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NHS
Stoke-on-Trent
Clinical Commissioning Group

COMMISSIONING POLICY
FOR
ASSISTED CONCEPTION

Policy Number/Version	1
Ratified by	Governing Body
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Action Required: Dissemination within primary and secondary care providers, tertiary providers	

CONSULTATION AND RATIFICATION SCHEDULE

Name and Title of Individual	Date Consulted
Public Health Department	May 2013
Dr Steven Fawcett	May 2013

Name of Committee	Date of Committee
Executive Forum	4 June 2013
Governing Body	26 November 2013

VERSION CONTROL

Policy Name: Commissioning Policy for Assisted Conception

This policy replaces all previous commissioning policies for fertility services relating to Stoke-on-Trent patients. Where patients commenced treatment under the terms of a policy adopted by Stoke-on-Trent Primary Care Trust, they are nonetheless now subject to the eligibility criteria and scope of treatment set out in this current NHS Stoke-on-Trent CCG policy.

Version	Valid from	Valid to	Document/Path
1.0	December 2014	December 2015	

Changes made to the commissioning of Assisted Conception for Stoke-on-Trent patients July 2013

Changes/Additions	**Evidence based on**
NHS Stoke-on-Trent CCG ('the CCG') will no longer fund: Intra Uterine Insemination (IUI)	NICE Clinical Guideline 156
Registration status Generally couples will both have to be registered with a Stoke-on-Trent GP. CCG responsibility as defined in - Who Pays? Determining responsibility for payments to providers	Best practice http://www.england.nhs.uk/wp-content/uploads/2012/12/who-pays.pdf
Previous History Patients, who have already received treatment as specified below, whether funded privately or by the NHS, will not be eligible for funding by the CCG. • 2 cycles of IVF/GIFT/ICSI. 1 cycle is defined as one fresh transfer and up to three frozen blastocyst/embryo transfers. This should be a consideration prior to starting a privately funded second cycle of IVF/GIFT/ICSI as this may result in the patient foregoing the right to NHS funding. Assisted conception will not be provided to couples if their sub-fertility is the result of sterilisation in either partner.	National best practice National best practice
Life Style Factors are now included in this policy BMI Smoking Alcohol	NICE Clinical Guideline 156 http://www.hfea.gov.uk/docs/CoP8_8welfareofthechild_V01.pdf
Couples with diagnosed or known cause of infertility that precludes natural conception do not need to wait for one year before Assisted Conception referral. This will include couples who cannot achieve full sexual intercourse due to disability.	NICE Clinical Guideline 156
Funding for Same Sex Couples included in this policy	NICE Clinical Guideline 156

Contents

1. Introduction

1.1. The purpose of this commissioning policy is to set out the CCG's commissioning responsibilities and the criteria for access to NHS funding for fertility services for the population of Stoke-on-Trent.

1.2. Assisted Conception services, i.e.: In Vitro Fertilisation (IVF) and Intracytoplasmic Sperm Injection (ICSI), will be commissioned for eligible patients from a tertiary care provider.

1.3. It is the purpose of the eligibility criteria set out in this policy to make the provision of fertility treatment fair, clear and transparent. This policy should be read in conjunction with:

- The National Institute for Health and Care Excellence ('NICE') Clinical Guideline CG156 "Fertility: assessment and treatment for people with fertility problems"(2013) available on their website at www.nice.org-pdfCG011niceguideline.pdf.url
- The Human Fertilisation & Embryology Authority (HFEA) document "Tomorrow's children" http://www.hfea.gov.uk/docs/TomorrowsChildren_report.pdf
- Regulated Fertility Services: A Commissioning Aid (2009) produced by the Department of Health available via the following link: http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_101068.pdf

2. Scope of the Policy

2.1. This policy is specifically for those couples, where neither member of the relationship has a living child from their current or any previous relationships, regardless of whether the child resides with them or not. This includes any legally adopted child within their current or previous relationships but does not include any foster children. This policy does not cover servicemen who are eligible for funding by NHS England.[1]

2.2 This policy will not provide fertility treatment for couples where their sub-fertility arises wholly or partly from sterilisation in either partner. Sterilisation is offered within the NHS as an irreversible method of contraception.

2.3. Stoke-on Trent CCG will fund the following assisted conception techniques regulated by the HFEA:

- In Vitro Fertilisation (IVF)
- Intracytoplasmic Sperm Injection (ICSI)
- Surgical Sperm Retrieval methods (SSR)
- Sperm and embryo cryopreservation

[1] NHS England is responsible for commissioning all infertility services for service personnel and their partners, regardless of whether infertility is injury-related. It is also responsible for commissioning specialised infertility treatment for injured servicemen and veterans whose sperm has been retrieved and is stored in Birmingham Hospital and, in the case of their death, for any partners/widows who wish to have treatment.

The revised NICE Clinical Guideline on fertility[2], CG156, states that there is no apparent health benefit from Intra Uterine Insemination (IUI) and there are potential risks associated with IUI both with and without stimulation when compared with expectant management (ie: encouraging conception through unprotected vaginal intercourse). In light of this recommendation and the evidence of a poor response rate, the CCG will not fund IUI, either with or without ovarian stimulation. Cases may be considered via the CCGs Individual Funding Request route but must demonstrate robust, clinical exceptionality.

2.4 Epidemiology

2.4.1 CG156 estimates that infertility affects 1 in 7 heterosexual couples in the UK. Since the original NICE guideline on fertility was published in 2004, there has been a small increase in the prevalence of fertility problems and a greater proportion of people are now seeking help for such problems.

2.4.2 The main causes of infertility in the UK are (percentage figures indicate approximate prevalence):

- unexplained infertility (no identified male or female cause - 25%)
- ovulatory disorders (25%)
- tubal damage (20%)
- factors in the male causing infertility (30%)
- uterine or peritoneal disorders (10%).

2.4.3 In about 40% of infertility cases disorders are found in both the man and the woman. Uterine or endometrial factors, gamete or embryo defects, and pelvic conditions such as endometriosis may also play a role. Given the range of causes of fertility problems, the provision of appropriate investigations is critical. These investigations include semen analysis; assessment of ovulation, tubal damage and uterine abnormalities; and screening for infections such as *Chlamydia trachomatis* and susceptibility to rubella.

2.4.4 Infertility can be primary, in people who have never conceived, or secondary, in people who have previously conceived. A typical CCG may therefore expect to see around 230 new consultant referrals (couples) per 250,000 population per year.

The expected demand for infertility referral for treatment per year for Stoke-on-Trent is:

Population estimate	286,000
Demand estimate per year	263 couples

3 Commissioning Responsibility

3.1 The specialist fertility services commissioned by Stoke-on-Trent CCG are considered as Level 3 services or tertiary services. Preliminary Levels 1 & 2 services are

[2] NICE (2013) Fertility: Assessment and treatment for people with fertility problems. NICE Clinical Guideline 156

commissioned from primary care and secondary services such as acute trusts. Before referral into Level 3 services, the preliminary investigations should be completed at Levels 1 & 2.

3.2 The Care Pathway

3.2.1 The care pathway for infertility begins in primary care where the first stage of treatment generally comprises the provision of counselling and lifestyle advice to increase the chance of conception happening naturally (expectant management). If this is not effective, initial assessment - such as semen analysis - will take place.

3.2.2 If appropriate, the couple will then be referred to secondary care services where further investigations will be carried out and, potentially, treatment offered, such as hormonal drugs to stimulate ovulation. If this is unsuccessful or inappropriate and the couple satisfy the CCG's eligibility criteria, they may be referred to tertiary care for assessment for assisted conception techniques such as IVF and ICSI.

3.2.3 All tertiary providers of fertility services must be licensed by the HFEA in order for their services to be commissioned under this policy.

3.3 Referrals to Tertiary Centre

Referral to the tertiary centre will be made via a consultant or GP.

4. General Access Criteria for Fertility Services

Couples must fulfil all the eligibility criteria for a referral for IVF/ICSI	
Couples who do not meet the criteria as per this policy should not be referred for assisted conception services. Cases may be considered via the CCGs Individual Funding Request route but must demonstrate robust, clinical exceptionality.	
Criteria that must be met	
Women must be aged between 23 and 39 years of age at the time of treatment.	An IVF/ICSI treatment cycle will not be commenced if the patient is less than 23 years of age, and a referral into tertiary care must be made before the female reaches her 39th birthday. If the cause of infertility is unknown. For women who have commenced treatment at 39 years of age, (treatment is defined as the start of the stimulating phase of the IVF cycle), the referring clinician will need to ensure that there is adequate time for completion of all treatments before the women reaches the age of 41 years.

Criteria that must be met	
Duration of infertility (NICE Guidance)	The couple must have been in a stable sexual relationship (involving sexual intercourse) for more than 2 years. A couple will be considered for treatment if they have been trying to conceive on a regular basis for more than 2 years if the female party is below the age of 35, or more than 1 year if the female is aged over 35 years. If cause of infertility is known. See below for application of this criterion to same sex couples.
Life Style Factors BMI Smoking Alcohol	The couple's health and social circumstances should pose no significant risk to conception, pregnancy or the resultant child. http://www.hfea.gov.uk/docs/CoP8_8welfareofthechild_V01.pdf The woman's Body Mass Index (BMI) should be in the range of 19 to 30 at the time of referral and commencement of treatment. If a patient is overweight or underweight she should be offered a referral to a dietician in order to improve her BMI. Women with a BMI of less than 19 and greater than **30** will not be funded. Smoking and passive smoking reduce fertility and have a detrimental effect on the unborn child. Couples should be non-smoking at the time of treatment. Referral to smoking cessation should be offered by the referring clinician. Alcohol – couples should score <5 on the Audit C test. Women who are trying to become pregnant should be informed not to drink more than 1 or 2 units of alcohol once or twice per week and to avoid episodes of intoxication. This will reduce the risk of alcohol related harm in a developing foetus. Men should be informed that excessive alcohol intake is detrimental to semen quality.
Parental status	Where either of the potential parents already has a living child (by this or any other union) or where the couple have an adopted child, the couple will **not** be eligible for NHS funded IVF treatment. Should a child be adopted, or a pregnancy leading to a live birth occur after the couple have been accepted for treatment, the couple will immediately cease to be eligible for treatment. Having one or more foster children does not make the couple ineligible for treatment.
Welfare of the child	In any circumstances where there are known adverse factors which might affect the welfare of a child that might be born, treatment will not be provided. Couples must conform to the statutory 'Welfare of the Child' requirements. http://www.hfea.gov.uk/docs/CoP8_8welfareofthechild_V01.pdf

Criteria that must be met	
HIV, Hepatitis B or C	People found to test positive, whilst undergoing IVF/ICSI treatment, for one or more of HIV, hepatitis B, or hepatitis C, should be offered specialist advice and counselling and appropriate clinical management. Please note that sperm washing is not a treatment for infertility and falls out of the scope of this policy.
In addition to the criteria above	
Same Sex Couples	The main aim of this policy is to assist couples with medical or physical limits to their fertility. Applying this policy to same sex couples requires some flexibility, from those seeking treatment and the clinical team referring or treating the couple, to ensure that the over-arching aim of this policy is met. The CCG will fund assisted conception treatment for same sex couples who demonstrate evidence of clinical infertility as would be required for couples in heterosexual relationships. (This is normally defined as failure to conceive after regular unprotected sexual intercourse as per the criteria in paragraph 4 above) or where there are already known or established anatomical cause(s) of infertility. In the case of a same sex female couple in which only one partner is sub fertile, NHS funded IVF treatment will only be offered where there is some clinical indication which prevents the other (fertile) partner from being offered the treatment. The CCG will not commission donor sperm for same sex couples but will fund the associated IVF/ICSI treatment in line with the eligibility criteria within this policy. Patients must make their own arrangements for donor sperm and are advised to check with the treating provider unit to ensure HFEA guidelines are adhered to before accessing donor sperm. The partner of a prospective birth mother who has undertaken NHS funded fertility treatment, if successful, will be deemed to have received their entitlement to NHS funded fertility treatment upon completion of this cycle in line with heterosexual couples and will not be eligible for a further NHS funded treatment.

5. Referral Criteria

5.1 This policy is for couples that meet the CCG's current criteria for NHS funding.

5.2 Couples should only be referred for assisted conception treatment if they meet all the eligibility criteria listed above and when all appropriate tests and investigations have been successfully completed in primary care (see appendix B) and in secondary care in line with NICE CG156.

5.3 Couples who do not meet the eligibility criteria but may have exceptional clinical circumstances should submit their requests for funding for consideration through the CCG's Individual Funding Requests (IFR) process.

5.4 Registration Status

Generally both patients must be registered with a General Practitioner whose practice is a member of the CCG.

5.5 Compliance criteria

The referring clinician must ensure that patients are aware of the implications of IVF/ICSI treatment, and the commitment required, before making a referral for assisted conception. If there is any doubt over the couple's ability to make the necessary commitment to comply with the treatment regime, they must be referred for counselling, in the first instance, to establish whether assisted conception is appropriate for them.

5.6 Cause of Infertility.

Couples with a diagnosed or known cause of infertility that precludes natural conception do not need to wait for one year before being referred for assisted conception treatment. This will include couples who cannot achieve full sexual intercourse due to disability.

5.7 Assisted conception will not be provided to couples if their sub-fertility is the result of sterilisation in either partner. Sterilisation is offered within the NHS as an irreversible method of contraception. Considerable time and expertise are expended in ensuring that individuals are made aware of this at the time of the procedure. Since the majority of requests for sterilisation arise for non medical reasons, the CCG considers that it is inappropriate to use NHS funds in reversing these procedures and funding fertility treatment following reversal.

5.8 Previous History

Patients who have already received treatment as specified below whether funded privately or by the NHS, will not be eligible for funding by the CCG.

2 cycles of IVF/GIFT/ICSI.
1 cycle is defined as one fresh transfer and up to three frozen blastocyst/embryo transfers. This should be a consideration prior to starting a second privately funded cycle of IVF/GIFT/ICSI, as this may result in the patient foregoing the right to NHS funding.

6. Commissioned Services

6.1 Stoke-on-Trent CCG will fund the following treatment for eligible couples:

Two Cycles of IVF/ICSI treatment. A cycle is defined as:

- One fresh transfer and up to three frozen blastocyst/embryo transfers and includes ovulation induction, egg retrieval, fertilisation and implantation, appropriate diagnostic tests, scans and drug therapy

6.2 An embryo transfer is defined as the process commencing from egg retrieval and fertilisation to transfer to the uterus. The fresh embryo transfer would constitute one such transfer.

6.3 A frozen transfer commences when a cryopreserved embryo or blastocyst is removed from storage in order to be thawed for transfer.

6.4 If the first cycle is successful and results in a live birth, the couple will no longer be eligible for NHS funding for fertility treatment.

6.5 If the first cycle is unsuccessful, with either the fresh or frozen transfers, the CCG will fund will fund a second cycle. (A cycle is defined in 5.1).

6.6 Stoke-on-Trent will fund the storage of any embryos, produced by IVF/ICSI and then frozen, for a total of 12 months. Costs relating to the continued storage of the embryos beyond the initial 12 months of cryopreservation will become the responsibility of the couple.

6.7 If conception occurs on completion of the second cycle, and a positive pregnancy test is confirmed by an ultra sound scan, the couple will not be eligible for further NHS funded fertility treatment, including the implantation of any embryos remaining in storage at the point of conception.

6.8 Abandoned cycle

A cycle will be considered to be abandoned when an IVF treatment cycle is cancelled after commencing administration of drugs but before egg collection. Clinical complications resulting from assisted conception treatment leading to an abandoned cycle will not constitute a treatment attempt for the purpose of establishing entitlement to funding by the CCG. Please note that a cycle abandoned for social reasons will still constitute a treatment attempt.

6.9 Donor Sperm

The CCG will not routinely commission donor sperm but will fund the associated IVF/ICSI treatment in line with the eligibility criteria within this policy provided that the donor sperm meets 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 adherence to HFEA guidelines before accessing the sperm.

6.10 Donor Eggs

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

6.11 Surgical Sperm Retrieval (SSR)
Surgical Sperm retrieval will be funded where clinically appropriate. In cases of azoospermia, funding for SSR will only be provided where the azoospermia is not the result of a sterilisation procedure. Storage of sperm retrieved surgically will only be funded by the CCG for 12 months from the date of cryopreservation. Patients must be provided with counselling and must agree that the costs of storage of sperm become their responsibility after the first 12 months.

6.12 Sperm and Embryo Storage

6.12.1 Embryo and sperm storage, for patients meeting the eligibility criteria under this policy, will be funded for 12 months from initial cryopreservation. Patients must be counselled and provide written consent to the costs of storage becoming their responsibility after the initial 12 month period.

6.12.2 The CCG will fund sperm banking for post-pubertal males under the age of 55 years who have not yet completed their family and are about to undergo treatment which is likely to result in long-term sub-fertility. The CCG will fund storage for a maximum of 10 years for these patients. At the end of this period, patients who wish to self-fund continued storage will be permitted to do so. Storage will be reviewed annually to ensure that the patient still satisfies current criteria for NHS funding for fertility treatment and wishes to continue to have their sperm stored. Patients who no longer meet the current eligibility criteria will be offered the option to self-fund continued storage.

Retrieval and storage of sperm or embryos should be in accordance with HFEA Guidelines.

6.12.3 Ovarian stimulation and embryo cryopreservation will be made available to women under the age of 39 years who are about to undergo treatment likely to cause sub-fertility provided this will not worsen their condition and sufficient time is available. The CCG will fund storage for a maximum of ten (10) years for these patients. Storage will be reviewed annually to ensure that the patient still satisfies current criteria for NHS funding for fertility treatment and wishes to continue to have their embryos stored. Patients who no longer meet the current eligibility criteria will be offered the option to self-fund continued storage.

6.13 Oocyte (egg) preservation and ovarian tissue preservation will not be routinely funded as there is limited clinical evidence regarding the success of this procedure.

6.14 Pre-implantation Genetic Diagnosis (PGD)
This policy does not deal with pre-implantation genetic screening, as this is not considered to be within the scope of fertility treatment.

6.15 Surrogacy
The CCG does not fund fertility treatment for surrogacy; this includes part funding during a surrogacy cycle. Cases may be considered via the CCGs Individual Funding Request route but must demonstrate robust, clinical exceptionality.

7. MONITORING AND COMPLIANCE

The CCG will review this policy annually or within 3 months of any legislative changes that may occur in the future. The monitoring of providers will be performed by the CCG requesting a quarterly return from the provider with regard to referrals and activity levels.

References:

NICE Clinical Guideline 156. Fertility – Assessment and treatment for people with fertility problems
http://www.nice.org.uk/nicemedia/live/14078/62769/62769.pdf

NICE Clinical Guideline CG11 'Fertility: assessment and treatment for people with fertility problems (2004). www.nice.org-pdfCG011niceguideline.pdf.url

The Human Fertilisation & Embryology Authority (HFEA) document 'The Best Possible Start to Life'
http://www.hfea.gov.uk/docs/The_best_possible_start_to_life.pdf

The report 'One Child at a Time' published by the Expert Group on Multiple Births after IVF set up by HFEA and can be accessed on their website.
http://www.hfea.gov.uk/Multiple-births-after-IVF.html

NHS NW London Planned Procedures with a Threshold Policy. Version 2.1 (April 2012)
http://www.northwestlondon.nhs.uk

East of England SCG Fertility Services Commissioning Policy.
http://www.eoescg.nhs.uk/Libraries/Policies_Docs/Fertility_Services_Commissioning_Policy_Final_June_2011.sflb.ashx

North Staffordshire Clinical Commissioning Group, Infertility and Assisted Reproduction Commissioning Policy and Eligibility Criteria (Dated 19 July 2012).

NHS Derby City, Derbyshire County NHS PCT, Commissioning Policy for Sub fertility Services V5.
http://www.derbycitypct.nhs.uk/UserFiles/Documents/DocumentsDownloads/policies/Derbyshire%20Subfertility%20Policy%20v5%2001%2012%2010.pdf

Appendix A: Definitions of terms

Infertility	In the absence of known reproductive pathology, infertility is defined as failure to conceive after regular unprotected sexual intercourse.
CCG	Clinical Commissioning Group
HFEA	Human Fertilisation and Embryology Authority
NICE	National Institute for Health and Care Excellence
GIFT	Gamete Intrafallopian Transfer is a technique whereby the healthiest sperm and eggs are placed together in the woman's fallopian tube. Fertilisation, if it occurs, takes place in the body not in vitro.
IVF	In-Vitro Fertilisation (IVF) is a technique whereby eggs are collected from a woman and fertilised with a man's sperm outside the body.
ICSI	Intracytoplasmic Sperm Injection (ICSI) is a variation of in-vitro fertilisation in which a single sperm is injected into the inner cellular structure of an egg.
BMI	Body Mass Index. The healthy weight range is based on this measurement. This is calculated as your weight in kilograms divided by the square of your height in metres. For further information. http://www.nhs.uk/Tools/Pages/Healthyweightcalculator.aspx
Semen cryostorage	Semen cryostorage is the freezing and storage of semen that may be thawed for use in future fertility treatment cycles.
Embryo cryostorage	Embryo cryopreservation is the freezing and storage of embryos that may be thawed for use in future in-vitro fertilisation treatment cycles. The patient will undergo the first stages of the IVF cycle, with the resulting embryos being frozen rather than implanted.
Surgical sperm recovery	Spermatozoa can be retrieved from both the epididymis and the testis using a variety of techniques with the intention of achieving pregnancies for couples where the male partner has obstructive or non-obstructive azoospermia. Sperm recovery is also used in ejaculatory failure and where only non-motile spermatozoa are present in the ejaculate. Surgically collected sperm in azoospermia are immature (because they have not traversed the epididymus) and have low fertilising ability with standard IVF. It is therefore necessary to use ICSI.
Surgical techniques for sperm retrieval from the epididymis or the testis:	
PESA	Percutaneous epididymal sperm aspiration (PESA)
TESA / TEFNA	Testicular sperm aspiration (TESA),
TESE	Testicular sperm extraction (TESE) from a testicular biopsy
MESA	Micro-surgical epididymal sperm aspiration (MESA).

Appendix B: Investigations to be done in Primary Care

		Insert Response & Date
Is age of female partner less than 39 years and will she be so at the start to treatment as per the assisted conception policy?		
Menstrual history	LMP	
	Cycle	
	Menorrhagia	
Social history of both partners	Female Smoking status	
	Female Alcohol intake	
	Male Smoking Status	
	Male Alcohol intake	
Sexual history	Frequency	
	Duration of trying	
	Dyspareunia	
Predisposing factors	PCOS	
	PID/STIs	
	Tubal Surgery	
	Erectile Dysfunction	
	History of scrotal lumps/surgery	
BMI of female patient <19 or >29	Excluded from treatment	
Preconception investigations done in primary care	Smear result	
	Rubella Status	
	Chlamydia screening	
	Mid luteal Progesterone	
	Day 2-5 LH/FSH in irregular cycle	
	FBC	
	TFT	
	Prolactin	
	Semen Analysis – Date	
Hospital Investigations	HSG or hysteroscopy findings	Direct access for GPs to be arranged
	Vaginal US	
	Laparoscopy	