NHS
Coventry and Warwickshire
Integrated Care Board

Specialist Treatment of Infertility

Reference Number:	This will be applied to all new ICB-wide PPSs by the Governance and Corporate Affairs Team and will be retained throughout its life span.
Version:	Version 1.0
Name of responsible Committee and date approved or recommended to Integrated Care Board Board:	Audit Committee
Date approved by the Integrated Care Board (if applicable):	1 July 2022
Next Review Date:	1 April 2024
Expiry Date:	1 July 2024
Name of author and title:	Public Health/Commissioning Dept
Name of reviewer and title:	
Department:	Corporate Office

VERSION HISTORY

Date	Version	Changes made to previous version	Consulting and Endorsing Stakeholders, Committees / Meetings / Forums etc.

1. Assisted Conception Policy Summary

- 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)

- Infertility is defined as:

- 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 and investigation along with her partner.

- Following the first year and clinical investigation:

    - 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 where all eligibility criteria are met.
    - 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 female has not conceived after 6 cycles of self-funded donor or partner insemination, 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.

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

    - 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 (ie 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 women under 40 years at the time of referral. For women aged 39 years, the expectation is that treatment, including any

frozen embryo transfers (FETs), is undertaken within 12 months of referral

- Age of Non-maternal Partner – there is no restriction on the age of the male 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/m^2 or >30kg/m^2 and patients should be encouraged to attend the weight management clinic to achieve the recommended09 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

2. Assisted Conception 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: • 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
Infertility	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. Following the first year and clinical investigation: - Where the cause of infertility is known, 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 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 female has not conceived after 6 cycles of self-funded donor or partner insemination, undertaken at a Human Fertilisation and Embryology Authority (HFEA) registered clinic, in the absence of any known medical cause of infertility

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 female. 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.
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 woman 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)

3. Assisted Conception Policy Content

- Providing that all eligibility criteria detailed in Appendix 1 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 woman 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.

- 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 woman 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.

4. References

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20. 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.
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22. 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

Appendix 1 – 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 either partner have 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 has had one or more previous NHS funded cycle (ie 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 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 3 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 impact of this on male fertility is uncertain), and that stopping	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. 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.

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	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 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]
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

Quality and Equality Impact Assessment

Scheme Title:	Specialist Treatment of Infertility policy		
Project Lead:	Clive Campton, IFR Manager	**Senior Responsible Officer:**	Matt Gilks, Director of Joint Commissioning
		Quality Sign Off:	
Intended impact of scheme:	The Specialist Treatment of Infertility policy 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.		
How will it be achieved:	The Governing Body adopts the policy.		

Name of person completing assessment:	**Clive Campton**
Position:	**IFR Manager**
Date of Assessment:	**May 2022**

Quality Review by:	
Position:	
Date of Review:	

Stage 1a: 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	✓			References support effectiveness				
	Patient experience	✓			Extent of policy will impact on patient experience				
	Patient safety			✓					
	Parity of esteem			✓					
	Safeguarding children or adults			✓					
NHS Outcomes Framework Could the scheme impact positively or negatively on the delivery of the five domains:	Enhancing quality of life	✓			Policy will offer patients opportunity to have a child				
	Ensuring people have a positive experience of care	✓			Policy offers potential positive outcomes for couples				
	Preventing people from dying prematurely			✓					

	Helping people recover from episodes of ill health or following injury			✓					
	Treating and caring for people in a safe environment and protecting them from avoidable harm			✓					
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			✓					
	Access to the highest quality urgent and emergency care			✓					
	Convenient access for everyone			✓					
	Ensuring that citizens are fully included in all aspects of service design and change			✓					
	Patient Choice			✓					
	Patients are fully empowered in their own care			✓					
	Wider primary care, provided at scale			✓					
Access	Patient choice			✓					

Could the proposal impact positively or negatively on any of the following:	Access			✓					
	Integration			✓					
Compliance with NHS Constitution	Quality of care and environment			✓					
	Nationally approved treatment/drugs			✓					
	Respect, consent and confidentiality			✓					
	Informed choice and involvement			✓					
	Complain and redress			✓					

*Risk score definitions are provided in the next section.

Risk rating score definition

Likelihood	Impact
1 – Rare	1 – Negligible
2 – Unlikely	2 – Minor
3 – Moderate	3 – Moderate
4 – Likely	4 – Major
5 – Almost certain	5 – Catastrophic

	Likelihood

Consequence	Rare (1)	Unlikely (2)	Possible (3)	Likely (4)	Almost Certain (5)
Catastrophic (5)	5	10	15	20	25
Major (4)	4	8	12	16	20
Moderate (3)	3	6	9	12	15
Minor (2)	2	4	6	8	10
Negligible (1)	X-1	2	3	4	5

How will a successful implementation of quality indicators be measured?

Quality Outcome	**Measured By**
Positive Health gain	Gathering information on successful outcomes and patient experience
Enhancing quality of life	Information from clinics on patient feedback

Stage 1b: Equality Questions

The Public Sector Equality Duty requires us to **eliminate** discrimination, **advance** equality of opportunity and **foster** good relations with protected groups. Consider how this policy / service will achieve these aims.

Other partners/stakeholders involved in scheme:	N/A
Who will be affected by this piece of work?	ICB registered patients

Stage 1c: Post

PROTECTED GROUP	Is there likely to be a differential impact? (Please tick one)			Evidence/Comments for answers. Where available please share any baseline data and research on the population that this piece of work will affect. Include any consultations with service users that have been carried out.
	YES	NO	UNKNOWN	
Gender		✓		The impact of this policy has been discussed by the Clinical Quality Group (CQG) and all protected characteristics and Human Rights values given due regard and only patient demographic issues that could impact on individual risk and/or clinical effectiveness were taken into account when reaching a decision. The evidence used to inform this policy consists of: Advice and guidance from the Department of Health, current relevant regional policies and guidance, NHS England commissioning policies. In summary, any negative impact on equality is unlikely and the policy is concordant with current advice and guidance from NICE, Department of Health and NHS England.
Race		✓		As above
Disability (including mental impairment, learning diff)		✓		As above
Religion/belief		✓		As above
Sexual orientation		✓		As above
Age	✓			

Social deprivation		✓		As above
Carers		✓		As above
Human rights		✓		As above
Pregnancy and Maternity		✓		As above

Implementation Review

Use the template below to record outcomes of reviews – if more than one is required cut and paste the box below:

Quality Impact	**Has there been a differential impact?** (Please tick one)			**Evidence/Comments for answers**	**Mitigations**
	YES	**NO**	**UNKNOWN**		