

# Fertility

<b>Assisted Reproduction Treatments</b>	<b>Category:</b> <i>(IFR / Prior Approval / Monitored Approval)</i>	<b>IFR &amp; Prior Approval</b> <i>(please see detail of policy)</i>
	<b>Local or National EBI (Evidence Based Interventions) Policy:</b>	<b>Local</b>

**Background:**

The Clinical Guideline on *fertility assessment and treatment* was published by NICE in February 2013 (NICE CG156, 2013) and covers all clinical procedures/pathways relating to fertility assessment and treatment.

This document provides a single specific commissioning policy for the NHS with the aim to ensure consistency in the application of the guideline across the North East & North Cumbria region.

Over 80% of couples in the general population will conceive within 1 year if:

- the woman is aged under 40 years

*AND*

- they do not use contraception and have regular sexual intercourse.

Of those who do not conceive in the first year, about half will do so in the second year (cumulative pregnancy rate over 90%). [NICE 2004, amended 2013].

The estimated prevalence of infertility is one in seven couples in the UK. A typical Integrated Care Board can expect about 230 new consultant referrals (couples) per 250,000 head of population per year (NICE CG11, 2004).

All couples are eligible for consultation and advice from the specialist service

**Policy:**

Investigations to determine fertility are routinely commissioned on the NHS.

IVF / ICSI carried out as part of pre-implantation genetic testing is commissioned directly by NHS England and is therefore not covered by this policy.

**The NHS does not routinely commission the following:**

- Any treatment requiring surrogacy (paid or altruistic).
- Intrauterine or other artificial insemination for an otherwise fertile woman.
- Treatment when sub fertility is due to previous sterilisation procedure.
- Treatment when any party to the pregnancy with proposed parental responsibility has living children.
- Treatment when any party to the pregnancy with proposed parental responsibility has not been registered with a ICB'S in the areas covered by the policy for at least 1 year.
- Treatment for patients who are not eligible for NHS treatment in line with the Overseas Visitors Charging Regulations.

- Fertility preservation for patients whose fertility has not been at risk from iatrogenic or other medical conditions.
- Gamete donation (noting that altruistically donated gametes may be used in treatment at the discretion of treatment providers).
- Treatment for women after their 43<sup>rd</sup> birthday.
- Treatment when the female hoping to become pregnant is a smoker
- Treatment when the female has a BMI <19 or >30.
- Treatment when the male party to the pregnancy has male factor infertility and is a smoker.

**Policy: NHS funded fertility treatment is available to treat established infertility in the following circumstances:**

#### **Treatment for male factor infertility**

Absolute or relative male factor infertility has been demonstrated on semen analysis.

In relative male factor sub fertility, there has been 2 years of regular vaginal intercourse\* following health optimisation (ie BMI <30 and non-smoking for both parties).

\*Regular vaginal intercourse is defined as 3 times per week.

#### **Treatment of female factor infertility**

Absolute or relative female factor infertility has been demonstrated on appropriate investigations.

In relative female factor sub fertility, if clinically appropriate, there has been either 2 years of regular heterosexual vaginal intercourse following health optimisation (BMI <30 & non-smoking for both parties) or 6 cycles of medically managed artificial insemination (by an HFEA licensed provider) with health optimisation (BMI <30 & non-smoking).

#### **Treatment of unexplained infertility**

There has been either 2 years of regular heterosexual vaginal intercourse following health optimisation (BMI <30 & non-smoking for both parties) or 6 cycles of medically managed artificial insemination (by an HFEA licensed provider) with health optimisation (BMI <30 & non-smoking).

Where the criteria for male factor, female factor or unexplained fertility have been met the NHS will fund IUI and/or IVF (inc ICSI) subject to the following criteria being met:

Ref	Policy	Access Criteria	Guidance Notes
1	<p><b>Fertility treatment female wishing to become pregnant under 40 years</b></p> <ol style="list-style-type: none"> <li>1. 12 cycles of artificial insemination using partner's sperm or 6 cycles of donor sperm (by an HFEA licensed provider).</li> <li>2. Up to 3* full cycles of IVF, with or without intracytoplasmic sperm injection (ICSI).</li> </ol>	<p>Female: BMI greater than 19.0 and lower than or equal to 30.0 and non-smoker at the start of treatment.</p> <p>Male factor infertility: Non-smoker at the start of treatment.</p> <p>If the woman reaches the age of 40 during treatment, complete the current full cycle but do not offer further full cycles.</p> <p>*Refer to Guidance Notes</p>	<p><b>3 full cycles of IVF</b></p> <p>Inform people that normally a full cycle of IVF treatment, with or without ICSI should comprise 1 episode of ovarian stimulation and the associated episode transfer of the fresh and frozen embryo(s) relating to that cycle.</p> <p>Access to three cycles is not an automatic right – the outcome of any previous cycle will be taken into account. Treatment must be medically indicated at the start of each cycle.</p> <p>As IVF success rates decline significantly after 3 cycles, previous cycles received irrespective as to whether they were funded by the NHS or privately will be taken into account.</p> <p>If patients have funded 3 or more IVF cycles privately they will not be entitled to any NHS funded cycles.</p> <p>If patients have funded 2 cycles privately they will be entitled to 1 NHS cycle.</p> <p>If patients have funded 1 cycle privately they will be entitled to 2 NHS cycles.</p>

Ref	Policy	Access Criteria	Guidance Notes
2	<p><b>Fertility treatment female wishing to become pregnant aged 40 to 42 years</b></p> <ol style="list-style-type: none"> <li>12 cycles of artificial insemination using partner's sperm or 6 cycles of donor sperm (by an HFEA licensed provider).</li> <li>Up to 1* full cycle of IVF, with or without intracytoplasmic sperm injection (ICSI). Treatment must start before the woman's 43rd birthday</li> </ol>	<p>Female: BMI greater than 19.0 and lower than or equal to 30.0 and non-smoker at the start of treatment</p> <p>Male factor infertility: Non-smoker at the start of treatment.</p> <p>Provided all the following 3 criteria are fulfilled:</p> <ul style="list-style-type: none"> <li>They have never previously had IVF treatment</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>There is evidence of good ovarian reserve as identified by a specialist clinician</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>There has been a discussion of the additional implications of IVF and pregnancy at this age</li> </ul> <p>*Refer to Guidance Notes</p>	<p><b>1 full cycle of IVF</b></p> <p>Inform people that normally a full cycle of IVF treatment, with or without ICSI should comprise 1 episode of ovarian stimulation and the associated episode transfer of the fresh and frozen embryo(s) relating to that cycle.</p> <p><b>Ovarian reserve testing</b></p> <p>The aim is to select those with at least 10% chance of successful treatment. The criteria remain under review. At present use the following criteria to predict the likely ovarian response to gonadotrophin stimulation in women who are eligible for IVF treatment:</p> <ul style="list-style-type: none"> <li>Total antral follicle count of more than or equal to 4</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>Anti-Müllerian hormone of more than or equal to 5.4 pmol/l.</li> </ul>

### Fertility Preservation

**Policy: The NHS will fund fertility preservation for anyone who is at high risk of premature infertility from iatrogenic or other medical conditions including women who are at high risk of idiopathic premature ovarian failure (POF).**

Note: in the case of idiopathic POF, high risk is defined as having more than one affected direct family member.

## **Embryo / Gamete Harvesting & Storage**

**Policy: The NHS will fund embryo / gamete harvesting and storage for those patients who have had their fertility preservation funded by the NHS in accordance with the fertility preservation policy for:**

- An initial period of one year (subject to clinical review at the end of the period)
- A further period of up to 10 years (subject to clinical review at the end of the period)
- For females up to a period for which the female remains eligible for NHS fertility treatment. Once the female has reached the maximum age for NHS fertility treatment the patient should have the option to privately fund storage should this be clinically appropriate.
- For males a period up to 55 years in total from fertility preservation.

Gametes stored by the NHS will not be preserved after the patient has deceased.

Patients who have had gamete storage funded by the NHS will be subject to the NHS fertility treatment policy at the time they wish to use the gametes.

### **Embryo Storage following NHS funded Assisted Reproduction Treatment**

The NHS will fund embryo storage for embryos which have been funded by the NHS in line with the Fertility Policy. Embryos will be stored by the NHS up to the time that the female reaches the maximum age for fertility treatment on the NHS. Any embryos stored or created by the NHS will not be preserved after the patient has deceased.

Note: Any embryos stored before the woman's 43<sup>rd</sup> Birthday may be implanted within 12 months of the date storage commenced\*.

\* The rationale for this is that the embryo has been created while the female is compliant in line with the policy.