Commissioning Policy

Assisted Conception Treatment Policy

Criteria Based Access (CBA)

Date adopted: March 2025

Version: V8

Authorisation and document control

Name of policy:	Assisted Conception Treatment Policy
Job title of author:	Commissioning Manager-Elective Care
Name of sign off group:	CPRG

Equality and Engagement Impact Assessment	
Date Equality and Engagement Impact Assessment was completed:	03/03/2025

Consultation – not considered to be required after discussion with Engagement Team.	
Name of group	**Date considered**
Insert relevant individuals/forums consulted during policy development	

Authorisation	
Name of group	**Date approved**
Commissioning Policy Review Group	11/03/2025
System Quality Committee	Not applicable

Date of adoption	20/08/2015
Date of publication	March 2025
Review date.	September 2026
To be reviewed by (job title) Commissioning Manager -Elective Care	

Version control				
Version number	**Date**	**Summary of changes**	**Author/Editor**	**Approved by**
1	20.08.15	Adoption from PCT policy	IFR Manager	Integrated Governance and Quality Committee

2	16.08.16	Preference of using frozen embryos to fresh where available	IFR Manager	Agreed by Executive Nurse and Quality Lead
3	23.12.18	Reduction of number of assisted attempts from 3 to 2 Plain English Summary amended	Commissioning Manager-Planned Care. IFR Manager.	Quality and Governance Committee
4	5.06.19	Minor wording change 17.7 The patient will forfeit a cycle of IVF in the following circumstances: Cancelling treatment once started for non-medical reasons or avoidable circumstances. Termination of a viable foetus for non-clinical reason	Commissioning Manager Planned Care	Agreed by Marion Andrews-Evans and Mark Walkingshaw
5	13.06.19	Minor word changes to incorporate the new fertility preservation policy: 16. Surrogacy- reference to the fertility preservation policy 20. People undergoing NHS treatments which may render them infertile	Commissioning Manager Planned Care	Quality and Governance Committee
6	17.09.20	Review date changed to September 2022. Minor wording changes at 9. To clarify funding position where couples have undergone previous infertility treatment 17.1 Fuller definition of 2 treatment cycles Policy Statement. Additional information for GP prescribing	Head of Planned Care	ECCP
7	01.05.21	Clarification of wording Policy Statement re contracted providers and ICB contributions to privately funded care	Commissioning Manager Planned Care	Agreed by Marion Andrews-Evans and Mark Walkingshaw

8	11.03.25	Reformatting of policy to new template. Updating of criteria to include single women. Clarification of nicotine products under smoking section in criteria. Addition of a minimum residency duration. Review date of September 2026 agreed.	Assisted Conception policy working group	Agreed by Commissioning Policy Review Group

NHS Gloucestershire Integrated Care Board (ICB) **will fund** the following assisted conception treatments for infertile patients who meet the defined eligibility criteria set out in Section 5.

- A maximum of two opportunities to have an elective single embryo transferred (unless advised differently by the embryologist to a maximum of up to two). This is equivalent to up two cycles as defined in section 4.
- Where frozen embryos can successfully be developed, the ICB will fund implantation(transfer) of these in preference to new fresh embryos, for a second cycle.
- If no frozen embryos are available, women will receive one further fresh embryo to ensure they receive two implantation attempts.

NHS Gloucestershire Integrated Care Board (ICB), **does not routinely fund**

- Artificial insemination
- Intra-uterine insemination (IUI), except for defined patients who meet the clinical criteria for sub-fertility treatment included with this policy, whereby up to 3 cycles of IUI will be funded.
- Surgical sperm retrieval

All other assisted reproduction interventions are a **LOW PRIORITY** for NHS funding within Gloucestershire.

Detailed information regarding eligibility criteria for achieving funding of assisted conception treatments is provided within the main body of this document. These eligibility criteria do not apply to the management or referral of subfertile couples to secondary care, the circumstances for which are outlined in section 3.

1.0 Background

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 ICB and the eligibility criteria patients need to meet to access.

The overall aim of the policy is to support the commissioning of the highest quality, most clinically and cost effective and affordable fertility services, which maximises health outcomes in terms of live births and patient/baby safety.

Infertility can be primary, in people who have never conceived, or secondary, in people who have previously conceived. It is estimated that infertility affects 1 in 7 heterosexual couples in the UK. A typical Integrated Care Board may therefore expect to see around 230 new consultant referrals (couples) per 250,000 population per year. The causes of primary infertility in the UK occur in the following approximate proportions:

- male infertility 30%
- unexplained (no identified male or female cause) 25%
- ovulatory disorder 25%
- tubal disease 20%
- uterine or peritoneal disorders 10%

In about 40% 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 pelvic conditions such as endometriosis may also play a role.

NICE CG 156 advice:

People who are concerned about their fertility should be informed that over 80% of couples in the general population will conceive within 1 year if:

- The woman is aged under 40 years
- 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%).

Inform people who are using artificial insemination to conceive and who are concerned about their fertility that:

- Over 50% of women aged under 40 years will conceive within 6 cycles of intra-uterine insemination (IUI)
- Of those who do not conceive within 6 cycles of intrauterine insemination, about half will do so with a further 6 cycles (cumulative pregnancy rate over 75%).

2.0 Scope

The policy affects couples and individuals who have diagnosed or undiagnosed infertility, seeking assisted conception services.

- Patients will only be referred for NHS funded assisted conception services if they meet the eligibility criteria in this policy and when all appropriate tests and investigations have been successfully completed in primary and secondary care in line with NICE clinical guidelines.
- Patients should be advised that impartial advice and information is available via the Human Fertilisation and Embryology Authority which regulates assisted reproductive therapies.

- 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.

This document relates to the following assisted conception treatments (ACT):

- In vitro fertilisation (IVF), with or without intra-cytoplasmic sperm injection (ICSI)
- Intra-uterine insemination (IUI) using donor or partner sperm.
- Ovulation induction/gonadotrophin injections.
- Use of donor eggs and sperm.

The following are outside of the scope of this policy:

- Investigations for general fertility problems and the primary treatment of conditions found during such investigation.
- Pre-implantation Genetic Diagnosis (PGD) and the associated assisted conception services are not covered by this commissioning policy as they are the commissioning responsibility of NHS England (PGD policy 2014). Patients should be referred to the Genetic Centre at University Hospital Bristol.
- Interventions to prevent the transmission of blood borne viruses in fertile serodiscordant couples (e.g., sperm washing for people living with HIV).
- Couples/individuals who are potentially at risk of infertility through a NHS pathway and wish to undergo assisted conception treatment for the purpose of cryopreservation of semen, oocytes and embryos should be managed in accordance with the commissioning policy entitled "Fertility Preservation Policy".
- Novel treatments or research trial treatments are not included in this policy.

Surrogacy: The ICB does not fund treatments for surrogacy, or any associated treatments (including fertility treatments) related to those in surrogacy arrangements.

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 ICB will not make any contribution to privately funded care to cover the cost of treatment that the patient could have accessed on the NHS.

In general, patients who pay the immigration health surcharge (HIS) are not eligible for assisted reproductive treatments funded by the ICB. The ICB will comply with government guidance (2024) regarding these patients.

Funding for Military Serving Personnel

Assisted conception services for current serving personnel and their partners is contained with the specific NHS England policy at https://www.england.nhs.uk/commissioning/policies/ssp/, as NHS England are the responsible commissioner.

Veterans who are in receipt of compensation for loss of fertility (received as a result of service/partner of same) and require access to assisted conception treatments, are also the commissioning responsibility of NHS England https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2016/10/armed-forces-comms-intent-1617-1819.pdf

Gloucestershire ICB will direct clinicians and patients towards these policies to access central NHS England funding.

Veterans without relevant injury impacting on fertility are the commissioning responsibility of ICBs and the content of this policy applies.

3.0 Treatment Pathway

Primary care assessment and referral

- 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).

- Primary care management, in general, with health advice and reassurance is advised after 1 year of trying to conceive naturally. If pregnancy has not occurred, referral for specialist consultation and investigations is appropriate.

- 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 should be made aware of all eligibility criteria to access specialist assessment and investigations for infertility and assisted conception treatments (as outlined in sections below) at the earliest possible opportunity.

- However, if there is no known cause for infertility even after these initial investigations, expectant management is advised for another year making it total of 2 years.

- Patients/couples who remain infertile despite lifestyle modification and who are aware of and working towards achieving the commissioning eligibility criteria in this policy may be referred by their GP to secondary care, utilising the referral form in appendix 1, when **one** of the following criteria is met:
  - A GP is satisfied that a patient/couple has tried unsuccessfully to conceive for 2 years.
  - For same sex couples, single individuals or those with a physical disability, the equivalent evidence would constitute 6 cycles of unstimulated intrauterine insemination in a licensed clinic over 12 months.
  - There is a “known” cause of infertility.
  - The woman is aged 36 years or over with evidence of infertility (< 12 months)
  - The woman is aged 39 years or over.

- Patients/couples requesting specialist infertility treatment must be referred to an infertility specialist in secondary care (not a general gynaecologist) and patient/couples should meet the eligibility criteria for further assisted conception treatment as set out in section 5 of this policy.

Referral for Assisted Conception Treatment (ACT)

- Following secondary clinical investigation, patient/couples who require assisted conception treatment and meet the eligibility criteria within this policy will be referred to a tertiary centre. The tertiary referral pathway for Gloucestershire patients is to one of the following providers: Care Fertility Bath, Create Fertility Bristol, London Women’s Clinic (Wales) The Fertility Partnership: Oxford.

Provider responsibilities

The NHS-funded specialist fertility unit providing the care will be solely responsible for the initial consultation, treatment planning, counselling/advising patients, treatment consent, all drugs, egg collection, semen analysis, embryo transfer (fresh or frozen), cryopreservation for patients on the fertility pathway for up to one year, pregnancy test(s), all consumables, pathology/urine tests, scans and the Human Fertilisation and Embryology Authority (HFEA) fee.

Note: All fertility drugs, such as gonadotrophins, (including gonadotrophin releasing hormone analogues and antagonist), and progestogens, should be prescribed only by the treating consultant.

See section 6.7 for details on exception for letrozole and clomiphene citrate (clomid).

The evidence base for the use of assisted conception techniques and their long-term safety is given in NICE Clinical Guideline CG156. Service providers are expected to follow the pathways and guidance outlined within CG156 which forms the basis of the eligibility criteria for accessing assisted conception treatment in Gloucestershire.

4.0 Definitions

Clinical definition of infertility is a disease of the reproductive system defined by the failure to achieve a clinical pregnancy after 12 months or more of regular unprotected sexual intercourse (International Committee for Monitoring Assisted Reproductive Technology and the World Health Organization revised glossary of ART terminology, 2009).

A fresh cycle of IVF with or without intracytoplasmic sperm injection (ICSI) treatment comprises: Ovulation induction, egg retrieval, fertilisation and implantation, and include appropriate diagnostic tests, scans and pharmacological therapy.

One cycle of NHS funded IVF treatment within Gloucestershire is either:

- One fresh cycle (as defined above)
- One frozen cycle (where up to two frozen embryo(s) are transferred)
- Up to six ovulation induction/gonadotrophin (OI) cycles
- Three cycles of Intra-uterine insemination (IUI)

Expectant management is a formal approach that encourages conception through unprotected vaginal intercourse, involving the provision of advice and information about the regularity and timing of intercourse and any lifestyle changes which might improve a couple's chances of conceiving. Expectant management does not involve any active clinical or therapeutic interventions.

The term "**where appropriate"** within this document means that clinical judgement is exercised in determining which aspects of the policy guidance can be applied to individual patients depending on their condition; ability to tolerate the listed treatment; and whether they have already undergone that treatment.

Abandoned/cancelled *cycle of IVF* is defined as one where an egg collection procedure is not undertaken. If an egg collection procedure is undertaken, it is considered to be a full cycle.

Artificial Insemination (AI) – refers to the deliberate introduction of semen into a female's vagina or oviduct for the purpose of achieving a pregnancy through fertilisation by means other than sexual intercourse.

Intra-cervical Insemination (ICI) – refers to the clinical delivery of sperm into the cervix usually by injecting it with a needleless syringe.

Intra-uterine Insemination (IUI) - refers to a relatively simple reproductive procedure in which a fine catheter (tube) is inserted through the cervix (the natural opening of the uterus) into the uterus (the womb) to deposit a sperm sample directly into the uterus. The purpose of IUI is to achieve fertilisation and pregnancy. This needs to be provided within a licensed fertility unit to ensure patient safety.

Intra Cytoplasmic Sperm Injections (ICSI) - refers to a reproductive technology in which an egg is removed from a woman and a sperm cell from a man is injected directly into the egg. If the cells fuse (achieve fertilisation) a single cell (zygote) is formed, which then starts dividing becoming an embryo.

When the zygote/embryo is only a few cells large, it is implanted into the woman's uterus and, if successful, will develop as a normal embryo.

In Vitro Fertilisation (IVF) - refers to a reproductive technology in which an egg is removed from a woman, joined with a sperm cell from a man in a test tube (in vitro). The cells fuse (achieve fertilisation) to form a single cell called a zygote, which then starts dividing, becoming an embryo. When the zygote/embryo is only a few cells large, it is implanted in the woman's uterus, and, if successful, will develop as a normal embryo.

In Vitro Maturation (IVM) – refers to a reproductive technology involving the removal of immature oocytes from unstimulated ovaries. The immature oocytes are retrieved trans-vaginally from 2mm to 8mm diameter antral follicles within unstimulated ovaries. The retrieved immature oocytes are then matured in vitro for 24–48 hours. The mature oocytes are then managed as per routine IVF i.e. fertilised with sperm, cultured to an embryo and implanted in the women's uterus.

5.0 Policy statement

Policy category *CBA*	Policy details **PATIENT ELIGIBILITY CRITERIA**
	5.1 Residency All patients and partners must be permanently registered for at least 12 months, with a documented history of sub-fertility before being considered for NHS funded fertility treatment, with one of the following: • registered with a Gloucestershire GP practice. • be resident in Gloucestershire with a General Practitioner (GP) registered in Wales. **5.2 Stable relationship** All couples seeking NHS funded assisted reproduction services must have been in a stable relationship for a period of at least two years. Single patients must also be assessed to ensure provision of a stable and supportive environment. This requirement supports the welfare of the child assessment as per HFEA Code of Practice. **5.3 Fertility investigations in primary and secondary care** All couples must undergo the fertility investigations in primary and secondary care appropriate to them before eligibility for NHS-funded assisted reproduction service is considered. Patients/couples must be referred from primary care to secondary care in sufficient time for all necessary investigation and interventions to be undertaken, so that patients/couples found to be infertile, can then be referred on to a tertiary specialist assisted conception service. **5.4 Age of woman at time of referral to tertiary care from secondary care** Female fertility declines with age and therefore women should seek help for fertility problems as early as possible, especially given that a period of expectant management and/or treatment is required before assisted reproduction services can be commenced. Women should be referred from primary care to secondary care in sufficient time for all necessary interventions to be undertaken, so that couples found to be infertile can be referred to a specialist assisted reproduction service. To initiate assisted conception treatment, referral to tertiary centre is required **at least** three months before the woman's 40th birthday. If women are referred to tertiary providers at the last point, then it is unlikely that they will be able to have more than 1 cycle, as once they are 40 years of age this will be the final funded NHS cycle. *Rationale:* *This is based on the fall in assisted conception success rates to 20% in women over 40 years of age.* **5.5 Age** **5.5.1** Funding will be provided for women in the age range: 18 to 39 at the time of treatment, i.e. before their 40th birthday. Referrals into the service should be made in appropriate time to ensure that treatment can take place by the woman's 40th birthday. Treatment must be completed within six months from referral to tertiary specialist centre.

5.5.2 There is no upper age limit for the partner of the woman undergoing fertility treatment.

There is limited evidence that male fertility declines with age. It is advised that patients are "informed" about this. The age of the father should be taken into account during "Welfare of the Child" considerations.

Rationale:
The decline in normal fertility with age increases markedly from the late 30s and infertility treatment is much less successful in women at this age. This is particularly evident for women aged 40 and above, where the balance of cost-effectiveness becomes uncertain.
For women aged 18-22 there is a lack of robust data but no evidence of ineffectiveness. The legal age for sexual consent is 16 years; the defined age for treatment of 18 years allows for 1 year proving fertility problems and a further 1 year of investigations in secondary care before treatment is initiated, in accordance with the definition for infertility.
There is reasonable evidence demonstrating that increasing male age adversely impacts on sperm parameters; the evidence of impact on live birth rates is more limited.

5.6 Ovarian Reserve Assessment

Ovarian reserve testing will be used to predict the likely ovarian response to IVF/ICSI. Women are required to meet 1 of these measures to determine clinical appropriateness of treatment; these tests will also determine the required dosing schedule for treatment:

- Serum Follicle Stimulating Hormone (FSH) must be less than or equal to 12iu/l, further assessment of ovarian reserve will be considered.
- Anti-Müllerian hormone (AMH) of greater than or equal to 5.4 pmol/l
- Antral follicle count (AFC) of at least 4 in total across both ovaries

These measures do not necessary apply to women with known reproductive pathology (e.g. patients with PCOS, ovarian failure).

5.7 Diagnosed and unexplained infertility access to specialist services

Patients with a diagnosed cause of infertility which significantly reduces the possibility of natural conception, and who meet all the other eligibility criteria, will have immediate access to NHS funded assisted reproduction services, as listed in Section 6 of this policy. (e.g. azoospermia, severe oligo astheno-terato- globozoospermia, tubal blockage and severe tubal dysfunction or damage from severe endometriosis or infection). This applies to all heterosexual, same sex and single sex individuals.

All other patients/couples, including those with unexplained infertility, must have infertility of at least two years duration.

The above time scales include one year of expectant management in primary care, despite regular unprotected vaginal sexual intercourse, before referral to NHS-funded assisted conception services.

For women in same-sex couples or single women, or couples who would find it difficult to have sexual intercourse, 6 or more self-funded cycles of intra-uterine insemination (IUI) over 12 months at a HFEA licensed clinic is deemed to provide an equivalent chance of pregnancy as two years of unprotected intercourse in heterosexual couples.

For women with a history of recurrent early miscarriage* who have entered the secondary care fertility investigations pathway, will be eligible for IVF one year after their last miscarriage providing, they meet all other eligibility criteria (*3 or more miscarriages).

5.8 Previous infertility treatment

Where patients or either partner within the couple (in previous or current relationships) have undergone previous assisted conception (IVF/ ICSI) however funded, resulting in two or more embryo transfers, they will **NOT** be eligible for further NHS funding.

However, if couples have previously undergone an IVF/ICSI cycle (however funded) which resulted in only one attempt of embryo transfer, they will only be eligible for one further NHS funded embryo transfer to bring the total number of embryo transfers to two (as defined above).

Any previous IVF cycles count towards the number offered, up to a maximum of 2 embryo transfers.

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.

Note 1: This does not affect a new patient's ability to receive fertility investigations if their partner has undertaken prior assisted conception treatment for fertility problems within an earlier relationship. Fertility investigations of this nature are undertaken *before* a patient, or couple are considered for assisted conception/fertility treatment and may be resolved by a different course of action.
Note 2: Where assisted conception was undertaken for the purpose of cryopreservation under an NHS pathway of care, 2 single treatments utilising any resultant gametes/embryos will be funded at NHS expense, subject to compliance with all other eligibility criteria within this policy.

Rationale:
The chance of success declines with each attempt at assisted conception.

5.9 Living Children

Treatment for assisted conception will only be funded if the patient/couple do not have any living children (regardless of age of the child at the time of presentation) from the current or a previous relationship. This includes adopted children but excludes fostered children. Once accepted for treatment, should a child be adopted or a pregnancy leading to live birth occur, the couple/patient will become ineligible for NHS funded treatment.

Rationale: The ICB policy decision was based on affordability grounds and prioritising treatment for couples/patients with no children.

5.10 Sterilisation

Assisted reproduction services will not be available if infertility is the result of a sterilisation procedure in either partner/patient.

Rationale:
Sterilisation is offered within the NHS as an irreversible method of contraception. Considerable time and expertise are expended in ensuring that individuals are made aware of this at the time of the procedure. Since most requests arise for non-medical reasons, ICBs consider that it is inappropriate that NHS funds are used in reversing these procedures.

5.11 Body Mass Index (BMI)

Women must have a BMI of between 19-29.5kg/m^2 documented in their clinical notes for a period of 6 months or more, at the time of referral for specialist assisted reproduction assessment and throughout the time of any specialist treatment.

Couples/patients presenting with fertility problems in primary care should be provided with information at the earliest opportunity, about the impact of BMI on their ability to conceive naturally. Where appropriate, patients should be offered advice and support to achieve weight loss and a referral to the healthy lifestyles service.

Couples will be informed of weight checks throughout NHS funded treatment, and where the eligibility criteria is not met the treatment cycle will be deferred until BMI falls within above limits.

Rationale:
The evidence is clear that obesity negatively impacts upon successful natural conception and fertility treatment. Prospective mothers with a BMI of 29.6 and above should be offered a referral to the healthy lifestyle service in order to reduce their weight prior to assessment and treatment by secondary care fertility services.
NICE CG156 states that low body weight is recognised as an important cause of hypo-oestrogenic amenorrhoea. In women, weight loss of over 15% of ideal body weight is associated with menstrual dysfunction and secondary amenorrhoea when over 30% of body fat is lost.

NICE CG also states that men who have a BMI of 30 or over are likely to have reduced fertility.

5.12 Smoking and other nicotine products

Couples and single women who smoke or vape or using any product containing nicotine will not be eligible for NHS funded specialist assisted reproduction assessment or treatment and should be informed of this criterion at the earliest possible opportunity in their progress through infertility investigations in primary care and secondary care. All women should be informed that passive smoking is likely to affect their chance of conceiving.

Smoking cessation support should be provided, as necessary.

Patients and their partner must be non-smoking and smoke free for a period of at least 6 months prior to assessment for fertility treatment and this must be maintained during treatment.

Individuals who are smokers can be added to the 'watchful-waiting' list and be referred to their local stop smoking service for support in quitting, but treatment will not commence until they are deemed non-smokers (i.e. no longer using a nicotine containing product).

During initial consultations patients will be informed that random carbon monoxide breath tests and where appropriate, urine tests (cotinine), or blood tests will be undertaken throughout treatment to evidence/enforce this requirement.

Where it is identified that during fertility treatment the patient/couple no longer complies with the eligibility criterion as defined within this section of the policy (e.g. has resumed smoking), NHS funded fertility treatment will be deferred until there is evidence to support compliance. (i.e. six months evidence of non-smoking status) supported by Gloucestershire NHS Stop Smoking Service. This deferral of fertility treatment will also result in the forfeiting of one treatment cycle.

Rationale:
Maternal and paternal smoking can adversely affect male and female fertility and the success rates of assisted reproduction procedures (includes use of nicotine replacement products as it is the nicotine in tobacco that may reduce fertility).

Smoking during the antenatal period leads to increased risk of adverse pregnancy outcomes.
Children exposed to smoke in the womb are more likely to experience respiratory disease and ENT problems, and psychological and behavioural problems which may impact on educational performance.

5.13 Alcohol, recreational drug use and opiate substitution therapy status

The couple/patient will be asked to give an assurance that their alcohol intake is within Department of Health guidelines and they are not using recreational drugs. Any evidence to the contrary will result in the cessation of treatment.

Patients presenting with fertility problems in primary care should be provided with information about the adverse impact of alcohol, the use of recreational drugs and the effect of opiate substitution treatment on their ability to conceive naturally. No treatment will be offered until proven to have stopped use of recreational drugs for 6 months. They should also be informed of the adverse health impacts of maternal and passive smoking, excessive alcohol consumption, recreational drugs and opiate substitution on the foetus, and the adverse health impacts of passive smoking on any children.

Support to stop smoking, treat alcohol misuse, stop taking recreational drugs or come off opiate substitutions should be provided as necessary by early GP referral to Gloucestershire NHS Stop Smoking Service or Via.

Rationale:
Drinking too much alcohol can damage the quality of sperm. NICE CG156 states that if men follow the current Department of Health's recommendations for the consumption of alcohol, it is unlikely their fertility will be affected but drinking more than this could make it difficult to conceive.
Illegal drugs such as marijuana and cocaine can seriously affect fertility, making ovulation (the monthly cycle where an egg is released from the ovaries) more difficult.

5.14 Human Fertilisation and Embryology Authority (HFEA) Code of Practice

To meet their duties under the HFEA Code of Practice, tertiary specialists will assess eligible couples/patients to determine whether it is appropriate for NHS-funded assisted reproduction services to be provided to them. The Code of Practice states:

"No treatment services regulated by the HFEA (including intra-uterine insemination–IUI) may be provided unless account has been taken of the welfare of any child who may be born as a result (including the need of that child for supportive parenting) and of any other child who may be affected by the birth".

5.15 Women in same sex partnerships, single women and couples unable to undertake vaginal intercourse.

When trying to conceive, single women and same sex couples and heterosexual couples unable to have vaginal intercourse, should have access to advice from NHS specialists in reproductive medicine on the clinical effectiveness and safety of the options available to them.

The assisted reproduction services described in Section 6 below will be available to single women or women in same sex couples (provided they meet the criteria in 5.7 above), or couples unable to have vaginal intercourse because of, for example, a clinically diagnosed disability or health problem, or a psychosexual problem, if those couples seeking NHS treatment are infertile.

NHS Funding is not available for access to donor insemination facilities for fertile woman. In the case of women in same sex partnerships in which only one partner is infertile, clinicians should discuss the possibility of the other partner becoming pregnant before proceeding to interventions involving the infertile partner.

SECTION 6 –ASSISTED CONCEPTION TREATMENTS FUNDED FOR ELIGIBLE COUPLES

The treatment options undertaken will depend on diagnosis and clinical appropriateness in accordance with this policy. Treatment options will be undertaken in the following sequential order. That is, it is not appropriate to receive IUI after failure of IVF/ICSI.

6.1 Artificial Insemination (AI)

AI including intra-cervical insemination (see 6.2 for intra-uterine insemination) is not routinely funded and does not form part of the NHS funded specialist fertility treatment pathway.

6.2 Intra-uterine insemination (IUI)

Intra-uterine insemination is not routinely funded for patients with unexplained infertility, mild endometriosis, or mild male factor infertility.

Unstimulated or stimulated IUI may be considered a treatment option for the following groups who have demonstrated infertility in accordance with section 5.7 of this document:

3 cycles of unstimulated or stimulated intra-uterine insemination (including donor sperm if required) will be funded for:

- people who are unable to, or would find it very difficult to, have vaginal intercourse because of a clinically diagnosed physical disability or psychosexual problem who are using partner or donor sperm.
- heterosexual couples with unexplained infertility where there is normal ovulation, tubal patency, and semen analysis, who have social, cultural or religious objections to IVF, as an alternative to one cycle of IVF/ICSI as described in the policy.
- people in same-sex relationships
- single women

Any IUI treatment, whether self-funded or NHS funded, will need to be provided by a licensed fertility unit. This will replace one cycle of IVF/ICSI.

Rationale:
Resources are limited but this serves to ensure that where appropriate, all effective interventions have been exhausted.

The use of a licensed fertility unit for IUI treatment is required to ensure patient safety is maintained at all times.

6.3 In-vitro fertilisation (IVF) and intra-cytoplasmic sperm injection (ICSI) and Gonadotrophin Ovulation Induction (OI)

One fresh cycle of IVF with or without intracytoplasmic sperm injection (ICSI) treatment comprises: Ovulation induction, egg retrieval, fertilisation and implantation, and include appropriate diagnostic tests, scans and pharmacological therapy.

One cycle of NHS funded IVF treatment within Gloucestershire is either:

- One fresh cycle (as defined above)
- One frozen cycle (where up to two frozen embryo(s) are transferred)
- Up to six ovulation induction/gonadotrophin (OI) cycles
- Three intra-uterine insemination cycles

	Patient/couples will receive NHS funding for a maximum of two fresh cycles of in-vitro fertilisation (IVF) **or** intra-cytoplasmic sperm injection (ICSI) (with or without donor sperm or donor egg as clinically appropriate) or up to six ovulation induction/gonadotrophin (OI) injection cycles **or** three intra-uterine insemination cycles.
	
	6.4 Gonadotrophin ovulation induction (OI)
	If gonadotrophin ovulation induction (OI) is indicated, up to six cycles of OI will be offered to selected patients with anovulatory cycles. This will replace one cycle of IVF/ICSI. A further assessment will be made after either three or six OI cycles and if unsuccessful, couples will then be eligible for up to one IVF/ICSI cycles as described in the policy.
	
	6.5 Number of treatment cycles
	6.5.1 All eligible women will continue to receive two opportunities to have an elective single embryo transferred (unless advised differently by the embryologist to a maximum of up to 2). This is equivalent to up to two cycles as defined above.
	6.5.2 Where frozen embryos can successfully be developed, the ICB will fund implantation (transfer) of these in preference to new fresh embryos, from a second cycle.
	6.5.3 If no frozen embryos are available from the first cycle, women will receive one further fresh cycle to ensure they receive two implantation attempts**.**
	6.5.4 If the woman reaches the age of 40 during treatment, the cycle should be completed.
	6.5.5 Where eggs are retrieved, but embryo development is not achieved or not clinically satisfactory, then this cycle is considered complete without embryo transfer.
	
	Rationale:
	• *The ICB considers that up to two cycles (as outlined above where suitable frozen embryos are transferred in preference to a new fresh cycle) maximise the success rate of a live birth within financial constraints and provides a choice of fertility treatment options. Consideration has been given to the success rate of live births following frozen embryo transfer.*
	• *NICE CG 156 Recommendations (informed by HFEA criteria) should be followed for embryo transfer to reduce multiple pregnancies following fertility treatment. The number of embryo's transferred will depend on a number of factors including female age, cycle of treatment and quality of the embryos:*
	  • *a maximum of 2 embryos (or 3 eggs) will be transferred per treatment.*
	  • *some patients will be assessed as suitable for single embryo transfer (eSET); where more than 1 embryo or egg is transferred, this clinical decision must be clearly documented in the patient's medical records and reported appropriately.*
	
	6.6 Donor eggs in IVF/ICSI
	IVF/ICSI using donated eggs from UK clinics licensed by the HFEA will be commissioned for eligible patients/couples where indicated.
	
	6.7 Donor sperm in IVF/ICSI
	The use of donor sperm in IVF/ICSI will be funded for:
	• Same sex couples where there is diagnosis of diagnosed or unexplained or absolute infertility. Same sex couples and single patients will need to have had 6 or more cycles of self-funded intrauterine insemination over 12 months in a licensed clinic to have the diagnosis of unexplained infertility.

	• Heterosexual couples where male factor infertility is diagnosed or where medical, surgical or other treatments are unlikely to result in sperm of the necessary quality; or where the use of partner sperm is contraindicated; or where infertile couples are unable to undertake vaginal intercourse also require donor sperm**.** **6.8 Abandoned and cancelled cycles and declining treatment** Where a clinical decision is made to abandon or cancel a treatment cycle prior to egg retrieval, then the abandoned cycle will not be counted i.e. Ovarian Hyperstimulation Syndrome. If a cycle has to be abandoned after the initiation of ovarian stimulation due to failure to respond, the abandoned cycle will count as one of the two funded cycles. If a patient decides to decline or withdraw from a treatment cycle, for avoidable or non-medical reasons, then this will count as a full cycle for the purpose of the number of attempts at assisted conception. *Rationale:* *Cancelled cycles are chargeable and rates have been agreed with Providers.* **6.9 Prescribing within the Treatment Pathway** GPs should not prescribe any fertility drugs. (The only exceptions will be Letrozole or Clomiphene citrate (Clomid). This treatment must be initiated only by the secondary care specialist after full assessment and the GP can prescribe only as per the secondary care specialist's instructions for repeat prescriptions. It will however be the responsibility of the secondary care specialist to monitor the patient subsequently). With regard to ovarian stimulation, the ICB will fund all necessary drugs up to 12 days of stimulation. **6.10 Treatments not Commissioned.** • Surgical Sperm Retrieval • Assisted hatching. • Gamete or zygote intrafallopian transfer • Growth hormone or dehydroepiandrosterone (DHEA) as adjuvant treatment in IVF protocols • In Vitro Maturation (IVM) • Natural cycle IVF treatment • Embryo 'glue' • Endometrial scratch • Embryoscope • Morphologically selected intracytoplasmic sperm injection (IMSI) **Assisted conception treatment may be denied on other medical grounds not explicitly covered in this document.**

7.0 Patients who are not eligible for treatment under this policy

Patients who are not eligible for treatment under this policy may be considered on an individual basis where their GP or consultant believes that the patient has exceptional clinical circumstances that warrant deviation from the rule of this policy.

The clinical responsibility for applying this policy to a presenting patient, rests with the clinician who is responsible for the patient at that point in the treatment pathway and should be done in consideration

of the patient's individual clinical circumstances, their place on the management pathway and following discussion with the patient.
Individual cases will be reviewed at the ICB's Individual Funding Request Panel upon receipt of a completed application form from the patient's GP, Consultant or Clinician. Applications cannot be considered from patients personally.

8.0 Connected policies

Fertility Preservation Policy
Surrogacy Policy

9.0 References

- NICE Clinical Guideline for Fertility problems: assessment and treatment (CG156); published in February 2013 and updated September 2017 www.publications.nice.org.uk/fertility-cg156
- NICE Fertility Problems Quality Standard (QS73) published October 2014 www.nice.org.uk/guidance/qs73
- The Equality Act 2010, including age discrimination legislation
- Human Fertilisation and Embryology Authority (HFEA) campaign to reduce multiple births https://www.hfea.gov.uk/about-us/our-campaign-to-reduce-multiple-births/
- Human Fertilisation and Embryology Association (HFEA) Code of Practice 9th edition (December 2019) https://portal.hfea.gov.uk/knowledge-base/read-the-code-of-practice/
- NHS Choices; Stop Smoking
- Smokefree NHS Advice
  http://www.nhs.uk/smokefree/help-and-advice/prescription-medicines
  https://www.nhs.uk/live-well/quit-smoking/using-e-cigarettes-to-stop-smoking/
- *Royal College of Obstetricians & Gynaecologists Green-top Guideline Recurrent Miscarriage No. 17 https://www.rcog.org.uk/guidance/browse-all-guidance/green-top-guidelines/recurrent-miscarriage-green-top-guideline-no-17/

Appendix 1

Fertility Assessment Referral Form

Please follow the Subfertility pathway on G-care, then if a referral is still required complete this form in full and attach it to your referral.

Important Notes

Maximum age
The maximum age for the female partner/prospective mother to be referred into specialist fertility clinic for assessment is 45 years. **However**, women must be referred from primary care to secondary care in sufficient time for all necessary investigation and interventions to be undertaken, so that couples found to be infertile, can be referred on to a tertiary specialist assisted conception service. To be eligible for NHS funded assisted conception, the female partner/prospective mother's **age limit is 39 years and 6 months to start treatment having completed all investigations in secondary care.**

Therefore, the female partner/prospective mother needs to be referred without delay if they are 39 years old.

BMI
Female partner/prospective mothers and their partners with a BMI of over 29.9 kg/m2 should be offered a referral to Healthy Lifestyles services to reduce their weight, as obesity can impact on fertility.

The service will not accept referrals for female partner/prospective mothers with a BMI of over 35 unless exceptional funding has been obtained from NHS Gloucestershire.

Female partner/prospective mothers with a BMI between 30 and 35 kg/m2 will be seen and given advice to work on weight loss and individual circumstances but fertility treatment, if needed, will commence only when BMI is under 30.

Registered GP details
Where you are not the registered GP of both patients, please ensure that the GP of the partner registered elsewhere is aware of this referral as they may need to supply clinical data to Fertility services.

Referrer details		**Patient 1 details:**			
Name:	<Sender Name>	Name:	<Patient name>	DOB:	<Date of birth>
Address:	<Sender Address>	Address:	<Patient Address>	NHS no:	<NHS number>
				Gender:	<Gender>
				Carer status:	<Diagnoses>
Tel no:	<Sender Details>	Tel no:	<Patient Contact Details> <Patient Contact Details>	Language:	<Main spoken language>
Email:	<Organisation Details>	Communication needs:			
Referral date:	<Today's date>				

Patient 2 details:
Note: if you are the registered GP for both patients, please complete the details below. If patient 2 has a different GP, please complete Name, DOB and GP as a minimum.

Name:		DOB:	
GP Practice: *(if not same as patient 1)*			
Address:		NHS no:	<NHS number>
		Gender:	<Gender>
		Carer status:	<Diagnoses>
Tel no:	<Patient Contact Details> <Patient Contact Details>	Language:	<Main spoken language>
Communication needs:			

MALE PARTNER SEMEN ANALYSIS - mandatory results field to complete for referral (in last 2 months) Attach results as screenshot or copy .doc. *Referrals to the service will not be accepted without the required test results listed below.*		
Test	**Date**	**Result**
(Viscosity)		
Volume (ml)		
pH		
Total count x 109/l		
Motility (%)		
Rapid motility (%)		
Sluggish motility (%)		
Non-progressive motility (%)		
Immotile (%)		
Normal Forms (%)		
NOTE: If semen test results show low numbers/ suboptimal results, they should be repeated before referral is made and both sets of results shared with the service.		
FEMALE PARTNER/PROSPECTIVE MOTHER - mandatory results field to complete for referral (in last 2 months) *Referrals to the service will not be accepted without the required test results listed below.*		
Test	**Date**	**Result**
FSH (Day 1-5)		<Arden's Ltd - Investigations: Pathology last 2m (view)>
LH (Day 1-5)		<Arden's Ltd - Investigations: Pathology last 2m (view)>
Prolactin (Day 1-5)		<Arden's Ltd - Investigations: Pathology last 2m (view)>
Testosterone (Day 1-5)		<Arden's Ltd - Investigations: Pathology last 2m (view)>
STSH (Day 1-5)		<Arden's Ltd - Investigations: Pathology last 2m (view)>
L2 C> TRACHOMATIS antibodies (Day 1-5)		<Arden's Ltd - Investigations: Pathology last 2m (view)>
Progesterone (luteal phase)		<Arden's Ltd - Investigations: Pathology last 2m (view)>
Rubella immunisation date or if no evidence Rubella antibody result		<Arden's Ltd - Investigations: Pathology last 2m (view)>

Minimum dataset *(in last 3 months)*			
Height	<Numerics>	BMI (mandatory field) *(If BMI is >35 referral will not be accepted)*	<Numerics>
Weight	<Numerics>	Smoking status *(If smoker/vaper refer to the smoking cessation service)*	<Diagnoses>
Alcohol intake	<Diagnoses>, <Numerics>		

Clinical details *Please detail your conclusions, purpose of referral and what needs excluding or attach referral letter . Attach semen analysis where applicable.*
Reason for referral
<Event Details>
Medical problems
<Problems> <Summary>
Relevant Family history
Allergies
<Allergies & Sensitivities>
Medication

Acutes	<Medication>
Repeats	<Repeat templates>

Radiology *(in last 6 months)*
<Arden's Ltd - Investigations: Radiology last 6m (view)>

Referral Details		
Please refer via e-RS *to 'Fertility Assessment Service - DO NOT ATTEND - Gloucestershire Hospitals NHS Foundation Trust - RTE'*. For queries regarding your referral, please contact the service using the details below:		
Fertility Assessment Service, Gloucestershire Hospitals NHS Foundation Trust Service ID 119983	0300 4223225	