

Infertility and Assisted Reproduction Commissioning Policy and Eligibility Criteria

Policy Folder	Commissioning
Version:	Version 2
Ratified by:	Governing Body
Date ratified:	04 June 2020
Name of originator/author:	Gemma Smith – Commissioning Manager Dr Mona Arora – Clinical Associate Gina Gill – Senior IFR Improvement Manager Jackie Newman – IFR Officer
Name of responsible committee/individual:	Gina Gill – Senior IFR/Improvement Manager
Date approved by Committee/individual	04 June 2020
Date issued:	July 2020
Review date:	31 March 2021
Date of first issue	July 2012
Target audience:	CCGs, NHS Trusts, GPs, Fertility Providers, Service Users

Abbreviations

Abbreviations Used	
CCG	Clinical Commissioning Group
HFEA	Human Fertilisation and Embryology Authority – UK’s independent regulator overseeing the use of gametes and embryos in fertility treatment and research
ICSI	Intracytoplasmic Sperm Injection – a single sperm is injected into the egg
IUI	Intra-Uterine insemination – insemination of sperms into a woman’s uterus
IVF	In Vitro fertilisation – patients eggs and her partners sperm are collected and placed together within a laboratory setting to achieve fertilisation outside of the body. The embryos produced are then transferred to the female patient.
NICE	National Institute of Clinical Excellence – an independent organisation responsible for providing national guidance on promoting good health and preventing and treating ill health
BMI	Body Mass Index – this is calculated by you weight in kilograms divided by the square of your height in meters
HIV	Human immunodeficiency virus
GUM	Genito Urinary Medicine
IFR	Individual Funding Request – CCGs process for applications for services/treatments that are not routinely commissioned. Patients must demonstrate exceptionality to secure funding.

VERSION CONTROL

Version Number	Date	Outline of Amendments
1.0	July 2012	Initial Policy
2.0	June 2020	<ul style="list-style-type: none">• Surgical Sperm Retrieval amended to reflect NHSE commissioning responsibility• Revision to cryopreservation• Revision to same sex couples criterion

1. Introduction

- 1.1 Fertility problems are common in the UK and affect around one in seven couples. It is estimated that 84% of couples will conceive within one year if 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 of c.92%). The remaining 8% of couples will be unable to conceive without medical intervention and will be considered to be infertile.¹
- 1.2 NICE defines infertility as either the presence of known reproductive pathology, or for heterosexual couples, failure to conceive after two years of regular unprotected sexual intercourse in the absence of known reproductive pathology.² There are a number of causes of infertility and causes are unidentified in a quarter of cases. NICE estimate that a typical CCG can expect 230 new consultant referrals (couples) per 250,000 population per year.
- 1.3 The main aim of this policy is to assist couples with medical or physical limits to their infertility and is based on the principles that fertility services must be commissioned from centres with better than national average rates and that the patient eligibility criteria should reflect the highest probability of success from assisted conception techniques in line with national evidence.
- 1.4 This policy sets out the criteria for access to specialist fertility services for the population of North Staffordshire Clinical Commissioning Group, specifically the entitlement to ICI, IVF and ICSI. Access to fertility services is governed by the principal of all other services, namely clinical effectiveness, cost effectiveness and the outcomes of the CCGs annual Joint Strategic Needs Assessment. Research within the area of fertility is fast moving and this policy will be reviewed annually in line with the CCG's prioritisation process and within 3 months of any changes in the national guidance in relation to fertility. All fertility providers must be licensed with the HFEA in order to be commissioned under this policy.
- 1.5 The intention of this policy is to set out the commissioning arrangements for fertility services in a manner that is clear, fair and transparent, and the criteria has been developed in line with clinical evidence taking in account the success rates of fertility treatments and the impact that different factors have on this. This paper should be read in conjunction with the following supporting evidence:
- NICE Guidance CG011 'Fertility: assessment and treatment for people with fertility problems' (2004)
 - The Human Fertilisation and Embryology Authority (HFEA) document 'The Best Start to Life' (2007)
 - Regulated Fertility Services: A Commissioning Aid (2009)
 - Clinical Knowledge Summary, www.cks.nhs.uk/infertility
 - Schmidt L. Infertility and assisted Reproduction in Denmark. Epidemiology and psychosocial consequences. *Dan Med Bull.* (2006) Nov;53 (4):390-417

¹ DH Regulated Fertility Services. 2009

² NICE Clinical Guideline 11. 2004

- Department of Health: Regulated Fertility Services (2009)

2 Commissioned Services

- 2.1 The criteria in the below table should be applied to all couples from point of referral into secondary care. Patients who do not meet the criteria will not be eligible to commence investigations for infertility or any subsequent treatment for infertility.
- 2.2 Treatment for infertility problems should include drugs, surgery, lifestyle advice and assisted conception techniques such as IVF. Counselling should also be offered in relation to the impact that this treatment can have on a couple's life. The care pathway for infertility begins in primary care where the first stage of treatment is generally lifestyle advice to increase the chance of conception happening naturally. If this is not effective, initial assessment such as semen analysis should take place. If appropriate and the patients meet the CCG criteria, they are eligible to be referred to secondary care where further investigations and treatment will be carried out such as hormonal drugs to stimulate ovulation. If this is unsuccessful or inappropriate and the couple fit North Staffordshire CCGs eligibility criteria then they will be referred to tertiary care for assessment for assisted conception techniques such as IUI, ICSI and IVF.³
- 2.3 Tertiary services include IUI, ICSI and IVF. Other assisted reproduction and fertility services are **not** routinely commissioned. All tertiary centres providing this service must be licensed with the HFEA in order to be commissioned under this policy.

3. IVF/ICSI/IUI

- 3.1 North Staffordshire CCG will commission ONE funded cycle of IVF/ICSI **or** a maximum of THREE cycles of IUI (stimulated or non-stimulated) for couples with unexplained fertility, mild endometriosis or mild male factor infertility taking into account patient choice.
- 3.2 One cycle of IVF/ICSI treatment is defined as one fresh cycle including ovulation induction, egg retrieval, fertilisation and implantation, and includes appropriate diagnostic tests, scans and pharmacological therapy. The CCG will also commission as part of a cycle blastocyst transfer. North Staffordshire CCG will not fund any subsequent cycles using frozen embryos following the completion of a first full cycle.
- 3.3 IUI, or intrauterine insemination, is a relatively simple infertility treatment, where a small tube is used to place specially washed sperm directly into the uterus. Each attempt at this is classed as a cycle of IUI. Donor sperm will not be funded as part of the treatment in line with this policy

4. Abandoned Cycles

Abandoned cycles will be funded up to the point of failed fertilisation. Beyond this a cycle would not be considered to have been abandoned. Couples will be eligible for one

³ DH Regulated Fertility Services. 2009

abandoned cycle as part of their treatment where the previous cycle has been abandoned for medical reasons. Social reasons will not be taken into account.

5. **Donor Sperm**

North Staffordshire CCG will not routinely fund donor sperm but will fund the associated IUI/IVF/ICSI treatment in line with the eligibility criteria within this policy providing the sperms meet the criteria set out by the treating provider unit. Patients wishing to access donor sperm treatments must make their own arrangements but are advised to check with the treating provider unit to ensure HFEA guidelines before accessing donated sperms.

6. **Donor Eggs**

North Staffordshire CCG will not routinely fund donor eggs but will fund the associated IUI/IVF/ICSI treatment in line with the eligibility criteria within this policy providing the eggs meet the criteria set out by the treating provider unit. Patients wishing to access donor eggs must make their own arrangements but are advised to check with the treating provider unit to ensure HFEA guidelines before accessing donated eggs

7. **Surgical Sperm Retrieval**

Surgical sperm retrieval (SSR) is the funding responsibility of NHSE and therefore will not be funded by the CCG. <https://www.england.nhs.uk/wp-content/uploads/2018/07/Surgical-sperm-retrieval-for-male-infertility.pdf>

8. **Egg and Sperm Storage**

Embryo and sperm storage will be funded for patients fitting the CCGs eligibility criteria and undergoing NHS funded assisted reproduction treatment in line with North Staffordshire CCGs Fertility Policy. Storage will be funded for up until the end of the year in which the first cycle of IVF/ICSI is completed and should the patient wish to continue to store the frozen embryos or sperm, this would have to be funded privately by the patient. The CCG will not fund any additional cycles of IVF/ICSI/IUI following the failure of a complete first cycle.

9. **Fertility Preservation**

9.1 Cryopreservation of gametes will be available to all patients undergoing medical treatment that may render them infertile. Any funding requests for cryopreservation will be subject to prior approval. There is no lower age for eligibility under these circumstances. The CCG will pay for storage for a maximum of 5 years. After this period, patients wishing to continue to store may self-fund in line with HEFA Guidance.

9.2 Freezing method – Where oocytes are being preserved, the CCG will only fund freezing by vitrification. Other methods of freezing oocytes are not routinely funded.

9.3 Patients wishing to use stored gametes **must** meet the eligibility criteria within this policy at the time of application for assisted conception in an NHS setting.

10. **Single Embryo Transfer**

Multiple Births are associated with greater risk to mothers and children and the HFEA therefore recommends that steps are taken by providers to minimise multiple births. We support the HFEA guidance on single embryo transfer and monitoring mechanisms will be put in place with tertiary providers to ensure that the HFEA targets are met. All providers are required to have a multiple birth minimisation strategy.⁴

11. **Sperm Washing**

North Staffordshire CCG will fund sperm washing for IUI/IVF/ICSI in infertile couples where the male partner is HIV positive and the female partner is HIV negative in line with the eligibility criteria set out within this document.

Patients who are fertile will be eligible for NHS funding for sperm washing, but the CCG will not fund any subsequent IVF/ICSI/IUI for this group of patients.

12. **Pre Implantation Diagnosis/Pre Implantation Screening**

Pre Implantation Diagnosis and Pre Implantation Screening are not covered within the scope of this policy. Please refer to the CCGs Pre Implantation Genetic Diagnosis policy for guidance on this area.

13. **Surrogacy**

Surrogacy will not be routinely funded by North Staffordshire CCG. Cases will be considered via the CCG's Individual Funding Request route and must demonstrate exceptionality.

14. **Risks associated with assisted conception methods**

Risks such as the chance of multiple pregnancies and a slightly higher risk of ectopic pregnancy should be clearly explained to couples prior to them deciding to embark on any assisted reproduction pathway.

15. **IVF treatment for seriously injured veterans**

The independent Medical Expert Group set up as a result of the Lord Boyce Review of the Armed Forces Compensation Scheme recommend that veterans suffering serious genital injuries be guaranteed at least three cycles of IVF. The CCG will implement this recommendation and applications should be made via the Individual Funding Request route.

16. **Eligibility Criteria**

16.1 Please see appendix 1 for the referral pathway through primary, secondary and tertiary care.

16.2 It is the responsibility of the referring GP to ensure that patients meet the below criteria's numbers 1-12 prior to any referral being made into secondary or tertiary care. Patients should not be started on a pathway whereby they would not be in a position to be referred

⁴ HFEA 2009

into secondary care at least 6 months before the woman's 35th birthday. Patients who do not meet criteria 1-12 at point of presentation to their GP are not eligible for NHS funding for investigations of infertility or any corresponding treatments relating to infertility within secondary or tertiary care.

- 16.3 It is the responsibility of the referring GP to ensure that patients are aware of the eligibility criteria for funding across the whole pathway and that they understand that the criteria below are applicable across each stage.
- 16.4 Please note that there are additional criteria for same sex couples and single women in addition to criteria numbers 1-12
- 16.5 Please note that there are additional criteria for patients who are undergoing medical treatment that is likely to make them infertile.

Criteria	Description
1. Woman's Age	<p>Any treatment cycle will not be commenced if the patient is less than 23 years of age but a referral into tertiary care must be made before the female reaches her 35th birthday.</p> <p>Any female meeting the CCGs eligibility criteria must be referred to secondary care at least 6 months prior to her 35th birthday.</p> <p>It is the responsibility of service providers to ensure that eligible couples have been referred into tertiary care for their IVF/ICSI/IUI treatment before the 35th birthday of the female undergoing treatment. If the patient does not undergo their treatment within the 6 months following their 35th birthday they will no longer be eligible for NHS funding.</p> <p>Women who are above the age of 35 or who are likely to be above the age of 35 at the point of entering tertiary care are not eligible for any tests or investigations in secondary or tertiary care.</p>
2. Women's BMI	<p>Obesity and smoking reduce fertility and increase risks to mother and baby during pregnancy. The woman should have a BMI of between 19 and 30 at the time of commencement of secondary care treatment. Women who are overweight or underweight will be offered referral to dieticians/lifestyle interventions in order to improve their BMI before being eligible to commence investigations in secondary and tertiary care. Women with a BMI of less than 19 and greater than 30 will not be funded.</p>
3. Man/Patient's partners age	Under 55 years of age
4. Identified cause/duration of	Couples who have an identified cause for their fertility problems OR have infertility of at least 2 years duration

sub fertility	
5. Previous IVF Treatment	Previous treatment, however funded precludes patients from being eligible for NHS funded cycles. This is not applicable where same –sex couples have self-funded donor insemination/IUI for the purpose of demonstrating infertility in line with criterion 15 below.
6. Previous sterilisation	Couples are ineligible if previous sterilisation has taken place (either partner), even if it has been reversed
7. Relationship	Couples should be in a stable relationship of at least two years duration and should be married, or cohabiting, with each other. Couples should also be seen together within primary, secondary and tertiary services as fertility treatment concerns both partners. The referring clinician must ensure that couples are aware of the implications of IVF treatment and the commitments required before making a referral for assisted conception.
8. GP Registration	The female partner must be resident and registered with a North Staffordshire GP
9. Parental status	Couples must not have a living child from their current or any previous relationships, regardless of whether the child resides with them. This includes any adopted child within their current or previous relationship. Once accepted for treatment, should a child be adopted or a pregnancy leads to a live birth the couple will no longer be eligible for treatment. Foster children are <u>not</u> included within this criteria
10. Smoking Status	Where couples smoke, only those who agree to take part in a supportive programme of smoking cessation will be accepted on any assisted conception or IVF waiting list and should be non-smoking at the time of commencing investigations within secondary care.
11. Child welfare	The welfare of any resulting child is paramount. In order to take into account the welfare of the child, consideration should be given to factors that are likely to cause serious psychological or medical harm to the child that is born. Consideration should be given to any alcohol or substance misuse by the couple. The above are a requirement of the HFEA and the following HFEA guidance should be used when making these decisions: http://www.hfea.gov.uk/code.html
12. Medical Conditions	Treatment may be denied on other medical grounds not explicitly covered in this document. Consideration should be given to the couple's use of alcohol, caffeine, tobacco and illegal substances prior to the patient being referred for any assisted conception or IVF treatment as these factors are detrimental to the success of the procedures.

<p>13. HIV in addition to the above criteria</p>	<p>Sperm washing will be commissioned for infertile couples where the male is HIV positive and the female is HIV negative and where patients fit all eligibility criteria within this policy.</p> <p>A consultant in Genito Urinary Medicine or Infectious Diseases will be required to confirm the couples suitability for NHS fertility funding.</p>
<p>14. Same sex couples in addition to the above criteria</p>	<p>Same Sex Female Couples and Single Females</p> <p>The aim of this policy is to assist couples with medical or physical limits to their infertility.</p> <p>Infertility is defined as the failure of a female of reproductive age to conceive after 1 year of regular unprotected vaginal intercourse, in the absence of any known medical cause of infertility.</p> <p>In circumstances where the above definition cannot be applied (for example same sex couple) infertility may be demonstrated by the failure to conceive after 6 cycles of self-funded donor insemination/IUI during the previous 12 months, undertaken at a Human Fertilisation and Embryology Authority (HFEA) licensed clinic, in the absence of any known reproductive pathology.</p> <ul style="list-style-type: none"> • Same sex couples and single women will be required to demonstrate infertility prior to commencing any investigations in line with the policy for heterosexual couples. • Patients who have been having regular sexual intercourse with a male for a minimum of 2 years in an attempt to conceive would have to have medical proof that the male had no fertility issues prior to commencing on an infertility pathway against the above criteria 1-12 in line with the policy for heterosexual couples. • Where only one partner is sub fertile, clinicians should discuss the possibility of the other partner trying to conceive before proceeding to interventions involving the sub fertile partner • The partner of the prospective mother is 55 years old or younger • North Staffordshire CCG will not routinely fund donor sperm but will fund the associated IUI or IVF/ICSI treatment in line with the eligibility criteria within this policy providing the sperms meet the criteria set out by the treating provider unit. Patients wishing to access donor sperm treatments must make their own arrangements but are advised to check with the treating provider unit to ensure HFEA guidelines before accessing donated sperms • Both members of the couple must accept joint legal responsibility for any child produced through fertility treatment. • The partner of a prospective mother who has undertaken NHS funded fertility treatment, whether successful or not, will be

	<p>deemed to have received their entitlement to NHS funded fertility treatment upon completion of this cycle in line with the criteria for heterosexual couples and will not be eligible for additional cycles with their partner or any future partners.</p> <ul style="list-style-type: none"> • Same sex fertile couples or fertile single women will not be funded for assisted conception methods under this policy. • Couples will required to fit all other criteria within this policy in line with heterosexual couples <p>Same sex male couples</p> <ul style="list-style-type: none"> • Same sex male couples will not be able to access fertility treatment within their relationship but may be eligible for some assistance if there are medical infertility issues in both partners and both partners fit the above criteria for funding. These cases will considered via the Individual Funding Request panel on the basis of exceptionalty.
--	--

Bibliography

- Stoke on Trent Clinical Commissioning Group, Service Specification for Assisted Conception (2010)
- NHS Bristol, North Somerset and South Gloucestershire, Fertility Treatment (2010)
- East of England Specialised Commissioning Group, Fertility Services Commissioning Policy (2011)
- Oxfordshire PCT, Assisted Conception Services (2010)
- Infertility Network UK, Standardising Access Criteria to NHS Fertility Treatment (2010)
- South Staffordshire Primary Care Trust, Commissioning Policy and Referral Guidelines for Assisted Reproduction Treatments (2010)
- Yorkshire and the Humber Specialised Commissioning Group, Commissioning Policy for Fertility Services (2011)
- NICE Guidance CG001 'Fertility: assessment and treatment for people with fertility problems' (2004)
- The Human Fertilisation and Embryology Authority (HFEA) document 'The Best Start to Life' (2007)
- Regulated Fertility Services: A Commissioning Aid (2009)
- Schmidt L. Infertility and assisted Reproduction in Denmark. Epidemiology and psychosocial consequences. *Dan Med Bull.* (2006) Nov;53 (4):390-417

General reading was obtained from the following sources:

- Department of Health Website
- HFEA website
- Infertility UK website

