|  |  |
| --- | --- |
| Policy Number | **MSEICB 077** |
| Policy Name | **Tertiary Fertility Services** |
| Status | **Individual Prior Approval** |
| Effective Date | 1 April 2023 |
| Next Review Date | 1 April 2024 |

Mid and South Essex ICB commission [Assisted Conception using IVF/ICSI for Infertility](#Index) in accordance with the criteria defined in this policy.

In creating this policy, the ICB has reviewed this clinical condition and the options for its treatment. It has considered the place of this treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources.

Assisted conception is the name given to treatments that can help a woman get pregnant without the need for sexual intercourse. There are a variety of treatments, and what is suitable for each individual will depend on their particular circumstances.

The interventions referenced in this policy are:

* Intrauterine Insemination (IUI)
* In vitro fertilisation (IVF)
* IVF with intracytoplasmic sperm injection (ICSI)
* The use of donor sperm (donor insemination) or eggs (egg donation)
* Sperm Retrieval - testicular sperm extraction (TESE) and percutaneous epididymal sperm aspiration (PESA)
* Surrogacy

Certain forms of assisted reproduction (IVF, ICSI, donor insemination and egg donation) are regulated by law and their use is controlled by the [Human Fertilisation and Embryology Authority](https://www.hfea.gov.uk/) (HFEA).

This policy document defines the arrangements for funding of this treatment for the people ordinarily resident in the UK and registered with a GP with Mid and South Essex ICB.

**Treatments excluded from this policy:**

* Pre-implantation Genetic Diagnosis and associated IVF/ICSI. This service is commissioned by NHS England
* Donor eggs used to avoid transmission of inherited disorders to a child, are also commissioned by NHS England via a Pre-implantation Genetic Diagnosis and associated IVF/ICSI.
* Specialist Fertility Services for members of the Armed Forces are commissioned separately by NHS England

For Egg and Sperm storage associated with fertility preservation- see [Sperm, Embryo or Oocyte Cryopreservation](https://www.midandsouthessex.ics.nhs.uk/content/uploads/2022/09/A.-JC-FP001-Mid-South-Essex-STP-SRP-v1.2-July-2019.docx) policy

**Referrals**

* Referrals to fertility specialist services must be made by the secondary care provider following prerequisite investigations or treatments required, which may be undertaken at either the primary level or secondary level as appropriate.
* The agreed referral forms will need to be completed and include information such as any investigations, information on patients and clearly state whether the patient is eligible for specialist treatment.

All referrals must be individually approved for funding prior to referral.

1. **Eligibility for Fertility Treatment**

Couples must have experienced unexplained infertility for two (2) years or more of regular unprotected sexual intercourse or they are using artificial insemination to conceive and have not become pregnant after 6 cycles.

For couples with a diagnosed cause of infertility, as listed below, there is no time criterion and therefore can be referred for assessment for assisted conception if they meet all the required criteria.

1. Tubal damage, which includes:
   1. Bilateral salpingectomy
   2. Moderate or severe distortion not amenable to tubal surgery
2. Premature Menopause (defined as amenorrhoea for a period more than 6 months together with a raised FSH (follicle stimulating hormones) >25 and occurring before age 40 years)
3. Male factor infertility. Results of semen analysis conducted as part of an initial assessment.should.be.compared.with.the.following.World.Health.Organization reference values\*:
   1. semen volume: 1.5 ml or more
   2. pH: 7.2 or more
   3. sperm concentration: 15 million spermatozoa per ml or more
   4. total sperm number: 39 million spermatozoa per ejaculate or more
   5. total motility (percentage of progressive motility and non-progressive motility): 40% or more motile or 32% or more with progressive motility
   6. vitality: 58% or more live spermatozoa
   7. sperm morphology (percentage of normal forms): 4% or more.
4. Ovulation problems adequately treated but not successfully treated i.e., no successful pregnancy achieved
5. Endometriosis where Specialist opinion is that IVF is the correct treatment
6. Patients meeting the criteria defined in the Sperm, Embryo or Oocyte Cryopreservation Policy.
7. **Additional Criteria**

**In addition to the above eligibility criteria, ALL the following criteria must also be met:**

* Both individuals in the couple must be ordinarily resident in the UK and have been registered with a GP within Mid and South Essex ICB for a minimum of 12 months
* The woman or person assigned female at birth must be between their 23rd and 42nd birthday, with a BMI of more than 19kg/m2 and less than 30kg/m2
* The man or person assigned male at birth must have a BMI of less than 35kg/m2.
* There should be no surviving children from this relationship including adopted children but excluding fostered children. There should be no children from previous relationships. There is an explicit and recorded assessment that the social circumstances of the family unit have been considered within the context of the assessment of the welfare of the child.
* The welfare of any resulting children is paramount. In order to take into account, the welfare of the child, the clinician should consider factors which are likely to cause serious physical, psychological or medical harm, either to the child to be born or to any existing children of the family. This is a requirement of the licencing body, Human Fertilisation and Embryology Authority (HFEA).
* If any fertility treatment results in a surviving child, then the couple will no longer be considered childless and will not be eligible for further NHS funded fertility treatments, including the implantation of any stored embryos. Any costs relating to the continued storage of the embryos beyond the first calendar year of the retrieval date is the responsibility of the couple.
* Both partners must be confirmed non-smokers
* Written consent to treatment is required from both partners
* Neither partner has been sterilised

1. **Intrauterine Insemination (IUI) and Donor Insemination (DI)**

IUI and DI are separate from IVF treatment; however, the couple may then access IVF treatment if appropriate.

For the purposes of this policy:

**Donor insemination** is defined as the placement of donor sperm into the vagina or cervix and is not funded.

**Intrauterine insemination** is defined as the clinical delivery of sperm into the uterine cavity.

IUI in same-sex relationships: Up to 6 cycles of IUI must be self- funded a treatment option for people in same-sex relationships, followed by further assisted conception if required

People with unexplained infertility, mild endometriosis, or mild male factor infertility, who are having regular unprotected vaginal sexual intercourse: IUI either with or without ovarian stimulation will not be funded routinely; instead, couplesshould try to conceive for a total of 2 years (this can include up to 1 year before their fertility investigations) before IVF will be considered. Couples must meet all criteria as defined in this policy.

**3.1 Donor Sperm**

The availability of donor sperm is currently limited in the UK. The patient may be able to provide a sperm donor, alternatively patients who require donor sperm will be placed on the waiting list for an initial period of 3 years, after which they will be reviewed to assess whether the fertility policy eligibility criteria are still met.

The ICB will fund the use of up to a maximum of one batch of donor sperm. If either of the couple exceeds the age criteria prior to donor sperm becoming available, they will no longer be eligible for treatment.

**3.2 Donor Eggs**

Patients are eligible for donor eggs if they have undergone premature ovarian failure (amenorrhoea >6 months and a raised FSH >25) due to an identifiable pathological or iatrogenic cause before the age of 40 years.

Unfortunately, the availability of donor eggs remains severely limited in the UK. The patient may be able to provide an egg donor; alternatively, the patient will be placed on the waiting list for an initial period of 3 years, after which they will be reviewed to assess whether the fertility policy eligibility criteria are still met. The ICB will fund the use of up to a maximum of six donor eggs. If either of the couple exceeds the age criteria prior to a donor egg becoming available, they will no longer be eligible for treatment.

1. **Intracytoplasmic sperm injection ICSI**

For some Patients, their sperm are not capable of fertilising eggs in the usual way. If this is the case, they and their partner may be offered a procedure called intracytoplasmic sperm injection (ICSI), in which a single sperm is injected directly into an egg. Patients should only be offered ICSI if:

* there are few sperm in their semen, or they are of poor quality, OR.
* there are no sperm in their semen (either because of a blockage or another cause) but there are sperm in their testes which can be recovered surgically, OR.
* they have already tried IVF but there was poor or no fertilisation of the eggs. In these situations,

ICSI increases the chance of fertilising eggs compared with IVF used on its own. However, it does not make any difference as to whether this will lead to a successful pregnancy. If a man/ person assigned male at birth is unable to ejaculate, it is possible to obtain their sperm using surgical sperm recovery (this procedure is not covered by this policy). They should be offered the chance to freeze some of their sperm for possible use at a later date.

1. **Gametes and Embryo Storage**

The cost of egg and sperm storage will be included in the funding of treatment for which it is required, to be commissioned in accordance with this policy and the funding policy of the ICB Storage will be funded by the ICB for a maximum of 3 years or until four embryo transfers have been undertaken or until 6 months post successful live birth, whichever is the shorter. Following this period continued storage may be self-funded.

Patients should be advised at the start of treatment that this is the level of service available on the NHS and following this period continued storage will need to be funded by themselves or allowed to perish.

Any embryo storage funded privately prior to the implementation of this policy will remain privately funded.

1. **In-Vitro Fertilisation (IVF)**

**Women before their 40th birthday**

A woman or person assigned female from her 23rd birthday but before her 40th birthday will be funded for a maximum of 4 embryo transfers (fresh and frozen) obtained from a maximum of 2 cycles of IVF, with or without ICSI, which includes any abandoned/cancelled cycles (as defined) if:

* they have a diagnosed cause of infertility

OR

* they have been trying to get pregnant through regular unprotected sexual intercourse for a total of two (2) years

OR

* they are using artificial insemination to conceive and have not become pregnant after six (6) cycles of intrauterine insemination

AND

* there is no evidence of low ovarian reserve (defined as FSH 9 IU/l or more (using Leeds assay); OR antral follicle count of 4 or less; OR AMH of 5 pmol/l or less

**Women and people assigned female at birth before their 43rd birthday.**

A woman or person assigned female at birth from their 40th birthday but before their 43rd birthday will be funded a maximum of two (2) embryo transfers (fresh and frozen) obtained from a maximum of one (1) cycle of IVF, with or without ICSI, which includes any abandoned/cancelled cycles (as defined) if all of the following apply:

* they have a diagnosed cause of infertility

OR

* they have been trying to get pregnant through regular unprotected sexual intercourse for a total of one (1) year

OR

* for same sex couples they have not become pregnant after six (6) cycles of intrauterine insemination.

AND

* there is no evidence of low ovarian reserve (defined as FSH 9 IU/l or more (using Leeds assay); OR antral follicle count of 4 or less; OR AMH of 5 pmol/l or less
* there has been a discussion of the additional implications of IVF and pregnancy at this age

1. **Outline of IVF cycle**

IVF involves four basic steps: ovarian stimulation, egg collection, insemination and finally embryo transfer.

Under this policy, all stored and viable embryos from an IVF treatment cycle up to the maximum number of embryos according to age as defined must be used before a new IVF treatment cycle (stimulation/egg collection/insemination) will be funded. This includes embryos resulting from previously self-funded cycles. Where maximum number of embryos according to age have been transferred, no further IVF treatment cycles will be funded.

**7.1 Frozen Embryo**

Embryos that are not used during the fresh transfer should be quality graded using the UK NEQAS embryo morphology scheme and may be frozen for subsequent use.

**7.2 Abandoned/Cancelled Cycles**

An abandoned/cancelled IVF/ICSI cycle is defined as the failure of egg retrieval, usually due to lack of response (where less than three mature follicles are present) or excessive response to gonadotrophins; failure of fertilisation and failure of cleavage of embryos. Beyond this stage, a cycle will be counted as complete whether or not a transfer is attempted. If a cycle is commenced and ovarian response is poor, a clinical decision would need to be taken as to whether a further cycle should be attempted, or if the use of a donor egg may be considered for further IVF cycles

**7.3 Age of person intending to become pregnant**

Age as a criterion for access to fertility treatments is applied in line with the NICE Clinical Guideline on Fertility which is based on a comprehensive review of the relationship between age and the clinical effectiveness of fertility treatment. The patient intending to become pregnant must be between the ages of 23 – 42 years (as defined in this policy) to be eligible for NHS funding. No embryo transfers (fresh or frozen) will be funded on or after the patient’s 43rd birthday. Referrers should be mindful of the patient’s age at the point of referral and the age limit for new cycle.

**7.4 Number of cycles and embryo transfers funded**

Women and people assigned female at birth from their 23rd birthday and before their 40th birthday will be funded for a maximum of 4 embryo transfers (fresh and frozen) obtained from a maximum of 2 cycles of IVF, with or without ICSI, which includes any abandoned/cancelled cycles. All viable embryos from each cycle must be used before a further cycle will be funded, and then only if the maximum of 4 embryo (fresh and frozen) transfers has not been exceeded.

Women and people assigned female at birth aged from their 40th birthday and before their 43rd birthday will be funded a maximum of two (2) embryo transfers (fresh and frozen) obtained from a maximum of one (1) cycle of IVF, with or without ICSI, which includes any abandoned/cancelled cycles.

Where couples have previously self-funded a cycle then the couples must utilise any previously frozen embryos as part of the NHS funded embryo transfers, rather than undergo ovarian stimulation, egg retrieval and fertilisation again. Previous IVF cycles, whether self- or NHS-funded, will count towards the total cycles of IVF. No new cycle or embryo transfers will be funded after the patient’s 43rd birthday.

**7.5 Single Embryo Transfer**

Fresh embryo(s) transfer to the uterus constitutes one transfer and each subsequent transfer to the uterus of frozen embryos would constitute another transfer.

Multiple births are associated with greater risk to mothers/ birthing partners and children and the HFEA therefore recommends that steps are taken by providers to minimize them. This is currently achieved by only transferring a single embryo for couples who are at high risk.

We support the HFEA guidance on single embryo transfer. All providers are required to have a multiple births minimisation strategy.

We commission ultrasound guided embryo transfer in line with NICE Fertility Guideline.

Embryo transfer strategies:

* For women and people assigned female at birth before their 37th birthday only one embryo or blastocyst to be transferred in the first cycle of IVF and for subsequent cycles only one embryo/blastocyst to be transferred unless no top-quality embryo/blastocyst available then no more than 2 embryos to be transferred
* For women and people assigned female at birth from their 37th birthday and up to but not including their 39th birthday only one embryo/blastocyst to be transferred unless no top-quality embryo/blastocyst available then no more than 2 embryos to be transferred.
* For women and people assigned female at birth from their 40th birthday and up to but not including their 43rd birthday consider double embryo transfer.
* No embryo transfers will be funded from their 43rd birthday.

1. **Surgical Sperm Recovery**

Surgical sperm retrieval methods included for service provision are testicular sperm extraction (TESE) and percutaneous epididymal sperm aspiration (PESA).

Micro surgical Sperm recovery is not routinely funded.

Surgical sperm recovery will not be funded for patients who have undergone a vasectomy.

1. **Surrogacy**

There are two types of surrogacies:

Full surrogacy (also known as host or gestational surrogacy) is when the eggs of the intended mother or a donor are used and there is therefore no genetic connection between the baby and the surrogate.

Partial surrogacy (also known as straight or traditional surrogacy) involves the surrogate’s egg being fertilised with the sperm of the intended father. If you go down this route, we recommend you have treatment at a licensed UK fertility clinic.

Surrogacy is not funded. This includes part funding during a surrogacy cycle