

<b>Policy title</b>	<b>Gamete (sperm/egg) Storage for those undergoing fertility-threatening treatment V2.0</b>
<b>Policy position</b>	<b>Criteria Based Access</b>
<b>Date of Forum recommendation</b>	<b>February 2022</b>
<b>Date of ICB recommendation</b>	<b>September 2022, Updated November 2023</b>

### **Condition or Intervention**

Cryopreservation is the process of freezing and storing of an egg, sperm or embryo for future use for fertility preservation. A gamete is defined as a mature sexual reproductive cell, as a sperm or egg, that unites with another cell to form an embryo.

This policy covers cryopreservation of gametes (sperms/eggs) for individuals about to commence a treatment that is likely to lead to permanent infertility and would like to have their gametes preserved for future use. The process of gamete retrieval and cryopreservation generally involves collection and storage of multiple gametes available at the time of procedure.

The funding of gamete retrieval and cryopreservation does not commit the ICB to funding for Assisted Conception services.

### **Access Criteria:**

BLMK ICB fund gamete storage and cryopreservation under the following circumstances:

Patients are about to commence treatment deemed likely to cause permanent infertility. This treatment should be carried out in a recognised NHS pathway or advised by a specialist.

It should be noted that following some treatments fertility may recur, in which case ongoing gamete preservation will be reassessed. Conditions considered appropriate for gamete cryopreservation are:

- Medical conditions requiring treatment with cytotoxic drugs (including malignancies).  
**OR**
- Conditions requiring total body irradiation or radiotherapy that may affect an individual's reproductive organs.  
**OR**
- Conditions requiring male urological or female gynaecological surgery, which are likely to lead to permanent infertility (including gender reassignment surgery).

When requested under gender reassignment surgery, the patient should be undergoing treatment at a nationally accredited clinic.

**OR**

- Hormone therapy causing permanent infertility secondary to the inability to produce gametes.

The following conditions must also be met:

- After thorough counselling and a discussion regarding risks and implications of the procedure the patient would like to have gamete storage (shared decision making).

**AND**

- The patient is aware that funding for gamete retrieval and cryopreservation of material does not guarantee future funding of assisted conception or fertility treatment. Please see this link for the Fertility Services Commissioning Policy in BLMK: <https://bedfordshirelutonandmiltonkeynes.icb.nhs.uk/our-publications/policies/evidence-based-clinical-policies/>

**AND**

- Female patients must be referred for gamete storage before their 43rd birthday.

**AND**

- 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)

**AND**

- The patient is registered with a BLMK ICB GP

#### **Storage Duration:**

The initial storage period funded will be up to 10 years, in accordance with the Human Fertilisation and Embryology Authority (HFEA) regulations and guidance and the agreed period of patient consent. Storage could continue if the following criteria is met:

1. The provider has gained continued consent from the patient every 10 years in line with HFEA guidelines
2. The provider must confirm with the patient that they understand eligibility for IVF treatment funded by the NHS means they must have started treatment before the age of 43, as well as meeting other eligibility criteria.
3. At the time of re-consent (every 10 years), individuals, regardless of gender, remain aged below 43 years and demonstrate compliance with all other aspects of the patient eligibility criteria within this policy at the time of renewal.
4. For all patients, if fertility returns as demonstrated by conception, funding for ongoing storage of remaining stored material will cease.

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

## **Number of attempts at gamete extraction**

For patients eligible for gamete extraction, up-to two attempts from an accredited provider are funded. The commissioned providers for BLMK are listed in Table 1 of this policy.

## **Exclusion Criteria**

The following circumstances will not be eligible for ICB funding:

- Gamete harvesting and cryopreservation in pre-pubertal patients.
- Cryopreservation of gametes requested for social reasons.
- Cryopreservation of ovarian and testicular tissue.

Note that ovarian and testicular cryopreservation for patients receiving gonadotoxic treatment who are at high risk of infertility and cannot store mature eggs or sperm is the commissioning responsibility of NHS England (All ages). Please see the following link for information on these services: <https://www.england.nhs.uk/publication/manual-for-prescribed-specialised-services/>

## **Cryopreservation Services Funded**

When considering and using cryopreservation for people before starting chemotherapy or radiotherapy that is likely to affect their fertility, follow recommendations in 'The effects of cancer treatment on reproductive functions' (2007).

When using cryopreservation to preserve fertility, use sperm or oocytes.

Females of reproductive age should be offered oocyte cryopreservation if they meet all of the following criteria:

- They are well enough to undergo ovarian stimulation and egg collection
- The procedure will not worsen their condition
- Enough time is available before the start of their treatment

Offer sperm cryopreservation to males of reproductive age who are preparing for the treatments outlined above that are likely to make them permanently infertile. Local protocols should exist to ensure that health professionals are aware of the values of semen cryopreservation in these circumstances, so that they deal with the situation sensitively and effectively.

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.

## **Human Fertilisation and Embryology Act 1990 and Health & Social Care Act 2022**

Cryopreservation of gametes must meet the current legislative standards.

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

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

Patients will need to provide consent for continued storage in line with HFEA Guidelines. 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.

The provider must ensure appropriate consent to storage is in place and that the patient understands the need for on-going consent.

**NOTE:**

- Where a patient does not meet the policy criteria or the intervention is not normally funded by the NHS, an application for clinical exceptionality can be considered via the ICB's Individual Funding Request (IFR) Policy and Process.
- This policy will be reviewed in the light of new evidence or new national guidance, eg, from NICE.

### **Rationale for an upper age limit in female patients**

Research has shown that fertility decreases with age in females, particularly after the age of 35 because both the number and quality of eggs gets lower. This means it is harder to get pregnant, whether naturally or by assisted conception and the rates of miscarriage are higher. The upper age limit for females has been based upon NICE CG156 Fertility problems: assessment and treatment which recommends treatment for a cycle of IVF is offered to women up to and including the age of 42, providing certain criteria are met. Whilst there is some limited evidence that fertility may also decline with age in males, the data is less clear and therefore no age limit has been set.

**Table 1:**

#### **List of Bedfordshire, Luton & Milton Keynes Integrated Care Board (ICB) Tertiary Fertility Providers that are contracted to provide Fertility Services including Gamete Storage**

<b>Tertiary Providers</b>	
<b>Bourn Hall Clinic</b>  Click <a href="#">here</a> for the referral form.  Bourn Hall Clinic, Bourn, Cambridge, CB23 2TN. Tel: 01954 7171210 <a href="https://www.bournhall.co.uk/clinics/cambridge/">https://www.bournhall.co.uk/clinics/cambridge/</a>  Bourn Hall Clinic, Unit 3, The Apex Gateway 11, Farrier Close, Wymondham Norwich, Norfolk, NR18 0WF. <a href="https://www.bournhall.co.uk/clinics/norwich/">https://www.bournhall.co.uk/clinics/norwich/</a>  Bourn Hall Clinic, 25 London Road, Wickford, Essex, SS12 0AW <a href="https://www.bournhall.co.uk/clinics/essex/">https://www.bournhall.co.uk/clinics/essex/</a>	<b>CARE Fertility</b>  E-mail <a href="#">here</a> to make a referral.  Care Fertility Northampton, 67 The Avenue, Northampton, NN1 5BT <a href="https://www.carefertility.com/our-clinics/ivf-clinic-northampton/">https://www.carefertility.com/our-clinics/ivf-clinic-northampton/</a>  Care Fertility London, Park Lorne, 111 Park Road, London, NW8 7JL <a href="https://www.carefertility.com/our-clinics/ivf-clinic-london/">https://www.carefertility.com/our-clinics/ivf-clinic-london/</a>

<p><b>Cambridge IVF</b></p> <p>Click <a href="#">here</a> for male referral form.  <b>E-mail both addresses below for female cryopreservation referrals:</b>  <a href="mailto:Add-tr.cambridgeivf@nhs.net">Add-tr.cambridgeivf@nhs.net</a>  <a href="mailto:add-tr.ivfnurses@nhs.net">add-tr.ivfnurses@nhs.net</a></p> <p>Cambridge IVF, Cambridge University Hospitals Foundation Trust, Kefford House, Maris Lane, Trumpington, Cambridge, CB2 9LG  <a href="https://www.cambridge-ivf.org.uk/">https://www.cambridge-ivf.org.uk/</a></p>	<p><b>Guy's &amp; St Thomas'</b></p> <p>Click <a href="#">here</a> for the referral form.</p> <p>Guy's &amp; St Thomas', Guy's Hospital, 11th floor, Tower Wing, Great Maze Pond  London SE1 9RT. Tel: 020 7188 2300  <a href="http://www.guysandstthomas.nhs.uk/our-services/acu/overview.aspx">http://www.guysandstthomas.nhs.uk/our-services/acu/overview.aspx</a></p>
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**References:**

1. National Institute of Health and Clinical Excellence (NICE), October 2014. Fertility Problems Quality Standard [QS73], London: NICE.
2. National Institute of Health and Clinical Excellence (NICE), February 2013; updated September 2017. Fertility problems: assessment and treatment. Clinical Guidance [CG156], London: NICE.
3. NHS England, 2018. Service specification: Gender Identity Services for Adults (Surgical Interventions), London: NHS England.
4. Royal College of Physicians, The Royal College of Radiologists, Royal, November 2007. The Effects of Cancer Treatment on Reproductive Functions - Guidance on Management, Report of a Working Party, London: RCP.
5. Yasmin, E., Balachandren, N., Davies, M. C., Jones, G. L., Lane, S., Mathur, R., Webber, L., Anderson, R. A., & British Fertility Society (2018). Fertility preservation for medical reasons in girls and women: British fertility society policy and practice guideline. Human fertility (Cambridge, England), 21(1), 3–26.

Key words: Gamete, Sperm, Eggs, Oocyte, Gamete Storage, Cryopreservation

<b>Policy update record</b>	
November 2023 BLMK ICB QP meeting v2.0	Storage after the initial 10 year period has changed from a prior approval process to criteria based access. A list of BLMK ICB providers that are contracted to provide fertility services including gamete storage has been added. Minor wording changes to improve clarity have also been made. Inclusion of commissioning responsibility of ovarian and testicular tissue cryopreservation (funded by NHS England).