NORTH LINCOLNSHIRE CCG EVIDENCE-BASED INTERVENTIONS POLICY DOCUMENT

Interventions subject to Prior Approval or an Individual Funding Request

NOVEMBER 2019 (VERSION 3)
NORTH LINCOLNSHIRE CCG

Introduction

This document outlines commissioning policy statements on clinical interventions, individual to North Lincolnshire CCG, that are not routinely commissioned or are restricted. **Please note that the majority of policies implemented by North Lincolnshire CCG are included in the Humber CCG aligned policy document, accessed via link at the bottom of the page.**

The objective of this policy is to support CCG decision-making on these interventions and procedures, aiming to provide a statement on interventions based on the available evidence to enable a reasoned and structured process for individual cases to be considered for funding by the CCG.

Humber CCG aligned policy statements

Hull, East Riding of Yorkshire, North Lincolnshire, and North East Lincolnshire Clinical Commissioning Groups (CCGs) have worked together to align the majority of CCG clinical commissioning policy statements across the Humber area. As part of this process, some of these statements have been amended and updated as per recommendations for interventions from the NHS England National Evidence-based Interventions Programme.

Contents

Fertility Interventions

Intervention	**Assisted Reproductive Techniques (ART) - Infertility**
For the treatment of	Infertility
Commissioning Position	This intervention is NOT routinely commissioned. This intervention is a Category One Evidence Based Intervention; therefore, any requests to fund must be made as an Individual Funding Request. The care pathway for infertility problems and the access criteria for routine referral to specialist tertiary care are outlined below. In addition, the CCG will consider, via the Individual Funding Request (IFR) process: • Requests from clinicians for individual fertility related treatments not explicitly included in this policy; • Requests for ART treatment for patients who fall outside the stated eligibility criteria. The referring clinician must explain in full why exceptional clinical circumstances apply. **THE CARE PATHWAY:** Treatment for infertility problems may include counselling, lifestyle advice, drugs, surgery and assisted reproduction techniques such as IVF. The care pathway for infertility begins in primary care where the first stage of treatment is generally lifestyle advice to increase the chance of conception happening naturally. If this is not effective, initial assessment such as semen analysis will take place. If appropriate the couple will then be referred to secondary care services where further investigations and treatment will be carried out. This might involve surgical treatment or use of hormonal drugs to stimulate ovulation. If this is unsuccessful or inappropriate and the couple fit the eligibility criteria they will then be referred to tertiary care for assessment for assisted conception techniques such as IVF, DI, IUI and ICSI. All clinically appropriate couples are entitled to medical advice and investigation, and may be referred to a secondary care clinic for further investigation. However, only those meeting the eligibility criteria should be referred to tertiary care fertility services. **DEFINING INFERTILITY & ACCESS TO TERTIARY FERTILITY SERVICES:** Infertility in women of reproductive age is defined as the presence of known reproductive pathology; • OR, in the absence of any known cause of infertility, the inability to conceive after 1 year of regular unprotected vaginal sexual intercourse; • OR, if using artificial insemination (AI) (with partner or donor sperm), failure to conceive after 6 cycles of AI attempts OR, for same sex- couples, 6 self-funded rounds of IUI. Women meeting this definition will be offered further clinical assessment and investigation along with their partner (unless donor sperm has been used). However, in certain circumstances, earlier referral to Fertility Services will be offered, where:

- Treatment is planned that may result in infertility (such as treatment for cancer);
- The woman is aged 36 years or over;
- There is a known clinical cause of infertility or a history of predisposing factors for infertility;
- The person concerned about their fertility is known to have a chronic viral infection (such as hepatitis B, hepatitis C or HIV) in which case referral to a specialist tertiary centre may be required.

ELIGIBILITY CRITERIA FOR ASSISTED REPRODUCTION TECHNIQUES:

Eligibility criteria apply at the point patients are referred to tertiary care and apply equally to all assisted reproduction treatments whether using partner or donor sperm:

- Couples must meet the definition of infertility, as described above.
- To be eligible for referral the woman to receive ART treatment must be registered with a North Lincolnshire GP contracted and/or aligned to NHS North Lincolnshire CCG. [Women living within the geographical boundary of North Lincolnshire but not registered with any GP should note that the care pathway for fertility treatment starts in primary care and therefore it is essential to be registered with a GP to go on to access ART.]
- Neither partner within a couple should have any children (biological or adopted) from the current or any previous relationships
- This policy uses the same age-related criteria as the access criteria for IVF, which is founded on clinical reasoning and reflects the decreasing chances of successful conception with increasing age up to 42. However, referrers should be mindful of patients' age at the point of referral and the age limit for new IVF cycles (see below)
- The female patient's BMI should be between 19 and 30 prior to referral to tertiary services. Women with a higher BMI should be directed to healthy lifestyle interventions prior to referral. However, BMIs outside this range will be considered via the Individual Funding Request (IFR) process in the context of other individual factors including age.

NHS North Lincolnshire CCG will not commission ART for patients who are sterilised or have unsuccessfully undergone reversal of sterilisation.

ACCESS CRITERIA FOR IVF:

<u>Definition of a full cycle of IVF Treatment</u>

A full cycle of IVF is defined as one episode of ovarian stimulation and the transfer of any resultant fresh and frozen embryos. This includes subsequent transfers of any remaining embryos should the first transfer be unsuccessful.

<u>Age and number of cycles</u>

In women aged under 40 years either with a known cause of infertility or unexplained infertility and no conception after 2 years of regular unprotected intercourse (or 12 cycles of AI, where 6 or more are by IUI), **the CCG will commission one full cycle of IVF**, with or without ICSI.

If the woman reaches the age of 40 during treatment, the full cycle will be completed.

In women aged 40-42 years either with a known cause of infertility or unexplained infertility and no conception after 2 years of regular unprotected intercourse (or 12 cycles of AI, where 6 or more are by IUI), NHS North Lincolnshire CCG will commission 1 full cycle of IVF, with or without ICSI, provided the following 3 criteria are fulfilled:

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

Where investigations show there is no chance of pregnancy with expectant management OR where, after assessment, IVF is considered as the only effective treatment, the woman may be referred directly to a specialist team for IVF treatment.

The provider will take into account the outcome of previous IVF treatment when assessing the likely effectiveness and safety of any further IVF cycles.

Previous self-funded cycles

Any previous full IVF cycle, whether self- or NHS-funded, will count towards the single full cycle that may be offered by the NHS. Therefore, consideration of NHS funded treatment should be undertaken prior to exploring self-funding options.

Treatment limits

Treatment limits are per couple e.g. where a woman in a heterosexual relationship undergoes a maximum number of cycles with one partner, she is not entitled to further cycles with a different partner. Where a woman in a same sex couple undergoes the maximum number of cycles with one partner, her partner is not then also entitled to a maximum number of cycles.

Intrauterine Insemination (IUI)

NHS North Lincolnshire CCG will commission an initial consultation to discuss the options for attempting conception 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 donor sperm;
- People with conditions that require specific consideration in relation to methods of conception (for example, after sperm washing where the man is HIV positive);
- People in same-sex relationships.

Where clinically appropriate in these groups (e.g. unexplained infertility after a number of AI attempts), a minimum of 6 cycles of IUI may be offered as an alternative to vaginal sexual intercourse, up to a total of 12 cycles, before IVF will be considered.

In women over 36, OR where clinical investigations suggest IUI would not be considered the most effective treatment, the minimum number of IUI cycles offered may be reduced.

SPECIAL ART PROCEDURES:

IVF with Intracytoplasmic Sperm Injection (ICSI)

The recognised indications for treatment by ICSI include couples where the male partner shows:

- Severe deficits in semen quality;
- Obstructive azoospermia;

- Non-obstructive azoospermia.

In addition, treatment by ICSI will be considered for couples in whom a previous IVF treatment cycle has resulted in failed or very poor fertilisation.

Donor sperm / Donor insemination

Donor sperm will be funded but it will be the responsibility of the Provider to source.

The use of donor insemination is considered effective in managing fertility problems in couples affected by the following conditions:

- Obstructive azoospermia;
- Non-obstructive azoospermia;
- Severe deficits in semen quality in couples who do not wish to undergo ICSI.

Donor insemination should be considered in conditions such as:

- Where there is a high risk of transmitting a genetic disorder to the offspring;
- Where there is a high risk of transmitting infectious disease to the offspring or woman from the man;
- Severe rhesus isoimmunisation.

Couples using donor sperm should be offered IUI in preference to ICSI, and where the woman is ovulating regularly they should be offered up to 6 cycles of donor insemination (dependent on the availability of donor sperm) for conditions listed under this recommendation, without ovarian stimulation to reduce the risk of multiple pregnancy and its consequences.

Donor eggs

The use of donor oocytes will be commissioned for the following conditions:

- Premature ovarian failure;
- Gonadal dysgenesis including Turner syndrome;
- Bilateral oophorectomy;
- Ovarian failure following chemotherapy or radiotherapy;
- Certain cases of IVF treatment failure.

Oocyte donation will be considered in certain cases where there is a high risk of transmitting a genetic disorder to the offspring.

Patients eligible for treatment with donor eggs will be placed on the waiting list for treatment with donor eggs. Unfortunately, the availability of donor eggs is severely limited in the UK. There is therefore no guarantee that eligible patients will be able to proceed with treatment.

Patients will be placed on the waiting list for an initial period of 3 years, after which they will be reviewed to assess whether the eligibility criteria are still met.

NHS North Lincolnshire CCG will fund the additional costs associated with treatment using donor eggs but the responsibility for sourcing donor eggs will be with the Provider.

CRYOPRESERVATION:

Embryo and sperm storage will be funded for patients who are undergoing NHS fertility treatment (excluding patients affected by the need to preserve fertility as a consequence of being diagnosed with cancer – see below). Storage will be funded for a maximum of 3 years or until 6 months post successful live birth, whichever is the shorter. Any embryo storage funded privately prior to the implementation of this

	policy, will remain privately funded. **CRYOPRESERVATION TO PRESERVE FERTILITY IN PATIENTS DIAGNOSED WITH CANCER OR UNDERGOING GENDER REASSIGNMENT SURGERY:** Patients preparing to have treatment for Cancer or Gender Dysphoria that is likely to result in fertility problems should be offered cryopreservation and arrangements to enable this pathway to be adhered to where clinically appropriate should be evidenced. Cryopreserved material should be stored for an initial period of 10 years where the intended outcome is to preserve fertility in patients diagnosed with Cancer or undergoing Gender Reassignment. Continued storage of cryopreserved sperm beyond 10 years should be offered to men who remain at risk of significant infertility. The existence of living children should not be a factor that precludes the provision of fertility treatment. There should not be a lower age limit for cryopreservation for fertility preservation in patients diagnosed with Cancer or undergoing Gender Reassignment. **Cryopreservation for women**: women of reproductive age, including adolescent girls, should be offered oocyte or embryo cryopreservation as appropriate (refer to Quality Standard for pathway). **Cryopreservation for men:** sperm cryopreservation should be offered for men and adolescent boys. **HIV / HEPATITIS B / HEPATITIS C:** Special procedures for treatment apply and patients may be referred to a different specialist tertiary centre
Evidence/Summary of Rationale	In couples having unprotected regular vaginal intercourse, after 2 years the overall cumulative pregnancy rate is about 92%, leaving 8% of couples unable to conceive without medical intervention. The main causes of infertility in the UK are (percent figures indicate approximate prevalence): • Factors in the male causing infertility (30%) • Unexplained infertility (no identified male or female cause) (25%) • factors in the female, e.g. ovulatory disorders (15%), tubal damage • (15%), other factors (5%) • Problems in both partners (10%). Once a diagnosis has been established, treatment falls into 3 main types: • Medical treatment to restore fertility (for example, the use of drugs for ovulation induction) • Surgical treatment to restore fertility (for example, laparoscopy for ablation of endometriosis) • Assisted reproduction techniques (ART) – any treatment that provides a means of conception other than vaginal intercourse. Tertiary Fertility Services provide: Intrauterine Insemination (IUI), Intracytoplasmic Sperm Injection (ICSI) and IVF. They may also include the provision of donor sperm and donor eggs.
Effective From	1st December 2019
Policy Review Date	1st December 2021

Intervention	**Gamete Harvesting and Storage**
For the treatment of	Harvesting and Storage of viable gametes in patients undergoing NHS funded medical treatment (s) that cause infertility
Commissioning Position	Humber CCGs agree to fund the harvesting and subsequent storage (cryopreservation) of viable gametes, for an initial period of 10 years, for patients undergoing NHS funded medical treatment that may leave them infertile. If after the initial 10 year period storage is still required, an IFR application should be made as an exceptional request, provided the patient wishes to keep their sample for potential future use. Each case will be considered on its own merit and in line with the HFEA legislation. Approval for harvesting and cryopreservation does not guarantee future funding of assisted conception or fertility treatment – in this instance the specific CCG policy for assisted conception should be applied. Prior to fertility preservation, the secondary care clinician at the organisation providing the fertility service must confirm: • That the planned treatment is likely to affect future fertility (and document this for the commissioners' audit purposes) • That the impact of the treatment on fertility has been discussed with the patient • That the patient is able to make an informed choice to undertake gamete harvesting and cryopreservation of semen, oocytes or embryos for an initial period of 10 years • That the patient is aware that funding for gamete harvesting and cryopreservation does not guarantee future funding of assisted conception treatment **Cryopreservation in males** In general, it is recommended that at least two semen samples are collected over a period of one week. The CCGs will commission a maximum of three samples of semen; this is considered sufficient to provide future fertility. Testicular tissue freezing is considered experimental and will not be funded. Note: testicular sperm retrieval is commissioned by NHS England and not by the CCGs. **Cryopreservation in Females** The CCG will normally fund one cycle of egg retrieval, with or without fertilisation. If fewer than 10 eggs are retrieved following this first cycle of egg retrieval, then one further cycle can be offered. Ovarian tissue storage is considered experimental and will not be funded. **Age** There are no specific age limits to this policy for males or females. The decision to attempt to preserve fertility is a clinical decision.

	Previous sterilisation Gamete retrieval and cryopreservation will not be funded where the patient has previously been sterilised. **NHS Funded Assisted Conception** Access to NHS funded harvesting and cryopreservation will not be affected by previous attempts at assisted conception. However, funding for further assisted conception attempts will be subject to the criteria stated in the CCG's IVF policy at the time of any funding application. **Expectations of Providers** Cryopreservation of gametes or embryos must meet the current legislative standards, i.e. under Human Embryo and Fertility Act 1990. The provider of the service must ensure the patient receives appropriate counselling and provides full consent. The patient and their partner must be made aware of the legal position on embryo ownership should one partner remove consent to their ongoing storage or use. The provider of the service must ensure patients are aware of legal issues on posthumous use of gametes and embryos should they wish a partner to be able to use these should their treatment not be successful. Patients will need to provide annual consent for continued storage. The provider must ensure appropriate consent to storage is in place and that the patient understands the need for on-going consent and has outlined the purposes for which they can be used. **Expectation of the Patient** The patient will be responsible for ensuring the storage provider has up to date contact details. Failure to provide on-going consent may result in the destruction of stored materials.
Effective From	1st December 2019
Policy Review Date	1st December 2021

Appendix 1 – References (in order of appearance)

FERTILITY INTERVENTIONS

Assisted Reproductive Techniques (ART) – Infertility

NICE Clinical Guideline 156 (Feb 2013) Fertility Assessment and treatment for people with fertility problems. http://guidance.nice.org.uk/CG156

Yorkshire and the Humber Specialised Commissioning Group. Commissioning Policy Specialised Fertility Services (Ref 21/11) Sept 2011

NHS Commissioning Board (Feb 2013) Commissioning fertility services factsheet http://www.england.nhs.uk/wp-content/uploads/2013/02/fertility-facts.pdf

NHS Fertility Treatment: A Short Guide (Stonewall) https://www.stonewall.org.uk/documents/fertility_treatment_guide.pdf *"This (NICE 2013) guidance does not stipulate whether couples need to try and conceive using a fertility clinic, or whether attempts to conceive at home with donor sperm makes you eligible for NHS treatment. This is a decision for your local NHS Trust to make. Many NHS Trusts will require same-sex couples to use fertility."*

Gamete Harvesting and Storage

Appendix 2 – OPCS Codes (in order of appearance)

FERTILITY INTERVENTIONS	
Assisted Reproductive Techniques (ART) – Infertility	Q13*, Q21*, Y96*, N345, N344, N342, N346
Gamete Harvesting and Storage	