Value Based Clinical Commissioning Policies

Version 1.5

September 2013

Document History

Revision History

Date of creation: January 2012

Date of this revision: September 2013

Revision date	Summary of Changes
May 2012	Removed the policy on Gender Reassignment surgery in Adults as this is included in Specialised Services Commissioning for Mental Health Services. Removed the reference to Gender Reassignment in the policy on the treatment of hirsutism. Modified the criteria for orthodontic treatment in line with DH guidance. Clarification of the criteria for mastopexy. Clarification of the criteria for Pre-implantation Genetic Diagnosis.
August 2012	BMI criteria specified to one decimal point. BMI added as a criterion for mastopexy- as excess weight is likely to be a contributing to the magnitude of the problems experienced. BMI added as a criterion for thigh lift- as excess weight is likely to be a contributing to the magnitude of the problems experienced. Excimer laser laser for refractive error limited to patients when all other conservative interventions have failed. This moves the policy in line with prevailing clinical practice Clarification is offered on the rationale for age limits for pinnaplasty. Laser treatment for hirsutism limited to face and neck only- bringing the wording of the policy in line with decision precedents.
December 2012	Cosmetic surgery – inclusion of a general statement applying to a number of procedures. Breast augmentation replacement needing a new funding application. Breast reduction – clarifying the degree of neck ache, back ache and intertrigo; rewording the assessment of breast size. Gynaecomastia – endocrine problems treated before referral Pinnaplasty – removed age criteria. Repair of ear lobe - clarifying the timing of surgery following trauma. Varicose veins – inclusion of progressive skin changes due to venous insufficiency. Resurfacing procedures – clarification of criteria Removal of benign skin lesions – one change in the order of the wording.
September 2013	See table below

Topic	Action
Varicose veins	Policy reviewed in light NICE guideline (CG168) published in July 2013 and discussed with chair of the cardiovascular network. Recommended interventions include the newer treatments: endothermal (radiofrequency) ablation endovenous laser treatment of the long saphenous vein and ultrasound-guided foam sclerotherapy. The policy now refers to Interventional rather than surgical treatment the removal of the criterion for patients to have tried at least 6 months of conservative management, for lack of an evidence base
BMI criterion for safe surgery	Consideration of evidence base for this criterion- all weight related eligibility criteria reviewed
Tonsillectomy	Complete new criterion based policy(s) based on RCS guidance (section on sleep disordered breathing in adults remains
Fertility treatment	Policy revised in light of NICE guidelines- age limit raised (in restricted circumstances) but priority for families where both parents are childless remains The policy covers eligibility for fertility treatments as covered in NICE guidelines. There are further elements of guidance that require consideration, particularly embryo transfer and fertility preservation. Further analysis on these topics is available on request.
Hyperhidrosis	Added link to CKS best practice guidance Added criteria based on CKS medical management of hyperhidrosis
Collagen cross-linking for corneal irregularities including keratoconus	specialised service commissioned by NHS England, policy removed

Topic	Action
Hirsuitism	Eligibility for treatment restricted, no longer available routinely for those with excessive facial hair
Excimer laser for corneal erosions	specialised service commissioned by NHS England, policy removed
Ophthalmology- correction of refractive error	Policy removed as not in Cumbria policy and not considered as a priority- NE and Cumbria policies now consistent
Rhinophyma	Included Cumbria policy
Decision making framework	Framework reviewed in light of NHS England policies
Vulvoplasty	Clarification that this is not usually funded
Keloid scarring	Included Cumbria policy within Benign skin lesions policy
Breast asymmetry	Default to breast reduction- as in Cumbria policy- new policy guidance and clearer criteria- as distinct from breast augmentation policy
Breast prosthesis removal or replacement	NHS funding position on part payment clarified
Gynaecomastia	Changed default to not routinely funded- primary consideration is already of exceptionality
Pre-implantation genetic diagnosis	specialised service commissioned by NHS England, policy removed
Reversal of male sterilisation	Clarification that this is not normally funded
Reversal of female sterilisation	Clarification that this is not normally funded

Contents

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Introduction

Across the country most, if not all, CCGs have a set of policies and procedures for limiting the number of low clinical value interventions. The Audit Commission's report 'Reducing expenditure on low clinical value treatments'[1] analyses variation on approaches to this work. The report is supported by an online tool[2] that looks at expenditure on treatments of limited clinical value. The tool is in turn based on the 'Save to Invest' programme developed by the London Health Observatory[3] incorporating the 'Croydon List' of 34 low priority treatments.

Historically, PCTs in the North East developed a similar set of policies in 2010 with a view to adoption by commissioners across the region. These were reviewed in 2012 with a view to ensuring consistency. While reviewing the original 2010 set of policies, any intervention covered by a NICE Technology Appraisal were removed as there is an obligation for NHS bodies to implement their recommendation. A list of relevant recommendations from NICE can be found in Appendix 2. Procedures prescribed as Specialist Services and therefore the remit of NHS England has also been removed. A list of these services (as at August 2012) is included in Appendix 3.

There are other national and regional guidelines, and reviews of the effectiveness and cost-effectiveness of treatments, where the mandate for the NHS is less clear cut. These include Interventional Procedure Guidance produced by NICE, technology assessments by bodies other than NICE, and guidance from professional bodies. These therefore need some clarification about what procedures NHS funding will routinely be available for, and under what circumstances.

The following document lists the interventions that the NHS commissioners in the North East have agreed to adopt as policies for limiting low clinical value interventions. The list includes procedures where there is evidence that they are not clinically effective, procedures where there is a lack of evidence for their effectiveness, and procedures that are effective for some patients and not others. We have included the funding policies for infertility and pre-implantation genetic diagnosis. The reason for their inclusion here is that CCGs have agreed to limit funding for these interventions to those who will gain the most benefit and not about their value as a clinical intervention.

The purpose of this document is to support a consistent approach to decommissioning treatments of low clinical value across the North East. The aim is to make it easier for GPs and consultants to use in clinical practice, and to ensure that the policies are applied consistently across all CCGs. These policies will be included in contracts between commissioners and providers and will be regularly monitored by the contracting teams.

[1]Reducing expenditure on low clinical value treatments. Audit Commission, April 2011.. http://www.audit-commission.gov.uk/nationalstudies/health/financialmanagement/lowclinicalvalue/Pages/Default.aspx
[2]Reducing PCT expenditure on treatments with low clinical value online tool. http://www.audit-commission.gov.uk/nationalstudies/health/financialmanagement/lowclinicalvalue/pages/lowclinicalvaluetool.aspx
[3]Save to Invest: Developing criteria-based commissioning for planned health care in London. Malhotra N. Jacobson B. 2007. http://www.lho.org.uk/Download/Public/11334/1/Save%20To%20Invest%20-%20Commissioning%20for%20Equity.pdf

The mechanisms available for supporting local implementation of these policies include audit, monitoring within the Quality Schedules of contracts with NHS Trusts, service specifications, contract review meetings, incentive schemes, and service reform initiatives. The application of these tools will be at the discretion of each CCG. There is further information about the decision making process in the Q&A section in Appendix 4.

Contributions

The first north East policy document was drawn up by Sue Gordon, Mark Lambert, Mike Lavender and Toks Sangowawa representing the four Primary Care Trust clusters.

The 2013 review has included Sue Gordon, Dawn Scott, Wendy Burke, Jane Mathieson, Mark Lambert, Mike Lavender, Tanja Braun, Pam Lee, Toks Sangowawa, Gillian O'Neill (fertility), Liz Lingard (varicose veins), Craig Blundred (fertility preservation) as well as Ros Berry, Sharon Cornwell and Elspeth Godwin (comparison with Cumbria policies) and was co-ordinated by Mark Lambert, using the PHINE online platform to enable group communications and access to resources.

Acknowledgements:

We are indebted to colleagues in other parts of the country for advice and information. In particularly we are grateful to the Health Commission Wales for permission to base our work on published National Public Health Service of Wales guidance. We would like to thank the following colleagues for their suggestions and comments on specific policies:

Tonsillectomy: Mr Sean Carrie, Consultant ENT Surgeon, Newcastle upon Tyne NHS Foundation Trust

Infertility
Professor Alison Murdoch, Consultant Gynaecologist, Newcastle upon Tyne NHS Foundation Trust

And Dr Jane Stewart, Consultant Gynaecologist, Newcastle upon Tyne NHS Foundation Trust

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Cosmetic Surgery

Surgery for primarily cosmetic reasons is not eligible for NHS funding. A significant degree of exceptionality must be demonstrated before funding can be considered outside of these policies. Specifically, psychological factors are not routinely taken into consideration in determining NHS funding.

Whilst some degree of distress is usual among people who consider aspects of their physical appearance as undesirable, the degree of this will not routinely be taken into account in any funding decision. Further, it is expected clinicians consider the possibility of psychological problems including Body Dysmorphic Syndrome (NICE Clinical Guideline 31), assess for these and ensure appropriate management before considering any referral for plastic surgery.

This guidance applies to many of the following policies, in particular:

Breast augmentation (Breast enlargement)
Breast prosthesis removal or replacement
Breast reduction
Gynaecomastia
Inverted nipple correction
Mastopexy
Revision mammoplasty
Blepharoplasty
Pinnaplasty
Repair of lobe of external ear
Rhinoplasty
Orthodontic treatments
Varicose veins
Circumcision
Vaginoplasty, Labial Vulvoplasty and Vulvar lipoplasty
Hirsutism
Removal of tattoos
Resurfacing procedures
Abdominoplasty or Apronectomy
Face lift or brow lift
Liposuction
Removal of benign skin lesions
Removal of lipomata
Thigh lift, buttock lift and arm lift
Hair grafting - Male pattern baldness

Carpal Tunnel Syndrome (OPCS Code: A65.1 A65.8)

Background: Evidence from observational studies shows that symptoms resolve spontaneously in some people: good prognostic indicators are short duration of symptoms, a young age, and carpal tunnel syndrome due to pregnancy.

There is good evidence that surgical treatment relieves the symptoms of carpal tunnel syndrome (CTS) more effectively than splinting. However splinting is effective in about 50% of people in the short term.

Carpal tunnel surgery is a low priority procedure for patients with intermittent or mild to moderate symptoms. The exception to this are patients who have not responded to 3 months of conservative management, including:

- At least 8 weeks of night-time use of wrist splints and/or
- Corticosteroid injection in appropriate patients

Referral guidance: Consider referral for electromyography and nerve conduction studies if the diagnosis is uncertain.

Policy: Carpal tunnel surgery will be funded if the following criteria are met:

- Symptoms persist or recur after conservative therapy with either local corticosteroid injections and/or nocturnal splinting

OR

- There is neurological deficit, for example sensory blunting, thenar muscle wasting or motor weakness

OR

- There are severe symptoms that significantly interfere with daily activities.

Implementation

Web based system entry? YES
Other implementation interventions? *To be agreed*

References:

1. NHS Clinical Knowledge Summaries http://www.cks.nhs.uk/carpal_tunnel_syndrome#337731001
2. Marshall SC, Tardif G, Ashworth NL. Local corticosteroid injection for carpal tunnel syndrome. *Cochrane Database of Systematic Reviews* 2007, Issue 2. Art. No.: CD001554. DOI: 10.1002/14651858.CD001554.pub2.
3. ScholtenRJPM, Mink van der Molen A, Uitdehaag BMJ, Bouter LM, deVet HCW. Surgical treatment options for carpal tunnel syndrome.*CochraneDatabase of SystematicReviews* 2007, Issue 4.Art.No.:CD003905.DOI: 10.1002/14651858.CD003905.pub3.
4. O'Connor D, Marshall SC, Massy-Westropp N. Non-surgical treatment (other than steroid injection) for carpal tunnel syndrome. *Cochrane Database of Systematic Reviews* 2003, Issue 1. Art. No.: CD003219. DOI: 10.1002/14651858.CD003219.
5. Verdugo RJ, Salinas RA, Castillo JL, Cea JG. Surgical versus non-surgical treatment for carpal tunnel syndrome. *CochraneDatabase of Systematic Reviews* 2008, Issue 4. Art. No.: CD001552. DOI: 10.1002/14651858.CD001552.pub2.

Breast augmentation (Breast enlargement) (OPCS Code: B31.2)

Background: Breast augmentation/enlargement is the most popular cosmetic procedure. It involves inserting artificial implants behind the normal breast tissue to improve its size and shape. It should not be carried out for "small" but normal breasts or for breast tissue involution (including post partum changes). Breast implants have a 'life span' of viability and any approval granted is for one course of treatment and any complications of that initial treatment. Should there be a desire for implant replacement, this will need consideration as a new application.

This policy includes those who have congenital absence of breast tissue or who have had a mastectomy for high risk of breast cancer

Policy: Breast augmentation will only be funded in accordance with the criteria specified below.

Surgery for primarily cosmetic reasons is not eligible for NHS funding- see p 8.

For women:

- with a complete absence of breast tissue unilaterally or bilaterally;

Breast asymmetry

Concerns about breast size and shape are common. Only those instances where there are large demonstrable differences in breast size will be considered for NHS funding. Where correction of asymmetry is requested, consideration will be made for reduction of the larger breast.

Referral guidance:
Include the cup size of each breast in your referral letter

Policy: Correction of breast asymmetry will only be funded in accordance with the criteria specified below.

Surgery for primarily cosmetic reasons is not eligible for NHS funding- see p 8.

For women:

- with of a significant degree of asymmetry of breast shape of two or more cup sizes (as assessed by a difference in breast measurement of at least 2 inches).

Breast prosthesis removal or replacement (OPCS Code: B30.-)

Background: breast prosthesis may have to be removed after some complications such as leakage of silicone gel or physical intolerance or social unacceptability by the individual. It may have to be replaced after the 'life span' of the implant is over.

Policy: Breast prosthesis removal or replacement will only be funded in accordance with the criteria specified below.

Surgery for primarily cosmetic reasons is not eligible for NHS funding- see p 8.

- Revision surgery will only be considered if the NHS commissioned the original surgery. If revision surgery is being carried out for implant failure, the decision to replace the implant(s) rather than simply remove them should be based upon the clinical need for replacement and **whether the patient meets the criteria for augmentation at the time of revision**.

- For patients who had original surgery carried out privately, **removal to make safe only will be provided**. Further treatment will only be commissioned in light of appropriate evidence being provided to prove that the patient meets the criteria for breast augmentation at the time of application based on their original breast size before private implants were inserted.

- For any patients meeting these above criteria, no departure will be made from the principle of mixed funding for procedures. If patients choose to subsequently undergo insertion of prosthesis, this will not be eligible for NHS funding.

Breast reduction (OPCS Code: B31.1)

Background: excessively large breasts can cause physical and psychological problems. Breast reduction procedure involves removing excess breast tissue to reduce size and improve shape.

As excess weight is likely to exacerbate symptoms associated with large breasts, it is assumed that patients going forward for surgery will be near normal weight.

Assessing eligibility for surgery is problematic not least because there are several recognised approaches to measuring bra size http://www.wikihow.com/Measure-Your-Bra-Size, some of which relate to historical manufacturing standards.

The following approach to calculating cup size is recommended for standardisation (extracted from Modern Sizing section of above reference): subtract band size (below the breast) from the bust size (at the widest point). The difference between the two numbers determines cup size:
Less than 1 inch difference = AA
1 inch difference= A
2 inches = B
3 inches = C
4 inches = D
5 inches = DD
6 inches = DDD (E in UK sizing)
7 inches = DDDD/F (F in UK sizing)
8 inches = G/H (FF in UK sizing)
9 inches = I/J (G in UK sizing)
10 inches = J (GG in UK sizing)

Policy: Breast reduction will only be funded in accordance with the criteria specified below.

Surgery for primarily cosmetic reasons is not eligible for NHS funding- see p 8.

For women:

- suffering from chronic or repeated neck ache or, backache or intractable intertrigo;

AND

- wearing a professionally fitted brassiere has not relieved the symptoms;

AND

- has a preoperative body mass index (BMI) of less than 27.0 kg/m^2.

As a guide, at least 500gms of tissue will be removed from each breast. The table below indicates how this relates to band and bust measurement.

Band size (inches)	Minimum cup size
32 / 34	>= E
36	>= EE (approx 6.5 inches difference between breast and bust measurement)
38	>= F
40/42*	>F

*once women have reached this size, they are likely to have a significant weight problem which should be addressed prior to surgery.

Gynaecomastia (OPCS Code: B31.1)

Background: Gynaecomastia (ICD-10 Code: N62X) is benign enlargement of the male breast. Most cases are idiopathic. For others endocrinological disorders and certain drugs such as oestrogens, gonadotrophins, digoxin, spironolactone, cimetidine and proton pump inhibitors could be the primary cause. Obesity can also give the appearance of breast development as part of the wide distribution of excess adipose tissue.

Full assessment of men with gynaecomastia should be undertaken, including screening for endocrinological and drug related causes and necessary treatment is given prior to request for NHS funding.

Policy: Surgery to correct gynaecomastia will not be routinely funded

Inverted nipple correction (OPCS Code: B35.6)

Background: the term inverted nipple (ICD-10 Code: N64.5) refers to a nipple that is tucked into the breast instead of sticking out or being flat. It can be unilateral or bilateral. It may cause functional and psychological disturbance. Nipple inversion may occur as a result of an underlying breast malignancy and it is essential that this be excluded.

Policy: Surgery for the correction of inverted nipple for cosmetic reasons will not be funded.

Surgery for primarily cosmetic reasons is not eligible for NHS funding- see p 8.

Mastopexy (OPCS Code: B31.3)

Background: breasts begin to sag and droop with age as a natural process. Pregnancy, lactation and substantial weight loss may escalate this process. This is sometimes complicated by the presence of a prosthesis which becomes separated from the main breast tissue leading to “double bubble” appearance.

Policy: Mastopexy will only be funded in accordance with the criteria specified below.

- Whilst this is routinely part of treating breast asymmetry and reduction it is not available for purely cosmetic/aesthetic purposes, such as postlactational ptosis. The presence of a prosthesis does not change eligibility for mastopexy.
- Criteria for asymmetry or breast reduction should be met to qualify for mastopexy including a preoperative body mass index (BMI) of less than 27.0 kg/m^2.

Surgery for primarily cosmetic reasons is not eligible for NHS funding- see p 8.

Revision mammoplasty (OPCS Codes: B31.4, B30.2)

Background: the term mammoplasty refers to breast reduction or augmentation procedures. Revision mammoplasty may be indicated if desired results are not achieved or as a result of problem with implants.

Policy: Revision mammoplasty will only be funded in accordance with the criteria specified below.

- Revisional surgery will only be considered if the NHS commissioned the original surgery. If revisional surgery is being carried out for implant failure, the decision to replace the implant(s) rather than simply remove them should be based upon the clinical need for replacement and whether the patient meets the policy for augmentation at the time of revision.

Surgery for primarily cosmetic reasons is not eligible for NHS funding- see p 8.

Autologous Serum Eye Drops

Background: Autologous serum eye drops treat severe keratoconjunctivitis sicca (dry eye). Dry eyes can be helped with intensive treatment with artificial teardrops however for some patients the symptoms are not completely relieved. The National Blood Service has developed an alternative to these artificial drops. Autologous serum eye drops are a last resort measure where all other conservative interventions have failed.

Policy: Autologous serum eye drops will only be funded in accordance with the criteria specified below.

- Patients have been treated with maximal tolerated artificial tear therapy (preservative free).
- Indefinite NHS funding will be subject to the submission of a progress report following a 5 month trial.

Excimer laser for cases with poor refraction after corneal transplant or cataract surgery (OPCS Codes: C46.1.)

Background: This is a last resort measure where all other conservative and surgical interventions have failed.

Policy: This procedure will only be funded if all other conservative and surgical interventions have failed.

Blepharoplasty (OPCS Code: C13.)

Background: blepharoplasty is a surgical procedure performed to correct puffy bags below the eyes and droopy upper eyelids. It can improve appearance and widen the field of peripheral vision. It is usually done for cosmetic reasons. Consideration should be given to whether blepharoplasty or brow lift is the more appropriate procedure, particularly in the case of obscured visual fields.

Policy: Blepharoplasty will only be funded in accordance with the criteria specified below.

- Impairment of visual fields in the relaxed, non-compensated state;

- Clinical observation of poor eyelid function, discomfort, e.g. headache worsening towards end of day and/or evidence of chronic compensation through elevation of the brow.

Surgery for primarily cosmetic reasons is not eligible for NHS funding- see p 8.

Pinnaplasty (OPCS Code: D03.3)

Background: pinnaplasty is performed for the correction of prominent ears or bat ears (ICD-10 Code: Q17.5). Prominent ears are a condition where one's ears stick out more than normal. This condition does not cause any physical problems but may lead to significant psychosocial dysfunction for children and adolescents and impact on the education of young children as a result of teasing and truancy.

However, correction is considered to primarily a cosmetic procedure. Surgery for primarily cosmetic reasons is not eligible for NHS funding- see p 6.

This policy does not cover other congenital abnormalities of the external ear. These should be managed by plastic surgeons and do not need prior approval through the IFR process.

Policy: Pinnaplasty will not normally be funded.

Repair of lobe of external ear (OPCS Code: D06.2)

Background: the external ear lobe can split partially or completely as result of trauma or wearing ear rings. Correction of split earlobes is not always successful and the earlobe is a site where poor scar formation is a recognised risk.

Policy: Repair of lobe of external ear will only be funded in accordance with the criteria specified below.

- If the totally split ear lobes is a result of direct trauma and the treatment is required at the time of, or soon after the acute episode and before permanent healing has occured.

Surgery for primarily cosmetic reasons is not eligible for NHS funding- see p 8.

Rhinoplasty (OPCS Codes: E02.3, E02.4, E02.5, E02.6)

Background: rhinoplasty is a surgical procedure performed on the nose to change its size or shape or both. People usually ask for this procedure to improve self image.

Policy: Rhinoplasty will only be funded in accordance with the criteria specified below.

- Problems caused by obstruction of the nasal airway;

OR

- Objective nasal deformity caused by trauma;

OR

- Correction of complex congenital conditions e.g. cleft lip and palate.

Surgery for primarily cosmetic reasons is not eligible for NHS funding- see p 6.

Tonsillectomy (OPCS Code: F34.-)

Background: Tonsillectomy is one of the most common surgical procedures in the UK. There is good evidence for the effectiveness of tonsillectomy in children but only limited evidence in adults.

Policy: Tonsillectomy will only be funded in accordance with the criteria specified below.

Patients must meet the criteria for one of the three groups

1. For recurrent severe sore throat in adults and children in the following circumstances:

   The sore throats are due to acute tonsillitis;

   AND

   The episodes of sore throat are disabling and prevent normal functioning

   AND

   Seven or more well documented, clinically significant, adequately treated episodes of sore throat in the previous year;

   OR

   Five or more such episodes have occurred in each of the preceding two years

   OR

   Three or more such episodes have occurred in each of the preceding three years.

OR

2. For management of Infective complications of tonsillitis such as quinsy

OR

3. For specific conditions and syndromes which require a tonsillectomy as part of their clinical management including severe tonsillar bleeding, severe neck infection

OR

4. For sleep disordered breathing (apnoea) in children if primary and secondary care assessments confirm large tonsils

   AND

   Impact on development, behaviour and quality of life.

References:

1. Commissioning Guide for tonsillectomy. Royal College of Surgeons and ENTUK. 2013 http://www.rcseng.ac.uk/providers-commissioners/nscc/docs/tonsillectomy-guide-out-for-consultation-17-may-5-july-2013- due to be published in August 2013

Apicectomy (OPCS Code: F12.1)

Background: Apicectomy is a surgical procedure involving the removal of infected tip of the root of a tooth and a small amount of surrounding bone and tissue. The success rate of apical surgery on molar teeth is low and should not be routinely undertaken. It is also sufficiently destructive that it may also compromise the chances of a subsequent dental prosthesis.

Policy: Apicectomy will only be funded in exceptional clinical circumstances based on the following criteria.

- presence of periradicular disease, with or without symptoms in a root filled tooth, where non surgical root canal re-treatment cannot be undertaken or has failed, or where conventional re-treatment may be detrimental to the retention of the tooth. For example, obliterated root canals, small teeth with full coverage restorations where conventional access may jeopardise the underlying core. It is recognised that non-surgical root canal treatment is the treatment of choice in most cases;

OR

- presence of periradicular disease in a tooth where iatrogenic or developmental anomalies prevent non surgical root canal treatment being undertaken;

OR

- where a biopsy of periradicular tissue is required;

OR

- where visualisation of the periradicular tissues and tooth root is required when perforation, root crack or fracture is suspected;

OR

- where procedures are required that require either tooth sectioning or root amputation;

OR

- where it may not be expedient to undertake prolonged non surgical root canal re-treatment because of patient considerations.

References

1. British Association Oral and Maxillofacial Surgeons. Referral guidelines. Apical surgery. Available at: http://www.baoms.org.uk/CD- ROM/guidelines/Apical%20surgery.pdf. Accessed 3rd October 2007.
2. Royal College of Surgeons of England. *Guidelines for surgical endodontics*. RCS 2001. Available at: http://www.rcseng.ac.uk/fds/clinical_guidelines/documents/surg_end_guideline.pdf [Accessed 1st Oct 2007]

Dental implants (OPCS Code: F11.5)

Background: An endosseous dental implant is a surgically implanted device which replaces the lost roots of a tooth and which can offer the possibility of a stable prosthesis for individuals who have suffered extensive loss of oral tissue. Osseointegrated dental implants have been shown to be a successful and predictable treatment for replacing missing teeth by providing support for fixed bridge prostheses, individual crowns, and overdentures. They are also useful to provide support for maxillofacial prostheses providing a functional dentition for patients with the severe disfiguring oral and dental

pathology that may result from developmental conditions, major trauma or following the resection of malignancies.

The technique relies on the principle of osseointegration. The titanium implants become integrated within the jaw bone giving the implant stability and permitting the attachment of prostheses to the implant(s).

Policy: Dental implants will only be funded in accordance to the criteria specified below.

Implants should be considered for NHS funding in the following groups, where there is no practical alternative and other alternatives have been demonstrably explored and excluded:

- Patients with maxillofacial and cranial defects.

OR

- Individuals with considerable amounts of missing hard tissue and/or teeth, which may result from developmental disorders or tumours. These include:
  - Clefts of the hard and / or soft palate
  - Major maxillary / mandibular resections
  - Extensive alveolar ridge deformities
  -
- Patients with anodontia (congenital absence of all teeth), or oligodontia (≥6 congenitally missing teeth).

OR

- Patients who have suffered major trauma

OR

- Dental implants would not normally be considered where there is significant risk of failure because of: tobacco smoking, misuse of drugs or alcohol, severe psychiatric problems, or medical conditions of the bone or bleeding disorders, poor oral hygiene, uncontrolled dental caries, untreated periodontal disease, bruxism or other parafunctional habits, participation in contact sports.

OR

- Dental implants are not suitable for those who are still growing.

References

1. NHS North East Criteria for Provision of Dental Implants. Sandra Whiston – SpR in Dental Public Health, November 2010.
2. The guidelines for selecting appropriate patients to receive treatment with dental implants: Priorities for the NHS. Faculty of Dental Surgery, National Clinical Guidelines, Royal College of Surgeons of England, 1997.
3. Dental Implants. Scottish Needs Assessment Report, 2004.
4. The SAC classification in implant dentistry. Dawson, A. et al. Ed.by A. Dawson and S. Chen. Quintessence Publishing Co., 2009.

Orthodontic treatments for essentially cosmetic nature (OPCS Codes: F14.-, F15.-)

Background: Orthodontic dentistry specialises in aligning crooked teeth. The treatment involves wearing braces. Quite often this treatment is undertaken for cosmetic reasons. The Index of Orthodontic Treatment Need (IOTN) is used to assess a patient's need for orthodontic treatment and the Peer Assessment Rating (PAR) to quantify the severity of a malocclusion both before and after treatment so that the quality of the outcome of treatment can be measured. The need for orthodontic treatment is evaluated both in terms of dental health and aesthetics. There are two components to the IOTN index:

- Dental health component (DHC)
- Aesthetic component (AC)

Policy: Orthodontic treatments for cosmetic reasons will only be funded in accordance with the criteria specified below.

NHS treatment will normally be limited to patients with

- A DHC of 4 or 5 (1 being no need for treatment and 5 being great need)

OR

- A DHC of 3 with an AC of 6 or more (the AC is based on a 10 point scale).

Surgery for primarily cosmetic reasons is not eligible for NHS funding- see p 8.

References

1. Brook PH, Shaw WC. The development of an index of orthodontic treatment priority. *European Journal Orthodontics* 1989; 11: 309-20.
2. Richmond S; Shaw WC; Stephens CD et al. Orthodontics in the general dental service of England and Wales: Critical assessment of standards. *Br Dent J* 1993; 174: 315.
3. Strategic Commissioning of Primary Care Orthodontic Services. Department of Health 2006 http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4139176

Cholecystectomy (for asymptomatic gall stones) (OPCS Code: J18.-)

Background: Cholecystectomy is the surgical removal of the gall bladder. Prophylactic cholecystectomy is not indicated in most patients with asymptomatic gallstones (Code: K80.2). Possible exceptions include patients who are at increased risk for gallbladder carcinoma or gallstone complications, in which prophylactic cholecystectomy or incidental cholecystectomy at the time of another abdominal operation can be considered. Although patients with diabetes mellitus may have an increased risk of complications, the magnitude of the risk does not warrant prophylactic cholecystectomy.

Policy: Cholecystectomy (for asymptomatic gall stones) will only be funded in exceptional clinical circumstances through an Individual Funding Request.

References:

1. Afdhal N. Approach to the patient with incidental gallstones. Webpage. [Cited 19th Sept 2007] *Up-To-Date.* Available at: http://patients.uptodate.com/topic.asp?file=biliaryt/8759

Varicose veins in the legs (OPCS Codes: L84.-, L85.-, L86.-, L87.-, L88.-)

Background

Varicose veins are dilated, often palpable subcutaneous veins with reversed blood flow. They are most commonly found in the legs. Estimates of the prevalence of varicose veins vary. Visible varicose veins in the lower limbs are estimated to affect at least a third of the population. Risk factors for developing varicose veins are unclear, although prevalence rises with age and they often develop during pregnancy.

In some people varicose veins are asymptomatic or cause only mild symptoms, but in others they cause pain, aching or itching and can have a significant effect on their quality of life. Varicose veins may become more severe over time and can lead to complications such as changes in skin pigmentation, bleeding or venous ulceration. It is not known which people will develop more severe disease but it is estimated that 3–6% of people who have varicose veins in their lifetime will develop venous ulcers.

Referral to a vascular service guidance[1]
Refer people with bleeding varicose veins to a vascular service[4] immediately.

Referral guidance: Refer people to a vascular service[1] if they have any of the following:

- History of bleeding from a varicosity and are at risk of bleeding again
- Ulceration which is progressive and/or painful despite treatment
- Active or healed ulceration and/or progressive skin changes that may benefit from surgery
- Recurrent superficial thombophlebitis
- Discomfort attributable to varicose veins having a severe impact on quality of life.

Assessment and treatment in a vascular service[1]

Assessment
Use duplex ultrasound to confirm the diagnosis of varicose veins and the extent of truncal reflux, and to plan treatment for people with suspected primary or recurrent varicose veins.

Interventional treatment
For people with confirmed varicose veins and truncal reflux:

- Offer endothermal ablation and Endovenous laser treatment of the long saphenous vein
- If endothermal ablation is unsuitable, offer ultrasound-guided foam sclerotherapy
- If ultrasound-guided foam sclerotherapy is unsuitable, offer surgery.

If incompetent varicose tributaries are to be treated, consider treating them at the same time.

Non-interventional treatment
Compression hosiery to treat varicose veins is not recommended unless interventional treatment is unsuitable for clinical reasons or patient choice.

Policy

Interventional treatments for varicose veins outlined above will only be funded in accordance with the criteria specified below.

- Persistent ulceration that is painful or progressive (ICD-10 Codes: I83.0, I83.2)

OR

- Recurrent superficial thombophlebitis (ICD-10 Codes: I83.1, I83.2) where there is significant pain and disability

OR

- Progressive skin changes that suggest potential ulceration due to venous insufficiency

OR

- Significant haemorrhage from a ruptured superficial varicosity

OR

- Patients with significant discomfort likely to be due to varicose veins

Uncomplicated varicose veins that are asymptomatic or cause only mild symptoms

[4]A team of healthcare professionals who have the skills to undertake a full clinical and duplex ultrasound assessment and provide a full range of treatment.

Patients whose primary concern is cosmetic will not be funded for surgical treatment. Surgery for primarily cosmetic reasons is not eligible for NHS funding - see page 10.

References

1. NICE Clinical Guidance (CG168) for Varicose Veins in the Legs, July 2013 (available at: http://publications.nice.org.uk/varicose-veins-in-the-legs-cg168)
2. NICE Interventional Procedure Guideline for Radiofrequency ablation of varicose veins (IPG8), September 2003 (available at: http://guidance.nice.org.uk/IPG8)
3. NICE Interventional Procedure Guideline for Endovenous laser treatment of the long saphenous vein (IPG52), March 2004 (available at: http://guidance.nice.org.uk/IPG52)
4. NICE Interventional Procedure Guideline for Ultrasound-guided foam sclerotherapy for varicose veins (IPG440), February 2013 (available at: http://guidance.nice.org.uk/IPG440)
5. NHS Clinical Knowledge Summaries http://www.cks.nhs.uk/varicose_veins#337903004
6. Recommendations for the referral and treatment of patients with lower limb chronic venous insufficiency (including varicose veins) Venous forum of the Royal Society of Medicine December 2010 http://www.rsm.ac.uk/academ/downloads/venous_referral_guidelines_jan11.pdf

Reversal of male sterilisation (OPCS Codes: N18.1)

Background: Reversal of male sterilisation is a surgical procedure that involves the reconstruction of the vas deferens.

Sterilisation procedure is available on the NHS and couples seeking sterilisation should be fully advised and counselled (in accordance with RCOG guidelines) that the procedure is intended to be permanent.

Policy: Reversal of sterilisation will not be routinely funded.

Reversal of female sterilisation (OPCS Codes: Q29.-, Q27.-)

Background: Reversal of sterilisation is a surgical procedure that involves the reconstruction of the fallopian tubes.

Sterilisation procedure is available on NHS and couples seeking sterilisation should be fully advised and counselled (in accordance with RCOG guidelines) that the procedure is intended to be permanent.

Policy: Reversal of sterilisation will not be routinely funded.

Circumcision (OPCS Code: N30.3)

Background: Circumcision is a surgical procedure that involves partial or complete removal of the foreskin of the penis. It is an effective procedure and confers benefit for a range of medical indications.

Policy: Circumcision will only be funded for specific medical reasons in accordance with the criteria specified below.

Medical reasons for funding circumcision include:

- Phimosis in children with spraying, ballooning and/or recurrent infection;

- Adult Phimosis;
- recurrent balantitis;
- Balanitis xertotica obliterans;
- Paraphimosis;
- Suspected malignancy;
- Dermatological disorders unresponsive to treatment;
- Congenital urological abnormalities when skin is required for grafting;
- Interference with normal sexual activity in adult males.

References:

1. Ehman AJ. Cut circumcision from list of routine services, Saskatchewan MDs advised. *CMAJ* 2002; 167:532. Available at: http://www.cmaj.ca/cgi/reprint/167/5/532-a [Accessed 19th Sept 2007]
2. Lerman SE, Liao J: Neonatal circumcision. *Paediatric Clinics of North America* 2001; 48: 1539-57
3. Rickwood AMK. Medical indications for circumcision. *British Journal Urology International* 1999; 83(Suppl): 45-51
4. Gatrad AR, Sheikh A, Jacks H. Religious circumcision and the Human Rights Act. *Archives Diseases Childhood* 2002; 86; 76-80
5. English Court of Appeal – Re J (Specific Issue Orders: Child's Religious Upbringing and Circumcision) *Journal of Law and Med* 2000; 9: 68 -75
6. Siegfried N, Muller M, Volmink J, Deeks J, Egger M, Low N, et al. Male circumcision for prevention of heterosexual acquisition of HIV in men. *Cochrane Database of Systematic Reviews* 2003, Issue 3. Available at: http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD003362/pdf_fs.html [Accessed 2nd Oct 2007]
7. Baillis SA, Halperin DT. Male circumcision: time to re-examine the evidence. *Student BMJ* 2006; 14: 179

Vaginoplasty, Labial Vulvoplasty and Vulvar lipoplasty (OPCS Codes: P21.3)

Surgery for Vaginoplasty, Labial Vulvoplasty and Vulvar lipoplasty are all cosmetic procedures. This policy does not cover vaginal repair following delivery and is part of obstetric or gynaecological treatment.

Surgery for primarily cosmetic reasons is not eligible for NHS funding- see p 8.

Policy: Vaginoplasty will not routinely be fundedo.

Hirsutism (OPCS Codes: S09.2.1, S60.6,)

Background: Laser treatment is increasingly being used as a cosmetic intervention to remove body hair. Patients with excessive body hair are described as having hirsutism. Hair depilation (for the management of hypertrichosis – code L68) involves permanent removal/reduction of hair from face, neck, legs, armpits and other areas of body usually for cosmetic reasons. Hair depilation is most effectively achieved by laser treatment.

Policy: Hair depilation will only be funded in accordance with the criteria specified below.

One course of treatment will be funded for those patients:

- Who are undergoing treatment for pilonidal sinuses to reduce recurrence,

OR

- For patients with excessive hair who have undergone reconstructive surgery leading to abnormally located hair-bearing skin*.*

Surgery for primarily cosmetic reasons is not eligible for NHS funding- see p 8.

Removal of tattoos (OPCS Codes: S60.1, S60.2, S60.3)

Background: A tattoo (ICD-10 Code: L81.8) is a mark made by inserting pigment into the skin. People choose to be tattooed for various cosmetic, social, and religious reasons. It carries certain health risks such as infection and allergic reaction. A tattoo can be removed by laser, surgical excision, or dermabrasion.

Policy: Tattoo removal will only be funded in accordance with the criteria specified below.

- Where the tattoo is the result of trauma, inflicted against the patient's will ("rape tattoo");

OR

- The patient was not Gillick competent, and therefore not responsible for their actions, at the time of the tattooing.

Surgery for primarily cosmetic reasons is not eligible for NHS funding- see p 8.

Resurfacing procedures: Dermabrasion, chemical peels and laser treatment (OPCS Codes: S60.1, S60.2, S09.-, S10.3, S11.3)

Background: dermabrasion, involves removing the top layer of the skin with an aim to make it look smoother and healthier. Scarring and permanent discolouration of skin are the rare complications.

Policy: Procedures requested for primarily cosmetic reasons are not eligible for NHS funding- see p 6. **Resurfacing procedures including dermabrasion, chemical peels and laser will only be funded in accordance with the criteria specified below.**

- **Post-traumatic scarring** (including post surgical) and **severe acne scarring** on the face and neck once the active disease is controlled.

OR

- **Capillary Haemangiomas (Port Wine Stains):** Laser treatment of capillary haemangiomas on the face and neck will be supported.

OR

- **Symptomatic Facial telangiectasia following rosacea** or severe rhinophyma will be supported, but only after confirmation of the diagnosis by an experienced dermatologist. Treatment for facial telangiectasia and vascular complications following other conditions will not be supported.

Abdominoplasty or Apronectomy (OPCS Codes: S02.1, S02.2)

Background: abdominoplasty (also known as tummy tuck) is a surgical procedure performed to remove excess fat and skin from mid and lower abdomen. Many people develop loose abdominal skin after pregnancy or substantial weight loss. However, surgery is not part of the usual response to these normal, physiological processes.

Policy: Abdominoplasty or Apronectomy will only be funded in accordance with the criteria specified below.

- Stable BMI between 18 and less than 27.0 Kg/m2

AND

- be suffering from severe functional problems that interfere with activities of daily living.

IN ADDITION the patient must fulfil **ONE** of the following criteria:

- Scarring following trauma or previous abdominal surgery;

OR

- Required as part of abdominal hernia correction or other abdominal wall surgery.

OR

- Correction of problems associated with poorly fitting stoma bags:

OR

- Those who are undergoing treatment for morbid obesity and have excessive abdominal skin folds. To fulfil this criteria the patient must also:
  - Have achieved a loss of 10 points in BMI scale

  AND
  - Have maintained their weight loss for at least 2 years from the date they have achieved the 10 point BMI loss.

Surgery for primarily cosmetic reasons is not eligible for NHS funding- see p 8.

Face lift or brow lift (OPCS Code: S01.-)

Background: these surgical procedures are performed to lift the loose skin of face and forehead to get firm and smoother appearance of the face. These procedures will not be funded to treat the natural processes of ageing.

Policy: Face lift or brow lift will only be funded in accordance with the criteria specified below.

These procedures will be considered for treatment of:

- Congenital facial abnormalities (Code: Q18) ;
- Facial palsy (congenital or acquired paralysis) (Code: G51.0);
- As part of the treatment of specific conditions affecting the facial skin eg. Cutis laxa, pseudoxanthoma elasticum, neurofibromatosis;
- To correct the consequences of trauma;
- To correct deformity following surgery;
- In some cases of impaired visual fields, where it may be a more appropriate primary procedure than blepharoplasty

Surgery for primarily cosmetic reasons is not eligible for NHS funding- see p 8.

Liposuction (OPCS Codes: S62.1, S62.2)

Background: Liposuction (also known as liposculpture), is a surgical procedure performed to improve body shape by removing unwanted fat from areas of the body such as abdomen, hips, thighs, calves, ankles, upper arms, chin, neck and back. Liposuction is sometimes done as an adjunct to other surgical procedures.

Policy: Liposuction simply to correct the distribution of fat will not normally be funded.

Removal of benign skin lesions including scars (OPCS Codes: S04.-, S05.-, S06.-, S09.-, S10.-, S11.-)

Background: benign skin lesions include wide range of skin disorders such as sebaceous cyst, dermoid cyst, skin tags, hirsutism, milia, molluscum contagiosum, seborrhoeic keratoses (basal cell papillomata), spider naevus (telangiectasia), warts, sebaceous cysts, xanthelasma, dermatofibromas, benign pigmented moles, comedones and corn/callous. Disfiguring scars and keloid whether arising from prior injury or surgery are also included in the scope of this policy.

Mostly these are removed on purely cosmetic grounds. The risks of surgical scarring must be balanced against the appearance of the lesion.

Policy: Removal of benign skin lesions will only be funded in accordance with the criteria specified below.

Patients with large, prominent lesions that cause significant facial disfigurement

lesions in other parts of the body where they interfere with the physical functioning of the, specifically:

- when the lesion becomes infected;

OR

- subjected to recurrent trauma.

This guidance covers benign skin lesions only.

Where the lump is rapidly growing or abnormally located, specialist assessment should be sought.

Surgery for primarily cosmetic reasons is not eligible for NHS funding- see p 8.

Removal of lipomata

Background: Lipomata (ICD-10 Codes: D17, E882) are benign tumours commonly found on the trunk and shoulder. These are removed mostly on cosmetic grounds. Patients with multiple subcutaneous lipomata may need a biopsy to exclude neurofibromatosis.

Policy: Removal of lipomata will only be funded accordance with criteria specified below.

- the lipoma (-ta) is / are symptomatic;

OR

- there is functional impairment.

OR

- for diagnostic purposes to exclude the possibility of malignancy

Surgery for primarily cosmetic reasons is not eligible for NHS funding- see p 8.

Thigh lift, buttock lift and arm lift, excision of redundant skin or fat (OPCS Code: S03.-)

Background: These surgical procedures are performed to remove loose skin or excess fat to reshape body contours. As the patient groups seeking such procedures are similar to those seeking abdominoplasty (see above), the functional disturbance of skin excess in these sites tends to be less and so surgery is less likely to be indicated except for appearance, in which case it should not be available on the NHS.

Policy: These procedures will only be funded accordance with criteria specified below.

If there is documented evidence of:

- significant interference with normal daily activities

OR

- intractable intertrigo.

AND

- a stable preoperative body mass index (BMI) of less than 27.0 kg/m^2

Surgery for primarily cosmetic reasons is not eligible for NHS funding- see p 8.

Hair grafting - Male pattern baldness and hair transplantation (OPCS Code: S33.-)

Background: male pattern baldness (ICD-10 Codes: L64.8, L64.9) is a common type of hair loss and for many men it is a normal process at whatever age it occurs. Almost all men have some baldness in their 60s. Hair grafting is mostly done for aesthetic reasons.

Policy: Hair grafting for male pattern baldness will not be funded. Hair transplantation will not normally be funded

Surgery for primarily cosmetic reasons is not eligible for NHS funding- see p 8.

Hyperhidrosis treatment with Botulinum Toxin (OPCS Code: S53.2)

Background: Hyperhidrosis (ICD-10 Code: R61) is a condition characterised by excessive sweating, and can be generalised or focal. Generalised hyperhidrosis involves the entire body, and is usually part of an underlying condition, most often an infectious, endocrine or neurological disorder. Focal hyperhidrosis is an idiopathic disorder of excessive sweating that mainly affects the axillas, the palms, the soles of the feet, armpits and the face of otherwise healthy people. The principal management strategies for hyperhidrosis are medical http://cks.nice.org.uk/hyperhidrosis#!scenario.

BTX-A is only licensed for the treatment of severe axillary hyperhidrosis and it's cost effectiveness compared to other treatment options is yet to be established.

Policy: Botulinum Toxin will only be funded in management severe *axillary* hyperhidrosis in accordance with the criteria below:

Search for an underlying cause has been exhausted

AND

Advice on lifestyle management has been followed (Use an antiperspirant frequently, Avoid tight clothing and manmade fabrics, wear white or black clothing to minimize the signs of sweating, consider dress shields to absorb excess sweat)

AND

20% aluminium chloride hexahydrate has failed or is contraindicated.

AND

Any underlying anxiety has been identified and managed

AND

In the opinion of an experienced determatologists, other treatment options ahve been exhausted

Ganglia (OPCS Code: T59.-, T60.-)

Background: Ganglia are benign fluid filled, firm and rubbery lumps attached to the adjacent underlying joint capsule, ligament, tendon or tendon sheath. They occur most commonly around the wrist, but also around fingers, ankles and the top of the foot. They are usually painless and completely harmless. Many resolve spontaneously especially in children (up to 80%). Reassurance should be the first therapeutic intervention. Aspiration alone can be successful but recurrence rates are up to 70%. Surgical excision is the most invasive therapy but recurrence rates up to 40% have been reported. Complications of surgical excision include scar sensitivity, joint stiffness and distal numbness.

Referral guidance

- Include reference to the degree of pain and restriction of normal activities caused by the ganglion.

Policy: Surgical treatment for ganglia will only be funded in accordance with the criteria specified below.

- The ganglia are symptomatic;

OR

- There is functional impairment.

References:

1. Vroon P, Weert , van HCPM, Scholten RJ. Interventions for ganglion cysts in adults. *Cochrane Database of Systematic Reviews* 2005, Issue 2. Available at: http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD005327/pdf_fs.html [Accessed 2nd Oct 2007]
2. FD Burke; Melikyan EY; Bradley MJ et al. Primary care referral protocol for wrist ganglia. *Postgraduate Medical Journal* 2003 79:329-331
3. Bandolier. Wrist ganglia. Webpage. [Cited 19th Sept 2007]. Available at: http://www.jr2.ox.ac.uk/bandolier/booth/miscellaneous/wristgang.html

Infertility Treatment

This policy describes the eligibility criteria for NHS funded infertility treatment including:

- In vitro fertilisation;
- Intracytoplasmic sperm injection;
- Intra-uterine insemination;
- Donor insemination;
- Follicle Stimulating Hormone.
- Ovulation induction using gonadotrophins

Background: The Clinical Guideline on *fertility assessment and treatment* was published by NICE in February 2013 (NICE CG156, 2013) and covers all clinical procedures/pathways relating to fertility assessment and treatment.

This document provides a single infertility specific commissioning policy for the NHS with the aim to ensure consistency in the application of the guideline across the North East region.

Over 80% of couples in the general population will conceive within 1 year if:

- the woman is aged under 40 years and
- they do not use contraception and have regular sexual intercourse (every 2 – 3 days).

Of those who do not conceive in the first year, about half will do so in the second year (cumulative pregnancy rate over 90%). [NICE 2004, amended 2013]

The estimated prevalence of infertility is one in seven couples in the UK. A typical Clinical Commissioning Group can expect about 230 new consultant referrals (couples) per 250,000 head of population per year (NICE CG11, 2004).

All couples are eligible for consultation and advice from the specialist service.

Definition of infertility:

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

Offer an earlier referral for specialist consultation to discuss the options for attempting conception, further assessment and appropriate treatment where:

- the woman is aged 36 years or over
- there is a known clinical cause of infertility or a history of predisposing factors for infertility.

The main causes of infertility in the UK are (% approximate prevalence)

- Unexplained infertility (25%)
- Ovulatory disorders (25%)
- Tubal damage (20%)
- Factors in the male causing infertility (30%)
- Uterine or peritoneal disorders (10%)
- In about 40% of cases disorders are found in both the man and the woman

Definition of a full cycle:

This term is used to define a full IVF treatment, which should include 1 episode of ovarian stimulation and the transfer of any resultant fresh and frozen embryo(s).

Policy: IVF treatment will be funded in accordance with the criteria specified below.

Ref	Eligibility criteria for treatment	Definition	Additional Notes
1.	**Female Age – under 40 years**	In women aged under 40 years who have not conceived after 2 years of regular unprotected intercourse or 12 cycles of artificial insemination using partner's sperm or 6 cycles of donor sperm (where six or more are by intrauterine insemination), offer 3 full cycles of IVF, with or without intracytoplasmic sperm injection (ICSI). If the woman reaches the age of 40 during treatment, complete the current full cycle but do not offer further full cycles. For people with unexplained infertility, mild endometriosis or 'mild male factor infertility', who are having regular unprotected sexual intercourse: do not routinely offer intrauterine insemination, either with or without ovarian stimulation (exceptional circumstances include, for example, when people have social, cultural or religious objections to IVF) advise them to try to conceive for a total of 2 years before IVF will be considered.	**3 full cycles of IVF** Inform people that normally a full cycle of IVF treatment, with or without ICSI should comprise 1 episode of ovarian stimulation and the transfer of any resultant fresh and frozen embryo(s) The age limit also applies to all treatments including those using gonadotrophins for fertility treatment including ovulation induction and for donor insemination. Access to three cycles is not an automatic right – the outcome of any previous cycle will be taken into account. Treatment must be medically indicated at the start of each cycle. As IVF success rates decline significantly after 3 cycles, previous cycles received irrespective as to whether they were funded by the NHS or privately will be taken into account. If patients have funded 3 or more IVF cycles privately they will not be entitled to any NHS funded cycles. If patients have funded 2 cycles privately they will be entitled to 1 NHS cycle. If patients have funded 1 cycle privately they will be entitled to

Ref	Eligibility criteria for treatment	Definition	Additional Notes
			2 NHS cycles
2.	**Female Age – 40 to 42 years**	In women aged 40–42 years who have not conceived after 2 years of regular unprotected intercourse or 12 cycles of artificial insemination using partner's sperm or 6 cycles of donor sperm (where 6 or more are by intrauterine insemination), offer 1 full cycle of IVF, with or without ICSI, provided all the following 4 criteria are fulfilled: • They have never previously had IVF treatment And • Evidence of good ovarian reserve as identified by specialist clinician And • There has been a discussion of the additional implications of IVF and pregnancy at this age And • Specialist clinical opinion that there is no likelihood of pregnancy with expectant management e.g. confirmed tubal blockage (absolute infertility)	**1 full cycle of IVF** (Including associated frozen/thaw transfers) provided that all other criteria are met. **Ovarian reserve testing** The aim is to select those with at least 10% chance of successful treatment. The criteria remain under review. At present use the following criteria to predict the likely ovarian response to gonadotrophin stimulation in women who are eligible for IVF treatment. - • total antral follicle count of more than or equal to 4 **and** • anti-Müllerian hormone of more than or equal to 5.4 pmol/l.
3.	**Minimum length of**	2 years of regular	Unexplained infertility is a

Ref	Eligibility criteria for treatment	Definition	Additional Notes
	unexplained infertility	unprotected intercourse and unexplained infertility at time of treatment.	diagnosis made by exclusion in couples who have not conceived and in whom standard investigations including semen analysis, tubal patency tests and assessment of ovulation have not detected any abnormality.
4.	**Female Body Mass Index (BMI)**	BMI greater than 19.0 and lower than or equal to 30.0 at the start of treatment. This applies to all treatments including those using gonadotrophins for fertility treatment including ovulation induction and for donor insemination.	This criterion reflects the increased efficacy of infertility treatment in this weight range. Women with a BMI of 30 or above should be informed that: • They are likely to take longer to conceive • If they are not ovulating then losing weight is likely to increase their chance of conception Women who have a BMI less than 19 and who have irregular menstruation or are not menstruating should be advised that increasing body weight is likely to improve their chance of conception
5.	**Male Body Mass Index (BMI)**	If the male partner has mild male factor infertility which, after clinical assessment could be improved should weight be reduced, then the male partner should be re-assessed for fertility once weight has reduced to a BMI of 30 or below	Men who have a BMI of 30 or over should be informed that they are likely to have reduced fertility
6.	**Existing children**	Treatment will only be offered to couples where neither partner has any living children from current or previous relationship	This criterion includes adopted children, but excludes fostered children.

Ref	Eligibility criteria for treatment	Definition	Additional Notes
		This applies to all treatments including those using gonadotrophins for fertility treatment including ovulation induction and for donor insemination.	
7.	**Smoking Status**	Both partners should be non-smokers when referred for IVF. This is part of primary care general assessment procedure. Assessment of smoking status will be through the use of carbon monoxide monitors in primary care or stop smoking services. This applies to all treatments including those using gonadotrophins for fertility treatment including ovulation induction and for donor insemination.	Women who smoke should be informed that this is likely to reduce their fertility Women who smoke should be offered a referral to a smoking cessation programme to support their efforts to stop smoking Women should be informed that passive smoking is likely to affect their chance of conceiving Men who smoke should be informed that there is an association between smoking and reduced semen quality
8.	**Same sex couples**	Treatment will only be offered where the partner wishing to become pregnant is sub-fertile Evidence for subfertility is either no live birth following donor insemination for up to six cycles over two years or absolute infertility documented after clinical investigation.	Treatment is offered to couples irrespective of sexual orientation. The NHS does not fund donor insemination to establish fertility in same sex couples.
9.	**Previous Sterilisation**	No previous sterilisation history in either partner. This applies to all treatments including those using gonadotrophins for fertility treatment including ovulation induction and induction of spermatogenesis, and for donor insemination.	

Ref	Eligibility criteria for treatment	Definition	Additional Notes
10.	**Length of time resident in catchment area**	Both partners should be patients registered for one year with a GP practice that is itself a member of one of the Clinical Commissioning Groups subscribing to these policies This applies to all treatments including those using gonadotrophins for fertility treatment including ovulation induction and for donor insemination.	This excludes short term students who are otherwise eligible for NHS treatment.
11.	**Residence in UK**	Must be eligible for free hospital treatment in line with the Overseas Visitors Charging Regulations. This applies to all treatments including those using gonadotrophins for fertility treatment including ovulation induction and for donor insemination.	

Additional background notes to accompany policy are available on request.

Abbreviations
IVF - In vitro fertilisation (IVF)
ICSI - Intracytoplasmic sperm injection
NICE - National Institute for Health and Clinical Excellence
BMI - Body Mass Index

Appendix 1. NICE Technology Appraisals and Clinical Guidelines

As at 10 October 2011

In the alphabetical order that they appear:

Included:

Elective interventions or procedures

Surgical interventions or devices

Excluded:

Pharmacological interventions

Guidance on management of chronic conditions in primary and secondary care (eg diabetes foot care or retinopathy)

Treatments for cancer or pre-malignant disease

Choice or timing of interventions or technologies by specialist teams (eg implantable cardiac defibrillators, ECT, stapled haemarrhoidopexy) this criterion probably applies to ALL TAs

Technology assessments

TA167 Abdominal aortic aneurysm - endovascular stent-grafts

TA73 Angina and myocardial infarction - myocardial perfusion scintigraphy

TA166 Hearing impairment - cochlear implants

TA44 Hip disease - metal on metal hip resurfacing

TA2 Hip disease - replacement prostheses

TA71 Ischaemic heart disease - coronary artery stents

TA78 Menstrual bleeding - fluid-filled thermal balloon and microwave endometrial ablation

TA159 Pain (chronic neuropathic or ischaemic) - spinal cord stimulation

TA139 Sleep apnoea - continuous positive airway pressure (CPAP)

TA1 Wisdom teeth - removal

Clinical guidelines

CG13 Caesarean section

CG85 Glaucoma

CG44 Heavy menstrual bleeding

CG30 Long-acting reversible contraception

CG88 Low back pain

CG97 Lower urinary tract symptoms

CG43 Obesity

CG31 Obsessive compulsive disorder (OCD) and body dysmorphic disorder (BDD)

CG59 Osteoarthritis

CG126 Stable angina

CG60 Surgical management of otitis media with effusion OME

CG40 Urinary incontinence

Appendix 2. Specialised Services Commissioning

Specialised cancer services (adult)
Specialised services for blood and marrow transplantation (all ages)
Specialised services for haemophilia and other related bleeding disorders (all ages)
Specialised services for women's health
Assessment and provision of equipment for people with complex physical disability
Specialised spinal services (all ages)
Specialised rehabilitation services for brain injury and complex disability (adult)
Specialised neurosciences services (adult)
Specialised burn care services (all ages)
Cystic fibrosis services (all ages)
Specialised renal services (adult)
Specialised intestinal failure and home parenteral nutrition services (adult)
Specialised cardiology and cardiac surgery services (adult)
Cleft lip and palate services (all ages)
Specialised immunology services (all ages)
Specialised allergy services (all ages)
Specialised services for infectious diseases (all ages)
Specialised services for liver, biliary and pancreatic medicine and surgery (adult)
Medical genetic services (all ages)
Specialised mental health services (all ages)
Specialised services for children
Specialised dermatology services (all ages)
Specialised rheumatology services (all ages)
Specialised endocrinology services (adult)
Specialised respiratory services (adult)
Specialised vascular services (adult)
Specialised pain management services (adult)
Specialised ear services (all ages)
Specialised colorectal services (adult)
Specialised orthopaedic services (adult)
Specialised morbid obesity services (all ages)
Specialised services for metabolic disorders (all ages)
Specialised ophthalmology services (adult)
Specialised haemoglobinopathy services (all ages)

Appendix 3. Guide for making referrals

This guide has been developed to assist clinicians answer questions in relation to individual funding requests (IFRs). At the end of this guide you will find quick links to qualifying criteria of individual policies contained within the Value based clinical commissioning Treatment Policies document.

FAQs (hyperlink to responses)

1. Why do we need policies?

NHS resources come under ever greater pressures each year. Ensuring that treatment and care is focused where it can make the biggest difference is a key part of making best use of these resources. This is a key challenge for all NHS organisations, and a prime focus for commissioning among CCGs. These policies help clinicians identify interventions with limited benefit, thereby providing potential for reinvesting elsewhere, where potential benefits are greater.

The alternative to having policies of this kind is to leave each decision to individual GPs, to manage individual dilemmas without guidance and without the context of the health needs of the wider population.

2. What do these policies cover?

These cover interventions where there is significant risk that patients undergoing them will gain little health benefit.

The procedures have low rather than no clinical value. Some may be effective, but may have low value because other (medical) treatments could be tried first. Other effective procedures may provide large benefits for some patients but less to those with few symptoms, where risks and benefits are closely balanced. There are interventions which are effective in some but give no clinical value in others. Finally, there are those interventions that whilst effective, are undertaken for primarily cosmetic reasons, which commissioners often consider as providing low clinical value.

3. Who are they for?

They are to assist GPs in making referral decisions, where the principal reason for referral is for surgical intervention.

They are also to assist providers of surgical services- a statement about what the NHS will pay for.

4. How has the list been compiled?

The list of procedures is a historical one, starting with declarations about plastic surgery and IVF, and have grown with greater understanding about health benefits from surgical intervention, publication of authoritative national guidelines and unexplained variations in clinical practice.

5. How have they been developed?

Every effort has been made to get an up to date view of practice. However, some will contain contentious criteria- for example among eligibility for plastic surgery and IVF.

We aim to take account of the most up to date clinical evidence, legal precedent and gain consensus before publication. A full review of these policies is currently underway, led by public health staff across the North East. And keeping these up to date will require significant ongoing efforts.

6. Do I need approval before referring for plastic surgery?

Where your patient meets the criteria in the policy, you can assume that NHS funding is available; authorisation is NOT required before referral is made. Some providers may still ask for confirmation of funding.

7. Can you give any general guidance about what is in the policies?

Here is some general advice about those policies which are most commonly referred to.

For procedures that are often carried out for cosmetic reasons: **breast surgery** (reduction or augmentation), **benign skin lesions or lipomata**, you should consider extent to which the individual deviates from the normal range, and the impact of any anomaly on activities of daily living.

Unhappiness is common experience among people wanting plastic surgery who do not receive NHS funding. This unhappiness is not, on its own, sufficient to make an individual exceptional.

Much **varicose vein surgery** undertaken in England is for cosmetic reasons, so you should also consider the impact on activities of daily living before referring.

For **IVF**- there is an age limit for starting treatment that is based on the probability of success. Treatment must start by the patient's 40th birthday. Please alert couples about the lead time to establish infertility (two years) and to undertake relevant investigation and medical treatment. Age and lack of understanding of the pathway are not exceptional reasons for access to IVF.

8. Is securing funding a guarantee of treatment?

Approval for NHS funding is NOT the same as a guarantee of treatment. Funding (the role of the commissioner for a whole population) is often requested before specialist assessment. However, the ultimate decision about safety and appropriateness of treatment is clinical one, which must be done with the patient.

9. What if funding is declined?

If there are individual circumstances to be considered, and the decision is to decline funding, you will be sent details of how to appeal.

10. Who tells the patient if funding is declined?

We will tell the referring clinician, who remains responsible for ongoing treatment and care. The correspondence lays out this responsibility, and any time scales for action.

11. What about treatments that have already started under private arrangements?

If treatments have already been started under private arrangements, the assumption is that a whole package of care has been purchased and its potential complications taken account of. Therefore, it would be unreasonable to expect the NHS to pick up the costs associated with private treatment unless there is a medical emergency, or some other exceptional circumstance. Running out of funds, whilst unfortunate, is not exceptional.

12. What if I have a patient whose needs are exceptional?

We welcome Individual Funding Requests- either for patients who are clearly different from the group of patients covered by the policy- or for those with very unusual conditions or clinical presentations. Please:

- check the policies (see list below),
- use the referral forms and guidance that are available on the CCG's website to indicate how your patient is exceptional.

13. What about psychological considerations?

Some CCGs have taken account of psychological factors in arriving at a decision about eligibility for NHS funding. But this is hard to do in a clear and fair way. These considerations have been removed from the current draft of these policies.

NICE guidance indicates that clinicians should consider the possibility of Body Dysmorphic Syndrome when making referral for plastic surgery (NICE Clinical Guideline 31).

14. Are photographs helpful?

Photographs are not used in consideration of exceptionality- and handling them presents significant risks of compromising confidentiality. Please do NOT submit photographs. Any photographs received will be returned to sender upon receipt.

15. What if GPs make referrals outside the criteria outlined these policies?

The implication is that there is no guarantee of payment, although the level of detail in these policies is not fully reflected in financial agreements with hospital providers.

16. What if surgeons undertake procedures outside the indications in these policies?

The implication is that there is no guarantee of payment, although legally binding contracts govern financial transactions.

17. Where can I find out more?

The National Prescribing Centre provide further guidance on this topic: http://www.npc.co.uk/faqs_ldm.php

If you have any questions or comments about these policies then contact one of the working group members. Contact details are in Appendix 1.