

Hampshire and Isle of Wight Integrated Care Board Priorities Committee

Policy title	Policy 002: Assisted reproduction services for infertile patients
Policy position	Criteria Based Access
Date of issue	18 June 2024
Update	This policy will be updated in light of a substantial body of new evidence or new national guidance.

Assisted reproduction or assisted reproductive treatments (ART) is the name given to treatments that can help people get pregnant without having sexual intercourse. Examples include in vitro fertilisation (IVF) and intrauterine insemination (IUI). This policy sets out which assisted reproductive treatments are funded by HIOW ICB and the eligibility criteria patients need to meet to access these.

This policy relates to and has been informed by the National Institute of Health and Care Excellence (NICE) Clinical Guideline (CG) 156 'Fertility: assessment and treatment for people with fertility problems' (2013, updated 2017).

The overall aim of the local policy is to support the commissioning of the highest quality, clinical and cost-effective services that are affordable, to maximise health outcomes in terms of live births and patient/ baby safety.

Commissioning notes:

- Patients requesting specialist infertility treatment and meeting the eligibility criteria must be referred for specialist infertility treatment(s) by an NHS Consultant Gynaecologist using the standard referral form available from the ICB Commissioners.
- The ICB Commissioners will confirm funding, and advise the patients' managing clinician of the preferred provider of their infertility treatment. N.B. NHS-funded specialist assisted conception services are commissioned only from approved providers.
- The NHS-funded specialist fertility unit providing the care will be solely responsible for initial consultation; treatment planning; counselling/advising patients; treatment consent; all drugs; egg collection; semen analysis; embryo transfer; pregnancy test(s); all consumables; pathology tests; scans; and the HFEA fee.
- All fertility drugs, such as anti-oestrogens, (e.g. clomiphene citrate), gonadotrophins, (including gonadorelin analogues), and progestogens, should be prescribed only by the treating consultant. GPs are advised not to prescribe any drugs for fertility.
- This policy should be read in conjunction with the HIOW ICB policy on fertility preservation.
- Preimplantation genetic diagnosis (PGD) and associated reproductive treatments are the commissioning responsibility of NHS England.
- In general, patients who pay the immigration surcharge are not eligible for assisted reproductive treatments funded by the ICB. The ICB will comply with government Guidance (2022) regarding these patients.
- It is anticipated that, rarely, patients who are not eligible for treatment because they do not fulfil the eligibility criteria set out in this document may, by virtue of their personal circumstances, be considered an exceptional case for NHS funding. If this is thought to be applicable, the patients' GP or hospital consultant may contact the HIOW ICBIFR panel, which is responsible for considering funding for individual cases.

Glossary	
Abandoned IVF cycle	Defined as an IVF cycle where an egg collection procedure has not been undertaken. Usually occurs due to a lack of response to the medication to stimulate the ovaries (where fewer than three mature follicles are present) or if there has been an excessive response to ovarian stimulation and the patient is at risk of severe ovarian hyperstimulation syndrome (OHSS). May also be referred to as a 'cancelled cycle'.
Artificial insemination (AI)	Artificial insemination (AI) is the introduction of sperm into the vagina, cervix or uterine cavity for the purpose of achieving pregnancy. Intrauterine insemination (IUI) is a type of AI undertaken at a fertility clinic where sperm is filtered to produce a concentrated 'healthy' sample which is placed directly into the uterus (womb). AI undertaken at home would normally be intra-vaginal insemination.
Assisted reproductive treatment (ART)	The collective name for treatments designed to lead to conception by means other than sexual intercourse. Includes: intrauterine insemination (IUI) and in vitro fertilisation (IVF).
Azoospermia	A condition where there are no sperm in the ejaculate.
BMI	Body mass index. A measure that relates body weight to height.
Cryopreservation	The freezing and storage of embryos, sperm or eggs for future use in assisted reproductive treatment cycles.
Donor insemination (DI)	Artificial insemination using donated sperm.
Egg (oocyte) donation	The process by which a fertile donor donates eggs to be used in the treatment of others.
Embryo transfer	The procedure in which one or more embryos are placed in the uterus.
Embryo transfer strategies	Defines the number of embryos that should be transferred in an embryo transfer procedure, depending on factors such as the quality of the embryos and the age of the woman or person trying to conceive.
Endometriosis	A condition where tissue similar to the lining of the uterus starts to grow in other places, such as the ovaries and fallopian tubes. Endometriosis is a known clinical cause of fertility problems.
Expectant management	NICE define expectant management as a formal approach that encourages conception through unprotected vaginal intercourse. It involves supportively offering an individual or couple information and advice about the regularity and timing of intercourse or insemination and any lifestyle changes which might improve their chances of conceiving. It does not involve active clinical or therapeutic interventions.
Fertilisation	The union of an egg and sperm.
Fertility policies	Integrated care boards (ICBs) are responsible for commissioning most fertility treatments; most ICBs therefore have policies in place specifying which interventions are funded and eligibility criteria for access to these. These policies typically explain when the ICB will fund assisted reproductive treatments for people experiencing fertility problems.
Fresh IVF cycle	Comprises an episode of ovarian stimulation and the transfer of embryos created that have not previously been frozen.
Frozen embryo transfer (FET)	Where an excess of embryos is available following a fresh IVF cycle, these may be frozen for future use. Once thawed, these embryos may be transferred to the patient as a 'frozen embryo transfer'. Also known as a 'frozen IVF cycle'.

Glossary cont.	
Full IVF cycle	Defined by NICE as one episode of ovarian stimulation and the transfer of any resultant fresh and frozen embryo(s).
Gonadal dysgenesis	Abnormal development of an ovary or testicle.
HFEA	Human Fertilisation and Embryology Authority. The HFEA is the UK's independent regulator of fertility treatment and research using human embryos. They license and inspect clinics and set standards.
Infertility	<p>The World Health Organisation states infertility is a disease of the male or female reproductive system defined by the failure to achieve a pregnancy after 12 months or more of regular unprotected sexual intercourse. NICE indicates that for people trying to conceive using artificial insemination (including, but not limited to, female same sex couples and single women), infertility may be indicated after 6 unsuccessful cycles.</p> <p>In the male reproductive system, infertility is most commonly caused by problems in the ejection of semen, absence or low levels of sperm, or abnormal shape (morphology) and movement (motility) of the sperm; this is commonly called 'male factor infertility'. In the female reproductive system, infertility may be caused by a range of abnormalities of the ovaries, uterus, fallopian tubes, and the endocrine system, among others. In around a quarter of cases, infertility is unexplained.</p>
In vitro fertilisation (IVF)	IVF involves ovarian stimulation and then collection of eggs. The eggs are then fertilised with sperm in a lab. If fertilisation is successful, the embryo is allowed to develop for between two and six days and is then transferred to the uterus to hopefully continue to a pregnancy. Ideally one embryo is transferred to minimise the risk of multiple pregnancy. Where the patient is older, or the quality of the embryos is poor, two embryos may sometimes be transferred. It is best practice to freeze any remaining good quality embryos to use later in a frozen embryo transfer, if the first transfer is unsuccessful.
Intracytoplasmic sperm injection (ICSI)	IVF with ICSI treatment is similar to standard IVF. However, instead of mixing the sperm with the eggs and leaving them to fertilise in a dish, an embryologist will inject a single sperm into each mature egg. This maximises the chance of fertilisation as it bypasses any potential problems the sperm may have in penetrating the egg.
Intrauterine insemination (IUI)	IUI is a type of fertility treatment in which the better quality sperm are separated from sperm that are sluggish, non-moving or abnormally shaped. This sperm is then placed directly in the uterus. This can either be performed with partner sperm or donor sperm (known as donor insemination).
Natural cycle IVF	An IVF cycle in which eggs are collected from the ovaries during a spontaneous menstrual cycle without any drug use.
NICE	National Institute for Health and Care Excellence. NICE provide national guidance and advice to improve health and social care. One of the ways that NICE does so is by publishing guidelines, which are evidence-based recommendations for health and care in England. Organisations commissioning and delivering services are expected to take the recommendations contained within NICE guidelines into account when planning and delivering services. NICE has published a guideline on fertility problems – Clinical Guideline (CG 156).

Glossary cont.	
Oophorectomy	An operation to remove one (unilateral) or both (bilateral) ovaries.
Ovarian hyper-stimulation syndrome (OHSS)	A condition in which the ovarian response to stimulation results in clinical problems, including abdominal distension, dehydration and potentially serious complications due to thrombosis and lung and kidney dysfunction. It is more likely in patients who are excessively sensitive to medicines used for ovarian stimulation.
Ovarian stimulation	Stimulation of the ovary to achieve growth and development of ovarian follicles with the aim of increasing the number of eggs released.
Pathological problem	One that relates to medical conditions/ diseases (physical or psychological).
Pre-implantation genetic diagnosis	A technique used to identify inherited genetic defects in embryos created through IVF. Only embryos with a low genetic risk for the condition are then transferred to the uterus. Any resulting pregnancy should be unaffected by the condition for which the diagnosis is performed.
Premature ovarian insufficiency	Where menopause happens before the age of 40 (also sometimes called premature menopause).
Rhesus (Rh) isoimmunisation	A condition where antibodies in a pregnant person's blood destroy the baby's blood cells. Also known as rhesus disease.
Sperm donation	The process by which a fertile donor donates sperm to be used in the treatment of others. The HFEA regulates sperm donation undertaken at UK fertility clinics.
Surgical sperm retrieval (SSR)	Extracting sperm by a surgical procedure. Types of SSR include percutaneous epididymal sperm aspiration (PESA), microsurgical epididymal sperm aspiration (MESA), testicular sperm aspiration (TESA), testicular sperm extraction (TESE) and microscope-assisted testicular sperm extraction (MicroTESE).
Surrogacy	Where a person carries and gives birth to a baby for another person or couple. This may involve the eggs of the surrogate, the intended parent, or a donor.
Unsuccessful cycle of IVF/ ICSI	Includes failure of fertilisation, failure of development of embryos and failure to become pregnant following transfer of embryos.

Treatment pathway

This policy is intended, as per NICE guidance, for people who have a possible pathological problem (physical or psychological) to explain their infertility.

The process for demonstrating subfertility will necessarily be different for people trying to conceive through sexual intercourse and people trying to conceive through artificial insemination; these differences are reflected in sections below.

Primary care assessment for infertility

People who are concerned about delays in conception should be offered an initial assessment in primary care. A specific enquiry about lifestyle and sexual history should be taken and advice provided as appropriate (as per NICE Clinical Guideline 156).

An initial consultation in primary care should be offered to discuss the options for attempting conception to people who are unable to, or would find it very difficult to, have vaginal intercourse (as per NICE Clinical Guideline 156). Patients trying to conceive through artificial insemination using donor sperm can be directed to the [HFEA website](#) for more information.

Patients presenting with concerns about fertility in primary care should be provided with information about the impact of smoking and BMI on their ability to conceive naturally. Where appropriate, patients should be informed of the adverse health impacts of maternal and passive smoking on the foetus and any children born, and smoking cessation support should be provided as necessary. Where relevant, patients should also be offered advice and support to achieve weight loss if overweight.

Patients should be informed of the BMI and smoking criteria which are in place to access assisted reproductive treatments (as outlined in sections below) at the earliest possible opportunity.

Referral for specialist assessment and investigations for infertility

Women or people trying to conceive who are of reproductive age can be offered clinical assessment and investigation along with their partner (where relevant) if:

- There is a known clinical cause of infertility or a history of predisposing factors for infertility, OR
- In the absence of any known cause of infertility, the patient has not conceived after 1 year of unprotected vaginal sexual intercourse or 6 cycles of artificial insemination

Patients do not need to fulfil additional eligibility criteria outlined in subsequent sections of this document to access specialist assessment and investigations for infertility.

Referral for consideration of NHS-funded IVF

Patients can only be referred for IVF, as per section 7 of this document, if they meet the eligibility criteria outlined below in sections 1 to 6 and when all appropriate tests and investigations have been successfully completed in primary and secondary care in line with NICE Clinical Guideline 156.

Where investigations show there is no chance of pregnancy with expectant management and where IVF is the only effective treatment, eligible patients can be referred for consideration of NHS funded IVF without delay. All other eligible patients can be offered IVF if they have not conceived after 2 years of regular unprotected intercourse or 12 cycles of artificial insemination (at least 6 of which should be IUI).

Eligibility criteria

Patients can only be referred for assisted reproductive treatments if they meet the eligibility criteria below and when all appropriate tests and investigations have been successfully completed in primary and secondary care in line with NICE Clinical Guideline 156.

1. Age of the woman or person trying to conceive at time of referral to tertiary care from secondary care	The age at referral should be before the patient's 35th birthday. Patients approaching the age of 35 years must be referred in time to be able to commence treatment before their 35th birthday.
2. Previous infertility treatment	People who have previously self-funded treatment are eligible for one NHS-funded cycle as long as they have not already received more than 2 self-funded fresh IVF cycles, and have no frozen embryos stored from a previous cycle. If patients have had frozen embryos transferred as part of earlier self-funded treatment, the frozen cycles will not be counted as previous cycles when assessing eligibility for NHS funded IVF. Any previous NHS funded fresh cycles of IVF treatment will be an exclusion criterion.
3. Existing children	Assisted reproductive treatments will only be funded if the couple/ patient does not have a living child from their relationship or from any previous relationship. This includes a child adopted by the couple or in a previous relationship. Once accepted for treatment, should a child be adopted or a pregnancy leading to a live birth occur the couple will no longer be eligible for treatment.
4. Sterilisation	Assisted reproductive treatments will not be available if the sub fertility is the result of a sterilisation procedure in an individual or either partner in a couple. This criterion applies even if reversal of sterilisation has been attempted.
5. Body mass index (BMI) in the woman or person trying to conceive	Patients must have a BMI of between 19.0 and 29.9 inclusive for a period of 6 months or more before receiving any treatment.
6. Smoking	Patients who smoke will not be accepted on the waiting list for assisted reproductive treatments. This applies to the woman or person undergoing treatment and their partner, if they have one, and they are providing sperm for treatment. Patients should stop smoking at least 6 months prior to infertility treatment and agree to take a carbon monoxide test. Vaping and nicotine replacement therapy will be allowed.

Additional eligibility criteria to access different treatments are outlined in the sections below.

Access to assisted reproductive treatments

Unless otherwise specified, patients need to fulfil the eligibility criteria outlined in sections 1 to 6 to access NHS funded assisted reproductive treatments.

<p>7. In vitro fertilisation (IVF) with or without intracytoplasmic sperm injection (ICSI)</p>	<p>HIOW ICB will fund one cycle of IVF treatment per eligible couple or individual in the case of a single person.</p> <p>One cycle of IVF treatment is defined as one cycle of ovarian stimulation, egg retrieval and fertilisation and up to two separate embryo transfer procedures (fresh/ frozen or frozen/ frozen as clinically indicated). It includes appropriate diagnostic tests, scans and pharmacological therapy. The cycle may be with or without intracytoplasmic sperm injection (ICSI).</p> <p>If egg collection is undertaken but the cycle does not proceed any further, it will be considered an unsuccessful IVF cycle. It will therefore count towards the patient's NHS provision and the patient will not be eligible to start another NHS-funded IVF cycle.</p> <p>Embryo transfer strategies outlined in NICE CG156 should be followed to minimise the number of multiple births¹.</p> <p>The transfer of frozen stored embryos from previous cycles of IVF will not be funded. It is expected that all frozen embryos from a previous cycle will be used in advance of a fresh cycle of IVF.</p> <p>Freezing and storage of viable embryos from NHS funded IVF will be funded for up to 3 years so that patients have the option to use stored embryos at a later stage if they choose to do so.</p> <p>Natural cycle IVF is not routinely funded.</p>
<p>8. Intra uterine insemination (IUI) using partner sperm</p>	<p>Up to 6 cycles of unstimulated IUI using partner sperm is funded for eligible patients where there is evidence of normal ovulation, tubal patency and semen analysis and either:</p> <ul style="list-style-type: none"> • they are unable to, or would find it very difficult to, have vaginal intercourse because of a clinically diagnosed physical disability or psychosexual problem, and have not conceived after 6 self-funded cycles of artificial insemination, or • they have conditions that require specific consideration in relation to methods of conception (for example, people with spinal cord injuries who are undergoing electro-ejaculation). <p>Where appropriate, IVF may be funded for the above groups – see section on referral for consideration of IVF for more information. Note, if the nature of a patient's physical disability or psychosexual problem is such that IVF is the only effective treatment, eligible patients can be referred for consideration of NHS funded IVF without delay, as outlined in the section on referral for consideration of IVF.</p> <p>IUI is not routinely funded for people with unexplained infertility, mild endometriosis or mild male factor infertility unless it is as an alternative to IVF for people who have social, cultural or religious objections to IVF. In these cases, up to 6 cycles of unstimulated IUI may be funded for patients who fulfil the eligibility criteria for IVF. Note, this would be an alternative to receiving IVF treatment and therefore IVF would not subsequently be funded for patients accessing IUI in these circumstances.</p>
<p>9. IUI using donor sperm</p>	<p>Up to 6 cycles of unstimulated IUI using donor sperm is funded for eligible patients where there is evidence of normal ovulation and tubal patency and either:</p>

	<ul style="list-style-type: none"> • obstructive or non-obstructive azoospermia • severe deficits in semen quality in couples who do not wish to undergo ICSI • there is a high risk of transmitting a genetic disorder or infectious disease to the child and/ or partner • severe rhesus isoimmunisation • individuals, or couples trying to conceive using donor insemination who have not conceived after 6 self-funded cycles of artificial insemination (for the avoidance of doubt, this may include: single people, people in same-sex relationships, heterosexual relationships or where one or both partners are transgender). <p>Where appropriate, IVF using donor sperm may be funded for the above groups – see section on referral for consideration of IVF.</p>
10. IVF using donor eggs	<p>IVF using donated eggs will be funded for eligible patients with one of the following:</p> <ul style="list-style-type: none"> • premature ovarian failure • gonadal dysgenesis including Turner syndrome • bilateral oophorectomy • where there is a high risk of transmitting a genetic disorder to the offspring • in certain cases of IVF treatment failure
11. Surgical sperm retrieval (SSR) for azoospermia	<p>Surgical sperm retrieval is only funded when the eligibility criteria set out in the NHS England policy are met. In addition, the patient must meet the eligibility criteria for IVF as set out in sections 1 to 6 of this document.</p> <p>Cryopreservation facilities for the freezing of any viable sperm must be available at the time of SSR to avoid the need for repeat surgery. Where an eligible patient has undergone successful NHS funded surgical sperm retrieval, cryopreservation and storage of sperm will be funded by HIOW ICB for up to 3 years.</p> <p>Where an eligible patient has undergone successful NHS funded surgical sperm retrieval, usual progress is to IVF with ICSI which will be funded as per section 7 of this policy.</p>
12. Surrogacy	<p>Assisted reproductive treatments involving surrogates are not routinely funded.</p>
13. Novel technologies and treatment add-ons	<p>Treatment add-ons with limited evidence (as outlined on the HFEA website), are not routinely funded by the ICB.</p>

Version	Date agreed at the Priorities Committee	Reason for change
Version 1	2014 legacy policy	
Version 2	2016	Re-issued
Version 3	2019	Review and update
Version 4	2024	Review and update