

DRAFT FOR ENGAGEMENT

North East London CCG Fertility Policy

June 2022

This policy will, if implemented, replace the legacy policies of the previous Barking and Dagenham, Havering, Redbridge, City and Hackney, Waltham Forest, Tower Hamlets, and Newham CCGs.

DRAFT North East London CCG fertility policy

Introduction

North East London (NEL) CCG (which will be known as NHS North East London from 1 July 2022) is responsible for commissioning a range of health services including hospital, mental health and community services for the local population. CCGs have a statutory duty to maintain financial balance, which means that it must make judgements about the affordability of any proposed service for local patients.

This policy has been developed following:

- Consideration of national guidance and the current evidence base
- Discussions with stakeholders, including GPs, specialist clinicians, service users and residents
- Identification and consideration of potential equality and equity issues

In developing this policy, the CCG's starting point has been to consider the National Institute for Health and Care Excellence (NICE) relevant [clinical guidelines](#) on fertility problems. However, it has also taken into account wider system factors such as service demand and the health needs of our communities. This was considered alongside the all the pressures on NHS budgets as while we are not trying to make changes to our fertility policy in order to save money, we do need to make best use of NHS money. As a result, some sections of the policy vary from the full recommendations or guidance made by NICE.

Scope of the policy

This clinical policy is intended to support individuals and couples who want to have a baby, but who have a clinical problem which means that they are potentially infertile. The policy sets out the assisted conception treatments funded by NEL CCG and the eligibility criteria patients need to meet to access these.

Eligibility for NHS funding is not the same as a guarantee of treatment. The treatment should only be considered if the eligibility criteria are met, but it is important that the final decision to treat is an informed decision between the responsible clinician and the patient.

In general, patients who pay the immigration surcharge are not eligible for assisted conception services funded by the CCG. The CCG will comply with [government guidance](#) regarding these patients.

Preimplantation genetic diagnosis (PGD) is not funded by NEL CCG because this is commissioned by NHS England.

This policy applies to people who are registered with a GP in NEL CCG's area, as outlined in NHS England [Who pays?](#) guidance.

Individual Funding Requests (IFR)

This policy cannot anticipate every possible individual clinical or fertility situation. Clinicians may submit IFR for patients who they consider have exceptional clinical circumstances and whose needs are not fully addressed by this policy. The CCG will consider such requests in accordance with its policy on IFR. **Contact:** nelcsu.ifr@nhs.net

Patients accessing IVF should be fully informed of likely success rates and alternative approaches to parenting, including fostering and adoption.

Glossary	
Abandoned IVF cycle	Defined as an IVF cycle where an egg collection procedure has not been undertaken. Usually occurs due to a lack of response to the medication to stimulate the ovaries (where fewer than three mature follicles are present) or if there has been an excessive response to ovarian stimulation and the patient is at risk of severe ovarian hyperstimulation syndrome (OHSS). May also be referred to as a 'cancelled cycle'.
Artificial insemination (AI)	AI is the introduction of sperm into cervix or uterine cavity for the purpose of achieving pregnancy. Intrauterine insemination (IUI) is a type of AI undertaken at a fertility clinic where sperm is filtered to produce a concentrated 'healthy' sample which is placed directly into the uterus (womb). AI undertaken at home would normally be intra-vaginal insemination.
Assisted conception treatment (ACT)	The collective name for treatments designed to lead to conception by means other than sexual intercourse. Includes: intrauterine insemination (IUI), in vitro fertilisation (IVF), intracytoplasmic sperm injection (ICSI) and donor insemination (DI).
Azoospermia	Where there are no sperm in the ejaculate.
Cryopreservation	The freezing and storage of embryos, sperm or eggs for future use in assisted conception treatment cycles.
Donor insemination (DI)	Artificial insemination using donated sperm.
Egg (oocyte) donation	The process by which a fertile donor donates eggs to be used in the treatment of others.
Embryo transfer	The procedure in which one or more embryos are placed in the uterus.
Embryo transfer strategies	Defines the number of embryos that should be transferred in an embryo transfer procedure, depending on factors such as the quality of the embryos and the age of the woman or person trying to conceive.
Endometriosis	A condition where tissue similar to the lining of the uterus starts to grow in other places, such as the ovaries and fallopian tubes. Endometriosis is a known clinical cause of fertility problems.
Expectant management	NICE define expectant management as a formal approach that encourages conception through unprotected vaginal intercourse. It involves supportively offering an individual or couple information and advice about the regularity and timing of intercourse and any lifestyle changes which might improve their chances of conceiving. It does not involve active clinical or therapeutic interventions.
Fertilisation	The union of an egg and sperm.
Fertility policies	CCGs are responsible for commissioning most fertility treatments; most CCGs therefore have policies in place specifying which treatments interventions are funded and eligibility criteria for access to these. These policies typically explain when the CCG will fund assisted conception treatments for people experiencing fertility problems and for patients who require interventions for other reasons e.g. fertility preservation for patients due to undergo a gonadotoxic treatment.
Fertility preservation (FP)	Fertility preservation involves storing eggs, sperm, embryos or reproductive tissue with the aim of having biological children in the future.
Fresh IVF cycle	Comprises an episode of ovarian stimulation and the transfer of embryos created that have not previously been frozen.
Frozen embryo transfer (FET)	Where an excess of embryos is available following a fresh cycle, these embryos may be frozen for future use. Once thawed, these embryos may be transferred to the patient as a 'frozen embryo transfer'. Also known as a 'frozen IVF cycle'.

Full IVF cycle	Defined by NICE as one episode of ovarian stimulation and the transfer of any resultant fresh and frozen embryo(s).
Gonadal dysgenesis	Abnormal development of an ovary or testicle.
Gonadotoxic treatment	Treatments that can cause fertility problems, such as some chemotherapies.
HFEA	Human Fertilisation and Embryology Authority. The HFEA is the UK's independent regulator of fertility treatment and research using human embryos. They license and inspect clinics and set standards.
Infertility	The World Health Organisation states infertility is a disease of the male or female reproductive system defined by the failure to achieve a pregnancy after 12 months or more of regular unprotected sexual intercourse. NICE indicates that for people trying to conceive using artificial insemination (including, but not limited to, female same sex couples and single women), infertility may be indicated after six unsuccessful cycles. In the male reproductive system, infertility is most commonly caused by problems in the ejection of semen, absence or low levels of sperm, or abnormal shape (morphology) and movement (motility) of the sperm; this is commonly called 'male factor infertility'. In the female reproductive system, infertility may be caused by a range of abnormalities of the ovaries, uterus, fallopian tubes, and the endocrine system, among others.
In vitro fertilisation (IVF)	IVF involves ovarian stimulation and then collection of eggs. The eggs are then fertilised with sperm in a lab. If fertilisation is successful, the embryo is allowed to develop for between two and six days and is then transferred to the uterus to hopefully continue to a pregnancy. Ideally one embryo is transferred to minimise the risk of multiple pregnancy. Where the woman or person trying to conceive is older, or the quality of the embryos is poor, two embryos may be transferred. It is best practice to freeze any remaining good quality embryos to use later on in a frozen embryo transfer if the first transfer is unsuccessful.
Intracytoplasmic sperm injection (ICSI)	IVF with ICSI treatment is similar to standard IVF. However, instead of mixing the sperm with the eggs and leaving them to fertilise in a dish, an embryologist will inject a single sperm into each mature egg. This maximises the chance of fertilisation as it bypasses any potential problems the sperm may have in penetrating the egg.
Intrauterine insemination (IUI)	IUI is a type of fertility treatment in which the better quality sperm are separated from sperm that are sluggish, non-moving or abnormally shaped. This sperm is then placed directly in the uterus. This can either be performed with partner sperm or donor sperm (known as donor insemination).
Natural cycle IVF	An IVF procedure in which one or more eggs are collected from the ovaries during a spontaneous menstrual cycle without any drug use.
NICE	National Institute for Health and Care Excellence. NICE provide national guidance and advice to improve health and social care. One of the ways that NICE does so is by publishing clinical guidelines, which are evidence-based recommendations for health and care in England. Organisations commissioning and delivering services are expected to take the recommendations contained within NICE clinical guidelines into account when planning and delivering services. NICE has published a Clinical Guideline (CG 156) on fertility problems.
Oophorectomy	An operation to remove one or both ovaries.
Ovarian Hyper-Stimulation Syndrome (OHSS)	A condition in which the ovarian response to stimulation results in clinical problems, including abdominal distension, dehydration and potentially serious complications due to thrombosis and lung and kidney dysfunction. It is more likely in patients who are excessively sensitive to medicines used for ovarian stimulation.

Ovarian reserve	Ovarian reserve tests were developed by fertility clinics to predict how a person having IVF treatment would respond to the medication used to stimulate the ovaries and ultimately how many eggs they may produce. Ovarian reserve can be assessed through blood tests to measure two important hormones: follicle stimulating hormone (FSH) and anti-Müllerian hormone (AMH) or by an ultrasound scan that counts the growing follicles within each ovary (antral follicle count; AFC).
Ovarian stimulation	Stimulation of the ovary to achieve growth and development of ovarian follicles with the aim of increasing the number of eggs released.
Ovarian tissue cryopreservation	Involves removing and freezing ovarian tissue. At a later date, the ovarian tissue strips can be thawed and either re-implanted into the ovary, to allow the patient to try to conceive naturally, or the eggs can be retrieved and fertilised in vitro and the embryo implanted in the uterus.
Pathological problem	One that relates to medical conditions/ diseases (physical or psychological).
Pre-implantation genetic diagnosis	A technique used to identify inherited genetic defects in embryos created through IVF. Only embryos with a low genetic risk for the condition are then transferred to the uterus. Any resulting pregnancy should be unaffected by the condition for which the diagnosis is performed.
Premature ovarian insufficiency	If menopause happens before the age of 40 it is called premature ovarian insufficiency (or premature menopause).
Rhesus (Rh) isoimmunisation	A condition where antibodies in a pregnant woman's or pregnant person's blood destroy the baby's blood cells. Also known as rhesus disease.
Sperm donation	The process by which a fertile donor donates sperm to be used in the treatment of others. The HFEA regulates sperm donation undertaken at UK fertility clinics.
Sperm washing	Sperm washing is used to reduce the viral load (for example, of HIV) in prepared sperm to a very low or undetectable level. The washed sperm can then be transferred to the uterus using IUI, or used to fertilise eggs in IVF or ICSI.
Supernumerary embryos	Embryos created from a fresh IVF cycle that are left over after an embryo(s) have been transferred.
Surgical sperm retrieval (SSR)	Extracting sperm by a surgical procedure. Types of SSR include: percutaneous epididymal sperm aspiration (PESA), microsurgical epididymal sperm aspiration (MESA), testicular sperm aspiration (TESA), testicular sperm extraction (TESE) and microscope-assisted testicular sperm extraction (MicroTESE).
Surrogacy	Surrogacy is where a person carries and gives birth to a baby for another person or couple. This may involve the eggs of the surrogate, the intended mother/ parent, or a donor.
Unsuccessful cycle of IVF/ ICSI	Includes failure of fertilisation, failure of development of embryos and failure to become pregnant following transfer of embryos.

Eligibility criteria

Patients can only be referred for assisted conception treatments if they meet the eligibility criteria below and when all appropriate tests and investigations have been successfully completed in primary and secondary care in line with NICE guidelines.

1. Age of the woman or person trying to get pregnant	Assisted conception treatments are funded for eligible women or people trying to get pregnant who are aged under 43 years. Referring clinicians should be aware of the work up time required by the provider and ensure that referrals are made in time for women to start egg retrieval before their 43 rd birthday.
2. Body mass index (BMI)	The woman or person trying to get pregnant must have a body mass index (BMI) of between 19 and 30 at the time treatment begins.
3. Smoking	The woman or person trying to get pregnant must be a non-smoker and continue to be a non-smoker throughout treatment. The man or partner providing sperm for assisted conception treatment must be a non-smoker.
4. Existing children	Assisted conception treatment will not be offered to couples who have a child together or people who are trying to have a baby on their own who already have a child. Assisted conception treatment will be offered to eligible couples where: <ul style="list-style-type: none">• neither partner has a child, or• where one of the partners has a child from a previous relationship, but the other does not. For the purposes of this policy, 'child' is living son or daughter, regardless of their age or where they live. Foster children are not included in these restrictions.
5. Previous sterilisation	Couples: neither partner in a couple should have undergone sterilisation. People who are trying to have a baby on their own: should not have undergone sterilisation. The above still applies if sterilisation reversal has unsuccessfully been attempted.
6. Ovarian reserve	There should not be evidence of low ovarian reserve, defined in this policy as more than one of the following: <ul style="list-style-type: none">• antral follicle count (AFC) of less than or equal to 4• anti-Müllerian hormone (AMH) of less than or equal to 5.4 pmol/l• follicle-stimulating hormone (FSH) greater than 8.9 IU/l Note, ovarian reserve testing will be undertaken by fertility clinics; patients can therefore be referred prior to receiving these test results, if they fulfil the remaining eligibility criteria.

Additional eligibility criteria to access different treatments are outlined in the sections below.

Provision of IVF

Unless otherwise specified, patients need to fulfil the eligibility criteria outlined in sections 1–6 of this document to access NHS funded IVF.

7. Definition of an IVF cycle	<p>For the purposes of this policy, a full IVF cycle is defined as one episode of ovarian stimulation and the transfer of any resultant fresh and frozen embryo(s). The cycle may be with or without intracytoplasmic sperm injection ((ICSI).</p> <p>All good quality frozen embryos should be transferred before starting the next NHS funded fresh IVF cycle. Embryo transfer strategies outlined in NICE CG156 should be followed to minimise the number of multiple births.</p> <p>Storage of cryopreserved supernumerary embryos will be funded for a maximum of two years following each fresh cycle.</p> <p>Natural cycle IVF is not routinely funded.</p>
8. IVF where the woman or person trying to get pregnant is under 40 years old	<p>For eligible patients requiring IVF where the woman or person trying to get pregnant is aged under 40, NEL CCG will fund up to three full IVF cycles. If the patient reaches the age of 40 during treatment, the current full cycle will be completed but no further full cycles will be available.</p> <p>Treatment will not be funded for patients aged under 40 years old who have previously had three cycles of IVF, including privately funded cycles. This means if a patient has had one previous IVF cycle, up to two NHS funded IVF cycles will be funded. If a patient has had two previous IVF cycles, one NHS funded IVF cycle will be funded.</p>
9. IVF where the woman or person trying to get pregnant is aged 40–42 years old	<p>For eligible patients requiring IVF where the woman or person trying to get pregnant is aged 40–42, NEL CCG will fund one full IVF cycle.</p> <p>Treatment will not be funded for patients aged 40–42 years old who have previously had any IVF treatment, including privately funded cycles.</p> <p>Before starting treatment, patients aged 40–42 years old should be made aware of the additional implications of IVF and pregnancy at this age.</p>
10. Abandoned cycles	<p>One abandoned cycle (defined as a cycle where an egg collection procedure has not been undertaken) does not count towards the number of cycles funded. However, further cycles will not be started if the treating doctor thinks it would be clinically inappropriate.</p>

Treatment pathways

This policy is intended, as per NICE guidance, for people who have a possible pathological problem (physical or psychological) to explain their infertility. NEL CCG will fund treatment for eligible individuals and couples provided there is evidence of subfertility.

The process for demonstrating subfertility will necessarily be different for people trying to conceive through sexual intercourse and people trying to conceive through artificial insemination; these differences are reflected in sections 11a and 11b below.

Note, patients do not need to fulfil the eligibility criteria outlined in sections 1–6 of this document to access assessment and investigations for infertility.

11a People trying to conceive through sexual intercourse

If there is a known clinical cause of infertility or a history of predisposing factors for infertility, patients can be referred for specialist consultation. Otherwise, referral for assessment and investigations can be made for people of reproductive age who have not become pregnant after one year of regular unprotected vaginal intercourse two to three times per week. If the woman or person trying to get pregnant is aged 36 or over then such assessment and investigations should be considered after six months of unprotected regular intercourse.

Where investigations show there is no chance of pregnancy with expectant management and where IVF is the only effective treatment, eligible patients can be referred for consideration of NHS funded IVF without delay. Otherwise, IVF can be offered to eligible patients who have not conceived after two years of regular unprotected intercourse. If the woman or person trying to get pregnant is aged 36 or over, IVF can be offered after one year of regular unprotected intercourse.

11b People trying to conceive through artificial insemination

If there is a known clinical cause of infertility or a history of predisposing factors for infertility, patients can be referred for specialist consultation. Otherwise, referral for assessment and investigations can be made for people of reproductive age who have not become pregnant after six self-funded cycles of Intrauterine insemination (IUI). If the woman or person trying to get pregnant is aged 36 or over then such assessment and investigations should be considered after three cycles of IUI.

Where investigations show there is no chance of pregnancy with expectant management and where IVF is the only effective treatment, eligible patients can be referred for consideration of NHS funded IVF without delay. Otherwise, IVF can be offered to eligible patients who have not conceived after 12 cycles of IUI. If the woman or person trying to get pregnant is aged 36 or over, IVF can be offered after six cycles of IUI.

Note, up to six cycles of NHS funded IUI may be available to eligible patients, as outlined in sections 12 and 13 of this document.

Other assisted conception treatments

Unless otherwise specified, patients need to fulfil the eligibility criteria outlined in sections 1–6 of this document to access NHS funded assisted conception treatments.

12. Intra uterine insemination (IUI) using partner sperm

Up to six cycles of unstimulated IUI using partner sperm is funded for the eligible patients where there is evidence of normal ovulation, tubal patency and semen analysis and either:

- they are unable to, or would find it very difficult to, have vaginal intercourse because of a clinically diagnosed physical disability or psychosexual problem, and have not conceived after six self-funded IUI cycles
- they have conditions that require specific consideration in relation to methods of conception (for example, after sperm washing where the man or person providing sperm is living with HIV).

Where appropriate, IVF will be funded for the above groups – see section 11b for more information. Note, if the nature of a patient’s physical disability or psychosexual problem is such that IVF is the only effective treatment, eligible patients can be referred for consideration of NHS funded IVF without delay, as outlined in section 11a.

IUI is not routinely funded for people with unexplained infertility, mild endometriosis or mild male factor infertility unless it is as an alternative to IVF for people who have social, cultural or religious objections to IVF. Note, this would be an alternative to receiving IVF treatment and therefore IVF would not subsequently be funded for patients accessing IUI in these circumstances.

13. Intra uterine insemination (IUI) using donor sperm

Up to six cycles of unstimulated IUI using donor sperm is funded for eligible patients where there is evidence of normal ovulation and tubal patency and either:

- obstructive or non-obstructive azoospermia
- severe deficits in semen quality in couples who do not wish to undergo ICSI
- there is a high risk of transmitting a genetic or infectious disorder to the child and/or partner
- severe rhesus isoimmunisation
- individuals, or couples trying to conceive using donor insemination who have not conceived after six cycles of self-funded IUI

[The CCG would like to fund donor sperm for eligible patients, however we are aware that there are practical and logistical barriers to this; comments on how this could be achieved would be welcomed from stakeholders by emailing nelondon.nelcommunications@nhs.net]

Where appropriate, IVF using donor sperm will be funded for the above groups – see section 11b for more information.

14. IVF using donor eggs

IVF using donor eggs will be funded for eligible patients with the following conditions:

- premature ovarian failure
- gonadal dysgenesis including Turner syndrome
- bilateral oophorectomy
- where there is a high risk of transmitting a genetic disorder to the offspring

For eligible patients, IVF using donor eggs will be available as per sections 7–10 of this policy. Note, the ovarian reserve criteria does not need to be met by patients undergoing IVF using donor eggs.

	<p>[The CCG would like to fund donor eggs for eligible patients however we are aware that there are practical and logistical barriers to this; comments on how this could be achieved would be welcomed from stakeholders by emailing nelondon.nelcommunications@nhs.net]</p>
<p>15. Fertility preservation</p>	<p>Cryopreservation (freezing) of eggs, embryos and sperm will be funded for eligible patients who do not currently have fertility problems but are either:</p> <ul style="list-style-type: none"> • due to undergo a gonadotoxic treatment; this may include patients undergoing interventions for gender affirmation, or • have a medical condition that, in their case, is likely to progress such that it will lead to infertility in the future <p>To access cryopreservation and storage of sperm, eggs or embryos, fertility preservation patients do not need to meet the eligibility criteria outlined in sections 1–6 of this document. However, fertility preservation patients who require cryopreservation of eggs or embryos must be:</p> <ul style="list-style-type: none"> • 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 gonadotoxic treatment, where applicable. <p>For patients aged under 32 years at the time of cryopreservation: storage of sperm, embryos and eggs will be funded until the patient reaches their 43rd birthday. For patients aged 32 and over at the time of cryopreservation: storage of sperm, embryos and eggs will be funded for 10 years duration. NHS funding of storage will end sooner where:</p> <ul style="list-style-type: none"> • the patient is no longer eligible for NHS fertility treatment, or • the patient dies and no written consent has been left permitting posthumous use. <p>To access assisted conception treatments using cryopreserved sperm, eggs or embryos, fertility preservation patients must meet the same eligibility criteria as other patients with fertility problems as set out in sections 1–6 of this document. An exception to this is that fertility preservation patients do not need to fulfil the ovarian reserve criterion to access IVF using their cryopreserved eggs or embryos.</p> <p>Ovarian tissue cryopreservation is not routinely funded for adults.</p>
<p>16. Surgical sperm retrieval for azoospermia</p>	<p>Surgical sperm retrieval is the commissioning responsibility of NHS England and is not routinely funded by NEL CCG.</p> <p>The NHS England policy on surgical sperm retrieval states it will only be funded where the patient has confirmed funding for subsequent stages of their fertility treatment pathway (i.e. cryopreservation and/or ICSI). The responsible clinician should therefore ensure NEL patients meet the relevant eligibility criteria outlined in this document prior to undertaking surgical sperm retrieval.</p> <p>Where an eligible patient has undergone successful surgical sperm retrieval funded by NHS England, cryopreservation and storage of sperm will be funded for up to two years.</p> <p>Where an eligible patient has undergone successful surgical sperm retrieval funded by NHS England, IVF/ICSI will be funded as per sections 7–10 of this policy.</p> <p>Storage of sperm and ICSI for patients undergoing surgical sperm retrieval prior to fertility preservation are covered by section 15 of this policy.</p>

17. Sperm washing	<p>Sperm washing will be funded for eligible couples where the woman or person trying to get pregnant is not living with HIV, but the sperm is from a partner who is living with HIV and is either:</p> <ul style="list-style-type: none"> • non-adherent with antiretroviral treatment, or • has an HIV viral load is 50 copies/ml or greater. <p>Where a successful sperm washing procedure has been undertaken, storage of washed sperm will be funded for up to two years.</p> <p>Where the sperm washing procedure is successful, depending on their clinical circumstances, patients may access IUI (as set out in section 12 of this policy) and/ or IVF (as set out in sections 7–10 of this policy).</p>
18. Surrogacy	<p>Assisted conception treatments involving surrogates are not routinely funded.</p>

<p>Useful websites:</p> <ul style="list-style-type: none"> • NHS webpage on infertility • NICE Clinical Guideline 156 on fertility problems • NICE Clinical Knowledge Summary on infertility • HFEA (Human Fertilisation and Embryology Authority) • Fertility Network UK • Donor Conception Network • Surrogacy UK • Stonewall – page on donor insemination and fertility treatment • Terrence Higgins Trust – page on parenthood • Endometriosis UK – page on fertility and pregnancy
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