Buckinghamshire, Oxfordshire & Berkshire West
Integrated Care Board

BOB ICB and Frimley ICB Priorities Committee Clinical Commissioning Policy Statement

Policy Number/ Name	BOBFPC11g Assisted Reproduction Services for Infertile Patients
Date of BOBFPC Recommendation	February 2024

Introduction
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 the ICBs' position on funding assisted reproductive treatments for infertile patients. The policy also outlines when patients can be referred for specialist assessment and investigations to establish fertility.

The 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) and takes account of the Equality Act 2010, including age discrimination legislation.

Purpose
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.

The local NHS recognises the life-long distress that childlessness causes for some people, and that ART are clinically effective treatments that enable many infertile people to have a child.

Unfortunately, ART are not effective for all people, and the cost of ART means that the NHS cannot afford to provide this treatment for all infertile people. To fund treatment for all people who might benefit from ART would require other health care services to be cut.

The local NHS has therefore had to make difficult decisions about how to allocate the funding it has available for ART services. With the advice of fertility specialists and GPs, a local policy has been developed that offers ART to those people who are most likely to have a successful outcome – a healthy baby and a healthy parent.

Scope

The policy affects couples and individuals who want to become parents but who have a possible pathological problem (physical or psychological) leading to fertility problems. The policy sets out the assisted reproductive treatments funded by the ICBs and the eligibility criteria patients need to meet to access these. Eligibility for NHS funding is not the same as a guarantee of treatment. The treatment should only be considered if the eligibility criteria are met, but it is important that the final decision to treat is an informed decision between the responsible clinician and the patient.

Consistent with Department of Health guidance (2009), the ICB does not partially fund treatments for patients who do not meet the eligibility criteria in this policy.

- The following are outside the scope of this policy:
- Pre-implantation genetic diagnosis (PGD) and the associated assisted reproductive treatments which are commissioned by NHS England through Specialised Commissioning Area Teams, as per NHS England Clinical Commissioning Policy (2014) on PGD.
- Interventions to prevent the transmission of blood borne viruses in fertile serodiscordant couples (e.g., sperm washing for people living with HIV).
- 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.

This policy should be read in conjunction with: BOBFPC17 (2018) – policy for the preservation of fertility (i.e. freezing of eggs, sperm or embryos for future use).

It is anticipated that, rarely, patients who are not eligible for treatment because they do not fulfil the eligibility criteria may, by virtue of their individual circumstances, be considered an exceptional case for NHS funding. If this is thought to be applicable, the patient's GP or hospital consultant may apply to the relevant ICB's 'Individual Funding Request' (IFR) panel. The ICB responsible for considering the IFR will be dependent on the GP practice where the female partner or the partner who is trying to conceive is registered.

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	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. 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.
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 woman or person trying to conceive 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.

Glossary cont.	
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 156 (CG 156).
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 – Assessments and investigations

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 CG156).

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 CG156). 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.

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

Referral for specialist assessment and investigations for infertility

Women and people who wish 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 woman or person trying to conceive is aged under 34 years and has not conceived after 1 year of unprotected vaginal sexual intercourse or 6 cycles of artificial insemination (with either partner or donor sperm)
  - The woman or person trying to conceive is aged 34 years or older and has not conceived after 6 months of unprotected vaginal sexual intercourse or 3 cycles of artificial insemination (with either partner or donor sperm)

In addition, patients must meet both of the following eligibility criteria to be referred for specialist assessment and investigation for infertility:

- The woman or person trying to conceive should have a BMI of between 19 and 34.9 inclusive
- Patients should be non-smokers; this applies to both individuals in a couple being investigated.

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

Treatment pathway – Referral for ART

Patients must be referred for ART by a NHS Consultant Gynaecologist using the standard referral form available from their ICB. The tertiary provider of the patient's choice will offer an appointment to eligible patients. Patients may choose one of the designated NHS centres. Details of designated centres are listed on the standard referral form and held by the patient's ICB and by the secondary care fertility clinic.

Referral for consideration of NHS-funded IUI after specialist assessment and investigations for infertility

Patients can only be referred for IUI, as per sections 9 and 10 of this document, if they meet the eligibility criteria outlined in sections 1 to 7 and when all appropriate tests and investigations have been successfully completed in primary and secondary care in line with NICE guidelines.

Where eligible patients have been diagnosed with conditions outlined in sections 9 and 10 of this document, they can be referred for consideration of NHS funded IUI without delay. All other eligible patients who are trying to conceive through artificial insemination can be offered IUI if they have not conceived after 6 self-funded cycles of artificial insemination.

Referral for consideration of NHS-funded IVF after specialist assessment and investigations for infertility

Patients can only be referred for IVF, as per section 11 of this document, if they meet the eligibility criteria outlined below in sections 1 to 7 and when all appropriate tests and investigations have been successfully completed in primary and secondary care in line with NICE guidelines.

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' duration 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	Female fertility declines with age and therefore people who wish to conceive should seek help for fertility problems as early as possible, especially given that in most cases a period of expectant management and/or treatment is required before assisted reproduction services can be commenced. The age at referral to a specialist assisted reproduction service must be before the patient's 35th birthday. Patients should be referred from primary care to secondary care in sufficient time for all necessary interventions to be undertaken so that those found to be infertile can be referred to a specialist assisted reproduction service before their 35th birthday.
2. Age of woman or person trying to conceive at time of treatment	Following referral to a specialist assisted reproduction service (before the patient's 35th birthday), treatment must be commenced within 6 months.
3. Previous infertility treatment – NHS and privately funded	Any previous NHS-funded fresh cycles of IVF treatment is an exclusion criterion. Patients who have previously self-funded treatment are eligible for one NHS-funded cycle as long as they have not already undertaken more than two self-funded fresh IVF cycles. The outcome of previous self-funded IVF treatment will be taken into account when assessing the likely effectiveness and safety of any further IVF treatment. If patients have had frozen-thawed embryos transferred as part of earlier self-funded treatment, the number of frozen cycles will not be included when assessing eligibility for NHS-funded IVF.
4. Existing Children	Assisted reproduction services 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/ patient or adopted in a previous relationship. Patients will become ineligible if they adopt a child or achieve a pregnancy leading to a live birth after they have been accepted for NHS-funded assisted reproduction services.
5. Sterilisation	Assisted reproduction services will not be available if infertility is the result of a sterilisation procedure in either partner.
6. Body mass index (BMI)	The women or person undergoing treatment must have a BMI of between 19 and 29.9 inclusive at the time of any specialist treatment.
7. Smoking	Patients who smoke will not be eligible for NHS-funded specialist assisted reproduction treatment. This applies to the person undergoing treatment and their male partner if they have one and they are providing sperm for treatment. Patients must have maintained their non-smoking status for at least six months at the time of referral from secondary care for specialist infertility treatment.
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 7 to access NHS funded assisted reproductive treatments.	
9. Intra uterine insemination (IUI) using partner sperm	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: • 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. • 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). 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. 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. 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.
10. Intra uterine insemination (IUI) using donor sperm	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: • 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). Where appropriate, IVF using donor sperm may be funded for the above groups – see section on referral for consideration of IVF and flow chart in Appendix 1 for more information.
11. In vitro fertilisation (IVF) with or without intracytoplasmic sperm injection (ICSI)	In this policy a cycle of IVF comprises 1 episode of ovarian stimulation, fertilisation and 1 transfer of any resultant fresh embryo(s). This includes appropriate diagnostic tests, scans and pharmacological therapy. The cycle may be with or without intracytoplasmic sperm injection (ICSI). NHS funding will be available for 1 cycle of IVF treatment per eligible couple or individual.

Access to assisted reproductive treatments cont.	
11. IVF with or without ICSI cont.	If egg collection is undertaken but the cycle does not proceed any further, it will count towards the patient's NHS provision and the patient will not be eligible to start another NHS-funded cycle. Patients eligible for NHS-funded IVF can only have embryos from their NHS- funded fresh cycle transferred with NHS funding; the transfer of frozen-thawed embryos from previous cycles of IVF will not be funded. The cryopreservation (freezing and storage) of good quality embryos following NHS-funded IVF will be funded for up to 3 years to enable patients to have the option to use the frozen-thawed embryos in subsequent self-funded frozen embryo transfer cycles. Embryo transfer strategies outlined in NICE CG156 should be followed to minimise the number of multiple births1. In vitro maturation is not routinely funded, due to limited evidence of effectiveness. Natural cycle IVF is not routinely funded, consistent with NICE CG156.
12. IVF/ ICSI using donor eggs	IVF/ICSI using donated eggs from UK clinics licensed by the HFEA will be commissioned for eligible patients with one of the following: • premature ovarian failure • gonadal dysgenesis including Turner syndrome • bilateral oophorectomy • where there is a high risk of transmitting a genetic disorder to the offspring Patients must be identified as requiring donated eggs and be on the waiting list before the woman or person trying to conceive is aged 35. Funding approval will be retained for two years from the date of funding approval.
13. Surgical sperm retrieval (SSR) for azoospermia	Surgical sperm retrieval is the commissioning responsibility of NHS England and is not routinely funded by the ICBs. The NHS England policy on surgical sperm retrieval states it will only be funded where the patient has confirmed funding for subsequent stages of their fertility treatment pathway (i.e. cryopreservation and/or ICSI). The responsible clinician should therefore ensure patients meet the relevant eligibility criteria outlined in this document prior to undertaking surgical sperm retrieval. 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 surgical sperm retrieval funded by NHS England, cryopreservation and storage of sperm will be funded for up to 3 years. Where an eligible patient has undergone successful surgical sperm retrieval funded by NHS England, usual progress is to IVF/ICSI which will be funded as per section 11 of this policy.

Access to assisted reproductive treatments cont.	
14. Surrogacy	Assisted reproductive treatments involving surrogates are not routinely funded.
15. Novel technologies and treatment add-ons	Treatment add-ons with limited evidence (as outlined on the HFEA website), are not funded by the ICB including: • embryo 'glue' • assisted hatching • blood test for Y chromosome deletion

1. "A multiple birth is the single biggest risk of IVF for both mothers and babies" (HFEA).

Provider responsibilities

The NHS-funded specialist fertility unit providing the care will be solely responsible for, initial consultation, follow up consultation, and counselling sessions, all ultrasound scans and hormone assessments during the treatment cycle, oocyte recovery, embryo, or blastocyst transfer, all embryology including sperm preparation, a pregnancy test, and a maximum of two scans to establish the viability of the pregnancy. The commissioned provider of the IVF service will prescribe and supply the necessary drugs.

NB 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 should not prescribe any fertility drugs.

The specialist assisted reproduction treatments described in this document will be funded for infertile patients who meet the eligibility criteria set out in this document; all other assisted reproduction interventions are not normally funded.

Patients accessing assisted reproductive services should be fully informed of likely success rates of treatments and alternative approaches to parenting, including fostering and adoption.

Patients should also be advised that impartial advice and information is available via the Human Fertilisation and Embryology Authority (HFEA) which regulates assisted reproductive therapies.

NOTES:

- Potentially exceptional circumstances may be considered by a patient's ICB where there is evidence of significant health status impairment (e.g. inability to perform activities of daily living) and there is evidence that the intervention sought would improve the individual's health status.
- This policy will be reviewed in the light of new evidence or new national guidance, e.g., from NICE.
- BOBFPC clinical policies can be viewed at Clinical Commissioning Policies & IFRs | BOB ICB

Version	Date	Reason for change
Version	November 2013	Legacy policy
Version	November 2017	Update to wording of 'definitions' and 'provider responsibilities' only, to reflect contract specification, no change to referral criteria.
Version	November 2019	New additions to the policy; inclusion of not normally funded position for surrogacy and the inclusion of single women for funding of reproductive services. Other updates are clarifications to the current policy wording.
Version	October 2020	Minor amendment to reflect NHS England Commissioning responsibility for SSR.
Version	November 2023 v3.0	Policy review and update; amendment of AI provision and reformatting of the policy for clarity. No other key changes to commissioning position.
Version 4.0	n/a	Small amendment to terminology following feedback by Frimley ICB Equality, diversity and inclusion programme co-ordinator.

Appendix 1 – Flowchart illustrating patient pathway for assisted reproductive treatments using donor sperm