

Policy for Specialist Treatment of Infertility

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Name of author and title:	Public Health Warwickshire & ICB Medical Directorate
Name of reviewer and title:	Dr Mike Caley, Deputy Chief Medical Director
Department:	Medical Directorate

VERSION HISTORY

Date	Version	Changes made to previous version	Consulting and Endorsing Stakeholders, Committees / Meetings / Forums etc.
26.08.2022	V2	<p>Addition of preferred providers previously omitted in V1</p> <p>Policy wording has been updated to provide greater clarity and maintain consistency throughout the policy</p>	Audit Committee 01.07.2022

18.01.2024	V3	<p>Update to preferred providers</p> <p>Policy wording has been updated to provide greater clarity regarding point of referral and guidance to clinicians around interruption of treatment due to NHS medical treatment</p> <p>Policy reformatted to Clinical Commissioning Policy template</p> <p>Addition of 2 cycles of self-funded IVF to the definition of infertility section</p> <p>Update to reference of self-funded treatment applying to 'the couple' to provide clarity to patients and clinicians</p> <p>Addition to definition of Transgender male in a relationship to ensure consistency with definition of other partner/couple</p>	<p>Clinical Commissioning Policy Development Groups 17.10.2023 & 19.12.2023</p>
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1. Category: Threshold

Threshold procedures and therapies are those in which a clinical threshold has been set which needs to be met before funding will be made available for treatment.

For patients who **DO NOT** meet the eligibility criteria, the ICB will only consider funding the treatment if an Individual Funding Request (IFR) detailing the patient's clinical presentation is submitted to the ICB.

2. Background

One cycle of infertility treatment (IVF or ICSI), including drug costs, will be made available to couples who meet the definition for infertility and eligibility criteria, together with up to two associated frozen cycles (including drug costs if necessary).

3. Indication

- Infertility is defined as the period of time people have been trying to conceive without success after which formal investigation is justified and possible treatment implemented.
- Investigations for infertility are not usually recommended until the couple has been unable to conceive after 1 year of regular unprotected sexual intercourse. However, investigations should be offered earlier than 1 year to couples who have been identified as less likely to conceive (for example if the maternal partner is aged 36 years and older).

Following the first year and clinical investigation:

- Where the cause of infertility is known and all of the eligibility criteria, set out below, are met, the couple should be offered NHS funded infertility treatment without further delay.
- In the absence of any known cause of infertility, the couple should be offered NHS infertility treatment where all eligibility criteria are met after a further 1 year of regular unprotected vaginal sexual intercourse.

In circumstances where the above definition cannot be applied, for example, females in a same sex relationship, 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 or a transgender male, infertility is identified where the couple have not conceived after 6 cycles of self-funded donor/partner insemination, **OR** 2 cycles of self-funded IVF, undertaken at a HFEA registered clinic, in the absence of any known medical cause of infertility, and therefore should be offered NHS infertility treatment where all eligibility criteria are met.

4. Eligibility Criteria

Eligibility criteria to access NHS funded infertility treatment once infertility has been defined is as follows:

- Childlessness – treatment will only be available where neither partner has living or adopted children of any age
- Sterilisation – treatment will not be available if infertility is the result of a sterilisation procedure in either partner
- Previous Infertility Treatment - any couple who has had one or more previous NHS funded

cycle (i.e., including embryo implantation) of stimulated IVF/ICSI funded on the NHS or had three or more privately funded cycles will not be eligible

- Age of Maternal Partner - Where the protocol indicates the use of the named infertility procedures within the policy then they will only be offered to the maternal partner under 40 years at the time of referral. For maternal partner's aged 39 years, the expectation is that treatment, including any frozen embryo transfers (FETs), is undertaken within 12 months of referral. Where preliminary infertility investigations and/or treatment unexpectedly delay referral to the fertility provider, the ICB considers the point of referral to be at the point of starting investigations as long as these can be reasonably considered to be part of the same episode of care.
- Age of Non-maternal Partner – there is no restriction on the age of the non-maternal partner, although this issue may be raised under medical suitability or welfare of the child considerations
- Body Mass Index – treatment will not be provided or commence where the maternal partner has a Body Mass Index (BMI) <19 kg/m² or >30kg/m² and patients should be encouraged to attend the weight management clinic to achieve the recommended BMI. If there are special circumstances relating to BMI then the final paragraph in Section 3 relating to Individual Funding Requests can be followed
- Smoking Status - the expectation is that couples accepted for treatment would be non-smoking. Smokers should initially be referred to the Smoking Cessation Service and should have stopped smoking for at least 4 weeks prior to referral for infertility treatment and continue to refrain from smoking throughout the treatment process
- Preferred providers - The ICB's local provider, the Centre of Reproductive Medicine, University Hospitals of Coventry and Warwickshire NHS Trust, is preferred; however other providers are available under Right to Choose.

5. Specialist Treatment of Infertility Policy Definitions

Item	Definition
Assisted Conception	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.
Partner/ Couple	Any reference to a female/partner/couple could relate to any of the following: <ul style="list-style-type: none"> • Heterosexual couple; a male and a female in a relationship • Same sex female couple; two females in a relationship • Transgender male; biologically born as a female, gender reassigned to male, retention of female reproductive organs in a relationship

Infertility	<p>A Maternal partner 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.</p> <p>Following the first year and clinical investigation:</p> <ul style="list-style-type: none"> • Where the cause of infertility is known, and all the eligibility criteria are met, the couple should be offered NHS infertility treatment without further delay. • In the absence of any known cause of infertility, the couple should be offered NHS infertility treatment where all eligibility criteria are met after a further 1 year of regular unprotected vaginal sexual intercourse <p>In circumstances where the above definition cannot be applied, for example females in a same sex relationship, 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 or a transgender male, infertility is identified where the couple have not conceived after 6 cycles of self-funded donor/partner insemination, OR 2 cycles of self-funded IVF, undertaken at a Human Fertilisation and Embryology Authority (HFEA) registered clinic, in the absence of any known medical cause of infertility</p>
One cycle of fertility treatment	A cycle will consist of ovulation induction, egg retrieval, fertilisation and embryo transfer to the uterus, including all appropriate diagnostic tests, scans and pharmacological therapy.
In Vitro Fertilisation (IVF)	A female's egg and a male's sperm are collected and mixed together in a laboratory to achieve fertilisation outside the body. The embryos produced may then be transferred into the maternal partner. A clinic may also use donor sperm or eggs, where clinically indicated.
Intra-Cytoplasmic sperm injection (ICSI)	In conjunction with IVF, where a single sperm is directly injected, by a recognised practitioner, into the egg. A clinic may also use donor sperm or eggs, where clinically indicated.
Frozen Embryo Transfer (FET)	Funding will include the costs of cryopreservation/freezing of embryos for one year. It is expected that the associated frozen cycles funded under this policy would be completed during this time period. Frozen embryo transfer can be undertaken after a gap of 2-3 months, if a previous attempt has not resulted in a pregnancy. So, it is anticipated that 2 FETs can be concluded within a year of cryopreservation. Following commencement of Specialist Treatment of Infertility, where NHS medical treatment is required resulting in a cycle of treatment being interrupted, the ICB will allow an extension to the 12 months completion timeframe to allow the NHS medical treatment to complete. Once the patient is recovered from the NHS medical treatment, the ICB expects the cycle to continue where left off as long as the couple continue to meet the policy criteria and conclude within the timescales set out in the policy, i.e. if the cycle has not resulted in a pregnancy, embryo transfer should be undertaken after a gap of 2-3 months.

Intrauterine insemination (IUI)	Insemination of sperm into the uterus of a woman. (HFEA) Not commissioned in line with Clinical Guideline Addendum 156.1 August 2016
Donor Insemination (DI)	Uses sperm from a donor to help a maternal partner become pregnant. (HFEA)
Azoospermia	An absence of viable sperm in the semen
Oligospermia	A subnormal concentration of viable sperm in the ejaculated semen.
Body Mass Index (BMI)	BMI is the most widely used way to measure your weight and is calculated using your weight in kilograms divided by your height in metres squared. (NHS Choices)

6. Specialist Treatment of Infertility Policy Content

- Providing that all eligibility criteria detailed above are met, for couples in whom this is clinically indicated, the Commissioner will fund **1 cycle**¹ of In Vitro Fertilisation (IVF) or Intra-Cytoplasmic Sperm Injection (ICSI) and up to a maximum of **2 frozen** embryo transfers (FETs).
- The Commissioner will fund **donor sperm** procedures where the male partner has Azoospermia or Oligospermia.
- The Commissioner will fund **donor egg** procedures where the maternal partner has undergone premature ovarian failure.
- The Commissioner will ensure that at least one appropriate Provider is commissioned to provide infertility treatment. The provider(s) will conform to all statutory responsibilities including Care Quality Commission and Human Fertilisation and Embryology Authority (HFEA).
- The Provider(s) will be registered with and operate in adherence to HFEA Code of Practice including a child welfare assessment, and HFEA Policy particularly in relation to multiple births and single embryo transfer. NICE Guidance will be followed including the promotion of advice and guidance around alcohol and caffeine use to increase chances of conception, for example.
- The Commissioner will fund the **cryopreservation and storage** of any suitable surplus embryos following a completed NHS funded cycle for a period of 12 months, in line with Human Fertilisation and Embryology Authority (HFEA) guidelines. Following this period, the couple may self-fund continued storage.
- Following commencement of Specialist Treatment of Infertility, where NHS medical treatment is required resulting in a cycle of treatment being interrupted, the ICB will allow an extension to the 12 months completion timeframe to allow the NHS medical treatment to complete. Once the patient is recovered from the NHS medical treatment, the ICB expects the cycle to continue where left off as long as the couple continue to meet the policy criteria and conclude within the timescales set out in the policy, i.e. if the cycle has not resulted in a pregnancy, embryo transfer should be undertaken after a gap of 2-3 months.
- The Commissioner will **not part-fund** assisted conception/infertility treatment for individuals or couples that are ineligible for NHS-funded services under this policy.

- Where previous NHS treatment is a causal factor of the sub/infertility, and cryopreserved gametes are available, this policy will allow the use of cryopreserved gametes for infertility treatment in line with specialist clinical input and assuming patients meet all other eligibility criteria.
- **Early investigations** should be offered where a maternal partner is 35 years or over, or there is a history of predisposing factors (e.g., amenorrhoea, oligomenorrhoea, pelvic inflammatory disease).
- In **cancer patients**, however, it would not be productive to wait until they are 23 to begin treatment. In these cases, treatment can commence at an earlier age to enable removal of eggs/sperm prior to starting treatment. Support will still be subject to the other patient criteria being met including that relating to living children.
- It is acknowledged that a cycle could fail at any time after commencement due to a number of reasons. For example, ovulation induction failure, failure to retrieve an egg, failure to fertilise or a failure to transfer/implantation an embryo into the uterus. 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. However, if a cycle is abandoned prior to egg collection then one further attempt for the couple will be funded.
- It is anticipated that, rarely, couples who would not be eligible for treatment because they do not fulfil the eligibility criteria may, by virtue of extenuating circumstances, be considered an exceptional case for NHS funding. If there is a case on the grounds of exceptional circumstances, the couples' GP or consultant should submit their request to the Commissioner's Individual Funding Request Panel.

¹ Due consideration has been applied and the decision to fund one cycle of IVF therapy has been based on best clinical practice and financial modelling.

7. Eligibility Criteria and Rationale

Ref	Feature	NICE Guideline	Proposed Criterion	Rationale
1.	Childlessness	n/a	NHS infertility treatment will be funded if neither partner has living children of any age; this includes an adopted child or a child 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 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.
2.	Sterilisation	n/a	NHS infertility treatment will not be available where either partner has received a sterilisation procedure, which is the cause of the infertility.	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.
3.	Previous Infertility Treatment	n/a	NHS infertility treatment will not be offered to any couple who have had one or more previous NHS funded cycle (i.e., including embryo implantation) of stimulated IVF/ICSI or had three or more privately funded cycles will not be eligible.	The ability of the commissioner to provide infertility treatment to the optimal number of couples.

4.	Body Mass Index	Where the maternal partner has a body mass index (BMI) of 30 or over they should be informed that they are likely to take longer to conceive. Men who have a BMI of 30 or over should be informed that they are likely to have reduced fertility.	Treatment will not be provided or commence where a maternal partner has a Body Mass Index (BMI) <19 kg/m ² or >30kg/m ² and patients should be encouraged to attend the weight management clinic to achieve the recommended BMI. If there are special circumstances relating to BMI then the final paragraph in Section 1 relating to Individual Funding Requests can be followed.	Consistent with NICE Guideline.
5.	Smoking Status	Maternal partners who smoke 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, and informed that passive smoking is likely to affect their chance of conceiving. Men who smoke should be informed that there is an association between smoking and reduced semen quality (although the level of impact of this on male fertility is uncertain), and that stopping smoking will improve their general health.	The expectation is that couples accepted for treatment would be non-smoking. Smokers should initially be referred to the Smoking Cessation Service and should have stopped smoking for at least 4 weeks prior to referral for infertility treatment and continue to refrain from smoking throughout the treatment process.	Maternal and paternal smoking can adversely affect the success infertility treatment and smoking during the antenatal period can lead to increased risk of adverse pregnancy outcomes. Maternal partners should be informed that passive smoking is likely to affect their chance of conceiving. There is an association between smoking and reduced semen quality.

6.	Age of Maternal Partner	Where the maternal partner is aged under 40 years, offer NHS infertility treatment. If the maternal partner reaches the age of 40 during treatment, complete the current full cycle	Where the protocol indicates the use of the named infertility procedures within the policy then they will only be offered to maternal partners under 40 years at the time of referral. Where the maternal partner is aged 39 years, the expectation is that treatment, including any frozen embryo transfers (FETs), is undertaken within 12 months of referral. Where preliminary infertility investigations and/or treatment unexpectedly delay referral to the fertility provider, the ICB considers the point of referral to be at the point of starting investigations as long as these can be reasonably considered to be part of the same episode of care.	<p>Consistent with NICE Guideline. Fall off in treatment success with increasing maternal age. Increased maternal and child complication rate. Prevention of delays in treatment where appropriate</p> <p>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]</p>
7.	Age of Non-maternal Partner	Both female fertility and (to a lesser extent) male fertility decline with age. [CG 1.2.1]	There is no restriction on the age of the Non-maternal partner, although this issue may be raised under medical suitability or welfare of the child considerations	Maintain current policy

8. Guidance/References

British Fertility Society (2005). Key facts on infertility, IVF and NHS provision. Bristol: BFS Secretariat.

De La Rochebrochard E et al. Paternal age over 40 years: the “amber light” in the reproductive life of men? *J Androl.* 2003 24(4):459-65.

de La Rochebrochard E, de Mouzon J, Thépot F, Thonneau P. Fathers over 40 and increased failure to conceive: the lessons of in vitro fertilization in France. *FertilSteril.* 2006; 85 (5):1420-4.

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Nelson SM, Lawlor DA (2011) Predicting Live Birth, Preterm Delivery, and Low Birth Weight in Infants Born from In Vitro Fertilisation: A Prospective Study of 144,018 Treatment Cycles. *PLoS Med* 8(1): e1000386. doi:10.1371/journal.pmed.1000386

NHS Choices; [BMI calculator | Check your BMI - NHS | Please fill in your details \(www.nhs.uk\)](https://www.nhs.uk/health/a-z/bmi-calculator/)

Oakley L, Doyle P, Maconochie N. Lifetime prevalence of infertility and infertility treatment in the UK: results from a population based survey of reproduction. *Hum Reprod* 2008; 23: 447–450.

Spandorfer SD, Avrech OM, Colombero LT, Palermo GD, Rosenwaks Z. Effect of parental age on fertilization and pregnancy characteristics in couples treated by intracytoplasmic sperm injection. *Hum Reprod.* 1998; 13(2):334-8.

Templeton A, Fraser C, Thompson B. The epidemiology of infertility in Aberdeen. *Br Med J* 1990; 301: 148– 152

Wilkes, S. and Chinn, D. and Murdoch, A. and Rubin, G. (2009) 'Epidemiology and management of infertility: a population based-study in UK primary care', *Family practice* 26 (4). pp. 269-274.

Mackenna A.I., Zegers-Hochschild F., Fernandez E.O., Fabres C.V., Huidobro C.A., Guadarrama A.R. Intrauterine insemination: Critical analysis of a therapeutic procedure. *Human Reproduction.* 1992; 7/3: 351-354

Peek J.C., Godfrey B., Matthews C.D. Estimation of fertility and fecundity in women receiving artificial insemination by donor semen and in normal fertile women. British Journal of Obstetrics and Gynaecology.1984; 91/10:1019-1024

9. Equality and Quality Impact Assessment Tool

The following assessment screening tool will require judgement against all listed areas of risk in relation to quality. Each proposal will need to be assessed whether it will impact adversely on patients / staff / organisations.

Insert your assessment as positive (P), negative (N) or neutral (N/A) for each area.

Record your reasons for arriving at that conclusion in the comments column. If the assessment is negative, you must also calculate the score for the impact and likelihood and multiply the two to provide the overall risk score. Insert the total in the appropriate box.

Quality Impact Assessment

Quality and Equality Impact Assessment

Scheme Title:	Policy for Specialist Treatment of Infertility		
Project Lead:	Lucy Dyde, IFR Team Manager	Senior Responsible Officer:	Dr Michael Caley, Deputy CMO
		Quality Sign Off:	Quality Team staff as below
Intended impact of scheme:	<p>To provide a fair, equitable and transparent process for all patients of the NHS Coventry and Warwickshire Integrated Care Board (ICB), for which the ICB has commissioning responsibility.</p> <p>The policy for Specialist Treatment of Infertility supports the objective to prioritise resources and provide interventions with the greatest proven health gain, within ICB budgetary constraints. The intention is to ensure equity and fairness in respect of access to NHS funding for interventions and to ensure that interventions are provided within the context of the needs of the overall population and the evidence of clinical and cost effectiveness and desired outcomes for patients it is intended for.</p>		
How will it be achieved:	Through the process detailed in this document.		

Name of person completing assessment:	Lucy Dyde
Position:	IFR Team Manager
Date of Assessment:	12 June 2024

Quality Review by:	Lee Hill, Petty Trowell, read by Micaela Loveridge, Sarah Chamberlain, Anna Crane
Position:	Quality Team Staff
Date of Review:	20 06 24

High level Quality and Equality Questions

The risk rating is only to be done for the potential negative outcomes. We are looking to assess the likelihood of the negative outcome occurring and the level of negative impact. We are also seeking detail of mitigation actions that may help reduce this likelihood and potential impact.

AREA OF ASSESSMENT		OUTCOME ASSESSMENT (Please tick one)			Evidence/Comments for answers	Risk rating (For negative outcomes)			Mitigating actions
		Positive	Negative	Neutral		Risk impact (I)	Risk likelihood (L)	Risk Score (IxL)	
Duty of Quality Could the scheme impact positively or negatively on any of the following:	Effectiveness – clinical outcome	✓			Policy to implement access for eligible couples to receive clinically effective specialist infertility treatment following NICE CG156.				
	Patient experience	✓			Policy to implement access for eligible couples will be assured that they are accessing evidenced based practice to receive clinically appropriate specialist infertility treatment.				

	Patient safety	✓			The provider will follow the Patient Safety Incident Response Framework (PSIRF) national guidance on reporting learning from patient safety incidents as per individual policy/procedures to protect couples and maintain safety.				
	Parity of esteem	✓			Policy to implement access for eligible couples to receive clinically appropriate treatment which includes access to mental health and physical health support within the infertility services following best practice and NICE CG156.				
	Safeguarding children or adults	✓			Usual ICB and/or Provider Safeguarding policies and mechanisms will apply.				
NHS Outcomes Framework Could the scheme impact positively or negatively on the delivery of the five domains:	Enhancing quality of life	✓			Couples that are eligible for specialist infertility treatment will experience an improved access to service and desired outcome.				
	Ensuring people have a positive experience of care	✓			Increased opportunity for couples to access the service locally and nationally via patient choice.				
	Preventing people from			✓	Policy to implement				

	dying prematurely				access for eligible couples to receive clinically effective specialist infertility treatment.				
	Helping people recover from episodes of ill health or following injury			✓	Policy to implement access for eligible couples to receive clinically effective specialist infertility treatment.				
	Treating and caring for people in a safe environment and protecting them from avoidable harm	✓			The ICB expectation is that all providers of service hold an NHS standard contract where delivery of the service is stipulated under the core requirements to safeguard quality of care in line with the Care Quality Commission (CQC) "quality statements".				
Patient services Could the proposal impact positively or negatively on any of the following:	A modern model of integrated care, with key focus on multiple long-term conditions and clinical risk factors			✓	Policy supports access for eligible couples to receive clinically effective specialist infertility treatment.				
	Access to the highest quality urgent and emergency care			✓	Policy supports access for eligible couples to receive clinically effective specialist infertility treatment.				
	Convenient access for everyone	✓			This policy applies to all couples registered at an NHS Coventry and Warwickshire ICB GP practice and is available under patient choice for eligible couples to receive				

					clinically effective specialist infertility treatment.				
	Ensuring that citizens are fully included in all aspects of service design and change			✓	Nationally patient engagement and participation has been key to the policy design Patients are invited to participate in current providers National/Local staff satisfaction surveys to ensure ongoing engagement continues.				
	Patient Choice	✓			This policy applies to all couples registered at an NHS Coventry and Warwickshire ICB GP practice and is available under patient choice for eligible couples to receive clinically effective specialist infertility treatment.				
	Patients are fully empowered in their own care	✓			Eligible couples will be fully involved in their care planning through shared decision-making, personalised care, and support planning following best practice and NICE CG156.				
	Wider primary care, provided at scale			✓	Policy to implement access for eligible couples to receive clinically effective specialist infertility treatment at Specialist NHS services.				

					Within Coventry and Warwickshire this service is provided at University Hospitals Coventry and Warwickshire, however other NHS specialist services are available nationally.				
Access Could the proposal impact positively or negatively on any of the following:	Patient choice	✓			This policy applies to all couples registered at an NHS Coventry and Warwickshire ICB GP practice and is available under patient choice for eligible couples to receive clinically effective specialist infertility treatment.				
	Access	✓			Policy to implement access for eligible couples to receive clinically effective specialist infertility treatment at Specialist NHS services. Within Coventry and Warwickshire this service is provided at University Hospitals Coventry and Warwickshire, however other NHS specialist services are available nationally.				
	Integration	✓			There is collaboration across the pathway at system level across primary and secondary care.				

Compliance with NHS Constitution	Quality of care and environment	✓			The ICB expectation is that all providers of service hold an NHS standard contract where delivery of the service is stipulated under the core requirements to safeguard quality of care in line with the Care Quality Commission (CQC) "quality statements".				
	Nationally approved treatment/drugs	✓			Policy to implement access for eligible couples to receive clinically effective specialist infertility treatment following best practice and NICE CG156.				
	Respect, consent and confidentiality	✓			All usual ICB and/or Provider respect, consent and confidentiality policies and mechanisms will apply.				
	Informed choice and involvement	✓			Patients will be fully involved in their care planning through shared decision-making, personalised care, and support planning following best practice and NICE CG156.				
	Complain and redress	✓			Usual ICB and/or Provider compliment, complaint and redress policies and mechanisms will apply.				

*Risk score definitions are provided in the next section.

10. Equality Impact Assessment Project / Policy Details

What is the aim of the project / policy?

To provide a fair, equitable and transparent process for all patients of the NHS Coventry and Warwickshire Integrated Care Board (ICB), for which the ICB has commissioning responsibility.

The policy for Specialist Treatment of Infertility supports the objective to prioritise resources and provide interventions with the greatest proven health gain, within ICB budgetary constraints. The intention is to ensure equity and fairness in respect of access to NHS funding for interventions and to ensure that interventions are provided within the context of the needs of the overall population and the evidence of clinical and cost effectiveness.

Who will be affected by this work? e.g staff, patients, service users, partner organisations etc.

Patients

Is a full Equality Analysis Required for this project?

Yes	Proceed to complete this form.	No	Explain why further equality analysis is not required.
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If no, explain below why further equality analysis is not required. For example, the decision concerned may not have been made by the ICB or it is very clear that it will not have any impact on patients or staff.

Equality Analysis Form

1. Evidence used

What evidence have you identified and considered? This can include national research, surveys, reports, NICE guidelines, focus groups, pilot activity evaluations, clinical experts or working groups, JSNA or other equality analyses.

British Fertility Society (2005). Key facts on infertility, IVF and NHS provision. Bristol: BFS Secretariat.

De La Rochebrochard E et al. Paternal age over 40 years: the “amber light” in the reproductive life of men? *J Androl.* 2003 24(4):459-65.

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of infertility. *Br edClin Res Ed*, 1985; 291: 1693–1697.

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NHS Choices; [BMI calculator | Check your BMI - NHS | Please fill in your details \(www.nhs.uk\)](#)

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Peek J.C., Godfrey B., Matthews C.D. Estimation of fertility and fecundity in women receiving artificial insemination by donor semen and in normal fertile women. *British Journal of Obstetrics and Gynaecology*.1984; 91/10:1019-1024

2. Impact and Evidence:

In the following boxes detail the findings and impact identified (positive or negative) within the research detailed above; this should also include any identified health inequalities which exist in relation to this work.

Age: A person belonging to a particular age (e.g. 32 year olds) or a range of ages (e.g. 18-30 year olds)

This policy does not contain any statements which may exclude clinicians of the NHS Coventry and Warwickshire Integrated Care Board from applying this policy. However, age as a criterion for access to fertility treatments is applied in line with the NICE CG156 Guideline which is based on a comprehensive review of the relationship between age and the clinical effectiveness of fertility treatment.

Disability: A person has a disability if he/she has a physical, hearing, visual or mental impairment, which has a substantial and long-term adverse effect on that person's ability to carry out normal day-to-day activities

This policy does not contain any statements which may exclude clinicians of the NHS Coventry and Warwickshire Integrated Care Board from applying this policy. The recommendation for couples who are unable to have vaginal intercourse due to physical disability or psychosexual problems to undergo six cycles of artificial insemination (AI) or 2 cycles of IVF before NHS funded treatment is made by the NICE CG156 Guideline Development Group (GDG). The rationale behind this recommendation includes considerations of the financial cost of AI, ethical and practical issues related to establishing equivalence with couples who have unprotected vaginal intercourse for 12 months before seeking NHS assessment and possible treatment. The use of AI or IVF in a HFEA registered clinic is likely recommended for reasons related to regulation, quality control, and standardised practices in fertility treatments to ensure the best possible outcomes for patients. Additionally, the use of such clinics may help ensure the ethical and legal aspects of donor insemination are properly managed for the following reasons:

- In the UK it is not legal for patients to purchase donated sperm from a licensed sperm bank to use at home
- Donated sperm used at licensed clinics must be checked for infections including HIV, hepatitis, syphilis and gonorrhoea
- The donor's family medical history will have been taken to identify any serious heritable diseases
- Clinics undertaking AI or IVF provide counselling to everyone involved in the donation process
- Semen analysis (to check motility and morphology) will have been undertaken to ensure the donor sperm is good quality
- AI undertaken at a clinic will maximise efficacy (e.g. sperm will be placed in the uterus rather than the vagina and timing will be optimised)
- Having treatment at a clinic will mean that the donor is not a legal parent to any child born and ensure that the partner of the person trying to conceive will be recognised as the second legal parent.

Gender reassignment (including transgender): Where a person has proposed, started or completed a process to change his or her sex.

This policy does not contain any statements which may exclude clinicians of the NHS Coventry and Warwickshire Integrated Care Board from applying this policy. The recommendation for couples who are unable to have vaginal intercourse due to gender reassignment (a transgender male) to undergo six cycles of artificial insemination (AI) or 2 cycles of IVF before NHS funded treatment is made by the NICE CG156 Guideline Development Group (GDG). The rationale behind this recommendation includes considerations of the financial cost of AI, ethical and practical issues related to establishing equivalence with couples who have unprotected vaginal intercourse for 12 months before seeking NHS assessment and possible treatment. The use of AI or IVF in a HFEA registered clinic is likely recommended for reasons related to regulation, quality control, and standardised practices in fertility treatments to ensure the best possible outcomes for patients. Additionally, the use of such clinics may help ensure the ethical and legal aspects of donor insemination are properly managed for the following reasons:

- In the UK it is not legal for patients to purchase donated sperm from a licensed sperm bank to use at home
- Donated sperm used at licensed clinics must be checked for infections including HIV, hepatitis, syphilis and gonorrhoea
- The donor's family medical history will have been taken to identify any serious heritable diseases
- Clinics undertaking AI or IVF provide counselling to everyone involved in the donation process
- Semen analysis (to check motility and morphology) will have been undertaken to ensure the donor sperm is good quality
- AI undertaken at a clinic will maximise efficacy (e.g. sperm will be placed in the uterus rather than the vagina and timing will be optimised)
- Having treatment at a clinic will mean that the donor is not a legal parent to any child born and ensure that the partner of the person trying to conceive will be recognised as the second legal parent.

Marriage and civil partnership: A person who is married or in a civil partnership.

This policy does not contain any statements which may exclude clinicians of the NHS Coventry and Warwickshire Integrated Care Board from applying this policy.

Pregnancy and maternity: A woman is protected against discrimination on the grounds of pregnancy and maternity. With regard to employment, the woman is protected during the period of her pregnancy and any statutory maternity leave to which she is entitled. Also, it is unlawful to discriminate against women breastfeeding in a public place.

This policy does not contain any statements which may exclude clinicians of the NHS Coventry and Warwickshire Integrated Care Board from applying this policy.

Race: A group of people defined by their race, colour, and nationality (including citizenship) ethnic or national origins.

This policy does not contain any statements which may exclude clinicians of the NHS Coventry and Warwickshire Integrated Care Board from applying this policy.

Religion or belief: A group of people defined by their religious and philosophical beliefs including lack of belief (e.g. atheism). Generally a belief should affect an individual's life choices or the way in which they live.

This policy does not contain any statements which may exclude clinicians of the NHS Coventry and Warwickshire Integrated Care Board from applying this policy.

Sex: A man or a woman

This policy does not contain any statements which may exclude clinicians of the NHS Coventry

and Warwickshire Integrated Care Board from applying this policy.

Sexual orientation: Whether a person feels generally attracted to people of the same gender, people of a different gender, or to more than one gender (whether someone is heterosexual, lesbian, gay or bisexual).

This policy does not contain any statements which may exclude clinicians of the NHS Coventry and Warwickshire Integrated Care Board from applying this policy. The recommendation for couples who are unable to have vaginal intercourse such as female same sex couples to undergo six cycles of artificial insemination (AI) or 2 cycles IVF before NHS funded treatment is made by the NICE CG156 Guideline Development Group (GDG). The rationale behind this recommendation includes considerations of the financial cost of AI, ethical and practical issues related to establishing equivalence with couples who have unprotected vaginal intercourse for 12 months before seeking NHS assessment and possible treatment. The use of AI or IVF in a HFEA registered clinic is likely recommended for reasons related to regulation, quality control, and standardised practices in fertility treatments to ensure the best possible outcomes for patients. Additionally, the use of such clinics may help ensure the ethical and legal aspects of donor insemination are properly managed for the following reasons:

- In the UK it is not legal for patients to purchase donated sperm from a licensed sperm bank to use at home
- Donated sperm used at licensed clinics must be checked for infections including HIV, hepatitis, syphilis and gonorrhoea
- The donor's family medical history will have been taken to identify any serious heritable diseases
- Clinics undertaking AI or IVF provide counselling to everyone involved in the donation process
- Semen analysis (to check motility and morphology) will have been undertaken to ensure the donor sperm is good quality
- AI undertaken at a clinic will maximise efficacy (e.g. sperm will be placed in the uterus rather than the vagina and timing will be optimised)
- Having treatment at a clinic will mean that the donor is not a legal parent to any child born and ensure that the partner of the person trying to conceive will be recognised as the second legal parent.

Carers: A person who cares, unpaid, for a friend or family member who due to illness, disability, a mental health problem or an addiction cannot cope without their support

This policy does not contain any statements which may exclude clinicians of the NHS Coventry and Warwickshire Integrated Care Board from applying this policy.

Other disadvantaged groups:

This policy does not contain any statements which may exclude clinicians of the NHS Coventry and Warwickshire Integrated Care Board from applying this policy.

3. Human Rights

FREDA Principles / Human Rights	Question	Response
Fairness – Fair and equal access to services	How will this respect a person's entitlement to access this service?	To provide a fair, equitable and transparent process for all patients of the NHS Coventry and Warwickshire Integrated Care Board (ICB),

		<p>for which the ICB has commissioning responsibility.</p> <p>The policy for Specialist Treatment of Infertility supports the objective to prioritise resources and provide interventions with the greatest proven health gain, within ICB budgetary constraints. The intention is to ensure equity and fairness in respect of access to NHS funding for interventions and to ensure that interventions are provided within the context of the needs of the overall population and the evidence of clinical and cost effectiveness.</p>
Respect – right to have private and family life respected	How will the person’s right to respect for private and family life, confidentiality and consent be upheld?	The patient will not be contacted by the ICB. If the patient contacts the ICB of their own accord then all communication, written or verbal, will be provided in a confidential, clear, understandable, format.
Equality – right not to be discriminated against based on your protected characteristics	How will this process ensure that people are not discriminated against and have their needs met and identified?	This policy is applied to all patients of the NHS Coventry and Warwickshire Integrated Care Board to prioritise resources and provide interventions with the greatest proven health gain, within ICB budgetary constraints. The intention is to ensure equity and fairness in respect of access to NHS funding for interventions and to ensure that interventions are provided within the context of the needs of the overall population and the evidence of clinical and cost effectiveness.
Dignity – the right not to be treated in a degrading way	How will you ensure that individuals are not being treated in an inhuman or	All communication, written or verbal, will be provided in a confidential, clear,

	degrading way?	understandable, format.
Autonomy – right to respect for private & family life; being able to make informed decisions and choices	How will individuals have the opportunity to be involved in discussions and decisions about their own healthcare?	Individuals will have the opportunity to discuss their healthcare with the requesting clinician. If the patient contacts the ICB of their own accord then all communication, written or verbal, will be provided in a confidential, clear, understandable, format.
Right to Life	Will or could it affect someone's right to life? How?	No
Right to Liberty	Will or could someone be deprived of their liberty? How?	No

4. Engagement, Involvement and Consultation		
If relevant, please state what engagement activity has been undertaken and the date and with which protected groups:		
Engagement Activity	Protected Characteristic/ Group/ Community	Date
N/A	N/A	N/A
For each engagement activity, please state the key feedback and how this will shape policy / service decisions (E.g. patient told us So we will):		
N/A		

5. Mitigations and Changes
Please give an outline of what you are going to do, based on the gaps, challenges and opportunities you have identified in the summary of analysis section. This might include action(s) to mitigate against any actual or potential adverse impacts, reduce health inequalities, or promote social value. Identify the recommendations and any changes to the proposal arising from the equality analysis.
N/A

6. How will you measure how the proposal impacts health inequalities?
e.g Patients with a learning disability were accessing cancer screening in substantially lower numbers than other patients. By revising the pathway the ICB is able to show increased take up from this group, this is a positive impact on health inequalities. You can also detail how and when the service will be monitored and what key equality performance indicators or reporting requirements will be included within the contract.
Acute Contracting/Business Intelligence will monitor the activity and review as appropriate.
7. Is further work required to complete this assessment?

Please state what work is required and to what section. e.g additional consultation or engagement is required to fully understand the impact on a particular protected group (e.g disability).

Work needed	Section	When	Dare completed
N/A	N/A	N/A	N/A

8. Sign off

The Equality Analysis will need to go through a process of **quality assurance** by a Senior Manager within the department responsible for the service concerned before being submitted to the Policy, Procedure and Strategy Assurance Group for approval. Committee approval of the policy / project can only be sought once approval has been received from the Policy, Procedure and Strategy Assurance Group.

Requirement	Name	Date
Senior Manager Signoff	Dr Michael Caley, Deputy CMO	13.06.2024
Which committee will be considering the findings and signing off the EA?	F&P	04.09.2024
Approved by the Policy Procedure and Strategy Assurance Group.		

Once complete, please send to the ICB's Governance Team