

**Invitro Fertilisation (IVF) and Intracytloplasmic Sperm Injection (ICSI)
Commissioning Statement
Statement number: 28**

<p>Treatment</p>	<p>Invitro Fertilisation (IVF) and Intracytloplasmic Sperm Injection (ICSI)</p>
<p>Background</p>	<p>In December 2014 the CCG agreed to implement a policy of immediate access to one cycle of IVF for couples who met the agreed criteria.</p> <p>Following a review of its Access to Infertility Treatment Policy, in July 2020, the CCG updated the policy to reflect the recent review of the Yorkshire and Humber Fertility Policy. The changes to the NHS Vale of York CCG policy makes:</p> <ul style="list-style-type: none"> • One funded cycle of IVF available where the female is aged 40-43 (to 43rd birthday) • One funded cycle of IVF available where the female is aged 18 – 23yrs. <p>Subject to meeting existing eligibility criteria.</p>
<p>Commissioning position</p>	<p>The Executive Committee agreed to implement a policy of immediate access to one cycle of IVF for couples who meet the following criteria:</p> <ul style="list-style-type: none"> • Female age: 18 – 43rd birthday (at the time of treatment) • Female BMI: 19 to 29 female for six months prior to a referral • Smoking status: Non-smoking couple for six months prior to a referral • Existing children: To not have living or adopted children • Relationship: To be in a stable relationship for at least two years (including same sex couples) and currently cohabiting <p>Other criteria:</p> <ul style="list-style-type: none"> • For heterosexual couples: to have had regular unprotected intercourse (attempts to conceive) for at least two years prior to referral within the same stable relationship, in the absence of any known reproductive pathology • For same-sex couples and where a medical condition exists (such as physical disability, an infection requiring sperm washing, or a psychosexual disorder prevents natural conception), IUI for up to 6 cycles may be funded, followed by further assisted conception if required • Couples who have previously self-funded treatment are eligible for one NHS funded cycle as long as they have not received more than two self-funded cycles

Frequently Asked Questions

A copy of a list of Frequently Asked Questions can be found [here](#).

For Frequently Asked Questions specifically for same sex couples [click here](#).

Careful consideration will be given to previously eligible couples currently seeking IVF services. To ensure this process is fair and as effective as possible, the CCG is working closely with local Assisted Conception Units to develop a pathway into services.

Access Criteria

- Female age – years at the time of treatment
The age of women at the time of treatment must be less than 43rd birthday and over 18 years

- Female BMI 19 to 29 for 6 months prior to a referral
Body Mass Index within the range 19 to 29 kg/m² (this means that a BMI of 29.1 is outside the criteria). GPs should advise patients regarding weight loss support if they meet all other criteria. Assisted conception treatments will only be provided when BMI is within the range stipulated and has been maintained within 19 to 29 kg/m² for the previous 6 months.
- Partners: both must be:-
 - Non-smokers for 6 months prior to a referral
 - Both partners must be non-smokers for 6 months prior to a referral. Non-smoking status for both partners will be tested with a carbon monoxide breath test prior to commencement of any treatment. GPs should refer any smokers who meet all other criteria, to a smoking cessation programme to support their efforts in stopping smoking. Previous smokers must be non smoking for 6 months prior to being put forward for assisted conception treatment and register below 5 on the Carbon Monoxide test.
 - Existing children
 - Neither partner should have any living children from either current or any previous relationships. The adoption of children confers the legal status of parent to the adoptive parents; this will apply to both adoptions in and out of the family. If any fertility treatment results in a live birth (and the child is still alive), then the couple will

	<p>not be eligible for further fertility treatments, including the implantation of any stored frozen embryos.</p> <ul style="list-style-type: none"> ○ Stable 2 year relationship <ul style="list-style-type: none"> ▪ To be in a stable relationship for at least two years (including same sex couples) and currently cohabiting. ○ Having regular unprotected intercourse for the 2 years prior to referral within the same stable relationship <ul style="list-style-type: none"> ▪ Couples must have been having regular unprotected intercourse for a 2 year period, reported to and documented by GP. Attempts to conceive should be based upon using recognised ovulation indicators at the appropriate time in the cycle. Couples who conceive naturally and who subsequently miscarry up to twice within 2 years will be investigated for recurrent miscarriages. These women will not automatically received assisted conception treatment unless clinically appropriate as they are able to conceive naturally. ○ Previous treatment history <ul style="list-style-type: none"> ▪ Any previous NHS funded IVF treatment will be an exclusion criterion. Couples who have previously self-funded treatment are eligible for 1 NHS funded cycle as long as they have not received more than 2 self-funded cycles.
Summary evidence rationale	of / The CCG Access to Infertility Treatment Commissioning Policy reflects the latest guidelines from the National Institute for Clinical Excellence (https://www.nice.org.uk/guidance/cg156).
Date effective from	July 2020
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Approved by	CCG Executive Committee, July 2020
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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