NHS North of Tyne

Clinical Governance

Policy No: NoT MD04

Individual Exceptional Treatment Requests Policies and Procedure

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Consultation Process:	See section 8
Mandatory/Statutory Standards or Requirements	

Contents

Individual Exceptional Treatment Requests

Section 1: Introduction

1.1 The following document sets out the procedure that needs to be followed in considering a request for individual treatment which is not usually funded by the PCO.

Section 2: Definitions

2.1 Exception – a particular case which falls within the application of a rule, but to which the rule is not applicable.

2.2 Exceptional – of the nature of or forming an exception; unusual or special.

2.3 General guidelines

2.3.1 When considering an individual case the PCO will expect to see evidence that demonstrates why those underlying reasons do not apply.

For example, where a healthcare intervention has not been commissioned because of concerns over its effectiveness, consideration will be given to evidence that shows that the benefit from the treatment for the individual patient would be significantly greater than would be expected for an average patient or for the defined cohort or patient population who may benefit.

2.3.2 By definition, 'exceptional' may not necessarily be predicted or spelled out in advance. However, where a cohort of patients can be identified with characteristics that suggest a greater capacity to benefit from a healthcare intervention than the usual population with the health care problem this cohort will be identified in the commissioning policy.

2.3.3 The fact that a patient's clinical features match 'accepted indications' for a treatment which is not normally provided is not, in itself, sufficient reason to deviate from the general policy.

2.3.4 The fact that the treatment is (or is likely to be) effective for a particular patient is not, in itself, sufficient reason to deviate from the general policy.

Section 3: The referral process

3.1 All requests for commissioning (funding) exceptional treatments or exceptional packages of care will be directed through one route.

3.2 A referral form (see appendix 1) must be completed by the GP or clinician responsible for the clinical care of a patient.

3.3 Requests received directly from patients will be referred back to the patient's GP/clinician who will be asked to complete the referral form accordingly.

3.4 The GP/clinician will be expected to complete the referral form having first consulted local policy statements or protocols which state the local and NHS views on whether funding for such treatment is likely to be supported. The PCOs have a number of exceptional treatment policies which have been approved by the Board. These are:

- breast enlargement and revision surgeries
- breast reduction surgery
- complementary therapies (ie acupuncture, aromatherapy, traditional chinese medicine, spinal manipulation therapies, homeopathy, hypnotherapy)
- cosmetic surgery (ie breast enlargement, breast reduction, gynaecomastia, mastopexy, surgery of head and face, abdominoplasty,

buttock lift, buttock reduction, cosmetic surgery of obesity, arm and thigh reductions, liposuction, tattoos

- cosmetic surgery following weight loss (ie arm and thigh reductions, apronectomy)
- electrolysis and laser treatment for hirsutism
- ENT (ie Insertion of grommets, tonsillectomy and adenoidectomy)
- infertility treatment
- circumcision
- orthopaedic surgery (ie carpal tunnel syndrome, dupytren's contracture, trigger finger, ganglion, therapeutic arthroscopy, bunionectomy, hammer toe surgery, spinal manipulation under anaesthesia (SMUA))
- sterilisation reversal
- varicose vein surgery

3.5 Any requests received that are not on the referral form will be returned to the GP/clinician who will be asked to complete the referral form.

3.6 The following information must be provided on the referral form:

Patient NHS Number

Patient's Name and Address

Referrer's name and contact details

Requested treatment with supportive evidence of:

- Scenario including diagnosis, brief history
- Personal exceptional needs
- Effectiveness of the treatment; and
- Cost and duration

3.7 This will ensure that the PCO receives all of the correct information needed to make a decision as quickly as possible. Referrers can also provide supporting letters with evidence of clinical need or exceptionality from other clinicians and health professionals involved in the patient's care, if this is relevant.

Section 4: Decision Making Process

4.1 Once a referral has been received it will be checked to ensure that all of the information required has been supplied.

4.2 All requests will be initially considered by a senior manager within the PCO. The senior manager will consider whether the request for funding meets the criteria set down for the individual treatment. Where there is no set criteria for a treatment, the case will be referred to the PCOs Medical Director for consideration.

4.3 All decisions will be documented on the Individual Assessments Consideration Form (see Appendix 2). In some cases, the Medical Director may feel that the request needs further consideration. In these circumstances, the case will be referred to the 'Individual Assessment' panel for consideration.

4.4 Once a decision has been reached, a letter will be sent to the GP/Clinician (a copy of which will also be sent to the patient) advising them of the decision and outlining reasons why the request has been refused (if applicable). If a referral is made to the 'Individual Assessment' panel, the GP/clinician will be advised of this and notified when the panel will be meeting to consider the case. Once the panel have met to consider the case, the GP/clinician will be advised of the outcome. All decisions of the panel will be documented on the Individual Assessment Panel Outcome Form (see Appendix 3).

4.5 If the panel decide that the circumstances are not exceptional and therefore will not be funded, the GP/clinician has the right to refer the case to the Appeals Panel. Details on how to do this will be included in the letter of response.

Section 5: The Individual Assessment Panel

5.1 The Individual Assessment Panel meet on a monthly basis.

5.2 Each request is considered on a case by case basis.

5.3 The following outline is a guide to material that might be appropriate for the panel to consider. Where this is appropriate, the Medical Director will provide relevant information:

5.3.1 Background

- The patient's health problems and circumstances of the case
- Previous treatment, funding, promises and patient expectations
- The proposed treatment and provider details
- Why this case is being brought to the Panel

5.3.2 Clinical assessment

- Opinion of General Practitioner
- NHS consultant or other specialist opinion
- Exceptional clinical features which distinguish the patient's condition from other patients with a similar illness

5.3.3 Treatment options

- What are the range of treatment options appropriate to the patient's clinical need?
- Have any of the treatment options been tried and failed?
- Which of the treatment options have the best safety profiles?
- Which carry the highest risks of complications or possible harmful effects?
- Are any of the treatment options experimental and if so, has the patient been informed?

5.3.4 Health gain

- How effective is the treatment of choice – i.e. is it of proven benefit?

- Is the treatment equally effective across all patient groups?
- Given the patient's clinical history and defined medical condition, what is the nature and extent of the likely health gain?
- Does the likely clinical benefit outweigh treatment risks?

5.3.5 Clinical governance

- Has the treatment been requested from a provider with an established reputation for safety, audit and clinical governance, i.e., is the provider competent and does it command the confidence of NHS clinicians?

5.3.6 Commissioning policy and priorities

- Relevant PCO commissioning policy and priorities
- Relevant NHS policy guidance and priorities.

5.3.7 Using NHS resources wisely

- What are the range and location of local services, relevant to patient's clinical needs, available within existing SLAs?
- Are there equally effective but less costly interventions available?
- Are there comparable but less costly providers available?
- Are adequate financial resources available to proceed with an affirmative funding decision?

5.3.8 Equity

- What precedence for funding is there?
- Would the decision to fund the proposed treatment set a precedent? If not, what are the special circumstances or exceptional clinical needs of this particular case?

5.3.9 The Decision

- Is the treatment request reasonable?
- Has all material of significant relevance to the case been considered?

- Is the decision reasonable in the context of cost, local service provision, anticipated health gain, national and local clinical priorities and impact on other health care programmes?
- Does the medico-legal position require further exploration

5.4 The outcome of the Individual Assessment Panel will be relayed to the GP/Clinician in writing.

5.5 Membership of the Individual Assessment Panel

Non-executive Director of the PCO

Clinical Member of PEC

Director of Public Health

NB The Medical Director or Deputy Medical Director to provide advice and support to the Panel

Section 6: The Appeals Panel

6.1 The Appeals Panel will consider whether the correct process has been followed in assessing individual cases.

6.2 The Appeals Panel will meet on an as and when basis.

6.3 The Appeals Panel will consider all aspects of the individual case and decide whether due process has been followed. They do not have the power to overturn the decision of the Individual Assessment Panel. However, if the appeals panel feel that a referral has not been considered through the correct process they can refer the case back to the Individual Assessment Panel for further consideration.

6.4 The outcome of the Appeals Panel will be relayed to the GP/Clinician in writing.

6.5 Membership of the appeals panel

Non-executive Director or Chair of PCO

Director of Public Health

Clinical Member of PEC

NB these members will be different to those that sit on the Individual Assessment Panel.

Section 7: Re-referrals

7.1 The GP/clinician can only re-refer the same patient for the same treatment if the circumstances of the patient have changed. Any requests received that are identical to the original request will not be considered and the GP/clinician will be advised accordingly.

Referral Form for Exceptional Treatment

To be completed by the GP/Clinician responsible for the clinical care of the patient

Section A – Patient Details

NHS Number	
Full Name	
Address	

Section B – Clinicians Details

Full Name	
Address	
Telephone Number	

Section C – Referral Details

Treatment required	
Treatment provider	
Provisional costs of treatment	
Duration of treatment (if known)	

Section D – Supporting Evidence

Please specify below the reasons for making this application and attach any relevant information in support of this application (please continue on separate sheet if necessary)

Signed : _____

Dated : _____

Form should be returned to: Corporate Affairs, NHS North of Tyne, Bevan House, 1 Esh Plaza, Sir Bobby Robson Way, Great Park, Newcastle upon Tyne, NE13 9BA Fax: 0191 217 2701

Exceptional Treatment Policy

Individual Assessments - Consideration Form

To be completed by the senior manager within the PCO

NHS Number										
Full Name										
PCO:	Northumberland									
	North Tyneside									
	Newcastle									
Surgery Requested:										
Criteria	**Guidance**									
Comments										

Recommendation		
Further Info needed:	YES	Date:
Details:		
Approved	YES	Date:
Rejected	YES	Date:
Refer to Stage 1 Panel	YES	Date:
Signature		

Individual Assessment Panel - Outcome Form

To be completed by the Chair of the Individual Assessment Panel

Section A – Patient Details

NHS Number	
Full Name	

Section B – Panel Members

Name	Job Title

Section C – Consideration of Referral

Please enter information on discussions in considering this request

Are there any exceptional clinical circumstances to support this application?

Section D – Decision of Panel

Decision to Fund	Yes/No
Reasons for refusal (if applicable)	

Signed : _____ (chair of panel)

Dated : _____

Appeals Panel - Review Form

To be completed by the Chair of the Appeals Panel

Section A – Patient Details

NHS Number	
Full Name	

Section B – Panel Members

Name	Job Title

Section C – Review of Case

Referral form completed	Yes/No
Individual requests consideration form completed	Yes/No
GP/Clinician advised of decision in writing with reasons for refusal (if appropriate)	Yes/No
Individual Requests Panel outcome form completed	Yes/No
GP/Clinician advised of decision of the Individual Requests Panel	Yes/No

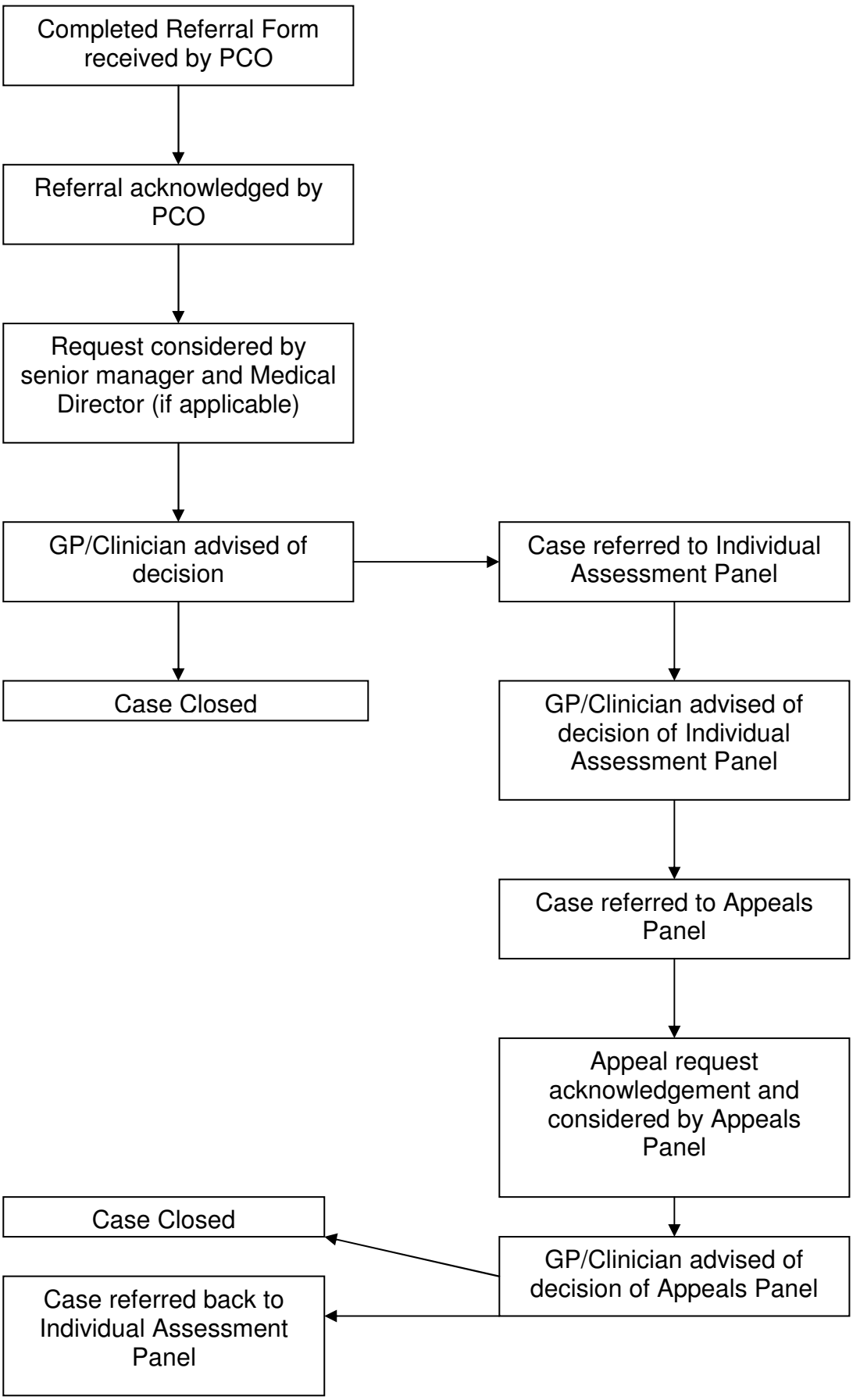
Section D – Comments

The panel is asked to comment on the way the request has been processed

Signed : _____ (chair of panel)

Dated : _____

Flowchart of Process for Individual Exceptional Treatments



NHS NE EXCEPTIONAL TREATMENT POLICIES

The following document is a commissioning guide which lists the interventions that the primary care organizations in the NHS NE would not normally fund. It is backed by the evidence base which supports the policies and this can be found in the appendix at the back.

The document is an amended and locally customized form of the National Public Health Service of Wales publication and we are grateful for being allowed to build on their work.

The strategic aim of the document is to achieve

- **Consistency of decision making across the NHS NE**
- **Decisions supported by an evidence base**
- **Each organization will continue to run its own exceptional treatment application process but will use the policies in this document to support decision making**

The content of the document will be subject to regular review within the NHS NE as policies and the evidence base changes

Table 1 Grading of recommendations

Hierarchy of evidence		Grading of recommendations	
Level	**Type of evidence**	**Level**	**Type of evidence**
Ia	Evidence from systematic reviews or meta analysis of randomised controlled trials	**A**	Based on hierarchy I evidence
Ib	Evidence from at least one randomised controlled trial		
IIa	Evidence from at least one controlled study without randomisation	**B**	Based on hierarchy II evidence or extrapolated from hierarchy I evidence
IIb	Evidence from at least one other type of quasi experimental study		
III	Evidence from non experimental descriptive studies, such as comparative studies, correlation studies and case control studies	**C**	Based on hierarchy III evidence or extrapolated from hierarchy I or II evidence
IV	Evidence from expert committee reports or opinions and/or clinical experience of respected authorities	**D**	Directly based on hierarchy IV evidence or extrapolated from hierarchy I, II or III evidence
NICE	Evidence from NICE guidelines or Health Technology Appraisal programme	**NICE**	Evidence from NICE guidelines or Health Technology Appraisal programme
HSC	Evidence from Health Service Circulars	**HSC**	Evidence from Health Service Circulars

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44	Removal of asymptomatic wisdom teeth
45	Autologous cartilage transplantation
46	Complementary and alternative medicine (CAM) for acute low back pain
47	Hip prostheses
48	Hip resurfacing techniques
49	Internal fixation of fracture of the distal radius and tibial shaft
50	Intramedullary fixation with cephaloconddylic nail for extra-capsular hip fractures
51	Therapeutic use of ultrasound
52	Drug treatment for erectile dysfunction
53	Reversal of male sterilisation

1. 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. The aim of abdominoplasty is to get a firm and flatter abdomen.

Advice: Evidence (grade D) indicates that Abdominoplasty or Apronectomy may only be funded in accordance with the guidance specified below.

Guidance

Abdominoplasty and apronectomy may be offered to the following groups of patients who should have achieved a stable BMI between 18 and 27 Kg/m^2 and be suffering from severe functional problems:

- Those with scarring following trauma or previous abdominal surgery
- Those who are undergoing treatment for morbid obesity and have excessive abdominal skin folds
- Previously obese patients who have achieved significant weight loss and have maintained their weight loss for at least two years
- Where it is required as part of abdominal hernia correction or other abdominal wall surgery

2. 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.

Advice: Evidence (grade D) indicates that blepharoplasty may only be funded in accordance with the guidance specified below.

Guidance

For those who have:

- 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

3. 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 is an effective intervention but should only be available on the NHS in exceptional circumstances.

Advice: Evidence (grade D) indicates that breast augmentation may only be funded in accordance with the guidance specified below.

Guidance

Exception should be made for women:

- with an absence of breast tissue unilaterally or bilaterally
- with of a significant degree of asymmetry of breast shape and/or of more than two or more cup sizes caused by a pathological and not a physiological problem.

4. 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. It is an effective intervention but should be available on NHS in exceptional circumstances.

Advice: Evidence (grade D) indicates that breast reduction may only be funded in accordance with the guidance specified below.

Guidance

Exception should be made for women if the following criteria are met:

- The patient is suffering from neck ache, backache and/or intertrigo
- The wearing of a professionally fitted brassiere has not relieved the symptoms
- The patient has a body mass index (BMI) of less than 30 kg/m2

5. 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 given age of the implant is over.

Advice: Evidence (grade D) indicates that breast prosthesis removal or replacement may only be funded in accordance with the guidance specified below.

Guidance

- 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.

6. 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.

Advice: Evidence (grade D) indicates that face lift or brow lift may only be funded in accordance with the guidance specified below.

Guidance

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 e.g. cutis laxa, pseudoxanthoma elasticum, neurofibromatosis
- To correct the consequences of trauma
- To correct deformity following surgery
- They will not be available to treat the natural processes of ageing

7. 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 and cimetidine etc. could be the primary cause. Surgical removal of excess skin, fat and glandular tissue (mastectomy) is an effective intervention.

Advice: Evidence (grade D) indicates that surgery to correct gynaecomastia may only be funded in accordance with the guidance specified below.

Guidance

Surgery to correct gynaecomastia is allowable if the patient is:

- Post pubertal and of normal BMI (<= 25 Kg/m^2)

There should be a pathway established to ensure that appropriate screening for endocrinological and drug related causes and/or psychological distress occurs prior to consultation with a plastic surgeon.

8. Hair depilation

Background: 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. It is usually achieved by electrolysis or laser therapy.

Advice: Evidence (grade D) indicates that hair depilation may only be funded in accordance with the guidance specified below.

Guidance:

For those patients who:

- Have undergone reconstructive surgery leading to abnormally located hair-bearing skin
- have a proven underlying endocrine disturbance resulting in hirsutism (e.g. polycystic ovary syndrome)
- Are undergoing treatment for pilonidal sinuses to reduce recurrence
- Have hirsutism leading to significant psychological impairment – psychological impairment will be assessed after an exceptional clinical circumstances application

9. Hair grafting - Male pattern baldness (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.

Advice: Funding hair grafting for male pattern baldness may not be considered (evidence grade D).

10. 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.

There are a number of treatments available for focal hyperhidrosis:

- First line treatment usually comprise of aluminium chloride-based topical treatments e.g. Aluminium salts are the most common ingredient in over-the-counter antiperspirants

- Second line treatment could be Iontophoresis, which is primarily used for the hands and feet (the easiest parts of the body to submerge), this procedure entails placing the hands or feet in a shallow basin of water, through which electric current is passed

- Botulinum Toxin: BTX-A is the best-studied treatment to date for focal hyperhidrosis. When used to treat focal hyperhidrosis BTX-A is injected intradermally, and acts to inhibit the release of acetylcholine at the presynaptic nerve endings of the motor endplates, so excessive sweating is reduced.

  Hyperhidrosis treatment with botulinum toxin has a good safety profile and is an effective treatment option of focal hyperhidrosis, especially when other treatment options have proven ineffective. BTX-A is reported to produces high levels of patient satisfaction. However, the effectiveness is of limited duration and repetitive treatments are necessary.

  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.

- Surgical treatments, such as endoscopic thoracic sympathectomy

- The role of alternative and systemic treatments in focal hyperhidrosis remains to be established

Advice: Evidence (grade D) indicates that treatment with Botulinum Toxin may only be funded in management severe axillary hyperhidrosis provided the first line treatment has failed or is contraindicated.

11. 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.

Advice: Evidence (grade D) indicates that surgery for correction of inverted nipple may only be funded in accordance with the guidance specified below.

Guidance

- Surgical correction of nipple inversion should only be available for functional reasons in a post-pubertal woman and if the inversion has not been corrected by correct use of a non-invasive suction device.

12. 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.

Advice: liposuction simply to correct the distribution of fat may not be funded (Evidence grade D).

13. 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. Mastopexy is an effective surgical procedure to raise and reshape breasts.

Advice: Evidence (grade D) indicates that mastopexy may only be funded in accordance with the guidance specified below.

Guidance

- This is included as part of the treatment of breast asymmetry and reduction (see above) but not for purely cosmetic/aesthetic purposes such as postlactational ptosis. So criteria for breast reduction should be met to qualify for mastopexy.

14. 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.

Advice: Evidence (grade D) indicates that pinnaplasty may only be funded in accordance with the guidance specified below.

Guidance

- The patient must be under the age of 19 years at the time of referral
- Patients seeking pinnaplasty should be seen by a plastic surgeon and following assessment, if there is any concern, assessed by a psychologist.
- Patients under 5 years of age will not be considered for this procedure

15. 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, religious and magical reasons. It carries certain health risks such as infection and allergic reaction. A tattoo can be removed by laser, surgical excision, or dermabrasion.

Advice: Evidence (grade D) indicates that tattoo removal may only be funded in accordance with the guidance specified below.

Guidance

- Where the tattoo is the result of trauma, inflicted against the patient's will ("rape tattoo")
- The patient was not Gillick competent, and therefore not responsible for their actions, at the time of the tattooing.
- When the application has been taken through executive clinical cases process on the application of a clinician. Exceptions may also be made for tattoos inflicted under duress during adolescence or disturbed periods where it is considered that psychological rehabilitation, break up of family units or prolonged unemployment could be avoided, given the treatment opportunity.

16. Removal of benign skin lesions (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. Mostly these are removed on purely cosmetic grounds. Patients with moderate to large lesions that cause actual facial disfigurement may benefit from surgical excision. The risks of scarring must be balanced against the appearance of the lesion.

Advice: Evidence (grade D) indicates that removal of benign skin lesions may only be funded in accordance with the guidance specified below.

Guidance

- Benign lesion becomes Infected
- Interferes with physical functioning of the body
- if located on a site where they are subjected to recurrent trauma

17. 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.

Advice: Evidence (grade D) indicates that removal of lipomata may only be funded accordance with guidance specified below.

Guidance

Lipomata of any size should be considered for treatment by the NHS in the following circumstances:

- The lipoma (-ta) is / are symptomatic
- There is functional impairment
- The lump is rapidly growing or abnormally located (e.g. sub-fascial, submuscular)

18. 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.

Advice: Evidence (grade D) indicates that repair of lobe of external ear may only be funded in accordance with the guidance specified below.

Guidance

For those who:

- Have totally split ear lobes as a result of direct trauma for the acute episode only

19. 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.

Advice: Evidence (grade D) indicates that resurfacing procedures including dermabrasion, chemical peels and laser may only be funded in accordance with the guidance specified below.

Guidance:

For those with post-traumatic scarring (including post surgical) and severe acne scarring once the active disease is controlled.

20. 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.

Advice: Evidence (grade D) indicates that revision mammoplasty may only be funded in accordance with the guidance specified below.

Guidance

- 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.

21. 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.

Advice: Evidence (grade D) indicates that rhinoplasty may only be funded in accordance with the guidance specified below.

Guidance

- Problems caused by obstruction of the nasal airway
- Objective nasal deformity caused by trauma
- Correction of complex congenital conditions e.g. Cleft lip and palate

22. 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.

Advice: As these procedures are mostly done for aesthetic reasons so may not be funded (Evidence grade D), unless there is documented evidence of interference with activities of daily living or intractable intertigo.

References (interventions 1 – 22)

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23. Grommet insertion (OPCS Code: D15.1)

Background: Grommets are small tubes that are put inside children's ears to help drain away sticky fluid that is trapped there and to their hearing. Evidence suggests that the benefit of grommets on children's hearing gradually decreases in first year of insertion. Potentially adverse effects on the tympanic membrane (e.g. tympanosclerosis) are common after grommet insertion. One review found that grommets did not significantly improve cognition, language comprehension or expression compared with no ventilation tubes.

Advice: Evidence (grade A) of insufficient clinical effectiveness of grommet insertion indicates that it may only be funded in accordance with the guidance specified below.

Guidance

Grommets should only be considered if glue ear persists, and the child also suffers from one of the followings:

1. Recurrent acute otitis media with more than 5 episodes per year.

2. Delay in speech development

3. Educational problem

4. Behavioural problem

5. A second disability, such as Down's syndrome

6. Severe collapse of the eardrum

Children with hearing impairment should have a period of at least 3 months of watchful waiting from the onset of the symptoms. Patients and parents should be advised of the risk of potential harm e.g. tympanosclerosis.

References

1. Lous J, Burton MJ, Felding JU, Ovesen T, Rovers MM, Williamson I. Grommets (ventilation tubes) for hearing loss associated with otitis media with effusion in children. *Cochrane Database of Systematic Reviews* 2005, Issue 1. Available at: http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD001801/pdf_fs.html [Accessed 2nd Oct 2007]
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24. Tonsillectomy (OPCS Code: F34.-)

Background: Tonsillectomy is one of the most frequently performed surgical procedures in the UK. There is no high quality evidence in adults for the effectiveness of tonsillectomy. Any benefits from tonsillectomy may be outweighed by the morbidity associated with surgery in children who are not severely affected by tonsillitis.

Advice: Insufficient evidence of clinical effectiveness of tonsillectomy indicates that it may only be funded in accordance with the guidance specified below (Evidence grade D).

Guidance

Patients (both adult* and children) should meet **all** of the following criteria for consideration of tonsillectomy:

1. sore throats are due to tonsillitis
2. five or more episodes of sore throat per year
3. symptoms for at least a year
4. the episodes of sore throat are disabling and prevent normal functioning

A six-month period of watchful waiting by an ENT surgeon is recommended prior to tonsillectomy to establish firmly the pattern of symptoms and allow the patient to consider fully the implications of the operation.

Once a decision is made for tonsillectomy, this should be performed as soon as possible, to maximise the period of benefit before natural resolution of symptoms might occur.

*Consensus statement (NSAG – ENT surgeons): a fixed numerical number of attacks may not be appropriate for adults with particularly severe episodes tonsillitis causing severe morbidity. So that particular criterion (No. 2) should not apply to adults.

References

1. McKerrow W. Tonsillitis. Tonsillectomy versus antibiotics in children. *BMJ Clinical Evidence* 2006. Available at: http://clinicalevidence.bmj.com/ceweb/about/index.jsp [Accessed 19th Sept 2007]
2. Royal College of Paediatrics and Child Health. *Guidelines for good practice. Management of acute and recurring sore throat and indications for tonsillectomy*. London: RCPCH; 2000
3. Scottish Intercollegiate Guidance Network. *Management of sore throat and indications for tonsillectomy.* Edinburgh: SIGN; 1999. Available at: http://www.sign.ac.uk/guidelines/fulltext/34/index.html [Accessed 19th Sept 2007]
4. National Specialist Advisory Group (NSAG) of ENT Surgeons of Wales. (e-mail communication)

25. 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

Advice: Insufficient evidence of clinical effectiveness of Cholecystectomy (for asymptomatic gall stones) indicates that it may only be funded in accordance with the guidance specified below (Evidence grade D).

Guidance

We will consider on the application of a clinician exceptional clinical circumstances to this rule.

References

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

26. 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. Sometimes it is requested on cultural, social and religious reasons. These non medical circumcisions do not confer any health gain but do carry measurable health risk.

Advice: Evidence (grade D) indicates that circumcision may only be funded for specific medical reasons (subject to specialist surgical assessment and advice) **in accordance with the guidance specified below.**

Guidance

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

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27. Day case elective surgery versus inpatient surgery

Background: There are many publications concerning the performance of day case surgery in Wales. **One of the Department of Health's '10 High Impact Changes' is the recommendation that day case surgery should be the preferred form of elective surgery.**

Service users reportedly like day surgery and there is evidence that day surgery may reduce the overall cost of hospital care. One UK trial found that day surgery for general surgical emergencies was as effective as inpatient care. GPs and service users were equally satisfied with day surgery and day surgery saved about £150 per person compared with inpatient care. Day surgery has also been found to be cost-effective for e.g. cataracts, haemorrhoidectomy, hernia and cholecystectomy. One trial in Canada found however, that whilst day surgery reduced costs and had similar clinical outcomes to inpatient surgery, service users reported a preference for an overnight stay.

A postal survey of 785 patients found that on the day of surgery, more patients undergoing laparoscopic sterilization experienced severe pain. By the third postoperative day, more of those who had been operated on for hernia repair, followed by varicose vein surgery and laparoscopic sterilization, continued to experience severe pain.

Advice: Commissioners may fund day case elective surgery in accordance with local circumstances and facilities available (Evidence grade D).

References

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10. Pineault R, Contandriopoulos AP, Valois M et al. Randomized clinical trial of one-day surgery. Patient satisfaction, clinical outcomes, and costs. *Medical Care* 1985; 23: 171-82.
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28. Ganglia (OPCS Code: T59.-, T60.-)

Background: Ganglia are benign fluid filled, firm and rubbery in texture lumps. 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.

Advice: Evidence (grade A) of insufficient clinical effectiveness of invasive surgery for ganglia indicates that it may only be funded in accordance with the guidance specified below.

Guidance

Surgery for ganglia will only be funded if the ganglion is very painful and restricts work and hobbies (subject to specialist surgical assessment and advice).

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]
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29. Gastroplasty (OPCS Code: G30.-)

Background: Gastroplasty is a surgical procedure performed to decrease the size of the stomach. This procedure is mainly used to treat morbid obesity. Commonly performed gastroplasty procedures include vertical (mesh) banded gastroplasty, silicone elastomer ring vertical gastroplasty and horizontal banded gastroplasty.

Evidence suggests that bariatric surgery (vertical banded gastroplasty, gastric bypass, or gastric banding) increased weight loss compared with non-surgical treatment (low calorie diet or usual care) in morbidly obese adults. Two systematic reviews found that vertical banded gastroplasty is effective in promoting clinically important weight loss in morbidly obese adults. However, there is insufficient evidence to draw conclusions about the relative benefits and harms of vertical banded gastroplasty compared with gastric banding or gastric bypass.

Advice: Evidence (NICE) indicates that gastroplasty may only be funded in accordance with the guidance specified below.

Guidance

NICE guidance states that surgery should be considered for children and young people only in exceptional circumstances, and if:

- they have achieved or nearly achieved physiological maturity
- they have a BMI of 40 kg/m^2 or more, or between 35 kg/m^2 and 40 kg/m^2 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
- they are generally fit for anaesthesia and surgery
- they commit to the need for long-term follow-up

Surgery should be considered as a first-line option for adults with a BMI of more than 50 kg/m^2 in whom surgical intervention is considered appropriate; consider orlistat or sibutramine before surgery if the waiting time is long.

References

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2. National Institute for Health and Clinical Excellence. *Obesity. Guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children*. London: NICE; 2006. Available at: http://www.nice.org.uk/guidance/CG43 [Accessed 19th Sept 2007]

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30. Gender reassignment surgery (OPCS Code: X15.1, X15.2)

Background: Gender reassignment surgery is usually performed for non medical reasons. Evidence suggests that the degree of uncertainty about any of the effects of gender reassignment is such that it is impossible to make a judgement about whether the procedure is clinically effective.

Advice: Evidence (grade D) of insufficient clinical effectiveness of gender reassignment surgery indicates that it may not be funded.

1. **Pending outcome of the regional group looking into these criteria we would advise local precedents are followed**

2. **When the regional group advises what is in a gender reassignment package we will adjust these criteria**

References

1. Aggressive Research Intelligence Facility. Gender reassignment surgery. Webpage. [Cited 19th Sept 2007] Available at: http://www.arif.bham.ac.uk/requests/g/genderreass.htm

31 Haemorrhoidectomy (OPCS Codes: H51.-, H52.-)

Background: Haemorrhoids (ICD-10 Code: 184), also known as piles, are enlarged and swollen blood vessels in or around the lower rectum and anus. They can occur at any age and affect both sexes. They get worse overtime and should be treated as soon as they occur.

First and second degree haemorrhoids are classically treated with some form of non-surgical ablative/fixative intervention, third degree ones are treated with rubber band ligation or haemorrhoidectomy, and fourth degree with haemorrhoidectomy.

Advice: Evidence indicates that haemorrhoidectomy may only be funded in accordance with the guidance specified below (Evidence grade D).

Guidance

Haemorrhoidectomy should be considered only in case of:

- Recurrent haemorrhoids
- Persistent bleeding
- Failed conservative treatment

References

1. Davies RJ. Haemorrhoids. *BMJ Clinical Evidence.* 2006. Available at: http://clinicalevidence.bmj.com/ceweb/about/index.jsp [Accessed 19th Sept 2007]
2. Brisinda G. How to treat haemorrhoids. *BMJ* 2000; 321: 582-3

32. Laparoscopic surgery for repair of primary inguinal hernia (OPCS Code: T20.- , Subsidiary code Y75.2)

Background: An inguinal hernia (ICD-10 Code: K40) is a protrusion of sac of peritoneum (often containing intestine or other abdominal contents) into the groin through a weakness or tear in the abdominal wall. Treatment options include open surgical repair and laparoscopic surgery.

NICE guidance states that laparoscopic surgery is one of the treatment options for the repair of inguinal hernia. Patients should be fully informed of all the risks and benefits of open and laparoscopic surgery by either the transabdominal preperitoneal (TAPP) or the totally extraperitoneal (TEP) approaches, to enable them to choose between the procedures.

Advice: Evidence (NICE) indicates that laparoscopic surgery for repair of primary inguinal hernia may only be funded in accordance with NICE guidance.

References

1. National Institute for Health and Clinical Excellence. *Hernia – laparoscopic surgery review*. London: NICE; 2004. Available at: http://guidance.nice.org.uk/TA83 [Accessed 19th Sept 2007]

33. Lymphoedema

Background: Lymphoedema (ICD-10 Code: I89.0, I97.2, Q82.0) is a medical condition in which excessive fluid (or 'lymph') is accumulated in the tissues as a result from impaired lymphatic drainage. Mostly, it affects the legs but any part of the body can be affected. Although it is not life-threatening it can be very distressing and can become a major physical and social problem.

There is no known cure for lymphoedema. Various treatment strategies have been suggested for the management of the condition that aim to reduce the volume of the affected limb and retain or restore function and cosmesis to improve an individual's health outcomes and quality of life.

- The long-term use of low-stretch elastic garments or compression bandaging is effective in reducing and/or controlling limb swelling and may be an essential component of combination physical therapies.
- Favourable outcomes have been described for complex physical therapy; however, some of the evidence is inconsistent and further trial evidence is required to define an optimal strategy.
- Current evidence regarding the use of drug therapy is inconclusive.
- Surgical procedures may be indicated in select patients who have not responded to physical therapy.

The NICE palliative care guidance states that commissioners, working through cancer networks, should ensure they can provide the range and volume of rehabilitation services appropriate to meet the needs of the local population and this will include providing services from lymphoedema therapists.

Advice: Evidence (NICE) indicates that services for management of lymphoedema may only be funded in accordance with NICE guidance.

References

1. Medical Services Advisory Committee. *Review of current practices and future directions in the diagnosis, prevention and treatment of lymphoedema in Australia.* Canberra: Commonwealth of Australia 2006. Available at: http://www.health.gov.au/internet/msac/publishing.nsf/Content/AD35ED216E990FC7CA2571420004A192/$File/Lymphoedema_13feb2006_final.pdf
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4. National Institute for Health and Clinical Excellence. *Improving supportive and palliative care for adults with cancer. The manual* .London: NICE; 2004. Available at: http://guidance.nice.org.uk/csgsp [Accessed 2nd Oct 2007]

34. Varicose veins (OPCS Codes: L84.-, L85.-, L86.-, L87.-, L88.-)

Background: Varicose veins (ICD-10 Code: I83) are dilated superficial veins in the leg caused by incompetent venous valves. Surgery or sclerotherapy can improve symptoms in the short term rather than long term. Sclerotherapy is less effective than surgery at improving symptoms and cosmetic appearance. After surgery 20-30% of patients develop recurrent varicose veins within 10 years.

Advice: Evidence (grade D) indicates that surgery for mild and moderate varicose veins may not be normally funded. Surgery for severe varicose veins will be available routinely in accordance with the guidance specified below.

Guidance

Asymptomatic or mild varicose veins (ICD-10 Code: I83.9): present as a few isolated, raised palpable veins with no associated pain, discomfort or any skin changes.

Moderate varicose veins (ICD-10 Code: I83.9): present as local or generalised dilatation of subcutaneous veins with associated pain or discomfort and slight ankle swelling.

Severe varicose veins: may present with phlebitis, ulceration and haemorrhage. Surgical treatment will be available if one or more of the following criteria are met:

1. Persistent ulceration (ICD-10 Codes: I83.0, I83.2)
2. Recurrent phlebitis (ICD-10 Codes: I83.1, I83.2) 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)
3. Significant haemorrhage from a ruptured superficial varicosity, for instance serious enough to consider transfusion/admission

References

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35. Caesarean section for non-clinical reasons (OPCS Code: R17.-)

Background

Caesarean section rates are progressively rising in many parts of the world. One suggested reason is increasing requests by women for caesarean section in the absence of clear medical indications, such as placenta praevia (ICD-10 Code: Q44), HIV infection (ICD-10 Code: B20 – B24, Z21), contracted pelvis (ICD-10 Code: O33), pelvic organ abnormalities (ICD-10 Code:O34) and, arguably, breech presentation (ICD-10 Code: O32) or previous caesarean section (ICD-10 Code: O34.2). There is no evidence from randomised controlled trials, upon which to base any practice recommendations regarding planned caesarean section for non-medical reasons at term.

Advice: Evidence (grade A) indicates that caesarean section for non-clinical reasons may not be funded.

References

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36. Dilatation and curettage (OPCS Codes: Q10.3, Q10.8, Q10.9)

Background

Dilatation and curettage (D&C) is a common gynaecological operation performed for both diagnostic and therapeutic purposes especially for menorrhagia. It involves scraping if the inner lining (endometrium) of the uterus. There is limited evidence on the effectiveness of D&C in management of menorrhagia.

Advice: Evidence (grade D) indicates that dilatation and curettage for the management of menorrhagia may only be funded in accordance with the guidance specified below.

Guidance

- as an investigation for structural and histological abnormalities where ultrasound has been used as a first line diagnostic tool and where the outcomes are inconclusive
- post-dilatation, pre-procedure when undertaking endometrial ablation

References

1. National Institute for Health and Clinical Excellence. *Heavy menstrual bleeding. Investigation and treatment.* London: NICE; 2007. Available at: http://guidance.nice.org.uk/CG44 [Accessed 19th Sept 2007]
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37. Hysterectomy for heavy menstrual bleeding (OPCS Codes: Q07.-, Q08.-)

Background

Hysterectomy is one of the most frequently performed surgery on women. Common indications include menorrhagia, fibroids, endometriosis, uterine prolapse and cancer of uterus and cervix. Hysterectomy is an effective procedure for treatment of heavy menstrual bleeding (menorrhagia) (ICD-10 Codes: N92.0, N92.1, N92.2, N92.4) but associated with more complications compared to treatment with progestogens.

Advice: Evidence (NICE) indicates that hysterectomy for heavy menstrual bleeding may only be funded in accordance with the guidance specified below.

Guidance

Hysterectomy should not be used as a first-line treatment solely for heavy menstrual bleeding. Hysterectomy should be considered only when:

- other treatment options have failed, are contraindicated or are declined by the woman
- there is a wish for amenorrhoea
- the woman (who has been fully informed) requests it
- the woman no longer wishes to retain her uterus and fertility

References

1. National Institute for Health and Clinical Excellence. *Heavy menstrual bleeding. Investigation and treatment.* London: NICE; 2007. Available at: http://guidance.nice.org.uk/CG44 [Accessed 19th Sept 2007]

38. Reversal of female sterilisation (OPCS Code: Q29.-, Q37.-)

Background

Reversal of sterilisation is a surgical procedure that involves the reconstruction of the fallopian tubes. One study of 85 women concluded that reversal of sterilisation is a safe and effective method of restoring fertility.

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.

Advice: Commissioners may only fund reversal of female sterilisation in exceptional individual circumstances such as:

- If the death of an existing child has occurred within the family unit
- Following remarriage/partnership if there are existing children of either partner this would not be allowed on the NHS

A list of exceptional circumstances cannot realistically be comprehensive. Each case should be considered on an individual basis. **(Evidence grade D)**

References

1. Royal College of Obstetricians and Gynaecologists. *Male and female sterilisation, Guideline summary*. London: RCOG Press; 2004. Available at: http://www.rcog.org.uk/resources/Public/pdf/Sterilisation_summary.pdf [Accessed 19th Sept 2007]
2. Prabha S; Burnett LC;Hill R. Reversal of sterilisation at Glasgow Royal Infirmary. *Journal of Family Planning and Reproductive Health Care* 2002; 29: 32–3.
3. National Public Health Service for Wales. *Reversal of sterilisation and reversal of vasectomy.* Cardiff: NPHS; 2004.

39. Laser surgery for short sight (OPCS Code: C46.1)

Background

Short sight or myopia (ICD-10 Code: H52.1) is a condition where distant objects appear blurred. Current evidence suggests that photorefractive (laser) surgery for the correction of refractive errors is safe and efficacious for use in appropriately selected patients. The safety and efficacy of photorefractive surgery should be considered against the alternative methods of correction: spectacles and contact lenses.

Advice: laser surgery for correction of short sight may not be funded as a systematic review (Evidence grade A) has determined the safety and efficacy of this procedure against other alternative cost effective procedures is yet to be established.

References

1. National Institute for Health and Clinical Excellence. *Photorefractive (laser) surgery for the correction of refractive errors*. London: NICE; 2006. Available at: http://www.nice.org.uk/IPG164 [Accessed 19th Sept 2007]
2. Murray A, Jones L, Milne A et al. *A systematic review of the safety and efficacy of elective photorefractive surgery for the correction of refractive error.* Aberdeen: University of Aberdeen; 2005.

40. Photodynamic therapy for age-related macular degeneration (OPCS Code: C88.2)

Background

Age-related macular degeneration (ARMD) (ICD-10 Code: H35.3) is characterised by loss of central vision, where as peripheral vision is retained. This condition has two forms, dry (non-exudative or non-neovascular) and wet (exudative or neovascular). Choroidal neovascularisation (CNV) can be subdivided into classic and occult forms according to its appearance on angiography.

Photodynamic therapy (PDT) is based upon the ability of chemical agents, known as photosensitisers, to produce cytotoxicity in the presence of oxygen after stimulation by light of an appropriate wavelength. NICE have considered the use of PDT for age related macular degeneration and consider it to be clinically effective and cost effective for patients who have "classic with no occult" subfoveal CNV.

Advice: Evidence (NICE) indicates that photodynamic therapy for wet age-related macular degeneration may only be funded in accordance with the guidance specified below.

Guidance

- PDT the treatment of age-related wet macular degeneration is recommended for those who have a confirmed diagnosis of classic with no occult subfoveal CNV and best-corrected visual acuity 6/60 or better

- PDT is not recommended for the treatment of people with predominantly classic subfoveal CNV (i.e. 50% or more classic CNV with some occult CNV) associated with wet age-related macular degeneration except for research purposes

References

1. Wormald R; Evans J; Smeeth L et al. Photodynamic therapy for neovascular age-related macular degeneration. *Cochrane Database of Systematic Reviews* 2005, Issue 4. Available at: http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD002030/pdf_fs.html [Accessed 2nd Oct 2007]
2. National Institute for Health and Clinical Excellence. *Guidance on the use of photodynamic therapy for age-related macular degeneration.* London: NICE; 2003. Available at: http://guidance.nice.org.uk/TA68/guidance/pdf/English [Accessed 2nd Oct 2007]

41. Apicectomy (OPCS Code: F12.1)

Background: Apicectomy is a surgical procedure involving the removal of infected tip of the root and a small amount of surrounding bone and tissue.

Literature shows that the success rate of apical surgery on molar teeth is low and should not be routinely undertaken.

Advice: Evidence (grade D) indicates that apicectomy may only be funded in accordance with the guidance specified below.

Guidance

The Faculty of Dental Surgery guidance states that apicectomy is indicated in the following conditions:

- 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
- Presence of periradicular disease in a tooth where iatrogenic or developmental anomalies prevent non surgical root canal treatment being undertaken
- Where a biopsy of periradicular tissue is required
- Where visualisation of the periradicular tissues and tooth root is required when perforation, root crack or fracture is suspected
- Where procedures are required that require either tooth sectioning or root amputation
- 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]

42. Dental implants (OPCS Code: F11.5)

Background: An endosseous dental implant is a surgically implanted device which replaces the lost roots of a tooth. An artificial tooth, partial denture, or denture can be attached to the implant. Dental implants have been shown to be a successful treatment for replacing missing teeth by providing support for fixed bridge prostheses, individual crowns, and overdentures. Evidence from randomised controlled trials shows increased ability to chew tough food, and increased patient satisfaction with implants in comparison to normal dentures. Complications of implant surgery include swelling, pain, bleeding, possible infection, and partial numbness at implant site. Nerve disturbances that may be permanent and bone fracture can occur, as can rejection of the implant. However, severe complications are rare.

Advice: Evidence (grade D) indicates that dental implants may only be funded in accordance with the guidance specified below.

Guidance

- Post cancer reconstruction, major trauma with bone loss and anodontia
- The Faculty of Dental Surgery has produced guidance on the selection of patients for dental implant treatment within the NHS. These include three groups of patients for consideration:

1. Edentulous in one or both jaws:

   • severe denture intolerance (e.g. gagging, pain);
   • prevention of severe alveolar bone loss.

2. Partially dentate:
   • preservation of remaining healthy teeth
   • complete unilateral loss of teeth in one jaw

3. Maxillofacial and cranial defects:

   • intraoral prostheses, e.g., considerable amounts of missing hard and soft tissue

   • extraoral/cranial prostheses, e.g., partial or total loss of ears, eyes or nose

References

1. Royal College of Surgeons. Guidelines for selecting appropriate patients to receive treatment with dental implants: Priorities For the NHS. RCS 1997. Available at : :http://www.rcseng.ac.uk/dental/fds/pdf/ncg97.pdf. accessed 3rd October 2007.
2. Awad MA, Locker D, Korner-Bitensky N et al. Measuring the effect of intra-oral implant rehabilitation on health related quality of life in a randomised controlled clinical trial. *J Dent Res* 2000; 79:1659.
3. McCord JF, Michelinakis G. Systematic review of the evidence supporting intra-oral maxillofacial prosthodontic care. *European Journal of Prosthodontics and Restorative Dentistry*. 2004;12:129-35.
4. Attard NJ, Zarb GA, Laporte A. Long-term treatment costs associated with implant-supported mandibular prostheses in edentulous patients. *International Journal of Prosthodontics*. 2005;18: 117-23.

43. 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.

Advice: Commissioners may only fund orthodontic treatments for essentially cosmetic nature in accordance with the guidance specified below (Evidence grade D).

Guidance

Orthodontic treatment is usually not offered to people with a score of less than 4 or 5 on the Index of Orthodontic Treatment Need (IOTN).

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.

44. Removal of asymptomatic wisdom teeth (OPCS Codes: F09.1, F09.3)

Background: Wisdom teeth erupt usually between the ages of eighteen and twenty four years. Wisdom teeth may erupt normally into correct dental alignment and function or conversely develop in non- or minimally functional positions. Impaction occurs when there is prevention of complete eruption due to lack of space, obstruction or development in an abnormal position.

The surgical removal of impacted third molars (symptomatic and asymptomatic) is the most common procedure performed by oral and maxillofacial surgeons. Whilst it is clear that symptomatic impacted wisdom teeth should be surgically removed, it appears that extracting asymptomatic, disease-free wisdom teeth is not advisable due to the risk of damage to the inferior alveolar nerve. Some non-RCT evidence suggests that extraction of the asymptomatic tooth may be beneficial if caries are present in the adjacent second molar, or if periodontal pockets are present distal to the second molar.

Advice: Evidence (NICE) indicates that removal of asymptomatic wisdom teeth may only be funded in accordance with the guidance specified below.

Guidance

NICE Guidance states:

- Surgical removal of impacted third molars should be limited to patients with evidence of pathology. Such pathology includes unrestorable caries, non-treatable pulpal and/or periapical pathology, cellulitis, abcess and osteomyelitis, internal/external resorption of the tooth or adjacent teeth, fracture of tooth, disease of follicle including cyst/tumour, tooth/teeth impeding surgery or reconstructive jaw surgery, and when a tooth is involved in or within the field of tumour resection.
- Plaque formation is a risk factor but is not in itself an indication for surgery
- First episode of pericoronitis, unless particularly severe, should not be considered an indication for surgery. Second or subsequent episodes should be considered the appropriate indication for surgery

References

1. Mettes TG, Nienhuijs ME,; van der Sanden WJM et al. Interventions for treating asymptomatic impacted wisdom teeth in adolescents and adults. *Cochrane Database of Systematic Reviews* 2005, Issue 2. Available at: http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD003879/pdf_fs.html [Accessed 2nd Oct 2007]
2. National Institute for Health and Clinical Excellence. *Wisdom teeth –removal.* London*:* NICE; 2000. Available at: http://guidance.nice.org.uk/TA1 [Accessed 2nd Oct 2007]
3. Esposito M. Impacted wisdom teeth. *BMJ Clinical Evidence* 2006. Available at: http://clinicalevidence.bmj.com/ceweb/about/index.jsp [Accessed 19th Sept 2007]

45. Autologous cartilage transplantation

Background: NICE guidance states that autologous chondrocyte implantation (ACI) is not recommended for the treatment of articular cartilage defects of the knee joint, except in the context of ongoing or new clinical studies that are designed to generate robust and relevant outcome data, including the measurement of health-related quality of life and long-term follow-up. Patients should be fully informed of the uncertainties about the long-term effectiveness and the potential adverse effects of this procedure

Advice: Evidence (NICE) indicates that autologous cartilage transplantation may not be funded.

- **Any consideration of this should go to the exceptional treatments panel**

References

1. National Institute for Health and Clinical Excellence. *Cartilage injury - autologous chondrocyte implantation (ACI) (review).* London: NICE; 2005. Available at: http://www.nice.org.uk/page.aspx?o=72659 [Accessed 19th Sept 2007]
2. National Public Health Service. *Autologous chondrocyte implantation for the ankle joints*. Cardiff: NPHS; 2006.

46. Complementary and Alternative Medicine (CAM) for acute low back pain (LBP) (OPCS Code: X61 (complementary therapy), A70.6 (acupuncture))

Background: Acute LBP (ICD-10 Code: M54.5) is one of the most commonly reported conditions in primary care. It has been suggested that CAM may be useful where effectiveness gaps (i.e. where conventional treatment is unsatisfactory) exist in primary care.

An NPHS review identified nineteen guidelines for the primary care management of acute LBP. In general the quality of most of the guidelines was satisfactory and the publication of the Prodigy guidelines in November 2005 provides up to date guidelines specifically for United Kingdom primary care.

Spinal manipulation: The published guidelines did not distinguish between osteopathy and chiropractic treatment. **The European, UK, US, New Zealand and Danish guidelines considered SM a useful treatment for acute LBP for patients, who are not able to return to normal activities.** In the Dutch, Australian and Israeli guidelines, SM was not recommended for acute LBP, although the Dutch advise its consideration after 6 weeks. The guidelines emphasised that treatment should be provided by professionals with competent skills (code of practice given below). Current guidelines contraindicate SM in people with severe or progressive neurological deficit.

Massage: Massage is popular in many countries, but there was a lack of high quality evidence to support its effectiveness and it may be associated with adverse effects.

Acupuncture: Systematic review evidence failed to find evidence to support the effectiveness of acupuncture in the treatment of acute LBP.

Other CAM Therapies: There was no evidence for the use in acute LBP of other CAM therapies, such as homeopathy or botanical medicines.

Advice: Evidence (grade D) indicates massage, acupuncture, and other CAM therapies such as homeopathy or botanical medicines may not be funded for the management of acute LBP. Spinal manipulation for the management of acute low back pain may only be considered in accordance with the guidance specified below.

Guidance

- For patients who are failing to return to normal activities

CODES OF PRACTICE & COMPETENCIES FOR OSTEOPATHIC & CHIROPRACTIC PROFESSIONALS

OSTEOPATHIC PROFESSIONALS

General Osteopathy Council, May 2005 Code of practice. Available at: : http://www.osteopathy.org.uk/about_gosc/4387CodesOfPractice_A_W.pdf

General Osteopathy Council, March 1999 Standard 2000 Standard of Proficiency. Available at: http://www.osteopathy.org.uk/about_gosc/standard_2000.pdf

SUMMARY OF CODE OF PRACTICE FOR OSTEOPATHS

AS AN OSTEOPATH YOU MUST:

- Make the care of your patient your first concern,
- Respect the rights of patients to be fully involved in decisions about their care
- Justify public trust and confidence
- Maintain, respect and protect patient information

CHIROPRACTIC PROFESSIONALS

General Chiropractic Council Code of Practice and Standard of Proficiency December 2005. Available at: http://www.gcc-uk.org/files/link_file/COPSOP_8Dec05.pdf [Accessed 19th Sept 2007]

SUMMARY OF CODE OF PRACTICE FOR CHIROPRACTORS

- Chiropractors must be open with patients and show respect for their dignity, individuality and privacy
- Chiropractors must respect patients' rights to be involved in decisions about their treatment and healthcare
- Chiropractors must justify public trust and confidence by being honest and trustworthy
- Chiropractors must provide a good standard of practice and care
- Chiropractors must protect patients and colleagues from risk of harm
- Chiropractors must cooperate with colleagues from their own and other professions

References

1. National Public Health Service for Wales. *A rapid review of the evidence on the effectiveness of complementary and alternative medicine in acute low back pain.* [Internal document] Cardiff: NPHS; 2007.

47. Hip prostheses

Background: Elective total hip replacement (THR). is one of the most effective orthopaedic procedure and approximately 35,000 are carried out in England and 2,800 in Wales in the NHS. 60 different prostheses with a cost ranging from £400 to £2,000 are available.

The current 'benchmark' in the selection of prostheses for primary THR is that the best prostheses (using long term viability as the determinant) demonstrate a revision rate of 10% or less at 10 years. A minimum of three years revision rate experience (collected from well conducted observational studies or randomised control trials) is acceptable performance is consistent with the benchmark.

Advice: Evidence (NICE) indicates that hip prostheses may only be funded in accordance with the guidance specified below.

Guidance

- Only if performance of the prostheses is consistent with the benchmark

References

1. National Institute for Health and Clinical Excellence. *Guidance on the selection of prostheses for primary total hip replacement*. London: NICE; 2000. Available at: http://www.nice.org.uk/page.aspx?o=510 [Accessed 2nd Oct 2007]
2. National Audit Office. Hip replacements: an update. London: NAO; 2003. Available at: http://www.nao.org.uk/publications/nao_reports/02-03/0203956.pdf [Accessed 1st Oct 2007]

48. Hip resurfacing techniques (OPCS Code: W58.1 (Primary resurfacing arthroplasty of joint), Z84.3 (Hip joint))

Background: Metal on metal (MoM) hip resurfacing arthroplasty involves removal of the diseased or damaged surfaces of the head of the femur and the acetabulum. The femoral head is fitted with a metal surface and the acetabulum is lined with a metal cup to form a pair of metal bearings.

There is sufficient short-term evidence of the effectiveness of metal on metal resurfacing arthroplasty to conclude that they are at least as effective as conventional THR for patients younger than 55 years.

Nice Guidance states that when considering MoM hip resurfacing surgeons should bear in mind:-

- how active the individual is
- that the evidence available at: the moment for the clinical effectiveness and cost effectiveness of MoM hip resurfacing comes mainly from studies that have involved people less than 65 years of age.

Advice: Evidence (NICE) indicates that MoM hip resurfacing techniques may be funded in accordance with the guidance specified below.

Guidance

Those who otherwise qualify for primary total hip replacement, but are likely to outlive conventional primary hip replacements: young and active.

References

1. Wyness L, Vale L, McCormack K et al. The effectiveness of metal on metal hip resurfacing: a systematic review of the available evidence published before 2002. *BMC Health Service Research* 2004; 4:39.
2. National Institute for Health and Clinical Excellence. *The clinical effectiveness and cost effectiveness of metal on metal hip resurfacing*. London: NICE 2002. Available at: http://www.nice.org.uk/page.aspx?o=ta044 [Accessed 19th Sept 2007]
3. Chard J, Smith C, Lohmander S et al. Osteoarthritis of the hip. Surgery for OA of the hip. *BMJ Clinical Evidence.* 2006. Available at: http://clinicalevidence.bmj.com/ceweb/about/index.jsp [Accessed 19th Sept 2007]

49. Internal fixation of fracture of the distal radius and tibial shaft (OPCS Codes: W19.2, W19.3, W20.2, W20.3, W24.2, W24.3 Subsidiary codes: Z70.3, Z77.2)

Background: Treatment modalities for fracture of the tibial shaft and distal radius include operative (internal fixation) and conservative treatments. The evidence is inconclusive regarding internal fixation in the primary management of distal radius fractures, and there is little or no evidence to indicate the relative benefits of internal fixation versus other treatments for other classifications of tibial shaft fractures. There is some evidence to suggest the effectiveness of internal fixation for Gustilo grade IIIB tibial fractures, with the proviso that deep sepsis rates are checked.

Advice: Inconclusive evidence on clinical effectiveness of Internal fixation of fracture of the distal radius indicates that it may only **be funded** as with the guidance below **(Evidence grade A), and internal fixation of fracture of the tibial shaft may only be funded in accordance with the guidance specified below (Evidence grade D).**

Guidance

- Internal fixation of distal radial fractures is necessary in cases where anatomical reduction and geometric function can only be achieved by the procedure being performed acutely
- Internal fixation may be performed in cases with Gustilo grade IIIB tibial fractures

References

1. Handoll HHG, Madhok R. Surgical interventions for treating distal radial fractures in adults. *Cochrane Database of Systematic Reviews* 2003, Issue 3. Available at: http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD003209/pdf_fs.html [Accessed 2nd Oct 2007]
2. Calvert N. Internal fixation of fractures of the shaft of the tibia and of the distal radius in adults. Webpage. *Research Findings Register.* Available at: http://www.refer.nhs.uk/ViewRecord.asp?ID=500 [Accessed 19th September 2007]

50. Intramedullary fixation with cephalocondylic nail for extracapsular hip fractures (vs. extramedullary fixation)

Background: Two types of implants used for the surgical fixation of extracapsular hip fractures are cephalocondylic intramedullary nails, which are inserted into the femoral canal proximally to distally across the fracture, and extramedullary implants.

One systematic review found no significant difference between intramedullary fixation with a short cephalocondylic nail (e.g. Gamma nail) and extramedullary fixation with a sliding hip screw in mortality, pain at follow up, ability to return to a previous residence, and ability to walk after 3–12 months. The review also found no significant difference between treatments in wound infection or cut-out of the implant, but found that cephalocondylic intramedullary fixation increased intra-operative and later femoral fractures and re-operation rates.

The limited evidence from published RCTs is insufficient to determine whether there are important differences in outcome between different designs of intramedullary nails used in the internal fixation of extracapsular hip fractures. Given the evidence of superiority of the sliding hip screw compared with intramedullary nails for extracapsular hip fractures, further studies comparing different designs of intramedullary nails are not a priority.

Advice: Evidence (grade A) indicates that Intramedullary fixation with cephalocondylic nail for extracapsular hip fractures may not be funded.

References

1. Handoll H, Parker M. Intramedullary fixation with short cephalocondylic nails versus sliding hip screw for extracapsular hip fracture. *BMJ Clinical Evidence.* 2006. Available at: http://clinicalevidence.bmj.com/ceweb/about/index.jsp [Accessed 19th Sept 2007]
2. Parker MJ, Handoll HHG. Gamma and other cephalocondylic intramedullary nails versus extramedullary implants for extracapsular hip fractures in adults. *Cochrane Database of Systematic Reviews* 2005, Issue 4.
3. Parker MJ, Handoll HHG. Intramedullary nails for extracapsular hip fractures in adults. *Cochrane Database of Systematic Reviews* 2006, Issue 3.

51. Therapeutic use of ultrasound in Hip and knee osteoarthritis (OPCS Code: U13.2 – Ultrasound of bone, includes ultrasound of joint)

Background: Therapeutic ultrasound is commonly being used in the management of soft tissue lesions including rheumatic complaints. It is said to have a role in the management of osteoarthritis of large and small joints. It has been estimated that over a million NHS treatments involve its use.

Literature suggests that it has no benefit over placebo or short wave diathermy for people with hip or knee osteoarthritis (OA). Evidence for or against the use of ultrasound in smaller joints such as the wrist or hands is also lacking. Also there is a little evidence for benefit in the management of soft tissue injuries.

Ultrasound therapy was not shown to have a clinically important effect on pain relief for people with patellofemoral pain syndrome. No conclusions can be drawn concerning the use, or non-use, of ultrasound for treating patellofemoral pain syndrome. More well-designed studies are needed.

Advice: Evidence (grade A) indicates that therapeutic use of ultrasound in Hip and knee osteoarthritis may not be funded.

References

1. Robinson VA, Brosseau L, Peterson J et al. Therapeutic ultrasound for osteoarthritis of the knee. *Cochrane Database of Systematic Reviews* 2001, Issue 3. Available at: http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD003132/pdf_fs.html [Accessed 1st Oct 2007]
2. Brosseau L; Casimiro L; Robinson V et al. Therapeutic ultrasound for treating patellofemoral pain syndrome. *Cochrane Database of Systematic Reviews* 2001, Issue 4. Available at: http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD003375/pdf_fs.html [Accessed 1st Oct 2007]
3. Speed CA. Therapeutic ultrasound in soft tissue lesions. *British Society of Rheumatology* 2001; 40: 1331-36.

52. Drug treatment for erectile dysfunction (OPCS Code: N32.4 – injection of therapeutic substance into penis)

Background

Erectile dysfunction may affect 30-50% of men aged 40-70 years, with age, smoking and obesity being the main risk factors, although 20% of cases have psychological causes. Evidence suggests that drugs such as Sildenafil, Tadalafil,vardenafil, Intracavernosal alprostadil, intraurethral alprostadil, and intracavernosal papaverine improve erections and increases the likelihood of successful intercourse overall. Sublingual apomorphine, ginseng and yohimbine may increase successful erections and intercourse compared with placebo. Vacuum devices may be as effective as intracavernosal alprostadil at increasing rigidity, but less effective for orgasm, and may block ejaculation. There is consensus that penile prostheses may be beneficial, but they can cause infections and are only used if less invasive treatments have failed. Psychosexual counselling and cognitive behavioural therapy may improve sexual functioning in men with psychological erectile dysfunction, but few good quality studies have been found.

Advice: Evidence (HSC) indicates that drug treatment for erectile dysfunction may only be funded in accordance with the guidance specified below.

Guidance

In 1999, circulars, containing frameworks for the drug treatment of erectile dysfunction of the penis were issued.

- Treatment for erectile dysfunction will only be available for men who have the following medical conditions:

  diabetes, multiple sclerosis, Parkinson's disease, poliomyelitis, prostate cancer, prostatectomy, radical pelvic surgery, renal failure treated by dialysis or transplant , severe pelvic injury, single gene neurological disease, spinal cord injury , spina bifida
- All prescriptions must be endorsed "SLS"
- No more than one treatment a week will be prescribed

References

1. Tharyan P, Gopalkrishanan G. Erectile dysfunction. *BMJ Clical Evidence* 2006. Available at: http://www.wales.nhs.uk/sites3/docmetadata.cfm?orgid=520&id=49511 [Accessed 19th Sept 2007]
2. Bandolier. Erectile dysfunction and premature ejaculation. Webpage. [Cited 19th Sept 2007] Available at: http://www.jr2.ox.ac.uk/bandolier/booth/booths/erect.html
3. Spark R. Treatment of male sexual dysfunction. Webpage. [Cited 19th Sept 2007] *UpToDate.* Available at: http://www.utdol.com/utd/content/topic.do?topicKey=r_endo_m/6961
4. Welsh Office: *Treatment for impotence*. WHC (99) 96. Cardiff: WO; 1999.
5. Welsh Office: *Treatment for impotence*. WHC (99) 125. Cardiff: WO; 1999.
6. Welsh Office: *Treatment for impotence – patients with severe distress*. WHC (99) 148. C ardiff: WO; 1999.

53. Reversal of male sterilisation (OPCS Code: 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.

Advice: Commissioners may only fund reversal of male sterilisation in exceptional individual circumstances such as:

- Death of an existing child has occurred within the family unit
- Following remarriage/partnership if there are existing children of either partner this would not be allowed on the NHS

A list of exceptional circumstances cannot realistically be comprehensive. Each case should be considered on an individual basis. **(Evidence grade D)**

References

1. Royal College of Obstetricians and Gynaecologists. *Male and female sterilisation. Guideline summary.* London: RCOG Press; 2004. Available at: http://www.rcog.org.uk/resources/Public/pdf/Sterilisation_summary.pdf [Accessed 19th Sept 2007]

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Appendix 2

EVIDENCE BASE SUMMARY TABLES
OF INTERVENTIONS
NOT NORMALLY FUNDED ON THE NHS

INTERVENTIONS NOT NORMALLY FUNDED - EVIDENCE UPDATE[1]

[1] Evidence was obtained initially from reputable secondary sources and supplemented with other literature, where required.

INTERVENTION	EVIDENCE SUMMARY	REFERENCES
GENERAL SURGERY		
Gastroplasty	Two systematic reviews found that vertical banded gastroplasty is effective in promoting clinically important weight loss in morbidly obese adults. Three RCTs found inconclusive results regarding weight loss with vertical banded gastroplasty compared with gastric banding. One systematic review also identified six RCTs, which compared gastric bypass versus vertical banded gastroplasty. Four of these RCTs found that vertical banded gastroplasty was less effective than gastric bypass in increasing weight loss at 1–3 years, but another two RCTs found no significant difference between the procedures. Two subsequent RCTs also found that laparoscopic vertical banded gastroplasty was less effective than laparoscopic gastric bypass for increasing weight loss at 1 and 2 year follow up. One small RCT identified by the systematic review found no significant difference in weight loss at 1 year or in hospital stay between open and laparoscopic vertical banded gastroplasty, but found that operating time was significantly longer with laparoscopic gastroplasty. There is a small risk of perioperative death with vertical banded gastroplasty, but postoperative complications are common and may require reoperation. There is insufficient evidence to draw conclusions about the relative benefits and harms of vertical banded gastroplasty compared with gastric banding or gastric bypass. NICE concludes that surgery is not generally recommended for children or young people and that surgery should be considered for young people only 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	Arteburn DE; Delaet DE; Schauer D. Obesity. Vertical banded gastroplasty. *BMJ Clinical Evidence* 2006. Available at: http://clinicalevidence.bmj.com/ceweb/about/index.jsp [Accessed 19th Sept 2007]

INTERVENTION	EVIDENCE SUMMARY	REFERENCES
	loss for at least 6 months • they are receiving or will receive intensive specialist management • they are generally fit for anaesthesia and surgery • they commit to the need for long-term follow-up. For adults with severe obesity surgery should only be considered if: • 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 • they are generally fit for anaesthesia and surgery • they commit to the need for long-term follow-up. Surgery should be considered as a first-line option for adults with a BMI of more than 50 kg/m2 in whom surgical intervention is considered appropriate; consider orlistat or sibutramine before surgery if the waiting time is long. NICE have produced a costing report and this provides the financial consequences of offering bariatric surgery to patients in England. Two systematic reviews identified one prospective, multicentre cohort study, which found that bariatric surgery (vertical banded gastroplasty, gastric bypass, or gastric banding) increased weight loss compared with non-surgical treatment (low calorie diet or usual care) in morbidly obese adults. Long term follow up of the prospective cohort study found that the differences in	National Institute for Health and Clinical Excellence. *Obesity. Guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children*. London: NICE 2006. Available at:: http://www.nice.org.uk/guidance/CG43 [Accessed 19th Sept 2007] National Institute for Health and Clinical Excellence. *Guidance on the use of surgery to aid weight reduction for people with morbid obesity.* London: NICE; 2002. Available at: http://guidance.nice.org.uk/page.aspx?o=obesity [Accessed 19th Sept 2007] National Institute for Health and Clinical Excellence. *Obesity. Costing report.* London: NICE; 2006. Available at: http://www.nice.org.uk/usingGuidance/costreport/pdf/English [Accessed 19th Sept 2007] Arteburn DE; Delaet DE; Schauer D. Obesity. Surgery in morbidly obese adults. Bariatric surgery versus non–surgical treatment. *BMJ Clinical Evidence* 2006. Available at:

INTERVENTION	EVIDENCE SUMMARY	REFERENCES
	weight loss between surgery and non-surgical treatments were sustained at 10 years. Evidence regarding the efficacy and safety of bariatric surgical procedures comes from studies of mostly younger, white women and therefore may not be generalisable to other populations.	http://clinicalevidence.bmj.com/ceweb/about/index.jsp[Accessed 19th Sept 2007]
Haemorrhoidectomy	First and second degree haemorrhoids are classically treated with some form of non-surgical ablative/fixative intervention, third degree treated with rubber band ligation or haemorrhoidectomy, and fourth degree with haemorrhoidectomy. Rubber band ligation is known to be highly effective in treating first, second and some third degree haemorrhoids. • Rubber band ligation can produce some immediate adverse effects, and the clinician should therefore always gain informed consent. Closed haemorrhoidectomy appears to be an effective treatment for relieving symptoms in people with first to fourth degree haemorrhoids. • Although effective, closed haemorrhoidectomy does appear to be associated with greater postoperative complications than haemorrhoidal artery ligation or stapled haemorrhoidectomy. Open excisional haemorrhoidectomy may also be effective in treating all grades of haemorrhoids, although it produces similar levels of adverse effects as closed haemorrhoidectomy. Infrared coagulation may be as effective as rubber band ligation and injection sclerotherapy in the treatment of first and second degree haemorrhoids. We did not find sufficient evidence to judge the effectiveness of injection sclerotherapy or haemorrhoidal artery ligation.	Davies RJ. Haemorrhoids. *BMJ Clinical Evidence.* 2006. Available at: http://clinicalevidence.bmj.com/ceweb/about/index.jsp [Accessed 19th Sept 2007]
Circumcision	AM already completed, but two extra references	Siegfried N, Muller M, Volmink J et al. Male circumcision for prevention of heterosexual acquisition of HIV in men. *Cochrane Database of Systematic Reviews* 2003, Issue 3.

INTERVENTION	EVIDENCE SUMMARY	REFERENCES
		Baillis SA, Halperin DT. Male circumcision: time to re-examine the evidence. *Student BMJ* 2006; 14**:** 179
Asymptomatic gall stones - Cholystectomy - Lithotripsy	There are no prospective trials of therapy, either surgical or medical, for asymptomatic gallstones. Prophylactic cholecystectomy is not indicated in most patients with asymptomatic gallstones. Possible exceptions include patients who are at increased risk for gallbladder carcinoma or gallstone complications, in whom 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.	Afdhal N. Approach to the patient with incidental gallstones. Webpage. [Cited 19th Sept 2007] *UpToDate.* Available at: http://patients.uptodate.com/topic.asp?file=biliaryt/8759
Gender reassignment surgery, except where mental health problems result.	The overall conclusion reached by ARIF was that the degree of uncertainty about any of the effects of gender reassignment is such that it is impossible to make a judgement about whether the procedure is clinically effective.	Aggressive Research Intelligence Facility. Gender reassignment surgery. Webpage. [Cited 19th Sept 2007] Available at: http://www.arif.bham.ac.uk/requests/g/genderreass.htm
Laparoscopic surgery for repair of primary inguinal; hernia	This guidance replaces Technology Appraisal Guidance No. 18 issued in January 2001. The review and re-appraisal of the use of laparoscopic surgery for inguinal hernia repair has resulted in changes in the guidance. Specifically there has been: • a recommendation that laparoscopic surgery is one of the treatment options for the repair of inguinal hernia • a recommendation that patients should be fully informed of all the risks and benefits of open and laparoscopic surgery by either the transabdominal preperitoneal (TAPP) or the totally extraperitoneal (TEP) approaches, to enable them to choose between the procedures.	National Institute for Health and Clinical Excellence. *Hernia - laparoscopic surgery review.* London: NICE: 2004. Available at: http://guidance.nice.org.uk/TA83 [Accessed 19th Sept 2007]
Ganglia	• Reassurance should be the first therapeutic intervention for most patients (and all children) because of the high rate of spontaneous resolution and because it avoids the potential	Vroon P; van Weert HCPM; Scholten RJ. Interventions for ganglion cysts in adults. *Cochrane Database of Systematic Reviews* 2005, Issue 2. Available at:

INTERVENTION	EVIDENCE SUMMARY	REFERENCES
	complications of invasive therapy. • Aspiration alone can be successful, but recurrence rates are 60 to 70%. For patients who remain concerned about malignancy, seeing the aspiration fluid can reinforce verbal reassurance, and reduce demand for surgical intervention. • Surgical excision is the most invasive therapy. Recurrence rates as low as 1% have been reported, but most studies have rates between 14 and 40%. In addition, 15 to 28% of patients report scar sensitivity, joint stiffness or distal numbness. Patients should be made aware of these problems before referral for surgery. • Arthroscopic excision may reduce recurrence and complication rates .	http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD005327/pdf_fs.html [Accessed 2nd Oct 2007] Bandolier. Wrist ganglia. Webpage. [Cited 19th Sept 2007]. Available at: http://www.jr2.ox.ac.uk/bandolier/booth/miscellaneous/wristgang.html Bittner JG, Kang R, Stern PJ. Management of flexor tendon sheath ganglions: a cost analysis. *J Hand Surg[Br]* 2002; 27A: 586
COSMETIC SURGERY		
	The Action on Plastic Surgery Programme has developed national guidelines in relation to aesthetic (cosmetic) surgery. The programme reviewed policies that exist as well as taking into account any available evidence in terms of the effectiveness and outcomes for individual procedures. In line with these guidelines cosmetic surgery (surgery undertaken exclusively to improve appearance) will usually be excluded from NHS provision in the absence of previous trauma, disease or congenital deformity. In exceptional circumstances and after special consideration, the local stakeholder commissioning group may allow a referral for cosmetic surgery to proceed. **Removal of tattoos** Tattoo removal under the NHS will be provided:- • Where the tattoo is the result of trauma, inflicted against the patient's will ("rape tattoo") • The patient was not Gillick competent, and therefore not responsible for their actions, at the time of the tattooing. • Exceptions may also be made for tattoos inflicted under duress during adolescence or disturbed periods where it is considered that psychological rehabilitation, break up of family units or prolonged unemployment could be avoided,	NHS Modernisation Agency. *Action on plastic surgery. Referrals and guidelines in plastic surgery. Information for commissioners of plastic surgery services*. London: NHS Modernisation Agency; 2005. NHS Modernisation Agency. *Action on plastic surgery: a strategic approach to the delivery of the NHS plastic, reconstructive and aesthetic surgery service*. London: NHS Modernisation Agency; 2005. Department of Health. Cosmetic surgery and non-surgical cosmetic treatments. Webpage. [Cited 19th Sept 2007] Available at: http://www.dh.gov.uk/en/Policyandguidance/Healthandsocialcaretopics/CosmeticSurgery/index.htm Fitzpatrick R, Klassen A, Jenkinson C, Goodacre T. Contrasting evidence of the effectiveness of cosmetic surgery from two health-related quality of life measures. *J Epidemiology Community Health* 1999; 53: 440-41.

INTERVENTION	EVIDENCE SUMMARY	REFERENCES
	given the treatment opportunity. **Dermabrasion – Chemical peel** All resurfacing techniques, including laser, dermabrasion and chemical peels may be considered for post-traumatic scarring (including post surgical) and severe acne scarring once the active disease is controlled. **Male pattern baldness (hair grafting)** Is excluded from treatment by the NHS because "male pattern" baldness is a normal process for many men at whatever age it occurs. **Hair depilation** Hair depilation will be commissioned on the NHS for patients who: • Have undergone reconstructive surgery leading to abnormally located hair-bearing skin • Those with a proven underlying endocrine disturbance resulting in • hirsutism (e.g. polycystic ovary syndrome) • Are undergoing treatment for pilonidal sinuses to reduce recurrence • Hirsutism leading to significant psychological impairment **Repair of lobe of external ear** This procedure is only available on the NHS for the repair of totally split ear lobes as a result of direct trauma. Correction of split earlobes is not always successful and the earlobe is a site where poor scar formation is a recognised risk. **Pinnaplasty** To be available on the NHS the following criteria must be met: • The patient must be under the age of 19 years at the time of referral • Patients seeking pinnaplasty should be seen by a plastic surgeon and following assessment, if there is any concern, assessed by a psychologist. • Patients under 5 years of age at the time of referral may benefit from referral with their family for a multi-disciplinary assessment that includes a child psychologist	

INTERVENTION	EVIDENCE SUMMARY	REFERENCES
	The rationale behind this decision is that prominent ears 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. The national service framework for children defines childhood as ending at 19 years. Some patients are only able to seek correction once they are in control of the own healthcare decisions. Children under the age of five rarely experience teasing and referrals may reflect concerns expressed by the parents rather than the child. **Rhinoplasty** Rhinoplasty should be available on the NHS for: • Problems caused by obstruction of the nasal airway • Objective nasal deformity caused by trauma • Correction of complex congenital conditions e.g. Cleft lip and palate Patients with isolated airway problems (in the absence of visible nasal deformity) may be referred initially to an ENT consultant for assessment and treatment. **Blepharoplasty** This procedure will be commissioned by the NHS to correct functional impairment (not purely for cosmetic reasons), as demonstrated by: • 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 **Abdominoplasty and Apronectomy** Abdominoplasty and apronectomy may be offered to the following groups of patients who should have achieved a stable BMI between 18 and 27 Kg/m2 and be suffering from severe functional problems: • Those with scarring following trauma or previous abdominal	

INTERVENTION	EVIDENCE SUMMARY	REFERENCES
	surgery • Those who are undergoing treatment for morbid obesity and have excessive abdominal skin folds • Previously obese patients who have achieved significant weight loss and have maintained their weight loss for at least two years • Where it is required as part of abdominal hernia correction or other abdominal wall surgery **Liposuction** Liposuction is sometimes an adjunct to other surgical procedures. It will not be commissioned simply to correct the distribution of fat. **Thigh lift, buttock lift and arm lift, excision of redundant skin or fat** These procedures will only be commissioned in exceptional circumstances. The rational behind this decision is that whilst 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. **Face lift or brow lift** These procedures will be considered for treatment of: • Congenital facial abnormalities • Facial palsy (congenital or acquired paralysis) As part of the treatment of specific conditions affecting the facial skin e.g. cutis laxa, pseudoxanthoma elasticum, neurofibromatosis • To correct the consequences of trauma • To correct deformity following surgery • They will not be available to treat the natural processes of ageing **Botox injections for hyperhidrosis –** no guidance	Naumann M, Lowe NJ. Botulinum toxin type A in treatment of bilateral primary axillary hyperhidrosis: randomised, parallel group, double blind, placebo controlled trial. *BMJ* 2001;323: 596 - U.S. Food and Drug Administration. FDA approves Botox to treat frown lines. *FDA Talk Paper* 2002. Available at:: http://www.fda.gov/bbs/topics/ANSWERS/2002/ANS01147.html [Accessed 19th Sept 2007]

INTERVENTION	EVIDENCE SUMMARY	REFERENCES
	Botox Injection for ageing face – no guidance **Breast augmentation** Will only be performed by the NHS on an exceptional basis and should not be carried out for "small" but normal breasts or for breast tissue involution (including post partum changes). Exception should be made for women with an absence of breast tissue unilaterally or bilaterally, or in women with of a significant degree of asymmetry of breast shape and/or volume. **Breast reduction** Breast Reduction Surgery is an effective intervention that should be available on the NHS if the following circumstances are met: • The patient is suffering from neck ache, backache and/or intertrigo • The wearing of a professionally fitted brassiere has not relieved the • symptoms • The patient has a body mass index (BMI) of less than 30 kg/m2 **Breast Asymmetry Correction – no guidance** **Breast prosthesis removal or replacement** 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. **Gynaecomastia** Surgery to correct gynaecomastia is allowable if the patient is: • Post pubertal and of normal BMI (<= 25 Kg/m2) There should be a pathway established to ensure that appropriate screening for endocrinological and drug related causes and/or psychological distress occurs prior to consultation with a plastic surgeon. **Mastopexy** This is included as part of the treatment of breast asymmetry and reduction (see above) but not for purely cosmetic/aesthetic	

INTERVENTION	EVIDENCE SUMMARY	REFERENCES
	purposes such as postlactational ptosis. **Inverted nipple correction** Nipple inversion may occur as a result of an underlying breast malignancy and it is essential that this be excluded. Surgical correction of nipple inversion should only be available for functional reasons in a post-pubertal woman and if the inversion has not been corrected by correct use of a non-invasive suction device. **Revision mammoplasty** 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. **Scar Revision –** no guidance **Removal of benign skin lesions** Clinically benign skin lesions should not be removed on purely cosmetic grounds. This will include, amongst other conditions, skin tags and seborrhoeic keratoses (warts). Patients with moderate to large lesions that cause actual facial disfigurement may benefit from surgical excision. The risks of scarring must be balanced against the appearance of the lesion. Epidermoid or pilar cysts (commonly known as "sebaceous cysts") are always benign but some may become infected or be symptomatic. Some may require surgical excision particularly if large or located on the face or on a site where they are subjected to trauma. **Removal of pigmented lesions** **Removal of small lipomata** Lipomata of any size should be considered for treatment by the NHS in the following circumstances: • The lipoma (-ta) is / are symptomatic • There is functional impairment The lump is rapidly growing or abnormally located (e.g. sub-fascial, submuscular)	

INTERVENTION	EVIDENCE SUMMARY	REFERENCES
OBSTETRICS and GYNAECOLOGY		
Caesarean section for non-clinical reasons	Caesarean section rates are progressively rising in many parts of the world. One suggested reason is increasing requests by women for caesarean section in the absence of clear medical indications, such as placenta praevia, HIV infection, contracted pelvis and, arguably, breech presentation or previous caesarean section. • There is no evidence from randomised controlled trials, upon which to base any practice recommendations regarding planned caesarean section for non-medical reasons at term. In the absence of trial data, there is an urgent need for a systematic review of observational studies and a synthesis of qualitative data to better assess the short- and long-term effects of caesarean section and vaginal birth.	Lavender T, Hofmeyr GJ, Neilson JP et al. Caesarean section for non-medical reasons at term. *Cochrane Database of Systematic Reviews* 2006, Issue 3. National Institute for Health and Clinical Excellence. *Caesarean section.* London: NICE; 2004. Available at: http://guidance.nice.org.uk/CG13 [Accessed 19th Sept 2007]
Hysterectomy for heavy menstrual bleeding.	One systematic review found that surgery (hysterectomy or endometrial destruction) reduced menstrual blood loss over 1 year compared with intrauterine progestogens but that hysterectomy was associated with more serious adverse effects than progestogens. Two systematic reviews found that hysterectomy reduced menstrual blood loss and the number of women requiring further operations, and increased participant satisfaction compared with endometrial destruction. Five small RCTs found no evidence of a difference in effectiveness between different types of hysterectomy, although operating and recovery times differed. One large cohort study reported major or minor complications in about a third of women having hysterectomy. Hysterectomy should not be used as a first-line treatment solely for heavy menstrual bleeding . Hysterectomy should be considered only when: • other treatment options have failed, are contraindicated or are declined by the woman • there is a wish for amenorrhoea • the woman (who has been fully informed) requests it	Duckett K, McCully K. Menorrhagia. Hysterectomy. *BMJ Clinical Evidence* 2005. Available at: http://clinicalevidence.bmj.com/ceweb/about/index.jsp [Accessed 19th Sept 2007] National Institute for Health and Clinical Excellence. *Heavy menstrual bleeding. Investigation and treatment.* London: NICE; 2007. Available at: http://guidance.nice.org.uk/CG44 [Accessed 19th Sept 2007]

INTERVENTION	EVIDENCE SUMMARY	REFERENCES
	• the woman no longer wishes to retain her uterus and fertility.	
Reversal of female sterilisation	Reversal of sterilisation is a surgical procedure that involves the reconstruction of the fallopian tubes. The authors of one study of 85 women concluded that reversal of sterilisation is a safe and effective method of restoring fertility. The actual incidence of pregnancy after reversal is likely to be higher than the 43.5% recorded due to difficulties in achieving 100% follow-up.	Royal College of Obstetricians and Gynaecologists. *Male and female sterilisation, Guideline summary*. London: RCOG Press; 2004. Available at: http://www.rcog.org.uk/resources/Public/pdf/Sterilisation_summary.pdf [Accessed 19th Sept 2007] Prabha S; Burnett LC;Hill R. Reversal of sterilisation at Glasgow Royal Infirmary. *Journal of Family Planning and Reproductive Health Care* 2002; 29: 32–3. National Public Health Service for Wales. *Reversal of sterilisation and reversal of vasectomy*. Cardiff: NPHS; 2004. Available at: http://nww2.nphs.wales.nhs.uk. [Accessed 19th Sept 2007].
Assisted conception techniques/in vitro fertilisation (IVF)	In January 2005 Health Commission Wales published access criteria for referral for NHS IVF treatment:- The cycle of treatment should start before the female patient's 40th birthday. • The upper age limit of the female patient, at time of referral to the tertiary service, should be no more than 38 years 6 months. • Three or more IVF cycles by the female patient will exclude any further NHS IVF treatment. • Any previous completed cycles of NHS IVF treatment by the female patient will exclude further NHS IVF treatment. • Subfertility must be demonstrated before there can be access to NHS funded IVF treatment. Subfertility for heterosexual couples is defined as inability to conceive after 2 years unprotected intercourse or fertility problem demonstrated at investigation Subfertility for same sex • couples/single women is defined as no live birth following insemination at or just prior to the known time of ovulation on at least ten non-stimulated cycles or fertility problem demonstrated at investigation.	Welsh Assembly Government. Specialised infertility treatment. Website. [Cited 19th Sept 2007] Available at: http://new.wales.gov.uk/topics/health/hcw/SpecialisedInfertilityTreatment/?lang=en

INTERVENTION	EVIDENCE SUMMARY	REFERENCES
	• For couples – there are no children (biological or adopted) living with the couple and one of the partners has never had a biological or adopted child. For single women – that the woman has never had a biological or adopted child. • Subfertility is not the result of a sterilisation procedure in either partner/single women (this does not include conditions where sterilisation occurs as a result of another medical problem) • The couple/single women must have a body mass index of between at least 19 and up to and including 30. Couples/single women outside this range will be added to the waiting list but must have achieved this range at time of treatment • Where either of the couple/single women smokes – Only couples/single women who agree to take part in a supported programme of smoking cessation will be accepted on the IVF treatment waiting list and must be non-smoking at time of treatment. • Patients not conforming to the Human Fertilisation and Embryology Authority (HFEA) Code of Practice will be excluded from having access to NHS funded assisted fertility treatment.	
Dilatation and curettage	• Dilatation and curettage alone should not be used as a diagnostic tool. • Dilatation and curettage should not be used as a therapeutic treatment. • Limited evidence is available on the use of therapeutic dilatation and curettage for menorrhagia, but the one study that was identified showed that any effect is temporary.	National Institute for Health and Clinical Excellence. *Heavy menstrual bleeding. Investigation and treatment.* London: NICE; 2007. Available at: http://guidance.nice.org.uk/CG44 [Accessed 19th Sept 2007] Coulter A, Kelland J, Long A. The management of menorrhagia. *Effective Health Care Bulletin* 1995; (9). Emanuel MH, Wamsteker K, Lammes FB. Is dilatation and curettage obsolete for diagnosing intrauterine disorders in premenopausal patients with persistent abnormal uterine bleeding? *Acta Obstet Gynecol Scand* 1997; 76: 65.
Routine Doppler ultrasound of umbilical +/-	The use of umbilical artery Doppler ultrasound for the prediction of foetal growth restriction should not be offered routinely.	National Institute for Health and Clinical Excellence. *Antenatal care. Routine care for the healthy pregnant*

INTERVENTION	EVIDENCE SUMMARY	REFERENCES
uterine artery in antenatal care	The use of uterine artery Doppler ultrasound for the prediction of pre-eclampsia should not be offered routinely.	*woman.* London: NICE 2003. Available at: http://www.nice.org.uk/CG006 [Accessed 19th Sept 2007]
UROLOGY		
Reversal of male sterilisation	Reversal of sterilisation is a surgical procedure that involves the reconstruction of the vas deferens.	Royal College of Obstetricians and Gynaecologists. *Male and female sterilisation, Guideline summary*. London: RCOG Press; 2004. Available at: http://www.rcog.org.uk/resources/Public/pdf/Sterilisation_summary.pdf [Accessed 19th Sept 2007]
Erectile dysfunction	Erectile dysfunction may affect 30-50% of men aged 40-70 years, with age, smoking and obesity being the main risk factors, although 20% of cases have psychological causes. • Sildenafil improves erections and increases the likelihood of successful intercourse overall and in men with diabetes mellitus, heart disease, spinal cord injury, prostate cancer or after radical prostatectomy. • Tadalafil and vardenafil are also effective overall and in men with diabetes, and vardenafil may be effective after prostatectomy. • Intracavernosal alprostadil improves erections compared with placebo, intraurethral alprostadil and intracavernosal papaverine, but can cause penile pain in up to 40% of men. • Intracavernosal alprostadil may be as effective as sildenafil and bimix, while topical alprostadil may also be effective. • Adding phentoloamine to intracavernosal papaverine (bimix) may increase effectiveness compared with papaverine alone, and adding alprostadil to bimix (trimix) may be more effective again. However, papaverine injections may cause altered liver function, and penile bruising and fibrosis. • Sublingual apomorphine, ginseng and yohimbine may increase successful erections and intercourse compared with placebo. • Vacuum devices may be as effective as intracavernosal	Tharyan P; Gopalkrishanan G. Erectile dysfunction. *BMJ Clinical Evidence* 2006. Available at: http://clinicalevidence.bmj.com/ceweb/about/index.jsp [Accessed 19th Sept 2007] Bandolier. Erectile dysfunction and premature ejaculation. Webpage. [Cited 19th Sept 2007] Available at: http://www.jr2.ox.ac.uk/bandolier/booth/booths/erect.html Spark R. Treatment of male sexual dysfunction. Webpage. [Cited 19th Sept 2007] UpToDate. Available at: http://www.utdol.com/utd/content/topic.do?topicKey=r_endo_m/6961

INTERVENTION	EVIDENCE SUMMARY	REFERENCES
	alprostadil at increasing rigidity, but less effective for orgasm, and may block ejaculation. • There is consensus that penile prostheses may be beneficial, but they can cause infections and are only used if less invasive treatments have failed. nd cognitive behavioural therapy may improve sexual functioning rectile dysfunction, but few good quality studies have been found.	
OPHTHALMOLOGY		
Surgery for short sight	Current evidence suggests that photorefractive (laser) surgery for the correction of refractive errors is safe and efficacious for use in appropriately selected patients. The safety and efficacy of photorefractive surgery should be considered against the alternative methods of correction: spectacles and contact lenses. Also, the surgical technologies are changing rapidly and some lasers and microkeratomes used in studies reviewed have been superseded. Most adverse events were statistically rare. It was unclear what effect refractive surgery had on commonly reported subjective visual symptoms, such as dry eye and night driving difficulty.	National Institute for Health and Clinical Excellence. *Photorefractive (laser) surgery for the correction of refractive errors*. London: NICE; 2006. Available at: http://www.nice.org.uk/IPG164 [Accessed 19th Sept 2007] Murray A, Jones L, Milne A et al. *A systematic review of the safety and efficacy of elective photorefractive surgery for the correction of refractive error.* Aberdeen: University of Aberdeen; 2005.
Screening for diabetic retinopathy by consultants	One of the key elements in the Welsh NSF for diabetes was the establishment of an all Wales diabetic retinopathy screening service. In 1990, the St Vincent Declaration recognised diabetes and diabetic retinopathy to be a major and growing European health problem, a problem at all ages and in all countries. In 2002, NICE recommended the eyes of people with type 2 diabetes are screened at the time of diagnosis and at least annually thereafter. Screening should use tests with a sensitivity > 80%, specificity > 95% and technical failure rate < 5%. In 2004, NICE recommended annual screening for people with Type 1 Diabetes by visual acuity and digital photography after mydriasis with tropicamide. There was no clear evidence to show who best performs the screening or which location was best but screeners should have	Anon. Diabetes care and research in Europe: the Saint Vincent declaration. *Diabet Med* 1990; 7.0: 360. National Institute for Health and Clinical Excellence. *Management of type 2 diabetes – retinopathy*. *Early management and screening*. London: NICE; 2002. Available: at::http://www.nice.org.uk/page.aspx?o=guidelinee [Accessed 19th Sept 2007] National Institute for Health and Clinical Excellence. *Type 1 diabetes in adults. National clinical guideline for diagnosis and management in primary and secondary care.* London: NICE; 2004. Available at:

INTERVENTION	EVIDENCE SUMMARY	REFERENCES
	a sufficient case load to acquire expertise and should be permanent staff providing continuity of care. • Ophthalmologists, although the most competent to do it, have insufficient time to screen for as well as treat retinopathy. • Diabetologists, although usually competent, can only screen those patients attending hospital clinics. • GPs, although well placed to screen their own patients, rarely have a large enough case load to become competent and are limited by using ophthalmosopes which have a low sensitivity. • Clinical assistants, specifically trained and using a good instrument, are ideal. • Junior medical staff are not suitable as they do not acquire sufficient experience in their training period. • Optometrists are ideally placed to provide screening in the community, but need extra training and should be part of an organised programme with a direct referral system and specific funding arrangements. • Technicians may operate photographic or SLO systems but the films need to be read by an ophthalmologist, diabetologist or clinical assistant. No studies reported whether differences found in sensitivities of healthcare professionals undertaking tests were statistically significant. Comparable sensitivity is achieved by GPs and optometrists using a direct ophthalmoscope through dilated pupils. Optometrists using slit lamp biomicroscopy only achieved moderate sensitivity (62% sensitivity at 95% specificity). The greatest sensitivity was found in comparative studies used in a systematic review with trained graders using mydriatic and non-mydriatic photography.	http://www.nice.org.uk/page.aspx?o=213575 [Accessed 19th August 2007] Jenkins LM, Mayon-White VA. Screening for diabetic retinopathy *Journal Community Eye Health* 1996; 9: 54. Norris SL, Saadine J, Chowdhury FM et al. Interventions to promote screening for diabetic retinopathy. *Cochrane Database of Systematic Reviews* 2005, Issue 1. Hutchinson A, McIntosh A, Peters J et al. Effectiveness of screening and monitoring tests for diabetic retinopathy: a systematic review. *Diabet Med* 2000;17:495-506 National Institute for Health and Clinical Excellence. *Management of type 2 diabetes – retinopathy. Early management and screening*. London: NICE; 2002. Available at: http://www.nice.org.uk/page.aspx?o=guidelinee [Accessed 19th Sept 2007] National Screening Committee. Diabetic Retinopathy. Webpage. [Cited 19th Sept 2007]London: NSC. Available at : http://www.nscretinopathy.org.uk/pages/nsc.asp?ModT=A&Sec=16 National Institute for Health and Clinical Excellence. *Type 1 diabetes in adults. National clinical guideline for diagnosis and management in primary and secondary care.* London: NICE; 2004. Available at: http://www.nice.org.uk/page.aspx?o=213575 [Accessed 19th Sept 2007]
Screening for glaucoma	Glaucoma is a group of eye diseases commonly, but not invariably associated with an increase in intraocular pressure that, if left untreated, can eventually cause blindness. The most common form of glaucoma is chronic open angle glaucoma. Approximately 10% of UK blindness registrations are ascribed to	

INTERVENTION	EVIDENCE SUMMARY	REFERENCES
	glaucoma. The National Screening Committee (NSC) in co-ordination with the Welsh Assembly convened a workshop on screening for glaucoma in September 2001. The NSC Policy Position in July 2006 (this position will be reviewed in 2007) was that screening should not be offered. A systematic review has been commissioned by the Health Technology Assessment program with the aim of assessing the extent to which screening for open angle glaucoma meets the UK National Screening Committee criteria for a screening program; this will be published in 2008. On the basis of current evidence, population-based screening for chronic open angle glaucoma (OAG) cannot be recommended, although much can be done to improve awareness and encourage at risk individuals to seek testing. In wealthy countries with equitable access to high quality eye care and health education, blindness from chronic OAG should become increasingly rare; much greater challenges face poor and emerging economies and countries where there are substantial health and wealth inequalities. Effectiveness of screening for OAG can be established only by high quality RCTs. A NICE guideline on glaucoma is due in 2009	National Screening Committee UK. *National Screening Committee policy – glaucoma screening*. London: NSC; 2006. Available at: http://www.library.nhs.uk/guidelinesfinder/ViewResource.aspx?resID=61003 [Accessed 19th Sept 2007] Hatt S, Wormald R, Burr J. Screening for prevention of optic nerve damage due to chronic open angle glaucoma. *Cochrane Database of Systematic Reviews* 2006, Issue 4..
Photodynamic therapy for macular degeneration	Photodynamic therapy (PDT) is based upon the ability of chemical agents, known as photosensitizers, to produce cytotoxicity in the presence of oxygen after stimulation by light of an appropriate wavelength. NICE have considered the use of PDT for age related macular degeneration and consider it to be clinically effective and cost effective for patients who have "classic with no occult" subfoveal neovascularisation.	Wormald R, Evans J, Smeeth L et al. Photodynamic therapy for neovascular age-related macular degeneration. *Cochrane Database of Systematic Reviews* 2005, Issue 4. National Institute for Health and Clinical Excellence. *The clinical effectiveness and cost effectiveness of photodynamic therapy for age related macular degeneration.* London: NICE 2003. Available at: http://guidance.nice.org.uk/TA68 [Accessed 19th Sept 2007]
NEUROLOGY and NEUROSURGERY		
Spinal cord stimulation for	There is limited randomised controlled trial evidence (two trials)	Aggressive Research Intelligence Facility. Spinal Cord

INTERVENTION	EVIDENCE SUMMARY	REFERENCES
chronic pain	that spinal cord stimulation is effective for chronic neuropathic pain due to failed back surgery and complex pain syndrome The Ontario health technology assessment also assessed cost-effectiveness and the authors felt there was evidence that the costs of spinal cord stimulation were justified by the observed benefits. This may have been the reason why their conclusion was less cautious than the Cochrane review, the Ontario recommendation being for: "Increased access to this technology (spinal cord stimulation) for the management of chronic intractable neuropathic pain within the context of a multi-disciplinary comprehensive pain management program." NICE does not believe that this procedure falls within its remit because the procedure is considered standard clinical practice with risks and benefits that are sufficiently well-known	Stimulation Chronic Neuropathic Pain "Failed" Back Surgery Syndrome Complex Regional Pain Syndrome. Webpage. [Cited 19th Sept 2007] Available at: http://www.arif.bham.ac.uk/requests/s/spinal-cord-stimulation-neuropathic-pain-back.htm Mailis-Gagnon A, Furlan AD, Sandoval JA et al. Spinal cord stimulation for chronic pain. *Cochrane Database of Systematic Reviews* 2004, Issue 3. Available at: http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD003783/frame.html [Accessed 1st Oct 2007] Ontario Ministry of Health and Long-Term Care. *Medical Advisory Secretariat. Spinal cord stimulation for the management of neuropathic pain*. Health technology literature review Ontario: Ministry of Health and Long-Term Care (MAS) 2005:80 http://www.health.gov.on.ca/english/providers/program/ohtac/tech/reviews/pdf/rev_scs_030105.pdf [Accessed 1st Oct 2007]
Computer based cognitive behavioural therapy (CCBT)	Computerised cognitive behaviour therapy (CCBT) is a self-help option that offers patients the potential benefits of CBT with less therapist involvement. One health technology assessment identified 20 studies, the analysis of which showed some evidence that CCBT is as effective as therapist-led cognitive behaviour therapy (TCBT) for the treatment of depression/anxiety and phobia/panic and is more effective than treatment as usual in the treatment of depression/anxiety. The quality of evidence on response to therapy, longer term outcomes and quality of life is poor. NICE has reviewed the evidence for several forms of CCBT to treat depression and anxiety and concludes that:- • Beating the Blues is recommended for people with mild and moderate depression.	Kaltenthaler E; Brazier J; De Nigris E et al. Computerised cognitive behaviour therapy for depression and anxiety update: a systematic review and economic evaluation. *Health Technology Assessment* 2006;10 (33). National Institute for Health and Clinical Excellence. *Computerised cognitive behaviour therapy for depression and anxiety (review).* London: NICE; 2006. Available at: http://guidance.nice.org.uk/TA97 [Accessed 1st Oct 2007]

INTERVENTION	EVIDENCE SUMMARY	REFERENCES
	• FearFighter is recommended for people with panic and phobia. • The evidence is insufficient to recommend COPE and Overcoming Depression for managing depression, except as part of ongoing or new clinical trials. OCFighter is not recommended for people with obsessive-compulsive disorder who are not already using it. People who are currently using OCFighter should have the option to continue with the treatment until they, their GP and/or specialist think it is right to stop.	
Acetylcholinesterase inhibitors for non-Alzheimer's dementia.	The NICE guidance on acetylcholinesterase inhibitors donezepil, rivastigmine, galantamine and tacrine for people with Alzheimer's disease does not extend to people with other forms of dementia. The evidence given below is for non Alzheimer's forms of dementia:-	Fajemisin B. Acetylcholinesterase inhibitors: donepezil, rivastigmine, tacrine or galantamine for non-Alzheimer's dementia. In: Foxcroft DR, Muthu V (eds) *STEER*: *Succinct and timely evaluated evidence reviews* 2002; 2(2). Southampton: Wessex Institute for Health Research and Development. Available at: http://www.wihrd.soton.ac.uk/projx/signpost/steers/STEER_2002(2).pdf [Accessed 1st Oct 2007]
	DONEZEPIL • One systematic review found that donezepil (10mg daily) improved cognitive function but not global state compared with placebo at 24 weeks. Adverse effects and withdrawal from treatment compared with placebo were also significantly increased. • There were no RCTs for people with Lewy body dementia	Warner J; Butler R; Wunktal B. Dementia. Donezepil. *BMJ Clinical Evidence.* 2006. Available at: http://clinicalevidence.bmj.com/ceweb/index.jsp [Accessed 1st Oct 2007]
	GALANTAMINE • One systematic review concluded that galantamine use in mild cognitive impairment is not recommended. • One systematic review identified 2 RCTS comparing galantamine with placebo. The evidence from these trials was inconclusive. In both trials galantamine produced higher rates of gastrointestinal side-effects compared with placebo.	Werner J, Butler R, Wunktal B. Dementia. Galantamine. *BMJ Clinical Evidence* 2006. Available at: http://clinicalevidence.bmj.com/ceweb/index.jsp [Accessed 1st Oct 2007] Craig D, Birks J. Galantamine for vascular cognitive impairment.. *Cochrane Database of Systematic Reviews* 2006, Issue 1. Available at: http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD004746/pdf_fs.html [Accessed 1st Oct 2007
	RIVASTIGMINE	Warner J, Butler R, Wunktal B. Dementia. Rivastigmine.

INTERVENTION	EVIDENCE SUMMARY	REFERENCES
	• Two RCTs found that, compared with placebo, rivastigmine improved cognitive and global functioning in people with Lewy body dementia or dementia due to Parkinson's disease. Adverse effects such as nausea, vomiting, and anorexia were common with rivastigmine treatment. No RCTs were identified of rivastigmine in people with vascular dementia	*BMJ Clinical Evidence* 2006. Available at: http://clinicalevidence.bmj.com/ceweb/index.jsp [Accessed 1st Oct 2007]
	TACRINE • High quality RCT evidence was not found for the effects of tacrine in people with dementia.	Warner J; Butler R; Wunktal B. Dementia. Tacrine. *BMJ Clinical Evidence* 2006. Available at: http://clinicalevidence.bmj.com/ceweb/index.jsp [Accessed 1st Oct 2007]
Subthalmic nucleotomy for Parkinson's disease	Surgery for Parkinson's disease is carried out on structures within the brain that are responsible for the modification of movements, such as the thalamus, the globus pallidus and the subthalamic nucleus. Surgical treatment aims to correct the imbalance created by diminished function of the substantia negra, the underlying abnormality in Parkinson's Disease. All these procedures carry the risk of stroke, confusion and speech and visual problems. In subthalamotomy (subthalmic nucleotomy), a part of the subthalamic nucleus is destroyed using heat or radiofrequency. • The evidence was limited to small case series, with only two case series assessing efficacy on a total of 32 patients. Both these studies suggested an improvement in motor skills as measured by the Unified Parkinson Disease Rating Scale (UPDRS) at 12 months' follow-up. • Current evidence on the safety and efficacy of subthalamotomy for Parkinson's disease does not appear adequate to support the use of this procedure without special arrangements for consent and for audit or research. Subthalamotomy for Parkinson's disease is a treatment option in the PD Surgery trial, which is expected to complete randomisation in 2005/6. (www.pdsurg.bham.ac.uk/trial/).	Goetz CG, Poewe W, Rascol O, et al. Evidence-based medical review update: pharmacological and surgical treatments of Parkinson's disease. *Movement Disorders* 2005;20:523–39 National Institute for Health and Clinical Excellence Subthalamotomy for Parkinson's disease. London: NICE; 2004. Available at: http://guidance.nice.org.uk/IPG65 [Accessed 1st Oct 2007] Clark CE; Moore AP. Parkinson's disease. *BMJ Clinical Evidence* 2006. Available at: http://clinicalevidence.bmj.com/ceweb/index.jsp [Accessed 1st Oct 2007]

INTERVENTION	EVIDENCE SUMMARY	REFERENCES
MENTAL HEALTH		
Propentofylline – mental health.	Propentofylline is a novel therapeutic agent for dementia that readily crosses the blood-brain barrier and acts by blocking the uptake of adenosine and inhibiting the enzyme phosphodiesterase. In vitro and in vivo its mechanism of action appears to be twofold; it inhibits the production of free radicals and reduces the activation of microglial cells. It therefore interacts with the inflammatory processes that are thought to contribute to dementia, and given its mechanism of action is a possible disease modifying agent rather than a purely symptomatic treatment. There is limited evidence that propentofylline might benefit cognition, global function and activities of daily living of people with Alzheimer's disease and/or vascular dementia. The reported meta-analyses are unsatisfactory as a summary of the efficacy of propentofylline, considering the unpublished information on another 1200 patients in randomized trials that exists. Aventis has been unwilling to correspond with the authors of the Cochrane review, significantly limiting the scope of the review. A systematic review published in 2004, concluded that cognition (general and specific) was improved by propentofylline.	Frampton M, Harvey RJ, Kirchner V. Propentofylline for dementia. *Cochrane Database of Systematic Reviews* 2003, Issue 2. Available at: http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD002853/pdf_fs.html [Accessed 1st Oct 2007] Santaguida P; Raina P; Booker L; et al. Pharmacological treatment of dementia. *Evidence Report Technology Assessment* 2004; (97)
Therapeutic community method for treatment of borderline personality	The Cochrane review suggests that some of the problems frequently encountered by people with borderline personality disorder may be amenable to talking/behavioural treatments, but all therapies remain experimental and the studies are too few and small to make definite conclusions about effectiveness. The one study by Hafner specifically on therapeutic community treatment was excluded from the Cochrane review.	Binks CA, Fenton M, McCarthy L et al. Psychological therapies for people with borderline personality disorder. *Cochrane Database of Systematic Reviews* 2006, Issue 1. Available at: http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD005652/pdf_fs.html [Accessed 1st Oct 2007] Hafner RJ, Holme G. The influence of a therapeutic community on psychiatric disorder. *Journal Clinical Psychology* 1996; 52: 461.
Electroconvulsive therapy (ECT) other than in-line with NICE guidance	NICE has recommended that ECT should only be used for the treatment of severe depressive illness, a prolonged or severe episode of mania, or catatonia if the conditions described in the NICE guidance (TA059) are applied. NICE recommends that	National Institute for Health and Clinical Excellence. *The clinical effectiveness and cost effectiveness of electroconvulsive Therapy (ECT) for depressive illness, schizophrenia, catatonia and mania*. London: NICE; 2003.

INTERVENTION	EVIDENCE SUMMARY	REFERENCES
	ECT should not to be used as a long-term treatment to prevent recurrence of depressive illness, and that it should not be used in the general management of schizophrenia. The NICE guidelines do not recommend ECT as a treatment for moderate depressive episodes. As discussed in the response to the appraisal from the Royal College of Psychiatrists' special committee on ECT and the Scottish electroconvulsive therapy audit network (SEAN), the RCTs that form the evidence base for ECT were carried out mainly on moderately or moderately severely depressed patients, excluding those with severe depressive episodes who were unable to give informed consent. Studies into its long term effects on cognitive function are lacking, but in 1 systematic review, 29-55% of patients report persistent memory loss. However, the validity of this figure is questionable because of the poor methodological design of the studies included. People with obsessive compulsive disorder and depression are sometimes treated with ECT. No published high quality evidence was found.	Available at: http://www.nice.org.uk/TA059 [Accessed 1st Oct 2007] National Institute for Health and Clinical Excellence. *Appraisal of electroconvulsive therapy. Decision of the appeal panel*. London: NICE; 2003. Available at: http://guidance.nice.org.uk/page.aspx?o=62452 [Accessed 1st Oct 2007] Butler R; Carney S; Cipriani A et al. Depression in adults. Interventions in mild, moderate or severe depression. Electroconvulsive therapy. *BMJ Clinical Evidence* 2005. Available at: http://clinicalevidence.bmj.com/ceweb/about/index.jsp [Accessed 1st Oct 2007] Rose D, Wykes T, Leese M, Bindman J, Fleischmann P. Patients' perspectives on electroconvulsive therapy: systematic review. *BMJ* 2003;326: 1363-5 Soomro GM. Obsessive compulsive disorder. *BMJ Clinical Evidence* 2006. Available at: http://clinicalevidence.bmj.com/ceweb/about/index.jsp [Accessed 1st Oct 2007]
Gender reassignment surgery, except where mental health problems result.	There is no systematic review of the available research literature and the higher quality reviews identified do not give sufficient detail about the review method to assure that bias has been avoided. The overall conclusion reached by the authors of a comprehensive review in 2004 was that the degree of uncertainty about any of the effects of gender reassignment is such that it is impossible to make a judgement about whether the procedure is clinically effective.	Day P. Trans-gender reassignment surgery. NZHTA Technology Brief Report 2002; 1: (1) Christchurch: New Zealand. Available at: http://nzhta.chmeds.ac.nz/publications/trans_gender.pdf [Accessed 1st Oct 2007] Aggressive Research Intelligence Facility. *Gender reassignment surgery*. Webpage. [Cited 1st Oct 2007] Birmingham: ARIF; 2004. Available at: http://www.arif.bham.ac.uk/requests/g/genderreass.htm
ORTHOPAEDIC		

INTERVENTION	EVIDENCE SUMMARY	REFERENCES
SURGERY		
Internal fixation of fracture of the distal radius and tibial shaft.	The 48 randomised trials do not provide robust evidence for most of the decisions necessary in the management of radial fractures. It is also unclear whether surgical intervention of most fracture types will produce consistently better long-term outcomes. The evidence is inconclusive regarding internal fixation in the primary management of distal radius fractures, and there is little or no evidence to indicate the relative benefits of internal fixation versus other treatments for other classifications of tibial shaft fractures. There is some evidence to suggest the effectiveness of internal fixation for Gustilo grade IIIB tibial fractures, with the proviso that deep sepsis rates are checked. Cost effectiveness has yet to be demonstrated in high quality studies.	Handoll HHG, Madhok R. Surgical interventions for treating distal radial fractures in adults. *Cochrane Database of Systematic Reviews* 2003, Issue 3. Available at: http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD003209/pdf_fs.html [Accessed 1st Oct 2007] Calvert N. Internal fixation of fractures of the shaft of the tibia and of the distal radius in adults. *Research Findings Register*. Summary number 500. Available at: http://www.ReFeR.nhs.uk/ViewRecord.asp?ID=500 [Accessed 10th Oct 2007]
Treatment (including surgery) outside National Guidelines for acute low back pain	The two guidelines most frequently used in the UK are listed. There is some controversy over the evidence used to support the recommendations in these two guidelines, particularly for physiotherapy and spinal manipulation (see NPHS review of acute back pain)	van Tulder, M, Becker, A, Bickering, T et al *European guidelines for the management of acute non-specific low back pain in primary care.* European Commission, Research Directorate General 2004. Available at:. http://www.backpaineurope.org/web/files/WG1_Guidelines.pdf [Accessed 1st Oct 2007] Prodigy guidance – Back pain – lower. Available at: http://www.cks.library.nhs.uk/back_pain_lower. [Accessed 1st Oct 2007]
Therapeutic ultrasound in physiotherapy	Ultrasound therapy appears to have no benefit over placebo or short wave diathermy for people with hip or knee osteoarthritis (OA). These conclusions are limited by the poor reporting of the characteristics of the device, the population, the stage of OA, therapeutic application of the ultrasound and overall low methodological quality of the trials included. No conclusions can be drawn about the use of ultrasound in smaller joints such as the wrist or hands. Ultrasound therapy was not shown to have a clinically important effect on pain relief for people with patellofemoral pain syndrome. Similar caveats apply to the conclusions as for hip and knee OA. No conclusions can be drawn concerning the use, or non-use, of	Robinson VA, Brosseau L, Peterson J et al. Therapeutic ultrasound for osteoarthritis of the knee. *Cochrane Database of Systematic Reviews* 2001, Issue 3. Available at: http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD003132/pdf_fs.html [Accessed 1st Oct 2007] Brosseau L, Casimiro L, Robinson V et al. Therapeutic ultrasound for treating patellofemoral pain syndrome. *Cochrane Database of Systematic Reviews* 2001, Issue 4. Available at: http://www.mrw.interscience.wiley.com/cochrane/clsysrev/art

INTERVENTION	EVIDENCE SUMMARY	REFERENCES
	ultrasound for treating patellofemoral pain syndrome. More well-designed studies are needed	icles/CD003375/pdf_fs.html [Accessed 1st Oct 2007]
Geriatric Orthopaedic Rehabilitation Units	A geriatric orthopaedic rehabilitation unit (GORU) is a ward or part of a ward in which beds are used for the treatment and care of inpatients of sixty-five years and over who have had an orthopaedic injury requiring an operation and need long rehabilitation. The observed trends favour GORUs over conventional management, with a reduction in deaths and an increase in functional improvement. GORUs can increase the efficiency of acute bed use by taking on potentially long stay patients, for example, patients needing prolonged rehabilitation prior to discharge or patients who are unable to return home and are awaiting an alternative placement. As GORUs tend to increase the chance of a patient returning to their own home, they may be cost-effective in reducing the costs of residential care. High quality evidence for the effectiveness of GORUs compared with mixed assessment and rehabilitation units is lacking	Cameron I, Crotty M, Currie C et al. Geriatric rehabilitation following fractures in older people: a systematic review. *Health Technology Assessment* 2000; 4 (2). Cameron I, Handoll H, Finnegan T et al. Co-ordinated multidisciplinary approaches for inpatient rehabilitation of older patients with proximal femoral fractures. *Cochrane Database of Systematic Reviews* 2001., Issue 1. Available at: http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD000106/pdf_fs.html [Accessed 1st Oct 2007] Scottish Intercollegiate Guideline Network. *Prevention and management of hip fracture in older people*. Edinburgh: SIGN; 2002. Available at: http://www.sign.ac.uk/guidelines/fulltext/56/index.html [Accessed 1st Oct 2007]
Intramedullary fixation with cephalocondylic nail for extracapsular hip fractures (vs. extramedullary fixation	One systematic review found no significant difference between intramedullary fixation with a short cephalocondylic nail (e.g. Gamma nail) and extramedullary fixation with a sliding hip screw in mortality, pain at follow up, ability to return to a previous residence, and ability to walk after 3–12 months. The review also found no significant difference between treatments in wound infection or cut-out of the implant, but found that cephalocondylic intramedullary fixation increased intraoperative and later femoral fractures and reoperation rates. The limited evidence from published RCTs is insufficient to determine whether there are important differences in outcome between different designs of intramedullary nails used in the internal fixation of extracapsular hip fractures. Given the evidence of superiority of the sliding hip screw compared with intramedullary nails for extracapsular hip fractures, further studies comparing different designs of intramedullary nails are not a priority.	Handoll H; Parker M. Intramedullary fixation with short cephalocondylic nails versus sliding hip screw for extracapsular hip fracture. *BMJ Clinical Evidence* 2006. Available at: http://clinicalevidence.bmj.com/ceweb/about/index.jsp [Accessed 1st Oct 2007] Parker MJ, Handoll HHG. Gamma and other cephalocondylic intramedullary nails versus extramedullary implants for extracapsular hip fractures in adults. *Cochrane Database of Systematic Reviews* 2005, Issue 4. Available at: http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD000093/pdf_fs.html [Accessed 1st Oct 2007] Parker MJ, Handoll HHG. Intramedullary nails for extracapsular hip fractures in adults. *Cochrane Database of Systematic Reviews* 2006, Issue 3. Available at: http://www.mrw.interscience.wiley.com/cochrane/clsysrev/art

INTERVENTION	EVIDENCE SUMMARY	REFERENCES
		icles/CD004961/pdf_fs.html [Accessed 1st Oct 2007]
Hip prostheses not reaching a benchmark of 10% revision rate at 10 years.	Using the most recent available evidence of clinical effectiveness, the best prostheses (using long term viability as the determinant) demonstrate a revision rate of 10% or less at 10 years. This should be regarded as the current 'benchmark' in the selection of prostheses for primary Total Hip Replacement (THR).	National Institute for Health and Clinical Excellence. *Guidance on the selection of prostheses for primary total hip replacement.* London: NICE; 2000. Available at: http://guidance.nice.org.uk/TA2 [Accessed 1st Oct 2007] National Audit Office. *Hip replacements: an update.* London: NAO; 2003. Available at: http://www.nao.org.uk/publications/nao_reports/02-03/0203956.pdf [Accessed 1st Oct 2007]
Autologous cartilage transplantation	• Autologous chondrocyte implantation (ACI) is not recommended for the treatment of articular cartilage defects of the knee joint, except in the context of ongoing or new clinical studies that are designed to generate robust and relevant outcome data, including the measurement of health-related quality of life and long-term follow-up. • Patients should be fully informed of the uncertainties about the long-term effectiveness and the potential adverse effects of this procedure	National Institute for Health and Clinical Excellence. *Cartilage injury - autologous chondrocyte implantation (ACI)* (review). London: NICE; 2005. Available at: http://guidance.nice.org.uk/TA89 [Accessed 1st Oct 2007] National Public Health Service. *Autologous chondrocyte implantation for the ankle joints*. Cardiff: NPHS; 2006. Available at: http://nww2.nphs.wales.nhs.uk. [Accessed 1st Oct 2007]
Hip resurfacing techniques	Metal on Metal (MoM) hip resurfacing arthroplasty involves removal of the diseased or damaged surfaces of the head of the femur and the acetabulum. The femoral head is fitted with a metal surface and the acetabulum is lined with a metal cup to form a pair of metal bearings. • The systematic review published by Wyness found three reviews and one RCT comparing different prostheses for total hip replacement (THR). There were no RCTs or comparative observational studies comparing THR with metal-on-metal hip resurfacing arthroplasty. • The NICE guidance concluded that patients who are likely to outlive conventional primary hip replacements should have the choice of MoM resurfacing arthroplasty. The decision was made on the basis that there is sufficient short-term evidence of the effectiveness of	Wyness L, Vale L, McCormack K et al. The effectiveness of metal on metal hip resurfacing: a systematic review of the available evidence published before 2002. *BMC Health Service Research* 2004; 4:39. National Institute for Health and Clinical Excellence. *The clinical effectiveness and cost effectiveness of metal on metal hip resurfacing.* London: NICE; 2002. Available at: http://guidance.nice.org.uk/TA44 [Accessed 1st Oct 2007] Chard J, Smith C, Lohmander S et al. Osteoarthritis of the hip. Surgery for OA of the hip. *BMJ Clinical Evidence* 2006. Available at: http://clinicalevidence.bmj.com/ceweb/about/index.jsp

INTERVENTION	EVIDENCE SUMMARY	REFERENCES
	metal on metal resurfacing arthroplasty to conclude that they are at least as effective as conventional THR for patients younger than 55 years. • The guidance also states that when considering MoM hip resurfacing surgeons should bear in mind:- • how active the individual is that the evidence available at: the moment for the clinical effectiveness and cost effectiveness of MoM hip resurfacing comes mainly from studies that have involved people less than 65 years of age.	[Accessed 1st Oct 2007]
ORAL SURGERY		
Dental implants - all circumstances except post cancer reconstruction, major trauma with bone loss and anodontia	Dental implants have been shown to be a successful treatment for replacing missing teeth by providing support for fixed bridge prostheses, individual crowns, and overdentures. Evidence from randomised controlled trials shows increased ability to chew tough food, and increased patient satisfaction with implants in comparison to normal dentures. Complications of implant surgery include swelling, pain, bleeding, possible infection, and partial numbness at implant site. Nerve disturbances that may be permanent and bone fracture can occur, as can rejection of the implant. However, severe complications are rare.	Royal College of Surgeons. *Guidelines for selecting appropriate patients to receive treatment with dental implants: priorities for the NHS.* London: RCS; 1997. Awad M A; Locker D; Korner-Bitensky N; et al. Measuring the effect of intra-oral implant rehabilitation on health related quality of life in a randomised controlled clinical trial. *Journal Dental Research* 2000; 79:1659. McCord JF, Michelinakis G. Systematic review of the evidence supporting intra-oral maxillofacial prosthodontic care. *European Journal of Prosthodontics and Restorative Dentistry*. 2004;12:129-35 Attard N J, Zarb GA, Laporte A. Long-term treatment costs associated with implant-supported mandibular prostheses in edentulous patients. *International Journal of Prosthodontics*. 2005; 18: 117-123.
Removal of asymptomatic wisdom teeth	The surgical removal of impacted third molars (symptomatic and asymptomatic) is the most common procedure performed by oral and maxillofacial surgeons. • Whilst it is clear that symptomatic impacted wisdom teeth should be surgically removed, it appears that extracting asymptomatic, disease-free wisdom teeth is not advisable due to the risk of damage to the inferior alveolar nerve.	Mettes TG; Nienhuijs MEL; van der Sanden WJM et al. Interventions for treating asymptomatic impacted wisdom teeth in adolescents and adults. *Cochrane Database of Systematic Reviews* 2005, Issue 2. Available at: http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD003879/pdf_fs.html [Accessed 1st Oct 2007]

INTERVENTION	EVIDENCE SUMMARY	REFERENCES
	• Some non-RCT evidence suggests that extraction of the asymptomatic tooth may be beneficial if caries are present in the adjacent second molar, or if periodontal pockets are present distal to the second molar.	National Institute for Health and Clinical Excellence. *Wisdom teeth –removal.* London: NICE; 2000. Available at: http://www.nice.org.uk/page.aspx?o=509 [Accessed 1st Oct 2007] Esposito M. Impacted wisdom teeth. *BMJ Clinical Evidence* 2006. Available at: http://clinicalevidence.bmj.com/ceweb/about/index.jsp [Accessed 1st Oct 2007]
Apicectomy – adult molar teeth	The success rate of apical surgery on molar teeth is low and should not be routinely undertaken.	British Association Oral and Maxillofacial Surgeons. *Referral guidelines. Apical surgery.* London: BAOM; 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]
Orthodontic treatments for essentially cosmetic nature	Orthodontic treatment is usually not offered to people with a score of less than 4 or 5 on the Index of Orthodontic Treatment Need (IOTN).	Brook PH, Shaw WC. The development of an index of orthodontic treatment priority. *European Journal of Orthodontics* 1989; 11: 309-320. Richmond S; Shaw WC; Stephens CD et al. Orthodontics in the General Dental Service of England and Wales: Critical assessment of standards. *British Dental Journal* 1993; 174: 315.
ENT SURGERY		
Tonsillectomy	• Despite the lack of evidence of benefit, tonsillectomy, with or without adenoidectomy, is one of the most frequently performed surgical procedures in the UK. • There is no high quality evidence in adults for the effectiveness of tonsillectomy. • Any benefits from tonsillectomy may be outweighed by the morbidity associated with surgery in children who are not severely affected by tonsillitis. • The indications for tonsillectomy are that patients should meet all of the following criteria:- • Sore throats are due to tonsillitis	McKerrow W. Tonsillitis. Tonsillectomy versus watchful waiting with antibiotics. Webpage. [Cited 1st Oct 2007] *BMJ Clinical Evidence* 2006. Available at: http://clinicalevidence.bmj.com/ceweb/about/index.jsp Royal College of Paediatrics and Child Health. *Guidelines for good practice. Management of acute and recurring sore throat and indications for tonsillectomy*. London; RCPCH; 2000 The National Institute for Health and Clinical Excellence have published guidance on electrosurgery, laser and

INTERVENTION	EVIDENCE SUMMARY	REFERENCES
	• Five 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	ultrasonic scalpel techniques for tonsillectomy. Available at: http://www.nice.org.uk/ [Accessed 1st Oct 2007]
Grommets	• The benefits of grommets in children appear small. • The effects of grommets on hearing decreased during the first year post insertion. • Potentially adverse effects on the tympanic membrane are common after grommet insertion. • One review found that grommets did not significantly improve cognition, language comprehension or expression compared with no ventilation tubes.	Lous J, Burton MJ, Felding JU et al.. Grommets (ventilation tubes) for hearing loss associated with otitis media with effusion in children. *Cochrane Database of Systematic Reviews* 2005, Issue 1. Available at: http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD001801/pdf_fs.html [Accessed 1st Oct 2007] Langton Hewer CD, McDonald S, Nunez DA. Grommets (ventilation tubes) for recurrent acute otitis media in children. (Protocol) *Cochrane Database of Systematic Reviews* 2004, Issue 2. Available at: http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD004741/pdf_fs.html [Accessed 1st Oct 2007] Williamson I. Otitis media with effusion. Treatment. Surgery (ventilation tubes, adenoidectomy, or both). *BMJ Clinical Evidence* 2006. Available at: http://clinicalevidence.bmj.com/ceweb/about/index.jsp [Accessed 1st Oct 2007] Paradise JL, Feldman HM, Campbell TF et al. Tympanostomy tubes and developmental outcomes at 9 to 11 years of age. *NEJM* 2007; 356: 248-261.
Sleep apnoea treatment (surgery or CPAP)	Obstructive sleep apnoea is the periodic reduction (hypopnoea) or cessation (apnoea) of breathing due to narrowing or occlusion of the upper airway during sleep. Continuous positive airway pressure (CPAP) is the main current method of management of sleep apnoea. Surgery is performed less often. CPAP is effective in reducing symptoms of sleepiness and improving quality of life measures in people with moderate and severe obstructive sleep apnoea (OSA). It is more effective than oral appliances in reducing respiratory disturbances in these people	Giles TL, Lasserson TJ, Smith BJ et al. Continuous positive airways pressure for obstructive sleep apnoea in adults. *Cochrane Database of Systematic Reviews* 2006, Issue 3. Available at: http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD001106/pdf_fs.html . [Accessed 1st Oct 2007]

INTERVENTION	EVIDENCE SUMMARY	REFERENCES
	but subjective outcomes are more equivocal. Certain people tend to prefer oral appliances to CPAP where both are effective. This could be because they offer a more convenient way of controlling sleep apnoea. Short-term data indicate that CPAP leads to lower blood pressure than control. Long-term data are required for all outcomes in order to determine whether the initial benefits seen in short-term clinical trials persist. Compliance with CPAP is problematical.. The type of CPAP delivery interface is likely to influence a patient's acceptance of CPAP therapy and long term compliance. Due to the limited number of studies available comparing various interface types, the optimum form of CPAP delivery interface remains unclear. NICE are in the process of appraising CPAP and the appraisal is due for publication in January 2008. There are now a small number of trials assessing different surgical techniques with inactive and active control treatments. The studies assembled in the review do not provide evidence to support the use of surgery in sleep apnoea/hypopnoea syndrome, as overall significant benefit has not been demonstrated	Chai CL, Pathinathan A, Smith B. Continuous positive airway pressure delivery interfaces for obstructive sleep apnoea. *Cochrane Database of Systematic Reviews* 2006, Issue 4. Available at: http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD005308/pdf_fs.html . [Accessed 1st Oct 2007] Sundaram S, Bridgman SA, Lim J et al. Surgery for obstructive sleep apnoea. *Cochrane Database of Systematic Reviews* 2005, Issue 4. Available at: http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD001004/pdf_fs.html [Accessed 1st Oct 2007]
CANCER		
Radiotherapy in upper gastro-intestinal cancers	For oesophageal and junctional tumours two randomised controlled trials found that surgery was significantly more likely than radiotherapy to improve both swallowing and survival (p=0.002) in patients with operable tumours. For carcinomas of the oesophagus and gasto-oesophageal junction external beam radiotherapy, intraluminal radiotherapy (brachytherapy), a combination of external beam radiotherapy and brachytherapy, and laser therapy are commonly used palliative modalities to improve dysphagia	Melville A, Eastwood A, Morris E et al. Management of upper gastrointestinal cancers *Quality in. Health Care* 2001;10;57 Homs MYV, v.d. Gaast A, Siersema PD et al. Chemotherapy for metastatic carcinoma of the esophagus and gastro-esophageal junction. *Cochrane Database of Systematic Reviews* 2006, Issue 4. Available at: http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD004063/pdf_fs.html [Accessed 1st Oct 2007]

INTERVENTION	EVIDENCE SUMMARY	REFERENCES
Ovarian ablation (vs. Tamoxifen) as first line hormonal treatment in premenopausal women with metastatic breast cancer.	One systematic review and one subsequent RCT in premenopausal women found no significant difference in response rate, duration of response, or survival between ovarian ablation (surgery or irradiation) and tamoxifen as first line treatment. Ovarian ablation is associated with substantial adverse effects such as hot flushes and "tumour flare".	Stebbing J, Slater S, Slevin M. Breast cancer (metastatic). First line hormonal treatment. Ovarian ablation in premenopausal women. *BMJ Clinical Evidence* 2007. Available at: http://clinicalevidence.bmj.com/ceweb/about/index.jsp [Accessed 1st Oct 2007]
High dose chemotherapy (vs. conventional chemotherapy) as first line chemotherapy in metastatic breast cancer	One systematic review and one subsequent RCT found no significant difference in overall survival over 1–5 years between high dose chemotherapy (requiring haematopoietic transplant) and standard dose chemotherapy. The review and the RCT found that high dose chemotherapy increased treatment-related morbidity and mortality compared with standard chemotherapy	Stebbing J, Slater S, Slevin M. Breast cancer (metastatic). First line chemotherapy. High dose versus standard dose chemotherapy. *BMJ Clinical Evidence* 2007. Available at: http://clinicalevidence.bmj.com/ceweb/about/index.jsp [Accessed 1st Oct 2007]
Laparoscopic (vs. open) resection in colorectal cancer	Previous guidance from NICE on the use of laparoscopic surgery for colorectal cancer was that open rather than laparoscopic surgery was the preferred procedure and that laparoscopic surgery should only be undertaken as part of a randomised controlled trial (RCT). This guidance was based on a technology assessment review conducted in 2000.1 New data have become available since then, particularly from three large RCTs Laparoscopic resection is associated with a quicker recovery (shorter time to return to usual activities and length of hospitalisation) and no evidence of a difference in mortality or disease-free survival up to 3 years following surgery. However, operation times are longer and a significant number of procedures initiated laparoscopically may need to be converted to open surgery. The rate of conversion may be dependent on experience in terms of both patient selection and performing the technique. Laparoscopic resection appears more costly to the health service than open resection, with an estimated extra total cost of between pound250 and pound300 per patient. In terms of relative cost-effectiveness, laparoscopic resection is associated with a modest additional cost, short-term benefits associated with more rapid recovery and similar long-term outcomes in terms of survival and cure rates up to 3 years.	National Institute for Health and Clinical Excellence. *Laparoscopic surgery for colorectal surgery*. London: NICE; 2000. Available at: http://guidance.nice.org.uk/TA105 [Accessed 1st Oct 2007] Murray A, Lourenco T, de Verteuil R et al. Clinical effectiveness and cost-effectiveness of laparoscopic surgery for colorectal cancer: systematic reviews and economic evaluation. *Health Technol Assess* 2006 (45)

INTERVENTION	EVIDENCE SUMMARY	REFERENCES
	Based on evidence mainly from non-randomized studies, laparoscopic total mesorectal excision appears to have clinically measurable short-term advantages in patients with primary resectable rectal cancer. The long-term impact on oncological endpoints awaits the findings from large on-going randomized trials.	Breukink S; Pierie J; Wiggers T. Laparoscopic versus open total mesorectal excision for rectal cancer. *Cochrane Database of Systematic Reviews* 2006, Issue 4. Available at: http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD005200/pdf_fs.html [Accessed 1st Oct 2007]
Prostate brachytherapy – other than in line with NICE guidance	A recent review of the evidence and the local commissioning status for both low and high dose brachytherapy for prostate cancer has been produced by Caerphilly Local Health Board. Health Commission Wales (HCW) approved a policy for the commissioning of brachytherapy at the June 2006 meeting of its National Commissioning Advisory Board. Currently however, brachytherapy for prostate cancer is not available in Wales. On the 13th February 2007 BBC Wales reported that the National Assembly for Wales had announced that brachytherapy will be available in Velindre NHS trust from April 2007 CHECK **High dose brachytherapy** • NICE concluded that current evidence on the safety and efficacy of high dose rate (HDR) brachytherapy in combination with external-beam radiotherapy for localised prostate cancer appears adequate to support the use of these procedures, provided that consent is obtained and monitoring is performed. The caveats are:- • These recommendations do not apply to HDR brachytherapy for localised prostate cancer, when used as monotherapy. Use of the procedure as monotherapy is currently the subject of research studies. The data were difficult to interpret because of the heterogeneous groups of men in the studies and the variety of radiation dosage schedules.	Deacon T. *Brachytherapy for localised prostate cancer*. Caerphilly Local Health Board 2006. Available at: National Institute for Health and Clinical Excellence. *High dose rate brachytherapy in combination with external-beam radiotherapy for localised prostate cancer – guidance.* London: NICE; 2006. Available at: http://guidance.nice.org.uk/IPG174/guidance/pdf/English [Accessed 1st Oct 2007] National Institute for Health and Clinical Excellence. *Interventional procedure overview of high dose rate brachytherapy for prostate cancer*. London: NICE; 2005. Available at: http://guidance.nice.org.uk/page.aspx?o=ip309overview [Accessed 1st Oct 2007]
	Low dose brachytherapy	National Institute for Health and Clinical Excellence. *Low*

INTERVENTION	EVIDENCE SUMMARY	REFERENCES
	NICE made identical conclusions for low dose brachytherapy (LDR) as those for HDR with the following caveats:- • Most of the evidence on the efficacy of LDR for localised prostate cancer relates to the reduction of prostate-specific antigen (PSA) levels and to biopsy findings. The effects on quality of life and long-term survival remain uncertain. Clinicians should ensure that patients understand these uncertainties and the alternative treatment options. • The data are difficult to interpret because of other treatment modalities often used alongside this procedure. A clinical guideline on the diagnosis and treatment of prostate cancer is currently being developed by NICE and will be published in November 2007.	*dose rate brachytherapy for localised prostate cancer – guidance.* London: NICE; 2005. Available at: http://guidance.nice.org.uk/IPG132/guidance/pdf/English [Accessed 1st Oct 2007] National Institute for Health and Clinical Excellence. *Low dose rate brachytherapy for localised prostate cancer*. London: NICE; 2005. Available at: http://guidance.nice.org.uk/IPG132/guidance/pdf/English [Accessed 1st Oct 2007]
CARDIOVASCULAR DISEASE		
Implantable Cardioverter Defibrillators	Implantable cardioverter defibrillators (ICDs) are recommended for patients in the following categories. 'Secondary prevention', 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: a history of previous (more than 4 weeks) myocardial infarction (MI) and: • **either** ○ left ventricular dysfunction with an LVEF of less	National Institute for Health and Clinical Excellence. *Implantable cardioverter defibrillators (ICDs) for the treatment of arrhythmias*. London: NICE; 2006. Available at: http://guidance.nice.org.uk/TA95 [Accessed 1st Oct 2007]

INTERVENTION	EVIDENCE SUMMARY	REFERENCES
	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 ○ 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. One systematic review found that implantable cardiac defibrillators reduced mortality in people with heart failure who have experienced a near fatal ventricular arrhythmia or are at high risk of sudden death. A second systematic review found that implantable cardiac defibrillators reduced mortality in people with heart failure due to non-ischaemic cardiomyopathy. The systematic reviews suggest that implantable cardiac defibrillators are more beneficial than drug therapy for secondary prevention of sudden cardiac death and for primary prevention in certain high risk groups. However, the therapy is expensive and must be used appropriately in those for whom the indications for therapy clearly exist. Further research is required to develop accurate risk stratification tools, to determine the impact of implantable cardiac defibrillators therapy in different subgroups of patients, and to evaluate quality of life issues.	Robert McKelvie. Heart failure. Implantable cardioverter defibrillators. *BMJ Clinical Evidence* 2007. Available at: http://clinicalevidence.bmj.com/ceweb/about/index.jsp [Accessed 1st Oct 2007]
Transmyocardial revascularisation	Transmyocardial laser revascularization (TMR) is used in selected patient groups with chronic refractory angina, good or	Wilson RJ, Slack R, Calvert N et al. Transmyocardial laser revascularisation for angina not controlled by medication or

INTERVENTION	EVIDENCE SUMMARY	REFERENCES
	only slightly depressed left ventricular function and inoperable coronary artery disease refractory to maximum medical therapy. Patients with poor left ventricular ejection fraction are not good candidates for laser therapy. • A systematic review with methodological problems suggested a short term benefit, but survival at 12 months was not improved. • The European Society for Cardiology Joint Study Group on the Treatment of Refractory Angina does not currently recommend TMR. • A poorly designed and reported meta-analysis of survival and relief of angina after TMR evaluated seven randomized trials that used TMR as sole therapy in 1053 patients. The authors concluded that TMR significantly improved angina at 1 year, but did not significantly alter mortality. • The author of a literature review for BestBets concluded that in selected stable patients with 'no option' CCS grade 11-1V angina TMR can significantly reduce the grade of angina at the cost of a peri-operative mortality of approximately 5%. • NICE will publish an appraisal on TMR in Spring 2007	amenable to surgery. *The Research Register Findings.* Summary no. 531. Available at: http://www.refer.nhs.uk/ViewRecord.asp?ID=531 [Accessed 2nd Oct 2007] Liao L, Sarria-Santamera A, Matchar D B et al.. Meta-analysis of survival and relief of angina pectoris after transmyocardial revascularization. *Am J Cardiol* 2005;95:1243-1245 Sanni A, Dunning J. Is transmyocardial revascularisation of benefit to people with 'no option' angina? Webpage. [Cited 2nd Oct 2007] *BestBets* 2004. Available at: http://www.bestbets.org/cgi-bin/bets.pl?record=00363
Cholesterol – population based screening	• The SIGN guideline, published in 1999, concludes that whole population screening for hyperlipidaemia is not recommended and a population-directed lifestyle programme with a targeted high risk approach should be adopted. • As a result of the Diabetes, Heart Disease and Stroke (DHDS) prevention project, the National Screening Committee recommend to the four Chief Medical Officers, the introduction of a Vascular Risk Management Programme, in which the whole population would be offered risk assessment that could include measurement of risk factors such as blood pressure, cholesterol and glucose. • A number of different options are being used by the Department of Health, NICE, and the National Screening	PRODIGY. *Hyperlipidaemia.* 2005. Available at: http://www.prodigy.nhs.uk/guidance.asp?gt=Hyperlipidaemia [Accessed 2nd Oct 2007] Scottish Intercollegiate Guideline Network. *Lipids and the primary prevention of coronary heart disease.* Edinburgh: SIGN; 1999. Superseded by SIGN 97. Risk estimation and the prevention of cardiovascular disease. Available at: http://www.sign.ac.uk/pdf/sign97.pdf. Accessed 3rd October 2007. Joint British Societies JBS 2: Joint British Societies' guidelines on prevention of cardiovascular disease in clinical practice. *Heart* 2005; 91(Suppl 5): v1.

INTERVENTION	EVIDENCE SUMMARY	REFERENCES
	Committee at present. These include primary care population-based risk assessment which would use the primary care populations to offer those who are not at highest risk, as identified by record-based assessment, the opportunity of risk assessment • Guidance is currently being prepared and will be presented to the National Screening Committee in March 2007. It is expected that the guidance will be issued to primary care in April 2007.	National Institute for Health and Clinical Excellence. *Cardiovascular risk assessment: the modification of blood lipids for the primary and secondary prevention of cardiovascular disease*. Publication date December 2007. National Screening Committee. *Policy- screening for vascular risk.* NSC 2006. Available at: http://www.library.nhs.uk/screening/ViewResource.aspx?resID=60601 [Accessed 2nd Oct 2007]
Carotid endarterectomy	Evidence from a pooled analysis of individual patient data from three RCTs in people with symptomatic carotid artery stenosis found that carotid endarterectomy increased the risk of stroke or operative death in people with less than 30% carotid stenosis compared with no endarterectomy, was of no benefit in people with 30–49% stenosis, and reduced stroke and death in people with 50–69% carotid stenosis, compared with no endarterectomy. The RCTs found that carotid endarterectomy reduced the risk of stroke and death compared with no endarterectomy in people with more than 70% carotid stenosis, although no benefit was found in people with near occlusion. One systematic review and one subsequent RCT found that carotid endarterectomy reduced perioperative stroke, death, and subsequent ipsilateral stroke in people with asymptomatic but severe stenosis compared with medical treatment. However, because the absolute risk of stroke in asymptomatic people is relatively low, the benefit from surgery is small. Current evidence suggests that stent placement for carotid artery stenosis is safe and efficacious in the short term. However, long-term efficacy in terms of prevention of stroke and restenosis is unknown, and there are uncertainties about the benefits for asymptomatic patients. NICE are currently producing a guideline on stroke – publication date July 2008	Gregory YHL, Rothwell P, Sudlow C. Stroke prevention. Carotid endarterectomy for people with recent carotid territory ischaemia. *BMJ Clinical Evidence* 2006. Available at: http://clinicalevidence.bmj.com/ceweb/about/index.jsp [Accessed 2nd Oct 2007] National Institute for Health and Clinical Excellence. Interventional Procedure Guidance 191. *Carotid artery stent placement for carotid stenosis*. London: NICE; 2006. Available at: http://guidance.nice.org.uk/IPG191 [Accessed 2nd Oct 2007]
OTHERS		

INTERVENTION	EVIDENCE SUMMARY	REFERENCES
Complementary therapy	It has been suggested that complementary and alternative medicine (CAM) may be useful where effectiveness gaps (i.e. where conventional treatment is unsatisfactory) exist in primary care. Musculoskeletal problems are one of the most commonly reported conditions with such gaps and for which general practitioners and patients would consider treatment with CAM. A review of the evidence in the treatment of acute low back pain indicated that there was a recommendation for spinal manipulation in 5 clinical guidelines for acute LBP; no other CAM treatments were recommended. Appraisal of the evidence used to inform these guidelines and supplementary evidence demonstrated that this evidence base was weak and subject to misinterpretation. **ACUPUNCTURE** Acupuncture is used to treat a range of conditions but the question of whether it works remains controversial. The best current evidence suggests that it is effective as a symptomatic treatment of dental pain, fibromyalgia, nausea/vomiting, knee osteoarthritis, insomnia, epicondylitis, chronic back pain, idiopathic headache, resolution of breech presentation and as an aid to gastric endoscopy. The author of the review suggests that this evidence may be unreliable due to inadequate control of placebo effects in most of the trials. He considers that if acupuncture alleviates suffering through a powerful placebo effect then it should be accepted as a useful treatment. A subsequent systematic review of systematic reviews (SRs) of acupuncture found 35 SRs, in which qualified support for acupuncture had been found in 12/35 SRs and strong support in 6. Applying stricter inclusion criteria showed, however, that none of the 35 SRs supported acupuncture because there were too few patients in the double blind trials. The evidence from the 6 reviews with >200 patients in double blind studies also showed no benefit.	Fisher P, Van Haseln R, Hardy K et al. Effectiveness gaps: a new concept for evaluating health service and research needs applied to complementary and alternative medicine. *Journal Alternative Complementary Medicine* 2004; 10: 627-632 National Public Health Service. *A rapid review of the evidence on the effectiveness of complementary and alternative medicine in acute low back pain*. Cardiff: NPHS 2006. National Public Health Service. *Complementary and alternative medicine.* Cardiff; NPHS; 2005. Public Health Advice 2. Ernst E. Acupuncture – a critical analysis. *Journal Internal Medicine* 2006; 259:125-137 Derry CJ, Derry S, McQuay HJ et al. Systematic review of systematic reviews of acupuncture published 1996-2005. *Clinical Medicine* 2006; 6:381-386 Smallwood C. *The role of complementary and alternative medicine in the NHS. An investigation into the potential contribution of mainstream complementary therapies to healthcare in the UK*. FreshMinds; 2005. Available at:: http://www.getwelluk.com/uploadedFiles/publications/smallwood%20enquiry.pdf [Accessed 2nd Oct 2007]

INTERVENTION	EVIDENCE SUMMARY	REFERENCES
	The Smallwood report concluded that the evidence for the effectiveness of acupuncture supported its use for pain management, post operative nausea and pain and post chemotherapy nausea. The evidence was of lesser quality for chronic low back pain, osteoarthritis, headache/migraine and stroke rehabilitation. This report has been heavily criticised for the conclusions drawn from the evidence the authors reviewed.	
	SPINAL MANIPULATION (Osteopathy and chiropractic treatment) Sixteen papers were included in 1 recently published systematic review of SRs. There were 3 papers on back pain, 3 on neck pain and 1 each for non-spinal pain, primary and secondary dysmenorrhoea, infant colic, asthma, allergy, cervicogenic dizziness and any medical problem. Collectively the data do not demonstrate a beneficial effect of manipulation for any of these conditions, except for back pain where it is superior to sham manipulation but not better than conventional treatments.	Ernst E, Canter PH. A systematic review of systematic reviews of spinal manipulation. *J R Soc Med* 2006; 99: 189-193
	HOMEOPATHY The metaanalysis published in the Lancet concluded that there was no evidence for the effectiveness of homeopathy in a wide variety of medical conditions. This paper received a lot of criticism and the results have been questioned.	Shang A, Huwiler K, Nartey L. et al. Are the clinical effects of homoeopathy placebo effects? Comparative study of placebo-controlled trials of homoeopathy and allopathy. *Lancet*. 2005; 366:726-
	AROMATHERAPY The authors of one review concluded that the data do not support a hypothesis that there may be legitimate clinical indications for the prescription of aromatherapy massage in a health care setting; it seems to have no lasting effects, good or bad. There was insufficient evidence to draw conclusions about the benefits of massage and aromatherapy massage for cancer patients	Cooke B, Ernst E. Aromatherapy: a systematic review. *BJGP* 2000; 50: 493 Fellowes D, Barnes K, Wilkinson S. Aromatherapy and massage for symptom relief in patients with cancer. *Cochrane Database of Systematic Reviews* 2004, Issue 3. Available at:: http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD002287/pdf_fs.html [Accessed 2nd Oct 2007] Thorgrimsen L, Spector A, Wiles A, Orrell M. Aroma therapy

INTERVENTION	EVIDENCE SUMMARY	REFERENCES
	There was insufficient evidence to demonstrate the effectiveness of aromatherapy for dementia. **REFLEXOLOGY** Evidence for reflexology in a variety of conditions was inconsistent. In premenstrual syndrome one RCT found limited evidence that reflexology was better than sham reflexology in reducing premenstrual symptoms at 8 weeks whilst another demonstrated no beneficial effect compared with foot massage. The Cochrane review did not find any trials on the use of reflexology for labour pain management. Reflexology appears to help improve symptoms for women with leg oedema, but this is based on one small study.	for dementia. *Cochrane Database of Systematic Reviews* 2003, Issue 3. Available at: http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD003150/pdf_fs.html [Accessed 2nd Oct 2007] Ernst E, Koeder K. An overview of reflexology. *European Journal of General Practice* 1997;**3**:52–7. Oleson T, Flocco W. Randomized controlled study of premenstrual symptoms treated with ear, hand, and foot reflexology. *Obstet Gynecol* 1993;82:906–911 Williamson J, White A, Hart A et al. Randomised controlled trial of reflexology for menopausal symptoms. *Br J Obstet Gynaecol* 2002; 109 :1050-5 Smith CA, Collins CT, Cyna AM, Crowther CA. Complementary and alternative therapies for pain management in labour. *Cochrane Database of Systematic Reviews* 2006, Issue 4. Available at: http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD003521/pdf_fs.html [Accessed 2nd Oct 2007] Bamigboye AA, Smyth R. Interventions for varicose veins and leg oedema in pregnancy. *Cochrane Database of Systematic Reviews* 2007, Issue 1. Available at: http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD003521/pdf_fs.html [Accessed 2nd October 2007]
Hyperbaric oxygen – other than for decompression sickness or carbon monoxide poisoning N.B. HCW is reviewing)	Hyperbaric oxygen therapy (HBO or HBOT) is a mode of treatment in which a patient breathes 100% oxygen at pressures greater than normal atmospheric (i.e., sea level) pressure. It has been used to treat a large number of conditions, evidence for which is often lacking. HBO therapy is the standard of care in the primary treatment of acute carbon monoxide poisoning, arterial gas embolism, and decompression sickness. NICE has concluded that HBO does not fall within its remit and has not appraised the intervention.	

INTERVENTION	EVIDENCE SUMMARY	REFERENCES
	TINNITUS One small RCT in people who had idiopathic sudden sensorineural hearing loss over 6 months previously found no significant difference in tinnitus between hyperbaric oxygen and control	Cook S, Savage J, Waddell A. Tinnutus. Hyperbaric oxygen. Webpage. [Cited 2nd Oct 2007] *BMJ Clinical Evidence* 2006. Available at: http://clinicalevidence.bmj.com/ceweb/about/index.jsp
	CHRONIC WOUNDS - DIABETIC FOOT ULCERS AND AMPUTATIONS • One RCT identified by a systematic review found that systemic hyperbaric oxygen plus usual care reduced amputation rates at 10 weeks compared with usual care alone in people with severely infected diabetic foot ulcers. • One small RCT found no significant difference in major amputation rates between systemic hyperbaric oxygen plus usual care compared with usual care alone, but may have been too small to detect a clinically important difference. • One small RCT in people with non-infected neuropathic foot ulcers found no significant difference between hyperbaric oxygen plus usual care and usual care alone in ulcer healing at 4 weeks, but again, may have been too small to detect a clinically important difference. The review author concludes that systemic hyperbaric oxygen therapy may be considered in an individual with severe infected diabetic foot ulcers with full thickness gangrene or abscess, or with a large infected ulcer that has not healed in over 30 days. More widespread application of this technology cannot be recommended given the limited RCT data. A subsequent review found six RCTs, five in diabetes and one in venous ulcers with a total of 191 patients. Methodological quality was poor in 3 trials. Significant improvements were found for wound size reduction soon after therapy and for major amputation, where the RR for major amputation with HBO was	Hunt D. Foot ulcers and amputations in diabetes. *BMJ Clinical Evidence*. February 2006. Available at: http://www.clinicalevidence.com/ceweb/conditions/dia/0602/0602_l4.jsp Kranke P, Bennett M, Roeckl-Wiedmann I, Debus S. Hyperbaric oxygen therapy for chronic wounds. *Cochrane Database of Systematic Reviews* 2004, Issue 1. Available at: http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD004123/frame.html [Accessed 2nd Oct 2007] Hyperbaric oxygen for chronic wounds. Webpage. [Cited 2nd Oct 2007] *Bandolier* 2005. Available at: http://www.jr2.ox.ac.uk/bandolier/band133/b133-5.html

INTERVENTION	EVIDENCE SUMMARY	REFERENCES
	0.3 (0.1 to 0.7) and the NNT to prevent major amputation was 4 (2.7 to 12). Two cases of pressure trauma to the ear were recorded. The authors conclude that HBO is expensive but the cost of one major amputation is substantial	
	PERINATAL ASPHYXIA One systematic review found lower rates of mortality and adverse neurological outcomes in infants treated with hyperbaric oxygen. However, the RCTs included in the review used poor methods, and potential publication bias was reported. Therefore, the results should be approached with caution.	McGuire W. Perinatal asphyxia. Hyperbaric oxygen. Webpage. [Cited 2nd Oct 2007] *BMJ Clinical Evidence.* 2006. Available at: http://clinicalevidence.bmj.com/ceweb/about/index.jsp
	MALIGNANT OTITIS EXTERNA No clear evidence exists to demonstrate the efficacy of hyperbaric oxygen therapy when compared with treatment with antibiotics and/or surgery. No data were found to compare rates of complication between the different treatment modalities.	Phillips JS, Jones SEM. Hyperbaric oxygen as an adjuvant treatment for malignant otitis externa. *Cochrane Database of Systematic Reviews* 2005, Issue 2. Available at: http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD004617/pdf_fs.html [Accessed 2nd Oct 2007]
	MULTIPLE SCLEROSIS The authors found no consistent evidence to confirm a beneficial effect of hyperbaric oxygen therapy for the treatment of multiple sclerosis and do not believe routine use is justified. The small number of analyses, suggestive of benefit are isolated and need to be confirmed in future well-designed trials. Such trials are not, in their view, justified by this review.	Bennett M., Heard R. Hyperbaric oxygen therapy for multiple sclerosis. *Cochrane Database of Systematic Reviews* 2004, Issue 1. Available at: http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD003057/pdf_fs.html [Accessed 2nd Oct 2007]
	FRACTURE HEALING The systematic review failed to locate any relevant clinical evidence to support or refute the effectiveness of HBOT for the management of delayed union or established non-union of bony fractures.	Bennett MH, Stanford R, Turner R. Hyperbaric oxygen therapy for promoting fracture healing and treating fracture non-union. *Cochrane Database of Systematic Reviews* 2005, Issue 1. Available at: http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD004712/pdf_fs.html [Accessed 2nd Oct 2007]
	ACUTE CORONARY SYNDROME For people with ACS, individual small trials suggest the addition of HBOT reduces the risk of Major Adverse Cardiac Events, some dysrrhythmias, and reduces the time to relief from ischaemic pain, but does not reduce mortality. In view of the small number of patients, methodological shortcomings and poor reporting, this result should be interpreted cautiously, and an	Bennett M, Jepson N, Lehm JP. Hyperbaric oxygen therapy for acute coronary syndrome. *Cochrane Database of Systematic Reviews* 2005, Issue 2. Available at: http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD004818/pdf_fs.html [Accessed 2nd Oct 2007]

INTERVENTION	EVIDENCE SUMMARY	REFERENCES
	appropriately powered trial of high methodological rigour is justified to define those patients (if any) who can be expected to derive most benefit from HBOT. The routine application of HBOT to these patients cannot be justified from this review	
	ACUTE ISCHAEMIC STROKE The systematic review did not find evidence to show that HBOT improves clinical outcomes when applied during the acute presentation of ischaemic stroke. While evidence from the three randomised controlled trials is insufficient to provide clear guidelines for practice, clinical benefit does not seem likely. Further research is required to define more clearly the role of HBOT in this condition.	Bennett MH, Wasiak J, Schnabel A,et al. Hyperbaric oxygen therapy for acute ischaemic stroke. *Cochrane Database of Systematic Reviews* 2005, Issue 3. Available at: http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD004954/pdf_fs.html [Accessed 2nd Oct 2007]
	ADJUNCTIVE TREATMENT TRAUMATIC BRAIN INJURY In people with traumatic brain injury, the addition of HBOT significantly reduces the risk of death, however, there is little evidence that more survivors have a good outcome. The routine application of HBOT to these patients cannot be justified from this review. In view of the modest number of patients, methodological shortcomings and poor reporting, this result should be interpreted cautiously. An appropriately powered trial of high quality is required to define those patients (if any) who can be expected to derive most benefit from HBOT.	Bennett MH, Trytko B, Jonker B. Hyperbaric oxygen therapy for the adjunctive treatment of traumatic brain injury. *Cochrane Database of Systematic Reviews* 2004, Issue 4. Available at: http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD004954/pdf_fs.html [Accessed 2nd Oct 2007]
	THERMAL BURNS The systematic review found insufficient evidence to support or refute the effectiveness of HBOT for the management of thermal burns. Evidence from the two randomised controlled trials is insufficient to provide clear guidelines for practice. Further research is needed to define the role of HBOT in the treatment of thermal burns	Villanueva E, Bennett MH, Wasiak J et al. Hyperbaric oxygen therapy for thermal burns. *Cochrane Database of Systematic Reviews* 2004, Issue 2. Available at: http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD004727/pdf_fs.html [Accessed 2nd Oct 2007]
	TUMOUR SENSITISATION PRIOR TO RADIOTHERAPY There is some evidence that HBO improves local tumour control and mortality for cancers of the head and neck, and local tumour recurrence in cancers of the head and neck, and uterine cervix. These benefits may only occur with unusual fractionation schemes. HBO is associated with significant adverse effects including oxygen toxic seizures and severe tissue radiation	Bennett M, Feldmeier J, Smee R et al. Hyperbaric oxygenation for tumour sensitisation to radiotherapy. *Cochrane Database of Systematic Reviews* 2005, Issue 4. Available at: http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD005007/pdf_fs.html [Accessed 2nd Oct 2007]

INTERVENTION	EVIDENCE SUMMARY	REFERENCES
	injury. The methodological and reporting inadequacies of the primary studies included in this review make interpretation difficult. More research is needed for head and neck cancer, but is probably not justified for bladder cancer. There is little evidence available concerning malignancies at other anatomical sites.	
	OSTEORADIONECROSIS There are a number of well conducted reviews, which generally conclude that there is evidence for the effectiveness of hyperbaric oxygen therapy in osteoradionecrosis. However the evidence is inconsistent and the published trials have methodological problems. The cost effectiveness has not been evaluated in the UK. A subsequent RCT of the treatment of mild to moderate osteoradionecrosis of the jaw comparing hyperbaric oxygen with placebo in 68 subjects shows no benefit for hyperbaric oxygen in terms of recovery, time to treatment failure and time to pain relief at 1 year. The lack of consistency of the evidence suggests that commissioning hyperbaric oxygen as a routine therapy for osteoradionecrosis may need to be reconsidered.	Aggressive Research Intelligence Facility. Hyperbaric oxygen – osteradionecrosis. Webpage. [Cited 2nd Oct 2007] ARIF 2004. Available at: http://www.arif.bham.ac.uk/Requests/h/hyperbaric-oxygen-osteoradionecrosis.htm NHS Quality Improvement Scotland. Hyperbaric oxygen therapy (HBOT) for the prevention and treatment of osteoradionecrosis following radiotherapy of head and neck cancer. *Evidence Note* 2007; (15) Available at: http://www.nhshealthquality.org/nhsqis/files/EN15_HBOT_Final.pdf
	CLUSTER HEADACHE AND MIGRAINE The available evidence is inconclusive. A protocol for a Cochrane Review has been published. The objective of the review will be to examine the effectiveness and safety of normobaric oxygen therapy (NBOT) and hyperbaric oxygen therapy (HBOT) in the treatment and prevention of migraine and cluster headache. Effectiveness will be assessed using a number of clinically important outcomes, including pain.	Bennett MH, French C, Kranke P et al. Normobaric and hyperbaric oxygen therapy for migraine and cluster headache. (Protocol) *Cochrane Database of Systematic Reviews* 2005, Issue 2. Available at: http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD005219/pdf_fs.html [Accessed 2nd Oct 2007]
Photodynamic therapy, other than in line with NICE guidance	Photodynamic therapy is used in many clinical situations and a summary of its major applications is given.	
	BARRETT'S OESOPHAGUS Photodynamic therapy represents an advance in the treatment of Barrett's esophagus with high-grade dysplasia. Advantages include its ease of use, the need for fewer endoscopic sessions compared with thermal ablative techniques, and reduced	Davila M, Van Dam J. Photodynamic therapy for ablation of Barrett's esophagus. *UpToDate* February 2006.

INTERVENTION	EVIDENCE SUMMARY	REFERENCES
	morbidity, mortality, and cost when compared to surgery. However, limited data are available on the long-term outcome of this approach. Photodynamic therapy can be considered for patients with high-grade dysplasia who are poor operative candidates after thorough discussion of the risks and alternatives. Notably, PDT for high-grade dysplasia reduces, but does not eliminate, the risk of progression to cancer. NICE concludes that current evidence on the safety of PDT for high-grade dysplasia in Barrett's oesophagus appears adequate to support the use of this procedure.	National Institute for Health and Clinical Excellence. Photodynamic therapy for high-grade dysplasia in Barrett's oesophagus. London: NICE; 2004. Available at: http://guidance.nice.org.uk/IPG82 [Accessed 2nd Oct 2007]
	LUNG CANCER In experienced hands, PDT provides a safe, nonsurgical therapy for malignant airway obstruction and also offers the possibility of curing early stage non-small cell lung cancer. PDT complements, rather than replaces, other treatment modalities whenever possible. New photosensitizers with more specificity for cancerous tissue and thus less associated photosensitivity are under development and may further improve the safety and efficacy of the procedure	Ernst A, Loicero J. Photodynamic therapy of lung cancer. *UpToDate* August 2004.
	OESOPHAGEAL CANCER NICE concludes that current evidence on the safety and efficacy of palliative PDT for advanced oesophageal cancer is of poor quality but appears adequate to support the use of this procedure to relieve symptoms in patients with a poor prognosis. The efficacy of PDT for treatment of patients with superficial esophageal cancer has not been thoroughly evaluated. PDT should be reserved for patients with large early cancers in the setting of extensive Barrett's who are poor surgical candidates. Small tumours are better treated with endoscopic mucosal resection. Current evidence on the safety of PDT for early-stage	National Institute for Health and Clinical Excellence. *Palliative photodynamic therapy for advanced oesophageal cancer.* London: NICE; 2007. Available at: http://guidance.nice.org.uk/IPG206/?template=ipcat.aspx [Accessed 2nd Oct 2007] Wright CD. Management of superficial esophageal cancer. *UpToDate* August 2006. National Institute for Health and Clinical Excellence. Interventional Procedure Guidance 200. *Photo-dynamic therapy for early oesophageal cancer: guidance*. London: NICE; 2007. Available at: http://guidance.nice.org.uk/IPG200 [Accessed 2nd Oct 2007]

INTERVENTION	EVIDENCE SUMMARY	REFERENCES
	oesophageal cancer appears adequate. PDT appears efficacious in reducing tumour bulk in carefully selected patients with small[2] early-stage tumours. However, the current evidence is of poor quality and relates only to short-term outcomes; it is therefore not adequate to support the use of this procedure without special arrangements for consent, audit and clinical governance.	
	NON-MELANOMA SKIN TUMOURS Current evidence suggests that there are no major safety concerns associated with PDT for non-melanoma skin tumours (including premalignant and primary nonmetastatic skin lesions). Evidence of efficacy of this procedure for the treatment of basal cell carcinoma, Bowen's disease and actinic (solar) keratosis is adequate to support its use for these conditions, provided that the normal arrangements are in place for consent, audit and clinical governance. Evidence is limited on the efficacy of this procedure for the treatment of invasive squamous cell carcinoma. Recurrence rates are high and there is a risk of metastasis. Clinicians should ensure that patients understand these risks and that retreatment may be necessary. **SKIN CANCER INCLUDING MELANOMA** There is expert review and observational study evidence to suggest that PDT can be very effective in clearing superficial basal cell carcinomas, actinic keraqtoses and squamous cell carcinomas in	National Institute for Health and Clinical Excellence. Photodynamic therapy for non-melanoma skin tumours (including premalignant and primary non-metastatic skin lesions). London: NICE 2007. Available at: http://guidance.nice.org.uk/IPG155 [Accessed 2nd Oct 2007 National Institute for Health and Clinical Excellence. *Improving outcomes for people with skin tumours including melanoma: The manual.* London: NICE; 2006. Available at: http://guidance.nice.org.uk/csgstim/guidance/pdf/English [Accessed 2nd Oct 2007]

[2] Note difference in recommendation for suitable size of tumours for PDT treatment.

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	situ (Bowen's disease), and is useful in patients who cannot undergo surgical therapy. The 2-year recurrence rate after treatment of nodular BCC of the skin is approximately 20%, and this needs to be taken into account when deciding on this treatment. Guidelines from the British Photodermatology Group state that topical PDT is an effective treatment for patients with actinic keratoses on the face and scalp, Bowen's disease (with results comparable to fluorouracil or cryotherapy) and superficial bsal cell carcinoma. (with results comparable to cryotherapy).	
	BILE CANCER Current evidence on the safety and efficacy of PDT for bile duct cancer does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research	National Institute for Health and Clinical Excellence. Photodynamic therapy for bile cancer. London: NICE; 2005. Available at: http://guidance.nice.org.uk/IPG134 [Accessed 2nd Oct 2007]
	WARTS There is a considerable lack of evidence on which to base the rational use of topical treatments for common warts. The benefits and risks of PDT remain to be determined.	Gibbs S, Harvey I. Topical treatments for cutaneous warts. *Cochrane Database of Systematic Reviews* 2006, Issue 3. Available at: http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD001781/pdf_fs.html [Accessed 2nd Oct 2007].
	ENDOMETRIAL ABLATION Current evidence on the safety and efficacy of PDT for endometrial ablation does not appear adequate to support the use of this procedure outside formal research. It is suitable for use only within good quality research studies approved by a research ethics committee and with explicit patient consent.	National Institute for Health and Clinical Excellence Photodynamic endometrial ablation. London: NICE; 2004. Available at: http://guidance.nice.org.uk/IPG47 [Accessed 2nd Oct 2007]
Beta interferon for multiple sclerosis.	Multiple sclerosis (MS) is characterised by central nervous system lesions causing neurological dysfunction and other problems such as fatigue, pain, depression and anxiety. Early disease is usually relapsing and remitting, but most people develop secondary progressive disease over time. No treatment has been shown to affect long term outcome. In people with relapsing and remitting disease beta interferon may reduce both exacerbations and disease progression. Beta interferon has been associated with serious adverse effects. It is not known whether beta interferon delays disease progression in people with secondary progressive MS as studies have given	Nicholas R; Chataway J. Multiple sclerosis. *BMJ Clinical Evidence* 2006. Available at: http://clinicalevidence.bmj.com/ceweb/about/index.jsp [Accessed 2nd Oct 2007]

INTERVENTION	EVIDENCE SUMMARY	REFERENCES
	conflicting results:- Two RCTs in people experiencing a first demyelinating event found that beta interferon decreased the risk of conversion to clinically definite multiple sclerosis over 2–3 years compared with placebo. One systematic review in people with active relapsing and remitting multiple sclerosis found limited evidence that beta interferon reduced exacerbations and disease progression over 2 years compared with placebo. One RCT in people with relapsing and remitting multiple sclerosis found that beta interferon on alternate days reduced the proportion of people with relapse over 2 years compared with weekly interferon beta-1a. Another RCT found that both immunoglobulin and beta interferon reduced relapse rates over 1 year in people with relapsing and remitting multiple sclerosis with no significant difference between groups. NICE does not recommend beta interferon for the treatment of multiple sclerosis.	National Institute for Health and Clinical Excellence. *Multiple sclerosis - beta interferon and glatiramer acetate.* London: NICE; 2002. Available at: http://guidance.nice.org.uk/TA32 [Accessed 2nd Oct 2007]
Lymphoedema	There is no known cure for lymphoedema. Various treatment strategies have been suggested for the management of the condition that aim to reduce the volume of the affected limb and retain or restore function and cosmesis to improve an individual's health outcomes and quality of life. Existing systematic reviews have documented the lack of high quality evidence available to guide clinical practice. Their findings indicate that much of the evidence available to support current treatment strategies is based on small case series (Level IV evidence). Recommendations for preventive behaviours to reduce limb swelling and infection rates such as exercise and avoiding infection and trauma are based on expert opinion. Comparative studies or trials to define optimal strategies are awaited. • The long-term use of low-stretch elastic garments or compression bandaging is effective in reducing and/or controlling limb swelling and may be an essential component of combination physical therapies. • Favourable outcomes have been described for complex physical therapy; however, some of the evidence is inconsistent and further trial evidence is required to define an optimal	Medical Services Advisory Committee. *Review of current practices and future directions in the diagnosis, prevention and treatment of lymphoedema in Australia.* Canberra: Commonwealth of Australia 2006. Available at: http://www.health.gov.au/internet/msac/publishing.nsf/Content/AD35ED216E990FC7CA2571420004A192/$File/Lymphoedema_13feb2006_final.pdf [Accessed 2nd Oct 2007] Kligman L, Wong R K, Johnston M, Laetsch N S The treatment of lymphedema related to breast cancer: a systematic review and evidence summary. *Supportive Care in Cancer* 2004 12:421. Badger C, Preston N, Seers K, Mortimer P. Physical therapies for reducing and controlling lymphoedema of the limbs. *Cochrane Database of Systematic Reviews* 2004, Issue 4. Available at: http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD003141/pdf_fs.htmlm [Accessed 2nd Oct 2007]

INTERVENTION	EVIDENCE SUMMARY	REFERENCES
	strategy. • Current evidence regarding the use of drug therapy is inconclusive. • Surgical procedures may be indicated in select patients who have not responded to physical therapy. The NICE palliative care guidance sates that commissioners, working through Cancer Networks, should ensure they can provide the range and volume of rehabilitation services appropriate to meet the needs of the local population and this will include providing services from lymphoedema therapists.	National Institute for Health and Clinical Excellence. Improving supportive and palliative care for adults with cancer. The manual 2004. Available at: http://guidance.nice.org.uk/csgsp [Accessed 2nd Oct 2007]
Day case elective surgery versus inpatient surgery.	There are many publications concerning the performance of day case surgery in Wales. One of the Department of Health's '10 High Impact Changes' is the recommendation that day case surgery should be the preferred form of elective surgery. Service users reportedly like day surgery and there is evidence that day surgery may reduce the overall cost of hospital care. One UK trial found that day surgery for general surgical emergencies was as effective as inpatient care. GPs and service users were equally satisfied with day surgery and day surgery saved about £150 per person compared with inpatient care. Day surgery has also been found to be cost-effective for e.g. cataracts, haemorrhoidectomy, hernia and cholecystectomy. One trial in Canada found however, that whilst day surgery reduced costs and had similar clinical outcomes to inpatient surgery, service users reported a preference for an overnight stay. A postal survey of 785 patients found that on the day of surgery, more patients undergoing laparoscopic sterilization experienced severe pain. By the third postoperative day, more of those who had been operated on for hernia repair, followed by varicose vein surgery and laparoscopic sterilization, continued to experience	Wales Audit Office. *Making better use of NHS day surgery in Wales.*Cardiff: The Welsh Audit Office; 2006. Available at: http://www.wales.nhs.uk/documents/WAO_Day_Surgery_Eng_web.pdf [Accessed 2nd Oct 2007] National Leadership and Innovation Agency for Healthcare. *A guide to good practice: day surgery in Wales.* Cardiff: The Welsh Assembly Government; 2004. Available at: http://www.wales.nhs.uk/sites3/Documents/484/DS%20GPG.pdf [Accessed 2nd Oct 2007] NHS Modernisation Agency. *10 high impact changes* for *service improvement and delivery: a guide for NHS leaders*. Available at: http://www.ogc.gov.uk/documents/Health_High_Impact_Changes.pdf [Accessed 2nd Oct 2007] . Singh, D. *Making the Shift: Key Success Factors. A rapid review of best practice in shifting hospital care into the community*. Birmingham: University of Birmingham; 2006. Available at: http://www.hsmc.bham.ac.uk/news/MakingtheShift6882.pdf [Accessed 2nd Oct 2007] Conaghan PJ, Figueira E, Griffin MA et al. Randomized clinical trial of the effectiveness of emergency day surgery against standard inpatient treatment. *Br J Surg* 2002; 89: 423

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	severe pain.	Fedorowicz Z, Lawrence D, Gutierrez P. Day care versus inpatient surgery for age-related cataract. *Cochrane Database of Systematic Reviews* 2005; 1. Available at: http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD004242/pdf_fs.html [Accessed 2nd Oct 2007] Ho YH, Lee J, Salleh I et al. Randomized controlled trial comparing same-day discharge with hospital stay following haemorrhoidectomy. *ANZ Journal Surgery* 1998; 68: 334-6. Cheek C M; Black N A; Devlin H B et al. Groin hernia surgery: a systematic review. *Annals Royal College Surgeons of England* 1998; 80 suppl 1: S1-S80 Johansson M, Thune A, Nelvin L, Lundell L. Randomized clinical trial of day-care versus overnight-stay laparoscopic cholecystectomy. *British Journal Surgery* 2006; 93: 40-5. Pineault R, Contandriopoulos AP, Valois M et al. Randomized clinical trial of one-day surgery. Patient satisfaction, clinical outcomes, and costs. *Medical Care* 1985; 23: 171-82. Coll AM; Ameen J. Profiles of pain after day surgery: patients' experiences of three different operation types. *Journal Advanced Nursing* 2006; 53: 178.

Appendix 3 – Equality & Diversity Impact Assessment

Background

When contemplating a new project, or significant changes to existing policies or services, the planning process should take into account health determinants, especially their effect on disadvantaged groups. Services and amenities should be targeted according to need. This means that those who are most disadvantaged should be prioritised and protected from negative health impacts.

This checklist focuses on vulnerable groups and completing it at an early stage of the planning process will assist planners to address these issues. Many negative responses in section 2 may indicate the need for a more detailed assessment.

Section 1

Whose needs is this paper designed to address? (e.g. whole administrative area, a named, prioritised group)	The population of Wales
What is the paper designed to achieve?	A standardised evidence based approach to inform commissioning decisions on interventions not normally funded for all LHBs and HCW
Will people whom the paper could potentially benefit be subject to access problems? Please consider matters such as location, gender of practitioner, medium and language.	N/A

Section 2

Please consider the following issues and briefly describe in the appropriate box the paper's potential impacts.

Population Characteristic	Potential Impact on Health

	Positive	Negative	No Change
Material disadvantage (e.g. low income, no car, poor housing, unemployment, homelessness)	Standardised approach in Wales – informing commissioning decisions		
Minority culture or ethnic group (e.g. those who find communication in English difficult, cultural and religious beliefs)	Standardised approach in Wales – informing commissioning decisions		
Families with children (e.g. pregnant women, babies, children and teenagers)	Standardised approach in Wales – informing commissioning decisions		
Physical or mental frailty (e.g. advanced age, learning difficulties, physical disability, carers)	Standardised approach in Wales – informing commissioning decisions		
Gender or sexuality (e.g. access to services, issues of prejudice)	Standardised approach in Wales – informing commissioning decisions		

How will the impact of this paper on health in general and vulnerable groups in particular be monitored?	An audit will be undertaken