ENCLOSURE: H

Agenda Item: 53/13

NHS Bexley Clinical Commissioning Group

Governing Body (Public) Meeting

DATE: 30th May 2013

Title	**Procedures of Limited Clinical Effectiveness**
Recommended action for the Governing Body	That the Governing Body: **Approve** the 2013 iteration of the South East London Treatment Access Policy (TAP) in relation to Procedures of Limited Clinical Effectiveness **Note** on-going work with the Commissioning Support Unit (CSU) to understand poor levels of compliance in respect of Prior Approvals activity in 2012/13 where such approval was not sought. **Note** comparative analysis with Treatment Access Policies adopted in other health economies and potential impact if a similar policy were applied within Bexley.
Executive Summary	**2013 South East London Treatment Access Policy** The 2013 TAP has been developed by clinicians across Bexley, Bromley, Greenwich, Lambeth, Lewisham and Southwark CCGs. The 2013 TAP replaces the previous policy published in April 2012 as developed by then SE London Primary Care Trusts/Care Trusts. Amendments made in the 2013 policy are summarised as below: **1. Cosmetic procedures** Breast reduction – addition of pain criterion Septorhynoplasty - clarification of criteria Cosmetic genital surgery – not funded on the NHS **2. Fertility treatment** Same sex couple – clarification of how infertility needs to be demonstrated **3. Dilatation and curettage** – removed as duplication with section on heavy menstrual bleeding **4. Bariatric surgery** – addition regarding revision for weight re-gain **5. Botulinum for hyperhidrosis** – new section **Compliance during 2012/13 with Prior Approvals process outlined in TAP** The 2012 Treatment Access Policy noted the following procedures were subject to Prior Approval: • Cosmetic procedures • Non-medical circumcisions

- Alternative therapies
- Reversal of vasectomy or female sterilisation
- Functional electrical stimulation
- Caesarean section for non-clinical reasons

Current compliance with Treatment Access Policy – Prior Approvals

Analysis of activity (April12 to January13) showed 1,177 activity spells had taken place in the above areas where Prior Approval should have been sought compared to only 347 Individual Funding Requests (IFRs), i.e. the process via which Prior Approval is granted. Of the IFRs reviewed only 182 cases were authorised meaning an even more marked disparity between the existing Prior Approval process and actual activity being undertaken.

The CCG are to review with CSU how the SE London Treatment Access Policy may be better enforced to ensure that activity undertaken by Bexley's acute providers is in strict accordance with the established policy.

Benchmarking SE London to other health economy Treatment Access Policies

A high-level comparison between operation of the SEL TAP and similar policy adopted in Staffordshire has been undertaken. Further reviews will assess differences between SE London and other economies such as NW London and Surrey & Sussex.

The Staffordshire Excluded and Restricted Procedures policy highlights some areas not currently assessed as either a restrictive of excluded treatment under current CCG arrangements.

Initial benchmark analysis suggests a slightly more comprehensive Treatment Access Policy such as operated in Staffordshire could yield between £450k and £850k via reductions in appropriate activity.

The above figures are for illustrative purposes only but look to suggest more restrictive processes are in operation in other health economies.

Governing Body are asked to:

Approve – the 2013 SE London Treatment Access Policy (SEL TAP) noting amendments from the existing 2012 policy.

Note – poor compliance with existing Prior Approval mechanism within the SEL TAP.

Note – comparison between Staffordshire Excluded and Restricted Procedures policy and SEL TAP and potential cost saving if adopting a more restrictive access policy.

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 BCCG 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)	
	Equality and Diversity	
	Patient impact	Treatment Access Policy is designed to reduce inappropriate activity but may be deemed as a restrictive process
	Financial	Commissioning of healthcare within allocated resources.
	Legal Issues	
	NHS constitution	
Consultation (Public, member or other)		
Audit (Considered / Approved by Other Committees / Groups)		
Communications Plan		
Author	Neil Hales Interim Head of Acute Commissioning	
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Date	16May2013	

Procedures of Limited Clinical Effectiveness

Why is a Treatment Access Policy needed ?

Bexley Clinical Commissioning Group (CCG) is responsible for planning and paying for health services for the people of Bexley. We have a duty to spend public money on services and treatment that benefit as many people as possible. This therefore also means agreeing on treatments which are not funded. This may be because there is limited clinical evidence that they are effective, or that the small amount of health improvement the patient may see could be outweighed by a particular risk posed to their health.

It is vital that CCGs ensure that public money is being spent as wisely as possible. A policy for 'procedures of limited clinical effectiveness', has therefore been agreed by Bexley CCG working with our fellow neighbouring CCGs in Bromley, Greenwich, Lambeth, Lewisham and Southwark to form one policy covering all of South East London.

The policy, the South East London Treatment Access Policy (SEL TAP), is based on international evidence and the opinions of clinicians and medical bodies in the UK. This means certain operations and treatments will no longer be funded on the NHS, including some cosmetic procedures and others which may pose more risk than benefit to a particular patient's health. Other procedures will be offered to patients at a later stage, or only when other courses of treatment have been followed.

We are keen to reassure patients that this is about making sure that treatments are effective, not about stopping treatments that are beneficial.

A South East London Treatment Access Policy has operated for several years. The policy enclosed represents the 2013 version of which there have been some minor changes to the previous year's policy.

While some doctors are already following some of the guidance, the policy is designed to ensure that doctors are clear exactly what treatment they should be referring patients for. This will reduce variations between doctors, improve quality, and mean a more equitable, fairer system for patients.

2013 South East London Treatment Access Policy

The 2013 iteration of the South East London Treatment Access Policy (SEL TAP) is detailed at Appendix 1.

The policy details procedures where Restricted Access criteria must be met. This is split into 2 groups: procedures requiring Prior Approval and procedures subject to audit by the CCG.

Providers are contractually required to seek Prior Approval authorisation for all procedures undertaken in Section 1 (Prior Approvals) of the Treatment Access Policy. The CCG is not liable for payment for treatments where Prior Approval is required but has not been sought.

Should referring clinicians believe a patient should be referred for a procedure on the Restricted Access list but they do not meet the specified criteria a request for funding may be made to the Individual Funding Requests (IFR) panel. The IFR panel will determine on a case by case basis whether funding for such treatments will be approved.

Changes to the SEL TAP in 2013 version

Key changes between the 2012 and 2013 iterations of the policy are summarised below.

1. Cosmetic procedures
Breast reduction – addition of pain criterion
Septorhynoplasty - clarification of criteria
Cosmetic genital surgery – not funded on the NHS

2. Fertility treatment
Same sex couple – clarification of how infertility needs to be demonstrated

3. Dilatation and curettage – removed as duplication with section on heavy menstrual bleeding

4. Bariatric surgery – addition regarding revision for weight re-gain

5. Botulinum for hyperhidrosis – new section

Botulinum Toxin treatment for Hyperhidrosis is a new restricted procedure hence significant change from the 2012 policy. This has been selected to restrict treatment to severe cases only as defined by the Hyperhidrosis Disease Severity Scale (HDSS).

Compliance during 2012/13 with Prior Approvals process outlined in SEL TAP

The 2012 Treatment Access Policy noted the following procedures were subject to Prior Approval:

- Cosmetic procedures
- Non-medical circumcisions
- Alternative therapies
- Reversal of vasectomy or female sterilisation
- Functional electrical stimulation
- Caesarean section for non-clinical reasons

Analysis of activity during April12 to January13 (Page 8) showed 1,177 spells had taken place in the above areas where Prior Approval should have been sought.

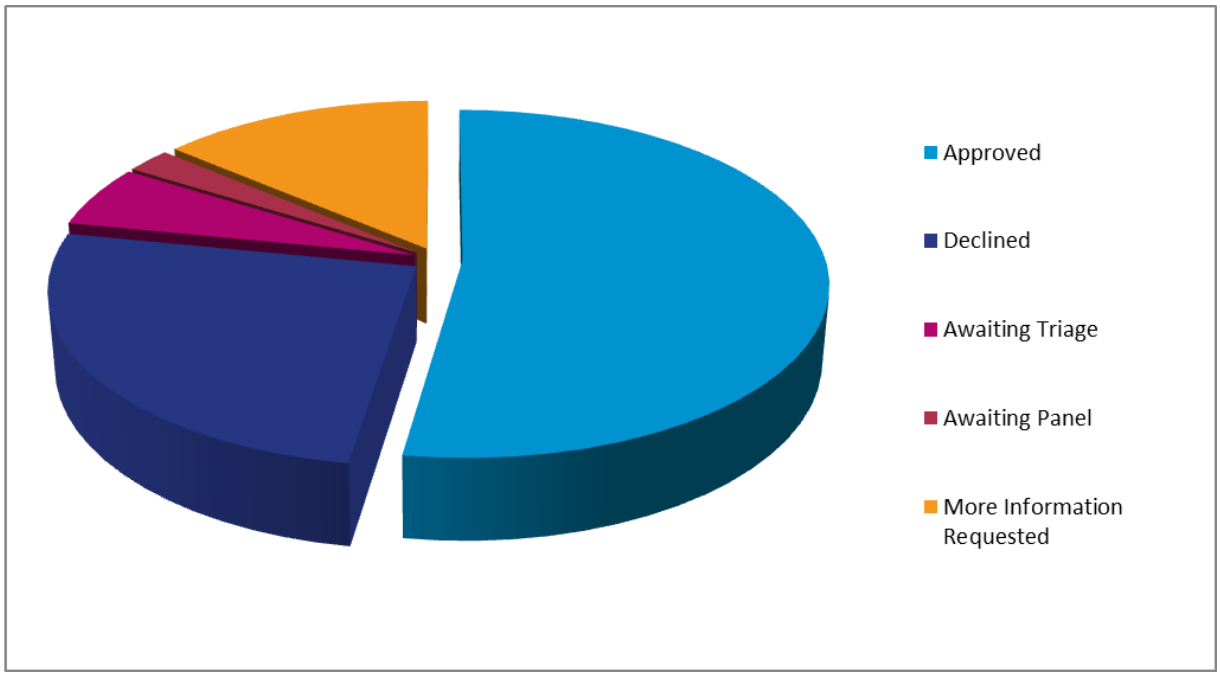
Assessment of Bexley 1213 activity (all providers) against SE London Treatment Access Policy and existing IFR process					
Scheme	Month 1-10 Data Activity	Month 1-10 Data Cost	FOT Activity	FOT Cost	Status in SE London TAP (2012)
Dermatology and Plastic Surgery	751	£513,399	901	£616,079	Prior Approval Required - 1.1 Cosmetic procedures / Restricted Access 2.1 Excision of Other Skin Lesions
Circumcision	148	£137,777	178	£165,332	Prior Approval Required - 1.2 Non Medical Circumcisions
Elective Caesarean Section	278	£826,440	334	£991,728	Prior Approval Required - 1.6 Caesarean Section For Non Clinical Reasons
Prior Approval Required - Sub-total	**1,177**	**£1,477,616**	**1,412**	**£1,773,139**	
Carpal Tunnel Syndrome	162	£182,513	194	£219,016	Restricted Access - 2.10 Common Hand Procedures
Extraction of wisdom teeth	214	£172,080	257	£206,496	Restricted Access - 2.10 Dental and Orthodontic procedures
Tonsillectomy	208	£264,458	250	£317,350	Restricted Access - 2.11 Tonsillectomy
Grommets	125	£112,281	150	£134,737	Restricted Access - 2.12 Grommets
Surgery for asymptomatic gallstones	214	£520,673	257	£624,808	Restricted Access - 2.17 Surgery for Asymptomatic Gallstones is not routinely funded
Hysterectomy for menorrhagia	170	£571,331	204	£685,597	Restricted Access - 2.5 Hysterectomy For Heavy Mentrual Bleeding
Restricted Access - Sub-total	**1,093**	**£1,823,336**	**1,312**	**£2,188,003**	

The Commissioning Support Unit (CSU) notes that Prior Approval was only granted however on 182 occasions during the same period (graphic below).

The 182 Prior Approvals were derived from just 347 Individual Funding Requests (IFRs). Hence a significant proportion of activity subject to Prior Approval looks to have bypassed the system, i.e. the Individual Funding Requests (IFR) process.

BEXLEY CCG IFR Data 2012-13

Total Cases		**347**
Approved	182	52.45%
Declined	89	25.65%
Awaiting Triage	20	5.76%
Awaiting Panel	8	2.31%
More Information Requested	48	13.83%
	347	**100%**



Source: SLCSU IFR Team

The CCG are to review with CSU how the SE London Treatment Access Policy may be better enforced to ensure that activity undertaken by Bexley's acute providers is in strict accordance with the established policy.

Due to the Cap and Collar contract in place during 1213 with Bexley's main provider South London Healthcare (SLHT) it is less likely the lack of rigour around the current IFR process and moreover the requirement to enact the existing Prior Approvals policy has had a material financial impact. However this is currently being quantified by provider.

Given different contractual arrangements for 1314 and not least the CCGs existing QIPP programme it is essential for the CCG to be given assurance that current systems and processes to administer the SEL TAP are fit for purpose. Urgent discussions are being held with the CSU to that end.

The analysis on Page 8 also highlights that in addition to Prior Approval activity, £1,823k of activity or 1,093 spells has also been undertaken in the same April12 – January13 period in respect of Restricted Access treatments. Whilst by definition, such activity is not subject to Prior Approval, the level of Restricted Access procedures undertaken across all providers seems very high when compared to CSU assumptions of around £800k for SLHT alone.

A review of Restricted Access activity by provider is being assessed against 1213 data and verified to CSU data to assess if this is also so an area where inappropriate activity may be being treated.

Benchmarking SE London to other health economy Treatment Access Policies

A high-level comparison between operation of the SEL TAP and similar policy adopted in Staffordshire has been undertaken. Further reviews will assess differences between SE London and other economies such as NW London and Surrey & Sussex.

The Staffordshire Excluded and Restricted Procedures policy highlights some areas not currently assessed as either a restrictive of excluded treatment under current CCG arrangements.

These include:

- Investigations for patients under 45 years who have had a single bright red rectal bleed
- Surgery for prostatism
- Facet Joint Injections
- Spinal epidural injections/ therapeutic lumbar epidural injection
- General joint injections for pain

The CCG currently spends £1.2m on the above procedures annually.

In addition to the above the Staffordshire policy applies restrictive access criteria to:

- Hip and Knee Replacements
- Cataract Surgery

Both areas have been excluded from the analysis below noting potential savings if adopting the Staffordshire model. Local referral criteria are applied to Cataracts though not detailed in the SE London policy. No assumptions have been made around potential restrictive criteria to be applied to Hip and Knee Replacements as this would need significant clinical dialogue but in addition any potential financial reduction could be double-counted in terms of the CCGs existing QIPP programme (MSk Prime Contractor redesign).

The lack of an existing threshold or scoring system for Hip and Knee Replacement in the current SE London TAP is noteworthy however.

Initial benchmark analysis (Page 12) suggests a slightly more comprehensive Treatment Access Policy such as operated in Staffordshire could yield between £450k and £850k via reductions in appropriate activity. These figures are derived from very broad assumptions as to the level of any excluded / restricted treatments adoption of a policy similar to Staffordshire could yield but are based on a part year impact from 1st July 2013 onwards.

Whilst the above figures are for illustrative purposes only and require a detailed clinical review they look to suggest more restrictive processes are in operation in other health economies than currently operated in Bexley and South East London as a whole.

Assessment of Bexley 1213 activity (all providers) against Restricted Treatment Policies - Staffordshire (100+ spell volume areas only)

Potential QIPP impact from 1st July 2013 implementation

Scheme	Excluded / Restricted	Month 1-10 Data Activity	Month 1-10 Data Cost	FOT Activity	FOT Cost	Jul13-Mar14 Element	Excluded Assumption	Restricted Assumption	Lower Restricted Assumption	Rationale	Status in SE London TAP
							50%	10%	5%		
Surgery for asymptomatic gallstones	Excluded	214	£520,673	257	£624,808	£468,606	£234,303				Restricted Access - 2.17 Surgery for Asymptomatic Gallstones is not routinely funded
Dermatology and Plastic Surgery	Excluded	751	£513,399	901	£616,079	£462,059	£231,030				Prior Approval Required - 1.1 Cosmetic procedures / Restricted Access 2.1 Excision of Other Skin Lesions
Investigations for patients under 45 years who have had a single bright red rectal bleed	Excluded	372	£232,969	446	£279,563	£209,672	£104,836				Not listed in SEL TAP 2012
Excluded Sub-total					**£1,520,449**	**£1,140,337**	**£570,168**				
Hip and Knee Replacement	Restricted	428	£3,030,732	514	£3,636,878	£2,727,659	n/a	n/a	n/a	Not included - potential double count of MSk QIPP	Not listed in SEL TAP 2012
Cataract Surgery	Restricted	1,243	£1,047,053	1,492	£1,256,464	£942,348	n/a	n/a	n/a	Not included - existing Ophthalmology QIPP	Not listed in SEL TAP 2012 (existing local gateway in operation though and has been included in prior year iterations)
Elective Caesarean Section	Restricted	278	£826,440	334	£991,728	£743,796			£37,190	Higher cost / volume areas assumed lower % restricted reduction	Prior Approval Required - 1.6 Caesarean Section For Non Clinical Reasons
Hysterectomy for menorrhagia	Restricted	170	£571,331	204	£685,597	£514,198			£25,710	Higher cost / volume areas assumed lower % restricted reduction	Restricted Access - 2.5 Hysterectomy For Heavy Mentrual Bleeding
Surgery for prostatism	Restricted	151	£424,363	181	£509,236	£381,927			£19,096	Higher cost / volume areas assumed lower % restricted reduction	Not listed in SEL TAP 2012
Tonsillectomy	Restricted	208	£264,458	250	£317,350	£238,012		£23,801			Restricted Access - 2.11 Tonsillectomy
Carpal Tunnel Syndrome	Restricted	162	£182,513	194	£219,016	£164,262		£16,426			Restricted Access - 2.10 Common Hand Procedures
Facet Joint Injections	Restricted	247	£172,199	296	£206,639	£154,979		£15,498			Not listed in SEL TAP 2012
Extraction of wisdom teeth	Restricted	214	£172,080	257	£206,496	£154,872		£15,487			Restricted Access - 2.10 Dental and Orthodontic procedures (check covered in Guys, Kings & St Thomas Dental Institute protocols)
Spinal epidural injections/ therapeutic lumbar epidural injection	Restricted	164	£143,551	197	£172,261	£129,196		£12,920			Not listed in SEL TAP 2012
Circumcision	Restricted	148	£137,777	178	£165,332	£123,999		£12,400			Prior Approval Required - 1.2 Non Medical Circumcisions
Grommets	Restricted	125	£112,281	150	£134,737	£101,053		£10,105			Restricted Access - 2.12 Grommets
General joint injections for pain	Restricted	86	£87,134	103	£104,561	£78,421		£7,842			Not listed in SEL TAP 2012
Restricted Sub-total					**£8,606,294**	**£6,454,721**		**£114,479**	**£81,996**		
Grand Total				5,953	£10,126,744	£7,595,058	£570,168	£114,479	£81,996		
Note:											
Activity not included in SEL TAP 2012 (excl Hip&Knee / Cataract)		**1,020**	**£1,060,216**	**1,224**	**£1,272,259**						

Option 1

Assumptions:

Start date 1July to allow time for clinical review, buy-in and appropriate governance mechanisms

Excludeds reduced to **50%** for Year 1 impact

Restricteds assumed as **10%** non compliant with revised policy in 1314 exc high cost areas £500k

Restricted assumed as **5%** in high cost areas £500k+ only

Potential impact:	
Existing SE London TAP policy (Qtr1 1314)	£105,000
New 'Staffordshire' policy (Qtr2-4 1314) - Excludeds	£570,168
New 'Staffordshire' policy (Qtr2-4 1314) - Restricteds	£196,475
Combined Treatment Access Policy impact in 1314	£871,644
Current QIPP expectation	£420,000
Maximum additional QIPP possible via new 'Staffordshire TAP' from 1st July 2013	**£451,644**

Option 2

Assumptions:

Start date 1July to allow time for clinical review, buy-in and appropriate governance mechanisms

Excludeds reduced to **70%** for Year 1 impact

Restricteds assumed as **20%** non compliant with revised policy in 1314 exc high cost areas £500k pa

Restricted assumed as **10%** in high cost areas £500k+ only

Potential impact:	
Existing SE London TAP policy (Qtr1 1314)	£105,000
New 'Staffordshire' policy (Qtr2-4 1314) - Excludeds	£798,236
New 'Staffordshire' policy (Qtr2-4 1314) - Restricteds	£392,951
Combined Treatment Access Policy impact in 1314	£1,296,187
Current QIPP expectation	£420,000
Maximum additional QIPP possible via new 'Staffordshire TAP' from 1st July 2013	**£876,187**

Summary:

Governing Body are asked to:

Approve – the 2013 SE London Treatment Access Policy (SEL TAP) noting amendments from the existing 2012 policy.

Note – poor compliance with existing Prior Approval mechanism within the SEL TAP.

Note – comparison between Staffordshire Excluded and Restricted Procedures policy and SEL TAP and potential cost saving if adopting a more restrictive access policy.

Appendix 1

South East London

Treatment Access Policy

April 2013

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

South East London

Treatment Access Policy

This policy deals with treatments and procedures for which restricted access criteria have been agreed. The access criteria are based on the same principles and correspondingly derived criteria as are in the South East London Individual Funding Request (IFR) Policy , e.g., evidence of clinical effectiveness.

Background

The six Primary Care Trusts (PCTs), latterly Clinical Commissioning Groups (CCGs), in the South East London Sector have been working together 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 discussion, and policy 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, formerly PCTs, latterly CCGs and the National Commissioning Board/Specialist Commissioning Groups, no guidelines are available. The PCTs/CCGs are therefore obliged to consider treatments and interventions in the absence of any recommendations from NICE. Development of a joint process across the SE and SW London will clearly be beneficial in terms of reducing the variations between the PCTs.

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 PCTs/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.

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 on-going 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
- waist to hip ratio of 0.85 or less for women (0.94 for men)
- 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.

[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) **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.

xv) **Repair of Lobe of External Ear**

This procedure is not available on cosmetic grounds.

xvi) **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.

xvii) **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.

xviii) **Tattoo Removal**

This procedure is not available on cosmetic grounds.

xix) **Removal of Birthmarks**

Available for children up to the age of 18 for permanent large or prominent lesions on face or neck.

xx) **Other Benign Skin Lesions**

Other benign skin lesions e.g. 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

xxi) **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.

xxii) **Viral Warts in Adults**

Properly compliant treatment with keratolytics is as effective as cryotherapy.

xxiii) **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 PCT. 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 fulfills those guidelines.

[2] National Institute for Health and Clinical Excellence. NICE Clinical Guideline 132: Caesarean Section. NICE, November 2011.

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

General Remarks

Varicose veins are dilated superficial veins in the leg which are caused by incompetent venous valves. The clinical presentation of varicose veins differs and some people are symptomatic. National Institute of Clinical Excellence (NICE) provides referral advice from primary care to specialist service for varicose veins. It stratifies patients into groups based on clinical criteria and advises GPs on the urgency for specialist referral.

Although treatment for varicose veins is generally effective, recurrence is estimated at around 50% within five years. Surgical treatment of asymptomatic or mild varicose veins is not recommended in the Department of Health's Healthcare Needs Assessment document[3]. In view of the lack of evidence for any prophylactic benefit of varicose vein surgery, high rates of recurrence and the current financial situation, treatment of asymptomatic, mild and moderate varicose veins is considered to be a low priority.

Most patients can be managed in primary care. Surgical treatment of asymptomatic, mild and moderate varicose veins will therefore only be purchased in individual exceptional circumstances. Severe cases may be referred routinely

Surgery (excision of the vein) or sclerotherapy (injection of irritant substances into the vein, which collapses and thus destroys the vein) can improve symptoms in the short term rather than long term .Sclerotherapy is less effective than surgery at improving symptoms and cosmetic appearance.

NICE is currently developing guide lines for varicose veins in the legs: the diagnosis and management of varicose veins. (http://guidance.nice.org.uk/CG/Wave24/11)

i) **Asymptomatic and Mild Varicose Veins**

- Asymptomatic or mild varicose veins present as a few isolated, raised palpable veins with no associated pain, discomfort or any skin changes.
- The main problems with asymptomatic varicose veins are likely to be cosmetic anxiety.
- Mild varicose veins are associated with moderate ankle swelling, feelings of heaviness, pain and other discomfort, with local or generalised dilation of subcutaneous veins.
- Generally, only the superficial veins are involved

Surgical treatment of asymptomatic and mild varicose veins or referral to specialist services will not be available routinely.

ii) **Moderate Varicose Veins**

- Moderate varicose veins present as local or generalised dilatation of subcutaneous veins with associated pain or discomfort and slight ankle swelling.
- Moderate varicose veins are associated with the symptoms described above for mild varicose veins with prominent local or generalized dilation of subcutaneous veins.
- Moderate varicose veins are more likely to be associated with skin changes but not actual ulceration or pre-ulcerative changes.

Surgical treatment of moderate varicose veins or referral to specialist services will not be available routinely.

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[3] Robbins MA, Frankel SJ, Nanchal K, Coast J, Williams MH. *Varicose Vein Treatment in Health Care Needs Assessment : The Epidemiologically Based Needs Assessment Reviews*. Edited by A Stevens and J Raftery. Oxford. Radcliffe Medical Press 1994.

iii) **Severe Varicose Veins**

- Severe varicose veins: may present with phlebitis, ulceration and haemorrhage.
- Surgical treatment will be available if one or more of the following criteria are met:
  - Persistent ulceration
  - Recurrent phlebitis where there is significant pain and disability from this condition and after unsuccessful 6 month trial of conservative management (compression stockings, exercise and daily elevation 2-3 times a day)
  - Significant haemorrhage from a ruptured superficial varicosity, for instance serious enough to consider transfusion/admissionassociated with obvious skin changes including lipodermatosclerosis, moderate to severe oedema(itching is insufficient for referral)
  - Intractable ulceration secondary to venous stasis
  - More than one episode of minor haemorrhage from a ruptured superficial or significant haemorrhage from a ruptured superficial varicosity, eg if serious enough to consider transfusion

Surgical treatment for severe varicose veins will be available routinely.

Please note that a referral to specialist services does not necessarily imply surgical management. The Specialist services can do a number of things which include investigate, diagnose and reassure, offer advice on, and/or provide, treatment, supplement advice given in primary care on the application of compression hosiery and bandaging or undertake surgery if indicated.

Conservative management of varicose veins, as detailed in the Department of Health funded Healthcare Needs Assessment should continue to be offered to all appropriate patients [2]
Treatment should be in line with the recommendations of the NHS R & D Health Technology Assessment (2006).[4]

[4] Michaels JA, Campbell WB, Brazier JE, MacIntyre JB, Palfreyman SJ, Ratcliffe J, Rigby K. *Randomised clinical trial, observational study and assessment of cost-effectiveness of the treatment of varicose veins (REACTIV trial).* Health Technology Assessment 2006; Vol. 10: No. 13

2.3 FERTILITY TREATMENTS[5]

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 PCT 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 PCT will pay.

ELIGIBILITY CRITERIA

All couples must be registered with a General Practitioner within the boundaries of the PCT 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:

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

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[5] National Collaborating Centre for Women's and Children's Health. *NICE Clinical Guideline: Fertility. Assessment and treatment for people with fertility problems.* RCOG Press, February 2004. Available at: http://www.nice.org.uk/nicemedia/live/10936/29267/29267.pdf.

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 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[6].

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 above criteria 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. An additional 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. [7]

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 PCTs 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 PCT 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 PCT does not currently 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. At present any decisions regarding sperm washing should be referred to the Individual Funding Request Panel for consideration

2.4 HYSTERECTOMY FOR HEAVY MENSTRUAL-BLEEDING

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

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

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
`

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.

2.5 IMPLANTABLE CARDIAC DEFIBRILLATORS

Implantable Cardiac Defibrillators (ICDs) are recommended for patients in the following categories:

<u>Secondary prevention</u> that is, for patients who present, in the absence of a treatable cause, with one of the following:

- having survived a cardiac arrest due to either ventricular tachycardia (VT) or ventricular fibrillation (VF)
- spontaneous sustained VT causing syncope or significant haemodynamic compromise

- sustained VT without syncope or cardiac arrest, and who have an associated reduction in ejection fraction (LVEF of less than 35%, no worse than class III of the New York Heart Association functional classification of heart failure).

Primary prevention that is, for patients who have:

(i) a history of previous (more than 4 weeks) myocardial infarction (MI) and:
either
- left ventricular dysfunction with an LVEF of less than 35% (no worse than class III of the New York Heart Association functional classification of heart failure)
- **and** non-sustained VT on Holter (24-hour electrocardiogram [ECG]) monitoring, **and**
- inducible VT on electrophysiological (EP) testing

or
- left ventricular dysfunction with an LVEF of less than 30% (no worse than class III of the New York Heart Association functional classification of heart failure) **and**
- QRS duration of equal to or more than 120 milliseconds

(ii) a familial cardiac condition with a high risk of sudden death, including long QT syndrome, hypertrophic cardiomyopathy, Brugada syndrome or arrhythmogenic right ventricular dysplasia (ARVD), or have undergone surgical repair of congenital heart disease.

2.6 COCHLEAR IMPLANTS

This procedure is available at specialist centres only and is offered to both adults and children. The service requires considerable pre-operative counseling and assessment and post-operative support from speech therapy services.

It is proposed that children up to the age of 18 should have first priority on the allocation of scarce funding. In accordance with their protocols, referrals will be on a tertiary basis from a consultant audiological physician or ENT surgeon.

The criteria for patient selection (NICE 2009)[8]:

A cochlear implant in one ear is recommended as a possible option for everyone with severe to profound deafness if they do not get enough benefit from hearing aids after trying them for 3 months. Cochlear implants in both ears are recommended for the following groups with severe to profound deafness only if they do not get enough benefit from hearing aids after trying them for 3 months and the implants are placed during the same operation:

- children
- adults who are blind or have other disabilities which mean that they depend upon hearing sounds for spatial awareness.

The cochlear implant team should carry out an assessment to find out if an implant would help before they consider a cochlear implant. They should take into account any disabilities or difficulties in communicating, which might mean that the usual hearing tests are not suitable. In such cases they should consider other methods for testing hearing. A later operation to place a cochlear implant in the second ear is only recommended for the following groups if they already had a cochlear implant in the other ear when the guidance was issued:

- children

[8] National Institute for Health and Clinical Excellence. *NICE technology appraisal guidance 166: Cochlear implants for children and adults with severe to profound deafness.* NICE January 2009. Available at: http://guidance.nice.org.uk/TA166/Guidance/pdf/English.

- adults who are blind or have other disabilities which mean that they depend upon hearing sounds for spatial awareness.

In all cases, if more than one type of cochlear implant is suitable, the least expensive should be used. Costs should include the cost of the implant and the support package, and how reliable the system is. When an implant is placed in a second ear during the same operation the cost for the second implant should include currently available discounts on list prices of 40% or more.

2.7 FILTERED / COLOURED LENSES

These are not offered for specific reading difficulties.

2.8 TREATMENT OF GENDER DYSPHORIA

Patients should be treated in line with local draft guidance available on this issue, giving information on the ‘core’ and ‘non-core’ interventions associated with this condition. National guidance from the Royal College of Psychiatrists is also in preparation. Treatment can be undertaken through a specialist unit following referral by a local consultant psychiatrist. Treatment is covered by specialist commissioning arrangements.

2.9 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

2.10 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

2.11 GROMMETS[9]

PCTs 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

2.13 ADENOIDECTOMY FOR OTITIS MEDIA IN CHILDREN

Adenoidectomy combined with grommets may be considered in children who fulfil the criteria for grommets (see 2.12).

9 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

2.14 BARIATRIC SURGERY[10]

This includes but is not limited to gastric banding and gastric by-pass surgery.

NICE issued clinical guidance on obesity, which are comprehensive guidance on identification, prevention and management of obesity. The guidance also includes criteria for bariatric surgery. The PCTs have to take this guidance into account when planning services.

NICE guidelines should be adhered to for medical management for six months prior to surgery.

Criteria for bariatric surgery

Due to the capacity and financial constraints, priority for bariatric surgery will be offered to patients who fulfil the following criteria:

- 50 BMI – straight to surgery
- BMI 45-49 plus one major co-morbidity - straight to surgery
- BMI 40-44 plus two major co-morbidities – straight to surgery
- Transplant patients would need to be considered on a case by case basis.

The major co-morbidities, which evidence suggests can be improved by losing weight, are the following:

- Type 2 Diabetes
- Non-alcoholic steatohepatitis (NASH) / Hepaticatosis(fatty liver disease)
- Lymphoedema
- Hypertension

  Count only if the patient meets one of the following criteria:
  1. Requiring three antihypertensive drugs to control hypertension
  2. Taking three antihypertensive drugs but hypertension not controlled
  3. Taking fewer than three antihypertensive drugs, hypertension not controlled (>140/90), and unable to increase antihypertensive medication further due to clear contraindication or proven poor tolerance of additional medications
- Asthma

  Count only if the patient meets at least one of the following criteria:
  1. Attended ED within the last year with acute asthma exacerbation
  2. Any previous admission to hospital ward with acute asthma exacerbation
  3. Any previous asthma exacerbation judged near-fatal
  4. Currently requiring significant corticosteroid treatment – ongoing inhaled corticosteroid treatment (i.e. BTS Step 2), or more than two courses of oral corticosteroid treatment in the last year?
  5. Currently requiring three or more classes of asthma medication (i.e BTS Step 3)
  6. “Brittle” asthma
  7. Is asthma impeding the patient’s ability to exercise and hence lose weight?

- Immediate Family history of heart disease and patient’s CVD risk >20%
- Hypercholesteraemia or High triglyceride- count if patient already has one severe comorbidity and BMI>40
- Sleep Apnea requiring Continuous positive airway pressure (CPAP)

Surgery

Surgery should be performed by a multidisciplinary team. The surgeon in the multidisciplinary team should have undertaken a supervised training programme, have specialist experience in bariatric surgery and be willing to submit data for a national clinical audit scheme.

The team should have expertise in:

- preoperative assessment, including risk-benefit analysis and specialist assessment for eating disorders
- providing information on the procedures, including potential weight loss and risks
- postoperative assessment including dietetic and surgical follow-up and management of co-morbidities,
- psychological support before and after surgery,
- providing information on, or access to, plastic surgery

and should have access to suitable equipment, including scales, theatre tables, hoists, bed frames and pressure relieving mattresses, and staff trained to use them.

Surgery is not generally recommended for children or young people.
Funding for surgery for young people should only be considered in exceptional circumstances, and if:

- they have achieved or nearly achieved physiological maturity
- they have a BMI of 40 kg/m2 or more, or between 35 kg/m2 and 40 kg/m2 and other significant disease (for example, type 2 diabetes, high blood pressure) that could be improved if they lost weight
- all appropriate non-surgical measures have failed to achieve or maintain adequate clinically beneficial weight loss for at least 6 months
- they are receiving or will receive intensive specialist management and they are generally fit for anaesthesia and surgery, and commit to the need for long-term follow-up.

Surgery should be performed by a multidisciplinary team who meet the same criteria as those specified for adult teams (see above)

Any cosmetic surgery is not part of the bariatric surgery service and patients should be advised about it.

<u>Revision for weight re-gain</u>
Any surgical revisions for weight re-gain will be considered using the same criteria as for original bariatric surgery

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[10] National Institute for Health and Clinical Excellence. NICE clinical guideline 43 Obesity: guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children. NICE. December 2006. Available at: http://www.nice.org.uk/nicemedia/live/11000/30365/30365.pdf

Eneli IU, Skybo T, Camargo CA. Weight loss and asthma: a systematic review. Thorax 2008;63(8):671-6. Reddy RC, Baptist AP, Fan Z, Carlin AM, Birkmeyer NJ. The effects of bariatric surgery on asthma severity.Obes Surg. 2011 Feb;21(2):200-6.

Stenius-Aarniala B, Poussa T, Kvarnstrom J, Gronlund EL, Ylikahri M, Mustajoki P. Immediate and long term effects of weight reduction in obese people with asthma: randomised controlled study. BMJ 2000; 320(7238):827-832.

Rutter P, Arowobusoye N. Asthma as a co-morbidity to justify bariatric surgery. Evidence review. Greenwich PCT, 2011.

2.15 KNEE WASHOUT AND DEBRIDEMENT FOR OSTEOARTHRITIS[11]

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).

2.16 HAEMORROIDS[12]

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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11 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.

12 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)

2.17 SURGERY FOR ASYMPTOMATIC GALLSTONES[13]

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.

DENTAL AND ORTHODONTIC PROCEDURES[14]

All dental and orthodontic referrals should follow the agreed dental referral protocol with Guy's, King's and St Thomas' Dental Institute. This includes restorative dentistry, orthodontics and oral and maxillo-facial surgery.

2.19 HYBERBARIC OXYGEN TREATMENT (HBOT) OF DECOMPRESSION SICKNESS

A Cochrane review[15] and two Health Technology Assessment (HTA) reports have considered the effectiveness and safety of HBOT for decompression sickness. These concluded that recompression therapy is standard treatment for decompression sickness although there is no supportive RCT evidence. Given the theoretical evidence, observational case series data and widespread clinical use, HBOT remains the treatment of choice for decompression sickness. Such treatment will not be funded, however, unless the following criteria are met.

- The facility in which the treatment has been provided must be a member of the British Hyperbaric Association (BHA)
- The facility is registered with the Care Quality Commission (CQC) as a hyperbaric facility
- Patients receiving emergency care, ie within 24 hours of the decompression incident, must have been referred to the unit by an NHS A&E Dept, an NHS Ambulance Service or HM Coast Guard. Where referral by one of these agencies is not possible, or where

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13 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.

14 Guy's, King's & St Thomas' Dental Institute Referral Protocols. 2010.

Other documents to inform the content of this guidance:

Kerac M. *Commissioning of clinically effective healthcare interventions: a review of evidence underlying potentially cost-saving PoLCE procedures (procedures of limited effectiveness).* Lewisham PCT, December 2010.

15 Bennet MH et al. Recompression therapy and adjunctive drug therapy for decompression illness. Cochrane Review, 2010

the need for such a referral will introduce unnecessary and harmful delay, divers may refer themselves.

- Patients receiving elective care must have been referred to the unit by an appropriate secondary care provider. Self-referrals or referrals from General Practitioners cannot be funded.
- Funding of treatment of elective cases must be agreed before treatment is provided.
- A report is provided, including details of the source of referral, the presenting symptoms and signs, the number and duration of sessions of treatment and the outcome of treatment

2.20 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

Implantable Cardiac Defibrillators

OPCS 4 K591 K 592 K593 K594 K595 K598 K599

Cochlear Implants

OPCS 4 Procedure codes D241 D242

Ganglion

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

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

Bariatric Surgery

OPCS 4 Procedure code G284 G285 G716 G387

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

Haemorroids

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