NHS
Bath and North East Somerset, Swindon and Wiltshire
Clinical Commissioning Group

Assisted Conception Policy for Infertile Patients

PRIOR APPROVAL REQUIRED

1. Introduction

This policy sets out the BSW Clinical Commissioning (CCG) position for funding assisted conception services for infertile patients. The policy also relates to and have been informed by National Institute of Health and Care Excellence (NICE) Clinical Guideline CG 156 'Fertility: assessment and treatment for people with fertility problems', 2013 (updated 2017).

2. Purpose

The overall aim of the local policy is to support the commissioning of the highest quality, most clinically and cost effective and affordable fertility services, that maximise health outcomes in terms of live births and patient/baby safety. This policy supersedes and updates the positions of the former locality specific fertility policies of BaNES CCG, Swindon CCG and Wiltshire CCG to become BSW CCG.

3. Scope

The policy affects couples and individuals who have diagnosed or undiagnosed infertility, seeking assisted conception services.

- Patients will only be referred for NHS Funded assisted conception services if they meet the eligibility criteria in this policy and when all appropriate tests and investigations have been successfully completed in primary and secondary care in line with NICE clinical guidelines.
- CCG does not partially fund treatments for patients who do not meet the eligibility criteria in this policy.
- Patients accessing assisted conception services should be fully informed of likely success rates and alternative approaches to parenting, including fostering and adoption.
- Patients should also be advised that impartial advice and information is available via the Human Fertilisation and Embryology Authority which regulates assisted reproductive therapies.

This document relates to the following assisted reproductive technologies (ART):

- In vitro fertilisation (IVF), with or without intra-cytoplasmic sperm injection (ICSI)
- Intra-uterine insemination (IUI) using donor or partner sperm
- Surgical sperm retrieval (SSI)
- Sperm washing
- Surrogacy/Gestational Carriers
- Use of donor eggs and sperm

The following is outside of the scope of the policy:

- Investigations for general fertility problems and the primary treatment of conditions found during such investigation.
- Medical treatment to restore fertility (for example, the use of drugs for ovulation induction)
- Surgical treatment to restore fertility (for example, laparoscopy for ablation of endometriosis)
- Pre-implantation Genetic Diagnosis (PGD) and the associated assisted conception services are commissioned by NHS England through Specialised Commissioning Area Teams, as per NHS England Clinical Commissioning Policy (2014) Pre-implantation Genetic Diagnosis.
- For Preservation of fertility (cryopreservation i.e., freezing of eggs, sperm or embryos for future use) please refer to separate BSW CCG Policy 'Preservation of fertility'.

Novel treatments or research trial treatments are not included in this policy. Patients taking part in trials of new treatments will be considered separately within the governance arrangements of that research trial.

New developments in assisted reproductive technologies will be dealt with through the agreed local processes and would need to be proposed via a business case.

4. Equality Statement

Promoting equality and addressing health inequalities are at the heart of Commissioners values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it.
- Given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities.

5. Definitions

Clinical definition of infertility is a disease of the reproductive system defined by the failure to achieve a clinical pregnancy after 12 months or more of regular unprotected sexual intercourse (International Committee for Monitoring Assisted Reproductive Technology and the World Health Organization revised glossary of ART terminology, 2009).

Cycle of IVF/ICSI this policy refers to a cycle of IVF treatment, with or without intracytoplasmic sperm injection (ICSI) and comprises of ovulation induction, egg retrieval, fertilisation and the transfer of a resultant fresh and a frozen embryo. This includes appropriate diagnostic tests, scans and pharmacological therapy.

Expectant management is a formal approach that encourages conception through unprotected vaginal intercourse or artificial insemination (AI), involving the provision of advice and information about the regularity and timing of intercourse and any lifestyle changes which might improve a couple's chances of conceiving.

NICE CG 156 advice:

People who are concerned about their fertility should be informed that over 80% of couples in the general population will conceive within 1 year if:

- The woman is aged under 40 years
- They do not use contraception and have regular sexual intercourse.

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

Inform people who are using artificial insemination to conceive and who are concerned about their fertility that:

- Over 50% of women aged under 40 years will conceive within 6 cycles of intrauterine insemination (IUI)
- Of those who do not conceive within 6 cycles of intrauterine insemination, about half will do so with a further 6 cycles (cumulative pregnancy rate over 75%).

Artificial insemination (AI) - The placement of sperm into the vagina, cervix or womb.

Intrauterine insemination IUI is a form of **AI** - Sperm are introduced into the uterine cavity around the time of ovulation in a clinical setting.

ELIGIBILITY CRITERIA

1. Residency

Patients must be registered with a General Practitioner (GP) in BSW CCG area. Where a patient moves during treatment, every effort should be made to ensure continuity of care

2. Expectant Management and Initial Investigations

Primary care management, in general, with health advice and reassurance is advised for 1 year of trying to conceive naturally. If pregnancy has not occurred, referral for specialist consultation and investigations is appropriate. However, if there is no known cause for infertility even after these initial investigations expectant management is advised for another year making it total of 2 years.

People who are concerned about delays in conception should be offered an initial assessment in primary care (GP). A specific enquiry about lifestyle and sexual history should be taken to identify people who are less likely to conceive.

A woman of reproductive age who has not conceived after 1 year of unprotected vaginal sexual intercourse, in the absence of any known cause of infertility, should be offered further specialist assessment along with her partner.

A woman of reproductive age who is using artificial insemination (AI) to conceive (with either partner or donor sperm) should be offered further specialist assessment if she has not conceived after 6 cycles of treatment (self-funded), in the absence of any known cause of infertility. Where a couple is attempting to conceive using AI with the male partner's sperm, or a single woman is using AI with a known donor's sperm, the referral for assessment should include both parties.

Where the woman is aged 36 years, she should be offered an earlier referral for specialist consultation to discuss the options for attempting conception, further assessment and appropriate treatment.

Female same sex couples are encouraged to maximise opportunities within these cycles by exploring the option of both partners undergoing artificial insemination. Where one partner is sub-fertile with fertility issues i.e., blocked fallopian tubes or anovulation, the partner who is fertile should try to conceive before proceeding to interventions involving the sub-fertile partner.

Male same sex couples and single men can be referred for infertility assessment if no pregnancy results following 6 cycles of AI (self-funded) for which the man's donated sperm has been used.

Of note, the NHS does not fund any type of surrogacy arrangement. This includes any costs associated with the use of a surrogacy arrangement and any associated fertility treatment costs.

3. Number of cycles funded: In vitro fertilisation (IVF) with or without intra-cytoplasmic sperm injection (ICSI)

Eligible patients requiring IVF, with or without ICSI, will have available a maximum of 2 embryo transfers including no more than 1 transfer from a fresh cycle.

A cycle of IVF treatment, with or without ICSI, should comprise 1 episode of ovarian stimulation and the transfer of a resultant fresh embryo and a frozen embryo, to a maximum of 2 embryo transfers. 1 fresh and 1 frozen transfer.

Rationale:

Eligible couples are funded for one full cycle of IVF with or without ICSI rather than 3 as recommended by NICE Clinical Guideline 156 – NHS BSW CCG has concluded that provision of 3 full cycles of IVF/ICSI for eligible couples is currently unaffordable in the context of local priorities. When making resource allocation decisions in this context, CCGs need to consider the needs of the population suitable for fertility treatment, as well as their wider population.

4. Treatment of Diagnosed and Unexplained Infertility

Individuals/couples with a diagnosed cause of infertility or absolute infertility which precludes any possibility of natural conception, and who meet all the other eligibility criteria, should be referred without delay for appropriate assisted conception assessment.

All other patients with unexplained fertility must have infertility of at least 2 years of ovulatory cycles, despite regular unprotected vaginal sexual intercourse with the partner seeking treatment or after 12 cycles of artificial insemination (please see also section 13. IUI).

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. Age of Woman at Time of treatment

Funding is available where the woman is aged between 25 years and 40 years of age.
Fertility treatment for a prospective mother must commence no later than 18 weeks before the patients 40th birthday. If the woman reaches the age of 40 during treatment, complete the started treatment but do not offer anything further.

Rationale:

NICE CG156 concludes that treatment with IVF is cost effective for women aged less than 39 years. There is considerable uncertainty about whether IVF is cost effective in any sub-groups of women aged between 40 and 42. The clinical and health economic evidence is overwhelming in indicating that IVF should not be offered to women aged 43 years or older.

This policy decision is based on affordability grounds and prioritising treatment for patients where the woman is over the age of 35 years when the success rate of live births begins to decline.

6. Age of Male Partner at Time of treatment

The age of the male partner must be before the 55th birthday.

Rationale:

NICE CG156 does not provide guidance on the age of the male partner.
HFEA guidance recommends that the upper age limit for sperm donors should be 45 years; by contrast the professional guidance recommends 40 years or younger. In discussion with providers BSW CCG has concluded that 55 years is a suitable age limit.

7. Previous Cycles

Patients will not be funded if either partner has already had three previous cycles of IVF, with or without ICSI, irrespective of how these were funded.

This means that eligible couples will be funded: 1 fresh cycle of IVF, with or without ICSI, if no previous cycles have been funded by the NHS, or if they have already received up to 2 non-NHS funded fresh cycles.

Rationale:

NICE CG156 states that there is an inverse relationship between IVF success and the number of prior unsuccessful attempts. A maximum of three NHS funded IVF cycles is recommended by NICE CG156.There is a reduced likelihood of a live birth for the 4th cycle for women who have had 3 previous IVF cycles.

8. Definition of Childlessness

Funding will be made available to couples who do not have a living child from their current relationship and where either partner does not have a living child from a previous relationship (i.e., one of the partners may have a child, the other must not). Single patients are also expected not to have children.

A child adopted by a patient or adopted in a previous relationship is considered to have the same status as a biological child.

9. Female and Male Body Mass Index (BMI)

Women will be required to achieve a BMI of 19-30kg/m2 documented in clinical notes for a period of 6 months or more before each period of treatment begins. They should be informed of this criterion at the earliest possible opportunity in their progress through infertility investigations in primary and secondary care.

Men who have a BMI of 30 or over should be informed that they are likely to have reduced fertility.

Rationale:

NICE CG156 states that low body weight is recognised as an important cause of hypo-oestrogenic amenorrhoea. In women, weight loss of over 15% of ideal body weight is associated with menstrual dysfunction and secondary amenorrhoea when over 30% of body fat is lost. Restoration of body weight may help to resume ovulation and restore fertility.

NICE CG also states that men who have a BMI of 30 or over are likely to have reduced fertility.

10. Smoking

Couples and single women who smoke will not be eligible for NHS funded specialist assisted reproduction assessment or treatment and should be informed of this criterion at the earliest possible opportunity in their progress through infertility investigations in primary care and secondary care. All women should be informed that passive smoking is likely to affect their chance of conceiving.

Couples and single women presenting with fertility problems in primary care should be provided with information about the impact of smoking on their ability to conceive naturally.

- The adverse health impacts of maternal and passive smoking on the foetus.
- The adverse health impacts of passive smoking on children.

Smoking cessation support should be provided as necessary.

Patients and their partner must be non-smoking and smoke free for a period of at least 6 months prior to assessment for fertility treatment and this must be maintained during treatment.

Providers should also include this undertaking on the consent form and ask patients to acknowledge that smoking will result either in cessation of treatment or treatment costs being applied.

Providers should seek evidence of smoke free status. Non-smoking status should continue throughout treatment and be confirmed by a CO reading of <6ppm.

Rationale:

NICE CG156 states that smoking is likely to reduce women's' fertility. In addition, maternal and paternal smoking can adversely affect the success rates of assisted reproduction procedures, including IVF treatment.

11. Drugs and Alcohol

Patients will be asked to give an assurance that their alcohol intake is within Department of Health guidelines and they are not using recreational drugs. Any evidence to the contrary will result in either non referral or the cessation of treatment.

12. Reversal of Sterilisation and Treatment Following Reversal

Subfertility treatment will not be provided where this is the result of a voluntary sterilisation procedure in either partner. The surgical reversal of either male or female sterilisation not normally funded.

Rationale:

Sterilisation is offered within the NHS as an irreversible method of contraception. Considerable time and expertise are expended in ensuring that individuals are made aware of this at the time of the procedure. Since most requests arise for non-medical reasons, CCGs consider that it is inappropriate that NHS funds are used in reversing these procedures.

13. Intra–Uterine Insemination (IUI)

Unstimulated intrauterine insemination is offered as a treatment option in the following groups as an alternative to vaginal sexual intercourse.

- Women in same-sex relationships and single women who have not conceived following self-funded artificial insemination (AI) of up to 10 cycles (4 of which should be IUI).

Patients who have not conceived after 6 self-funded cycles of artificial insemination, despite evidence of normal ovulation, tubal patency, and semen analysis, should consider a further 4 cycles of self-funded IUI. Therefore, a total of 10 cycles of insemination should be self-funded. Should this still not be successful a further 2 cycles of IUI will be funded by the NHS before IVF is considered.

14. Surgical Sperm Retrieval (SSI)

Surgical sperm retrieval for azoospermia (SSR) is supported and funded by NHS England as per the criteria outlined in the NHSE Clinical Commissioning Policy: 'Surgical sperm retrieval for male infertility'.

15. Sperm Washing

One sperm washing procedure will be funded within the local NHS for couples where the man is HIV positive and either he is not compliant with HAART or his plasma viral load is 50 copies/ml or greater and where the female partner is HIV negative.

Where the procedure is successful, couples may access IUI or IVF, with or without ICSI, depending on their clinical circumstances.

To access NHS funded sperm washing and subsequent assisted conception treatments, patients will be required to fulfil all relevant eligibility criteria.

Rationale:

According to **NICE CG156,** the evidence shows that sperm washing appears to be very effective in reducing viral transmission; no cases of seroconversion of the woman or the baby have been documented. In comparison with pregnancy outcomes following treatment without sperm washing, higher live full-term singleton birth rates are seen with IVF following sperm washing. This is likely to be because couples undergoing sperm washing were having ACT to avoid HIV transmission rather than for fertility problems.

A comparison of pregnancy outcomes for different ACT methods using washed sperm was also undertaken. Consistent with other studies, IUI cycles had fewer singleton live births than both IVF cycles with and without ICSI, but it also had fewer multiple births. This may reflect the transfer of more than one embryo in IVF cycles.

Sperm washing is unavailable on the NHS for couples where the male is hepatitis C positive, because NICE CG156 recommends that couples who want to conceive and where the man has hepatitis C should be advised that the risk of transmission through unprotected sexual intercourse is thought to be low.

16. Use of donor gametes

The use of donor sperm is supported when clinically indicted for:

- Heterosexual couples where the male partner has diagnosed absolute infertility.
- Single women and women in same sex partnerships in line with criteria in the policy.

The use of donor eggs is supported for women with diagnosed infertility identified in requiring donor eggs as part of the IVF/ICSI treatment.

The donation of eggs, sperm and embryos is subject to strict UK regulations. Donors may be family, friends, or strangers. In 2005, the law was changed so that donors can no longer remain anonymous.

Now children born as a result of using donor gametes or embryos can, once they reach 18, discover their donor's identity (HFEA, 2007b). The regulation of donors in other countries is different to that in the UK.

17. Surrogacy/Gestational Carriers

- BSW CCG will not commission or part fund any form of fertility treatment to those in surrogacy arrangements (i.e., the use of a third party to bear a child for another couple).

Rationale:

Surrogacy was not included within the scope of NICE CG156. There are significant medico-legal issues involved in surrogacy arrangements that would pose risks to an NHS organisation funding this intervention.

The Surrogacy Arrangements Act 1985 states that commercial surrogacy is illegal in the UK. However, the surrogate can be paid reasonable expenses such as travel expenses and loss of earnings. The HFEA states that fertility clinics cannot identify surrogates for their patients.

Surrogacy arrangements are not legally enforceable, even if a contract has been signed and the expenses of the surrogate have been paid. The surrogate will be the legal mother of the child unless or until parenthood is transferred to the intended mother through a parental order or adoption after the birth of the child. This is because, in law, the woman who gives birth is always treated as the mother.

There is an absence of evidence on the long-term psychological impact or social consequences for commissioning couples, surrogates or children born to surrogates.

ADDITIONAL INFORMATION

Figures for average success rate for IVF & ICSI

- 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+

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

IVF Definition of Abandoned Cycles

A fresh cycle of IVF/ICSI comprises; ovulation induction, egg retrieval, fertilisation, and implantation, and include appropriate diagnostic tests, scans, and pharmacological therapy. Up to one frozen cycle using frozen embryos will follow a fresh cycle if deemed clinically appropriate.

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 cycle of IVF/ICSI. Therefore, if a cycle is abandoned for clinical reasons this is still counted as a cycle.

Embryo storage

BSW CCG will fund storage of good quality embryos from NHS funded IVF for up to 2 years or 18 weeks prior to the female partners 40th birthday if it is sooner.

Patients must be counselled by the clinician and infertility counsellor to this effect. Any costs relating to the continued storage of the embryos beyond the second calendar year of the retrieval date is the responsibility of the couple**.**

Exceptional Funding

Patients who are not eligible for treatment under this policy may be considered on an individual basis where their GP or Consultant believes there are clinical circumstances in place that warrant deviation from the rule of this policy.

Individual cases will be reviewed by the BSW CCG's Exceptional funding Committee upon receipt of a completed application form from the patient s GP, Consultant, or clinician. Applications will not be considered from the patient personally.