|  |  |  |  |
| --- | --- | --- | --- |
|

|  |
| --- |
| **Access to Infertility Treatment –** **Commissioning Policy Document****Yorkshire and Humber**  |
|  |
| **Adopted by** **Barnsley CCG****January 2020 – April 2023** |

 |
|

|  |  |
| --- | --- |
| **Document Title:** | Access to Infertility Treatment – Commissioning Policy Document Yorkshire and Humber |
| **Author/Lead****Name:****Job Title:** | Michelle ThompsonAssistant DirectorWomen’s and Children’s Services |
| **Version No:** | V13 |
| **Latest Version Issued On**  | July 2021 |
| **Supersedes:** | All previous Access to infertility treatment policies |
| **Date of Next Review:** | April 2023 |
| **Completion Equality Impact Statement****Name:****Job Title:****Date:** | Philippa DoyleHempsons Solicitors August 2018  |
| **Target Audience:** | Public  |
| **Dissemination:** | CCG Weekly Bulletin, Internet & Intranet |

|  |
| --- |
| **APPROVAL RECORD** |
|  | **Committees / Groups / Individual** | **Date**  |
| **Consultation:**  | Yorkshire and Humber Expert Fertility Panel | 2 March 201731 January 201825 June 201825 January 2019 |
|  | Hempsons Solicitors  | August 2018 |
| **Ratified by Committees:** | Governing Body Quality and Patient Safety CommitteeQuality and Patient Safety Committee | 16 January 202020 February 202017 June 2021 |

|  |
| --- |
| **CHANGE RECORD** |
| **Version** | **Author** | **Nature of Change** | **Uploaded**  |
| V12 | DL | Readability of section 6.1 Application of Eligibility Criteria |  |
| V13 | Allison Ball | Immigration Health Surcharge: Right to Assisted Conception Services section updated to clarify position in relation to charges for non UK residents |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**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 CCG’s internet.*** |
| Commissioning Policy Statement:**Commissioning**This document represents the commissioning policy of Barnsley 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 Barnsley CCG. **Funding** The policy on funding of specialist fertility services for individual patients is a policy of Barnsley 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 Barnsley CCG for patients who meet the access criteria set out in the shared policy is 2. 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; Right to Assisted Conception Services** Amendments to the NHS (Charges to Overseas Visitors) Regulations 2015 were introduced intoParliament on 19 July 2017 and as a result, from 21 August 2017, assisted conception services are no longer included in the scope of services.Our eligibility criteria for access to assisted conception services relates to couples rather than individuals. Therefore to enable the ordinarily resident person to have freely available access to services, where at least one partner is eligible for these services, the couple can be referred.Where two people are seeking assisted conception services with NHS funding, and one of the two people is covered by health surcharge arrangements and the other is ordinarily resident in the UK and therefore not subject to charge, the services required by the health surcharge payer will be chargeable. Any services required by the ordinarily resident person will continue to be freely available, subject to the established local or national commissioning.This relates to people subject to immigration control applying to come to the UK for longer than six months, or to extend a period of leave to remain in the UK. It does not relate to those coming to the UK for six months or less, those on visitor visas, or those coming to the UK who are not subject to immigration control.Working group membership and Conflicts of Interest See appendices E and F**For Further Information about this policy.**Please contact your local Clinical Commissioning Group. Barnsley CCGHillder House49-51 Gawber RoadBarnsleyS75 2PY Contents[1. Aim of Paper 7](#_Toc523324716)[2. Background 7](#_Toc523324717)[3. Clinical Effectiveness 8](#_Toc523324718)[4. Cost Effectiveness 8](#_Toc523324719)[5. Description of the Treatment 9](#_Toc523324721)[5.1 Principles of Care 9](#_Toc523324722)[5.2 The Care Pathway for Fertility Investigation and Referral (fig, 1)](#_Toc523324723) 10[5.3 Definition of a Full Cycle 10](#_Toc523324724)[5.4 Frozen Embryo 10](#_Toc523324725)[5.5 Abandoned Cycles........................................................................................................10](#_Toc523324726)[5.6 IUI and DI 10](#_Toc523324727)[5.7 Gametes and Embryo Storage 11](#_Toc523324728)[5.8 HIV/HEP B/ HEP C 12](#_Toc523324729)[5.9 Surrogacy 12](#_Toc523324730)[5.10 Single Embryo Transfer 12](#_Toc523324731)[5.11 Counselling and Psychological Support 12](#_Toc523324732)[5.12 Sperm Washing and Pre-implantation Diagnosis 12](#_Toc523324733)[5.13 Service Providers 12](#_Toc523324734)[6. Eligibility Criteria for Treatment 12](#_Toc523324735)[6.1 Application of Eligibility Criteria 12](#_Toc523324736)[6.2 Overarching Principles 13](#_Toc523324737)[6.3 Existing Children 13](#_Toc523324738)[6.4 Female Age 13](#_Toc523324739) 6.5 Pre-Referral Requirements for Assisted Conception……………………………………..15 [6.6 Reversal of Sterilisation 14](#_Toc523324740)[6.7 Previous NHS funded Full Cycles 14](#_Toc523324741)[6.8 Length of Relationship 16](#_Toc523324743)[6.9 Welfare of the Child 16](#_Toc523324744)Appendix A 17Appendix B 18Appendix C 19Appendix D 22Appendix E 27Appendix F Aim of Paper1.1 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.Background* 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]](#footnote-1). In February 2013 NICE published revised guidance[[2]](#footnote-2) which was reviewed and updated in 2016.
	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.
	3. In this policy document infertility is defined as:

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 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.* 1. 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. 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]](#footnote-3). All specialist providers of fertility services must be licensed with the HFEA in order to be commissioned under this policy.
	3. NICE Clinical Guidelines 156 (2013) covering infertility recommends that:

Barnsley CCG will fund ***2*** 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.* 1. 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 EffectivenessIt 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* 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.
	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.

Description of the TreatmentPrinciples of Care* + 1. Couples who experience problems in conceiving should be seen together because both partners are affected by decisions surrounding investigation and treatment.
		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.
		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.

The Care Pathway for fertility investigation and referral (fig, 1)**People who are concerned about their fertility****Providing information including information about healthy lifestyle interventions for example smoking cessation, weight management, alcohol advice and referral according to locally commissioned pathways.** **Patients in primary and Secondary Care****Initial advice to people concerned about delays in conception.****Initial diagnostic investigations****Secondary Care****Further Investigation of fertility problems and any appropriate initial treatment to address identified barriers to conception****Defining infertility and considering onward referral for assisted reproduction if couple meet eligibility criteria****Patients in tertiary Care (referred to a Specialist IVF Provider)****Assisted reproduction****(IVF Pathway)**The Care pathway for fertility investigation and referral will take account of NICE guidance.* + 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. * + 1. 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]](#footnote-4) annual review via their traffic light report, any other emerging technologies which may then need consideration for incorporation in this policy.Definition of a Full CycleFrozen 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.Abandoned CyclesAn 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.IUI and DIIUI and DI are separate from IVF treatment; however, the couple may then access IVF treatment if appropriate.* + 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.  * + 1. 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. * + 1. 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.* + 1. 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 StorageThe 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.HIV/HEP B/ HEP CPeople 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).SurrogacyAny 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.Single Embryo TransferPlease 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]](#footnote-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. Counselling and Psychological SupportAs 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.Sperm washing and pre-implantation diagnosisSperm washing and pre-implantation genetic diagnosis are not treatments for infertility and fall outside the scope of this policy. Prior approval is required.Service ProvidersProviders 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 Treatment6.1 Application of Eligibility CriteriaEligibility criteria should apply at the point of referral to specialist care. Women aged between 40–42 will need further assessment within specialist care in order to ascertain whether or not they are eligible, see Section 6.4.6.2 Overarching Principles6.2.1 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 ChildrenNeither partner should have any living children (this includes adopted children but not fostered) from that or any previous relationship.6.4 Female AgeAge 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**6.5.1Female BMIThe 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. People should be informed that maternal and paternal smoking can adversely affect the success rates of assisted reproduction procedures, including IVF treatment.6.6 Reversal of SterilisationWe will not fund IVF treatment for patients who have been sterilised or have unsuccessfully undergone reversal of sterilisation. 6.7 Previous CyclesPrevious cycles whether self-funded or NHS funded 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 either person has had a previous cycle with a previous partner. 6.8 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. 6.9 Welfare of the childHFEA guidance concerning the welfare of the child should be followed. |
| **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, BContents

|  |  |  |
| --- | --- | --- |
| **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](http://www.bbc.co.uk/)NHS Direct[http://www.nhsdirect.nhs.uk](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](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 DoyleHempsons Solicitors  |
| Date of Assessment from – toReview date | Aug 2018Nov 2019 | Feb 2021April 2023 |

|  |
| --- |
| **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** | Yes | positive | Gender reassignment is specifically referenced in the definition of infertility |
| **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**  | Barnsley CCG | **Review date:** | February 2021 |
|  |
| **6.Sign off on behalf of the local CCG** |
| **Lead Officer** |  |
| **Director** |  | **Date approved:** |  |

 |
|  |

Appendix D, Version Control

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| VERSION | DATE | AUTHOR | STATUS | COMMENT |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| V11 | Feb 19 | H Lewis and M Thompson |  | Changes to page 3 – immigration health surcharge – reworked following updated adviceMoved list of panel members to Appendix for easier access to contents of document |
| V10 | November 2019 | M Thompson on behalf of Panel |  | Changes to:* Page 2 & 3 – Immigration Health Surcharge – sentences reworded
* 6.5.2 – Smoking Status – sentences reworded
* 6.7 – Previous Self-funded Cycles – titles changed to Previous Cycles - sentences reworded
* 6.8 – Previous Self-Funded Cycles - sentence removed
* 6.10 – Welfare of the Child - sentence reworded
 |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 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](https://www.nice.org.uk/guidance/cg156/chapter/recommendations#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

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

Commissioner Final Proof Read Panel (Amendments November 2019)

Michelle Thompson Assistant Director, Women’s and Children’s Services – NHS North East Lincolnshire CCG

Helen Lewis Head of Planned Care – NHS Leeds CCG

Clare Freeman Lead Medical Advisor – Sheffield CCG

Karen Leivers Head of Strategy and Delivery, Planned Care - Doncaster CCG

Debbie Stovin Commissioning Manager – Elective Care – Sheffield CCG

Appendix F 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.

1. Yorkshire and the Humber Commissioning Policy for Fertility Services, 2010. [↑](#footnote-ref-1)
2. Fertility: Assessment and treatment for people with fertility problems 2012, NICE Clinical Guideline 156. [↑](#footnote-ref-2)
3. <https://www.hfea.gov.uk/> [↑](#footnote-ref-3)
4. <https://www.hfea.gov.uk/> [↑](#footnote-ref-4)
5. <https://www.hfea.gov.uk/> [↑](#footnote-ref-5)