

# Oldham Clinical Commissioning Group:

## Assisted Conception Policy

Version: 2.0 (19 September 2018)

### 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 this instrument, which insert a new regulation (9A) and amend regulation 10 and 11 respectively.

Exemption 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.

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## 1. Commissioning Statement

Assisted conception care is commissioned in line with [NICE CG156: Fertility problems: assessment and treatment](#), except where a CCG has opted for a variation in the number of IVF cycles offered. Please see [Section 1.13 Number of funded cycles](#) and [Section 8 Adherence to NICE Guidance](#).

Individual treatments are funded by the CCG with whom the patient is registered, with the exception of those treatments where the specified commissioner is NHS England. When treating a couple, it is the female partner's CCG that is the responsible CCG. In same sex (female) couples it will be the CCG with whom the patient wishing to carry the pregnancy is registered.

### Funding Mechanism

Unless otherwise stated in the policy funding will be via the normal local contracting arrangements.

#### 1.1 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.

#### 1.2 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

#### 1.3 Reversal of Sterilisation

The surgical reversal of either male or female sterilisation will not be funded routinely.

In cases where the sterilisation was carried out to treat an underlying condition and not for family planning purposes, applications for funding the reversal of the sterilisation can be made via the IPA route. All relevant clinical information should be included with the application.

Reversal of vasectomy for reasons other than to restore fertility e.g. to treat rare cases of post vasectomy pain is commissioned. Applications for funding the reversal of vasectomy can be made via the IPA route. All relevant clinical information should be included with the application.

Sub-fertility treatment will not normally be provided where sub-fertility is the result of a sterilisation procedure in either partner. Where subfertility remains after reversal of sterilisation, assisted conception will not be funded routinely. Where proof is supplied of successful reversal of sterilisation and if the infertility issues are with the partner IVF applications can be submitted via the IFR (Exceptional Case) route for consideration.

### Funding Mechanism

Reversal of sterilisation done as a result of an underlying condition: Individual prior approval at Clinical Triage. Requests must be submitted with all relevant supporting evidence.

Reversal of vasectomy for reasons other than to restore fertility: Individual prior approval at Clinical Triage. Requests must be submitted with all relevant supporting evidence.

Reversal of sterilisation done for family planning purposes: Individual funding request (exceptional case) approval: Requests must be submitted with all relevant supporting evidence.

## 1.4 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.

For the purposes of both the Human Fertilisation and Embryology Acts and the nationality legislation, the surrogate mother is to be treated as the mother of the child. Paternity is more complicated and will depend on the legislation in place at the time of the birth<sup>3,4</sup>.

For the commissioning parents to become the legal parents a parental order must be made according to the active legislation at the time of the child's birth<sup>4</sup>.

The citizenship status of the child will depend on one of the commissioning couple being a British Citizen at the time the parental order came into effect<sup>4</sup>.

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](#).

## 1.5 Managing Viral Status

People who are concerned about their fertility and who are known to have chronic viral infections such as Hepatitis B, Hepatitis C or HIV should be referred to centres that have appropriate expertise and facilities to provide safe risk-reduction investigation and treatment. Fertility management should be discussed between the couple, a fertility specialist and a specialist in blood borne viruses.

Where indicated using the criteria in NICE CG156 patients should be referred for sperm washing at a centre with the appropriate expertise.

Sperm washing is particularly indicated for:

- couples where the man is HIV positive and is either non-compliant with HAART (highly active anti-retroviral therapy) or his plasma viral load is 50 copies per ml or greater
- couples who still perceive a risk after discussion with their HIV specialist

For Hepatitis:

- Offer vaccination for individuals whose partner has Hepatitis B prior to starting fertility treatment
- Men with Hepatitis C should discuss treatment options for the eradication of their Hepatitis with their specialist before conception is considered

All Investigation and treatment aimed at managing viral status during fertility treatment should be offered in line with NICE CG156.

## 1.6 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

## 1.7 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%<sup>5</sup>.

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 who have had their funding approved via the IFR (Exceptional Case) route offer a further 6 cycles of IUI post referral, to be carried out in a 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 or letrozole) 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)

## 1.8 Managing Male Factor Infertility

### 1.8.1 Hypogonadism

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

### 1.8.2 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.

## 1.9 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.

### 1.9.1 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.

## 1.10 Managing Female Infertility

### 1.10.1 Ovulation Disorders

Please refer to [GMMMG website](#) for up to date guidance on any restrictions to drugs.

The World Health Organization classifies<sup>6</sup> 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 hypogonadotropic 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.

#### **1.10.2 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
- certain cases of IVF treatment failure

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.

## **1.11 Tubal and Uterine Abnormalities**

### **1.11.1 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.

### **1.11.2 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.

### 1.11.3 Endometriosis

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

## 1.12 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

### 1.12.1 Access criteria<sup>2</sup>

All couples referred for IVF must have had their infertility investigated and managed in line with NICE CG156 prior to referral.

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.'*

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.

Infertility must not be as a result of previous sterilisation for family planning reasons. Where a partner has had a successful reversal of sterilisation and the infertility to be treated is in the other partner then application can be made via the IFR (Exceptional Case) route, all relevant clinical information should be included with the application.

The female body mass index must 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 – application for funding in this case is via the IFR (Exceptional Case) route and must include the alternative measure of body fat. Obtaining the alternative measure is the responsibility of the individual and must be self-funded.).

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).

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

### 1.13 Number of funded cycles

The total number of cycles undertaken as listed below added to those funded privately must not exceed 3. Where cycles have been funded privately, the CCG will take this into account when determining how many cycles to fund in accordance with the below.

For women aged 39 and under:

The CCG funds 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.

For women aged 40-42 (i.e. before her 43<sup>rd</sup> birthday), 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)
- There is no evidence of low ovarian reserve
- There has been a discussion about the implications of IVF at this age

Treatment must have commenced before the woman's 43<sup>rd</sup> birthday.

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.

Extensions to the storage time or age limit 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.

### 1.14 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.

### 1.15 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 the CCG has a current arrangement with that provider.

Individuals who have undergone privately funded cycles will still have a 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).

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 (Exceptional Case) route to fund the safe transfer of the frozen material from the old to the new provider.

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 IPA route, as NHS providers cannot offer an egg share scheme under current NHS rules.

### **Funding Mechanism**

Transfer of frozen material from old to new provider: Individual funding request (exceptional case) approval: Requests must be submitted with all relevant supporting evidence.

Use of donor eggs: Individual prior approval at Clinical Triage. Requests must be submitted with all relevant supporting evidence.

### **1.16 Policy Exclusions**

Individuals undergoing sperm, oocyte or embryo storage to retain fertility post chemotherapy or radiotherapy for cancer (or for any lifesaving treatment resulting in infertility) are excluded from the restrictions within this policy. Patients rendered infertile following cancer (or for any lifesaving treatment resulting in infertility) are not restricted in their access to assisted conception with the exception of IVF where they will need to meet the qualifying criteria and will be eligible for the same number of cycles as other infertile couples.

Individuals under the age of 42 (i.e. prior to their 43<sup>rd</sup> birthday) undergoing treatment for cancer (or for any lifesaving treatment resulting in infertility) or gender reassignment, 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.

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 43<sup>rd</sup> Birthday) with exceptional reasons for requesting gamete storage can apply via the IFR (Exceptional Case) route.

Individuals undergoing retrieval and storage should be managed in line with NICE CG156.

Storage of retrieved sperm and oocytes will be for 10 years in line with HFEA licencing requirements

Any resultant embryos will be stored for 10 years in line with HFEA licencing requirements, provided the individuals are under the upper age limits for IVF treatment at the time of storage.

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.

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.

#### **1.16.1 Pre-Implantation Genetic Diagnosis (PIGD)**

This is currently commissioned by NHS England and application should be made through them.

Referral for genetic counselling for couples not qualifying for PIGD should be done as indicated in NICE CG156.

### **1.16.2 Claiming Exceptionality to the policy**

Clinicians can submit an Individual Funding Request (IFR) outside of this guidance if they feel there is a good case for exceptionality.

Exceptionality means 'a person to which the general rule is not applicable'. Greater Manchester sets out the following guidance in terms of determining exceptionality; however the over-riding question which the IFR process must answer is whether each patient applying for exceptional funding has demonstrated that his/her circumstances are exceptional. A patient may be able to demonstrate exceptionality by showing that s/he is:

- Significantly different to the general population of patients with the condition in question.

#### ***and as a result of that difference***

- They are likely to gain significantly more benefit from the intervention than might be expected from the average patient with the condition.

## **2. Policy Statement**

Greater Manchester Shared Services (GMSS) Effective Use of Resources (EUR) Policy Team in conjunction with GM EUR Steering Group have developed this policy on behalf of Clinical Commissioning Groups (CCGs) within Greater Manchester, who will commission treatments/procedures in accordance with the criteria outlined in this document.

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.

This policy document outlines the arrangements for funding of this treatment for the population of Greater Manchester.

This policy follows the principles set out in the ethical framework that govern the commissioning of NHS healthcare and those policies dealing with the approach to experimental treatments and processes for the management of individual funding requests (IFR).

## **3. Equality & Equity Statement**

GMSS/CCGs have a duty to have regard to the need to reduce health inequalities in access to health services and health outcomes achieved, as enshrined in the Health and Social Care Act 2012. GMSS/CCG is committed to ensuring equality of access and non-discrimination, irrespective of age, gender, disability (including learning disability), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, gender or sexual orientation. In carrying out its functions, GMSS/CCG will have due regard to the different needs of protected characteristic groups, in line with the Equality Act 2010. This document is compliant with the NHS Constitution and the Human Rights Act 1998. This applies to all activities for which they are responsible, including policy development, review and implementation.

In developing policy the GMSS Policy Team will ensure that equity is considered as well as equality. Equity means providing greater resource for those groups of the population with greater needs without disadvantage to any vulnerable group.

The Equality Act 2010 states that we must treat disabled people as *more equal* than any other protected characteristic group. This is because their 'starting point' is considered to be further back than any other group. This will be reflected in GMSS evidencing taking 'due regard' for fair access to healthcare information, services and premises.

An Equality Analysis has been carried out on the policy. For more information about the Equality Analysis, please contact [policyfeedback.gmscu@nhs.net](mailto:policyfeedback.gmscu@nhs.net).

## 4. Governance Arrangements

Greater Manchester EUR policy statements will be ratified by the Greater Manchester Association Governing Group (AGG) prior to formal ratification through CCG Governing Bodies. Further details of the governance arrangements can be found in the Greater Manchester EUR Operational Policy.

## 5. Aims and Objectives

This policy document aims to ensure equity, consistency and clarity in the commissioning of treatments/procedures by CCGs in Greater Manchester by:

- reducing the variation in access to treatments/procedures.
- ensuring that treatments/procedures are commissioned where there is acceptable evidence of clinical benefit and cost-effectiveness.
- reducing unacceptable variation in the commissioning of treatments/procedures across Greater Manchester.
- promoting the cost-effective use of healthcare resources.

## 6. 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.

This policy assumes that all services are provided in line with the requirements of NICE CG156 and that the provider's prescribers will use a drug's summary of product characteristics to inform the treatment decisions relating to individual patients.

This policy applies to all couples in a stable relationship including same sex couples and couples who have a stable relationship at the time of treatment. The commissioning CCG is the one where the female partner wishing to be the biological mother is resident.

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.

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 NHS commissioners in Greater Manchester.

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

Reversal of sterilisation and IVF treatment as a result of sterilisation is not commissioned in Greater Manchester.

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.

## **6.1 Subfertility / Infertility**

Where a woman of reproductive age (post menarche – pre-menopause) has not conceived after 1 year of unprotected sex (6 months aged over 36 years), the couple should be referred for investigation into causes of infertility. For women in a same sex relationship, 6 attempts at artificial insemination would be considered the equivalent of 1 years unprotected sex (3 cycles if aged over 36 years). If the woman is aged 36 years or older or has a previously identified cause of infertility (or a history of pre-disposing factors for infertility) then referral should occur earlier.

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 – see NICE NG73)
- 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.

All patients should be offered access to clinical investigations if they have sub-fertility of at least 1 year duration (6 months for women aged 36 and over) and offered assisted conception if they have sub-fertility of at least 2 years duration (12 months for women aged 36 and over). The second 12 month period (6 months for women aged 36 and over) being a time of expectant management, which is a formal approach that encourages conception through unprotected vaginal intercourse. It involves supportively offering an individual or couple information and advice about the regularity and timing of intercourse and any lifestyle changes which might improve their chances of conceiving. It does not involve active clinical or therapeutic interventions.

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.

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.

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

## **6.2 Definitions of IVF Cycles**

### **6.2.1 Full Cycle**

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.



### 6.2.2 Cancelled Cycle

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

### 6.2.3 Abandoned Cycle

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

## 6.3 Definition of Childlessness

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.

## 6.4 Rationale behind the policy statement

Investigation, diagnosis and subsequent treatment for individuals with fertility issues is a complex and constantly developing field. The current Greater Manchester Assisted Conception policy needs updating in light of the recent NICE CG156 and as a result of increasing variation to the current policy across Greater Manchester. This policy is aimed at ensuring consistency of approach in the referral, investigation, diagnosis and treatment of individuals with fertility issues across Greater Manchester.

## 7. 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 (percentage figures indicate approximate prevalence)<sup>1</sup>:

- 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.

### 7.1 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%.<sup>1</sup>

### 7.2 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.

#### 7.2.1 Problems with the Testicles

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<sup>1</sup> Data from NICE CG156



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)

### **7.2.2 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.

### **7.2.3 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.

### **7.2.4 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

### **7.2.5 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).

### **7.2.6 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.

### **7.2.7 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.

## 7.3 Female Factor Infertility

### 7.3.1 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

### 7.3.2 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 woman 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.

### 7.3.3 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.

### 7.3.4 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.

## 8. Adherence to NICE Guidance

This policy adheres fully to the recommendations made in NICE CG156.

## 9. Audit Requirements

There is currently no national database. Service providers will be expected to collect and provide audit data on request.

## 10. Date of Review

Three years 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.

## 11. 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 can not be seen by ultrasound.
Antisperm antibodies	Blood proteins produced in 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.
Hyperprolactinaemia	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	Hypothalamic dysfunction is a problem with the region of the brain called the hypothalamus, which helps control the pituitary gland and regulate

amenorrhoea or hypogonadotropic hypogonadism)	many body functions. The pituitary, in turn, controls the: <ul style="list-style-type: none"> <li>• Adrenal glands</li> <li>• Ovaries</li> <li>• Testes</li> <li>• Thyroid gland</li> </ul>
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).
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 (PIGD)	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.
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.

## 12. 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.

## 13. References

1. Greater Manchester Effective Use of Resources 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](http://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

## 14. Governance Approvals

Name	Date Approved
Greater Manchester Effective Use of Resources Steering Group	16/11/2016
Greater Manchester Chief Finance Officers / Greater Manchester Directors of Commissioning	13/06/2017
Greater Manchester Association Governing Group	01/08/2017
Oldham Clinical Commissioning Group	04/09/2017



## Appendix 1 – Version History

The latest version of this policy can be found here: [Oldham CCG Assisted Conception Policy](#)

Version	Date	Details
0.1	29/04/2015	Initial draft
0.2	24/08/2015	<p>Changes made following the GM EUR Steering Group Meeting on the 8<sup>th</sup> July 2015:</p> <ul style="list-style-type: none"> <li>• <u>Section 1 Introduction (single women)</u> - Final paragraph amended to read as follows: <i>'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.'</i></li> <li>• <u>Section 2.1 Subfertility / Infertility (same sex couples)</u> - 4<sup>th</sup> paragraph amended to read as follows: <i>'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).'</i></li> </ul> <p><u>Section 4.3 Reversal of Sterilisation</u></p> <ul style="list-style-type: none"> <li>• The Steering Group agreed to include the following option in this section: <i>'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.'</i></li> <li>• Further sentence added to the second paragraph as follows: <i>'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.'</i></li> <li>• <u>Section 4.4 Surrogacy</u> - The Steering Group agreed that following statement should be included in this section of the policy template: <i>'The NHS does not fund any type of surrogacy arrangement. Commissioning parents must undertake the whole process privately.'</i></li> </ul> <p><u>Section 4.7 Managing Unexplained Infertility</u></p> <ul style="list-style-type: none"> <li>• The final sentence of the second paragraph has been amended to read as follows: <i>'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).'</i></li> <li>• The following wording has been removed from this section: <i>'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.'</i></li> <li>• <u>Section 4.10 Managing Female Infertility (Group III: ovarian failure)</u> - A definition of premature menopause and a statement about premature or iatrogenic ovarian failure added to this section of the policy template.</li> </ul> <p><u>Section 4.13 Number of funded cycles</u></p> <ul style="list-style-type: none"> <li>• Wording slightly amended in the section to read <i>'may allow'</i> rather than <i>'allows'</i>.</li> <li>• Wording amended to read: <i>'for women aged 40-42 (inclusive), the CCG</i></li> </ul>



		(NWCSU) changed to Greater Manchester Shared Services (GMSS)
0.4	16/03/2016	<p>GM EUR Steering Group reviewed the draft policy template on 16 March 2016 following legal advice and the following changes were approved:</p> <ul style="list-style-type: none"> <li>• Minor spelling/grammatical errors amended throughout the document as well as wording changed as follows: <ul style="list-style-type: none"> <li>○ <i>'Reviewed this clinical condition'</i> to be replaced with <i>'considered the range of causes of fertility problems'</i></li> <li>○ <i>'Does not'</i> to be replaced with <i>'has not been shown to'</i></li> <li>○ <i>'Does not'</i> to be replaced with <i>'is not shown to'</i> and <i>'research suggests it'</i></li> <li>○ <i>'The effect of'</i> to be inserted before pulsatile gonadotrophin-releasing hormone</li> <li>○ <i>'This'</i> to be replaced with <i>'research indicates that this'</i></li> </ul> </li> <li>• The last sentence under section '1. Introduction' removed which read: <i>'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).'</i></li> <li>• Changes made throughout the policy template to ensure requirements are consistent for women over 36.</li> <li>• The word <i>'only'</i> added to the last paragraph of section '4.9.1 Surgical recovery of sperm' which reads <i>'Requests for funding these techniques in non-cancer patients with azoospermia should <b>ONLY</b> be made....'</i></li> <li>• Under section 4.10.1 under 'Group III: ovarian failure' the start of the first sentence amended to read: <i>'Treatment will be commissioned for women with...'</i></li> <li>• Under section 4.12.1 in the 5<sup>th</sup> paragraph, first sentence reworded to read: <i>'Both partners must be non-smoking and not using any product containing nicotine in order...'</i></li> <li>• <i>'40<sup>th</sup> birthday'</i> in the last paragraph under section 4.13 amended to <i>'42<sup>nd</sup> birthday'</i>.</li> <li>• The statement: <i>'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.'</i> added to the end of the last paragraph in section 4.13 as per section 4.16.</li> <li>• Under section 4.15 in the 5<sup>th</sup> paragraph, <i>'storage of retrieved sperm, oocytes or resultant embryos...'</i> amended to read: <i>'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 42<sup>nd</sup> 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.'</i></li> <li>• Comma added after <i>'Storage of retrieved sperm'</i> and before <i>'oocytes'</i> in section 4.16.</li> <li>• <i>'4.16.2 Claiming Exceptionality to the policy'</i> added as a heading in order to separate the section which relates to exceptionality.</li> <li>• Wording for date of review amended to read <i>'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)'</i> on 'Policy Statement' and section 13. Date of Review.</li> </ul> <p>Following the amendments it was agreed the policy template could go out for a period of clinical engagement.</p>

0.5	20/07/2016	<p>The GM EUR Steering Group reviewed the clinical engagement feedback and agreed the following changes to the policy template:</p> <p><u>Section 1 Introduction</u></p> <ul style="list-style-type: none"> <li>• The words <i>'but are not co-habiting'</i> taken out of paragraph 6.</li> <li>• The following paragraphs added: <ul style="list-style-type: none"> <li>○ <i>'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.'</i></li> <li>○ <i>'Transgender patients should be managed as their preferred sex at all stages of investigation and treatment.'</i></li> <li>○ <i>'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.'</i></li> <li>○ <i>'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.'</i></li> </ul> </li> <li>• The fourth paragraph under section 2.1 Sub-Fertility amended to read: <i>'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.'</i> and the following paragraph added: <i>'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.'</i></li> <li>• The paragraph under section 2.3 Definition of Childlessness changed to include 3 separate options for CCG's to choose from.</li> <li>• Under section 4.2 Investigating Female Infertility' the following added to the end of the first paragraph: <i>'in the appropriate primary or secondary care setting as indicated clinically'</i></li> <li>• In paragraph 2 under section 4.7 Managing Unexplained Infertility, <i>'AI or IUI'</i> changed to <i>'IUI'</i> and <i>'self-reported'</i></li> <li>• The final sentence in section <i>'4.9 Managing Female Infertility'</i> changed to: <i>'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.'</i></li> <li>• The sentence <i>'as it is the nicotine in tobacco that may reduce fertility'</i> added to the 5th bullet point under section 4.12 Managing Infertility with IVF.</li> <li>• Under section 4.12.1 Access criteria the definition of childlessness changed to include 3 separate options for CCG's to choose from.</li> <li>• Under section 4.13 Number of funded cycles, <i>'23-39'</i> changed to <i>'under 39'</i>.</li> <li>• The following paragraphs added under section 4.16 Policy Exclusions: <i>'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.'</i> and <i>'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.'</i></li> </ul>
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		<ul style="list-style-type: none"> <li>Under section 14 Glossary, the definition for <i>'Artificial Insemination (AI)'</i> changed to: <i>'Any method of introducing sperm to the female body other than by sexual intercourse – includes Intravaginal Insemination and Intrauterine insemination.'</i></li> </ul>
0.6	21/09/2016	<p>The GM EUR Steering Group agreed all the changes made following the previous meeting and made the following further changes to the policy template:</p> <ul style="list-style-type: none"> <li><u>Introduction</u> - In paragraph 8 the word <i>'available'</i> has been removed. In paragraph 10 the first sentence has been removed.</li> <li><u>2.3 Definition of Childlessness</u> - The last paragraph title amended to read Option 3 not 2.</li> <li><u>4.3 Reversal of Sterilisation</u> - Paragraph added: <i>'Reversal of vasectomy for reasons other than to restore fertility is commissioned e.g. to treat rare cases of post vasectomy pain.'</i></li> </ul> <p><u>4.13 Number of Cycles Funded</u></p> <ul style="list-style-type: none"> <li>The first sentence in the last paragraph now reads <i>'until the woman's 40<sup>th</sup> birthday'</i> rather than <i>'42<sup>nd</sup> birthday'</i>.</li> <li>The last sentence in the final paragraph amended from <i>'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.'</i> to read: <i>'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.'</i></li> </ul> <p><u>4.16 Policy Exclusions</u></p> <ul style="list-style-type: none"> <li>Second paragraph removed. In the original third paragraph the following words added after <i>'infertility'</i> in the first sentence <i>'including gender reassignment'</i>.</li> <li>The following paragraph added between the original third and fourth paragraphs <i>'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'</i></li> <li>The seventh and eight paragraphs reworded from <i>'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.'</i> to read <i>'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.'</i></li> <li>The final paragraph in this section reworded from <i>'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.'</i> to read <i>'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.'</i></li> </ul>
0.7	16/11/2016	Amendments made by the GM EUR Steering Group on 16/11/2016 following

		<p>legal advice:</p> <ul style="list-style-type: none"> <li>• New format applied to policy template.</li> <li>• 'Funding Mechanism' boxes added where necessary throughout policy template.</li> <li>• <u>1.12.1 Access Criteria and 6.3 Definition of Childlessness</u>: the definition: '<i>A child adopted by a patient or adopted in a previous relationship is considered to have the same status as a biological child.</i>' added to Option 1 and Option 3's second sentence amended to read the same.</li> <li>• <u>1.13 Number of funded cycles</u>: the word '<i>must</i>' added to the first paragraph and, in 2<sup>nd</sup> from bottom paragraph, '40<sup>th</sup>' amended to '42<sup>nd</sup>'.</li> <li>• <u>1.16 Policy Exclusions</u>: the word '<i>therapy</i>' removed from the 1<sup>st</sup> paragraph; the word '<i>including</i>' changed to '<i>or</i>' in the 2<sup>nd</sup> paragraph; and; the word '<i>and</i>' added to the 6<sup>th</sup> paragraph.</li> <li>• <u>2. Policy Statement</u>: the 2<sup>nd</sup> paragraph reworded to: '<i>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.</i>'</li> <li>• <u>References</u>: Amended to incorporate the previous policy template format's 'Documents which have informed this policy' section.</li> </ul> <p>Approved to go through the CCG Governance Process.</p>
	12/04/2017	<p><u>1.12.1 Access Criteria and 6.3 Definition of Childlessness</u>): Whilst the policy template was going through the CCG Governance Process the Directors of Commissioning requested the definition of childlessness be clarified and put into one statement.</p>
1.0	01/08/2017	Policy template approved by Greater Manchester Association Governing Group
1.1	21/08/2017	Note added to front of policy template - 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.
	04/09/2017	Oldham CCG Management Executive Team adopted the policy template and agreed that the CCG should fund 3 cycles (includes abandoned or cancelled cycles).
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	<ul style="list-style-type: none"> <li>• <u>1.6 Intrauterine Insemination</u>: Bullet point '<i>single women (i.e. women not in a stable relationship)</i>' added</li> <li>• <u>1.7 Managing Unexplained Infertility</u>: <ul style="list-style-type: none"> <li>○ In second paragraph, the words '<i>who have had their funding approved via the IFR route</i>' removed and '<i>to be carried out in a clinical setting</i>' added.</li> <li>○ The last sentence '<i>All services should be offered in line with the recommendations of NICE CG156.</i>' moved before '<i>Do not offer</i>'.</li> <li>○ '<i>(exceptional circumstances include, for example, when people have social, cultural or religious objections to IVF)</i>' added to the second bullet point under '<i>Do not offer</i>'</li> </ul> </li> <li>• <u>1.10.1 Ovulation Disorders</u>: <ul style="list-style-type: none"> <li>○ '<i>(unless they can show by an alternative measure to BMI that they have a normal body fat ratio).</i>' added to the first bullet point under '<i>Group I: hypothalamic pituitary failure...</i>'</li> <li>○ The antral follicle count sentence removed following '<i>Premature ovarian failure is defined...</i>' in the second paragraph under '<i>Group III: ovarian failure</i>' and replaced with '<i>...as in the paragraph above.</i>'</li> </ul> </li> </ul>

		<ul style="list-style-type: none"> <li>• <u>1.10.2 Use of Donor Oocytes:</u> The antral follicle count detail removed from the first bullet point following '<i>premature ovarian failure</i>' and replaced with '<i>...occurring before the age of 40 years</i>'</li> <li>• <u>1.11.3 Endometriosis:</u> Section replaced to read: '<i>Endometriosis should be managed in line with NICE NG73 Endometriosis: diagnosis and management.</i>'</li> <li>• <u>1.12 Managing Infertility with IVF:</u> Fourth bullet point amended from '<i>...1 unit of alcohol per day</i>' to '<i>...the current Department of Health's recommendations for the consumption of alcohol</i>'</li> <li>• <u>1.12.1 Access criteria:</u> The body mass index amended from '<i>19-29</i>' to '<i>19-30</i>'; '<i>BMI above 29</i>' amended to read '<i>BMI above 30 or below 19</i>', and '<i>not clinically obese</i>' amended to read '<i>not clinically obese or too thin</i>'.</li> <li>• <u>1.13 Number of funded cycles:</u> '<i>For women aged 40-42 (inclusive)</i>' amended to read '<i>40-42 (i.e. before her 43rd birthday)</i>' and '<i>42nd birthday</i>' amended to read '<i>43rd birthday</i>'.</li> <li>• <u>1.15 Switching providers:</u> Removal of the word 'contract' from first paragraph.</li> <li>• <u>1.16 Policy Exclusions:</u> '<i>Individuals under the age of 42</i>' amended to read '<i>Individuals under the age of 42 (i.e. prior to their 43rd birthday)</i>'; '<i>Individuals over the age of 42</i>' amended to read '<i>Individuals over the age of 42 (i.e. after their 43rd Birthday)</i>' and '<i>42nd birthday</i>' amended to read '<i>43rd birthday</i>'.</li> <li>• <u>6. Treatment / Procedure:</u> Sixth paragraph amended to read '<i>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.</i>' from '<i>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.</i>'</li> <li>• <u>6.1 Subfertility / Infertility:</u> '<i>see NICE NG73</i>' added to second bullet point.</li> <li>▪ <u>7.2.7 Alcohol:</u> '<i>current</i>' added before '<i>Department of Health's</i>' and '<i>...of drinking no more than three to four units of alcohol a day</i>' amended to read '<i>for the consumption of alcohol</i>'</li> <li>• <u>11. Glossary:</u> Definition of '<i>Premature ovarian failure</i>' amended.</li> </ul> <p>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 <b>no longer</b> be made to the policy:</p> <ul style="list-style-type: none"> <li>• <u>1.6 Intrauterine Insemination:</u> Bullet point '<i>single women (i.e. women not in a stable relationship)</i>' added 17/1/2018 – <b>removed 21/03/2018</b></li> <li>• <u>1.7 Managing Unexplained Infertility:</u></li> <li>• In second paragraph, the words '<i>who have had their funding approved via the IFR (Exceptional Case) route</i>' removed 17/1/2018 – <b>added back in 21/03/2018</b></li> </ul> <p>The following amendments were also made for clarify:</p> <ul style="list-style-type: none"> <li>• Where appropriate, instances of '<i>IFR</i>' or '<i>EUR</i>' throughout policy were amended to read '<i>IFR (Exceptional Case)</i>' or '<i>IPA</i>' and funding mechanisms were also clarified.</li> </ul>
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2.0	19/09/2018	<p>Reviewed at GM EUR Steering Group where the following changes were made:</p> <ul style="list-style-type: none"> <li>• <u>Section 1. Commissioning Statement</u> <ul style="list-style-type: none"> <li>○ Link added to NICE CG156.</li> <li>○ Paragraph added regarding who funds treatment.</li> <li>○ Following sentence removed from the funding mechanism <i>‘in some cases this will include monitored approval or, where stated in this policy, individual prior approval.’</i></li> </ul> </li> <li>• <u>Section 1.4 Surrogacy:</u> Link added to <i>‘GOV UK guidance: Having a child through surrogacy’</i> at the end of the section.</li> <li>• <u>Section 1.9.1 Surgical Recovery of Sperm:</u> In final paragraph link add to <i>‘NHS England: 16040/P – Clinical Commissioning Policy: sperm retrieval for male infertility’</i>.</li> <li>• <u>Section 1.10.1 Ovulation Disorders</u> <ul style="list-style-type: none"> <li>○ Following sentence added: <i>‘Please refer to GMMMG website for up to date guidance on any restrictions to drugs.’</i></li> <li>○ Under <i>‘Group II’ – ‘First line treatment’</i> the following added to the first bullet point: <i>‘who have a BMI over 30’</i></li> </ul> </li> <li>• <u>Section 1.13 Number of funded Cycles</u> The following paragraph reworded from: <i>‘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 43<sup>rd</sup> 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.’</i> to <i>‘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.’</i></li> <li>• <u>Section 1.16 Policy Exclusions:</u> <i>‘(or until a woman’s 43<sup>rd</sup> birthday)</i> removed from the 7<sup>th</sup> paragraph</li> <li>• <u>Section 10. Date of Review:</u> Amended to <i>‘Three years’</i></li> </ul> <p>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.</p>
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