

Fertility Policy

Introduction

This policy sets out the limits within which WCCG will fund treatment with either Intrauterine Insemination [IUI], ovulation induction medication or donor insemination [DI] as well as IVF treatment if necessary for patients who meet the criteria for treatment.

The objective of treatment for subfertility is to achieve a successful pregnancy quickly and safely with the least intervention required and the delivery of a healthy child.

This document lists all policies related to assisted reproductive technologies (ART), i.e. the policy statements for:

- In vitro fertilisation (IVF), with or without intra-cytoplasmic sperm injection (ICSI)
- Intra-uterine insemination (IUI) using Donor Insemination (DI)
- Surgical sperm retrieval
- Sperm washing
- Fertility preservation for patients who are to undergo therapy with oncology treatments which are likely to compromise their future fertility
- Sperm donation, oocyte donation, in-vitro maturation (IVM), and Surrogacy/Gestational Carriers
- Same sex couple and single women

In order to access NHS funded IVF, with or without ICSI; patients will be required to fulfil relevant eligibility criteria.

These eligibility criteria are only applicable to policies set out in this document. They do not apply to:

- Investigations for general fertility problems and the primary treatment of conditions found during such investigation.
- Medical treatment to restore fertility (for example, the use of drugs for ovulation induction)
- Surgical treatment to restore fertility (for example, laparoscopy for ablation of endometriosis)
- Pre-implantation genetic diagnosis and services for members of the armed forces and some veterans, commissioning of which fall under the remit of NHS England

Wiltshire CCG does not partially fund treatments for patients who do not meet the criteria within this policy.

Eligible couples requiring IVF, with or without ICSI, will have available to them a maximum of THREE embryo transfers including no more than ONE transfer from fresh cycles.

Individuals who do not meet the eligibility criteria set out in the relevant section of this policy or have received NHS funded IVF treatment elsewhere or have previously had a pregnancy via NHS funded assisted conception methods are not eligible for treatment under this policy.

A full cycle of IVF treatment, with or without ICSI, should comprise one episode of ovarian stimulation and the transfer of resultant fresh and frozen embryo(s), in line with the relevant policy to a maximum of three embryo transfers.

Other forms of assisted reproductive technologies are not included. Any new treatments or research trial treatments are not included – patients taking part in trials of new treatments will be considered separately and will be within the governance arrangements of that research trial. New developments in assisted reproductive technologies will be dealt with through the agreed local processes and would need to be proposed via a business case.

Reference:	Policy Name	Date of WCAG	Date of WCAG	Review Date	Version
WCCG-CP022	Fertility Policy	05/12/2017	06/03/2018	March 2021	4

ELIGIBILITY CRITERIA

Duration of Infertility/Waiting Time

Couples with unexplained fertility must have infertility of at least three years of ovulatory cycles, despite regular unprotected vaginal sexual intercourse with the partner seeking treatment or 12 cycles of artificial insemination over a period of at least:

- Three years duration for women under 35 years of age
- Two years duration for women who are 35 - 40 years of age

(i.e. All women with unexplained infertility who reach their 35th birthday will be referred after 2 years of trying to become pregnant).

In both of the above time scales this includes one year of expectant management in primary care, despite regular unprotected vaginal sexual intercourse, before referral to NHS-funded assisted conception services.

If the woman has a miscarriage, the couple will wait for a further:

- Three years duration for women under 35 years of age
- Two years duration for women who are 35 - 40 years of age

Of unexplained infertility from the date of the miscarriage to be eligible for NHS funded IVF.

Couples with a diagnosed cause of absolute infertility which precludes any possibility of natural conception, (i.e. Azoospermia, or bilateral tubal blockage) and who meet other eligibility criteria, will have immediate access to NHS funded assisted reproduction services as long as all other eligibility criteria are met.

Rationale

This policy decision is based on affordability grounds and prioritising treatment for couples where the woman is over the age of 35 years when the success rate of live births begins to decline.

Stable Relationship

All couples seeking NHS funded assisted reproduction services must have been in a stable relationship for a period of at least two years. This requirement supports the welfare of the child assessment as per HFEA Code of practice.

Residency

Both partners must be registered with a GP practice in Wiltshire Clinical Commissioning Groups. Where a patient moves during the course of treatment, every effort should be made to ensure continuity of care.

Age of Woman at Time of Treatment

Funding is available where the woman is aged between 30 years and 40 years of age. No treatment will be offered beyond these dates.

Fertility treatment for a prospective mother must commence no later than 18 weeks before the patients 40th birthday.

Comments:

NICE CG156 concludes that treatment with IVF is cost effective for women aged less than 39 years. There is considerable uncertainty about whether IVF is cost effective in any sub-groups of women aged between 40 and 42. The clinical and health economic evidence is overwhelming in indicating that IVF should not be offered to women aged 43 years or older.

This policy decision is based on affordability grounds and prioritising treatment for couples where the woman is over the age of 35 years when the success rate of live births begins to decline.

Reference:	Policy Name	Date of WCAG	Date of WCAG	Review Date	Version
WCCG-CP022	Fertility Policy	05/12/2017	06/03/2018	March 2021	4

Age of Male Partner at Time of Treatment

The age of the male partner must be before the 55th birthday.

Comments:

NICE CG156 does not provide guidance on the age of the male partner.

HFEA guidance recommends that the upper age limit for sperm donors should be 45 years; by contrast the professional guidance recommends 40 years or younger. In discussion with providers Wiltshire CCG has concluded that 55 years is a suitable age limit.

Previous Cycles

Couples will not be funded if either partner has already had three previous fresh cycles of IVF, with or without ICSI, irrespective of how these were funded.

This means that eligible couples will be funded: One fresh cycle of IVF, with or without ICSI, if no previous cycles have been funded by the NHS, or if they have already received up to two non-NHS funded fresh cycles.

Comments:

NICE CG156 states that there is an inverse relationship between IVF success and the number of prior unsuccessful attempts. A maximum of three NHS funded IVF cycles is recommended by NICE CG156. There is a reduced likelihood of a live birth for the 4th cycle for women who have had 3 previous IVF cycles.

Definition of Childlessness

Funding will be made available to patients who do not have a living child from their current relationship and where either of the partners does not have a living child from a previous relationship (i.e. one of the partners may have a child, the other must not).

- A child adopted by a patient or adopted in a previous relationship is considered to have the same status as a biological child.
- Once a patient is accepted for treatment they will no longer be eligible for treatment if a pregnancy leading to a live birth occurs or the patient adopts a child.

Female Body Mass Index (BMI)

Women will be required to achieve a BMI of 19-30kg/m² documented in the clinical notes for a period of 6 months or more before each period of treatment begins. They should be informed of this criterion at the earliest possible opportunity in their progress through infertility investigations in primary and secondary care.

Comments:

NICE CG156 states that low body weight is recognised as an important cause of hypo-oestrogenic amenorrhoea. In women, weight loss of over 15% of ideal body weight is associated with menstrual dysfunction and secondary amenorrhoea when over 30% of body fat is lost. Restoration of body weight may help to resume ovulation and restore fertility.

Reference:	Policy Name	Date of WCAG	Date of WCAG	Review Date	Version
WCCG-CP022	Fertility Policy	05/12/2017	06/03/2018	March 2021	4

Smoking

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 maternal and passive smoking on the foetus, and the adverse health impacts of passive smoking on any children; and smoking cessation support should be provided as necessary.

Patients and their partner must be non-smoking and smoke free for a period of 6 months in order to access any fertility treatment and maintained during treatment.

Providers should also include this undertaking on the consent form and ask patients to acknowledge that smoking will result either in cessation of treatment or treatment costs being applied.

Providers should seek evidence of smoke free status. Non-smoking status should continue throughout treatment as confirmed by a CO reading of <6ppm.

Comments:

NICE CG156 states that smoking is likely to reduce women's' fertility. In addition, maternal and paternal smoking can adversely affect the success rates of assisted reproduction procedures, including IVF treatment.

Drugs and Alcohol

Patients will be asked to give an assurance that their alcohol intake is within Department of Health guidelines and they are not using recreational drugs. Any evidence to the contrary will result in either non referral or the cessation of treatment.

Reversal of Sterilisation and Treatment Following Reversal

Subfertility treatment will not be provided where this is the result of a sterilisation procedure in either partner. The surgical reversal of either male or female sterilisation will not be funded.

Comments:

Sterilisation is offered within the NHS as an irreversible method of contraception. Considerable time and expertise are expended in ensuring that individuals are made aware of this at the time of the procedure. Since the majority of requests arise for non-medical reasons, CCGs consider that it is inappropriate that NHS funds are used in reversing these procedures.

POLICY STATEMENTS

In vitro fertilisation (IVF) with or without intra-cytoplasmic sperm injection (ICSI)

- Eligible couples requiring IVF, with or without ICSI, will have available to them a maximum of THREE embryo transfers including no more than ONE transfer from fresh cycles
- In order to access NHS funded IVF, with or without ICSI, patients will be required to fulfil relevant eligibility criteria.

Comments:

Eligible couples are funded for one full cycle of IVF with or without ICSI rather than three – as recommended by NICE Clinical Guideline 156 – because NHS Wiltshire CCG has concluded that provision of three full cycles of IVF/ICSI for eligible couples is currently unaffordable in the context of local priorities. When making resource allocation decisions in this context, CCGs need to take into account the needs of the populations suitable for fertility treatment, as well as their wider population.

Reference:	Policy Name	Date of WCAG	Date of WCAG	Review Date	Version
WCCG-CP022	Fertility Policy	05/12/2017	06/03/2018	March 2021	4

Intra-Uterine Insemination (IUI) / Donor Insemination (DI)

Unstimulated intrauterine insemination is offered as a treatment option in the following groups as an alternative to vaginal sexual intercourse.

- Patients with conditions that require specific consideration in relation to methods of conception (for example, after sperm washing where the man is HIV positive).
- Women in same-sex relationships
- Single women who have no live birth following self-funded artificial insemination (AI) of up to 10 cycles.

Patients who are receiving self-funded IUI who have not conceived after 10 cycles of donor or partner insemination, despite evidence of normal ovulation, tubal patency and semen analysis, should be offered a further 3 cycles of NHS funded unstimulated intrauterine insemination before IVF is considered.

- Procedures involving donor genetic materials are not funded within the local NHS for any patient group.
- Sperm donation will be funded only where the sperm are altruistically donated without charge or can be accessed from an NHS sperm bank or equivalent.

Rationale

When making resource allocation decisions in this context, CCGs need to take into account the needs of the populations suitable for assisted reproductive technologies, as well as their wider population. The decision not to fund assisted conception treatments using donated genetic materials was taken on the basis of the relative clinical- and cost-efficacy of different interventions and absolute affordability following consideration of the established principles and prioritisation agreed by the CCGs.

In the UK, donated genetic materials are in short supply, with demand commonly exceeding supply. An unintended consequence of any policy making ACT using donated genetic materials available on the NHS locally may be that patients could seek NHS funded treatments abroad. This is undesirable as clinics may be unregulated and treatments undertaken could pose significant health risks to patients.

Surgical Sperm Retrieval

- Eligible couples where the male has obstructive azoospermia will have one surgical sperm retrieval procedure funded
- In order to access NHS funded surgical sperm retrieval, couples will be required to fulfil eligibility criteria
- Surgical sperm retrieval will not be available if sub-fertility is the result of sterilisation (Where patients have consented to sterilisation)
- Where the procedure is successful, couples can access IVF with ICSI, in line with the relevant policy
- Cryopreservation of surgically retrieved sperm will be funded for a maximum of two years 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.

Reference:	Policy Name	Date of WCAG	Date of WCAG	Review Date	Version
WCCG-CP022	Fertility Policy	05/12/2017	06/03/2018	March 2021	4

Sperm Washing

One sperm washing procedure will be funded within the local NHS for couples where the man is HIV positive and either he is not compliant with HAART or his plasma viral load is 50 copies/ml or greater and where the female partner is HIV negative.

Where the procedure is successful, couples may access IUI or IVF, with or without ICSI, depending on their clinical circumstances, in line with the relevant policy.

In order to access NHS funded sperm washing and subsequent assisted conception treatments, patients will be required to fulfil relevant eligibility criteria.

Rationale

According to NICE CG156, the evidence showed that sperm washing appears to be very effective in reducing viral transmission; no cases of seroconversion of the woman or the baby have been documented. In comparison with pregnancy outcomes following ACT without sperm washing, higher live full-term singleton birth rates are seen with IVF following sperm washing. This is likely to be because couples undergoing sperm washing were having ACT to avoid HIV transmission rather than for fertility problems. A comparison of pregnancy outcomes for different ACT methods using washed sperm was also undertaken. Consistent with other studies, IUI cycles had fewer singleton live births than both IVF cycles with and without ICSI, but it also had fewer multiple births. This may reflect the transfer of more than one embryo in IVF cycles.

Sperm washing is unavailable on the NHS for couples where the male is hepatitis C positive, because NICE CG156 recommends that couples who want to conceive and where the man has hepatitis C should be advised that the risk of transmission through unprotected sexual intercourse is thought to be low.

Fertility preservation for patients who are to undergo therapy with oncology treatments which are likely to compromise their future fertility

Wiltshire CCG will fund the collection and storage of eggs, embryos and sperm for individuals who are to be treated with oncology treatments which are likely to compromise their future fertility with the following conditions:

- Wiltshire CCG will fund the storage for first ten years only (in addition to the age criteria below being applied)
- Wiltshire CCG will not fund for the continued storage of eggs/embryos for a woman aged over 40
- Wiltshire CCG will not fund for the continued storage of sperm for a man aged over 55.
- Patients must have commenced puberty and not be older than the limits for treatment set out above.

At the time of fertility preservation, patients do not need to be able to demonstrate that they comply with the requirements of the Wiltshire CCG Fertility Policy in respect to BMI and smoking status, as delaying treatment until a patient could comply may compromise oncology treatment.

Women should be offered egg or embryo cryostorage as appropriate only if they are well enough to undergo ovarian stimulation and egg collection, provided that this will not worsen their condition and that sufficient time is available.

Cryopreservation of ovarian tissue preservation is still an early stage of development and will not be funded. The eligibility criteria set out in the Wiltshire CCG Fertility Treatment Policy must be applied to any subsequent use of the stored material. NHS funding of cryopreservation of materials will cease where:

- Fertility is established through tests or conception
- A live birth has occurred
- The patient dies and no written consent has been left permitting posthumous use

The CCG considers that the cryopreservation of gametes for patients who are about to undergo gender reassignment is not appropriate for commissioning as the patient is considered to be consenting to sterilisation as part of gender reassignment treatment. This treatment may be available via the NHSE treatment pathway.

Rationale

NICE CG156 recommends offering sperm cryopreservation to men and adolescent boys who are preparing for medical treatment for cancer that is likely to make them infertile. For women of reproductive age who are preparing for medical treatment for cancer that is likely to make them infertile, CG156 recommends offering oocyte or embryo cryopreservation as appropriate 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.

Storage of cryopreserved material is recommended for an initial period of 10 years.

Reference:	Policy Name	Date of WCAG	Date of WCAG	Review Date	Version
WCCG-CP022	Fertility Policy	05/12/2017	06/03/2018	March 2021	4

Sperm donation, oocyte donation, in-vitro maturation (IVM), and Surrogacy/Gestational Carriers

- Sperm donation will be funded only where the sperm are altruistically donated without charge or can be accessed from an NHS sperm bank or equivalent.
- Egg donation where no other treatment is available. This will be available to women who have undergone premature ovarian failure (longer than six months amenorrhoea and FSH greater than 25IU/L) 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 meets the other eligibility criteria. The patient may be able to provide an egg donor; alternatively the patient 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.
- IVM will not be funded, due to limited evidence of effectiveness
- Wiltshire CCG will not commission any form of fertility treatment to those in surrogacy arrangements (i.e. the use of a third party to bear a child for another couple).

Rationale

Surrogacy was not included within the scope of NICE CG156. There are significant medico-legal issues involved in surrogacy arrangements that would pose risks to an NHS organisation funding this intervention.

The Surrogacy Arrangements Act 1985 states that commercial surrogacy is illegal in the UK. However, the surrogate can be paid reasonable expenses such as travel expenses and loss of earnings. The HFEA states that fertility clinics cannot identify surrogates for their patients.

Surrogacy arrangements are not legally enforceable, even if a contract has been signed and the expenses of the surrogate have been paid. The surrogate will be the legal mother of the child unless or until parenthood is transferred to the intended mother through a parental order or adoption after the birth of the child. This is because, in law, the woman who gives birth is always treated as the mother.

There is an absence of evidence on the long-term psychological impact or social consequences for commissioning couples, surrogates or children born to surrogates.

The donation of eggs, sperm and embryos is subject to strict UK regulations. Donors may be family, friends or strangers. In 2005, the law was changed so that donors can no longer remain anonymous.

Now children born as a result of using donor gametes or embryos can, once they reach 18, discover their donor's identity (HFEA, 2007b). The regulation of donors in other countries is different to that in the UK.

Same sex couple and single women - Same Sex Couples (female)

- Same sex couples will be required to demonstrate infertility prior to commencing any investigations in line with the policy for heterosexual couples.
- Same sex couples must have undergone a minimum of self-funded 10 verified and documented cycles of artificial insemination before being eligible to access NHS funded fertility assessment and treatment. All must be undertaken in a clinical setting with an initial clinical assessment and appropriate investigations
- Couples are encouraged to maximise opportunities within these cycles by exploring the option of both partners undergoing artificial insemination. Where one partner is sub-fertile with fertility issues i.e. blocked fallopian tubes or anovulation, the partner who is fertile should try to conceive before proceeding to interventions involving the sub-fertile partner.
- In line with the policy for heterosexual couples, same sex couples with unexplained infertility must wait a total of three years if aged less than 35 years or two years if aged between 35-40 years before becoming eligible for IVF treatment. Couples are encouraged to continue to try and conceive during this waiting period by safe methods. Couples with a diagnosed cause of absolute infertility which precludes any possibility of a natural conception, and who meet other eligibility criteria, will have immediate access to NHS funded assisted reproduction services.
- CCGs will not routinely fund donor sperm, but will fund the associated IVF/ICSI treatment in line with the eligibility criteria within this policy, providing the sperm meet the criteria set out by the treating provider unit.
- The partner of a prospective mother who has undertaken NHS funded fertility treatment, whether successful or not, will be deemed to have received their entitlement to NHS funded fertility treatment upon completion of this cycle, in line with the criteria for heterosexual couples, and will not be eligible for additional cycles with their partner or any future partners.
- Same sex fertile couples will not be funded for assisted conception methods under this policy.
- Couples will be required to fit all other criteria within this policy in line with heterosexual couples.
- Both members of the couple must accept joint legal responsibility for any child produced through fertility treatment.

Reference:	Policy Name	Date of WCG	Date of WCG	Review Date	Version
WCCG-CP022	Fertility Policy	05/12/2017	06/03/2018	March 2021	4

ADDITIONAL INFORMATION

IVF Definition and Cancelled and Abandoned Cycles

A full fresh cycle of IVF/ICSI comprises; ovulation induction, egg retrieval, fertilisation and implantation, and include appropriate diagnostic tests, scans and pharmacological therapy. Up to two frozen cycles using frozen embryos will follow a fresh cycle if deemed clinically appropriate.

For the purposes of this policy, the commencement of IVF/ICSI cycle is defined as commencement of ovarian stimulation by fertility services, or if no drugs are used, when an attempt is made to collect eggs/oocytes. Any patient who completes this step, regardless of the outcome, is deemed to have had one full cycle of IVF/ICSI. Therefore if a cycle is abandoned for clinical reasons this is still counted as a full cycle.

Number of Transferred Embryos

In keeping with the Human Fertilisation and Embryology Authority's (HFEA) multiple birth reduction strategy patients will be counselled about the risks associated with multiple pregnancies and advised that they will receive a single embryo transfer (whether fresh or frozen) unless there is a clear clinical justification for not doing so (e.g. a single top quality embryo is not available). In any event a maximum of 2 embryos will be transferred per procedure (either fresh or frozen).

Previously Infertility Treatment - NHS and Privately Funded

Couples, where either partner in current or previous relationship has undergone three or more previous IVF/ICSI cycles (either NHS or privately funded) will be ineligible for NHS funding within Wiltshire.

Couples who have previously self-funded treatment may be considered for further NHS funded embryo transfers to bring the total number of cycles to three embryo transfers in line with Wiltshire IVF policy statement.

The outcome of previous self-funded IVF treatment will be taken into account when Couples who have previously self-funded treatment may be considered for further NHS funded cycle(s) to bring the total number of cycles to three (as defined above).

Embryo storage

The CCG will fund storage of good quality embryos from NHS funded IVF for up to 2 years or 18 weeks prior to the female partners 40th birthday if it is sooner.

Patients must be counselled by the clinician and infertility counsellor to this effect. Any costs relating to the continued storage of the embryos beyond the second calendar year of the retrieval date is the responsibility of the couple.

Reference:	Policy Name	Date of WCAG	Date of WCAG	Review Date	Version
WCCG-CP022	Fertility Policy	05/12/2017	06/03/2018	March 2021	4