

# Greater Manchester EUR Policy Statement on:

## Other Aesthetic Surgery

GM Ref: GM040

Version: 1.1 (15 Nov 2017)



## Commissioning Statement

<b>Other Aesthetic Surgery</b>	
<b>Policy Exclusions</b>	<p>Strabismus surgical procedures in children and young adults under the age of 18 are excluded from this policy.</p> <p>Strabismus surgical procedures (including Botulinum Toxin A injections to extraocular muscles) carried out to correct double vision, restore ocular alignment (where vision is affected) and promote, improve or restore binocular function are excluded from this policy.</p> <p>Operations on congenital anomalies of the face and skull are excluded from this policy.</p> <p>Aesthetic procedures undertaken to correct the consequences of trauma or to correct deformity following surgery (unless that surgery was undertaken for aesthetic surgery) is excluded from this policy.</p> <p>Aesthetic procedures undertaken as part of the treatment localised fat atrophy or pathological hypertrophy (e.g. multiple lipomatosis, lipodystrophies) or as an adjunct to other surgical procedures is excluded from this policy.</p> <p>Botox used as an agreed and recognised part of a care pathway e.g. cerebral palsy or stroke management is excluded from this policy.</p> <p>Limb lengthening surgery to address deficiency or inequality in leg length resulting in a limp or limiting functional ability is excluded from this policy.</p> <p>Surgical correction of pigeon chest where cardiac or pulmonary functioning is affected is excluded from this policy.</p> <p>This policy does not apply to individuals under the age of 16 years.</p> <p>Treatment/procedures undertaken as part of an externally funded trial or as a part of locally agreed contracts / or pathways of care are excluded from this policy, i.e. locally agreed pathways take precedent over this policy (the EUR Team should be informed of any local pathway for this exclusion to take effect).</p>
<b>Policy Inclusion Criteria</b>	<p>Any procedures carried out for purely aesthetic reasons are not commissioned, this includes the treatment of birthmarks (for Haemangiomas please see specific criteria below).</p> <div style="background-color: #e6f2ff; padding: 5px; margin-top: 10px;"> <p><b>Funding Mechanism</b></p> <p><u>If the requested procedure is NOT commissioned:</u> Individual funding request (exceptional case) approval: Requests <u>must</u> be submitted with all relevant supporting evidence.</p> <p><u>If the procedure IS commissioned for certain criteria:</u> This will be stated below.</p> </div> <div style="background-color: #e6f2ff; padding: 5px; margin-top: 10px;"> <p><b>Vaginoplasty</b></p> <p>Vaginoplasty for aesthetic reasons only is <u>not</u> commissioned.</p> </div> <div style="background-color: #e6f2ff; padding: 5px; margin-top: 10px;"> <p><b>Vitiligo</b></p> <p>Surgical treatment is <u>not</u> commissioned. The usual treatment for hypo-pigmentation / vitiligo is Cosmetic Camouflage.</p> </div>

### Haemangiomas

Surgical intervention AND / OR laser therapy is commissioned for those haemangiomas effecting the eyes and nose where haemangiomas have failed to resolve naturally and they are causing significant deformity or impacting on functioning interventions. This is in line with the [GM Common Benign Skin Lesions Policy](#).

#### Funding Mechanism

Individual prior approval provided the patient meets the above criteria. Requests must be submitted with all relevant supporting evidence that the criteria have been met.

### Face Lifts / Brow Lifts (including Rhytidectomy)

These are not commissioned to treat the natural processes of ageing.

Where there is significant deformity or an impact on normal functions then a request can be made for clinical exceptionality. Supporting evidence must be provided with the request.

For brow lifts to treat visual field problems, please refer to the [GM Correction of Eyelid Ptosis Policy](#)

#### Funding Mechanism

Significant deformity or an impact on normal functions: Individual funding request (exceptional case) approval: Requests must be submitted with all relevant supporting evidence.

### Liposuction

Not commissioned to correct the distribution of fat unless the abnormal distribution is due to true severe lipodema.

May be commissioned in cases of true severe lipodema with supporting evidence.

Applications for non-aesthetic use of liposuction must be made for clinical exceptionality with supporting evidence.

For body contouring procedures, including panniculectomy (apronectomy) please refer to the [GM Body Contouring Policy](#). Please also note policy exclusions.

#### Funding Mechanism

True severe lipodema: Individual prior approval at Clinical Triage, with requests to go to IFR Panel if a decision cannot be made. Supporting evidence must be provided with the application and wherever possible should include non-identifiable photographs of the affected area.

Non-aesthetic use of liposuction: Individual funding request (exceptional case) approval: Requests must be submitted with all relevant supporting evidence.

### Rhinophyma

The commissioned first line of this condition of the nasal skin is medical. Severe cases or those that do not respond to medical treatment may be considered for surgery or laser treatment.

### Funding Mechanism

Individual prior approval provided the patient meets the above. Requests should be submitted with all relevant supporting evidence, which must be provided with the request.

### Botulinum toxin

Botulinum toxin is not available for the treatment of ageing or excessive wrinkles.

Botulinum toxin may be commissioned for:

- Frey's syndrome
- Blepharospasm

Botox for hyperhidrosis and migraine are covered by separate policies: [GM Hyperhidrosis policy](#) and [GM Headache Disorders Policy](#). Please also note policy exclusions above.

### Funding Mechanism

Frey's Syndrome and Bepharospasm: Individual prior approval. Requests must be submitted with all relevant supporting evidence.

### Limb Lengthening / Shortening

Length deficiency can occur in one or both legs, and may be acquired (for example, secondary to trauma or infection) or, more rarely, be congenital (for example, due to hypoplasia or dysplasia). The femur, tibia or both can be involved. Deficiency or inequality in leg length can result in a limp and may limit functional ability.

Bilateral limb lengthening / shortening solely to increase / decrease height is not commissioned.

Please also note policy exclusions above.

### Pigeon Chest

Surgical correction of pigeon chest for purely aesthetic reasons is not commissioned.

Please also note policy exclusions above.

### Correction of squint

Correction of adult (aged over 18 years) squint for purely aesthetic reasons is not routinely commissioned but may be considered where the squint is having an excessive effect on the individual. Supporting evidence must be provided with the application.

Please also note policy exclusions above for squint surgery to correct a functional problem (e.g. double vision).

### Funding Mechanism

Individual funding request (exceptional case) approval: Requests must be submitted with all relevant supporting evidence.

### Clinical

Clinicians can submit an Individual Funding Request (IFR) outside of this guidance if

<b>Exceptionality</b>	<p>they feel there is a good case for exceptionality.</p> <p>Exceptionality means ‘a person to which the general rule is not applicable’. Greater Manchester sets out the following guidance in terms of determining exceptionality; however the over-riding question which the IFR process must answer is whether each patient applying for exceptional funding has demonstrated that his/her circumstances are exceptional. A patient may be able to demonstrate exceptionality by showing that s/he is:</p> <ul style="list-style-type: none"><li>• Significantly different to the general population of patients with the condition in question.</li></ul> <p><b><i>and as a result of that difference</i></b></p> <ul style="list-style-type: none"><li>• They are likely to gain significantly more benefit from the intervention than might be expected from the average patient with the condition.</li></ul>
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## Policy Statement

Greater Manchester Shared Services (GMSS) Effective Use of Resources (EUR) Policy Team, in conjunction with the GM EUR Steering Group, have developed this policy on behalf of Clinical Commissioning Groups (CCGs) within Greater Manchester, who will commission treatments/procedures in accordance with the criteria outlined in this document.

In creating this policy GMSS/GM EUR Steering Group have reviewed this clinical condition and the options for its treatment. It has considered the place of this treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources.

This policy document outlines the arrangements for funding of this treatment for the population of Greater Manchester.

This policy follows the principles set out in the ethical framework that govern the commissioning of NHS healthcare and those policies dealing with the approach to experimental treatments and processes for the management of individual funding requests (IFR).

## Equality & Equity Statement

GMSS/CCGs have a duty to have regard to the need to reduce health inequalities in access to health services and health outcomes achieved, as enshrined in the Health and Social Care Act 2012. GMSS/CCGs are committed to ensuring equality of access and non-discrimination, irrespective of age, gender, disability (including learning disability), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, gender or sexual orientation. In carrying out its functions, GMSS/CCGs will have due regard to the different needs of protected characteristic groups, in line with the Equality Act 2010. This document is compliant with the NHS Constitution and the Human Rights Act 1998. This applies to all activities for which they are responsible, including policy development, review and implementation.

In developing policy the GMSS EUR Policy Team will ensure that equity is considered as well as equality. Equity means providing greater resource for those groups of the population with greater needs without disadvantage to any vulnerable group.

The Equality Act 2010 states that we must treat disabled people as *more equal* than any other protected characteristic group. This is because their 'starting point' is considered to be further back than any other group. This will be reflected in GMSS evidencing taking 'due regard' for fair access to healthcare information, services and premises.

An Equality Analysis has been carried out on the policy. For more information about the Equality Analysis, please contact [policyfeedback.gmscu@nhs.net](mailto:policyfeedback.gmscu@nhs.net).

## Governance Arrangements

Greater Manchester EUR policy statements will be ratified by the Greater Manchester Association Governing Group (GMAGG) prior to formal ratification through CCG Governing Bodies. Further details of the governance arrangements can be found in the [GM EUR Operational Policy](#).

## Aims and Objectives

This policy document aims to ensure equity, consistency and clarity in the commissioning of treatments/procedures by CCGs in Greater Manchester by:

- reducing the variation in access to treatments/procedures.

- ensuring that treatments/procedures are commissioned where there is acceptable evidence of clinical benefit and cost-effectiveness.
- reducing unacceptable variation in the commissioning of treatments/procedures across Greater Manchester.
- promoting the cost-effective use of healthcare resources.

## **Treatment / Procedure**

Increasing concern over appearance and a desire for “normalcy” alongside a developing aesthetic surgical specialty has led to an increase in requests for aesthetic surgery. This in turn leads to increasing numbers of procedures where revision surgery is required. Where there is no associated functional problem this is not necessarily the best use of limited NHS resources. This policy sets out the conditions under which aesthetic procedures may be commissioned to ensure equity of access for those with functional issues.

As these procedures are normally carried out to enhance appearance there is limited evidence of effectiveness available. Where there is a clinical reason for carrying out an “aesthetic” procedure this has been taken into account in developing this policy.

This policy covers all aesthetic procedures (also referred to as plastic surgery procedures) not covered by individual GM policies (please also refer to Aesthetic Breast Surgery; Body Contouring; Pinnaplasty; Rhinoplasty / Septoplasty / Septo-Rhinoplasty; Skin Resurfacing Techniques; Surgical Revision of Scarring; Tattoo Removal; Repair of Split / Torn Earlobes; Hair Replacement Technologies for Alopecia; Electrolysis & Laser Hair Removal For Hirsutism; Labiaplasty; Common Benign Skin Lesions; Common Benign Eyelid Lesions and Correction of Eyelid Ptosis policies). This policy covers all remaining surgery carried out for aesthetic reasons; it includes but is not limited to:

- Vaginoplasty
- Rhytidectomy (Face Lift / Brow Lift)
- Botox for the ageing face
- Liposuction
- Limb lengthening
- Vitiligo
- Revision of cosmetic procedures

## **Rationale behind the policy statement**

As with all surgery these techniques are not without risk(s) and as the benefits are mainly aesthetic these procedures are either restricted or are not commissioned when being done for aesthetic reasons.

## **Epidemiology and Need**

As these are carried out mostly for aesthetic reasons there is no standard epidemiological data available. Current activity data reflects demand rather than need.

## **Adherence to NICE Guidance**

NICE have not currently issued clinical guidance on these treatments

## **Audit Requirements**

There is currently no national database. Service providers will be expected to collect and provide audit data on request.



## Date of Review

One year from the date of approval by Greater Manchester Association Governing Group and thereafter at a date agreed by the Greater Manchester EUR Steering Group, unless new evidence or technology is available sooner.

The evidence base for the policy will be reviewed and any recommendations within the policy will be checked against any new evidence. Any operational issues will also be considered at this time. All available additional data on outcomes will be included in the review and the policy updated accordingly. The policy will be continued, amended or withdrawn subject to the outcome of that review.

## Glossary

Term	Meaning
Aesthetic	Concerned with beauty or the appreciation of beauty.
Anomalies	Deviation from what is standard, normal, or expected.
Blepharospasm	Involuntary tight closure of the eyelid.
Botulinum toxin (Botox)	Seven type-specific, immunologically differentiable exotoxins (types A to G) produced by <i>Clostridium botulinum</i> , neurotoxins usually found in imperfectly canned or preserved foods. They cause botulism by preventing release of acetylcholine by the cholinergic fibers. Type A is one of the most powerful poisons known; it is also used therapeutically by injection to inhibit muscular spasm in the treatment of dystonic disorders such as blepharospasm and strabismus, to treat wrinkles of the upper face, and to reduce anal sphincter pressure to promote healing of chronic anal fissure. Type B is injected in treatment of cervical dystonia. Called also botulin.
Cerebral palsy	A condition marked by impaired muscle coordination (spastic paralysis) and/or other disabilities, typically caused by damage to the brain before or at birth
Cerebrovascular Event	(stroke) A clinical syndrome caused by disruption of blood supply to the brain, characterised by rapidly developing signs of focal or global disturbance of cerebral functions, lasting for more than 24 hours or leading to death.
Congenital	(of a disease or physical abnormality) present from birth.
Cosmetic camouflage	The application of make-up creams and/or powders to conceal colour or contour irregularities or abnormalities of the face or body.
Cutis laxa	A disorder of connective tissue, which is the tissue that forms the body's supportive framework. Connective tissue provides structure and strength to the muscles, joints, organs, and skin.
Deformity	A deformed part, especially of the body; a malformation.
Dysplasia	The enlargement of an organ or tissue by the proliferation of cells of an abnormal type, as a developmental disorder or an early stage in the development of cancer.
Facial palsy	Weakness or paralysis of the muscles of the side of the face on which the facial nerve is affected.
Fat atrophy	Fatty infiltration secondary to an atrophy (wasting away, or degeneration of cells of the essential elements of an organ or tissue).
Femur	The bone of the thigh, between the hip and the knee.

Frey's syndrome	(also known as Baillarger's syndrome, Dupuy's syndrome, auriculotemporal syndrome, or Frey-Baillarger syndrome) is a rare neurological disorder resulting from damage to or near the parotid glands responsible for making saliva, and from damage to the auriculotemporal nerve often from surgery.
Haemangioma(s)	Benign tumour of blood vessels, often forming a red birthmark.
Hyperhidrosis	Excessive sweating.
Hypo-pigmentation	Excessive pigmentation of the skin.
Hypoplasia	Underdevelopment or incomplete development of a tissue or organ.
Lipodystrophies	Abnormal or degenerative conditions of the body's adipose (fat) tissue.
Lipoedema	A long-term (chronic) condition typically involving an abnormal build-up of fat cells in the legs, thighs and buttocks. The condition occurs almost exclusively in women, although there have been rare cases reported in men.
Lipomatosis	Local or generalized deposits of fat or replacement of other tissue by fat
Lymphoedema	Also known as lymphatic obstruction, is a condition of localized fluid retention and tissue swelling caused by a compromised lymphatic system, which normally returns interstitial fluid to the thoracic duct and then the bloodstream.
Neurofibromatosis	A disease in which neurofibromas (tumours formed on a nerve cell sheath, frequently symptomless but occasionally malignant) form throughout the body.
NICE CKS	NICE Clinical Knowledge Summaries
NICE IPG	NICE Interventional Procedure Guidance
Normalcy	The condition of being normal; the state of being usual, typical, or expected.
Pathological hypertrophy	A non-tumorous enlargement of an organ or a tissue as part of a disease process.
Pseudoxanthoma elasticum	Also known as Grönblad–Strandberg syndrome, is a genetic disease that causes fragmentation and mineralization of elastic fibers in some tissues. The most common problems arise in the skin and eyes, and later in blood vessels in the form of premature atherosclerosis.
Revision surgery	Surgery to correct the unwanted results of previous surgery or to address an issue that has recurred.
Rhinophyma	A condition causing development of a large, bulbous, ruddy nose associated with granulomatous infiltration, commonly due to untreated rosacea (a condition where facial blood vessels enlarge, giving the cheeks and nose a flushed appearance).
Rhytidectomy	Surgical removal of wrinkles - a type of cosmetic surgery procedure used to give a more youthful facial appearance.
Spasm	Sudden involuntary muscular contraction or convulsive movement.
Tibia	The inner and typically larger of the two bones between the knee and the ankle parallel with the fibula.
Trauma	Physical injury.
Vaginoplasty	Plastic surgery performed to create or reshape a vagina.
Vitiligo	A condition in which the pigment is lost from areas of the skin, causing whitish

	patches, often with no clear cause.
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## References

1. Greater Manchester Effective Use of Resources Operational Policy
2. Modernisation Agency Action on Plastic Surgery - Information for Commissioners of Plastic Surgery Services: Referrals and Guidelines in Plastic Surgery, British Association of Plastic Reconstructive and Aesthetic Surgeons (BAPRAS)

## Governance Approvals

Name	Date Approved
Greater Manchester Effective Use of Resources Steering Group	18/01/2017
Greater Manchester Chief Finance Officers / Greater Manchester Directors of Commissioning	12/09/2017
Greater Manchester Association Governing Group	02/10/2017
Bury Clinical Commissioning Group	02/10/2017
Bolton Clinical Commissioning Group	27/10/2017
Heywood, Middleton & Rochdale Clinical Commissioning Group	02/10/2017
Manchester Clinical Commissioning Group	30/11/2017
Oldham Clinical Commissioning Group	02/10/2017
Salford Clinical Commissioning Group	02/10/2017
Stockport Clinical Commissioning Group	02/10/2017
Tameside & Glossop Clinical Commissioning Group	02/10/2017
Trafford Clinical Commissioning Group	17/10/2017
Wigan Borough Clinical Commissioning Group	06/12/2017

## Appendix 1 – Evidence Review

### Other Aesthetic Surgery GM040

#### Search Strategy

The following databases are routinely searched: NICE Clinical Guidance and full website search; NHS Evidence and NICE CKS; SIGN; Cochrane; York; BMJ Clinical Evidence; and the relevant royal college websites. A Medline / Open Athens search is undertaken where indicated and a general google search for key terms may also be undertaken. The results from these and any other sources are included in the table below. If nothing is found on a particular website it will not appear in the table below:

Database	Result
NICE	<ul style="list-style-type: none"> <li>• NICE IPG90: Intralesional photocoagulation of subcutaneous congenital vascular disorders, Published: September 2004</li> <li>• NICE IPG197: Intramedullary distraction for lower limb lengthening, Published: December 2006</li> <li>• NICE IPG251: Liposuction for chronic lymphoedema, Published: February 2008</li> </ul>
NHS Evidence and NICE CKS	<ul style="list-style-type: none"> <li>• Vaginoplasty - Numerous papers on the types of procedure available and clinical guidelines on the management of patients (mostly relates to reconstruction and gender dysphoria) – not cited here as not done for aesthetic reasons and the number of results found (search can be replicated by typing Vaginoplasty into the NICE evidence home page)</li> <li>• Modernisation Agency Action on Plastic Surgery: Information for Commissioners of Plastic Surgery Services: Referrals and Guidelines in Plastic Surgery, British Association of Plastic Reconstructive and Aesthetic Surgeons (BAPRAS)</li> <li>• NICE CKS: Vitiligo</li> </ul>
Cochrane	<ul style="list-style-type: none"> <li>• Interventions for infantile haemangiomas (strawberry birthmarks) of the skin, Leonardi-Bee J, Batta K, O'Brien C, Bath-Hextall FJ., <i>Cochrane Database of Systematic Reviews</i> 2011, Issue 5. Art. No.: CD006545. DOI: 10.1002/14651858.CD006545.pub2.</li> <li>• Interventions for vitiligo, Whitton ME, Pinart M, Batchelor J, Leonardi-Bee J, González U, Jiyad Z, Eleftheriadou V, Ezzedine K., <i>Cochrane Database of Systematic Reviews</i> 2015, Issue 2. Art. No.: CD003263. DOI: 10.1002/14651858.CD003263.pub5.</li> </ul>
BMJ Clinical Evidence	<ul style="list-style-type: none"> <li>• Vitiligo in adults and children: surgical interventions, <i>Rubeta Matin</i>, Search date: April 2014</li> <li>• Patient information from the BMJ Group: Wrinkles, Published Dec 2016</li> </ul>
General Search (Google)	Not done as initial searches delivered mainly cosmetic surgery providers
Medline / Open Athens	Not done due to topic
Other	British Association of Dermatologists (BAD) – Patient Information Leaflet: Rhinophyma, Published: October 2014

## Summary of the evidence

As these procedures are mainly aesthetic there is limited evidence of effectiveness available. However there is guidance for commissioners as well as some guidance on when these procedures could be performed at NHS expense.

As with all surgery these techniques are not without risk so are not commissioned for aesthetic reasons.

## The evidence

Levels of evidence	
Level 1	Meta-analyses, systematic reviews of randomised controlled trials
Level 2	Randomised controlled trials
Level 3	Case-control or cohort studies
Level 4	Non-analytic studies e.g. case reports, case series
Level 5	Expert opinion

### 1. LEVEL N/A: GUIDANCE TO COMMISSIONERS

**Modernisation Agency Action on Plastic Surgery: Information for Commissioners of Plastic Surgery Services: Referrals and Guidelines in Plastic Surgery, British Association of Plastic Reconstructive and Aesthetic Surgeons (BAPRAS)**

#### Face lifts and brow lifts (Rhytidectomy)

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

#### Rationale

There are many changes to the face and brow as a result of ageing that may be considered normal, however there are a number of specific conditions for which these procedures may form part of the treatment to restore appearance and function.

#### **Liposuction**

Liposuction may be useful for contouring areas of localised fat atrophy or pathological hypertrophy (e.g.. Multiple lipomatosis, lipodystrophies). Liposuction is sometimes an adjunct to other surgical procedures. It will not be commissioned simply to correct the distribution of fat.

#### **Skin hypo-pigmentation**

The recommended NHS suitable treatment for hypo-pigmentation is Cosmetic Camouflage. Access to a qualified camouflage beautician should be available on the NHS for this and other skin conditions requiring camouflage.

#### **Rhinophyma**

The first-line treatment of this disfiguring condition of the nasal skin is medical. Severe cases or those that do not respond to medical treatment may be considered for surgery or laser treatment.

#### **Botulinum toxin**

Botulinum toxin has many uses within the NHS. It is available for the treatment of pathological conditions by appropriate specialists in cases such as:

- Frey's syndrome
- Blepharospasm
- Cerebral palsy
- Hyperhidrosis

Botulinum toxin is not available for the treatment of facial ageing or excessive wrinkles.

## **2. LEVEL 1: NICE INTERVENTIONAL PROCEDURE GUIDANCE**

**NICE IPG90: Intralesional photocoagulation of subcutaneous congenital vascular disorders, Published: September 2004**

### **1 Guidance**

- 1.1 Current evidence on the safety and efficacy of intralesional photocoagulation of subcutaneous congenital vascular disorders does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research.
- 1.2 Clinicians wishing to undertake intralesional photocoagulation of subcutaneous congenital vascular disorders should take the following actions.
  - Inform the clinical governance leads in their Trusts.
  - Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. Use of the Institute's information for the public is recommended.
  - Audit and review clinical outcomes of all patients having intralesional photocoagulation of subcutaneous congenital vascular disorders.
- 1.3 Publication of safety and efficacy outcomes will be useful in reducing the current uncertainty. The Institute is not undertaking further investigation at present.

### **2 The procedure**

#### **2.1 Indications**

- 2.1.1 Intralesional photocoagulation is a laser treatment for people with congenital abnormalities of the blood vessels of the skin (including haemangiomas, port wine stains and arteriovenous malformations). Often these abnormalities require no treatment because they may resolve spontaneously or cause only mild cosmetic problems.
- 2.1.2 Laser treatment is often recommended for lesions near the eyes or orifices, or if lesions bleed, ulcerate or become infected. However, external laser treatment of these vascular abnormalities may not be effective because the laser beam does not penetrate far beneath the skin.

#### **2.2 Outline of the procedure**

- 2.2.1 Intralesional photocoagulation involves inserting a laser fibre into the lesion to deliver light deep within it. More than one treatment may be needed.

#### **2.3 Efficacy**

- 2.3.1 The evidence was limited to small case series studies. The largest study, which only included children, reported that after intralesional photocoagulation, 46% (46/100) of patients had a greater than 90% reduction in the size of the lesion, and the other 54% (54/100) had a 50–90% reduction in the size of the lesion. In this study, 76% (76/100) of patients had a subsequent surgical resection and reconstruction. In another study of patients with periorbital haemangiomas, 83% (19/23) of patients had a 50% or greater reduction in the size of the lesion within 8 months. For more details, refer to the Sources of evidence section.
- 2.3.2 The Specialist Advisors noted that use of the procedure in the UK was very limited.

#### **2.4 Safety**

- 2.4.1 The following complications were reported in the identified studies: ulceration 17% (4/23) to 25% (3/12); continued gradual bleeding requiring surgical control 8% (1/12); scar contracture needing surgical revision 8% (1/12); infection 4% (1/23); residual weakness of branches of the facial nerve

2% (2/100); requirement for transfusion during treatment 2% (2/100); and small burns 2% (2/100). For more details, refer to the Sources of evidence section.

2.4.2 The Specialist Advisors listed the main potential adverse events as ulceration, nerve injury, tissue necrosis, scarring, contracture, and arteriovenous fistula formation.

## **2.5 Other comments**

2.5.1 The commonest outcome measure in the studies was reduction in the size of the lesions. Evidence on other outcome measures, such as function or the need for further treatment, was very limited.

2.5.2 The procedure may sometimes be used as an adjunct to surgery; this can make interpretation of outcomes more difficult.

2.5.3 There is particular uncertainty in the literature about the severity and consequences of ulceration and scarring caused by the procedure.

2.5.4 Facial nerve damage is an important potential complication.

## **3. LEVEL 1: NICE INTERVENTIONAL PROCEDURE GUIDANCE**

**NICE IPG197: Intramedullary distraction for lower limb lengthening, Published: December 2006**

### **1 Guidance**

1.1 Current evidence on the safety and efficacy of intramedullary distraction for lower limb lengthening does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research. Although there is evidence of efficacy in lengthening the femur, evidence on its safety is inadequate. There is inadequate evidence on both efficacy and safety in lengthening the tibia.

1.2 Clinicians wishing to undertake intramedullary distraction for lower limb lengthening should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients understand the uncertainty about the procedure's safety and efficacy in its use for lengthening the tibia and its safety in use for lengthening the femur
- Provide them with clear written information. In addition, use of the Institute's information for patients is recommended.
- Audit and review clinical outcomes of all patients having intramedullary distraction techniques for lower limb lengthening (see section 3.1).

1.3 A number of devices are available for the procedure which may have different safety and efficacy profiles. The technology is continuing to evolve and clinicians should consider the choice of device on the basis of the most current available evidence.

1.4 Publication of safety and efficacy outcomes will be useful. The Institute may review the procedure upon publication of further evidence.

### **2 The procedure**

#### **2.1 Indications**

2.1.1 Length deficiency can occur in one or both legs, and may be acquired (for example, secondary to trauma or infection) or, more rarely, be congenital (for example, due to hypoplasia or dysplasia). The femur, tibia or both can be involved. Deficiency or inequality in leg length can result in a limp and may limit functional ability.

2.1.2 Lengthening of the shorter leg can be attempted using external fixation devices. However, these devices are associated with significant morbidity, including infection of the pin tracts, pain, hip and knee subluxation or dislocation, and angulation deformity of the bone. External fixation devices may also be impractical or aesthetically unacceptable to some patients.

#### **2.2 Outline of the procedure**

2.2.1 Intramedullary distraction devices are similar to the intramedullary nails used in the management of fractures of the femur and tibia. They have two interlocking sections, allowing controlled movement between the two pieces. The device is implanted into the intramedullary space under general anaesthesia. An osteotomy is performed, avoiding damage to the periosteum and blood supply. The proximal and distal sections of the distraction system are then fixed to the relevant sections of the bone with locking screws. The device exerts a force along the long axis of the bone, which stimulates new bone formation and lengthening. This process occurs very slowly. Different devices achieve distraction in different ways.

### **2.3 Efficacy**

2.3.1 The evidence reviewed was based on case series only. The reported mean values for lengthening achieved were 46 mm (n = 48 patients), 50 mm (n = 23) and 63 mm (n = 10) in the femur, and 49 mm (n = 18) in a mixed tibial and femoral case series. The rate of lengthening achieved ranged from 0.82 mm to 1.11 mm per day.

2.3.2 In a case series, the range of knee movement in 21 patients treated with unilateral lengthening was not significantly altered following the procedure. Average knee extension was  $2.5 \pm 5.9^\circ$  at baseline and  $2.5 \pm 6.1^\circ$  at follow-up. Knee flexion was  $155 \pm 19.2^\circ$  at baseline and  $145 \pm 19^\circ$  at follow-up.

2.3.3 In one series, results described as 'excellent' (evaluated using a composite outcome that included criteria of joint movement, gait, pain and functional ability) were achieved in 75% (18/24) of patients. Full weight bearing was achieved at a mean of 67 days after the intervention in 48 patients in one case series. For more details, refer to the 'Sources of evidence' section.

2.3.4 The Specialist Advisers considered the procedure to be novel and stated that it was still being refined. They also stated that, compared with external fixation devices, there is a lack of control, which may lead to premature or delayed consolidation.

### **2.4 Safety**

2.4.1 Few studies reporting safety outcomes were identified. One case series (n = 52) reported femoral fissure and spontaneous bony section (not otherwise defined) during bone reaming in one patient. A second case series reported transient palsy of the peroneal nerve in 9% (2/23) of patients, which resolved within 3 months.

2.4.2 The most common postoperative adverse event reported was pain during limb lengthening. In one case series, all 31 patients experienced some degree of pain or discomfort during the lengthening process, and 39% (12/31) required readmission and general anaesthesia to allow ratcheting (the motion that delivers extension of the nail). In two other series, analgesia was required for ratcheting in 4% (2/48) and 9% (2/23) of patients. In a case series that reported pain outcomes quantitatively, pain during ratcheting was rated as between 1.5 and 2.4 on a four-point scale among 48 patients undergoing lengthening of one or both femurs, and 1.5 points during bone-consolidation periods. However, in two case series of 18 and 12 patients, no patient required pain control during lengthening.

2.4.3 Bone fractures (either during lengthening or after removal of the nail) were reported in 1 out of 52 (2%) and 2 out of 31 (6%) patients. The reported incidence of mechanical failure of the lengthening nail ranged between 4% (1 out of 24 treated bones) and 16% (4 out of 25 patients). Mechanical failures included nail bending, failure or locking, broken wire, motor failure and ratchet wear. For more details, refer to the 'Sources of evidence' section.

2.4.4 The Specialist Advisers stated that potential complications include poor bone formation, bone lengthening at an inappropriate rate (resulting in either bone weakness or premature consolidation), fat embolisation, deep vein thrombosis, respiratory distress syndrome and equinus ankle deformity.

## **3 Further information**

3.1 This guidance requires that clinicians undertaking the procedure make special arrangements for audit. The Institute has identified relevant audit criteria and developed an audit tool (which is for use at local discretion).



## **4. LEVEL 1: NICE INTERVENTIONAL PROCEDURE GUIDANCE**

### **NICE IPG251: Liposuction for chronic lymphoedema, Published: February 2008**

#### **1 Guidance**

- 1.1 Current evidence on liposuction for chronic lymphoedema is based on small numbers of patients but suggests that there are no major safety concerns; however, the evidence on efficacy is limited in quantity. Therefore, this procedure should be used with special arrangements for clinical governance, consent, and audit or research.
- 1.2 Clinicians wishing to undertake liposuction for chronic lymphoedema should take the following actions.
  - Inform the clinical governance leads in their Trusts.
  - Ensure that patients understand the uncertainty about the procedure's efficacy in the long term, and that they will be required to wear compression garments for at least 1 year after the procedure.
  - Provide patients with clear, written information. In addition, use of the Institute's information for patients ('Understanding NICE guidance') is recommended.
  - Audit and review clinical outcomes of all patients having liposuction for chronic lymphoedema (see section 3.1).
- 1.3 Further publication of efficacy outcomes will be useful. The Institute may review the procedure upon publication of further evidence.

#### **2 The procedure**

##### **2.1 Indications and current treatments**

- 2.1.1 Lymphoedema is the abnormal accumulation of lymph fluid in body tissues that results from an impaired lymphatic system. It most commonly affects the arms and legs. It can limit mobility and cause recurrent infection, pain, disfigurement and distress.
- 2.1.2 Secondary lymphoedema results from damage to the lymphatic system or removal of lymph nodes by surgery, radiation, infection or injury, while primary lymphoedema results from congenital inadequacy of the lymphatic system. In the UK, the most common type of chronic lymphoedema is secondary lymphoedema of the arm following breast cancer.
- 2.1.3 Treatment for lymphoedema aims to decrease swelling, pain and discomfort, and is usually conservative. Manual lymph drainage (MLD) uses massage techniques to help drain lymph fluid away from the limb. Decongestive lymphatic therapy (DLT) consists of a combination of MLD followed by graduated compression bandaging, skin care advice and 'decongestive exercises'. This application is repeated up to once or twice daily to reduce limb volume progressively. Once it is judged that no further limb volume reduction is possible, the patient is fitted with a custom-made garment to be worn daily.
- 2.1.4 Surgery can be used to treat lymphoedema, either with the aim of reducing the size of the affected limb by removing lymphoedematous skin and subcutaneous tissue, often in stages and followed by skin grafting (debulking), or with the aim of restoring lymphatic flow from the limb – for example, attempting to construct an alternative lymph drainage pathway by creating a lymphovenous anastomosis.

##### **2.2 Outline of the procedure**

- 2.2.1 Liposuction for chronic lymphoedema involves the surgical removal of excess subcutaneous fat tissue through several small incisions. It can be performed under general or regional anaesthesia. Cannulas connected to a vacuum pump are inserted into small incisions and lymphoedematous fat tissue is removed by vacuum aspiration.
- 2.2.2 Immediately after liposuction, a compression bandage is applied to the limb to control bleeding and to minimise the development of postoperative oedema, and the limb is elevated for a few days. In the upper limb, a glove is placed on the hand after the operation and a custom-made compression garment is applied to the limb about 2 weeks later. The compression garment is replaced with a new one three or four times during the next year until the swelling has been reduced as much as possible.

Sections 2.3 and 2.4 describe efficacy and safety outcomes which are available in the published literature and which the Committee considered as part of the evidence about this procedure. For more details, refer to the Sources of evidence.

### **2.3 Efficacy**

- 2.3.1 In a case series, 35 patients underwent liposuction combined with controlled compression therapy (CCT) and 14 underwent CCT alone. CCT involves wearing a custom-made sleeve-and-glove garment taken in gradually and replaced with new custom-made garments, usually at 3, 6 and 12 months after the operation. Compared with baseline, mean reductions in oedema volume at 12 months were 103% and 50%, respectively, for the two groups ( $p < 0.0001$ ).
- 2.3.2 A non-randomised study using matched-pairs analysis ( $n = 16$  in each group) reported that liposuction with CCT was significantly more effective in reducing oedema volume than CCT alone ( $p < 0.0001$ ).
- 2.3.3 In the above study and in a further case series of 28 patients, mean pre treatment oedema volumes of 1745 ml and 1845 ml were reduced to 30 ml and -122 ml (that is, the removed oedema volume exceeded the baseline volume), respectively, at 12-month follow-up.
- 2.3.4 In the case series of 35 patients treated with liposuction and CCT, all had reductions in self-rated pain, swelling and fatigue, and increases in mobility and activities of daily living at 12-month follow-up ( $p < 0.01$  for all outcomes). In the 14 patients treated with CCT alone, only swelling of the arm improved significantly ( $p < 0.04$ ).
- 2.3.5 Four Specialist Advisers considered key efficacy outcomes to include reduction in limb volume and swelling, patient comfort, patient satisfaction, quality of life and lymphatic function. They also considered that the long-term benefit and durability of the procedure and its efficacy compared with optimal compression regimens were unknown.

### **2.4 Safety**

- 2.4.1 Three of the five studies reported that there were no complications associated with the procedure. In the case series of 28 patients, 1 patient sustained transient paraesthesia, 2 patients developed temporary superficial abrasion at the wrist caused by the compression garment, and 2 patients developed erysipelas 3 months after the operation. In addition, 8 patients required blood transfusions. A case series of 15 patients reported 1 patient with cellulitis, 1 patient with hypaesthesia and 1 patient with necrosis of the wound margins.
- 2.4.2 The Specialist Advisers stated that theoretical adverse events include haemorrhage, skin necrosis, infection, bruising, pain, scarring and neurovascular injury. One Specialist Adviser stated that the risk of adverse events is significantly different between treatment of the upper and lower limb.

## **3 Further information**

- 3.1 This guidance requires that clinicians undertaking the procedure make special arrangements for audit. The Institute has identified relevant audit criteria and has developed an audit tool (for use at local discretion).

## **5. LEVEL 1: COCHRANE SYSTEMATIC REVIEW**

**Interventions for infantile haemangiomas (strawberry birthmarks) of the skin, Leonardi-Bee J, Batta K, O'Brien C, Bath-Hextall FJ., Cochrane Database of Systematic Reviews 2011, Issue 5. Art. No.: CD006545. DOI: 10.1002/14651858.CD006545.pub2.**

### **Treatments for strawberry birthmarks of the skin in infants and children**

Infantile haemangiomas are soft, raised swellings on the skin, often with a bright, red surface. They are a non-cancerous overgrowth of blood vessels in the skin. They are commonly known as 'strawberry birthmarks', 'strawberry naevi', or 'capillary haemangiomas'. They occur in five per cent of babies, with the majority appearing within the first few weeks of life, and reach their full size at about three to six months of age. The vast majority are uncomplicated and will shrink on their own by five to seven years of age and require no further treatment. However, some infantile haemangiomas may occur in high-risk areas (such as near the eyes and nose which can result in impairment to vision and airway obstruction, respectively) and some of them are disfiguring and psychologically distressing to the children and their parents. Some may also develop complications so early medical treatment may be necessary.

Corticosteroids are currently the standard treatment; however, it is not known which of a variety of treatments is best.

Four trials (ranging from 20 to 121 participants) were included in this review. Two assessed treatments which are no longer used (bleomycin and radiation), with neither trial finding clinically important improvements. From the other two trials limited evidence in relation to clinically important improvements were seen.

One trial assessed the use of photodynamic laser (PDL) therapy. Haemangiomas were more likely to completely clear with PDL when compared to a 'wait and see' approach at one year. However, there were significant side-effects, and it was noted that most of the birthmarks treated with PDL would have resolved naturally over time.

One trial compared an oral corticosteroid (prednisolone) with an intravenous corticosteroid. Haemangiomas were more likely to reduce in size using the oral corticosteroid as compared to the intravenous corticosteroid at three months and one year. Similar numbers of side-effects were being seen in both groups.

We found eight ongoing trials, four of which were designed to assess the effectiveness of oral propranolol either against placebo or an oral corticosteroid. Propranolol has become the second-line treatment since the publication of the protocol of this review in 2007; therefore, it is important that this review is updated within the next three years so these studies can be assessed and added to the evidence base to inform clinical practice.

There is limited evidence of the effectiveness of treatments for those birthmarks that require treatment because the data has come from small trials. The treatments used for haemangiomas need to be tested in large, well-designed trials.

## 6. LEVEL N/A: NICE CLINICAL KNOWLEDGE SUMMARIES

### NICE CKS: Vitiligo

#### MANAGEMENT

##### Assessment

##### *How should I assess a person with vitiligo?*

- Determine the person's skin type (that is, skin colour and ability to tan - Skin type may affect the person's choice of treatment (including no treatment).
- Determine whether the person has non-segmental or segmental vitiligo.
- Ask about any previous episodes of spontaneous repigmentation, previous treatments and their effectiveness, and any trauma preceding the skin changes (as in Koebner phenomenon).
- Assess the impact of the condition on the person's quality of life, including anxiety or depression, and if necessary, offer treatment. For more information, see the CKS topics on Generalized anxiety disorder and Depression.
- For people with non-segmental vitiligo:
  - Note whether the face is affected.
  - Estimate the percentage of the body surface area affected using the 'Rule of Nines' or the Lund and Browder chart
  - Ask about duration of lesions and whether they are active and progressing over weeks to months; stable (over the past 6 months); or regressing.
  - Assess for symptoms of other autoimmune diseases.
    - Check blood for thyroid function tests and thyroid autoantibodies. Monitor thyroid function annually thereafter, if the results are normal. For more information, see the CKS topics on Hyperthyroidism and Hypothyroidism.
    - Checking autoantibodies for other autoimmune conditions is only recommended if the person's history, family history, and/or other test results are suggestive of other autoimmune disease.

##### *Basis for recommendation*

The recommendations on how to assess a person with suspected vitiligo are based on expert opinion in a guideline published by the British Association of Dermatologists (BAD) on the diagnosis and management of vitiligo [Gawkrodger et al, 2008]; the guideline *Vitiligo: concise evidence based guidelines on diagnosis and management* [Gawkrodger et al, 2010]; a guideline published by the Vitiligo Society for the management of vitiligo in primary care [Davison, 2012b]; a European guideline published by the European Dermatology Forum consensus [Taieb et al, 2013]; the Cochrane systematic review *Interventions for vitiligo* [Whitton et al, 2011]; the cross-sectional study *Comorbid autoimmune diseases in patients with vitiligo* [Gill et al, 2016]; and expert opinion in review articles on the diagnosis and management of vitiligo [Gawkrodger, 2009] [Taieb and Picardo, 2009].

- Various factors identified at assessment may affect the management of people with vitiligo.
- The information on methods for estimating surface area is derived from chapters in the textbooks *Vitiligo* [Adrigo et al, 2010] and *Pigmentary disorders: a comprehensive compendium* [Gupta and Ramam, 2014].
- The recommendation to assess for symptoms of autoimmune disease is based on evidence that people with non-segmental vitiligo are at increased risk of autoimmune conditions compared with the general population [Gawkrodger et al, 2008] [Taieb et al, 2013] [Whitton et al, 2015] [Gill et al, 2016]. Adults with non-segmental vitiligo have a particularly high risk (30%) of autoimmune thyroid disease, most commonly Hashimoto's thyroiditis [Gawkrodger, 2009] [Taieb and Picardo, 2009].
- The recommendation to monitor thyroid function annually if the test results are normal is based on expert opinion in a review article [Taieb and Picardo, 2009].

### **Skin type**

**Table 1:** Fitzpatrick skin type

<b>Skin type</b>	<b>Typical features</b>	<b>Tanning ability</b>
I	Pale white skin, blue/hazel eyes, blonde/red hair	Always burns, does not tan
II	Fair skin, blue eyes	Burns easily, tans poorly
III	Darker white skin	Tans after initial burn
IV	Lighter brown skin	Burns minimally, tans easily
V	Brown skin	Rarely burns, tans darkly easily
VI	Dark brown or black skin	Never burns, always tans darkly

Data from: [www.dermnetz.org](http://www.dermnetz.org)

### **Extent of body surface area involvement**

- The extent of the person's body surface area that is affected by vitiligo can be estimated in the same way as for burns, using one of these two methods:
  - The 'Rule of Nines':
    - Arm - 9%
    - Head - 9%
    - Neck - 1%
    - Leg - 18%
    - Anterior trunk - 18%
    - Posterior trunk - 18%
  - The Lund and Browder chart - see [www.wounds-uk.com](http://www.wounds-uk.com) for more information.

### **Initial management**

- **Provide an explanation about the condition**, including its causes and the prognosis without treatment.

- Explain that although a number of treatments are available, normal skin colour is not completely restored in all people, treatment may not stop the spread of the condition, and further treatment may be necessary as loss of pigmentation often recurs after successful treatment.
- Inform the person about the Vitiligo Society (website available at [www.vitigosociety.org.uk](http://www.vitigosociety.org.uk)) which offers support to people with vitiligo and their families. For further information offer the patient information leaflet Vitiligo, which can be found on the British Association of Dermatologists (BAD) website and is available at [www.bad.org.uk](http://www.bad.org.uk).
- **Advise the person not to use sunbeds and to use appropriate protection from sunlight**, such as a high-factor sunscreen with protection against ultraviolet A and B (for example Uvistat®, or Sensense®). These can be prescribed on the NHS, but the prescription must be endorsed ACBS.
- **Offer referral to a skin camouflage service.**
- **Offer the option of no other treatment**, for example to people with skin types I and II and localized vitiligo, who are not overly distressed.
- **For all other people:**
  - Offer to prescribe a topical corticosteroid in primary care if appropriate, and/or
  - Offer referral to a dermatologist.

### ***Basis for recommendation***

#### Providing information and advice

- The recommendation to offer an explanation about the condition, including its causes and prognosis, is based on what CKS considers to be good clinical practice.
- The recommendation to inform the person about the Vitiligo Society is based on expert opinion in the guideline *Vitiligo: concise evidence based guidelines on diagnosis and management* [Gawkrodger et al, 2010].

#### Giving advice on sunbeds and sunscreens

- The recommendation to advise people with vitiligo to avoid sunbeds and use a sunscreen is based on expert opinion in a guideline published by the British Association of Dermatologists (BAD) on the diagnosis and management of vitiligo [Gawkrodger et al, 2008]; the guideline *Vitiligo: concise evidence based guidelines on diagnosis and management* [Gawkrodger et al, 2010]; and expert opinion in review articles on the management of vitiligo [Douglas and Whitton, 2008] [Halder and Chappell, 2009].
  - The absence of melanin reduces the skin's natural protection against sunburn, skin ageing, and (possibly) skin cancer [Douglas and Whitton, 2008].
  - Avoidance of sunbeds and the use of sunscreen may prevent new lesions developing as a result of a Koebner response to sunburn [Halder and Chappell, 2009].
  - Less tanning of the uninvolved skin will lessen the contrast with vitiligo lesions [Halder and Chappell, 2009].

#### Offering referral to a skin camouflage service

- The recommendation to offer referral to a skin camouflage service is based on expert opinion in a guideline published by the British Association of Dermatologists (BAD) on the diagnosis and management of vitiligo [Gawkrodger et al, 200 ] ; the guideline *Vitiligo: concise evidence based guidelines on diagnosis and management* [Gawkrodger et al, 2010]; a European guideline on the management of vitiligo published by the European Dermatology Forum consensus [Taieb et al, 2013]; and the Cochrane systematic review *Interventions for vitiligo* [Whitton et al, 2015] .
  - Evidence on the effect of camouflage cosmetics on quality of life in people with vitiligo is limited, as a Cochrane systematic review did not find any randomized controlled trials, although small observational studies and case reports do suggest a benefit from camouflage cosmetics [Whitton et al, 2015].
    - One small uncontrolled observational study cited in the Cochrane review compared quality of life before and after the use of camouflage for at least 1 month in people with vitiligo. Of the 78 people who were initially recruited and assessed by questionnaire, 62 people used

camouflage and returned a second questionnaire, which showed quality of life improved significantly with the use of camouflage ( $p = 0.006$ ). Items that showed particular improvement were 'feelings of embarrassment and self-consciousness' and 'choice of clothing' [Ongenaes et al, 2005].

- Various case reports and expert opinion suggest that camouflage cosmetics are acceptable and beneficial [Tanioka and Miyachi, 2008] [Tanioka and Miyachi, 2009].

#### Offering the option of no treatment

- The recommendation to offer the option of no treatment is based on expert opinion in the BAD guideline on the diagnosis and management of vitiligo [Gawkrodger et al, 2008].

#### Treatment with a topical corticosteroid

##### ***What topical corticosteroid treatment should I prescribe in primary care?***

- **Prescribe a potent topical corticosteroid to adults who meet all of the following criteria:**
  - They have non-segmental vitiligo that is localized or limited (affecting less than 10% of the body surface area).
  - The person prefers the option of a treatment.
  - Treatment is not applied to the face.
  - For women, they are not pregnant.
  - They are aware of the risks of adverse effects of corticosteroids.
- **For people who do not meet these criteria** (including children), see the section on Referral .
  - For people awaiting referral, if lesions are of recent-onset, localized, or rapidly progressing, seek specialist dermatology advice and consider prescribing a topical corticosteroid.
- **If a topical corticosteroid is indicated:**
  - Advise the person that topical corticosteroids are not licensed for the treatment of vitiligo and are commonly associated with adverse effects (including skin atrophy, telangiectasia, striae, and excess hair growth).
  - Prescribe treatment for up to 2 months with a potent topical corticosteroid applied once daily (such as fluticasone propionate, betamethasone valerate 0.1%, hydrocortisone butyrate, betamethasone dipropionate, mometasone furoate, fluocinolone acetonide 0.025%, fluocinonide, or diflucortolone valerate 0.1%).
    - Prescribe an ointment or cream, depending on the person's preference and the site of lesions (for example, use a cream in the flexures).
    - For more prescribing information, see the CKS topic on Corticosteroids - topical (skin), nose, and eyes.
  - Review the person after 1 month to assess the response and monitor for adverse effects. If there are adverse effects, or the person has already responded well, consider discontinuing treatment.
  - After 2 months of topical corticosteroid treatment:
    - If there is no response, discontinue treatment and refer the person to a dermatologist.
    - If there is a partial response, continue treatment (possibly with an immediate break of 2 weeks, and further breaks after every 3 weeks of treatment), and refer the person to a dermatologist. Monitor for adverse effects monthly whilst awaiting specialist assessment.
    - If there is a complete response, discontinue the treatment.

#### ***Basis for recommendation***

The recommendations on prescribing topical corticosteroids are based on expert opinion in a guideline published by the British Association of Dermatologists (BAD) on the diagnosis and management of vitiligo [Gawkrodger et al, 2008] ; the guideline *Vitiligo: concise evidence based guidelines on diagnosis and management* [Gawkrodger et al, 2010] ; a guideline published by the Vitiligo Society for the management of vitiligo in primary care [Davison, 2012a] ; a European guideline on the management of vitiligo published by the European Dermatology Forum consensus [Taieb et al, 2013] ; the Cochrane systematic review *Interventions for vitiligo* [Whitton et al, 2015] ; expert opinion in review articles

[Forschner et al, 2007] [Douglas and Whitton, 2008] [Halder and Chappell, 2009] [Colucci et al, 2012] [Zhang et al, 2014] ; and information in the British National Formulary (BNF) [BNF 70, 2015].

#### Prescribing a potent topical corticosteroid

- A Cochrane systematic review of six small randomized controlled trials (n = 363), which reported repigmentation in more than 75% of people, suggests that potent or very-potent topical corticosteroids used for 2-9 months are efficacious in people with non-segmental vitiligo. However, the review found no RCTs that compared topical corticosteroids with placebo, and none included people with segmental vitiligo [Whitton et al, 2015] .
  - One small parallel-group study (n = 84) of adults with non-segmental vitiligo affecting the face and/or neck found a statistically significant difference in favour of topical hydrocortisone-17 butyrate (applied twice daily for three periods of 3 weeks) plus laser (for 12 weeks) compared with laser alone (for 12 weeks) (relative risk [RR] 2.57; 95% CI 1.20 to 5.50).
  - One parallel-group comparison study (n = 135) of adults with vitiligo on the arms, legs, or trunk compared topical fluticasone propionate 0.05% (applied once daily), ultraviolet A light (UVA), or a combination of the two, for 9 months. There was no statistically significant difference between the combination treatment and topical fluticasone propionate alone, or between the combination treatment and UVA alone. Topical fluticasone propionate either alone or in combination with UVA was superior to UVA alone (RR 3.94; 95% CI 1.16 to 13.43).
  - Adverse effects were common with the use of potent topical corticosteroids, although one study in the review reported that fluticasone propionate used for 9 months did not result in skin atrophy.
  - Limitations included that in most of the studies participants and clinicians were not blinded and in only a few was the assessor blinded. In several studies, the method of allocation concealment was unclear. Sample size was generally small (20-135 people). Meta-analysis was not performed because of differences between the studies in the interventions under evaluation.
  - The authors concluded that there is moderate-quality evidence for the use of topical corticosteroids, although long-term use is likely to lead to adverse effects.
  - In addition, expert opinion in various guidelines [Gawkrodger et al, 2008] [Gawkrodger et al, 2010] [Davison, 2012a] and review articles [Forschner et al, 2007] [Douglas and Whitton, 2008] [Halder and Chappell, 2009] [Colucci et al, 2012] [Taieb et al, 2013] almost universally recommends potent or very-potent topical corticosteroids as first-line treatment for people with localized or limited non-segmental vitiligo.

#### Seeking specialist dermatology advice before prescribing a topical corticosteroid for people awaiting referral

- The recommendation to seek specialist dermatology advice before prescribing a topical corticosteroid for people awaiting referral, who have recent-onset, localized, or rapidly progressing lesions, is a pragmatic approach based on the increased risk of adverse effects with the prolonged use of potent topical corticosteroids.
  - Compared with longstanding lesions, lesions of recent onset are more likely to clear with treatment [Douglas and Whitton, 2008], and treatment may be most effective on the face and neck, in childhood, and when patches are small [Gawkrodger et al, 2010] [Davison, 2012a]. For people awaiting referral, this may indicate a window of opportunity when topical corticosteroids might be more effective and this is supported by the majority of expert opinion of previous external reviewers of this CKS topic.

#### Choice of topical treatment

- In the absence of any direct comparisons between potent and very-potent topical corticosteroids, CKS recommends the use of a potent topical corticosteroid (as it is less likely to cause adverse effects) [BNF 70, 2015]. The list of potent topical corticosteroids is derived from the British National Formulary [BNF 70, 2015].
- CKS notes that for adults and children with vitiligo (lesions that are new, spreading, and on thin skin), expert opinion in some guidelines [Davison, 2012 ] [Taieb et al, 2013] and review articles [Colucci et al, 2012] [Zhang et al, 2014] recommends prescribing topical calcineurin inhibitors (such as

tacrolimus 0.1% ointment) as an alternative first-line treatment in view of their better safety profiles compared with potent topical corticosteroids (reduced risk of skin atrophy).

- Compared with potent topical corticosteroids, topical calcineurin inhibitors remain relatively expensive [BNF 70, 2015] , and although they may be prescribed in primary care, limited experience to date in primary care has resulted in CKS not recommending them as a first-line treatment option.

#### Application frequency

- A guideline for the diagnosis and management of vitiligo by the British Association of Dermatologists (BAD) makes no recommendation on application frequency [Gawkrodger et al, 2008], and there appears to be no consensus in the literature, [Douglas and Whitton, 2008].
- The recommendation on once-daily application is based on the expert opinion of previous external reviewers of this CKS topic.

#### Duration of use

- The recommendation on the duration of use is based on the BAD guideline [Gawkrodger et al, 2008].
- In the studies included in the Cochrane systematic review, topical corticosteroids were applied for 2-9 months [Whitton et al, 2015].

#### Prescribing ointments or creams

- The recommendation on prescribing ointments or creams according to the person's preference and the site of lesions is based on the expert opinion of previous external reviewers of this CKS topic.

#### Arranging review after 1 month

- The recommendation to review the person after 1 month and consider discontinuing treatment if there are adverse effects or the person has already responded well, is based on what CKS considers to be good clinical practice.

#### Discontinuing treatment if no response after 2 months

- The recommendation to discontinue treatment and to refer the person to a dermatologist if there is no response after 2 months of treatment (to minimize the risk of corticosteroid adverse effects), is based on expert opinion in the BAD guideline [Gawkrodger et al, 2008], and other guidelines on the management of vitiligo [Gawkrodger et al, 2010] [Davison, 2012a], which recommend no more than 2 months' treatment.

#### Continuing treatment if partial response after 2 months

- CKS found no published evidence or opinion on how to manage people with a partial response after 2 months of treatment, and there was no consensus amongst previous external reviewers of this CKS topic. The recommendations are therefore based on what CKS considers to be safe and effective clinical practice. The suggestion to prescribe a topical corticosteroid intermittently is derived from one trial cited in the Cochrane systematic review [Whitton et al, 2015].

#### Complete response after 2 months

- This recommendation is based on what CKS considers to be good clinical practice.

#### Referral

- **Offer referral to a dermatologist if:**
  - The diagnosis is uncertain.
  - The person has segmental vitiligo and requests treatment.
  - The face is affected and the person requests treatment.
  - A child requires treatment.
  - A woman who is pregnant requires treatment.
  - Large areas of the body are affected (more than 10% of body surface area ).
  - The person (or their parent or carer) is particularly distressed by the condition.
  - The potential adverse effects of topical corticosteroids are not acceptable.
  - Initial treatment in primary care has been unsuccessful.



- **Offer referral to a dermatology skin camouflage service or one provided by the charity Changing Faces** (formerly provided by the British Red Cross).
  - Changing Faces provides education by trained volunteer practitioners on the use and application of cosmetic camouflage creams and powders, and people may self-refer. Details of the nearest skin camouflage service can be found at [www.changingfaces.org.uk](http://www.changingfaces.org.uk).
  - Cosmetic camouflage creams can be used on any part of the body. The aim is to provide natural-looking cover. They are waterproof, and may remain on the body for up to 4 days, and on the face for 12-18 hours.
  - Four brands of camouflage product, in a range of shades, are available to prescribe on the NHS and the prescription must be endorsed 'ACBS'.
    - Covermark classic foundation (10 shades) and Covermark finishing powder.
    - Dermacolor camouflage cream (100 shades) and Dermacolor fixing powder.
    - Keromask masking cream (9 shades) and Keromask finishing powder.
    - Veil cover cream (40 shades) and Veil finishing powder.

### **Basis for recommendation**

The recommendations on referral are based on expert opinion in the guideline *Vitiligo: concise evidence based guidelines on diagnosis and management* [Gawkrodger et al, 2010]; a guideline published by the Vitiligo Society for the management of vitiligo in primary care [Davison, 2012a]; a European guideline on the management of vitiligo published by the European Dermatology Forum Consensus [Taieb et al, 2013] ; the Cochrane systematic reviews *Interventions for vitiligo* [Whitton et al, 2015] and *Safety of topical corticosteroids in pregnancy* [Chi et al, 2015] ; expert opinion in review articles [Gawkrodger, 2009] [Falabella and Barona, 2009] [Halder and Chappell, 2009] [Coondoo et al, 2014]; the retrospective study *High-potency steroid use in children with vitiligo* [Kwinter et al, 2007]; and information in the British National Formulary [BNF 70, 2015].

- There is a lack of evidence on interventions for segmental vitiligo in primary care, but expert opinion suggests segmental vitiligo does not respond to conventional treatments such as topical corticosteroids [Whitton et al, 2015]. Therefore CKS has recommended referral to a dermatologist.
- Children are more vulnerable to the adverse effects of prolonged use of potent topical corticosteroids than adults [BNF 70, 2015], including the systemic adverse effects as children have a greater ratio of body surface area to weight [Coondoo et al, 2014]. Children who need frequent or prolonged courses of potent topical corticosteroids should be referred to a dermatologist, so that alternative treatments may be considered, and growth, development, and pituitary function monitored [Kwinter et al, 2007].
  - One small retrospective study of children with vitiligo (n = 73), treated with a moderate-to-high potency topical corticosteroid (intermittently or continuously), reported that 21 children (29%) had abnormal cortisol levels, and two children were diagnosed with corticosteroid-induced adrenal suppression [Kwinter et al, 2007].
- The recommendation on referring pregnant women is based on the expert opinion of previous external reviewers of this CKS topic. Although a Cochrane systematic review found no causal associations between maternal exposure to topical corticosteroids (of all potencies) and pregnancy outcomes including congenital abnormalities, preterm delivery, and foetal death, uncertainty remains regarding the safety of long-term potent topical corticosteroids in pregnancy [Chi et al, 2015].
- The recommendation on referring if large areas of the body are affected, is based on expert opinion in a guideline published by the British Association of Dermatologists [Gawkrodger et al, 2008] and review articles [Falabella and Barona, 2009] [Halder and Chappell, 2009].
  - The threshold of 10% of body surface area is extrapolated from evidence on the safety of potent topical corticosteroids in adults with atopic eczema.
- Adverse effects (including skin atrophy) are common with the use of potent topical corticosteroids on the face [Whitton et al, 2015]. Considering the high risk of adverse effects, the assumed cosmetic importance of the face, and the fact that topical corticosteroids are not licensed for the treatment of vitiligo [BNF 70, 2015], the recommendation on referral if the face is affected and the person prefers a treatment option, is based on what CKS considers to be good clinical practice.

- The recommendation on referral for skin camouflage also takes into account expert opinion in the British Medical Journal Best practice article *Skin camouflage* [BMJ, 2012], the review article *Camouflage for vitiligo* [Tanioka and Miyachi, 2009], and information in the British National Formulary [BNF 70, 2015] and the Drug tariff [Prescription Pricing Authority, 2016].

### **Secondary care treatments**

- **Secondary care treatments may include:**

- **For children**

- Topical pimecrolimus or tacrolimus as alternatives to highly potent topical corticosteroids in view of their better short-term safety profile.
- Narrow-band ultraviolet B (NB-UVB) phototherapy for children who cannot be managed with topical treatments, have widespread vitiligo, or have localized vitiligo associated with a significant impact on their quality of life.

- **For adults**

- Topical pimecrolimus or tacrolimus as an alternative to topical corticosteroids.
- NB-UVB phototherapy for adults who cannot be managed with topical treatments, have widespread vitiligo, or have localized vitiligo associated with a significant impact on their quality of life.
- Surgical treatments may be an option for cosmetically-sensitive sites where there have been no new lesions, no extension of the lesion in the previous 12 months, and no Koebner phenomenon. Surgical treatments aim to achieve complete repigmentation using the transfer of melanocytes from normal skin (the donor site) to the skin affected by vitiligo.
- Depigmentation (using topical p-benzyloxyphenol [monobenzyl ether of hydroquinone] or 4-methoxyphenol) for adults with severe vitiligo (that is, more than 50% of body surface area depigmentation or extensive depigmentation on the face or hands) who cannot (or choose not to) seek repigmentation and who can accept a permanent inability to tan.

## **7. LEVEL 1: COCHRANE SYSTEMATIC REVIEW**

**Interventions for vitiligo, Whitton ME, Pinart M, Batchelor J, Leonardi-Bee J, González U, Jiyad Z, Eleftheriadou V, Ezzedine K., *Cochrane Database of Systematic Reviews* 2015, Issue 2. Art. No.: CD003263. DOI: 10.1002/14651858.CD003263.pub5.**

**Background:** Vitiligo is a chronic skin disorder characterised by patchy loss of skin colour. Some people experience itching before the appearance of a new patch. It affects people of any age or ethnicity, more than half of whom develop it before the age of 20 years. There are two main types: generalised vitiligo, the common symmetrical form, and segmental, affecting only one side of the body. Recent genetic research suggests that generalised vitiligo is, at least in part, an autoimmune condition which destroys melanocytes (pigment cells). Although our understanding of vitiligo has increased, its causes are still poorly understood. Several treatments are available. Some can restore pigment but none can cure it or prevent its spread or recurrence. Vitiligo patches can have a major psychosocial impact, especially for people with dark or tanned skin or when the face or hands are affected. People with vitiligo can be stigmatised, often experiencing low self-esteem and a lack of self-confidence. Children with vitiligo may be teased and bullied at school. Despite this, we found only one study assessing psychological therapy for vitiligo.

**Review question:** What treatments work best to help manage vitiligo?

**Study characteristics:** In this update search we found 39 new randomised controlled trials which, added to the 57 studies included previously, makes a total of 96 studies with 4512 participants.

**Key results:** Twenty-one (21/39, 54%) of the new studies assessed new treatments, most of which involved the use of light. Narrowband UVB (NBUVB) light was used in 35/96 (36% of all included studies), either alone or in combination with other therapies and achieved the best results. There were 18 surgical studies and 31 studies compared active treatment versus placebo.

Half of the studies lasted longer than six months. Most of them 69/96 (72%) had fewer than 50 participants. Only seven studies assessed children and one study only recruited men.

The majority of studies (53/96, 55%), most of which were of combination treatments with light, assessed more than 75% repigmentation. Eight studies reported a statistically significant result for this outcome, including the following four results: topical corticosteroids were better than PUVA (psoralen with sunlight), hydrocortisone plus laser light was better than laser light alone, *ginkgo biloba* was better than placebo and oral minipulse of prednisolone (OMP) plus NB-UVB was better than OMP alone. None of the studies reported the long-term benefit of the treatment i.e. two years' sustained repigmentation. The maximum follow-up time, reported in only one study, was one year post-treatment.

Only 9/96 (9%) reported the quality of life of participants, but the majority of all studies (65/96, 68%) reported adverse effects, mainly for topical treatments, some of which caused itching, redness, skin thinning, telangiectasia and atrophy. Neither mometasone furoate nor hydrocortisone produced adverse effects. Some NB-UVB studies reported phototoxic reaction and Koebnerisation whereas some PUVA (psoralen with artificial light UVA as a light source) studies caused dizziness and nausea.

Six studies reported cessation of spread of vitiligo, one of which showed that *ginkgo biloba* was more than twice as likely to stop vitiligo spreading than placebo. This review has highlighted the recent surge in vitiligo research providing insights into its causes. The majority of the studies reporting successful repigmentation were combinations of various interventions with light, indicating this is an effective, though not necessarily permanent, treatment for generalised vitiligo.

In view of the fact that vitiligo has no cure, providing ways of coping with it could be of benefit to patients and should be part of standard care. Better designed studies, consensus on how to measure treatment success, more studies involving children and studies assessing psychological interventions, are needed.

**Quality of the evidence:** Since the last update (2010), the design and reporting of vitiligo trials have not greatly improved. Only five studies met the criteria for a well-designed trial. Poor design, the number and complexity of the treatments and the fact that many of the studies assessed individual vitiligo patches in the same participant, made comparison of the studies difficult. Consequently, we could only perform one metaanalysis of three studies comparing NB-UVB with PUVA which showed that NB-UVB has fewer side effects and is marginally better than PUVA.

## 8. LEVEL 1: BMJ SYSTEMATIC REVIEW

**Vitiligo in adults and children: surgical interventions, *Rubeta Marin*, Search date: April 2014**

### ABSTRACT

**Introduction:** Vitiligo is an acquired skin disorder characterised by white (depigmented) patches in the skin, due to the loss of functioning melanocytes. The extent and distribution of vitiligo often changes during the course of a person's lifetime and its progression is unpredictable.

**Methods and Outcomes:** We conducted a systematic review and aimed to answer the following clinical question: What are the effects of surgical interventions for vitiligo in adults and in children? We searched: Medline, Embase, The Cochrane Library, and other important databases up to April 2014 (BMJ Clinical Evidence reviews are updated periodically, please check our website for the most up-to-date version of this review). We included harms alerts from relevant organisations such as the US Food and Drug Administration (FDA) and the UK Medicines and Healthcare products Regulatory Agency (MHRA).

**Results:** We found four studies that met our inclusion criteria. We performed a GRADE evaluation of the quality of evidence for interventions.

**Conclusions:** In this systematic review we present information relating to the effectiveness and safety of the following interventions: blister grafts, cultured cellular transplantation, non-cultured cellular transplantation, punch/mini grafts, and split thickness skin grafts.

### Key Points:

- Vitiligo is an acquired skin disorder characterised by white (depigmented) patches in the skin, caused by the loss of functioning melanocytes.
  - Vitiligo patches can appear anywhere on the skin, but common sites are usually around the orifices, the genitals, or sun-exposed areas such as the face and hands. The extent and distribution of vitiligo often changes during the course of a person's lifetime, and its progression is unpredictable.

- Vitiligo patches in certain body areas such as the acral sites, palms and soles, lips, mucosa, and nipples, and segmental forms in any area are relatively resistant to all conventional medical treatment modalities. This is thought to be related to the lack of melanocyte reservoir in non-hair bearing sites.
  - In these cases, counselling and cosmetic camouflage become a priority, and often in these sites re-pigmentation is unlikely to be achieved unless surgical methods are used.
- There are a variety of medical treatments used for vitiligo, but this review has focused on surgical therapeutic options as this is an expanding field worldwide. Surgery is considered in people with stable vitiligo unresponsive to standard medical therapies.
  - We do not know whether surgical treatments of vitiligo in adults and children (blister grafts, cultured cellular transplantation, non-cultured cellular transplantation, punch/mini grafts, split-thickness skin grafts) are effective, as we found limited evidence from RCTs and systematic reviews. The evidence found was of low or very low quality.
  - We searched for RCTs comparing blister grafts, cultured cellular transplantation, non-cultured cellular transplantation, punch/mini grafts, and split-thickness grafts with no active treatment or with each other.
  - There are significant challenges undertaking robust RCTs assessing surgical treatments, as it is difficult to offer suitable control treatments and the high cost of surgical studies can be limiting.

## **9. LEVEL N/A: BMJ GROUP PATIENT LEAFLET**

### **Patient information from the BMJ Group: Wrinkles**

#### **Wrinkles**

Almost everyone gets wrinkles as they get older. There's no cure for wrinkles, but if they bother you there are treatments that can make your skin look and feel smoother.

We've looked at the best and most up-to-date research to produce this information.

You can use it to help decide which treatments are right for you.

#### **What are wrinkles?**

Wrinkles are lines or creases on the surface of your skin. They are a natural part of ageing. But other things can affect the way your skin looks, too.

- The most common cause of wrinkles is simply getting older. As you get older your skin gets thinner, more fragile, and less elastic (stretchy), so it tends to wrinkle and crease.
- Too much exposure to the sun's rays can also damage collagen and elastin - the parts of your skin that keep it smooth, firm, and elastic.
- Smoking also causes wrinkles. The toxins in cigarette smoke stop your skin from producing as much new collagen. Collagen is a protein that makes up a large part of your skin.

#### **What are the symptoms?**

Having wrinkles is not an illness. But wrinkles can alter the way you look and this may change the way you feel about yourself.

Wrinkles are often especially noticeable on your face, particularly across your forehead, between your eyebrows, and around your mouth. You may also get lines around the front of your neck and on your hands.

#### **What treatments work?**

There are many treatments for wrinkles, ranging from creams to injections and facelifts. Many people use more than one treatment. You should always read the labels on any treatments carefully to check for possible side effects. You can also ask your doctor about side effects, especially if you are thinking about some of the more complicated treatments. The treatments that might suit you will depend on how visible your wrinkles are and how much they bother you, as well as on things such as:

- your age
- your skin's type and texture
- your skin's thickness

- how damaged your skin has been by the sun
- what you want from your treatment
- your lifestyle.

Treatments are likely to work better and for longer if you:

- don't smoke
- avoid exposing the treated areas to too much sun
- use high sun protection factor (SPF) sunscreen on treated areas when in direct sun.

### **Treatments for fine wrinkles**

For fine wrinkles, or for wrinkles that are only visible with certain facial expressions (for example, 'laugh lines' when you smile), the most common treatments are retinoid creams. But there are other treatments, such as superficial (mild) chemical peels.

**Retinoids:** Research suggests that creams containing retinoids work better than other creams for preventing and treating fine wrinkles. Retinoids work by encouraging the replacement of the very top layer of skin, and by helping to repair damage to skin and small blood vessels. Retinoids may cause side effects in some people, including skin irritation and lightening or, sometimes, darkening of the skin. These colour changes are temporary.

**Antioxidants:** Antioxidants include green tea and vitamins, and come as creams and sometimes as tablets. They are intended to help prevent damage caused by sun, stress, and air pollution.

**Superficial chemical peels:** Superficial chemical peels are creams containing acid. They work by destroying the very top layer of the skin, revealing the younger, less-damaged skin beneath. This treatment is similar to treatments used to rub away (exfoliate) old skin cells. This treatment can cause side effects in some people, including dry skin or skin irritation.

**Botulinum toxin injections (Botox):** This treatment works by affecting the nerves in the skin. This stops some of the muscles under the skin from moving normally. This means that the treated areas of skin don't wrinkle as much as usual when your face moves: for example, when you smile, frown, or laugh. One treatment of Botox lasts about six months. If you have had a chemical peel, you must allow the skin to recover completely before you use Botox.

Botox can cause side effects, including pain at the site of the injection, bruising, headache, muscle weakness, and short-term loss of some feeling at the site of the injection.

### **Treatments for deeper wrinkles**

There are several treatments that can help with deeper wrinkles.

**Medium-to-deep thickness chemical peels:** These are stronger versions of the chemical peels used for fine wrinkles. They remove more skin than the superficial chemical peels. They can cause side effects, including cold sores, changes in skin colour (which are usually temporary), and scarring.

**Fillers:** Fillers are substances that can be injected under the skin to fill wrinkles and make the skin look smoother. There are many different kinds and they vary in how long their effects last. Examples of fillers include collagen, hyaluronic acid, or your own fat. Each has different advantages and disadvantages. For example, some substances may carry a risk of allergic reaction. Using fat means your own fat has to be extracted first.

### **Treatments for very deep wrinkles**

If you have very deep wrinkles there are treatments that can help improve the texture and appearance of the skin. But you should think carefully before having any of these treatments. You will need a local anaesthetic for many of these treatments. It also takes several days or even weeks to recover from some of them.

**Dermabrasion:** This treatment involves a therapist scraping or sanding away several layers of skin using a hand-held tool called a dermabrader, allowing fresh skin to take its place. It takes between 7 and 10 days for the skin to heal. If you have the treatment, you will be given a local anaesthetic and another painkiller called a nerve block. Dermabrasion can have side effects, including scarring and skin infections.

**Microdermabrasion:** This treatment is similar to dermabrasion but involves tiny crystals or other abrasive substances being blown onto the face to remove old and damaged skin.

**Fractional photothermolysis:** This is a type of laser therapy that only targets damaged skin. It's quite a new treatment, which possibly has fewer side effects than other similar treatments.

**Laser ablation:** This treatment uses laser therapy to remove several layers of skin. As with other treatments that remove layers of skin, your skin will need time to recover after laser ablation.

**Autologous fat grafting:** With this treatment, a therapist removes fat from other parts of your body - usually your thighs, belly, or buttocks - and injects it under areas of wrinkled skin in your face to make it look smoother and less wrinkled. This treatment is often favoured by older people who lose weight as they age. This weight loss can cause skin on the face to look sunken or wrinkled in places. The difference between this and using fillers is that this technique only uses your own body fat, not any other substances.

**Rhytidectomy (facelift):** This is another treatment that may be suitable for older people, as skin tends to sag as we age. This operation tightens and lifts the skin of the face that has sagged. But it is not a treatment for wrinkles or for the texture of the skin. The results of facelifts can last longer than many other treatments. But a facelift is surgery and, like all operations, it carries risks, including infections. Side effects of facelifts can include scarring, bruising, hair loss, and nerve damage.

### **Is there anything I can do to prevent wrinkles?**

There's no scientifically proven way to prevent wrinkles. But there are a few things you can try.

- High-factor sunscreens help to protect your skin from the sun, so it's possible that they might help prevent wrinkles.
- Avoiding too much sun. It's important for your health to get some sun. But too much sun can play a part in causing skin cancer, not just wrinkles. So it makes good sense to be sensible in the sun and avoid getting sunburn. That means using sunscreens, covering up, wearing a hat, and staying out of strong sunshine. Some treatments for wrinkles need to be used alongside sun avoidance.
- Stopping smoking. Smoking speeds up skin ageing. So stopping smoking is important.

## **10. LEVEL N/A: PATIENT INFORMATION LEAFLET**

**British Association of Dermatologists (BAD) – Patient Information Leaflet: Rhinophyma, Published: October 2014**

### **What is rhinophyma?**

Rhinophyma is a swelling of the nose. If the condition progresses, the nose becomes redder, swollen at the end and gains a bumpy surface which changes its shape. This swelling is because there is formation of scar-like tissue and the sebaceous glands (which produce oil on the skin) get bigger. Much more rarely, swellings can arise on other parts of the face such as the ears and chin.

The condition is mainly seen in those who have rosacea, a rash that can affect the cheeks, forehead and nose (see rosacea leaflet for further information). Rhinophyma usually only develops in rosacea which has been active for many years. However, although rosacea affects woman more than men, rhinophyma is seen mainly in fair-skinned men aged 50 to 70 years.

### **What causes rhinophyma?**

The causes of rhinophyma are not fully understood. Rhinophyma can occur as a more severe stage of rosacea. However, some people have rhinophyma without having rosacea. Although commonly believed to be due to alcohol, there is no link between rhinophyma and excessive drinking.

### **Is rhinophyma hereditary?**

There is no clear genetic link.

### **What does rhinophyma look like?**

Initially there may just be redness of the nose and a few small bumps. Over time however the nose becomes more swollen and bulbous. The growth can become quite large with prominence of the skin pores.

### **How is rhinophyma diagnosed?**

The diagnosis is usually made based on the site involved and appearance of the skin. If the diagnosis is unclear a dermatologist may take a small skin biopsy under local anaesthetic for examination under the microscope.

### **Can rhinophyma be cured?**

Although there is no cure for rhinophyma, treatments can be effective in controlling it.

### **How can rhinophyma be treated?**

Rosacea can be helped a little with topical treatments such as creams and gels, as well as by courses of antibiotics lasting several months. Another option is oral isotretinoin, a tablet also used for acne. However, these treatments do not usually work very well in rhinophyma, and surgery is often necessary. The aims of surgical treatments are to remove the excess tissue and restore the natural shape of the nose. Additional treatments can reduce the redness of the nose. Depending on the severity and extent of the rhinophyma a doctor may offer some of the following treatments:

- *Dermabrasion* – a device which uses a wire brush or a burr (a wheel with rough edges) which rotates rapidly and removes the upper layers of the skin. This effect can also be achieved with lasers.
- *Electrosurgery and Electrocautery* – this treatment uses devices that deliver high frequency electrical currents that heat up and help remove excess tissue.
- *Scalpel or razor blade excision* – this involves using either a scalpel or razor blade in a controlled manner to help remove the excess tissue.

These treatments can be performed either by dermatologists, plastic surgeons or ear nose and throat surgeons. There are advantages and disadvantages with all of the above treatments which your specialist will go through with you. Sometimes more than one attempt or a combination of different treatments is required to obtain a good outcome. It is important to note that these treatments do not cure rhinophyma; they aim to remove overgrowth of excess tissue and reshape the nose. Recurrence of the problem can occur which may then require further treatments.

## Appendix 2 – Diagnostic and Procedure Codes

### Other Aesthetic Surgery GM040

(All codes have been verified by Mersey Internal Audit's Clinical Coding Academy)

<b>GM040 - Other Aesthetic Surgery</b>	
Reconstruction of vagina NEC	P21.2
Vaginoplasty NEC	P21.3
Other specified plastic operations on vagina	P21.8
Unspecified plastic operations on vagina	P21.9
Vaginoplasty using a mould and skin graft	P32.6
Vaginoplasty using a mould NEC	P32.7
Ultraviolet A light therapy to skin	S12.1
Ultraviolet B light therapy to skin	S12.2
Combined photochemotherapy and ultraviolet A light therapy to skin	S12.3
Combined photochemotherapy and ultraviolet B light therapy to skin	S12.4
Graft of skin to external nose	E09.7
Hair bearing graft to eyebrow	C10.3
Graft to skin of eyelid	C14.2
Meshed split autograft of skin to head or neck	S35.1
Meshed split autograft of skin NEC	S35.2
Split autograft of skin to head or neck NEC	S35.3
Other specified split autograft of skin	S35.8
Unspecified split autograft of skin	S35.9
Full thickness autograft of skin to head or neck	S36.1
Full thickness autograft of skin NEC	S36.2
Composite autograft of skin to head or neck	S36.3
Composite autograft of skin NEC	S36.4
Pinch graft of skin to head or neck	S36.5
Pinch graft of skin NEC	S36.6
Other specified other graft of skin	S36.8
Unspecified other graft of skin	S36.9
Allograft of skin to head or neck	S37.1
Allograft of skin NEC	S37.2



Laser destruction of lesion of skin of head or neck	S09.1
Infrared photocoagulation of lesion of skin of head or neck	S09.4
Facelift and tightening of platysma	S01.1
Facelift NEC	S01.2
Submental lipectomy	S01.3
Browlift NEC	S01.4
Direct browlift	S01.5
Internal browlift	S01.6
Liposuction of subcutaneous tissue of head or neck	S62.1
Liposuction of subcutaneous tissue NEC	S62.2
Excision of lesion of external nose	E09.1
Destruction of lesion of external nose	E09.2
Dermabrasion of skin of head or neck (secondary to E09.2 for dermabrasion)	S60.1
Laser destruction of lesion of external nose	E09.6
Torsion dystonias and other involuntary movements drugs Band 1	X85.1
Tenotomy NEC	T70.2
Application of external ring fixation to bone NEC	W30.4
Open osteoclasia and angular correction and external fixation HFQ	W10.2
Open osteoclasia and external fixation NEC	W10.5
Closed osteoclasia	W11.1
Bilateral operation (secondary to one or a number of the above or other procedure codes)	Z94.1
Correction of pectus deformity of chest wall	T02.1
Recession of medial rectus muscle and resection of lateral rectus muscle of eye	C31.1
Bilateral recession of medial recti muscles of eyes	C31.2
Bilateral resection of medial recti muscles of eyes	C31.3
Bilateral recession of lateral recti muscles of eyes	C31.4
Bilateral resection of lateral recti muscles of eyes	C31.5
Recession of lateral rectus muscle and resection of medial rectus muscle of eye	C31.6
Other specified combined operations on muscles of eye	C31.8
Unspecified combined operations on muscles of eye	C31.9
Recession of medial rectus muscle of eye NEC	C32.1
Recession of lateral rectus muscle of eye NEC	C32.2
Recession of superior rectus muscle of eye	C32.3

Recession of inferior rectus muscle of eye	C32.4
Recession of superior oblique muscle of eye	C32.5
Recession of inferior oblique muscle of eye	C32.6
Recession of combinations of muscles of eye	C32.7
Other specified recession of muscle of eye	C32.8
Unspecified recession of muscle of eye	C32.9
Resection of medial rectus muscle of eye NEC	C33.1
Resection of lateral rectus muscle of eye NEC	C33.2
Resection of superior rectus muscle of eye	C33.3
Resection of inferior rectus muscle of eye	C33.4
Resection of superior oblique muscle of eye	C33.5
Resection of inferior oblique muscle of eye	C33.6
Resection of combinations of muscles of eye	C33.7
Other specified resection of muscle of eye	C33.8
Unspecified resection of muscle of eye	C33.9
<b>With the following ICD-10 diagnosis code(s):</b>	
Other plastic surgery for unacceptable cosmetic appearance	Z41.1
Vitiligo	L80.X
Other degenerative disorders of eyelid and periocular area	H02.7
Haemangioma, any site	D18.0
Rhinophyma	L71.1
Acquired deformity of chest and rib	M95.4
Pectus carinatum	Q67.7
Other paralytic strabismus	H49.8
Paralytic strabismus, unspecified	H49.9
Convergent concomitant strabismus	H50.0
Divergent concomitant strabismus	H50.1
Vertical strabismus	H50.2
Intermittent heterotropia	H50.3
Other and unspecified heterotropia	H50.4
Heterophoria	H50.5
Mechanical strabismus	H50.6
Other specified strabismus	H50.8

Unspecified strabismus	H50.9
<b>The following are ICD-10 Exceptions</b>	
Personal history of female genital mutilation	Z91.7
Other congenital malformations of vagina	Q52.4
Stricture and atresia of vagina	N89.5
Localised oedema	R60.0
Generalized oedema	R60.1
Oedema, unspecified	R60.9
Lymphoedema, not elsewhere classified	I89.0
Other specified open extirpation of lesion of duodenum	G50.8
Blepharospasm	G24.5
Spastic quadriplegic cerebral palsy	G80.0
Spastic diplegic cerebral palsy	G80.1
Spastic hemiplegic cerebral palsy	G80.2
Dyskinetic cerebral palsy	G80.3
Ataxic cerebral palsy	G80.4
Other cerebral palsy	G80.8
Cerebral palsy, unspecified	G80.9
Sequelae of subarachnoid haemorrhage (secondary to another condition)	I69.0
Sequelae of intracerebral haemorrhage (secondary to another condition)	I69.1
Sequelae of other nontraumatic intracranial haemorrhage (secondary to another condition)	I69.2
Sequelae of cerebral infarction (secondary to another condition)	I69.3
Sequelae of stroke, not elsewhere classified (secondary to another condition)	I69.4
Unequal limb length (acquired)	M21.7
Longitudinal reduction defect of femur	Q72.4
Longitudinal reduction defect of tibia	Q72.5
Longitudinal reduction defect of fibula	Q72.6
Other reduction defects of lower limb(s)	Q72.8
Reduction defect of lower limb, unspecified	Q72.9
Diplopia (may or may not be in a secondary position to H49.8-H50.9)	H53.2
Congenital ptosis	Q10.0
Congenital ectropion	Q10.1

Congenital entropion	Q10.2
Other congenital malformations of eyelid	Q10.3
Absence and agenesis of lacrimal apparatus	Q10.4
Congenital stenosis and stricture of lacrimal duct	Q10.5
Other congenital malformations of lacrimal apparatus	Q10.6
Congenital malformation of orbit	Q10.7
Sinus, fistula and cyst of branchial cleft	Q18.0
Preauricular sinus and cyst	Q18.1
Other branchial cleft malformations	Q18.2
Webbing of neck	Q18.3
Macrostomia	Q18.4
Microstomia	Q18.5
Macrocheilia	Q18.6
Microcheilia	Q18.7
Other specified congenital malformations of face and neck	Q18.8
Congenital malformation of face and neck, unspecified	Q18.9
Craniosynostosis	Q75.0
Craniofacial dysostosis	Q75.1
Hypertelorism	Q75.2
Macrocephaly	Q75.3
Mandibulofacial dysostosis	Q75.4
Oculomandibular dysostosis	Q75.5
Other specified congenital malformations of skull and face bones	Q75.8
Congenital malformation of skull and face bones, unspecified	Q75.9
Follow-up care involving plastic surgery of head and neck	Z42.0
Follow-up care involving plastic surgery of breast	Z42.1
Follow-up care involving plastic surgery of other parts of trunk	Z42.2
Follow-up care involving plastic surgery of upper extremity	Z42.3
Follow-up care involving plastic surgery of lower extremity	Z42.4
Follow-up care involving plastic surgery of other body part	Z42.8
Follow-up care involving plastic surgery, unspecified	Z42.9
Lipodystrophy, not elsewhere classified	E88.1
Lipomatosis, not elsewhere classified	E88.2

## Appendix 3 – Version History

### Other Aesthetic Surgery GM040

The latest version of this policy can be found here: [Other Aesthetic Surgery Policy](#)

Version	Date	Details
0.1	02/05/2016	Initial draft
0.2	18/05/2016	<p>Amendments made by GM EUR Steering Group on 18/05/2016:</p> <ul style="list-style-type: none"> <li>• Paragraph added under Section 4 Criteria for Commissioning – <i>“The following list of procedures will require an IFR or a prior approval request if being done for other than aesthetic reasons or under exceptionality.”</i></li> </ul> <p><b>Mandatory Criteria</b></p> <ul style="list-style-type: none"> <li>• Haemangiomas - 1<sup>st</sup> and 2<sup>nd</sup> paragraphs joined together and the following sentence added <i>“This is in line with the benign skin lesion policy”</i>.</li> <li>• Liposuction - reworded to provide clarity when funding is being requested for non-aesthetic reasons and for body contouring procedures.</li> <li>• Rhinophyma - Words <i>“Individual prior approval”</i> added to this paragraph as follows: - application for individual prior approval should be made via the IFR route.</li> <li>• Botulinum Toxin - Word <i>“facial”</i> removed from the first paragraph. Following 3 bullet points also removed:- <ul style="list-style-type: none"> <li>○ Cerebral Palsy</li> <li>○ Spasm secondary to a cerebrovascular event</li> <li>○ Hyperhidrosis (see separate policy)</li> </ul> </li> <li>• Following paragraph added to this section <i>“Botox for hyperhidrosis and migraine are covered by separate policies. Please also note policy exclusions.”</i></li> <li>• Limb Lengthening – <i>“/Shortening”</i> added to the title of this section. Also second paragraph reworded to include shortening as well as lengthening. Third paragraph added as follows <i>“Please also note policy exclusions”</i>.</li> <li>• Commissioning criteria for Pigeon Chest and Correction of Squint also added to the Mandatory Criteria section of the policy.</li> <li>• Following 2 paragraphs added to the Policy Exclusion section: <ul style="list-style-type: none"> <li>○ <i>‘Botox used as an agreed and recognised part of a care pathway e.g. cerebral palsy or stroke management is excluded from this policy.’</i></li> <li>○ <i>‘Surgical correction of pigeon chest where cardiac or pulmonary functioning is affected is excluded from this policy.’</i></li> </ul> </li> <li>• Funding Mechanism updated</li> </ul>
0.3	20/07/2016	<p>GM EUR Steering Group agreed the changes made to the policy since the last meeting and made the following changes:</p> <ul style="list-style-type: none"> <li>• Section 4 ‘Commissioning Criteria’ under ‘Vitiligo’ changed from <i>‘commissioned’</i> to <i>‘usual’</i> in the second sentence as cosmetic camouflage is not a commissioned treatment.</li> <li>• The funding mechanism for correction of a squint affecting visual function amended to read <i>‘will be via prior approval from the Greater Manchester Shared Services EUR Team’</i>. Funding mechanism in policy also update to reflect this change.</li> <li>• Commissioning Recommendation updated to reflect the above 2 changes. Subject to the above changes being made the GM EUR Steering Group agreed that the policy was ready to go out for a period of clinical engagement.</li> </ul>
0.4	16/11/2016	Amendments made by the GM EUR Steering Group on 16/11/2016 following

		<p>clinical engagement feedback:</p> <ul style="list-style-type: none"> <li>• New policy format applied.</li> <li>• <u>Policy Inclusion Criteria:</u> <ul style="list-style-type: none"> <li>○ 'Funding Mechanism' box added and text reworded for new policy format.</li> <li>○ Under 'Liposuction', first paragraph amended to state '<i>Not commissioned to correct the distribution of fat unless the abnormal distribution is due to true severe lipodema. May be commissioned in cases of true severe lipodema with supporting evidence.</i>' and funding mechanism amended to state: '<i>Individual prior approval at Clinical Triage, with requests to go to IFR Panel if a decision cannot be made. Supporting evidence must be provided with the application and wherever possible should include non-identifiable photographs of the affected area.</i>'</li> <li>○ Under 'Correction of squint' wording amended to state '<i>Correction of adult (aged over 18 years) squint for purely aesthetic reasons is not routinely commissioned but may be considered where the squint is having an excessive effect on the individual. Supporting evidence must be provided with the application. Squint surgery to correct a functional problem (e.g. double vision) is a policy exclusion.</i>'</li> </ul> </li> <li>• <u>Policy Exclusions:</u> Exclusions added for '<i>Strabismus surgical procedures in children and young adults under the age of 18</i>' and '<i>Strabismus surgical procedures (including Botulinum Toxin A injections to extraocular muscles) carried out to correct double vision, restore ocular alignment (where vision is affected) and promote, improve or restore binocular function</i>'.</li> </ul>
0.5	18/01/2017	<p>The GM EUR Steering Group agreed following amendment to the policy:-  <u>Commissioning Statement: Policy Inclusion Criteria</u></p> <ul style="list-style-type: none"> <li>• Funding mechanism added for Rhinophyma: "<i>Individual prior approval provided the patient meets the above. Requests should be submitted with all relevant supporting evidence, which <u>must</u> be provided with the request.</i>"</li> </ul> <p>The GM EUR Steering Group also agreed that following the above amendment the policy could go through the CCG Governance Process.</p>
1.0	02/10/2017	Approved by Greater Manchester Association Governing Group
1.1	15/11/2017	<p>GM EUR Steering Group agreed the following amendment to the policy for clarity:</p> <ul style="list-style-type: none"> <li>• <u>Policy Inclusion Criteria:</u> '<i>this includes the treatment of birthmarks (for Haemangiomas please see specific criteria below)</i>' added to the end of the first sentence.</li> </ul>