

CLINICAL POLICY ADVISORY GROUP (CPAG)

Gamete Storage Policy

Statement

Derby and Derbyshire CCG has agreed that Gamete Storage should be commissioned only when the eligibility criteria listed within the policy are met.

These commissioning intentions will be reviewed periodically. This is to ensure affordability against other services commissioned by the CCG.

1. Background

This policy relates to the preservation of gametes (oocytes and semen) and embryos, in post-pubertal patients, in advance of chemotherapy or radiotherapy treatment for cancer or conditions requiring male urological or female gynaecological surgery that carries a high risk of infertility.

This policy was developed following a review of the NICE Clinical Guideline for Fertility, published in February 2013, NICE Quality Standards for Fertility Problems and takes account of the Equality Act 2010, including age discrimination legislation. The policy includes criteria which are outside of the recommendations laid out within the associated NICE Clinical Guidelines. CCG Governing Bodies considered these recommendations in the context of their budget allocation for assisted reproduction services and the associated opportunity costs.

Adverse effects associated with a number of medical treatments can impact on fertility, either by direct injury or via systemically administered agents. In some cases the individual's fertility will return after the treatment is completed but in other cases fertility never returns, or is severely impaired. Technological advances mean that cryopreservation of semen, oocytes, embryos and ovarian/testicular tissue offers opportunities to preserve fertility prior to the start of treatment.

In line with the recommendation by the NICE Fertility Guideline, access to cryopreservation and storage associated with treatment induced infertility has been considered separately to assisted reproduction services and the general fertility pathway.

Cryopreservation is a technique that freezes an individual's eggs or sperm for use in future fertility treatment. Cryopreservation of sperm is a well-established technique used to maintain an individual's fertility. Cryopreservation of eggs is a newer technology, though has been widely used in relation to cancer treatment for a number of years.

2. Recommendation

Gamete cryopreservation will be commissioned in individuals undergoing medical or surgical treatment who may be at risk of permanent infertility as a result of their treatment. Gamete cryopreservation will not be commissioned for social reasons, or if gametes are being frozen for use by individuals other than the patient receiving treatment.

It should be noted that the policy does not address NHS funding for the future use of frozen gametes. Provision of gamete freezing and storage under the terms of this policy is made without prejudice to the future determination of funding of any subsequent fertility treatment.

The following are outside the scope of this policy:

- Cryopreservation of gametes and embryos in pre-pubertal patients.
- Cryopreservation of gametes and embryos and sperm requested for social reasons.

Criteria for Commissioning

Patients eligible for NHS-funded gamete cryopreservation should be about to commence treatment that is thought to cause permanent infertility as a result of their treatment.

Conditions considered appropriate for gamete cryopreservation are:

- Malignancies requiring chemotherapy
- Malignancies requiring total body irradiation or radiotherapy that may affect an individual's reproductive organs
- Conditions requiring male urological or female gynaecological surgery
- The impact of the treatment on the patient's fertility has been discussed between the patient and the treating clinician.
- The patient is able to make an informed choice and consent to undertake gamete harvesting and cryopreservation.
- The patient is aware that funding for gamete harvesting and cryopreservation of material does not guarantee future funding of assisted conception or fertility treatment.
- The patient has no living children. This includes a child adopted by the patient. Continued storage will not be funded if the patient subsequently adopts a child or achieves a pregnancy leading to a live birth.
- Females of reproductive age up to 42 years old (stimulation treatment to take place prior to individual's 43rd birthday)
- Males of reproductive age up to 55 years old (sperm retrieval to take place prior to individual's 56th birthday)
- Transgender patients receiving treatment for gender dysphoria which may cause permanent infertility (hormone therapy, reconstructive surgery etc.).
- Registered with a GP in Derbyshire
- Individuals who have previously been sterilised will not be eligible for cryopreservation
- Written consent to treatment and gamete storage is required

Women, who are preparing for medical treatment for cancer that is likely to make them infertile, should only be offered oocyte cryopreservation if they meet all of the following criteria:

- They are well enough to undergo ovarian stimulation and egg collection; **and**
- there is sufficient time available to harvest eggs before the start of their cancer treatment

Women who are undergoing gynaecological surgery should only be offered oocyte cryopreservation if, following surgery, pregnancy would still be viable.

Approval of cryopreservation does not guarantee future funding of assisted conception or fertility treatment. Local fertility policies and criteria for eligibility in place in the commissioning area in which the patient is living at the time of application will apply.

Cryopreservation Services Funded

Oocyte, embryo and sperm cryopreservation will be funded for eligible patients. Embryo storage using donor sperm is not routinely commissioned.

Male patients must have a sperm test one year after treatment; this test will be carried out by the fertility unit. If sperm analysis is within the normal range continued storage will not be funded.

Sperm will be stored for an initial period of 5 years, automatic renewal for a further 5 years is authorised providing the patient continues to meet all eligibility criteria.

Oocytes and embryos will be stored for an initial period of 5 years, automatic renewal for a further 5 years or up until the patients 42nd birthday, whichever is soonest, is authorised for patients who continue to meet all other eligibility criteria.

Storage of sperm beyond 10 years is not normally funded.

Patients who have undergone NHS funded cryopreservation but no longer meet eligibility criteria may choose to self-fund continued cryopreservation of stored material.

Exclusion Criteria

Individuals will not be eligible for NHS-funded gamete cryopreservation if:

- Gametes are being frozen for non-medical or non-surgical reasons, for example for social reasons
- their infertility is as a result of a congenital disorder

Future use of frozen gametes will be in line with all relevant policies in place at the time. Cryopreservation of ovarian or testicular tissue is still considered to be an experimental procedure and therefore funding of this is not included under this policy.

3. Appendices

Appendix 1- Consultation

Consultee	Date
CPAG	July 2019
Consultant in Public Health	June 2018-ongoing
East Midlands Affiliated Commissioning Committee	June 2018-ongoing
Clinical and Lay Commissioning Committee	August 2019

Clinical Policies Advisory Group	October 2019
Clinical and Lay Commissioning Committee	November 2019

Appendix 2- Document Update

Document Update	Date Updated
Version 1	July 2016
Version 1.1	July 2019
Version 1.2 – Addition of transgender patients	October 2019