Commissioning Policy

Redditch and Bromsgrove Clinical Commissioning Group

South Worcestershire Clinical Commissioning Group

Wyre Forest Clinical Commissioning Group

Tertiary Treatment for Assisted Conception Services

May 2019

This policy applies to patients for whom the following Clinical Commissioning Groups are responsible:

- NHS South Worcestershire Clinical Commissioning Group (CCG)
- NHS Redditch & Bromsgrove Clinical Commissioning Group (CCG)
- NHS Wyre Forest Clinical Commissioning Group (CCG)

Collectively referred to as the Worcestershire CCGs

COMMISSIONING STATEMENT:

NHS Redditch & Bromsgrove Clinical Commissioning Group, NHS South Worcestershire Clinical Commissioning Group and NHS Wyre Forest Clinical Commissioning Group (also termed "the Commissioner" in this document) **does not routinely fund**:

- artificial insemination (including intra-cervical insemination)
- intra-uterine insemination (IUI), except for defined patients who meet the clinical criteria for sub-fertility treatment included within this document, whereby up to 3 cycles of IUI will be funded

NHS Redditch & Bromsgrove Clinical Commissioning Group, NHS South Worcestershire Clinical Commissioning Group and NHS Wyre Forest Clinical Commissioning Group (also termed "the Commissioner" in this document) **will fund** the following assisted conception treatment for patients meeting the defined eligibility criteria within this policy:

- A maximum of 1 fresh cycle of in-vitro fertilisation (IVF) ***or*** intra-cytoplasmic sperm injection (ICSI) (with or without donor sperm or donor egg as clinically appropriate)

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 9.

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Name	Date
Clinical Commissioning Policy Collaborative, which includes: GPs, Commissioners, Medicines Commissioning, Public Health, Patient and Public Representatives	June 2018
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Version No	Type of Change	Date	Description of change
V2.2	Significant	May 2014	• Review of the policy in line with NICE CG 156 • Review of policy in line with service provision and clinical expertise/opinion
V3.0	Significant	June 2017	• Further definition of eligibility criteria in relation to smoking • Inclusion of reference to sperm DNA fragmentation commissioning statement • Re-format to comply with updated policy format, incorporating additional background information • Reduction in the number of cycles offered from 2 to 1 • Expansion of policy scope to reference military personnel
V3.2	Minor	June 2018	Clarity regarding: • Secondary and tertiary care referral • Smoking and use of e-cigarettes • Male BMI • Treatments not commissioned including In Vitro Maturation • Surrogacy arrangements • Updated values for Ovarian Reserve Testing in accordance with NICE recommended limits • Clarification of arrangements for use of cryopreserved material
V3.3	Minor	May 2019	Updates to: Section 1.10 and 6.3 of the policy, the Fertility Management Referral Form and the Assisted Conception Referral Form to clarify that IUI should to be provided by a licensed fertility unit. This requirement applies to: • self funded Stimulated or Unstimulated cycles; AND • NHS funded cycles

Table of Contents

1. Definitions 5
2. Scope of policy 7
3. Background 9
4. Relevant National Guidance and Facts 10
5. Patient Eligibility 11
5.2.1 Age 11
5.2.2 Body Mass Index (BMI) 11
5.2.3 Nature of Infertility 12
5.2.4 Living Children 12
5.2.5 Previous Assisted Conception 12
5.2.6 Sterilisation 12
5.2.7 HFEA Code of Practice 13
5.2.8 Smoking 13
5.2.9 Other Lifestyle Issues 14
5.2.10 Residency 14
6. Assisted Conception Treatment 15
6.1 *Male Factor Infertility* 15
6.2 *Artificial Insemination (AI)* 15
6.3 *Intra-Uterine Insemination (IUI)* 15
6.4 *In-Vitro Fertilisation (IVF) / Intra-cytoplasmic sperm Injection (ICSI)* 16
6.5 *Donor Sperm and Eggs* 16
6.6 *Cancelled Cycles, Declining and Withdrawal from Treatment* 17
6.7 *Prescribing within Treatment Pathway* 17
7. Principles in NHS Funded Treatment Options 18
8. Co-Payment and Retrospective Funding 19
9. Initial GP Assessment and Referral 20
10. Supporting Documents 22
11. Appendices 23
12. Equality Impact Assessment 27

1. Definitions

1.1 ***Exceptional -*** refers to a person who demonstrates characteristics, which are highly unusual, uncommon or rare.

1.2 ***Exceptional clinical circumstances*** are clinical circumstances pertaining to a particular patient, which can properly be described as exceptional, when compared to the clinical circumstances of other patients with the same clinical condition and at the same stage of development of that condition (i.e. similar patients). A patient with ***exceptional clinical circumstances*** will have clinical features or characteristics which differentiate that patient from other patients in that cohort and result in that patient being likely to obtain significantly greater clinical benefit (than those other patients) from the intervention for which funding is sought.

1.3 A ***Similar Patient*** is a patient who is likely to be in the same or similar clinical circumstances as the requesting patient and who could reasonably be expected to benefit from the requested treatment to the same or a similar degree. The existence of more than one similar patient indicates that a decision regarding the commissioning of a **service development** or commissioning policy is required of the Commissioner.

1.4 An ***individual funding request (IFR)*** is a request received from a provider or a patient with explicit support from a clinician, which seeks exceptional funding for a single identified patient for a specific treatment.

1.5 An ***in-year service development*** is any aspect of healthcare, other than one which is the subject of a successful individual funding request, which the Commissioner agrees to fund outside of the annual commissioning round. Such unplanned investment decisions should only be made in exceptional circumstances because, unless they can be funded through disinvestment, they will have to be funded as a result of either delaying or aborting other planned developments.

1.6 ***Infertility/Sub Fertility –*** For the purposes of this document infertility is defined as either:

Absence of Known Reproductive Pathology[1] - "A woman of reproductive age who has not conceived after 2 years of regular unprotected vaginal sexual intercourse or 12 cycles of unstimulated artificial insemination, in the absence of any known cause of infertility".

OR

Known 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

[1] Diagnosis of infertility based on a failure to conceive within 1 year has been argued to exaggerate the risk of infertility, since up to 50% of women who do not conceive in the first year are likely to do so in the second year. The required evidence for assuring infertility is extrapolated from NICE Clinical Guidelines

- 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 physical disability preventing vaginal sexual intercourse
- Planned/received treatment that may/has resulted in infertility eg. cancer treatment

1.7 ***Coasting -*** refers to a clinical process used, when clinically appropriate, to avoid the over stimulation of the ovaries and to help couples achieve a fresh cycle. ***Coasting*** is defined as the discontinuation of stimulation injections, with daily measurement of blood oestrogen hormone levels and then continuing with treatment when the blood oestrogen hormone levels have dropped to a safe level.

1.8 ***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.

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

1.10 ***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.

1.11 ***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.

1.12 ***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 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.

1.13 ***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 ie. fertilised with sperm, cultured to an embryo and implanted in the women's uterus.

2. Scope of policy

2.1 This policy is part of a suite of locally endorsed Commissioning Policies. Copies of these Commissioning Policies are available on the following website address: http://www.redditchandbromsgroveccg.nhs.uk/about-us/strategies-policies-and-procedures/commissioning-ifr/

2.2 This policy applies to all patients for whom the Worcestershire Clinical Commissioning Groups (CCGs) have responsibility including:

- People provided with primary medical services by GP practices which are members of any one of the CCGs and
- People usually resident in any of the areas covered by the CCG's and not provided with primary medical services by any CCG.

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

2.4 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 discharged without intervention.

2.5 For patients who do not fall within the eligibility criteria set out in the policy but where there is demonstrable evidence that the patient has exceptional clinical circumstances, an Individual Funding Request may be submitted for consideration. The referring clinician should consult the Commissioner's "Operational Policy for Individual Funding Requests" document for further guidance on this process.

For a definition of the term "exceptional clinical circumstances", please refer to the Definitions section of this document.

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

2.7 Couples/individuals wishing 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 "Cryopreservation for Infertility associated with Medical Treatment or Surgery".

2.8 **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

Worcestershire CCGs 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 CCGs and the content of this policy applies.

2.9 **Pre-Implantation Genetic Diagnosis** (PiGD) and **Surrogacy** are not covered by this commissioning policy as they are the commissioning responsibility of NHS England. Patients should be referred to the Genetic Centre at Birmingham Women's & Children's Hospital.

2.10 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 following criteria for accessing assisted conception treatment in Worcestershire. Where there are deviations with NICE CG156 a rationale is provided.

3. Background

3.1 The NHS constitution which details principles and values that guide the NHS have been applied in the agreement of this policy.

3.2 NHS Redditch & Bromsgrove Clinical Commissioning Group, NHS South Worcestershire Clinical Commissioning Group and NHS Wyre Forest Clinical Commissioning Group consider all lives of all patients whom they serve to be of equal value and, in making decisions about funding treatment for patients, will seek not to discriminate on the grounds of sex, age, sexual orientation, ethnicity, educational level, employment, marital status, religion or disability except where a difference in the treatment options made available to patients is directly related to a particular patient's clinical condition or is related to the anticipated benefits to be derived from a proposed form of treatment.

3.3 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. A typical Clinical Commissioning Group 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 37%
- unexplained (no identified male or female cause) 32%
- ovulatory disorder 13%
- tubal disease 12%
- endometriosis 6%

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.

3.4 Over 80% of 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%).

4. Relevant National Guidance and Facts

4.1 **NICE Guidance CG 156 (Last updated August 2016): Fertility: Assessment and treatment for people with fertility problems.**
These guidelines outline recommendations for management of patients based on an assessment of available evidence.

4.2. **Human Fertilisation and Embryology Authority (HFEA) Code of Practice**
The HFEA is the UK's independent regulator overseeing use of gametes and embryos in fertility treatment. Its Code of Practice sets out both mandatory requirements and recommended guidance (incorporating an interpretation of mandatory guidance) for organisations involved in this area of health care.

5. Patient Eligibility

5.1 The Commissioner considers all lives of all patients whom it serves to be of equal value and, in making decisions about funding treatment for patients, will seek not to discriminate on the grounds of sex, age, sexual orientation, ethnicity, educational level, employment, marital status, religion or disability except where a difference in the treatment options made available to patients is directly related to the patient's clinical condition or is related to the anticipated benefits to be derived from a proposed form of treatment.

5.2 All of the following criteria apply to couples seeking Assisted Conception treatment:

Note:	Alternative interventions may be available in secondary care for those not eligible for assisted conception.

5.2.1 Age

Funding will be provided for women in the age range 18 to 39 at the time of treatment, i.e. up to 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.

Where it is determined that a woman needs egg donation they must meet all other applicable clinical eligibility criteria and be below the age of 40 at the time this clinical decision is made.

Where a women with cryopreserved material is clinically unable (due to their treatment) to use this before the age of 40, they may use their cryopreserved material up to the age of 42 (in accordance with NICE criteria), providing they meet all other applicable clinical eligibility criteria.

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:

i. *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.*

ii. *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.*

iii. *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.*

5.2.2 Body Mass Index (BMI)

Women must have a body mass index (BMI) in the range 19 to 29 inclusive. Patients/couples should be informed of this criterion at the earliest possible opportunity in their progress through infertility investigations in primary and secondary care.

Where male factor infertility is identified, the BMI should be 29 or less.
For men unable to lose weight, specialist assessment may determine that their chance of success is limited and therefore tertiary referral for assisted conception treatment is not guaranteed.

Rationale:

i. There is clinical evidence to demonstrate that a female BMI within this range improves pregnancy rates, reduces miscarriage and prevents pre-term delivery.

ii. Men who have a BMI above 29 are likely to have reduced fertility arising from altered sperm quality and erectile function (where co-existing risk factors).

5.2.3 Nature of Infertility

Assisted conception treatment is available for patients with infertility as defined in section 1.6 of this document. This applies to all heterosexual, same sex and single sex individuals.

Patients may be referred to secondary care at an earlier stage (see section 9) to facilitate investigations, identify any known causes and undertake appropriate interventions in secondary care.

Earlier referral for specialist consultation should be offered to:

- Women aged 36-39 years
- Individuals with a known clinical cause of infertility or a history of predisposing factors (see identified causes listed in section 1.6)

Where one of the partners has a blood bourne virus the couple should be referred to a specialist centre with appropriate facilities and expertise. These patients should meet all other eligibility criteria within this policy and are entitled to assisted conception treatment in accordance with this policy.

5.2.4 Living Children

Treatments 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 either the current or a previous relationship. This includes a child adopted by the patient/couple or a child from a previous relationship, but excludes fostered children. Once accepted for treatment, should a child be adopted or a pregnancy leading to a live birth occur the patient/couple will no longer be eligible for NHS funded treatment.

Rationale:

i. Local resources are limited and therefore priority is given to couples with no children.

5.2.5 Previous Assisted Conception

Where any prior attempts of assisted conception (IVF/ICSI) for fertility problems have been received by either partner, regardless of whether the treatment was funded by the NHS or privately, no further NHS funding will be available.

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, 1 single treatment utilising any resultant gametes/embryos will be funded at NHS expense, subject to compliance with all other eligibility criteria within this policy.

Rationale:

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

5.2.6 Sterilisation

NHS funded fertility treatment will not be available if the patient or either partner within a couple has received a sterilisation procedure or has undertaken a reversal of sterilisation procedure.

Rationale:

i. *Resources are limited therefore priority is given to individuals with greatest need. Patients undergoing sterilisation receive counselling and all the consequences are explained to them at the time.*

5.2.7 HFEA Code of Practice

Patients/couples who do not conform to the HFEA's current Code of Practice (latest version, 8th edition – revised April 2017) will be excluded from having access to NHS funded assisted fertility treatment. This includes consideration of the "welfare of the child which may be born". This will take account of a patient/couple's ability to provide a stable and supportive environment for a child and family medical histories. Treatment Centres will undertake this assessment.

5.2.8 Smoking

Couples (both partners) who smoke are not eligible for NHS-funded fertility assessment by a tertiary care provider.

Couples should be informed of this criterion at the earliest opportunity and should be provided with information on the impact of smoking on their ability to conceive naturally and the adverse health impacts of maternal and passive smoking on the foetus and resultant child.

Smokers should be advised to stop smoking and directed to nationally accredited resources to support smoking cessation e.g NHS Choices website 'Stop Smoking'; Smokefree NHS Advice. Stopping smoking offers the best outcomes for individuals, partners and any resultant child; it is recognised that there are products available to facilitate smoking cessation where clinically appropriate.

Couples are not eligible for referral to tertiary care fertility services until they have stopped smoking for a consecutive period of 6 months. Verification of this will be sought following referral and couples will be advised that random carbon monoxide breath tests and where appropriate, urine tests (cotinine), or blood tests, will be undertaken during investigations and treatment to enforce this requirement. During the 6 month stop smoking period it is acceptable to use stop smoking products including e-cigarettes, providing that this is considered appropriate by a patient's GP or hospital clinician.

Where it is identified that during fertility treatment the individual/couple no longer complies with the eligibility criteria within this section of the policy (i.e. has resumed smoking), NHS funded fertility treatment will be deferred until there is evidence to support compliance (i.e. 6 consecutive months non-smoking status); following the deferral period patients will be required to meet all eligibility criteria within the assisted conception policy applicable at the time they recommence the pathway, in order to receive NHS funded assisted conception.

Rationale:

i. *Maternal and paternal smoking can adversely affect male and female fertility and the success rates of assisted reproduction procedures.*
ii. *Smoking during the antenatal period leads to increased risk of adverse pregnancy outcomes.*
iii. *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.*
iv. *There are many other associations of smoking for both parent and child in terms of ill-health; i.e. cancer*, heart disease and diabetes.

5.2.9 Other Lifestyle Issues

Additional lifestyle advice in relation to fertility should be given regarding (see section 9):

- Diet
- Alcohol
- Caffeinated beverages
- Tight underwear
- Prescribed, over-the-counter and recreational drug use
- Complementary therapy
- Folic acid supplementation
- Occupation

5.2.10 Residency

Patients must be permanently registered with a GP in Worcestershire for at least 12 months and have a documented history of sub-fertility as defined in section 5.2.3 in this document before being considered for NHS funded fertility treatment, unless a prior arrangement is made with commissioners to transfer care from an existing pathway elsewhere in the country with commissioner confirmation of the funding arrangement.

6. Assisted Conception Treatment

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

6.1 ***Male Factor Infertility***

The NICE CG pathway should be followed for suspected male factor infertility.

Where *corrective* surgery is not appropriate, men with obstructive azoospermia may receive at NHS expense, either one needle aspiration ***or*** one open testicular biopsy for surgical sperm recovery. A decision to use the most appropriate procedure to recover a patient's sperm should be made by the specialist clinician during the treatment process.

In extremely rare cases, a second aspiration or biopsy procedure will be funded if the sperm taken at the initial biopsy was not of a satisfactory quality once thawed and a second procedure is required on the day of the female partner's treatment.

Sperm DNA fragmentation testing is not undertaken with NHS funding in Worcestershire. Further information can be found in the Worcestershire CCGs Commissioning Statement: **Worcestershire Clinical Commissioning Policy Collaborative Brief Technology Assessment: Sperm DNA Fragmentation Testing,** available via **http://www.redditchandbromsgroveccg.nhs.uk/about-us/strategies-policies-and-procedures/commissioning-ifr/**

Where patients choose to have this test done privately, the outcome cannot be used to inform an NHS funded treatment pathway (as this would constitute co-payment, see section 8).

6.2 ***Artificial Insemination (AI)***

AI including intra-cervical insemination (see 6.3 for intra-uterine insemination) is not routinely funded and does not form part of the NHS funded specialist fertility treatment pathway.

6.3 ***Intra-Uterine Insemination (IUI)***

IUI is not routinely funded for patients with unexplained infertility, mild endometriosis or mild male factor infertility.

Unstimulated IUI may be considered as a treatment option for the following groups who have demonstrated infertility in accordance with section 1.6 of this document:

- 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
- people in same-sex relationships

Stimulated IUI may be considered as a treatment option for patients with "known reproductive pathology" as defined in section 1.6 (excluding those patient groups defined above), where this is clinically appropriate.

IUI will be funded at NHS expense for up to 3 attempts. Where donor sperm is required as part of the treatment pathway this will also be funded at NHS expense.

Any IUI treatment, whether self funded or NHS funded, will need to be provided by a licensed fertility unit.

Rationale:

i. *Resources are limited but this serves to ensure that where appropriate, all effective interventions have been exhausted.*
ii. *The use of a licensed fertility unit for IUI treatment is required to ensure patient safety is maintained at all times.*

6.4 ***In-Vitro Fertilisation (IVF) / Intra-cytoplasmic sperm Injection (ICSI)***

Ovarian reserve testing will be used to predict the likely ovarian response to IVF. Women are required to meet 2 or more of these measures to determine clinical appropriateness of treatment; these tests will also determine the required dosing schedule for treatment:

1. Total Antral Follicle Count (AFC) > 4 across both ovaries[2]
2. Anti-Müllerian Hormone (AMH) > 5.4 pmol/l OR > 0.75 ng/ml[2]
3. Follicle-Stimulating Hormone < 9 IU/l[2]

These measures do not necessarily apply to women with known reproductive pathology (for example, patients with poly-cystic ovarian syndrome, ovarian failure).

Couples who meet all defined clinical eligibility criteria outlined in section 5.2 and have satisfactory ovarian reserve testing, will be able to receive NHS funding for:

1 fresh cycle of in-vitro fertilisation (IVF) ***or*** intra-cytoplasmic sperm injection (ICSI) (with or without ovarian stimulation and with or without donor sperm or donor egg as clinically appropriate).

Note 1:	A cycle of IVF treatment, with or without intra-cytoplasmic sperm injection (ICSI), usually comprises 1 episode of ovarian stimulation and the transfer of any resultant fresh embryo(s).
Note 2:	Where eggs are retrieved, but embryo development is not achieved or not clinically satisfactory then this cycle is considered complete without embryo transfer.
Note 3:	Frozen gametes/embryo's may be used as part of the NHS funded cycle in patients who have undertaken prior NHS cryopreservation and who meet all other eligibility criteria within this policy.
Note 4:	If the woman reaches the age of 40 during treatment, the cycle should be completed.
Note 5:	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.

6.5 ***Donor Sperm and Eggs***

Donor sperm will only be funded if it is included within the NHS treatment cycle in the circumstances previously defined.

Donor eggs will be funded for managing fertility problems associated with the following conditions:

- Premature ovarian failure
- Gonadal dysgenesis including Turner syndrome
- Bilateral oophorectomy
- Ovarian failure following chemotherapy or radiotherapy

[2] NICE Clinical Guideline CG156

Egg donation is also advocated in certain cases of repeated IVF failure but as only 1 cycle of IVF is being funded, this does not apply. As a result egg donation will not be funded for managing fertility problems associated with repeated failure of IVF.

6.6 ***Cancelled Cycles, Declining and Withdrawal from Treatment***

Where a clinical decision is made to cancel a treatment cycle prior to egg retrieval, then patients remain eligible for up to 1 further cycle in accordance with the policy.

If a patient decides to decline or withdraw from a treatment cycle, then this will count as a full cycle for the purpose of the number of attempts at assisted conception and patients/couples will not be eligible for further NHS funded treatment.

Following patient/couple consultation and determination of an appropriate donor type, if a patient declines donor gametes, then they are not entitled to any further NHS treatment.

Rationale:

i. Cancelled cycles are chargeable and rates have been agreed with Providers.

6.7 ***Prescribing within Treatment Pathway***

For couples who meet the clinical criteria for NHS funded treatment for assisted conception, the prescribing of any drugs to increase fertility and/or assist with conception should be undertaken by the Provider to which that couple was referred. These drugs include, but are not limited to: gonadotrophin drugs for men with hypo-gonadotrophic hypogonadism and anti-oestrogens, gonadotrophins and gonadotrophin-releasing hormone analogues in women. Under no circumstances should the patient's GP be approached to prescribe these drugs as they are part of the treatment pathway provided by the Service Provider.

All drugs should be provided in accordance with the recommendations of NICE CG156.

The Commissioner does not support the NHS funding of any drugs to assist in conception outside of an agreed NHS treatment pathway.

6.9 ***Treatments not Commissioned***

The following treatments have been reviewed by either NICE or the Worcestershire CCGs and are not commissioned:

- 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
- Surgery for varicoceles

7. Principles in NHS Funded Treatment Options

7.1 NHS principles have been applied in the agreement of this policy.

This policy covers the specialist fertility treatments, provided in tertiary care, of:

- Artificial insemination (AI)
- Intrauterine insemination (IUI)
- In vitro fertilisation (IVF)
- Intra cytoplasmic sperm injection (ICSI)
- Egg and sperm donation

Any other interventions or treatments not covered by this policy are not routinely commissioned

7.2 The policy was originally written following the publication in February 2004 of NICE clinical guidance entitled "Fertility, assessment and treatment for people with fertility problems". There have been a number of subsequent revisions following NICE updates and CCG re-evaluation of local commissioning priorities. The latest policy update has been made in order to clarify ambiguities within the previous policy version; the nature of the **changes** that have been made are outlined in the version control section at the beginning of this document.

8. Co-Payment and Retrospective Funding

8.1 The Commissioner has adopted the NHS England Commissioning Policy "Defining the boundaries between NHS and private care", which provides further clarification on the Commissioner's position on co-payment and retrospective funding. This, along with all other commissioning policies, is available at the following internet address:
http://www.redditchandbromsgroveccg.nhs.uk/strategies-policies-and-procedures/commissioning-ifr-policies-a-z/

8.2 Co-payment is seldom permitted in the NHS, other than where, pursuant to Regulations made under the National Health Service Act 2006, specified patients are required to make a specified contribution e.g. prescriptions.

Note:	A patient or couple who has chosen to pay privately for an element of their care, such as a diagnostic test (or insemination to prove fertility problems) is entitled to access other elements of care as NHS commissioned treatment, provided that the patient or couple meet the clinical eligibility criteria identified to receive NHS funded treatment. However, at the point that the patient or couple seeks to transfer back to NHS care: • the commissioner is at liberty to request that the patient/couple be reassessed by an NHS clinician (or to have an NHS clinician review the clinical notes pertinent to the treatment pathway) • the patient/couple will not be given any preferential treatment by virtue of having accessed part of their care privately; AND • the patient/couple will be subject to standard NHS waiting times

8.3 The Commissioner will not make any contribution to the privately funded care to cover the cost of treatment that the patient could have accessed via the NHS.

9. Initial GP Assessment and Referral

9.1 An initial assessment of a patient/couple's sub-fertility should be undertaken by their GP. This should include lifestyle advice in accordance with NICE recommendations, for example on BMI, smoking cessation, occupational hazards, alcohol and caffeine consumption and prescribed, over the counter and recreational drug use in order to optimise fertility. For example:

- Patient/Couples should be advised that excess weight resulting in BMI above 29 can significantly affect fertility and other pregnancy related outcomes. Weight loss through weight management programmes should be encouraged, utilising Tier 2 Living Well services in the first instance or if necessary Tier 3 weight management services.

- Patient/Couples should be informed that the consumption of more than one unit of alcohol per day reduces the effectiveness of assisted reproduction procedures, including in vitro fertilisation treatment.

- Patient/Couples should be informed that either partner smoking can adversely affect the success rates of assisted reproduction procedures, including in vitro fertilisation treatment.

- Patient/Couples should be informed that caffeine consumption has adverse effects on the success rates of assisted reproduction procedures, including in vitro fertilisation treatment.

9.2 Patients/couples should be made aware of all eligibility criteria for assisted conception treatment at the earliest opportunity. They should also be away that these eligibility criteria do not preclude referral to secondary care for fertility assessment and treatment within the secondary care setting.

9.3 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 1 year
- For same sex couples, single individuals or those with a physical disability, the equivalent evidence would constitute 6 cycles of unstimulated artificial insemination
- There is a "known" cause of infertility
- The female/host is aged 36 years or over with evidence of infertility (< 12 months)
- The female/host is aged 39 years or over

Where a patient has recently registered with a GP Practice, the new GP should seek and evidence the period of reported infertility in the patient/couple's medical notes (see also 5.2.10 Residency).

9.4 Patients may choose a provider from the gynaecology choice menu. However, the Commissioner recommends referral to a Consultant Obstetrician and Gynaecologist with a special interest in infertility at Worcestershire Acute Hospitals NHS Trust. Referrals should be marked "Infertility Clinic". A range of diagnostic tests will be undertaken within secondary care; the following tests should be undertaken in primary care prior to referral:

Female partner:	FSH/LH (Day 2-5 of cycle; any time if amenorrhoeic) Prolactin, Testosterone, TSH Rubella (if non-immune, give MMR & advise 1 month abstinence) Pelvic USS (where available) Chlamydia screen
Male partner:	Semen analysis Chlamydia screen

9.5 Following secondary clinical investigation, patient/couples who require assisted conception treatment and meet the eligibility criteria within section 3 of this policy will be referred to a tertiary centre. The tertiary referral pathway for Worcestershire patients is to BMI The Priory Hospital, Birmingham or to Birmingham Women's & Children's Hospital.

9.6 In cases where a patient/couple meet the eligibility criteria noted within this policy for NHS funded assisted conception treatment and the woman is approaching 40, GPs may refer direct to one of the providers noted in section 9.3 to ensure a patient's treatment is completed by the time of her 40th birthday, utilising the tertiary care referral form in appendix 2.

9.7 Patients identified as having a **Blood Bourne Viral Disease** requiring specialist screening and treatment will be referred onto a regional specialist. At the time of publication this is currently via University Hospitals of Coventry and Warwickshire NHS Trust for Worcestershire patients.

10. Supporting Documents

- Worcestershire Clinical Commissioning Policy Collaborative: Assisted Conception - Assessment of Smoking Impact. January 2015
- Worcestershire Clinical Commissioning Policy Collaborative: Assisted Conception – Clinical Update March 2018
- Public Health England: E-cigarettes: An Evidence Update. August 2015
- NHS Worcestershire: Individual Funding Request Process
- NHS Worcestershire: Prioritisation Framework for the Commissioning of Healthcare Services
- NHS England: Ethical Framework for Priority Setting and Resource Allocation
- NHS England: In-Year Service Developments
- NHS England: Defining the boundaries between NHS and private care
- NHS England: Implementation and Funding of NICE Guidance
- National Institute of Health and Clinical Excellence (NICE) Clinical Guidelines CG156: Fertility
- HFEA Statement on Elective Single Embryo Transfer Guidelines:
- http://www.hfea.gov.uk/405.html
- http://www.hfea.gov.uk/401.html#guidanceSection3909
- HFEA (Human Fertilisation Embryology Authority) Code of Practice 8th Edition – revised April 2017
- NHS Cornwall & Isles of Scilly, NHS Devon, NHS Plymouth Torbay Care Trust Policy June 2011
- NHS Choices; Stop Smoking: http://www.nhs.uk/livewell/smoking/Pages/stopsmokingnewhome.aspx
- Smokefree NHS Advice:
- http://www.nhs.uk/smokefree/help-and-advice/prescription-medicines
- http://www.nhs.uk/smokefree/help-and-advice/e-cigarettes

11. Appendices

REFERRAL FORM TO SECONDARY CARE FOR SUBFERTILITY MANAGEMENT

PATIENT DETAILS			
Date of Referral:		Date Referral Received:	
Referring GP:		Contact Number:	
Patient Initials:		Partners Initials: (if registered at practice)	
NHS Number:		NHS Number:	
Patient DoB:		Patient DoB:	
Hospital Number (if known):		Hospital Number (if known):	
GP Practice:		Partner's GP Practice:	

POLICY STATEMENT – extract from full policy, which is accessible via this link
http://www.redditchandbromsgroveccg.nhs.uk/about-us/strategies-policies-and-procedures/commissioning-ifr/?assetdet1029359=39308

The commissioner will support referral of patients/couples to secondary care for fertility investigations and treatments when the following eligibility criteria are met:	**Female/Host**	**Male/Partner**
	Complete as appropriate for registered patient(s)	
1. **Infertility** defined as "failure to conceive after regular unprotected sex for a period of not less than 1 year (or < 1 year in women aged 36 to 39 years), in the absence of known reproductive pathology" *For single people and same sex couples, has there been a failure to conceive following artificial insemination at or just before the known time of ovulation for at least 6 non-stimulated cycles (undertaken at a licensed fertility unit)?* **OR**	**Yes** ☐ **No** ☐	
2. **Known reproductive issue** diagnosed in either partner? *Refer without delay if there is known reproductive pathology and specify nature:* **OR**	**Yes** ☐ **No** ☐	**Yes** ☐ **No** ☐
3. **Refer without delay if:**		
• Female/host aged over 39 years	**Yes** ☐ **No** ☐	**N/A**
• History of chronic viral infection (HIV, HBC, HCV)	**Yes** ☐ **No** ☐	**Yes** ☐ **No** ☐
• Patient awaiting treatment that may result in infertility (see Cryopreservation policy)	**Yes** ☐ **No** ☐	**Yes** ☐ **No** ☐

Investigations in Primary Care (arrange 1 year after UPSI)

FEMALE/HOST:		
FSH/LH (Day 2-5 of cycle)	**Yes** ☐	
Prolactin	**Yes** ☐	
Testosterone	**Yes** ☐	
TSH	**Yes** ☐	
Rubella (if non-immune, give MMR & advise 1 month abstinence)	**Yes** ☐	
Pelvic ultrasound scan	**Yes** ☐ **No** ☐	
MALE/PARTNER:		
Semen analysis Please put requester ***Danielle Williams, Fertility Specialist Nurse, Kings Court, WRH, WR5 1DD*** with results to be copied to ***Danielle.williams14@nhs.net*** *www.treatmentpathways.worcsacute.nhs.uk/womens/gynaeoverview/fertility/primarycarefertility/semen-analysis/*		**Yes** ☐

General Advice	Female/Host	Male/Partner
Preconception advice leaflet – Copy given to patient	Yes ☐	Yes ☐
Folic acid 400micrograms (5mg if BMI > 29 or PMH of: diabetes, epilepsy, previous/FH of neural tube defects, coeliac disease, sickle cell anaemia)	Yes ☐	N/A
Smoking cessation advice	Yes ☐ No ☐	Yes ☐ No ☐
Weight loss: exercise and dietary advice accessing Tier 2 and 3 services if necessary	Yes ☐ No ☐	Yes ☐ No ☐
Lifestyle advice regarding: • Alcohol • Tight underwear • Prescribed, over-the-counter & recreational drug use • Occupation • Caffeinated beverages • Complementary therapy	Yes ☐ No ☐	Yes ☐ No ☐

Patient Awareness of Eligibility Criteria for Future Assisted Conception (tertiary referral)

Please confirm that the patient has been made aware of the following NHS Worcestershire eligibility criteria for tertiary referral should the need arise: Yes ☐ No ☐

Female Age between 18 and 39 inclusive (*Please ensure timely referral for patient's approaching 40)*

Female BMI between 19 and 29 inclusive ; **Male BMI** 29 or less (where male factor infertility identified)

Is the patient/couple childless? - *Eligibility requires no living children (of any age), including adopted children or children from the current or any previous relationship*

Smoking Status – *Eligibility requires a minimum period of 6 months as a non-smoking couple (this may include use of stop smoking products if clinically appropriate)*

Prior Assisted Conception Treatment – *Eligibility requires no prior treatment (NHS or private)*

Sterilisation - *Eligibility requires no prior sterilisation*

EXAMINATION/PMH/DH/ALLERGIES

REFERRAL CRITERIA

Are there any co-morbidities that need to be considered in relation to this referral? (Please provide details above)	**Yes** ☐ **No** ☐

PATIENTS NOT MEETING THE POLICY

For patients who do not fall within the eligibility criteria set out in the policy but where there is demonstrable evidence that the patient has clinically exceptional circumstances, an Individual Funding Request may be considered. The referring clinician should consult the Commissioner's "Operational Policy for Individual Funding Requests" document for further guidance on this process.
http://www.redditchandbromsgroveccg.nhs.uk/strategies-policies-and-procedures/commissioning-ifr-policies-a-z/

REFERRAL FORM FOR CONSIDERATION OF TERTIARY REFERRAL FOR ASSISTED CONCEPTION

PATIENT DETAILS

Date of Referral:		Date Referral Received:	
Referring GP/Consultant:		Contact Number:	
Patient Initials:		Partners Initials:	
NHS Number:		NHS Number:	
Patient DoB:		Patient DoB:	
Hospital Number (if known):		Hospital Number (if known):	
GP Practice:		Partner's GP Practice:	

POLICY STATEMENT – extract from full policy, which is accessible via this link

http://www.redditchandbromsgroveccg.nhs.uk/about-us/strategies-policies-and-procedures/commissioning-ifr/?assetdet1029359=39308

The commissioner will support referral of patients/couples for consideration of assisted conception treatment where the following eligibility criteria are met:	**Female/Host**	**Male/Partner**
Female Age between 18 and 39 inclusive *Please enter value and ensure timely referral for patient's approaching 40*		
Female BMI between 19 and 29 inclusive **Male BMI** 29 or less (where male factor infertility identified) *Please enter value and state height and weight measurements and date taken*		
Infertility defined as "failure to conceive after regular unprotected sex for a period of not less than 2 years (in the absence of known reproductive pathology), including a minimum period of 6 months as a non-smoking couple" *For single people and same sex couples, has there been a failure to conceive following insemination at or just before the known time of ovulation, on at least 10 non-stimulated cycles or 6 cycles of clinically delivered insemination (undertaken at a licensed fertility unit), including a minimum non-smoking period of 6 months*	**Yes** ☐ **No** ☐	
Known reproductive issue diagnosed in either partner? *Refer without delay if there is known reproductive pathology and specify nature*	**Yes** ☐ **No** ☐	**Yes** ☐ **No** ☐
Is the patient/couple childless? *Eligibility requires no living children (of any age), including adopted children or children from the current or any previous relationship*	**Yes** ☐ **No** ☐	
Prior Assisted Conception Treatment – Is this the first attempt at fertility treatment? *Eligibility requires no prior treatment (NHS or private)*	**Yes** ☐ **No** ☐	
Sterilisation - Has either partner received prior sterilisation or reversal of sterilisation? *Eligibility requires no prior sterilisation*	**Yes** ☐ **No** ☐	**Yes** ☐ **No** ☐
Welfare of the Child - As far as you are aware, does the patient/couple comply with the HFEA Code of Practice? ie. the ability to provide a stable & supportive environment? *See www.hfea.gov.uk Code of Practice for more details*	**Yes** ☐ **No** ☐	

Smoking Status - Have either the patient or their partner (please detail):		
Ever smoked?	**Yes** ☐ **No** ☐	**Yes** ☐ **No** ☐
Smoked within the last 6 months?	**Yes** ☐ **No** ☐	**Yes** ☐ **No** ☐
Quit smoking in the last 6-12 months?	**Yes** ☐ **No** ☐	**Yes** ☐ **No** ☐
For recent smokers: has the patient/couple been directed to nationally accredited resources to support smoking cessation?	**Yes** ☐ **No** ☐	**Yes** ☐ **No** ☐
For recent quitters: has the patient provided evidence and timescale for stop smoking (6 months no smoking required)?	**Yes** ☐ **No** ☐	**Yes** ☐ **No** ☐
Does the patient/partner use NRT or e-cigarettes (please state)?	**Yes** ☐ **No** ☐	**Yes** ☐ **No** ☐
Eligibility requires 6 consecutive months no smoking in both partners; this period may include use of stop smoking product		
Lifestyle Advice - has advice in relation to fertility been provided regarding: • Diet • Alcohol • Caffeinated beverages • Tight underwear • Prescribed, over-the-counter & recreational drug use • Complementary therapy • Folic acid supplementation • Occupation	**Yes** ☐ **No** ☐	**Yes** ☐ **No** ☐
Are either the patient or partner:		
➢ A suspected or known alcohol or substance misuser?	**Yes** ☐ **No** ☐	**Yes** ☐ **No** ☐
➢ A recreational drug user?	**Yes** ☐ **No** ☐	**Yes** ☐ **No** ☐
➢ Undergoing current treatment with opiate substitution?	**Yes** ☐ **No** ☐	**Yes** ☐ **No** ☐
Yes to any of the above 3 questions would be ineligible		

EXAMINATION/PMH/DH/ALLERGIES

REFERRAL CRITERIA

Are there any co-morbidities that need to be considered in relation to this referral? (Please provide details above)	Yes ☐ No ☐

PATIENTS NOT MEETING THE POLICY

For patients who do not fall within the eligibility criteria set out in the policy but where there is demonstrable evidence that the patient has clinically exceptional circumstances, an Individual Funding Request may be considered. The referring clinician should consult the Commissioner's "Operational Policy for Individual Funding Requests" document for further guidance on this process.
http://www.redditchandbromsgroveccg.nhs.uk/strategies-policies-and-procedures/commissioning-ifr-policies-a-z/

12. Equality Impact Assessment

Organisation	Worcestershire CCGs		
Department	Commissioning	Department	Fiona Bates/Helen Bryant
Piece of work being assessed	Worcestershire CCGs: Tertiary Referral for Assisted Conception Policy		
Aims of this piece of work	To assess the impact of this policy on equality		
Date of EIA	04/03/2014 review May 2014 minor updates July 2017 major updates June 2018 minor updates January 2019 minor updates		
Who will be affected by this piece of work?	Couples seeking to start a family		

Single Equality Scheme Strand	**Baseline data and research on the population that this piece of work will affect.** What is available? E.g. population data, service user data. What does it show? Are there any gaps? Use both quantitative data and qualitative data where possible. **Include consultation with service users wherever possible**	**Is there likely to be a differential impact?** Yes, no, unknown
Gender	Both sexes susceptible to infertility. Approximately 3% men and 7% women will have fertility problems.	Yes
	There are issues in relation to a treatment naive male partner with known reproductive issues being denied assisted conception where their partner has previously had treatment at NHS expense without success (with a different partner) and is therefore no longer eligible for further treatment.	Yes
	Male and females who have previously chosen to be sterilised are not eligible within the existing policy; the decision to undertake sterilisation should not be made lightly and full counselling is provided to the patient/couple with awareness that the decision is a permanent one.	No - The patient has chosen this course of action
Race	There is research to suggest that black women have a higher prevalence compared to white women (Mosher and Aral, 1985). Data from a national survey in the US found that a significantly higher proportion of African-American and Hispanic women had tubal factor infertility compared to Caucasian women (Jain, 2006). Is any UK evidence available? Regardless, all women who meet the defined circumstances would be eligible for treatment.	No
	People from some ethnic groups marry very young (eg Gypsies and Travellers) and would be discriminated against by the old policy 23yr rule unless this can be clinically substantiated. For instance, a Gypsy girl who married at 16	Yes

Single Equality Scheme Strand	Baseline data and research on the population that this piece of work will affect. What is available? E.g. population data, service user data. What does it show? Are there any gaps? Use both quantitative data and qualitative data where possible. Include consultation with service users wherever possible	Is there likely to be a differential impact? Yes, no, unknown
	could have been trying to get pregnant for 7 years before she became eligible for assessment. The NICE update has removed any lower age limit on the basis of a lack of evidence of ineffectiveness. This policy has a lower age limit of 19 on the basis of 2 years to prove infertility (from age of sexual consent of 16) and 1 year workup for fertility treatment in tertiary care. The numbers are likely to be small (0.35% treatment for women aged 18-22 years) and negligible financial impact.	
Disability	There may be reduced access to fertility treatment for those with a disability as clinicians can deny access if fertility treatment/pregnancy could worsen your medical condition. In some cases a disability may inhibit a person even having sexual intercourse; although the new NICE guidance makes allowances around artificial insemination for such patients has been reflected in local update. Some particular disabilities may affect a person's fertility, for example if a male suffered a spinal cord injury this may lead to reduced ability to ejaculate and reduce the quality and quantity of semen. (http://www.facingdisability.com/expert-topics/how-does-a-spinal-cord-injury-affect-male-fertility/diane-m-rowles-ms-np) People with HIV may also be at an increased risk of infertility due both to the virus itself and the drugs that are taken to control it. Men with HIV are more likely to experience decreased sex drive and an estimated 60% experience erectile or ejaculatory dysfunction. However specialist services provided by C&W make provision for treatment of these patients. (http://www.aidsbeacon.com/news/2011/07/14/hiv-aids-and-antiretroviral-therapy-may-affect-fertility/) The reduced provision of cycles offered may have a negative impact on patients with a physical disability who may be less likely to self-fund further treatment cycles. However, this would be equitable for all patients with or without disability. Some physical disabilities may impede sexual intercourse. Also some medical treatments can cause long-term infertility and so an individual may request harvesting of eggs or sperm prior to treatment which is covered by a separate commissioning policy: cryopreservation for infertility associated with medical treatment or surgery).	No –clinical decision not policy Yes Yes Yes but not within this policy context No Yes
Religion/ belief	No evidence of a link between religion and fertility.	No
Sexual orientation	Homosexual males, due to the heightened risk of HIV may experience reduced fertility due to the virus and treatment. However specialist services provided by C&W make provision for treatment of these patient; this is excluded from this policy There is no evidence to suggest any difference in fertility between homosexual and heterosexual females. However, one of the most common causes of infertility is damage caused by Chlamydia infection which is less likely in homosexual women.	Yes but not within this policy context No
Age	Females: Fertility declines with age from the age of mid-thirties onwards but becomes more significant beyond the age of 39. There is no evidence to suggest that fertility is reduced in younger women (under 23), and this age limit was removed in the 2013 NICE update. This policy version has a lower age limit of 18 on the basis of 1 years to	Yes

Single Equality Scheme Strand	**Baseline data and research on the population that this piece of work will affect.** What is available? E.g. population data, service user data. What does it show? Are there any gaps? Use both quantitative data and qualitative data where possible. **Include consultation with service users wherever possible**	**Is there likely to be a differential impact?** Yes, no, unknown
	prove infertility (from age of sexual consent of 16) and 1 year workup for fertility treatment in secondary care. The numbers are likely to be small (0.35% treatment for women aged 18-22 years) and negligible financial impact. Males: There is evidence of declining male fertility with age (10% lower success rates at 40 compared with 35). The old Worcestershire policy limits male age to 55 years; this limit was made on the basis of a parent's ability to care for a child at an older age in life. It has been removed from this current version with any concerns addressed through "Welfare of the Child". In the 2017 policy version which involves a reduction in the number of cycles of assisted conception offered, smoking individuals/couples approaching the age of 40 will find it harder to access assisted conception services in a timely manner prior to their 40th birthday, which may make them ineligible for treatment.	Yes Yes
Social deprivation	With the noted link between social deprivation and increased risk of obesity, the occurrence of infertility in those who are obese may be due to the excessive weight affecting menstrual cycles. There is also a link between social deprivation and smoking with higher rates reported in socially deprived areas; therefore those people who do not comply with the requirement to stop smoking will be affected by the proposed changes. Also, people in this category would be less able to self-fund private treatment as an alternative to NHS funded care.Social deprivation indirectly impacts upon those living in socially deprived areas as those women who have a Body Mass Index <19 kg/m2 or >30kg/m2 are not eligible for NHS funded treatment as the chance of conception is lowered.	Yes Yes
Carers	There is no evidence that being a carer has an impact on the ability to conceive	No
Human rights	Will this piece of work affect anyone's human rights?	No – enhances the right to family life

Equality Impact Assessment Action Plan

Strand	Issue	Action required	How will you measure the outcome/impact	Timescale	Lead
Gender	7% women affected by infertility; those women may be in a relationship or not and heterosexual, bisexual or lesbian. Males in a relationship with a partner who has previously received their "share" of assisted conception treatment.	Ensure updated policy supports all those women and specifically refers to the eligibility of women in all of these situations. Make provision for males to undergo any other necessary treatment for their infertility up to the point of assisted conception.	Analysing data to observe trends in cases. Clarify in policy that treatment prior to assisted conception is considered part of the standard NHS treatment pathway and therefore available to all patients.	Completed/ Ongoing Completed	HB/PT
Race	People from some ethnic groups marry very young but the current policy will not look at women under 23yrs	Remove the 23yr age specification from the policy. The new policy has used a lower age limit of 19 on the basis of 2 years to prove infertility (from age of sexual consent of 16) and 1 year workup for fertility treatment in tertiary care.	Change in policy	Completed	FB
Disability	Reduced fertility/sexual intercourse due to disability	Accommodated within updated NICE guidance, ensure local adoption.	Change in policy	Completed	FB
Disability	Long term infertility cause by medical or surgical treatment	Where a disability is a cause of infertility (for example male factor infertility related to spinal injury) eligibility for cryopreservation is first considered through the cryopreservation policy; use of cryopreserved material when required, is subsequently considered in accordance with the assisted conception policy.	Accommodated through Cryopreservation Policy	Completed	FB
Age	Female under 23 year olds not eligible	This policy has used a lower age limit of 19 on the basis of 2 years to prove infertility (from age of sexual consent of 16) and 1 year workup for fertility treatment in tertiary care.	See above under Race	Completed	FB
Age	Males restriction < 55yrs	Although the ability to bare children lies with a female and this has undeniable physical constraints, the male age limit offers some equality on the basis of the ability to care for a child at an older age in life. There is also some evidence regarding reduced fertility in men with increasing age. Legal advice suggests this age limit restriction should be removed.	Remove male age limit.	Completed	FB
Age	One cycle only – individuals approaching 40 - harder to	This issue will be highlighted to GPs upon publication of the new policy in an attempt to minimize impact. It is acceptable	Referred patients using stop-smoking products	August 2017 initially then	FB

Strand	Issue	Action required	How will you measure the outcome/impact	Timescale	Lead
	access assisted conception services in a timely manner	to use stop smoking products, providing that this is considered appropriate by a patient's GP or hospital clinician.	will be captured through provider services and audited. It will not be possible to monitor patients ineligible for treatment.	annually thereafter	
Social Deprivation	People from poorer areas are at increased risk of being underweight or overweight and thus not eligible for treatment	There is a clear clinical rationale for denying treatment to people with a high BMI.	N/A		
Social Deprivation	People from deprived communities are more likely to smoke.	The evidence clearly demonstrates that smoking adversely impacts on: ability to conceive, efficacy of assisted conception, pregnancy outcomes, health of resulting, therefore no action. All patients have the opportunity to stop smoking and if they remain infertile following this they may subsequently be eligible for assisted conception treatment. It is not expected that couples are referred for fertility investigations until they have been non-smokers for a period of 6 months. Options to support patients to cease smoking will be explored with Worcestershire County Council who is the responsible commissioner for these services.	Audit through tertiary providers	2018/19	FB
Social Deprivation	People in this category would be less able to self-fund private treatment as an alternative to NHS funded care.	The inequity with respect to self-funding private treatment already applies where patients exhaust the NHS pathway	N/A		

General Comments and observations of this document.

Rationale for denying treatment needs to be explicit.

NICE guidance is now clear that the marital/partnership status and sexual orientation of patients is of no relevance therefore the policy needs to be explicit in the evidence that needs to be provided of infertility by patients prior to treatment. A comparable level of "proof" has been defined within the new policy:

- A referral to secondary care should not be made until the GP is satisfied that a patient/couple has tried unsuccessfully to conceive for 1 year.
- For same sex couples, single individuals or those with a physical disability, the equivalent evidence would constitute 6 cycles of unstimulated artificial insemination

Note: A separate Equality Impact Assessment was undertaken (July 2017) in relation to the changes being made in this policy compared with the previous version; this is available upon request.