

Cryopreservation for Infertility Associated with Medical Treatment or Surgery

August 2018

This policy applies to patients for whom the following Clinical Commissioning Groups are responsible:

- NHS South Worcestershire Clinical Commissioning Group (CCG)
- NHS Redditch & Bromsgrove Clinical Commissioning Group (CCG)
- NHS Wyre Forest Clinical Commissioning Group (CCG)

Collectively referred to as the Worcestershire CCGs

COMMISSIONING SUMMARY

NHS Redditch & Bromsgrove Clinical Commissioning Group, NHS South Worcestershire Clinical Commissioning Group and NHS Wyre Forest Clinical Commissioning Group (also termed “the Commissioner” in this document) funds the provision of cryopreservation for patients meeting the defined eligibility criteria within this policy and who are embarking on an NHS pathway of care involving either medical or surgical treatment that has the potential to render the patient infertile:

- Gamete cryopreservation is available to all eligible individuals.
- Embryo cryopreservation is available to affected women where both they and their partner have no living children.
- Cryopreserved material will be stored for up to 10 years in the first instance.
- Service providers supporting eligible patients are required to complete a “Request for Renewal of NHS Funded Gamete Storage” when their existing period of consent ends, in accordance with the policy.
- Patients who wish to use their cryopreserved material are referred to the “Tertiary Treatment for Assisted Conception Services” Policy

Detailed information regarding eligibility criteria for access to cryopreservation and cryostorage is provided within the main body of this document.

Do you need this document in other languages or formats (i.e. large print)? Please contact the Communications Team on 01905 681956

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Lead Executive/Director:	Ms Christina R Emerson – PMO Specialist Adviser
Name of originator/author:	Mrs Helen Bryant – Senior Contracts Manager Mrs Fiona Bates – Medicines Commissioning and Public Health Liaison
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Circulated to the following individuals/groups for comments:

Name	Date
Clinical Commissioning Policy Collaborative, which includes: GPs, Commissioners, Medicines Commissioning, Public Health, Patient and Public Representatives	December 2014 January 2015 October 2015 May 2018

Version Control:

Version No	Type of Change	Date	Description of change
1.1	Minor	07/03/16	Inclusion of a statement in the original document missed due to administrative error
1.2	Minor	03/01/18	Updated to reflect the changes made to the local Worcestershire Policy: Tertiary Treatment for Assisted Conception policy in July 2017
1.3	Minor	04/06/18	Inclusion of reference to British Fertility Society (BFS) Guidance and NHSE consultation regarding Gender Identity Services. Extension of eligibility criteria to include BFS recommendations Clarification of scope in relation to cryopreservation and use of cryopreserved material. Updated values for Ovarian Reserve Testing in accordance with NICE recommended limits Clarification of rationale associated with storage renewals for women up to the age of 40

Table of Contents

1.	Definitions	4
2.	Scope of policy	5
3.	Background.....	6
4.	Relevant National Guidance and Facts	7
5.	Patient Eligibility.....	10
6.	Pathway of Care	11
7.	Co-Payment and Retrospective Funding.....	14
8.	Supporting Documents	15
9.	Equality Impact Assessment.....	16
10.	Request for Renewal of NHS Funded Gamete Storage	20

1. Definitions

- 1.1 **Cryopreservation** - Cryopreservation is a process where cells, whole tissues, or any other substances susceptible to damage caused by chemical reactivity or time are preserved by cooling to sub-zero temperatures. At low enough temperatures, any enzymatic or chemical activity which might cause damage to the material in question is effectively stopped. Cryopreservation methods seek to reach low temperatures without causing additional damage caused by the formation of ice during freezing.
- 1.2 **Gametes**- A gamete is the male or female reproductive cell that contains half the genetic material of the organism. Human gametes are egg cells and sperm.
- 1.3 **Oocytes**- An oocyte, is a female gametocyte or germ cell involved in reproduction. In other words, it is an immature ovum, or egg cell. An oocyte is produced in the ovary during female gametogenesis. The female germ cells produce a primordial germ cell (PGC), which then undergoes mitosis, forming oogonia. During oogenesis, the oogonia become primary oocytes.
- 1.4 **Embryo**- An embryo is a multicellular diploid eukaryote in its earliest stage of development, from the time of fertilisation until birth, hatching, or germination. In humans, it is called an embryo until about eight weeks after fertilisation (i.e. ten weeks after the last menstrual period or LMP in most cases), from which point it is then called a foetus.
- 1.5 **Infertility**- According to the World Health Organization (WHO), infertility can be described as the inability to become pregnant, maintain a pregnancy, or carry a pregnancy to live birth.
- 1.6 **Iatrogenic** - Iatrogenesis or iatrogenic effect, a term with Greek origins meaning "brought forth by the healer", is any consequence of medical treatment or advice to a patient. Some iatrogenic effects are clearly defined and easily recognised, such as a complication following a surgical procedure.
- 1.7 **Exceptional clinical circumstances** are clinical circumstances pertaining to a particular patient, which can properly be described as exceptional when compared to the clinical circumstances of other patients with the same clinical condition and at the same stage of development of that condition (ie. similar patients). A patient with **exceptional clinical circumstances** will have clinical features or characteristics which differentiate that patient from other patients in that cohort and result in that patient being likely to obtain significantly greater clinical benefit (than those other patients) from the intervention for which funding is sought.
- 1.8 A **Similar Patient** is a patient who is likely to be in the same or similar clinical circumstances as the requesting patient and who could reasonably be expected to benefit from the requested treatment to the same or a similar degree. The existence of more than one similar patient indicates that a decision regarding the commissioning of a service development or commissioning policy is required of the Commissioner.
- 1.9 An **individual funding request (IFR)** is a request received from a provider or a patient with explicit support from a clinician, which seeks exceptional funding for a single identified patient for a specific treatment.
- 1.10 An **in-year service development** is any aspect of healthcare, other than one which is the subject of a successful individual funding request, which the Commissioner agrees to fund outside of the annual commissioning round. Such unplanned investment decisions should only be made in exceptional circumstances because, unless they can be funded through disinvestment, they will have to be funded as a result of either delaying or aborting other planned developments.

2. Scope of policy

- 2.1 This policy is part of a suite of locally endorsed commissioning policies. Copies of these commissioning policies are available on the following website address: <http://www.redditchandbromsgroveccg.nhs.uk/about-us/strategies-policies-and-procedures/commissioning-ifr/>
- 2.2 This policy applies to all patients for whom the Worcestershire CCGs have responsibility including:
- People provided with primary medical services by GP practices which are members of any one of the CCGs and
 - People usually resident in any of the areas covered by the CCG's and not provided with primary medical services by any CCG.
- 2.3 The policy applies to patients embarking on an NHS pathway of care involving either medical or surgical treatment that has the potential to render the patient infertile; this is described as iatrogenic infertility.
- 2.4 Cryopreservation is not available for any other patient group, for example, patients embarking on a private pathway of care likely to cause infertility, patients with congenital infertility or patients wishing to delay conception.
- 2.5 This policy only covers eligible patients for cryopreservation and any subsequent cryostorage; patients will need to meet the eligibility criteria within the Worcestershire Policy: Tertiary Treatment for Assisted Conception Services for subsequent use of cryopreserved material (see section 4.1)
- 2.6 For patients who do not fall within the eligibility criteria set out in the policy but where there is demonstrable evidence that the patient has clinically exceptional circumstances, an Individual Funding Request may be considered. The referring clinician should consult the Commissioner's "Operational Policy for Individual Funding Requests" document for further guidance on this process.
- For the meaning of the term "exceptional clinical circumstances", please refer to the Definitions section of this document.
- 2.6 Commissioner responsibility for services and treatments associated with Gender Reassignment may be subject to change following NHS England consultation. CCG commissioning arrangements will reflect these changes at the time of publication; this may mean that aspects of this commissioning policy are no longer valid.

3. Background

- 3.1. The NHS Constitution, which details the principles and values that guide the NHS, has been applied in the agreement of this policy.
- 3.2. NHS Redditch & Bromsgrove Clinical Commissioning Group, NHS South Worcestershire Clinical Commissioning Group and NHS Wyre Forest Clinical Commissioning Group consider all lives of all patients whom they serve to be of equal value and, in making decisions about funding treatment for patients, will seek not to discriminate on the grounds of sex, age, sexual orientation, ethnicity, educational level, employment, marital status, religion or disability except where a difference in the treatment options made available to patients is directly related a particular patient's clinical condition or is related to the anticipated benefits to be derived from a proposed form of treatment.
- 3.3. Cryopreservation was originally included within the Worcestershire Policy: Tertiary Treatment for Assisted Conception but was removed from that policy when it was updated in July 2014 following publication of the updated NICE Clinical Guideline 156 in February 2013.
- 3.4. Iatrogenic infertility is typically caused by cancer treatments such as radiation, chemotherapy, or surgical removal of reproductive organs. Less frequently, fertility is compromised by treatments for autoimmune disorders such as systemic lupus erythematosus, rheumatoid arthritis or Crohn's disease, when high dose chemotherapeutic agents are used. Infertility may also be caused by medical and surgical treatments for gender dysphoria.
 - 3.4.1 Approximately 3% of all tumours are diagnosed in patients younger than 40 years: the most common types of cancer in young women are breast carcinoma, tumours of the thyroid, melanoma, carcinoma of the cervix and carcinoma of the colon-rectum. Concerning breast cancer incidence, approximately 6% of women with breast carcinoma are diagnosed before the age of 40; recent data has shown that the incidence of breast cancer diagnosed in young women is increasing.
 - 3.4.2 Roughly 15% of cases of newly diagnosed cancer in men are in those younger than 55 years of age, and about one quarter of them are younger than age 20. Over half of cancer patients desire future fertility, including over three quarters of those without children at the time of their cancer diagnosis. Less than a quarter of cancer patients are reported to bank sperm prior to treatment.
 - 3.4.3 Information from Charing Cross Hospital specialist gender identity clinic suggests low uptake of cryopreservation in patients wishing to change their gender: 0.007% for female gamete cryopreservation and 2.5% for sperm cryopreservation.
- 3.5. The preservation of fertility involves freezing of eggs, embryos or semen. There are two available methods 1) slow freezing and 2) vitrification. In males semen can be produced and stored without surgical or pharmacological intervention if there is no underlying obstruction. Females need to undergo pharmacological and surgical intervention to produce the eggs and/or embryos before they are stored.
- 3.6. All patients about to embark on a treatment within an NHS pathway of care that might cause infertility should be offered an opportunity to discuss their circumstances with a fertility specialist regardless of potential eligibility for cryopreservation.

4. Relevant National Guidance and Facts

4.1. NICE Guidance CG 156 (February 2013): Fertility: Assessment and treatment for people with fertility problems

Pathway to cryopreservation:

The impact of the medical or surgical NHS treatment pathway on future fertility should be discussed between the person diagnosed with the condition and their relevant medical and/or surgical team(s).

When deciding whether to offer fertility preservation to individuals on these NHS pathways of care, the following factors should be taken into account:

- Diagnosis
- Treatment plan
- Expected outcome of subsequent fertility treatment
- Prognosis of the treatment
- Viability of stored/post-thawed material

NICE advises against using a lower age limit for cryopreservation for fertility preservation in people on an NHS pathway of care likely to result in infertility.

Patients diagnosed with conditions for which NHS treatment carries a significant probability of infertility should be informed that the eligibility criteria used in conventional infertility treatment do not apply in the case of fertility cryopreservation provided by the NHS. However, those criteria will apply when it comes to using stored material for assisted conception in an NHS setting.

Cryopreservation and Storage:

NICE Clinical Guideline 156 advises the following in relation to cryopreserving sperm, embryos or oocytes.

- Use freezing in liquid nitrogen vapour as the preferred cryopreservation technique for sperm.
- In cryopreservation of oocytes and embryos, use vitrification instead of controlled-rate freezing if the necessary equipment and expertise is available.
- Store cryopreserved material for an initial period of 10 years.
- Offer continued storage beyond 10 years to those who remain at risk of significant infertility.

4.2. Human Fertilisation and Embryology Authority (HFEA) Code of Practice

The HFEA is the UK's independent regulator overseeing use of gametes and embryos in fertility treatment. Its Code of Practice set out both mandatory requirements and recommended guidance (incorporating an interpretation of mandatory guidance) for organisations involved in this area of health care.

The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009 provide a mechanism for successive 10-year extensions of storage, up to a maximum of 55 years. Old 1991 regulations allowed a statutory storage period of 10 years for a gamete and 5 years for an embryo, with periods reviewable up until the patients 55th birthday. The 2009 update removed the association with the age of the gamete provider and allowed for equal storage periods for gametes and embryos.

4.3. Royal College of Physicians, Royal College of Radiologists and Royal College of Obstetricians and Gynaecologists (2007) – Joint Guidance “The effects of cancer treatment on reproductive functions”

This guidance makes recommendations specifically around cancer diagnosis and treatment of induced infertility. It recommends the use of cryopreservation of material prior to commencing a treatment pathway that could potentially make a patient infertile. It was published in 2007 just before the legislation changed as regards to storage, therefore the guidance on storage up to the 55th birthday of the gamete provider is superseded by the legislation detailed above. They recommend:

At diagnosis, the impact of the cancer and its treatment on future fertility should be discussed between the person diagnosed with cancer and their cancer team.

When deciding to offer fertility preservation to people diagnosed with cancer, the following factors should be taken into account:

- Diagnosis
- Treatment plan
- Expected outcome of subsequent fertility treatment
- Prognosis of the cancer treatment
- Viability of stored/post-thawed material.

These recommendations have been reflected in the recent NICE Clinical Guideline (CG156)

4.4. NHS England

4.4.1 Fertility Policy for Armed forces

NHS England commissions the whole pathway for assisted conception for members of the armed forces, including commissioning of cryopreservation for those that require this. The NHS England policy is commensurate with both NICE Guideline CG156 and also the Royal Colleges joint recommendations detailed in 4.3 above.

4.4.2 Gender Identity Dysphoria

NHS England commissions the gender identity dysphoria pathway. Cryopreservation is advised in the service specification of NHS England to be the responsibility of the patient's CCG and is not commissioned by NHS England.

4.4.3 In 2017, NHS England undertook a consultation exercise on how Gender Identity Clinics will deliver specialised outpatient services and how surgical units will deliver surgical interventions. A draft update to the Gender Identity Services Commissioning Policy is also apparent but has not been finalised. The latter incorporates eligibility criteria for cryopreservation, which suggests that this may revert to NHSE commissioning responsibility.

4.5. British Fertility Society Policy and Practice Guideline: Fertility preservation for medical reasons in girls and women. January 2018.

This document provides a series of recommendations based on the available evidence including:

- Pregnancy outcome in cancer survivors
- The risk of loss of fertility
- Cryopreservation of embryos and oocytes, specifically that:
 - i. women in reproductive age range should be offered fertility preservation if:
 - There is material risk of infertility as a result of the intended treatment
 - The treatment for the disease has curative intent or there is a good prospect of long term survival
 - The woman is fit for ovarian stimulation and oocyte collection
 - The time required for ovarian stimulation and oocyte collection does not jeopardise prognosis.

ii. embryo and oocyte cryopreservation are established and successful techniques

- Controlled ovarian stimulation regimens
- Duration of storage, which refers to HFEA statutory consent periods of 10 years (and up to 55 years), providing the patient remains infertile at each 10 year extension period.
- Pregnancy and outcome using cryopreserved embryos and oocytes
- Ovarian tissue cryopreservation and in vitro maturation are described as “not established” and “experimental respectively, with recommendations only for use in specialist centres.
- Ovarian suppression
- Fertility preservation in special conditions including premature ovarian insufficiency, benign conditions treated with chemotherapy, pelvic surgery and individuals transitioning from female to male gender.

5. Patient Eligibility

All of the following criteria apply to individuals seeking to access cryopreservation within the scope of this policy:

5.1 Clinical Circumstances

- There is material risk of infertility as a result of the intended treatment
- The treatment for the disease has curative intent or there is a good prospect of long term survival
- The woman is fit for ovarian stimulation and oocyte collection
- The time required for ovarian stimulation and oocyte collection does not jeopardise prognosis.

5.2 Age

Cryopreservation will be available for:

- Women of reproductive age (including adolescent girls) up to and including the age of 39.
- Men and adolescent boys.

Rationale:

The decline in normal fertility with age increases markedly from the late 30s and infertility treatment is much less successful in women at this age. This is particularly evident for women aged 40 and above, where the balance of cost-effectiveness becomes uncertain.

5.3 Living children

Cryopreservation will only be available if the patient does not have any living children (regardless of age at the time of presentation) from either the current or a previous relationship. This includes a child adopted by the patient, but excludes fostered children.

Where the patient's partner has living children, the patient will only be offered cryopreservation of their own gametes.

Rationale:

Local resources are limited and therefore priority is given to individuals with no children.

5.4 Previous assisted conception

Where any previous attempts at assisted conception (IVF/ICSI) have been undertaken, regardless of whether the treatment was funded by the NHS or privately, NHS funded cryopreservation will not be supported.

Rationale:

Local resources are limited and therefore priority is given to individuals with no children.

5.5 Sterilisation

NHS-funded cryopreservation will not be available if the patient has received a sterilisation procedure or has undertaken a reversal of sterilisation procedure.

Rationale:

Resources are limited therefore priority is given to individuals with greatest need. Sterilisation is considered a procedure of permanent intent; patients undergoing sterilisation receive counselling and all the consequences are explained to them at the time.

6. Pathway of Care

Patients eligible under the terms of the policy will follow the following pathway of care:

6.1 Assessment of Suitability for Gamete Preservation

6.1.1 Ovarian Reserve Testing

Ovarian reserve testing will be used to predict the likely ovarian response to stimulation and oocyte production. Women are required to meet 2 or more of these measures to determine clinical appropriateness of treatment; these tests will also determine the required dosing schedule for treatment:

1. Total Antral Follicle Count (AFC) > 4 across both ovaries¹
2. Anti-Müllerian Hormone (AMH) > 5.4pmol/l OR > 0.75 ng/ml¹
3. Follicle-Stimulating Hormone < 9 IU/l¹

Where patients do not meet these criteria, cryopreservation of gametes will not be offered.

6.1.2 Sperm Analysis

Sperm analysis will be undertaken to determine the quality, viability and potential success of the gametes.

6.2 Gamete Retrieval

Retrieval of either semen or oocytes, with or without embryo production, is available to eligible patients as follows:

6.2.1 Semen

May be directly provided by the patient or retrieved using surgical sperm recovery: men identified with obstructive azoospermia may receive at NHS expense either one needle aspiration or one open testicular biopsy for the purpose of surgical sperm recovery.

6.2.2 Oocyte Production

Women with satisfactory ovarian reserve testing will receive one NHS funded cycle of assisted conception stimulation treatment to produce oocytes for storage.

6.2.3 Embryo Production

Embryo production is available to affected women where both they and their partner are childless ie. Neither the patient nor the partner has any living children (regardless of age at the time of presentation) from either the current or a previous relationship. This includes a child adopted by the patient/couple or a child from a previous relationship, but excludes fostered children.

Where a woman chooses to develop and preserve an embryo, funding will be supported on the NHS using the partner's sperm (with consent).

Rationale:

Embryo cryopreservation is well established and currently has a greater chance of successful outcome.

Sperm cryopreservation is well established and for males there is no necessity for embryo production at this stage.

6.2.3 Ovarian and Testicular Tissue

Retrieval is regarded as experimental and therefore will not be funded by the Worcestershire CCGs.

¹ NICE Clinical Guideline CG156

6.3 Cryopreservation and Storage

6.3.1 Cryopreservation

Cryopreservation of either sperm or oocytes or embryos (if eligible) is available and will be undertaken by providers in accordance with best practice. Cryopreservation of both a gamete and embryos is not available, in accordance with section 6.2 above.

6.3.2 Storage

The period of cryostorage will primarily be governed by consent of the individual(s) to store preserved gametes; where an embryo is involved, both individuals must give concurrent consent for the embryo to remain stored.

- The **initial storage period** funded will be up to 10 years, in accordance with HFEA regulations and guidance and the agreed period of patient consent.
- Requests to re-apply for **further “consented” periods of storage** may be made in the year preceding the expiry of the current consent, up to a maximum period of storage of 25 years regardless of gender.
- Service providers are required to complete a **“Request for Renewal of NHS Funded Gamete Storage”** form (Appendix 1) for individuals wishing to continue NHS funded storage beyond an expiring period of consent; this includes individuals with NHS material cryopreserved prior to the introduction of this policy. Requests will only be considered where consenting individuals, regardless of gender, remain aged below 40 years and demonstrate compliance with all other aspects of the patient eligibility criteria within this policy at the time of renewal.
- Patients who reach the **end of their NHS storage period** but who wish to further extend the period of cryopreservation may make their own private arrangements for ongoing cryostorage.

Rationale:

Local discussions concluded that it was equitable (with the assisted conception policy which applies for use of cryopreserved material) to allow renewals for storage of cryopreserved material up to a patient's 40th birthday. The maximum storage period of 25 years allows for the majority of adolescents presenting at circa 15 years of age to use their cryopreserved material before they reach the age of 40.

6.3.3 Patients Moving Area

6.3.3.1 Patients moving into Worcestershire

Where patients moving into Worcestershire have had material previously cryopreserved whilst living in another CCG area, Worcestershire CCGs will apply the policy of the original decision maker in terms of ongoing storage. This would be the same as any other treatment commenced whilst resident in another area. Once the original policy agreement has elapsed (or is about to), then an application for continuing storage in accordance with the local policy would need to be made; at this time the applicant needs to demonstrate compliance with the local policy for further storage to be supported.

6.3.3.2 Patients moving out of Worcestershire

When a patient is de-registered from a GP practice in Worcestershire and no longer resides in the area, Worcestershire CCGs are no longer responsible for ongoing funding of storage. This is a transfer of

care to the new CCG responsible based on the registered GP/residence of the patient (see section 2.2). The new CCG will need to honour and apply Worcestershire's original policy until it expires ie. the end of the currently agreed period of storage. After this time the new CCG policy will apply.

6.3.4 Using Cryopreserved Material

Patients wishing to use cryopreserved material are referred to the NHS Worcestershire Commissioning Policy: Tertiary Treatment for Assisted Conception Services published at that time.

***Note:** In accordance with the scope of this policy, women who meet the criteria for cryopreservation are not necessarily eligible for subsequent use of cryopreserved material on the NHS. Cryopreservation and assisted conception are two discreet episodes of care that might be undertaken years apart and it is necessary to meet the relevant eligibility criteria, in accordance with Worcestershire clinical commissioning policy, at each stage that treatment is being considered.*

6.4 Prescribing within Treatment Pathway

For patients who meet the clinical criteria for NHS funded treatment to assist with gamete retrieval for the purpose of cryopreservation, the prescribing of any drugs to assist with gamete production should be undertaken by the Provider to which the patient was referred. These drugs include, but are not limited to: gonadotrophin drugs for men with hypo-gonadotrophic hypogonadism and anti-oestrogens, gonadotrophins and gonadotrophin-releasing hormone analogues in women. Under no circumstances should the patient's General Practitioner be approached to prescribe these drugs as they are part of the treatment pathway provided by the Service Provider.

All drugs should be provided in accordance with the recommendations of NICE CG156.

The Commissioner does not support the NHS funding of any drugs to assist in conception outside of an agreed NHS treatment pathway.

7. Co-Payment and Retrospective Funding

- 7.1 The Commissioner has adopted the NHS England Commissioning Policy “Defining the boundaries between NHS and private care”, which provides further clarification on the Commissioner’s position on co-payment and retrospective funding. This, along with all other commissioning policies, is available at the following internet address:
<http://www.worcestershire.nhs.uk/policies-and-procedures/commissioningindividual-funding-requests-ifr/>
- 7.2 Co-payment is seldom permitted in the NHS, other than where, pursuant to Regulations made under the National Health Service Act 2006, specified patients are required to make a specified contribution e.g. prescriptions.

	<p>NOTE: A patient or couple who has chosen to pay privately for an element of their care, such as a diagnostic test (or insemination to prove fertility problems) is entitled to access other elements of care as NHS commissioned treatment, provided that the patient or couple meet the clinical eligibility criteria identified to receive NHS funded treatment. However, at the point that the patient or couple seeks to transfer back to NHS care:</p> <ul style="list-style-type: none"> • the commissioner is at liberty to request that the patient/couple be reassessed by an NHS clinician (or to have an NHS clinician review the clinical notes pertinent to the treatment pathway) • the patient/couple will not be given any preferential treatment by virtue of having accessed part of their care privately; AND • the patient/couple will be subject to standard NHS waiting times
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- 7.3 The Commissioner will not make any contribution to the privately funded care to cover the cost of treatment that the patient could have accessed via the NHS.

8. Supporting Documents

American College of Obstetrics and Gynaecology committee opinion oocyte cryopreservation. January 2014. Accessed on 01/12/2014 at <http://www.acog.org/-/media/Committee-Opinions/Committee-on-Gynecologic-Practice/co584.pdf?dmc=1&ts=20141201T0601527936>

British Fertility Society Policy and Practice Guideline: Fertility preservation for medical reasons in girls and women. January 2018.

Cancer Research UK Cancer Incidence Statistics. Accessed on 01/12/2014 at <http://www.cancerresearchuk.org/cancer-info/cancerstats/incidence/uk-cancer-incidence-statistics>

Human Fertilisation and Embryology Act 1990
<http://www.legislation.gov.uk/ukpga/1990/37/contents>

Human Fertilisation and Embryology Act 2008
http://www.legislation.gov.uk/ukpga/2008/22/pdfs/ukpga_20080022_en.pdf

NHS England Interim Gender Dysphoria protocol and service specification
Accessed on 01/12/2014 at <http://www.england.nhs.uk/wp-content/uploads/2013/10/int-gend-proto.pdf>

NHS England policy for armed forces personnel Accessed on 01/12/2014 at <http://www.england.nhs.uk/wp-content/uploads/2013/11/N-SC037.pdf>

NHS England 2013/14 NHS standard contract for reconstructive surgery service for adolescents with congenital malformation of the female genital tract. Accessed on 01/12/2014 at <http://www.england.nhs.uk/wp-content/uploads/2013/06/e10-recon-surg-adolescents.pdf>

NHS England: Ethical Framework for Priority Setting Resource Allocation

NHS England: Individual Funding Requests

NHS England: Who Pays? Determining responsibility for payments to providers August 2013

NHS Constitution, updated 27th July 2015

NICE Clinical Guideline (CG156) Fertility: Assessment and treatment for people with fertility problems February 2013. Accessed on 01/12/2014 at <https://www.nice.org.uk/guidance/cg156>

NICE Clinical Guideline (CG11) Fertility: assessment and treatment for people with fertility problems February 2004. Accessed on 01/12/2014 at <https://www.nice.org.uk/guidance/cg11>

The effects of cancer treatment on reproductive functions Guidance on management Report of a Working Party Royal College of Physicians, Royal college of Radiologists and Royal College of Obstetricians and Gynaecologists November 2007. Accessed on 01/12/2014 at http://www.rcr.ac.uk/docs/oncology/pdf/Cancer_fertility_effects_Jan08.pdf

Three Worcestershire CCGs Policy on Tertiary treatment for assisted conception services. Accessed on 03/01/2018 at <http://www.redditchandbromsgroveccg.nhs.uk/about-us/strategies-policies-and-procedures/commissioning-ifr/?assetdet1029359=39306>

Worcestershire CCGs: Operational Policy for Individual Funding Requests

Worcestershire CCGs: Prioritisation Framework for the Commissioning of Healthcare Services

Worcestershire CCGs: Operational Policy for Individual Funding Requests

Worcestershire CCGs: Prioritisation Framework for the Commissioning of Healthcare Services

9. Equality Impact Assessment

Organisation

Department Name of lead person

Piece of work being assessed

Aims of this piece of work

Date of EIA Other partners/stakeholders involved

Who will be affected by this piece of work?

Single Equality Scheme Strand	Baseline data and research on the population that this piece of work will affect. What is available? Eg population data, service user data. What does it show? Are there any gaps? Use both quantitative data and qualitative data where possible. Include consultation with service users wherever possible	Is there likely to be a differential impact? Yes, no, unknown
Gender	<p>Transgender patients who are on an NHS pathway of care for gender dysphoria are at risk of being made infertile even though they are choosing to have surgery or hormonal treatment and are given a significant amount of counselling on the implication that this has generally and more specifically on their fertility before they undergo treatment it could be argued as their choice.</p> <p>Female patients have to undergo more invasive treatments to produce an egg or an embryo. Particularly in patients who are unwell, the clinical time allowed before commencing treatment for cancer means that due to clinical reasons they may only have one viable chance at having a stimulated cycle to produce the eggs. Males on the other hand could potentially have a number of chances to produce viable gametes that could then be frozen. This is a clinical issue but this is addressed in the policy that men who require surgical sperm retrieval are also offered one attempt at that if required</p> <p>The issue was raised that those patients who require cryopreservation and are currently with a partner who has children and the issue of whether they should be excluded from accessing cryopreservation due to current living children.</p> <p>There are almost twice as many cancer cases in women aged 25-49 (an average of 21,747 cases per year in the UK between 2009 and 2011) compared with men of the same age (11,090).</p> <p>Males and females who have chosen to be sterilised are not eligible within the existing policy; the decision to undertake sterilisation should not be made lightly and full counselling is provided to the patient/couple with awareness that the decision is a permanent one.</p>	<p>Yes</p> <p>Yes</p> <p>No</p> <p>No- the patient has chosen this course of action</p>

Race	As ethnicity has not been systematically recorded by cancer registries in the UK there are no reliable data on patterns of cancer incidence, mortality and survival specific to Black and Minority Ethnic (BME) communities living in the UK. However there is growing evidence, often from smaller scale studies, that BME communities may experience differing rates of some cancers. <ul style="list-style-type: none"> • Breast cancer in South Asian women appears to be lower than the rate found in the general population • Prostate cancer among Black Caribbean and African men appears to be higher • Mouth cancer among South Asians appears to be higher. 	No
Disability	No evidence of a link between disability and cryopreservation. Some injuries associated for example with spinal cord damage may cause infertility issues, any issues arising from this would be addressed through the assisted conception policy, cryopreservation would not be necessary.	No
Religion/ belief	No evidence of a link between religion and cryopreservation.	No
Sexual orientation	It is estimated that a higher percentage of gay and lesbian teenagers and adults are smokers compared to the general population and that among the latter a high proportion are heavy smokers. Current estimates put smoking rates at between 41 and 25 per cent among lesbians and gay men. This could mean that they are more at risk of cancer and may potentially require cryopreservation as a result of the clinical treatment for this. There is no reliable evidence to support greater incidences of cancer in gay and lesbian populations. The ability to cryopreserve oocytes and sperm as an alternative to embryos means that lesbian and gay people are not disadvantaged from the absence of the alternative sex partner at the time when cryopreservation is necessary.	No - This policy benefits single people by offering oocyte and sperm cryopreservation.
Age	Cancer is relatively rare in teenagers and young adults, accounting for less than one per cent of all new cancer cases (UK, 2009-2011). Adults aged 25-49 contribute around a tenth (10%) of all new cancer cases (UK, 2009-2011). These include brain, Central Nervous System (CNS) intracranial tumours and testicular cancers in males and thyroid, cervix, bowel and ovary, malignant melanoma and cervical cancer being the most common cancers in young women. The vast majority of breast cancers diagnosed in young women will be once they have caused symptoms, since most women aged 25-49 are too young for routine breast screening.	Yes
Social deprivation	Survival rates for most types of cancer have risen steadily since the 1970s. However, because rates have increased faster among more affluent groups the survival gap between the least and most deprived patients has increased. The relationship between deprivation and cancer is complex and multifaceted. Certain types of cancer – such as lung, mouth and oesophagus which are more likely in an older age – are more likely to be diagnosed in the most deprived groups. For other types of cancer – such as breast and prostate – death rates are higher among the most deprived despite the fact that incidence rates are lower. Much of these inequalities relate to higher smoking prevalence among the most deprived populations which leads to a greater incidence of smoking related diseases including cancer. Jarvis and Wardle estimate that smoking accounts for over half of the difference in the risk of dying early between socioeconomic groups.	Yes, socially deprived patients may be less likely to access cryopreservation due to later presentation of disease.
Carers	There is no evidence that being a carer has an impact on cryopreservation.	No
Human rights	Will this piece of work affect anyone's human rights?	No – enhances the right to family life

Action Plan

Strand	Issue	Action required	How will you measure the outcome/impact	Timescale	Lead
Gender	Gender Dysphoria is a diagnosed medical condition and it is through the diagnosed treatment that they undergo that they risk loss of fertility. National guidance is being developed around being equitable to transgender patients in these circumstances and there is a current Clinical Reference Group (CRG) in recognition that patients around the country get access to differing levels of cryopreservation of gametes, with many CCGs calling it "social freezing". Discussions with Gender Identity Clinic expert Dr James Barrett and discussions of an advisory sub group of public health and CCG concluded that it would be inequitable not to let patients undergoing hormonal or surgical treatment for gender dysphoria access a cryopreservation policy.	The definition of the population will therefore not exclude patients on a NHS gender dysphoria pathway.	Monitor local prevalence data on gender dysphoria and complete audits on access to cryopreservation.		
Patients about to proceed on to NHS pathways of care that have potential to have a detrimental effect on fertility who do not have living children but their current partners do	It was felt and debated by both the clinical and commissioning groups that the decision could not be made on a partner basis it should only be made on the basis of the person requiring the cryopreservation due to their treatment pathway. The policy has made this clear that embryos will only be created and preserved in cases where the woman and her partner have no living children. This is due to evidence of the increased likelihood of success with an embryo. Males on treatment pathways who have no living children will have sperm preserved and females with no living children will have oocytes preserved.	The policy has made this clear that embryos will only be created and preserved in cases where the woman and her partner have no living children. This is due to evidence of the increased likelihood of success with an embryo. Males on treatment pathways who have no personal living children will have sperm preserved and females with no living children will have oocytes preserved.			
Race Patients likely to present at an advanced stage of	In some instances it also appears to be the case that specific cancers affect BME communities at different ages. It has been found that women of African and West Indian descent were being	Public health efforts at targeted screening for different populations at different cancer risks	Monitor local incidences prevalence's and mortality rates from these cancers in BME groups to help		

Strand	Issue	Action required	How will you measure the outcome/impact	Timescale	Lead
cancer	diagnosed with breast cancer on average 21 years earlier than their white counterparts. Further to this, the type of cancer that was being diagnosed within this group was more likely to be an aggressive form of the disease which was unresponsive to newer drug regimens and had poorer outcomes.		identify action plans and targeted campaigns if necessary		
Age	Females are unable have gametes preserved beyond the age of 40 years whereas there is no upper age limit on males	Due to a significant evidence base that fertility declines in females past age 40 cryopreservation is not recommended beyond this age. There is no similar evidence of fertility decline in males and therefore although there is an age inequality there is clinical evidence to support the reason for this.	The policy allows for 10 year periods of gamete storage, renewals of storage will only be considered when the patient remains under the age of 40 and continues to meet the other access criteria for cryopreservation; this is the same for men and women.	Storage audits every 10 years	
Social deprivation	Those people from socially deprived backgrounds are more likely to smoke and also to present late for treatment of a cancer therefore having poorer survival. They are also less likely to be able to access cryopreservation due to later presentation and poorer health at that time.	The evidence above shows that those from harder to reach groups are more likely to have undertaken lifestyle factors which could negatively impact upon cancer rates. Targeted health information and support should be developed that increases knowledge of healthy lifestyles.	Monitor local incidences and prevalence's of cancer related morbidity and mortality in socially deprived groups Targeted national and local campaigns around reducing smoking prevalence in these groups.		

10. Request for Renewal of NHS Funded Gamete Storage

- The **initial gamete storage period** funded is up to 10 years, in accordance with HFEA legislation and guidance and the agreed period of patient consent.
- Requests to re-apply for **further "consented" periods of storage** may be made in the year preceding the expiry of the current consent, up to a maximum period of storage of 25 years.
- Service Providers are required to complete and submit for approval a "Request for Renewal of NHS Funded Gamete Storage" form.
- Renewal requests will only be considered where the consenting individuals remain aged below 40 years and demonstrate compliance with all other aspects of the patient eligibility criteria within the cryopreservation policy at the time of renewal.
- Patients who reach the **end of their NHS storage period** but who wish to further extend the period of cryopreservation may make their own private arrangements for ongoing cryostorage.

	Primary Consent	Secondary Consent (where applicable)
Patient Initials		
NHS Number		
Date of Birth		
Nature of Cryopreserved Material	Oocyte <input type="checkbox"/> Embryo <input type="checkbox"/> Sperm <input type="checkbox"/>	Embryo
Existing Cryostorage Provider	Name: Address:	
Requesting Clinician Details:	Name: Title: Email Contact:	
Commencement of Cryostorage		
Expiry Date of Existing Consent Period		
Living Children from either a current or previous relationship; including adopted children?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/> <input type="checkbox"/>
Total Number of Previous Attempts at Assisted Conception (NHS or private)	1 or more <input type="checkbox"/> None <input type="checkbox"/>	1 or more <input type="checkbox"/> None <input type="checkbox"/>

Completed forms should be sent to: nhsworcs.fundingrequests@nhs.net