FOR USE BY PRIMARY CARE REFERRERS



Referral Form for Fertility Assessment Only – CRITERIA BASED ACCESS Patients from the BNSSG Clinical Commissioning Group area only

	Patients from the BNSSG Clinical	Commissioni	ng Group	area on	<u>ly</u>	
Patient 1 Name			Male		Female	
Address						
Post Code						
Date of Birth		NHS Number				
Patient 2 Name			Male		Female	
Address						
Post Code						
Date of Birth		NHS Number				
Criteria for Refe	erral for Assessment by Fertility Servi	ices				
The Access to Fertility Assessment and Treatments Policy is available on the relevant CCG website.						
In order to refer a couple for assessment by the Fertility Services, couples must answer "Yes" to relevant questions below.						
Any "No" responses will mean that the couple do not qualify for routinely funded fertility assessment or treatment and funding approval must therefore be secured from the Exceptional Funding Request (EFR)						

application. Please note:

• Recurrent miscarriage is not an indication for patients to access Fertility Services although, if appropriate, patients may be referred for gynaecological investigations rather than fertility services and treatments.

Panel prior to referral. A copy of this form should be completed and forwarded on with an Exceptionality

• Prospective fathers with a BMI of over 29.9 kg/m2 should be offered a referral to weight management services to reduce their weight, as obesity can impact on fertility.

1.a	For couples in a heterosexual relationship - The couple have failed to conceive after regular unprotected sexual intercourse for two years.	Yes No	
	Patients may be referred outside this timeframe if there is a known condition which is likely to affect the fertility of either partner, for example:	N/A	
	 severe oligomenorrhoea previous testicular surgery) oncology treatment is likely to compromise the fertility of either the prospective mother or father 		
	Heterosexual couples who have failed to conceive after regular unprotected sexual intercourse for more than one year but less than two years and where the prospective mother will be older than 18 weeks before her fortieth birthday may also be referred.		
1.b	For same sex couples - insemination on at least 10 cycles at an HFEA licenced centre, over a period of 2 years, has failed to lead to a pregnancy.	Yes No N/A	
2.	The couple have been in a stable relationship for two years or more.	Yes No	

3.	3. The prospective mother is aged less than 18 weeks before her 40 th birthday at assessment.					
4.	The prospective father in a heterosexual relati	onship is age	ed 54 years or less.	Yes No N/A		
5.a	Neither partner in a heterosexual relationship been reversed.	has been ste	rilised in the past even if it has	Yes No		
5.b	The prospective mother in a same sex relation has been reversed.	nship has not	been sterilised in the past even if it	Yes No		
6.	Both partners are non-smokers.			Yes No		
7.a The prospective mother's BMI must be between 19 and 29.9 kg/m² for a period of six months, as documented in her Primary Care records. Please note that patients with a BMI of 30 kg/m² or above should be offered a referral to weight management services to reduce their weight, prior to assessment and treatment by Fertility Services.			Yes No N/A			
7.b The prospective mother is aged between 37 years and 39 years, 34 weeks and her BMI is between 30 and 35 kg/m² and she has been referred to weight management services at the same time as being referred to fertility services, in order assist her to lose weight and aid fertility.				Yes No N/A		
8.	At least one member of the couple is registered with a GP in the BNSSG area.					
g. For same sex couples - has the possibility of the other partner trying to conceive before proceeding to interventions involving the sub-fertile partner been discussed and rejected?				Yes No N/A		
10.	At least one partner does not have living offsp	ring.		Yes No		
11.	Neither partner has received an NHS funded or previously.	cycle a cycle	of NHS funded treatment	Yes No		
l ar	n the registered GP of: The prospective moth	er: 🗌 The	e partner: Both:			
else Wh are	Where you are not the registered GP of both patients, please ensure that the GP of the partner registered elsewhere is aware of this referral as they may need to supply clinical data to Fertility Services. Where appropriate, please refer to the website of the service you are referring your patients to, so that you are aware of the information that should be supplied by letter with this referral. The website of Bristol Centre for Reproductive Medicine is available here: http://www.nbt.nhs.uk/bcrm/referral-and-costs/nhs-referrals					
Please confirm:						
	 ☐ I recommend proceeding to an assessment by Fertility Services for this couple. ☐ I have informed the patients that this intervention is only funded where criteria are met. ☐ The couple are aware of the limits of treatments offered under the NHS under this care pathway. ☐ I have included a covering letter summarising the clinical history of my patient / both my patients. 					
Sig	ned:	Date:				
Nar	ne:	Practice Address:				

This form should now be sent to the service you are referring your patients to.

In order to access assisted conception services following investigation and assessment, couples will also be assessed against the following criteria. Please ensure your patients are informed of these criteria prior to referral and the couple are aware that this referral may **not** lead to fertility treatment:

For Assisted Conception

The BMI of the prospective mother must remain between 19 and 29.9 kg/m2 whilst accessing fertility treatment. This is because the success of fertility treatment is significantly reduced where the prospective mother is outside of these limits.

Account will be taken of additional factors such as active hepatitis, alcoholism, intra-venous drug misuse that may adversely affect the welfare of any child born as a result of treatment or give rise to complex treatment issues.

The male partner must have normal sperm function (except for ICSI, donor sperm or surgical sperm recovery).

The prospective mother must have

a. an AMH of greater than or equal to 5.4 pmol/l OR b. a FSH level less than or equal to 15iu/l.

If donor sperm / oocytes are used the couple must be able to demonstrate in writing joint legal responsibility for any child born as a result of treatment.

For IVF or ICSI

The prospective mother's serum FSH must be less than or equal to 12iu/l at the time of treatment **AND / OR** an AMH of greater than or equal to 5.4 pmol/l.

The prospective father's serum FSH level must be less than 15 iu/l or testicular volume must be greater than 8ml (as assessed by a fertility specialist) for surgical sperm recovery and storage to be undertaken.

GUIDANCE FOR GENERAL PRACTITIONERS

Assessment and Treatment of Couples with Fertility Problems

Version	Date	Reviewer	Comment
1	30/11/2017	NBT / UHB / BNSSG CCG	First version
2	01/12/2017	Gill Ryan	External document agreed with Fertility consultants at NBT and UHB
3	15/12/2017	Gill Ryan	Amended to reflect agreement (lost in formatting) that GPs could refer to fertility service at UHB, NBT or RUH (pages 2 and 3) and Bath Fertility / RUH reflected on single line in table on page 3 for clarity (at RUH request)
4	30/01/2018	IFR Team	Administrative changes
5	04/05/2018	IFR Team	Changes to services provided by BCRM and additional provider information.
5.01	04/05/2018	IFR Team	To correct additional provider info.

North Bristol NHS Trust & University Hospitals Bristol NHS Trust In collaboration with BNSSG CCGs

Guidance for General Practitioners

Assessment and treatment of Couples with Fertility Problems

Introduction

Whilst criteria apply to fertility treatments, it is appropriate for all people experiencing fertility problems to be investigated and, if necessary, referred to a specialist with an interest in fertility so that they can have more complex investigations and be informed as to the causes of their fertility problems. This will allow them to decide on the options they may wish to pursue.

Prior to referral

Simple investigations in primary care should be undertaken if a couple are recognized as having an identified problem, regardless of the period of infertility. A full history and examination of both partners is recommended. It is important to cover a sexual history and testicular problems in the male. Social factors such as alcohol and smoking should also be noted. There may also be certain factors which merit early referral to a specialist unit such as lack of periods (Amenorrhoea) or absent sperm (Azoospermia).

Assessment in primary care

Many couples presenting with a delay in conception of 1 year duration may only need simple investigations and reassurance (see algorithm). The following are the only necessary routine investigations:

Female Partner

- FSH, LH and Estradiol (taken on day 1-4 of menstrual cycle)
- Full blood count
- Rubella status
- Chlamydia serology
- Serum progesterone (Mid luteal i.e. 7 days prior to expected menstruation)
- Prolactin (in women with irregular periods)
- TSH

Male Partner

• Semen analyses (one test is adequate if normal, a second test is required if the first is abnormal which should be at least 3 months apart).

If all of the above (history, examination and investigation of both partners) are normal, and the period of infertility is less than 24 months, referral can be deferred until then, unless where the prospective mother will be older than 18 weeks before her 40th birthday.

Referral

Patients seeking further investigation and treatment for their fertility problems should be referred to any of the following clinics:

- NBT General Fertility Clinic, Southmead Hospital
- Reproductive Medicine Clinic, St. Michael's Hospital
- Gynae Reproductive Medicine, RUH, Bath

To enable appropriate referrals please ensure the patients fulfill the BNSSG eligibility criteria under the latest Fertility Assessment and Treatment Policy available from the CCG website.

Please also complete the specialist Fertility Assessment Referral Form.

Patients who require assisted conception treatment such as IVF:

Patients requiring <u>NHS funded</u> specialist infertility treatment such as IVF, who meet the eligibility criteria, must be referred for treatment by an NHS Gynaecology consultant/ specialist using the "Fertility Treatment Funding Application Form" available from their CCG website.

The Fertility Treatment provider of the patient's choice will be sent the referral form and a summary of test results.

Details of funded NHS fertility services for BNSSG patients	Assessment including laparoscopy	Semen analysis	Treatment including surgery and clomifene	Ovulation induction and monitoring	Assisted conception e.g. IVF/ ICSI/ IUI	IVF lab in Bristol/Bath
Reproductive Medicine Clinic, St. Michael's Hospital	~		~	V	IUI	
Southmead General Fertility Clinic, North Bristol NHS Trust (NBT) (located in BCRM)	~		~	~		
Bristol Centre for Reproductive Medicine (BCRM)		~			~	BRISTOL
Bath Fertility Centre (which also hosts the NHS Reproductive Medicine Service on behalf of the RUH)	~	V	~	~	~	V
Create Fertility, Bristol		V			~	~
London Women's Clinic (Cardiff) Bristol satellite		V			~	
Fertility Exeter					V	
The Centre for Reproductive & Genetic Health, London		Expected in Bristol from Sep 2018			~	Expected in Bristol from Sep 2018

GP GUIDANCE ALGORITHM

Check:

- Confirm ovulation (progestetrone)
- Ensure BMI normal (>18, <30) advise on weight as appropriate
- Advise on folic acid, smoking and alcohol
- Advise regular intercourse 2 or 3 times a week.
- Undertake tests including semen analysis

If normal reassure and advise couple try further (for up to 2 years - unless where the prospective mother will be older than 18 weeks before her 40th birthday)

Significant Abnormality (e.g. amenorrhoea, azoospermia, tubal blockage)

Or ≥2 years infertility

Referral to NHS fertility clinic:

Southmead Fertility Clinic St. Michael's Fertility Clinic RUH, Bath Reproductive Medicine Clinic

- 1. Confirm couple fulfill referral eligibility criteria (or consider IFR)
- 2. Complete referral form to specialist fertility clinic
- 3. Please arrange that test results are available for the following:

<u>Female partner:</u> FSH, LH and Estradiol (taken on day 2-5 of menstrual cycle), FBC, Prolactin (in women with irregular periods), TSH, HIV, Hepatitis B & C, Syphilis, Rubella and Chlamydia serology

Male partner: Semen analysis, HIV, Hepatitis B & C, Syphilis



Commissioning Policy Individual Funding Request

Fertility Assessment and Treatment

Prior Approval and Criteria Based Access Policy

Date Adopted: 01 December 2017

Version: 1718.3.03

Document Control

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1718.3.0	07/11/2017	Head of IFR	Agreed by JCE
1718.3.01	06/12/2017	IFR Co-ordinator	Admin change to clarify Referral Routes
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			by NHS England
1718.3.03	26/03/2018	IFR Coordinator	Rebranded to BNSSG CCG

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REFERRAL FOR ASSESSMENT IS SUBJECT TO CRITERIA BASED ACCESS (Sections B, C, G and I)

TREATMENT UNDER THIS POLICY REQUIRES PRIOR APPROVAL (Sections D, E and H)

THIS POLICY RELATES TO ADULTS WITHIN THE AGE RANGES SPECIFIED BELOW

Fertility Assessment and Treatment

Policy Statement

Fertility assessment and treatment is not routinely funded by the CCG and is subject to this restricted policy.

General Principles

Funding approval will only be given in line with these general principles. Where patients are unable to meet these principles in addition to the specific treatment criteria set out in this policy, funding approval will not be given.

- 1. Primary Care clinicians should assess their patients against the criteria within this policy prior to referring patients for Assessment in Secondary Care. Referring patients to Secondary Care who do not meet the criteria not only incurs significant costs in out-patient appointments for patients that may not qualify for treatment, but inappropriately raises the patient's expectation of treatment.
- 2. In line with the published document "Guidance Who Applies for Funding?", where referrals to secondary care are accepted without funding approval having been secured, responsibility for securing funding approval will fall to secondary care.
- 3. On limited occasions, the CCG may approve funding for an assessment only in order to confirm or obtain evidence demonstrating whether a patient meets the criteria for funding. In such cases, patients should be made aware that the assessment does not mean that they will be provided with treatment, and treatment will only be provided where it can be demonstrated that the patient meets the criteria to access treatment in this policy.
- 4. Where funding approval is given by the Individual Funding Panel, it will be available for a specified period of time, normally one year. Patients will be expected to have commenced the fertility pathway within this year but, given the potentially lengthy nature of the pathway, may not have completed their treatment within the year. As long as they have commenced treatment within a year of funding approval being given, funding will be available in line with this published policy to complete their pathway.

Background

Bristol, North Somerset and South Gloucestershire (BNSSG) CCG has limited resources to fund fertility treatments and has therefore targeted the limited funds specifically in order to allow couples in a stable relationship, a chance to conceive. Given the limits on resources, provision of treatments under this policy is aimed at patients with a realistic clinical opportunity of having a child.

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An estimated one in seven couples have difficulty conceiving. In the general population (which includes people with fertility problems), it is estimated that 84% of women would conceive within one year of regular unprotected sexual intercourse. This rises cumulatively to 92% after two years and 93% after three years.

Infertility can be primary, in couples who have never conceived, or secondary, in couples who have previously conceived. There are several possible reasons why it may not happen naturally. In men, a fertility problem is usually because of low numbers or poor quality of sperm. Female fertility decreases with increasing age. For women aged 35, about 95% who have regular unprotected sexual intercourse will get pregnant after three years of trying. For women aged 38, only 75% will do so.

Other factors which affect fertility success rates include obesity, smoking and social factors such as alcohol and drug misuse and therefore this policy has criteria on these subjects.

The following figures give the average success rate for In-Vitro Fertilisation (IVF) and Intracytoplasmic Sperm Injection (ICSI) treatment using a woman's own fresh eggs in the UK in 2009.

- 32.3% for women under 35
- 27.2% for women aged 35-37
- 19.2% for women aged 38-39
- 12.7% for women aged 40-42
- 5.1% for women aged 43-44
- 1.5% for women aged 45+

This policy sets out the limits within which BNSSG CCG will fund treatment with either Intrauterine Insemination (IUI), ovulation induction medication or donor insemination (DI) as well as IVF treatment if necessary for patients who meet the criteria for treatment.

This policy also sets out treatments patients can expect to access prior to and following oncology treatment in order to preserve fertility as well as our commissioning stance on Cryopreservation, posthumous assisted reproduction, sperm washing and pre-implantation genetic diagnosis.

BNSSG CCG does not partially fund treatments for patients who do not meet the criteria within this policy. This includes patients who wish to access assisted conception advice and treatments such as testing and medications following a previous birth, patients who wish to harvest oocytes or sperm, or store embryos prior to third party surrogacy or patients who wish to preserve fertility prior to Gender Dysphoria treatment.

All statistics quoted in this section are referenced from the Human Fertilisation and Embryology Authority (HFEA) website at: https://www.hfea.gov.uk/ and NICE Guidelines on Fertility Treatments at: https://www.nice.org.uk/guidance/cg156

Glossary of Terms

АМН	Anti-Müllerian hormone - Comparison of an individual's AMH level with respect to average levels is useful in fertility assessment, as it provides a guide to ovarian reserve and identifies women that may need to consider either egg freezing or trying for a pregnancy sooner rather than later if their long-term future fertility is poor.	
Embryos	Refers to a fertilised Oocyteoocyte. It is called an embryo until about eight weeks after fertilisation and from then it is instead called a foetus.	
FSH	Follicle-Stimulating Hormone - FSH regulates the development, growth, pubertal maturation, and reproductive processes of the human body.	

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ICSI	Intracytoplasmic Sperm Injection (ICSI) is a variation of in-vitro fertilisation in which a single sperm is injected into the inner cellular structure of an egg.
Infertility	In the absence of known reproductive pathology, infertility is defined as failure to conceive after regular unprotected sexual intercourse for 2 years.
IUI	Intrauterine Insemination (IUI) involves timed insemination of sperm into the uterus. This can be completed as part of a natural unstimulated cycle (unstimulated IUI) or following stimulation of the ovaries using oral anti-oestrogens or gonadotrophins (stimulated IUI).
IVF	In-Vitro Fertilisation (IVF) is a technique whereby eggs are collected from a woman and fertilised with a man's sperm outside the body.
Ooctye (Eggs)	Refers to a female gametocyte or germ cell involved in reproduction. In other words, it is an immature ovum, or egg cell.
Sperm	Refers to the male reproductive cells
Sperm, Oocyte or Embryo Cryopreservation	Sperm, Oocyte or Embryo Cryopreservation is the freezing and storage of Sperm, Oocyte or Embryos that may be thawed for use in future in-vitro fertilisation treatment cycles.

More information regarding Fertility Treatment is provided on the HFEA website at:

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

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Section A - General Principles for all Patients

FERTILITY ASSESSMENT - CRITERIA BASED ACCESS / FERTILITY TREATMENT - PRIOR APPROVAL

Points that should be noted when considering whether patients are eligible to access NHS funded fertility treatments:

- Fertility treatment should be offered in the least invasive format appropriate, namely investigation and assessment, followed by assisted conception and finally IVF or ICSI. All referrals for assessment and treatment should be made on the form published on the BNSSG websites and accompanied by a referral letter setting out detailed clinical information and background.
- Couples who do not meet the eligibility criteria set out in the relevant section of this policy or have received NHS funded IVF treatment elsewhere are not eligible for treatment under this policy.
- **3.** The prospective mother must not be older than 18 weeks before her 40th birthday at referral as no female patient will be placed on the waiting list for secondary care fertility assessment within 18 weeks of their 40th birthday.
- **4.** Where a member of the couple has previously received NHS funded treatment as part of another couple, they will not be barred from accessing NHS funded treatment under their current relationship where they meet all criteria.
- 5. At least one partner must have no living offspring/children to qualify for funding. This includes genetic and legally adopted children and offspring who are adults but does not include foster children or step children. If the couple adopt a child or become pregnant naturally during assessment or treatment the couple are no longer eligible for fertility assessment or treatment.
- **6.** Patients who have secondary sub-fertility will not be eligible to have NHS funded consultations with fertility services in order to assess their condition and secure treatment advice.
- 7. For the purposes of this policy, the commencement of IVF/ICSI cycle is defined as commencement of ovarian stimulation by fertility services, or if no drugs are used, when an attempt is made to collect eggs/oocytes. Any patient who completes this step, regardless of the outcome, is deemed to have had one full cycle of IVF/ICSI. Therefore if a cycle is abandoned for clinical reasons this is still counted as the fresh cycle that the couple are entitled to. One frozen cycle using frozen embryos will follow a fresh cycle if deemed clinically appropriate. Patients will not be eligible for further NHS funded investigation and fertility treatment following completion of this cycle.
- **8.** A full IVF/ICSI treatment cycle includes:
 - Diagnostic tests, scans and pharmacological therapy
 - > Counselling for couples
 - > Stimulation of prospective mother's ovaries to produce oocytes
 - Harvesting of the oocytes
 - Fertilisation using IVF or ICSI (assisted hatching is not provided)
 - One fresh embryo transfer
 - ➤ If unsuccessful, within twelve months of cryopreservation, one frozen embryo transfer from remaining frozen embryos. [maximum of 2 embryos per cycle]
 - ➤ A follow up consultation with fertility services post IVF treatment
 - Where patients have completed their NHS funded full cycle of IVF treatment but have frozen embryos remaining in storage, they can elect to self-fund further treatment with the fertility services.
- 9. Both partners' GPs must have given their positive recommendation to proceed to treatment. Account must be taken of additional factors such as active hepatitis, alcoholism, intra-venous drug misuse that may adversely affect the welfare of any child born as a result of treatment or give rise to complex treatment issues (see HFEA Code of Practice for details https://ifqlive.blob.core.windows.net/umbraco-website/2062/2017-10-02-code-of-practice-8th-edition-full-version-11th-revision-final-clean.pdf)

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Section B - Investigation, Assessment and Advice on Fertility Issues for Heterosexual Couples

CRITERIA BASED ACCESS

For review and consideration by the GP at time of referral to the Fertility Service

In order to access services to investigate and assess issues with fertility, couples must meet all of the following criteria:

- **1.** The couple have been in a stable relationship for at least two years.
- 2. Hetero-sexual couples have failed to conceive after regular unprotected sexual intercourse for two years. Patients may be referred outside this timeframe if there is a known condition which is likely to affect the fertility of either partner (e.g. severe oligomenorrhoea or previous testicular surgery) or oncology treatment is likely to compromise the fertility of either the prospective mother or father.
- **3.** Hetero-sexual couples who have failed to conceive after regular unprotected sexual intercourse for more than one year but less than two years and where the prospective mother will be older than 18 weeks before her fortieth birthday may also be referred.
- **4.** Recurrent miscarriage is not an indication for patients to access fertility services although they may be referred for gynaecological investigations and treatments if appropriate.
- 5. At least one of the partners must be registered with a GP in the BNSSG area.
- **6.** The couple must not have previously received a cycle of NHS funded fertility treatment to the level outlined in this policy.
- 7. Patients who have previously self-funded unsuccessful fertility treatment are eligible for NHS funded fertility treatment as long as they meet the criteria within this policy. Outcomes from previous fertility treatment will be considered as part of the clinical assessment and patients should be aware that multiple failures to conceive through fertility treatment is indicative of poor conception success rates.
- **8.** Both partners must be non-smokers as confirmed in their primary care records. Individuals who are smokers should be referred to smoking cessation services and be able to demonstrate by compliance with that service that they are non-smokers prior to assessment. Prospective fathers who smoke should be informed that there is an association between smoking and reduced semen quality and, although the impact of this on male fertility is uncertain, they should cease smoking prior to treatment to improve sperm quality.
- **9.** The prospective mother's body mass index (BMI) must be between 19 and 29.9 kg/m² for a period of six months as evidenced from her primary care record. The evidence is clear that obesity negatively impacts upon successful natural conception and fertility treatment. Prospective mothers with a BMI of 30 and above should be offered a referral to weight management services in order to reduce their weight prior to assessment and treatment by fertility services. (see https://www.nice.org.uk/guidance/cg156/chapter/Recommendations)
- **10.** Where the prospective mother is aged between 37 and up to 18 weeks before her fortieth birthday, her BMI must be between 19 and 35 kg/m² prior to referral for assessment. Prospective mothers with a BMI above 29.9 in this age group should be referred to weight management services at the same time as being referred to fertility services in order assist her to lose weight and aid fertility.
- **11.** The prospective father should aim to have a BMI of 29.9 and under. There is evidence that obesity negatively impacts upon successful natural conception and fertility treatment due to reduced sperm quality (see https://www.nice.org.uk/guidance/cg156/chapter/Recommendations)
- **12.** The prospective father is aged 54 years or less. Male fertility has been shown to decrease with age, with evidence of greater incidence of disability poor sperm function and DNA degradation. ^{1, 2}
- **13.** Neither partner has been sterilised in the past even if it has been reversed and the sterilisation is the cause of the fertility problems.

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Section C - Investigation, Assessment and Advice on Fertility Issues for Same Sex Couples

CRITERIA BASED ACCESS

For review and consideration by the GP at time of referral to the Fertility Service

In order to access services to investigate and assess issues with fertility, couples must meet all of the following criteria:

- **1.** The couple have been in a stable relationship for at least two years.
- 2. Same sex couples may be assessed if self-funded insemination on at least ten non-stimulated cycles over a period of two years has failed to lead to a pregnancy, or oncology treatment is likely to compromise the fertility of the prospective mother. NHS funding is not available for access to donor insemination facilities for fertile women or surrogacy.
- Either a. both partners have fertility issues, i.e. blocked fallopian tubes or anovulation, or
 where only one partner is sub-fertile, where possible, the partner who is fertile should try to conceive before proceeding to interventions involving the sub-fertile partner.
- **4.** Recurrent miscarriage is not an indication for patients to access fertility services although they may be referred for gynaecological investigations and treatments if appropriate.
- 5. At least one of the partners must be registered with a GP in the BNSSG area.
- **6.** The couple must not have previously received a cycle of NHS funded fertility treatment to the level outlined in this policy.
- 7. Patients who have previously self-funded unsuccessful fertility treatment are eligible for NHS funded fertility treatment as long as they meet the criteria within this policy. Outcomes from previous fertility treatment will be considered as part of the clinical assessment and patients should be aware that multiple failures to conceive through fertility treatment is indicative of poor conception success rates.
- **8.** The prospective mother must be a non-smoker as confirmed in their primary care records. Patients who are smokers should be referred to smoking cessation services and be able to demonstrate that they are non-smokers prior to assessment. Partners of prospective mothers who smoke should also be offered a referral to smoking cessation services in order to improve their health and support their partner.
- **9.** The prospective mother's body mass index (BMI) must be between 19 and 29.9 kg/m². The evidence is clear that obesity negatively impacts upon successful natural conception and fertility treatment. Prospective mothers with a BMI of 30 and above should be offered a referral to weight management services in order to reduce their weight prior to assessment and treatment by fertility services.
- **10.** Where the prospective mother is aged between 37 and up to 18 weeks before her fortieth birthday, her BMI must be between 19 and 35 kg/m² prior to referral for assessment. Prospective mothers with a BMI above 29.9 in this age group should be referred to weight management services at the same time as being referred to fertility services in order assist her to lose weight and aid fertility.
- **11.** The partner of a prospective mother who has undertaken NHS funded fertility treatment, whether successful or not, will be deemed to have received their entitlement to NHS funded fertility treatment upon completion of this cycle in line with heterosexual couples and will not be eligible for a further NHS funded treatment with their partner.
- **12.** The prospective mother has not been sterilised in the past even if it has been reversed and the sterilisation is not the cause of the fertility problems.
- **13.**Both members of the couple must accept joint legal responsibility for any child produced through fertility treatment.

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Section D - Assisted Conception

PRIOR APPROVAL

The Fertility Service is required to secure funding from the CCG following assessment and before treatment commences under Sections D, E and F.

Assisted conception services include IUI, ovulation induction medication and donor insemination. In order to access assisted conception services following investigation and assessment, couples must be assessed against the following criteria:

- 1. Each couple will be offered up to three treatment cycles of IUI and up to a total of six treatments of the three techniques.
- 2. The BMI of the prospective mother must remain between 19 and 29.9 kg/m² whilst accessing fertility treatment. This is because the success of fertility treatment is significantly reduced where the prospective mother is outside of these limits.
- **3.** An assessment of a prospective mothers overall chance of successful pregnancy through natural conception or with IVF should be made with one of the following measures to predict the likely ovarian response to gonadotrophin stimulation in women who are considering treatment:
 - a. anti-Müllerian hormone [AMH], or
 - **b.** timed follicle-stimulating hormone [FSH] and Estrogen.
- 4. The prospective mother must have
 - a. an AMH of greater than or equal to 5.4 pmol/l or
 - **b.** a FSH level less than or equal to 15iu/l
- 5. The male partner must have normal sperm function (except for ICSI and donor sperm)
- **6.** If donor sperm / oocytes are used the couple must be able to demonstrate in writing joint legal responsibility for any child born as a result of treatment.

Section E - In-Vitro Fertilisation or Intracytoplasmic Sperm Injection - PRIOR APPROVAL

For Fertility Service consideration when planning treatment – see above.

1. One full treatment cycle of IVF or ICSI (with oocyte donation and/or surgical sperm recovery if required) in line with **Section A Points 7 and 8**, will be offered to couples where other assisted conception techniques have failed.

In addition to all of the criteria above, the following criteria must also be satisfied at the time of treatment:

- 2. The prospective mother's serum FSH must be less than or equal to 12iu/l at the time of treatment or an AMH of greater than or equal to 5.4 pmol/l.
- **3.** The prospective father's serum FSH level must be less than 15 iu/l or testicular volume must be greater than 8ml (as assessed by a fertility specialist) for surgical sperm recovery and storage to be undertaken.

Section F - Surgical Sperm Retrieval for Male Infertility - NHS England

This treatment is funded by **NHS England** please refer to the NHS England Clinical Commissioning Policy **Surgical Sperm Retrieval for Male Infertility** at:

https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2013/05/16040_FINAL.pdf

Or contact NHS England for more information.

NB: Patients must meet the criteria to access treatment under this policy in order to access treatment under the NHS England policy

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Section G - Fertility Preservation Prior to Oncology Treatment

CRITERIA BASED ACCESS

For Oncology and Fertility Service consideration when planning treatment

- 1. Patients who are to be treated with oncology treatments which are likely to compromise their fertility are eligible for fertility preservation treatment including:
 - **a.** for single individuals or those not in a stable relationship: sperm collection and storage, or oocyte harvesting and storage, or
 - **b.** storage for couples in a stable relationship: oocyte harvesting, fertilisation and embryo Cryopreservation prior to any oncology treatment to allow subsequent IVF treatment in line with this policy as long as they meet the requirements for funding below.
- 2. Patients must have commenced puberty and not be older than the limits for treatment set out in this policy (18 weeks before the prospective mother's fortieth birthday and under 55 for a prospective father)
- **3.** At the time of fertility preservation treatment, patients do not need to be able to demonstrate that they comply with the requirements of this policy in respect of smoking and BMI, as delaying treatment until a patient could comply may compromise oncology treatment.
- **4.** Fertility preservation for the following patients is not commissioned and will not be funded by BNSSG where:
 - **a.** the patient wishes to undergo a vasectomy or female sterilisation and wishes to preserve fertility, or
 - b. the patient wishes to delay conception, or
 - **c.** the patient has living offspring and therefore does not qualify for funding for fertility preservation treatment. This includes genetic and legally adopted children and offspring who are adults but does not include foster children or step children.
 - **d.** the patient has previously received an NHS funded cycle of fertility treatment as set out in Section A, point 7, either locally or elsewhere in the UK.

<u>Section H - Fertility Treatment including Assisted Conception and IVF following Fertility Preservation Treatment</u>

PRIOR APPROVAL

For Fertility Service consideration when planning treatment

- 1. Once the patient has completed oncology treatment and been advised by clinicians that they may safely commence fertility treatment, they must meet all of the requirements of this policy to be eligible for treatment.
- 2. Sperm, oocyte and embryo storage will be handled in line with the BNSSG Cryopreservation policy in place at the time of collection as set out in this policy.

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Section I - Cryopreservation of Sperm, Oocytes and Embryos - CBA

Cryopreservation is term use to describe the freezing and storage of sperm, oocytes and embryos for patients.

- 1. BNSSG will fund Cryopreservation for patients on the fertility pathway for up to one year.
- **2.** Patients who have had sperm, oocyte or embryo cryopreserved prior to oncology treatment will be funded for Cryopreservation:
 - **a.** until a patient is two years post remission (up to a maximum of five years post collection, freezing and storage), or
 - **b.** until a patient's 25th birthday (up to a maximum of ten years)
- **3.** Funding for storage will cease six months following the death of the patient, or if the patient or their partner reaches the upper age limit.
- **4.** Once the period of NHS funding ceases, patients or their family can elect to self-fund for a further period, not to exceed appropriate HFEA regulations on length of storage.
- **5.** Patients with cryopreserved sperm, oocytes or embryos must comply with all requirements of the fertility services and the HFEA or NHS funding for these products will cease. This includes Consent, in a manner as set down by HFEA regulations, must be obtained at the outset and at regular intervals (usually annually) during the period of storage for storage to continue.
- **6.** Commencement of Cryopreservation does not entitle patients to fertility treatments. There is the potential for patients to meet the access criteria for Cryopreservation and not to meet the criteria for fertility treatments at a later date. Patients in this category may elect to self-fund further fertility treatment using the cryopreserved sperm, oocytes or embryos.

Section J - Posthumous Assisted Reproduction - IFR

Funding approval must be sought by the GP or the Fertility Service prior to referral by submission of an Individual Funding application form

Patients who wish to use cryopreserved sperm, oocytes or embryos following the death of their partner, may only do so where appropriate consents have been obtained prior to the death of their partner, as set down in HFEA guidelines.

1. BNSSG does not fund fertility treatments associated with posthumous assisted reproduction.

Section K - Sperm Washing - IFR

Funding approval must be sought by the GP or the Fertility Service prior to referral by submission of an Individual Funding application form

Sperm washing is a technique used to decrease the risk of HIV transmission in HIV positive prospective fathers, because the HIV infection is carried by the seminal fluid rather than the sperm. Research has shown that it can reduce the risk of transmission by 96%. However, there may still be a small risk of HIV transmission which some couples may find unacceptable.

Patients can be seen, assessed and treated by local fertility services although a sperm-washing service is only available at the Chelsea & Westminster (C&W) Hospital in London, and at the time of drafting this policy, no other clinics in the UK offer a sperm-washing service.

- **1.** BNSSG will approve funding for sperm washing with one full cycle of fertility treatment in conjunction with this policy where:
 - a. the couple qualify for fertility treatment under this policy, and
 - **b.** the prospective father is HIV positive.

Prospective mothers who are HIV positive should be advised that there is a risk of between 5% and 40% of Mother-to-Child transmission of HIV during pregnancy, labour and delivery or by breastfeeding and should seek advice from their managing clinicians prior to conception in order to minimise the risk. http://www.who.int/hiv/topics/mtct/en/index.html

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Section L - Pre-Implantation Genetic Diagnosis

This is funded by **NHS England** – please contact them for more information.

Section M - Funding of Surrogacy Arrangements and Treatments - IFR

Funding approval must be sought by the GP or the Fertility Service prior to referral by submission of an Individual Funding application form

Background

In a surrogacy arrangement a woman agrees to bear a child for another woman or couple and surrender it at birth. The commissioning couple are the people (or in some cases, person) who wish to bring up the child after his or her birth.

Patients may wish to utilise surrogacy arrangements for a number of reasons:

- absence or malformation of the womb (either congenital or through hysterectomy for e.g. cancer or postpartum haemorrhage or menorrhagia)
- recurrent pregnancy loss or repeated in vitro fertilisation (IVF) implantation failures
- where pregnancy would be a life-threatening condition, or
- a prospective single father (or fathers in a same sex relationship) wishes to have a child.

The Commissioner has limited resources to provide fertility services and therefore has to target those patients with a realistic clinical opportunity to conceive (with assistance) and carry a child to birth.

Policy

The Commissioner does not support or fund treatments for surrogacy. In addition support and funding will not be provided for any associated treatments (including fertility treatments) related to those in surrogacy arrangements.

The Commissioner will not therefore:

- Be involved in the recruitment of surrogate mothers.
- Fund that element of treatment which relates specifically to addressing fertility treatments directly associated with surrogacy arrangements.
- Fund any payments to the surrogate mother (to cover expenses, legal costs, treatments abroad or transport costs).

This section of the policy has been developed taking into account that surrogacy is specifically excluded from NICE guidelines.

Maternity Care Arrangements

The Commissioner commissions maternity services to provide appropriate support, guidance and care to women during and after pregnancy and these services will continue to be available to surrogates.

Exceptionality

Notwithstanding this general policy on Surrogacy, Clinicians may on behalf of patients apply for exceptional funding for fertility treatments to assist surrogacy arrangements. In doing so, the Clinician should demonstrate why their case is exceptional in comparison to the large cohort of patients who may wish to access such treatments. In addition, funding approval would normally only be provided where it can be demonstrated that the patients meet the criteria.

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Patients who are not eligible for treatment under this policy may be considered on an individual basis where their GP or consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy.

Individual cases will be reviewed at the CCG's Individual Funding Request Panel upon receipt of a completed application form from the patient's GP, Consultant or Clinician. Applications cannot be considered from patients personally.

If you would like further copies of this policy or need it in another format, such as Braille or another language, please contact the Patient Advice and Liaison Service on 0800 073 0907 or 0117 947 4477.

This policy has been developed with the aid of the following references:

NICE – Fertility Guidelines Consultation https://www.nice.org.uk/guidance/cg156

HFEA – Guidance and Protocols including PGD http://www.hfea.gov.uk/

Chelsea and Westminster – Sperm Washing

http://www.chelwest.nhs.uk/services/womens-health-services/assisted-conception-unit-acu/treatment-options/sperm-washing

Paternal age and reproduction, Human reproduction update, Jan; Feb 2010, vol./is. 16/1(65-79), 1460-2369 (2010 Jan-Feb) Sartorius G.A., Nieschlag E.

http://www.fertstert.org/article/S0015-0282%2800%2901679-4/abstract

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