



Kent and Medway CCGs' schedule of policy statements for assisted reproductive technologies (ART)

March 2016

Issued by: SE CSU Health Policy Support Unit (HPSU)

On behalf of: Kent and Medway Clinical Commissioning Groups (NHS Ashford Clinical Commissioning Group [CCG]; NHS Canterbury and Coastal CCG; NHS Dartford, Gravesham and Swanley CCG; NHS Medway CCG; NHS South Kent Coast CCG; NHS Swale CCG; NHS Thanet CCG; NHS West Kent CCG)

Contact for further information:

Email: SECSU.HPSU@nhs.net

Purpose of document

This document lists all Kent and Medway CCGs' 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 partner sperm
- Surgical sperm retrieval
- Sperm washing
- Fertility preservation for patients receiving gonadotoxic treatments
- Assisted conception treatments (ACT) using donated genetic materials
- ACT involving surrogates
- Time-lapse systems for embryo incubation and assessment
- Adherence compounds in embryo transfer media for ART

It also sets out the specified eligibility criteria patients are required to fulfil in order to access NHS funded ART.

Scope

NICE (2013) define assisted reproductive technologies (ART) as *“any treatment that deals with means of conception other than vaginal coitus; frequently involving the handling of gametes or embryos”*.

The policies listed in this document only apply to couples who are registered with a Kent and Medway GP.

Patients are required to fulfil specified eligibility criteria in order to access NHS funded ART. Relevant eligibility criteria for each ART policy are listed in Table 1. CCGs have put in place eligibility criteria for access to ART in order to focus resources on groups of patients most likely to have successful outcomes, and prioritise groups of patients who are most likely to have the greatest need. See Appendix A for the rationale for specific eligibility criteria.

These eligibility criteria are only applicable to the ART 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, commissioning of which falls under the remit of NHS England
- Services for members of the armed forces and some veterans, commissioning of which fall under the remit of NHS England

Other forms of assisted reproductive technologies are not included. New developments in assisted reproductive technologies or new information on existing technologies will be dealt with through the agreed local processes.

The NHS in Kent and Medway follow Department of Health (DH) guidance on NHS patients who wish to pay for additional private care (2009) in relation to ART, the principals of which are as follows:

- The NHS should never subsidise private care with public money, which would breach core NHS principles

- Patients should never be charged for their NHS care, or be allowed to pay towards an NHS service (except where specific legislation is in place to allow this) as this would contravene the founding principles and legislation of the NHS
- Patients should not be able to choose to mix different elements of the same treatment between NHS and private care
- To avoid these risks, there should be as clear a separation as possible between private and NHS care.

See Appendix B for more details.

Table 1 – Kent and Medway CCGs' eligibility criteria for ART policies

Eligibility criteria		Policy ¹						
		IVF/ICSI	IUI using partner sperm	Surgical sperm retrieval	Sperm washing	Cryopreservation of embryos or oocytes	Cryopreservation of sperm	ACT using cryopreserved materials
Duration of sub-fertility	Funding will be available for couples with unexplained infertility, mild endometriosis or mild male factor infertility ² , who have been having regular unprotected sexual intercourse and attempting to conceive for at least 24 months. Where investigations show there is no chance of pregnancy with expectant management and where IVF is the only effective treatment, patients can be referred directly for IVF treatment, with or without ICSI.	✓		✓				✓
Age of woman	Funding is available where the woman is aged under 40 years. Women must start medication with the ART provider before their 40th birthday; women must only be referred to fertility clinics if there is adequate time to complete work up. If the woman reaches the age of 40 during treatment, the current full cycle will be completed but no further full cycles will be available. 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.	✓	✓	✓	✓	✓		✓
Previous cycles	Couples will <i>not</i> 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: <ul style="list-style-type: none"> • Two fresh cycles of IVF, with or without ICSI, if no previous fresh cycles have been funded by the NHS, or if they have already received one non-NHS funded fresh cycle • One fresh cycle of IVF, with or without ICSI, if the couple has already received one NHS funded fresh cycle or two non-NHS funded fresh cycles 	✓	✓	✓	✓	✓	✓	✓

¹ The following are not routinely funded for any patient group and therefore eligibility criteria do not apply: ACT using donated genetic materials, ACT involving surrogates, time lapse systems for embryo incubation and assessment, adherence compounds in embryo transfer media for ART

² Two or more semen analyses have one or more variables below the 5th centile.

Eligibility criteria		Policy ¹						
		IVF/ICSI	IUI using partner sperm	Surgical sperm retrieval	Sperm washing	Cryopreservation of embryos or oocytes	Cryopreservation of sperm	ACT using cryopreserved materials
	Overall, eligible couples will be funded for a maximum of four embryo transfers (including no more than two transfers from fresh IVF cycles), in line with the relevant policy. An abandoned IVF cycle is one where an egg collection procedure has not been undertaken. Once egg collection has commenced, this is considered a complete cycle and will count towards one of the couples' NHS funded and 'previous' cycles.							
BMI of woman	Women must have a body mass index (BMI) within the range 19-30 kg/m ²	✓	✓	✓	✓	✓		✓
Smoking	Couples will <i>not</i> be funded if either partner smokes tobacco	✓	✓	✓	✓	✓	✓	✓
Ovarian reserve	Women should have an AMH of more than 5.4 pmol/l	✓	✓	✓	✓	✓		✓
Previous children	Neither partner in a couple should have a living child from their relationship or any previous relationship. A child adopted by the couple or adopted in a previous relationship is considered to have the same status as a biological child. 'Child' refers to a living son or daughter irrespective of their age or place of abode.	✓	✓	✓	✓	✓	✓	✓
Previous sterilisation	Funding will not be available if sub-fertility is the result of sterilisation ³ in either partner	✓	✓	✓	✓	✓	✓	✓

³ Where patients have consented to sterilisation

ART policies

Kent and Medway CCGs' ART policies are set out in the following pages:

1. In vitro fertilisation (IVF), with or without intra-cytoplasmic sperm injection (ICSI)
2. Intra-uterine insemination (IUI) using partner sperm
3. Surgical sperm retrieval
4. Sperm washing
5. Fertility preservation for patients receiving gonadotoxic treatments
6. Assisted conception treatments (ACT) using donated genetic materials
7. ACT involving surrogates
8. Time-lapse systems for embryo incubation and assessment
9. Adherence compounds in embryo transfer media for ART

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

Background

IVF may be an option for a range of patients including women with blocked fallopian tubes and those with unexplained infertility, mild endometriosis, and mild male factor infertility for whom expectant management has not resulted in natural conception. Indications for ICSI include severe deficits in semen quality, azoospermia, and failed or very poor fertilisation during previous IVF cycles.

During IVF, eggs are removed from the woman's ovaries and fertilised with sperm in a dish. The best one or two embryos that are created are then placed in the woman's womb a few days later. If there are a number of unused good quality embryos left following a treatment cycle, these may be cryopreserved (frozen) for use in later cycles, called frozen embryo transfers. The procedure for ICSI is similar to that for IVF, but instead of fertilisation taking place in a dish, a single sperm is injected directly into each egg by an embryologist.

Policy

- Eligible couples requiring IVF, with or without ICSI, will have available to them a maximum of four embryo transfers including no more than two transfers from fresh cycles
- In order to access NHS funded IVF, with or without ICSI, patients will be required to fulfil relevant eligibility criteria set out in Table 1.
- Cryopreservation of supernumerary embryos will be funded for a maximum of two years following each fresh cycle⁴

Rationale

Eligible couples are funded for up to two full cycles of IVF with or without ICSI rather than three – as recommended by NICE Clinical Guideline 156 – because Kent and Medway CCGs have concluded that extending provision of IVF/ICSI to three full cycles 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 ART, as well as their wider population.

Local clinicians agree the NHS should fund cryopreservation of supernumerary embryos for two years as this is a reasonable time period for infertile patients to complete a full IVF/ICSI cycle⁴. Patients will have the opportunity to fund continued cryopreservation of any unused embryos for future self-funded FET after the NHS funded storage period concludes.

See Appendix A for the rationale for eligibility criteria.

⁴ Cryopreservation of embryos for couples undergoing IVF, with or without ICSI, for fertility preservation prior to receiving gonadotoxic treatment is addressed by a different policy

2. Intra-uterine insemination (IUI) using partner sperm

Background

IUI has previously been used as a treatment for fertility problems such as unexplained infertility, mild endometriosis and mild male factor infertility. It can also be used as an alternative to vaginal sexual intercourse, for example, where there is a disability that prevents vaginal intercourse.

During IUI, sperm are inserted into the uterine cavity around the time of ovulation. IUI can be carried out in a natural cycle, without the use of drugs, or the ovaries may be stimulated with oral anti-oestrogens or gonadotrophins. IUI can be undertaken using partner or donor sperm; this policy addresses the former circumstances only. Procedures involving donor genetic materials are not funded within the local NHS for any patient group (this is addressed in a separate policy).

Policy

- Up to six cycles of IUI with partner sperm will be funded as a treatment option for eligible 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
 - who are clinically indicated to receive IUI following a successful sperm washing procedure where the man is HIV positive (access to NHS funded sperm washing is addressed in a separate policy)
- In order to access NHS funded IUI using partner sperm, patients will be required to fulfil relevant eligibility criteria set out in Table 1.

Rationale

NICE clinical guidelines (CG156) no longer recommend IUI for people with unexplained infertility, mild endometriosis or mild male factor infertility because a review of the literature concluded that IUI without stimulation is no better than expectant management. It is unclear if IUI with stimulation is more effective than expectant management for these groups, however it is likely to increase the risk of multiple pregnancies, which is the single biggest risk of fertility treatment.

See Appendix A for the rationale for eligibility criteria.

3. Surgical sperm retrieval

Background

Surgical sperm retrieval is indicated in cases of male sub-fertility where there is testicular sperm production but an absence of sperm in the semen (azoospermia).

Surgical sperm retrieval is a set of techniques for collecting sperm from within the male reproductive organs for use in ICSI. ICSI involves an embryologist selecting a single sperm from the sample and injecting it directly into an egg. The fertilised egg (embryo) is then transferred to the woman's womb. The development of ICSI means that as long as some sperm can be obtained (even in very low numbers), fertilisation is possible.

Policy

- 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 relevant eligibility criteria set out in Table 1
- 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

Rationale

NHS funded surgical sperm retrieval is only available to patients with obstructive azoospermia because the available evidence suggests that the success rate for surgical sperm retrieval is good for men with obstructive azoospermia (between 85% and 100% depending on the procedure). Success rates are lower for men with non-obstructive azoospermia (between 44% and 88% depending on procedure). Furthermore, studies have found that outcomes of ICSI using testicular sperm from men with non-obstructive azoospermia are generally inferior compared to those with obstructive azoospermia.

See Appendix A for the rationale for eligibility criteria.

4. Sperm washing

Background

Sperm washing is a process that has been developed to minimise the risk of onward transmission of HIV, primarily to the female partner and subsequently the unborn child. The purported utility of sperm washing rests on the premise that HIV-infected material is carried primarily in the seminal fluid rather than in the sperm itself. The technique involves purifying sperm from seminal fluid. The sperm is then used in assisted conception treatments such as IUI or IVF/ICSI.

Sperm washing is normally indicated for couples who wish to have a child where the male is HIV-positive and the female is HIV-negative, or to minimise the risk of transmission of resistant virus in HIV seroconcordant couples. The use of sperm washing has also been proposed in couples where the male is hepatitis C positive and the female is negative.

Policy

- 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 set out in Table 1

Rationale

According to NICE CG156, the evidence shows 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. In a comparison of pregnancy outcomes for different ACT methods using washed sperm, IUI cycles had fewer singleton live births than IVF cycles with and without ICSI; IUI 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.

See Appendix A for the rationale for eligibility criteria.

5. Fertility preservation for patients receiving gonadotoxic treatments

Background

The treatment of cancer frequently involves the use of radiotherapy and/or chemotherapy. These treatments can impact on fertility, either by direct injury to the ovaries or testes from radiotherapy or via systemically administered chemotherapeutic agents. Some treatments for autoimmune disorders such as systemic lupus erythematosus, multiple sclerosis and Crohn's disease can also have gonadotoxic effects. In some cases the individual's fertility will return after their treatment is completed but in other cases fertility never returns, or is severely impaired.

ART can offer an opportunity to affected patients to preserve their fertility prior to the start of potentially gonadotoxic treatment. Preservation of fertility normally involves cryopreservation of semen, oocytes or embryos. Following completion of the potentially gonadotoxic treatment, patients can undergo assisted conception treatments such as IUI, IVF, with or without ICSI, or frozen embryo transfer (FET) using their cryopreserved materials.

Policy

- Cryopreservation of sperm, embryos or oocytes will be available for fertility preservation for eligible patients due to receive gonadotoxic treatments
- In order to access cryopreservation of sperm for fertility preservation, men will be required to fulfil relevant eligibility criteria set out in Table 1
- In order to access cryopreservation of embryos for fertility preservation, couples will be required to fulfil relevant eligibility criteria set out in Table 1
- In order to access cryopreservation of oocytes for fertility preservation, women will be required to fulfil relevant eligibility criteria set out in Table 1.
- Women undergoing gonadotoxic treatment should have access to a consultation with an NHS fertility specialist before and after undergoing gonadotoxic treatment
- Storage of sperm, embryos and oocytes should be funded for up to ten years after cryopreservation
- 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
- In order to access assisted conception treatments using cryopreserved materials, couples will be required to fulfil relevant eligibility criteria set out in Table 1

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.

While no separate recommendations are made by NICE for other populations of people receiving gonadotoxic treatments, the NICE Guideline Development Group (GDG) felt that the recommendations made in the guideline should be extrapolated to other groups within the population who may be at risk of losing their fertility due to treatment.

See Appendix A for the rationale for eligibility criteria.

6. ACT using donated genetic materials

Background

ACT such as IUI, IVF with or without ICSI, and FET can be undertaken using donated sperm, oocytes (eggs) or embryos. Donor conception can be an option for patients:

- who are not producing eggs/ sperm
- whose own sperm or eggs are unlikely to result in the conception of a baby
- where there is a high risk of passing on an inherited disease
- who are single or in same sex relationships

Policy

- Procedures involving donor genetic materials are not funded within the local NHS for any patient group
- Funding of procedures involving donor genetic materials abroad will not be reimbursed by the local NHS

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 to not fund assisted conception treatments using donated genetic materials was taken on the basis of the relative clinical- and cost-effectiveness of different interventions and absolute affordability following consideration of the established principles and priorities 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.

7. ACT involving surrogates

Background

Surrogacy is when a woman who is not the intended mother carries and gives birth to a baby for a couple or individual who want to have a child. Partial surrogacy uses sperm from the intended father and an egg from the surrogate. Here, fertilisation is usually facilitated by artificial insemination or IUI. Full surrogacy involves IVF, with or without ICSI, and the implantation of an embryo which is not created using the surrogate's eggs.

Full or partial surrogacy may be considered an option for women who have a medical condition that makes it impossible or dangerous to get pregnant and/or give birth, for example:

- absence or malformation of the womb
- recurrent pregnancy loss
- repeated IVF implantation failures

Partial surrogacy can also be considered an option for single men and male same sex couples.

Policy

- Assisted conception treatments involving surrogates are not funded within the local NHS for any patient group

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.

8. Time-lapse systems for embryo incubation and assessment

Background

Traditionally, assessment of embryo quality has been achieved by removing embryos from a conventional incubator daily for evaluation by an embryologist under a light microscope. Recently, time-lapse systems (TLS) have been developed which can take digital images of embryos at frequent time intervals. This allows embryologists, with or without the assistance of computer algorithms, to assess the quality of the embryos without physically removing them from the incubator.

Policy

- Time lapse systems for embryo incubation and assessment are not funded within the local NHS

Rationale

Time-lapse systems were not included within the scope of NICE CG156.

According to the available evidence, there is considerable uncertainty regarding the likely benefit of using time lapse systems for Kent and Medway NHS ART patients.

9. Adherence compounds in embryo transfer media for ART

Background

Adherence compounds such as hyaluronic acid (HA) and fibrin sealant have recently been introduced into subfertility management with the aim of increasing the success rate of assisted reproductive technologies (ART). Adherence compounds are added to the embryo transfer medium to increase the likelihood of embryo implantation, with the potential for higher clinical pregnancy and live birth rates.

Policy

- Adherence compounds in embryo transfer media for assisted reproductive technologies are not funded within the local NHS

Rationale

Adherence compounds were not included within the scope of NICE CG156.

According to the available evidence, an increase in live birth rates was not observed where a single embryo transfer strategy was used or in patients with good prognosis, suggesting the benefits to Kent and Medway NHS patients may be limited considering:

- In Kent and Medway, eligibility criteria are in place for access to ART to ensure resources are focused on patients most likely to benefit from treatment i.e. those with a good prognosis.
- The Human Fertilisation and Embryology Authority (HFEA) have implemented a national strategy to reduce the number of multiple pregnancies by promoting the use of single embryo transfer; this is supported by recommendations in NICE CG 156.

References

- KMCS Health Policy Support Unit (2013) *Confidential final report: Assisted reproductive technologies*
- KMCS Health Policy Support Unit (2013) *PR 2013-15: Surgical sperm retrieval*
- KMCS Health Policy Support Unit (2013) *PR 2013-16: Assisted conception treatments (ACTs) using donated genetic materials*
- KMCS Health Policy Support Unit (2013) *PR 2013-17: Assisted conception treatments (ACTs) involving surrogates*
- KMCS Health Policy Support Unit (2013) *TP 2013-01: Sperm washing*
- KMCS Health Policy Support Unit (2013) *TP 2013-02: Intra-uterine insemination (IUI) using partners sperm*
- National Collaborating Centre for Women's and Children's Health (2013) *Fertility: assessment and treatment for people with fertility problems (update)*, Online: <https://www.nice.org.uk/guidance/cg156/resources/cg156-fertility-full-guideline3>
- NICE (2013) *Clinical Guideline 156: Fertility: Assessment and treatment for people with fertility problems*, Online: <https://www.nice.org.uk/Guidance/CG156>
- NICE (2014) Quality standard 73: Fertility problems, Online: www.nice.org.uk/guidance/qs73
- NICE (2015) Evidence Update 74: A summary of selected new evidence relevant to NICE Clinical Guideline 156. Online: www.nice.org.uk/guidance/cg156/evidence/fertility-evidence-update-march-20152
- SE CSU Health Policy Support Unit (2014) *Assisted conception treatments involving surrogates – A briefing note*
- SE CSU Health Policy Support Unit (2014) *Assisted conception treatments using donated genetic materials – A briefing note*
- SE CSU Health Policy Support Unit (2014) *Assisted reproductive technologies for women aged over 39 years – A briefing note*
- SE CSU Health Policy Support Unit (2014) *Cryopreservation of oocytes for fertility preservation for patients receiving gonadotoxic treatments – A briefing note*
- SE CSU Health Policy Support Unit (2014) *In vitro fertilisation (IVF), with or without intra-cytoplasmic sperm injection (ICSI) – A briefing note*
- SE CSU Health Policy Support Unit (2014) *TP 2014-01: Assisted reproductive technologies (ART) for fertility preservation for patients receiving gonadotoxic treatments*
- SE CSU Health Policy Support Unit (2015) *Template Criteria for NHS Funded Assisted Reproductive Technologies*
- SE CSU Health Policy Support Unit (2015) *PR 2015-14: In vitro fertilisation (IVF), with or without intra-cytoplasmic sperm injection (ICSI)*
- SE CSU Health Policy Support Unit (2015) *PR 2015-15: Time lapse systems for embryo incubation and assessment*
- SE CSU Health Policy Support Unit (2015) *PR 2015-16: Adherence compounds in embryo transfer media for assisted reproductive technologies*
- SE CSU Health Policy Support Unit (2015) *Assisted reproductive technologies – Final report*
- ART Impact Equality Analysis* (2015)

Appendix A – Rationale for criteria for NHS funding of ARTs

Criteria		Rationale and comments
Duration of sub-fertility	<p>Funding will be available for couples with unexplained infertility, mild endometriosis or mild male factor infertility⁵ who have been having regular unprotected sexual intercourse and attempting to conceive for at least 24 months.</p> <p>Where investigations show there is no chance of pregnancy with expectant management and where IVF is the only effective treatment, patients can be referred directly for IVF treatment, with or without ICSI.</p>	<p>NICE Clinical Guideline 156 (CG156) recommends couples with unexplained infertility try to conceive for a total of two years, before IVF with or without ICSI is considered. There is good evidence that waiting for three years will not be beneficial to the vast majority of patients who have not conceived after two years. In addition, waiting a third year may reduce the success rates for couples who go on to have IVF because the chance of a live birth following IVF treatment falls with rising female age.</p>
Age of woman	<p>Funding is available where the woman is aged under 40 years. Women must start medication with the ART provider before their 40th birthday; women must only be referred to fertility clinics if there is adequate time to complete work up.</p> <p>If the woman reaches the age of 40 during treatment, the current full cycle will be completed but no further full cycles will be available. 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.</p>	<p>NICE CG156 concludes that treatment with IVF is cost effective for women aged under 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. Analysis of local data confirms that IVF is less cost effective for couples where the woman is aged between 40 and 42 than those aged 39 and under.</p> <p>Referring clinicians must ensure 39 year old patients have adequate time to complete work up in order to start medication with the ART provider before their 40th birthday.</p> <p>Cryopreservation of supernumary embryos is funded for a period of two years for all eligible patients. During this period, women who turn 40 can complete their current full cycle; depending on previous treatment and the embryos available, this may be up to three frozen embryo transfers.</p>
Previous cycles	<p>Couples will <i>not</i> be funded if either partner has already had three previous fresh cycles of IVF, with or without ICSI, irrespective of how these were funded.</p> <p>This means that eligible couples will be funded:</p> <ul style="list-style-type: none"> • Two fresh cycles of IVF, with or without ICSI, if no previous fresh cycles have been funded by the NHS, or if they have already received one non-NHS funded fresh cycle • One fresh cycle of IVF, with or without ICSI, if the couple 	<p>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 previous IVF cycles.</p> <p>NICE CG156 recommends that if an egg collection procedure is undertaken, this should count as a full cycle and one of those that is offered on the NHS.</p>

⁵ Two or more semen analyses have one or more variables below the 5th centile

Criteria		Rationale and comments
	<p>has already received one NHS funded fresh cycle or two non-NHS funded fresh cycles</p> <p>Overall, eligible couples will be funded for a maximum of four embryo transfers (including no more than two transfers from fresh IVF cycles), in line with the relevant policy.</p> <p>An abandoned IVF cycle is one where an egg collection procedure has not been undertaken. Once egg collection has commenced, this is considered a complete cycle and will count towards one of the couples' NHS funded and 'previous' cycles.</p>	
Body mass index of woman	Women must have a body mass index (BMI) within the range 19-30 kg/m ²	<p>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.</p> <p>Women with BMI over 30 kg/m² take longer to conceive, compared with women with lower BMI, even after adjusting for other factors such as menstrual irregularity. For infertile anovulatory women with a BMI of over 29 kg/m², there is evidence that a supervised weight loss programme or a group programme including exercise, dietary advice and support helps to reduce weight, resume ovulation and improve pregnancy rates.</p>
Smoking	Couples will <i>not</i> be funded if either partner smokes tobacco	<p>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.</p> <p>There is insufficient evidence currently to suggest nicotine replacement therapies or electronic cigarettes (e-cigarettes) have a negative effect on fertility or the outcome of ART and therefore patients who use them should not be excluded from NHS funded treatment.</p>
Ovarian reserve	Women should have an AMH of more than 5.4 pmol/l	NICE CG156 states that ovarian reserve is effective in predicting response to IVF. The anti-Müllerian hormone (AMH) test has significantly less inter- and intra-menstrual cycle variability compared with follicle-stimulating hormone (FSH) testing. Also, AMH can be measured at any point during the menstrual cycle.
Previous children	Neither partner in a couple should have a living child from their relationship or any previous relationship. A child adopted by the couple or adopted in a previous relationship is considered to have the same status as a biological child. 'Child' refers to a living son or daughter irrespective of their age or place of abode.	It is recognised nationally that NHS organisations need to focus their budgets on patients who have the most need and can obtain the maximum health gain. Local priority is therefore being given to those who are completely childless.

Criteria		Rationale and comments
Previous sterilisation	Funding will not be available if sub-fertility is the result of sterilisation ⁶ in either partner	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. CCGs consider it inappropriate that NHS funds are used in reversing these procedures.

⁶ Where patients have consented to sterilisation

Appendix B – Q&A on the interface between NHS and private ART treatment

Can patients use sperm, eggs or embryos obtained privately or obtained during private treatment in NHS funded cycles?

No. Department of Health (DH) guidance states: *patients should never be... allowed to pay towards an NHS service (except where specific legislation is in place to allow this) as this would contravene the founding principles and legislation of the NHS.*

Can private patients access NHS funded drugs and/or tests?

No. DH guidance states: *The patient should bear the full costs of any private services. NHS resources should never be used to subsidise the use of private care.*

Can NHS patients pay for additional aspects of care not funded by the local NHS?

No. DH guidance states: *patients should never be... allowed to pay towards an NHS service (except where specific legislation is in place to allow this) as this would contravene the founding principles and legislation of the NHS.*

Can patients who have undergone NHS-funded ART, pay for continued cryopreservation of any unused sperm, eggs or embryos for future self-funded treatment after the NHS funded storage period concludes?

Yes, because the NHS element of care and the private element of care can be delivered separately.

For more information see NHS Choices: <http://www.nhs.uk/chq/Pages/2572.aspx>