reviewer Name(s)	Comments
EoE 1	15.08.08		
2	01.07.10		
EoE 3	01.06.11		
4	01.12.14	Sasha Hewitt	
5	January 2017	Nadia Hart	Minor wording amendments made to the body of the policy
6	January 2018	Sarah Danahar	Changes in specialist fertility services. Minor wording amendments and layout changes.
7	September 2018	Sarah Danahar	Changes to cryopreservation storage

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Fertility treatment and referral criteria for tertiary level assisted conception

1. Introduction

- 1.1.1 This policy specifically sets out the entitlement and service that will be provided by the NHS West Essex Clinical Commissioning Group (CCG) for In Vitro Fertilisation (IVF) and Intracytoplasmic Sperm Injection (ICSI). These services are commissioned by clinical commissioning groups and provided via tertiary care providers.

It is the purpose of the criteria set out in this policy to make the provision of fertility treatment fair, clear and explicit. This policy should be read in conjunction with NICE Guidance CG156 "Fertility: assessment and treatment for people with fertility problems" (2013) available on their website at

<http://publications.nice.org.uk/fertility-cg156>

Couples will be eligible to receive IVF/ICSI where they meet the specified referral criteria.

2. Access Criteria overview

- 2.1.1 The female patient should have an FSH (follicle-stimulating hormone) reading within 3 months of referral and on day 2 of the menstrual cycle of <9.
- 2.1.2 Women aged 23 to 42 years old may be funded for 1 cycle of IVF when they meet the criteria of this policy.
- 2.1.3 West Essex CCG retains a maximum paternal age threshold of 55 years.
- 2.1.4 Body mass index (BMI) requirements are set out within this policy. The BMI will be at least 19 and up to 30 for female and less than 35 for male.
- 2.1.5 Couples should have experienced unexplained infertility for three years or more of regular intercourse or 12 cycles of artificial insemination over a period of 3 years. There is no criterion on time length for couples with a diagnosed cause of infertility.
- 2.1.6 This policy is for couples who have had no previous privately or NHS funded cycles of IVF.

- 2.1.7 Couples who smoke will not be eligible for NHS-funded specialist assisted reproduction assessment or treatment.
- 2.1.8 This policy is specifically for those couples who do not have a living child from their current or any previous relationships, regardless of whether the child resides with them.
- 2.1.9 Couples will be ineligible if previous sterilisation has taken place (male or female), even if it has been reversed.
- 2.1.10 The couple should be registered with a GP within the West Essex CCG footprint for 12+ months.

This access criterion is in depth at the end of the policy in table form, appendix A.

2.2 Review

- 2.2.1 This policy will be reviewed bi-annually and within 3 months of any legislative changes that should or may occur in the future.

2.3 Key Terms

In vitro Fertilisation (IVF) - A process by which an egg is fertilised with a sperm outside the body (in vitro). The fertilized egg (embryo) is then transferred to the woman's uterus.

Intra-cytoplasmic sperm injection (ICSI) - Involves injecting a single sperm directly into an egg in order to fertilise it. The fertilized egg (embryo) is then transferred to the woman's uterus.

Full cycle of IVF/ICSI - "One full cycle" of IVF/ICSI treatment comprises: Ovulation induction, egg retrieval, fertilisation and the transfer of resulting fresh or frozen embryos. It also includes appropriate diagnostic tests, scans and pharmacological therapy.

Frozen embryo transfer - Where an excess of embryos is available following a fresh cycle, these embryos may be frozen for future use. Once thawed, these embryos are transferred to the patient as a frozen cycle.

Abandoned/cancelled cycle of IVF – An abandoned or cancelled cycle is defined as one where an egg collection procedure is not undertaken. If an egg collection procedure is undertaken, it is considered to be a full cycle.

3. Commissioning responsibility

- 3.1.1 Specialist fertility services are considered as Level 3 services or tertiary services. Preliminary Levels 1 and 2 are provided and commissioned within primary care and secondary services such as acute trusts. To access Level 3 services the preliminary investigations should be completed at Level 1 and 2.
- 3.1.2 Specialist fertility treatments within the scope of this policy are,:
- In-vitro fertilisation (IVF) and Intra-cytoplasmic sperm injection (ICSI)
 - Surgical sperm retrieval methods
 - Donor Insemination (DI)
 - Intra Uterine Insemination (IUI) unstimulated
 - Sperm, embryo and male gonadal tissue cryostorage and replacement techniques.
 - Egg donation where no other treatment is available
 - Blood borne viruses (ICSI + sperm washing)
 - Egg and sperm storage for patients undergoing medical treatment that may result in infertility.
- 3.1.3 Treatments excluded from this policy:
- Pre-implantation Genetic Diagnosis and associated IVF/ICSI. This service is commissioned by NHS England
 - Specialist fertility services for members of the Armed Forces are commissioned separately by NHS England
 - Surrogacy
- 3.1.4 Formal IVF commissioning arrangements will support the implementation of this policy including a contract between East and North Herts CCG (ENHCCG) (have delegated responsibility for procurement) and each tertiary centre. Quality standards and clinical governance arrangements will be put in place with these centres and outcomes will be monitored and performance managed in accordance with the Human Fertilisation & Embryology Authority Licensing requirements or any successor organisations.
- 3.1.5 This policy is specifically for those couples who do not have a living child from their current or any previous relationships, regardless of whether the child resides with them. This includes any adopted child within their current or previous relationships; this will apply to adoptions either in or out of the current or previous relationships. Since the aim of treatment is to have a child, those couples who have a child already would not benefit from successful treatment as much as those couples who are currently childless.
- 3.1.6 Couples who do not meet the criteria and consider they have exceptional circumstances should be considered under the Individual Funding Request (IFR) policy of the CCG. All IFR funding queries should be directed to the IFR team of the CCG who may liaise with the central contracting team. Funding of such exceptional cases is the responsibility of the CCG.
- 3.1.7 Couples will be offered a choice of providers that have been commissioned by the CCG.

4. Specialist Fertility services policy and criteria

4.1.1 The CCG only commissions the following fertility techniques regulated by the Human Fertilisation & Embryology Authority (HFEA).

4.2 In-Vitro Fertilisation (IVF)

4.2.1 An IVF procedure includes the stimulation of the women's ovaries to produce eggs which are then placed in a special environment to be fertilised. The fertilised eggs are then transferred to the woman's uterus.

4.2.2 For women aged 23 to 39 years old WECCG will fund 1 fresh cycle and a maximum of 2 frozen embryo transfers providing they have never previously had IVF treatment (NHS or private).

4.2.3 For women age 40-42 years old WECCG will fund a maximum of 2 embryo transfers, including 1 fresh cycle of IVF, or IVF with ICSI, provided the following criteria are met:

- They have never previously had IVF treatment (NHS or private)
- There is no evidence of low ovarian reserve
- There has been a discussion of the additional implications of IVF and pregnancy, specifically in this age range

4.2.4 A full cycle of IVF treatment, with or without intracytoplasmic sperm injection (ICSI), should comprise 1 episode of ovarian stimulation and the transfer of any resultant fresh and frozen embryo(s). This will include the storage of any frozen embryos for 1 year following egg collection. Patients should be advised at the start of treatment that this is the level of service available on the NHS. If they wish to continue storage of any frozen embryos after this period they will need to fund this by themselves or the embryos will no longer be stored.

4.2.5 An embryo transfer is from egg retrieval to transfer to the uterus. The fresh embryo transfer would constitute one such transfer and each subsequent transfer to the uterus of frozen embryos would constitute another transfer.

4.2.6 Embryo transfer strategies:

- For women age 23-39 years only one embryo/blastocyst to be transferred unless no top quality embryo/blastocyst available then no more than 2 embryos to be transferred.
- For women 40-42 years specialist may consider double embryo transfer.

4.2.7 A fresh cycle would be considered completed with the attempt to collect eggs and transfer of a fresh embryo.

4.2.8 If any fertility treatment results in a living child, then the couple will no longer be considered childless and will not be eligible for further NHS funded fertility treatments, including the implantation of any stored embryos. Any costs relating to the continued storage of the embryos beyond the first calendar year of the retrieval date is the responsibility of the couple.

4.2.9 Clinical Indications:

In order to be eligible for treatment couples should have experienced unexplained infertility for three years or more, and been having regular intercourse, or 12 cycles of artificial insemination over a period of 3 years. There is no criterion on time length for couples with a diagnosed cause of infertility – see below:

- (a) Tubal damage, which includes:
 - Bilateral salpingectomy
 - Moderate or severe distortion not amenable to tubal surgery
- (b) Premature Menopause (defined as amenorrhoea for more than 6 months together with a raised FSH >25 and occurring before age 40 years)
- (c) Male factor infertility. Results of semen analysis conducted as part of an initial assessment should be compared with the following World Health Organisation reference values*:
 - semen volume: 1.5 ml or more
 - pH: 7.2 or more
 - sperm concentration: 15 million spermatozoa per ml or more
 - total sperm number: 39 million spermatozoa per ejaculate or more
 - total motility (percentage of progressive motility and non-progressive motility): 40% or more motile or 32% or more with progressive motility
 - vitality: 58% or more live spermatozoa
 - sperm morphology (percentage of normal forms): 4% or more.
- (d) Ovulation problems adequately treated but not successfully treated, that is no successful pregnancy achieved
- (e) Endometriosis where specialist opinion is that IVF is the correct treatment
- (f) Cancer treatment causing infertility necessitating IVF/ICSI (eligibility criteria still apply). (This principle may apply for any treatment causing infertility and an application for prior approval should be submitted to the CCG).

4.3 Surgical Sperm Recovery

- 4.3.1 Surgical sperm retrieval methods included for service provision are testicular sperm extraction (TESE) and percutaneous epididymal sperm aspiration (PESA).
- 4.3.2 Micro surgical sperm recovery is not routinely funded and an application for prior approval should be submitted to the CCG.
- 4.3.3 Sperm recovery techniques outlined in this section are not available to patients who have undergone a vasectomy.

4.4 Donor insemination

- 4.4.1 The use of donor insemination is considered effective in managing fertility problems associated with the following conditions:
 - obstructive azoospermia
 - non-obstructive azoospermia
 - severe deficits in semen quality in couples who do not wish to undergo ICSI.
 - Infectious disease of the male partner (such as HIV)
 - Severe rhesus isoimmunisation
 - Where there is a high risk of transmitting a genetic disorder to the offspring

- 4.4.2 Donor insemination is funded up to a maximum of 6 cycles of Intrauterine Insemination (IUI). (Please see appendix A for number of cycles relevant to CCG)

4.5 Donor semen as part of IVF/ICSI

- 4.5.1 Funded up to same number of cycles of IVF.
- 4.5.2 Donor semen is used for same sex couples as part of IVF/ICSI treatment.

4.6 Intra Uterine Insemination (IUI)

- 4.6.1 NICE guidelines state that unstimulated intrauterine insemination is a treatment option in the following groups as an alternative to vaginal sexual intercourse:
- people who are unable to, or would find it very difficult to, have vaginal intercourse because of a clinically diagnosed physical disability or psychosexual problem who are using partner or donor sperm
 - people with conditions that require specific consideration in relation to methods of conception (for example, after sperm washing where the man is HIV positive)
 - people in same-sex relationships
- 4.6.2 A maximum of 6 cycles of IUI will only be offered if prior approval for funding is obtained from the CCG for one of the above reasons. This is because IUI is less successful than IVF/ICSI and for this reason is not routinely funded as an alternative for IVF/ICSI for those couples with objections to IVF.

4.7 Egg donation where no other treatment is available

- 4.7.1 The patient may be able to provide an egg donor; alternatively they can be placed on the waiting list, until an altruistic donor becomes available. If either of the couple exceeds the age criteria prior to a donor egg becoming available, they will no longer be eligible for treatment.
- 4.7.2 Egg donation will be available to women who have undergone premature ovarian failure (amenorrhoea >6 months and a raised FSH >25) due to an identifiable pathological or iatrogenic cause before the age of 40 years or to avoid transmission of inherited disorders to a child where the couple meet the other eligibility criteria.

4.8 Egg and sperm storage for patients undergoing cancer treatments and other medical treatments that can cause infertility

- 4.8.1 When considering and using cryopreservation for people before starting chemotherapy or radiotherapy that is likely to affect their fertility, follow recommendations in 'The effects of cancer treatment on reproductive functions' (2007).
- 4.8.2 When using cryopreservation to preserve fertility in people diagnosed with cancer, use sperm, embryos or oocytes.

- 4.8.3 Offer sperm cryopreservation to men and adolescent boys who are preparing for medical treatment that is likely to make them infertile.
- 4.8.4 Local protocols should exist to ensure that health professionals are aware of the values of semen cryostorage in these circumstances, so that they deal with the situation sensitively and effectively.
- 4.8.5 Offer oocyte or embryo cryopreservation as appropriate to women of reproductive age (including adolescent girls) who are preparing for medical treatment for cancer / other conditions that is likely to make them infertile if:
- they are well enough to undergo ovarian stimulation and egg collection and
 - this will not worsen their condition and
 - enough time is available before the start of their cancer treatment.
- 4.8.6 Cryopreserved material will be stored for an initial period of 10 years or up to the age of eligibility for fertility treatment stated within this policy, whichever is soonest. After this period a further request for funding should be submitted if storage is still required and the patient still meets the eligibility of this policy.
- 4.8.7 Following cancer treatment, couples seeking fertility treatment must meet the defined eligibility criteria.

Please note that these principles may apply to patients undergoing any treatment likely to affect fertility and an application for prior approval should be submitted to the CCG for funding of egg and sperm storage in such instances.

4.9 Pre-implantation Genetic Diagnosis (PGD)

- 4.9.1 This policy does not include pre-implantation genetic screening as it is not considered to be within the scope of fertility treatment. This service is commissioned by NHS England. Providers should seek approval from Specialist Commissioning at NHS England.

4.10 Chronic Viral Infections

- 4.10.1 The need to prevent the transmission of chronic viral infections, during conception, such as HIV, hepatitis C etc. requires the use of ICSI technology.
- 4.10.2 As per NICE guidance (section 1.3.9) - Sperm washing is not offered as part of fertility treatment for men with hepatitis B.
- 4.10.3 ICSI for this purpose may not be a fertility treatment, but should be considered as a risk reduction measure for a couple who wish to have a child, but do not want to risk the transmission of a serious pre-existing viral condition to the woman and any subsequent embryo.

4.11 Privately funded care

- 4.11.1 This policy covers NHS funded fertility treatment only. For clarity, patients will not be able to pay for any part of the treatment within a cycle of NHS fertility treatment. This includes, but is

not limited to, any drugs (including drugs prescribed by the couple's GP), recommended treatment that is outside the scope of the service specification agreed with the secondary or tertiary provider or experimental treatments.

- 4.11.2 Where a patient meets this eligibility criterion but agrees to commence treatment on a privately funded basis, they may not retrospectively apply for any associated payment relating to the private treatment.

4.12 Surrogacy

- 4.12.1 Surrogacy is not commissioned as part of this policy. This includes part funding during a surrogacy cycle.

5 Referrals

- 5.1 Couples who experience problems with their fertility must attend their GP practice to discuss their concerns and options. The couple will be assessed within the primary and secondary care setting.
- 5.2 A decision to refer a couple for IVF or other fertility services will be based on an assessment against the eligibility criteria in this policy which is based on the NICE guidelines and the HFEA recommendations as detailed in the clinical pathways.
- 5.3 Referral to the tertiary centre must be via a consultant gynecologist.

Appendix A

Detailed Access Criteria

No	Criterion	Description
1	Ovarian Reserve Testing, use one of the following: <ul style="list-style-type: none">FSH	To be eligible, the patient should have an FSH within 3 months of referral and on day 2 of the menstrual cycle of <9.
2	Maternal age	<p>Women aged 23 to 39 years old may be entitled to 1 cycle of IVF where they satisfy to the criteria of this policy and have never had any private or NHS funded IVF treatment.</p> <p>Women aged between 40-42 may be entitled to 1 cycle of IVF where:</p> <ul style="list-style-type: none">They have never previously had private or NHS funded IVF treatmentThere is no evidence of low ovarian reserveThere has been a discussion of the additional implications of IVF and pregnancy at this stage
3	Paternal Age	West Essex CCG retains a maximum paternal age threshold of 55 years because there is evidence (see NICE CG156) that male fertility decreases with age.
4	Minimum / Maximum BMI	<p>Between at least 19 and up to 30 for female and less than 35 for male. Patients outside of this range will not be added to the waiting list and should be referred back to their referring clinician and/or general practitioner for management if required.</p> <p>NICE CG156 advises that female and male fertility is reduced in BMI >30. NICE advise that female BMI should ideally be in the range 19–30 before commencing assisted reproduction, and that a female BMI outside this range is likely to reduce the success of assisted reproduction procedures.</p>
5	Duration of sub-fertility	Unexplained infertility for 3 years or more of regular intercourse or an equivalent 12 self-funded cycles of artificial insemination over a period of 3 years. There is no criterion for cases with a diagnosed cause of infertility.
6	Previous Fertility treatment for Women <40 years	<p>West Essex CCG funds up to maximum of 3 embryo transfers, with a maximum of 1 fresh cycle of assisted conception (IVF or IVF with ICSI if required and including sperm retrieval where indicated).</p> <p>Previous privately or NHS funded cycles will count towards the total number of fresh cycles funded by the NHS</p>

7	Previous fertility treatment for women ≥40 years	<p>West Essex CCG will fund up to maximum of 2 embryo transfers, including a maximum of 1 fresh cycle of IVF, or IVF with ICSI.</p> <p>Previous privately or NHS funded cycles will count towards the total number of fresh cycles funded by the NHS</p>
8	Smoking Status	<p>Couples who smoke will not be eligible for NHS-funded specialist assisted reproduction assessment or treatment because NICE CG156 advises that smoking adversely impacts on the success rates of assisted reproduction procedures. Couples should be informed of this criterion at the earliest possible opportunity in their progress through infertility investigations in primary care and secondary care.</p> <p>Couples presenting with fertility problems in primary care should be provided with information about the impact of smoking on their ability to conceive naturally, the adverse health impacts of possible smoking on any children and smoking cessation support should be provided as necessary.</p> <p>Both partners must be non-smoking at the time of referral from secondary care to specialist IVF services and maintained during treatment. Smoking status should be ascertained by carbon monoxide testing in secondary care and specialist IVF services.</p>
9	Parental Status	<p>Couples are ineligible for treatment if there are any living children from the current or any previous relationships, regardless of whether the child resides with them. This includes any adopted child within their current or previous relationships; this will apply to adoptions either in or out of the current or previous relationships.</p> <p>The policy restricts access to treatment to those couples without any living children because limited financial resources require that the CCG prioritises those likely to gain more benefit from treatment. Since the aim of treatment is to have a child, those couples who have a child already would not benefit from successful treatment as much as those couples who are currently childless.</p>
10	Previous sterilisation	Ineligible if previous sterilisation has taken place (male or female), even if it has been reversed.
11	Child Welfare	Providers must meet the statutory requirements to ensure the welfare of the child. This includes HFEA's Code of Practice which considers the 'welfare of the child which may be born' and takes into account the importance of a stable and supportive environment for children as well as the pre-existing health status of the parents.

12	Medical Conditions	Treatment may be denied on other medical grounds not explicitly covered in this document.
13	Residential Status	The couple should either be registered with a GP within the West Essex CCG footprint for 12+ months, or if their GP registration is less than 12 months, they can be eligible if they can demonstrate residency of 12+ months in the West Essex CCG footprint.
14	The cause of Infertility	<p>In order to be eligible for treatment couples should have experienced unexplained infertility for three years or more of regular intercourse or 12 cycles of artificial insemination over a period of 3 years. There is no time length criterion for couples with a diagnosed cause of infertility – see below:</p> <ul style="list-style-type: none"> (a) Tubal damage, which includes: <ul style="list-style-type: none"> • Bilateral salpingectomy • Moderate or severe distortion not amenable to tubal surgery (b) Premature Menopause- amenorrhoea >6m and FSH >25 and aged <40 (c) Male factor infertility (d) Ovulation problems adequately treated but not successfully treated ie. no successful pregnancy achieved (e) Endometriosis where specialist opinion is that IVF is the correct treatment (f) Cancer treatment causing infertility necessitating IVF/ICSI (eligibility criteria still apply) (This principle may apply for any treatment causing infertility and an application for prior approval should be submitted to the CCG).
15	The minimum investigations required prior to referral to the tertiary centre are:	<p>Female:</p> <ul style="list-style-type: none"> • Laparoscopy and/or hysteroscopy and/or hysterosalpingogram or ultrasound scan where appropriate • Rubella antibodies • Day 2 FSH. • Chlamydia screening • Hepatitis B including core antibodies and hepatitis C and HIV status and core, within the last 3 months of treatment and repeated every 2 years. <p>Male:</p> <ul style="list-style-type: none"> • Preliminary semen analysis and appropriate investigations where abnormal (including genetics) • Hepatitis B including core antibodies and Hepatitis C, within the last 3 months and repeated after 2 years. • HIV status

16	Pre-implantation Genetic Diagnosis	PGD and associated specialist fertility treatment is the commissioning responsibility of NHS England and is excluded from the CCG commissioned service.
17	Rubella Status	The woman must be rubella immune
18	IUI (Unstimulated)	As per NICE guidance 2013. Maximum of 6 cycles of IUI will only be offered if prior approval for funding is obtained from the CCG. IUI is less successful than IVF/ICSI and for this reason is not routinely funded as an alternative for IVF/ICSI for those couples with religious/belief objections to IVF.
19	Number of cycles of IVF	Women aged 23-39 years old - 1 full cycle as long as they have had no previous private or NHS cycles of IVF. Women 40-42 years old -1 full cycle as long as they have never previously had private or NHS funded IVF treatment, there is no evidence of low ovarian reserve and there has been a discussion of the additional implications of IVF and pregnancy at this age.