

**Hertfordshire and West Essex STP**

**Fertility treatment and referral criteria  
for tertiary level assisted conception**

**September 2019**

## DOCUMENT CONTROL SHEET

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**Effective Date:** TBC

### Change History:

Version	Date	Reviewer(s)	Revision Description
V3	22.11.17	Raj Nagaraj, Rachel Joyce, Geraldine Woods, Jan Ashcroft	Revised policy based on the current policy. Key changes are; Section 4.2.2 – AMH level of more than 5.4mol/l measured in the last 12 months Section 4.2.3 – ENHCCG supports a maximum of 1 fresh cycle of IVF (with or without ICSI) and a maximum of 2 embryo transfer cycle one fresh and one frozen
V3.1	29.11.17	Rebecca Cornish	Amending typos and formatting document.
	November 2017	Raj Nagaraj	Final changes made to wording
	November 2017	Medical Director approved policy	
	7.12.17	Governing Body approved policy	

	4.1.18	Secondary to tertiary referral form updated	<p>should have an AMH level of more than 5.4pmol/l within 12 months of referral from secondary care to the specialist IVF provider</p> <p>Or</p> <p>should have an FSH of &lt;9IU/L on day two of any menstrual cycle done within three months of referral from secondary care to a specialist IVF provider</p>
V4	Jan 19	Linda Mercy, Jo Oliver, Jan Ashcroft	<p>Policy wording updated to make criteria clearer to read. Amending typos.</p> <p>Definition of male factor infertility</p>
V4.1	June 2019	Miranda Sutters	<p>a. Rebranding and merging of Herts Valley CCG and west Essex CCG specialist fertility policy with East and North Herts CCG policy document.</p> <p>b. Change of threshold criteria as follows:</p> <p>1. BMI:</p> <p>Men's BMI to change from 35 to 30.</p> <p>Rationale</p> <p>NICE guidelines [CG156] states: Men who have a BMI of 30 or over should be informed that they are likely to have reduced fertility.</p> <p>2. AMH:</p> <p>For HVCCG and ENHCCG AMH level should be tested within three months of referred into a specialist fertility provider.</p> <p>Rationale</p> <p>The evidence supports the proposal of decreasing the AMH time frame to within 3 months.</p>

			<p>All studies measuring AMH levels In the context of IVF, had AMH measured within 3 months, and the majority of these were within 28 days of COH (controlled ovarian hyperstimulation) (2, 3, 4). This suggests that it would be reasonable to have a 3 month limit on AMH levels, as we do not have evidence that outside this 3 month window, how AMH levels can change or if this affects IVF results.</p> <p>The previous 12 month Time frame is not supported by evidence, as there are no high quality papers that measure AMH levels outside a 3 month window for the purposes of IVF.</p> <p>3. IUI (unstimulated):</p> <p>For HVCCG same-sex couples are entitled to IVF treatment on the NHS following 6 cycles of self-funded IUI and 6 cycles of NHS funded unstimulated IUI, an increase from the current 2 cycles currently funded.</p> <p>Rationale For heterosexual couples they must have had three years sub fertility before they could be eligible for specialist fertility treatment. Funding for same-sex couples should be reflect the time period heterosexual couples should be experiencing sub fertility.</p> <p>4. Previous Fertility Treatment:</p> <p>For ENHCCG: Previous privately or NHS funded cycles and embryo transfers will count towards the total number of fresh cycles and embryo transfers funded by the NHS. Therefore anyone who has had specialist fertility treatment is not eligible for NHS funding. This is a change from the current policy which stipulates:</p>
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			<p>For those couples who have previously self-funded, ENHCCG will fund one more cycle of IVF as per 4.2.3 unless they have already received the NICE recommended 3 cycles of IVF treatment. For couples who have had previous NHS funded IVF treatment will not be entitled to further NHS treatment.</p> <p>Where couples have frozen embryos from previous private treatment they must first utilise these embryos rather than undergo ovarian stimulation, egg retrieval and fertilisation again.</p> <p><b>Rationale:</b></p> <p>Overall chance of a live birth following IVF treatment falls as the number of unsuccessful cycle's increases.</p> <p>5. Parental Age</p> <p>For WECCG the upper age limit of 55 years for male partners has been removed as there was insufficient evidence to support this particular age to be a cut-off.</p> <p>Rationale: Female age is known to be the dominant factor in predicting a couple's chance of conception, but are limited studies that have explored the impact of male age. While the age of the male partner had no effect on IVF success in women aged 40-42, it had a significant influence in younger women. For example, couples where the woman was under 30 and the man aged 40-42 had a 46 % chance of having a baby through IVF, compared with a 73 percent chance if the man was aged 30-35.</p>
V4.2	September 2019	Linda Mercy Public Health Consultant	Final changes agreed by Governing Body

### Implementation Plan:

<b>Development and Consultation</b>	East and North Herts CCG, HERTS Valleys CCG and west Essex CCG conducted a 10 week (6 <sup>th</sup> July – 14 <sup>th</sup> September 2017) public consultation programme called 'Let's talk' which included this issue. Engagement activities included: public meetings in all localities; discussions with local community groups and young people; attendance at community events including Herts Pride and places with high public footfall; promotion via local media; a major social media campaign – primarily via Twitter and Facebook; and sessions in GP practices. In total 2,500 people responded to the survey and thousands more have had access to the consultation information as a whole.
<b>Dissemination</b>	To community, secondary and tertiary providers To other key stakeholders such as GP practices
<b>Training</b>	n/a
<b>Monitoring</b>	Through contract, prior approval and IFR data
<b>Review</b>	TBC
<b>Equality, Diversity and Privacy</b>	October 2017 - Equality Impact Assessment
<b>Associated Documents</b>	Referral forms – Appendix 1 and 2
<b>References</b>	Link to Joint Committee Papers, which includes the EIA.  <a href="https://healthierfuture.org.uk/sites/default/files/publications/2017/October/Joint-Committee-Papers-v1.pdf">https://healthierfuture.org.uk/sites/default/files/publications/2017/October/Joint-Committee-Papers-v1.pdf</a>

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## **Key Terms**

**In vitro Fertilisation (IVF):** 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 (embryos) are 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 fertilised egg (embryo) is then transferred to the woman's uterus.

**Full cycle of IVF/ICSI:** A full cycle of IVF treatment, with or without intracytoplasmic sperm injection, should comprise of one episode of ovarian stimulation, uterine transfer of resultant fresh embryo(s) and storage of viable embryos.

An IVF cycle would be considered completed with the attempt to collect eggs and transfer of a fresh embryo and freezing of viable non-transferred embryos. Patients should be advised at the start of treatment that this is the level of service available on the NHS and following this period continued storage will need to be funded by them or allowed to perish.

**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 transfer.

**Abandoned/cancelled cycle of IVF:** an abandoned or cancelled cycle is defined as one where an egg collection procedure is not undertaken.

**Male Factor Infertility:** Is defined into two groups.

1. Mild male factor infertility (or subfertility) in accordance with NICEcg156 is defined as when two or more semen analyses have 1 or more variables below the 5th centile (as defined by the World Health Organization [WHO], 2010). The effect on the chance of pregnancy occurring naturally through vaginal intercourse would then be similar to people with unexplained infertility or mild endometriosis.

2. Severe male factor infertility (a total motile sperm number  $< 0.5 \times 10^6$ ) which has been fully investigated by local fertility consultant to rule out any underlying treatable cause and precludes any possibility of natural conception i.e. Absolute infertility. See section 4.3.1.

## Policy Summary

No.	Criterion	Description
1.	<b>Test for ovarian reserve using Anti-Müllerian Hormone (AMH) level</b>	<p>AMH is the preferred test for ovarian reserve. To be eligible, the patient should have; AMH levels of more than 5.4pmol/l measured in the last 3 months of referral from secondary care to the specialist IVF provider or</p> <p>If any investigations are out of date at the point of referral it is the responsibility of the secondary care provider to repeat these tests.</p>
2.	<b>Maternal age, number of cycles and embryo transfers</b>	<p>For women aged 23 to less than 43 years from the date of referral from secondary care to specialist IVF provider with funding prior approved; Funding will be valid for 12 months or for women over the age of 42 funding will be valid until their 43<sup>rd</sup> birthday.</p> <p>The CCG will fund one full cycle of IVF with a maximum of two embryo transfers with or without ICSI (either one fresh and one frozen or two frozen if a fresh embryo transfer was not initially possible). This includes any abandoned IVF cycles and no further IVF cycles will be funded. All frozen embryos should be used before a new fresh cycle is funded.</p>
3.	<b>Number of embryos placed into the uterus during each embryo transfer.</b>	<p>Women aged 23 to 37 years – A single embryo will be placed into the uterus during each embryo transfer.</p> <p>Women aged 37-39 – A single embryo will be placed into the uterus during each embryo transfer if there are 1 or more top-quality embryos. If there are no top-quality embryos then a double embryo transfer can be considered.</p> <p>Women aged 40 to less than 43 years – Up to two embryos may be placed into the uterus during each embryo transfer.</p> <p>See section 4.2.3</p>
3.	<b>Previous specialist Fertility treatment</b>	<p>Previous privately or NHS funded specialist fertility treatment including IVF cycles and embryo transfers will count towards the total number of fresh cycles and embryo transfers or other specialist fertility treatment funded by the NHS. Therefore anyone who has had IVF treatment or other specialist fertility treatment covered in this policy is not eligible for NHS funding.</p> <p>To ensure equality of access between two genders, if a male partner in the relationship has received the full entitlement of specialist fertility treatment (as per CCG policy) for his infertility either in current relationship or previous relationship, the couple are not eligible for additional treatment.</p>
4.	<b>Paternal age</b>	<p><b>Age-</b> None specified.</p>

5.	<b>Minimum / Maximum BMI</b>	<p>Women must have a BMI of between at least 19 and up to 30 and men must have a BMI of less than 30. 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 weight management, advice and support if required.</p> <p>In female same sex couples, BMI criteria should only apply to the partner undergoing fertility treatment.</p>
6.	<b>Duration of sub-fertility</b>	<p>Couples with unexplained infertility or mild male factor infertility/subfertility must have infertility of at least three years of ovulatory cycles, despite regular unprotected vaginal sexual intercourse.</p> <p>Where mild male factor infertility has been diagnosed evidence should be provided to demonstrate that any underlying treatable cause has been investigated and ruled out.</p> <p>Couples who have had 12 cycles of unsuccessful IUI in line with section 4.7.1</p> <p>If the woman has a miscarriage, the couple will wait for a further 3 years of unexplained infertility from the date of the miscarriage to be eligible for NHS funded IVF.</p> <p>Couples with unexplained infertility should be referred from primary care after 12 months expectant management.</p> <p>Couples with a diagnosed cause of absolute infertility which precludes any possibility of natural conception, and who meet all the other eligibility criteria, will have immediate access to NHS funded assisted reproduction services. See section 4.3</p>
7.	<b>Smoking Status</b>	<p>Couples who smoke will not be eligible for NHS-funded specialist assisted reproduction assessment or treatment, and 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 passive 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 to the tertiary provider, IVF treatment starting and maintained during treatment. This applies equally for same-sex couples as passive smoking may affect the fertility of the partner undergoing fertility treatment.</p> <p>Smoking status should be ascertained by carbon monoxide testing from Stop Smoking Service prior to IVF treatment starting.</p>
8.	<b>Parental Status</b>	<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>
9.	<b>Previous sterilisation</b>	<p>Couples are ineligible if previous sterilisation has taken place (either partner), even if it has been reversed.</p>

10.	<b>Child Welfare</b>	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.
11.	<b>Medical Conditions</b>	Treatment may be denied on other medical grounds not explicitly covered in this document.
12.	<b>Residential status</b>	The couple should either be registered with a GP in the CCG area 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 CCG area they are currently residing.
13.	<b>The minimum investigations required prior to referral from secondary care to the tertiary centre</b>	<p>Female:</p> <ul style="list-style-type: none"> <li>• Laparoscopy and/or hysteroscopy and/or hysterosalpingogram or ultrasound scan where appropriate</li> <li>• Rubella antibodies</li> <li>• Chlamydia screening</li> <li>• Hep B including core antibodies and Hep C and HIV status and core, within the last 3 months of treatment and repeated every 2 years.</li> </ul> <p>Male:</p> <ul style="list-style-type: none"> <li>• Preliminary Semen Analysis and appropriate investigations and management where abnormal (including genetics)</li> <li>• Hep B including core antibodies and Hep C, within the last 3 months and repeated after 2 years</li> <li>• HIV status</li> </ul> <p>If any investigations are out of date at the point of referral (after funding has been approved) it is the responsibility of the secondary care provider to repeat these tests.</p>
14.	<b>Pre-implantation Genetic Diagnosis</b>	PGD and associated specialist fertility treatment is the commissioning responsibility of NHS England and is excluded from the CCG commissioned service.
15.	<b>Rubella Status</b>	The woman must be rubella immune.
16.	<b>IUI (Unstimulated)</b>	Due to poor clinical evidence of effectiveness, NHS funding for IUI will only be offered under exceptional circumstances and once the couple have self-funded 6 cycles. An Individual Funding Request will be required. See section 4.7.
17.	<b>Date of eligibility</b>	Eligibility for treatment commences on the date that the secondary care provider refers the patients to the IVF specialist provider with funding prior approved.
18	<b>Length of funding validation</b>	<p>Couples must complete their cycle within 12 months of funding being agreed. An extension of this period will only be considered in exceptional clinical circumstances and with prior agreement from the Individual Funding request team.</p> <p>For patients that are over the age of 42 years at the point of referral into a specialist fertility provider, funding will only be valid until their 43<sup>rd</sup> birthday.</p>

## **1. Introduction**

1.1 This Commissioning Policy sets out the criteria for access to NHS funded specialist fertility services for the population of Hertfordshire and west Essex CCGs.

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.

The paper specifically sets out the entitlement and service that will be provided by the NHS for IVF and other specialist fertility treatments. These services are commissioned by Clinical Commissioning Groups and provided via tertiary care providers.

## **2. Commissioning responsibility**

2.1 Specialist fertility services are considered as level 3 services or tertiary services. Preliminary levels 1 & 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 levels 1 & 2.

2.2 Specialist Fertility Treatments within the scope of this policy are:

- In-vitro fertilisation and Intra-cytoplasmic sperm injection (IVF & ICSI)
- 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)

2.3 Treatments excluded from this policy:

- Pre-implantation Genetic Diagnosis (PGD) 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.
- Specialised surgical sperm retrieval – This is commissioned by NHS England

2.4 Formal IVF commissioning arrangements will support the implementation of this policy including a contract between Hertfordshire and west Essex CCGs 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.

- 2.5 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.

- 2.6 Where couples do not meet the criteria however their clinician feels they have exceptional circumstances the clinician can make an application for exceptional funding to the relevant CCG's Individual Funding Request (IFR) Team. All applications will be assessed in line with the relevant CCG's IFR policy and funding of any exceptional cases is the responsibility of the CCG.
- 2.7 Couples will be offered a choice of providers that have been commissioned by Hertfordshire and west Essex CCGs.

### **3. Review**

The next revision to the policy will be undertaken following a change in national policy or after two years of its ratification.

### **4. Specialist fertility services criteria**

- 4.1 The CCGs only commissions the following fertility techniques recommended by NICE and regulated by the Human Fertilisation & Embryology Authority (HFEA).

#### **4.2 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 Ovarian reserve; to be eligible for IVF the patient should have an AMH level of more than 5.4pmol/l measured in the last 3 months of referral from secondary care to the specialist IVF provider. AMH should be the preferred test for ovarian reserve.

- 4.2.3 For women aged 23 to less than 43 years at the start of treatment, the CCG will fund one cycle of IVF with a maximum of two embryo transfers with or without ICSI (either one fresh and one frozen or two frozen if a fresh embryo transfer was not initially possible). This includes any abandoned IVF cycles.

For women aged 40 to less than 43 years the following criteria will need to be met

- They have never previously had IVF treatment
- There is no evidence of low ovarian reserve
- There has been a discussion of the additional implications of IVF and pregnancy at this age.

Funding is valid for 12 months or for women over the age of 42 until their 43<sup>rd</sup> birthday.

#### **4.2.4 Embryo transfer strategies - Number of embryos to be transferred**

Women aged 23 to 37 years – A single embryo will be placed into the uterus during each embryo transfer.

Women aged 37-39 – A single embryo will be placed into the uterus during each embryo transfer if there are 1 or more top-quality embryos. If there are no top-quality embryos then a double embryo transfer can be considered.

Women aged 40 to less than 43 years – Consider double embryo transfers

4.2.5 Hertfordshire and west Essex CCGs will fund storage of frozen embryos for 1 year following egg collection. Following this period, continued storage will need to be funded by the couple.

4.2.6 If a full IVF cycle is commenced and initial ovarian response is poor, a clinical decision would need to be taken as to whether a further treatment should be attempted, or if the use of a self-funded donor egg may be considered as part of further treatment. If a donor egg is required the couple must self-source and self-fund this (see section 4.9).

4.2.7 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.

4.2.8 Further details of lifestyle and social criteria are summarised in the policy summary table.

### **4.3 Clinical Indications**

4.3.1 In order to be eligible for IVF treatment, service users should have experienced unexplained or mild male factor infertility or subfertility for three years or more of regular vaginal intercourse or 12 cycles of intrauterine insemination over a period of 3 years.

Mild male factor infertility or subfertility can be defined in line with NICEcg156 as; when 2 or more semen analyses have 1 or more variables below the 5th centile (as defined by the World Health Organization [WHO], 2010). The effect on the chance of pregnancy occurring naturally through vaginal intercourse would then be similar to people with unexplained infertility.

There is no 3 year wait for couples with a diagnosed cause of infertility as below:

- (a) Tubal damage, which includes:
  - Bilateral salpingectomy
  - Moderate or severe distortion not amenable to tubal surgery.  
Evidence shows that for women with moderate or severe tubal damage tubal surgery solely for the purpose of fertility is not recommended, although tubal surgery itself may be part of the management plan for the condition causing the tubal damage.
- (b) Premature Menopause (defined as amenorrhoea for a period of more than 6 months together with a raised FSH >25 and occurring before the age of 40 years).
- (c) Azoospermia
- (d) Severe Male factor infertility which has been investigated to rule out any underlying treatable cause and precludes any possibility of natural conception. Results of semen analysis conducted as part of an initial assessment should be compared with the following World Health Organization 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
- (e) Ovulation problems adequately treated but not successfully treated i.e. no pregnancy achieved.
- (f) Severe Endometriosis where specialist opinion is that IVF is the appropriate treatment (eligibility criteria still apply).
- (g) Essential medical treatment causing infertility as a side effect necessitating IVF/ICSI e.g. chemotherapy for cancer. (Eligibility criteria still apply). See individual CCG policy.

#### **4.4 Surgical Sperm Retrieval for male infertility**

- 4.4.1** Surgical sperm retrieval for male infertility is the commissioning responsibility of NHS England and is excluded from the CCG commissioned service.

## **4.5 Donor insemination**

**4.5.1** 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

**4.5.2** Donor insemination is funded up to a maximum of 6 cycles of Intrauterine Insemination in exceptional circumstances. See section 4.7.

## **4.6 Donor semen as part of IVF/ICSI**

**4.6.1** One cycle of IVF is funded with the use of donor sperm. However, patients are expected to self-source and self-fund the donor semen, storage and transport. The CCG do not hold any responsibility for the quality and genetics of donor semen.

**4.6.2** Donor semen is used for same sex couples as part of IVF/ICSI treatment.

## **4.7 Intra Uterine Insemination (unstimulated)**

**4.7.1** Due to poor clinical evidence of effectiveness, NHS funding for unstimulated IUI will only be offered under exceptional circumstances supported by an Individual Funding Request (IFR). NICE guidelines state that unstimulated intrauterine insemination (IUI) is a treatment option as an alternative to vaginal sexual intercourse in the following groups:

- 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 self-funded 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 relationship. See section 4.8.

**4.7.2** A maximum of 6 cycles of unstimulated IUI will only be offered if prior approval for funding is obtained from the CCG and the couple have previously self-funded 6 cycles. This is because unstimulated IUI is less successful than IVF/ICSI and for this reason it is not routinely funded as an alternative for IVF/ICSI for those couples with objections to IVF.

#### **4.8 Same sex couples**

- Same-sex couples are entitled to IVF treatment on the NHS following 6 cycles of self-funded IUI and a maximum of 6 cycles of NHS funded unstimulated IUI which will only be offered if prior approval for funding is obtained from the CCG.
- Both partners must be non-smoking at the time of referral
- BMI eligibility criteria above apply only to the female partner undergoing fertility treatment
- The couple must meet all the other relevant eligibility criteria.
- Couples with a diagnosed cause of absolute infertility which precludes any possibility of natural conception, and who meet the other eligibility criteria, will have immediate access to NHS funded assisted reproduction services.

#### **4.9 Egg donation where no other treatment is available**

4.9.1 The couple are expected to self-source and self-fund an egg donor. Alternatively, they may choose to be placed on a waiting list until an altruistic donor becomes available. The CCG do not hold any responsibility for the quality and genetics of donor eggs. When funding has been approved it is valid for 12 months only, this should be taken in consideration when sourcing a donor.

4.9.2 IVF using self-funded donor egg will be available to women who have undergone premature ovarian failure (defined as 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 all of the other eligibility criteria.

#### **4.10 Egg and Sperm storage for patients undergoing essential treatments which might render them infertile**

This is covered in separate CCG policies.

#### **4.11 Pre-implantation Genetic Diagnosis (PGD)**

4.11.1 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 the Specialist Commissioning team at NHS England.

#### **4.12 Chronic Viral Infections**

4.12.1 Patients with chronic viral infections who are eligible for IVF treatment should be referred to one of Hertfordshire or west Essex CCG commissioned IVF specialist providers who have the appropriate processing facilities to accommodate these patients.

4.12.2 Sperm washing without IVF can be offered to couples with chronic viral infection (Hep C and HIV) as a risk reduction measure to prevent further transmission of infection to the partner and unborn child.

4.12.3 The need to prevent the transmission of chronic viral infections, during conception, such as HIV, Hep C etc. requires the use of ICSI technology.

4.12.4 As per NICE guidance, the CCG do not offer sperm washing as part of fertility treatment for men with hepatitis B.

#### **4.13 Privately funded care**

4.13.1 This policy covers NHS funded fertility treatment only. For clarity, other than for egg and sperm donation, patients will not be able to pay for any treatment which cannot be separated from what is included in the NHS funded package.

Further information and guidance on the provision of 'top-up' private fertility services can be found at the following link <http://www.enhertsccg.nhs.uk/ivf>

4.13.2 Patients who meet the eligibility criteria but agree to commence treatment on a privately funded basis cannot retrospectively apply for NHS funding for any associated costs relating to the private treatment.

#### **4.14 Surrogacy**

4.14.1 Surrogacy and any associated treatment is not commissioned by Hertfordshire or west Essex CCGs. This includes part funding during a surrogacy cycle.

Our policy on NHS funding for Surrogacy can be found at the following link <http://www.enhertsccg.nhs.uk/ccg-guidance-and-policies-final>

### **5. Referrals**

5.1 Couples who experience problems with their fertility will attend their GP practice to discuss their concerns and options. The patients will be assessed within the Primary care in the first instance and then referred to the community provider or Secondary Care setting using the referral form in Appendix 1.

5.2 After assessment in community provider/Secondary Care the decision to refer a couple for IVF or other fertility services will be based on an assessment against the eligibility criteria in this policy and a request for funding made with the relevant CCG in line with their Individual Funding Request and Prior Approval Policy.

5.3 After funding has been approved, referral to the tertiary centre will be via a consultant gynaecologist or an accredited GP with Special Interest (GPwSI) in gynaecology using the referral form in Appendix 2.

**Appendix 1 - Specialist Fertility Funding Request Form**

**Referral for Fertility Assessment**

**This form is for referring patients from primary care to secondary care for fertility assessment.**

If you are referring for consideration of the following fertility treatments please read the eligibility criteria in the Fertility Treatment policy [www.enhertsccg.nhs.uk/ivf](http://www.enhertsccg.nhs.uk/ivf) prior to referral; In-vitro fertilisation (IVF), Intrauterine Insemination (IUI), Donor Insemination (DI) and Oocyte Donation (OD).

Couples who do not meet the policy eligibility criteria and who are considered to have exceptional clinical circumstances can have an Individual Funding Request submitted by a clinician. The IFR form can be found at <http://www.enhertsccg.nhs.uk/ifr>

Patient Information			
<b>Name:</b>			
<b>Address:</b>		<b>DOB:</b>	
		<b>NHS No:</b>	
		<b>Home Tel No:</b>	
		<b>Mobile Tel No:</b>	
<b>GP Surgery</b>		<b>GP Tel no. and email address</b>	
<b>Length of time registered at this surgery</b>			

Partner Information			
<b>Name:</b>			
<b>Address:</b>		<b>DOB:</b>	
		<b>NHS No:</b>	
		<b>Home Tel No:</b>	
		<b>Mobile Tel No:</b>	
<b>GP surgery</b>		<b>GP tel no. and email address</b>	
<b>Length of time registered at this surgery</b>			

**To be completed by GP prior to referral to secondary care**

Initial Lifestyle advice	Tick
Provide patient information on conception rates and reassurance	
Consider referral to smoking cessation and weight management	
Advise on alcohol intake and recreation drug use	
Recommend folic acid supplementation	
Other lifestyle advice (tight underwear, occupation)	
GP registered or residency in CCG area for at least 12 months	
Establish by direct questioning to both parents if there is any reason due to past medical or social history of either partner, which may be of concern with regard to the welfare of the unborn child? ( <i>this includes history of social care, crime against a child</i> ) <i>Answer yes/no. If the answer is 'Yes', but you still wish to refer the couple, please provide full details of any relevant concerns or extenuating circumstances</i>	
The couple have been unable to conceive despite trying for at least 1 year or 6 cycles of artificial insemination	

Investigations	Date
<b>Female</b>	
Regular menstrual cycle	<input type="checkbox"/> YES <input type="checkbox"/> NO
Serum FSH Level (Day 1-3)	
Serum LH Level (Day 8)	
Serum Progesterone at mid-luteal:	
Serum Prolactin:	
Serum Testosterone	
<b>Male</b>	
Semen Analysis: (if abnormal repeat in 6 weeks)	
Count	
Motility	
Morphology	

**Other investigations (if previous result available):**

Investigations	Date	Results
Tubal Surgery		
Laparoscopy & Dye		
Hysteroscopy		
Hysterosalpingogram		
Ultrasound		

Screening				
Test	Female		Male	
	Date	Result	Date	Result
Chlamydia Screening				
Rubella				
Cervical Smear				

**Pregnancy history/child:**

Comments i.e. previous pregnancy including outcomes, child, adoption, miscarriage, TOP etc	
Female patient	
Partner	

Any other relevant information, e.g. allergies, medical history requiring pre-conceptual care i.e. diabetes, epilepsy, genetic conditions and others.  
Provide full details and confirm that referral for pre-conceptual care has occurred.

- Assess and manage ovulation disorders appropriately and consider referral to secondary care at this stage
- Refer to secondary care for further investigations for suspected uterine and tubal abnormalities
- Refer for unexplained infertility if all hormonal profile and semen analysis normal
- This completed form should be sent with your referral.

Referrer Information		
Sign and print name		
Base		Tel No:
Date form completed:		

**Prior funding approval is not required at this stage.**

If you have any questions around the Fertility policy please contact the Clinical Funding Team on 01707 685354 or email [priorapproval.hertfordshire@nhs.net](mailto:priorapproval.hertfordshire@nhs.net)

**Appendix 2 - Assisted Conception – Secondary Care Consultant Referral to Specialist Provider for IVF treatment**

**Request for Funding  
Assisted Conception –Specialist fertility treatment**

All referrals from secondary care or community gynaecology services must have funding prior approved before the referral is made to one of the locally commissioned specialist fertility services.

Please securely email the completed pages 1 – 4 of this form to [priorapproval.hertfordshire@nhs.net](mailto:priorapproval.hertfordshire@nhs.net) and attach electronic copies of any relevant correspondence or clinical letters/reports.

Once funding is approved refer the patient to their chosen provider and include ALL pages of this form. If you have any questions the Clinical Funding Team can be contacted on 01707 685354.

Couples who do not meet the CCG Assisted Conception Policy eligibility criteria and who are considered to have exceptional clinical circumstances can have an Individual Funding Request submitted by a clinician. The IFR form can be found at <http://www.enhertsccg.nhs.uk/ifr>

<b>Patient consent to share data</b>		<i>Mark as appropriate</i>		<b>Yes</b>	<b>No</b>
The couple are aware of this funding request and referral and they consent to the content of this form being shared with the CCG Clinical Funding Team and specialist fertility provider?					
<b>Patient Information</b>					
<b>Name:</b>					
<b>Address:</b>	<b>DOB:</b>				
	<b>NHS No:</b>				
	<b>Home Tel No:</b>				
	<b>Mobile Tel No:</b>				
<b>GP Surgery</b>		<b>GP Tel no. and email address</b>			
<b>Length of time registered at this surgery</b>					
<b>Partner Information</b>					
<b>Name:</b>					
<b>Address:</b>	<b>DOB:</b>				
	<b>NHS No:</b>				
	<b>Home Tel No:</b>				
	<b>Mobile Tel No:</b>				
<b>GP surgery</b>		<b>GP tel no. and email address</b>			
<b>Length of time registered at this surgery</b>					

Consultant Information			
Sign and print name		Telephone No:	
Hospital or community service			
Date form completed:			

CCG Eligibility Criteria	Response
<b>Unexplained infertility: Has the couple had infertility for at least three years of ovulatory cycles, despite regular unprotected vaginal sexual intercourse?</b>	Yes / No
<b>Date first presented to GP.</b>	
<b>Date referred for subfertility investigations.</b>	
<b>Or state the diagnosed cause of absolute infertility which precludes any possibility of natural conception.</b>	
<b>In the case of male factor infertility please state the severity</b> <b>Mild</b> - The effect on the chance of pregnancy occurring naturally through vaginal intercourse would be similar to people with unexplained infertility. <b>Severe</b> - Precludes any possibility of natural conception i.e. absolute infertility.	Mild / Severe
<b>Have either of the couple had any previous IVF cycles? (whether self or NHS funded)</b>	Yes / No
<b>Has the male partner ever received NHS funded IVF treatment for his infertility either in this current relationship or in a previous relationship?</b>	Yes / No
<b>Age of female at date of referral to IVF provider service</b> <b>NB: for women over the age of 42 funding will be valid until their 43rd birthday.</b>	Years:
<b>BMI of female patient (receiving treatment) (policy states it must be between 19-30 kg/m<sup>2</sup>):</b>	BMI: Date measured:
<b>BMI of male partner (policy states must be less than 30 kg/m<sup>2</sup>):</b>	BMI: Date measured:
<b>To be eligible the female patient should have an AMH level of more than 5.4pmol/l measured within the last 3 months of referral from secondary care to the specialist IVF provider.</b>	AMH Level: Date taken:
<b>Residency: Both partners must be registered with a GP in this CCG area for at least 12 months. If less than 12 months of GP registration in this CCG area, they must demonstrate residency in the CCG area for at least 12 months prior to referral. This evidence must be attached.</b>	How long have the couple been registered with a local GP? <b>Patient:</b>  <b>Partner:</b>

<b>Smoking – does either the patient or partner smoke?</b>	Patient: Yes / No Partner: Yes / No
<b>Parental Status – are there any living children (including adopted) from either the patient or their partner’s current or previous relationships regardless of whether the child resides with them?</b>	Yes / No
<b>Have either the patient or their partner ever been sterilised or had sterilisation reversed?</b>	Yes / No
<b>Is the female patient rubella immune?</b>	Yes / No
<b>HIV1, HIV2, Hepatitis B &amp; Hepatitis C results for both partners are all dated within the last 2 months from the date the sample was obtained.</b> This is to facilitate the implementation of the HFEA guidelines of a 3 month duration between blood test date and when the patient first provides their gametes for use in fertility treatment.  <b>The results of these tests are not required for the funding application and as such should remain confidential for the patient.</b>	Patient Yes / No Date of test:  Partner Yes / No Date of test:
<b>Has the female partner receiving treatment had a pregnancy within the last 3 years?</b> If yes please provide dates of pregnancy and details of outcome.	Yes / No Date: Outcome:
<b>Does either partner have any medical conditions which may impact on the IVF treatment or their safety?</b> If yes please provide full details in a supporting clinic letter.	Yes / No
<b>Welfare of the Unborn Child</b> Is there any reason, due to past medical or social history of either partner, why there may be a concern for the welfare of the child which may be born? ( <i>this includes history of social care or crime against a child and takes into account the importance of a stable and supportive environment for children</i> ) <i>If the answer is ‘Yes’, but you still wish to refer the couple, please provide full details in a supporting clinic letter</i>	Yes / No
<b>Same sex female couples. Have the couple had 12 cycles of unstimulated IUI (6 self-funded and 6 NHS funded)</b> If yes please provide supporting evidence.	Yes / No

Investigations for female partner receiving treatment	Date:	Result:
Ultrasound or pelvic/uterine assessment (specify procedure):		
LH (day 2-4):		
Estradiol (day 2-4):		
Tubal Patency		

Male investigations		
<b>Semen analysis</b>	Date:	Volume:
Sperm Count:	Progressively motiles=:	Normal forms:
<b>Repeat semen analysis</b>	Date:	Volume:
Sperm Count:	Progressively motiles=:	Normal forms:

Sperm storage (if required)	
Nature of diagnosis requiring this procedure:	Date of diagnosis:
Planned treatment/surgery:	Treatment start date:

Provider Choice <i>(tick as appropriate)</i>		
<b>Bourn Hall Clinic Bourn</b> <input type="checkbox"/> High Street Bourn Cambridge CB23 2TN Tel: 01954 717210	<b>CREATE Fertility</b> <input type="checkbox"/> CREATE Fertility St Paul's 150 Cheapside, City of London London EC2V 6ET Tel: 0333 240 7300	<b>London Women's Clinic</b> <input type="checkbox"/> 113-115 Harley Street London W1G 6AP Tel: 0207 563 4309 <a href="http://www.londonwomensclinic.com/">http://www.londonwomensclinic.com/</a>
<b>Bourn Hall Clinic Colchester</b> <input type="checkbox"/> Charter Court Newcomen Way Colchester Essex CO4 9YA Tel: 01954 717210	<b>CREATE Fertility Wimbledon</b> <input type="checkbox"/> St Georges House 3-5 Pepys Road West Wimbledon SW20 8NJ Tel: 0208 947 9600 NHS net: <a href="mailto:Create.herts@nhs.net">Create.herts@nhs.net</a> Web: <a href="http://www.createhealth.org/">http://www.createhealth.org/</a>	<b>London Women's Clinic The Bridge Centre</b> <input type="checkbox"/> 1, St Thomas Street London SE1 9RY Tel: 0203 819 3282 <a href="http://www.thebridgecentre.co.uk">http://www.thebridgecentre.co.uk</a> NHS Tel: 0207 563 4309 Email: david.hoskins@nhs.net
<b>Bourn Hall Clinic Norwich</b> <input type="checkbox"/> Unit 3 The Apex Gateway 11, Farrier Close Wymondham Norfolk NR18 0WF Tel: 01954 717210 NHS net: <a href="mailto:boornhall.referrals@nhs.net">boornhall.referrals@nhs.net</a>	<b>Guy's &amp; St Thomas'</b> <input type="checkbox"/> Guy's Hospital 11th floor, Tower Wing Great Maze Pond London SE1 9RT Tel: 0207 188 2300 <a href="mailto:gst-tr.guysacuffunding@nhs.net">gst-tr.guysacuffunding@nhs.net</a>	<b>The Centre for Reproductive and Genetic Health</b> <input type="checkbox"/> 230-232 Great Portland Street London, W1W 5QS Tel: 020 7837 2905 NHS net: <a href="mailto:s.lola@nhs.net">s.lola@nhs.net</a>

Procedure requested	Tick
<p><b>IVF with or without ICSI</b> (Standard package will include):</p> <ul style="list-style-type: none"> <li>• Initial consultation, follow up consultation, and counselling sessions.</li> <li>• All ultrasound scans and hormone assessments during the treatment cycle</li> <li>• Oocyte stimulation</li> <li>• Oocyte recovery - by vaginal ultrasound guided aspiration under sedation or local anaesthesia; laparoscopy as appropriate under general anaesthesia</li> <li>• IVF or ICSI to produce embryos and blastocyst culture as appropriate.</li> <li>• Embryo or blastocyst transfer into uterine cavity.</li> <li>• Pregnancy test and a maximum of two scans to establish pregnancy viability</li> <li>• Drug costs and sperm preparation</li> </ul>	
<p><b>Embryo/blastocyst freezing and storage</b> Commissioned as part of the service requirement and will be funded for up to 12 months following completion of NHS Treatment.</p>	
<p><b>Surgical sperm recovery</b> (TESA/PESA) This is the specialist commissioning responsibility of NHS England <a href="https://www.england.nhs.uk/commissioning/spec-services/">https://www.england.nhs.uk/commissioning/spec-services/</a> Sperm storage will be funded by the CCG at one of our commissioned fertility providers only and for up to 12 months following completion of the NHS England specialist surgical sperm retrieval.</p>	
<p><b>IUI- unstimulated</b> Individual Funding Request (IFR) required – <a href="https://www.enhertsccg.nhs.uk/ifr">https://www.enhertsccg.nhs.uk/ifr</a></p>	
<p><b>Donor oocyte cycle</b> For individual with embryo/blastocyst stored (Must be self-sourced and self-funded by the couple)</p>	
<p><b>Donor Sperm insemination</b> (Donor sperm must be self-sourced and self-funded by the couple)</p>	
<p><b>Chronic Viral Infections</b> Patients with chronic viral infections who are eligible for IVF treatment should be referred to one of the commissioned providers above who have the appropriate processing facilities to accommodate these patients.</p>	

**REFERRAL INFORMATION ONLY  
NOT REQUIRED FOR THE APPLICATION FOR FUNDING**

Clinical Information	
Number of TOPs:	
Number of miscarriages/ectopics:	

Screening				
HIV & Hep B and C Must be dated within the last 2 months to facilitate implementation of HFEA guidelines on 3 month duration between the date of the test and start of treatment				
Test	Female		Male	
	Date of test	Results	Date of test	Results
HIV Screening				
Hep B Surface Antigen				
Hep B Core Antibody				
Chlamydia Screening				
Hep C				
Haemoglobinopathy Electrophoresis (if indicated)				
Rubella				
Cervical Smear				

If any investigations are out of date at the point of referral (after funding has been approved) it is the responsibility of the secondary care provider to repeat these tests

<p>Any other relevant information, e.g. allergies or medical history requiring pre-conceptual care i.e. diabetes, epilepsy, genetic conditions and others. If yes to the above, please confirm that a referral for pre-conceptual care has occurred.</p>	Patient: Yes / No
	Partner: Yes / No
<p>Details</p>	

I, the referring clinician confirm that the couple meet the CCG IVF policy eligibility criteria and funding has been prior approved.

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Name and Position: \_\_\_\_\_

Prior Approval reference number \_\_\_\_\_

**This must be stated on invoices to enable payment of treatment provided.**