NHS
Luton
Clinical Commissioning Group

LCCG Fertility Services Commissioning Policy

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Equality Impact Assessment assured by

Date	**Name and Designation**
23/12/2014	**Current officer is Sandra Legate, Equality and Diversity Lead** **Sandra.legate@luton.gov.uk**

Review and Amendment Log

Version No	Type of Change	Date	Description of change
V5.2/Final	No change	28th February 2019	No changes following review at LCCG Clinical Commissioning Committee 28/02/19
V5.1/Final	No change	30th November 2017	No changes following review at LCCG Clinical Commissioning Committee 30/11/17
V5/Final	Internal LCCG review and updates following receipt of ENHCCG reviewed Policy	2nd June 2016	Lorraine Kavanagh & Dr Sudha Maroju – Authors. Changes following internal review of use of Policy, updates from ENHCCG Consortium Lead and comments from LCCG Clinical Commissioning Committee.
V4/Final	Part of ENHCCG Consortium	1st December 2014	Changes to NICE Guidelines 2013 Emma Dwyer & Dr Fiona Sim - Authors

Equality Impact Analysis

Luton Clinical Commissioning Group is committed to promoting equality in all its responsibilities – as commissioner of services, as a provider of services, as a partner in the local economy and as an employer. This policy will contribute to ensuring that all users and potential users of services and employees are

treated fairly and respectfully with regard to the protected characteristics of age, disability, gender, reassignment, marriage or civil partnership, pregnancy and maternity, race, religion, sex and sexual orientation.

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Fertility treatment and referral criteria for tertiary level assisted conception

1. Introduction

1.1.1 This Commissioning Policy replaces all previous versions. Where service users 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.

1.1.2 This Commissioning Policy sets out the criteria for access to NHS funded specialist fertility services for the population of Luton CCG, along with the commissioning responsibilities and service provision. This policy applies to couples only, not single men or women.

1.1.3 This policy is sets out criteria adopted by LCCG, is based on the ENHCCG led Consortium Guidelines and explains certain variation from the NICE Guidelines.

1.1.4 Couples are ineligible for treatment if there are any living children from the 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.

1.1.5 The paper specifically sets out the entitlement and service that will be provided by the NHS for In Vitro Fertilisation (IVF) and Intracytoplasmic Sperm Injection (ICSI). These services are commissioned by Luton Clinical Commissioning Group and provided via tertiary care providers.

1.1.6 It is the purpose of the criteria set out in this policy to make the provision of fertility treatment fair, clear and explicit. This paper should be read in conjunction with NICE Guidance CG156 "Fertility: assessment and treatment for people with fertility problems"(2013) available on their website at http://publications.nice.org.uk/fertility-cg156

1.2 Key Terms

1.2.1 In Vitro Fertilisation (IVF): is a process by which an egg is fertilized with a sperm outside the body (in vitro). The fertilised egg (embryo) is then transferred to the woman's uterus.

1.2.2 Intra-cytoplasmic sperm injection (ICSI): involves injecting a single sperm directly into an egg in order to fertilise it. The fertilised egg (embryo) is then transferred to the woman's uterus.

1.2.3 Full cycle of IVF/ICSI: "One full cycle" of IVF/ICSI treatment comprises: ovulation induction, egg retrieval, fertilization and the transfer of resultant fresh or frozen embryos. It also includes appropriate diagnostic tests, scans and pharmacological therapy.

1.2.4 Frozen embryo transfer: where an excess of embryos is available following a fresh cycle, these embryos may be frozen for future use. Once thawed, these embryos are transferred to the service user as a frozen cycle.

1.2.5 Abandoned/cancelled cycle of IVF: an abandoned or cancelled cycle is defined as one where an egg collection procedure is not undertaken. If an egg collection procedure is undertaken, it is considered to be a full cycle.

1.3 Review

This policy will be reviewed annually and within 3 months of any legislative changes that should or may occur in the future. The date of the next review will be December 2016.

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 Specialist Fertility Treatments within the scope of this policy are:

- In-vitro fertilisation (IVF) and Intra-cytoplasmic sperm injection (ICSI)
- Surgical sperm retrieval methods
- Donor Insemination (DI)
- Intra Uterine Insemination (IUI) unstimulated
- Sperm, embryo and male gonadal tissue cryostorage and replacement techniques.
- Egg donation where no other treatment is available
- Blood borne viruses (ICSI + sperm washing)
- Egg and sperm storage for service users undergoing cancer treatment.

2.1.3 Treatments **excluded** from this policy:

- Pre-implantation Genetic Diagnosis and associated IVF/ICSI. This service is commissioned by NHS England
- Specialist Fertility Services for members of the Armed Forces are commissioned separately by NHS England
- Surrogacy

2.1.4 Formal IVF commissioning arrangements will support the implementation of this policy including a contract between ENHCCG (have delegated responsibility for procurement) and each tertiary centre. 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.

2.1.5 Couples are ineligible for treatment if there are any living children from the 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.

2.1.6 Couples who do not meet the criteria and consider they have exceptional circumstances should be considered under the Individual Funding Request (IFR) policy. All ITP funding queries should be directed to the ITP team of the relevant CCG who may liaise with the central contracting team. Funding of such exceptional cases is the responsibility of the CCG.

2.1.7 Couples will be offered a choice of providers commissioned by the East of England Commissioning Consortium, LCCG is part of this Consortium.

3. Specialist Fertility Services Policy and Criteria

The CCG only commissions the following fertility techniques regulated by the Human Fertilisation & Embryology Authority (HFEA). www.hfea.gov.uk

3.1 In-Vitro Fertilisation (IVF)

3.1.1 An IVF procedure includes the stimulation of the women's ovaries to produce eggs which are then placed in a special environment to be fertilised. The fertilised eggs are then transferred to the woman's uterus.

3.1.2 For women aged under 40 years this policy supports a maximum of 6 embryo transfers with a maximum of 3 fresh cycles of IVF, with or without ICSI, this includes any abandoned cycles. Where a woman reaches the age of 40 years during treatment they will complete that cycle in the 40th year and will not be entitled to commence further cycles. For women aged under 40 years any previous full IVF cycles, whether self or NHS-funded, will count towards the total number of full cycles offered.

3.1.3 Women age 40-42 years may be entitled to 1 fresh cycle of IVF, or IVF with ICSI, provided the following 3 criteria are met:

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

3.1.4 A full cycle of IVF treatment, with or without intracytoplasmic sperm injection (ICSI), should comprise 1 episode of ovarian stimulation and the transfer of any resultant fresh and frozen embryo(s). This will include the storage of any frozen embryos for 1 year following egg collection. Service users should be advised at the start of treatment that this is the level of service available on the NHS and following this period continued storage will need to be funded by themselves or allowed to perish. In the case of exceptional circumstances, or if the service user wishes to fund 'top up' treatment, the service user must apply to the ITP Office to request extension, at least three months prior to the expiry of this storage period.

3.1.5 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.

3.1.6 Before a new fresh cycle of IVF can be initiated any previously frozen embryo(s) must be utilised.

3.1.7 Where couples have previously self-funded a cycle then the couples must utilise the previously frozen embryos, rather than undergo ovarian stimulation, egg retrieval and fertilisation again, unless exceptional circumstances apply.

3.1.8 Embryo transfer strategies:

- For women less than 37 years of age only one embryo or blastocyst to be transferred in the first cycle of IVF and for subsequent cycles only one embryo/blastocyst to be transferred unless no top quality embryo/blastocyst available then no more than 2 embryos to be transferred.
- For women age 37-39 years only one embryo/blastocyst to be transferred unless no top quality embryo/blastocyst available then no more than 2 embryos to be transferred.
- For women 40-42 years consider double embryo, *but* no more than two embryos, transferred.

3.1.9 A fresh cycle would be considered completed with the attempt to collect eggs and transfer of a fresh embryo.

3.1.10 If a cycle is commenced and ovarian response is poor, a clinical decision would need 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.

3.1.11 If any fertility treatment results in a **living child,** 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.

3.2 Clinical Indications

3.2.1 In order to be eligible for treatment, service users should have experienced unexplained infertility **for 3 years** or more of regular unprotected sexual intercourse or 12 cycles of artificial insemination over a period of 3 years. Couples with a diagnosed cause of absolute infertility (such as in the list below) which precludes any possibility of natural conception and who meet other eligibility criteria, will have immediate access to NHS funded assisted reproduction services.

(a) Tubal damage, which includes:
- Bilateral salpingectomy
- Moderate or severe distortion not amenable to tubal surgery

(b) Premature Menopause (defined as amenorrhoea for a period more than 6 months together with a raised FSH >25 and occurring before age 40 years)

(c) Male factor infertility. Results of semen analysis conducted as part of an initial assessment should be compared with the following World Health Organization reference values:
- Semen volume: 1.5 ml or more
- pH: 7.2 or more
- Sperm concentration: 15 million spermatozoa per ml or more
- Total sperm number: 39 million spermatozoa per ejaculate or more
- Total motility (percentage of progressive motility and non-progressive motility):
- 40% or more motile or 32% or more with progressive motility
- Vitality: 58% or more live spermatozoa
- Sperm morphology (percentage of normal forms): 4% or more.

(d) Ovulation problems adequately treated but not successfully treated i.e. no successful pregnancy achieved

(e) Endometriosis where Specialist opinion is that IVF is the correct treatment

(f) Cancer treatment causing infertility necessitating IVF/ICSI (eligibility criteria still apply)

3.3 Surgical Sperm Recovery

3.3.1 Surgical sperm retrieval methods included for service provision are testicular sperm extraction (TESE) and percutaneous epididymal sperm aspiration (PESA).

3.3.2 Micro surgical Sperm recovery is not routinely funded and must be considered as an ITP application.

3.3.3 Sperm recovery techniques outlined in this section are not available to service users who have undergone a vasectomy.

3.4 Donor insemination

3.4.1 The use of donor insemination is considered effective in managing male fertility problems associated with the following conditions:

- obstructive azoospermia
- non-obstructive azoospermia
- Severe deficits in semen quality in couples who do not wish to undergo ICSI.
- Infectious disease of the male partner (such as HIV or Hep B,C)
- Severe rhesus isoimmunisation
- Where there is a high risk of transmitting a genetic disorder to the offspring

3.4.2 Donor insemination is funded up to a maximum of 6 cycles of Intrauterine Insemination (IUI).

3.5 Donor semen as part of IVF/ICSI

3.5.1 Donor semen is used for same sex couples as part of IVF/ICSI treatment.

3.5.2 Funded up to same number of cycles of IVF.

3.6 Intra Uterine Insemination (IUI)

3.6.1 NICE guidelines state that unstimulated intrauterine insemination is a treatment option in the following groups as an alternative to vaginal sexual intercourse:

- 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.

3.6.2 Due to poor clinical evidence, a maximum of 6 cycles of IUI (as a replacement for IVF/ICSI and without donor sperm) will only be offered under exceptional circumstances and an ITP application for funding must be made to the CCG.

3.7 Egg donation where no other treatment is available

3.7.1 The service users may be able to provide an egg donor; alternatively the service user can be placed on the waiting list, until an altruistic donor becomes available. If the woman exceeds the age criterion prior to a donor egg becoming available, they will no longer be eligible for treatment.

3.7.2 This will be available to women who have undergone premature ovarian failure (amenorrhea >6 months and a raised FSH >25) due to an identifiable pathological or iatrogenic cause before the age of 40 years. For couples with diagnosed inherited disorders likely to be transmitted to their child may be eligible for egg donation where the couple meet the other eligibility criteria.

3.8 Egg and Sperm storage for service users undergoing cancer treatments

3.8.1 When considering and using cryopreservation for people before starting chemotherapy or radiotherapy that is likely to affect their fertility, follow recommendations in 'The effects of cancer treatment on reproductive functions' (2007).

3.8.2 When using cryopreservation to preserve fertility in people diagnosed with cancer, use sperm, embryos or oocyctes.

3.8.3 Offer sperm cryopreservation to men and adolescent boys who are preparing for medical treatment for cancer that is likely to make them infertile.

3.8.4 Local provider protocols should 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.

3.8.5 Offer oocyte or embryo cryopreservation as appropriate to women of reproductive age (including adolescent girls) who are preparing for treatment of rare medical conditions or cancer which is likely to make them infertile, if:

- they are 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 cancer treatment.

3.8.6 Cryopreserved material may be stored for an initial period of 10 years unless advised otherwise by specialist provider.

3.8.7 Following cancer treatment, couples seeking fertility treatment must meet the defined eligibility criteria. However, if a service user met the age criterion at the time of diagnosis, she should be considered as still meeting criteria upon completion of treatment as long as that is within two years of diagnosis.

3.9 Pre-implantation Genetic Diagnosis (PGD)

This policy does not include pre-implantation genetic screening as it is not considered to be within the scope of fertility treatment. This service is commissioned by NHS England. Providers should seek approval from Specialist Commissioning NHS England.

3.10 Chronic Viral Infections

3.10.1 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.

3.10.2 The need to prevent the transmission from male to female partner of chronic viral infections, during conception, such as HIV, Hep C etc. requires the use of ICSI technology, as per NICE guidance (section 1.3.9).

3.11 Same sex couples

- Same-sex couples are entitled to treatment on the NHS following 6 cycles of self-funded IUI.
- Both partners must be non-smoking at the time of referral.
- BMI eligibility criteria above apply only to the female partner undergoing fertility treatment.
- Couples with a diagnosed cause of absolute infertility which precludes any possibility of natural conception, and who meet other eligibility criteria, will have immediate access to NHS funded assisted reproduction services.

3.12 Privately funded care

3.12.1 This policy covers NHS funded fertility treatment only. For clarity, service users 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.

3.12.2 Where a service user meets these 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.

3.13 Surrogacy

Surrogacy is not commissioned as part of this policy. This includes part funding during a surrogacy cycle. Therefore, LCCG will not fund surrogacy in any circumstances.

4 Referrals

4.1 Couples who experience problems with their fertility will attend their GP practice to discuss their concerns and options. The service users will be assessed initially within the Primary Care setting and then referred to secondary care, if indicated.

4.2 A decision to refer a couple for IVF or other fertility services will be based on an assessment against the eligibility criteria in this LCCG document, which are based on the NICE guidelines and the HFEA recommendations as detailed in the clinical pathways.

4.3 Referral to the tertiary centre will be via a consultant gynecologist.

5 Access Criteria

NO	Criterion	Description
1	Ovarian Reserve Testing, use FSH	To be eligible, the patient should have an FSH level on day 1, 2, 3 of the menstrual cycle of of <8.9 IU/L (within three months of referral from secondary care to a specialist IVF provider).
2	Maternal age and number of cycles:	Women aged 23 to 39 years at the start of treatment – **THREE fresh cycles.** Where a woman reaches the age of 40 years during treatment they will complete that cycle in the 40th year and will not be entitled to commence further cycles. Women aged 40 to 42 years may be entitled to ONE cycle of IVF where: • They have never previously had IVF treatment • There is no evidence of low ovarian reserve • There has been a discussion of the additional implications of IVF • and pregnancy at this stage
3	Embryo transfers:	Women aged 23 to 39 years – ONE embryo will be transferred during each cycle to reduce the risk of multiple pregnancies. A maximum of six embryo transfers (fresh plus frozen) will be funded. All frozen embryos should be used before a new fresh cycle is funded. Women aged between 40 to 42 years – Up to TWO embryos may be transferred during each cycle. A maximum of two embryo transfers (fresh plus frozen) will be funded.
4	Paternal Age	No cut-off age specified by LCCG.
5	Minimum / Maximum BMI	Between at least 19 and up to 30 for female and less than 35 for male. Service users outside of this range will not be added to the waiting list and should be referred back to their referring clinician and/or general practitioner for management if required. In female same sex couple, BMI criteria should only apply to the partner undergoing fertility treatment.
6	Duration of sub-fertility	Unexplained infertility for 3 years or more of regular unprotected sexual intercourse or an equivalent 12 self-funded cycles of artificial insemination over a period of 3 years. Couples with a diagnosed cause of absolute infertility which precludes any possibility of natural conception and who meet other eligibility criteria will have immediate access to NHS funded assisted reproduction services.

7	Fertility treatment for Women <40 years	NHS treatment limit up to maximum of 6 embryo transfers, with a maximum of 3 fresh cycles of assisted conception (IVF or IVF with ICSI if required and including sperm retrieval where indicated). Previous privately or NHS funded cycles will count towards the total number of fresh cycles funded by the NHS
8	Fertility treatment for women aged 40-42 years	Maximum of 2 embryo transfers, including a maximum of 1 fresh cycle of IVF, or IVF with ICSI. Previous privately or NHS funded cycles will count towards the total number of fresh cycles funded by the NHS
9	Smoking Status	Couples who smoke will not be eligible for NHS-funded specialist assisted reproduction assessment or treatment, and should be informed of this criterion at the earliest possible opportunity in their progress through infertility investigations in primary care and secondary care. Couples presenting with fertility problems in primary care should be provided with information about the impact of smoking on their ability to conceive naturally, the adverse health impacts of passive smoking on any children and smoking cessation support should be provided as necessary. Both partners must be non-smoking at the time of referral from secondary care to specialist IVF services and maintained during treatment. This applies equally for same-sex couples as passive smoking may affect the fertility of the partner undergoing fertility treatment. Smoking status should be ascertained by carbon monoxide testing in secondary care and specialist IVF services.
10	Known Parental Status	Couples or individuals are ineligible for treatment if there are any living children from the current or any previous relationships, to either partner, 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.
11	Previous sterilisation	Couples are ineligible if previous sterilisation has taken place (either partner), even if it has been reversed.
12	Child Welfare	Providers must meet the national statutory requirements to ensure the welfare of the child. This includes HFEA's Code of Practice which considers the 'welfare of the child which may be born' and takes into account the importance of a stable and supportive environment for children as well as the pre-existing health status of the parents.

13	Medical Conditions	Treatment may be denied on other medical grounds not explicitly covered in this document. These will always be explained to the service user by the consultant concerned.
14	Residential Status	The couple should be registered with a GP in Luton CCG for 12+ months.
15	The cause of Infertility	In order to be eligible for treatment, service users should have experienced unexplained infertility **for 3 years** or more of regular unprotected sexual intercourse or 12 cycles self-funded artificial insemination over a period of 3 years or IUI in consultation through ITP application process. Couples with a diagnosed cause of absolute infertility which precludes any possibility of natural conception and who meet other eligibility criteria, will have immediate access to NHS funded assisted reproduction services. (a) Tubal damage, which includes: • Bilateral salpingectomy • Moderate or severe distortion not amenable to tubal surgery (b) Premature Menopause- amenorrhoea >6m and FSH >25 and aged <40 (c) Male factor infertility (d) Ovulation problems adequately treated but not successfully treated i.e. no successful pregnancy achieved (e) Endometriosis where Specialist opinion is that IVF is the correct treatment (f) Cancer treatment causing infertility necessitating IVF/ICSI (eligibility criteria still apply)
16	The minimum investigations required prior to referral to the Tertiary centre are:	<u>Primary care investigations after 1 year</u> • Female partner with irregular cycles check FSH levels on Day 1-3 of cycle. Female partner with regular cycles check serum progesterone on Day 21 of 28 day cycle. • Male partner-Semen analysis, repeat if abnormal in 3 months, recheck ASAP if Oligo or Azoospermia. • Screening tests for both as per preconception advice. • Other tests if clinical history, i.e. TFTs, prolactin. • Both partners tested for Hep B including core antibodies, Hep C, HIV status and core within the last 3 months and repeated every 2 years • Both partners - Test chlamydia status **<u>Information for GP</u>** <u>Treatment options (L&D or other Hospital fertility centres) as advised by gynaecologist may include:</u> • Female partner - tubal patency, ovulation induction, treatment

		for PCOS, treatment of endometriosis, adhesiolysis • Male partner (depending on semen analysis results) - surgery for obstructive causes, cancer Treatment. • Referral to tertiary centre for procedures such as IUI, IVF
17	Pre-implantation Genetic Diagnosis	PGD and associated specialist fertility treatment is the commissioning responsibility of NHS England and is excluded from the CCG commissioned service.
18	Rubella Status	The woman must be rubella immune
19	IUI (Unstimulated)	As per NICE guidance 2013. Maximum of 6 cycles of IUI (as a replacement for IVF/ICSI and without donor sperm) will only be offered under exceptional circumstances and an ITP application for funding must be made to the LCCG.