Berkshire West Clinical Commissioning Group

Thames Valley Priorities Committee Commissioning Policy Statement

Policy No. TVPC 11g **Assisted reproduction services for infertile patients**

Recommendation made by the Priorities Committee: November 2013, updated November 2017[1] and November 2019

Date of issue: **February 2020**

The specialist assisted reproduction treatments described in Section 2 will be funded for infertile patients who meet the eligibility criteria set out in Section 1, all other assisted reproduction interventions are not normally funded.

Scope of this policy:
The following indications for assisted reproduction services are outside the scope of this policy:

- Preimplantation Genetic Diagnosis and the associated IVF/ICSI (this service is commissioned by NHS England through their Specialised Commissioning Area Teams)
- Interventions to prevent the transmission of blood borne viruses in fertile serodiscordant couples (eg, where the male partner has HIV)

This policy should be read in conjunction with:
TVPC2 2018 - Treatments for gender dysphoria and
TVPC17 2018 - Policy for the preservation of fertility

Underpinning evidence and equalities framework:
This policy was developed following a review of the NICE Clinical Guideline for Fertility, published in February 2013 (updated 2017 and 2019), and takes account of the Equality Act 2010, including age discrimination legislation.

Definition of infertility:
Infertility - clinical definition; 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).

For this policy a couple is expected to be two people in a relationship trying to conceive over 2 years of regular unprotected intercourse or 12 cycles of artificial insemination (AI). Vaginal sexual intercourse every 2 to 3 days optimises the chance of pregnancy.
People who are using AI should have their insemination timed around ovulation.
Further definitions in section 1 point 6.

Expectant management is a formal approach that encourages conception through unprotected vaginal intercourse, involving the provision of advice and information about the regularity and timing of intercourse and any lifestyle changes which might improve chances of conceiving. Expectant management does not involve any active clinical or therapeutic interventions.

Cycle of IVF/ICSI in this policy refers to a cycle of IVF treatment, with or without intracytoplasmic sperm injection (ICSI), comprising 1 episode of ovarian stimulation and
1 transfer of any resultant fresh embryo(s).

Abandoned / cancelled cycle of IVF. An "abandoned" cycle is one which does not reach the stage of embryo transfer. An embryo transfer is from egg retrieval to transfer to the uterus.

How to refer eligible patients:

Patients requesting specialist infertility treatment and meeting the eligibility criteria must be referred for specialist infertility treatment(s) by a NHS Consultant Gynaecologist using the standard referral form available from their Clinical Commissioning Group.

The tertiary provider of the patient's choice will offer an appointment to eligible patients. Patients may choose one of the designated NHS centres. Details of designated centres are listed on the standard referral form and held by the patient's Clinical Commissioning Group and by the secondary care fertility clinic.

NB It is anticipated that, rarely, patients who are not eligible for treatment because they do not fulfil these criteria may, by virtue of their individual circumstances, be considered an exceptional case for NHS funding. If this is thought to be applicable, the patient's GP or Hospital Consultant may apply to the relevant Clinical Commissioning Group's 'Individual Funding Request' panel. The location of the GP practice where the female partner is registered informs the responsible CCG.

Provider responsibilities:

The NHS-funded specialist fertility unit providing the care will be solely responsible for, initial consultation, follow up consultation, and counselling sessions, all ultrasound scans and hormone assessments during the treatment cycle, oocyte recovery, embryo, or blastocyst transfer, all embryology including sperm preparation and sperm retrieval where indicated, a pregnancy test and a maximum of two scans to establish the viability of the pregnancy. The commissioned provider of the IVF service will prescribe and supply the necessary drugs.

NB All fertility drugs, such as anti-oestrogens, (e.g. clomiphene citrate), gonadotrophins, (including gonadorelin analogues), and progestogens, should be prescribed only by the treating consultant. GPs should not prescribe any fertility drugs.

SECTION 1 - REFERRAL CRITERIA

1. Fertility investigations prior to referral
All patients must undergo the fertility investigations in primary and secondary care appropriate to them before eligibility for NHS-funded assisted reproduction services is considered**.**

2. Age of woman at time of referral to tertiary care from secondary care
Female fertility declines with age and therefore women should seek help for fertility problems as early as possible, especially given that a period of expectant management and/or treatment is required before assisted reproduction services can be commenced. Women should be referred from primary care to secondary care in sufficient time for all necessary interventions to be undertaken so that patients found to be infertile can be referred to a specialist assisted reproduction service before the woman's 35th birthday. The age at referral to a specialist assisted reproduction service must be before the woman's 35th birthday.

3. Age of woman at time of treatment
Following referral to a specialist assisted reproduction service (before the woman's 35th birthday), treatment must be completed within six months.

4. Age of male partner
There is no upper age limit for the male partner.

5. Diagnosed and unexplained infertility - access to specialist services
People with a diagnosed cause of absolute infertility which precludes any possibility of natural conception, and who meet all the other eligibility criteria, will have immediate access to NHS funded assisted reproduction services, including IVF/ICSI. All other patients, including those with unexplained infertility, must have infertility of at least two years' duration, including one year of expectant management in primary care, despite regular unprotected vaginal sexual intercourse, before referral to NHS-funded assisted reproduction services.

6. Women in same sex partnerships, single women and couples unable to undertake vaginal intercourse
When trying to conceive, all patients should have access to advice from NHS specialists in reproductive medicine on the clinical effectiveness and safety of the options available to them. The assisted reproduction services described in Section 2 below will be available to single women, women in same sex partnerships, and couples unable to have vaginal intercourse because of, for example, a clinically diagnosed disability or health problem, or a psychosexual problem, if those couples seeking NHS treatment are infertile.

Referral to specialist services can be considered after 12 cycles of artificial insemination (self-funded), 6 of which should be intrauterine insemination (IUI), to establish fertility status.

In circumstances in which women in same sex partnerships, and couples unable to have vaginal intercourse, have established their fertility status and are seeking NHS-funded assisted reproduction services, the other criteria for eligibility for NHS- funded treatment will also apply.

In the case of women in same sex partnerships in which only one partner is infertile, clinicians should discuss the possibility of the other partner becoming pregnant before proceeding to interventions involving the infertile partner.

7. Previous infertility treatment – NHS and privately funded
Any previous NHS-funded fresh cycle of IVF/ICSI treatment is an exclusion criterion. Patients who have previously self-funded treatment are eligible for one NHS-funded cycle as long as they have not already undertaken more than two self- funded fresh cycles. The outcome of previous self-funded IVF treatment will be taken into account when assessing the likely effectiveness and safety of any further IVF treatment.

8. Childlessness
Treatments for infertility will be funded if the couple/patient does not have a living child, from their relationship or from any previous relationship. This includes a child adopted by the couple/patient or adopted in a previous relationship. Patients will become ineligible if they adopt a child or achieve a pregnancy leading to a live birth after they have been accepted for NHS-funded assisted reproduction services.

9. Sterilization
Assisted reproduction services will not be available if infertility is the result of a sterilization procedure in either partner.

10. Body Mass Index
Women must have a BMI of between 19 and 29.9 inclusive at the time of referral for specialist assisted reproduction assessment and at the time of any specialist treatment. Patients presenting with fertility problems in primary care should be provided with information about the impact of BMI on their ability to conceive naturally. Where appropriate, they should be offered advice and support to achieve weight loss, and women should be informed of the weight criterion in relation to NHS-funded assisted reproduction services at the earliest appropriate opportunity in their progress through infertility investigations in primary care and secondary care.

11. Smoking status of both partners
Patients 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. Patients 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 fetus, and the adverse health impacts of passive smoking on any children and smoking cessation support should be provided as necessary.

Patients must have maintained their non-smoking status for at least **six months** at the time of referral from secondary care for specialist infertility assessment and treatment.

12. Human Fertilisation and Embryology Authority (HFEA) *Code of Practice*
To meet their duties under the HFEA *Code of Practice*, tertiary specialists will assess eligible patients to determine whether it is appropriate for NHS-funded assisted reproduction services to be provided to them. The *Code of Practice* includes a requirement for providers of specialist assisted reproduction services to consider the, "*welfare of the child which may be born as a result [of assisted reproduction treatment] (including the need of that child for supportive parenting) and of any other child who may be affected by the birth, as well as the health status of the parents".*

SECTION 2 - TREATMENTS FUNDED FOR ELIGIBLE PATIENTS

13. In vitro fertilisation (IVF) and intracytoplasmic sperm injection (ICSI)

13.1 Number of cycles
NHS funding will be available for 1 cycle of IVF/ICSI treatment per eligible patients. If this cycle has to be abandoned (for whatever reason) after the initiation of ovarian stimulation, patients will not be eligible to start another NHS-funded cycle.

Patients eligible for NHS-funded IVF/ICSI can have only embryos from their NHS- funded fresh cycle transferred with NHS funding; the transfer of frozen-thawed embryos from previous cycles of IVF will not be funded.

If patients have had frozen-thawed embryos transferred as part of earlier self-funded treatment, the number of frozen cycles will not be included when assessing eligibility for NHS-funded IVF/ICSI.

13.2 Storage (cryopreservation) of surplus embryos following a fresh cycle of NHS-funded IVF
The cryopreservation (freezing and storage) of good quality embryos following NHS-funded IVF/ICSI will be funded for up to 3 years to enable patients to have the option to use the frozen-thawed embryos in subsequent self-funded cycles.

13.3 Indications for IVF/ICSI and surgical sperm retrieval (SSR)[2]
Where it is clinically appropriate, surgical sperm retrieval is supported and is funded by NHS England as per the criteria outlined in the NHSE Clinical Commissioning Policy: Surgical sperm retrieval for male infertility. Cryopreservation facilities for the freezing of any viable sperm must be available at the time of SSR to avoid the need for repeat surgery.

13.4 Embryo transfer strategies[3]
Where top quality embryos are available, blastocyst culture and transfer can be considered for patients undergoing single embryo transfer. Double embryo transfer will only be funded if no top-quality embryos are available. Patients undergoing double embryo transfer should be advised of the risk of multiple pregnancy associated with this strategy.

13.5 In vitro maturation (IVM)
In vitro maturation will not be funded, due to limited evidence of effectiveness.

13.6 Donor eggs in IVF/ICSI
IVF/ICSI using donated eggs from UK clinics licensed by the HFEA will be commissioned for eligible patients. Women must be identified as requiring donated eggs and be on the waiting list by the age of 35. Funding approval will be retained for two years from the date of funding approval.

13.7 Donor sperm in IVF/ICSI

The use of donor sperm in IVF/ICSI will be funded for

- Single women and women in same sex partnerships where the female to be treated has diagnosed or undiagnosed infertility.
- Heterosexual couples where the male partner has diagnosed infertility or where medical, surgical, SSR or other treatments are unlikely to result in sperm of the necessary quality; or where the use of partner sperm is contraindicated; or where infertile couples are unable to undertake vaginal intercourse also require donor sperm.
- Patients with undiagnosed infertility where there is normal ovulation, tubal patency and semen analysis, who have social, cultural or religious objections to IVF, may be offered up to 6 cycles of unstimulated intrauterine insemination as an alternative to one cycle of IVF/ICSI.

14. Novel assisted reproduction technologies

The following interventions are a low priority for NHS funding as there is currently insufficient clinical evidence of their clinical and cost effectiveness:

- embryo 'glue'
- assisted hatching
- blood test for Y chromosome deletion

15. Surrogacy is not normally funded by the CCGs.

[1] Update to wording of 'definitions' and 'provider responsibilities' only, to reflect contract specification, no change to referral criteria

[2] October 2020 amendment to reflect NHS England Commissioning responsibility

[3] "A multiple birth is the single biggest risk of IVF for both mothers and babies" (HFEA, 12 January 2012 http://www.hfea.gov.uk/6876.html)

NOTES:

- Potentially exceptional circumstances may be considered by a patient's CCG where there is evidence of significant health status impairment (e.g. inability to perform activities of daily living) and there is evidence that the intervention sought would improve the individual's health status.
- This policy will be reviewed in the light of new evidence or new national guidance, e.g., from NICE.
- Thames Valley clinical policies can be viewed at http://www.fundingrequests.cscsu.nhs.uk/