NHS Rotherham Clinical Commissioning Group

Operational Executive – 22 November 2019

Strategic Clinical Executive – 27 November 2019

GP Members Committee (GPMC) – Date

Clinical Commissioning Group Governing Body – 8 January 2020

Access to Infertility Treatment Commissioning Policy

Lead Executive:	Ian Atkinson, Deputy Chief Officer
Lead Officer:	Jacqui Tuffnell, Head of Commissioning
Lead GP:	Phil Birks, SCE GP Lead

Purpose:

To brief Governing Body on the updates to the Access to Infertility Treatment Commissioning Policy (appendix 1) and the results of patient engagement in relation to these changes.

Background:

In January 2017, CCGs across Yorkshire and the Humber produced a joint commissioning policy setting out the commissioning requirements for specialist fertility services across the region. All CCGs within the region adopted and implemented the policy which set out the service pathway and eligibility criteria.

The recent refresh of the Commissioning Policy for specialist fertility services for adults saw a number of changes and clarifications.

The first clarification is around the need for patients required to pay an NHS surcharge for treatment of 'Assisted Conception Services' as it is no longer eligible for them under the NHS. This has been in place since 21 August 2017 when the amendments to the NHS (Charges to Overseas Visitors) Regulations 2015 came into force, but it had not previously been made clear in the policy.

For women with anovulvatory infertility, funding will now be available for up to 6 cycles of ovulation induction with the Gonadotropin therapy. This had not previously been available.

There is now an expectation that couples requiring a referral for infertility treatment will be non-smokers for a period of 3 months prior to referral. Non-smoking status will be confirmed in secondary care with a carbon monoxide breath test.

For same sex couples, the requirement to self-fund 6 rounds of Intrauterine Insemination (IUI) prior to accessing 6 rounds of IUI via the NHS has now been removed. Same sex couples can now access NHS funding without having to fund privately first.

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Analysis of key issues and of risks

Legal challenges regarding eligibility have been considered in the refresh of the policy and resulting proposed changes.

The relaxation of eligibility around same sex couples, as well as the requirement to fund ovulation induction with the Gonadotropin therapy will have an impact on the overall contract value. It is not possible at present to determine what this impact will be as it is not possible to identify how many same sex couples have undertaken private procedures.

Patient, Public and Stakeholder Involvement:

Patient engagement took place between 8 August 2019 and 6 October 2019. The engagement information has been made available on the CCG website and also circulated to interest groups.

With regards to patient feedback on the policy changes, the engagement took place between 8 August 2019 and 6 October 2019. Responses have been received from 28 residents across South Yorkshire and Bassetlaw, with only one Rotherham resident providing feedback – "*i think they need to take care of all people whatever their sexuality, race, religion please do not discriminate due to austerity aka spending cuts*"

Equality Impact:

An Equality Impact Assessment has been undertaken by Philippa Doyle at Hempsons Solicitors as part of the development of the policy.

Financial Implications:

IUI Cycles

There is likely to be a financial impact for IUI procedures as there is no activity in plan for this. .For the period 1/4/17 to 31/3/18 there were 20 couples receiving IUI through the Care Sheffield contract, with a total of 26 IUI procedures carried out (an average of 1.3 procedures per couple). For the period 1/4/18 – 31/3/19, there were 26 privately funded IUI cycles undertaken for same sex couples (x19 couples in total). Five couples had two cycles each, with one couple paying for three cycles. The remaining 13 couples received one cycle of IUI. Care Sheffield cannot determine which of these patients would be classed as a Rotherham registered patient as they received private treatment.

The cost of a single IUI procedure is currently £838. Therefore the additional cost could be approximately £21,788 if these are all Rotherham registered patients however it is expected to be higher as we anticipate that more patients will request this procedure once it is NHS funded.

Ovulation induction with Gonadotropin Therapy

With regards to patients requiring ovulation induction with Gonadotropin therapy, Care Sheffield has confirmed that in the period 01/09/18 – 31/08/19 x 5 cycles were provided (x4 patients). The cost of this procedure at Care Sheffield is currently £875 per ovulation induction cycle plus medication at approx. £400 per cycle. Therefore if activity remains as current levels the cost would be £6,375 however it is expected that this will

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be higher as we anticipate that more patients will request this procedure once it is NHS funded.
Human Resource Implications:
Not applicable
Procurement Advice:
Not applicable
Data Protection Impact Assessment
Not applicable
Approval history:
Recommendations:
This is a Yorkshire and Humber Policy and whilst all CCGs have had the opportunity to contribute and comment, ultimately this is a consensus policy. It is considered that the revisions to the policy ensure the CCGs are offering fair and equitable access the fertility treatment and that RCCG should therefore approve the adoption of this policy noting the financial risk this poses.
Paper is for Approval

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Access to Infertility Treatment –

Commissioning Policy Document

Yorkshire and Humber

Adopted by
Insert CCG Name

June 2019 – April 2022

Document Title:	Access to Infertility Treatment – Commissioning Policy Document Yorkshire and Humber
Author/Lead **Name:** **Job Title:**	 Michelle Thompson Assistant Director Women's and Children's Services
Version No:	V9
Latest Version Issued On	June 2019
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Date of Next Review:	April 2022
Completion Equality Impact Statement **Name:** **Job Title:** **Date:**	 Philippa Doyle Hempsons Solicitors August 2018 (Update based on notes)
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	Committees / Groups / Individual	**Date**
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	Hempsons Solicitors	August 2018
Ratified by Committees:	INSERT LOCAL COMMITTEE	

CHANGE RECORD			
Version	**Author**	**Nature of Change**	**Date**
		Update as per local CCG	

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 xxxx(insert own CCG processes)***

Commissioning Policy Statement:

Commissioning

This document represents the commissioning policy of insert name of CCG 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 insert name of CCG.

Funding

The policy on funding of specialist fertility services for individual patients is a policy of insert name of CCG 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 insert name of CCG for patients who meet the access criteria set out in the shared policy is xxx. Insert number of cycles for the named CCG. 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, this includes initial fertility investigations.

Where there is discordance in immigration status then treatment will not be funded if one partner is not eligible as the policy applies as a couple.

Panel Members: (March 2017)

Dr Virginia Beckett	Consultant in Obstetrics and Gynaecology - Bradford Teaching Hospital FT
Dr Fiona Day	Consultant in Public Health Leeds and Associate Medical Director Leeds CCG
Chris Edward	Accountable Officer - Rotherham CCG
Dr Steve Maguiness	Medical Director - The Hull IVF Unit, Hull Women and Children's Hospital and honorary contract with HEY
Dr John Robinson	Scientific Director - IVF Unit, Hull and East Yorkshire Hospitals FT
Prof Adam Balen	Professor of Reproductive Medicine and Surgery - Leeds Teaching Hospitals NHS Trust
Michelle Thompson	Assistant Director, Women's and Children's Services - NHS North East Lincolnshire CCG
Richard Maxted	Service Manager, Directorate of Obstetrics, Gynaecology and Neonatology - Sheffield Teaching Hospital NHS Trust
Dr Margaret Ainger	Clinical Director for Children, YP and Maternity - NHS Sheffield CCG
Dr Bruce Willoughby	Lead for Planned Care - NHS Harrogate and Rural District CCG
Dr Clare Freeman	Medical Advisor to IFR Panel - South Yorkshire and Bassetlaw CCGs

Panel Members (amendments January 2018)

Dr Virginia Beckett	Consultant in Obstetrics and Gynaecology - Bradford Teaching Hospital FT
Dr Fiona Day	Consultant in Public Health Leeds and Associate Medical Director Leeds CCG
Michelle Thompson	Assistant Director, Women's and Children's Services - NHS North East Lincolnshire CCG
Dr Bruce Willoughby	Lead for Planned Care - NHS Harrogate and Rural District CCG
Jonathan Skull	Consultant in Reproductive Medicine & Surgery – Sheffield Teaching Hospital NHSFT

Karen Thirsk	Fertility Policy Manager – NHS England
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)

Dr Virginia Beckett	Consultant in Obstetrics and Gynaecology - Bradford Teaching Hospital FT
Dr Fiona Day	Consultant in Public Health Leeds and Associate Medical Director Leeds CCG
Michelle Thompson	Assistant Director, Women's and Children's Services - NHS North East Lincolnshire CCG
Jonathan Skull	Consultant in Reproductive Medicine & Surgery – Sheffield Teaching Hospital NHSFT
Brigid Reid	Chief Nurse – NHS Barnsley CCG
Helen Lewis	Head of Planned Care – NHS Leeds CCG
Dr Bryan Power	(GP) - NHS Leeds CCG
Adam Balen	(Consultant) - Leeds Fertility
Clare Freeman	Lead Medical Advisor – Sheffield CCG.

Panel Members (amendments January 2019)

Dr Virginia Beckett	Consultant in Obstetrics and Gynaecology - Bradford Teaching Hospital FT
Jonathan Skull	Consultant in Reproductive Medicine & Surgery – Sheffield Teaching Hospital NHSFT
Michelle Thompson	Assistant Director, Women's and Children's Services - NHS North East Lincolnshire CCG
Martine Tune	Acting Chief Nurse – NHS Barnsley CCG
Liz Micklethwaite	Business Manager IFR - NHS Leeds CCG

Conflicts of Interest

See appendix E

For Further Information about this policy.

Please contact your local Clinical Commissioning Group. xxxx add own CCG contact details

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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 in keeping with current eligibility, are able to benefit from NHS funded treatment and 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 policy[1]. In February 2013 NICE published revised guidance[2] which was reviewed and updated in 2016.

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 as:

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 people with a physical disability, people with psychosexual disorders or transgender and same sex couples) this will be considered as inability to conceive for the purposes of this policy.

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 the remaining couples about 30% of cases are due to the male partner being unable to produce

[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.

or ejaculate sufficient normal sperm, 30% are due to problems found with the female partner such as failure to ovulate or blockage to the passage of the eggs, and 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)[3]. 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.

Insert name of CCG will fund *insert number of nhs funded cycles by CCG* cycle(s) of IVF treatment. Where an individual feels that they have exceptional circumstances that would merit consideration of an additional cycle being funded by the NHS 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.

[3] https://www.hfea.gov.uk/

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.

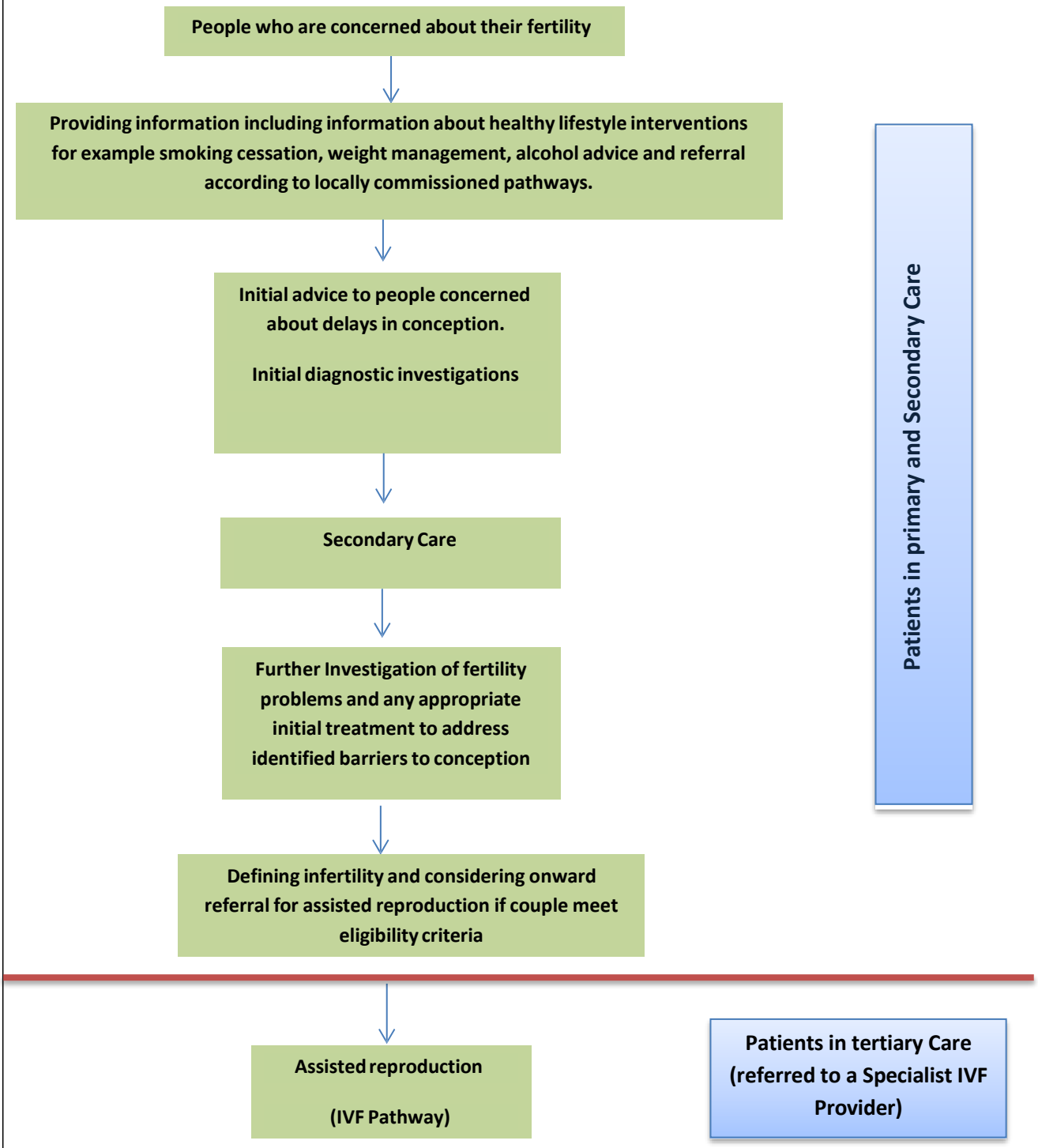
5.1.2 People should have the opportunity to make informed decisions regarding their care and treatment via access to evidence-based information. These choices should be recognised as an integral part of the decision-making process.

Information should be provided in the following formats:

- Face to face discussions with couples
- Written information and advice
- Culturally sensitive
- Sensitive to those with additional needs e.g. physical or cognitive, or those for whom English is not their first language.

5.1.3 As infertility and infertility treatments have a number of psychosocial 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)



The Care pathway for fertility investigation and referral will take account of NICE guidance.

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 local wellbeing services and/or locally commissioned lifestyle services. 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 or accepted local equivalent.

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 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 involves:

- Controlled ovarian stimulation
- 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 clinically appropriate*)
- 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 HFEA[4] 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

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.

All stored and viable embryos should be used before a new cycle commences. This includes embryos resulting from previously self-funded cycles.

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 are 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 2.3 Definition of Infertility):

Where a medical condition exists, such as physical disability up to 6 cycles of IUI 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.

[4] https://www.hfea.gov.uk/

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, 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, in keeping with current NICE guidance.

5.6.4 Gonadotrophin Therapy - for women with anovulatory 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:
Patients who require donor gametes 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 is still met. If it is anticipated that there will be difficulty finding a suitable donor exceptionality would need to be considered. At this point consideration may need to be given to sourcing from alternative providers via IFR.

Donor Sperm

Where clinically indicated up to six cycles of donor insemination will be offered. 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.

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 continued storage may be self-funded.
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 embryo 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. We will, however, 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 HFEA[5] therefore recommends that steps are taken by providers to minimize them. 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.

6.0 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 6.10, which should be undertaken within specialist care). Couples must meet the definition of infertility as described in section 2.3.

[5] https://www.hfea.gov.uk/

6.2 Overarching Principles

6.2.1 All clinically appropriate individuals/couples are entitled to medical advice and investigation. Couples may be referred to a secondary care clinic for further investigation.

6.2.2 Assisted conception is only funded for those couples who meet the eligibility criteria.

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 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 for 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 Smoking Status

GP should discuss smoking with couples prior to referral to secondary care, support their efforts in stopping smoking by referring to a smoking cessation programme and, where possible, offer carbon monoxide breath testing to confirm non-smoking status.

Non-smoking status for both partners will be confirmed in Secondary Care with a carbon monoxide breath test. Both partners must be non-smokers for 3 months before referral for assisted conception.

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 and currently co-habiting to be entitled to treatment.

6.10 Welfare of the child

The couple should be assessed as meeting the requirement contained within the HFE A 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 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)

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	Insert CCG	**Review date:**	xx2021

6.Sign off on behalf of the local CCG			
Lead Officer			
Director		**Date approved:**	

Appendix D, Version Control

Version	Date	Author	Status	Comment
V9	January 2019	M/ Thompson on behalf of Panel	Draft	Changes to: - Funding - Immigration health surcharge – sentence added - 1.2 - sentence reworded - 2.3 – change of order in sentence in brackets - 5.2 – sentence included after pathway - 5.2.1 – third bullet point, wording changed - 5.2.2 – first two bullet points replaced with Controlled Ovarian Stimulation - 5.4 – heading changed to Frozen Embryo - 5.6.1 – sentence reworded - 5.6.3 – link to mild male factor infertility removed - 5.6.3 – wording added - 5.6.4 – spelling corrected - 5.6.5 – new paragraph inserted - 5.6.5 - Donor Sperm - sentence reworded - 5.7 – sentence reworded - 6.2.1 and 6.2.2 - swopped around and reworded - 6.5.2 – title changed - 6.5.2 – sentence reworded - 6.9 – sentence reworded

v8	June 2018	M. Thompson on behalf of Panel	Draft	Changes to:- - 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 Added additional sentence - 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	- 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.

Review 2017	22.2.17	F Day on behalf of panel	Final draft	- 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)

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.