Kingston Clinical Commissioning Group

Policy statement

Fertility treatments

This policy is unchanged from the version approved by the CCG in July 2014.

Title	Policy statement: Fertility treatments v2.0		
Author	Jacky Walters		
Approved by	Kingston CCG Governing Body		
Date of approval	July 2014	Review date	July 2018
Key changes	The clinical thresholds relating to Fertility treatments were not amended in the SWL ECI policy version 2.0 which was ratified in November 2017, and remain unchanged from the version agreed by the Kingston CCG Governing Body in 2014. This policy statement ensures that policies remain in place for the population of Kingston CCG for the above clinical area.		

Version Control:

Version	Description of Change(s)	Reason for Change	Author	Date
1.0	NHSE Policies removed from 2013-14 Policy	Updated as per NHSE commissioning arrangements	SL CSU	February 2014
1.6	• Kingston IVF Policy updated	Appendices updated	SL CSU	Jul 2014
2.0	Lifted from SWL v1.8(3.1) to become a standalone document. No policy changes.	New version 2 SWL ECI standalone policy commences 1st Jan 2018.	Jacky Walters	December 2017

Assisted Conception Commissioning Guidelines
Kingston Clinical Commissioning Group

Principles

When commissioning healthcare for its population, Kingston CCG, in line with the RCGP Ethical Commissioning Guidance 2011, aims to 'use limited resources to do as much good as possible whilst being fair.'

With respect to assisted conception, Kingston CCG aims to:

(1) Treat subfertility secondary to disease processes
(2) Follow NICE guidance as far as it is compatible with the CCG's resources to treat its population
(3) Treat any couple with no existing children (from either party, including adopted children), or woman with no existing children.
(4) Limit treatment to one live birth per couple.

Equality Statement

"This document demonstrates Kingston CCG's commitment to create a positive culture of respect for all individuals, including staff, patients, their families and carers as well as community partners. The intention is, as required by the Equality Act 2010, to identify, remove or minimise discriminatory practice in the nine named protected characteristics of age, disability, sex, gender reassignment, pregnancy and maternity, race, sexual orientation, religion or belief, and marriage and civil partnership. It is also intended to use the Human Rights Act 1998 and to promote positive practice and value the diversity of all individuals and communities".

Engagement

Kingston CCG's previous In Vitro Fertilization (IVF) guidelines were developed by the South West London Effective Commissioning Group with lay representation from the South West London.

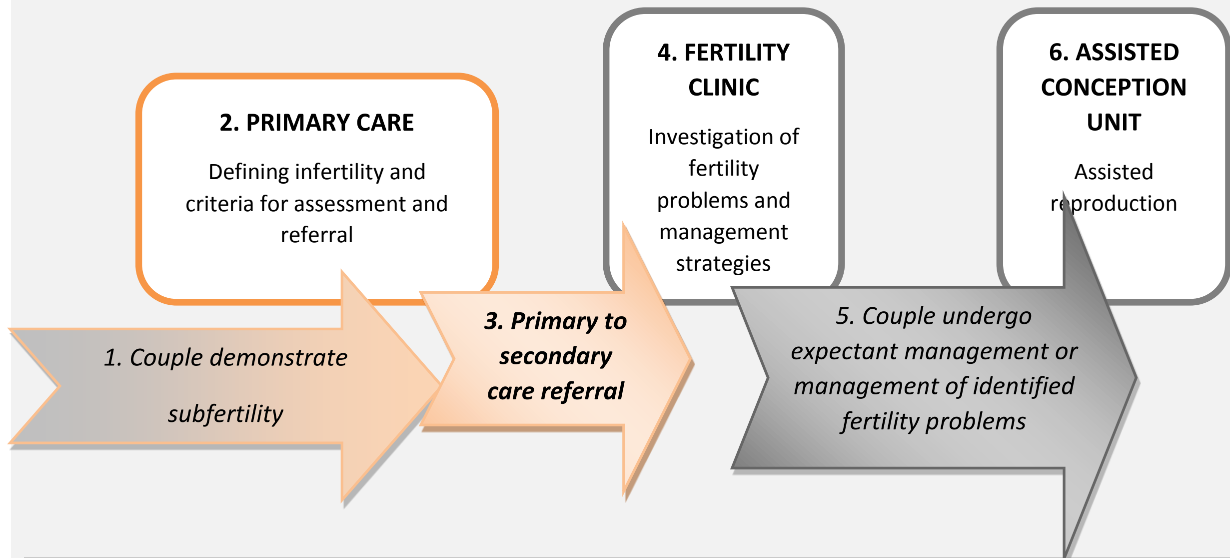
The working group responsible for updating local IVF guidelines included representation from Kingston CCG (lead GP), Royal Borough of Kingston (Public Health consultant and senior registrar) and Kingston Hospital NHS Foundation Trust (two Consultant Gynaecologist Leads from the Assisted Conception Unit and a service manager). Kingston Hospital NHS Foundation Trust representatives provided a clinical perspective and they also provided the working group with the views of their service users.

The final draft of the updated KCCG guidelines was shared with Kingston Healthwatch. It was also discussed at Kingston Governing Body Seminars and presented to the Kingston Integrated Governance Committee before approval was granted by the Kingston Governing Body.

Kingston CCG Assisted Conception Pathway

Note to Kingston GPs about the timing of referrals to secondary care

Assessment and management of fertility problems involves several stages (see diagram) so **it is imperative that referrals for further investigation are timely.**



Refer for further clinical assessment and investigation, with her partner,

- a woman of reproductive age who has not conceived after 1 year of unprotected vaginal sexual intercourse (or six cycles of artificial insemination) in the absence of any known cause of infertility

Offer an earlier referral when:

- the woman is aged 36 years or over (please note that if IVF is considered a possible treatment option, referral should be by the 42nd birthday to allow sufficient time for investigation and expectant management)
- there is a known cause of infertility or a history of predisposing factors of infertility.

Even if patients do not meet the criteria set out in the guidelines for assisted conception treatments, patients who demonstrate subfertility can still be referred to the Fertility Clinic for further investigations (subject to agreement by the GP and patient and approval by the CCG).

The Fertility Clinic consultant will decide if assisted conception is indicated and if so forward the names of the couple to the Assisted Conception Unit (ACU) at Kingston Hospital NHS Foundation Trust. The ACU will ensure that the CCG criteria are met and if so will offer treatment. Once treatment is offered the couple will be treated within an appropriate 18 week timetable.

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Policy statement 1. IVF

Kingston CCG will fund 1 fresh IVF cycle (cycle starts once ovarian stimulation has been commenced) and 2 frozen embryo transfer (FET) cycles with embryos generated from the fresh cycle[1], with or without ICSI, for the following groups of women:

Group 1:	Age at treatment[iii]: up to 40th birthday AND Have had a maximum of two previous self-funded cycles

OR

Group 2:	Age at treatment[iii]: 40 up to 43rd birthday AND No previous self-funded cycles[iv]

Who also meet the additional criteria outlined below:

	Criteria	Rationale
Duration of subfertility	Couples will be eligible for referral for treatment if they have not conceived after 2 years of regular unprotected intercourse or up to 12 cycles of intrauterine insemination. **OR** where investigations show there is no chance of pregnancy with expectant management and where IVF is the only effective treatment (for example women with apparently occluded fallopian tubes or severe endometriosis, or obstructive azoospermia).	84% of women will conceive within one year of regular unprotected sexual intercourse, this increases to 92% after 2 years and 93% after 3 years (te Velde et al., 2000)[1,2].

[1] The storage cost for frozen embryos for up to three years or a live birth (whichever is sooner) would be paid for KCCG. Requests for funding for storage beyond three years should be made via an Individual Funding Request.

[iii] this is defined as age at egg collection.

[iv] this is in line with NICE recommendations stating that, due to the lower chance of successful IVF in this age-group, IVF is only cost-effective when offered to women who have not had any previous cycles.

Body mass index of woman	19 – 30 kg/m^2 weight to be maintained for the last 6 months prior to application.	Female BMI outside this range reduces the probability of success associated with assisted conception techniques[3].
Smoking status of couple	Both partners should have been non-smokers for at least six months prior to commencement of treatment.	Smoking can adversely affect the success rates of assisted reproductive techniques[3].
Childlessness	Neither partner must have any living children from this or previous relationships (including adopted children)	As funding for assisted conception is limited, priority will be given to couples with the greatest need.
Sterilisation	Treatments will not be available if either partner has undergone previous sterilisation.	Sterilisation is offered as an irreversible method of contraception and individuals on the NHS are made aware of this at the time of the procedure.
Same sex couples and women not in a partnership	IVF treatment will be funded for same sex couples or women not in a partnership if those seeking treatment are demonstrably subfertile and have undergone a period of expectant management. They would first need to demonstrate subfertility through 6 self-funded attempts at artificial insemination using donor sperm in a clinical setting, and undergo a period of expectant management involving up to a further 6 cycles of self or NHS-funded donor intra-uterine insemination (see policy statement 4). Note: Men in same-sex relationships wanting a baby can either adopt or use some form of surrogacy. The	Same-sex couples should have access to IVF on equivalent grounds to heterosexual couples. In this respect, failure to conceive after six cycles of self-funded artificial insemination has been deemed an equivalent indicator of sub-fertility, given clinical and practical considerations[3]. Further NHS-funded cycles of intra-uterine insemination (up to six) constitutes the period of expectant management

	CCG will not fund surrogacy arrangements. However, when a pregnancy does not occur through surrogacy after 6 cycles of self-funded intra-uterine insemination in a clinical setting there is an increased risk of some underlying problem. In those circumstances, the man whose sperm is being used and the surrogate partner would be eligible to be referred for further clinical assessment and possible treatment[4]. In the case of same sex couples where only one partner is sub fertile, clinicians should discuss the possibility of the other partner receiving treatment before proceeding to interventions involving the sub fertile partner. The other criteria for eligibility for IVF will also apply. All same sex couples and women not in a partnership should have access to professional experts in reproductive medicine to obtain advice on the options available to them.	required prior to being eligible for IVF, during which pregnancy may be achieved (based on NICE recommendation[3] and advice of local clinicians).
FSH	Women aged 40 up to 43rd birthday only: There is no evidence of low ovarian reserve when assessed in accordance with the treatment provider's protocol.	In this age group, falling ovarian reserve is the commonest cause of infertility. The use of ovarian reserve testing allows IVF to be targeted to women with a demonstrable chance of success[3].

Rationale

The likelihood of a live birth following assisted conception declines with age. Chances of live birth per IVF cycle[5] are:

- 32.2% for women aged 18-34
- 27.7% for women aged 35-37
- 20.8% for women aged 38-39
- 13.6% for women aged 40-42
- 5.0% for women aged 43-44

The overall chance of a live birth following IVF treatment also falls as the number of unsuccessful cycles increases. Model-based evidence for cost-effectiveness of treatment for women aged 40 years and over is based on the assumption they have not previously attempted IVF[3].

Policy statement 2. Cryopreservation & cryostorage for pre-cancer treatment

Criteria

Sperm cryopreservation to men and adolescent boys who are preparing for medical treatment for cancer that is likely to make them infertile. **OR** 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

Kingston CCG will fund cryopreservation in the following circumstances:

Storage

- Will be funded up until one of the following (whichever is soonest)
    - 10 years after the collection
    - [For oocytes or embryos] the woman's 43rd birthday
    - a live birth.
- Requests for storage beyond 10 years should be assessed on a case by case basis via an individual funding request (IFR).

Post storage treatments

- Will be made available on the same basis as other patients who have not undergone such storage (see criteria for IVF). There is thus the potential for individuals to meet the criteria for cryopreservation and not to meet the criteria for infertility treatments at a later date, which should be explained to them.

Egg preservation for delayed conception in other (non-medical) circumstances

- This will not be funded on the NHS

Rationale

- Cryopreservation of sperm, oocytes and embryos is an effective method of achieving future clinical pregnancies or live births to people undergoing treatment for cancer which has the potential to affect fertility[3].

Policy statement 3. Intrauterine Insemination

3.1 Using partner sperm

Criteria

Kingston CCG will fund up to 6 cycles of unstimulated intrauterine insemination (IUI) in the following groups as an alternative to vaginal intercourse:

1. Couples who are unable to, or would find it very difficult to, have vaginal intercourse because of a clinically diagnosed physical disability or psychosexual problem
2. Couples with conditions that require specific consideration in relation to methods of conception (for example after sperm washing where the man is HIV positive)

Intra-uterine insemination should not be offered routinely to people with unexplained fertility, mild endometriosis or mild male factor infertility.

Rationale

- The NICE guideline[3] states that for these groups, where vaginal sex is inappropriate or not possible, that IUI without stimulation with sperm from a male partner or donor would be the first-line approach.

3.2 Using donor sperm (donor insemination)

Criteria

Kingston CCG will fund up to 6 cycles of unstimulated donor insemination (including donor sperm), without ovarian stimulation, for

- obstructive azoospermia
- non-obstructive azoospermia
- severe deficits in semen quality in couples who do not wish to undergo ICSI
- couples in a same-sex relationship who can demonstrate subfertility through failure to conceive following 6 self-funded cycles of intra-uterine insemination within a clinical setting.

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.

Rationale

Donor insemination is an effective treatment option for male factor infertility, although in some men with azoospermia, semen can be surgically extracted and be used in intracytoplasmic sperm injection (ICSI) procedures[3].

Donor insemination is also indicated where the male partner is likely to pass on an inheritable genetic condition, an infection such as HIV or if severe rhesus incompatibility has been a problem because of the male partner's homozygous status[3].

Up to six cycles of donor insemination for subfertile same-sex couples constitutes the period of expectant management required prior to being eligible for IVF, during which pregnancy may be achieved[3].

Donor insemination is specified since this provides a number of benefits: (i) donor screening and cryopreservation of sperm to protect against transmission of sexually transmitted infections, (ii) optimisation of timing of insemination to maximise chance of conception, and (iii) early identification of sub-fertility.

Policy statement 4. Surgical Sperm Retrieval

Criteria

Surgical sperm retrieval as part of ICSI will be commissioned in appropriately selected patients provided the azoospermia is not the result of a sterilisation procedure or the proven absence of sperm and the couple meets all other criteria for ICSI.

Cryopreservation of remaining sperm will be funded for up to 1 year or a live birth, whichever is sooner.

Rationale

Spermatozoa can be retrieved from both the epididymis and the testis using a variety of techniques with the intention of achieving pregnancies for couples where the male partner has obstructive or non-obstructive azoospermia. Sperm recovery is also used in ejaculatory failure and where only non- motile spermatozoa are present in the ejaculate. Surgically collected sperm in azoospermia are immature (because they have not traversed the epididymus) and have low fertilising ability with standard IVF. It is therefore necessary to use ICSI.

Policy statement 5. Ovulation Induction

Criteria

Kingston CCG will fund up to 3 cycles of ovulation induction using pulsatile administration of gonadotrophin-releasing hormone or gonadotrophins with luteinising hormone activity, for women with WHO Group I ovulation disorders (hypothalamic pituitary failure), to be used with timed intercourse. Couples may proceed to IVF if they meet the criteria outlined in that policy should ovulation induction fail.

Rationale

Evidence from case series studies have demonstrated that pulsatile GnRH induces ovulation, achieving cumulative pregnancy rates of up to 82% in women with hypogonadotrophic hypogonadism and 95% in women with weight-related amenorrhoea after 12 cycles. The corresponding figures for live birth rates were 65% and 85%, respectively [Evidence level 3] [3].

References;

1. *te Velde ER, Eijkemans R, Habbema HDF. Variation in couple fecundity and time to pregnancy, an essential concept in human reproduction. Lancet 2000;355:1928–9, as quoted in NICE Clinical guideline 156 (2013). Fertility; Assessment and treatment for people with fertility problems.*
2. *Bongaarts J. A method for the estimation of fecundability. Demography 1975;12:645–60, as quoted in NICE Clinical guideline 156 (2013). Fertility; Assessment and treatment for people with fertility problems.*
3. *NICE Clinical guideline 156 (2013). Fertility; Assessment and treatment for people with fertility problems.*
4. *NICE Full guideline: Fertility; Assessment and treatment for people with fertility problems. National Collaborating Centre for Women's and Children's Health. February 2013.*
5. *HFEA, Fertility treatment in 2011: Trends and Figures (www.hfea.gov.uk/104.html))*