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NHS Somerset Integrated Care Board

FERTILITY ASSESSMENT AND TREATMENT PRIOR APPROVAL (PA) POLICY

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Application Form	Fertility Prior Approval Form

FERTILITY ASSESSMENT AND TREATMENT PRIOR APPROVAL (PA) POLICY

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Section A - Version Control

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Section B - 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 people 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
Cis-gender	Cis-gender is the term used to describe someone whose sex assigned at birth matches that of their gender identity. It can also be written as cis-man (assigned male at birth and identifies as a man) or cis-woman (assigned female at birth and identifies as a woman).
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
Female	For the purposes of this policy, we use the term “female” to refer to a person’s sex rather than gender identity. This is mainly where there is a physiological or clinical reason to do so.
Fresh Cycle	For the purposes of this policy, the term ‘fresh cycle’ refers to fresh embryo transfers (FET’s) to a woman’s uterus.
Frozen Cycle	For the purposes of this policy, the term ‘frozen cycle’ refers to frozen embryos that have been thawed for transfer to a woman’s uterus.
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 female and fertilised with male sperm outside the body
Male	For the purposes of this policy, we use the term “male” to refer to a person’s sex rather than their gender identity. This is mainly where there is a physiological or clinical reason to do so.
Man/men	For the purposes of this policy, we use the terms “man” or “men” to refer to a person’s gender identity, be that cis-man/cis-men or transman/transmen.
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
Woman/women	For the purposes of this policy, we use the terms “woman” or “women” to refer to a person’s gender identity, be that cis-woman/cis-women or transwoman/transwomen.

Human Fertilisation & Embryology Authority
Treatments | HFEA

Section C - Background

NHS Somerset ICB is committed to making best use of limited resources for fertility assessment and treatment to enable:

- Couples in a stable relationship, without a child a chance to conceive.
- Patients receiving oncology and other medical interventions that may compromise fertility or the management of post-treatment fertility problems; the opportunity to store sperm, oocytes and embryos until a later date.

This policy outlines the parameters for funding fertility assessment and treatment, to ensure treatments are aimed at patients with a realistic clinical opportunity to conceive (with assistance) and carry a child to birth.

Infertility can be primary, in couples who have never conceived, or secondary, in couples who have previously conceived. There are many possible reasons why conception may not happen naturally:

In males, a fertility problem is usually because of low numbers or poor-quality sperm due to conditions such as diabetes or hormonal variations or,

- Sexual problems like premature ejaculation or erectile dysfunction or,
- Overexposure to certain chemicals or,
- Smoking, alcohol, drug misuse and,
- Certain medications

In females, fertility decreases with increasing age.
Other factors that affect fertility success rates are:

- Ovulation disorders due to variations in hormones or,
- Uterine abnormalities or,
- Endometriosis – thickening of the uterine walls or,
- Obesity or,
- Smoking, alcohol, drug misuse or,
- Infections that are sexually transmitted and,
- Being exposed to certain types of chemicals

The most common reasons for IVF treatment cycles being carried out are male infertility (37% of recorded reasons), unexplained (32%), an ovulatory disorder (13%), tubal disease (12%) and endometriosis (6%).
https://www.hfea.gov.uk/media/2894/fertility-treatment-2017-trends-and-figures-may-2019.pdf

NHS Somerset ICB will fund fertility treatment with either: Intra-uterine Insemination [IUI], ovulation induction medication or donor insemination [DI] including IVF treatment, if necessary, for patients who meet the specific criterion that reflects their current status as outlined in this policy.

Section D Principles for approving funding of fertility assessment and treatment

Funding for fertility assessment and treatment is determined and approved by the following principles:

1 **Patients must meet the specific criterion that reflects their status**, as outlined in the relevant sections of this policy.

2 **Clinicians must be able to** demonstrate (where applicable for a couple) a clinically identified cause of Infertility **OR** Clinical Subfertility, prior to applying for funding of fertility treatment.

3 **Evidence must be provided** to demonstrate that the treatment requested is effective and the patient has the potential to benefit from the proposed treatment.

Please note
Patients that have previously received treatment with limited or diminishing benefit, will not be eligible for funding.

4 **Primary or Secondary Care must receive notification of approved funding** prior to referring or treating patients.

5 **Funding may be approved for an assessment only** to confirm or obtain evidence to ensure a patient meets the specific criteria.

Please note
Patients should be made aware that an assessment does not mean that they will be provided with treatment. Treatment will only be provided to patients who meet the criteria to access treatment in this policy.

6 **Funding is approved for donor sperm** where patients meet the specific criterion that reflects their status in the relevant sections of this policy.

N.B. NHS Somerset ICB will not fund the purchase of donor sperm for surrogacy.

7 **Funding is not approved for patients with an elevated BMI of 30 or more**. To increase the efficacy of treatment and reduce the risks associated with treatment patients should be encouraged to lose weight prior to seeking treatment or surgery (thelwall, 2015).

8 **Funding is not approved for patients who are smokers**. To reduce the risks associated with treatment and improve healing, patients should be referred to Stop Smoking Services (loof s., 2014).

9 **NHS Somerset ICB does not partially fund treatments** for patients who do not meet the specified criterion that reflects their status.

10 **Couples with unexplained fertility problems that are not eligible to apply for fertility treatment funding** should be advised to contact fertility support groups (information will be available from the clinic).

11 **Patients who have secondary sub fertility** will not be eligible to have NHS funded consultations with fertility services, to assess their condition and secure treatment advice.

12 **Funding is not approved for couples who have received NHS funded IUI/IVF/ICSI treatment elsewhere** UNLESS a member of the couple has received treatment as part of another couple and is now requesting treatment under their current relationship.

13 **NHS Somerset ICB does not commission any clinical services associated with surrogacy.**

14 **Funding approved by the Evidence Based Interventions Panel, is available for one year.**

15 Patients who are not eligible for treatment under this policy, please refer to Section I **EVIDENCE BASED INTERVENTIONS APPLICATION PROCESS** on how to apply for funding with evidence of clinical exceptionality.

Section E Principles for administering fertility assessment and treatment to ALL patients:

1 **Approval for funding does not confirm that a patient will receive treatment**. A consent discussion will need to be undertaken with a clinician prior to treatment or surgery.

2 **People who are unable to, or would find it very difficult to, have vaginal intercourse,** should be offered an initial consultation to discuss the options for attempting conception.

3 **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.

4 **Up to 6 initial unstimulated intrauterine insemination IUI will be funded**, **followed by a further 3 IUI** where clinically appropriate.

N.B unstimulated intrauterine insemination IUI, MUST be considered as a treatment option in the following groups who fulfil the criteria as an alternative to vaginal sexual intercourse:

- People in same sex relationships

- 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
- People with conditions that require specific consideration in relation to methods of conception (for example, after sperm washing where the male is HIV positive)

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

6 **Couples who experience problems in conceiving should be seen together.**

7 **For couples where the male is HIV positive**, the couple should be advised that the risk of HIV transmission to the female partner is negligible through unprotected sexual intercourse when all of the following criteria are met:

- The male is compliant with highly active antiretroviral therapy (HAART).
- The male has had a plasma viral load of less than 50 copies/ml for more than six months.
- There are no other infections present.
- Unprotected intercourse is limited to the time of ovulation.
- For partners of people with hepatitis B, offer vaccination before starting fertility treatment.

8 **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.

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

10 **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).

11 **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.

12 **One further full 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.

13 **A full IVF/ICSI treatment cycle includes:**

- Diagnostic tests, scans and pharmacological therapy
- Counselling for couples
- Stimulation of prospective birth parent ovaries to produce oocytes
- Harvesting of the oocytes

14 **One fresh embryo is transferred:**

- 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.
- If unsuccessful, within twelve months of cryopreservation **one frozen embryo will be transferred**
- **A single embryo transfer will be undertaken** where a top-quality blastocyst is available
- **A follow up consultation with fertility services is undertaken** post IVF treatment.
- **Patients who have completed their NHS funded full cycle of IVF treatment**, but have frozen embryos remaining in storage, can elect to self-fund further treatment with the fertility service

Section F Policy Criteria

F1 Couples

1.1 **Both partners must be registered with a GP** within the NHS Somerset area.

Please note
Where one member of the couple is registered with a GP outside the NHS Somerset ICB area due to residing on the border line of NHS Somerset ICB; Either member of the couple must not have received fertility treatment through any other NHS area.

1.2 **Both partners' GPs and gynaecologist as appropriate,** must have given their positive recommendation to proceed to treatment

1.3 **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.

1.4 **The prospective birth parent must have a body mass index** of >19 and <30

1.5 **A male partner's 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

1.6 **The prospective birth parent must be aged between 23 – 39 years, inclusive**

1.7 **Neither partner should have undergone a sterilisation procedure.**

1.8 **Neither partner should smoke** (patients who smoke can be referred to the Stop Smoking Service).

1.09 **There should be no living children from the current relationship or previous relationships for either partner**, including adopted children but excluding fostered children.

1.10 **There is evidence the couple have been in a stable relationship for two years.**

N.B. Couples should conform to the statutory "Welfare of the Child" requirements.

1.11 **There is evidence the couple have been trying to conceive for 2 years (where applicable to the couple) with either a** clinically identified cause of Infertility **OR** Clinical Subfertility.

1.12 **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.

1.13 **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.

1.14 **Previous privately funded treatment will not preclude patients from being eligible to NHS Somerset ICB funded fertility treatment.** However previous cycles, privately funded, will be considered by the responsible clinician in determining the clinical appropriateness of commencing further cycles.

1.15 **A female of reproductive age who is using artificial insemination to conceive** (with either IUI funded treatment, 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.

N.B. Where the female is in a civil partnership married or in a relationship lasting 2 years, the referral for clinical assessment and investigation should include both partners.

1.16 **For people in the recommendation above who have not conceived after 6 cycles of IUI funded treatment, 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.**

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

F2 FERTILITY Preservation Prior to oncology and other medical treatments.

Cryopreservation Sperm/Oocytes/Embryos (for Oncology, gender identity services and Fertility Services consideration when planning treatment).

The treating NHS provider is required to forward a completed Fertility Preservation form (this can be accessed on the website) to an appropriate NHS service who provides the treatment requested.

A copy of the completed Fertility Preservation form to be forwarded to the EBI Service to advise of the referral for treatment.

2.1 **Before patients receive treatments that are likely to affect fertility,** or the management of post-treatment fertility problems, the procedures recommended by the Royal College of Physicians and the Royal College of Radiologists should be followed.

2.2 **Patients who will receive treatments which are likely to compromise their fertility**, are eligible for fertility preservation treatment including:

- **For single individuals or those not in a stable relationship**: sperm collection and storage, or oocyte harvesting and storage, **or**
- **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.

2.3 **Patients must have commenced puberty** (presently there is insufficient evidence to support the clinical effectiveness of ovarian or testicular tissue collection for pre-pubescent people). Please refer to the following link; https://www.hfea.gov.uk/treatments/fertility-preservation/information-for-trans-and-non-binary-people-seeking-fertility-treatment

2.4 **Female patient must not be older than 40 years of age**

2.5 **Male patients must not be older than 54 years of age**

2.6 **For those patients who are undergoing gonad toxic treatment**, taking into consideration cancer incidence and survival among this age group

2.7 **Fertility preservation for the following patient(s) is not commissioned and will not be funded where:**

- The patient wishes to undergo a vasectomy or female sterilisation and wishes to preserve fertility, **or**
- The patient wishes to delay conception, **or**
- The patient has living offspring from their current relationship or previous relationships, including adopted children but excluding fostered children.
- The patient has previously received an NHS funded cycle of fertility treatment.

2.8 **The funding time period for patients who fulfil the criteria**:

- Up to 5 years or up to 25 years of age, if age is less than 20 years at the time of preservation
- 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
- If continued funding is required a funding application should be made to the NHS Somerset ICB Evidence Based Interventions Panel.

2.9 **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

2.10 **Patients would be eligible for fertility preservation treatment including:**

- Sperm collection and storage **or**
- Egg harvesting and storage for single individuals or those not in a stable relationship **or**
- 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.

2.11 **A patient who is to receive oncology and other medical treatments that are likely to compromise their fertility**, should be offered cryopreservation appropriate to their status.

Please note:
To qualify for funding for fertility preservation treatment, **there should be no living children from the current relationship or previous relationships for either partner**, including adopted children but excluding fostered children.

2.12 **At the time of fertility preservation treatment, patients do not need to demonstrate they comply with the criteria below** as NHS Somerset ICB recognises this would be unfair and delaying treatment until a patient could comply would be dangerous:

- Of a non-smoker
- A BMI between >19 - <30
- Have documented history of unexplained infertility

2.13 **Transgender individuals preparing for gender reassignment** should be offered cryopreservation prior to commencing hormone replacement therapy and/or transgender re-assignment surgery as appropriate to their status.

Please note:
To qualify for funding for fertility preservation treatment, **there should be no living children from the current relationship or previous relationships for either partner**, including adopted children but excluding fostered children.

2.14 **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.

2.15 **Females 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 and is NOT CURRENTLY FUNDED.

2.16 **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.

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

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

F3 **Fertility Treatment** including Assisted Conception & IVF following Fertility Preservation Treatment

3.1 **Patients who have completed oncology or other medical treatments** and been advised by clinicians that they may safely commence fertility treatment, must meet all the requirements of the NHS Somerset ICB

Fertility Assessment and Treatment policy to be eligible for NHS funded fertility treatment.

F4 **Assisted Conception -** Intra-uterine Insemination

4.1 **Couples must fulfil the criteria within section F**

4.2 **Unstimulated intrauterine insemination must be considered as a treatment option** in the following groups as an alternative to vaginal sexual intercourse:

- People in same-sex relationships,
- 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,
- People with conditions that require specific consideration in relation to methods of conception (for example, after sperm washing where the man is HIV positive).

4.3 **Couples with mild male factor fertility problems, unexplained fertility problems or minimal to mild endometriosis** should be offered up to 6 cycles of stimulated intra-uterine insemination (IUI) because this increases the chance of pregnancy.

4.4 **Ovarian stimulation should not be offered where intra-uterine insemination is used to manage male factor fertility problems**, as it is deemed to be no more clinically effective than unstimulated intra-uterine insemination and carries a risk of multiple pregnancy.

4.5 **Where intra-uterine insemination is used to manage unexplained fertility problems**, both stimulated and unstimulated intra-uterine insemination is 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.

4.6 **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.

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

4.8 **Tubal and uterine surgery, Tubal microsurgery, and laparoscopic tubal surgery**
For women with mild tubal disease, tubal surgery may be more effective than no treatment. In centres where appropriate expertise is available it may be considered as a treatment option.

Tubal catheterisation or cannulation
For women with proximal tubal obstruction, selective salpingography plus tubal catheterisation, or hysteroscopic tubal cannulation, may be treatment options because these treatments improve the chance of pregnancy.

Surgery for hydro salpinges before in vitro fertilisation treatment
Women with hydro salpinges should be offered salpingectomy, preferably by laparoscopy, before IVF treatment because this improves the chance of a live birth.

Uterine surgery
Women with amenorrhoea who are found to have intrauterine adhesions, should be offered hysteroscopic adhesiolysis because this is likely to restore menstruation and improve the chance of pregnancy.

4.9 **Assisted conception services include IUI, ovulation induction medication and donor insemination**. To access assisted conception services following investigation and assessment, couples must also be assessed against the following criteria:

An assessment of a prospective birth parent's 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:

- Anti-Müllerian hormone [AMH], **or**
- Timed follicle-stimulating hormone [FSH] and Oestrogen

The prospective birth parent must have:

- An AMH of greater than or equal to 5.4 pmol / l **or**
- A FSH level less than or equal to 15iu/l
- The male partner must have normal sperm function (except for ICSI and donor sperm)
- 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.

F5 In-Vitro Fertilisation or Intracytoplasmic Sperm Injection

5.1 **The recognised indications for treatment by intracytoplasmic sperm injection include**:

- Severe deficits in semen quality
- Obstructive azoospermia
- Non-obstructive azoospermia

5.2 **One full treatment cycle of IVF or ICSI (with oocyte donation for females with premature ovarian failure POF** i.e., raised FSH and amenorrhoea for at least 12 months in a female under 40 years of age

and/or surgical sperm recovery SSR if required) may be offered to couples where other assisted conception techniques have failed.

5.3 **The following criteria must also be satisfied at the time of treatment:**

- The prospective birth parent serum FSH must be less than or equal to 15 iu / l at the time of treatment or an AMH of greater than or equal to 5.4 pmol/l
- 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.

F6 Surgical Sperm Recovery or Electro-ejaculation

6.1 **Surgical sperm recovery** is commissioned by NHS England Reference: NHS England: 16040/P
https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2013/05/16040_FINAL.pdf

F7 Posthumous Assisted Reproduction

7.1 **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.

7.2 **NHS Somerset ICB does not fund fertility treatments associated with posthumous assisted reproduction**

F8 Sperm Washing

8.1 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.

8.2 Patients can be seen, assessed, and treated by local fertility services.

8.3 **NHS Somerset ICB will approve funding for sperm washing with one full cycle of fertility treatment in conjunction with this policy where:**

- The couple qualify for fertility treatment under this policy **and**
- The prospective father is HIV positive

8.4 **Prospective birth parents who are HIV positive** should be advised that there is a risk of between 5 and 40% of birth parent 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

F9 Pre-Implantation Genetic Diagnosis

Commissioned by NHS England

9.1 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.

9.2 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.

9.3 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.
Website search | HFEA

9.4 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 G Surrogacy Arrangements and Treatments

In line with the principles of this policy and taking into account that surrogacy is specifically excluded from NICE guidelines; NHS Somerset ICB aims to support patients with a realistic clinical opportunity to conceive (with assistance) and carry a child to birth. The ICB does not therefore support surrogacy arrangements and treatments and will not:

- Be involved in the recruitment of surrogate birth parents
- Fund any element of treatment that directly relate to surrogacy arrangements
- Fund any payments to the surrogate birth parent (legal costs, expenses etc.)
- Fund maternity care arrangements

NHS Somerset ICB commissions maternity services to provide support, guidance and care to women during and after pregnancy and these services are available to surrogates

Section H NHS (Charges to Overseas Visitors) Regulations 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. www.legislation.gov.uk/uksi/2017/756

Section I EVIDENCE BASED INTERVENTIONS APPLICATION PROCESS

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

2 Completion of a **Generic EBI Application Form** by a patient's GP or Consultant is required

3 Applications cannot be considered from patients personally

4 Only electronically completed EBI applications will be accepted to the EBI Service

5 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 EBI Panel. This will reassure the Panel that the patient has a reasonable expectation of the outcome of the application and its context

6 EBI applications are reviewed and considered against clinical exceptionality

For further information on 'clinical exceptionality' please refer to the NHS Somerset ICB website and input into the 'Search this website' box clinical exceptionality.

Social, Emotional and Environmental factors *i.e., income, housing, environmental pollution, access to services, family, friends, ethnicity, life experiences etc.* CANNOT be considered with an application

7 Where appropriate photographic supporting evidence can be forwarded with the application form

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

Section J ACCESS TO POLICY

1 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

2 **Or write to us**: NHS Somerset ICB, Freepost RRKL-XKSC-ACSG, Yeovil, Somerset, BA22 8HR or **Email** us: somicb.pals@nhs.net

Section K References

The following sources have been considered when drafting this policy:

1 NICE – CG156 2013
https://www.nice.org.uk/guidance/cg156

2 HFEA – Guidance and Protocols including PGD
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Appendix 1 - Version Control		
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)
5	February 2020	Final Version following approval of the CCPF/CEC. To include rebranding from IFR to EBI/ amendments to section F2 FERTILITY Preservation Prior to oncology and other medical treatments/ Section D 6 Donor sperm is not funded
6	March 2020	Amendment numbering in contents/F6 removal of spinal cord wording
6a	March 2020	Section D point 6 amended to read ‘Funding is approved for donor sperm where patients meet the specific criterion that reflects their current status in the relevant sections of this policy. Somerset CCG will not fund the purchase of donor sperm for surrogacy.
6b	May 2022	Amendment to wording for couples unable to conceive and commissioned IUI’s for same sex couples complies with our duties as defined in the Equality Act 2010 and furthermore, supports the requirement for us to pay due regard to the Public Sector Equality Duty 2011 (PSED). Section E 2/4, F1 2.6/7

7	July 2022	Clear pathway for same sex couples with IUI. Amendment from SCCG to NHS Somerset ICB. New PALS email address. Subsequent amendment SCCG to NHS Somerset ICB in section D13
7a	March 2023	Wording change section I6