1. Introduction

1.1 This policy describes circumstances in which Merton CCG will fund treatment for assisted conception as defined in appendix 1.

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

1.3 The criteria set out in this policy apply irrespective of where the residents of Merton CCG have their treatment. A Merton CCG patient is defined as someone registered with a GP practice which is part of Merton CCG.

1.4 This policy has drawn on guidance issued by the Department of Health, Infertility Network UK and the revised NICE guidance (CG 156) published in February 2013.


http://guidance.nice.org.uk/CG156 (summary guidance)


2. Defining infertility

2.1 Infertility is a disease of the reproductive system defined by the failure to achieve a clinical pregnancy after 12 months or more of regular unprotected sexual intercourse.

3. Types of infertility treatment

3.1 There are three main types of infertility treatment –

- medical management (such as drugs for ovulation induction),
- surgical treatment (i.e. to correct a physical cause for infertility such as blocked fallopian tubes)
- assisted conception

3.2 Assisted conception is a collective name for treatments designed to lead to conception by means other than sexual intercourse where gametes are manipulated. Assisted conception techniques include intrauterine insemination (IUI), in vitro fertilisation (IVF), donor insemination (DI), intracytoplasmic sperm injection (ICSI) and cryopreservation (of sperm, oocytes and embryos).
This policy only deals with assisted conception.

4. Pathway and provider arrangements for assisted conception (IUI, IVF, ICSI, DI)

4.1 Merton CCG will have a waiting list for assisted conception at three providers:
- Epsom and St Helier University Hospitals Trust
- Guys and St Thomas NHS Foundation Trust
- Kingston Hospital NHS Foundation Trust
- Chelsea and Westminster NHS Foundation Trust
- Create Fertility

5. Commissioning policy

5.1 In Vitro Fertilisation (IVF) / Intracytoplasmic sperm injection (ICSI):

5.1.1 Definition:

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

5.1.2 Policy statement:

Merton CCG will fund one (1) fresh cycle of IVF or ICSI for patients who meet all of the criteria in Appendix 1.

Where the couple produces more than one good quality embryo and have an elective single embryo transfer, the PCT will fund 12 months of cryopreservation of the remaining embryos. If the initial embryo transfer does not result in a live birth, the CCG will then fund a single HRT frozen embryo transfer.

It is expected that the majority of patients receiving Merton CCG funded IVF/ICSI will undergo single embryo transfer. This will reduce the number of multiple pregnancies within Merton CCG and falls within HFEA guidance. The IVF providers will be expected to have in place a “Minimisation of Multiple Birth Strategy” which gives precise details of those couples who will be required to have single embryo transfer.

More information is available at www.oneatatime.org.uk

5.2 Intrauterine insemination (IUI)

5.2.1 Definition:

Intra-uterine insemination (IUI) is a technique to place sperm into a woman’s womb through the cervix.

5.2.2 Policy statement

Merton CCG will fund three (3) cycles of intrauterine insemination for couples undergoing insemination for the following conditions:

- Unexplained infertility where IVF not an acceptable option for the couple
- When vaginal intercourse is not appropriate or possible
5.3 Pre-implantation genetic diagnosis

5.3.1 Definition:
Pre-implantation genetic diagnosis can be used when one partner is known to have a faulty gene. It involves having in-vitro fertilization (IVF) treatment, then genetically testing the embryo in a laboratory to see if it has the faulty gene. The embryo will only be placed inside the woman if it does not have the faulty gene.

5.3.2 Policy statement
Merton CCG will consider funding up to one fresh cycle of IVF or ICSI for couples who have had this recommended by the Pre-implantation Genetic Diagnosis (PGD) Clinical Advisory Group.

5.3.3 Rationale
The Pre-implantation Genetic Diagnosis (PGD) Clinical Advisory Group has been set up by the Genetics Consortium to consider individual requests for funding and make recommendations to commissioners of member CCGs on the clinical appropriateness to fund individual PGD cases. Couples wishing to access PGD will therefore not be treated in the same way as couples requesting assisted conception. As such they will not be limited by the requirements of this policy (e.g. joining the centrally managed list, other aspects of the clinical criteria). However, each case will need to receive specific prior approval for funding from the CCG which will then act on the recommendations of the PGD Clinical Advisory Group. Funding for PGD does not fall within the financial allocation for assisted conception.

5.4 Egg Donation

5.4.1 Definition:
Egg donation is the process by which a fertile woman donates her eggs for use in the treatment of other women

5.4.2 Policy statement
Merton CCG will fund one cycle of IVF/ICSI using egg donation for women with:

- Premature ovarian failure
- Gonadal dysgenesis including Turner’s syndrome
- Bilateral oophorectomy
- Ovarian failure following chemotherapy of radiotherapy

Women must meet all of the criteria in Appendix 1.

Eggs must be donated through an altruistic donor, egg sharing schemes or sourcing eggs from overseas will not be funded

5.4.3 Rationale:
Some women cannot produce eggs, usually because their ovaries are not functioning, have been removed or they have a chromosomal abnormality.

5.5 Donor insemination

5.5.1 Definition:
This form of treatment involves using sperm donated anonymously by another man.

5.5.2 Policy statement
Merton CCG will fund donor insemination using IUI for the following conditions if appropriate:
Non-obstructive azoospermia
Where there is a high risk of transmitting a genetic disorder to the offspring
Where there is high risk of transmitting an infectious disease from the man to the woman or to the offspring
Severe rhesus isoimmunisation

5.6 Surrogacy

5.6.1 Definition:
Surrogacy is a way for a childless couple to become parents, with a surrogate mother carrying their child. In traditional surrogacy, the surrogate may be the child's genetic mother i.e. her egg is fertilized using sperm from the man who wishes to raise the child. In gestational surrogacy, the pregnant woman is not biologically related to the baby.

5.6.2 Policy statement
Merton CCG does not fund any element of surrogacy arrangements or associated fertility treatments and procedures.

5.6.3 Rationale:
The funding of surrogacy arrangements and associated fertility treatments raises numerous legal and ethical issues which present significant risk to commissioners. These risks arise from the complexities associated with surrogate arrangements including: issues relating to the parentage of the child; change of mind by any of the parties involved in the surrogate arrangement (including termination of pregnancy or refusal to surrender child); problems arising from “unwanted baby” or genetic or congenital defects. Given that these are either unresolved and that the legal position on many of these aspects are presently unclear, the legal advice to CCGs is not to fund any element of surrogacy procedures.

5.7 Private/Self Funding Patients

5.7.1 Policy statement
Patients who are undergoing treatment outside of an NHS pathway will not be funded or reimbursed for drugs or additional tests incurred as a result of self-funded/private treatment.

5.8 In vitro maturation

5.8.1 Definition:
In vitro maturation involves removing immature eggs that have yet to complete their growth, and subsequently maturing these eggs in the laboratory.

5.8.2 Policy statement
In vitro maturation will only be funded in exceptional circumstances.

5.8.3 Rationale
There is limited evidence for the effectiveness of in vitro maturation of eggs

5.9 HIV infection and sperm washing

5.9.1 Definition:
Sperm washing is a process in which individual sperm are removed from the semen then used in IUI or IVF. Its use in reducing male to female HIV transmission is based on the observation that HIV is found in the seminal fluid rather than the sperm cells.
5.9.2 Policy statement
Funding of Sperm washing for the prevention of transmission HIV will be considered on an individual patient basis.

5.9.3 Rationale:
Where the man is HIV positive, the risk of HIV transmission through unprotected sexual intercourse is negligible when all of the following criteria are met:

- the man is complying with highly active antiretroviral therapy (HAART)
- the man has a plasma viral load of less than 50 copies/ml
- there are no other infections present
- unprotected intercourse is limited to the time of ovulation

If all of the criteria above are met, sperm washing may not further reduce the risk of infection and may actually reduce the likelihood of pregnancy. In addition, sperm washing reduces, but does not eliminate, the risk of HIV transmission.

5.10 Cryopreservation and cryostorage

5.10.1 Definition
Cryopreservation entails freezing of eggs, sperm and/or embryos that may be thawed for use in future IVF treatment cycles. Cryostorage entails storage of frozen eggs, sperm and/or embryos that may be thawed for use in future IVF treatment cycles.

5.10.2 Policy statement
i) Merton CCG will fund sperm cryostorage, egg cryostorage and embryo cryostorage in the following circumstances:

- Medical or surgical treatment that is likely to have a permanent harmful effect on subsequent sperm or egg production. Such treatment includes radiotherapy or chemotherapy for malignant disease.
- Ongoing medical treatment that, whilst on treatment, causes harmful effects on sperm or egg production or has possible teratogenic effects, and in whom stopping treatment for a prolonged period of time to enable conception is not an option.

ii) Commencement of cryostorage does not entitle people to assisted conception treatments. In this circumstance and individual funding request can be applied

iii) Storage:
- May not exceed five (10) years.
- Will not be available where a man or woman chooses to undergo medical or surgical treatment whose primary purpose is infertility, such as sterilisation;
- Will not be available where a man or woman requests cryostorage for personal lifestyle reasons, such as wishing to delay trying to conceive

iv) Post-storage Treatment
- Funding of assisted conception treatments would be made available on the same basis as other patients who have not undergone such storage

5.11 Surgical sperm retrieval/recovery

5.11.1 Definition:
A surgical procedure to obtain sperm from the testicles in men who cannot ejaculate or have a blockage in the flow of sperm from their testicles.
5.11.2 Policy statement
Surgical sperm retrieval will be commissioned in appropriately selected patients provided the azoospermia is not the result of a sterilisation procedure or the absence of sperm and the couple meets all other criteria.

5.11.3 Rationale
Spermatozoa can be retrieved from both the epididymis and the testis using a variety of techniques with the intention of achieving pregnancies for couples where the male partner has obstructive or non-obstructive azoospermia. Sperm recovery is also used in ejaculatory failure and where only non-motile spermatozoa are present in the ejaculate. Surgically collected sperm in azoospermia are immature (because they have not traversed the epididymus) and have low fertilising ability with standard IVF. It is therefore necessary to use ICSI.
### Appendix 1: Merton CCG Criteria for Access to Intrauterine Insemination (IUI), In Vitro Fertilisation (IVF), Intracytoplasmic Sperm Injection (ICSI)

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<tr>
<th>Title</th>
<th>Criteria</th>
<th>Rationale</th>
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<tr>
<td>Duration of subfertility</td>
<td>• Couples will be eligible for referral for treatment if they have experienced twenty four months of unexplained infertility or have an identified cause of infertility</td>
<td>• 84% of women will conceive within one year of regular unprotected sexual intercourse, this increases to 92% after 2 years and 93% after 3 years.</td>
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<td>Age of woman at start of treatment cycle</td>
<td>• Woman is aged 23 – 42 at the time of treatment i.e she has not had her 43rd birthday  &lt;br&gt; • Couples will not be able to be referred from secondary to tertiary care where the women is aged over 42.5 years. This is because treatment must take place before her 43rd birthday and clinics will be operating an 18 week pathway The lower age limit will not apply to women accessing treatment due to clinical care that is likely to result in long-term infertility</td>
<td>The likelihood of a live birth following assisted conception declines with age. Chances of live birth per IVF cycle are:  &lt;br&gt; • &gt;20% for women aged 23-35  &lt;br&gt; • 15% for women aged 36-38  &lt;br&gt; • 10% for women aged 39 years  &lt;br&gt; • 6% for women aged 40 years and over  &lt;br&gt;</td>
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<td>Body mass index of woman</td>
<td>• 19 – 30 kg/m2, weight to be maintained for the last 6 months prior to application.</td>
<td>• Higher body mass index reduces the probability of success associated with assisted conception techniques</td>
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<td>Smoking status of couple</td>
<td>• Both partners should have been non-smokers for at least six months prior to commencement of treatment.</td>
<td>• Smoking can adversely affect the success rates of assisted reproductive techniques.</td>
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<td>Previous cycles</td>
<td>• Couples will be eligible for NHS funding of one fresh cycle of IVF or ICSI. Where the couple produces more than one good quality embryo and have an elective single embryo transfer, the PCT will fund 12 months of cryopreservation of the remaining embryos. If the initial embryo transfer does not result in a live birth, Merton CCG will then fund a single frozen embryo transfer  &lt;br&gt; • Where couples have self-funded previous cycles, these must not exceed two.  &lt;br&gt; • Couples will not be eligible for treatment if they have received any previous NHS funded treatment</td>
<td>• The probability of a live birth following the IVF is consistent for the first three cycles but effectiveness of subsequent cycles is uncertain.</td>
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| whose sperm is being used and the surrogate partner would be eligible to be referred for further clinical assessment and possible treatment. | achieved (based on NICE recommendation and advice of local clinicians).  
-  |
|---|---|
| In the case of same sex couples where only one partner is sub fertile, clinicians should discuss the possibility of the other partner receiving treatment before proceeding to interventions involving the sub fertile partner.  
The other criteria for eligibility for IVF will also apply.  
- All same sex couples and women not in a partnership should have access to professional experts in reproductive medicine to obtain advice on the options available. |  |

### FSH

- FSH levels should be checked between day 2 and 4 of the menstrual cycle, where day 1 is the first full day of menstrual bleeding, with Oestradiol level. Only women whose FSH has never exceeded a level of 11.9 iu/L or less when an oestradiol level checked on the same day is 249 pmol/l or less will be eligible for treatment with the sample timed within 6 months of date of treatment. For those with no periods the sample can be timed at any date but the same maximum levels apply. The clinic will be expected to repeat the FSH blood test if the level was checked more than 6 months prior to treatment and treatment will be withdrawn if the repeated level exceeds 11.9iu/L.

### Investigations

- The couple must have been appropriately investigated within a recognised NHS fertility clinic in secondary care. The couple can only be referred for assisted conception once all of these investigations have been completed and a proforma referral document completed. The referring clinic will check to ensure that the couple fulfil the relevant criteria and at that point will start an 18 week clock. Couples must NOT be referred for assisted conception until all other relevant procedures have been completed and the patient discharged from secondary care.