NHS
Vale of York
Clinical Commissioning Group

# Access to infertility treatment

## Commissioning Policy Document Yorkshire and Humber (NHS Vale of York CCG adapted)

Published February 2018

# Commissioning Policy Statement:

**Commissioning**

This document represents the commissioning policy of NHS Vale of York Clinical Commissioning Group for the clinical pathway which provides access to tertiary fertility services. This commissioning policy has been developed in partnership with the Yorkshire and The Humber Expert Fertility Panel. It is intended to provide a framework for the commissioning of services for those couples who are infertile and require infertility interventions.

The policy was developed jointly by Clinical Commissioning Groups in the Yorkshire and Humber area and provides a common view of the clinical pathway and criteria for commissioning services which have been adapted by NHS Vale of York CCG.

**Funding**

The policy on funding of tertiary fertility services for individual patients is a policy of this CCG. It is not part of the shared policy set out in the rest of this document. The number of full IVF cycles currently funded by the CCG for patients who meet the access criteria set out in the shared policy is one. This is unchanged from the previous funding policy in December 2014. This policy will be updated in accordance with the review period of the policy or earlier should sufficient changes in practice or evidence base require it.

# Panel Members:

| | |
|---|---|
| Dr. Virginia Beckett | Consultant in Obstetrics and Gynaecology Bradford Teaching Hospital FT |
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# For further information about this policy:

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**Summary of CCGs in Yorkshire and Humber position with regards number of cycles in January 2017** (note this may be subject to change, please check with the individual commissioner for the current position):

| CCG | Age 18 - 40 | Age 40 - 42 |
|---|---|---|
| Airedale Wharfedale and Craven CCG | 1 | 1 |
| Barnsley CCG | 2 | 1 |
| Bassetlaw CCG | 3 | 1 |
| Bradford District CCG | 1 | 1 |
| Calderdale CCG | 1 | 1 |
| Doncaster CCG | 2 | 1 |
| East Riding of Yorkshire CCG | 1 | 1 |
| Greater Huddersfield CCG | 1 | 1 |
| Hambleton, Richmondshire and Whitby CCG | 2 | 1 |
| Harrogate and Rural District CCG | 1 | 1 |
| Hull CCG | 3 | 1 |
| Leeds North CCG | 1 | 1 |
| Leeds South & East CCG | 1 | 1 |
| Leeds West CCG | 1 | 1 |
| North Kirklees CCG | 1 | 1 |
| Rotherham CCG | 2 | 1 |
| Scarborough & Ryedale CCG | 1 | 1 |
| Sheffield CCG | 1 | 1 |
| Vale of York CCG | 1 (23-40) | 1 |
| Wakefield CCG | 1 | 1 |
| North East Lincolnshire CCG | 1 | 1 |
| North Lincolnshire CCG | 1 | 1 |

# Contents

## 1. Aim of Paper

1.1 This document represents the commissioning policy for tertiary fertility services for adults registered with a Clinical Commissioning Group (CCG) in the Yorkshire and Humber region.

1.2 The policy aims to ensure that those most in need and able to benefit from NHS funded treatment are given equitable access to tertiary fertility services across the Yorkshire and Humber Area, by identifying the clinical care pathway and relevant access criteria.

## 2. Background

2.1 On April 1st, 2013 Clinical Commissioning Groups (CCGs) across the Yorkshire and the Humber regions adopted the existing Yorkshire and the Humber Fertility policy[1]. In February 2013 NICE published revised guidance [2] which was reviewed by NICE in 2016 and which updated previous NICE guidance published in 2004[3].

2.2 CCGs across the Yorkshire and the Humber agreed to work collaboratively to update the existing policy in light of the new NICE guidance and changing commissioning landscape.

2.3 In this policy document infertility is defined:

***Definition of Infertility:***

*For all couples: The presence of known reproductive pathology.*

*For heterosexual couples: The failure to conceive after regular unprotected sexual intercourse for a period of 2 years in the absence of known reproductive pathology.*

*For same-sex couples: the failure to conceive after a minimum of six rounds of self-funded donor insemination via IUI, in the absence of any known reproductive pathology.*

*For couples where one partner has a known medical condition: this must be a medical condition which prevents natural conception such as physical disability, an infection requiring sperm washing, or a psychosexual disorder.*

*Note - For couples where ovulation can be induced with simple techniques such as clomiphene, these patients are <u>not</u> regarded as infertile on this basis alone - and therefore would not meet the eligibility criteria for access to IVF at that stage.*

[1] Yorkshire and the Humber Commissioning Policy for Fertility Services, 2010.
[2] Fertility: Assessment and treatment for people with fertility problems 2012, NICE Clinical Guideline 156.
[3] Fertility: Assessment and Treatment for people with fertility problems 2004, NICE Clinical Guideline 11.

2.4 Fertility problems are common in the UK and it is estimated that they affect 1 in 7 couples with 80% of couples in the general population conceiving within 1 year, if:

- The woman is aged under 40 years and
- They do not use contraception and have regular sexual intercourse (NICE, 2013)

Of those who do not conceive in the first year about half will do so in the second year (cumulative pregnancy rate is 90%).

The remaining 10% of couples will be unable to conceive without medical intervention and are therefore considered infertile.

2.5 In 25% of infertility cases, the cause cannot be identified. However, it is thought that in remaining couples about a third of cases are due to the male partner being unable to produce or ejaculate sufficient normal sperm, a third are due to problems found with the female partner such as:

- Failure to ovulate
- Blockage to the passage of the eggs

10% are due to problems with both partners.

2.6 The most recent DH costing tool estimates that there are 98 attendances at a fertility clinic for every 10,000 head of population. In Yorkshire and the Humber, this could range between 4,000 and 5,000 attendances per year which would result in approximately 1,450 couples likely to be assessed as eligible for IVF treatment.

2.7 Tertiary fertility services include IUI, ICSI and IVF. They may also include the provision of donor sperm and donor eggs. The majority of treatment in the UK is statutorily regulated by the Human Fertility and Embryo Authority (HFEA). All tertiary providers of fertility services must be licensed with the HFEA in order to be commissioned under this policy.

2.8 NICE Clinical Guidelines 156 (2013) covering infertility recommends that:

> Up to three full cycles of IVF will be offered to eligible couples where the woman is aged between 18 – 39 and 1 cycle for eligible couples where the woman is aged 40 - 42.

2.9 NHS Vale of York CCG will fund one cycle of IVF treatment for eligible couples where the woman is aged between 23 – 42 and who meet the access criteria set out in section 6. Where an individual feels that they have exceptional circumstances that would merit consideration of an additional cycle being funded by the CCG they should speak to their doctor about submitting an individual funding request to their local CCG.

Same sex and heterosexual couples will have equal access to services.

2.10 In addition to commissioning effective healthcare, CCGs are required to ensure that resources are allocated equitably to address the health needs of the population. Therefore CCGs will need to exercise discretion as to the number of cycles of IVF that they will fund up to the maximum recommended by NICE.

## 3. Clinical Effectiveness

3.1 It is considered to be clinically effective by NICE to offer up to 3 stimulated cycles of IVF treatment to couples where the woman is aged between 18 – 39 and 1 cycle where the woman is aged between 40 – 42 and who have an identified cause for their infertility or who have infertility of at least 2 years duration.

## 4. Cost Effectiveness

4.1 Evidence shows (NICE, 2013) that as the woman gets older the chances of successful pregnancy following IVF treatment falls. In light of this, NICE has recommended that the most cost effective treatment is for women aged 18 – 42 who have known or unknown fertility problems.

4.2 As research within this field is fast moving, new interventions and new evidence needs to be considered on an on-going basis to inform commissioning decisions.

### 4.3 Risks

Fertility treatment is not without risks. A summary of potential risks is outlined below:

**Risks**

- There are risks of multiple pregnancies during fertility treatment, which is associated with a higher morbidity and mortality rate for mothers and babies.
- Women who undergo fertility treatment are at slightly higher risk of ectopic pregnancy.
- Ovarian hyper stimulation, which is a potentially fatal condition, is also a risk. The exact incidence of this has not been determined but the suggested number is between 0.2 – 1% of all assisted reproductive cycles.
- Current research shows no cause for concern about the health of children born as the result of assisted reproduction.
- A possible association between ovulation induction therapy and ovarian cancer in women who have undergone treatment is uncertain.
- Further research is needed to assess the long-term effects of ovulation induction agents.

# 5. Description of the Treatment

## 5.1 Principles of Care

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

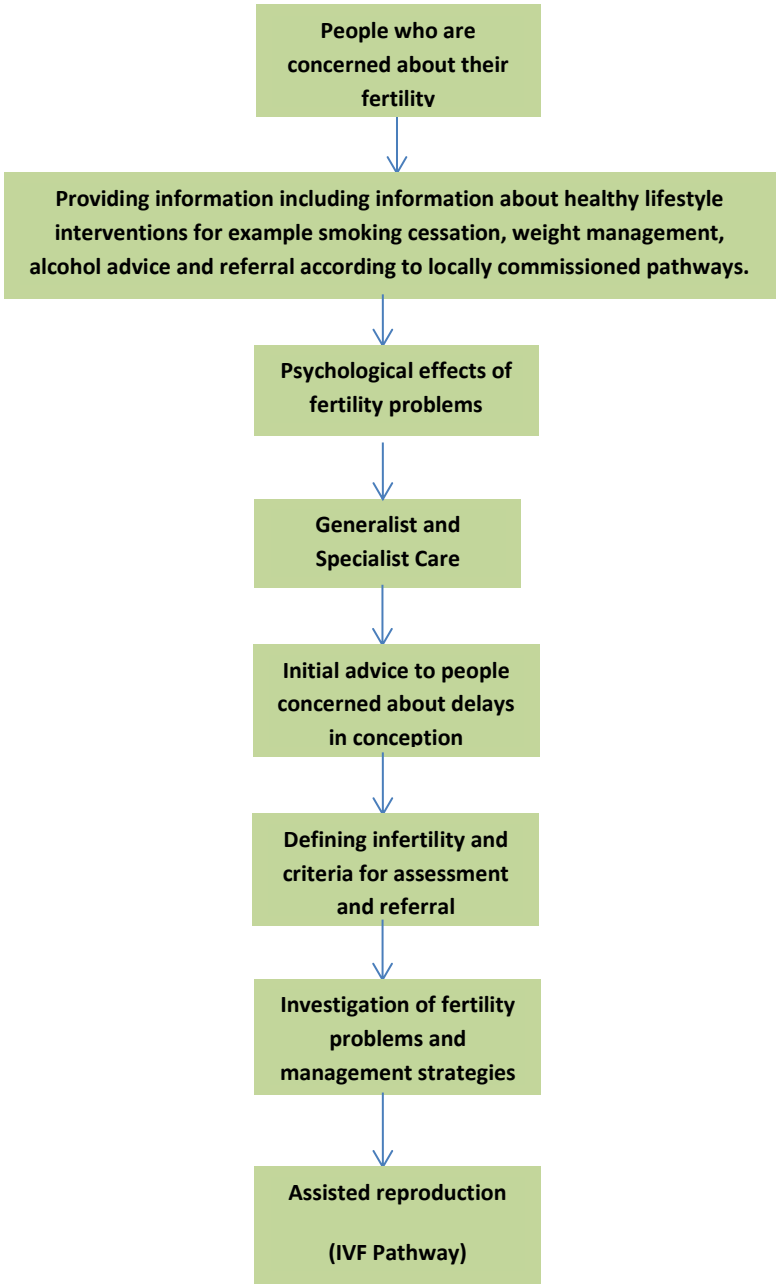
5.1.2 People should have the opportunity to make informed decisions regarding their care and treatment via access to evidence-based information. These choices should be recognised as an integral part of the decision-making process.

Information should be provided in the following formats:

- Face to face discussions with couples
- Written information and advice
- Culturally sensitive
- Be sensitive to those with additional needs e.g. physical or cognitive, or sensitive disabilities, or those who do not speak English.

5.1.3 As infertility and infertility treatments have a number of psycho-social effects on couples, access to psychological support prior to and during treatment should be considered as integral to the care pathway.

## 5.2 The Care Pathway (fig, 1)




5.2.1 Treatment for infertility problems may include counselling, lifestyle advice, drug treatments, surgery and assisted conception techniques such as IVF.

- Providers of specialist fertility services are expected to deliver appropriate interventions to support lifestyle behaviour changes which are likely to have a positive impact on the outcome of assisted conception techniques and resulting pregnancies. Recommendations covering screening, brief advice and onward referral are outlined in NICE Public Health Guidance (PH49) and, specifically in relation to fertility and pre-conception, smoking (PH26, PH48), weight management (PH27, PH53), healthy eating and physical activity (PH11, NG7) and alcohol (PH24).

- Use any appointment or meeting as an opportunity to ask women and their partners about their general lifestyle including smoking, alcohol consumption, physical activity and eating habits. If they practice unhealthy behaviours, explain how health services can support people to change behaviour and sustain a healthy lifestyle.

- Offer those who support a referral to Lifestyle Services using local arrangements to make a referral. For those that are unable or do not want to attend support services direct them to appropriate self-help information such as the national ‘One You' website or local websites.

- Record this in the patient’s record.

The care pathway (fig 1) begins in primary care, where the first stage of treatment is general lifestyle advice and support to increase a couple's chances of conception happening without the need for medical intervention.

If primary care interventions are not effective, initial assessment such as semen analysis will take place. Following these initial diagnostics, it may be appropriate for the couple to be referred to secondary care services where further investigation and potential treatments will be carried out, such as hormonal therapies to stimulate ovulation. It may be appropriate at this stage for the primary care clinician to consider and discuss the care pathway and potential eligibility for IVF. It may also be appropriate for healthy lifestyle interventions to be discussed.

If secondary care interventions are not successful and the couple fulfils the eligibility criteria in section 6, they may then be referred through to tertiary care for assessment for assisted conception techniques, such as IVF, DI, IUI, and ICSI.

5.2.2 IVF involves:

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

## 5.3 Definition of a Full Cycle

*Full cycle is the term used to define a full IVF treatment; it should include one episode of ovarian stimulation and the transfer of any resultant fresh and frozen embryo(s) (NICE, 2013). Or*

*The definition of a single full treatment cycle is the replacement of a fresh embryo and subsequent sequential replacement of all frozen embryos derived from the cycle until pregnancy is successful or harvested embryos have been exhausted. (Not expected to be more than 4).*

*Adherence in this way to the NICE guidelines would encourage and not disadvantage patients agreeing to single embryo transfer.*

## 5.4 Frozen Embryo Transfers

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

## 5.5 Abandoned Cycles

An abandoned IVF/ICSI cycle is defined as the failure of egg retrieval, usually due to lack of response (where less than three mature follicles are present) or excessive response to gonadotrophins; failure of fertilisation and failure of cleavage of embryos. Beyond this stage, a cycle will be counted as complete whether or not a transfer is attempted. One further IVF/ICSI cycle only will be funded after an abandoned cycle. Further IVF/ICSI cycles will not be offered after any subsequent abandoned cycles.

## 5.6 IUI and DI

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

### 5.6.1 People with physical disabilities, psychosexual problems, or other specific conditions with infertility (as defined in section 2)

Where a medical condition exists (such as physical disability, an infection requiring sperm washing, or a psychosexual disorder prevents natural conception), IUI for up to 6 cycles may be funded, followed by further assisted conception if required. In some circumstances, IUI may be impractical and so is not a requirement for further fertility treatment. Treatment will be funded providing other criteria are met.

### 5.6.2 IUI and DI in same-sex relationships

Up to 6 cycles of IUI will be funded as a treatment option for people in same-sex relationships who meet the definition of infertility, followed by further assisted conception if required.

### 5.6.3 People with unexplained infertility, mild endometriosis or mild male factor infertility, who are having regular unprotected sexual intercourse

Up to 3 cycles of IUI and DI (stimulated or non-stimulated) will be provided for couples with unexplained fertility, mild endometriosis or mild male factor. They will then access IVF treatment if appropriate.

5.6.4 Donor Gametes including azoospermia:

**Donor Sperm**

Up to 6 cycles of donor insemination (dependent on availability of donor sperm) will be offered for couples with male azoospermia via donor sperm.

The cost of donor sperm is included in the funding of treatment for which it is required, to be commissioned in accordance with this policy and the funding policy of the CCG.

**Donor Eggs**

Patients eligible for treatment with donor eggs, in line with NICE recommendations, will be placed on the waiting list for treatment with donor eggs. Unfortunately, the availability of donor eggs remains severely limited in the UK. There is, therefore, no guarantee that eligible patients will be able to proceed with treatment. Patients who require donor eggs will be placed on the waiting list for an initial period of 3 years, after which they will be reviewed to assess whether the fertility policy eligibility criteria are still met.

## 5.7 Gametes and Embryo Storage

The cost of egg and sperm storage will be included in the funding of treatment for which it is required, to be commissioned in accordance with this policy and the funding policy of the CCG. Storage will be funded by the CCG for a maximum of 3 years or until 6 months post successful live birth, whichever is the shorter. This will be explained by the provider prior to the commencement of treatment. Following this period the woman/couple may self-fund continued storage.

Any embryos frozen prior to implementation of this policy will be funded by the CCG to remain frozen for a maximum period of 3 years from the date of policy adoption.

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

## 5.8 HIV/HEP B/ HEP C

People undergoing IVF treatment should be offered testing for HIV, hepatitis B and hepatitis C (NICE, 2013).

People found to test positive for one or more of HIV, hepatitis B, or hepatitis C should be offered specialist advice and counselling and appropriate clinical management (NICE, 2013).

## 5.9 Surrogacy

Any costs associated with use of a surrogacy arrangement will not be covered by funding from CCGs, but we will fund provision of fertility treatment (IVF treatment and storage) to identified (fertile) surrogates, where this is the most suitable treatment for a couple's infertility problem and the couple meets the eligibility criteria for tertiary fertility services set out in this policy.

## 5.10 Single Embryo Transfer

Please refer to 5.3 for the definition of a full cycle.

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

We support the HFEA guidance on single embryo transfer and will be performance monitoring all tertiary providers to ensure that HFEA targets are met. All providers are required to have a multiple births minimisation strategy. The target for multiple births should now be an upper limit of 10% of all pregnancies.

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

## 5.11 Counselling and Psychological Support

As infertility and infertility treatment has a number of negative psychosocial effects access to counselling and psychological support should be offered to the couple prior to and during treatment.

Given the strict eligibility criteria and the relatively low success rates for IVF, couples and individuals may wish to consider finding out more about adoption, as another route to becoming parents. The Government's national information service is the best place to start http://www.first4adoption.org.uk or information line – 0300 222 0022.

## 5.12 Sperm Washing and Pre-implantation Diagnosis

Sperm washing and pre-implantation genetic diagnosis are not treatments for infertility and fall outside the scope of this policy. Prior approval is required.

## 5.13 Service Providers

Providers of fertility treatment must be HFEA registered and comply with any service specification drawn up by Yorkshire and the Humber Clinical Commissioning Groups.

# 6.0 Eligibility Criteria for Treatment

## 6.1 Application of Eligibility Criteria

Eligibility criteria should apply at the point at which patients are referred to tertiary care (with the exception of 6.11, which should be undertaken within tertiary care). Couples must meet the definition of infertility as described in section 2.3.

## 6.2 Overarching Principles

6.2.1 Eligibility criteria should apply equally to all assisted conception treatments (IUI, IVF, and ICSI).

6.2.2 All clinically appropriate individuals/couples are entitled to medical advice and investigation. Couples may be referred to a secondary care clinic for further investigation. Only couples meeting the eligibility criteria should be referred to tertiary care. If referrals are made in error the service will not accept these referrals nor commence assisted conception treatments. Clinicians wishing to seek exceptionality on behalf of the couple would have to seek funding via the individual funding request panel.

6.2.3 Treatment limits are per couple and per individual. Referrals should be as a couple and include demographic information for both partners in heterosexual and same-sex couples.

## 6.3 Female Age

Age as a criterion for access to fertility treatments is applied in line with the NICE Clinical Guideline on Fertility which is based on a comprehensive review of the relationship between age and the clinical effectiveness of fertility treatment.

The woman intending to become pregnant must be between the ages of 23 – 42 years (at the time of treatment). No new cycle should start after the woman's 42nd birthday. Referrers should be mindful of the woman's age at the point of referral and the age limit for new cycles.

Women aged 40–42 years who meet the eligibility criteria for infertility in section 2.3, will receive one full cycle of IVF, with or without ICSI, provided the following 3 criteria are fulfilled:

- They have never previously had IVF treatment **and**
- There is no evidence of low ovarian reserve (defined as FSH 9 IU/l or more (using Leeds assay); OR antral follicle count of 4 or less; OR AMH of 5 pmol/l or less) **and**
- There has been a discussion of the additional implications of IVF and pregnancy at this age

Where investigations show there is no chance of pregnancy with expectant management and where IVF is the only effective treatment,

women aged between 40-42 should be referred directly to a specialist team for IVF treatment.

## 6.4 Female BMI

The female patient's BMI should be between 19 and 29 for 6 months prior to referral to tertiary services. Patients with a higher BMI should be referred for healthy lifestyle interventions including weight management advice. Patients should not be re-referred to tertiary services until their BMI is within the recommended range.

## 6.5 Smoking

Both partners must be non-smokers for 6 months prior to a referral. Non-smoking status for both partners will be tested with a carbon monoxide breath test prior to commencement of any treatment. GPs should refer any smokers who meet all other criteria, to a smoking cessation programme to support their efforts in stopping smoking. Previous smokers must be non-smoking for 6 months prior to being put forward for assisted conception treatment and register below 5 on the Carbon Monoxide test.

## 6.6 Existing Children

Neither partner should have any living children (this includes adopted children but not fostered) from that or any previous relationship. The adoption of children confers the legal status of parent to the adoptive parents; this will apply to both adoptions in and out of the family. If any fertility treatment results in a live birth (and the child is still alive), then the couple will not be eligible for further fertility treatments, including the implantation of any stored frozen embryos.

## 6.7 Length of Relationship

Cohabiting couples must have been in a stable relationship for a minimum of 2 years to be entitled to treatment.

## 6.8 Having regular unprotected intercourse for the two years prior to referral within the same stable relationship

Couples must have been having regular unprotected intercourse for a 2 year period, reported to and documented by GP. Attempts to conceive should be based upon using recognised ovulation indicators at the appropriate time in the cycle.

Couples who conceive naturally and who subsequently miscarry up to twice within 2 years will be investigated for recurrent miscarriages. These women will not automatically received assisted conception treatment unless clinically appropriate as they are able to conceive naturally.

## 6.9 Previous Self-funded or NHS Funded Couples

Any previous NHS funded IVF treatment will be an exclusion criterion. Couples who have previously self-funded treatment are eligible for one NHS funded cycle as long as they have not received more than two self-funded cycles.

This includes where any one person in the couple has had a previous NHS funded cycle with a previous partner. The allocation is per person and per couple, so a previous cycle for one person in the couple will count towards their NHS funding allocation.

## 6.10 Reversal of Sterilisation

We will not fund IVF treatment for patients who have been sterilised or have unsuccessfully undergone reversal of sterilisation.

## 6.11 Welfare of the Child

The couple should be assessed as meeting the requirement contained within the HFEA Appendix entitled ‘Welfare of the child’.

## Appendix A

## Abbreviations

| Abbreviations used | |
|---|---|
| BMI | Body Mass Index |
| DI | Donor Insemination |
| GP | General Practitioner |
| HFEA | Human Fertilisation and Embryology Authority |
| ICSI | Intracytoplasmic sperm injection |
| IUI | Intra-uterine insemination |
| IVF | In vitro fertilisation |
| NICE | National Institute of Clinical Excellence |
| CCG | Clinical Commissioning Group |

## Appendix B

## Contents

| Term | Definition | Further information |
|---|---|---|
| **BMI** | The healthy weight range is based on a measurement known as the **Body Mass Index (BMI**). This can be determined if you know your weight and your height. This is calculated as your weight in kilograms divided by the square of your height in metres. In England, people with a body mass index between 25 and 30 are categorised as overweight, and those with an index above 30 are categorised as obese. | BBC Healthy Living<br><br>http://www.bbc.co.uk<br><br>NHS Direct<br><br>http://www.nhsdirect.nhs.uk |
| **ICSI** | **Intra Cytoplasmic Sperm Injection (ICSI)**: Where a single sperm is directly injected into the egg. | Glossary, HFEA<br><br>http://www.hfea.gov.uk |
| **IUI** | **Intra Uterine Insemination (IUI)**: Insemination of sperm into the uterus of a woman. | As above |
| **IVF** | **In Vitro Fertilisation (IVF)**: Patient's eggs and her partner's sperm are collected and mixed together in a laboratory to achieve fertilisation outside the body. The embryos produced may then be transferred into the female patient. | As above |
| **DI** | **Donor Insemination (DI)**: The introduction of donor sperm into the vagina, the cervix or womb itself. | As above |

## Appendix C

## Equality Impact Assessment

| | | |
|---|---|---|
| **Title of policy** | Fertility Policy | |
| **Names and roles of people completing the assessment** | Fiona Day Consultant in Public Health Medicine, and Associate Medical Director Leeds West CCG, on behalf of YH fertility panel | |
| **Date of Assessment from - to** | 3.3.17 | 3.3.17 |

| | |
|---|---|
| **1. Outline** | |
| **Give a brief summary of the policy** | The purpose of the commissioning policy is to enable officers of the relevant CCG to exercise their responsibilities properly and transparently in relation to commissioned treatments including individual funding requests, and to provide advice to general practitioners, clinicians, patients and members of the public about the fertility policy. Implementing the policy ensures that commissioning decisions are consistent and not taken in an ad-hoc manner without due regard to equitable access and good governance arrangements. Decisions are based on best evidence but made within the funding allocation of the CCGs. This policy relates to requests for specialist fertility treatment. |
| **What outcomes do you want to achieve** | We commission services equitably and only when medically necessary and in line with current evidence on cost effectiveness. |
| **2. Evidence, data or research** | |
| **Give details of evidence, data or research used to inform the analysis of impact** | NICE fertility guidance https://www.nice.org.uk/guidance/cg156 (accessed 3/3/17) |
| **3. Consultation, engagement** | |
| **Give details of all consultation and engagement activities used to inform the analysis of impact** | Discussion with panel of experts in Yorkshire and Humber representing commissioners and providers. All changes from the previous policy are in line with NICE guidelines which have had extensive engagement and consultation. See https://www.nice.org.uk/guidance/cg156/history |

| **4. Analysis of impact** | | | |
|---|---|---|---|
| This is the core of the assessment, using the information above detail the actual or likely impact on protected groups, with consideration of the general duty to;<br><br>eliminate unlawful discrimination; advance equality of opportunity; foster good relations | | | |
| | **Are there any likely impacts?**<br><br>**Are any groups going to be affected differently?**<br><br>**Please describe.** | **Are these negative or positive?** | **What action will be taken to address any negative impacts or enhance positive ones?** |
| **Age** | yes | both | See below |
| **Carers** | no | | |
| **Disability** | yes | positive | See below |
| **Sex** | yes | positive | See below |
| **Race** | no | | |
| **Religion or belief** | no | | |
| **Sexual orientation** | yes | both | See below |
| **Gender reassignment** | no | | |
| **Pregnancy and maternity** | yes | positive | See below |
| **Marriage and civil partnership** | no | | |
| **Other relevant group** | | | |

| | |
|---|---|
| **If any negative/positive impacts were identified are they valid, legal and/or justifiable?**<br><br>**Please detail.** | CCGs have a duty under the Equality Act 2010 to:<br><br>(a)eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under this Act;<br><br>(b)advance equality of opportunity between persons who share a relevant protected characteristic and persons who do not share it;<br><br>(c)foster good relations between persons who share a relevant protected characteristic and persons who do not share it. It also has responsibilities under the Public Sector Equality Duty to have due regard to the need to advance equality of opportunity.<br><br>Overall the policy will have a positive impact on all the 9 protected characteristics.<br><br>This commissioning policy as a whole aims to provide equal access and to support all heterosexual and same-sex couples, cohabiting, married or in civil partnerships who meet the eligibility criteria to achieve conception who have infertility.<br><br>As stated in NICE CG156 guidance all couples without known reproductive pathology are required to test their fertility and meet a threshold definition of unexplained infertility before they will be eligible for funded tertiary treatment. This is defined in 2.3:<br><br>For couples that do not have identified fertility pathology preventing them from conceiving there are two options available to enable them to test their fertility to access tertiary services:<br><br>*For all couples: The presence of known reproductive pathology.*<br><br>*For heterosexual couples: The failure to conceive after regular unprotected sexual intercourse for a period of 2 years in the absence of known reproductive pathology.*<br><br>*For same-sex couples: the failure to conceive after a minimum of six rounds of self-funded donor insemination via IUI, in the absence of any known reproductive pathology.*<br><br>*For couples where one partner has a known medical condition: this must be a medical condition which prevents natural conception such as physical disability, an infection requiring sperm washing, or a severe psychosexual disorder.*<br><br>*Note - For couples where ovulation can be induced with simple techniques such as clomiphene, these patients are <u>not</u> regarded as infertile on this basis alone - and therefore would not meet the eligibility criteria for access to IVF at that stage.* |

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| | The requirement to self-fund will have an adverse financial impact on same-sex couples. It is likely that the number of same-sex couples affected is likely to be proportionately higher. It is also recognised that for same-sex couples there are innate biological issues which affect the couples' own resources to access the policy.<br><br>This policy relates to access to infertility treatment, i.e. tertiary services for those who have identified fertility problems (whether known reproductive pathology, physical disability or unexplained fertility as define in the NICE CG156 guidance. The CCGs consider that NHS financial resources in this area should be directed to meeting the medical needs of those with identified fertility problems. If the CCG were to fund IUI for couples who did not have identified fertility problems, significant NHS resources would be being spent on treatment for individuals who do not have (and proportionality are not likely to have) an identified fertility problem which would require tertiary treatment on the grounds of infertility. The CCGs have also considered discriminating against heterosexual couples in this regard.<br><br>The CCG considers that appropriate focusing of scarce NHS resources is a legitimate aim, and that not providing funding of IUI treatment in these circumstances is a proportionate means of achieving that aim having regard to the rest of the policy and broad access for all couples with identified fertility problems. The innate barriers to conception are known in same-sex couples and are therefore something that can be planned for in advance. Alternative restrictions would involve reducing funding to individuals with identified fertility problems (in heterosexual, same-sex female and same-sex male couples) or other clinical areas and the CCGs do not consider that funding this treatment outweighs other demands on NHS resources.<br><br>CCGs will always consider exceptional cases on an individual basis via their Individual Funding Request Process.<br><br>Age as a criterion for access to fertility treatments is applied in line with the NICE Clinical Guideline on Fertility which is based on a comprehensive review of the relationship between age and the clinical effectiveness of fertility treatment.<br><br>This is a policy for couples to access fertility treatment, it is not a policy to provide conception for single adults.<br><br>Information on fertility services will be provided in a wide range of formats to meet the diverse needs of couples.<br>• Face to face discussions with couples<br>• Written information and advice<br>• Culturally sensitive<br>Be sensitive to those with additional needs e.g. physical or |

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| | cognitive, or sensitive disabilities, or those who do not speak English. | | |
| **5. Monitoring, Review and Publication** | | | |
| **How will you review/monitor the impact and effectiveness of your actions** | Each CCG to monitor individual funding requests for this procedure and identify if there are issues with the policy which require a policy refresh. | | |
| **Lead Officer** | Fiona Day | **Review date:** | Jan 2020 |
| **6.Sign off on behalf of the local CCG** | | | |
| **Lead Officer** | | | |
| **Director** | | **Date approved:** | |