NHS
Somerset
Clinical Commissioning Group

FERTILITY ASSESSMENT AND TREATMENT PRIOR APPROVAL POLICY

Version:	1516.v5
Recommendation by:	Somerset CCG Clinical Commissioning Policy Forum (CCPF)
Date Ratified:	February 2016
Name of Originator/Author:	IFR Manager
Approved by Responsible Committee/Individual:	Somerset CCG Clinical Operations Group (COG)
Publication/issue date:	1 April 2016
Review date:	Earliest of either NICE publication or 3 years from issue
Target audience:	SCCG: • Contracts Team • Providers • GP Practices SCCG • GP Bulletin • Web Site IFR Page **Medical Directors:** • Taunton & Somerset NHS FT • Yeovil District Hospital NHS FT • Royal United Hospitals Bath NHS FT • United Hospitals Bristol NHS FT • Weston Area Health NHS Trust • Somerset Partnership NHS FT
Application Form	Fertility Prior Approval Form

FERTILITY ASSESSMENT AND TREATMENT PRIOR APPROVAL POLICY
CONTENTS

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VERSION CONTROL

Document Status:	Current policy
Version:	1516.v5

Version	Date	Comments
1.0	August 2006	Draft version
1.1	August 2006	Version incorporating amendments made by the Individual Funding Review Panel
1.2	November 2006	Final draft version following approval with the Individual Funding Review Panel
1.3	November 2006	Final version following comments from Chair of Professional Executive Committee
1.4	July 2007	NICE Age criteria adopted
1.5	December 2007	Version incorporating amendments made by the Individual Funding Review Panel
1.6	January 2009	Version incorporating amendments made by the Professional Executive Committee
1.7	February 2009	Version incorporating the amendments made by the Professional Executive Committee
1.8	April 2009	Version incorporating the amendments made by the Individual Funding Review Panel
1.8a	September 2010	Version incorporating the amendments made by the Individual Funding Review Panel
1.9a	June 2012	Version incorporating the amendments made by the Individual Funding Review Panel Approved by the Professional Executive Committee
1.9b	July 2014	Version incorporating the amendments from Primary Care Trust to Clinical Commissioning Group
2	July 2015	Draft SCCG CCPF amend the criteria to 1 cycle +1 FET, 2 years with subfertility or infertility
3	Dec 2015	Draft following public consultation
4b	Feb 2016	SCCG COG & GB Approved New Criteria
4b	March 2016	Amendment to version control of application form to 1516.v5
4c	July 2017	Change CSU template to SCCG template
5	August 2017	Include a section on Immigration Health Surcharge; Removal of assisted conception services (charges to Overseas Visitors)

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Equality Impact Assessment (EIA) Form OR EIA Screening Form completed. Date:	May 2015 & January 2016

Sponsoring Director: **Author(s):**	Sandra Corry
Document Reference:	1516.v5

Glossary of Terms

AMH	anti-Müllerian hormone - Comparison of an individual's AMH level with respect to average levels[13] is useful in fertility assessment, as it provides a guide to ovarian reserve and identifies women that may need to consider either egg freezing or trying for a pregnancy sooner rather than later if their long-term future fertility is poor
Embryos	refers to a fertilised oocyte. It is called an embryo until about eight weeks after fertilisation and from then it is instead called a foetus
FSH	follicle-stimulating hormone - FSH regulates the development, growth, pubertal maturation, and reproductive processes of the human 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
Infertility	In the absence of known reproductive pathology, infertility is defined as failure to conceive after regular unprotected sexual intercourse for 2 years with the same partner
IUI	Intrauterine Insemination (IUI) involves timed insemination of sperm into the uterus. This can be completed as part of a natural unstimulated cycle (unstimulated IUI) or following stimulation of the ovaries using oral anti-oestrogens or gonadotrophins (stimulated IUI)
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

Oocyte (Eggs)	refers to a female gametocyte or germ cell involved in reproduction. In other words, it is an immature ovum, or egg cell
Sperm	refers to the male reproductive cells
Sperm, Oocyte or Embryo Cryopreservation	Sperm, Oocyte or Embryo Cryopreservation is the freezing and storage of Sperm, Oocyte or embryos that may be thawed for use in future in-vitro fertilisation treatment cycles

A full glossary of the terms relating to Fertility are set out on the HFEA website: http://www.hfea.gov.uk/glossary_c.html

FERTILITY ASSESSMENT AND TREATMENT POLICY

Fertility Assessment and Treatment is not routinely funded by the CCG is subject to this restricted policy**.**

General Principles

Funding approval will only be given in line with these general principles. Where patients are unable to meet these principles in addition to the specific treatment criteria set out in this policy, funding approval will not be given.

1. Funding approval must be secured by primary care/secondary care prior to referring/treating patients

2. Referring patients to secondary care without funding approval having been secured not only incurs significant costs in out-patient appointments for patients that may not qualify for surgery, but inappropriately raises the patient's expectation of treatment.

3. On limited occasions, the CCG may approve funding for an assessment only in order to confirm or obtain evidence demonstrating whether a patient meets the criteria for funding. In such cases, patients should be made aware that the assessment does not mean that they will be provided with surgery and surgery will only be provided where it can be demonstrated that the patients meets the criteria to access treatment in this policy.

4. Funding approval will only be given where there is evidence that the treatment requested is effective and the patient has the potential to benefit from the proposed treatment. Where it is demonstrated that patients have previously been provided with the treatment with limited or diminishing benefit, funding approval is unlikely to be agreed.

5. Patients should be advised that receiving funding approval does not confirm that they will receive treatment or surgery for a condition as a consent discussion will need to be undertaken with a clinician prior to treatment.

6. Where funding approval is given by the Individual Funding Panel, it will be available for a specified period of time, normally one year.

BACKGROUND

Fertility Assessment and Treatment

Somerset CCG has limited resources to fund fertility treatments and have therefore targeted the limited funds specifically in order to allow couples in a stable relationship, without a child a chance to conceive. Given the limits on resources the provision of treatments under this policy are aimed at patients with a realistic clinical opportunity of having a child.

Infertility can be primary, in couples who have never conceived, or secondary, in couples who have previously conceived. There are several possible reasons why conception may not happen naturally. In men, a fertility problem is usually because of low numbers or poor quality of sperm. Female fertility decreases with increasing age. Other factors which affect fertility success rates include obesity, smoking and social factors such as alcohol and drug misuse and therefore this policy has criteria on these subjects.

The following figures give the average success rate for In-Vitro Fertilisation [IVF] and Intracytoplasmic Sperm Injection [ICSI] treatment using a woman's own fresh eggs in the UK in 2009

- 32.3% for women under 35
- 27.2% for women aged 35-37
- 19.2% for women aged 38-39
- 12.7% for women aged 40-42
- 5.1% for women aged 43-44
- 1.5% for women aged 45+

This policy sets out the limits within which Somerset CCG will fund treatment with either Intra-uterine Insemination [IUI], ovulation induction medication or donor insemination [DI] as well as IVF treatment if necessary for patients who meet the criteria for treatment.

This policy also sets out treatments patients can expect to access prior to and following oncology treatment in order to preserve fertility as well as our commissioning stance on Cryopreservation, posthumous assisted reproduction, sperm washing and pre-implantation genetic diagnosis.

Somerset CCG does not partially fund treatments for patients who do not meet the criteria within this policy. This includes patients who wish to access assisted conception advice and treatments such as testing and medications following a previous birth, patients who wish to harvest oocytes or sperm, or store embryos prior to third party surrogacy or patients who wish to preserve fertility prior to Gender Dysphoria treatment.

All statistics quoted in this section are referenced from the HFEA http://www.hfea.gov.uk/ivf-figures-2006.html Human Fertilisation and Embryology Authority and NICE Guidelines on Fertility Treatments. http://www.nice.org.uk/nicemedia/pdf/CG011niceguideline.pdf

NATIONAL HEALTH SERVICE REGULATIONS

IMMIGRATION HEALTH SURCHARGE UPDATE

Immigration health surcharge; removal of assisted conception services

Amendments to the NHS (Charges to Overseas Visitors) Regulations 2015 were introduced into Parliament on 19 July 2017. As a result, from 21 August 2017, assisted conception services will no longer be included in the scope of services available for free for those who pay the immigration health surcharge. It is therefore very important that all CCGs update their online and publicly available policies in this area, to ensure potential users of these services are aware of the changes. Further information can be found in the Explanatory Memorandum for these regulations.

Section A - Principles for All Patients

1. One cycle of NHS funded in vitro fertilisation (IVF or ICSI) will be offered (a full cycle includes the transfer of frozen embryo(s)) where patients fulfil the criteria

2. Up to 3 IUI will be funded where clinically appropriate

3. Consider unstimulated intrauterine insemination as a treatment option in the following groups who fulfil the criteria as an alternative to vaginal sexual intercourse:
    a. 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 who are using partner or donor sperm
    b. people with conditions that require specific consideration in relation to methods of conception (for example, after sperm washing where the man is HIV positive)
    c. people in same-sex relationships

4. Fertility treatment should be offered in the least invasive format appropriate, namely investigation and assessment, followed by assisted conception and finally IVF or ICSI

5. Fertility treatment is not commissioned or funded for patients who are not in a stable relationship

6. Patients who have secondary sub-fertility will not be eligible to have NHS funded consultations with fertility services in order to assess their condition and secure treatment advice

7. NHS funding is not available for access to donor insemination facilities for fertile women or surrogacy

8. Couples who do not meet the eligibility criteria set out in the relevant section of this policy or have received NHS funded IVF treatment elsewhere are not eligible for treatment under this policy

9. Where a member of the couple has previously received NHS funded treatment as part of another couple, they will not be barred from accessing NHS funded treatment under their current relationship where they meet all criteria

10. Couples who experience problems in conceiving should be seen together

11. For couples where the man is HIV positive, any decision about fertility management should be the result of discussions between the couple, a fertility specialist and an HIV specialist.

12. Advise couples where the man is HIV positive that the risk of HIV transmission to the female partner is negligible through unprotected sexual intercourse when all of the following criteria are met:
    i. the man is compliant with highly active antiretroviral therapy (HAART)
    ii. the man has had a plasma viral load of less than 50 copies/ml for more than 6 months
    iii. there are no other infections present
    iv. unprotected intercourse is limited to the time of ovulation.
    v. for partners of people with hepatitis B, offer vaccination before starting fertility treatment

13. Evidence based information will be available at every step of the care pathway to enable couples to make informed decisions about their care and treatment

14. Every couple will receive counselling

15. Couples with fertility problems will be advised that they may find it helpful to contact fertility support groups (information will be available from the clinic)

16. Somerset Clinical Commissioning Group does not commission any clinical services associated with surrogacy

17. There will be a choice of referral to in vitro fertilisation facilities in the local area

18. Couples contemplating assisted reproduction should be given up-to-date information about the health of children born as a result of assisted reproduction. Current research is broadly reassuring about the health and welfare of children born as a result of assisted reproduction

19. For the purposes of this policy, the commencement of IVF/ICSI cycle is defined as commencement of ovarian stimulation by fertility services, or if no drugs are used, when an attempt is made to collect eggs/oocytes. Any patient who completes this step, regardless of the outcome, is deemed to have had one full cycle of IVF/ICSI. Therefore if a cycle is abandoned for clinical reasons this is still counted as the fresh cycle that the couple are entitled to

20. One frozen cycle using frozen embryo(s) will follow a fresh cycle if deemed clinically appropriate. Patients will not be eligible for further NHS funded investigation and fertility treatment following completion of this cycle

Cont.

21. A full IVF/ICSI treatment cycle includes:
    a) Diagnostic tests, scans and pharmacological therapy
    b) Counselling for couples
    c) Stimulation of prospective mother's ovaries to produce oocytes
    d) Harvesting of the oocytes
    e) Fertilisation using IVF or ICSI (assisted hatching is not provided)
    f) One fresh embryo transfer
        - To balance the chance of a live birth and the risk of multiple pregnancy and its consequences, no more than one top quality embryo should be transferred during a cycle of in vitro fertilisation treatment or a FET
        - Only in the absence of one top quality embryo should two be transferred
    g) If unsuccessful, within twelve months of cryopreservation, one frozen embryo transfer
    h) Where a top-quality blastocyst is available, use single embryo transfer
    i) A follow up consultation with fertility services post IVF treatment
    j) Where patients have completed their NHS funded full cycle of IVF treatment but have frozen embryos remaining in storage, they can elect to self-fund further treatment with the fertility services

Section B – Heterosexual Couples Criteria

1. Both partners must be registered with a GP within the NHS Somerset area. Where one member of the couple is registered with a GP outside the NHS Somerset CCG area due to residing on the border line of NHS Somerset CCG the couple must not have received fertility treatment through the other NHS area

2. Both partners' GPs and gynaecologist must have given their positive recommendation to proceed to treatment

3. Consider unstimulated intrauterine insemination as a treatment option in the following groups who fulfil the criteria, as an alternative to vaginal sexual intercourse:
    a. 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 who are using partner or donor sperm
    b. people with conditions that require specific consideration in relation to methods of conception (for example, after sperm washing where the man is HIV positive)
    c. people in same-sex relationships

4. Account must be taken of additional factors such as active hepatitis, alcoholism, intra-venous drug misuse that may adversely affect the welfare of any child born as a result of treatment or give rise to complex treatment issues [see HFEA Code of Practice for details - http://www.hfea.gov.uk/code.html]

5. The prospective mother must be aged between 23 – 39 years, inclusive

6. The prospective mother must have a body mass index of >19 and <30

7. The male partner age is <54 years of age. Male fertility has been shown to decrease with age, with evidence of greater incidence of disability, poor sperm function and DNA degradation

8. Neither partner should smoke (patients who smoke can be referred to the smoking cessation service)

9. Neither partner should have undergone a sterilisation procedure

10. There is evidence the couple have been in a stable relationship for two years with either
    a. A clinical identified cause of infertility
    b. An established two year history of unexplained infertility or clinical subfertility

11. There should be no living children from the current relationship including adopted children but excluding fostered children

12. There should be no children from previous relationships for either partner

13. Couples should conform to the statutory “Welfare of the Child” requirements

14. There is an explicit and recorded assessment that the social circumstances of the family unit have been considered within the context of the assessment of the welfare of the child

15. There is an explicit and recorded assessment that the social circumstances of the family unit have been considered within the context of the assessment of the welfare of the child

16. Recurrent miscarriage is not an indication for patients to access fertility services although they may be referred for NHS gynaecological investigations and treatments if appropriate

17. Previous privately funded treatment will not preclude patients from being eligible to NHS Somerset CCG funded fertility treatment. However previous cycles, privately funded, will be taken into account by the responsible clinician in determining the clinical appropriateness of commencing further cycles. In line with current clinical evidence, couples should undergo no more than five cycles in total

18. Treatment may be denied on other medical grounds not explicitly covered in this document

Section C - Same Sex Couples Criteria

1. A woman of reproductive age who is using artificial insemination to conceive (with either partner or donor sperm) should be offered further clinical assessment and investigation if she has not conceived after 6 cycles of treatment, in the absence of any known cause of infertility. Where this is using partner sperm, the referral for clinical assessment and investigation should include her partner

2. Consider unstimulated intrauterine insemination as a treatment option in the following groups who fulfil the criteria, as an alternative to vaginal sexual intercourse:
    a. 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 who are using partner or donor sperm
    b. people with conditions that require specific consideration in relation to methods of conception (for example, after sperm washing where the man is HIV positive)
    c. people in same-sex relationships

3. For people in the recommendation above who have not conceived after 6 cycles of donor or partner insemination, despite evidence of normal ovulation, tubal patency and semen analysis, offer a further 3 cycles of unstimulated intrauterine insemination before IVF is considered

4. Both partners must be registered with a GP within the NHS Somerset area. Where one member of the couple is registered with a GP outside the NHS Somerset due to residing on the border line of NHS Somerset the couple must not have received fertility treatment through the other NHS area

6. Neither partner should have undergone a sterilisation procedure

7. Both partners' GPs and gynaecologist must have given their positive recommendation to proceed to treatment

8. Account must be taken of additional factors such as active hepatitis, alcoholism, intra-venous drug misuse that may adversely affect the welfare of any child born as a result of treatment or give rise to complex treatment issues

    - HFEA Code of Practice for details - **http://www.hfea.gov.uk/code.html**

9. The prospective mother must be aged between 23 – 39 years, inclusive

10. The prospective mother must have a body mass index of >19 and <30

11. Neither partner should smoke (patients who smoke can be referred to the smoking cessation service)

12. There is evidence the couple have been in a stable relationship for two years with either ;
    a. A clinical identified cause of infertility
    b. An established two year history of unexplained infertility or clinical subfertility

13. There should be no living children from the current relationship including adopted children but excluding fostered children

14. There should be no children from previous relationships for either partner

15. Couples should conform to the statutory “Welfare of the Child” requirements

16. Where both partners have fertility issues i.e. blocked fallopian tubes or anovulation **or** where only one partner is sub-fertile, where possible, the partner who is fertile should try to conceive before proceeding to interventions involving the sub-fertile partner

17. Recurrent miscarriage is not an indication for patients to access fertility services although they may be referred for NHS gynaecological investigations and treatments if appropriate

18. Previous privately funded treatment will not preclude patients from being eligible to NHS Somerset CCG funded fertility treatment. However previous cycles, privately funded, will be taken into account by the responsible clinician in determining the clinical appropriateness of commencing further cycles. In line with current clinical evidence, couples should undergo no more than five cycles in total

19. There is an explicit and recorded assessment that the social circumstances of the family unit have been considered within the context of the assessment of the welfare of the child

20. Treatment may be denied on other medical grounds not explicitly covered in this document

Section D - FERTILITY Preservation Prior to Oncology Treatment

Cryopreservation Sperm/Oocytes/Embryos
(For Oncology and Fertility Services consideration when planning treatment)

1. Cryopreservation is a term use to describe the freezing and storage of sperm, oocytes and embryos for patients

2. Before patients are to be treated with oncology treatments, chemotherapy or radiotherapy, likely to affect fertility, or management of post-treatment fertility problems, the procedures recommended by the Royal College of Physicians and the Royal College of Radiologists should be followed.

3. Patients who are to be treated with oncology treatments which are likely to compromise their fertility are eligible for fertility preservation treatment including:
    a. **for single individuals or those not in a stable relationship**: sperm collection and storage, or oocyte harvesting and storage, **or**
    b. **storage for couples in a stable relationship**: oocyte harvesting, fertilisation and embryo Cryopreservation prior to any oncology treatment to allow subsequent IVF treatment in line with this policy as long as they meet the requirements for funding below

4. Patients must have commenced puberty

5. Female patient must not be older than 40 years of age

6. Male patients must not be older than 54 years of age
7. For those patients who are undergoing gonadotoxic treatment, taking into consideration cancer incidence and survival among this age group

8. Fertility preservation for the following patient(s) is not commissioned and will not be funded where;
    a. the patient wishes to undergo a vasectomy or female sterilisation (including patients undergoing gender reassignment surgery) and wishes to preserve fertility, or
    b. the patient wishes to delay conception, or
    c. the patient has living offspring and therefore does not qualify for funding for fertility preservation treatment. This includes genetic and legally adopted children and offspring who are adults but does not include foster children or step children
    d. the patient has previously received an NHS funded cycle of fertility treatment

9. Funding time period for patients who fulfil the criteria;
    a. up to 5 years **or**
    b. until a patient's 25th birthday
    c. funding for storage will cease 6 months following the death of the patient **or** if the patient or their partner reaches the upper age limit
    d. if continued funding is required a funding application should be made to the CCG's Individual Funding Requests Panel

10. Once the period of NHS funding ceases, patients or their family can elect to self-fund for a further period, not to exceed appropriate HFEA regulations on length of storage

11. Patients would be eligible for fertility preservation treatment including;
    a. sperm collection and storage **or**
    b. egg harvesting and storage for single individuals or those not in a stable relationship **or**
    c. egg harvesting, fertilisation and embryo storage for couples in a stable relationship prior to any oncology treatment to allow subsequent IVF treatment in line with this policy as long as they meet the requirements for funding

12. A patient who is to receive oncology treatment which is likely to compromise their fertility, either they or their partner must have no children to qualify for funding for fertility preservation treatment. This includes genetic and legally adopted children

13. At the time of fertility preservation treatment, patients **do not need** to demonstrate they comply with the criteria below as Somerset CCG recognises this would be unfair and delaying treatment until a patient could comply would be dangerous;
    a. of a non-smoker
    b. a BMI between >19 - <30
    c. have a documented history of unexplained infertility

14. Men and adolescent boys preparing for medical treatment that is likely to make them infertile should be offered semen cryostorage because the effectiveness of this procedure has been established

15. Local protocols should exist to ensure that health professionals are aware of the value of semen cryostorage in these circumstances, so that they deal with the situation sensitively and effectively

16. Women preparing for medical treatment that is likely to make them infertile should be informed that oocyte cryostorage has very limited success, and that cryopreservation of ovarian tissue is still in an early stage of development

17. People preparing for medical treatment that is likely to make them infertile should be offered counselling from someone who is independent of the treatment unit to help them cope with the stress and the potential physical and psychological implications for themselves, their partners and any potential children resulting from cryostorage of gametes and/or embryos

18. Where cryostorage of gametes and/or embryos is to be undertaken because of medical treatment that is likely to make people infertile, this should occur before such treatment begins

19. Sperm, Egg and Embryo storage will be handled in line with the provider facility Cryopreservation Policy which is in place at the time of collection

Section E - Fertility Treatment including Assisted Conception & IVF following Fertility Preservation Treatment

1. Once the patient has completed oncology treatment and been advised by clinicians that they may safely commence fertility treatment, they must meet all of the requirements of the Somerset CCG Fertility Assessment and Treatment policy to be eligible for NHS funded fertility treatment

Section F - Assisted Conception - INTRA-UTERINE INSEMINATION

1. Couples must fulfil the criteria within section B and C

2. Consider unstimulated intrauterine insemination as a treatment option in the following groups as an alternative to vaginal sexual intercourse:
   a. 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 who are using partner or donor sperm;
   b. people with conditions that require specific consideration in relation to methods of conception (for example, after sperm washing where the man is HIV positive);
   c. people in same-sex relationships

3. Couples with mild male factor fertility problems, unexplained fertility problems or minimal to mild endometriosis should be offered up to three cycles of stimulated intra-uterine insemination (IUI) because this increases the chance of pregnancy

4. Where intra-uterine insemination is used to manage male factor fertility problems, ovarian stimulation should not be offered because it is no more clinically effective than unstimulated intra-uterine insemination and carries a risk of multiple pregnancy

5. Where intra-uterine insemination is used to manage unexplained fertility problems, both stimulated and unstimulated intra-uterine insemination are more effective than no treatment. However, ovarian stimulation should not be offered, even though it is associated with higher pregnancy rates than unstimulated intra-uterine insemination, because it carries a risk of multiple pregnancy

6. Where intra-uterine insemination is used to manage minimal or mild endometriosis, couples should be informed that ovarian stimulation increases pregnancy rates compared with no treatment, but that the effectiveness of unstimulated intra-uterine insemination is uncertain

7. Where intra-uterine insemination is undertaken, single rather than double insemination should be offered

8. Where intra-uterine insemination is used to manage unexplained fertility problems, fallopian sperm perfusion for insemination (a large-volume solution, 4 ml) should be offered because it improves pregnancy rates compared with standard insemination techniques: Factors affecting the outcome of in vitro fertilisation treatment;

Cont.

a. surgery for hydrosalpinges before in vitro fertilisation treatment
b. women with hydrosalpinges should be offered salpingectomy, preferably by laparoscopy, before in vitro fertilisation treatment because this improves the chance of a live birth

9. Assisted conception services include IUI, ovulation induction medication and donor insemination. In order to access assisted conception services following investigation and assessment, couples must also be assessed against the following criteria:

    a) An assessment of a prospective mothers overall chance of successful pregnancy through natural conception or with IVF should be made with one of the following measures to predict the likely ovarian response to gonadotrophin stimulation in women who are considering treatment:
        i. anti-Müllerian hormone [AMH], **or**
        ii. timed follicle-stimulating hormone [FSH] and Estrogen
    b) The prospective mother must have;
        i. an AMH of greater than or equal to 5.4 pmol/l **or**
        ii. a FSH level less than or equal to 15iu/l
    c) The male partner must have normal sperm function (except for ICSI and donor sperm)
    d) If donor sperm / oocytes are used the couple must be able to demonstrate in writing joint legal responsibility for any child born as a result of treatment

Section G - In-Vitro Fertilisation or Intracytoplasmic Sperm Injection

1. Indications for intracytoplasmic sperm injection

   The recognised indications for treatment by intracytoplasmic sperm injection include:
    a. severe deficits in semen quality
    b. obstructive azoospermia
    c. non-obstructive azoospermia

2. One full treatment cycle of IVF or ICSI (with oocyte donation and/or surgical sperm recovery if required) in line with Section A, points 7 and 8, may be offered to couples where other assisted conception techniques have failed

3. The following criteria must also be satisfied at the time of treatment:

    a. The prospective mother's serum FSH must be less than or equal to 12iu/l at the time of treatment or an AMH of greater than or equal to 5.4 pmol/l

    b. The prospective father's serum FSH level must be less than 15 iu/L or testicular volume must be greater than 8ml (as assessed by a fertility specialist) for surgical sperm recovery and storage to be undertaken

Section H - Surgical Sperm Recovery or Electro-ejaculation

1. Surgical sperm recovery before intracytoplasmic sperm injection may be performed using several different techniques depending on the pathology of the patient. In all cases, facilities for cryopreservation of spermatozoa should be available

2. Surgical sperm recovery is not commissioned for patients who have azoospermia due to a previous vasectomy, including patients who have undergone a vasectomy reversal

3. Surgical sperm recovery is commissioned for the following patients:
    a. the patients must qualify for fertility treatment under this policy **and**
    b. the prospective father has no sperm in the ejaculate (azoospermia) **or**
    c. has a physical disability **or**
    d. suffered a trauma **or** neurologic impairment meaning they are unable to ejaculate

4. Genetic issues and counselling;
    a. Before considering treatment by intracytoplasmic sperm injection, couples should undergo appropriate investigations, both to establish a diagnosis and to enable informed discussion about the implications of treatment
    b. Before treatment by intracytoplasmic sperm injection, consideration should be given to relevant genetic issues
    c. Where a specific genetic defect associated with male infertility is known or suspected, couples should be offered appropriate genetic counselling/testing
    d. Where the indication for intracytoplasmic sperm injection is a severe deficit of semen quality or non-obstructive azoospermia, the man's karyotype should be established
    e. Men who are undergoing karyotype testing should be offered genetic counselling regarding the genetic abnormalities that may be detected
    f. Testing for Y chromosome microdeletions should not be regarded as a routine investigation before intracytoplasmic sperm injection. However, it is likely that a significant proportion of male infertility results from abnormalities of genes on the Y chromosome involved in the regulation of spermatogenesis, and couples should be informed of this

5. For couples where the man is HIV positive, any decision about fertility management should be the result of discussions between the couple, a fertility specialist and an HIV specialist

6. Advise couples where the man is HIV positive that the risk of HIV transmission to the female partner is negligible through unprotected sexual intercourse when all of the following criteria are met:
    a. the man is compliant with highly active antiretroviral therapy (HAART)
    b. the man has had a plasma viral load of less than 50 copies/ml for more than 6 months
    c. there are no other infections present
    d. unprotected intercourse is limited to the time of ovulation.
    e. for partners of people with hepatitis B, offer vaccination before starting fertility treatment

Section I - Posthumous Assisted Reproduction

1. Patients who wish to use cryopreserved sperm, oocytes or embryos following the death of their partner, may only do so where appropriate consents have been obtained prior to the death of their partner, as set down in HFEA guidelines

2. SCCG does not fund fertility treatments associated with posthumous assisted reproduction

Section J - Sperm Washing

1. Sperm washing is a technique used to decrease the risk of HIV transmission in HIV positive prospective fathers, because the HIV infection is carried by the seminal fluid rather than the sperm. Research has shown that it can reduce the risk of transmission by 96%. However, there may still be a small risk of HIV transmission which some couples may find unacceptable

2. Patients can be seen, assessed and treated by local fertility services although a sperm-washing service is only available at the Chelsea & Westminster (C&W) Hospital in London, and at the time of drafting this policy, no other clinics in the UK offer a sperm-washing service

3. SCCG will approve funding for sperm washing with one full cycle of fertility treatment in conjunction with this policy where;
    a. the couple qualify for fertility treatment under this policy and
    b. the prospective father is HIV positive

4. Prospective mothers who are HIV positive should be advised that there is a risk of between 5 and 40% of Mother to Child transmission of HIV during pregnancy, labour and delivery or by breastfeeding and should seek advice from their managing clinicians prior to conception in order to minimise the risk **http://www.who.int/hiv/topics/mtct/en/index.html**

Section K - Pre-Implantation Genetic Diagnosis

Pre-Implantation Genetic Diagnosis is commissioned by NHS England

1. Pre-implantation genetic diagnosis (PGD) involves genetically testing an embryo in a laboratory prior to implantation, and is usually used by patients with a known pre-disposition to a specific genetic disorder. PGD is an established technique that is becoming more widely used in this country under license from the HFEA for the diagnosis of genetic and chromosomal abnormalities for couples with a high risk of having an offspring with the genetic disorder

2. It is an additional step in an IVF treatment cycle, and involves removal of a cell from an embryo which is then tested for the faulty gene that causes the disorder in the family. Those embryos which do not contain the faulty gene can then be implanted as appropriate

3. PGD is currently HFEA licensed for a small number of centres, and a specific set of conditions. At the date of drafting this policy, the HFEA has licensed in excess of 100 separate conditions for PGD.http://www.hfea.gov.uk/cps/hfea/gen/pgd-screening.htm

4. There are alternatives to PGD, including adoption, not having a child, using donor sperm or Oocytes, or prenatal diagnosis. Any patients who are considering PGD should be counselled on the options available to them

Section L – Surrogacy

The Commissioner does not support or fund treatments for surrogacy

Background

1. In a surrogacy arrangement a woman agrees to bear a child for another woman or couple and surrender it at birth. The commissioning couple are the people (or in some cases, person) who wish to bring up the child after his or her birth
2. Patients may wish to utilise surrogacy arrangements for a number of reasons:
    a. absence or malformation of the womb (either congenital or through hysterectomy for e.g. cancer or postpartum haemorrhage or menorrhagia)
    b. recurrent pregnancy loss or repeated in vitro fertilisation (IVF) implantation failures
    c. where pregnancy would be a life-threatening condition, or
    d. a prospective single father (or fathers in a same sex relationship) wishes to have a child
3. The Commissioner has limited resources to provide fertility services and therefore has to target those at patients with a realistic clinical opportunity to conceive (with assistance) and carry a child to birth

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4. The Commissioner will not therefore:

a. Be involved in the recruitment of surrogate mothers
b. Fund that element of treatment which relates specifically to addressing fertility treatments directly associated with surrogacy arrangements
c. Fund any payments to the surrogate mother (to cover expenses, legal costs, treatments abroad or transport costs)
d. This section of the policy has been developed taking into account that surrogacy is specifically excluded from NICE guidelines
e. Maternity Care Arrangements
f. The Commissioner commission's maternity services to provide appropriate support, guidance and care to women during and after pregnancy and these services will continue to be available to surrogates.

Patients who are not eligible for treatment under this policy may be considered on an individual basis where their GP or consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy.

Applications cannot be considered from patients personally.

Provided these patients receive the full support of their general practitioner, or clinician, in pursuing their funding request an application may be made to the Individual Funding Request Panel for consideration.

It is expected that clinicians will have ensured that the patient, on behalf of who they are forwarding the application for, is appropriately informed about the existing policies prior to an application to the IFRP. This will reassure the Panel that the patient has a reasonable expectation of the outcome of the application and its context.

An application put forward for consideration must demonstrated some unusual or unique clinical factor about the patient that suggests they are exceptional as defined below:

- Significantly different to the general population of patients with the condition in question

- Likely to gain significantly more benefit from the intervention than might be expected from the average patient with the condition

If you would like further copies of this policy or need it in another format, such as Braille or another language, please contact the Patient Advice and Liaison Service on Telephone number: 08000 851067.

Or write to us: NHS Somerset Clinical Commissioning Group, Freepost RRKL-XKSC-ACSG, Yeovil, Somerset, BA22 8HR or **Email** us: somccg.pals@nhs.net

References: This policy has been developed with the aid of the following references:

1. NICE – CG156 2013
   http://guidance.nice.org.uk/CG/WaveR/90/Consultation/DraftGuidance/pdf/English

2. HFEA – Guidance and Protocols including PGD
   http://www.hfea.gov.uk/index.html

3. Chelsea and Westminster – Sperm Washing
   http://www.chelwest.nhs.uk/services/womens-health-services/assisted-conception-unit-acu/treatment-options/sperm-washing