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CHESHIRE & MERSEYSIDE PRIOR APPROVAL SCHEME

Incorporating

Procedures of Lower Clinical Priority (PLCP)

Supporting Cheshire and Merseyside PCT

VERSION CONTROL

VERSION 1	CISSU Original document	19/02/10
VERSION 2	Western Cheshire schedule added	30/30/10
VERSION 3	Western Cheshire schedule updated	20/10/10
VERSION 4	Updated following decommissioning workstream	21/12/10
VERSION 5	• 2011/12 CISSU policy. • Western Cheshire annexe split into separate document • CISSU policies amended under local agreement highlighted in grey – please refer to Western Cheshire annexe for agreed wording	28/03/11

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1. INTRODUCTION

This document is intended to be a guidance document for clinicians and other referrers in primary and secondary care. It sets out the eligibility criteria under which Cheshire and Merseyside PCTs will commission the service, either via existing contracts or on an individual basis. It gives guidance to referrers on the policies of the PCTs in relation to the commissioning of procedures of low clinical priority, thresholds for certain treatment and those procedures requiring individual approval.

Health benefits must be maximised from the resources available. As new services become available, demand increases and procedures that give maximum health gain must be prioritised. **This means that certain procedures will not be commissioned by PCTs unless exceptional clinical grounds can be demonstrated.** The success of the scheme will depend upon commitment by GPs and other clinicians to restrict referrals falling outside this protocol.

The NHS standard contract specifies that the Co-ordinating Commissioner will agree with the Provider the circumstances where the Provider will need to seek prior approval (PA) to confirm the appropriateness of a proposed intervention or course of treatment. It is expected that such schemes focus on procedures of limited/low clinical effectiveness, or infrequent high cost and/or complex procedures. In designing and implementing PA schemes, individual patient needs must remain paramount. (Reference Guidance on the Standard NHS contract for Acute Hospital Services, community and Mental Health & Learning Disabilities)

Ideally the Co-ordinating Commissioner will agree a single set of PA requirements with which each Provider is expected to comply. However, there may be exceptional circumstances in which an Associate PCT needs to specify its own PA requirements. These would have to be approved by the SHA.

Agreeing a Cheshire and Merseyside Prior Approval Policy will improve equity of access to services, value for money and clinical effectiveness across the network.

PCTs will not pay for activity unless it meets the criteria set out in the document or individual approval has been given and the Referral and Approval Process as set out has been followed. This prior approval scheme will be incorporated into all NHS standard NHS contracts agreed by PCTs. Compliance with this policy will be monitored via regular benchmarking reports produced by CISSU and case note audits.

To support this approach a set of **Core Clinical Eligibility Criteria** have been developed and are set out below, patients may be referred in accordance with the referral process if they meet these criteria. In some limited circumstances, a '**Procedure of Lower Clinical Priority' (PLCP)** may be the most clinically appropriate intervention for a patient. In these circumstances, agreed eligibility criteria have been established and these are explained, in the later sections of the document, if the criteria are met the procedure will be commissioned by the PCT.

2. CORE CLINICAL ELIGIBILITY:

- All NICE Technology Appraisals will be implemented except where specified.
- In cancer care (including but not limited to skin, head and neck, breast and sarcoma any lesion that has features suspicious of malignancy, must be referred to an appropriate specialist for urgent assessment under the 2-week rule.
- Reconstructive surgery post cancer or trauma including burns.
- Congenital deformities: Operations on congenital anomalies of the face and skull are usually available on the NHS. Some conditions are considered highly specialised and are commissioned in the UK through the National Specialised Commissioning Advisory Group (NSCAG). As the incidence of some cranio-facial congenital anomalies is small and the treatment complex, specialised teams, working in designated centres and subject to national audit, should carry out such procedures.
- Tissue degenerative conditions requiring reconstruction and/or restoring function e.g. Leg ulcers, dehisced surgical wounds, necrotising fasciitis.
- Any patient who needs urgent treatment will always be treated.
- No treatment is completely ruled out if an individual patient's circumstances are exceptional. Requests for consideration of exceptional circumstances should be made to the patients responsible PCT see contact details at appendix 1.
- Children under 16 years are eligible for surgery to alter appearance, improve scars, excise facial or other body lesions, where such conditions cause obvious psychological distress.

3. REFERRAL AND APPROVAL PROCESS

Conditions and interventions specified in this document are not commissioned unless clinical criteria are met as detailed in pages 14 to 52, except in exceptional circumstances. Where clinical criteria are met treatment identified will form part of the normal contract activity.

REFERRAL PROCESS

If a General Practitioner/Optometrist/Dentist considers a patient might reasonably fulfil the eligibility criteria for a Procedure of Lower Clinical Priority, as detailed in this document **(i.e. they meet the specific criteria listed for each treatment)** the General Practitioner/Optometrist/Dentist should follow the local process for referral or seek approval to refer from the patient's PCT. If in doubt over the local process, the referring clinician should contact the patient's PCT using the email or telephone number shown in Appendix 1. Failure to comply with the local process may delay a decision being made. The referral letter should include specific information regarding the patient's **potential** eligibility.

Diagnostic procedures to be performed with the sole purpose of determining whether or not a Procedure of Lower Clinical Priority is feasible ***should not*** be carried out unless the eligibility criteria are met or approval has been given by the PCT or GP (as set out in the approval process of the patients responsible PCT) or as agreed by the PCT as an exceptional case.

The referral process to secondary care will be determined by the responsible PCTs. Referrals will either

- Have been prior approved by the PCT
  OR
- Clearly state how the patient meets the criteria
  OR
- Be for a clinical opinion to obtain further information to assess the patient's eligibility.

The secondary care consultant will then also determine whether the procedure is clinically appropriate for a patient and whether the eligibility criteria for the procedure are fulfilled or not, they may request additional information before seeing the patient. Patients who fulfil the criteria may then be placed on a waiting list according to their clinical need. The patient's notes should clearly reflect exactly how the criteria were fulfilled, to allow for case note audit to support contract management. Should the patient not meet the eligibility criteria this should be recorded in the patient's notes and the consultant should return the referral back to the GP with a copy to the PCT, explaining why the patient is not eligible for treatment.

If the referral letter does not clearly outline how the patient meets the criteria then the letter should be returned to the referrer for more information and the PCT notified. Where a GP requests only an opinion the patient should not be placed on a waiting list or treated, but the opinion given to the GP and the patient returned to the GPs care, in order for the GP to make a decision on future treatment.

Should a patient not fulfil the clinical criteria but the referring clinician is willing to support the application as clinically exceptional, the case can be referred to individual PCTs for approval contact details for each PCT can be found in appendix 1.

Prior approval for treatment should always be sought from the responsible PCT when using medicines as follows:

1. Any new PbR excluded drug where the drug has not yet been approved / prioritised for use in agreement with the local PCT.
2. Any existing PbR excluded drugs to be used outside of previously agreed clinical pathways/indication.
3. Any PbR excluded drugs that are being used out with the parameters set by NICE both in terms of disease scores or drug use. It must not be assumed that a new drug in the same class as one already approved by NICE can be used, this must be subject to the process in Point 1.
4. Any drug used out with NICE GUIDANCE (where guidance is in existence).
5. Any proposed new drug / new use of an existing drug (whether covered by NICE or PBR excluded or not) should first be approved by the relevant Area Medicines Management Committee, and funding (where needed) agreed in advance of its use by the relevant PCT.
6. Any medicines that are classed by the PCT as being of limited clinical value.
7. Any medicines that will be supplied via a homecare company agreement.

The Primary Care Trust does not expect to provide funding for patients to continue treatment commenced as part of a clinical trial. This is in line with the Medicines for Human Use (Clinical Trials) Regulations 2004 and the Declaration of Helsinki which stipulates that the responsibility for ensuring a clear exit strategy from a trial, and that those benefiting from treatment will have on-going access to it, lies with those conducting the trial. This responsibility lies with the trial initiators indefinitely

NOTE : For all cancer drugs (haematology and oncology)a revised process and prioritised list has been developed.

In 3rd quarter of each year, specialists will be asked to nominate drugs which they would like to be considered within the prioritisation process. The Northwest Cancer Prioritisation Steering group (attended by representatives from the three cancer networks, specialised commissioning and PCT representatives) co-ordinate the requests and create a single list. This list is reviewed and scored at two prioritisation meetings which are held across the region. Prioritisation will be completed in the 4th quarter of each year prior to being submitted to the commissioning process, with recommendations rated as red (not for routine IFRs or funding), amber (IFRs may be submitted in certain circumstances or green (for routine funding). Any drug requested outside of this prioritisation process will not routinely be funded by any PCT in-year.

Cheshire & Merseyside PCTs have endorsed through the PCT Alliance a description of exceptionality contained in a paper by the NW Medicines and Treatment Group, this is set out below:

In dealing with exceptional case requests for an intervention that is considered to be a poor use of NHS resources, it is now widely accepted that in order for a patient to be considered as exceptional the PCT panel must be persuaded that

> *The patient has a clinical picture that is significantly different to the general population of patients with that condition* ***and as a result of that difference;*** *the patient is likely to derive greater benefit from the intervention than might normally be expected for patients with that condition.*

Increasingly commissioners are of the opinion that exceptionality should be defined solely in clinical terms; to consider social and other non clinical factors automatically introduces inequality, implying that some patients have a higher intrinsic social worth than others with the same condition. It runs contrary to a basic tenet of the NHS namely, that people with equal need should be treated equally.

In essence, it is a question of equity. The PCT must justify the grounds upon which it is choosing to fund this patient when the treatment is unavailable to others with the condition.

4. MAP OF MEDICINE

Where a Map of Medicine pathway is available it is expected that this will be followed.

5. CONDITIONS & INTERVENTIONS

The conditions & interventions have been broken down into two groups based on the London Health Observatory work as follows:

Group 1

- Potentially cosmetic interventions and not normally commissioned by the PCT
- Low volume, high-cost complex cases

Group 2

- Relatively ineffective interventions
- Effective interventions where usually a cost effective alternative should be tried first

GPs should only refer if the patient meets the criteria set out or individual approval has been given by the PCT as set out in the PCTs process as set out in section 3 of this document. Requests for purely cosmetic surgery will not be considered. Patients meeting the core clinical eligibility criteria set out above can be referred, all other referrals should be made in accordance with the specified criteria and referral process. The PCT may request photographic evidence to support a request for treatment

Patient's treatment will not be funded unless:

- they meet the stated clinical criteria – see each clinical presentation
- and/or they have Psychiatric Condition – see definition below
- and/or Interference with physical function is proven – see definition below

Psychiatric condition must be one that requires treatment, is clearly related to the relevant physical problem and has not been effectively addressed by adequate psychiatric or psychological intervention and does not pre date the condition. Severe psychosocial dysfunction will be alleviated. Patient must have assessment by psychologist prior to referral to PCT.

Interference with physical function - The condition has become complicated e.g. by infection or it is interfering with physical function such as activities of daily living.

Where a procedure is not listed in this document (includes new and experimental treatments) requests for funding will be judged on an individual basis. NICE will be the definitive guidance where available. However, it is recognised that many new treatments have not been subject to NICE. In such cases other recognised expert appraisals will be used as guidance including Cochrane, SIGN, MeREc and the London Cancer Consortium. The PCTs will also be guided by research subject to internal and external evaluation of merit.

Additional Overall Principle

From time to time, PCTs may need to make commissioning decisions that may suspend some treatments/criteria currently specified within this policy.

***** For policies which have been highlighted in grey – please refer to Western Cheshire annexe*****

6. GROUP 1 PROCEDURES

These procedures are not routinely commissioned except where the criteria specified are met.

6.1 Skin and Subcutaneous Procedures

	Condition or Intervention	Criteria **Please also see core eligibility criteria when considering the application of the policy**	Source of Evidence	Remarks
6.1.1 **	**Minor skin lesions** E.g. benign pigmented moles, milia, skin tags, keratoses (basal cell papillomata), sebaceous cysts, corn/callous, dermatofibromas, comedones. Molluscum Contagiosum Chalazion	Will only be commissioned in the following circumstances: • Symptomatic e.g. on-going pain or functional impairment • Risk of infection • Significant face disfigurement • Treatment of multiple lipomatosis or neurofibromatosis • All vascular lesions except benign, acquired vascular lesions such as thread veins and spider naevi.	Modernisation Agency's Action on Plastic Surgery 2005 London Health Observatory	Uncomplicated benign skin lesions should **NOT** be referred. **Suspected malignant melanoma or squamous cell carcinoma should always be referred under two-week rule for referral of suspected cancers** GPs must ensure that all alternative treatments have been sought. Community Dermatology Service may be available for advice

	Condition or Intervention	Criteria **Please also see core eligibility criteria when considering the application of the policy**	Source of Evidence	Remarks
6.1.2 **	**Viral warts excluding genital warts**	Will only be commissioned in the following circumstances: • Painful, • Persistent or • Extensive warts (particularly in the immuno-suppressed patient). Patients with the above exceptional symptoms may need specialist assessment, usually by a dermatologist. For a small proportion surgical removal (cryotherapy, cautery, laser or excision) may be appropriately performed within Primary Care.	Modernisation Agency's Action on Plastic Surgery 2005	Most viral warts will clear spontaneously or following application of topical treatments.

	Condition or Intervention	Criteria **Please also see core eligibility criteria when considering the application of the policy**	Source of Evidence	Remarks
6.1.3 **	**Xanthelasma palpebrum** Fatty deposits on the eyelids	Only commissioned for**:** • Larger lesions. OR • Those that have not responded to treatment for underlying Familial Lipoprotein Lipase Deficiency. AND • If the lesion is disfiguring.	Local PCT consensus - review conducted 2007 DermNet NZ information resources updated 15 Jun 2009. Resourced in NHS evidence website. (note NZ as opposed to UK)	The following treatments should be considered for patients with xanthelasma: • Many Xanthelasma may be treated with topical trichloroacetic acid (TCA) or cryotherapy. • Xanthelasma may be associated with abnormally high cholesterol levels and this should be tested for before referral to a specialist. • Patients with xanthelasma should always have their lipid profile checked before referral to a specialist.

	Condition or Intervention	Criteria **Please also see core eligibility criteria when considering the application of the policy**	Source of Evidence	Remarks
6.1.4 **	**Scar revision**	Funding of treatment will be considered only for scars which interfere with function following burns, treatments for keloid, or post-surgical scarring.		

	Condition or Intervention	Criteria **Please also see core eligibility criteria when considering the application of the policy**	Source of Evidence	Remarks
6.1.5 **	**Hirsuitism - Hair depilation** **ALSO SEE GENDER RE-ASSIGNMENT POLICY**	Only commissioned in the following clinical circumstances and will be limited to six treatments: • Abnormally located hair-bearing skin following reconstructive surgery located on face and neck. • With a proven underlying congenital and/or endocrine disturbance, resulting in abnormally placed excessive hair e.g. polycystic ovary syndrome. • Those undergoing treatment for pilonidal sinuses to reduce recurrence.	Modernisation Agency's Action on Plastic Surgery 2005 BMJ Clinical Evidence (http://clinicalevidence.bmj.com/ceweb/conditions/woh/1408/1408.jsp) – The latest clinical evidence on hirsutism Haedersdal M, Gotzsche PC. Laser and photo epilation for unwanted hair growth. Cochrane Database Syst Rev 2006;(4):CD004684 BMJ2009;338:b847 Management of hirsutism O Koulouri, research fellow in endocrinology, G. S Conway	The method of depilation (hair removal) considered will be the most appropriate form usually diathermy, electrolysis performed by a registered electrologist, or laser centre. All cases will be subject to individual approval by the responsible PCT and be accompanied by an opinion from a secondary care consultant (i.e. dermatologist or endocrinologist). Photographs will also be required to allow the PCTs to visibly asses the severity equitably.

	Condition or Intervention	Criteria **Please also see core eligibility criteria when considering the application of the policy**	Source of Evidence	Remarks
6.1.6 **	**Tattoo removal**	Only commissioned in the following circumstances: • Tattoo is result of trauma inflicted against the patient's will. • The patient was a child and not responsible for his/her actions at the time of tattooing. • Inflicted under duress. • During adolescence or disturbed periods (only in very exceptional circumstances where tattoo causes marked limitations of psycho-social function).	Modernisation Agency's Action on Plastic Surgery 2005	

6.2 Breast Procedures

(This guidance does not cover breast reconstruction following mastectomy)

	Condition or Intervention	Criteria **Please also see core eligibility criteria when considering the application of the policy**	Source of Evidence	Remarks
6.2.1 **	**Female breast reduction** (Reduction mammoplasty) **ALSO SEE GENDER RE-ASSIGNMENT POLICY**	Commissioned only in the following circumstances: Where symptoms are not due to other causes and • There is at least a two-year history with documented evidence of visiting the GP throughout the duration of the problem. • Evidence that all other approaches E.g. NSAIDS, physiotherapy or other have been tried. • Evidence that the patient has had unresponsive treatment for functional symptoms and is suffering from gravitational pain, shoulder dysfunction, neck ache, backache, lordotic posture	Modernisation Agency's Action on Plastic Surgery 2005 London Health Observatory	Ideally best not performed on young teenagers and delayed until any planned family is complete.

	Condition or Intervention	Criteria **Please also see core eligibility criteria when considering the application of the policy**	Source of Evidence	Remarks
		(curvature of the spine), or Ulnar pain from the thoracic nerve root compression. • Evidence that the patient has had unresponsive treatment for intertigo between the breasts and the chest wall. • Evidence that the wearing of a professionally fitted brassiere has not relieved the symptoms. • Evidence that the patient has a body mass index (BMI) of less than 26 kg/m2 for a period of not less than twelve months. • The waist to hip ratio should be 0.85 or less for women. • Where there is a proposed reduction of greater than 500g per side (American Medical Association criteria). For younger patients the application for the procedure should be delayed until any planned family is complete.		

	Condition or Intervention	Criteria **Please also see core eligibility criteria when considering the application of the policy**	Source of Evidence	Remarks
6.2.2 **	**Breast enlargement** (Augmentation Mammoplasty) **ALSO SEE GENDER RE-ASSIGNMENT POLICY**	Only commissioned in the following circumstances: • Asymmetry greater than 150 cc as measured by a breast care nurse or advanced practitioner. • Congenital absence i.e. no obvious breast tissue. • In special circumstances reconstructive surgery may be appropriate for tubular breast abnormality.	Modernisation Agency's Action on Plastic Surgery 2005 London Health Observatory	Patients should be made aware that : • Implants have a variable life span. Implant removal in the future might not be automatically followed by replacement of the implant (criteria for this may change). • Not all patients demonstrate improvement in psychosocial outcome measures following breast augmentation.

	Condition or Intervention	Criteria **<u>Please also see core eligibility criteria when considering the application of the policy</u>**	Source of Evidence	Remarks
6.2.3 **	**Revision of breast augmentation** (Removal and Replacement Of Silicone Implants) **ALSO SEE GENDER RE-ASSIGNMENT POLICY**	Revisional surgery will ONLY be considered if the NHS commissioned the original surgery and complications arise. If revisional surgery is being carried out for implant failure, the decision to replace the implant(s) rather than simply remove them will be based upon the clinical need for replacement and whether the patient meets the policy for augmentation at the time of revision.	Modernisation Agency's Action on Plastic Surgery 2005 London Health Observatory	Patients should be made aware that implant removal in the future might not be automatically followed by replacement of the implant.
6.2.4	**Breast lift** (mastopexy) **ALSO SEE GENDER RE-ASSIGNMENT POLICY**	Not routinely commissioned.		

	Condition or Intervention	Criteria **Please also see core eligibility criteria when considering the application of the policy**	Source of Evidence	Remarks
6.2.5 **	**Correction of nipple Inversion**	Surgical intervention may be commissioned if there is a history of recurrent infection.	Modernisation Agency's Action on Plastic Surgery 2005 London Health Observatory	Exclude malignancy as a cause - any recent nipple inversion might be suggestive of breast cancer and will require referral to the breast service under the rapid access two-week rule. This condition responds well to non-invasive suction device e.g. Nipplette device, for up to three months.
6.2.6	**Male breast reduction** (Gynaecomastia) **ALSO SEE GENDER RE-ASSIGNMENT POLICY**	Post pubertal patients and BMI < 25 kg/m^2	Modernisation Agency's Action on Plastic Surgery 2005 London Health Observatory	Ensure breast cancer has been excluded as a possible cause especially if there is a family history of breast cancer.

6.3 Body Contouring Procedures

Reference to North West Specialist Commissioning Bariatric Guidance 8.2 and Appendix 2.2

	Condition or Intervention	Criteria **<u>Please also see core eligibility criteria when considering the application of the policy</u>**	Source of Evidence	Remarks
6.3.1 **	**'Tummy tuck'** (Apronectomy or Abdominoplasty) **(following bariatric surgery also see local policy as additional criteria may apply)**	This procedure is not routinely commissioned post bariatric surgery. Only commissioned in the following circumstances: Stable BMI between 18 and 25 kg per m^2 AND Patients have severe functional problems that are refractory and for at least 6 months which may include: • Severe difficulties with daily living i.e. ambulatory restriction. • Post-trauma or surgical scarring leading to poor appearance and resulting in disabling psychological distress. • Severe intertigo beneath the skin fold • Poorly-fitting stoma bags.	Modernisation Agency's Action on Plastic Surgery 2005	Maintenance of a stable weight is important so that the risks of recurrent obesity are reduced. If there is severe and disabling psychological distress as a result of abdominal wall scarring, psychological therapy should be the initial treatment.

	Condition or Intervention	Criteria **Please also see core eligibility criteria when considering the application of the policy**	Source of Evidence	Remarks
6.3.2 **	**Other skin excisions/body contouring** e.g. Buttock lift, Thigh lift, Arm lift (brachioplasty)	Not routinely commissioned.	Modernisation Agency's Action on Plastic Surgery 2005	The functional disturbance of skin excess in these sites tends to be less than that in excessive abdominal skin folds and so surgery is less likely to be indicated except for appearance. Therefore it will not be available on the NHS.
6.3.3 **	**Liposuction**	Liposuction is sometimes an adjunct to other surgical procedures e.g. thinning of a transplanted flap. Not commissioned simply to correct fat distribution. May be commissioned as part of the management of true lipdystrophias or non-excisable clinical significant lipomata.	There is NICE guidance on liposuction for chronic lymphedema. This procedure is to be used with special arrangements for clinical governance, consent and audit or research.	

6.4 Head, Face and Neck Procedures

	Condition or Intervention	Criteria **Please also see core eligibility criteria when considering the application of the policy**	Source of Evidence	Remarks
6.4.1	**Skin resurfacing techniques** (including laser dermabrasion and chemical peels)	Only be commissioned in the following circumstances: • Severe scarring following acne, chicken pox or trauma (including post surgical) to head and neck only.	Modernisation Agency's Action on Plastic Surgery 2005 2008 evidence-based review of lasers, light sources and photodynamic therapy in the treatment of acne vulgaris. Haedersdal M, Togsverd-Bo K, Wulf HC. Department of Dermatology, Bispebjerg Hospital, University of Copenhagen, Copenhagen, Denmark. Collated on NHS evidence website suggests that short-term efficacy from optical treatments for acne	Skin resurfacing techniques, including laser, dermabrasion and chemical peels may only be considered for post-traumatic scarring and severe acne scarring once the active disease is controlled.

	Condition or Intervention	Criteria **Please also see core eligibility criteria when considering the application of the policy**	Source of Evidence	Remarks
			vulgaris with the most consistent outcomes for PDT.	
6.4.2	**Correction of hair loss** (Alopecia)	Only commissioned in the following circumstances: • result of previous surgery • Result of trauma, including burns.	Modernisation Agency's Action on Plastic Surgery 2005	
6.4.3	**Hair transplantation**	Commissioned only in exceptional circumstances, e.g. reconstruction of the eyebrow following cancer or trauma.	Modernisation Agency's Action on Plastic Surgery 2005	Will not be available on the NHS, regardless of gender for cosmetic reasons

	Condition or Intervention	Criteria **Please also see core eligibility criteria when considering the application of the policy**	Source of Evidence	Remarks
6.4.4	**Correction of male pattern baldness**	Not routinely commissioned	Modernisation Agency's Action on Plastic Surgery 2005	
6.4.5	**Face or Brow lift (Rhytidectomy)**	This procedure is NOT available under the NHS on cosmetic grounds. May be commissioned in the following circumstances: • Congenital facial abnormalities • Facial palsy • Treatment of specific conditions affecting the facial skin, e.g. cutis laxa, pseudoxanthoma elasticum, neurofibromatosis • To correct consequences of trauma • To correct deformity following surgery	Modernisation Agency's Action on Plastic Surgery 2005	Changes to the face and brow result due to normal ageing; however, there are a number of specific conditions for which these procedures may form part of the treatment to restore appearance and function.

	Condition or Intervention	Criteria **Please also see core eligibility criteria when considering the application of the policy**	Source of evidence (work ongoing to review sources)	Remarks
6.4.6	**Surgery on the upper eyelid** (Upper lid blepharoplasty)	Only commissioned in the following circumstances: • Eyelid function interferes with visual field.	Modernisation Agency's Action on Plastic Surgery 2005 London Health Observatory	Excess skin in the upper eyelids can accumulate due to the ageing and is thus normal. Hooded lids causing significant functional impaired vision confirmed by an appropriate specialist can warrant surgical treatment. Impairment to visual field to be documented
6.4.7	**Surgery on the lower eyelid** (Lower lid blepharoplasty)	Only commissioned in the following circumstances: • Correction of ectropion or entropion • Removal of lesions of eyelid skin or lid margin • Rehabilitative surgery for patients with thyroid eye disease	Local PCT consensus - review conducted 2007 Modernisation Agency's Action on Plastic Surgery 2005 London Health Observatory	Excessive skin in the lower lid may cause "eye bags" but does not affect function of the eyelid or vision and therefore does not need correction.

	Condition or Intervention	Criteria **Please also see core eligibility criteria when considering the application of the policy**	Source of Evidence	Remarks
**6.4.8 **	**Correction of prominent ears** (Pinnaplasty)	May be commissioned in the following circumstances: Ideally the patient should be between 5 and 19 years of age but preferably below 14 years of age. Patient assessed by plastic or ENT surgeon who has the option to refer, when appropriate to a specialist paediatric psychologist	DH Aug 2007. Local PCT consensus - review conducted 2007 Modernisation Agency's Action on Plastic Surgery 2005	Children under the age of five are usually oblivious and referrals may reflect concerns expressed by the parents rather than the child.
**6.4.9 **	**Remodelling of lobe of external ear**	Only commissioned if: • Repair of completely split ear lobes as a result of direct trauma.	Modernisation Agency's Action on Plastic Surgery 2005	Correction of split earlobes is not always successful and the earlobe is a site where poor scar formation is a recognised risk.

	Condition or Intervention	Criteria **Please also see core eligibility criteria when considering the application of the policy**	Source of Evidence	Remarks
6.4.10	**Surgery to reshape the nose** (Rhinoplasty)	This procedure is NOT available under the NHS on cosmetic grounds. Only commissioned in the following circumstances: • Objective nasal deformity caused by trauma • Problems caused by obstruction of nasal airway • 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 Ear Nose and Throat (ENT) consultant for assessment and treatment.

6.5 Miscellaneous

	Condition or Intervention	Criteria **<u>Please also see core eligibility criteria when considering the application of the policy</u>**	Source of Evidence (work ongoing to review sources)	Remarks
6.5.1	**Disease of the small bowel –** **Capsule Endoscopy / Pillcam**	ONLY considered for Disease of the small bowel if: • Overt or transfusion dependant bleeding from GI tract, when source not identified on OGD/Colonoscopy • Crohns Disease in whom strictures are not suspected Hereditary GI polyposis syndromes It can also be used in patients with refractory coeliac disease to look for coeliac associated complications	Wireless capsule endoscopy for investigation of small bowel NICE IPG 101 2004 R Sidhu, D S Sanders, A J Morris, et al. Guidelines on small bowel enteroscopy and capsule endoscopy in adults: *Gut* 2008 57: 125-136.	

	Condition or Intervention	Criteria **Please also see core eligibility criteria when considering the application of the policy**	Source of Evidence	Remarks
6.5.2	**Autologous Chondrocyte implantation**	Not routinely commissioned - NICE GUIDANCE Is not recommended for treating knee problems caused by damaged articular cartilage, unless it is used in studies that are designed to produce good quality information about the results of this procedure.	NICE TA 89 May 2005	
6.5.3	**Penile Implant** **ALSO SEE GENDER RE-ASSIGNMENT POLICY**	Not routinely commissioned		
6.5.4	**Complementary therapies**	Not routinely commissioned		
6.5.5	**Gastro-electrical stimulation**	Not routinely commissioned	NICE IPG 103 Dec 2004	

	Condition or Intervention	Criteria **Please also see core eligibility criteria when considering the application of the policy**	Source of Evidence	Remarks
6.5.6	**Pulmonary Hypertension**	Services are commissioned at Sheffield University Teaching Hospital Trust. A national commissioning policy has now been developed and agreed through the North West Specialist Commissioning Group. Pulmonary Hypertension Nationa		
6.5.7	**Chronic back and leg pain - Endoscopic laser foraminoplasty**	Not routinely commissioned	NICE 2003 (confirmed 2009) IPG31 Endoscopic laser foraminoplasty: guidance	

	Condition or Intervention	Criteria **Please also see core eligibility criteria when considering the application of the policy**	Source of Evidence	Remarks
6.5.8	**Labial reduction surgery**	Not routinely commissioned	• Bramwell R, Morland C, Garden A. (2007). Expectations and experience of labial reduction: a qualitative study. *BJOG* 2007; 114:1493-1499 • Department for Education and Skills. (2004). *Local Authority Social Services Letter. LASSAL (2004)4,* London, DfES. • Goodman, M. P. (2009). Female Cosmetic Genital Surgery. *Obstetrics and Gynaecology; 113: 154-159* • Liao, L-M; Michala, L; Creighton, SM. (2010). Labial Surgery for Well Women; a review of the literature. *BJOG: An International Journal of Obstetrics & Gynaecology; Volume 117: 20-25*	

7. GROUP 2 PROCEDURES

	Condition or Intervention	Criteria **Please also see core eligibility criteria when considering the application of the policy**	Source of evidence (work ongoing to review sources)	Remarks
7.1	**Treatment For Sub fertility And Reversal of Vasectomy or Female Sterilisation**	Cheshire & Merseyside policy FertilityPolicy.pdf Fertility policy 2008 CM Addendum.doc Please note that this policy is currently suspended for NHS Warrington. Please refer to NHS Warrington for details.	Cheshire & Merseyside Specialised Services Commissioning Team	Cheshire & Merseyside Specialised Services Commissioning Team produced unified guidance for PCTs across Cheshire, Merseyside and West Lancashire

	Condition or Intervention	Criteria **Please also see core eligibility criteria when considering the application of the policy**	Source of Evidence	Remarks
7.2	**Varicose Veins**	Treatment of varicose veins is not commissioned except in the following circumstances: • Ulcers/history of ulcers secondary to superficial venous disease. • Liposclerosis. • Varicose eczema. • History of phlebitis.	Referral Advice National Institute for Clinical Excellence 2001. http://www.nice.org.uk/media/A8F/DC/Referraladvice.pdf Most varicose veins require no treatment. The most common complaint about varicose veins is their appearance. When bleeding or ulceration occurs referral may be appropriate and of that number some may benefit from surgical intervention. London Health Observatory	Evidence from recent population surveys indicates very little relationship between symptoms and varicose veins – substantial numbers of patients without varicose veins have similar symptoms.

	Condition or Intervention	Criteria **Please also see core eligibility criteria when considering the application of the policy**	Source of Evidence	Remarks
7.3	**Glue Ear** (Otitis Media with effusion)	The PCT will commission treatment with grommets / Myringotomy for children with otitis media with effusion(OME) where: There is also a history of recurrent acute otitis media (RAOM) Or There has been a period of at least three months watchful waiting from the date of diagnosis of OME (by a GP/primary care referrer/ audiologist/ENT surgeon AND OME persists after three months AND the child (who must be over three years of age) suffers from at least one of the following: • Delay in speech development • Persistent bilateral OME with a hearing level in the better ear of 25-30 dBHL (averaged at 0.5, 1, 2 and 4kHz) or worse confirmed over 3 months • Persistent bilateral OME with hearing loss	NICE clinical guideline 60 February 2008	

	Condition or Intervention	Criteria **Please also see core eligibility criteria when considering the application of the policy**	Source of Evidence	Remarks
		• Less than 25-30 dBHL (averaged at 0.5, 1, 2 and 4kHz) and with significant impact on the child's developmental, social or educational status. • A significant second disability, such as Downs syndrome NB. In other cases where clinical judgment suggests this to be an appropriate course of action particularly for: • Suspicion of/ known underlying sensory neural loss • Cleft palate/ Craniofacial anomalies • Concerns re retracted eardrum • Balance problems		
7.4	**Extraction of Wisdom teeth**	NICE GUIDANCE Impacted Wisdom teeth free from disease should not be operated on. Removal is only indicated in cases with evidence of pathology	NICE TA 1 March 2000. London Health Observatory	

	Condition or Intervention	Criteria **Please also see core eligibility criteria when considering the application of the policy**	Source of Evidence	Remarks
7.5 ***see western schedule for further referral guidance***	**Low back pain: injections and fusion**	**Injections** of therapeutic substances: • Not commissioned for non-specific back pain **Fusion** • Not commissioned unless the patient has completed an optimal package of care, including a combined physical and psychological treatment programme; and • Still has severe non-specific low back pain for which they would consider surgery.	NICE 2009. CG88 Low back pain: quick reference guide	
7.6	**Osteoarthritis of the knee - Arthroscopic lavage and debridement**	**Arthroscopic lavage and debridement** for knee osteoarthritis will not be commissioned, unless there is a clear history of mechanical locking (not gelling, 'giving way' or X-ray evidence of loose bodies).	NICE 2008. CG59 Osteoarthritis. Section 3.1	

	Condition or Intervention	Criteria **Please also see core eligibility criteria when considering the application of the policy**	Source of Evidence	Remarks
7.7	**Heavy menstrual bleeding – surgical procedures** • **hysterectomy;** • **D&C**	**Hysterectomy** not commissioned unless all of the following requirements have been met: • An unsuccessful trial with a levonorgestrel intrauterine system (e.g. Mirena) unless medically contra-indicated or the woman has made an informed choice not to use this treatment. • The following treatments have failed, are not appropriate or are contra-indicated in line with NICE guidance. • Tranexamic acid or nonsteroidal anti-inflammatory drugs or combined oral contraceptives. • Norethisterone (15mg) daily from days 5 to 26 of the menstrual cycle, or injected long-acting progestogens. • Endometrial ablation has been tried (unless patient has fibroids >3cm) **Dilatation and curettage** not commissioned as a diagnostic or therapeutic procedure.	NICE 2007. CG44 Heavy menstrual bleeding: full guideline	

	Condition or Intervention	Criteria **Please also see core eligibility criteria when considering the application of the policy**	Source of Evidence	Remarks
7.8	**Idiopathic detrusor instability - Botulinum A toxin**	Only Commissioned when conservative treatment has failed.	NICE 2006. Urinary incontinence. Management of urinary incontinence in women	
7.9	**Asymptomatic incisional and ventral hernias**	**Surgery**: not commissioned if no symptoms, easily reducible (i.e. can be 'pushed back in') and not at significant risk of complications.	NHS Derbyshire Country Prior Approval/Procedures of Limited Clinical Value Summary, May 2010 http://phcn.nhs.uk/Derbyshire%20County%20Procedures%20of%20Limited%20Clinical%20Value%20100525%20draft.pdf	

	Condition or Intervention	Criteria **Please also see core eligibility criteria when considering the application of the policy**	Source of Evidence	Remarks
7.10	**Haemorrhoidectomy - Rectal surgery:**	Surgery commissioned for: • Grade III and IV haemorrhoids. • Grade I or II haemorrhoids if they are large, symptomatic, and have not responded to the following non-surgical treatments – - Diet modification to relieve constipation - Topical applications - Stool softeners and laxatives - Rubber band ligation - Sclerosant injections - Infrared coagulation Surgical treatment options include: • Surgical excision (haemorrhoidectomy) • Stapled haemorrhoidopexy • Haemorrhoidal artery ligation	• NICE 2010, Haemorrhoidal artery ligation • NICE 2007. TAG128, Stapled haemorrhoidopexy for the treatment of haemorrhoids • BMJ2008. Clinical Review: Management of Haemorrhoids. Austin G Acheson, John H Scholefield, BMJ 2008; 336:380 doi:10.1136/bmj.39465.674745.80 (Published 14 February 2008)	

	Condition or Intervention	Criteria **Please also see core eligibility criteria when considering the application of the policy**	Source of Evidence	Remarks
7. 11	**Carpal tunnel syndrome**	Conservative treatment in the community (local corticosteroid injection and splinting) may be appropriate for mild to moderate cases Surgery for mild to moderate cases is not commissioned unless: • Patients have not responded to 3 months of conservative treatments, including: - >8weeks of night-time use of wrist splints - Corticosteroid injection in appropriate patients • Conservative treatments contraindicated Severe cases: Carpal tunnel surgery (open or endoscopic) for severe symptoms	• Cochrane Database of Systematic Reviews, 2007: Local corticosteroid injection for carpal tunnel syndrome • American Academy of Orthopaedic Surgeons, 2008: clinical practice guideline on treatment of Carpal Tunnel Syndrome • NHS Oxfordshire, 2009. Interim Treatment Threshold Statement: Surgery for Carpal Tunnel Syndrome	

	Condition or Intervention	Criteria **Please also see core eligibility criteria when considering the application of the policy**	Source of Evidence	Remarks
		(constant pins and needles, numbness and muscle wasting) will be commissioned. Following assessment. The following treatments are **not** generally thought to be effective for carpal tunnel syndrome: • Diuretics • NSAIDS • Vitamin B6 • Activity modification • Heat treatment • Botulinum toxin		

	Condition or Intervention	Criteria **Please also see core eligibility criteria when considering the application of the policy**	Source of Evidence	Remarks
7.12	**Trigger finger**	Conservative management (including splinting, steroid injections, NSAIDS) is adequate in the majority of cases. Local steroid injections should be the first line treatment unless the patient is diabetic (where surgery preferred) Surgery not commissioned unless: • conservative treatments, (including at least 2 corticosteroid injections) have failed or are contraindicated or • Fixed flexion deformity that cannot be corrected is present	• Nimigan AS, Ross DC, Bing SG. Steroid injections in the management of trigger fingers. *American Journal of Physical Medicine and Rehabilitation 2006;* 85(1):36-43 • BMJ review: Akhtar S, Bradley MJ, Quinton DN, Burke FD. Management and referral for trigger finder/thumb. *BMJ* 2005; 331(7507):30-33 • NHS Oxfordshire, Interim Treatment Threshold Statement: Surgery for trigger finder (stenosing tenovaginosis)	

	Condition or Intervention	Funding Criteria **Please also see core eligibility criteria when considering the application of the policy**	Source of Evidence	Remarks
7. 13	**Wrist ganglion**	Aspiration and Surgery (open or arthroscopic) not commissioned Reassurance that no treatment is required should be given to the patient	Berkshire PCT, 2009. South Central Priorities Committee Policy statement 152: Wrist ganglions	
7.14	**Recurrent tonsillitis (excluding peri-tonsillar abscess)**	Sore throats are due to acute tonsillitis. The episodes of sore throat are disabling and prevent normal function. Seven or more well documented clinically significant adequately treated sore throats in the preceding year; or Five or more such episodes in each of the previous two years; or Three or more such episodes in each of the preceding three years. Is commissioned if appropriate following peri-tonsillar abscess.	Scottish intercollegiate guidelines network. Management of sore throat and indications for tonsillectomy (April 2010) see www.sign.ac.uk	Watchful waiting is more appropriate than tonsillectomy for children with mild sore throats. Tonsillectomy is recommended for severe recurrent sore throats in adults.

	Condition or Intervention	Funding Criteria **Please also see core eligibility criteria when considering the application of the policy**	Source of Evidence	Remarks
7.15	**Obstructive sleep apnoea/hypopnoea syndrome in Adults (OSAHS)**	Weight loss, stopping smoking and reducing alcohol should be encouraged prior to referral to secondary care for mild cases of sleep apnoea. For patients with moderate to severe symptoms, attempts at weight loss should not delay the initiation of further treatment. Dental devices, commissioned for: • Mild to Moderate OSAHs • For severe OSAHS where CPAP cannot be tolerated.	NICE (2008) TA 139 Map of medicine SIGN (2003) Clinical Guideline 73 SIGN (2003) Clinical Guideline 73 • Cochrane Intervention Review (2009) Oral appliances for obstructive sleep apnoea, Lim J et al • NICE (2008) TA 139 • SIGN (2003) Clinical Guideline 73	There is a lack of RCT evidence on lifestyle modification specific to the treatment of sleep apnoea. However, there is NICE Guidance on management of obesity, smoking cessation, physical activity and preventing harmful drinking. NB: 20-30% of symptomatic OSAHS are not overweight. The efficacy of dental devices has been established in clinical trials but as a treatment option for mild and moderate symptoms and for those unable to tolerate CPAP.

		Continuous positive Airway Pressure commissioned for adults: • With moderate or severe OSAHS(defined as Apnoea/hypnoea index 1 ≥15 • Patients with mild OSAHS(AHI 5-14) if symptoms affect their quality of life and ability to go about daily activities and advice about lifestyle and other relevant treatment options have been unsuccessful or are considered inappropriate. Drug therapy – not routinely commissioned	• SIGN (2003) clinical guideline 73 • Cochrane Intervention Review (2009) Drug therapy for obstructive sleep apnoea in adults, Smith I et al.	Weight loss, stopping smoking and reducing alcohol should be encouraged as an adjunct to CPAP. Pharmacological therapy should not be used as a first line therapy for OSAHS. There is currently insufficient evidence to recommend use of drug therapy.

		Surgery – not routinely commissioned	• SIGN (2003) National Clinical Guideline 73 see www.sign.ac.uk • Cochrane Intervention Review (2009) • Surgery for obstructive sleep apnoea in adults, Sundoram S et al.	Palatal surgery, such as Uvelopalatopharyngoplasty (UPPP) and Laser-assisted uvulopalatoplasty (LAUP) is not recommended by SIGN (2003) and it may compromise the patient's subsequent ability to use nasal CPAP, although the extent of this risk is not known. Current evidence on soft-palate implants for obstructive sleep apnoea (OSA) raises no major safety concerns, but there is inadequate evidence that the procedure is efficacious in the treatment of this potentially serious condition for which other treatments exist. Studies assembled for the Cochrane Review do not provide evidence to support the use of surgery for sleep apnoea as overall benefits have not been demonstrated.

7. 16	Snoring – Soft Palate Implants and Radiofrequency ablation of the soft palate	Not Routinely Commissioned	NICE (2007) Soft Palate Implants for snoring IPG240 NICE (2005) Radiofrequency ablation of the soft palate for snoring IPG 124 SIGN (2003) clinical guideline 73	NICE concludes that soft palate implants for snoring can only be recommended in the context of research, and radiofrequency ablation should only be used providing special arrangements are in place for audit, consent and research. For both, there are no major safety concerns, but the evidence on efficacy and outcomes is uncertain. UPPP may compromise the patient's subsequent ability to use nasal CPAP.
	Sodium Tetradecyl Sulfate (STS) injection or 'snoreplasty'	Not Routinely Commissioned	The British Snoring & Sleep Apnoea Association website and information from North West Medicines Information Centre	Research to date is exploratory and studies small and not randomised or blinded. The method of injecting a chemical into the soft palate known as 'Snoreplasty' is not well recognised in the UK as an effective method of treating snoring. This method has

				been used in the past and was found to be unsuccessful and ineffective.
7. 17 **	Hip and Knee Replacement Surgery	PCTs have agreed the principle of using a hip score and knee score threshold as part of a demand management approach. It has been agreed to work towards a threshold of 26 and in order to facilitate this, commissioners will be developing local pathways to ensure appropriate referrals to secondary care during 11.12. This approach will be phased into the Prior Approval policy during 11.12.		
7.18 **	Bariatric Surgery / Weight Management	Please see local policies and pathways for criteria		

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APPENDIX 1

Web links to Cheshire & Merseyside PCT Policies for Funding of a case on the basis of clinical exception:

Liverpool PCT
1 Arthouse Square
61-69 Seel Street
Liverpool L1 4AZ
0151 296 7000

http://www.liverpoolpct.nhs.uk/Your_PCT/about_us/Policies/policies.aspx

NHS Halton & St Helens
IPCC Office
The Gables
Cowley Hill Lane
St Helens
WA8 7GD
01744 457208
Gillian.Unsworth@hsthpct.nhs.uk

NHS Knowsley
PO Box 23
Nutgrove Villa
Westmorland Road
Huyton
Knowsley L36 6GA
0151 443 4900
Gillian.Unsworth@hsthpct.nhs.uk

Central & Eastern Cheshire PCT
Universal House
Pochin Way
Middlewich
Cheshire CW10 0TN
Janet Slack Tel: 01606 275379
www.cecpct.nhs.uk/about-us/individual-funding-requests-bespoke-care/

NHS Wirral
Old Market House
Hamilton Street
Birkenhead
CH41 5FL
0151 651 0011
www.wirral.nhs.uk/aboutnhswirral/planspoliciesandpublications/policies/commissioning.html

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NHS Warrington
Millennium House
930-932 Birchwood Boulevard
Millennium Park
Birchwood
Warrington WA3 7QN
01925 843600
www.warrington-pct.nhs.uk/pdf/Treatment%20Needing%20Prior%20Approval/PLCP%20statement.doc

NHS Sefton
6th Floor, Merton House,
Stanley road,
Bootle.
Liverpool
L20 3DL
Telephone: 0151 247 7000
www.seftonpct.nhs.uk/

NHS Western Cheshire
1829 Building
Countess of Chester Health Park
Liverpool Road
Chester
CH2 1HJ
01244 650300
http://www.wcheshirepct.nhs.uk/default.asp?page=Policies/default.asp-