

**Access to infertility treatment –
Commissioning Policy Document**

**Adopted by
NHS Barnsley Clinical Commissioning Group
December 2018 – January 2021**

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	Hempsons Solicitors	August 2018
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	Governing Body	8 November 2018

CHANGE RECORD			
Version	Author	Nature of Change	Date placed on Intranet

Any locally held old paper copies must be destroyed. When this document is viewed as a paper copy, the reader is responsible for checking that it is the most current version. This can be checked on the NHS Barnsley CCG website.

Commissioning Policy Statement:

Commissioning

This document represents the commissioning policy of NHS Barnsley Clinical Commissioning Group for the clinical pathway which provides access to specialist fertility services. This commissioning policy has been developed in partnership with the Yorkshire and 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 adopted by NHS Barnsley Clinical Commissioning Group

Funding

The policy on funding of specialist fertility services for individual patients is a policy of NHS Barnsley Clinical Commissioning Group and 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 NHS Barnsley Clinical Commissioning Group for patients who meet the access criteria set out in the shared policy is two. This is unchanged from the previous funding policy in March 2016. 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.

Immigration health surcharge; removal of assisted conception services. Amendments to the NHS (Charges to Overseas Visitors) Regulations 2015 were introduced into Parliament on 19 July 2017. As a result, from 21 August 2017, assisted conception services are no longer included in the scope of services. Those who are required to pay the NHS surcharge are no longer eligible for NHS funded assisted conception.

Panel Members: (March 2017)

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Brigid Reid – Chief Nurse – NHS Barnsley CCG

Helen Lewis - Head of Planned Care – NHS Leeds CCG.

Clare Freeman - Lead Medical Advisor – Sheffield CCG.

Panel Members (amendments June 2018)

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Conflicts of Interest

See appendix E

For Further Information about this policy.

Please contact your local Clinical Commissioning Group.
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1. Aim of paper

- 1.1 This document represents the commissioning policy for specialist 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 specialist 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 policy¹. In February 2013 NICE published revised guidance ² which was reviewed by NICE in 2016 and which updated previous NICE guidance published in 2004³.
- 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:

The inability to conceive through regular sexual intercourse for a period of 2 years in the absence of known reproductive pathology, or less than 2 years if there is specific reproductive pathology identified.

Where attempting to conceive by regular sexual intercourse is not possible (for example for same sex couples, people with a physical disability or people with psychosexual disorders) that will be considered as inability to conceive for the purposes of this policy.

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 4000 and 5000 attendances per year which would result in approximately 1450 couples likely to be assessed as eligible for IVF treatment

2.7 Specialist 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)⁴. All specialist 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 and 39 and 1 cycle for eligible couples where the woman is aged 40 - 42.

⁴ <https://www.hfea.gov.uk/>

NHS Barnsley CCG will fund **2** cycle of IVF treatment. 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.

- 2.9 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

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.

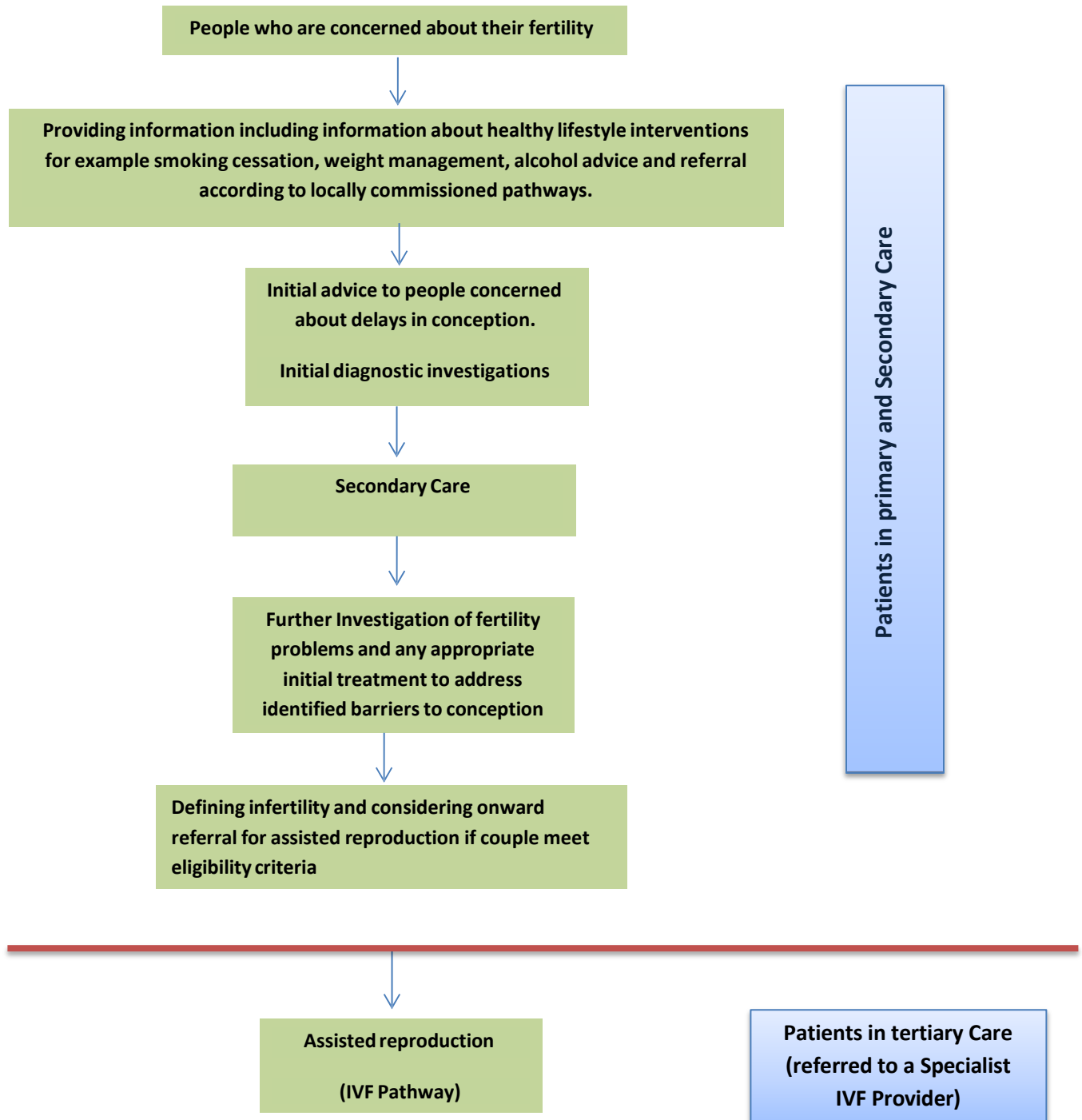
5.1.2 People should have the opportunity to make informed decisions regarding their care and treatment via access to evidence-based information. These choices should be recognised as an integral part of the decision-making process.

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 for fertility investigation and referral (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 (PH 26, PH48), weight management (PH27, PH53), healthy eating and physical activity (PH11, NG7) and alcohol (PH24).
- Use any appointment or meeting as an opportunity to ask women and their partners about their general lifestyle including smoking, alcohol consumption, and 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 would benefit from this, 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 hand-held record. If a hand-held record is not available locally, use local protocols to record this information.

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 further discussed.

If secondary care interventions are not successful and the couple fulfils the eligibility criteria in section 6.0, they may then be referred through to specialist

care for assessment for assisted conception techniques, such as IVF, DI, IUI, and ICSI.

5.2.2 IVF

IVF involves:

- The use of drugs to switch off the natural ovulatory cycle.
- Induction of ovulation with other drugs
- Monitoring the development of the eggs in the ovary
- Ultrasound guided egg collection from the ovary
- Processing of sperm
- Production of a fertilized embryo from sperm and egg cells in the laboratory
- Culture of embryos to blastocyst (*if clinical proven*)
- Single embryo transfer (subject to multiple birth minimisation policy)
- Use of progesterone to make the uterus receptive to implantation
- Transfer of selected embryos and freezing of those suitable but not transferred

The panel will review annually, following the HFEA⁵ annual review via their traffic light report, any other emerging technologies which may then need consideration for incorporation in this policy.

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.

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<https://www.hfea.gov.uk/>

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 add reference)

Where a medical condition exists (such as physical disability, after sperm washing to prevent infectious disease transmission, or a severe 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:

IUI either with or without ovarian stimulation will not be funded routinely (exceptional circumstances may include, for example, when people have social, cultural or religious objections to IVF), instead couples should try to conceive for a total of 2 years (this can include up to 1 year before their fertility investigations) before IVF will be considered.

5.6.4 Gonadotrophin Therapy - for women with an ovulatory infertility, ovulation induction with gonadotrophin therapy should be funded for up to 6 cycles, with or without IUI depending on the circumstances of the couple.

5.6.5 Donor Gametes including azoospermia:

Donor Sperm

Up to six cycles of donor insemination (dependent on availability of donor sperm) will be offered to all couples where this is a clinical requirement via donor Sperm. This is dependent on the availability of donor sperm which is currently limited in the UK

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 and sperm will be placed on the waiting list for an initial period of 3 years, after which they will be reviewed to assess whether the fertility policy eligibility criteria are still met. If it is anticipated that there will be difficulty finding suitable donor exceptionality would need to be considered.

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 specialist 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 HFEA⁶ 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 specialist 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.

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 <https://www.hfea.gov.uk/>

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 specialist care (with the exception of 6.9, which should be undertaken within specialist 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 specialist care.

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 Existing Children

Neither partner should have any living children (this includes adopted children but not fostered) from that or any previous relationship.

6.4 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 18 – 42 years. No new cycle should start after the woman's 43rd 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 1 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)

- 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.

6.5 Pre – referral requirement to specialist care

6.5.1 Female BMI

The female patient's BMI should be between 19 and 30 prior to referral to specialist services. Patients with a higher BMI should be referred for healthy lifestyle interventions including weight management advice. Patients should not be re-referred to specialist services until their BMI is within the recommended range.

6.5.2 Non-Smokers

Both partners must be non-smokers for 3 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, in both Primary and Secondary Care. If any smokers who meet all other criteria General Practitioners should refer them to a smoking cessation programme to support their efforts in stopping smoking to become eligible for referral to specialist care.

6.6 Reversal of sterilisation

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

6.7 Previous NHS funded Full Cycles

Previous NHS funded full cycles will be taken into consideration when assessing a couple's ability to benefit from treatment and will count towards the total number of cycles that may be offered by the NHS. This includes where any one person in the couple has had a previous NHS funded full cycle with a previous partner. The allocation is per person and per couple, so a previous full cycle for one person in the couple will count towards their NHS funding allocation.

6.8 Previous self-funded cycles

The number and effectiveness of previous self-funded cycles will inform the clinician's judgement as to whether further NHS funded infertility treatment would be appropriate.

6.9 Length of relationship

The stability of the relationship is very important with regards to the welfare of children; as such couples must have been in a stable relationship for a minimum of 2 years to be entitled to treatment. In order to confirm this, providers are required to seek documentary evidence such as, utility bills/bank statements for the same address for the given period of time.

6.10 Welfare of the child

The couple should be assessed as meeting the requirement contained within the HFE⁷A Appendix entitled 'Welfare of the child'.

⁷<https://www.hfea.gov.uk/>

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 http://www.bbc.co.uk NHS Direct http://www.nhsdirect.nhs.uk
ICSI	Intra Cytoplasmic Sperm Injection (ICSI) : Where a single sperm is directly injected into the egg.	Glossary, HFEA 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	Philippa Doyle Hempsons Solicitors	
Date of Assessment from - to	Aug 2018	Feb 2021

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)
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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; eliminate unlawful discrimination; advance equality of opportunity; foster good relations			
	Are there any likely impacts? Are any groups going to be affected differently? Please describe.	Are these negative or positive?	What action will be taken to address any negative impacts or enhance positive ones?
Age	Yes. IVF is only available to women aged between 18 and 42. As a woman ages the chances of successful pregnancy fall.	Both	Action cannot be taken to prevent this it is therefore incumbent simply to ensure clear age limitations are identified
Carers	No		
Disability	Yes. The policy has been enhanced to offer funding to couples who by reason of disability cannot conceive naturally	positive	The fact of this new change and opportunity to such couples can be publicised
Sex	No		
Race	No		
Religion or belief	No		
Sexual orientation	Yes. The policy has been enhanced to offer funding to couples in a same sex relationship without having to demonstrate they have self-funded other trials	positive	The fact of this new change and opportunity to such couples can be publicised

Gender reassignment	No		
Pregnancy and maternity	Yes. The policy enhances the ability to access fertility treatment and the potential to achieve pregnancy	positive	
Marriage and civil partnership	No		
Other relevant group			

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	NHS Barnsley CCG	Review date:	2021

6. Sign off on behalf of the local CCG			
Lead Officer	Chief Nurse (Acting)		
Director	Associate Medical Director via Quality & Patient Safety Committee	Date approved:	11.10.18

Appendix D, Version Control

Version	Date	Author	Status	Comment
v8	June 2018	M. Thompson on behalf of Panel	Draft	<p>Changes to:-</p> <ul style="list-style-type: none"> - 2.3 Definition of Infertility - 5.2.2. – IVF involves – additional bullets added - 5.3 – Definition of cycles – removed sentence in brackets - 5.6.4 - Gonadotrophin Therapy added - 5.6.5 – renumbered – added “all couples” where this is a clinical requirement (to replace the reference to male azoospermia) added limited to UK <p>Added additional sentence</p> <ul style="list-style-type: none"> - 6.5 – title updated to – Pre-referral requirement to specialist care - 6.5.2 – non-smokers section added. - 6.9 – Updated to include the stability of the relationship

v7	Jan 2018	M. Thompson on behalf of Panel	Draft	<ul style="list-style-type: none"> - Changes to 5.2 pathway - Changes to funding – adding refugees and asylum seekers - Removal of summary of CCGs - 2.3 – clarification of definition of infertility - 6.7 updated to NHS Funded full cycles - 6.10 – added section - Change tertiary to specialist throughout the policy.
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Review 2017	22.2.17	F Day on behalf of panel	Final draft	<ul style="list-style-type: none"> - changes to the definition of infertility for same sex and patients with psychosexual issues and disabilities to be more clear - the addition of public health requirements for providers in line with NICE guidance - clarification of the definition of an abandoned cycle - sections on intrauterine insemination and also egg donation updated in line with NICE guidance - Addition of People with unexplained infertility, mild endometriosis or mild male factor infertility, who are having regular unprotected sexual intercourse in line with NICE guidance - wording changed in various sections based on patient feedback to be more clear, not materially changed in content - embryo transfer wording updated to reflect NICE guidance - Addition of definition of low ovarian reserve (previously undefined)
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Appendix E Relevant Conflicts of Interest Declared:

Dr Steve Maguiness:

IVF in Hull is provided by a private company (ERFS Co Ltd), of which I am a Director and employee.

Prof Adam Balen:

NHS Consultant in Reproductive Medicine and Clinical lead for the Leeds Centre for Reproductive Medicine, which performs all fertility treatments funded by the NHS. Partner in Genesis LLP, the private arm of the Leeds Centre for Reproductive Medicine, which performs self-funded fertility treatments using identical protocols to the NHS. Chair, British Fertility Society. Chair, NHS England IVF Pricing Development Expert Advisory Group. Chair World Health Organisation Expert Working Group on Global Infertility Guidelines: Management of PCOS. Chair, British Fertility Society. Consultant for ad hoc advisory boards for Ferring Pharmaceuticals, Astra Zeneca, Merck Serono, Gideon Richter, Uteron Pharma. Research funding received in the past. Pharmasure / IBSA- Key note lecture at ESHRE 2016 & hospitality to attend meetings. OvaScience- Member of international ethics committee. Clear Blue National medical advisory board. IVI, UK- Chair, Clinical Board

Virginia Beckett FRCO:

I have a private practice where I see fertility patients.

I have received sponsorship from Pharmasure, Ferring & Serono to attend conferences.