ENCLOSURE: J

Agenda Item: 5I/15

NHS Bexley Clinical Commissioning Group

Governing Body (public) meeting

DATE: 26 March 2015

Title	**South East London Treatment Access Policy (SEL TAP) 2015**	
Recommended action for the Governing Body	That the Governing Body: **APPROVE** the revised South East London Treatment Access Policy (SEL TAP) for 2015.	
Executive summary	**Background** The six SE London CCGs have collaborated on this policy for numerous years. The policy has been regularly reviewed and updated to reflect changes in evidence base, national guidance or to provide clarification on identified issues. This work has been led by the SEL Public Health Commissioning Support Group and SEL Directors of Commissioning and Finance Group. **Summary of changes:** New sections • Fertility preservation – adopted SWL policy • Hair removal – not funded routinely Clarifications/updates • Varicose veins – based on new NICE guidelines • Caesarean section – reference to new NICE guidelines • Sperm washing – to follow NICE guidelines • Egg donation – not funded routinely	
Which objective does this paper support?	**Patients:** Improve the health and wellbeing of people in Bexley in partnership with our key stakeholders	✓
	People: Empower our staff to make NHS Bexley CCG the most successful CCG in (south) London	✓
	Pounds: Delivering on all of our statutory duties and become an effective, efficient and economical organisation	✓
	Process: Commission safe, sustainable and equitable services in line with the operating framework and which improves outcomes and patient experience	✓

Organisational implications	Key risks (corporate and/or clinical)	The policy provides access criteria for various interventions which may be controversial. However, these criteria are based on the current agreed evidence base, best practice and national guidance. Every policy review is accompanied by a very detailed critical appraisal of the literature which ensures that access criteria for a range of procedures are based on: • evidence of effectiveness • agreed care pathways with initial conservative therapy followed by surgery if necessary • appropriate threshold for intervention • value judgements on whether the NHS should provide such care In addition, legal advice is regularly sought.
	Equality and diversity	The impact on equity is unclear. However the implementation of consistent criteria should improve equity across South East London but there is also evidence that more articulate populations may be better able to negotiate the system when there are barriers to service access. Affluent patients will also seek care privately where it is not available on the NHS. Because of the nature of the procedures included, the proposals will impact on women more than men. At this point, these proposals do not appear to have any adverse impact on race equality as they will be applied consistently to all South East London communities.
	Patient impact	As above.
	Financial	The strict implementation of the policy is expected to make significant savings to the CCGs.
	Legal issues	Legal advice is sought when there are

		changes to the policy.
	NHS constitution	The policy is in line with the NHS Constitution.
Consultation (public, member or other)	This year only minor changes and updates were made to the policy, but when new sections are added or significant changes made to existing sections, SEL Stakeholder Reference Group will be consulted.	
Audit (considered/approved by other committees/groups)	Audit process is currently being considered and will be agreed with providers.	
Communications plan	It will not be developed this year as changes to the policy are minor.	
Author	Dr Nada Lemic, Director of Public Health	
	Clinical lead	Executive sponsor
Date	12 March 2015	

South East London

Treatment Access Policy

2015

This Policy has been produced by the South East London Individual Funding Requests Strategy and Policy Group.

A collaboration of the six CCGs in south east London – Bexley, Bromley, Greenwich, Lambeth, Lewisham, and Southwark.

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 with CCGs in South West London 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 Clinical 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 SE and SW London 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.

PLEASE NOTE

The treatments and interventions listed in Section 1 of this document will not receive funding from the funding commissioner unless they have been reviewed by the relevant Individual Funding Request Panel and prior funding agreed. Those listed in Section 2 will not require prior agreement, however the commissioners will monitor this activity and audit as required.

Services Now Commissioned By NHS England

Some services previously included in the TAP from April 2013 are now commissioned by NHS England (NHSE). These are:

- Implantable cardiac defibrillators (ICDs)
- Cochlear Implants,
- Treatment of Gender dysphoria,
- Bariatric Surgery,
- Hyperbaric oxygen for decompression sickness.

Details of services commissioned by NHSE can be found on their website
http://www.england.nhs.uk/resources/spec-comm-resources/

Specific details of the 143 services can be found in The Manual
http://www.england.nhs.uk/wp-content/uploads/2012/12/pss-manual.pdf

Whilst paediatric dentistry is included in The Manual commissioning for adult Dental and Orthodontic procedures is now through the dental team of NHSE, they can be contacted on England.lon-ne-dental@nhs.net

Should you wish to submit an IFR for a service commissioned by NHSE please email them at lonhscb.ifr@nhs.net

ELIGIBILITY CRITERIA FOR SPECIFIC PROCEDURES

All patients requiring a consultant opinion for diagnostic or symptomatic advice should continue to be referred by General Practitioners e.g. skin lesions that may be malignant.

SECTION 1 – PROCEDURES REQUIRING PRIOR APPROVAL

Procedures in Section 1 will still require prior approval through the 'Individual Funding Request Process' even if the restricted access criteria outlined are met.

1.1 COSMETIC PROCEDURES

General Remarks

Cosmetic procedures are generally effective but they are considered to be of low priority by local commissioners and will only be funded in exceptional circumstances.

To qualify under the Treatment Access Policy the patient should be over the age of 21 and have a severe physical disfigurement with a long standing reactive psychiatric disorder that would be improved by the cosmetic surgery.

The psychiatric problem should clearly be caused by the relevant physical problem. A psychiatric opinion undertaken by an NHS Consultant Psychiatrist / Clinical Director of the specialty should be provided, confirming that the problem is still ongoing despite being appropriately addressed by a psychiatric or psychological intervention. The psychiatrist should also confirm that the cosmetic procedure would improve the patient's underlying psychiatric condition. NHS Mental Health Trusts will not accept referrals for assessment purely for cosmetic surgery. The referral has to be for assessment and appropriate treatment of a psychiatric condition.

Individual Procedures

Detailed exceptions to the general restriction on cosmetic surgery are listed here:

i) **Blepharoplasty (Eyelid Reduction)**

This procedure is not available on cosmetic grounds. An exception may be made if the upper eyelid skin interferes with the visual field or if there is evidence that eyelids impinge on visual fields reducing field to 120˚ laterally and 40˚ vertically.

ii) **Cosmetic Breast Surgery**

This does not refer to breast reconstruction following treatment for cancer.

iii) **Breast Augmentation**

This procedure is not available on cosmetic grounds. An exception may be made for congenital absence or gross asymmetry (difference in size minimum 2 cup sizes).

iv) **Breast Reduction**

This procedure is not available on cosmetic grounds. An exception may be made for true virginal hyperplasia when the proposed volume of reduction is greater than 500g per side, gross asymmetry or if the patient has at least one of the following:

- unresponsive to treatment for ulceration of the shoulder from the bra straps
- unresponsive to treatment for intertrigo between the breasts and the chest wall
- severe pain, unresponsive to treatment and directly related to breast size
- ulnar pain from the thoracic nerve root compression

The patient should also meet the following criteria:

- Body Mass Index (BMI) of 25 (kg/m2) or less
- bra cup size of H or more

v) **Mastopexy (relocating the nipple and improving the shape of the breast)**

This procedure is not available on cosmetic grounds. Breast ptosis is inevitable in most women due to a combination of maturity, gravity and pregnancy/lactation. An exception may be made in gross cases when a nipple areola lies below the infra-mammary fold (Grade 3 ptosis).

vi) **Revision Mammoplasty**

This procedure is not available on cosmetic grounds unless the original procedure was performed locally on the NHS because of health reasons, and the patient now has a gross deformity.

vii) **Breast Implants**

Breast implants and instant replacements are not available on the NHS. Ruptured breast implants, however, will be removed on the NHS if they are considered to be of danger to the patient. Replacement implants must not be inserted as part of the same procedure even if the patient wishes to self-fund this part of the treatment.

viii) **Gynaecomastia**

This procedure is not available on cosmetic grounds.
Exceptional cases brought to the individual funding request panel for consideration would need to meet the following criteria:

- True gynaecomastia (i.e. breast tissue is present as opposed to adipose tissue) has been diagnosed.
- Gynaecomastia is classified as Grade III (marked breast enlargement with major skin redundancy[1])
- The BMI is less than or equal to 25
- Screening for endocrinological or drug related causes has taken place
- Underlying malignancy should be excluded, clinically or otherwise.

ix) **Correction of Congenital Nipple Inversion**

This procedure is not available on cosmetic grounds. Nipple inversion is a common condition which responds well to conservative treatment, e.g. use of Niplette device.

x) **Body Contouring (Abdominoplasty or Tummy Tuck, Thigh Lift and Buttock Lift, Excision of Redundant Skin or Fat Liposuction)**

These procedures are not available on cosmetic grounds. An exception may be made for post-traumatic surgery for contouring at diabetes injection sites or for lymphoedema.

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[1] Simon BE, Hoffman S, Kahn S. Classification and surgical correction of gynecomastia. Plast Reconstr Surg. 1973 Jan; 51(1):48-52.

xi) **Dermabrasion (Chemical Peel)**

This procedure is not available for skin rejuvenation. It does have a place in the treatment of severe scarring following acne or sometimes following trauma.

xii) **Face or Brow Lift**

This procedure is not available on cosmetic grounds. An exception may be made for the treatment of facial palsy.

xiii) **Male Pattern Baldness (Hair Grafting and Flaps with or without Tissue Expansion)**

This procedure is not available on cosmetic grounds. Baldness is a natural condition.

xiv) **Female baldness and alopecia – Hair replacement**

This procedure is not available on cosmetic grounds.

xv) **Pinnaplasty (Correction of prominent or Bat Ears)**

This procedure is not available on cosmetic grounds to adults. An exception may be made for children under the age of 18 at the time of referral for significant prominent or bat ears.

xvi) **Repair of Lobe of External Ear**

This procedure is not available on cosmetic grounds.

xvii) **Septo-rhinoplasty (Reshaping of the Nose)**

This procedure is not available on cosmetic grounds. Septo-rhynoplasty will be considered in cases involving severe nasal deformity with chronic and complete obstruction of at least one nostril due to congenital or traumatic causes with a demonstrable functional limitations.

xviii) **Scar Revision**

This procedure is not available on cosmetic grounds. An exception may be made with certain scars which interfere with function (e.g. following burns) or for treatment of keloid and post-surgical scarring.

xix) **Tattoo Removal**

This procedure is not available on cosmetic grounds.

xx) **Removal of Birthmarks**
Available for children up to the age of 18 for permanent large or prominent lesions on face or neck.

xxi) **Other Benign Skin Lesions**

Other benign skin lesions eg skin tags, fibroepithelial polyps, dermatofibromata, seborrhoeic warts will not be removed on cosmetic grounds. However, if symptomatic and inflamed at the time of consultation, removal will be considered.

Epidermoid (Sebaceous) cysts are always benign and are not removed in the Dermatology Department. Some may become infected and symptomatic and referral to General Surgeons is indicated in these cases

xxii) **Viral Warts and Molluscum Contagiosum in Children under 16 Years of Age**

These are self-limiting viral infections. Warts are appropriately treated in Primary Care by topical keratolytics. Cryotherapy is too painful and no other treatment is offered in Secondary Care for either condition.

xxiii) **Viral Warts in Adults**

Properly compliant treatment with keratolytics is as effective as cryotherapy.

xxiv) **Cosmetic Genital Surgery**

This procedure is not routinely funded by the NHS.

1.2 NON-MEDICAL CIRCUMCISIONS

General Remarks
Circumcision is an effective operative procedure with a range of medical indications. Some circumcisions are also requested for social, cultural or religious reasons, these procedures will not be funded on the NHS.

Medical Indications

Circumcisions should continue to be performed for medical indications only

- phimosis seriously interfering with urine flow and/or associated with recurrent infections
- some cases of paraphimosis
- suspected cancer or balanitis xerotica obliterans
- congenital urological abnormalities when skin is required for grafting
- interference with normal sexual activity in adult males

1.3 ALTERNATIVE THERAPIES

Osteopathy
- Osteopathy remains a low priority treatment due to the limited evidence of clinical effectiveness
- Future referral for osteopathy is not available on the NHS.

Acupuncture
- Acupuncture remains a low priority treatment due to the limited evidence of clinical effectiveness
- Future referrals for acupuncture should be made in exceptional circumstances only. Funding for cases of cases of dental pain, nausea and vomiting and back pain shall be considered by the local Individual Funding Request (IFR) Panels.

Homeopathy

- Homeopathy should remain a low priority treatment due to the authoritative evidence that homeopathy has no biological effectiveness.
- South London CCGs that hold contracts with the Royal London Homeopathic Trust may wish to consider terminating these but with arrangements to honour funding for existing patients currently being treated and patients currently on the waiting list
- Future requests for homeopathy will only be agreed by the local IFR Panels in exceptional circumstances.

All Other Complementary Therapies

The CCGs will not purchase these services in the Acute Sector.

1.4 REVERSAL OF VASECTOMY OR FEMALE STERILISATION

The decision to be sterilized is taken by mature adults on the understanding that it is an irreversible contraceptive choice. Therefore, any reversal or subsequent fertility treatment should be the responsibility of the individual and will not be funded by the CCG. Any requests with possible exceptions may be referred to the IFR Panel for consideration. There should be no live children from either of the partners.

Female

- The woman should not be older than 35 years
- The procedure should be conducted in a Regional Centre by a surgeon performing sufficient procedures to report a success rate of over 50%

Male

- The reversal of vasectomy should not be performed more than 10 years after the original sterilization procedure.
- The female partner should not be more than 36 years old

1.5 FUNCTIONAL ELECTRICAL STIMULATION

There is uncertainty about clinical effectiveness of this procedure and it will not be commissioned on a routine basis.
Note – non PBR Device not procedure, therefore coding unavailable

1.6 CAESAREAN SECTION FOR NON-CLINICAL REASONS

Caesarean section is only available for clinical reasons. Elective Caesarean section for non-clinical reasons, including maternal request, will not be funded on the NHS unless prior approval has been obtained. Such approval will only be granted if such an elective section is justified using recently published NICE guidelines2. Applicants will have to document carefully how the case fulfils those guidelines.

[2] National Institute for Health and Clinical Excellence. NICE Clinical Guideline 132: Caesarean Section. NICE, Modified August 2012.

1.7 SURGERY FOR ASYMPTOMATIC GALLSTONES[3]

Approximately 10-20% of people in western countries have gallstones, and some 50-70% are asymptomatic at the time of diagnosis. Asymptomatic disease has a benign natural course and progression to symptomatic disease is relatively low, ranging from 10-25%. The majority of patients rarely develop gallstone-related complications without first having at least one episode of pain.

There is no evidence, and in particular no evidence from randomized controlled trails that surgery for asymptomatic gallstones is beneficial and it will not therefore be routinely funded.

1.8 HAIR REMOVAL

This procedure will not be funded on the NHS as there is no evidence of permanent effect with any type of hair removal treatment

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[3] Gurusamy KS, Samraj K. *Cholecystectomy for patients with silent gallstones.* Cochrane Database of Systematic Reviews 2007, Issue 1.

Gurusamy KS, Davidson BR. *Surgical treatment of gallstones (review).* Gastroenterol Clin North Am. 2010 Jun;39(2):229-44, viii.

Sakorafas GH, Milingos D, Peros G. *Asymptomatic cholelithiasis: is cholecystectomy really needed? A critical reappraisal 15 years after the introduction of laparoscopic cholecystectomy*. Dig Dis Sci. 2007 May;52(5):1313-25. Epub 2007 Mar 28.

SECTION 2 – PROCEDURES NOT REQUIRING PRIOR AGREEMENT

The following procedures do not require prior agreement providing the restricted access criteria are met. An audit of these procedures will be undertaken routinely.

If the patient does not meet the relevant access criteria, but the clinician feels he/she has exceptional clinical circumstances, the request for funding should be taken through the Individual Funding Request process (IFR).

2.1 EXCISION OF OTHER SKIN LESIONS

General Remarks

If a GP or consultant is concerned that any skin lesion may be malignant the patient should continue to be referred and treated promptly. The general remarks about other cosmetic procedures also apply to the excision of benign skin lesions. Some benign skin lesions will continue to be excised in the acute sector for differential diagnosis. Some GPs also offer these procedures as part of their general practice, although not all patients currently have access to these services.

i) Pigmented Lesions

Removal of obviously clinically benign moles is not available on cosmetic grounds. In most cases the distinction between suspicious and purely benign moles is clear cut but suspicious pigmented lesions should always be subjected to excision biopsy.

ii) Tunable Dye Laser

This treatment is offered for the removal of vascular birthmarks (port wine stains) often present on the neck and face and is the only successful treatment for this type of birthmark. The criteria for patients requiring this type of treatment will be:

- On the face or neck above the collar line in children up to the age of 18 years
- Chest area on women

Patients above the age of 18 years will be considered on an individual basis taking into account psychological and psychiatric effects of the birthmarks on the patient.

Referrals should be made on a tertiary basis usually by a Consultant Dermatologist.

2.2 VARICOSE VEINS

Varicose veins are swollen and enlarged veins, usually blue or dark purple in colour. They may also be lumpy, bulging or twisted in appearance. They mostly occur in the legs. They are usually asymptomatic, but can be complicated by inflammation, skin changes including ulceration, rupture and bleeding as well as pain and discomfort.

Asymptomatic and Mild Varicose Veins
Asymptomatic and mild varicose veins present as a few isolated, raised palpable veins with little or no associated pain, discomfort or skin changes. They should be managed in primary care and patients offered advice and information. This will include:

- An explanation of varicose veins, possible causes, and the likelihood of progression.
- Treatment options aimed at symptom relief and an explanation of the limited role of compression therapy. Compression hosiery for symptomatic varicose veins should not be offered unless interventional treatment is unsuitable.
- The likelihood of progression and possible complications, including deep vein thrombosis, skin changes, leg ulcers, bleeding and thrombophlebitis. Address any misconceptions the person may have about the risks of developing complications.
- Advice on symptom relief, which should include advice on weight loss, the benefit of light to moderate physical activity, avoiding activities that make symptoms worse (standing for long periods) and when and where to seek further help.

SEL CCGs do not routinely commission surgery for asymptomatic and mild varicose veins. Therefore surgical treatment for patients presenting to primary care with mild or asymptomatic varicose veins will only be funded under exceptional clinical circumstances.

Moderate to Severe Varicose Veins
Moderate varicose veins present as local or generalised dilatation of subcutaneous veins with associated pain or discomfort and slight ankle swelling. Severe varicose veins may present with phlebitis, ulceration and haemorrhage.

People should be referred to a vascular service if they have any of the following:

- Bleeding varicose veins (immediate referral)
- Symptomatic (veins found in association with troublesome lower limb symptoms - typically pain, aching, discomfort, swelling, heaviness and itching) primary or symptomatic recurrent varicose veins where other causes of these symptoms can be ruled out.
- Lower-limb skin changes, such as pigmentation or eczema, thought to be caused by chronic venous insufficiency
- Superficial vein thrombosis (characterised by the appearance of hard, painful veins) and suspected venous incompetence
- A venous leg ulcer (a break in the skin below the knee that has not healed within 2 weeks)
- A healed venous leg ulcer

There is some evidence that the clinical severity of venous disease is worse in obese persons, so advice on weight loss may help reduce symptoms and would make any intervention safer.

Assessment of Individuals with Moderate to Severe Varicose Veins
Duplex ultrasound should be used to confirm the diagnosis of varicose veins and the extent of truncal reflux, and to plan treatment for people with suspected primary of recurrent varicose veins.

Following assessment, patients with confirmed varicose veins and truncal reflux should be referred on for appropriate interventional treatment.

Interventional Treatment

The main options include:

- Endothermal ablation, usually via radiofrequency or laser ablation (these methods heat the vein from inside causing irreversibly damage to the vein and its lining and closes it off).
- If endothermal ablation is unsuitable, offer ultrasound guided foam sclerotherapy (sclerosant foam (irritating agent) is injected into the vein to cause an inflammatory response which consequently closes it)
- If foam sclerotherapy is unsuitable, offer truncal vein stripping surgery (a traditional treatment that involves surgical removal by 'stripping' out the vein or ligation (tying off the vein))
- If incompetent varicose tributaries are to be treated, consider treating them at the same time.

Funding of Interventional Treatment

The Clinician proposing any of these interventions is required to secure Prior Approval from the SEL Individual Funding Request Team

Requests for Prior Approval for interventional treatment can only be obtained if the following criteria are fulfilled:

1. There is documented evidence of at least one of the following:

a. Varicose eczema
b. Lipodermatosclerosis or a venous ulcer
c. A venous ulcer that has taken over two weeks to heal
d. At least two episodes of documented superficial thrombophlebitis
e. A major episode of bleeding from a varicosity.

2. The patient has followed the above pathway

3. The diagnosis of varicose veins has been confirmed and there is evidence of truncal reflux

4. The patient has a normal BMI, or there is evidence that NICE guidance on measures to lose weight have been followed over a period of at least one year.

5. There is documented evidence that the patient is aware of the complications and limitations of the treatment

Treatment outside the criteria outlined will not be funded unless there are exceptional circumstances and approval has been gained via the Individual Funding Request (IFR) process.

Interventional treatment for varicose veins in pregnancy will not be funded unless exceptional circumstances apply and agreement is sought via the IFR process.

2.3 FERTILITY TREATMENTS[4]

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 Pharmaceutical advisor, 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 or Care Trust 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.

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

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[4] 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.

- 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 partners must not have had more than 2 previous Interuterine insemination (IUI)/IVF/ICSI attempts (either NHS or privately funded).

  - 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 sterilisation.

  - 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.

    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, if clinically appropriate. Criteria for IUI include: mild male factor infertility, unexplained infertility and minimal to mild endometriosis.

  or

  1 full cycle of IVF +/- ICSI**.** Indications for ISCI include severe deficits in semen quality, obstructive azoospermia and non-obstructive azoospermia. The proportion of couples undergoing IVF who require ICSI would not be expected to exceed 40%.

*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[5].

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). 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

Because of the known disadvantage that providing assisted conception to a single woman would cause both the child and the mother, funding of assisted conception for single women is not available in SE London. [6]

Definition of one full cycle (NICE 2004):

'Embryos not transferred during a stimulated in vitro fertilisation treatment cycle may be suitable for freezing. If two or more embryos are frozen then they should be transferred before the next stimulated treatment cycle because this will minimise ovulation induction and egg collection, both of which carry risks for the woman and use more resources'. The 'full cycle' of IVF is therefore regarded as the fresh cycle plus the transfer of frozen embryos where this is possible.

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.

Egg Donation/Donor Insemination

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].

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5 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

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

2.4 FERTILITY PRESERVATION TECHNIQUES

The following preservation techniques: semen cryostorage, oocyte cryostorage, embryo cryostorage, will be routinely funded by SWL 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.

2.5 HYSTERECTOMY FOR HEAVY MENSTRUAL-BLEEDING

Hysterectomy is an appropriate treatment for certain conditions such as malignancy. Its effectiveness in conditions such as heavy menstrual bleeding and fibroids where there are a number of treatment options is less clear cut. Funding for hysterectomy for heavy menstrual-bleeding and fibroids will be approved only when:
There has been a prior trial with a LNG-IUS (levonorgestrel intra-uterine system) intra-uterine device (unless contraindicated) or other hormonal treatments in line with NICE guidance, which has not successfully relieved symptoms

AND
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Other treatments (such as NSAIDs, Tranexamic Acid, Endometrial ablation and uterine-artery embolisation) have failed, are not appropriate or are contra-indicated in line with NICE guidelines.

Contraindications to LNG-IUS are:

- Severe anaemia, unresponsive to transfusion or other treatment whilst a LNG-IUS trial is in progress
- Distorted or small uterine cavity (with proven ultrasound measurements)
- Genital malignancy
- Active trophoblastic disease
- Pelvic inflammatory disease
- Established or marked immunosuppression
- In relation to a fibroid uterus above 12 weeks size, the LNG IUS or ablation techniques are unlikely to work.
- For those who for ethical reasons cannot accept the use of Mirena®, they should have tried at least two of the alternative treatments (NSAIDs, Tranexamic Acid, Endometrial ablation, uterine-artery embolisation).

Rationale
- The Mirena® device has been shown to be effective in the treatment of heavy menstrual-bleeding.
- It is considerably cheaper than performing a hysterectomy, even if required for many years.

  A number of effective conservative treatments are available as second line treatment after failure of Mirena or where Mirena is contra-indicated.

2.6 FILTERED / COLOURED LENSES

These are not offered for specific reading difficulties.

2.7 COMMON HAND CONDITIONS

♦ Ganglion

Cystic degeneration from joint capsule or tendon sheath. Lesions at the base of the digits are often small but very tender (Seed Ganglion). Mucoid cysts arise at the distal interphalangeal joint and may disturb nail growth. Ganglions arising at the level of the wrist are rarely painful and most will resolve spontaneously within 5 years. The recurrence rate after excision of wrist ganglia is between 10-45%.

Refer:

- Painful seed ganglia
- Mucoid cysts that are disturbing nail growth or have a tendency to discharge (risk of septic arthritis in distal interphalangeal joint)

There is no indication for the routine excision of simple wrist ganglia. These should not generally be referred.

♦ Carpal Tunnel Syndrome

Patients typically present with nocturnal dysaesthesia in the hands which wears off with activity. The presence of a positive Phalen's (wrist flexion test) or Tinel's sign confirms the diagnosis. Nerve conduction studies are NOT generally needed to confirm the diagnosis. In elderly patients the condition may develop insidiously. Conservative treatment may include adjustment of activities or posture with night splintage in neutral wrist position. Non-steroidal anti-inflammatory drugs and diuretics are occasionally of benefit. Steroid injections may be of value in uncomplicated cases (requires clinical experience). Refer:

- Acute severe symptoms (fewer than 5% of patients) uncontrolled by conservative measures, particularly pregnancy
- Mild to moderate symptoms with failure of conservative management (4 months)
- Neurological deficit ie sensory blunting or weakness of thenar abduction (APB)

♦ Dupuytren's Disease

Nodular or cord-like thickening of the palmar skin. May tend to cause tethering of the digits with loss of extension range. Refer:

- Loss of extension in one or more joints exceeding 25 degrees
- Young patients (under 45 years) with disease affecting 2 or more digits and loss of extension exceeding 10 degrees.

♦ Trigger Finger

Snapping of the fingers as they are extended from a fully flexed posture, associated with a tender nodule in flexor tendon at base of finger or thumb. Conservative treatment may include rest from precipitating activities or NSAIDs. Injection of hydrocortisone into the tissue in front of the tendon at the level of the distal palmar crease (MCPJ) will often settle early cases (requires clinical experience). Refer:

- Failure to respond to conservative treatment (maximum 2 injections)
- Fixed flexion deformity that cannot be corrected

2.8 TONSILLECTOMY

Tonsillectomy will not be funded except in cases of suspected malignancy or significant severe impact on quality of life indicated by:

- 5 or more episodes of sore throat per year
- symptoms for at least a year
- the episodes of sore throat are disabling and prevent normal functioning
- documented evidence of absence from school or attendance at GP or other health care setting.

Rationale:
Tonsillectomy offers relatively small clinical-benefit, measured best in terms of time taken away from school. The benefit in the year after the operation is roughly 2.8 days less taken away from school. Tonsillectomy carries a risk of mortality estimated to lie between 1 in 8,000 and 1 in 35,000 cases

2.9 GROMMETS[7]

CCGs will fund insertion of grommets (ventilation tubes) in

- Children with persistent bilateral Otitis media with effusion (OME) documented over a period of 3 months with a hearing level in the better ear of 25-30 dBHL or worse, averaged at 0.5, 1, 2 and 4 kHz (or equivalent dBA where dBHL not available)

- Children with persistent bilateral OME with a hearing loss less than of 25-30 d BHL where the impact of the hearing loss on the child's developmental, social or educational status is judged to be significant (e.g. documented absence from school)

- Children with Down's syndrome or cleft palate if this is considered clinically appropriate by a multidisciplinary team of professionals with expertise in assessing and treating such children

2.10 ADENOIDECTOMY FOR OTITIS MEDIA IN CHILDREN

Adenoidectomy combined with grommets may be considered in children who fulfil the criteria for grommets (see 2.8).

[7] National Institute for Health and Clinical Excellence. *NICE clinical guideline 60: Surgical management of otitis media with effusion in children*. NICE. February 2008. Available at: http://www.nice.org.uk/nicemedia/pdf/CG60NICEguideline.pdf

2.11 KNEE WASHOUT AND DEBRIDEMENT FOR OSTEOARTHRITIS[8]

NICE Guidance (2008) states that "exercise should be a core treatment for people with osteoarthritis, irrespective of age, comorbidity, pain severity or disability". Analgesia for pain relief is also important and is detailed in the NICE document. Neither Cochrane reviews nor NICE found benefits from knee washout or debridement for the treatment of osteoarthritis. Therefore, as recommended by NICE 2008:

Referral for arthroscopic lavage and debridement should not be offered as part of treatment for knee osteoarthritis, *unless* the person has a clear history of mechanical locking (not gelling, 'giving way' or X-ray evidence of loose bodies).

2.12 HAEMORRHOIDS[9]

First or second-degree internal haemorrhoids (or third-degree haemorrhoids that are quite small) usually respond to conservative treatments such as changing bowel habit, diet and lifestyle, and by using stool softeners or laxatives. Only abut 10% of people eventually require surgery to alleviate their symptoms.

Non-conservative treatments include rubber band ligation, sclerotherapy, infra-red photocoagulation and surgery (e.g. haemorrhoidectomy, stapled haemorrhoidectomy, haemorrhoidal artery ligation). These are indicated for:

- Failure to respond to conservative treatment.
- Fourth-degree haemorrhoids, or third-degree haemorrhoids that are either too large for non-operative measures or have not responded to them.
- Thrombosed haemorrhoids when bleeding is problematic, or there is chronic irritation or leakage.
- People with large skin tags that need removing.

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8 National Institute for Health and Clinical Excellence. *NICE Clinical guideline 59: The care and management of osteoarthritis in adults.* NICE, February 2008. Available at: http://www.nice.org.uk/nicemedia/live/11926/39557/39557.pdf. (Accessed 1.12.2010).

National Institute for Health and Clinical Excellence. *Interventional procedures guidance: Arthroscopic knee washout, with or without debridement, for the treatment of osteoarthritis.* NICE, August 2007. http://www.nice.org.uk/nicemedia/live/11326/35856/35856.pdf. (Accessed 1.12.2010).

Reichenbach S, Rutjes AWS, Nüesch E, Trelle S, Jüni P. Joint lavage for osteoarthritis of the knee. Cochrane Database of Systematic Reviews 2010, Issue 5.

Laupattarakasem W, Laopaiboon M, Laupattarakasem P, Sumananont C. Arthroscopic debridement for knee osteoarthritis. *Cochrane Database of Systematic Reviews* 2008, Issue 1.

9 NHS evidence. Clinical Topics: Haemmorrhoids. Available at: http://www.cks.nhs.uk/haemorrhoids/view_whole_topic. (Accessed 2.12.2010)

National Institute for Health and Clinical Excellence. NICE technology appraisal 128. Stapled heamorroidopexy for the treatment of haemorrhoids. NICE, September 2007. http://www.nice.org.uk/nicemedia/live/11835/36250/36250.pdf. (Accessed 2.12.2010)

National Institute for Health and Clinical Excellence. *Interventional procedures guidance:* Haemorrhoidal artery ligation. NICE, May 2010. http://www.nice.org.uk/nicemedia/live/12236/48673/48673.pdf. (Accessed 2.12.2010)

2.13 BOTULINUM TOXIN TYPE A FOR HYPERHIDROSIS

Botulinum toxin therapy for the treatment of Hyperhidrosis is considered a low priority treatment and funding will only be considered for **severe** (defined as HDSS score 3 or 4) **focal primary hyperhidrosis** of the **axillae,** when the patient has had a documented, 6 month trial of conservative management, including all the following:

- The use of topical aluminium chloride or extra-strength antiperspirants, which has been ineffective **or** resulted in a severe rash which does not resolve with topical steroids/recommended treatment;
- General measures have been addressed, including wearing light coloured, non tight fitting clothing, identifying and avoiding triggers e.g. spicy food, consider treating any underlying anxiety.

Funding for further treatments, at intervals of no less than 16 weeks, will only be approved provided at least a 2 point reduction on HDSS score can be shown during the 4 months following initial treatment.

The Hyperhidrosis Disease Severity Scale (HDSS) is a validated 4-point scale in which the patient rates the tolerability of their underarm sweating and the resulting interference with daily activities, as follows:
Score 1: My underarm sweating is never noticeable and never interferes with my daily activities
Score 2: My underarm sweating is tolerable but sometimes interferes with my daily activities
Score 3: My underarm sweating is barely tolerable and frequently interferes with my daily activities
Score 4: My underarm sweating is intolerable and always interferes with my daily activities

Please note: Botulinium toxin preparations are not interchangeable. Botox ® is the only preparation licensed for severe, axillary hyperhidrosis

Pregnant women and nursing mothers should avoid treatment.

APPENDIX: Codes

Blepharoplasty (Eyelid Reduction)
OPCS 4 Procedure codes C131 C132 C133 C134 C138 C139

Cosmetic Breast Surgery
OPCS 4 Procedure codes B301 B302 B303 B308 B309 B311 B312 B313 B314 B318 B319

Breast Augmentation
OPCS 4 Procedure codes B312 B301 B303 B308 B309

Breast Reduction
OPCS 4 Procedure code B311

Breast Reduction
OPCS 4 Procedure code B311

Mastopexy (relocating the nipple and improving the shape of the breast)
OPCS 4 Procedure code B313

Revision Mammoplasty
OPCS 4 Procedure codes B314 B302

Breast Implants
OPCS 4 Procedure codes B312 B301 B303 B308 B309

Gynaecomastia
OPCS 4 Procedure code B311

Correction of Congenital Nipple Inversion
OPCS 4 Procedure codes B351 B353 B354 B356 B358 B359

Body Contouring (Abdominoplasty or Tummy Tuck, Thigh Lift and Buttock Lift, Excision of Redundant Skin or Fat Liposuction)
OPCS 4 Procedure codes S021 S022 S028 S029 S031 S032 S033 S038 S039

Dermabrasion (Chemical Peel)
OPCS 4 Procedure codes S601 S602

Face or Brow Lift
OPCS 4 Procedure codes S011 S012 S013 S014 S015 S016

Male Pattern Baldness (Hair Grafting and Flaps with or without Tissue Expansion)
OPCS 4 Procedure codes S331 S332 S333 S338 S339

Pinnaplasty (Correction of prominent or Bat Ears)
OPCS 4 Procedure code D033

Repair of Lobe of External Ear
OPCS 4 Procedure codes D031 D032 D034 D038 D039

Rhinoplasty (Reshaping of the Nose)
OPCS 4 Procedure codes E021 E022 E023 E024 E025 E026 E028 E029 E027

Scar Revision
OPCS 4 Procedure codes S604

Tattoo Removal
OPCS 4 Procedure codes S091 S092 S065 S068 S069
ICD10 Z411 L818

Removal of Birthmarks
OPCS 4 Procedure codes S038 S039 S041 S042 S043 S048 S049 S051 S052 S053 S054 S055 S058 S059 S061 S062 S063 S064 S065 S068 S069 S081 S082 S083 S088 S089 S091 S092 S093 S098 S099 S101 S102 S103 S104 S108 S109 S111 S112 S113 S114 S118 S119
ICD 10 diagnostic code Q825

Other Benign Skin Lesions
OPCS 4 Procedure codes S038 S039 S041 S042 S043 S048 S049 S051 S052 S053 S054 S055 S058 S059 S061 S062 S063 S064 S065 S068 S069 S081 S082 S083 S088 S089 S091 S092 S093 S098 S099 S101 S102 S103 S104 S108 S109 S111 S112 S113 S114 S118 S119
ICD 10 diagnostic codes D170 D171 D172 D173
ICD 10 diagnostic codes D23 D230 D231 D232 D233 D234 D235 D236 D237 D239 L720 L721 L722 L728 L729

Viral Warts and Molluscum Contagiosum in Children under 16 Years of Age
ICD 10 diagnostic codes B07X

Viral Warts in Adults
ICD 10 diagnostic codes B081

Non-Medical Circumcisions
OPCS 4 Procedure codes N303
ICD10 Z412

Reversal of Vasectomy or Female Sterilisation
OPCS 4 Procedure codes Q291 Q292 Q298 Q299 Q371 Q378 Q379 N181

EXCISION OF OTHER SKIN LESIONS

Pigmented Lesions
ICD 10 diagnostic codes L810 L811 L812 L813 L814 L815 L816 L817 L818 L819
ICD10 diagnostic codes (moles) Q825 D220 D221 D222 D223 D224 D225 D226 D227 D228 D229 I781

Tunable Dye Laser
ICD 10 diagnostic codes Q825

Varicose Veins
OPCS 4 Procedure codes L841 L842 L843 L844 L845 L846 L848 L849 L851 L852 L853 L858 L859 L861 L868 L869 L871 L872 L873 L874 L875 L876 L878 L879
ICD 10 diagnostic codes I831 I839

Dilatation and Curettage
OPCS 4 Procedure codes Q103

Hysterectomy for Heavy Menstrual-Bleeding
OPCS 4 Q071 Q072 Q073 Q074 Q075 Q078 Q079 Q081 Q082 Q083 Q088 Q089
ICD10 N920 N921 N924

Ganglion
OPCS 4 Procedure codes T591 T592 T593 T594 T598 T599 T601 T602 T603 T604 T608 T609
ICD 10 diagnostic code M674

Codes Appendix

Carpal Tunnel Syndrome
ICD 10 diagnostic code G560

Dupuytren's Disease
ICD 10 diagnostic code M720

Trigger Finger
ICD 10 diagnostic code M653

Tonsillectomy
OPCS4 F341 F342 F344 F345 F346 F347 F348 F349

Grommets
OPCS 4 Procedure code D151
ICD 10 diagnostic code H650 H651 H652 H653 H654 H659

Adenoidectomy for Otitis Media in Children
OPCS 4 Procedure code E201 E208 E209
ICD 10 diagnostic code H650 H651 H652 H653 H654 H659

Knee Washout And Debridement For Osteoarthritis
OPCS 4 Procedure code W852;
In addition, an ICD-10 code from category M17-(arthrosis of the knee) would be recorded

Haemorrhoids
OPCS 4 Procedure codes H511 H512 H513 H518 H519 H521 H522 H523 H524 H528 H529 H531 H532 H533 H538 H539 H558 H559 H568 H569 H482

Surgery for Asymptomatic Gallstones
OPCS 4 Procedure codes J181 J182 J183 J184 J185 J188 J189 J211
ICD10 code K802