

CLINICAL POLICY ADVISORY GROUP (CPAG)

Intrauterine Insemination Policy

This policy is not a fertility treatment policy. The intention of this policy is to aid couples who are unable to have regular intercourse demonstrate infertility. The NHS treatment pathway for infertility starts once infertility is confirmed. For fertility treatment please see the <u>In Vitro</u> Fertilisation (IVF)/Intracytoplasmic Sperm Injection (ICSI) within Tertiary Infertility Services Policy.

Statement

• All couples or single women without a partner are eligible for fertility consultation and advice in Primary Care.

Derby and Derbyshire ICB (DDICB) has restricted the access of Intrauterine Insemination (IUI).

- DDICB will fund 6 cycles of IUI for the patient groups listed below ONLY once the patient has self-funded the initial 6 cycles of IUI and have been unsuccessful in achieving a pregnancy, despite evidence of normal ovulation, tubal patency and semen analysis.
 - For the purpose of access to NHS services, donor or partner insemination should be undertaken in a clinical setting with an initial clinical assessment and appropriate investigations.
- IUI should be considered as an alternative to vaginal sexual intercourse in the following groups of patients:
 - 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);
 - o People in a same-sex relationship where one of the partners has an intact uterus
 - Single women without a partner
- DDICB will fund the initial 6 IUI cycles where the male partner is HIV positive AND the couple is clinically indicated to receive IUI following a successful sperm washing procedure. This is because IUI in these circumstances is regarded as a harm reduction measure
 - o In these circumstances the initial 6 cycles of IUI will be funded
 - Where achieving a pregnancy has been unsuccessful after the initial 6 cycles of IUI, DDICB will fund another 6 cycles of IUI
 - Sperm washing should be offered where the man is:
 - not compliant with highly active antiretroviral treatment (HAART), OR
 - his plasma viral load is ≥50 copies/ml
- IVF will only be considered once single women/couples who fall into the groups of patients listed above are unsuccessful in achieving a pregnancy after completing 12 cycles of IUI.
- Where, after 12 cycles of IUI, a pregnancy has not been achieved the single woman/couple will be considered for IVF. See <u>IVF ISCI within Tertiary Infertility Services Policy</u>

These commissioning intentions will be reviewed periodically. This is to ensure affordability against other services commissioned by the ICB.

1. Background

This policy should be read in conjunction with <u>In Vitro Fertilisation (IVF)/Intracytoplasmic</u> Sperm Injection (ICSI) within Tertiary Infertility Services Policy.

IUI is a form of fertility treatment where better-quality sperm are separated from slower/nonmoving or abnormally shaped sperm and then inserted into the uterine cavity around the time of ovulation. IUI can be carried out in a natural cycle, without the use of drugs, or the ovaries can be stimulated with oral antioestrogens or gonadotrophins.

The IUI procedure can be provided using partner or donor sperm. As with any fertility treatment, the younger the woman is the higher her chances of getting pregnant. You're also more likely to get pregnant if you have fertility drugs to stimulate your natural cycle.

Over 50% of women aged under 40 years will conceive within 6 cycles of IUI. Of those who do not conceive within the initial 6 cycles of IUI, around half will do so after a further 6 cycles. This gives IUI a cumulative pregnancy rate of around 75% over 12 cycles.

2. Recommendation

This policy is not a fertility treatment policy. The intention of this policy is to aid couples who are unable to have regular intercourse demonstrate infertility. The NHS treatment pathway for infertility starts once infertility is confirmed. For fertility treatment please see the In Vitro Fertilisation (IVF)/Intracytoplasmic Sperm Injection (ICSI) within Tertiary Infertility Services Policy.

Eligibility Criteria:

- All single women without a partner/couples are eligible for fertility consultation and advice in Primary Care.
- DDICB will fund 6 cycles of IUI for the patient groups listed below ONLY once the patient has self-funded the initial 6 cycles of IUI and have been unsuccessful in achieving a pregnancy, despite evidence of normal ovulation, tubal patency and semen analysis.
 - For the purpose of access to NHS services, donor or partner insemination should be undertaken in a clinical setting with an initial clinical assessment and appropriate investigations.
- IUI should be considered as an alternative to vaginal sexual intercourse in the following groups of patients:
 - 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),
 - N.B The rationale for funding initial rounds of IUI for couples where the man is HIV positive, and the couple are clinically indicated to receive IUI following successful sperm washing serves to prevent transmission of HIV to the woman and the child
 - People in a same-sex relationship where one of the partners has an intact uterus
 - o Single women without a partner
- DDICB will fund the initial 6 IUI cycles where the male partner is HIV positive AND the couple is clinically indicated to receive IUI following a successful sperm washing procedure.

This is because IUI in these circumstances is regarded as a harm reduction measure

- In these circumstances the initial 6 cycles of IUI will be funded.
- Where achieving a pregnancy has been unsuccessful after the initial 6 cycles of IUI, DDICB will fund another 6 cycles of IUI.
- Sperm washing should be offered where the man is:
 - not compliant with highly active antiretroviral treatment (HAART), OR
 - his plasma viral load is ≥50 copies/ml.
 - NB. Sperm washing, where the sperm has come from a man who is hepatitis C positive is not necessary. It is advised that partners of individuals with hepatitis B should be vaccinated before fertility treatment is initiated.
- IVF will only be considered once single women/couples who fall into the groups of patients listed above are unsuccessful in achieving a pregnancy after completing 12 cycles of IUI.
- Where, after 12 cycles of IUI, a pregnancy has not been achieved the single woman without a partner/couple will be considered for IVF. See <u>IVF ISCI within Tertiary Infertility Services</u> <u>Policy.</u>

Exclusion Criteria:

IUI should not be routinely offered to:

- People who are having regular sexual intercourse and have:
 - o unexplained infertility
 - o mild endometriosis
 - mild male factor infertility (Instead, these patient groups should be advised to try and conceive for a total of 2 years)
- People who have been sterilized.
- People who have social objections to IVF who have an underlying fertility problem.
- An exception to these exclusion criteria is people who have cultural or religious objections to IVF who have an underlying fertility problem.
 - In these circumstances the option of IUI will be discussed as part of the assessment and treatment in the NHS.

Assessment Criteria for IUI Referral:

- Same-sex couples or single women without a partner who have been unsuccessful in conceiving after 6 cycles of self-funded IUI with the last IUI cycle being completed in the past 12 months.
- Age:
 - o up to 39 years for a woman
- BMI:
 - within 19-30 for a woman
- Consideration of the child's welfare:
 - Centre should consider factors which are likely to cause serious physical psychological or medical harm, either to the child to be born or to any existing children of the family. This is a requirement of the licensing body, Human Fertilization and Embryology Authority.

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- Family structure:
 - No living children from current or previous relationship(s), including adopted children, but excluding foster children. There needs to be an explicit and recorded assessment that the social circumstances of the family unit have been considered within the context of the assessment of the welfare of the child.
- Non-smoking status for either partner:
 - Ex-smokers must not have smoked a cigarette for at least 28 days before treatment commences
 - o Ex-smokers must continue not to smoke throughout treatment
 - Sole use of e-cigarettes without concurrent use of tobacco is classified as non-smoking for the purpose of this policy.

Referral to Other Services:

- Patients who fail to achieve a pregnancy after 12 cycles of IUI will be considered for IVF
- Where psychosexual problems prevent vaginal intercourse, the couple should, in the first instance, be referred for psychosexual counselling
- Same-sex couples considering surrogacy are referred to the <u>Surrogacy Policy</u>. This Policy states that the NHS "will not provide routine funding for the medical treatment required to give effect to a surrogacy arrangement".

Exceptional Circumstances:

• Cases may be considered via the ICB's Individual Funding Request route but must demonstrate robust, clinical exceptionality.

3. Rationale for Recommendation

This policy is commissioned in line with <u>NICE CG156: Fertility (2013)</u> updated in 2017:

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.

For people in recommendation above who have not conceived after 6 cycles of donor or partner insemination, despite evidence of normal ovulation, tubal patency and semen analysis, offer a further 6 cycles of unstimulated intrauterine insemination before IVF is considered.

For people with unexplained infertility, mild endometriosis or mild male factor infertility, who are having regular unprotected sexual intercourse:

 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) • advise them to try to conceive for a total of 2 years (this can include up to 1 year before their fertility investigations) before IVF will be considered.

The rationale for funding initial rounds of IUI for couples where the man is HIV positive, and the couple are clinically indicated to receive IUI following successful sperm washing serves to prevent transmission of HIV to the woman and the child.

Male partners who are Hepatitis C positive have a low likelihood of transmitting the virus through sexual intercourse (approximately 2%) and NICE state there is insufficient evidence about the value of sperm washing to reduce that risk even further.

NICE advises that partners of individuals with Hepatitis B should be vaccinated before fertility treatments begin and sperm washing should not be offered prior to having fertility treatment.

4. Useful Resources

- NHS Website. Infertility. <u>https://www.nhs.uk/conditions/infertility/</u>
- HFEA (Human Fertilisation & Embryology Authority) <u>https://www.hfea.gov.uk/</u> treatments/explore-all-treatments/intrauterine-insemination-iui/

5. References

- NICE (2013). CG156: Fertility Problems: Assessment and Treatment https://www.nice.org.uak/guidance/cg156
- HFEA. Fertility Treatment 2019: Trends and Figures (May 2021) https://www.hfea.gov.uk/about-us/publications/research-and-data/fertility-treatment-2019trends-and-figures/
- Stonewall. Donor Insemination and Fertility Treatment. <u>https://www.stonewall.org.uk/help-advice/parenting-rights/donor-insemination-and-fertility-treatment-0</u>

6. Appendices

Appendix 1 - Consultation

All relevant providers/stakeholders will be consulted via a named link consultant/specialist. Views expressed should be representative of the provider/stakeholder organisation. CPAG will consider all views to inform a consensus decision, noting that sometimes individual views and opinions will differ.

Consultee	Date
Consultant Obstetrician and Gynaecologist, CRHFT	March 2022
Consultant Obstetrician and Gynaecologist, UHDBFT	March 2022
Clinical Policy Advisory Group (CPAG)	April 2022
Clinical and Lay Commissioning Committee (CLCC)	May 2022
Clinical Policy Advisory Group (CPAG)	June 2023

Appendix 2 - Document Update

Document Update	Date Updated
Version 3.0	April 2022
Policy has been re-worded and reformatted to reflect the DDCCG	
clinical policies format. This includes the addition of background	
information, useful resources, references and consultation	
Version 3.1	May 2023
• Policy updated to reflect the change of organisation to DDICB	
 Inclusion of single women without a partner who are unable to evidence infertility 	