



Great Yarmouth and Waveney  
North Norfolk, South Norfolk  
Norwich, West Norfolk  
Clinical Commissioning Groups

**Norfolk and Waveney Clinical Policy Development Group  
Clinical Threshold Policy**

**Title: Assisted Conception Commissioning Policy  
(Level 3 Service)**

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### 1. Introduction

This Commissioning Policy sets out the criteria for access to NHS funded specialist fertility services (also known as Level 3) for the population of Norfolk and Waveney, along with the commissioning responsibilities and service provision.

The paper specifically sets out the entitlement and service that will be provided by the NHS 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 paper should be read in conjunction with NICE Guidance CG156 'Fertility Assessment and Treatment for People with Fertility Problems' (2013) on their website at <https://www.nice.org.uk/guidance/CG156> and also the NICE 2014 Quality Standard <https://www.nice.org.uk/guidance/qs73>

This policy will be reviewed annually and within 3 months of any legislative changes that should occur or may occur in the future. The date of the next review will be 2 years after policy approval date.

## 2. Commissioning Responsibility

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 care services such as acute trusts. To access Level 3 services the preliminary investigations should be completed at Level 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
- Egg Donation where no other treatment is available
- Blood borne viruses (ICSI + sperm washing)

For further details of what is funded by Norfolk and Waveney CCGs, please see Appendix 1

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

Formal IVF commissioning arrangements will support the implementation of this policy including a contract between 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 and Embryology Authority Licensing requirements or any successor organisations.

This policy is specifically for those prospective parents/parent who do not have a living child from their current or any previous relationship **prior to starting NHS funded treatment**, 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.

Prospective parents/parent who do not meet the criteria and consider they have exceptional circumstances should be considered under the Individual Funding Request (IFR) policy of their CCG. All IFR funding queries should be directed to the IFR team of the relevant CCG who may liaise with the central contracting team. Funding of such exceptional cases is the responsibility of the CCG.

Situations may arise where the criteria in this policy are not applicable for use by CCGs and in such instances, prospective parents/parent applications will need to be considered on a case by case basis.

Prospective parents/parent will be offered a choice of providers that have been commissioned by the CCG.

### 3. Specialist Assisted Conception Policy

The CCG only commissions the following fertility techniques regulated by the Human Fertilisation and Embryology Authority (HEFA)

Amendments to the NHS (Charges to Overseas Visitors) Regulations 2015 were introduced into Parliament on 19 July 2017. As a result, from 21 August 2017, assisted conception services will no longer be included in the scope of services available for free for those who pay the immigration health surcharge. Further information can be found on this web link:

<http://www.legislation.gov.uk/ukxi/2017/756/contents/made>

#### 3.1 In-Vitro Fertilisation (IVF)

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

For prospective parents/parent aged between **23 years and 39 years and 364 days**, the policy supports a **maximum of 4 embryo transfers** within a **maximum of 2 fresh cycles of IVF, with or without ICSI**, this includes any abandoned cycles (except in cases of Ovarian Hyperstimulation Syndrome)

In prospective parents/parent aged under 40 years any previous full IVF cycles, whether self or NHS-funded, will count towards the total number of full cycles offered by the relevant CCG.

For prospective parents/parent aged between **40-41 years and 364 days** NHS treatment limit will be determined by local CCG policy up to a **maximum of 2 embryo transfers**, including a **maximum of 1 fresh cycle of IVF or IVF with ICSI**, provided the following 3 criteria are 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.

**Please refer to Appendix 1 for number of funded cycles and embryo transfers funded by the CCGs.**

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.

Prospective parents/parent 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 themselves or allowed to perish.

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.

Before a new fresh cycle of IVF can be initiated any previously frozen embryo(s) must be utilised.

Where prospective parents/parent have previously self-funded a cycle then the prospective parents/parent must utilise the previously frozen embryos, rather than undergo ovarian stimulation, egg retrieval and fertilisation again.

Embryo transfer strategies:

- For prospective parent aged between **23 years and 39 years and 364 days** only one embryo or blastocyst to be transferred in the first cycle of IVF and for subsequent cycles only one embryo/blastocyst to be transferred unless no top quality embryo/blastocyst available then no more than 2 embryos to be transferred.
- For prospective parent aged **40-41 years and 364 days** consider double embryo transfer.

A fresh cycle would be considered completed with the attempt to collect eggs and transfer of a fresh embryo. However, if a patient is at risk of developing Ovarian Hyperstimulation Syndrome (OHSS) <https://www.rcog.org.uk/en/patients/patient-leaflets/ovarian-hyperstimulation-syndrome/> the treatment will be classed as deferred treatment rather than an abandoned cycle.

If a cycle is commenced and ovarian response is poor, a clinical decision would need to be taken as to whether a further cycle should be attempted, or if the use of a donor egg may be considered for further IVF cycles.

If any fertility treatment results in a **living child**, then the prospective parents/parent 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 prospective parents/parent.

Clinical Indications: In order to be eligible for treatment, prospective parents/parent should have experienced unexplained infertility for three years or more of regular intercourse or 6 cycles of self-funded artificial insemination over a period of three years. There is no qualifying criterion for prospective parents/parent with a diagnosed cause of infertility – please see the following link for common causes of infertility: <https://www.nhs.uk/conditions/infertility/causes/>

## 3.2 Surgical Sperm Recovery

Surgical sperm retrieval methods included for service provision are testicular sperm extraction (TESE) and percutaneous epididymal sperm aspiration (PESA).

Micro surgical sperm recovery is not routinely funded and must be considered as an IFR application to the relevant CCG.

Sperm recovery techniques outlined in this section are not available to prospective parents/parent who have undergone a vasectomy

## 3.3 Donor Insemination

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 prospective parents/parent who do not wish to undergo ICSI
- Infectious disease of the prospective parents/parent (such as HIV)
- Severe rhesus isoimmunisation
- Where there is high risk of transmitting a genetic disorder to the offspring

Donor insemination is funded up to a maximum of 6 cycles of Intrauterine Insemination (IUI) – please see Appendix 1 for number of cycles relevant to CCG.

## 3.4 Donor Semen as part of IVF/ICSI

Donor semen is used for same sex prospective parents/parent as part of IVF/ICSI treatment. Funded up to same number of cycles of IVF.

## 3.5 Intra Uterine Insemination (IUI)

NICE guidelines state that unstimulated intrauterine insemination as a treatment option in the following groups as an alternative to vaginal sexual intercourse:

- Prospective parents/parent 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

- Prospective parents/parent with conditions that require specific consideration in relation to methods of conception (for example, after sperm washing where the prospective parents/parent is HIV positive)
- Prospective parents/parent in same-sex relationships or single prospective parent.

A maximum of 6 cycles of IUI (as a replacement for IVF/ICSI and without donor sperm) will be offered.

### 3.6 Egg Donation where no other treatment is available

The prospective parents/parent may be able to provide an egg donor; alternatively the prospective parents/parents can be placed on the waiting list, until an altruistic donor becomes available. If either of the prospective parents/parent exceeds the age criteria prior to a donor egg becoming available, they will no longer be eligible for treatment.

This will be available to:

- Prospective parents/parent 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.
- Avoid transmission of inherited disorders to a child where the prospective parents/parent meet the other eligibility criteria.

### 3.7 Pre-Implantation Genetic Diagnosis (PGD)

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 NHS England.

### 3.8 Chronic Viral Infections

Please refer to NICE guidance CG156 <https://www.nice.org.uk/guidance/CG156>

- including sections 1.3.9 and 1.3.10

### 3.9 Zika Virus

Level 2 providers should advise prospective parents/parent not to travel to high or medium risk countries if referral to Level 3 is being considered. If prospective parents/parent has been to a high or medium risk country, Level 3 providers cannot treat them for 6 months afterwards.

### 3.10 Privately Funded Care

This policy covers NHS funded fertility treatment only. For clarity, prospective parents/parent 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 any drugs prescribed by the prospective parents/parent GP), recommended treatment that is outside of the scope of the service specification agreed with the Secondary or Tertiary provider or experimental treatments.

Where prospective parents/parent meet this eligibility criteria, but agrees to commence treatment on a privately funded basis, they may not retrospectively apply for any associated payment relating to the private treatment.

### 3.11 Surrogacy

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

## 4. Referrals

Prospective parents/parent who experience problems with their fertility will attend their GP practice to discuss their concerns and options. The prospective parents/parent will be assessed within the primary and secondary care setting. Prospective parents/parent who are having problems conceiving are offered counselling by Level 3 providers.

A decision to refer prospective parents/parent for IVF or other fertility services will be based on an assessment against this eligibility criteria which is based on the NICE guidelines and the HFEA recommendations as detailed in the clinical pathways.

Referral to the tertiary centre will be via a gynaecologist or GP with Special Interest (GPSI) in primary care.

Same-sex prospective parents/parent and prospective single parent are eligible for treatment if one prospective parent has experienced unexplained infertility for 3 years or more or 6 cycles of self-funded artificial insemination over a period of 3 years.

If a prospective parent is transgender then they are eligible for treatment if one partner has experienced unexplained infertility for 3 years or more of regular intercourse or 6 cycles of self-funded artificial insemination over a period of 3 years.

If the transgender prospective parent is living in the female role and is undergoing her transitioning and transgender process, for the purposes of eligibility the transgender prospective parent would be considered to be female and therefore the issue of sperm count

being a cause of infertility would be irrelevant. The prospective parent would therefore need to have had 6 inseminations with donor sperm or the female undergoing the fertility treatment would need to have been diagnosed with a known cause of infertility.

## **Appendix 1 – Access Criteria**

FEMINAL

No	Criterion	Great Yarmouth & Waveney, Norwich, North Norfolk, South Norfolk and West Norfolk CCGs
1	Ovarian Reserve Testing, use the following: AMH	To be eligible, the patient should have an AMH level of more than 5.4pmol/l measured in the last 12 months of referral from secondary care to the specialist IVF provider*.  *During the transition to AMH testing it is anticipated that some Trusts may not be able to offer AMH immediately. During this period, to be eligible the patient should have an FSH of <9 on day two of any menstrual cycle done within three months of referral from secondary care to a specialist IVF provider.
2	Maternal age/Number of cycles of IVF.	For prospective parents/parent aged <b>between 23 years and 39 years and 364 days</b> , the policy supports a maximum of 4 embryo transfers within a maximum of <b>2 fresh cycles of IVF</b> , with or without ICSI, this includes any abandoned cycles (except in cases of Ovarian Hyperstimulation Syndrome)  Prospective parents/parent aged <b>23 to 39 years and 364 days</b> at the start of super-ovulation (treatment) but where a woman reaches the age of 40 during treatment they will complete that cycle in the 40 <sup>th</sup> year and will not be entitled to commence further cycles
3	Paternal Age	No cut off age to be specified
4	Minimum / Maximum BMI	Between at least BMI 19 and up to BMI 30 for female. Prospective parents/parent 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.  <u>Same-Sex Couples</u>  BMI eligibility criteria above apply only:-  To the female partner undergoing fertility treatment
5	Duration of sub-fertility	Unexplained infertility for 3 years or more of regular intercourse or an equivalent 6 self-funded cycles of artificial insemination over a period of 3 years. There is no criterion for cases with a diagnosed cause of infertility. See also criteria no 14.

6	Previous Fertility treatment for Women <40 years	<p>NHS treatment limit up to <b>maximum of 4 embryo transfers</b>, with a maximum of <b>2 fresh cycles of assisted conception (IVF or IVF with ICSI)</b> 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>Women aged between <b>40-41 years and 364 days</b> are not eligible for further cycles 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> <p>Women aged <b>between 40-41 years and 364 days</b> may be entitled to <b>1 fresh cycle of IVF</b> but where:</p> <ul style="list-style-type: none"> <li>• They have never previously had IVF treatment</li> <li>• There is no evidence of low ovarian reserve</li> <li>• There has been a discussion of the additional implications of IVF and pregnancy at this stage</li> </ul>
8	Smoking Status	<p>Prospective parents/parent who smoke will not be eligible for NHS-funded specialist assisted reproduction assessment or treatment</p> <p>Where either a prospective parents/parent smokes, only those who agree to take part in a supportive and successful programme of smoking cessation with Carbon Monoxide verification as an evidence of non-smoking status will be accepted onto the IVF treatment waiting list.</p> <p>E-cigarette users are classed as e-cigarette users not smokers. It is recognised that vaping is not the same as smoking, as there is no burning of tobacco which produces some of the harmful chemicals in cigarettes. It has been recognised by Public Health England that the long terms effects of e-cigarettes are not known but PHE current state that they are 95% than safer cigarettes.</p> <p>There is no evidence whether there are any risks to the foetus from exposure to e-cigarette usage, therefore licensed stop smoking medications are currently the recommended option.</p>

9	Parental Status	Prospective parents/parent 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.
10	Previous sterilisation	Ineligible if previous sterilisation has taken place (either prospective parents/parent), even if it has been reversed.
11	Child Welfare	<p>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.</p> <p>Referrals forms to Level 2 and 3 fertility services ask the Provider to state whether there is any reason due to past medical or social history of either prospective parents/parent, which may be of concern with regard to the welfare of the unborn child. In the event of a disclosure, a referral should not be made, instead the GP or Level 2 clinician should contact the CCG Designated Nurse or Doctor and/or local children's services in order to assess the risk.</p>
12	Medical Conditions	Treatment may be denied on other medical grounds not explicitly covered in this document.
13	Residential Status	<p>For consideration of funding, prospective Parent/Parents must meet the following criteria:-</p> <ul style="list-style-type: none"> <li>• The prospective parent/parent must be registered with a GP within Norfolk &amp; Waveney CCG for 12+ months.</li> </ul> <p>and /or</p> <ul style="list-style-type: none"> <li>• In the case of prospective parents, one of the prospective parents must be registered with a GP within Norfolk and Waveney CCG area for 12+ months.</li> </ul> <p>If prospective parents/parent are registered at different GP Practices, the relevant CCG policy is where the female is registered.</p> <p><b>Great Yarmouth &amp; Waveney, North Norfolk, South Norfolk, Norwich and West Norfolk CCG</b></p>
14	The cause of Infertility	<p>Where infertility is the primary factor for the request for Assisted Conception, in order to be eligible for treatment, prospective parents/parent should have experienced unexplained infertility for three years or more of regular intercourse or 6 cycles of self-funded artificial insemination over a period of 3 years. There is no criterion for prospective parents/parent with a diagnosed cause of infertility – please see the following link for common causes of infertility:</p> <p><a href="http://www.nhs.uk/Conditions/Infertility/Pages/Causes.aspx">http://www.nhs.uk/Conditions/Infertility/Pages/Causes.aspx</a></p>

		This is distinguished from requests for Intra Uterine Insemination (IUI) as a treatment option, as described on page 6 of this policy which is in line with NICE guidance.
15	The minimum investigations required prior to referral to the Level 3 fertility service:	<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>• Day 2 FSH</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 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>
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)	<p>As per NICE guidance 2013.</p> <p>Maximum of 6 cycles of IUI (as a replacement for IVF/ICSI and without donor sperm)</p>