Assisted Conception Services for Infertile Patients

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Policy | Assisted Conception Services for Infertile Patients
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Policy Statement | This policy sets out the Sussex NHS Commissioners position for funding assisted conception services for infertile patients.
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1. **Introduction**

This policy sets out the Sussex NHS Commissioners position for funding assisted conception services for infertile patients. The policy relates to and have been informed by the National Institute of Health and Care Excellence (NICE) Clinical Guideline CG 156 ‘Fertility: assessment and treatment for people with fertility problems’, 2013 (updated 2017).

2. **Purpose**

The overall aim of the local policy is to support the commissioning of the highest quality, most clinically and cost effective and affordable fertility services, that maximise health outcomes in terms of live births and patient / baby safety. This policy supersedes and updates the positions of the former locality CCGs NHS Brighton and Hove CCG, NHS East Sussex CCG and NHS West Sussex CCG policies.

3. **Scope**

3.1. The policy affects couples and individuals who have diagnosed or undiagnosed infertility, seeking assisted conception services:

   - Patients will only be referred for NHS Funded assisted conception services if they meet the eligibility criteria in this policy and when all appropriate tests and investigations have been successfully completed in primary and secondary care in line with NICE clinical guidelines.
   - CCG does not partially fund treatments for patients who do not meet the eligibility criteria in this policy
   - Patients accessing assisted conception services should be fully informed of likely success rates and alternative approaches to parenting, including fostering and adoption
   - Patients should also be advised that impartial advice and information is available via the Human Fertilisation and Embryology Authority which regulates assisted reproductive therapies.

3.2. Pre-implantation Genetic Diagnosis (PGD) and the associated assisted conception services are commissioned by NHS England through Specialised Commissioning Area Teams, as per NHS England Clinical Commissioning Policy (2014) Pre-implantation Genetic Diagnosis.

3.3. For Preservation of fertility (cryopreservation i.e. freezing of eggs, sperm or embryos for future use) please refer to Appendix 1 for an interim statement.
4. **Equality Statement**

Promoting equality and addressing health inequalities are at the heart of Sussex NHS Commissioners values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it
- Given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities.

5. **Definitions**

5.1. **Clinical definition of 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 (International Committee for Monitoring Assisted Reproductive Technology and the World Health Organization revised glossary of ART terminology, 2009).

For this policy a couple is expected to be two people in a relationship, trying to conceive over two years of regular unprotected intercourse or an or an individual trying to conceive over 12 cycles of artificial insemination (AI).

Vaginal sexual intercourse every two to three days optimises the chance of pregnancy. People who are using AI should have their insemination timed around ovulation.

5.2. **Cycle of IVF / ICSI** refers to full cycle of IVF treatment, with or without intracytoplasmic sperm injection (ICSI) comprises of ovulation induction, egg retrieval, fertilisation and transfer of any resultant fresh and frozen embryos, and includes appropriate diagnostic tests, scans and pharmacological therapy.

5.3. **Expectant management** is a formal approach that encourages conception through unprotected vaginal intercourse or artificial insemination (AI), involving the provision of advice and information about the regularity and timing of intercourse and any lifestyle changes which might improve a couple’s chances of conceiving. Expectant management does not involve any active clinical or therapeutic interventions.

**NICE CG 156 advice:**

i. People who are concerned about their fertility should be informed that over 80% of couples in the general population will conceive within 1 year if:
   - The woman is aged under 40 years
   - 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%.

ii. Inform people who are using artificial insemination to conceive and who are concerned about their fertility that:
   - Over 50% of women aged under 40 years will conceive within 6 cycles of intrauterine insemination (IUI)
   - Of those who do not conceive within 6 cycles of intrauterine insemination, about half will do so with a further 6 cycles, cumulative pregnancy rate over 75%.

5.4. **Intrauterine insemination IUI** is a form of **artificial insemination (AI)**, the placement of sperm into the vagina, cervix or womb. IUI is a form of treatment where sperm are inserted into the uterine cavity around the time of ovulation.

6. **References and further information**

NICE Clinical Guideline CG 156. [www.nice.org.uk/guidance/cg156](http://www.nice.org.uk/guidance/cg156)

Human Fertilisation and Embryology Authority. [www.hfea.gov.uk/](http://www.hfea.gov.uk/)


7. **Equality**

In applying this policy, the CCGs will have due regard for the need to eliminate unlawful discrimination, promote equality of opportunity, and provide for good relations between people of diverse groups, in particular on the grounds of the following characteristics protected by the Equality Act (2010); age, disability, sex, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, and sexual orientation, in addition to offending background, trade union membership, or any other personal characteristic.
## 8. Eligibility criteria

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<thead>
<tr>
<th>Assisted conception services for infertile patients - Eligibility criteria</th>
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<tr>
<td><strong>1. Registered with a local GP</strong></td>
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| **2. Sub-fertility: Initial investigations** | People who are concerned about delays in conception should be offered an initial assessment. A specific enquiry about lifestyle and sexual history should be taken to identify people who are less likely to conceive.  
A woman of reproductive age who has not conceived after one 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.  
A woman of reproductive age who is using artificial insemination (AI) to conceive (with either partner or donor sperm) should be offered further clinical assessment and investigation if she has not conceived after six cycles of treatment (self-funded), in the absence of any known cause of infertility. Where a couple is attempting to conceive using AI with the male partner’s sperm, or a single woman is using AI with a known donor’s sperm, the referral for clinical assessment and investigation should include both parties.  
Where the woman is aged 36 years, she should be offered an earlier referral for specialist consultation to discuss the options for attempting conception, further assessment and appropriate treatment.  
Male same sex couples and single men can be referred for infertility investigation if no pregnancy results following six cycles of AI (self-funded) for which the man’s donated sperm has been used.  
Of note is that the NHS does not fund any type of surrogacy arrangement (as per point 17.) This includes any costs associated with the use of a surrogacy arrangement and any associated fertility treatment costs. |
| **3. Sub-fertility: Treatment of diagnosed and unexplained infertility** | Individuals / couples with a diagnosed cause of absolute infertility which precludes any possibility of natural conception, and who meet all the other eligibility criteria, should be referred without delay for appropriate assisted conception assessment.  
All other patients, including those with unexplained infertility, assisted conception treatment is offered if they have not conceived after two years of regular unprotected sexual intercourse or after 12 cycles of artificial insemination (including six self-funded cycles of AI), to |
establish fertility status. This includes expectant management up to one year before their fertility investigations.

| 4. Age of woman at time of referral and number of cycles funded | Women under the age of 40 (at the point of GP referral, the patient needs to be no older than 39 years and 6 months):
- Three full cycles of IVF, with or without ICSI is funded. If the woman reaches the age of 40 during treatment, complete the current full cycle but do not offer further full cycles. Frozen embryos are expected to be used before the next fresh cycle.

Women aged 40-42:
- One full cycle of IVF, with or without ICSI is funded provided that all of the following three criteria are fulfilled:
  o they have never previously had IVF treatment
  o there is no evidence of low ovarian reserve
  o there has been a discussion of the additional implications of IVF and pregnancy at this age |

| 5. Ovarian reserve Testing; Anti-Müllerian hormone (AMH) | AMH measure to predict the likely ovarian response to gonadotrophin stimulation in IVF will be requested by the specialist fertility services.

AMH of less than or equal to 5.4 pmol/l predicting a low response and greater than or equal to 25.0 pmol/l a high response. |

| 6. Previous NHS or private treatment and total number of cycles | In women aged under 40 years any previous full IVF cycle, whether self or NHS funded, counts towards the total of three full cycles that should be offered by the NHS. In women aged 40-42 any previous full IVF cycle, whether self or NHS funded, counts towards the total of one cycle that should be offered by the NHS. |

| 7. Cancelled cycle | A cancelled cycle is one where an egg collection procedure has not been undertaken. Once egg collection has commenced, this is considered a complete cycle and will count towards one of the NHS funded cycles.

If a patient decides to decline or withdraw from a treatment cycle, then this will count as a full cycle for the purpose of the number of attempts at assisted conception. |

| 8. Storage of surplus embryos following fresh cycle of NHS funded IVF | The cryopreservation (freezing and storage) of good quality embryos following NHS funded IVF/ICSI will be funded for up to five years to enable patients to have the option to use the frozen-thawed embryos in subsequent self-funded cycles. |
9. **IUI**  
Six unstimulated IUI cycles are offered as an alternative to vaginal sexual intercourse for:  
- People who are unable to, or would find it difficult, to have vaginal intercourse (such as people with a clinically diagnosed disability or psychosexual problem)  
- People with conditions that require specific consideration in relation to methods of conception (such as couples where the male is HIV positive)  
- Single women and women in same-sex relationships

10. **Childlessness**  
Treatments for infertility will be funded if 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.

11. **Sterilisation**  
Assisted reproduction services will not be available if infertility is the result of a voluntary sterilization procedure in either partner.

12. **BMI**  
Women must have a BMI of between 19 and 29.9 inclusive, at the time of referral for specialist assisted reproduction assessment and at the time of any specialist treatment.  
Men who have a BMI of 30 or over should be informed that they are likely to have reduced fertility.

13. **Smoking**  
Couple must be non-smokers minimum six months before referral to specialist assisted reproduction assessment and remain non-smokers at the time of any specialist treatment. All women should be informed that passive smoking is likely to affect their chance of conceiving.

14. **The use of donor sperm and donor eggs from HFEA licenced clinics**  
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 such as:  
- Where there is a high risk of transmitting a genetic disorder to the offspring  
- Where there is a high risk of transmitting infectious disease to the offspring or the woman from the man  
- Severe rhesus isoimmunisation

Donor eggs: the use of donor oocytes is considered effective in managing fertility problems associated with the following conditions:  
- Premature ovarian failure  
- 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.

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<tr>
<th>15. Blood borne viruses and sperm washing</th>
<th>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. For couples where the man is HIV positive and either he is not compliant with Highly active antiretroviral therapy (HAART) or his plasma viral load is 50 copies/ml or greater, one episode of sperm washing can be offered.</th>
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<tr>
<td>16. Surgical sperm retrieval (SSR)</td>
<td>Surgical sperm retrieval for azoospermia (SSR) is supported and funded by NHS England as per the criteria outlined in the NHSE Clinical Commissioning Policy: ‘Surgical sperm retrieval for male infertility’.</td>
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<td>17. Surrogacy</td>
<td>The CCG does not fund any type of surrogacy arrangement due to the significant medico-legal issues involved in surrogacy arrangements. Commissioning parents need to undertake the whole process, including any associated fertility treatment, themselves.</td>
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Appendix 1. Fertility preservation (as per East Sussex Assisted Reproductive Techniques (ART) Policy June 2020)

Cryopreservation of sperm, oocytes or embryos will be available for fertility preservation for eligible patients due to receive gonadotoxic treatments. Women undergoing gonadotoxic treatment should have access to a consultation with an NHS fertility specialist before and after undergoing gonadotoxic treatment.

Storage of embryos, oocytes and sperm will be funded for up to ten years after cryopreservation.

NHS funding of cryopreservation of materials will cease where:

- Fertility is established through tests or conception
- A live birth has occurred
- The patient dies and no written consent has been left permitting posthumous use.