NHS
in Greater Manchester

Assisted Conception Policy

Version 3.1: (17 Nov 2021)

PLEASE NOTE

Government issued Statutory Instrument: 'The National Health Service (Charges to Overseas Visitors) (Amendment) Regulations 2017 No. 756'

From 21 August 2017, NHS-funded assisted conception services will not be included in the exemption from charge applicable to people who are caught within surcharge arrangements (i.e. those who have paid the surcharge, or who are exempt from paying it (with certain exceptions) or in respect of whom it has been waived). This means that, unless another exemption applies, where NHS assisted conception services are provided to a person who is exempt under surcharge arrangements, overseas visitor charges will apply. This is brought forward through regulations 11, 12 and 13 of the above named instrument, which insert a new regulation (9A) and amend regulation 10 and 11 respectively to the National Health Service (Charged to Overseas Visitors) Regulations 2015.

Exemption from charges currently applies to:

- Serving members of the armed forces and their families (NHS England commissioned)
- Seriously injured serving members and veterans
- Further provision of care previously given
- Continuation of a course of treatment that commenced before 21 August 2017

Assisted conception services in the context of this instrument are defined as "*any medical, surgical or obstetric services provided for the purpose of assisting a person to carry a child*." This definition was based on the definition of "treatment services" in section 2 of the Human Fertilisation and Embryology Act 1990. Broadly speaking any medicines, surgery or procedures that are required to diagnose and treat infertility so a person can have a child. It includes procedures such as intrauterine insemination (IUI), *in vitro* fertilisation (IVF) and egg and sperm donation. The definition is not intended to refer to antenatal or maternity services.

In the operation of this policy, Greater Manchester Integrated Care will have regard to the Human Fertilisation and Embryology Act 1990 (as amended) which provides that a woman shall not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for supportive parenting).

Contents

Commissioning Statement

Assisted conception policy	
Prior to offering treatment covered by this policy, the individuals seeking assisted conception should be advised of the need for period of expectant management. They should have tried to conceive for a total of 2 years (The period of expectant management after diagnosis and up to 1 year before their fertility investigations began) before IVF will be considered. For same sex couples and single women offer a further 6 cycles of IUI post referral, to be carried out in an NHS clinical setting, in addition to the self-funded 6 cycles of self-reported vaginal insemination undertaken prior to referral (as the equivalent of expectant management in a heterosexual couple) or 3 cycles if aged over 36 years.	
Policy Exclusions **(Alternative commissioning arrangements apply)**	**Sperm, oocyte or embryo storage to retain fertility** Individuals undergoing treatment for cancer (or for any lifesaving treatment resulting in infertility) or gender reassignment, or as part of the management of a congenital condition which will affect fertility in later life and who are well enough to undergo the required procedures, should be offered gamete (sperm or egg) retrieval and cryopreservation (storage) provided this does not put them at risk of serious adverse health effects from either a delay in treatment or from the procedure needed to retrieve the egg / sperm. The resultant sperm, eggs or embryos will be stored in line with current Human Fertilisation & Embryology Authority (HFEA) regulations. Currently, there is no upper age limit for sperm. However, there is an upper age limit of 43 for eggs and embryos. These should be stored and used in line with HFEA regulations. The eligibility criteria used in conventional infertility treatment do not apply in the case of storage to retain fertility following treatment for cancer or any other treatment resulting in infertility. Policy criteria will apply when the stored material is used for assisted conception in an NHS setting. The only treatments where restrictions will apply to these individuals are; 1) eligibility for IVF/ICSI, if they require more than the currently commissioned cycles or do not meet the criteria an application for exceptionality can be submitted 2) Surrogacy as this is not commissioned by the NHS. All individuals should be informed at the time of storage that if, at the time of treatment for infertility, surrogacy is the only option that this will not be funded by NHS commissioners in Greater Manchester. Individuals over the age of 42 (i.e. after their 43rd Birthday) with exceptional reasons for requesting gamete storage can apply via the IFR (exceptional case) route. (Age limit does not apply to sperm) Individuals undergoing retrieval and storage of sperm and oocytes should be managed in line with NICE CG156. Storage of retrieved sperm and oocytes will be for 10 years in line with HFEA licensing requirements and guidance (such requirements /guidance to be checked for updates as required).

	Extensions to the storage time for sperm or oocytes or age limit for embryos will require IFR (exceptional case) approval. The application should comply with the process for extension of the statutory storage period as outlined in the HFEA code of practice and should not take the period of cryopreservation over the statutory upper limit of 55 years. The individual must be made aware of this at the time of storage. (Correct at the time this policy was produced but the current HFEA guidance should be followed if different from this statement). There is no lower age limit for cryopreservation in this group of patients. Any individuals outside the specified age ranges above can apply via the IFR (exceptional case) route, to avoid any delay in the start of treatment these requests will be dealt with as URGENT. Surgical sperm recovery is now the responsibility of NHS England (NHS England: 16040/P - Clinical Commissioning Policy: Surgical sperm retrieval for male infertility) and all requests for funding of these techniques should be made to NHS England using their form. **NOTE:** If NHS England website changes, this link may not be updated. **Recurrent miscarriage** Recurrent miscarriage is not covered by this policy as there are local services. All individuals should be referred in line with the pathway for that service. IVF/ICSI is not commissioned for recurrent miscarriage unless part of PGD which requires application to NHS England.
NHS England Commissioned Services	**Pre-Implantation Genetic Diagnosis (PGD) and sperm retrieval using TeSE or MicroTeSE** Pre-Implantation Genetic Diagnosis (PGD) and sperm retrieval using TeSE or MicroTeSE are both NHS England commissioned and applications for these procedures should be made to them directly or via the appropriate pathway as directed by NHS England. **Referral for genetic counselling** Referral for genetic counselling for couples who do not qualify for PGD should be done in line with the recommendation in NICE CG156. **IVF/ICSI for recurrent miscarriage** IVF/ICSI is not commissioned for recurrent miscarriage unless part of PGD which requires application to NHS England.
Research and Local pathways	Treatment / procedures undertaken as part of an externally funded trial or as a part of locally agreed contracts / or pathways of care are excluded from this policy, i.e. locally agreed pathways take precedent over this policy (the EUR Team should be informed of any local pathway for this exclusion to take effect).
Policy Criteria - not commissioned	**Surrogacy** The NHS does not fund any type of surrogacy arrangement. Commissioning parents must undertake the whole process privately.

	See: GOV.UK guidance: Having a child through surrogacy
Policy Inclusion Criteria - where restrictions apply	Assisted conception care is generally commissioned in line with NICE CG156: Fertility problems: assessment and treatment. Pages 6 to 13 summarise areas where qualifying criteria apply or that are not covered by CG156. Individual treatments are funded by the area with whom the patient's GP surgery is registered, with the exception of those treatments where the specified commissioner is NHS England (NHSE). When treating a couple, it is the GP surgery with whom the female partner is registered. In same sex (female) couples it will be the GP Surgery with whom the patient wishing to carry the pregnancy is registered. **Funding mechanism: Unless otherwise stated below funding will be via the normal local contracting arrangements**. **Reversal of sterilisation** The surgical reversal of either male or female sterilisation done for family planning purposes is **not** routinely commissioned. Note: If the exceptionality claims that sterilisation was carried out in a situation of abuse or coercion documented proof of the abuse must be provided e.g. letter from a social worker, police incident report etc. Requests must be submitted with all relevant supporting evidence. Reversal of steriiisation is commissioned in cases where the sterilisation was carried out to treat an underlying condition and not for family planning purposes. Reversal of vasectomy for reasons other than to restore fertility e.g. to treat rare cases of post vasectomy pain is commissioned. **NOTE**: Where subfertility remains after reversal of sterilisation, assisted conception will not be funded routinely, unless there is proof of a clinically successful reversal of sterilisation and the infertility issues are with the partner. **Intrauterine Insemination** Consider unstimulated intrauterine insemination as a treatment option in the following groups as an alternative to vaginal sexual intercourse: • people who are unable to, or would find it very difficult to, have vaginal intercourse because of a clinically diagnosed physical disability or psychosexual problem who are using partner or donor sperm • people with conditions that require specific consideration in relation to methods of conception (for example, after sperm washing where the man is HIV positive) • people in same-sex relationships • Single women

Access Criteria for IVF/ICSI

All couples referred for IVF must have had their infertility investigated and managed in line with NICE CG156 prior to referral and found to be infertile / subfertile. (See appendix one for full definitions in line with NICE CG 156).

IVF/ICSI up to the number of cycles commissioned by each area within Greater Manchester is commissioned for patients who meet the criteria as set out in this policy.

In all cases where IVF/ICSI is being considered all welfare of the child considerations as required by the HFEA should be addressed and a record made in the notes (in case of future audit) that there are no concerns.

Definition of Childless

IVF is only offered to childless couples. Childlessness is defined as: *'The couple have no living child from their current relationship and one of the partners 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.'*

Female same sex couples

In a same sex (both female) partnership only one partner will be eligible for treatment with IVF up to the current number of cycles commissioned. This does not affect the untreated partner's right to IVF in a new relationship provided they meet the eligibility criteria at that time.

Previous sterilisation

Infertility must not be as a result of previous sterilisation for family planning reasons, unless a partner has had a successful reversal of sterilisation and the infertility to be treated is in the other (not previously sterilised) partner (or the couple have been diagnosed with unexplained infertility)

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Female Body Mass Index

The female body mass index must ideally be in the range of 19-30 before treatment begins. Women outside this range can still undergo investigations and be added to the 'watchful-waiting' list but treatment will not commence until their BMI is within this range (exceptionally a woman with a BMI above 30 or below 19 may be able to demonstrate that they are not clinically obese or too thin through use of other acceptable measures e.g. an accurate body fat percentage).

Smoking status

Both partners must be non-smoking and not using any product containing nicotine in order to access any fertility treatment and must continue to be non-smoking throughout treatment. Individuals who are smokers can be added to the 'watchful-waiting' list and be referred to their local stop smoking service for support in quitting

but treatment will not commence until they are deemed non-smokers (i.e. no longer using a nicotine containing product).

Alcohol intake & recreational drugs

The couple should 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 the cessation of treatment.

Number of cycles of IVF Funded (including previous cycles)

Both NHS and privately funded cycles will be taken into account when determining how many cycles to fund.

NOTE: If a woman changes her registered practice to one that comes under a different area which offers a different number of IVF cycles, eligibility will depend on the number of IVF cycles offered by the area where she is currently registered.

The total number of cycles undertaken as listed below added to those funded privately must not exceed 3. Where cycles have been funded privately or by another area, these will be taken into account when determining how many cycles to fund in accordance with the below:

For women aged 39 and under:

Bolton, Bury, HMR, Manchester, Oldham & Trafford all commission 1 complete cycle of IVF (and allow a second attempt at a full cycle for a cancelled or abandoned cycles).

Salford, Stockport & Wigan all commission 2 cycles (includes abandoned or cancelled cycles).

Tameside commissions 3 cycles (includes abandoned or cancelled cycles).

If the woman turns 40 before all cycles are complete then no further treatment will be funded after the current cycle is completed

IVF for women aged 40-42 (i.e. before her 43rd birthday) - all areas in Greater Manchester 1 full cycle provided:

- They have never previously had IVF (including privately) – (For same sex female couples: neither partner has previously had IVF)
- There has been a discussion about the implications of IVF at this age

Their single cycle of IVF can be carried out with donor eggs if one of the following applies:

- total antral follicle count (AFC) of less than or equal to 4
- anti-Müllerian hormone (AMH) of less than or equal to 5.4 pmol/l
- follicle-stimulating hormone (FSH) greater than 8.9 IU/l

NB: These are the risk factors for a poor ovarian response in this age group as laid by NICE in 2013.

NOTE: Treatment must have commenced before the woman's 43rd birthday. If waiting times will take them beyond their 43rd birthday, they can apply via the IFR

(exceptionality) route for an extension to the age limit or transfer of care to a provider who can start treatment in time.

A single second attempt at a full cycle, with their own or donor eggs as appropriate, may be commissioned if the first attempt ends in a cancelled or abandoned cycle (Treatment MUST commence before the woman's 43rd birthday.)

HFEA guidance – Welfare of the Child

NOTE as per HFEA guidance: *"A woman shall not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for supportive parenting), and of any other child who may be affected by the birth".*

'Supportive parenting is a commitment to the health, wellbeing and development of the child. It is presumed that all prospective parents will be supportive parents, in the absence of any reasonable cause for concern that any child who may be born, or any other child, may be at risk of significant harm or neglect. Where centers have concern as to whether this commitment exists, they may wish to take account of wider family and social networks within which the child will be raised.'

Definitions of IVF Cycles

Full Cycle (with donor eggs – see below)
A full cycle of IVF treatment, with or without intracytoplasmic sperm injection (ICSI), should comprise 1 episode of ovarian stimulation and end with the final transfer of all resultant fresh and frozen embryo(s) or a successful live birth occurring during the cycle. Attracts full tariff.

Embryos must be transferred in line with NICE CG156.

Cancelled Cycle
A cancelled IVF cycle is one where the egg collection procedure is not undertaken. Paid at 1/3 tariff.

Abandoned Cycle
An abandoned cycle is one which ends before embryo implantation and after egg collection. Paid at 2/3 tariff.

Full cycle using donor eggs:
A full cycle of IVF treatment, with or without intracytoplasmic sperm injection (ICSI), should begin with preparation of the donor eggs either through a) ovarian stimulation and synchronising cycles with a live donor or b) preparation of frozen donor eggs and end with the final transfer of all resultant fresh and frozen embryo(s) or a successful live birth occurring during the cycle. Attracts full tariff. Definitions for a cancelled and abandoned cycle as the same as for other women undergoing IVF.

Switching providers

Where more than one cycle is funded then individuals have the right to undergo subsequent cycles at a different provider as long as that provider has an arrangement with the commissioner responsible for your treatment.

Private sector to NHS

Individuals who have undergone privately funded cycles will still have a right to transfer to NHS funded cycles (with an NHS approved provider) provided that the overall total number of cycles (NHS and Private) does not exceed three.
e.g. If an NHS commissioner (or commissioners if the couple have moved areas) has funded two cycles and the individual has funded one privately , they have undergone three cycles and are therefore at their maximum under this policy. The limit of three cycles applies to the number of cycles undergone by the couple irrespective of who has funded each of those cycles.

The actual number of cycles will depend on the number currently offered by that area within Greater Manchester (The relevant area is determined by the surgery which the female partner is registered with*).*

Change of NHS commissioned provider

Requests for a change of provider can be made at the same time as an IFR request for an additional cycle and will be considered if the additional cycle is approved.

NOTE: Before changing provider individuals with frozen sperm, oocytes or embryos from any current cycle and who are eligible for further cycles:

- must ensure that all frozen embryos have been implanted (thus completing the current cycle) prior to transferring to their new provider.

In exceptional circumstances application can be made via the IFR route to fund the safe transfer of the frozen material from the old to the new provider, this request must come from a clinician.

Donor Oocytes (Use of Donor Oocytes):

Donor eggs for **women under 40 years** will be commissioned if the woman has a condition which means no viable eggs can be produced OR has been assessed by a fertility specialist and found to have premature ovarian failure.

The use of donor oocytes is considered effective in managing fertility problems associated with the following conditions:

- premature ovarian failure occurring before the age of 40 years (diagnosis must be confirmed by a specialist in infertility)
- gonadal dysgenesis including Turner syndrome
- bilateral oophorectomy
- ovarian failure following chemotherapy or radiotherapy

For **women aged 40-42** (**i.e. before her 43rd birthday)** IVF can be carried out with donor eggs if one of the following applies:

- total antral follicle count (AFC) of less than or equal to 4
- anti-Müllerian hormone (AMH) of less than or equal to 5.4 pmol/l
- follicle-stimulating hormone (FSH) greater than 8.9 IU/l

	Transfer of frozen material Requests to transfer frozen material from an old provider to a new provider will only be considered in exceptional circumstances via the IFR route. **Access to donor eggs** Where donor eggs are required and the current provider cannot provide them, the individual may transfer to an alternative provider who can provide donor eggs (within a pre agreed tariff), as NHS providers cannot offer an egg share scheme under current NHS rules. **Sperm, oocyte or embryo storage to retain fertility** **Please also see Policy Exclusion section**. There is no upper age limit for the storage of sperm. Individuals over the age of 42 (i.e. after their 43rd Birthday) with exceptional reasons for requesting gamete storage can apply via the IFR (exceptional case) route. **Extensions to the storage time for sperm or oocytes or age limit for embryos will require IFR (exceptional case) approval.** The application should comply with the process for extension of the statutory storage period as outlined in the HFEA code of practice and should not take the period of cryopreservation over the statutory upper limit of 55 years. The individual must be made aware of this at the time of storage. (Correct at the time this policy was produced but the current HFEA guidance should be followed if different from this statement). If individuals move away from the area where their gametes or embryos are stored, they can apply via the IFR (exceptional case) route for the transfer of those embryos to their current area of residence, or for the cost of storage to be met by their new area of residence. **Storage of viable embryos** If treatment resulted in a live birth before all the viable embryos were implanted the remaining embryos should be cryopreserved for either 10 years (in line with HFEA guidance) or until the woman's 43rd birthday – whichever is shorter. Implantation of these embryos will not be funded by the NHS locally, but they are available to the individual for private treatment. (Correct at the time this policy was produced but the current HFEA guidance should be followed if different from this statement). Storage will be funded within the general contract in line with HFEA regulations- if the storage time in these regulations reduces then the woman must be informed and allowed to request an extension to storage time via the IFR route.
Clinical Exceptionality	Clinicians can submit an Individual Funding Request (IFR) outside of this guidance if they feel there is a good case for exceptionality. More information on determining clinical exceptionality can be found in the Greater Manchester (GM) IFR Operational Policy. Link to **GM IFR Operational Policy**. Link to **IFR Form**
Government issued	'The National Health Service (Charges to Overseas Visitors) (Amendment) Regulations 2017 No. 756'

Statutory Instrument	**From 21 August 2017**, NHS-funded assisted conception services will not be included in the exemption from charge applicable to people who are caught within surcharge arrangements (i.e. those who have paid the surcharge, or who are exempt from paying it (with certain exceptions) or in respect of whom it has been waived). This means that, unless another exemption applies, where NHS assisted conception services are provided to a person who is exempt under surcharge arrangements, overseas visitor charges will apply. This is brought forward through regulations 11, 12 and 13 of the above named instrument, which insert a new regulation (9A) and amend regulation 10 and 11 respectively. Exemption from charges currently applies to: • Serving members of the armed forces and their families (NHS England commissioned) • Seriously injured serving members and veterans • Further provision of care previously given • Continuation of a course of treatment that commenced before 21 August 2017 Assisted conception services in the context of this instrument are defined as "*any medical, surgical or obstetric services provided for the purpose of assisting a person to carry a child*." This definition was based on the definition of "treatment services" in section 2 of the Human Fertilisation and Embryology Act 1990. Broadly speaking any medicines, surgery or procedures that are required to diagnose and treat infertility so a person can have a child. It includes procedures such as intrauterine insemination (IUI), *in vitro* fertilisation (IVF) and egg and sperm donation. The definition is not intended to refer to antenatal or maternity services.
Fitness for Treatment	**NOTE:** All patients should be assessed as fit for the treatment being offered before going ahead, even though funding has been approved.
Best Practice Guidelines	Providers are expected to comply with NICE CG156: Fertility problems: assessment and treatment in the delivery of all investigations and treatments for infertility **with the exception of IVF, where the local qualifying criteria must be met and the number of cycles offered should be in line with each area in Greater Manchester.**

Rationale behind the policy statement

Investigation, diagnosis and subsequent treatment for individuals with fertility issues is a complex and constantly developing field. The previous Greater Manchester Assisted Conception policy needed updating in light of NICE CG156 and wide variation in in commissioning policies for assisted conception across Greater Manchester. The GM template was developed however it is an extensive document and difficult to reference quickly. This summary version, using the updated GM template, has been drafted for ease of reference and to make it easier to see what is in contract and what requires an application for funding. This policy is aimed at ensuring consistency of approach in the referral, investigation, diagnosis and treatment of individuals with fertility issues across Greater Manchester.

To commission services in line with NICE CG156 but to take account of individual areas fiscal limitations and to ensure fairness of access within those limitations.

Treatment / Procedure

Unless otherwise referenced all information, data etc. is taken from NICE CG156.

There are a range of causes of fertility problems. This policy assumes that individuals requesting assisted conception have been investigated in line with NICE CG156.

The range of investigations should include semen analysis; assessment of ovulation, tubal damage and uterine abnormalities; screening for infections such as *Chlamydia trachomatis* and susceptibility to rubella should also be undertaken.

With the exception of the areas outlined in the preceding section of this policy, it is assumed that all services are provided in line with best practice guidance and the treatment requirements of NICE CG156 and that where medication is involved the provider's prescribers will use a drugs summary of product characteristics to inform the treatment decisions relating to individual patients.

This policy applies including same sex couples. The commissioning area is the one where the female partner wishing to be the biological mother is resident.

This policy applies to all women provided all steps have been undertaken to ensure the welfare of the child as per HFEA guidance: *"A woman shall not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for supportive parenting), and of any other child who may be affected by the birth". 'Supportive parenting is a commitment to the health, wellbeing and development of the child. It is presumed that all prospective parents will be supportive parents, in the absence of any reasonable cause for concern that any child who may be born, or any other child, may be at risk of significant harm or neglect. Where centres have concern as to whether this commitment exists, they may wish to take account of wider family and social networks within which the child will be raised.*'

All couples should be informed that if, as a result of investigations into infertility, surrogacy is the only option that this will not be funded by the NHS in Greater Manchester.

Transgender patients should be managed as their preferred sex at all stages of investigation and treatment.

Epidemiology and Need

It is estimated that infertility affects 1 in 7 heterosexual couples in the UK. Since the original NICE guideline on fertility published in 2004 there has been a small increase in the prevalence of fertility problems, and a greater proportion of people now seeking help for such problems.

The main causes of infertility in the UK are (per cent figures indicate approximate prevalence):

- unexplained infertility (no identified male or female cause) (25%)
- ovulatory disorders (25%)
- tubal damage (20%)
- factors in the male causing infertility (30%)
- uterine or peritoneal disorders (10%).

In about 40% of cases disorders are found in both the man and the woman. Uterine or endometrial factors, gamete or embryo defects, and pelvic conditions such as endometriosis may also play a role.
Given the range of causes of fertility problems, the provision of appropriate investigations is critical. These investigations include semen analysis; assessment of ovulation, tubal damage and uterine abnormalities; and screening for infections such as *Chlamydia trachomatis* and susceptibility to rubella.

Once a diagnosis has been established, treatment falls into 3 main types:

- 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)
- assisted reproduction techniques (ART) – any treatment that deals with means of conception other than vaginal intercourse. It frequently involves the handling of gametes or embryos.

Adherence to NICE Guidance

This policy adheres to NICE CG156 with the exception of IVF where the local qualifying criteria must be met and the number of cycles offered should be in line with each area policy.

Audit Requirements

The HFEA maintains a record of all assisted conception cycles on a national database

Date of Review

One year from the date of the last review, unless new evidence or technology is available sooner.

The evidence base for the policy will be reviewed and any recommendations within the policy will be checked against any new evidence. Any operational issues will also be considered at this time. All available additional data on outcomes will be included in the review and the policy updated accordingly. The policy will be continued, amended or withdrawn subject to the outcome of that review.

Glossary

Term	Meaning
Ablation	The surgical removal of body tissue.

Amenorrhoea	The absence of periods in a woman of childbearing age.
Anti-Mullerian Hormone (AMH)	A substance produced by granulosa cells (also called follicular cells is a somatic cell of the sex cord that is closely associated with the developing female gamete (called an oocyte or egg) in the ovary of mammals.) in ovarian follicles. It is first made in primary follicles that advance from the primordial follicle stage (stages in the lifecycle of the area of the ovary that produces eggs). At these stages follicles are microscopic and cannot be seen by ultrasound.
Antisperm antibodies	Blood proteins produced to attack sperm which are mistaken for foreign proteins in the male body. (Antibodies combine chemically with substances which the body recognizes as alien, such as bacteria, viruses, and foreign substances in this case the sperm).
Antral Follicle Count (ATF)	Small follicles (2 to 8 mm in size) that are visible on the ovaries via ultrasound. They are also known as resting follicles. They appear in the beginning of the menstrual cycle, and their number can indicate the amount of microscopic primordial follicles (those present in the ovaries at birth that have not yet matured) contained within the ovary.
Artificial Insemination (AI)	Any method of introducing sperm to the female body other than by sexual intercourse – includes Intravaginal Insemination and Intrauterine insemination.
Azoospermia	The complete absence of sperm in the seminal fluid (ejaculate) of the male.
Bilateral oophorectomy	Removal of both ovaries.
Co-morbidities	The presence of one or more additional disorders (or diseases) co-occurring with a primary disease or disorder.
Cryopreservation	A process where cells or whole tissues are preserved by cooling to sub-zero temperatures.
Endometrial biopsy	Surgical removal of a sample of the lining of the womb for examination.
Endometriosis	The presence of endometrial tissue (cells that line the womb) outside the womb that causes pelvic pain, especially associated with menstruation.
Follicles	A cavity in the ovary containing a maturing ovum surrounded by its encasing cells.
Follicle Stimulating Hormone (FSH)	A hormone secreted by the anterior pituitary gland (an endocrine gland, the size of a pea attached to the base of the brain that is important in controlling growth and development as well as the functioning of the other endocrine glands) which promotes the formation of ova or sperm.
Galactorrhoea	A milky nipple discharge unrelated to the normal milk production of breast-feeding.
Gametes	A mature haploid male or female germ cell which is able to unite with another of the opposite sex in sexual reproduction to form a zygote i.e. An egg or a sperm.

Gonadal dysgenesis	Any congenital developmental disorder of the reproductive system characterized by a progressive loss of germ cells on the developing gonads (testes or ovaries) of an embryo.
Gonadotrophin	A group of hormones secreted by the pituitary which stimulate the activity of the gonads.
HAART "Highly Active Antiretroviral Therapy"	Antiretroviral therapy (ART) is treatment of people infected with human immunodeficiency virus (HIV) using anti-HIV drugs. The standard treatment consists of a combination of at least three drugs (often called "highly active antiretroviral therapy" or HAART) that suppress HIV replication. Three drugs are used in order to reduce the likelihood of the virus developing resistance. ART has the potential both to reduce mortality and morbidity rates among HIV-infected people, and to improve their quality of life.
Hydrosalpinx	A fallopian tube dilated with fluid. The plural term is "hydrosalpinges" The only way for a fallopian tube to become dilated with fluid is if it is blocked at the end of the tube away from the uterus.
Hyperprolactinaemiaa	Elevated serum prolactin. Prolactin is a 198-amino acid protein (23-kd) produced in the lactotroph cells of the anterior pituitary gland. Its primary function is to enhance breast development during pregnancy and to induce lactation (the production of milk).
Hypogonadism	Hypogonadism is an abnormally low level of testosterone – the male sex hormone that is involved in making sperm. This could be due to a tumour, taking illegal drugs or Klinefelter's syndrome (a rare genetic condition where a man is born with an extra female chromosome).
Hypothalamic pituitary failure (hypothalamic amenorrhoea or hypogonadotrophic hypogonadism)	Hypothalamic dysfunction is a problem with the region of the brain called the hypothalamus, which helps control the pituitary gland and regulate many body functions. The pituitary, in turn, controls the: • Adrenal glands • Ovaries • Testes • Thyroid gland
Hypothalamic-pituitary-ovarian dysfunction (predominately polycystic ovary syndrome)	See above
Hysterosalpingo-contrast-ultrasonography	An ultrasound enhanced by the use of a liquid that shows up clearly on the ultrasound which has been inserted into the fallopian tubes.
Hysterosalpingography (HSG)	The process of carrying out an ultrasound enhanced by the use of a liquid that shows up clearly on the ultrasound which has been inserted into the fallopian tubes.
Hysteroscopic adhesiolysis	Using a hysteroscope (a device designed to look into the uterus or womb) to remove adhesions (bands of fibrous tissue that form in response to inflammation).

Hysteroscopic tubal cannulation	Female sterilisation using a hysteroscope (a device designed to look into the uterus or womb) to access and block the fallopian tubes (the tubal part of the womb that allows eggs released by the ovary to enter the womb).
Hysteroscopy	Using a hysteroscope (a device designed to look into the uterus or womb) to examine the uterus (womb).
Infertile	An inability to conceive naturally
In vitro fertilisation (IVF)	Involves fertilizing an egg outside the body, in a laboratory dish, and then implanting it in a woman's uterus.
Intracytoplasmic Sperm Injection (ICSI)	An in vitro fertilization procedure in which a single sperm is injected directly into an egg.
Intrauterine adhesions	Bands of fibrous tissue that form in the uterus (womb) usually in response to inflammation).
Intra-Uterine Insemination (IUI)	The medical procedure of injecting semen directly into the uterus.
Laparoscopic adhesiolysis	Using a laparoscope (a device designed to look into the abdomen) to remove adhesions (bands of fibrous tissue that form in response to inflammation).
Laparoscopic cystectomy	Using a laparoscope (a device designed to look into the abdomen) to remove cysts on the ovaries.
Laparoscopic ovarian drilling	Using a laparoscope to undertake a surgical treatment that can trigger ovulation in women who have polycystic ovary syndrome (PCOS). Electrocautery or a laser is used to destroy parts of the ovaries.
Laparoscopy	Using a laparoscope to look into the abdomen.
Luteal Phase	A stage of the menstrual cycle. It occurs after ovulation (when the ovaries release an egg) and before a woman's period starts. During this phase, the lining of the uterus normally becomes thicker to prepare for a possible pregnancy.
Menarche	The natural start of the menstrual cycle in a woman.
Menopause	The natural end of the menstrual cycle in a woman.
Microsurgical Epididymal Sperm Aspiration (MESA)	A surgical technique used to retrieve sperm from the testes.
Oocytes	Eggs
Ovarian endometriomas	Benign, estrogen-dependent cysts found in women of reproductive age.
Ovarian failure	Loss of normal function of the ovaries which no longer produce eggs.
Ovarian Reserve	The ovarian reserve is the number of eggs left in a woman's ovaries. At birth the ovary contains the individual's lifetime supply of eggs. The action of the woman's hormones during her menstrual cycle causes some of these eggs to

	mature each month. Menopause occurs when the “reserve” of eggs is exhausted.
Percutaneous Epididymal Sperm Aspiration (PESA)	A surgical technique used to retrieve sperm from the testes.
Polycystic ovary syndrome (PCOS)	A condition that makes it more difficult for your ovaries to produce an egg.
Pre-Implantation Genetic Diagnosis (PGD)	Testing the genes and/or chromosomes of embryos created through IVF for potential inherited disorders.
Premature ovarian failure	Amenorrhea of at least 12 months duration with a hormone profile in the menopausal range, under the age of 40.
Proximal tubal obstruction	A blockage in the fallopian tube near to where it joins the uterus.
Rhesus isoimmunisation	A blood incompatibility disorder where the mother's blood type is not compatible with the fetus. This incompatibility results in antibodies from the mother's blood destroying the baby's red blood cells when they come into contact during pregnancy and after birth.
Selective salpingography	A minor outpatient operation which can treat proximally blocked fallopian tubes.
Sterilisation	A medical procedure to render an individual infertile.
Subfertile	The possibility of conceiving naturally exists but it takes longer than average
Surrogacy	Surrogacy is the practice whereby a woman (the surrogate mother) carries a child for another person and (usually) that person's partner (the commissioning couple) as the result of an agreement prior to conception that the child should be handed over to them after the birth.
Testicular Fine Needle Aspiration (TFNA)	A surgical technique used to retrieve sperm from the testes.
Tubal catheterisation	A procedure to help clear a blockage in the fallopian tubes.
Tubal disease	Disease of the fallopian tube(s).
Tubal occlusion	A blockage in the fallopian tube(s).
Varicoceles	A mass of varicose veins in the spermatic cord (a bundle of nerves, ducts, and blood vessels connecting the testicles to the abdominal cavity.
Vasectomy	The surgical procedure for male sterilisation. It involves cutting and sealing off the vas deferens (the tubes that carry sperm out of the testicles), so that semen will no longer contain any sperm. A vasectomy can be reversed, but reversals are not usually successful.

Evidence Summary

This policy is based on the evidence cited in NICE CG156 supported by additional references where needed. For further details please refer to NICE CG156 and the references cited below.

References

1. Greater Manchester IFR Operational Policy
2. NICE CG156: Assessment and treatment for people with fertility problems
3. HFEA Code of Practice Guidance: Note 14: Surrogacy
4. Determining the legal parentage of children from surrogacy guidance, GOV.UK: (2.1 Provision together with the definition of parent in the British Nationality Act 1981 under 2. Legal parentage of children resulting from surrogacy arrangements
5. Effectiveness and treatment for unexplained infertility. Fertil Steril. 2006;86(5 suppl):S111–S114. [PubMed]
6. www.who.int/classifications
7. Anderson K, Norman RJ, Middleton P. Preconception lifestyle advice for people with subfertility. *Cochrane Database of Systematic Reviews* 2010, Issue 4. Art. No.: CD008189. DOI: 10.1002/14651858.CD008189.pub2.
8. HFEA Code of Practice Guidance: Note 17 – Storage of Gametes and Embryos

Appendix 1 – Summary of NICE CG156
(Extract for areas in NICE CG156 not covered in the Commissioning Criteria section of this policy for quick reference)
For full details please refer to the policy on the NICE website

Female factor infertility

Ovulation disorders

Infertility is most commonly caused by problems with ovulation (the monthly release of an egg). Some problems stop women releasing eggs at all and some cause an egg to be released during some cycles, but not others. Ovulation problems can occur as a result of many conditions, such as:

- polycystic ovary syndrome (PCOS) – a condition that makes it more difficult for your ovaries to produce an egg
- thyroid problems – both an overactive thyroid gland (hyperthyroidism) and an underactive thyroid gland (hypothyroidism) can prevent ovulation
- premature ovarian failure – where a woman's ovaries stop working before she is 40

Womb and fallopian tubes

The fallopian tubes are the tubes along which an egg travels from the ovary to the womb. The egg is fertilised as it travels down the fallopian tubes. When it reaches the womb, it is implanted into the womb's lining, where it continues to grow. If the womb or the fallopian tubes are damaged, or stop working, it may be difficult to conceive naturally. This can occur following a number of factors:

- **Scarring from surgery:** Pelvic surgery can sometimes cause damage and scarring to the fallopian tubes. Cervical surgery can also sometimes cause scarring, or shorten the cervix (the neck of the womb).
- **Cervical mucus defect:** When a women is ovulating the mucus in their cervix becomes thinner so that sperm can swim through it more easily. If there is a problem with their mucus, it can make it harder to conceive.
- **Submucosal fibroids:** are benign (non-cancerous) tumours that grow in, or around, the womb. Submucosal fibroids develop in the muscle beneath the inner lining of the womb wall and grow into the middle of the womb. Submucosal fibroids can reduce fertility.
- **Endometriosis:** is a condition where small pieces of the womb lining, known as the endometrium, start growing in other places, such as the ovaries. This can cause infertility because the new growths form adhesions (sticky areas of tissue) or cysts (fluid-filled sacs) that can block or distort the pelvis. It can disturb the way that a follicle (fluid-filled space in which an egg develops) matures and releases an egg.
- **Pelvic inflammatory disease:** Pelvic inflammatory disease (PID) is an infection of the upper female genital tract, which includes the womb, fallopian tubes and ovaries. It is often the result of a sexually transmitted infection (STI). PID can damage and scar the fallopian tubes, making it virtually impossible for an egg to travel down into the womb.
- **Sterilisation:** Some women choose to be sterilised if they do not wish to have any more children. Sterilisation involves blocking the fallopian tubes to make it impossible for an egg to travel to the womb. This process is rarely reversible.
- **Medicines and drugs:** The side effects of some types of medication and drugs can affect your fertility. These medicines are:
    - Non-steroidal anti-inflammatory drugs (NSAIDs). Long-term use or a high dosage of NSAIDs, such as ibuprofen or aspirin, can make it more difficult to conceive.

- Chemotherapy. Medicines used for chemotherapy (a treatment for cancer) can sometimes cause ovarian failure. Ovarian failure can be permanent.
- Neuroleptic medicines are antipsychotic medicines often used to treat psychosis. They can sometimes cause missed periods or infertility.
- Spironolactone – this is a type of medicine used to treat fluid retention (oedema). Fertility should recover around two months after you stop taking spironolactone.

Illegal Drugs
Illegal drugs such as marijuana and cocaine can seriously affect fertility, making ovulation (the monthly cycle where an egg is released from the ovaries) more difficult.

Age
Infertility in women is also linked to age. The biggest decrease in fertility begins during the mid-thirties. Among women who are 35, 95% will get pregnant after three years of having regular unprotected sex. For women who are 38, only 75% will get pregnant after three years of having regular unprotected sex.

Investigating Female Infertility

The following should be undertaken in line with the recommendation in NICE CG156 in the appropriate primary or secondary care setting as indicated clinically:

- Ovarian reserve testing
- Regularity of menstrual cycles
- Hysterosalpingography (HSG) to screen for tubal occlusion in women not known to have relevant co-morbidities
- (Where the expertise is available) Hysterosalpingo-contrast-ultrasonography to screen for tubal occlusion in women not known to have relevant co-morbidities
- Women thought to have co-morbidities should be offered laparoscopy and dye to assess tubal and pelvic pathology
- Hysteroscopy for diagnostic reasons
- Blood test to measure prolactin levels **ONLY** In women who have a known ovulatory disorder, Galactorrhoea or a pituitary tumour
- Testing for susceptibility to Rubella.
- Cervical screening (unless up to date)
- Screening for Chlamydia with appropriate treatment and contact tracing

The following should **NOT** be done (in line with NICE CG156):

- Routine post coital testing of cervical mucus
- Thyroid function tests
- Endometrial biopsy to investigate the luteal phase
- Hysteroscopy as a treatment procedure

Managing Female Infertility

Ovulation Disorders

Please refer to GMMMG website for up to date guidance on any restrictions to drugs.

The World Health Organization classifies[6] ovulation disorders into 3 groups:

- Group I: hypothalamic pituitary failure (hypothalamic amenorrhoea or hypogonadotrophic hypogonadism)
- Group II: hypothalamic-pituitary-ovarian dysfunction (predominately polycystic ovary syndrome)
- Group III: ovarian failure

Group I: hypothalamic pituitary failure (hypothalamic amenorrhoea or hypogonadotrophic hypogonadism)

Advise women in this group to:

- increase their body weight if they have a BMI of less than 19 (unless they can show by an alternative measure to BMI that they have a normal body fat ratio).

AND / OR

- moderate their exercise levels if they undertake high levels of exercise

Offer women in this group pulsatile administration of gonadotrophin-releasing hormone or gonadotrophins with luteinising hormone activity to induce ovulation.

These should be administered and managed in line with NICE CG156.

Group II: hypothalamic-pituitary-ovarian dysfunction (predominately polycystic ovary syndrome)

First line Treatment

Advise women in this group:

- who have a BMI over 30 to lose weight and inform them that this alone may restore ovulation, improve their response to ovulation induction agents, and have a positive impact on pregnancy outcomes.

Offer women in this group one of the following treatments, taking into account potential adverse effects, ease and mode of use, the woman's BMI, and monitoring needed:

- clomifene citrate

OR

- metformin

OR

- a combination of the above

These should be administered and managed in line with NICE CG156.

Second-line treatments

For women with WHO Group II ovulation disorders who are known to be resistant to clomifene citrate, consider one of the following:

- laparoscopic ovarian drilling

OR

- combined treatment with clomifene citrate and metformin if not already offered as first-line treatment

OR

- gonadotrophins

Do not offer women with polycystic ovary syndrome who are being treated with gonadotrophins concomitant treatment with gonadotrophin-releasing hormone agonist. It is not shown to improve pregnancy rates and research suggests it is associated with an increased risk of ovarian hyperstimulation.

Do not offer adjuvant growth hormone treatment with gonadotrophin-releasing hormone agonist and/or human menopausal gonadotrophin during ovulation induction in women with polycystic ovary syndrome who do not respond to clomifene citrate because it is not shown to improve pregnancy rates.

The effect of pulsatile gonadotrophin-releasing hormone in women with clomifene citrate-resistant polycystic ovary syndrome is uncertain and this should only be offered within a funded research context.

Women with ovulatory disorders due to hyperprolactinaemia should be offered treatment with dopamine agonists such as bromocriptine. Consideration should be given to safety for use in pregnancy and minimising cost when prescribing.

These should be administered and managed in line with NICE CG156.

Group III: ovarian failure

Treatment will be commissioned for women with premature menopause, defined as amenorrhea of at least 12 months duration with a hormonal profile in the menopausal range, under the age of 40. The cause may be spontaneous, or as a result of other morbidity, or congenital abnormality or iatrogenic. NHS funding would not normally be available for women outside these groups who do not respond to follicular stimulation.

For premature or iatrogenic ovarian failure donor oocytes can be used, in line with NICE CG156. Premature ovarian failure is defined as in the paragraph above.

Use of Donor Oocytes

The use of donor oocytes is considered effective in managing fertility problems associated with the following conditions:

- premature ovarian failure occurring before the age of 40 years
- gonadal dysgenesis including Turner syndrome
- bilateral oophorectomy
- ovarian failure following chemotherapy or radiotherapy
- unexplained (or repeated) failure of ovarian stimulation during of IVF treatment

Oocyte donation should also be considered in certain cases where there is a high risk of transmitting a genetic disorder to the offspring.

For women undergoing IVF treatment with donor eggs, use an embryo transfer strategy that is based on the age of the donor.

Screening of donors and subsequent treatment with donor oocytes should be carried out in line with NICE CG156.
Oocyte sharing schemes should be managed in line with NICE CG156.

Tubal and Uterine Abnormalities

Tubal disease

In centres where appropriate expertise is available tubal surgery may be considered as a treatment option for women with mild tubal disease.

For women with proximal tubal obstruction, selective salpingography plus tubal catheterisation, or hysteroscopic tubal cannulation, may be offered as these treatments improve the chance of pregnancy.

Women with hydrosalpinges should be offered salpingectomy, preferably by laparoscopy, before IVF treatment, as research indicates that this improves the chance of a live birth.

Intrauterine adhesions

Women with amenorrhoea who are found to have intrauterine adhesions should be offered hysteroscopic adhesiolysis because research shows that this is likely to restore menstruation and improve the chance of pregnancy.

Endometriosis

Endometriosis should be managed in line with NICE NG73 Endometriosis: diagnosis and management.

Male factor infertility

Male infertility is caused by abnormal semen (the fluid containing sperm that is ejaculated during sex). Possible reasons for abnormal semen include:

- decreased number or absence of sperm
- decreased sperm
- abnormal sperm

Many cases of abnormal semen are unexplained, but can be due to a variety of factors.

Problems with the Testicles

The testicles are responsible for producing and storing sperm. If they are damaged, it can seriously affect the quality of the semen produced. This includes:

- an infection of the testicles
- testicular cancer
- testicular surgery
- a congenital defect
- undescended testicles – corrected or uncorrected
- trauma (injury)

Absence of sperm

The testes may produce sperm, but it may not reach the semen. The absence of sperm in semen is known as obstructive azoospermia. This could be due to a blockage in one of the tiny tubes that make up the male reproductive system, as a result of infection, injury or surgery.

Sterilisation

A vasectomy is the surgical procedure for male sterilisation. It involves cutting and sealing off the vas deferens (the tubes that carry sperm out of the testicles), so that semen will no longer contain any sperm. A vasectomy can be reversed, but reversals are not usually successful.

Ejaculation disorders
Some men experience problems that can make it difficult for them to ejaculate. Other ejaculation problems include:

- retrograde ejaculation - where semen is ejaculated into the bladder
- premature ejaculation – where ejaculation occurs too quickly

Hypogonadism
Hypogonadism is an abnormally low level of testosterone – the male sex hormone that is involved in making sperm. This could be due to a tumour, taking illegal drugs or Klinefelter's syndrome (a rare genetic condition where a man is born with an extra female chromosome).

Medicines and drugs
Certain types of medicines can sometimes cause infertility problems. These medicines are listed below:

- Sulfasalazine – an anti-inflammatory medicine used to treat conditions such as Crohn's disease (inflammation of the intestine) and rheumatoid arthritis (painful swelling of the joints). Sulfasalazine can decrease the number of sperm, but its effects are temporary and the sperm count should return to normal when the medication is stopped.
- Anabolic steroids – often used illegally to build muscle and improve athletic performance. Long-term use or abuse of anabolic steroids can reduce sperm count and sperm mobility.
- Chemotherapy – medicines used in chemotherapy can sometimes severely reduce sperm production.
- Herbal remedies – some herbal remedies, such as root extracts of Tripterygium wilfordii (a Chinese herb), can affect the production of sperm or reduce the size of testicles.

Illegal drugs such as marijuana and cocaine can also affect semen quality.

Alcohol
Drinking too much alcohol can damage the quality of sperm. NICE CG156 states that if men follow the current Department of Health's recommendations for the consumption of alcohol, it is unlikely their fertility will be affected but drinking more than this could make it difficult to conceive.

Investigating Male Infertility

Semen analysis and subsequent management of any abnormality found should be managed in line with NICE CG156 using the World Health Organization reference values as a benchmark.

Managing Male Factor Infertility

Hypogonadism
Men found to have true hypogonadism should be offered gonadotrophin drugs.

Other causes of male factor infertility
Do **not** offer men with idiopathic semen abnormalities antioestrogens, gonadotrophins, androgens, bromocriptine or kinin-enhancing drugs because they have not been shown to be effective.

Do **not** offer Men with leucocytes in their semen antibiotic treatment unless there is an identified infection because there is no evidence that this improves pregnancy rates.

The significance of antisperm antibodies is unclear and the effectiveness of systemic corticosteroids is uncertain.

Where the appropriate expertise is available, men with obstructive azoospermia should be offered surgical correction of epididymal blockage in line with NICE CG156. Surgical correction should be considered as an alternative to surgical sperm recovery and IVF.

Do **not** offer surgery for varicoceles as a form of fertility treatment because it has not been shown to improve pregnancy rates.

Ejaculatory failure should be managed in line with NICE CG156.

Use of donor sperm

The use of donor insemination is considered effective in managing fertility problems associated with the following conditions:

- obstructive azoospermia
- non-obstructive azoospermia
- severe deficits in semen quality in couples who do not wish to undergo ICSI

Donor insemination should be considered in conditions where there is:

- a high risk of transmitting a genetic disorder to the offspring
- a high risk of transmitting infectious disease to the offspring or woman from the man
- severe rhesus isoimmunisation

Screening of potential donors and treatments involving donor sperm should be carried out in line with NICE CG156.

Surgical recovery of sperm

Surgical recovery of sperm can be undertaken using a variety of techniques including:

- Testicular Fine Needle Aspiration (TFNA)
- Percutaneous Epididymal Sperm Aspiration (PESA)
- Microsurgical Epididymal Sperm Aspiration (MESA)

There is limited evidence available on the effectiveness of these techniques and surgical recovery of sperm is not included in NICE CG156.

Surgical sperm recovery is now the responsibility of NHS England (NHS England: 16040/P - Clinical Commissioning Policy: Surgical sperm retrieval for male infertility) and all requests for funding of these techniques should be made to NHS England using their form.

Unexplained infertility

When the results of a standard infertility evaluation are normal, practitioners assign a diagnosis of unexplained infertility. Although estimates vary, the likelihood that all such test results for an infertile couple are normal (i.e., that the couple has unexplained infertility) is approximately 15% to 30%.[1]

Managing Unexplained Infertility

When the results of a standard infertility evaluation are normal, practitioners assign a diagnosis of unexplained infertility. Although estimates vary, the likelihood that all such test results for an infertile couple are normal (i.e. that the couple has unexplained infertility) is approximately 15% to 30%[5].

Offer a period of expectant management by advising couples to try to conceive for a total of 2 years. (The period of expectant management after diagnosis and up to 1 year before their fertility investigations began) before IVF will be considered. For same sex couples and single women offer a further 6 cycles of IUI post referral, to be carried out in an NHS clinical setting, in addition to the self-funded 6 cycles of self-reported vaginal insemination undertaken prior to referral (as the equivalent of expectant management in a heterosexual couple) or 3 cycles if aged over 36 years.

Offer IVF treatment to couples with unexplained infertility who have not conceived after 2 years of regular unprotected sexual intercourse or after 12 cycles of AI (1 year and 6 cycles if aged over 36 years).

All services should be offered in line with the recommendations of NICE CG156.

Do **not** offer:

- ovarian stimulation agents (such as clomifene citrate, anastrozole orletrozole) to women with unexplained infertility.
- do not routinely offer intrauterine insemination, either with or without ovarian stimulation (exceptional circumstances include, for example, when people have social, cultural or religious objections to IVF)

Managing Infertility with IVF

The chance of a live birth following IVF treatment falls with:

- rising female age
- as the number of unsuccessful cycles increases. [new in NICE CG156 in 2013]
- a female BMI outside the range 19-30 before commencing assisted reproduction
- the consumption of more than the current Department of Health's recommendations for the consumption of alcohol
- maternal and paternal smoking (includes use of nicotine replacement products as it is the nicotine in tobacco that may reduce fertility)
- increasing caffeine consumption

Please see access criteria for IVF/ICSI in the Policy Inclusion Section

Indications for ICSI (Intra-cytoplasmic sperm injection)

The recognised indications for treatment by ICSI include:

- severe deficits in semen quality
- obstructive azoospermia
- non-obstructive azoospermia

In addition, treatment by ICSI should be considered for couples in whom a previous IVF treatment cycle has resulted in failed or very poor fertilisation.

The decision on whether to use IVF alone or IVF with ICSI should be undertaken by the specialist in line with NICE CG156.

IVF from Ovarian stimulation through to embryo transfer must be carried out in line with NICE CG156.

Appendix 2 – Version History

Version	Date	Details
0.1	29/04/2015	Initial draft
0.2	24/08/2015	Changes made following the GM EUR Steering Group Meeting on the 8th July 2015: • Section 1 Introduction (single women) - Final paragraph amended to read as follows: '*This policy applies to single women in exceptional circumstances however prior approval must be sought via the IFR route and all applications for funding should clearly demonstrate the exceptional circumstances, these should be evidenced wherever possible. Single women should demonstrate infertility either through evidence of previous investigations or by undertaking 6 cycles of donor insemination (these must be self-funded) prior to the individual applying for assisted conception treatment in line with this policy.'* • Section 2.1 Subfertility / Infertility (same sex couples) - 4th paragraph amended to read as follows: *'Subfertility in same sex couples will be defined as a failure to achieve a pregnancy following 6 cycles of donor insemination (these should be self-funded). Then in line with the period of expectant management a further 6 cycles of AI or 6 cycles of Intra-Uterine Insemination (IUI) should be offered (funded by the local NHS).'* Section 4.3 Reversal of Sterilisation • The Steering Group agreed to include the following option in this section: '*In cases where the sterilisation was carried out to treat an underlying condition and not for family planning purposes applications for funding can be made via the IFR route. All relevant clinical information should be included with the application.'* • Further sentence added to the second paragraph as follows: *'Where proof is supplied of successful reversal of sterilisation and if the infertility issues are in the partner IVF applications can be submitted via the IFR route for consideration.'* • Section 4.4 Surrogacy - The Steering Group agreed that following statement should be included in this section of the policy: '*The NHS does not fund any type of surrogacy arrangement. Commissioning parents must undertake the whole process privately.'* Section 4.7 Managing Unexplained Infertility • The final sentence of the second paragraph has been amended to read as follows: '*For same sex couples and single women who have had their funding approved via the IFR route offer a further 6 cycles of IUI post referral in addition to the self -funded 6 cycles undertaken prior to referral (as the equivalent of expectant management in a heterosexual couple)'.* • The following wording has been removed from this section: '*If exceptional circumstances apply, for example, when people have social, cultural or religious objections to IVF then application for this treatment can be made via the IFR route.'* • Section 4.10 Managing Female Infertility (Group III: ovarian failure) - A definition of premature menopause and a statement about premature or iatrogenic ovarian failure added to this section of the policy

		Section 4.13 Number of funded cycles
		• Wording slightly amended in the section to read *'may allow'* rather than *'allows'*.
		• Wording amended to read: *'for women aged 40-42 (inclusive), the CCG offers 1 full cycle providing:*
		  • *They have never previously had IVF (including privately) – (For same sex female couples: neither partner has previously had IVF.)'*
		• Storage of embryos following a live birth - paragraph amended to read as follows: '*If treatment resulted in a live birth before all the viable embryos were implanted the remaining embryos should be cyropreserved for either 10 years (in line with HFEA guidance) or until the woman's 40th birthday – whichever is shorter. Implantation of these embryos will not be funded by the NHS locally but they are available to the individual for private treatment.'*
		Section 4.15 Switching provider
		• The following wording added to the first paragraph: *'as long as the CCG has current contract arrangement with that provider*.'
		• Third paragraph reworded as follows*: 'Individuals with frozen sperm, oocytes or embryos who are eligible for further cycles:*
		  • *must ensure that all frozen embryos are implanted (thus completing the current cycle) prior to transferring to their new provider.*
		  In exceptional circumstances application can be made via the IFR route to fund the safe transfer of the frozen material from the old to the new provider.'
		• The fourth paragraph reworded as follows: '*Where donor eggs are required and the current provider cannot provide them the individual may apply for transfer to an alternative provider who can provide donor eggs (within a pre agreed tariff) via the IFR process as NHS providers cannot offer an egg share scheme under current NHS rules.'*

0.3	10/12/2015	Changes made following the GM EUR Steering Group Meeting on the 18th November 2015: Section 4.12.1 Access Criteria • Further sentence added to the second paragraph as follows: *In same sex (both female) partnership only one partner will be eligible for treatment with IVF up to the current number of cycles commissioned. This does not affect the untreated partner's right to IVF in a new relationship provided they meet the eligibility criteria at that time.* • The following sentence moved to 4.13 Number of funded cycles. '*The total number of cycles undertaken as listed below added to those funded privately does not exceed 3*'. Section 4.15 Switching providers: Second paragraph amended to read as follows: *'Individuals who have undergone privately funded cycles will still have to right to transfer to NHS funded cycles (at an NHS approved provider) provided that the overall total number of cycles (NHS and Private) does not exceed three. The actual number of cycles offered will depend on the number currently offered by the CCG (the relevant CCG is the one that the practice, with which the female partner is registered is part of).* Section 4.16 Policy Exclusions • In the first and second paragraphs after the word *'cancer'*, the following added for clarity *'(or for any lifesaving treatment resulting in fertility).'*

		• The fifth paragraph amended to read: *'Storage and retrieved sperm oocytes or resultant embryos will be for 10 years in line with HFEA licensing requirements provided the individuals are under the upper age limits for IVF treatment at the time of storage. Extensions to the storage time or age limit will require an IFR request, the individual must be made aware of this at the time of retrieval.'* Following the above amendments the GM EUR Steering Group approved the draft policy to be sent for a legal opinion.
	15/03/2016	Template unbranded and references to North West Commissioning Support Unit (NWCSU) changed to Greater Manchester Shared Services (GMSS)
0.4	16/03/2016	GM EUR Steering Group reviewed the draft policy on 16 March 2016 following legal advice and the following changes were approved: • Minor spelling/grammatical errors amended throughout the document as well as wording changed as follows: o *'Reviewed this clinical condition'* to be replaced with '*considered the range of causes of fertility problems'* o *'Does not'* to be replaced with '*has not been shown to'* o *'Does not'* to be replaced with '*is not shown to'* and *'research suggests it'* o *'The effect of'* to be inserted before pulsatile gonadotrophin-releasing hormone o *'This'* to be replaced with '*research indicates that this'* • The last sentence under section '1. Introduction' removed which read: *'In addition single women should demonstrate infertility either through evidence of previous investigations or by undertaking 6 cycles of donor insemination (these must be self-funded) prior to the individual applying for assisted conception treatment in line with this policy (3 cycles if aged over 36 years).'* • Changes made throughout the policy to ensure requirements are consistent for women over 36. • The word *'only'* added to the last paragraph of section '4.9.1 Surgical recovery of sperm' which reads *''Requests for funding these techniques in non-cancer patients with azoospermia should **ONLY** be made….'.* • Under section 4.10.1 under 'Group III: ovarian failure' the start of the first sentence amended to read: *'Treatment will be commissioned for women with…'* • Under section 4.12.1 in the 5th paragraph, first sentence reworded to read: *'Both partners must be non-smoking and not using any product containing nicotine in order…'*. • *'40th birthday'* in the last paragraph under section 4.13 amended to *'42nd birthday'*. • The statement: *'Extensions to the storage time or age limit will require an IFR request, the individual must be made aware of this at the time of retrieval.'* added to the end of the last paragraph in section 4.13 as per section 4.16. • Under section 4.15 in the 5th paragraph, *'storage of retrieved sperm, oocytes or resultant embryos…'* amended to read: *'Storage of retrieved sperm, oocytes will be for 10 years in line with HFEA licencing requirements.'* *Resultant embryos will be stored for 10 years in line with HFEA licencing requirements or until the woman's 42nd birthday provided the individuals*

		are under the upper age limits of IVF treatment at the time of storage. Extensions to the storage time or age limit will require an IFR request, the individual must be made aware of this at the time of retrieval.' • Comma added after *'Storage of retrieved sperm'* and before *'oocytes'* in section 4.16. • *'4.16.2 Claiming Exceptionality to the policy'* added as a heading in order to separate the section which relates to exceptionality. • Wording for date of review amended to read *'One year from the date of approval by Greater Manchester Association Governing Group thereafter at a date agreed by the Greater Manchester EUR Steering Group (unless stated this will be every 2 years)'* on 'Policy Statement' and section 13. Date of Review. Following the amendments it was agreed the policy template could go out for a period of clinical engagement.
0.5	20/07/2016	The GM EUR Steering Group reviewed the clinical engagement feedback and agreed the following changes to the policy: <u>Section 1 Introduction</u> • The words *'but are not co-habiting'* taken out of paragraph 6. • The following paragraphs added: o *'All couples should be informed that if, as a result of investigations into infertility, surrogacy is the only option that this will not be available funded by NHS commissioners in Greater Manchester.'* o *'Transgender patients should be managed as their preferred sex at all stages of investigation and treatment.'* o *'Couples where one or both partners are undergoing or have undergone gender re-assignment must be made aware that gamete storage is not available for this group as gender reassignment is considered to be a form of voluntary sterilisation. Reversal of sterilisation and IVF treatment as a result of sterilisation is not commissioned in Greater Manchester.'* o *'Recurrent miscarriage is not covered by this policy as there is a local service. All individuals should be referred in line with the pathway for that service.'* • The fourth paragraph under section 2.1 Sub-Fertility amended to read: *'Subfertility in same sex couples will be defined as a failure to achieve a pregnancy following 6 cycles of donor insemination (these should be self-funded) or 3 cycles if aged over 36 years. This would normally be self-reported attempts at vaginal insemination. Then in line with the period of expectant management a further 6 cycles of Intra-Uterine Insemination (IUI) should be offered (funded by the local NHS) 3 cycles of either if aged over 36 years in a clinical setting.'* and the following paragraph added: *'All patients undergoing fertility treatment covered by the HFEA (including IUI) must be assessed using the HFEA welfare of the child form and meet HFEA requirements.'* • The paragraph under section 2.3 Definition of Childlessness changed to include 3 separate options for CCG's to choose from. • Under section 4.2 Investigating Female Infertility' the following added to the end of the first paragraph: *'in the appropriate primary or secondary care setting as indicated clinically'* • In paragraph 2 under section 4.7 Managing Unexplained Infertility, *'AI or IUI'* changed to *'IUI'* and *'self-reported'*

		• The final sentence in section '4.9 Managing Female Infertility' changed to: *'Surgical sperm recovery is now the responsibility of NHS England and all requests for funding of these techniques should be made to NHS England using their form.'* • The sentence *'as it is the nicotine in tobacco that may reduce fertility'* added to the 5th bullet point under section 4.12 Managing Infertility with IVF. • Under section 4.12.1 Access criteria the definition of childlessness changed to include 3 separate options for CCG's to choose from. • Under section 4.13 Number of funded cycles, *'23-39'* changed to *'under 39'*. • The following paragraphs added under section 4.16 Policy Exclusions: *'Couples where one or both partners are undergoing or have undergone gender re-assignment can access services for the treatment and management of infertility however gamete storage is not available for this group at the time of transition surgery as gender reassignment is considered for the purposes of this policy to be a form of voluntary sterilisation. Reversal of sterilisation and IVF treatment as a result of sterilisation is not commissioned.'* and *'Any individuals outside these age ranges can apply via the IFR route, to avoid any delay in the start of treatment these requests will be dealt with as URGENT.'* • Under section 14 Glossary, the definition for *'Artificial Insemination (AI)'* changed to: *'Any method of introducing sperm to the female body other than by sexual intercourse – includes Intravaginal Insemination and Intrauterine insemination.'*
0.6	21/09/2016	The GM EUR Steering Group agreed all the changes made following the previous meeting and made the following further changes to the policy: • Introduction - In paragraph 8 the word *'available'* has been removed. In paragraph 10 the first sentence has been removed. • 2.3 Definition of Childlessness - The last paragraph title amended to read Option 3 not 2. • 4.3 Reversal of Sterilisation - Paragraph added: *'Reversal of vasectomy for reasons other than to restore fertility is commissioned e.g. to treat rare cases of post vasectomy pain.'* 4.13 Number of Cycles Funded • The first sentence in the last paragraph now reads *'until the woman's 40th birthday'* rather than *'42nd birthday'.* • The last sentence in the final paragraph amended from *'Extensions to the storage time or age limit will require an IFR request, the individual must be made aware of this at the time of storage.'* to read: *'Extensions to the storage time or age limit will require an IFR request for prior approval. The application should comply with the process for extension of the statutory storage period as outlined in the HFEA code of practice and should not take the period of cryopreservation over the statutory upper limit of 55 years, the individual must be made aware of this at the time of storage.'* 4.16 Policy Exclusions • Second paragraph removed. In the original third paragraph the following words added after *'infertility'* in the first sentence *'including gender reassignment'.* • The following paragraph added between the original third and fourth paragraphs *'All individuals should be informed at the time of storage that*

		if, at the time of treatment for infertility, surrogacy is the only option, this will not be funded by NHS commissioners in Greater Manchester' • The seventh and eight paragraphs reworded from '*Resultant embryos will be stored for 10 years in line with HFEA licencing requirements (or until a woman's 42nd birthday) provided the individuals are under the upper age limits of IVF treatment at the time of storage.* *Extensions to the storage time or age limit will require an IFR request, the individual must be made aware of this at the time of retrieval.'* to read '*Any resultant embryos will be stored for 10 years in line with HFEA licencing requirements (or until a woman's 42nd birthday) provided the individuals are under the upper age limits of IVF treatment at the time of storage.'* *Extensions to the storage time for sperm or oocytes or age limit for embryos will require an IFR request for prior approval. The application should comply with the process for extension of the statutory storage period as outlined in the HFEA code of practice and should not take the period of cryopreservation over the statutory upper limit of 55 years, the individual must be made aware of this at the time of storage.'* • The final paragraph in this section reworded from '*Any individuals outside these age ranges can apply via the IFR route, to avoid any delay in the start of treatment these requests will be dealt with as URGENT.'* to read '*Any individuals outside the specified age ranges above can apply via the IFR route, to avoid any delay in the start of treatment these requests will be dealt with as URGENT.'*
0.7	16/11/2016	Amendments made by the GM EUR Steering Group on 16/11/2016 following legal advice: • New policy format applied. • 'Funding Mechanism' boxes added where necessary throughout policy. • 1.12.1 Access Criteria and 6.3 Definition of Childlessness: the definition: *'A child adopted by a patient or adopted in a previous relationship is considered to have the same status as a biological child.'* added to Option 1 and Option 3's second sentence amended to read the same. • 1.13 Number of funded cycles: the word *'must'* added to the first paragraph and, in 2nd from bottom paragraph, '40th' amended to '42nd'. • 1.16 Policy Exclusions: the word 'therapy' removed from the 1st paragraph; the word 'including' changed to *'or'* in the 2nd paragraph; and; the word *'and'* added to the 6th paragraph. • 2. Policy Statement: the 2nd paragraph reworded to: *'In creating this policy GMSS has considered NICE guidance and taken account of the predecessor Greater Manchester policy in order to develop a policy of benefit to patients which makes the best use of available NHS resources.'* • References: Amended to incorporate the previous policy format's 'Documents which have informed this policy' section. Approved to go through the CCG Governance Process.
	12/04/2017	1.12.1 Access Criteria and 6.3 Definition of Childlessness): Whilst the policy was going through the CCG Governance Process the Directors of Commissioning requested the definition of childlessness be clarified and put into one statement.
1.0	01/08/2017	Approved by Greater Manchester Association Governing Group

1.1	21/08/2017	Note added to front of policy - From 21 August 2017, NHS-funded assisted conception services will not be included in the exemption from charge applicable to people who are caught within surcharge arrangements.
1.2	24/11/2017	Definition of premature ovarian failure added to 1.10.2: Use of Donor Oocytes and to 11: Glossary.
1.3	17/01/2018	• 1.6 Intrauterine Insemination: Bullet point *'single women (i.e. women not in a stable relationship)' added* • 1.7 Managing Unexplained Infertility: ○ In second paragraph, the words *'who have had their funding approved via the IFR route'* removed and *'to be carried out in a clinical setting'* added. ○ The last sentence *'All services should be offered in line with the recommendations of NICE CG156.'* moved before *'Do not offer'*. ○ *'(exceptional circumstances include, for example, when people have social, cultural or religious objections to IVF)'* added to the second bullet point under *'Do not offer'* • 1.10.1 Ovulation Disorders: ○ *'(unless they can show by an alternative measure to BMI that they have a normal body fat ratio).'* added to the first bullet point under *'Group I: hypothalamic pituitary failure...'* ○ The antral follicle count sentence removed following *'Premature ovarian failure is defined...'* in the second paragraph under *'Group III: ovarian failure'* and replaced with *'...as in the paragraph above.'* • 1.10.2 Use of Donor Oocytes: The antral follicle count detail removed from the first bullet point following *'premature ovarian failure'* and replaced with *'...occurring before the age of 40 years'* • 1.11.3 Endometriosis: Section replaced to read: *'Endometriosis should be managed in line with NICE NG73 Endometriosis: diagnosis and management.'* • 1.12 Managing Infertility with IVF: Fourth bullet point amended from *'...1 unit of alcohol per day'* to *'...the current Department of Health's recommendations for the consumption of alcohol'* • 1.12.1 Access criteria: The body mass index amended from *'19-29'* to *'19-30'*; *'BMI above 29'* amended to read *'BMI above 30 or below 19'*, and *'not clinically obese'* amended to read *'not clinically obese or too thin'*. • 1.13 Number of funded cycles: *'For women aged 40-42 (inclusive)'* amended to read *'40-42 (i.e. before her 43rd birthday)'* and *'42nd birthday'* amended to read *'43rd birthday'*. • 1.15 Switching providers: Removal of the word 'contract' from first paragraph. • 1.16 Policy Exclusions: *'Individuals under the age of 42'* amended to read *'Individuals under the age of 42 (i.e. prior to their 43rd birthday)'*; *'Individuals over the age of 42'* amended to read *'Individuals over the age of 42 (i.e. after their 43rd Birthday)'* and *'42nd birthday'* amended to read *'43rd birthday'*. • 6. Treatment / Procedure: Sixth paragraph amended to read *'This policy also applies to single women (i.e. women not in a stable relationship) who should be managed as for women in a same sex relationship however prior approval must be sought via the IFR (Exceptional Case) route if investigation and treatment shows that IVF is the best treatment option the application should clearly demonstrate the exceptional*

		circumstances with particular reference as to why the GM CCGs requirement for a stable relationship prior to undergoing IVF does not apply to them.' from 'This policy applies to single women in exceptional circumstances however prior approval must be sought via the IFR route and all applications for funding should clearly demonstrate the exceptional circumstances, these should be evidenced wherever possible.' • 6.1 Subfertility / Infertility: *'see NICE NG73'* added to second bullet point. ▪ 7.2.7 Alcohol: *'current'* added before *'Department of Health's'* and *'...of drinking no more than three to four units of alcohol a day'* amended to read *'for the consumption of alcohol'* • 11. Glossary: Definition of *'Premature ovarian failure'* amended.
	21/03/2018	Before the above changes were implemented the policy was sent back to GM EUR Steering Group to review the changes requested at the January meeting in relation to single women following advice from the Equality and Diversity Team. The GM EUR Steering Group agreed the following changes would **no longer** be made to the policy: • 1.6 Intrauterine Insemination: Bullet point *'single women (i.e. women not in a stable relationship)' added 17/1/2018 –* ***removed 21/03/2018*** • 1.7 Managing Unexplained Infertility: • In second paragraph, the words *'who have had their funding approved via the IFR (Exceptional Case) route'* removed 17/1/2018 – **added back in 21/03/2018** The following amendments were also made for clarify: • Where appropriate, instances of *'IFR'* or *'EUR'* throughout policy were amended to read *'IFR (Exceptional Case)'* or *'IPA'* and funding mechanisms were also clarified.
2.0	19/09/2018	Reviewed at GM EUR Steering Group where the following changes were made: • Section 1. Commissioning Statement o Link added to NICE CG156. o Paragraph added regarding who funds treatment. o Following sentence removed from the funding mechanism *'in some cases this will include monitored approval or, where stated in this policy, individual prior approval.'* • Section 1.4 Surrogacy: Link added to *'GOV UK guidance: Having a child through surrogacy'* at the end of the section. • Section 1.9.1 Surgical Recovery of Sperm: In final paragraph link add to *'NHS England: 16040/P – Clinical Commissioning Policy: sperm retrieval for male infertility'*. • Section 1.10.1 Ovulation Disorders o Following sentence added: *'Please refer to GMMMG website for up to date guidance on any restrictions to drugs.'* o Under *'Group II' – 'First line treatment'* the following added to the first bullet point: *'who have a BMI over 30'* • Section 1.13 Number of funded Cycles The following paragraph reworded from: *'If treatment resulted in a live birth before all the viable embryos were implanted the remaining embryos should be cyropreserved for either 10 years (in line with HFEA*

		guidance) or until the woman's 43rd birthday – whichever is shorter. Implantation of these embryos will not be funded by the NHS locally but they are available to the individual for private treatment.' to *"If treatment resulted in a live birth before all the viable embryos were implanted the remaining embryos should be cryopreserved for 10 years in line with HFEA guidance. Implantation of these embryos will not be funded by the NHS locally but they are available to the individual for private treatment.'* • Section 1.16 Policy Exclusions: *'(or until a woman's 43rd birthday)* removed from the 7th paragraph • Section 10. Date of Review: Amended to *'Three years'* The above changes were not considered to be material and therefore it was not necessary for the amended policy to go back through the governance process again.
2.1	21/01/2019	• 2: Policy Statement, 3: Equality & Equity Statement: References to GMSS changed to GMHCC. • 4: Governance Arrangements: Updated to reflect change of governance and link to GM EUR Operational Policy updated to new address.
2.2	16/01/2019 18/09/2019	GM EUR Steering Group approved the new layout of the policy template, which would make it more user friendly. New layout of policy reviewed by GM EUR Steering Group and the following changes were made:- Policy Exclusion Section **Recurrent miscarriage** – The following sentence has been added *'IVF/ICSI is not commissioned for recurrent miscarriage unless part of PGD which requires application to NHS England.'* Policy Inclusion Criteria **Change of provider to access donor eggs** - The following paragraphs have been added:- *Donor eggs for women under 40 years will be commissioned if the woman has failed to produce viable eggs on a regular basis and has been assessed by a fertility specialist and found to have premature ovarian failure.* *For women over 40 years see below - 'IVF for women aged 40-42 (inclusive)'* **Previous sterilisation** – This has been reworded for clarity and a funding mechanism of Individual Prior Approval added. **IVF for women aged 40-42 (inclusive)** – The following has been added Their single cycle of IVF can be carried out with donor eggs if one of the following applies: • total antral follicle count (AFC) of less than or equal to 4 • anti-Müllerian hormone (AMH) of less than or equal to 5.4 pmol/l • follicle-stimulating hormone (FSH) greater than 8.9 IU/l these are the risk factors for a poor ovarian response in this gage group as laid by NICE in 2013.

	20/11/2019 20/01/2020	**Definitions of IVF Cycles** – The following has been added to the funding mechanism '*Cycles where the treatment is for the partner of a previously sterilised individual who has undergone a clinically successful reversal: Individual prior approval – requires a statement from a clinician confirming successful reversal.'* **Use of Donor Oocytes** – The 5th bullet point amended from *'certain cases of IVF treatment failure'* to *'unexplained (or repeated) failure of ovarian stimulation during of IVF treatment '* GM EUR Steering Group approved the changes that had been made to the policy since the last meeting and agreed the following changes:- Clarified wording on funding for single women:- **Managing Unexplained Fertility** – Second paragraph reworded for clarity & **Treatment / Procedures** – Sixth paragraph reworded for clarity. Steering Group members agreed that the policy would not need to go through the governance process again as the changes made to the policy were still in line with NICE CG156. **Private Sector to NHS and Switching Providers** – The following has been added for clarity *e.g. If an NHS commissioner (or commissioners if the couple have moved areas) has funded two cycles and the individual has funded one privately , they have undergone three cycles and are therefore at their maximum under this policy. The limit of three cycles applies to the number of cycles undergone by the couple irrespective of who has funded each of those cycles.*
2.3	28/02/2020	**Reversal of sterilisation** (Page 6) The following wording has been amended to correspond with the funding mechanism on page 9 which states that '*cycles of IVF where the treatment is for the partner of a previously sterilised individual who has undergone a clinically successful reversal Individual prior approval. Requires a statement from a clinician confirming successful reversal.'* From; ***NOTE**: Where subfertility remains after reversal of sterilisation, assisted conception will not be funded routinely. Where proof is supplied of successful reversal of, and if the infertility issues are with the partner, IVF applications can be submitted via the IFR (Exceptional Case) route for consideration. IVF in these cases must be to treat infertility in the not (previously) sterilised partner* To;

		***NOTE**: Where subfertility remains after reversal of sterilisation, assisted conception will not be funded routinely. Where proof is supplied of a clinically successful reversal of sterilisation, and the infertility issues are with the partner, prior approval for IVF needs to be sought via the EUR route. Applications must include a statement from a clinician that the reversal was successful. IVF in these cases must be to treat infertility in the not (previously) sterilised partner.*
3.0	20/05/2020	Previous sterilisation – The final sentence has been amended for clarity. From:- *However where a partner has had a successful reversal of sterilisation and the infertility to be treated is in the other (not previously sterilised) partner then application can be made via the EUR route.* TO:- *However where a partner has had a successful reversal of sterilisation and the infertility to be treated is in the other (not previously sterilised) partner or the couple have been diagnosed with unexplained infertility, then application can be made via the EUR route* Equality and Equity Statement – GM EUR Policy Team email address updated
	18/11/2020	Policy Template reviewed at GM EUR Steering Group and the following changes were agreed: Cover Page Government issued Statutory Instrument - amended as follows (this has also been amended on page 13) o This is brought forward through regulations 11, 12 and 13 of ***the above-named*** instrument, which insert a new regulation (9A) and amend regulation 10 and 11 respectively ***to the National Health Service (Charged to Overseas Visitors) Regulations 2015.*** o Exemption ***from charges*** currently applies to: The following paragraph has been added '*In the operation of this policy, the CCG will have regard to the Human Fertilisation and Embryology Act 1990 (as amended) which provides that a woman shall not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for supportive parenting).'* Commissioning Statement Policy Exclusion Section - The following paragraph has been added; *"Prior to offering treatment covered by this policy, the individuals seeking assisted conception should be advised of the need for period of expectant management. They should have tried to conceive for a total of 2 years (The period of expectant management after diagnosis and up to 1 year before their fertility investigations began) before IVF will be considered. For same sex couples and single women offer a further 6 cycles of IUI post referral, to be carried out in an NHS clinical setting, in addition to the self-funded 6 cycles of self-reported vaginal insemination undertaken prior to referral (as the equivalent of expectant management in a heterosexual couple) or 3 cycles if aged over 36 years."*

		Sperm, oocyte or embryo storage to retain fertility – this section has been updated Pre-Implantation Genetic Diagnosis and sperm retrieval along with referral for genetic counselling moved to a new 'NHS England Commissioned Services' section of the policy. Research and local pathways – has been given its own section. A 'Not commissioned' section added for clarity, with 'Surrogacy' has been moved to this section Policy Inclusion Criteria – The words 'included but restrictions apply' have been added to the title. The first paragraph has been amended from '*Assisted conception care is generally commissioned in line with NICE CG156: Fertility problems: assessment and treatment, except for those interventions specifically mentioned in the following section:' to read '*Assisted conception care is generally commissioned in line with NICE CG156: Fertility problems: assessment and treatment. *Pages 6 to 13 summarise areas where qualifying criteria apply or that are not covered by CG156'* Access Criteria for IVF/ICSI – The following has been added to the first paragraph '(see appendix one for full definitions in line with NICE CG 156'. The seconded paragraph amended from 'who meet the following criteria' to read 'who meet the criteria as set out in this policy.' Number of cycles of IVF Funded a section has been added on HFEA guidance – Welfare of the Child'. Also funding the wording of the funding mechanism for cycles of IVF for single women has been amended to reflect this. Sperm, oocyte or embryo storage to retain fertility - the following sentence has been added 'There is no upper age limit for the storage of sperm. Storage of viable embryos - the following sentence has been added *'*Storage will be funded within the general contract in line with HFEA regulations- if the storage time in these regulations reduces, then the woman must be informed and allowed to request an extension to storage time via the IFR route.' Treatment / Procedure Section paragraphs 4, 5 & 6 have been amended and the final paragraph below removed '*Reversal of sterilisation and IVF treatment as a result of sterilisation is not commissioned in Greater Manchester*.' Glossary Section – The definitions for 'Infertility' and 'Subfertility' have been added. The definitions of the funding mechanisms with the policy have also been added Appendix 1 – The title of the appendix has been amended

		Surgical recovery of sperm – The following sentence has been removed; '*There is limited evidence available on the effectiveness of these techniques and surgical recovery of sperm is not included in NICE CG156'* Managing Unexplained Infertility **-** the following sentence has been amended; "For single women approval must be sought via the IFR (Exceptional Case) route for IVF. ***The application should contain a copy of the HFEA welfare of the child form."***
	20/01/2021	GM EUR Steering Group approved the changes that had been made to the policy template since the last meeting and agreed the following further changes:- A foot note has been added to the policy to state; "the policy is the predominant document and NICE CG156 is appended to provide clarity'. Policy Inclusion Criteria - The 'Intrauterine Insemination' section was moved to above the 'Access Criteria for IVF/ICSI' section. Number of cycles of IVF funded – The wording in the sentence regarding funding for women aged 40-42 was amended in relation to a second attempt at a full cycle. Under the 'Definition of IVF Cycles' the wording for 'Full cycle' was amended to reflect the use of donor eggs. Following these amendments it was agreed the policy template could go out for a period of clinical engagement.
	19/05/2021	GM EUR Steering Group agreed to the following further changes to be made to the policy template following feedback received during the period of clinical engagement:- Commissioning statement Policy Exclusions section: Sperm, oocyte or embryo storage to retain fertility The following paragraph has been amended: "Individuals undergoing treatment for cancer (or for any lifesaving treatment resulting in infertility) or gender reassignment ***or as part of the management of a congenital condition which will affect fertility in later life,*** and who are well enough to undergo the required procedures, should be offered sperm or egg retrieval and storage provided this does not put them at risk of serious adverse health effects from either a delay in treatment or from the procedure needed to retrieve the egg / sperm. The resultant sperm, eggs or embryos will be stored in line with current HFEA regulations. Currently, there is no upper age limit for sperm. However, there is an upper age limit of 43 for eggs and embryos. These should be stored and used in line with HFEA regulations." The following wording was added regarding when restrictions apply for clarity; "***The only treatments where restrictions will apply to these individuals are 1) eligibility for IVF/ICSI, if they require more than the currently commissioned cycles or do not meet the criteria they can***

		make an application for exceptionality and 2) Surrogacy is not commissioned by the NHS" The abbreviations "PlGD, TESSE and micro-TESSE" were amended to "PGD, TeSe and MicroTeSE". <u>Policy criteria – not commissioned section (Surrogacy):</u> The definition of surrogacy was removed. <u>Policy Inclusion criteria; Number of cycles of IVF funded</u> The following wording was added to the paragraph relating to treatment commencing the patient's 43rd birthday; "if waiting times will take them beyond their 43rd birthday, they can apply via the IFR (exceptionality) route for transfer of care" The wording in the paragraph relating to a second attempt at a full cycle was amended to " A single second attempt at a full cycle, with their own or donor eggs as appropriate, may be commissioned if the first attempt ends in a cancelled or abandoned cycle (this requires an application for prior approval and MUST commence before the woman's 43rd birthday.)" The following paragraph has been added; "**NOTE**: If a woman changes her registered practice to one that comes under a different CCG which offers a different number of IVF cycles – eligibility will depend on the number of IVF cycles offered by the CCG where she is currently registered." <u>Sperm, oocyte or embryo storage to retain fertility:</u> The following wording was added; "If individuals move away from the area where their gametes or embryos are stored, they can apply via the IFR (exceptional case) route for the transfer of those embryos to their current area of residence, or for the cost of storage to be met by their new CCG" <u>Access to donor eggs</u> The wording in the sentence regarding donor eggs for women under 40 was amended from" '*has failed to produce viable eggs on a regular basis*" to "*has a condition which means no viable eggs can be produced OR has been assessed by a fertility specialist and found to have premature ovarian failure."* <u>Intrauterine Insemination</u> A bullet point for single women was added to this section <u>Switching providers</u> The wording in this section relating to number of funded cycles was amended to; "The actual number of cycles will depend on the number currently offered by the CCG **(the relevant CCG is determined by the surgery which the female partner is registered with**.)" <u>Audit requirements:</u> This was amended to read "The HFEA maintains a record of all assisted conception cycles on a national database".

	13/07/2021	Date of review This was amended to one year Following the above changes the GM EUR Steering Group approved the policy to go through the governance process. Version 3.0 of the policy template was approved for implementation by the GM Directors of Commissioning
3.1	17/11/2021	GM EUR Steering Group agreed the policy template be amended as follows: Funding Mechanism for IVF Deleted that IVF for single women is via IFR (exceptional case) route. Now reads that *Cycles of IVF up to the number funded by the CCG for all women: Monitored approval provided that all steps have been taken to ensure the welfare of the child as per the HFEA statement above. May be subject to audit or contract challenge.* Treatment/Procedure - Changed from: *This policy also applies to single women who should be managed as for women in a same sex relationship up to the point when investigation and treatment shows that IVF is the best treatment option at this point approval must be sought via the IFR (exceptional case) route. The application should confirm that all steps have been taken to ensure the welfare of the child as per the HFEA statement above. NOTE as per HFEA guidance: "A woman shall not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for supportive parenting), and of any other child who may be affected by the birth". 'Supportive parenting is a commitment to the health, wellbeing and development of the child. It is presumed that all prospective parents will be supportive parents, in the absence of any reasonable cause for concern that any child who may be born, or any other child, may be at risk of significant harm or neglect. Where centers have concern as to whether this commitment exists, they may wish to take account of wider family and social networks within which the child will be raised.*' **To read:** *This policy applies to all women provided all steps have been undertaken to ensure the welfare of the child as per HFEA guidance: "A woman shall not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for supportive parenting), and of any other child who may be affected by the birth". 'Supportive parenting is a commitment to the health, wellbeing and development of the child. It is presumed that all prospective parents will be supportive parents, in the absence of any reasonable cause for concern that any child who may be born, or any other child, may be at risk of significant harm or neglect. Where centres have concern as to whether this commitment exists, they may wish to take account of wider family and social networks within which the child will be raised.'*

		Managing Unexplained Infertility - The following paragraph has been removed: *For single women approval must be sought via the IFR (exceptional case) route for IVF. The application should contain a copy of the HFEA welfare of the child form.*
	10/12/2021	Version 3.1 of the policy template was approved for implementation by the GM Directors of Commissioning