Shropshire, Telford and Wrekin
Clinical Commissioning Group

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Policy for the Provision of NHS Funded Gamete Retrieval and Cryopreservation of Gametes and Embryos for the Preservation of Fertility

NHS
Shropshire, Telford and Wrekin
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VERSION CONTROL

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Version 1.1	May 2021	MRJ	Updated to harmonise SCCG and T&WCCG policies and to bring in line with Commissioning Policy for the Management of Fertility Treatment
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Approvals

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NHS
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1. Introduction

This policy lays out the CCG commissioning intentions regarding the retrieval and storage of gametes for patients in certain clinical circumstances as outlined below.

2. Background

Gametes are sex cells. The male gametes are the sperm, and the female gametes are the eggs. Conception (getting pregnant) happens when a man's sperm fertilises a woman's egg, the fertilised egg develops into an embryo, and subsequently implants in the uterus.

In certain circumstances, a man or a woman's fertility may be compromised for a number of reasons, including:

- Certain types of treatment (e.g. cytotoxic therapy) which permanently prevents the individual producing gametes (eggs/sperm)
- Certain types of treatment (e.g. cytotoxic therapy) which cause permanent genetic abnormalities in the eggs/sperm.
- The ovaries or testes may, in certain clinically required circumstances, (e.g. to prevent the spread of disease) need to be surgically removed which results in infertility.
- The patient has premature ovarian failure.
- The patient has testicular failure
- The patient is undergoing gender reassignment

Gamete Retrieval is the extraction of gametes (by surgical or non-surgical methods), which can then be stored for future use.

Cryopreservation is the process of storing biological material at extreme temperatures; most commonly -196 °C/-321 °F in nitrogen (N_2) vapour. At these low temperatures, all biological activity stops

Patients undergoing treatments such as chemotherapy for cancer or radical surgery may be made sterile by such treatments. Where there is a significant likelihood of making a patient permanently infertile as an unwanted side-effect of NHS funded treatment, including gender reassignment, these patients will be eligible, under the CCG commissioned pathway, for gamete retrieval and cryopreservation to preserve fertility, provided they meet the criteria described below. This may be done by storing gametes (eggs or sperm) or embryos prior to treatment. Following the completion of the NHS funded treatment; these gametes or embryos may be used to assist conception. If the patient requires CCG funding for assisted conception, then the patient will be required to meet the current Commissioning Policy for the Management of Fertility Treatment.

Patients may also experience infertility due to chromosomal abnormalities, e.g. Turner's syndrome or through Premature Ovarian Insufficiency. In these cases it may be possible to store some eggs or embryos before the ovaries stop functioning completely.

3. Eligibility Criteria

3.1 The patient must be permanently registered with a Shropshire, Telford & Wrekin CCG GP practice.

AND

3.2 Age Upper age restrictions for both men and women will be in line with those in the Policy for the Management of Fertility Treatment, which is in place at the time of the funding request.

There is no lower age limit applied in this policy, however, all patients including those aged under 16 years must be able to understand the procedure being carried out and considered competent to give informed consent.

AND

3.3 The patient must meet ONE of the following clinical criteria:

3.3 a) The patient must be undergoing or about to undergo NHS funded treatment, which is likely to render the patient permanently infertile e.g. cytotoxic therapy or gender reassignment

OR

3.4 b) The patient is at immediate risk of premature ovarian or testicular failure.

For the purposes of this policy premature ovarian failure is defined as:

- A woman below the age of 35 years

AND

- With an absence of external factors/pathology which have impacted on fertility and who is experiencing a cessation of ovulation and menstruation

AND

- Ovarian failure is confirmed by measurement of ovarian reserve

OR

3.4. c) The patient has a diagnosed chromosomal abnormality which is likely to render the patient permanently infertile e.g. Turner's syndrome which carries a high risk of premature ovarian failure or Klinefelter syndrome, which carries a high risk of testicular failure.

OR

3.4 d) The patient's ovaries/testes are going to be removed as part of NHS funded treatment e.g. to prevent the spread of disease.

AND

3.5 The funding application must be supported by the NHS consultant providing the patient's care.

AND

3.6 The patient has not undergone a previous sterilisation and/or reversal of sterilisation procedure.

Gamete retrieval and cryopreservation will not be funded where the patient has previously undergone elective sterilisation (vasectomy or where fallopian tubes are blocked or sealed to prevent the eggs from becoming fertilised).

3.7 Previous Assisted Conception

Access to NHS funded Cryopreservation will not be affected by previous attempts at assisted conception. However, funding for further assisted conception attempts will be subject to the criteria stated in the currently commissioned Policy and Protocol for the Management of Fertility Treatment at the time of any funding application.

4 Timescales for NHS Funding for Storage of Gametes

Where the eligibility criteria listed in Section 3 are met, NHS funding will be available, as set out below, from the date of the retrieval of the patient's gametes.

The funding parameters set out below in Section 4.1 are ONLY for patients who have been assessed as eligible under the terms of Section 3 above, for the specific storage of eggs, sperm or embryos for the preservation of fertility and NOT as part of fertility treatment. Funding parameters for those patients undergoing fertility treatment are set out in Section 4.2.

4.1 a) The patient will give written consent for an initial storage term of 10 years. If the gametes are to be stored for longer than the initial 10 years for which consent was given, the patient's consent must be reviewed and re-acquired from the patient and the patient must continue to meet the existing legal criteria..

AND

4.1 b) If gamete storage is to be funded under the terms of this policy, the CCG will fund gamete storage for up to 10 years or until the patient reaches the upper age limit within the Commissioning Policy for the Management of Fertility Treatment, in place at the time the gametes are retrieved, whichever arrives sooner.

AND

4.1 c) The patient must have a valid written storage agreement with the provider in place.

AND

4.1 d) If the patient wishes for cryopreservation of his/her gametes to continue beyond the above timescales for CCG funded storage as long as the patient continues to meet the criteria for storage, then the patient will be solely responsible for the annual storage fee. **If the patient adopts a child or achieves a pregnancy leading to a live birth, CCG funding for gamete storage will cease with immediate effect.**

5 Where embryos are already in storage

If the patient has undergone unsuccessful IVF/ICSI treatment and has stored embryos and then experiences a loss of fertility, and meets the eligibility criteria set out in section 3, then the CCG will fund cryopreservation of the embryos with the consent of both partners for 10 years or until the female partner reaches the upper age limit within the CCG Commissioning Policy for the Management of Fertility Treatment, whichever comes sooner.

ALL funding renewals for gamete storage will be considered in line with the ages specified in the CCG Commissioning Policy for the Management of Fertility Treatment in place at the time of application.

Patients may choose to self-fund storage once NHS funding ceases, within the terms of the existing regulations..

6 Exclusions to this Policy

The following are not covered by this policy:

- Retrieval and storage of gametes and embryos in pre-pubertal patients
- Retrieval and storage of gametes and embryos for social reasons
- Storage of donor sperm
- Storage of donor eggs

7 National Guidance

This policy will be operated in accordance with the Human Fertilisation and Embryology Act 2008[2].

Cryopreservation of gametes or embryos must meet the current legislative standards.

The provider of the service must ensure that the patient receives appropriate counselling and provides full consent.

In the case of embryo preservation, both partners must be made aware of the legal position regarding embryos, which have been cryopreserved, should one partner remove consent to their ongoing storage or use.

Patients must also be made aware of the legal issues on the posthumous use of gametes and embryos should they wish a partner to be able to use these, should their NHS treatment not be successful.

The provider of the service should contact patients annually to confirm that they wish to continue storage. The patient will be responsible for ensuring the storage provider has up to date contact details. Failure to provide on-going consent may result in the destruction of stored gametes or embryos.

The provider must ensure that material is only stored where there is valid consent in place and that the patient understands the need for on-going consent.

8 References

1/ Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009.
https://www.legislation.gov.uk/uksi/2009/1582/contents/made

2/ Human Fertilisation and Embryology Act 2008.
https://www.legislation.gov.uk/ukpga/2008/22/contents/enacted

9 Acknowledgements

This policy has been adapted from:

Policy for the Provision of NHS funded Gamete Retrieval and Cryopreservation for the Preservation of Fertility 2018
NHS Birmingham and Solihull Clinical Commissioning Group
NHS Sandwell and West Birmingham Clinical Commissioning Group