South East London

Treatment Access Policy

2017

This policy has been developed by the South East London Public Health Commissioning Support Group, a collaboration of the six CCGs in south east London – Bexley, Bromley, Greenwich, Lambeth, Lewisham, and Southwark, and Public Health representatives from each borough.

Ratified by Bromley CCG Governing Body – 23 March 2017

South East London

Treatment Access Policy

This policy deals with treatments and procedures for which restricted access criteria have been agreed.

Background

The six Clinical Commissioning Groups (CCGs) in the South East London Sector have been working on developing a joint policy and process for dealing with Individual Funding Requests (IFRs). There are a number of reasons for a sector-wide process for dealing with IFRs.

Limited Resources

There will always be competing calls for limited resources and therefore a need for a clearly defined and co-ordinated approach to ensure that the resources are used in an equitable and effective way and that clear, consistent and fair procedures are in place. These are based on the principles of cost effectiveness found in the IFR policy.

Local Variations

Local variations in treatment funding decisions (postcode prescribing) are clearly undesirable, but there has been very little guidance at national level on the process of setting priorities for funding. The National Institute for Health and Care Excellence (NICE) has been established to provide guidelines on the implementation and introduction of new drugs and technologies. However, for a majority of requests for funding that are submitted to commissioners, no guidelines are available. Development of joint policies and processes across the South East will clearly be beneficial in terms of reducing the variations between the CCGs.

Efficiency

Joint working will avoid duplication of work and efforts across the area. It will also maximize the use of expertise and skills, building upon previous experience. This joint process will also enhance joint working and communication between the CCGs.

Review

This policy will be reviewed and updated annually.

Equality Statement:
"This document demonstrates the organizations' commitment to create a positive culture of respect for all individuals, including staff, patients, their families and carers as well as community partners**.** The intention is, as required by the Equality Act 2010, to identify, remove or minimize discriminatory practice in the nine named protected characteristics of age, disability, sex, gender reassignment, pregnancy and maternity, race, sexual orientation, religion or belief**,** and marriage and civil partnership. It is also intended to use the Human Rights Act 1998 and to promote positive practice and value the diversity of all individuals and communities".

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2.1 FERTILITY TREATMENTS[1]

Infertility is a condition that requires investigation, management and treatment in accordance with national guidance. As part of the provision of prevention, treatment and care Commissioners are committed to ensuring that access to NHS fertility services is provided fairly and consistently.

Initial Assessment

It will be the responsibility of the General Practitioners to initially assess that the person meets the local CCG's criteria for treatment for NHS funded cycles. Further support and advice is available from the CCG Medicines Optimisation Teams, Public Health Department and Commissioning team in implementing this guidance.

Referral to Hospital

Assisted conception services are provided by agreed providers. The units must comply with the Human Fertilisation and Embryology Authority (HFEA) regulations and follow appropriate protocols. Couples must take up the offer of Intracytoplasmic sperm injection (ICSI)/Invitro Fertilisation (IVF) within 3 months or risk being removed from the NHS waiting list.

Prescribing of medication

- The clinical prescribing of all drugs will be the responsibility of the providing Trust or the GP. (for local agreement)
- If a patient has started a privately funded cycle, the CCG will not fund the provision of prescribed drugs, which forms part of that treatment.

Timescale for treatment

Couples must be made aware at the time of being placed on the waiting list of the likely waiting time and the treatment for which the CCG will pay.

ELIGIBILITY CRITERIA

All couples must be registered with a General Practitioner within the boundaries of the CCG and be eligible for NHS treatment. Patients whose sperm or eggs have been stored prior to chemotherapy or radiotherapy will be entitled to NHS funded infertility treatment provided they meet the eligibility criteria.

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[1] National Institute for Health and Clinical Excellence. NICE Clinical Guidelines 156: Fertility: Assessment and treatment for people with fertility problems, February 2013.

Badawy SZ, Lopez A, Sarkar S, Dye T. *Cumulative Pregnancy Rates and Probability of Pregnancy in Various Indications for Intrauterine Insemination*. Arch Androl. 1996 Nov -Dec;37(3):171-7.

Cohlen BJ, Vandekerckhove P, te Velde ER, Habbema JD. *Timed intercourse versus intra-uterine insemination with or without ovarian hyperstimulation for subfertility in men.* Cochrane Database Syst Rev 2000;(2):CD000360.

Department of Health. *Regulated Fertility Services: A commissioning aid.* June 2009

Kanani N. *A Review of ICSI: Indications, Cost Effectiveness and Safety.* NHS Bromley, June 2010

van Rumste MM, Evers JL, Farquhar CM, Blake DA. *Intra-cytoplasmic sperm injection versus partial zona dissection, subzonal insemination and conventional techniques for oocyte insemination during in vitro fertilisation.* Cochrane Database Syst Rev. 2000;(2):CD001301.

The criteria for GP referrals for investigation and management of infertility should be in accordance with the following:

- Couples should be living together and in a stable relationship.

  - The partner who is to receive treatment must be aged between 23 and 39 years old (up to 39 years and 364 days) at the time of treatment.*

  - Couples who have been diagnosed as having male factor or female factor problems
    or
    have had unexplained infertility for at least 3 years, taking into consideration both age and waiting list times.

  - Persons aged under 23 years old will be considered for treatment where medical investigations have confirmed that conception is impossible without fertility treatment, e.g. following unsuccessful fallopian tube surgery.

  - The female partner should not have had any previous NHS funded attempts at IVF or ICSI and not more than three NHS funded attempts at IUI.

  - Women will be only considered for treatment if their BMI is between 19 and 30 (kg/m2). Women with the BMI>30 should be referred to the appropriate obesity management pathway.

  - Couples should be non-smoking at the time of treatment. Couples who smoke should be referred to smoking cessation.

  - IVF cannot be used as a substitute for reversal of sterilization.

  - There are no problems with signing a form concerning the welfare of the child.

  - There must be no other medical problems making the chance of success less than 20%.

  - This service will be only be available at agreed providers and will include all clinically prescribed drugs.

  - Fertility treatment will only be offered to couples where the following two criteria are met:
    a) where there are no living children in the current relationship
    b) where neither partner has children from previous relationships.

  - No individual (male or female) can access more than the number of NHS funded fertility treatments under any circumstances, even if they are in a new relationship.

  - Where the eligibility criteria are not met but clinicians feel there are exceptional reasons, a case should be referred to the Individual Funding Requests Panel for consideration.

<u>Eligible Couples will be offered:</u>

3 cycles of IUI, and / or 1 full cycle of IVF +/- ICSI

*NICE Guidance (CG 156, Feb 2013) have been noted but, due to resources prioritization, assisted conception will continue to be funded according to the current criteria.

Surrogate Pregnancy

The implications of a number of important legal points related to surrogate pregnancy mean that fertility treatment involving a surrogate mother will not be funded[2].

Same Sex Couples

As the consequence of the above legal opinion related to surrogacy, assisted conception for couples where both partners are male will not be provided by the SE London CCGs.

Where both partners are female, funding can be provided as long as the relevant criteria above are met. Infertility needs to be demonstrated in the partner who is seeking to become pregnant; that partner has to have undergone at least three attempts of IUI, but should not have had more than two previous attempts at IVF or ICSI (either NHS or privately funded).

If three cycles of privately funded IUI have been unsuccessful, the couple will be eligible for one NHS funded cycle of IVF or ICSI.

A final criterion for these couples is that they meet the HFEA requirements for parenthood and that both partners consent to be parents of the child. The HFEA guidance and a suitable statement for both partners to sign are available on request

Single Women

Funding of assisted conception for single women is not available in SE London.[3]

Definition of one full cycle (NICE, CG156, 2013):

The CCGs will fund up to 2 frozen embryos per patient for 2 years. This will include the cost of freezing and storage. For unsuccessful patients, i.e. those not resulting in a live birth, the CCG will also fund the transfer of these frozen embryos (maximum 2 frozen embryo transfers per patient). The age of mother at the time that the embryos are frozen is required to be within the age limits set out in the policy. This <u>does not</u> apply to the age at transfer.

A full cycle of IVF treatment, with or without intracytoplasmic sperm injection (ICSI), should comprise 1 episode of ovarian stimulation and the transfer of any resultant fresh and frozen embryo(s).

Egg Donation/Donor Insemination

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2 Cheshire and Merseyside Speci lalised Services Commissioning team Addendum to the Cheshire and Merseyside fertility Policy. May 07 Appendix 1 Legal Advice from Hill Dickenson

3 Surwar U. Fertility treatment for single women and same sex couples. SE London and Public Health Acute Commissioning Group. June 2011

The CCG does not routinely fund these procedures

Sperm Washing (for HIV and Other Viral Infections)

As this is not a treatment for infertility sperm washing is not covered by this policy. NICE guidelines should be followed[4].

2.4 FERTILITY PRESERVATION TECHNIQUES

The following preservation techniques: semen cryostorage, oocyte cryostorage, embryo cryostorage, will be routinely funded by South East London CCGs in the following circumstances:

- Where a man or a woman requires medical or surgical treatment that is likely to have a permanent harmful effect on subsequent sperm or egg production. Such treatment includes radiotherapy or chemotherapy for malignant disease

OR

- Where a man or a woman requires on going medical treatment that, whilst on treatment, causes harmful effects on sperm or egg production, impotence or has possible teratogenic effects, and in whom stopping treatment for a prolonged period of time to enable conception is not an option.

It is important to note that the eggs are extracted for cryostorage using drugs and procedures of egg collection normally used for assisted conception; therefore the funding includes assisted conception drugs and procedures as well as the storage costs. This will not progress to IVF/ ICSI or any other assisted conception procedures to form an embryo in these cases, unless this is sought separately later through the assisted conception pathway.

Note:

- Women should be offered oocyte or embryo cryostorage (without simultaneous assisted conception treatment) as appropriate if they are well enough to undergo ovarian stimulation and egg collection, provided this will not worsen their condition and that sufficient time is available.
- Women preparing for medical treatment that is likely to make them infertile should be informed that oocyte cryostorage has very limited success, and that cryopreservation of ovarian tissue is still in an early stage of development.

Storage

- If agreed, will be funded for five (5) years. The HFEA would grant a license to cryostore oocytes for ten years. The further extension up to ten years can still be offered to the patient but as a self-funded process.
- Will not be available where a man or woman chooses to undergo medical or surgical treatment whose primary purpose is that it will render her infertile, such as sterilisation.
- Will not be available where a man or woman requests cryostorage for personal lifestyle reasons, such as wishing to delay trying to conceive.

Post-storage Treatment

Funding of assisted conception treatments would be made available on the same basis as other patients who have not undergone such storage.

Self -funding following cessation of NHS funding

Once the period of NHS funding ceases, patients can elect to self-fund for a further period, not to exceed appropriate HFEA regulations on length of storage.

Embryo Cryostorage after NHS funded assisted conception

Suitable embryo's that are not transferred in IVF/ICSI cycle - Storage will be funded for a minimum period of one (1) year.