NHS
Great Yarmouth and Waveney
Clinical Commissioning Group

Fertility Services Commissioning Policy

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Superseded Documents	Individual PCTs documentation in the EoE commissioning fertility services
Action required	For dissemination within primary, secondary and tertiary care providers
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Contents

Fertility treatment and referral criteria for tertiary level assisted conception

1. Introduction

1.1 This commissioning policy sets out the criteria for access to NHS funded specialist fertility services for the population of NHS Great Yarmouth and Waveney Clinical Commissioning Group (CCG), along with the commissioning responsibilities and service provision.

1.2 This policy is specifically for those couples who do not have a living child from their current or any previous relationships **prior to starting NHS funded treatment**, 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.

1.3 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 the CCG and provided via tertiary care providers.

1.4 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

2. Review

2.1 This policy will be reviewed annually and within three months of any legislative changes that should or may occur in the future. The date of the next review will be September 2017.

3. Commissioning responsibility

3.1 Specialist fertility services are considered as Level 3 services or tertiary services. Preliminary levels, 1 and 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 and 2.

3.2 Specialist fertility treatments within the scope of this policy are:

- in vitro 5ertilization (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.

For further details of what is funded for each CCG, please see the Appendix 1.

3.3 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.

3.4 Formal IVF commissioning arrangements will support the implementation of this policy including a contract between NHS East and North Hertfordshire CCG (who 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 and Embryology Authority (HFEA) Licensing requirements or any successor organisations.

3.5 This policy is specifically for those couples who do not have a living child from their current or any previous relationships **prior to starting NHS funded treatment**, 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.

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

3.7 Couples will be offered a choice of providers that have been commissioned by the CCG.

4. Specialist fertility services policy and criteria

4.1 The CCG only commissions the following fertility techniques regulated by the Human Fertilisation and Embryology Authority (HFEA).

5. In-Vitro Fertilisation (IVF)

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

5.2 For women less than 40 years this policy supports a maximum of four embryo transfers with a maximum of two fresh cycles of IVF, with or without ICSI, this includes any abandoned cycles. Please refer to Appendix 1 for the number of cycles and embryo transfers funded by the CCG. In 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 by the CCG.

5.3 For women age 40-42 years NHS treatment limit will be determined by local CCG policy up to maximum of two embryo transfers, including a maximum of one fresh cycle of IVF, or IVF with ICSI, provided the following three 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.

5.4 A full cycle of IVF treatment, with or without intracytoplasmic sperm injection (ICSI), should comprise one 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 one 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 embryos will be allowed to perish.

5.5 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.

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

5.7 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.

5.8 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 two 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 two embryos to be transferred
- for women 40-42 years consider double embryo transfer.

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

5.10 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.

5.11 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.

6. Clinical indications

6.1 In order to be eligible for treatment, service users should have experienced unexplained infertility for three years or more of regular intercourse or 12 cycles of artificial insemination over a period of three years. There is no criterion for couples with a diagnosed cause of infertility, see below:

(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 six 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 ie 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).

7. Surgical Sperm Recovery

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

7.2 Micro surgical sperm recovery is not routinely funded and must be considered as an IFR application to the relevant CCG.

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

8. Donor insemination

8.1 The use of donor insemination is considered effective in managing 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)
- severe rhesus isoimmunisation
- where there is a high risk of transmitting a genetic disorder to the offspring.

8.2 Donor insemination is funded up to a maximum of six cycles of intrauterine insemination (IUI). Please see Appendix 1 for number of cycles relevant to CCG.

9. Donor semen as part of IVF/ICSI

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

9.2 Funded up to same number of cycles of IVF.

10. Intra Uterine Insemination (IUI)

10.1 NICE guidelines state that unstimulated intrauterine insemination as 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.

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

11. Egg donation where no other treatment is available

11.1 The service user 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 either of the couple exceeds the age criteria prior to a donor egg becoming available, they will no longer be eligible for treatment.

11.2 This will be available to women who have undergone premature ovarian failure (amenorrhoea >6 months and a raised FSH >25) 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 meet the other eligibility criteria.

12. Egg and Sperm storage for service users undergoing cancer treatments

12.1 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).

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

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

12.4 Local 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.

12.5 Offer oocyte or embryo cryopreservation as appropriate to women of reproductive age (including adolescent girls) who are preparing for medical treatment for cancer that 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.

12.6 Cryopreserved material may be stored for an initial period of 10 years. Please see Appendix 1 for relevant CCG length of storage time.

12.7 Following cancer treatment, couples seeking fertility treatment must meet the defined eligibility criteria.

13. Pre-implantation Genetic Diagnosis (PGD)

13.1 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.

14. Chronic viral infections

14.1 The need to prevent the transmission of chronic viral infections, during conception, such as HIV, Hepatitis C etc. requires the use of ICSI technology.

14.2 As per NICE guidance (section 1.3.9). Do not offer sperm washing not offered as part of fertility treatment for men with Hepatitis B.

14.3 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.

15. Privately funded care

15.1 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.

15.2 Where a service user meets this 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.

15.3 On 19 July 2017 Parliament introduced Amendments to the NHS (Charges to Overseas Visitors) Regulations 2015. As a result, from 21 August 2017, assisted conception services will no longer be included in the scope of services available for free for those who pay the immigration health surcharge.

16. Surrogacy

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

17 Referrals

17.1 Couples who experience problems with their fertility will attend their GP practice to discuss their concerns and options. The service users will be assessed within the primary and secondary care setting.

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

17.3 Referral to the tertiary centre will be via a consultant gynecologist or GP with special interest (GPwSI) in primary care.

18 Access Criteria

No	Criterion	Description
1	Ovarian reserve testing, use one of the following: • FSH	To be eligible, the service user should have an FSH within three months of referral and on day two of the menstrual cycle of <9.
2	Maternal age	Women aged 23 to 39 years at the start of super-ovulation (treatment) but where a woman reaches the age of 40 during treatment they will complete that cycle in the 40th year and will not be entitled to commence further cycles. Women aged between 40-42 may be entitled to one cycle of IVF but 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. See Appendix 1 in fertility policy document for CCG criteria and funding levels.
3	Paternal age	No cut off age to be specified. See Appendix 1 in fertility policy document for CCG criteria and funding levels.
4	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.
5	Duration of sub-fertility	Unexplained infertility for three years or more of regular intercourse or an equivalent 12 self-funded cycles of artificial insemination over a period of three years. There is no criterion for cases with a diagnosed cause of infertility. See also criteria no. 14.
6	Previous fertility treatment for women <40 years	This policy supports up to maximum of four embryo transfers, with a maximum of two fresh cycles of assisted conception (IVF or IVF with ICSI if required and including sperm retrieval where indicated). Please see Appendix 1. Previous privately or NHS funded cycles will count towards the total number of fresh cycles funded by the NHS.

7	Previous fertility treatment for women ≥40 years	This policy supports up to maximum of two embryo transfers, including a maximum of one 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.
8	Smoking status	Couples who smoke will not be eligible for NHS-funded specialist assisted reproduction assessment or treatment. Where either of a couple smokes, only couples who agree to take part in a supportive and successful program of smoking cessation with carbon monoxide verification as an evidence of non-smoking status. Will be accepted onto the IVF treatment waiting list.
9	Parental status	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. See Appendix 1 in fertility policy document for relevant CCG criteria and funding levels.
10	Previous sterilisation	Ineligible if previous sterilisation has taken place (either partner), even if it has been reversed.
11	Child welfare	Providers must meet the 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.
12	Medical conditions	Treatment may be denied on other medical grounds not explicitly covered in this document.
13	Residential status	The couple should either be registered with a GP in the CCG consortium for 12+ months, or if their GP registration is less than 12 months, they can be eligible if they can demonstrate residency of 12+ months in a CCG area within the consortium.

14	The cause of infertility	In order to be eligible for treatment, service users should have experienced unexplained infertility for three years or more of regular intercourse or 12 cycles of artificial insemination over a period of three years. There is no criterion for couples with a diagnosed cause of infertility – see below: (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 ie 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).
15	The minimum investigations required prior to referral to the tertiary centre are:	Female: • Laparoscopy and/or hysteroscopy and/or hysterosalpingogram or ultrasound scan where appropriate • Rubella antibodies • day 2 FSH • Chlamydia screening • Hepatitis B including core antibodies and Hepatitis C and HIV status and core, within the last three months of treatment and repeated every two years. Male: • Preliminary semen analysis and appropriate investigations where abnormal (including genetics) • Hepatitis B including core antibodies and Hepatitis C, within the last three months and repeated after two years • HIV status.
16	Pre-implantation Genetic Diagnosis (PGD)	PGD and associated specialist fertility treatment is the commissioning responsibility of NHS England and is excluded from the CCG commissioned service.
17	Rubella status	The woman must be rubella immune.

18	IUI (Unstimulated)	As per NICE guidance 2013. Maximum of six cycles of IUI (as a replacement for IVF/ICSI and without donor sperm) will only be offered under exceptional circumstances and an IFR application for funding must be made to the CCG. See Appendix 1 in fertility policy document for relevant CCG criteria and funding levels.
19	Number of cycles of IVF	Women <40 years: two full cycles. If the woman reaches the age of 40 during treatment, complete the current full cycle but do not offer further full cycles. Women 40-42 years: one full cycle, if following three criteria met: • 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. See Appendix 1 in fertility policy document for relevant CCG criteria and funding levels.
20	Waiting times	>three years See Appendix 1 in fertility policy document for relevant CCG criteria and funding levels.

Appendix 1: Outcome of NHS Great Yarmouth and Waveney CCG's policy review discussion

CCG	Number of cycles of IVF (criterion 19)	Maximum number of Embryo transfers including fresh and frozen (criterion 18)	Age extension (criterion 2)	Waiting times (criterion 20)	Paternal Age (criterion 3)	Child Welfare (criterion 11)
NHS Great Yarmouth and Waveney Clinical Commissioning Group	Up to 2 cycles	Up to 4	Max maternal age 42	3 years	No cut off age to be specified	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.