

General Commissioning Policy

Treatment	Assisted Reproduction Techniques (ART)
For the treatment of	Infertility
Background	<p>From April 2013 the responsibility for commissioning Fertility Services transferred from Specialist Commissioning Groups (SCGs) to NHS Clinical Commissioning Groups (CCGs). This policy represents NHS Hull CCG's commissioning position on tertiary fertility services.</p> <p>The commissioning position incorporates some updates made in the NICE Clinical Guideline 156 (2013) <i>Fertility Assessment and treatment for people with fertility problems</i> which replaced NICE Clinical Guideline 11 (2004). The commissioning position has been further revised following the issue of updated NICE Guidance on the Care Pathway for Cryopreservation dated 27 January 2015. http://pathways.nice.org.uk/pathways/fertility.</p> <p>It has also been revised to provide a more comprehensive policy on Assisted Reproduction Techniques (ART) and not just In Vitro Fertilisation (IVF).</p> <p>The policy aims to ensure that those most in need and able to benefit are given equitable access to tertiary fertility services.</p> <p>This policy focuses on treatment via assisted reproduction techniques (ART). However, NHS Hull CCG expects providers of fertility services to follow any clinical treatment recommendations in NICE CG156 that have not been explicitly included/excluded in this policy and to comply with any service specification drawn up by NHS Hull CCG, in order to be commissioned under this policy.</p> <p>Fertility services fall under the 18- week maximum waiting time. The majority of treatment in the UK is statutorily regulated by the Human Fertility and Embryo Authority (HFEA) and all tertiary providers of fertility services must be licensed by the HFEA.</p>
Commissioning position	<p>The care pathway for infertility problems and the access criteria for routine referral to specialist tertiary care are outlined below.</p> <p>In addition, NHS Hull CCG will consider, via the Individual Funding Request (IFR) process:</p> <ul style="list-style-type: none"> • 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. <p>The referring clinician must explain in full why exceptional clinical circumstances apply.</p> <p>THE CARE PATHWAY:</p> <p>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</p>

Notes

1. This Policy will be reviewed in the light of new evidence, or guidance from NICE.
2. General Commissioning Policies are agreed by the Planning and Commissioning Committee on behalf of NHS Hull CCG.

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 individuals and couples are entitled to medical advice and investigation. Couples may be referred to a secondary care clinic for further investigation. However, only couples 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 Hull GP contracted and/or aligned to NHS Hull CCG. [Women living within the geographical boundary of Hull 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 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 Hull CCG will not commission ART for patients who are sterilised or have unsuccessfully undergone reversal of sterilisation.

ACCESS CRITERIA FOR IVF:

Age and number of cycles

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), NHS Hull CCG will commission up to 3 full cycles of IVF, with or without ICSI.

If the woman reaches the age of 40 during treatment, the current full cycle will be completed but no further full cycles will be offered.

The approval for a 3rd cycle of IVF must be requested from the IFR panel, to gain assurance that the eligibility criteria are still met and the probability of conception remains above 10%, based on clinically accepted predictive models.

In women aged under 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 Hull 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 total of 3 full cycles that may be offered by the NHS.

The definition of a full IVF cycle is one episode of ovarian stimulation and the transfer of any resultant fresh and frozen embryos.

Treatment limits

Treatment limits are per couple and per individual 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 Hull 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 ICI, 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 Hull 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. 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:

NICE Guidance (Quality Standard 9) states that patients preparing to have treatment for cancer 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. 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.

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.
Effective from	July 2015 <i>(This policy supersedes Yorkshire and the Humber SCG Policy for Specialised Fertility Services 21/11 published September 2011 and NHS Hull PCT General Commissioning Policy Statement Fertility Treatment / Assisted Conception ref: T06/10. Published March 2011) and the NHS Hull CCG General Commissioning Policy – Assisted Reproduction Techniques (ART) September 2013.</i>
Summary of evidence / rationale	<p>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.</p> <p>The main causes of infertility in the UK are (percent figures indicate approximate prevalence):</p> <ul style="list-style-type: none"> • 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%). <p>Once a diagnosis has been established, treatment falls into 3 main types:</p> <ul style="list-style-type: none"> • 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. <p>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.</p> <p>The Department of Health (DH) costing tool (2009) estimates that there are 98 attendances at a fertility clinic for every 10,000 head of population. Using the DH assumptions and model, for Hull this would equate to an indicative 270 attendances per year which would result in 130 couples likely to be assessed as suitable for IVF treatment, with 46-83 couples being assessed as eligible (dependent on criteria used).</p>
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Glossary and Key Abbreviations Used

Acronym / Term	Definition
AI	<p>Artificial Insemination. A means of attaining pregnancy not involving sexual intercourse, by directly inserting sperm into the woman via needleless syringe or catheter. Covers four types of treatments, depending on where the sperm is placed:</p> <p>IVI - intravaginal insemination (placing a sample of sperm directly inside the vagina near the cervix). IVI can be performed at home using a sterile oral syringe.</p> <p>IUI - intrauterine insemination (involves a laboratory procedure to separate fast moving sperm from more sluggish or non-moving sperm;</p>

	<p>fast moving sperm are placed into the uterus close to the time of ovulation). By far the most common AI method.</p> <p>ICI - intracervical insemination (injection of unwashed sperm into the cervix)</p> <p>ITI - intratubal insemination (placing sperm into the fallopian tubes). Used rarely since it is significantly more invasive and no more successful than IUI.</p>
ART	Assisted Reproduction Techniques. Any treatment that deals with a means of conception other than vaginal intercourse.
BMI	<p>The healthy weight range is based on a measurement known as the Body Mass Index (BMI). This is calculated as your weight in kilograms divided by the square of your height in metres.</p> <p>In England, people with a body mass index between 25 and 30 are categorised as overweight, and those with an index above 30 are categorised as obese.</p>
DI	Donor Insemination: The introduction of donor sperm into the vagina (IVI), the cervix (ICI) or womb (IUI) itself.
GP	General Practitioner
HFEA	Human Fertilisation and Embryology Authority
ICSI	Intra Cytoplasmic Sperm Injection: involves injecting a single sperm directly into an egg in order to fertilise it. The fertilised embryo is then transferred to the woman's uterus.
IFR	Individual Funding Request
IVF	In Vitro Fertilisation: Patient's eggs and her partner's sperm are collected and mixed together in a laboratory to achieve fertilisation outside the body. The embryos produced may then be transferred into the female patient.
NICE	National Institute for Health and Care Excellence
Expectant management	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.
Surgical treatment	Some cases of infertility in both men and women can be helped with surgery. Sterilisation can sometimes be reversed; fallopian tubes can be unblocked using keyhole surgery and sperm can be retrieved surgically for use in fertility treatment. The HFEA does not regulate any surgery.

References:

1. NICE Clinical Guideline 156 (Feb 2013) Fertility Assessment and treatment for people with fertility problems. <http://guidance.nice.org.uk/CG156>
2. Yorkshire and the Humber Specialised Commissioning Group. Commissioning Policy Specialised Fertility Services (Ref 21/11) Sept 2011
3. NHS Commissioning Board (Feb 2013) Commissioning fertility services factsheet <http://www.england.nhs.uk/wp-content/uploads/2013/02/fertility-facts.pdf>
4. 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

clinics to conceive before considering funding treatment, meaning same-sex couples will need to pay fees before being eligible for NHS funded treatment.

Why might I be expected to pay for fertility treatment?

Your NHS Trust will make its own decision about whether they expect you to try and concave 6 times at a clinic (for a fee) or at home (for free). Stonewall expect many Trusts will have to say you have to try to do so at a clinic as they will want you to try to conceive using a safe and clinically effective method of contraception using approved and tested sperm". (Ref: Stonewall 2013)

5. Dept of Health. (June 2009) Regulated Fertility Services: A commissioning aid
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6. Dept of Health. (June 2009) Regulated fertility services spreadsheet model.
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