Policy for Assisted Conception
The CCG policy has been reviewed and developed by the Treatment Policies Clinical Development Group in line with the groups guiding principles which are:

1. CCG Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment;
2. CCG Commissioner require clear evidence of cost effectiveness before NHS resources are invested in the treatment;
3. The cost of the treatment for this patient and others within any anticipated cohort is a relevant factor;
4. CCG Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment;
5. CCG Commissioners will balance the needs of each individual against the benefit which could be gained by alternative investment possibilities to meet the needs of the community
6. CCG Commissioners will consider all relevant national standards and take into account all proper and authoritative guidance;
7. Where a treatment is approved CCG Commissioners will respect patient choice as to where a treatment is delivered; AND
8. All policy decision is considered within the wider constraints of the CCG’s legally responsibility to remain fiscally responsible.
1. Introduction

Infertility is when a couple cannot conceive (get pregnant) despite having regular unprotected vaginal sexual intercourse. A woman of reproductive age who has not conceived after 1 year of unprotected vaginal sexual intercourse, in the absence of any known cause of infertility, should be offered further clinical assessment and investigation along with her partner. Infertility can be primary, in people who have never conceived, or secondary, in people who have previously conceived. It is estimated that infertility affects one in six heterosexual couples in the UK.

The causes of primary infertility in the UK occur in the following approximate proportions:

- unexplained infertility (no identified male or female cause), 25%
- ovulatory disorders, 20%
- tubal damage, 15%
- factors in the male causing infertility, 30%
- uterine or peritoneal, 10%.

In about one third of cases, disorders are found in both the man and the woman.

Other factors may play a role, including uterine or endometrial factors, gamete or embryo defects, and any other pelvic condition such as endometriosis.

Over 80% of heterosexual couples in the general population will conceive within 1 year if:

- the woman is aged under 40 years and
- they do not use contraception and have regular sexual intercourse.

Of those who do not conceive in the first year, about half will do so in the second year (cumulative pregnancy rate over 90%).
2. Scope of the Policy

This policy applies to all patients for whom the Birmingham and Solihull Clinical Commissioning Group (CCG) has responsibility, if a couple are requesting assisted conception treatment, then **BOTH partners in the couple must be registered with a Sandwell & West Birmingham GP or BOTH partners in the couple must be registered with a Birmingham and Solihull GP.**

Where a patient’s clinical presentation does not clearly meet the requirements for secondary care referral within the context of this policy, and where a GP is uncertain or concerned about the appropriate treatment/management pathway, a GP Advice & Guidance request should be considered as an alternative to a referral for clinical assessment.

There may be occasions when a GP referral is made for specialist assessment which appears to meet the policy requirements, but which on specialist clinical examination either does not meet the clinical criteria or is not considered clinically suitable for intervention. Such patients should be discharged without intervention.

For patients who do not fall within the eligibility criteria set out in the policy (Sections 3 & 4 with reference to Appendix 1), but where there is demonstrable evidence that the patient has exceptional clinical circumstances, an Individual Funding Request may be submitted for consideration.

The policy applies to patients experiencing difficulty with conception who are being managed on an NHS pathway of care.

**Funding for Military Serving Personnel**

Assisted conception services for current serving personnel and their partners is contained with the specific NHS England policy at: https://www.england.nhs.uk/commissioning/policies/ssp/ as NHS England are the responsible commissioner.

Veterans who are in receipt of compensation for loss of fertility (received as a result of service/partner of same) and require access to assisted conception treatments, are also the commissioning responsibility of NHS England https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2016/10/armed-forces-comms-intent-1617-1819.pdf

Veterans without relevant injury impacting on fertility are the commissioning responsibility of CCGs and the content of this policy applies.

**Pre-Implantation Genetic Diagnosis** (PiGD) is not covered by this commissioning policy as it is the commissioning responsibility of NHS England. Patients should be referred to the Genetic Centre at Birmingham Women’s & Children’s Hospital. Definitions are to be found in Appendix 1.
3. Patient Eligibility Criteria (Summary: Appendix 2)

1. Age
   a. Age of Female Partner wishing to conceive
      - The age of the female partner at the time of treatment must be under 40 years of age.
      - If infertility is clinically identified in a female from the age of 20 years old - NHS infertility treatment should be offered without delay.
      - Where the woman is aged 38 - 39 years of age, the couple/single female should be offered referral to a specialist NHS infertility centre for assessment without further delay.
      - Referrals for NHS infertility treatment should be made on or before the females 39th birthday (i.e. at least 12 months before her 40th birthday) to ensure relevant investigations can be completed, and treatment must have commenced prior to the females 40th birthday.
      - The rationale for referral and treatment prior to a woman’s 40th birthday is due to the high quality evidence from the 2013 NICE Clinical Guideline, more recently published evidence and the HFEA, all of which confirm that increasing maternal age is a key predictor of failure to have a live birth following IVF treatment.
      - One large observational cohort study (Smith et al (2015) reported the live birth rate (LBR) for a full cycle of autologous IVF initiated between 2003 and 2010, for 156,947 women in the UK. After one full cycle (defined as an initial ovarian stimulation and all subsequent fresh and frozen embryos) the live birth rate (LBR) were:
         o For women <40 years: 32.3% (95%CI 32.0 to 32.5)
         o For women 40-42 years: 12.3% (95%CI 11.8 to 12.8)
         o For women >42 years: 3.7% (95% CI 3.2 to 4.3)
      - More recently, the HFEA reported LBR for women of different age bands who had an autologous IVF cycle which was initiated in 2013. There is a noticeable decline in LBR for women aged 38 years and older when compared to women up to and including 37 years.

<table>
<thead>
<tr>
<th>Maternal age</th>
<th>Live birth rate per treatment cycle started using patients’ fresh eggs in 2013 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All ages</td>
<td>26.5</td>
</tr>
<tr>
<td>18-34</td>
<td>32.8</td>
</tr>
<tr>
<td>35-37</td>
<td>29.5</td>
</tr>
<tr>
<td>38-39</td>
<td>21.8</td>
</tr>
<tr>
<td>40-42</td>
<td>13.7</td>
</tr>
</tbody>
</table>
b. **Age of Male Partner wishing to conceive**
   i. The age of the male partner at the time of treatment must be under 55 years of age.
   ii. HFEA regulations enable men to donate sperm to assist infertile people and recommend that sperm donors should be aged under 41 years; the possible effect of a donor’s age on assisted conception success is considered on a case by case basis.
   iii. There is limited evidence that IVF success decreases in men over the age of the 40. Men aged over 40 are half as likely to conceive with IVF compared to 30-year-old men when their female partner is aged 35-39 years (de La Rochebrochardet al, 2006). However, male age does not impact on the success of other infertility treatment such as ICSI (Spandorfer et al, 1998).
   iv. In light of some evidence that male age does impact on infertility, and may have an impact on IVF outcomes, and keeping in line with other CCG areas which stipulate a male age restriction of 55 years, we have included this as a criterion for eligibility.

2. **Childlessness**
   a. NHS infertility treatment will NOT be funded if either partner has living children of any age; this includes an adopted child or a child (biological or adopted) from either the present or a previous relationship. Once accepted for treatment, should a child be adopted or a pregnancy leading to a live birth occur, the couple / individual will no longer be considered childless and will not be eligible for NHS funded treatment.

3. **Previous Infertility Treatment**
   a. NHS infertility treatment will not be offered to people where either partner within the couple has already undertaken any previous infertility treatment (IVF/ICSI) for fertility problems, regardless of whether the treatment was funded by the NHS or privately funded.

4. **Sterilisation**
   a. NHS infertility treatment will not be available if either partner within the couple has received a sterilisation procedure or has undertaken a reversal of sterilisation procedure.
   b. Sterilisation is offered within the NHS as an irreversible method of contraception. Protocols for sterilisation include counselling and advice that NHS funding will not be available for reversal of the procedure or any fertility treatment consequently to this.

5. **Body Mass Index**
   a. Females who have a body mass index (BMI) of 30 or over should be informed that they are likely to take longer to conceive.
   b. The female wishing to conceive must have a BMI of <30kg/m² at the time of referral AND commencement of treatment. Females wishing to conceive must be informed of this criterion at the earliest opportunity and offered the support of local NHS services to optimise their BMI.
6. Smoking / Vaping Status
   a. Only non-smoking (including non-vaping) females/couples will be eligible for fertility treatment; smoking (including vaping) must have ceased by both partners three months prior to referral for infertility treatment.
   b. Females who smoke (including vaping) should be informed that this is likely to reduce their fertility, should be offered referral to a smoking cessation programme to support their efforts in stopping smoking (including vaping), and informed that passive smoking is likely to affect their chance of conceiving. Men who smoke (including vaping) should be informed that there is an association between smoking and reduced semen quality (although the impact of this on male fertility is uncertain), and that stopping smoking (including vaping) will improve their general health.
   c. Maternal and paternal smoking can adversely affect the success of infertility treatment and smoking during the antenatal period can lead to increased risk of adverse pregnancy outcomes. Females should be informed that passive smoking is likely to affect their chance of conceiving. There is an association between smoking and reduced semen quality. The impact of vaping on conception, pregnancy and the passive impact of vaping is uncertain and without further evidence of the safety of vaping in conception / pregnancy / childhood, this cannot be currently recommended as an alternative to smoking.

Once all of the above eligibility criteria have been met by the couple / single woman, Section 4 defines the clinical circumstances in which IVF / ICSI may be commissioned.

4: Definition of patients who may access Assisted Reproduction Treatments for the Management of Infertility.

4.1 For all couples / single women
   o The presence of known reproductive pathology as defined in Appendix 1.

4.2 For heterosexual couples:
   4.2.a. The failure to conceive after regular unprotected sexual intercourse for a period of 2 years. AND the absence of known reproductive pathology.
   OR
   4.2.b The failure to conceive after regular unprotected sexual intercourse for a period of one year. AND Known reproductive pathology (identified in tests run by GP after 1 year of failure to conceive – Male: semen analysis and Female: Female Stimulating Hormone (FSH) & Progesterone Level).
   OR
   4.3. Known reproductive pathology which would prevent natural
conception.

4.3 **For female same-sex couples / single women:**
   4.3.1. the failure to conceive after a minimum of six rounds of self-funded donor insemination via IUI
   AND
   the absence of any known reproductive pathology.

4.4 **For Male same-sex couples / single men**
The commissioner does not fund surrogacy arrangements or any associated treatments (including fertility treatments) related to those in surrogacy arrangements.

4.5 **For couples where one partner has a known permanent physical disability**
   4.5.1 The permanent disability must prevent natural conception as defined by the following clinical situations:
   - Permanent physical disability which prevents sexual intercourse
   - an infection requiring sperm washing,
   AND
   the couple have failed 6 rounds of CCG funded IUI / DI
   OR
   4.5.2. IUI/DI is not clinically appropriate, e.g. one or both of the couple have known reproductive pathology which would prevent or significantly reduce the chance of conception using IUI/DI.

For the purposes of this policy disability is defined as: a permanent physical impairment which prevents sexual intercourse.

**4. Commissioned Treatment**

Providing that all eligibility criteria detailed in Section 3 are met, for females/couples in whom IVF/ICSI is clinically indicated, the Commissioner will fund 1 fresh cycle of In Vitro Fertilisation (IVF) or Intra-Cytoplasmic Sperm Injection (ICSI).

**Definition of a cycle of IVF / ICSI**

The definition of a single treatment cycle for the purpose of this policy is as follows:

**The replacement of a fresh embryo(s) derived from the initial cycle.**

**Frozen Embryo Transfers**

Embryos that are not used during the fresh transfer should be quality graded using the UK NEQAS embryo morphology scheme and may be frozen for subsequent use. Cryopreservation and storage of any suitable surplus embryos following a completed NHS funded cycle is for a period of 12 months, in line with Human Fertilisation and Embryology Authority (HFEA) guidelines and is funded by the specialist tertiary treatment provider. Following this period, the woman/couple may self-fund continued
storage of the embryos. The CCG does NOT commission transfer of further frozen embryos.

**Failed or Abandoned Cycles**
It is acknowledged, that rarely, a cycle could fail at any time after commencement due to a number of reasons. For example; ovarian stimulation failure, failure to retrieve an egg, failure to fertilise or a failure of embryos to develop, all of which may result in embryo transfer to the uterus NOT taking place. These are known risks of infertility treatment and will be fully explained to the patient along with the likelihood of success. Should any such issue arise, the cycle will have failed and the Commissioner will not fund further cycles of IVF or ICSI.

**Part-funding of cycles**
The Commissioner will not part-fund or co-fund assisted conception/infertility treatment for individuals or couples that are ineligible or eligible for NHS-funded services under this policy.

**Use of previously stored gametes.**
Where cryopreserved gametes are available in line with the current CCG policy on gamete retrieval and cryopreservation, this policy will allow the use of cryopreserved gametes for infertility treatment in line with specialist clinical input where patients meet all other eligibility criteria (Section 3 & 4).

**IUI and DI**
IUI and DI is separate from IVF treatment, however, the couple / woman may then access IVF treatment if failure of IUI / DI has evidenced reproductive pathology.

IUI / DI is commissioned for patients in the following circumstances:
- Permanent physical disability which prevents sexual inter-course
- an infection requiring sperm washing,

Where a medical condition exists (such as permanent physical disability which prevents sexual intercourse or after sperm washing to prevent infectious disease transmission.), IUI for up to 6 cycles will be commissioned for patients who meet the criteria set out in Section 3 & 4, followed by further IVF / ICSI if reproductive pathology is established and the woman/couple continue to meet the criteria set out in Section 3.

**IUI and DI in same-sex relationships:**
6 cycles of IUI/DI must be SELF –FUNDED as a treatment option for people in same-sex relationships.

However, if 6 cycles of IUI /DI are unsuccessful and reproductive pathology has been established, further IVF / ICSI if clinically appropriate will be commissioned for patients who meet the criteria set out in Section 3 & 4.
Donor Gametes

- **Donor Sperm**
  Up to six cycles of donor insemination (dependent on availability of donor sperm) will be commissioned for heterosexual couples with azoospermia or oligospermia via donor Sperm.
  If donor sperm is required for IVF, in the case of azoospermia, ICSI must NOT be clinically indicated in the couple’s individual circumstance.

**Pre-Implantation Genetic Diagnosis** (PiGD) is not covered by this commissioning policy as it is the commissioning responsibility of NHS England. Patients should be referred to the Genetic Centre at Birmingham Women’s & Children’s Hospital.

- **Donor Eggs**
  Donor eggs will be funded where the patient is eligible for treatment with donor eggs, in line with NICE recommendations:

  - The patient has experienced premature ovarian failure (For the purposes of this policy premature ovarian failure is defined as a woman below the age of 35 years; with an absence of external factors / pathology where cessation of ovulation and menstruation has occurred and ovarian failure is confirmed by measurement of the ovarian reserve)
  - The patient has received cytotoxic therapy which has caused ovarian failure
  - The patient has a diagnosed chromosomal abnormality e.g. Turner’s syndrome
  - The patient’s ovaries have been removed

Unfortunately, the availability of suitably matched donor eggs remains variable due to the characteristics of the recipient. There is, therefore, no guarantee that eligible patients will be able to proceed with treatment. The average waiting time is as little as 18 months, but will be much longer for some patients. Patients who require donor eggs will be placed on the waiting list for an initial period of 1 year, after which they will be reviewed annually to assess whether the assisted conception policy eligibility criteria are still met.

**Pre-Implantation Genetic Diagnosis** (PiGD) is not covered by this commissioning policy as it is the commissioning responsibility of NHS England. Patients should be referred to the Genetic Centre at Birmingham Women’s & Children’s Hospital.

**In vitro Maturation (IVM)**
IVM is not routinely commissioned due to the lack of currently available clinical evidence to demonstrate the effectiveness of this technique.
HIV/HEP B/ HEP C
People undergoing IVF treatment should be routinely offered testing for HIV, Hepatitis B and Hepatitis C (NICE 2013). People found to test positive for one or more of HIV, Hepatitis B, or Hepatitis C should be offered specialist advice and counselling and appropriate clinical management (NICE 2013).

Surrogacy
The commissioner does not fund surrogacy arrangements or any associated treatments (including fertility treatments) related to those in surrogacy arrangements.

Single Embryo Transfer
Multiple births are associated with greater risk to mothers and children and the HFEA therefore recommends that steps are taken by providers to minimize multiple births. The CCG supports the HFEA guidance on single embryo transfer and will be performance monitoring commissioned tertiary providers to ensure that HFEA targets are met. All providers are required to have a multiple births minimisation strategy. The target for multiple births should now be an upper limit of 10% of all pregnancies.

5. Treatment Abroad under the European Union Cross Border Team.
The commissioner has commissioned a local tertiary specialist fertility pathway which they expect patients within their commissioning area of responsibility to follow. If the patient would like to make an application to the EU Cross Border team for treatment abroad, then the patient must meet all of the eligibility criteria set out in this policy and this must be evidenced to the EU Cross Border team in writing by the commissioned fertility treatment provider with a supporting letter from the commissioned specialist fertility centre, detailing the clinical reasons why treatment abroad is recommended for the individual patient / couple. Prior approval for an EU Cross Border application must be sought by the specialist fertility centre from the commissioner and the commissioner must be satisfied that the proposed EU provider meets the HFEA standards for treatment, for example, the proposed EU infertility service provider must have a multiple births minimisation strategy. The target for multiple births should now be an upper limit of 10% of all pregnancies. – All applications and consent for funding must be delivered in accordance with and not deviate from the Birmingham and Solihull CCG’s Assisted Conception Policy.

6. Principles of care
Couples who experience problems in conceiving should be seen together because both partners are affected by decisions surrounding investigation and treatment.

Both partners, or the individual if the individual alone is requesting infertility treatment, must have Birmingham and Solihull CCG as their responsible commissioner.

People should have the opportunity to make informed decisions regarding their care and treatment via access to evidence-based information. These choices should be recognised as an integral part of the decision-making process.
Information should be provided in the following formats:

- Face to face discussions with couples
- Written information and advice
- Culturally sensitive
- Be sensitive to those with additional needs e.g. physical or cognitive, or sensitive disabilities, or those who do not speak English.

- As infertility and infertility treatments have a number of psycho-social effects on couples, once referred to a specialist tertiary centre for fertility treatment, access to counselling prior to and during treatment should be considered as integral to the care pathway.

- Providers of specialist fertility services are expected to deliver appropriate interventions to support lifestyle behaviour changes which are likely to have a positive impact on the outcome of assisted conception techniques and resulting pregnancies. Recommendations covering screening, brief advice and onward referral are outlined in NICE Public Health Guidance (PH49) and, specifically in relation to fertility and pre-conception, smoking (PH 26, PH48), weight management (PH27, PH53), healthy eating and physical activity (PH11, NG7) and alcohol (PH24).

- Use any appointment or meeting as an opportunity to ask women and their partners about their general lifestyle including smoking, alcohol consumption, physical activity and eating habits. If they practice unhealthy behaviours, explain how health services can support people to change behaviour and sustain a healthy lifestyle.

In a heterosexual couple trying to conceive, if primary care interventions (i.e. lifestyle advice) are not effective following one year of unprotected regular sexual intercourse in the absence of known reproductive pathology or disability, then the couple should be offered the following initial assessments in primary care:

- Semen analysis
- Female Follicle Stimulating Hormone & Progesterone Levels

It would also be appropriate at this stage for the primary care clinician to discuss the care pathway and potential eligibility for fertility treatment with the couple.

Following these initial primary care diagnostics, if all results are within normal parameters then the couple (as long as the woman is below the age of 38 years) should be advised to continue with regular unprotected intercourse for a further year.

If, after a further year, conception has not taken place, then the couple should be referred to secondary care services for further investigations.

If initial diagnostic test results are abnormal then the couple should be referred to secondary care where further investigation and potential treatments will be carried out, such as hormonal therapies to stimulate ovulation. The couple should be advised again at this stage of the care pathway and potential eligibility criteria for IVF/ICSI treatment. It may also be appropriate for healthy lifestyle interventions to be reiterated.
If secondary care interventions are not successful and the couple fulfils the eligibility criteria, they may then be referred through to tertiary care for assessment for assisted conception techniques where clinically appropriate if the couple meets the eligibility criteria set out in Sections 3 & 4, such as, DI, IUI, IVF and ICSI.

IUI involves:

- High quality sperm are separated from sperm that is sluggish or non-moving.
- This sperm is then injected directly into the womb. IUI may be undertaken either with the woman’s partner’s sperm or donor sperm (known as donor insemination).
- It may be used in the treatment of:
  - People who need donated sperm but have no female fertility problems, including single women and same sex couples.
  - Couples who are unable (or would find it very difficult) to have vaginal intercourse, for example because of a permanent physical disability Those who have a condition which means they need specific help to get pregnant (for example, men who are HIV positive and have had sperm washing to reduce the risk of passing on the disease to their partner and potential child).

DI involves:

- The use of donor sperm or eggs to try and achieve a pregnancy
- It may be used in the treatment of:
  - Patients who are not producing sperm or eggs of their own
  - Patients where their own sperm or eggs are unlikely to result in a pregnancy
  - Patients who have a high risk of passing on an inherited disease
  - Patients in a same sex couple, or
  - Patients who are single.

IVF involves:

- The use of drugs to switch off the natural ovulatory cycle.
- Induction of ovulation with other drugs
- Monitoring the development of the eggs in the ovary
- Ultrasound guided egg collection from the ovary
- Processing of sperm
- Production of a fertilized embryo from sperm and egg cells in the laboratory
- Use of progesterone to make the uterus receptive to implantation
- Transfer of selected embryos and freezing of those suitable but not transferred

ICSI involves:

- Exactly the same treatment as with IVF for the female partner.
- The only difference is that instead of mixing the sperm with the eggs and leaving them to fertilise, a skilled embryologist (embryo specialist) will inject a single sperm into the egg.
This maximises the chance of fertilisation taking place as it bypasses any potential problems the sperm will have in actually getting to the egg.

The doctor may recommend ICSI if:
- The man has a very low sperm count
- The man’s sperm are abnormally shaped (poor morphology) or they don’t move normally (poor motility)

The man requires sperm to be collected surgically from the testicles or epididymis (a narrow tube inside the scrotum where sperm are stored and matured); for example because the man does not ejaculate sperm, or because the man has an extremely low sperm count.
- The man is using frozen sperm in the treatment which isn’t of the highest quality
- The couple require embryo testing for a genetic condition
Guidance

NICE 2018. Fertility Overview


NICE 2017 Fertility problems CG 156

https://www.nice.org.uk/guidance/cg156/ifp/chapter/egg-donation


http://guidance.nice.org.uk/CG156


https://www.nice.org.uk/guidance/ph49


https://www.nice.org.uk/guidance/ph26

NICE (2013) NICE Public Health Guidance (PH48) Smoking: acute, maternity and mental health services

https://www.nice.org.uk/guidance/ph48

NICE (2010) NICE Public Health Guidance (PH27) Weight management before, during and after pregnancy

https://www.nice.org.uk/guidance/ph27

NICE (2014) NICE Public Health Guidance (PH53) Weight management: lifestyle services for overweight or obese adults

https://www.nice.org.uk/guidance/ph53


https://www.nice.org.uk/guidance/ph11


https://www.nice.org.uk/guidance/ng7


https://www.nice.org.uk/guidance/ph24
### Appendix 1 - Definitions

<table>
<thead>
<tr>
<th>Item</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assisted Conception</td>
<td>The collective name for all techniques used artificially to assist conception and pregnancy, including In vitro fertilisation (IVF), Intra-cytoplasmic sperm injection (ICSI), Intrauterine insemination (IUI) and donor insemination (DI). These techniques are referred to as Infertility Treatment.</td>
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<tr>
<td>Female/Partner/Couple</td>
<td>Any reference to a female/partner/couple could relate to any of the following:</td>
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<td>- Heterosexual couple; a male and a female in a relationship; same sex female couple. A single female</td>
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<td></td>
<td>- Transgender male; biologically born as a female, gender reassigned to male, retention of female reproductive organs</td>
</tr>
<tr>
<td></td>
<td>- Transgender female, biologically born as a male, gender reassigned to female, retention of male reproductive organs</td>
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<tr>
<td>Infertility</td>
<td>• A female of reproductive age, who has not conceived after 1 year of unprotected vaginal sexual intercourse, in the absence of any known cause of infertility, should be offered further clinical assessment (FSH &amp; Progesterone levels) and investigation along with her partner (sperm analysis).</td>
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<td></td>
<td>• Following the first year and clinical investigation: Where the cause of infertility is known, the couple should be referred to secondary care services without further delay for further investigation and treatment as clinically required.</td>
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<tr>
<td></td>
<td>• In the absence of any known cause of infertility, and where the woman is below 38 years of age, the couple should be referred to secondary care services for further investigations and treatment after a further 1 year of regular unprotected vaginal sexual intercourse</td>
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<td></td>
<td>• A female who has a known cause of infertility, e.g. Turner Syndrome should be immediately referred for specialist assessment and where clinically indicated infertility treatment without delay.</td>
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<td>• In circumstances where the above definition cannot be applied, for example females in a same sex relationship, a single female, or a</td>
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<td><strong>Reproductive Pathology</strong></td>
<td>Diagnosis of a recognised condition that renders a patient infertile or reduces fertility, including confirmed diagnosis of:</td>
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<tr>
<td></td>
<td>• Polycystic Ovarian Syndrome (PCOS, including amenorrhea and oligomenorrhea)</td>
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<td>• Early onset of menopause</td>
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<td>• Complete amenorrhea</td>
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<td>• Endometriosis which has previously been surgically treated</td>
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<td>• Clinically significant fibroids</td>
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<td>• Pelvic Inflammatory Disease</td>
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<td>• Ovarian Failure including Turners syndrome and other genetic abnormalities</td>
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<td>• Azoospermia</td>
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<td>• Undescended testes</td>
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<td>• Tubal disorders and/or damage as a result of disease or trauma (e.g. blocked fallopian tubes, blocked seminal tubes); this does not include patients who have chosen to receive sterilisation surgery.</td>
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<td></td>
<td>• A permanent physical disability preventing vaginal sexual intercourse</td>
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<td>• Certain types of treatment (e.g. cytotoxic therapy) which permanently prevents the individual producing gametes (eggs/sperm)</td>
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<tr>
<td></td>
<td>• Certain types of treatment (e.g. cytotoxic therapy) which permanently causes genetic abnormalities in the eggs/sperm</td>
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<tr>
<td></td>
<td>• Oligozoospermia /Asthenozoospermia / Teraozoospermia, or any combination of these.</td>
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<td>• Chronic Anovulation</td>
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</tbody>
</table>

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<tr>
<th><strong>One cycle of fertility treatment</strong></th>
<th>A cycle will consist of ovulation induction, egg retrieval, fertilisation and one fresh embryo(s) transfer to the uterus, including all appropriate diagnostic tests, scans and pharmacological therapy.</th>
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<tbody>
<tr>
<td><strong>In vitro Maturation (IVM)</strong></td>
<td>In the IVM process, eggs are removed from your ovaries when they are still immature. They are then matured in the laboratory before being fertilised.</td>
</tr>
<tr>
<td><strong>Sperm washing</strong></td>
<td>Sperm washing has been developed for couples who wish to have a child where the male partner is HIV</td>
</tr>
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</table>
positive but the female is HIV negative (referred to as HIV discordant status). The aim is to reduce the risk of HIV transmission by attempting to achieve pregnancy through insemination of sperm washed free of HIV rather than through unprotected intercourse.

The technique used to do this is called sperm washing and rests on the observation that HIV infective material is carried in the fluid around the sperm (seminal fluid) rather than by sperm itself. The technique involves separating the HIV infected seminal fluid from the sperm by centrifugation and ‘washing’. The ‘washed’ sperm is then combined with nutritional fluid, tested for HIV using a sensitive test called a 'PCR' assay and, provided this is negative, inseminated into the female partner when she is ovulating and most likely to become pregnant. In couples with fertility problems washed sperm can be used in other fertility treatments such as IVF.
### Appendix 2 – Eligibility Criteria

**1a. Age of Female Partner wishing to conceive**

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Description</th>
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<tbody>
<tr>
<td>In females aged under 40 years, offer NHS infertility treatment.</td>
<td>If the woman reaches the age of 40 during treatment, complete the current full cycle but do not offer further full cycles.</td>
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<tr>
<td>The age of the female partner at the time of treatment must be under 40 years of age.</td>
<td>- If infertility is clinically identified in a female from the age of 18 years old - NHS infertility treatment should be offered without delay.</td>
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<tr>
<td>- Where the woman is aged 38 - 39 years of age, the couple should be</td>
<td>offered referral to specialist NHS infertility centre for assessment without further delay Referrals for NHS infertility treatment should be made on or before the females 39th birthday (i.e. at least 12 months before her 40th birthday) to ensure relevant investigations can be completed, and treatment must have commenced prior to the</td>
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<td>offered delay</td>
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<tr>
<td>Consistent with NICE Guideline. Fall off in treatment success with</td>
<td>Increased maternal and child complication rate. Prevention of delays in treatment where appropriate Whilst NICE recommend an extension of the female age to 42 where specific criteria are met, the success rates for this cohort of patients is relatively low. For females aged under 34, success rates are 41%; in females aged 40-42, this drops down to 21%. [HFEA Trends and Figures 2011]</td>
</tr>
</tbody>
</table>

| Age of Male Partner | Both female fertility and (to a lesser extent) male fertility decline with age. [CG 1.2.1] | The age of the male partner at the time of treatment must be under 55 years of age. | HFEA regulations enable men to donate sperm to assist infertile people and recommend that sperm donors should be aged under 41 years; the possible effect of a donor's age on assisted conception success is considered on a case by case basis. There is limited evidence that IVF success decreases in men over the age of the 40. Men aged over 40 are half as likely to conceive with IVF compared to 30-year-old men when their female partner is aged 35-39 years (de La Rochebrochardet al, 2006). However, male age does not impact on the success of other infertility treatment such as ICSI (Spandorfer et al, 1998). In light of some evidence that male age does impact on |
infertility, and may have an impact on IVF outcomes, and keeping in line with other CCG areas which stipulate a male age restriction of 55 years, we have included this as a criterion for eligibility.

| 2. Childlessness | n/a | NHS infertility treatment will NOT be funded if either partner has living children of any age; this includes an adopted child or a child (biological or adopted) from either the present or a previous relationship. Once accepted for treatment, should a child be adopted or a pregnancy leading to a live birth occur, the couple / individual will no longer be considered childless and will not be eligible for NHS funded treatment. | Resource Allocation: The priority of infertility treatment for childless couples. |
| 3. Previous Infertility Treatment | n/a | NHS infertility treatment will not be offered to people where either partner within the couple has already | The ability of the commissioner to provide infertility treatment to the optimal number of couples. |
undertaken any previous infertility treatment (IVF/ICSI) for fertility problems, regardless of whether the treatment was funded by the NHS or privately funded.

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<td>4.</td>
<td>Sterilisation</td>
<td>n/a</td>
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<td></td>
<td>NHS infertility treatment will not be available if either partner within the couple has received a sterilisation procedure or has undertaken a reversal of sterilisation procedure. Sterilisation is offered within the NHS as an irreversible method of contraception. Protocols for sterilisation include counselling and advice that NHS funding will not be available for reversal of the procedure or any fertility treatment consequently to this.</td>
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<tr>
<td>5.</td>
<td>Body Mass Index</td>
<td>Females who have a body mass index (BMI) of 30 or over should be informed that they are likely to take longer to conceive. The female wishing to conceive must have a BMI of &lt;30 kg/m² at the time of referral and commencement of treatment. Females wishing to conceive must be informed of this criterion at the earliest opportunity and offered the support of local NHS services to optimise their BMI. Consistent with NICE Guideline.</td>
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<tr>
<td>6. Smoking / Vaping Status</td>
<td>Females who smoke/vape should be informed that this is likely to reduce their fertility, should be offered referral to a smoking cessation programme to support their efforts in stopping smoking/vaping, and informed that passive smoking is likely to affect their chance of conceiving. Men who smoke/vape should be informed that there is an association between smoking and reduced semen quality (although the impact of this on male fertility is uncertain), and that stopping smoking/vaping will improve their general health.</td>
<td>Only non-smoking females/couples will be eligible for fertility treatment; smoking must have ceased by both partners three months prior to referral for infertility treatment.</td>
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