

Gamete harvesting and storage (Cryopreservation) Commissioning Policy

Intervention	Gamete harvesting and storage (Cryopreservation)
For the treatment of:	Harvesting and storage of viable gametes in patients undergoing NHS funded medical treatment(s) that cause infertility
Background	<p>To date, Scarborough and Ryedale and Vale of York CCGs have not had a formal policy on gamete harvesting and preservation for patients undergoing medical treatments that may leave them infertile.</p> <p>Cryopreservation is the process of freezing and storing sperm, oocytes and embryos so that they can potentially be used at a later date, typically in an attempt to conceive a pregnancy. The CCGs have a comprehensive fertility policy available on their website which covers the commissioning of cryopreservation for routine infertility treatment.</p> <p>One circumstance which is not covered by the fertility policy is the provision of cryopreservation for an individual who is expected to undergo NHS funded medical treatment(s) that cause infertility.</p>
Commissioning position	<p>NHS Scarborough & Ryedale and Vale of York CCGs agree to fund the harvesting and subsequent storage (cryopreservation) of viable gametes, for an initial period of 10 years, for patients undergoing NHS funded medical treatment that may leave them infertile.</p> <p>If after the initial 10 year period storage is still required, an IFR application should be made as an exceptional request, provided the patient wishes to keep their sample for potential future use. Each case will be considered on its own merit and in line with the HFEA legislation.</p> <p>Approval for harvesting and cryopreservation does not guarantee future funding of assisted conception or fertility treatment – in this instance the specific CCG policy for assisted conception should be applied.</p> <p>Prior to fertility preservation, the secondary care clinician at the organisation providing the fertility service must confirm:</p> <ul style="list-style-type: none"> • That the planned treatment is likely to affect future fertility (and document this for the commissioners’ audit purposes) • That the impact of the treatment on fertility has been discussed with the patient • That the patient is able to make an informed choice to undertake gamete harvesting and cryopreservation of semen, oocytes or embryos for an initial period of 10 years • That the patient is aware that funding for gamete harvesting and cryopreservation does not guarantee future funding of assisted conception treatment <p>Cryopreservation in males</p> <p>In general, it is recommended that at least two semen samples are collected over a period of one week. The CCGs will commission a maximum of three samples of semen; this is considered sufficient to</p>

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provide future fertility.

Testicular tissue freezing is considered experimental and will not be funded.

Note: testicular sperm retrieval is commissioned by NHS England and not by the CCGs.

Cryopreservation in Females

The CCG will normally fund one cycle of egg retrieval, with or without fertilisation. If fewer than 10 eggs are retrieved following this first cycle of egg retrieval, then one further cycle can be offered.

Ovarian tissue storage is considered experimental and will not be funded.

Age

There are no specific age limits to this policy for males or females. The decision to attempt to preserve fertility is a clinical decision.

Previous sterilisation

Gamete retrieval and cryopreservation will not be funded where the patient has previously been sterilised.

NHS Funded Assisted Conception

Access to NHS funded harvesting and 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 CCG's IVF policy at the time of any funding application.

Expectations of Providers

Cryopreservation of gametes or embryos must meet the current legislative standards, i.e. under Human Embryo and Fertility Act 1990

The provider of the service must ensure the patient receives appropriate counselling and provides full consent. The patient and their partner must be made aware of the legal position on embryo ownership should one partner remove consent to their ongoing storage or use.

The provider of the service must ensure patients are aware of legal issues on posthumous use of gametes and embryos should they wish a partner to be able to use these should their treatment not be successful.

Patients will need to provide annual consent for continued storage.

The provider must ensure appropriate consent to storage is in place and that the patient understands the need for on-going consent and has outlined the purposes for which they can be used.

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	<p>Expectation of the Patient 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 materials.</p>
<p>Summary of evidence / rationale</p>	<p>Following notification of a recent legal challenge¹ having been brought against NHS England by the Equality and Human Rights Commission (EHRC), the CCG wishes to ensure that all patients undergoing medical treatments that may affect fertility, including transgender treatments, have the same access to gamete preservation services as patients undergoing cancer treatment.</p> <p>The challenge relates to the commissioning and provision of gamete retrieval and storage services for transgender patients. The EHRC argues that:</p> <ul style="list-style-type: none"> • <i>NHS England wrongly interprets the words “Gender Identity Disorder Services” at paragraph 57, Schedule 4 of the NHS Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012 (“the 2012 Regulations”) as not including gamete retrieval and storage, and has thereby misdirected itself as to its obligation to provide that service to transgender patients;</i> • <i>NHS England has unlawfully failed to exercise its power under s.2 of the National Health Service Act 2006 (“the 2006 Act”), in the light of its obligations under domestic and European equalities provisions, to provide gamete retrieval and storage to transgender patients;</i> • <i>NHS England has unlawfully failed to exercise its power to issue guidance to clinical commissioning groups (“CCGs”) to discourage them from unlawfully failing to arrange for the provision of gamete retrieval and storage to transgender patients.</i> <p>NHS England’s position is that the commissioning of gamete retrieval and storage services is appropriately the commissioning responsibility of CCGs. Responsibility for developing clinical commissioning policy in this area extends as much to trans patients as it does to patients, for example, undergoing chemotherapy. When formulating clinical commissioning policy in this, and indeed all areas of commissioning responsibility, CCGs are under a number of legal duties including the Public Sector Equality Duty. NHS England's position is that no additional statutory guidance on this issue is required.</p> <p>NHS England advised CCGs: ‘in light of this challenge, [CCGs] may wish to review any commissioning policies ... in place in this area and how they apply to different groups of patients.</p>
<p>Date effective from</p>	<p>January 2019</p>
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<p>Review date</p>	<p>2021</p>

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References:

- ¹NHE England CCG Bulletin - Issue 247 - 25 October 2018, Review of clinical commissioning policies for gamete retrieval and preservation
- NICE (CG156 Fertility Problems: assessment and management)
 - Human Fertilisation and Embryology Act (1990) guidelines <https://www.hfea.gov.uk/>
 - Human Tissue Authority guidelines <https://www.hta.gov.uk/>
 - Leeds CCG Gynaecology and Urology Commissioning Policy

Version	Created /actioned by	Nature of Amendment	Approved by	Date
V1	GP Clinical Lead	Draft of initial statement	n/a	n/a
FINAL	GP Clinical Lead and Senior Service Improvement Manager	Final statement for approval	SRCCG Business Committee (via email) VoYCCG Executive Committee	Dec 18 Jan 19