North East Essex
Clinical Commissioning Group

Fertility Services Commissioning Policy

NEE CCG Policy Reference: NEE/CCG/2015/057

Where patients have commenced treatment in any cycle prior to this version becoming effective, they are subject to the eligibility criteria and scope of treatment set out in the relevant version.

Target Audience	CCGs, NHS Trusts, NHS England, commissioners, directors of finance, GPs, fertility nurses, service users
Brief Description (max 50 words)	This Commissioning Policy sets out the eligibility criteria for access to NHS funded specialist fertility services for the population of North East Essex, along with the commissioning responsibilities and service provision.
Action Required	Policy to be disseminated to all staff.

Title /Version Number/(Date)	Fertility Services Commissioning Policy/v1.4/February 2017
Document Status *(for information/ action etc)* and timescale	For circulation to all staff, and immediate implementation
Accountable Executive	Pam Green- Director of Transformation & Strategy
Responsible Post holder/Policy Owner	Business Delivery Manager/ Clinical Priorities Manager- Exceptional Clinical Cases & Individual Funding

Date Approved	7th February 2017
Approved By	Transformation and Delivery Committee
Review Date	7th February 2019
Equality Impact Assessment	**EQUALITY IMPACT ASSESSMENT** This document has been assessed for equality impact on the protected groups, as set out in the Equality Act 2010. This Policy is applicable to the Board, every member of staff within the CCG irrespective of their age, disability, sex, gender reassignment, pregnancy, maternity, race (which includes colour, nationality and ethnic or national origins), sexual orientation, religion or belief, marriage or civil partnership, and those who work on behalf of the CCG
Contact details for further information	Clinical Priorities Manager- Exceptional Clinical Cases & Individual Funding

Amendment History

Version	Date	Reviewer Name(s)	Comments
1.0	October 2014		Policy developed
1.1	December 2014	V. Pentney	Policy Amended
1.2	February 2015	V.Sawtell	Clauses 3.6.4, 4.1 amended in line with clarification received from NICE
1.3	October 2015	K West	Policy Amended
1.4	February 2017	F Jones	Policy wording reviewed and wording amended

Contents

Fertility treatment and referral criteria for tertiary level assisted conception

1. Introduction

1.1.1 This Commissioning Policy sets out the criteria for access to NHS funded specialist fertility services for the population of north east Essex, along with the commissioning responsibilities and service provision.

1.1.2 The paper specifically sets out the entitlement and service that will be provided by, and funded by, the NHS for In Vitro Fertilisation (IVF) and Intracytoplasmic Sperm Injection (ICSI) and other associated fertility services for the population of north east Essex. These services are commissioned for the population of north east Essex by North East Essex Clinical Commissioning Group (CCG) and provided via tertiary care providers.

1.1.3 It is the purpose of the criteria set out in this policy to make the provision of fertility treatment in north east Essex fair, clear and explicit. This paper should be read in conjunction with the CCG clinical priorities policy (insert link), including the policy statements related to assisted conception and sperm, embryo or oocyte storage/cryo preservation.

1.1.4 As stated in the CCG clinical priorities policy the CCG does **not** fund assisted conception services for infertility purposes alone. This policy details the circumstances where the CCG will fund and commission fertility services, and outlines the required eligibility criteria for access to fertility services. Fully eligibility criteria are detailed in section 4 of this policy.

1.1.5 This policy is specifically for couples where there is a need to prevent the transmission of chronic viral infections, during conception, such as HIV, Hep C etc. and requires the use of ICSI technology.

This may not be a fertility treatment, but should be considered as a risk reduction measure for a couple who wish to have a child, but do not want to risk the transmission of a serious pre-existing viral condition to the woman and therefore potentially their unborn baby.

1.1.6 This policy will also apply to couples undergoing cancer treatments or who have a disease or a condition requiring medical or surgical treatment that has a significant likelihood of making them infertile, excluding treatments where the primary purpose is infertility (e.g. sterilisation). Cancer patients are able to obtain NHS funded fertility preservation services (retrieval and storage) as part of the cancer pathway but are required to meet the overarching criteria for IVF, ICSI or IUI described in this policy in order to access these NHS funded assisted conception services for use of stored sperm, oocytes or embryos.

1.1.7 Couples who do not meet the criteria and consider they have exceptional circumstances may be considered by the CCG under the Prior Approval, individual Funding and Exceptional Cases Requests Policy of North East Essex CCG.

1.2 Review

1.2.1 North East Essex CCG will review this policy every two years and within 3 months of any legislative changes that should or may occur in the future. The date of the next review will be 1st March 2019.

2. Commissioning responsibility

2.1.1 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 Level 1 & 2.

2.1.2 Formal IVF commissioning arrangements will support the implementation of this policy including a contract between the North East Essex CCG and each tertiary centre, including arrangements made through coordinating commissioners. 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.

2.1.3 Where considering funding for fertility services North East Essex CCG will apply the eligibility criteria detailed in section 4 of this policy and in the CCG clinical priorities policy.

2.1.4 Couples who do not meet the criteria and consider they have exceptional circumstances may be considered by the CCG under the Prior Approval, individual Funding and Exceptional Cases Requests Policy of North East Essex CCG.

2.1.5 Couples will be offered a choice of providers that have been commissioned by East and North Hertfordshire CCG, the coordinating commissioner, on behalf of North East Essex CCG.

2.1.6 North East Essex CCG does not commission fertility services for members of the Armed Forces. NHS England Is the responsible commissioner for health services for members of the Armed Forces. For details of NHS England commissioned services please see https://www.england.nhs.uk/commissioning/policies/ssp/

3. North East Essex Clinical Commissioning Group Fertility services policy and criteria

3.1 Treatments funded

3.1.1 As stated in the North East Essex CCG clinical priorities policy fertility services, including assisted conception services and fertility preservation, are not routinely for infertility or for social or non-clinical reasons. Fertility services are only commissioned in the circumstances outlined in this policy.

3.1.2 The North East Essex CCG only commissions the following fertility techniques regulated by the Human Fertilisation & Embryology Authority (HFEA). Additional information on fertility techniques is available in section 6 of this policy.

3.2 In-Vitro Fertilisation (IVF)

3.2.1 IVF services and procedures will be funded, through prior approval, **only** where there is a need to prevent the transmission of chronic viral infections, during conception, such as HIV, Hep C etc. which requires the use of ICSI technology. This is subject to patients meeting the eligibility criteria detailed in section 4 of this policy

3.2.2 For couples requiring IVF or ICSI, where they meet the required eligibility criteria, this policy supports a maximum of two embryo transfers with a maximum of two fresh cycles (see 3.2.4) for women aged 23 – 39 years and a maximum of one embryo transfer (see 3.2.3) with a maximum of one fresh cycle for women aged 40 – 42 years (inclusive up until they reach their 43rd birthday), this includes abandoned cycles. Where couples have previously self-funded an IVF cycle without Pre-implantation Genetic Diagnosis (PGD) and pronucleate or cleavage stage frozen embryos (not blastocysts) exist, then the couples must utilise the previously frozen embryos, rather than undergo ovarian stimulation, egg retrieval and fertilisation again.

3.2.3 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. In all fresh cycles only one embryo, or blastocyst, will be transferred, unless there are medical mitigating circumstances.

3.2.4 A fresh cycle is considered to be completed once administration of drugs for the purpose of superovulation has occurred, or if no drugs are used, with the attempt to collect eggs.

3.2.5 For couples where the woman is under 38 years of age, a six month period between completion of the pregnancy test and commencement of drugs for

the next fresh cycle is required.

3.2.6 If a cycle is commenced and ovarian response is poor, a clinical decision is required 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.

3.2.7 Couples will be advised at the start of the treatment that this is the level of service that is available on the NHS in North East Essex. Patients must be counselled by the clinician and infertility counsellor to this effect.

3.2.8 If any fertility treatment results in a live birth, then the couple will no longer be considered childless (see 3.6.6) 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.

3.3 Sperm Recovery and Intra-Cytoplasmic Sperm Injection (ICSI)

3.3.1 Recovery of Sperm, including the use of a variety of available techniques, will be funded via prior approval as part of approved funded ICSI and sperm or embryo cryopreservation/storage, where patients meet the eligibility criteria outlined in section 4 of this policy. For details of approved techniques see section 6 of this policy.

3.3.2 Sperm recovery techniques outlined in this policy are not available to patients who have undergone a vasectomy.

3.4 Intra Uterine Insemination (IUI)

3.4.1 Due to poor clinical evidence, IUI will only be offered under exceptional circumstances.

3.5 Donor insemination

3.5.1 Donor insemination may be indicated where the male partner is likely to pass on an inheritable genetic condition or severe rhesus incompatibility has been a problem because of the male partners homozygous status. Funding for donor insemination may be available through prior approval where the patient meets the eligibility criteria outlined in section 4 of this policy.

3.6 Sperm, Egg and Embryo storage

3.6.1 The policy regarding Sperm, Egg and Embryo storage criteria is set out within the CCG's Clinical Priorities Policy and this section should therefore be read in accordance with this policy.

3.6.2 Fertility preservation will not routinely be offered for infertility, including for social or non-clinical reasons, such as patient choice to delay trying to conceive/conception or where a patient has chosen to undergo medical or

surgical treatment with the primary purpose of causing infertility, such as sterilisation or vasectomy.

3.6.3 Fertility preservation will **only** be offered to patients undergoing cancer treatments, or who have a disease or a condition requiring medical or surgical treatment that has a significant likelihood of making them infertile. This includes individuals/couples undergoing gender reassignment, where fertility preservation forms part of the clinical pathway.

3.6.4 Eligibility for fertility preservation does not entitle patients to assisted conception treatments such as in-vitro fertilisation (IVF). Patients requiring subsequent assisted conception treatments will only be funded if they meet the criteria specified in this fertility services commissioning policy.

3.6.5 The following fertility preservation methods will be considered for funding where the applicable criteria is met:

- Sperm cryostorage
- Embryo cryostorage
- Oocyte cryostorage

3.6.6 Patients will have to meet the following criteria:

- Commenced puberty and be aged up to 42 years (inclusive up until they reach their 43rd birthday) old for female patients or up to 55 years old for male patients.
- Female patients not only need to be well enough to undergo ovarian stimulation and egg collection but this should not worsen their condition and that sufficient time is available prior to starting treatment.
- Patients must not have any living children, from either current or previous relationships, regardless of whether the child resides with them. This includes biological and adopted children from within current or previous relationships; this will apply to adoptions either in or out of the family

3.6.7 The procedures recommended by the Royal College of Physicians and the Royal College of Radiologists should be followed before commencing chemotherapy or radiotherapy likely to affect fertility, or management of post- treatment fertility problems.

3.6.8 Men and adolescent boys preparing for medical treatment, that is likely to make them infertile, should be offered semen cryostorage. The effectiveness of this procedure has been established.

3.6.9 Services will ensure that local protocols exist to ensure that health professionals are aware of the values of semen cryostorage in these circumstances, so that they deal with the situation sensitively and effectively.

3.6.10 Female patients preparing for medical treatment that is likely to make them infertile should be offered oocyte or embryo cryostorage as appropriate, if they are well enough to undergo ovarian stimulation and egg collection, provided that this will not worsen their condition and that sufficient time is available.

3.6.11 The sperm, embryos or oocytes will be stored for an initial period of 10 years, with prior approval, as permitted in current legislation. It is possible to extend the time or storage, if the material has not been used. This will require additional approval from the CCG.

3.7 Use of stored Sperm, Eggs and Embryos following Assisted conception

3.7.1 If any fertility treatment results in a live birth, 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.

3.8 Egg donation where no other treatment is available

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

3.8.2 Use of donated eggs for assisted conception will be funded, through prior approval, for women who have undergone premature ovarian failure 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 meets the other eligibility criteria detailed in this policy.

3.9 Pre-implantation Genetic Diagnosis (PGD)

3.9.1 North East Essex CCG does not fund PDG as it is not considered to be within the scope of fertility treatment. PDG services for some patients may be funded by NHS England. For details of PGD services funded by NHS England please see https://www.england.nhs.uk/commissioning/spec-services/npc-crg/group-e/e01/

3.10 Chronic Viral Infections

3.10.1 The need to prevent the transmission of chronic viral infections, during conception, such as HIV, Hep C etc. requires the use of ICSI technology. This is a specialist service and is only available at a limited number of centres. The East and North Herts CCG commission these services, on

behalf of North East Essex CCG, from an appropriately designated unit.

3.10.2 This may not be a fertility treatment, but should be considered as a risk reduction measure for a couple who wish to have a child, but do not want to risk the transmission of a serious pre-existing viral condition to the woman and therefore potentially her unborn baby.

3.11 Privately funded care

3.11.1 This policy covers NHS funded fertility treatment only. For clarity, Patients will not be able to pay for any part of the treatment within a cycle of NHS fertility treatment. This includes, but is not limited to, any drugs (including drugs prescribed by the couple's GP), recommended treatment that is outside the scope of the service specification agreed with the Secondary or Tertiary Provider or experimental treatments.

3.11.2 Where a patient meets the North East Essex 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.

3.12 Surrogacy

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

4. Eligibility criteria for accessing fertility services

4.1 Minimum and maximum age

Any treatment cycle will not be commenced before the female is 23 years of age but must be commenced before the female reaches her 43rd birthday.

Any treatment cycle must be commenced before the male is 55 years of age.

4.2 North East Essex Resident

Couples must be resident within North East Essex for 12 months prior to treatment.

4.3 Body Mass Index

The woman must have a body mass index of between at least 19 and up to and including 30 prior to referral for fertility treatment and at any time throughout treatment.

4.4 Maximum FSH Level

A maximum follicle stimulating hormone (FSH) level of 9U/L on day 2 of any

menstrual cycle. Where couples are eligible for IUI treatment with donor eggs, the female must not have menstruated for 9 months.

4.5 Duration of sub-fertility

North East Essex CCG does not fund fertility services for infertility or sub fertility alone.

The criterion in this policy apply to couples where there is a need to prevent the transmission of chronic viral infections, during conception, such as HIV, Hep C etc. and requires the use of ICSI technology. AND for couples undergoing cancer treatments or who have a disease or a condition requiring medical or surgical treatment that has a significant likelihood of making them infertile.

This may not be a fertility treatment, but should be considered as a risk reduction measure for a couple who wish to have a child, but do not want to risk the transmission of a serious pre-existing viral condition to the woman and therefore potentially her unborn baby. Earlier access to IVF treatment may be considered if the woman is aged 36 or over.

4.6 Previous IVF treatment

Previous privately funded treatment will not preclude patients from being eligible to NHS funded cycles up to a maximum of two embryo transfers or two fresh cycles, where the patient meets the other criteria outlined in this policy. However previous cycles, whether NHS or privately funded, will be taken into account by the responsible clinician in determining the clinical appropriateness of commencing further cycles. In line with current clinical evidence, couples should undergo no more than 5 fresh cycles in total.

4.7 Smoking status

Where couples smoke, only those who agree to take part in a supportive programme of smoking cessation will be accepted on the IVF treatment waiting list, and should be non-smoking at the time of treatment.

4.8 Parental status

There should be no living child from the couples 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.

4.9 Previous sterilisation

Couples are ineligible if previous sterilisation has taken place (either partner), even if it has been reversed.

4.10 Child welfare

Couples must conform to the statutory 'Welfare of the Child' requirements. See http://www.hfea.gov.uk/5473.html

4.11 Medical conditions

Treatment may be denied on other medical grounds not explicitly covered in this document.

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 and Secondary Care setting.

5.2 A decision to refer a couple for IVF or other fertility services will be based on an assessment against the North East Essex CCG eligibility criteria outlined in this policy.

5.3 Referral to the tertiary centre will be via a relevant Consultant Specialist with a direct involvement in the patient's case.

6 Additional Information and Glossary

6.1 In-Vitro Fertilisation (IVF)

An IVF procedure includes four basic steps; ovarian stimulation, egg recovery, insemination and finally embryo replacement. The eggs produced are then placed in a special environment in a laboratory to be fertilised. The fertilised eggs produced are then transferred to the woman's uterus.

6.2 Sperm Recovery techniques

Spermatozoa can be retrieved from both the epididymis and the testes using a variety of techniques with the intention of achieving pregnancies or couples where the male partner has obstructive or non-obstructive azoospermia. Sperm recovery is also used in ejaculatory failure and where only non-motile spermatozoa are present in the ejaculate.

In obstructive azoospermia, sperm needs to be obtained directly from the testis by aspiration (TESA) or biopsy (TESE). In some men sperm can be recovered from naturally occurring spematoceles by percutaneous puncture.

In non-obstructive azoospermia, sperm needs to be obtained directly from the testis by aspiration (TESA) or biopsy (TESE). The chance of finding sperm is reduced. PESA and TESA can be performed under local anaesthesia in an outpatient clinic. Percutaneous epididymal Sperm Aspiration (PESA) does not

jeopardise future epididymal sperm retrieval.

6.3 Donor insemination

Male infertility affects about 25% of couples. Until ICSI became available the main technique for treating male factor infertility where azoospermia or severe abnormalities of semen quality were present was insemination with donated sperm.

The need to prevent transmission of sexually transmitted diseases (including HIV) by donor insemination has led to the mandatory quarantine of donor sperm for six months by cryopreservation prior to its use in the UK. Donor insemination may be indicated where the male partner is likely to pass on an inheritable genetic condition or severe rhesus incompatibility has been a problem because of the male partners homozygous status.

6.4 Intra Cytoplasmic Sperm Injection (ICSI)

Intra Cytoplasmic Sperm Injection (ICSI) may be used in conjunction with IVF. A single sperm is directly injected, into the egg to fertilise it.

6.5 Intra uterine insemination (IUI)

Insemination of sperm into the uterus of a woman, following collection and washing of the sperm.

6.6 Oocyte

Oocyte is another word for Egg, the female gamete used in reproduction.

6.7 Storage and cryopreservation/cryostorage

The storage of eggs/oocytes, embryos or sperm by freezing at low temperatures in order to preserve them.

6.8 Pre implantation genetic diagnosis (PGD)

PGD involves the removal of one or two cells from an embryo, in order for those cells to be tested for specific genetic disorders/characteristics before embryo transfer takes place.

6.9 Pro nucleate

A normal fertilised egg should contain two pro-nuclei, one from the egg and one from the sperm.

6.10 Cleavage stage frozen embryos

Embryos frozen at around day 3 after fertilization, when they have approximately 4

to 8 cells

6.11 Blastocyst

An embryo that has developed for five to six days after fertilisation

6.12 Pathological cause

A medical condition causing or resulting in certain medical circumstances, such as infertility. (see 3.8.2)

6.13 Iatrogenic cause

A medical condition, such as infertility, resulting from medical treatment or diagnostics (see 3.8.2)

6.14 Surrogacy

The process of a woman carrying a baby for another person. This may involve the implantation of an embryo created using either the eggs and sperm of the intended parents, a donated egg fertilised with sperm from the intended father or an embryo created using donor eggs and sperm. Partial surrogacy involves sperm from the intended father and an egg from the surrogate.

6.15 Primary care

Health services provided in the community, usually the first point of contact. E.g. a GP

6.16 Secondary services

Health services that are provided by a specialist or facility that requires more specialized knowledge, skill, or equipment than the primary care services. E.g. District general hospital services

6.17 Tertiary services/ Level 3 services

Health services that are provided by specialist, with advanced medical investigation and treatment or highly specialised expertise required.

Resources

The following resources have been reviewed to inform this policy:

- The NICE Guidance CG156 “Fertility: assessment and treatment for people with fertility problems” (2013) available on their website at https://www.nice.org.uk/guidance/CG156
- The Human Fertilisation & Embryology Authority (HFEA) document “The Best Possible Start to Life” (2007) available on their website www.hfea.gov.uk
- The report “One Child at a Time“ published by the Expert Group on Multiple

Births after IVF set up by HFEA available on their web site www.hfea.gov.uk/en/505.html

For more information on Fertility terminology please see the HFEA website: http://www.hfea.gov.uk/glossary.html