

POLICY DOCUMENT

Intrauterine (IUI) and Donor Insemination (DI) Policy (excluding In vitro fertilisation (IVF) & Intracytoplasmic sperm injection (ICSI) treatment)	
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Leicester City , East Leicestershire and Rutland & West Leicestershire Collaborative Policy

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1 Policy

This paper sets out the criteria for access to NHS funded fertility services for patients who are the responsibility of Leicester, Leicestershire and Rutland (LLR) Clinical Commissioning Groups (CCGs). This policy covers the provision of Donor Insemination (DI) and Intrauterine Insemination (IUI) only and should be read in conjunction with the East Midlands Specialised Commissioning Group Commissioning Policy for IVF / ICSI within Tertiary Infertility Services.

It sets out the minimum entitlement and service that will be provided for NHS fertility services across the health community. IVF and ICSI services are commissioned separately by the East Midlands Specialised Commissioning Group. Couples requiring Pre-Implantation Genetic Diagnosis will be considered under the current East Midlands Specialised Commissioning Group Commissioning Policy for Pre-Implantation Genetic Diagnosis.

Initial investigation of patients is usually carried out by a network of specialist gynaecologists at NHS Hospital Trusts throughout the East Midlands area. Access to fertility services for routine tests, investigation and diagnosis is available via GP referral.

In any healthcare system there are limits set on what NHS funded care is available and on what people can expect. CCGs are required to achieve financial balance; they have a complex task in balancing this with an individual's rights to health care. It is the purpose of the criteria set out here to make the limits on fertility treatment fair, clear and explicit.

The National Institute for Clinical Excellence (NICE) provides guidance on NHS fertility services and the same principles have been used to develop the local policy. This policy should be read in conjunction with the NICE Fertility Guidance available on their web site.

Review of clinical studies of couples seeking treatment; provide the following approximated proportions for the principal causes of infertility. A significant proportion of couples will have more than one cause and the distribution varies between primary and secondary infertility.

• Ovulatory failure	27%
• Low sperm count or quality	19%
• Tubal damage	14%
• Endometriosis	5%
• Others	5%
• Unexplained	30%

There is evidence that infertility causes considerable emotional stress and distress, which may affect many areas of couples' lives and can result in social handicap. There are three main types of fertility treatment: medical treatment (such as drugs for ovulation induction); surgical treatment (e.g. laparoscopy for ablation of endometriosis); and assisted reproduction.

Assisted conception techniques include:

- Intrauterine insemination (IUI)

- In vitro fertilisation (IVF)
- Intra-cytoplasmic sperm injection (ICSI)
- Donor insemination (DI), oocyte (egg) donation (OD) and cryo-preservation (oocytes and/or embryos)

NB: Provision for IVF/ICSI is not covered by this policy. Refer to the East Midlands Specialised Commissioning Group Commissioning Policy for IVF / ICSI within Tertiary Infertility Services.

NICE does not recommend assisted conception procedures like gamete intrafallopian transfer (GIFT) or zygote intrafallopian transfer (ZIFT) and these will not be funded by the NHS.

2 Criteria

All patients are eligible for consultation and advice in primary care.

Patients in the reproductive age group who fail to conceive after frequent unprotected sexual intercourse for one to two years (or by undertaking 6 cycles of Donor Insemination without conceiving or by having a defined tubal blockage thereby preventing conception) should be offered further clinical investigation including semen analysis and assessment of ovulation as appropriate.

Where there is clear reproductive pathology, infertility of any duration will be considered. This will include patients who cannot achieve full sexual intercourse due to disability. Eligibility for NHS funded treatment will be assessed against the treatment referral criteria and this may, in turn, affect the decision to investigate

Agreed eligibility criteria have been set so that patients with the best chance of success are given priority over others in order to produce the best outcomes. Following referral, patients should have a prognostic estimate that the successful outcome of a cycle will be greater than 10%.

Patients who do not meet the criteria within this policy are still entitled to access the primary and secondary care for consultation. Further investigations can be performed if appropriate. Ovulation induction with clomiphene citrate can be accessed within a dedicated secondary or tertiary care unit when clinically appropriate.. Medication should only be prescribed following clinical investigation in line with the NICE Clinical Practice Algorithm, Fertility - Assessment and treatment for people with fertility problems, 2013.

In order to achieve the maximum benefit for the resources available the following referral criteria should be used by referring physicians.

The establishment of these access criteria should be undertaken by the patients' GP to ensure that only appropriate patients who meet the terms of the policy are referred.

Woman's Age	<p>23 – 42 years</p> <p>NB: Patients should be informed that any stimulation treatment must take place before the patient's 43rd birthday. This applies to both fertility procedures under this policy and</p>
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	IVF/ICSI
Man's Age	55 years or younger, if applicable
Woman's BMI	>19 BMI <30
Welfare of Child	The welfare of any resulting children is paramount. In order to take into account the welfare of the child, the centre should consider factors which are likely to cause serious physical psychological or medical harm, either to the child to be born or any other child who may be affected by the birth. This is a requirement of the licensing body, Human Fertilization and Embryology Authority.
Family Structure	No living children from current or previous relationship(s), including adopted children, but excluding foster children. There needs to be an explicit and recorded assessment that the social circumstances of the family unit have been considered within the context of the assessment of the welfare of the child. In all considerations of parental status, there should be an explicit statement that children adopted by either partner should have the same status as biological children
Smoking	Neither partner is a current smoker
Registered GP	The patients are registered with an LLR GP
Consent	Written consent to treatment is required from both parties

Any cycle of infertility treatment already undertaken (whether NHS or self funded) will be taken into account when determining NHS funding entitlement.

In the rare or exceptional circumstances where a patient or clinician feel that the patient represents a special case then an application can be made to the CCG's Individual Funding Request Panel for consideration of exceptional funding. For patients to be considered for exceptional funding, an Individual Funding Request Form must be completed in full and submitted to the Individual Funding Request Team for consideration.

3 Treatment

The treatment protocol recommended by NICE (2013) should be followed. Lifestyle, medical treatments for infertility should be attempted before considering options like IUI, IVF and ICSI where clinically appropriate.

NHS funding will provide a maximum of 3 cycles of donor insemination (DI) or a maximum of 3 cycles of intrauterine insemination (IUI) treatment.

First treatment to start within 18 weeks of referral

Suitable patients should undertake DI (subject to availability and/or patient choice) or IUI before being considered for IVF/ICSI under the East Midlands Specialised Commissioning Group Commissioning Policy for Tertiary Infertility Services

Patients who do not conceive after treatment in accordance with this policy will have a full entitlement to IVF in line with the stated eligibility criteria in the East Midlands Specialised Commissioning Group Commissioning Policy for IVF / ICSI within Tertiary Infertility Services 1st April 2011v2)

Couples who choose not to have IUI and progress straight to IVF, will not be permitted to be offered IUI if IVF fails.

Donor Sperm will be funded only where azoospermia or severe oligospermia is present or to avoid transmission of inherited disorders to a child where the patients meet the other eligibility criteria.

Embryo freezing and storage is available to patients meeting the eligibility criteria for IVF / ICSI. Refer to the East Midlands Specialised Commissioning Group Commissioning Policy for IVF / ICSI within Tertiary Infertility Services for details.

Ovarian or testicular tissue storage will not be carried out outside a clinical trial. These are currently experimental.

In addition to the previous criteria the following patients will not be eligible for NHS funded IVF/ICSI treatment:

Sterilised patients and those patients who have had a sterilisation reversed
Surrogacy is not commissioned as part of this policy

4 Epidemiology

Infertility is defined, in accordance with the EMSCG Commissioning Policy for IVF / ICSI within Tertiary Infertility Services, as failure to conceive after frequent unprotected sexual intercourse for one to two years in couples in the reproductive age group or by undertaking 6 cycles of Donor Insemination without conceiving or by having a defined tubal blockage thereby preventing conception. If the couple fail to conceive after one year they are eligible to consultation. They can only proceed to assisted conception if they have tried for two years or if there is an obvious reproductive pathology such as tubal block or severe oligozoospermia.

Around 84% of couples attempting to conceive are successful after trying to one year, after two years this figure rises to 92%. Female fertility declines with age and for women aged 38, only about 77 out of 100 who have regular unprotected sexual intercourse will get

pregnant after 3 years.

The need for such services may increase due to the trend towards later first pregnancies and an increasing number of remarriages. Demand is increasing due to more public awareness of treatment possibilities. It is likely that there is unexpected and/or unmet demand, particularly from women with secondary infertility (those who have conceived before but do not necessarily have a child).

5 Glossary of terms:

Term	Meaning
In Vitro Fertilisation (IVF)	This is a process whereby eggs are removed from the ovaries and fertilised with sperm in the laboratory. It is utilised in the PGD process in order for the fertilised eggs (embryo's) to be tested for a specific genetic abnormality, with an unaffected embryo subsequently being placed in the woman's womb. (HFEA, 2009).
Intra-cytoplasmic Sperm Injection (ICSI)	This is a technique that can be used in IVF whereby a sperm is injected into the egg to assist in fertilisation. (NHS Direct, 2009).
Intra Uterine Insemination (IUI)	Insemination of sperm into the uterus of a woman
Donor Insemination (DI)	The introduction of donor sperm into the vagina, the cervix or womb itself
Oocyte (Egg) Donation (OD)	The process by which a fertile women donates her eggs to be used in the treatment of others or for research
Body Mass Index (BMI)	Body Mass Index (BMI) is a number calculated from a person's weight and height. BMI provides a reliable indicator of body fatness for most people and is used to screen for weight categories that may lead to health problems.

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Subfertility Assessment and Treatment Algorithm

Initial advice for couples concerned about delays in conception:

- Cumulative probability of pregnancy in general population:
 - 84% in first year
 - 92% in second year
- Fertility declines with a woman's age
- Lifestyle advice:
 - Sexual intercourse every 2-3 days
 - ≤ 1-2 units alcohol/week for women; ≤ 3-4 units/week for men
 - Smoking cessation programme for smokers
 - BMI 19-30 for women
 - Information about prescribed, over-the-counter and recreational drugs
 - Information about occupational hazards
- Offer preconception advice:
 - Folic acid

Initiate investigation if:

- Failure to conceive after regular unprotected sexual intercourse for 2 years in the absence of known reproductive pathology.
- Investigations
 - Semen analysis (compare with WHO reference values)
 - Ovulation assessment
 - Tests for tubal occlusion (should only be carried out if results of semen analysis and ovulation assessment are known)

Early investigation if:

- History of predisposing factors (such as amenorrhoea, oligomenorrhoea, pelvic inflammatory disease or undescended testes);
- Woman's age ≥ 35 years
 - People with HIV, Hepatitis B, Hepatitis C or those with prior treatment for cancer

Management strategies

Male factor fertility problems



Management strategies for subfertility

Female factor fertility problems

If no pregnancy with azoospermia, bilateral tubal occlusion or 2 years' infertility and the woman is aged 23-42 years offer 1 cycle of IVF/ICSI

