NHS
Black Country
Integrated Care Board

Assisted Conception

ICB/SC/084/04/V1.1

VERSION	DATE	AMENDMENT HISTORY
ICB/SC/084/04/V1.0	April 2023	Unique identifier issued and accessibility checked

REVIEWERS

This document has been reviewed by:

VERSION	DATE	NAME	TITLE/RESPONSIBILITY
1.0	May 2022	CPDG	
	February 2022	Dr Geeta Nargund	Medical Director, Create Fertility
	February 2022	Kirk Vian	Finance Director, Create Fertility
1.1	November 2025	Ananta Dave	Chief Medical Officer

APPROVALS

This document has been approved by:

VERSION	DATE	COMMITTEE
1.0	26th May 2022	BCWB CPDG
ICB/SC/084/04/V1.0	8th September 2022	ICB Strategic Commissioning Committee
ICB/SC/084/04/V1.1	3 November 2025	Peter McKenzie, Head of Corporate Governance Programme (Minor Amendment to reflect updated review date and clarification on review arrangements)

RELATED DOCUMENTS

These documents will provide additional information:

DOCUMENT TITLE	VERSION
BCWB Policy: Provision of NHS Funded Gamete Retrieval and Cryopreservation	1.0
BCWB Policy: Patient Choices	1.2

APPLICABLE LEGISLATION AND OTHER RELEVANT EXTERNAL DOCUMENTS

NHS England: The S2 funding Route
NICE CG156. Fertility Problems, Assessment and Treatment

GLOSSARY OF TERMS

ACRONYM	TERM
See Definitions, Appendix 1	

REVIEW DATE

April 2026 (See Below)

Black Country Integrated Care Board (BC ICB) Assisted Conception Clinical Policy Commissioning Statement

The Black Country Integrated Care Board (BC ICB) acknowledges the current Assisted Conception Commissioning Policy was scheduled for review in September 2025. However; given the National Institute for Health and Care Excellence (NICE) is undertaking its own review of the Fertility problems: assessment and treatment Guidance (CG156), the BC ICB Clinical Policy Development Group will pause the policy development and now intends to review the BC ICB Harmonised Assisted Conception Policy in the Spring of 2026, following the expected publication of NICE update 1 and 2 guidance in March 2026.

The BC ICB will take into consideration any new published guidance and ensure a thorough review of the current policy and eligibility criteria whilst reflecting the ICB's commitment to delivering a high level of quality care, reducing inequalities in health and healthcare, and remaining fiscally responsible.

Assisted Conception

INTRODUCTION

There are 6 key reasons for why Commissioning Policies may be required, which are: -

1. Good quality evidence indicates that the treatment does not work. These treatments should not be recommended or provided to patients in any setting.

2. The treatment is experimental. These treatments should not be provided to patients outside of a clinical study. If not funded as part of a study, they should not be provided. There are exceptions to this rule, and these are managed either through policy or the Individual Funding Request process.

3. The treatment is unproven. This is where the treatment has some evidence of benefit from good quality studies, but these are insufficient to indicate how the treatment should be use, when and in whom. As with the above, further evidence is needed before a decision can be made as to how the treatment will be moved into normally commissioned care.

4. The treatment works, but provides marginal health benefit, or the value that is placed on the benefit is considered lower when compared against other competing demands.

5. The treatment works, but the cost of the treatment means that it is not cost-effective such that by funding the treatment, the ICB will overall, deliver less health benefit to the population than by funding other treatments or services to the equivalent funding level.

6. The treatment has been difficult to contain at an affordable level.

DOCUMENT STATUS

This is a controlled document. Whilst this document may be printed, the electronic version posted on the intranet is the controlled copy. Any printed copies of the document are not controlled.

The ICB policy has been originally reviewed and developed by Sandwell and West Birmingham CCG, in partnership with BSol CCG.

The guiding principles of the Clinical Policy Development Group are:

1. Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment;

2. Commissioners require clear evidence of cost effectiveness before NHS resources are invested in the treatment;

3. The cost of the treatment for this patient and others within any anticipated cohort is a relevant factor;

4. Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment;

5. Commissioners will balance the needs of each individual against the benefit which could be gained by alternative investment possibilities to meet the needs of the community.

6. Commissioners will consider all relevant national standards and take into account all proper and authoritative guidance;

7. Where a treatment is approved Commissioners will respect patient choice as to where a treatment is delivered; AND

8. All policy decisions are considered within the wider constraints of the ICB's legal duty to remain fiscally responsible.

Contents

1.0 Commissioning Statement

Access to Assisted Conception is **Restricted** to individual females and/or couples, who meet the **Eligibility Criteria** outlined below.

Treatment is limited to **ONE** cycle of single treatment, defined as one cycle of IVF (In Vitro Fertilisation) or ICSI (Intra-Cytoplasmic Sperm Injection), using a fresh embryo.

NB: NHS funding of Intrauterine Insemination (IUI) or Donor Insemination, for up to 6 cycles, is additionally funded in patients with a permanent physical disability, as outlined in Section 2.10.4

2.0 Eligibility Criteria

Individuals/ Couples need to meet all the following criteria to qualify for treatment

2.1 Age

2.1.1 Females

- The female must be under the age of 40 at time of treatment
- Referral for treatment should be made on/ before the female's 39th birthday, to ensure all investigations can be completed

2.1.2 Males

- Male partners must be under 55 years of age

2.2 Childlessness

- Neither couple have living children of any age
- This includes any adopted children and children (either biological or adopted) from either the current or previous relationships

Note: once accepted for treatment, should a pregnancy leading to a live birth occur, or a child be adopted, the individual/ couple are no longer deemed childless and no longer qualify for NHS fertility treatment.

2.3 Previous Infertility Treatment

- Neither partner has had infertility treatment (IVF or ICSI) previously
- Previous treatment includes both NHS and privately accessed

2.4 Sterilisation

- Neither partner within the couple has undergone a sterilisation procedure (including sterilisation as part of their gender reassignment procedure).
- Neither partner has undertaken a reversal of sterilisation

2.5 Body Mass Index

- Both males and females have a BMI <30kg/m2
- This weight applies **both** at point of referral and treatment

2.6 Smoking (includes Vaping)

- The female (or couple) are both non-smokers
- This includes no use of vaping devices
- Any previous smoking has stopped **at least 3 months** prior to referral

2.7 Recreational Drug Use

- Females or couples do not take recreational drugs, such as cocaine, cannabis or heroin, and have not done so in the last 12 months
- Females/ couples are not registered on a substance misuse programme, or in the last 12 months

2.8 Welfare Concerns for future children

- There are no welfare concerns for any resulting children
- Considerations include risk of serious physical, psychological or medical harm, to either the unborn child or existing children of the family (as per the HFEA, licensing body in the UK for fertility treatment)

2.9 Compliance with Treatment

- The referring clinician has no concerns with patient's adherence to medication, particularly fertility drugs

2.10 Demonstrated absence of fertility

NB: Where clinical infertility is identified in a female from the age of 20 years old, NHS Infertility Treatment should be offered without delay (provided other Criteria 2.1 – 2.9 and 2.11 are met).

2.10.1 ALL patients

- The presence of known **Reproductive Pathology** (as defined in Appendix 1)

2.10.2 Heterosexual Couples

EITHER

- Failure to conceive after TWO years of regular unprotected sexual intercourse

and

- The ***absence*** of known reproductive pathology

OR

- Failure to conceive after ONE year of regular unprotected sexual intercourse

and either

- Presence of known factors identified at 1 year by GP, namely semen analysis (male partners) and FSH/ progesterone level (females)

or

- **Known** reproductive pathology reducing the chances of natural conception

2.10.3 Female same-sex couples and single women

- Failure to conceive after a minimum of six rounds of self-funded IUI (intrauterine insemination) **and**
- Absence of any known Reproductive Pathology
- IUI needs to have been undertaken at an HFEA-accredited facility

If only one partner is subfertile, the other partner should be approached to be the biological parent.

2.10.4 Couples where one partner has a known permanent physical disability

Either

- The male partner has an infection requiring sperm-washing (e.g. HIV)

or

- A partner has a permanent physical disability preventing natural conception from occurring

AND EITHER

- The couple have failed six rounds of NHS-funded IUI/ DI (donor insemination)

OR

- IUI/ DI is not clinically appropriate (e.g. one/ both partners have a known condition listed in Appendix 1, which prevents or greatly reduces successful conception)

2.11 GP Registration in the Black Country ICS

- Both partners need to be registered with a GP practice located within the Black Country ICS footprint

3.0 Exclusions from Policy

3.1. In-Vitro Maturation (IVM)

IVM is not routinely commissioned, on the grounds this is classified as an experimental/ unproven treatment.

3.2 Single males/ male same-sex couples

Surrogacy is **not** funded by the Commissioner.
This includes any fertility treatments related to delivering the surrogacy arrangement.

3.3 Pre-implantation Genetic Diagnosis (PiGD) (now known as PGD-M, Preimplantation Genetic Testing for Monogenic/ Single Gene Defects)

This is the commissioning responsibility of NHS England.

Patients should be referred to the Genetic Centre at Birmingham Women's and Children's Hospital.

3.4 Funding for Military Serving Personnel

Assisted conception for current serving personnel and their partners is covered by NHS England's Service-Specific Policies.

NHS England are also responsible for commissioning services to veterans in receipt of compensation for injury during service (i.e., WIS – Wounded, Injured and Sick Cohort)

- Who require access to fertility treatment
- Loss of fertility to themselves or their partner is attributed to their injury

NB: Veterans ***without*** **injury impacting on fertility** are the commissioning responsibility of ICBs/ ICSs and the contents of this policy apply.

3.5 Part-funding of cycles

The Commissioner will not part-fund nor co-fund assisted conception/ infertility treatment for individuals or couples that are ineligible or eligible for NHS-funded service under this policy, save for any explicit exemptions outlined in Sections 2 – 4 of the Policy.

4.0 Special Considerations (e.g. donor gametes, treatment interruption)

4.1 NHS Funding of Donor Gametes

4.1.1 Donor Sperm

Up to six cycles of Donor Insemination (dependent on availability of donor sperm) will be commissioned for heterosexual couples where the male partner has azoospermia or oligospermia.

4.1.2 Donor Eggs

Donor eggs will be funded in line with NICE recommendations, i.e.

- The patient has **premature ovarian failure**, defined as
  - Aged under 35 years **and**
  - Ovulation and menstruation no longer occur, and underlying cause is unknown **and**
  - Ovarian failure has been confirmed by measuring the ovarian reserve

As there is a limited supply of donor eggs, couples may experience long delays in commencing treatment. Patients will be placed on the waiting list for an initial period of 12 months, after which time they will be annually reviewed to ensure they continue to meet the Eligibility Criteria in Section 2.

4.2 Needing to convert from Fresh to Frozen Embryo Transfer (FET)

If transfer of fresh embryos is unable to take place for a clinical reason, the Commissioner will fund **one transfer** of frozen embryos.

The conditions for switching patient treatment to a “Freeze All”/ FET are: -

- If the success of a fresh embryo is compromised
- If the wellbeing of the child or mother is at risk
- If the patient develops an infection or bleeding, following extraction, thereby making a fresh transfer inappropriate

Further underpinning reasons include:

- OHSS (ovarian hyperstimulation syndrome)
- A significantly high risk of premature birth or low birth weight

4.3 Remaining embryos following fresh transfer

- Unused embryos left over, following fresh transfer will be quality graded, using the UK NEQAS embryo morphology scheme and may be frozen for subsequent use
- Cryopreservation and storage of any suitable surplus embryos following a completed NHS-funded cycle will be stored for 12 months, in line with HFEA (the Regulator) guidelines, and funded by the tertiary treatment provider
- After this period of 12 months is complete, ongoing storage will need to be self-funded by the woman/ couple

4.4 Use of previously stored gametes

If cryopreserved gametes are available in line with the current Commissioner Policy for Gamete Retrieval and Cryopreservation, these gametes may be used for NHS funded IVF treatment under specialist clinical input, where patients meet the Eligibility Criteria of this policy.

4.5 Failed or Abandoned Cycles

An IVF cycle may fail at any stage prior to embryo transfer to the uterus: e.g.

- Ovarian stimulation failure
- Failure to retrieve ova
- Failure to fertilise an embryo
- Embryonic developmental failure

These are known risks of treatment, which should be explained to the patient.

Should any issues arise, the treatment cycle will have failed; the Commissioner will **not** fund any further cycles of IVF or ICSI.

4.6 Intrauterine Insemination (IUI) and Donor Insemination (DI)

IUI and DI will only be commissioned for the cohort as outlined in 2.10.4.

If 6 cycles of NHS funded IUI/ DI are unsuccessful, IVF/ ICSI will be funded for patients who meet the Eligibility Criteria

4.7 Treatment Interruptions

Patients who are deemed at point of referral to meet the Eligibility Criteria, will receive treatment under the Specialist if in their clinical opinion, treatment is considered to still be appropriate.

Where there are unavoidable delays to treatment (e.g. due to Covid/ other sickness), the patient will ***remain*** in the system until the treatment is successfully expedited or the 1 commissioned cycle is deemed unsuccessful.

4.8 Treatment Abroad (EU states)

The main process for accessing treatment in European states or Switzerland is limited to the S2 Route, and only enables access to state-funded treatment.

You may be liable for a co-payment, i.e. you may have to pay costs upfront.
Travel and accommodation costs are not refundable.

You would also need to meet the Eligibility Criteria in Section 2.

NHS England would need to be satisfied that the same or equivalent treatment cannot be provided on the NHS within a medically justifiable timeframe.

Application for funding via the S2 route needs to be made upfront.

Please visit the following link for more information: The S2 funding route - NHS (www.nhs.uk)

5.0 Background

Infertility is when a couple cannot conceive (get pregnant) despite having regular unprotected vaginal sexual intercourse. A woman of reproductive age who has not conceived after 1 year of unprotected vaginal sexual intercourse, in the absence of any known cause of infertility, should be offered further clinical assessment and investigation along with her partner. Infertility can be primary in people who have never conceived, or secondary, in people who have previously conceived. It is estimated that infertility affects one in six heterosexual couples in the UK.

The causes of primary infertility in the UK occur in the following approximate proportions:

- unexplained infertility (no identified male or female cause), 25%
- ovulatory disorders, 20%
- tubal damage, 15%
- factors in the male causing infertility, 30%
- uterine or peritoneal, 10%

In about one third of cases, disorders are found in both the man and the woman.

Other factors may play a role, including uterine or endometrial factors, gamete or embryo defects, and any other pelvic condition such as endometriosis.

Over 80% of heterosexual 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%).

6.0 Aims and Scope

This policy applies to all patients for whom the Black Country Integrated Care System (ICS) has responsibility. If a couple are requesting assisted conception treatment, then BOTH partners in the couple must be registered with a Black Country GP. The couple are considered a single unit and to properly assess and treat, they both need to be registered patients within BC ICB.

Where a patient's clinical presentation does not clearly meet the requirements for secondary care referral within the context of this policy, and where a GP is uncertain or concerned about the appropriate treatment/management pathway, a GP Advice & Guidance request should be considered as an alternative to a referral for clinical assessment.

There may be occasions when a GP referral is made for specialist assessment which appears to meet the policy requirements, but which on specialist clinical examination either does not meet the clinical criteria or is not considered clinically suitable for intervention.
Such patients should be informed of the decision made by a specialist in secondary care to discharge without intervention.

For patients who do not fall within the eligibility criteria set out in the policy (Sections 3 & 4 with reference to the Definition section set out at Appendix 1), but where there is demonstrable evidence that the patient has exceptional clinical circumstances, an Individual Funding Request may be submitted for consideration.

This policy applies to patients experiencing difficulty with conception who are being managed on an NHS pathway of care.

7.0 Principles of care

Couples who experience problems in conceiving should be seen together because both partners are affected by decisions surrounding investigation and treatment.

Both partners, or the individual if the individual alone is requesting infertility treatment, must have Black Country ICB as their responsible commissioner.

People should have the opportunity to make informed decisions regarding their care and treatment via access to evidence-based information. These choices should be recognised as an integral part of the decision-making process.

Information should be provided in the following formats:

- Face to face discussions with couples
- Written information and advice
- Culturally sensitive
- Be sensitive to those with additional needs e.g. physical or cognitive, or sensitive disabilities, or those who do not speak English
- As infertility and infertility treatments have a number of psycho-social effects on couples, once referred to a specialist tertiary centre for fertility treatment, access to counselling prior to and during treatment should be considered as integral to the care pathway
- Providers of specialist fertility services are expected to deliver appropriate interventions to support lifestyle behaviour changes which are likely to have a positive impact on the outcome of assisted conception techniques and resulting pregnancies. Recommendations covering screening, brief advice and onward referral are outlined in NICE Public Health Guidance (PH49) and, specifically in relation to fertility and pre-conception, smoking (PH 26, PH48), weight management (PH27, PH53), healthy eating and physical activity (PH11, NG7) and alcohol (PH24)
- Use any appointment or meeting as an opportunity to ask women and their partners about their general lifestyle including smoking, alcohol consumption, physical activity and eating habits. If they practice unhealthy behaviours, explain how health services can support people to change behaviour and sustain a healthy lifestyle

In a heterosexual couple trying to conceive, if primary care interventions (i.e. lifestyle advice) are not effective following one year of unprotected regular sexual inter-course in the absence of known reproductive pathology or disability, then the couple should
be offered the following initial assessments in primary care:

- Semen analysis
- Female Follicle Stimulating Hormone & Progesterone Levels

It would also be appropriate at this stage for the primary care clinician to discuss the care pathway and potential eligibility for fertility treatment with the couple.

Following these initial primary care diagnostics, if all results are within normal parameters, then the couple (as long as the woman is below the age of 38years) should be advised to continue with regular unprotected intercourse for a further year.

If, after a further year, conception has not taken place, then the couple should be referred to secondary care services for further investigations.

If initial diagnostics test results are abnormal then the couple should be referred to secondary care where further investigation and potential treatments will be carried out, such as hormonal therapies to stimulate ovulation. The couple should be advised again at this stage of the care pathway and potential eligibility criteria for IVF/ICSI treatment. It may also be appropriate for healthy lifestyle interventions to be reiterated

If secondary care interventions are not successful and the couple fulfils the eligibility criteria, they may then be referred through to tertiary care for assessment for assisted conception techniques where clinically appropriate if the couple meets the eligibility criteria set out in Section 2, such as, DI, IUI, IVF and ICSI.

People undergoing IVF treatment should be routinely offered testing for HIV/, hepatitis B and hepatitis C (NICE 2013). People found to test positive for one or more HIV, Hepatitis B or Hepatitis C should be offered specialist advice and counselling and appropriate clinical management (NICE 2013).

IUI involves:

- High quality sperm are separated from sperm that is sluggish or non- moving
- This sperm is then injected directly into the womb. IUI may be undertaken either with the woman's partner's sperm or donor sperm (known as donor insemination)

- It may be used in the treatment of:
  - People who need donated sperm but have no female fertility problems, including single women and same sex couples

  - Couples who are unable (or would find it very difficult) to have vaginal intercourse, for example because of a permanent physical disability. Those who have a condition which means they need specific help to get pregnant (for example, men who are HIV positive and have had sperm washing to reduce the risk of passing on the disease to their partner and potential child)

DI involves: The use of donor sperm or eggs to try and achieve a pregnancy

- It may be used in the treatment of:
  - Patients who are not producing sperm or eggs of their own
  - Patients where their own sperm or eggs are unlikely to result in a pregnancy
  - Patients who have a high risk of passing on an inherited disease
  - Patients in a same sex couple, or
  - Patients who are single

IVF involves:

- The use of drugs to switch off the natural ovulatory cycle.
- Induction of ovulation with other drugs
- Monitoring the development of the eggs in the ovary
- Ultrasound guided egg collection from the ovary
- Processing of sperm
- Production of a fertilised embryo from sperm and egg cells in the laboratory
- Use of progesterone to make the uterus receptive to implantation
- Transfer of selected embryos and freezing of those suitable but not transferred

ICSI involves:

- Exactly the same treatment as with IVF for the female partner.
- The only difference is that instead of mixing the sperm with the eggs and leaving them to fertilise, a skilled embryologist (embryo specialist) will inject a single sperm into the egg

- This maximises the chance of fertilisation taking place as it bypasses any potential problems the sperm will have in actually getting to the egg.
- The doctor may recommend ICSI if:
    - The man has a very low sperm count
    - The man's sperm are abnormally shaped (poor morphology) or they don't move normally (poor motility)
- The man requires sperm to be collected surgically from the testicles or epididymis (a narrow tube inside the scrotum where sperm are stored and matured); for example, because the man does not ejaculate sperm, or because the man has an extremely low sperm count

- The man is using frozen sperm in the treatment which isn't of the highest quality
- The couple require embryo testing for a genetic condition

Single Embryo Transfer

Multiple births are associated with greater risk to mothers and children, and the HFEA therefore recommends that steps are taken by providers to minimise multiple births. The Commissioner supports the HFEA guidance on single embryo transfer and will be performance monitoring commissioned tertiary providers to ensure that HFEA targets are met. All providers are required to have a multiple births minimisation strategy. The target for multiple births should now be an upper limit of 10% of all pregnancies.

8.0 References

1. NICE 2018. Fertility Overview https://pathways.nice.org.uk/pathways/fertility#path=view%3A/pathways/fertility/fertilit y-overview.xml&content=view-node%3Anodes-defining-infertility-and-criteria-for-assessment-and-referral
2. NICE 2017 Fertility problems CG 156 https://www.nice.org.uk/guidance/cg156/ifp/chapter/egg-donation
3. National Institute for Health and Care Excellence (NICE). Fertility: assessment and treatment for people with fertility problems. NICE clinical guideline CG156, February 2013. http://guidance.nice.org.uk/CG156
4. NICE (2014) NICE Public Health Guidance (PH49) Behaviour change: individual

approaches.
https://www.nice.org.uk/guidance/ph49
5. NICE (2010) NICE Public Health Guidance (PH26) Smoking: stopping in pregnancy and after childbirth.
https://www.nice.org.uk/guidance/ph26
6. NICE (2013) NICE Public Health Guidance (PH48) Smoking: acute, maternity and mental health services
https://www.nice.org.uk/guidance/ph48
7. NICE (2010) NICE Public Health Guidance (PH27) Weight management before, during and after pregnancy
https://www.nice.org.uk/guidance/ph27
8. NICE (2014) NICE Public Health Guidance (PH53) Weight management: lifestyle services for overweight or obese adults
https://www.nice.org.uk/guidance/ph53
9. NICE (2008) NICE Public Health Guidance (PH11) Maternal and child nutrition
https://www.nice.org.uk/guidance/ph11
10. NICE (2015) NICE Guideline (NG7) Preventing excess weight gain.
https://www.nice.org.uk/guidance/ng7
11. NICE (2010) NICE Public Health Guidance (PH24) Alcohol-use disorders: prevention.
https://www.nice.org.uk/guidance/ph24
12. De la Rochebrochard E, De Mouzon J, Thepot, F, Thonneau P. Fathers over 40 and increased failure to conceive: the lessons of in vitro fertilisation in France. *Fertil. Steril* **2006**; 85 (5): 1420 – 4. Doi: 10.1016/j.fertnstert.2005.11.040

9.0 Appendix 1 - Definitions

Term	Definition
Assisted Conception	The collective name for all techniques used artificially to assist conception and pregnancy, including In vitro fertilisation (IVF), Intra-cytoplasmic sperm injection (ICSI), Intrauterine insemination (IUI) and donor insemination (DI). These techniques are referred to as Infertility Treatment.
Female/Partner/Couple	Any reference to a female/partner/couple could relate to any of the following: • Heterosexual couple; a male and a female in a relationship; same sex female couple. A single female • Transgender male; biologically born as a female, gender reassigned to male, retention of female reproductive organs • Transgender female, biologically born as a male, gender reassigned to female, retention of male reproductive organs
Infertility	• A female of reproductive age, who has not conceived after 1 year of unprotected vaginal sexual intercourse, in the absence of any known cause of infertility, should be offered further clinical assessment (Follicle Stimulating Hormone & Progesterone levels) and investigation along with her partner (semen analysis). • Following the first year and clinical investigation: Where the cause of infertility is known, the couple should be referred to secondary care services without further delay for further investigation and treatment as clinically required. • In the absence of any known cause of infertility, and where the woman is below 38 years of age, the couple should be referred to secondary care services for further investigations and treatment after a further 1 year of regular unprotected vaginal sexual intercourse • A female who has a known cause of infertility, • e.g. Turner Syndrome should be immediately referred for specialist assessment and where clinically indicated infertility treatment without delay. • In circumstances where the above definition cannot be applied, for example females in a same sex relationship, a single female, or a transgender male, infertility is identified where the female has not conceived after 6 cycles of self-funded donor or partner insemination, undertaken at a Human Fertilisation and Embryology Authority (HFEA) registered clinic, in the absence of any known medical cause of infertility.

Reproductive Pathology	Diagnosis of a recognised condition that renders a patient infertile or reduces fertility, including confirmed diagnosis of: • Polycystic Ovarian Syndrome (PCOS, including amenorrhea and oligomenorrhea) • Early onset of menopause • Complete amenorrhea • Endometriosis which has previously been surgically treated • Clinically significant fibroids • Pelvic Inflammatory Disease • Ovarian Failure including Turners syndrome and other genetic abnormalities • Azoospermia • Undescended testes • Tubal disorders and/or damage as a result of disease or trauma (e.g. blocked fallopian tubes, blocked seminal tubes); this does not include patients who have chosen to receive sterilisation surgery. • A permanent physical disability preventing vaginal sexual intercourse • Certain types of treatment (e.g. cytotoxic therapy) which permanently prevents the individual producing gametes (eggs/sperm) • Certain types of treatment (e.g. cytotoxic therapy) which permanently causes genetic abnormalities in the eggs/sperm/Oligozoospermia /Asthenozoospermia / Teraotozoospermia, or any combination of these. • Chronic Anovulation
One cycle of fertility treatment	A cycle will consist of ovulation induction, egg retrieval, fertilisation and one fresh embryo(s) transfer to the uterus, including all appropriate diagnostic tests, scans and pharmacological therapy.
In vitro Maturation (IVM)	In the IVM process, eggs are removed from your ovaries when they are still immature. They are then matured in the laboratory before being fertilised.
Sperm washing	Sperm washing has been developed for couples who wish to have a child where the male partner is HIV positive, but the female is HIV negative (referred to as HIV discordant status). The aim is to reduce the risk of HIV transmission by attempting to achieve pregnancy through insemination of sperm washed free of HIV rather than through unprotected intercourse. The technique used to do this is called **sperm washing** and rests on the observation that HIV infective material is carried in the fluid around the sperm (seminal fluid) rather than by sperm itself. The technique involves separating the HIV infected seminal fluid from the sperm by centrifugation and 'washing'. The 'washed' sperm is then combined with nutritional fluid, tested for HIV using a sensitive test called a 'PCR' assay and, provided this is negative, inseminated into the female partner when she is ovulating and most likely to become pregnant. In couples with fertility problems washed sperm can be used in other fertility treatments such as IVF.

10.0 Appendix 2 – Eligibility Criteria – Rationale and Evidence

Criteria	Criteria Description	Rationale	Evidence
2.1.1	Female Age must be under 40 at time of treatment. If the woman reaches the age of 40 during treatment, complete the cycle but do not offer further cycles	Consistent with NICE Guideline CG 156 (Fertility Problems: Assessment and Treatment) Reduction in treatment success with increasing maternal age Increased maternal and child complication rate with increasing age Maternal age Birth rate per embryo transferred using patient egg Under 35 32% 35 – 37 25% 38- 39 19% 40 – 42 11% Table 1: Live Birth rates (HFEA) per patient age band 2019	HFEA Fertility Treatment 2019: trends and figures. Published May 2021.
	The female patient should be aged 39 by the time of referral, i.e. at least 12 months before 40th birthday	Ensures relevant investigations can be completed, and treatment started as early as possible to maximise chances of successful treatment.	
2.1.2	Male Age - should be under 55 years of age	HFEA recommends sperm donors are well below this threshold -41 years of age. Men aged over 40 are half as likely to conceive with IVF compared to 30 year old men when their partner is aged between 35 and 39 years. Resource allocation – ensures NHS can pay for other treatments, within limits of financial budgets.	Rochebrochard E, *et al.* *Fertil Steril* 2006; 85 (5): 1420 – 4. Doi: 10.1016/j.fertnstert.2005.11.040.
2.2	Childlessness Neither couple have living children of any age	Resource allocation – ensures NHS can pay for other treatments within limits of financial budgets Ensures treatment prioritised to patients who have not had opportunity to be a parent	
2.3	Previous infertility treatment – neither partner has had infertility	Ensures NHS treatment is prioritised to those who have not been able to afford/ experience treatment previously	

	treatment previously		
2.4	Sterilisation – the patient has not been previously sterilised, nor had a reversal of sterilization	Sterilisation is offered as an irreversible means of contraception – standard protocols will usually advise that NHS funding isn't available to reverse the procedure, nor any consequent fertility treatment	
2.5	Body Mass Index – both partners should have a BMI below 30kg/m^2	Clinical evidence to demonstrate that a female BMI within this range improves pregnancy rates, reduces miscarriage and prevents preterm delivery. Men who have a BMI above 30 are likely to have reduced fertility arising from altered sperm quality and erectile function	Clark AM, Ledger W, Galletly C, Tomlinson L, Blaney F, Wang X, et al. Weight loss results in significant improvement in pregnancy and ovulation rates in anovulatory obese women. Hum Reprod 1995;10:2705–12. Clark AM, Thornley B, Tomlinson L, Galletley C, Norman RJ. Weight loss in obese infertile women results in improvement in reproductive outcome for all forms of fertility treatment. Hum Reprod 1998;13:1502– Kort HI, Massey JB, Elsner CW, Toledo AA, Mitchell-Leef D, Roudebush WE. Men with high body mass index values present with lower numbers of normal-motile sperm cells. Abstract no. P-355. Fertil Steril 2003;80 Suppl 3;S238. 90. Kort HI, Massey JB, Witt MA, Mitchell-Leef D, Durrance MH, Roudebush WE. Sperm chromatin integrity is related to body mass index: men presenting with high BMI scores have higher incidence of sperm DNA fragmentation. Abstract no. P-333. Fertil Steril 2003;80 Suppl 3;S232. Chung WS, Sohn JH, Park YY. Is obesity an underlying factor in erectile dysfunction? Eur Urol 1999;36:68–7
2.7	Recreational drug use – neither partner uses these, nor	Recreational Drugs interfere with male and female fertility. Impacts on overall success of treatment	Mueller BA, Daling JR, Weiss NS, Moore DE. Recreational drug use and the risk of primary infertility. Epidemiology 1990;1:195–200.

	has been enrolled on a substance misuse programme in the last 12 months.		Bracken MB, Eskenazi B, Sachse K, McSharry JE, Hellenbrand K, Leo-Summers L. Association of cocaine use with sperm concentration, motility, and morphology. Fertil Steril 1990;53:315–22.
2.8	Welfare concerns for future children – clinician has no concerns for unborn child nor existing children	This is a requirement taken directly from the licensing body for fertility treatment – HFEA (Human Fertilisation and Embryology Authority) Adopting this principle ensures that appropriate parent(s) are referred for specialist treatment	
2.9	Treatment Compliance The clinician has no concerns for patient compliance with the treatment, especially fertility drugs	Prescribed regimes for female patients to promote ovarian stimulation, are rigorous. Full compliance ensures patient's chances for success are optimised	
2.10.1 – 2.10.4	Absence of fertility demonstrated	These principles are generally commensurate with NICE CG156	
2.11	Both partners are registered with a Black Country GP	If a couple is applying for treatment, then both individuals need to be assessed for appropriate investigation and diagnosis.	