Shropshire, Telford and Wrekin
Clinical Commissioning Group

Document title:	Commissioning Policy for the Management of Fertility Treatment
CCG document ref:	COM001
Author / originator:	Fiona Smith
Date published:	See version control
Date of approval:	18.05.2022
Approving committee:	Strategic Commissioning Committee
Responsible director:	Executive Director of Transformation
Category:	Clinical Commissioning
Sub category:	
Date policy is due for review:	
Target audience:	CCGs, NHS Trusts, GPs, Fertility Providers and Service Users

VERSION CONTROL

Document Location

This document is only valid on the day it was printed. The current version of this document will be found at www.shropshiretelfordandwrekinccg.nhs.uk

Revision History

Version	Date	Author	Change Description
Version 1.0	April 2011	SM	
Version 1.1	March 2021	MRJ	Proposed revisions to harmonise SCCG and T&WCCG policies and to update in line with new NHSE and NICE guidance
Version 1.2	May 2021	MRJ	Revisions made following meeting of Task and Finish Group
Version 1.3	30 June 2021	FE	Revisions made as agreed during meeting with service clinical lead, CCG Medical Director and CCG Director of Transformation 29.06.2021.
Version 1.4	15 July 2021	FE	Glossary included.
Version 1.5	17 November 2021	FS	Revision to document, taken to SCC. Not Approved
Version 1.6	5 May 2022	FS	Revision to document after legal advice taken. Taken to SCC, Approved

Approvals

This document requires initial approval by the Executive Team. For subsequent changes approval is required as follows:

Type of change	Name / Committee	Title (if individual)
Major revision		
Minor revision		

Distribution

This document has been distributed to:

Name and job title / External organisation / 'All staff'	Date of Issue	Version

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1. Introduction

1.1 Fertility problems are common in the UK and affect around one in seven couples. It is estimated that 80% 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 over 90%). The remaining couples will be unable to conceive without medical intervention and will be considered to be infertile.[1]

1.2 NICE defines infertility as a woman of reproductive age not conceiving after one year of regular unprotected vaginal sexual intercourse, in the absence of any known cause of infertility or a woman of reproductive age who is using artificial insemination to conceive (with either partner or donor sperm) if she has not conceived after 6 cycles of treatment, in the absence of any known cause of infertility (NICE 2013). There are a number of causes of infertility, however in a quarter of cases the cause of infertility remains unidentified. NICE estimate that 0.52% of women aged 18-39 will receive in vitro fertilisation (IVF) treatment per year.[1]

1.3 The main aim of this policy is to assist couples with medical or physical limits to their fertility.

1.4 This policy sets out the criteria for access to *secondary* and *tertiary* level fertility services (intrauterine insemination (IUI), in-vitro fertilisation (IVF) and IVF with intracytoplasmic sperm injection (ICSI)) for the population covered by Shropshire, Telford and Wrekin Clinical Commissioning Group. Access to fertility services is governed by the same principles as all other services, namely clinical effectiveness, cost effectiveness and the outcomes of the CCG's Commissioning Needs Assessments.

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. The criteria have been developed in line with clinical evidence, taking into account the success rates of fertility treatments and the impact which different factors have on this. This policy should be read in conjunction with the following supporting evidence:

- NICE Clinical Guideline Fertility Problems: assessment and treatment (CG156) 2013 (updated 2017)
- NHS England Clinical Commissioning Policy: Assisted Conception 2014
- The Human Fertilisation and Embryology Authority (HFEA) document 'The Best Possible Start to Life' 2007 (updated 2017)
- NICE Clinical Knowledge Summary 2018.

2. Commissioned Services

2.1 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 and blood tests to check for ovulation should take place.

2.2 Patients who have been trying to conceive for one year can be referred to secondary care for further investigations and diagnosis.

2.3 Within secondary care couples will receive expert conception advice and investigations and may be offered ovulation induction or other treatment if appropriate.

2.4 The CCG's commissioning eligibility criteria for assisted reproduction are given in Section 15 and should be applied to all couples seeking referral from secondary care for assisted conception. Patients who do not meet these criteria will not be eligible for assisted conception treatment.

2.5 If the couple fit Shropshire, Telford and Wrekin CCG's commissioning criteria then they can be referred to tertiary care for assessment for assisted conception techniques such as IUI, IVF, ICSI and FET.[2]

2.6 Specialist counselling should be offered throughout secondary and tertiary care in relation to the impacts that seeking treatment for infertility, outcomes of treatment and of childlessness can have on a couple's life.

2.7 Tertiary services include IUI, IVF, ICSI and FET. 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. Specialist Treatment Options IVF/ ICSI/ IUI

3.1 Shropshire, Telford and Wrekin CCG will commission one full cycle of IVF/ICSI including one cycle of IUI (stimulated or non-stimulated) where appropriate for couples diagnosed with infertility, taking into account patient choice.

3.2 One full cycle of IVF/ICSI treatment is defined as one fresh cycle including: ovulation induction; egg retrieval; fertilisation and fresh embryo transfer with the freezing and subsequent transfer of any resultant frozen embryos if the fresh transfer is not successful[1]. It includes appropriate diagnostic tests, scans and pharmacological therapy. The CCG will also commission, as part of a cycle, blastocyst transfer where appropriate. Shropshire, Telford and Wrekin CCG will not fund any subsequent cycles using frozen embryos if a baby is born from prior treatment or conceived naturally, or if a child is adopted after the fresh IVF cycle.

3.3 Intrauterine insemination (IUI) is a relatively simple infertility treatment, where specially washed and processed sperm is placed directly into the uterus. Each attempt at this is classed as a cycle of IUI.

4. Abandoned Cycles

4.1 Abandoned cycles will be funded up to the point of embryo transfer. Couples will be eligible for one abandoned cycle as part of their treatment, where the previous cycle has been abandoned for medical reasons.

5. Donor Sperm

5.1 Shropshire, Telford and Wrekin CCG will fund the use of donor sperm for the management of fertility problems associated with the following conditions:

- Obstructive azoospermia
- Non-obstructive azoospermia
- Severe deficits in semen quality in couples who do not wish to undergo ICSI
- Where there is a high risk of transmitting a genetic disorder to the offspring
- Where there is a high risk of transmission of infectious disease
- Severe Rhesus iso-immunisation

6. Donor Eggs

6.1 Shropshire, Telford and Wrekin CCG will fund donor eggs for the management of fertility problems associated with the following conditions:

- Premature ovarian failure
- Gonadal dysgenesis including Turner Syndrome
- Bilateral oophorectomy
- Ovarian failure following chemotherapy or radiotherapy
- Where there is a high risk of transmitting a genetic disorder to the offspring

7. Surgical Sperm Retrieval

7.1 Surgical sperm retrieval (SSR) is the funding responsibility of NHS England and therefore will not be funded by the CCG.

8. Gamete and Embryo Storage

8.1 The CCG will fund embryo storage for one year for patients undergoing NHS funded assisted reproduction treatment. Should the patient wish to continue to store the frozen embryos beyond this date, this would have to be self-funded by the patient. Please see separate Policy for the Provision of NHS Funded Gamete Retrieval and Cryopreservation of Gametes and Embryos for the Preservation of Fertility

9. Fertility Preservation

9.1 Cryopreservation of gametes is commissioned for patients undergoing NHS treatment, which may render them infertile, in line with the criteria laid down in the Shropshire, Telford and Wrekin CCG's Policy for the Provision of NHS Funded Gamete Retrieval and Cryopreservation of the Gametes and Embryos for the Preservation of Fertility.

9.2 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

10.1 Multiple births are associated with greater risk to mothers and children and the HFEA therefore recommends that steps are taken by providers to minimise these. All providers must follow HFEA guidance and have a multiple birth minimisation strategy.3

11. Sperm Washing

11.1 Shropshire, Telford and Wrekin CCG will fund sperm washing for IUI/IVF/ICSI in couples where the male partner is HIV positive and the female partner is HIV negative, regardless of fertility.

11.2 Patients will be eligible for NHS funding for sperm washing and one full cycle of IVF/ICSI including one cycle of IUI (stimulated or non-stimulated) as per section 3 of this policy.

12. Pre-Implantation Diagnosis/Pre-Implantation Screening

12.1 Pre-implantation Diagnosis and Pre-implantation Screening are not covered within the scope of this policy. Please refer to NHS England Clinical Commissioning Policy: Pre-implantation Genetic Diagnosis (PGD) April 2013. https://www.england.nhs.uk/wp-content/uploads/2013/04/e01-p-a.pdf

13. Surrogacy

13.1 Surrogacy will not be routinely funded by Shropshire, Telford and Wrekin CCG in line with the 'Value Based Commissioning & Evidence Based Interventions Policy' this is the link to it on our website https://www.shropshiretelfordandwrekinccg.nhs.uk/wp-content/uploads/Final-version-VBC-EBI-Policy-Public-15.12.21-1.pdf .

14. IVF treatment for seriously injured veterans

14.1 The independent Medical Expert Group set up as a result of the Lord Boyce Review of the Armed Forces Compensation Scheme recommends that veterans suffering serious genital injuries be guaranteed at least three cycles of IVF. Funding for these patients should not be sought through the CCG. Prior approval should be sought from the NHS England and NHS Improvement Armed Forces Health team for all patients registered with a Defence Medical Service (DMS) practice. All Armed Forces health queries and applications should be submitted to the team at england.armedforcespriorapprovals@nhs.net.

15. Eligibility Criteria

15.1 Please see below for the referral pathway through primary, secondary and tertiary care and the CCG's commissioning criteria for this service.

15.2 Under this policy, treatment can be provided up until the woman's 40th birthday.

15.3 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.

15.4 Please note that there are additional criteria for same sex couples and single women, listed in the following table.

15.5 Please note that there are different criteria for patients who are undergoing NHS treatment, which is likely to make them infertile. Please refer to the CCG Policy for the Provision of NHS Funded Gamete Retrieval and Cryopreservation of the Gametes and Embryos for the Preservation of Fertility.

15.6
Referral from Primary Care to Secondary Care

Criteria	Description
1. Woman's Age	Women must be over the age of 18 to qualify for referral to secondary care. People over the age of 40 may be referred for expert advice but will be advised in primary care that their chances of achieving a successful pregnancy are low.
2. Woman's Body Mass Index	Obesity has a negative impact on fertility and increases risks to mother and baby during pregnancy. The woman should have a BMI between 19 and 35 to qualify for referral to secondary care for further investigations. Women who are obese or underweight should be offered support to meet the required BMI range for referral.
3. Identified cause/ duration of sub fertility	Couples who have an identified potential cause for their fertility problems can be referred immediately to secondary care. Otherwise, couples must have infertility of at least one year duration prior to referral. Same sex couples/single women may be referred to Secondary Care for advice on and assessment of fertility issues.
4. Previous IVF Treatment	Previous treatment, however funded, precludes patients from being eligible for NHS funded investigations or treatment. This is not applicable where same–sex couples have self-funded donor insemination/IUI for the purpose of demonstrating infertility (see below).
5. Previous Sterilisation	People are ineligible for referral if previous sterilisation (e.g. vasectomy or tubal ligation) has taken place (either partner), even if it has been reversed.
6. Relationships	Couples should be seen together within primary, secondary and tertiary services as fertility treatment concerns both partners.
7. GP Registration	The female partner must be registered with a Shropshire or a Telford and Wrekin GP Practice.

8. 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 a previous relationship. Foster children are not included within these criteria.
9. Child Welfare	It is the responsibility of the referring G.P. to ensure that any issues relating to the potential welfare of any children born as a result of fertility treatment are bought to the attention of the secondary/tertiary care provider as early as possible. Where serious concerns over the welfare of any future children exist, then referral should not be made.

15.7

Referral from Secondary Care to Tertiary Care

Criteria	**Description**
1. Woman's Age	Any treatment cycle will not be commenced if the woman is less than 18 years of age or has had her 40th birthday.
2. Woman's Body Mass Index	Obesity reduces fertility and increases risks to mother and baby during pregnancy. The woman should have a BMI of between 19 and 30 at the time of commencement of tertiary care treatment. Women who are obese or underweight should be offered support to meet the required BMI range for referral into tertiary care. Women with a BMI of less than 19 or greater than 30 will not be funded for assisted conception.
3. Identified cause/ duration of sub fertility	Couples who have an identified cause for their fertility problems OR have infertility of at least **2** years' duration if the woman seeking to conceive is under 35 years old, or **1** year's duration if over 35 years old.
4. 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 below.
5. Previous Sterilisation	Couples are ineligible if previous sterilisation has taken place (either partner), even if it has been reversed.
6. Relationships	Couples should be seen together within primary, secondary and tertiary services as fertility treatment concerns both

	partners. The referring secondary care clinician must ensure that couples are aware of the implications of fertility/IVF treatment and the commitments required before making a referral for assisted conception.
7. GP Registration	The female partner must be registered with a Shropshire or a Telford and Wrekin GP Practice.
8. 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 a previous relationship. Even if accepted for treatment, should a child be adopted or a pregnancy lead to a live birth the couple will no longer be eligible for treatment. Foster children are not included within these criteria.
9. 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 they must be non-smoking at the time of commencing treatment.
10. 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 HFEA Code of Practice should be used when making these decisions: https://portal.hfea.gov.uk/media/1605/2019-12-03-code-of-practice-december-2019.pdf
11. Medical Conditions	Treatment may be denied on other medical grounds not explicitly covered in this document on the authority of the treatment provider and in line with the principles of the HFEA code of practice and safe medical practice.
12. Compliance with Treatment	Consideration should be given to not referring any couple who are unlikely to accept or comply with the demands of adhering to a treatment plan. Consideration should also be given to a woman's willingness to adopt a healthier lifestyle during pregnancy.
13. HIV in addition to the above criteria	Sperm washing will be commissioned for all couples where the male is HIV positive and the female is HIV negative and where patients fit all eligibility criteria within this policy.

14. Same Sex Couples/Single Women in addition to the above criteria	<u>Same Sex Female Couples</u> The aim of this policy is to assist couples with medical or physical limits to their infertility. Infertility is defined as a female of reproductive age being unable to conceive after one year of regular unprotected vaginal intercourse, in the absence of any known medical cause of infertility. In circumstances where the above definition cannot be applied (for example a same sex couple/single woman) infertility may be demonstrated by the inability to conceive after 6 cycles of self-funded donor insemination/IUI, undertaken at a Human Fertilisation and Embryology Authority (HFEA) licensed clinic, in the absence of any known reproductive pathology. • Same sex female couples/single women will be required to demonstrate infertility prior to commencing any tertiary treatments 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 a prospective mother who has undertaken NHS funded fertility treatment, whether successful or not, will be 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. • Same sex fertile couples/fertile single women will not be funded for assisted conception methods under this policy. • Same sex female couples/single women will be required to fit all other criteria within this policy in line with heterosexual couples <u>Same-Sex Male Couples</u> Same sex male couples will not be able to access fertility treatment within their relationship as the CCG does not fund surrogacy.

16. Trans-gender Men or Women	Cryopreservation of gametes is commissioned for patients undergoing NHS-funded gender re-assignment, which may render them infertile, in line with the criteria laid down in the Shropshire Telford and Wrekin CCG Policy for the Provision of NHS Funded Gamete Retrieval and Cryopreservation of the Gametes and Embryos for the Preservation of Fertility. These gametes may be used to assist conception.

16. Glossary

Abandoned cycle	A treatment that does not result in the transfer of viable embryos up to six days after egg collection.
Bilateral Oophorectomy	Surgical removal of both ovaries.
Chemotherapy	A cancer treatment where medicine is used to kill cancer cells. Treatment can also damage eggs and sperm production and lead to infertility.
Cryopreservation	The freezing and storage of an item. In this case eggs, sperm or embryos.
DIUI (Donor Intrauterine Insemination)	As IUI but with donor sperm.
E2 (Oestrogen)	Female sex hormone produced by the ovary. Levels fluctuate during the menstrual cycle. Measured through blood tests as an indication of the level of stimulation.
Embryo	Formed from the fusion (fertilisation) of an egg with a sperm. A ball of cells that is grown in the IVF laboratory for two to seven days. An embryo may implant in the uterus and lead to a pregnancy.
FET (Frozen Embryo Transfer)	A treatment using embryos that have been frozen in previous cycle of IVF.
FSH (Follicle Stimulating Hormone)	Hormone produced by the pituitary gland which stimulates the production of follicles by the ovary. Used in assisted conception to stimulate the production of more than one follicle (ovulation induction).
Gamete	A sperm or an egg
Gonadal Dysgenesis	Abnormal development of the testicles or ovaries. This usually means that sperm and eggs are not produced or present.
ICSI (Intra-Cytoplasmic Sperm Injection)	An assisted reproductive technique which involves the injection of a single sperm into each egg. Particularly useful in cases of sperm dysfunction.
In-Vitro Fertilisation (IVF)	Technique whereby eggs are collected from the female and fertilised with the male's sperm outside the woman's body.
IUI (Intra Uterine Insemination IUI)	The technique of placing sperm in the uterus of a woman and by-passing the cervix using a fine catheter.

Luteinising Hormone (LH)	Hormone released by the pituitary gland in response to GnRH production. Essential for development of eggs and sperm.
Non-Obstructive Azoospermia	No sperm being produced in the ejaculate (sample). In these cases caused by a hormonal imbalance that is usually irreversible. May also be caused by anabolic steroid abuse in bodybuilders.
Obstructive Azoospermia	No sperm being produced in the ejaculate (sample). In these cases caused by a blockage of the tubes leading from the testicle.
P4- Progesterone	Hormone produced by the ovary and by the corpus luteum after ovulation. This encourages the growth of the lining of the womb.
Polycystic Ovarian Syndrome (PCOS)	Condition where many small cysts form on the ovary and hormonal imbalances result. Can cause infertility. Treatment can be in the form of drugs or surgery.
PESA- Percutaneous Epididymal Sperm Aspiration	A sperm recovery technique whereby a fine needle is passed through the skin of the scrotum and into the epididymal region of the testes. Sperm are withdrawn using gentle suction.
Primary care	Primary care services provide the first point of contact in the healthcare system, acting as the 'front door' of the NHS. Primary care includes general practice (your GP).
Premature Ovarian Failure	A condition where the number of eggs in a woman's ovaries declines too rapidly and she is unable to conceive. Leads to early menopause.
Radiotherapy	A treatment where radiation is used to kill cancer cells. The radiation may also damage or destroy eggs and sperm production, leading to infertility.
Rhesus Iso-immunisation	A condition that happens when a pregnant woman's blood protein is incompatible with the baby's, causing her immune system to react and destroy the baby's blood cells.
TESA- Testicular Sperm Aspiration	This sperm extraction technique involves the insertion of a needle into the lower region of the testes and the removal of a small piece of testicular tissue.
Turner Syndrome	A genetic disorder affecting females. A woman with Turner syndrome only has one normal X (sex) chromosome rather than two. Leads to gonadal dysgenesis leading to a lack of monthly periods and infertility.
Secondary Care	A hospital service that you are referred to by your GP for further investigations and specialist advice.

Surrogacy	When a woman carries a baby for a couple who are unable to conceive or carry a child themselves for medical or physical reasons. May use eggs from the surrogate (traditional surrogacy) or eggs from a female partner being treated for infertility (host surrogacy).
Tertiary Care	Highly specialised and complex healthcare services and treatments. Individuals are referred from secondary care to tertiary care to receive IVF and other highly specialised services.

17. References

1 NICE Clinical Guideline Fertility Problems: assessment and treatment (CG156). Published 20 February 2013. Updated 6 September 2017. https://www.nice.org.uk/guidance/cg156
2 NHS England Clinical Commissioning Policy: Assisted Conception 2014. https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2014/11/n-sc037.pdf
3 The Human Fertilisation and Embryology Authority (HFEA) 'The Best Possible Start to Life' 2007 (updated 2017). https://www.hfea.gov.uk/media/1312/the_best_possible_start_to_life.pdf

18. Acknowledgements

Adapted from North Staffordshire CCG Infertility and Assisted Reproduction Commissioning Policy and Eligibility Criteria June 2020.