NHS
South West London Alliance
Partnership of Clinical Commissioning Groups

South West London

Clinical Commissioning Groups

Assisted Conception Treatments

and

Fertility preservation

Policy version 1.0

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Assisted Conception Treatments

1. ASSISTED CONCEPTION TREATMENTS

1.1 Introduction and purpose

This policy updates and replaces the assisted conception policies of six South West London Clinical Commissioning Groups (SWL CCGs), namely: Croydon, Kingston, Merton, Richmond, Sutton and Wandsworth CCGs. The policy will ensure equitable access for patients across SW London, who require assisted conception treatments.

1.2 Objective

The policy objectives are the following:

- Reduce unwarranted variation in access to treatments/procedures;
- Ensure that treatments/procedures commissioned have acceptable evidence of clinical benefit and cost-effectiveness; and
- Promote the cost-effective use of healthcare resources.

1.3 Definition of Assisted Conception Treatments

Assisted Conception Treatments (ACT) can be broadly defined as “any medical, surgical or obstetric services provided for the purpose of assisting a person to carry a child.” This definition is based on the definition of “treatment services” in section 2 of the Human Fertilisation and Embryology Act 1990. This includes any medicines, surgery or procedures that are required to diagnose and treat sub-fertility so a person can have a child. See Section 4 for list of interventions covered by this policy.

1.4 Scope of policy

This policy addresses ACT for diagnosed sub-fertility, where the commissioning responsibility rests with SWL CCGs, rather than with NHS England. It details the commissioning position for patients and their partners, if they have one, regardless of their sexual orientation and their partnership status.

The policy applies to all adult patients, defined as aged 18 years or over.

1.5 Adherence to NICE guidance and constraints on NHS resources

While this policy gives due consideration to the recommendations of NICE clinical guidance, specifically CG156, it does not follow all its recommendations. This is a regulation 5 NICE clinical guidance, which allows commissioners discretion to

implement its recommendations. This is required as commissioners also have other statutory parliamentary obligations, which must also be met and not always compatible with fully implementing all clinical guidance issued by NICE.

NICE CG156 recommends three cycles of IVF, however, SWL CCGs will fund one cycle. The reason for this decision is that the CCGs have determined that within the currently available resources, they wish to enable more individuals to have access to IVF treatments rather than place restricted entry to a smaller number of individuals who are offered three cycles of NHS-funded IVF.

In 2017-18, almost two thirds of CCGs in England and Wales provided only one cycle of IVF. Four per cent of CCGs provide no IVF funding at all and only 13 per cent commissioned three cycles, as recommended by NICE CG156[1].

The summary of the access criteria for ACT is available in section 6.

2. Epidemiology of sub-fertility

2.1 Prevalence

Around 1 in 7 couples may have difficulty conceiving. 84% of women in the general population will conceive within 1 year if the woman is aged under 40 years AND they do not use contraception and have regular sexual intercourse (every 2 – 3 days). This increases to 92% after 2 years and 93% after 3 years.

The epidemiology of male and female sub-fertility is covered in detail in NICE CG156: The main causes of sub-fertility in the UK are

- Factors in the male causing infertility 30%
- Unexplained infertility 25%
- Ovulatory disorders 25%
- Tubal damage 20%
- Uterine or peritoneal disorders 10%

In about 40% of cases disorders are found in both the man and the woman.

2.2 Unexplained sub-fertility

Most causes of sub-fertility can be treated by medical or surgical interventions, after which patients can become fertile and achieve conception normally.

When the results of a standard sub-fertility evaluation are normal, practitioners assign a diagnosis of unexplained sub-fertility.

3. Investigations of sub-fertility and onward referrals

3.1 Access to investigations of sub-fertility

Anyone can be referred for investigation of their infertility if they meet the guidelines set by NICE, regardless of their eligibility status for ACT.

3.2 Initial consultation with patients in primary care

Patients and their partners if they have one, should be consulted with as a couple and the initial consultation with them should cover the following areas:

- Prevalence of sub-fertility and delays in conception
- Discussion of the patients and their partner's sexual history
- Advice on lifestyle
    - Smoking
    - Alcohol and recreational drug use
    - Caffeine intake
    - Weight management and healthy eating
- NHS-funded assisted conception treatments
    - Access criteria for IUI, IVF and ICSI
    - Success rates of IVF (national data 2014-2016)

Age of women	Live birth rate
Under 35	29%
35 - 37	23%
38 – 39	15%
40- 42	9%
43 – 44	3%
Over 44	2%
The above figures are for women using their own eggs and their partner's sperm, using the per embryo transferred measure.	

3.3 Expectant management for heterosexual couples

Couples in heterosexual relationships where the woman has not conceived after 12 months of regular unprotected vaginal intercourse, the couple should be investigated for the causes of sub-fertility. If the prospective mother is aged 36 years or over (i.e. after their 36th birthday) at the first time of presenting to primary care with sub-fertility concerns, they should be investigated after six months of regular unprotected vaginal intercourse.

During the investigation stage into sub-fertility heterosexual couples must continue to have regular unprotected vaginal intercourse as after a total of 24 months the cumulative pregnancy success rates rises to 92% for patients under 40.

This expectant management involves 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.

All couples must demonstrate 24 months of regular unprotected vaginal intercourse before they can access ACT.

Heterosexual couples who are unable to have unprotected vaginal intercourse must demonstrate their sub-fertility by receiving unstimulated Intrauterine Insemination (IUI) the same was as women in same sex relationship and single women in line with NICE CG156.

3.4 Women in a same sex relationship and single women

Women in a same sex relationship and single women, who have had six attempts at unstimulated Intrauterine Insemination (IUI) over a period of at least six months would be considered the equivalent of having 12 months of unprotected vaginal intercourse. If the prospective mother is aged 36 years or over (i.e. after their 36th birthday) at the first time of presenting to primary care with sub-fertility, they should be referred to specialists after three cycles of unstimulated IUI over a period of at least three months.

Women in a same sex relationship and single women must have a total of 12 attempts at IUI over a period of at least 12 months. Patients should provide documented evidence that IUI has taken place in a HFEA licensed clinical setting. Cycle summaries obtained from the unit where patients have had previous treatments must be shared with fertility specialists.

3.5 Men in a same sex relationship and single men

Men in a same sex relationship and single men are eligible for semen analysis, although it must be stated to them that surrogacy is not funded by the NHS for anyone.

3.6 Transgender people

Transgender people are eligible for a direct tertiary care referral on the recommendation of the NHS transgender provider they attend.

3.7 Primary care investigations of sub-fertility

The following investigations and interventions should be carried out in primary care.

A) Female partner

- Optimise BMI (target range between 19 and 30)
- Provide lifestyle advice and refer as appropriate on
    - Smoking
    - Alcohol and recreational drug use
    - Caffeine intake
- FSH taken between day two and five of the cycle
- Mid luteal phase (7 days before period) progesterone level
- Thyroid function tests only if there are symptoms of thyroid disease;
- Prolactin only if there are symptoms of ovulatory disorder, galactorrhoea or a pituitary tumour; and
- Rubella and Chlamydia testing via Polymerase chain reaction (PCR) swab.

B) Male partner

- Semen analysis test, repeat if results of first test are abnormal
- Optimise BMI (target range between 19 and 30)
- Provide lifestyle advice and refer as appropriate on:
    - Smoking;
    - Alcohol and recreational drug use; and
    - Caffeine intake.

3.8 Onward referral to secondary care

Patients and their partners if they have one, should only be referred to secondary care once the above investigations have been undertaken.

All patients are eligible for an onward referral for investigation of sub-fertility if clinically indicated even if they do not meet the access criteria for ACT set out in this policy.

If the prospective mother is aged 36 years or over (i.e. after their 36th birthday) at the first time of presenting to primary care with sub-fertility concerns, they should be referred after six months of regular unprotected vaginal intercourse or three cycles of unstimulated IUI over a period of at least three months.

If the sub-fertility has already been investigated and a cause for the sub-fertility has been diagnosed, or if as a result of previous investigations for another issue the individual is known to be sub-fertile, then they should be referred for appropriate treatment without further delay.

Primary care providers must ensure that all results for the patient and their partners if they have one are sent to secondary care and they attend as a couple if they are in a relationship.

3.9 Secondary care investigations of sub-fertility

Patients and their partners if they have one, should attend consultations as a couple.

All patients should be investigated in line with NICE CG156 and primary care must provide results of investigation undertaken to avoid unnecessary testing.

Please note

SWL CCG do not fund the following tests in line with NICE CG156.

- Routine post coital testing of cervical mucus;
- Thyroid function tests (unless symptoms of thyroid disease);
- Prolactin unless ovulatory disorder, galactorrhoea or a pituitary tumour;
- Screening for antisperm antibodies;
- Use of basal body temperature charts to confirm ovulation;
- Endometrial biopsy to investigate the luteal phase; and
- Hysteroscopy as a treatment procedure.

3.10 Referral to Assisted Conception Units (ACU)

Referral to Assisted Conception Units (ACU) should be considered for women and their partners if they have one, if they meet the access criteria for receiving NHS-funded ACT as detailed in section 6. If they do not meet the access criteria, they should be advised that they can access ACT privately.

Referrals must be made by the prospective mother's GP or the investigating gynaecology team, confirming that the patient meets the access criteria and provide the entire relevant medical history, including investigation results.

Referral must be made to HFEA licenced and SWL accredited ACU providers.

3.11 Specialist referral

Specialist referral should be considered for people with chronic viral infections such as hepatitis B, hepatitis C, or HIV, to centres that have appropriate expertise and facilities to provide safe risk-reduction investigation and treatment.

All individuals undergoing IVF treatment should be offered testing for HIV, hepatitis B and hepatitis C and referred in this way if found to be positive.

3.12 Additional tests and investigations

Primary care providers are only expected to undertake investigations and interventions listed in section 3.7.

Additional tests (e.g. anti-Mullerian hormone test, hepatitis B serology, HIV) and drug prescriptions are covered in secondary or tertiary care provider tariffs and should not be undertaken by primary care. This also includes request from private providers regardless if they provide NHS-funded treatment or on a self-funded basis.

The management of the patient and their partner if they have one becomes the responsibility of primary care once the pregnancy enters the antenatal care stage.

Additional medication requested from primary care must be in line with the recommendations of the Royal College of Obstetricians and Gynaecologists and HFEA traffic light system.

4. Treatments of sub-fertility

Once a diagnosis of sub-fertility has been established, treatment falls into three main categories:

- Medical treatments i.e.: the use of drugs for ovulation induction; OR
- Surgical treatments i.e.: repair of the fallopian tubes; OR
- Assisted Conception Treatments – any treatment that deals with means of conception other than vaginal intercourse.

This policy covers only the ACT, where natural conception is not possible.

SWL CCGs fund the following treatments based on the eligibility criteria set within:

- Sperm washing;
- Unstimulated Intrauterine Insemination (IUI);
- In Vitro Fertilisation (IVF) and Intracytoplasmic Sperm Injection (ICSI) including the cryopreservation of frozen embryos to complete a full cycle.

5. Sperm washing to prevent HIV transmission

Sperm washing is a process in which individual sperm are removed from the semen then used in assisted conception treatments. Its use in reducing male to female HIV transmission is based on the observation that HIV is found in the seminal fluid rather than the sperm cells. Hence, sperm washing decreases the transmission rate of HIV to an unborn child.

SWL CCGs will fund sperm washing for the prevention of HIV transmission when:

- Male patient is HIV positive and compliant with Highly active antiretroviral therapy (HAART); AND
- Plasma viral load is 50 copies/ml or greater; AND
- Female partner is HIV negative.

Please note

SWL CCGs do not routinely commission sperm washing for any other indication, such as hepatitis B or hepatitis C, as current evidence does not support this.

NHS England is responsible for the commissioning of all antiretroviral medicines for all indications.

6. Access criteria for Assisted Conception Treatments

The following table summarises the funding criteria for assisted conception treatments that SWL CCGs are responsible for commissioning. Additional clarification may be found in the sections directly referenced.

Title	Funding Criteria	Explanation
Commissioning status	The prospective mother must be a registered patient of a GP practice in SWL at the time of commencing on the ACT pathway. Patients already on the ACT pathway, who move to SWL and register with a GP practice in SWL will be treated in line with this policy.	Charges relating to ACT are linked to the prospective mother as receives the treatment. All SWL residents have access to one cycle of NHS-funded IVF/ICSI.
Sub-fertility or infertility	Patient either has an identified cause of sub-fertility/infertility or have had 24 months of unexplained infertility. For single women or same-sex female couples this means 12 cycles of unstimulated IUI over at least 12 months.	84% of women under the age of 40 conceive within 1 year if and they do not use contraception and have regular sexual intercourse. This increases to 92% after 2 years. Please see section 3 for further details.
Sterilisation	Neither the patient or their partner, if they have one, should have undergone previous sterilisation.	Sterilisation is offered by the NHS as an irreversible method of contraception. This criteria applies to those who have unsuccessfully undergone reversal of sterilisation regardless if any part of this was NHS-funded or not.
FSH level	Highest ever level of FSH taken between day 2 and 5 of the cycle must be less than or equal to 8.9iu/L.	NICE recommendation.
AMH level	AMH level has always been equal or greater than 5.4pmol/l.	NICE recommendation.

Childlessness	The couple have no living child from their current relationship and at least one of the prospective parents does not have any living children from a previous relationship. A child adopted by a patient or adopted in a previous relationship is considered to have the same status as a biological child.	If both partners have living children then they do not qualify for further NHS-funded ACT to priorities those without children.
Welfare of the child	Each patient and their partner, if they have one, must conform to the HFEA 'Code of Practice' to be able to access to NHS-funded ACT.	This includes consideration of the 'welfare of the child which may be born' which may take into account the importance of a stable and supportive environment for children as well as the pre-existing health status of the parents.
Age of woman	Prospective mothers must be aged no more than 42 years old (i.e. before their 43rd birthday) at start of the full IVF/ICSI treatment cycle. Please note that this policy only applies to adults only.	Age is a robust indicator of success of ACT and the younger the women are the higher the success rate is. The start of the treatment cycle is defined in section 8.4.
Body mass index (BMI)	Prospective mothers must have a BMI of between 19 and 30 for a period of at least six months prior to commencement of treatment.	NICE recommendation.
Smoking status	Each patient and their partner, if they have one, must have been non-smokers for at least six months prior to commencement of treatment.	Smoking and other nicotine products can adversely affect the success rates of ACT. Currently there is limited and uncertain evidence around the safety of vaping and patients are advised to avoid vaping. Consider carbon monoxide (CO) testing if there is suspicion that patients continue to smoke.

Alcohol and recreational drug use	Each patient and their partner, if they have one, must give assurances that their alcohol intake is within Department of Health guidelines and they are not currently using recreational drugs.	HEFA guidance. Any evidence to the contrary will result in the cessation of treatment.
Number of IUI cycles of treatment	SWL CCGs commission up to 12 NHS-funded unstimulated IUI cycle for eligible patients. Please note that IUI for single women and same-sex female couples is not routinely funded.	See section 7 for details of eligibility and exclusion criteria.
Number of IVF/ICSI cycles of treatment	SWL CCGs commission one NHS-funded IVF/ICSI cycle for eligible patients. Please note that patients who previously have had NHS-funded IVF/ICSI or those who have had more than two full cycles of IVF/ICSI either privately or NHS-funded will not receive any further NHS-funded IVF/ICSI.	See section 8 for details.

7. Intrauterine insemination (IUI)

Intrauterine insemination (IUI) is a technique to place sperm into a woman's womb through the cervix. This may be carried out using the partner's sperm, or using sperm donated by another man (either anonymously or not).
SWL CCGs will fund up to 12 cycles of unstimulated IUI, however this does not include any costs or expenses associated with donor sperm.

7.1 Indications for IUI

Patients will qualify for NHS-funded IUI if they meet the following criteria:

- Had all appropriate tests and investigations in primary and secondary care in line with NICE guidelines. **AND**
- Meet all the access all the criteria given in section 6 **AND**
- Heterosexual couples who are unable to, or would find it very difficult to, have vaginal intercourse because of:
    - A clinically diagnosed physical disability **OR**
    - Psychosexual problems formally diagnosed*.

7.2 Please note

SWL CCGs do not routinely fund the following:

- IUI for same sex female couples and single women.
- Stimulated IUI.

Patients must be advised that it is their responsibility to source and pay all costs associated with the donor sperm, including transportation cost to the ACU.

' Patients/couples with psychosexual problems must access psychosexual counselling services to address the underlying causes.*

8. In Vitro Fertilisation (IVF)

In Vitro Fertilisation (IVF) is a technique by which eggs are collected from a woman and fertilised with a man's sperm outside the body. Usually one or two resulting embryos are then transferred to the womb. If one of them attaches successfully, it results in a pregnancy.

Intracytoplasmic Sperm Injection (ICSI) is a variation of IVF in which a single sperm is injected into an egg in order to fertilise it, with the resulting embryo transferred to the womb.

8.1 Number of cycles to be funded

SWL CCGs will fund one full cycle of IVF/ICSI for eligible patients with proven sub-fertility. NICE states that the overall chance of a live birth following IVF treatment falls as the number of unsuccessful cycles increases.

Patients who previously have had NHS-funded IVF/ICSI or those who have had more than two full cycles of IVF/ICSI either privately or NHS-funded will not receive any further NHS-funded IVF/ICSI.

8.2 Indications for IVF

Patients will qualify for NHS-funded IVF if they meet the following criteria:

- Had all appropriate tests and investigations in line with NICE guidelines. **AND**
- Meet all the access criteria given in section 6.

8.3 Indications for ICSI

The decision on whether to use IVF alone or IVF with ICSI should be undertaken by the specialist in line with the HFEA Code of Practice 9th edition. The recognised indications for treatment by ICSI include:

- Severe deficits in semen quality.
- Obstructive azoospermia.
- Non-obstructive azoospermia.
- Previous IVF treatment cycle resulted in failed or very poor fertilization.

8.4 Definition of a full IVF/ICSI treatment cycles

The full IVF cycle, as defined by the SWL CCGs, will consist of one fresh embryo transfer followed by one Frozen Embryo Transfer (FET), if good quality embryos were frozen as part of the cycle. A successful fresh embryo transfer (in terms of a live birth) would make the couple ineligible for a FET.

A full cycle of IVF/ICSI as defined by the SWL CCG includes the following:

- Ovarian stimulation including all the drugs used in preparation for IVF/ICSI (including down regulation if required).
- Egg recovery.
- Fertilisation and fresh embryo transfer.
- Frozen Embryo Transfer (FET) if the fresh embryo transfer failed.
- Freezing of good quality spare embryos.

An NHS-funded cycle of IVF/ICSI treatment is considered to have commenced once ovarian stimulation drugs have been initiated. A cancelled cycle is one where an egg collection procedure is not undertaken. Patients may be eligible for another IVF/ICSI cycle if their ovarian reserves meet the eligibility criteria at this stage.

Beyond this stage, a cycle will be counted as complete whether or not a fresh embryo transfer is attempted.

Patients who had eggs or sperm frozen due to medical reasons (as per fertility preservation policy) will be eligible for two Frozen Embryo Transfer (FET) as in these circumstances a fresh embryo transfer is not available for them. If the thawing of frozen eggs or sperm fails this does not count as a completed FET. Patients may be eligible for another FET cycle if there are further frozen eggs or sperm.

All drug and investigation costs will be met by the ACU as part of the commissioned service and must not be prescribed by a GP.

Switching providers should not take place before the full IVF cycle is complete (including fresh and, where indicated, frozen embryo transfer).

8.5 Multiple births strategy

SWL CCGs require accredited SWL ACU providers to adhere to the ‘One Child at a Time’ HFEA guidance to minimising multiple births and the recommendations of NICE *Quality statement 8: Number of embryos transferred*.

https://www.nice.org.uk/guidance/qs73/chapter/Quality-statement-8-Number-of-embryos-transferred. The rationale for avoiding multiple pregnancies is based on the costs of mitigating the additional health risks to mother and child, which have been identified widely[1].

SWL CCGs will fund embryo transfers and freezing in order to support this single embryo transfer strategy.

8.6 Timeframes for IVF/ICSI

It is the responsibility of SWL accredited ACU to ensure that criteria set within this policy is adhered to including commencement of ACT specified for the ages of prospective mothers. The start of IVF/ICSI treatment is defined as the start of the stimulating phase of the IVF cycle.

Patients and their partners if they have one must take up the offer of IVF/ICSI within six months of being offered IVF/ICSI by the accredited SWL ACU.

Once the NHS-funded full IVF/ICSI treatment has commenced patients can delay treatment between the fresh cycle and frozen cycle for up to 12 months and the cryopreservation of the embryos following a fresh cycle is funded for up to 12 months.

[1] A report by the National Guideline Alliance about twin pregnancy costing. September 2018. Available at: http://www.multiplebirths.org.uk/twin_pregnancy_costing_final.pdf

9. Sperm donation for IUI/IVF/ICSI

Sperm donation is a process by which a man donates his sperm to enable a woman who is not his sexual partner to conceive as part of an assisted conception treatment.

SWL CCGs will not fund the actual donor sperm but will fund the associated IUI/IVF/ICSI treatment in line with the criteria in this policy providing the sperm meet the criteria laid down by the ACU.

Patients must be advised that it is their responsibility to source and pay all costs associated with the donor, including transportation cost to the SWL accredited ACU.

10. Egg donation for IUI/IVF/ICSI

Egg donation is the process by which a woman donates eggs to enable another woman to conceive as part of an assisted conception treatment.

SWL CCGs will not fund the actual egg donor but will fund the associated IUI/IVF/ICSI treatment in line with the criteria in this policy providing the eggs meet the criteria laid down by the accredited SWL ACU.

Patients must be advised that it is their responsibility to source and pay all costs associated with the donor, including transportation cost to the SWL accredited ACU.

11. Treatments and interventions not routinely funded by SWL CCGs

SWL CCGs will not routinely fund the following:

- Surrogacy in any form (e.g.: part surrogacy);
- Natural IVF, where no drugs are used;
- In vitro maturation (IVM). IVM involves removing immature eggs that have yet to complete their growth, and then maturing these eggs in the laboratory.
- Procurement, transport or storage of donor sperm or eggs;
- Endometrial scratch;
- Aneuploidy screening (NB Pre-implantation genetic diagnosis (PGD) is funded by NHS England);
- Varicocele surgery for male infertility;
- Experimental investigations including, but not limited to:
    - Assessment of sperm movements (e.g.: videomicrography, cinematography, time-exposure photography, computer assisted sperm analysis);
    - Analysis of ATP concentration (Adenosine triphosphate) in ejaculate;
    - Tubaloscopy;
    - Anti-zona pellucida antibodies;
    - Sperm hyaluronan binding assay (HBA);
    - Tests of sperm DNA integrity, including, but not limited to, sperm chromatin assays and sperm DNA fragmentation assays;
    - Hemizona assay;
    - Hypo-osmotic swelling test.
- Modifications of the IVF procedure including, but not limited to:
    - GIFT (gamete intrafallopian transfer);
    - ZIFT (zygote intrafallopian transfer);
    - PROST (pronuclear stage transfer);
    - TEST (tubal embryo stage transfer);
- TET (tubal embryo transfer).
- Other additional ‘add-on’ IVF treatments and procedures not listed here will not be funded unless they have received ‘green light’ approval from the HFEA.

Providers are not allowed to offer or charge for ‘add-on’ IVF treatments to those receiving NHS-funded ACT.

12. NHS England funded treatments

NHS England has commissioning responsibilities for the following interventions. For up to date details of the specific criteria please visit the NHS England website.

12.1 Pre-implantation genetic diagnosis (PGD)

Pre-implantation genetic diagnosis (PGD) is a technique that involves testing cell(s) from embryos created outside the body by IVF for a genetic disorder. Tests are carried out for the specific disorder that the embryos are known to be at significant risk of inheriting. Unaffected embryos are selected for transfer to the uterus in the hope that a normal birth will ensue. Whilst the PGD technology requires IVF and ICSI services, it is not part of tertiary assisted conception services, and as such does not form part of this policy. PGD is commissioned and funded by NHS England[2].

12.2 Surgical sperm retrieval

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 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. Surgical sperm retrieval is funded by NHS England[3].

Surgical sperm retrieval is always accompanied by cryopreservation, which is funded within SWL CCG as per this policy. Cryopreserved sperm will need to meet all the eligibility criteria before subsequent IVF/ICSI can take place.

[2] NHS England. Clinical Commissioning Policy: Pre-implantation Genetic Diagnosis (PGD) (Reference: E01/P/a). April 2014

[3] NHS England. Clinical Commissioning Policy: Surgical sperm retrieval for male infertility. July 2016. Available at: https://www.england.nhs.uk/wp-content/uploads/2018/07/Surgical-sperm-retrieval-for-male-infertility.pdf

Fertility preservation

13. FERTILITY PRESERVATION

13.1 Introduction and purpose

This policy updates and replaces the fertility preservation policies of six South West London Clinical Commissioning Groups (SWL CCGs), namely: Croydon, Kingston, Merton, Richmond, Sutton and Wandsworth CCGs. The policy will ensure equitable access for of patients across SW London, requiring fertility preservation services.

13.2 Objective

The policy objectives are the following:

- Reduce unwarranted variation in access to treatments/procedures;
- Ensure that treatments/procedures commissioned have acceptable evidence of clinical benefit and cost-effectiveness; and
- Promote the cost-effective use of healthcare resources.

13.3 Definition of fertility preservation

Fertility preservation may entail the harvesting and freezing of eggs or sperm that may be thawed for use in future assisted conception treatment (ACT). Alternatively, it may entail the creation of embryos for freezing that may be implanted in the womb later.

Cryopreservation or cryostorage may be used as a synonym for fertility preservation.

13.4 Funding of fertility preservation

SWL CCGs will fund one cycle of fertility preservation, including sperm, egg and embryo cryostorage in the following circumstances:

- Patient who are preparing to undergo medical, non-medical and surgical treatment that is likely to have a permanent harmful effect on subsequent sperm or egg production. Such treatment may include but not limited to:
    - Surgery, radiotherapy or chemotherapy for malignant disease

- Treatment for gender dysphoria[4], where the patient is following or has followed a recognised NHS transgender treatment pathway, as specified by NHS guidance.

- Patients whose ongoing medical condition or treatment causes harmful effects on sperm or egg production or has possible teratogenic effects and stopping treatment for a prolonged period of time to enable conception is not possible.

Please note

SWL CCGs do not routinely fund the following:

- Pre-pubertal individuals, as treatment is regarded as experimental.
- Egg (oocyte) or embryo cryostorage, if the female is over 42 years of age.
- Patients who choose to undergo medical or surgical treatment whose primary purpose is infertility, such as sterilisation.
- Patients who underwent sterilisation previously, even if it has been reversed.
- Cryopreservation of ovarian or testicular tissue, as it is regarded experimental.
- 'Elective freezing': where a man or woman requests this for non-medical reasons.
- Patients who are already infertile for any reasons.

14. Access to assisted conception following fertility preservation

The eligibility criteria used for fertility preservation is not be the same as the eligibility criteria for ACT. Commencement of NHS-funded fertility preservation does not automatically entitle patients to access NHS-funded ACT. Therefore, there is the potential for patients to meet the eligibility criteria for fertility preservation and not to meet the eligibility criteria for ACT at a later date.

The eligibility criteria for ACT, as detailed in the ACT policy, applies to patients who used fertility preservation. However, the ovarian reserve criteria of FSH and AMH do not apply in this subset of patients as treatment or condition compromised their fertility.

[4] NHS England. Service Specification: Gender Identity Services for Adults (Surgical Interventions). 2019. Available at: https://www.england.nhs.uk/wp-content/uploads/2019/07/service-specification-gender-dysphoria-surgical-interventions-may-2019.pdf

Patients who had eggs or sperm frozen due to medical reasons, funded by the NHS, will be eligible for two Frozen Embryo Transfer (FET) cycles, as in these circumstances a fresh cycle is not available for them.

15. Duration of fertility preservation

The duration of NHS-funded fertility preservation is based on the circumstances and needs of the patients and scenarios are detailed below.

15.1 Patients under 23 years of age

SWL CCGs fund fertility preservation for patients under 23 years of age until they reach their 23rd birthday. At the point which the patient reaches their 23rd birthday, funding will be available for up to an additional five years from this date, similarly to those aged 23 years or over detailed in section 17.2.

The combined funded storage period up to age 28 (23 + 5) gives those youngest patients entering the cryopreservation pathway the opportunity to reach an age of maturity approaching the UK averages at which men and women have children. In 2012, the most recent data at the time of writing, for first births the standardised average age of mothers was 28.1 years.

Example: a young person entering the cryopreservation pathway at 15 years of age, would be eligible for seven years funded storage up to age 23, then an additional five years funded storage up to age 28. Giving them a total funded storage period of potential 12 years.

15.2 Patients aged 23 years or over

SWL CCGs fund fertility preservation for patients aged 23 years or over for up to five years, and will only be terminated sooner in the following circumstances:

- Following a live birth. **OR**
- The period of cryostorage reaches five years, **OR**
- The woman's 43rd birthday for eggs or embryos, **OR**

If either partner dies after the freezing of gametes, the requirements of the Human Fertilisation and Embryology Act 1990 consent process must be followed.

15.3 Funding of additional years

Patients may choose to self-fund cryostorage for a further period in accordance with HFEA guidelines. Retrieval and storage of sperm, eggs or embryos should also be in accordance with HFEA guidelines.

Patients who continue to undergo active medical treatments that make them unable to start their families at the time their NHS-funded fertility preservation is over can apply for additional funding with the explicit written support from their treating clinician.

16. Commissioning considerations specific to fertility preservation

Fertility preservation may have a considerable duration for some patients, during which they may move and this section addresses the funding implications of this.

16.1 Patients moving into SWL CCG

Patients moving into SWL CCG, who have used NHS-funded fertility preservation services elsewhere will continue to be funded as per their previous CCG's commissioning arrangements. This is the same as any other treatment commenced whilst registered to another CCG's GP practice.

Once the original policy agreement has elapsed (or is about to), then an application for continuing storage in accordance with the local policy would need to be made; at this time the applicant needs to demonstrate compliance with the SWL CCG policy for further storage to be supported.

Fertility preservation services will continue to be funded at the same provider. When the sperm or egg requires transfer for an NHS-funded IUI/IVF/ICSI treatment the patient is responsible for all costs including transportation cost to the ACU.

16.2 Patients leaving SWL CCG

Patients leaving SWL CCG, who have used NHS-funded fertility preservation services, will no longer be the responsibility of SWL CCGs for ongoing funding of storage. In England the new CCG will need to honour and apply SWL CCG's original policy until it expires i.e. the end of the currently agreed period of storage. After this time the new CCG's policy will apply.

17. Appendix 1 Commissioning arrangements and scenarios

This section defines certain scenarios for clarity about commissioning responsibilities with special consideration to Assisted Conception Treatments (ACT) and Fertility Preservation.

17.1 Establishing the responsible CCG

ACT treatments are funded by the CCG with whom the prospective mother is registered, except for those treatments where the specified commissioner is NHS England.

17.2 Immigration health surcharge; removal of ACT

Amendments to the NHS (Charges to Overseas Visitors) Regulations 2015 were introduced into Parliament on 19 July 2017. As a result, from 21 August 2017, ACT services are no longer included in the scope of services. Those who are required to pay the NHS surcharge are no longer eligible for NHS-funded ACT.

17.3 Funding for military serving personnel

ACT for current serving personnel and their partners is contained within the specific NHS England policy, as NHS England are the responsible commissioner[5]. Veterans who are in receipt of compensation for loss of fertility (received as a result of service/partner of same) and require access to ACT, are also the commissioning responsibility of NHS England[6]. Veterans without relevant injury impacting on fertility are the commissioning responsibility of CCGs and the content of this policy applies.

17.4 Private and self-funded patients

Patients who are undergoing ACT outside of an NHS pathway will not be funded or reimbursed for drugs or additional tests incurred as a result of self-funded/private treatment. Nor will primary care carry out investigations or prescribe drugs for self-funded ACT.

All couples/patients including those who have previously self-funded must meet the eligibility criteria in section 6 in order to receive NHS-funded ACT cycles. The number

[5] NHS England: Health and Justice and Armed Forces service specific policies. Available at: https://www.england.nhs.uk/commissioning/policies/ssp/

[6] Armed Forces and their Families Commissioning Intentions – 2017/18 to 2018/19. Available at: https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2016/10/armed-forces-comms-intent-1617-1819.pdf

of previous self-funded fresh cycles of IVF/ICSI must not exceed two to be eligible for NHS-funded ACT cycle.

At the point that the patient or couple seeks to transfer back to NHS care they will be assessed against the eligibility criteria and their private medical records must be made available to accredited SWL ACU.

NHS treatment will only be available at the ACUs commissioned by SWL CCGs for ACT in the same way as for other NHS patients without preferential handling of patients previously accessed ACT.