Thinking Differently

NHS
Dudley
Clinical Commissioning Group

Evidence Based Interventions Commissioning Policy

Incorporating
Aesthetic Surgery (AS) Policy
Procedures of Limited Clinical Priority Policy (PLCP)
NHS England Evidence Based Interventions (EBI)

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CD/XX/091/V1	20.03.2019	Presented to Commissioning Development Committed & Ratified

Please Note: Evidence Based Interventions Commissioning Policy supersedes Dudley CCG Aesthetic Surgery Policy (CD/XX/069/V2), Dudley CCG Procedures of Limited Clinical Priority Policy (CD/XX/070/V2) and includes NHS England Evidence Based Interventions (EBI) national review – 2018/19.

A full audit trail of previous policies is available on request.

VERSION	DATE	HISTORY
CD/XX/069/V2	23.03.2016	Revised draft approved by Clinical Leads at Dudley CCG - superseded by EBI Policy.
CD/XX/070/V2	23.03.2016	Revised draft approved by Clinical Leads at Dudley CCG – superseded by EBI Policy.

REVIEWERS
The review policy document has been reviewed by:

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A full list of reviewers of AS and PLCP Policy is available on request.

APPROVALS
This document has been approved by:

NAME	DATE	TITLE/RESPONSIBILITY	VERSION
Commissioning Development Committee	20 March 2019	Approved at Commissioning Development Committee	V1

NB: The version of this policy posted on the intranet must be a PDF copy of the approved version.
ENGAGEMENT

This policy incorporates NHS England Evidence Based Interventions (EBI) subject to an NHSE public consultation in July – September 2018. This guidance was updated 11 January 2019 (version 2) to incorporate the outcome of that consultation.

Dudley CCG has collaborated with Birmingham & Solihull (BSOL) CCG, Sandwell and West Birmingham (SWB) CCG, Walsall CCG and Wolverhampton CCG. Dudley CCG are part of the Black Country Policy Review Group.

Distributed electronically to all GP Surgeries, Arden & GEM Commissioning Support Unit and all Acute Trusts across the Black Country.

DOCUMENT STATUS

This is a controlled document. Whilst this document may be printed, the electronic version posted on the intranet is the controlled copy. Any printed copies of the document are not controlled.

INTRODUCTION

This policy supersedes former policies known as Procedures of Limited Clinical Priority and Aesthetic Surgery policy and incorporates NHS England Evidence Based Intervention (EBI) clinical review. The policy incorporates evidence relating to clinical and cost effectiveness. The policy describes the exclusions and access criteria in respect of procedures and its application in accordance to both the clinical and administrative adherence.

PLEASE NOTE: Revision surgery following previous NHS aesthetic surgery is not commissioned. The financial risk of revision surgery lies with the provider. It is important to note revision of plastic surgery procedures originally performed in the private sector will not be funded. Referring clinicians should re-refer to the practitioner who carried out the original treatment.

DEFINITIONS

Exceptional clinical circumstances refers to a patient who has clinical circumstances which, taken as a whole, are outside the range of clinical circumstances presented by a patient within the normal population of patients with the same medical condition and at the same stage of progression as the patient.

There can be no exhaustive definition of the conditions which may potentially fall within the definition of an exceptional case. The word “exception” means “a person, thing or case to which the general rule is not applicable”. The following criteria, however, are indicative of the presence or absence of exceptionality in the present context:

- To be an exception, there must be unusual or unique clinical factors about the patient that suggest that he or she is:

  I. Significantly different from the wider group of patients with the same condition; or

  II. Likely to gain significantly more benefit from the intervention than might be expected from the average patient with the same condition.

- The fact that a treatment is likely to be effective for a patient is not, in itself, a sufficient basis for establishing an exception.

- If a patient’s clinical condition matches the ‘accepted indications’ for a treatment, but the treatment is not funded, then the patient’s circumstances are not, by definition, exceptional.

It is for the requesting clinician to make the case for clinically exceptional circumstances.

Social value judgments are not relevant to the consideration of exceptional status.

An ***Individual Funding Request (IFR)*** is a request received from a provider or clinician which seeks funding for a single identified patient for a specific treatment.

BACKGROUND

Dudley Clinical Commissioning Group operates within finite budgetary constraints. The policy makes explicit the need for Dudley CCG to prioritise resources and provide interventions with the greatest proven health gain. The intention is to ensure equity and fairness in respect of access to NHS funding for interventions and to ensure that interventions are provided within the context of the needs of the overall population and the evidence of clinical and cost effectiveness.

To do this the policy provides:

- The list of interventions 'not routinely funded' by Dudley CCG
- The specified criteria required for the funding of certain other interventions

Please note that the policy guidance relating to these interventions should be read with reference to the principles detailed below, which includes the definition of exceptionality from the Collaborative Commissioning Policy - Individual Funding Requests version 2.1 dated October 2018 agreed and implemented by:

- NHS BSOL Clinical Commissioning Group
- NHS Dudley Clinical Commissioning Group
- NHS Sandwell and West Birmingham Clinical Commissioning Group
- NHS Walsall Clinical Commissioning Group
- NHS Wolverhampton Clinical Commissioning Group

Commissioners, General Practitioners, Service Providers and Clinical Staff treating residents of Dudley CCG are expected to implement this policy. When interventions are undertaken on the basis of meeting criteria specified within the policy, **this should be clearly documented within the clinical notes and accompanied with the EMIS Template Referral**. Failure to do so will be considered by Dudley CCG as lack of compliance.

Dudley CCG explicitly recognise that for each of the interventions listed in the policy there may be exceptional clinical circumstances in which to fund these interventions. Whilst it is not feasible to consider every possible scenario within this document, they will be considered on a case by case basis to enable due consideration of the individual merits of each case.

Thus, funding for 'interventions not routinely funded' and for interventions where specified criteria are not met will be considered by Dudley CCG following application to the respective IFR Panel. This policy will be reviewed regularly to ensure that it reflects developments in the evidence base regarding clinical and cost effectiveness.

IMPLEMENTATION

Patients with problems/conditions that require treatments included in this policy should only be referred to a Consultant/Specialist **after a clinical assessment** is made by the GP and there is a symptomatic or functional requirement for surgery.

GPs wishing to seek a specialist opinion for patients who meet this policy criterion should complete the relevant EMIS Template and refer via E-Referral system when making a referral to secondary care to ensure the patient has been assessed in line with this policy.

PLEASE NOTE: - patients who do not meet the criteria will be 'rejected' by the provider in line with E-referral Guidance.

For further details on the application process – please refer to the Dudley CCG Referral Management Protocols and Procedure Document.

Consultants in secondary care and provider finance departments need to be aware that Dudley CCG will not pay for the procedures listed in this policy unless the patient meets the criteria outlined in this policy.

This is not a blanket ban. Dudley CCG recognises there will be exceptional, individual or clinical circumstances when funding for treatments designated as low priority will be appropriate.

Individual treatment requests should only occur in clinically exceptional circumstances where the patient does not meet the core criteria. In this instance the completion of an Individual Funding Request is required. Individual Funding Requests should ONLY be sent to NHS.net accounts or Safe Haven fax:

Dudley CCG C/O Arden & GEM Commissioning Support Unit
IFR Team
Kingston House
438-450 High Street
West Bromwich
B70 9LD
Telephone: 0121 612 1661
Fax: 0121 285 5990
Email: ifr.dudley@nhs.net

MONITORING

This policy will be subject to continued monitoring consisting of 400 records per annum split into 4 quarterly audits of 100 records using a mix of the following approaches:

Prior Approval Process
Post Activity monitoring through routine data
Post Activity monitoring through case note audits.

Where a clinical intervention is restricted, such as those deemed as category 1 by NHSE EBI review, or are not routinely commissioned, evidence of Individual Funding Request (IFR) and relevant approval number will be required to ensure compliance and payment is authorised.

The commissioner will negotiate with the supporting CSU for the CCGs to request and audit list of patient notes for audit to assure the objectivity of this audit.

SPECIFIC REFERRAL CRITERIA

Ref	Title
1	Abdominoplasty or Apronectomy
2	Thigh Lift, Buttock Lift and Arm Lift, Excision of Redundant Skin or Fat
3	Liposuction
4	Breast Augmentation
5	Breast Reduction
6	Mastopexy
7	Breast Implant Revision Surgery
8	Inverted Nipple Correction
9	Gynaecomastia
10	Labia Plasty
11	Vaginoplasty
12	Penile Implants
13	Pinnaplasty
14	Repair of External Ear Lobes (Lobules)
15	Rhinoplasty
16	Eye and Upper Eye Lid Surgery
17	Eye and Lower Eye Lid Surgery
18	Face Lift or Brow Lift (Rhytidectomy)
19	Hair Depilation
20	Alopecia
21	Intralace Hair System
22	Removal of tattoos and body piercings
23	Removal of Benign Skin Lesions
24	Removal of Lipomata
25	Medical and Surgical treatment of Scars and Keloids
26	Botox Injection for the Ageing Face
27	Viral Warts
28	Thread/Telangiectasis/Recticular Veins
29	Rinophyma
30	Resurfacing Procedures: Dermabrasion, Chemical Peels, Laser Treatment
31	Other Cosmetic Procedures
32	Revision of previous Aesthetic Surgery procedures
33	Adenoidectomy
34	Insertion of Grommets
35	Routine Ear Irrigation
36	Surgery for Snoring
37	Tonsillectomy
38	Carpal Tunnel Syndrome
39	Dupuytren’s Disease
40	Ganglion
41	Trigger Finger
42	Autologous Cartilage Transplantation
43	Arthroscopy for Knee Osteoarthritis
44	Elective Hip Surgery
45	Knee Replacement Surgery
46	Spinal Fusion for Chronic Back Pain
47	Joint Injections
48	Cholecystectomy for Gallstones
49	Male Circumcision
50	Surgical Haemorrhoidectomy
51	Varicose Veins
52	Removal of Anal Skin Tags
53	Hysterectomy for Heavy Menstrual Bleeding

54	**Diagnostic Hysteroscopy for Menorrhagia**
55	**Dilation and Curettage (D & C) for Menorrhagia Heavy Menstrual Bleeding**
56	**Reversal of Male Sterilisation**
57	**Reversal of Female Sterilisation**
58	**Routine Doppler Ultrasound of Umbilical and Uterine Artery in Antenatal Care**
59	**Non Specific, Specific and Chronic Back Pain**
60	**Cataract Surgery**
61	**Laser Surgery for Short Sight (Myopia)**
62	**Dental – Apicectomy, Dental Implants, Wisdom Teeth Removal**
63	**Botulinum Toxin Type A for Hyperhidrosis**
64	**Botulinum Toxin Type A for Spasticity**
65	**Complementary Medicines/Therapies**
66	**Extracorporeal Shockwave Therapy for Refractory Plantar**
67	**Extracorporeal Shockwave Therapy for Refractory Achilles Tendinopathy**
68	**Hyperbaric Oxygen Therapy**
69	**Inpatient Cognitive Behaviour Therapy (Residential Placements) for Chronic Fatigue Syndrome (CFS)/Mylagic Encephalomyelitis (MS)**
70	**Inguinal Hernia Repair**
71	**Arthroscopic Shoulder Decompression for Sub acromial shoulder pain**

Intervention	1. Abdominoplasty or Apronectomy
Policy Statement	Unless all of the criteria detailed below are met abdominoplasty or apronectomy following weight loss will not be funded:
Rationale	Excessive abdominal skin folds may occur following weight loss in the previously obese patient and can cause significant functional difficulty. There are many obese patients who do not meet the definition of morbid obesity but whose weight loss is significant enough to create these difficulties. These types of procedures, which may be combined with limited liposuction, can be used to correct scarring and other abnormalities of the anterior abdominal wall and skin. It is important that patients undergoing such procedures have achieved and maintained a stable weight so that the risks of recurrent obesity are reduced. Patients who go forward to have bariatric surgery should be counselled. This is to ensure that the patient has realistic expectations of the outcomes of surgery and understands that plastic procedures to remove excess skin folds following bariatric surgery will not be funded by the NHS unless required for medical reasons.
Minimum Eligibility Criteria	• Documented evidence of clinical pathology due to the excess of overlying skin e.g. recurrent infections, intertrigo which has led to ulcerations requiring repeated courses of systemic treatment for a minimum of one year or disability resulting in severe restriction in activities of daily living **AND** • The patients BMI before weight loss must have been 40kg/m² or above **AND** • The patients BMI must be < 25 kg/m² and has been within this range for 2 years as measured and recorded by primary care **N.B. Purely cosmetic procedures such as removal of surplus skin irrespective of site will not be funded.**
Evidence for inclusion and threshold	Information for commissioners of Plastic Surgery - referrals and guidelines in Plastic Surgery *Modernisation Agency (Action on Plastic Surgery) (2005)* Mammaplasty and Abdominoplasty. Dafydd, Juma, Myers, Shokrollahi (2009) The Contribution of Breast and Abdominal Pannus weight to Body Mass Index. Implications for rationing of Reduction Annals of Plastic surgery

Intervention	2. Thigh Lift, Buttock Lift and Arm Lift, Excision of Redundant Skin or Fat
Policy Statement	Unless **all** of the criteria detailed below are met, Thigh Lift, Buttock Lift and Arm Lift, Excision of Redundant Skin or Fat following weight loss will not be funded:
Rationale	Whilst the patient groups seeking such procedures are similar to those seeking abdominoplasty (Section 1), the functional disturbance of skin excess in these sites tends to be less and so surgery is less likely to be indicated except for appearance: in which case it should not be available on the NHS.
Minimum Eligibility Criteria	• Documented evidence of clinical pathology due to the excess of overlying skin e.g. recurrent infections, intertrigo which has led to ulcerations requiring repeated courses of systemic treatment for a minimum of one year or disability resulting in severe restriction in activities of daily living **AND** • The patients BMI before weight loss must have been 40kg/m² or above **AND**

	• The patients BMI must be < 25 kg/m² and has been within this range for 2 years as measured and recorded by primary care **N.B.** Purely cosmetic procedures such as removal of surplus skin irrespective of site will not be funded.
Evidence for inclusion and threshold	Information for commissioners of Plastic Surgery - referrals and guidelines in Plastic Surgery *Modernisation Agency (Action on Plastic Surgery) (2005)*

Intervention	**3. Liposuction**
Policy Statement	Liposuction will not be funded.
Rationale	Liposuction (also known as liposculpture) is a surgical procedure performed to improve body shape by removing unwanted fat from areas of the body such as abdomen, hips, thighs, calves, ankles, upper arms, chin, neck and back. Liposuction is sometimes done as an adjunct to other surgical procedures, such as cancer procedures. Liposuction is not routinely commissioned. This is because removal of unwanted fat from the above areas is deemed to be cosmetic and does not meet the principles laid out in this policy.
Minimum Eligibility Criteria	This means the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.
Evidence for inclusion and thresholds	Information for commissioners of Plastic Surgery - referrals and guidelines in Plastic Surgery *Modernisation Agency (Action on Plastic Surgery) (2005)*

Intervention	**4. Breast Augmentation**
Policy Statement	**Unless one or more of the following criteria are met breast augmentation will not normally be funded:**
Rationale	Demand for breast enlargement is rising in the UK. Breast implants may be associated with significant morbidity and the need for secondary or revisional surgery (such as implant replacement) at some point in the future is common. Implants have a variable life span and the need for replacement or removal in the future is likely in young patients. Not all patients demonstrate improvement in psychosocial outcome measures following breast augmentation. Patients who are offered breast augmentation on the NHS should be encouraged to participate in the UK national breast implant registration system and be fully counselled regarding the risks and natural history of breast implants. It would be usual to provide patients undergoing breast augmentation with a copy of the DH guidance booklet "Breast implants information for women considering breast implants": It is important that patients understand that they may not automatically be entitled to replacement of the implants in the future if they do not meet the criteria for augmentation at that time. Please see section 7 of the policy.
Minimum Eligibility Criteria	• Developmental failure resulting in unilateral or bilateral absence of breast tissue or asymmetry >3 cup sizes (Congenital amastia) **OR** • Total lack of breast development, marked by absence of inframammary fold **AND** • BMI between the normal range of <25kg/m² • Not less than 2 years post-delivery of a child **N.B.** The minimum age for surgery is 21 years of age.

	Breast Cancer Treatment of unaffected breast following cancer surgery will not be routinely commissioned. Reconstructive surgery on the affected breast will only be commissioned for patients as part of the original treatment plan.
Evidence for inclusion and threshold	Information for commissioners of Plastic Surgery - referrals and guidelines in Plastic Surgery *Modernisation Agency (Action on Plastic Surgery) (2005)* Murphy, Beckstrand and Sarwer 2009 Annals of Plastic Surgery. A prospective, mutli-centre study of psychosocial outcomes after augmentation with natrelle silicone-filled breast implants

Intervention	**5. Breast Reduction**
Policy Statement	Breast reduction surgery is a procedure used to treat women with breast hyperplasia (enlargement), where breasts are large enough to cause problems like shoulder girdle dysfunction, intertrigo and adverse effects to quality of life. Unless all of the following criteria are met breast reduction will not be funded:
Rationale	One systematic review and three non-randomized studies regarding breast reduction surgery for hypermastia were identified and showed that surgery is beneficial in patients with specific symptoms. Physical and psychological improvements, such as reduced pain, increased quality of life and less anxiety and depression were found for women with hypermastia following breast reduction surgery. Breast reduction surgery for hypermastia can cause permanent loss of lactation function of breasts, as well as decreased areolar sensation, bleeding, bruising, and scarring and often alternative approaches (e.g. weight loss or a professionally fitted bra) work just as well as surgery to reduce symptoms. For women who are severely affected by complications of hypermastia and for whom alternative approaches have not helped, surgery can be offered. The aim of surgery is not cosmetic, it is to reduce symptoms (e.g. back ache).
Minimum Eligibility Criteria	The NHS will only provide breast reduction for women if all the following criteria are met: • The woman has received a full package of supportive care from their GP such as advice on weight loss and managing pain AND • Is 21 years of age AND • In cases of thoracic/shoulder girdle discomfort, a physiotherapy assessment has been provided AND • Breast size results in functional symptoms that require other treatments/interventions (e.g. intractable candidal intertrigo; thoracic backache/kyphosis where a professionally fitted bra has not helped with backache, soft tissue indentations at site of bra straps) AND • Breast reduction planned to be 500gms or more per breast or at least 4 cup sizes AND • Body mass index (BMI) is <27 and stable for at least twelve months recorded in Primary Care. • Woman must be provided with written information to allow her to balance the risks and benefits of breast surgery.

	• Women should be informed that smoking increases complications following breast reduction surgery and should be advised to stop smoking. • Women should be informed that breast surgery for hypermastia can cause permanent loss of lactation. • Ideally, no further pregnancies are planned. Unilateral breast reduction is considered for asymmetric breasts as opposed to breast augmentation if there is an impact on health as per the criteria above. Surgery will not be funded for cosmetic reasons. Surgery can be approved for a difference of 4 cup sizes. The BMI needs to be <27 and stable for at least **twelve months** recorded in Primary Care. Resection weights, for bilateral or unilateral (both breasts or one breast) breast reduction should be recorded for audit purposes. This recommendation does not apply to therapeutic mammoplasty for breast cancer treatment or contralateral (other side) surgery following breast cancer surgery, and local policies should be adhered to. Gynaecomastia: Surgery for gynaecomastia is not routinely funded by the NHS. This recommendation does not cover surgery for gynaecomastia caused by medical treatments such as treatment for prostate cancer. Please see section 9 of the policy.
Evidence for inclusion and threshold	References 1. An investigation into the relationship between breast size, bra size and mechanical back pain. British School of Osteopathy (2010). Pages 13 & 14 2. Royal College of Surgeons – https://www.rcseng.ac.uk/-/media/files/rcs/library-and-publications/non-journal-publications/breast- reduction--commissioning-guide.pdf 3. Greenbaum, a. R., Heslop, T., Morris, J., & Dunn, K. W. (2003). An investigation of the suitability of bra fit in women referred for reduction mammaplasty. British Journal of Plastic Surgery, 56(3), 230–236. 4. Wood, K., Cameron, M., & Fitzgerald, K. (2008). Breast size, bra fit and thoracic pain in young women: a correlational study. Chiropractic & Osteopathy, 16(1), 1-7. 5. Singh KA, Losken A. Additional benefits of reduction mammaplasty: a systematic review of the literature. Plast Reconstr Surg. 2012 Mar;129(3):562-70. PubMed: PM22090252 6. Strong B, Hall-Findlay EJ. How Does Volume of Resection Relate to Symptom Relief for Reduction Mammaplasty Patients? Ann Plast Surg. 2014 Apr 10. PubMed: PM24727444 7. Valtonen JP, Setala LP, Mustonen PK, Blom M. Can the efficacy of reduction mammoplasty be predicted? The applicability and predictive value of breast-related symptoms questionnaire in measuring breast-related symptoms pre- and postoperatively. J Plast Reconstr Aesthet Surg. 2014 May;67(5):676-81. PubMed: PM24508223 8. Foreman KB, Dibble LE, Droge J, Carson R, Rockwell WB. The impact of breast reduction surgery on low-back compressive forces and function in individuals with macromastia. Plast Reconstr Surg. 2009 Nov;124(5):1393-9. PubMed: PM20009823 a. Shah R, Al-Ajam Y, Stott D, Kang N. Obesity in mammaplasty: a study of complications following breast reduction. J Plast Reconstr Aesthet Surg. 2011 Apr;64(4):508-14. doi: 10.1016/j.bjps.2010.07.001. Epub 2010 Aug 3. PubMed PMID: 20682461.

	9. Oo M, Wang Z, Sakakibara T, Kasai Y. Relationship Between Brassiere Cup Size and Shoulder-Neck Pain in Women. The Open Orthopaedics Journal. 2012;6:140-142. doi:10.2174/1874325001206010140. 10. https://www.nhs.uk/conditions/breast-reduction-on-the-nhs/ 11. Plast Reconstr Surg. 2011 Nov;128(5):395e-402e. doi:10.1097/PRS.0b013e3182284c05.The impact of obesity on breast surgery complications.Chen CL(1), Shore AD, Johns R, Clark JM, Manahan M, Makary MA

Intervention	**6. Mastopexy**
Policy Statement	Mastopexy is not routinely commissioned. Treatment of unaffected breast following cancer surgery will not be routinely commissioned. Reconstructive surgery on the affected breast will only be commissioned for patients as part of the original treatment plan.

Intervention	**7. Breast Implant Revision Surgery**
Policy Statement	Breast implant revision surgery is defined as "Any consequence of an implant that would require an operative approach to managing it (e.g. removal)". This can be subdivided in to breast implant removal (Policy A) and breast implant removal and replacement (Policy B). The population who may require breast revision surgery includes: • Patients with existing breast implants funded through the NHS. • Patients with existing breast implants privately funded.
Rationale	**Indications for breast implant revision surgery** **Capsular Contracture** Capsular contracture is an unavoidable complication of breast implant surgery. After having a breast implant, the body will create a capsule of fibrous scar tissue around the implant as part of the healing process. This is a natural reaction that occurs when any foreign object is surgically implanted into the body. Over time the scar tissue will begin to shrink. The shrinkage is known as capsular contraction. The rate and extent at which the shrinkage occurs varies from person to person. In some people, the capsule can tighten and squeeze the implant, making the breast feel hard and patients may also experience pain and discomfort. Individual studies have published incidence rates of capsular contracture ranging from 2.8% to 20.4%. A 2013 systematic review published a combined overall rate of 3.6% following augmentation surgery. A literature review in 2016 indicated an incidence of between 8% and 15%. **Rupture** A rupture is a split that occurs in the implant's casing. A rapid review of breast prosthesis implantation for reconstructive and cosmetic surgery reported Kaplan-Meier estimates of rupture at six years with a range of 1.5 to 9.3 per cent. **Wrinkling and rippling**

	Wrinkling and rippling during follow-up was estimated to occur in approximately 10% of cases over 10 years for silicone implants and 24.6% over 5 years for saline implants. **Implant rotation** Very occasionally teardrop-shaped implants can rotate behind the breast. The patient will notice a marked shape change, usually evident on waking in the morning. The implant will usually rotate back to its correct position by itself or can be gently pushed back in to position. **Nerve problems in nipples** A systematic review of nerve injuries in aesthetic breast surgery found the risk of any nerve injury after breast augmentation ranged from 13.57% to 15.44%.x For Mastectomy patients, nipples may not be preserved due to the original surgery. **Problems with lactation** Surgery to the breasts may impact on or prevent the ability of patients to breast feed. **Scarring** After breast surgery, all patients will have some degree of scarring. In most cases, the scarring is relatively mild. However, in approximately 1 in 20 women, the scarring is more severe. For these women, their scars may be red or highly coloured, lumpy, thick and/or painful. **Seroma** Seroma refers to a build-up of fluid around the breast which normally resolves without aspiration. **Anaplastic Large Cell Lymphoma (ALCL)** ALCL is a rare type of non-Hodgkin's lymphoma and most cases occur in the capsule surrounding the implant and it is thought to be potentially associated with prolonged inflammatory states, similar to the theoretical pathogenesis of capsular contracture. A 2014 review found the absolute risk of ALCL remains low, ranging from 1:500,000 to 1:3,000,000. **PIP implant removal** <u>The NHS offer detailed by the government regarding PIP implants is as follows:</u> • All women who have received an implant from the NHS will be contacted to inform them that they have a PIP implant and to provide relevant information and advice. If in the meantime NHS patients seek information about the make of their implant then this will be provided free of charge. • Women who wish to will able to seek a consultation with their GP, or with the surgical team who carried out the original implant, to seek clinical advice on the best way forward. • If the woman chooses, this could include an examination by imaging to see if there is any evidence that the implant has ruptured. The NHS will support removal of PIP implants if, informed by an assessment of clinical need, risk or the impact of unresolved concerns, a woman with her doctor decides that it is right to do so. The NHS will replace the implants if the original operation was done by the NHS, providing the *current* eligibility criteria is met.

Minimum Eligibility Criteria	**Policy A – Breast Implant Revision Surgery – Implant Removal** **Eligibility Criteria:** Removal of breast implants are commissioned where there is a clinical indication for removal (Rupture or Capsular contracture which is defined as grades III and IV capsular contracture), whether the implant was initially inserted by the NHS or privately funded.
	This means (for patients who DO NOT meet the above criteria) the CCG will only fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.
	Policy B – Breast Implant Revision Surgery – Implant Removal and Replacement **Eligibility criteria** Removal AND replacement of breast implants are commissioned where there is: 1. Clinical indication for removal (Rupture or Capsular contracture which is defined as grades III and IV capsular contracture), AND 2. The implant was initially inserted by the NHS and the patient meets the current eligibility criteria as outlined in section 4 of the policy. N.B. Lipofilling is a procedure not covered under this policy and will be reviewed in the future.

Intervention	**8. Inverted Nipple Correction**
Policy Statement	This policy explicitly relates to correction of inverted nipples for cosmetic reasons only. **a) For Non-Breast Cancer Patients.** Inverted Nipple Correction is not routinely commissioned. This is because correction of inverted nipples is deemed to be cosmetic and does not meet the principles laid out in this policy
	This means the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.
Rationale	This is because correction of inverted nipples is deemed to be cosmetic and does not meet the principles laid out in this policy.
Evidence for inclusion and threshold	Royal College of Surgeons - Cosmetic Surgery Categorisation Weblink: https://www.rcseng.ac.uk/surgeons/surgical-standards/working-practices/cosmetic- surgery/documents/cosmetic-surgery-categorisation-and-requirements/at_download/file

Intervention	**9. Gynaecomastia**
Policy Statement	Surgery for gynaecomastia is not funded under the NHS. Surgery can be performed for gynaecomastia secondary to treatment for prostate cancer.
Evidence for inclusion and threshold	References

	1. An investigation into the relationship between breast size, bra size and mechanical back pain. British School of Osteopathy (2010). Pages 13 &14 2. Royal College of Surgeons – https://www.rcseng.ac.uk/-/media/files/rcs/library- and-publications/non-journal-publications/breast-reduction--commissioning- guide.pdf 3. Greenbaum, a. R., Heslop, T., Morris, J., & Dunn, K. W. (2003). An investigation of the suitability of bra fit in women referred for reduction mammaplasty. British Journal of Plastic Surgery, 56(3), 230–236. 4. Wood, K., Cameron, M., & Fitzgerald, K. (2008). Breast size, bra fit and thoracic pain in young women: a correlational study. Chiropractic & Osteopathy, 16(1), 1-7. 5. Singh KA, Losken A. Additional benefits of reduction mammaplasty: a systematic review of the literature. Plast Reconstr Surg. 2012 Mar;129(3):562-70. PubMed: PM22090252 6. Strong B, Hall-Findlay EJ. How Does Volume of Resection Relate to Symptom Relief for Reduction Mammaplasty Patients? Ann Plast Surg. 2014 Apr 10. PubMed: PM24727444 7. Valtonen JP, Setala LP, Mustonen PK, Blom M. Can the efficacy of reduction mammoplasty be predicted? The applicability and predictive value of breast-related symptoms questionnaire in measuring breast-related symptoms pre- and postoperatively. J Plast Reconstr Aesthet Surg. 2014 May;67(5):676-81. PubMed: PM24508223 8. Foreman KB, Dibble LE, Droge J, Carson R, Rockwell WB. The impact of breast reduction surgery on low-back compressive forces and function in individuals with macromastia. Plast Reconstr Surg. 2009 Nov;124(5):1393-9. PubMed: PM20009823 9. Shah R, Al-Ajam Y, Stott D, Kang N. Obesity in mammaplasty: a study of complications following breast reduction. J Plast Reconstr Aesthet Surg. 2011 Apr;64(4):508-14. doi: 10.1016/j.bjps.2010.07.001. Epub 2010 Aug 3. PubMed PMID: 20682461. 10. Oo M, Wang Z, Sakakibara T, Kasai Y. Relationship Between Brassiere Cup Size and Shoulder-Neck Pain in Women. The Open Orthopaedics Journal. 2012;6:140-142. doi:10.2174/1874325001206010140. 11. https://www.nhs.uk/conditions/breast-reduction-on-the-nhs/ 12. Plast Reconstr Surg. 2011 Nov;128(5):395e-402e. doi:10.1097/PRS.0b013e3182284c05.The impact of obesity on breast surgery complications.Chen CL(1), Shore AD, Johns R, Clark JM, Manahan M,MakaryMA

Intervention	**10. Labiaplasty**
Policy Statement	A labiaplasty is a surgical procedure to reduce the size of the labia minora – the flaps of skin either side of the vaginal opening. This procedure is restricted. The CCG will fund this treatment if the patient meets the eligibility criteria below.
Rationale	This is because there is a lack of research and clinical evidence to determine how effective this procedure is. This means there is no guarantee it will achieve a long-lasting desired effect, and there are short- and long-term risks to consider. There are very few situations where this procedure is medically indicated, these are usually related to trauma. There is no scientific evidence to support the practice of labiaplasty and for girls under the age of **18 years**, the risk of harm is even more significant. Therefore except where the criteria is met, surgery to reduce the size of the labia is deemed to be cosmetic and does not meet the principles laid out in this policy.

Minimum Eligibility Criteria	Eligibility criteria is as follows: • Where there is anatomical distortion as a result of trauma (including obstetric) • Revision surgery - where original repair following trauma was performed on the NHS and there is sufficient supporting evidence of functional problems • Other trauma and vulval diseases (including vulval cancer) For patients who have undergone private labiaplasty surgery, it is important to note revision of plastic surgery procedures originally performed in the private sector will not be funded. Referring clinicians should re-refer to the practitioner who carried out the original treatment as outlined in section 32 of the policy. This policy does not apply to genital reconstruction or revision for gender dysphoria. Gender Reassignment Surgery falls under the remit of NHS England. Please refer to NHS England Gender Identity Services for Adults (Surgical Interventions)**https://www.england.nhs.uk/commissioning/spec-services/npc-crg/group-e/e10/** RCOG key points for clinicians to note are as follows: • Owing to anatomical development during puberty, FGCS should not be offered to individuals below 18 years of age. • In general, FGCS should not be undertaken within the National Health Service (NHS) unless it is medically indicated as outlined above. • In order to be able to demonstrate compliance with the FGM Act and with good medical practice as defined by the GMC for the purposes of revalidation, it is essential that all surgeons who undertake FGCS keep written records of the physical and mental health reasons which, in their view, necessitate the FGCS procedures they carry out. They should also keep patient consent forms and details of the information provided to the woman about the treatment offered and provided. This means **(for patients who DO NOT meet the above criteria)** the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.
Evidence for inclusion and threshold	NHS Choices – Guide to Labiaplasty Weblink: http://www.nhs.uk/Conditions/labiaplasty/Pages/Introduction.aspx#cosmetic Royal College of Obstetricians and Gynaecologists - Ethical considerations in relation to female genital cosmetic surgery (FGCS), October 2013 Weblink:https://www.rcog.org.uk/globalassets/documents/guidelines/ethics-issues-and-resources/rcog- fgcs-ethical-opinion-paper.pdf

Intervention	**11. Vaginoplasty**
Policy Statement	Vaginoplasty is a reconstructive plastic surgery and cosmetic procedure for the vaginal canal and its mucous membrane, and of vulvo-vaginal structures that might be absent or damaged because of congenital disease (e.g., vaginal hypoplasia) or because of an acquired cause (e.g., childbirth physical trauma, cancer). The term vaginoplasty generally describes any such cosmetic reconstructive and corrective vaginal surgery, and the term neovaginoplasty specifically describes the procedures of either partial or total construction or reconstruction of the

	vulvo-vaginal complex. Vaginoplasty and genital procedures are restricted. The CCG will fund this treatment if the patient meets the eligibility criteria below.
Rationale	This is because Vaginoplasty is deemed to be cosmetic and does not meet the principles laid out in this policy.
Minimum Eligibility criteria	The CCG will only fund vaginoplasty if the patient meets the eligibility criteria. • Cancer • Congenital malformation/absence or endocrine abnormalities of the vaginal canal • Repair of the vaginal canal after trauma (including obstetric trauma) • Revision surgery - where original repair following trauma was performed on the NHS and there is sufficient supporting evidence of functional problems For patients who have undergone private vaginoplasty surgery, it is important to note revision of plastic surgery procedures originally performed in the private sector will not be funded. Referring clinicians should re-refer to the practitioner who carried out the original treatment as outlined in section 32 of the policy. Surgery will only be considered for adults (over 18), excluding cancer and obstetric cases. This policy does not apply to genital reconstruction or revision for gender dysphoria. Gender Reassignment Surgery falls under the remit of NHS England. Please refer to NHS England Gender Identity Services for Adults (Surgical Interventions)**https://www.england.nhs.uk/commissioning/spec-services/npc-crg/group-e/e10/** RCOG key points for clinicians to note are as follows: • Owing to anatomical development during puberty, FGCS should not be offered to individuals below 18 years of age. • In general, FGCS should not be undertaken within the National Health Service (NHS) unless it is medically indicated as outlined above. • In order to be able to demonstrate compliance with the FGM Act and with good medical practice as defined by the GMC for the purposes of revalidation, it is essential that all surgeons who undertake FGCS keep written records of the physical and mental health reasons which, in their view, necessitate the FGCS procedures they carry out. They should also keep patient consent forms and details of the information provided to the woman about the treatment offered and provided. This means **(for patients who DO NOT meet the above criteria)** the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.
Evidence for inclusion and threshold	Royal College of Obstetricians and Gynaecologists - Ethical considerations in relation to female genital cosmetic surgery (FGCS), October 2013 Weblink: https://www.rcog.org.uk/globalassets/documents/guidelines/ethics-issues-and-resources/rcog- fgcs-ethical-opinion-paper.pdf

Intervention	12. Penile Implants
Policy Statement	Penile Implants are not routinely commissioned by Clinical Commissioning Groups (CCG's) as there are alternative therapies that are effective in the majority cases of erectile dysfunction. **Note:** NHS England on 26 August 2016 published: Clinical Commissioning Policy: Penile Prosthesis surgery for end stage erectile dysfunction. **In the policy document NHS England indicate that from the date of the policy they will now commission the treatment subject to the access criteria detailed in the policy**. Weblink: https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2016/08/clinical-com- pol-16059p.pdf
Rationale	Erectile dysfunction is defined as the persistent inability to attain and maintain an erection sufficient to permit satisfactory sexual performance. It is more common in older men, affecting about half the male population of 40–70 years of age. (PDE-5) inhibitors are effective in approximately 75% of patients, and for non-responders second and third line therapies can be offered including: • injection treatment using alprostadil; • vacuum constriction devices; • normalisation of testosterone levels may also convert PDE-5 non-responders into responders.
Minimum Eligibility criteria	Please see NHS England eligibility criteria. Weblink: https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2016/08/clinical-com- pol-16059p.pdf
Evidence for inclusion and threshold	NHS Choices - Erectile dysfunction (impotence) - Treatment Weblink: http://www.nhs.uk/Conditions/Erectile-dysfunction/Pages/Treatment.aspx NHS England – Evidence Review: Penile Prosthesis Surgery for End Stage Erectile Dysfunction (2016) Weblink: https://www.engage.england.nhs.uk/consultation/copy-of-clinical-commissioning- wave5/user_uploads/b14-x10-penile-pros-evidenc-rep.pdf

Intervention	13. Pinnaplasty
Policy Statement	Unless the following criteria is met pinnaplasty will not be funded:
Rationale	Prominent ears may lead to significant psychosocial dysfunction for children and adolescents and impact on the education of young children as a result of teasing and truancy. The national service framework for children defines childhood as ending at 19 years. Some patients are only able to seek correction once they are in control of the own healthcare decisions. Children under the age of five rarely experience teasing and referrals may reflect concerns expressed by the parents rather than the child.
Minimum Eligibility Criteria	• The patient must be under the age of 19 years at the time of referral

	N.B. It is anticipated that in the majority of cases General Practitioners will be able to verify whether the patient is suffering from substantial psychological distress that would be relieved by pinnaplasty. If there is any doubt regarding psychological distress the child may benefit from referral for a psychological assessment.
Evidence for inclusion and thresholds	Royal College of Surgeons and British Association of Plastic, Reconstructive and Aesthetic Surgeons Pinnaplasty Commissioning Guide (2013) Weblink: http://www.rcseng.ac.uk/healthcare-bodies/docs/published-guides/pinnaplasty/at_download/file

Intervention	**14. Repair of External Ear Lobes (Lobules)**
Policy Statement	Elective repair of split ear lobes in adults is not routinely commissioned. This is because repair of split ear lobes is deemed to be cosmetic and does not meet the principles laid out in this policy. **Ear lobe surgery includes:** Congenital Deformity - birth deformities of the earlobe surgery include a simple repair of a congenital cleft or with a significant abnormality, cartilage grafts and skin grafts may be required in one or more stages. Split Earlobes - earlobes are often split by heavy earrings gradually enlarging a piercing over many years. On other occasions, when an earring is forcefully pulled the earlobe can split acutely. Earlobe Reduction - correction of droopy earlobes is designed to rejuvenate the ear. Facelift Earlobe - the earlobe is pulled down. Earlobe Keloids - Keloids are scars growing in an uncontrolled manner. Elective repair of split ear lobes in children up to the age of 16 years of age is restricted for the surgical indications**.** Repair of the ear lobe resulting from deliberate expansion of piercing, such as gauge piercing and use of spacers is not commissioned.
Rationale	Elective repair of split ear lobes in adults is not routinely commissioned. This is because repair of split ear lobes is deemed to be cosmetic and does not meet the principles laid out in this policy. Elective repair of split ear lobes in children up to the age of 16 years of age is restricted for the surgical indications **ONLY**.
Minimum Eligibility Criteria	Elective repair of split ear lobes in children up to the age of 16 years of age is restricted for the surgical indications below **ONLY**: Surgical indications are defined as: • Congenital deformity • Earlobes split acutely.
	This means the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

Evidence for inclusion and thresholds	Information for commissioners of Plastic Surgery - referrals and guidelines in Plastic Surgery *Modernisation Agency (Action on Plastic Surgery) (2005)* Information for Commissioners of Plastic Surgery Services (2012) http://www.bapras.org.uk/docs/default-source/commissioning-and-policy/information-for-commissioners-of-plastic-surgery-services.pdf?sfvrsn=2

Intervention	**15. Rhinoplasty/Septorhinoplasty/Septoplasty**
Policy Statement	Unless one or more of the criteria below are met, rhinoplasty, septorhinoplasty and septoplasty will not be funded:
Rationale	Rhinoplasty, septorhinoplasty or septoplasty are surgical procedures performed on the nose to change its size or shape or both. People often ask for this procedure to improve self- image. **This procedure is not funded for cosmetic reasons.**
Minimum Eligibility Criteria	• Documented evidence of complete obstruction of either nostril as a result of a medical condition or trauma **AND** • All conservative treatments have been exhausted **OR** • Correction of complex congenital conditions e.g. Cleft lip and palate **N.B. Surgery will not be funded to improve the aesthetic outcome only.**
Evidence for inclusion and threshold	Royal College of Surgeons - Cosmetic Surgery Categorisation Weblink: https://www.rcseng.ac.uk/surgeons/surgical-standards/working-practices/cosmetic- surgery/documents/cosmetic-surgery-categorisation-and-requirements/at_download/file Royal College of Surgeons – Rhinoplasty Guide Weblink: http://www.rcseng.ac.uk/members/resources/pre-op-leaflets/Ear%20Nose%20Throat/Rhinoplasty.pdf/at_download/file

Intervention	**16. Eye & Upper Eye Lid**
Policy Statement	This procedure will be commissioned by the NHS to correct functional impairment (not purely for cosmetic reasons). **Xanthelasma – please see Minimum Eligibility Criteria** **CHALAZIA** This procedure involves incision and curettage (scraping away) of the contents of the chalazion. Chalazia (meibomian cysts) are benign lesions on the eyelids due to blockage and swelling of an oil gland that normally change size over a few weeks. Many but not all resolve within six months with regular application of warm compresses and massage.
Rationale	Upper eyelid surgery: Many people acquire excess skin in the upper eyelids as part of the process of ageing and this may be considered normal. However if this starts to interfere with vision or function of the eyelid apparatus then this can warrant treatment. **CHALAZIA** NICE recommend that warm compresses and lid massage alone are sufficient first line treatment for chalazia. If infection is suspected a drop or ointment containing an antibiotic (e.g. Chloramphenicol) should be added in addition to warm compresses. Only if there is spreading lid and

	facial cellulitis should a short course of oral antibiotics (e.g. co-amoxiclav) be used. Where there is significant inflammation of the chalazion a drop or ointment containing an antibiotic and steroid can be used along with other measures such as warm compresses. However, all use of topical steroids around the eye does carry the risk of raised intraocular pressure or cataract although this is very low with courses of less than 2 weeks. Many chalazia, especially those that present acutely, resolve within six months and will not cause any harm however there are a small number which are persistent, very large, or can cause other problems such as distortion of vision. In these cases surgery can remove the contents from a chalazion. However all surgery carries risks. Most people will experience some discomfort, swelling and often bruising of the eyelids and the cyst can take a few weeks to disappear even after successful surgery. Surgery also carries a small risk of infection, bleeding and scarring, and there is a remote but serious risk to the eye and vision from any procedure on the eyelids. Lastly in a proportion of successful procedures the chalazion can come back. The alternative option of an injection of a steroid (triamcinolone) also carries a small risk of serious complications such as raised eye pressure, eye perforation or bleeding.
Minimum Eligibility Criteria	Surgery on the upper eyelid (Upper lid blepharoplasty) • Impairment of visual fields in the relaxed, non-compensated state as determined by the Visual field test reducing visual field to 120° laterally and 40° vertically **OR** • Severe congenital ptosis **<u>XANTHELASMA</u>** Xanthelasma (yellow fatty deposits around the eyelids) may be associated with abnormally high cholesterol levels and this should be tested for. They may be unsightly and multiple and do not always respond to “medical” treatments. Surgery can require “blepharoplasty type” operations and/or skin grafts. Patients with xanthlelasma should always have their lipid profile checked before referral to specialist. Many xanthelasmata may be treated with topical TCA or cryotheraphy. Larger lesions or those that have not responded to these treatments may benefit from surgery if the lesion is disfiguring. Unless *one or more* of the following criteria are met, removal of xanthelasma will not be normally funded: • If the lesion is causing visual problems and primary care treatment is not effective **CHALAZIA** Incision and curettage (or triamcinolone injection for suitable candidates) of chalazia should only be undertaken if at least one of the following criteria have been met:

	• Has been present for more than 6 months and has been managed conservatively with warm compresses, lid cleaning and massage for 4 weeks • Interferes significantly with vision • Interferes with the protection of the eye by the eyelid due to altered lid closure or lid anatomy • Is a source of infection that has required medical attention twice or more within a six month time frame • Is a source of infection causing an abscess which requires drainage If malignancy (cancer) is suspected eg. Madarosis/recurrence/other suspicious features in which case the lesion should be removed and sent for histology as for all suspicious lesions
Evidence for inclusion and threshold	Commissioning Guide - Referrals and Guidelines in Plastic Surgery (Modernisation Agency 2005) http://filesdown.esecure.co.uk/NorthLancsPCT/Modernisation_Agency_Plastic_Surgery_Services.pdf_29072008-1722-24.pdf CHALAZIA 1) NICE clinical knowledge summaries: https://cks.nice.org.uk/meibomian-cyst-chalazion 2) Moorfield's Eye Hospital Patient Information: https://www.moorfields.nhs.uk/sites/default/files/chalazion-adult.pdf 3) Wu AY, Gervasio KA, Gergoudis KN, Wei C, Oestreicher JH, Harvey JT. Conservative therapy for chalazia: is it really effective? Acta Ophthalmol. 2018 Jan 16. doi: 10.1111/aos.13675. [Epub ahead of print] PubMed PMID: 29338124. 4) Goawalla A, Lee V. A prospective randomized treatment study comparing three treatment options for chalazia: triamcinolone acetonide injections, incision and curettage and treatment with hot compresses. Clin Exp Ophthalmol. 2007 Nov;35(8):706-12. PubMed PMID: 17997772. 5) Watson P, Austin DJ. Treatment of chalazions with injection of a steroid Suspension. British Journal of Ophthalmology, 1984, 68, 833-835. 6) Ben Simon, G.J., Huang, L., Nakra, T. et al. Intralesional triamcinolone acetonide injection for primary and recurrent chalazia (is it really effective?) . Ophthalmology. 2005; 112: 913–917. 7) Papalkar D, Francis IC. Injections for Chalazia? Ophthalmology 2006; 113:355–356. Incision and curettage vs steroid injection for the treatment of chalazia: a metaanalysis. Aycinena A, Achrion A et al. Ophthalmic Plastic and reconstructive surgery. 2016;32:220-224. 8) McStay. Stye and Chalazion. BMJ Best Practice https://bestpractice.bmj.com/topics/en-gb/214 (accessed 18/10/18)

Intervention	**17. Eye and Lower Eye Lid**

Policy Statement	This is available on the NHS for correction of ectropion or entropion or for the removal of lesions of the eyelid skin or lid margin. Xanthelasma – please see Minimum Eligibility Criteria **CHALAZIA** This procedure involves incision and curettage (scraping away) of the contents of the chalazion. Chalazia (meibomian cysts) are benign lesions on the eyelids due to blockage and swelling of an oil gland that normally change size over a few weeks. Many but not all resolve within six months with regular application of warm compresses and massage.
Rationale	**Note:** Excessive skin in the lower lid may cause "eyebags" but does not affect function of the eyelid or vision and therefore does not need correction. Blepharoplasty type procedures may form part of the treatment of pathological conditions of the lid or overlying skin and not for cosmetic reasons. The following procedures will not be funded: • Surgery for cosmetic reasons • Surgery for cyst of moll • Surgery for cyst of zeis • Removal of eyelid papillomas or skin tags • Surgery for pingueculum • Excision of other lid lumps **CHALAZIA** NICE recommend that warm compresses and lid massage alone are sufficient first line treatment for chalazia. If infection is suspected a drop or ointment containing an antibiotic (e.g. Chloramphenicol) should be added in addition to warm compresses. Only if there is spreading lid and facial cellulitis should a short course of oral antibiotics (e.g. co-amoxiclav) be used. Where there is significant inflammation of the chalazion a drop or ointment containing an antibiotic and steroid can be used along with other measures such as warm compresses. However, all use of topical steroids around the eye does carry the risk of raised intraocular pressure or cataract although this is very low with courses of less than 2 weeks Many chalazia, especially those that present acutely, resolve within six months and will not cause any harm however there are a small number which are persistent, very large, or can cause other problems such as distortion of vision. In these cases surgery can remove the contents from a chalazion. However all surgery carries risks. Most people will experience some discomfort, swelling and often bruising of the eyelids and the cyst can take a few weeks to disappear even after successful surgery. Surgery also carries a small risk of infection, bleeding and scarring, and there is a remote but serious risk to the eye and vision from any procedure on the eyelids. Lastly in a proportion of successful procedures the chalazion can come back. The alternative option of an injection of a steroid (triamcinolone) also carries a small risk of serious complications such as raised eye pressure, eye perforation or bleeding.

Minimum Eligibility Criteria	Correction of ectropion or entropion or for the removal of lesions of the eyelid skin or lid margin. **XANTHELASMA** Xanthelasma (yellow fatty deposits around the eyelids) may be associated with abnormally high cholesterol levels and this should be tested for. They may be unsightly and multiple and do not always respond to "medical" treatments. Surgery can require "blepharoplasty type" operations and/or skin grafts. Patients with xanthlelasma should always have their lipid profile checked before referral to specialist. Many xanthelasmata may be treated with topical TCA or cryotheraphy. Larger lesions or those that have not responded to these treatments may benefit from surgery if the lesion is disfiguring. Unless *one or more* of the following criteria are met, removal of xanthelasma will not be normally funded: • If the lesion is causing visual problems and • primary care treatment is not effective **CHALAZIA** Incision and curettage (or triamcinolone injection for suitable candidates) of chalazia should only be undertaken if at least one of the following criteria have been met: • Has been present for more than 6 months and has been managed conservatively with warm compresses, lid cleaning and massage for 4 weeks • Interferes significantly with vision • Interferes with the protection of the eye by the eyelid due to altered lid closure or lid anatomy • Is a source of infection that has required medical attention twice or more within a six month time frame • Is a source of infection causing an abscess which requires drainage If malignancy (cancer) is suspected eg. Madarosis/recurrence/other suspicious features in which case the lesion should be removed and sent for histology as for all suspicious lesions.
Evidence for inclusion and threshold	Commissioning Guide - Referrals and Guidelines in Plastic Surgery (Modernisation Agency 2005) http://filesdown.esecure.co.uk/NorthLancsPCT/Modernisation_Agency_Plastic_Surgery_Services.pdf_29072008-1722-24.pdf **CHALAZIA** 1) NICE clinical knowledge summaries: https://cks.nice.org.uk/meibomian-cyst-chalazion 2) Moorfield's Eye Hospital Patient Information, https://www.moorfields.nhs.uk/sites/default/files/chalazion-adult.pdf 3) Wu AY, Gervasio KA, Gergoudis KN, Wei C, Oestreicher JH, Harvey JT. Conservative therapy for chalazia: is it really effective? Acta Ophthalmol. 2018 Jan 16. doi: 10.1111/aos.13675. [Epub ahead of print] PubMed PMID: 29338124. 4) Goawalla A, Lee V. A prospective randomized treatment study comparing three treatment options for chalazia: triamcinolone acetonide injections, incision and curettage and treatment with hot

	compresses. Clin Exp Ophthalmol. 2007 Nov;35(8):706-12. PubMed PMID: 17997772. 5) Watson P, Austin DJ. Treatment of chalazions with injection of a steroid Suspension. British Journal of Ophthalmology, 1984, 68, 833-835. 6) Ben Simon, G.J., Huang, L., Nakra, T. et al. Intralesional triamcinolone acetonide injection for primary and recurrent chalazia (is it really effective?) . Ophthalmology. 2005; 112: 913–917. 7) Papalkar D, Francis IC. Injections for Chalazia? Ophthalmology 2006; 113:355–356. Incision and curettage vs steroid injection for the treatment of chalazia: a metaanalysis. Aycinena A, Achrion A et al. Ophthalmic Plastic and reconstructive surgery. 2016; 32:220-224. 8) McStay. Stye and Chalazion. BMJ Best Practice https://bestpractice.bmj.com/topics/en-gb/214 (accessed 18/10/18)

Intervention	**18. Face Lift or Brow Lift (Rhytidectomy)**
Policy Statement	Unless one or more of the following criteria are met, face lift or brow lift will not normally be funded and will not be funded to treat the natural aging process:
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.
Minimum Eligibility Criteria	• Recognised diagnosis of Congenital facial abnormalities **OR** • Facial palsy (congenital or acquired paralysis) **OR** • As part of the treatment of specific conditions affecting the facial skin e.g. cutis laxa, pseudoxanthoma elasticum, neurofibromatosis **OR** • To correct the consequences of trauma **OR** • To correct significant deformity following surgery however funding will not be approved to improve previous surgery.
Evidence for inclusion and threshold	Information for commissioners of Plastic Surgery - referrals and guidelines in Plastic Surgery *Modernisation Agency (Action on Plastic Surgery) (2005)*

Intervention	**19. Hair Depilation**
Policy Statement	**Unless one or more of the following criteria are met, hair depilation will not be funded.**
Rationale	Hair depilation can be used for excess hair in a normal distribution pattern, or for abnormally placed hair. It is usually achieved permanently by electrolysis or laser therapy. This policy does not fund hair depilation for cosmetic purposes. Funding for electrolysis and laser therapy to treat hirsuitism is not available on the NHS.
Minimum Eligibility Criteria	• Have undergone reconstructive surgery leading to abnormally located hair-bearing skin **OR** • Are undergoing treatment for recurrent pilonidal sinuses
Evidence for inclusion and threshold	British Association of Dermatologists - hirsutism patient information leaflet Weblink: http://www.bad.org.uk/shared/get-file.ashx?id=89&itemtype=document

Intervention	**20. Alopecia**
Policy Statement	**Treatment for Alopecia will only be funded in accordance with the criteria specified below:**
Rationale	Treatment for alopecia is not available on the NHS, regardless of gender. This is because surgical treatment for hair loss is deemed to be cosmetic and does not meet the principles laid out in this policy. Applications via Individual Funding Requests may be submitted for consideration if *clinically* exceptional circumstances can be demonstrated.

Minimum Eligibility Criteria	• Non-Surgical correction is only available on the NHS when it is as a result of previous surgery or trauma including burns or severe scarring from medical disease conditions (this does not include hair loss as a result of chemotherapy or radiotherapy). • Surgical Correction of hair loss both natural and as a result of treatment of malignancy - will not be funded. • Hair Management Systems including Intralace Hair Systems are not funded – please see section 21.
Evidence for inclusion and thresholds	Information for commissioners of Plastic Surgery - referrals and guidelines in Plastic Surgery *Modernisation Agency (Action on Plastic Surgery) (2005)* British Association of Dermatologists - Guidelines for the management of alopecia areata (2012): http://www.bad.org.uk/shared/get-file.ashx?id=41&itemtype=document British Association of Dermatologists - alopecia areata patient information leaflet: http://www.bad.org.uk/shared/get-file.ashx?id=1975&itemtype=document NHS Choices – Guide to Hair Loss Treatment: http://www.nhs.uk/Conditions/Hair-loss/Pages/Treatment.aspx NICE Guidelines: https://cks.nice.org.uk/alopecia-areata#!topicsummary

Intervention	**21. Intralace Hair Systems for Abnormal Hair Loss**
Policy Statement	**Treatment for Alopecia will only be funded in accordance with the criteria specified below:**
Rationale	Dudley Clinical Commissioning Group (CCG) has reviewed the evidence available for the use of 'Intralace' Hair system for abnormal hair loss and considers it to be a **LOW PRIORITY**, due to lack of clinical effectiveness. **Condition** There are several types of hair loss in women, female-pattern baldness, local hair loss and general hair loss. Female-pattern baldness tends to run in families, and usually causes the hair to thin in the front, on the crown, or on the sides, but seldom causing complete hair loss. The most common form of male baldness is a progressive hair thinning condition called androgenic alopecia or "male pattern baldness" that occurs in adult male humans. The amount and patterns of baldness can vary greatly. Local hair loss is usually patchy and confined to certain areas. It may result from several conditions e.g. alopecia areata, cancer therapy, trichotillomania (nervous, repeated hair pulling), or permanent skin damage from burns, or serious skin diseases. **Evidence** Current providers are unable to demonstrate clear evidence for any real effectiveness, limited to 'before and after' photos. NICE has not considered this intervention, although NICE Clinical guidelines (31) do outline treatment for associated psychological problems related to Body Dysmorphic Disorder. There was no other mention of the 'Intralace' system in any studies on alopecia. No further evidence can be found. **Conclusion**

	Due to the lack of clinical and cost effectiveness evidence Dudley CCG will not commission use of the 'Intralace' Hair System for abnormal hair loss for any of the conditions outlined above. Please note the list is not exhaustive.
Minimum Eligibility Criteria	Exceptional circumstances may be considered where the clinician can demonstrate a patient is likely to gain significantly more benefit from the intervention than might be expected from the average patient with the same condition or where there would be a significant reduction in other clinical services currently being used. Please read and apply via Arden & GEM Commissioning Support Unit (AGCSU) – Collaborative Commissioning Policy - Individual Funding Requests version 2.1 – October 2018. This policy will be reviewed in the light of new evidence or guidance from NICE.
Evidence for inclusion and thresholds	• NICE CG 31 • Delamere F et al. Cochrane Systematic Review 2009 : Interventions for alopecia areata • McDonald Hill S et al. Guidelines for the management of alopecia areata. Br J Derm 2003. 149:692-699 • Birch M et al. Hair density, hair diameter and the prevalence of female pattern hair loss. Br J Derm 2001. 144 (2):297-304

Intervention	**22. Removal of Tattoos / Surgical correction of body piercings and correction of respective problems**
Policy Statement	Removal of Tattoos/Surgical correction of body piercings and correction of respective problems are not funded. This is because surgical treatment for removal of tattoos/surgical correction of body piercings and correction of respective problems is deemed to be cosmetic and does not meet the principles laid out in this policy.
Minimum Eligibility Criteria	• Clinical exceptionality must be demonstrated. Application can be submitted via an Individual Funding Request
Evidence for inclusion and threshold	Information for commissioners of Plastic Surgery - referrals and guidelines in Plastic Surgery Modernisation Agency (Action on Plastic Surgery) (2005) NHS Choices – Guide to Non-surgical cosmetic procedures Weblink: http://www.nhs.uk/Conditions/non-surgical-cosmetic-treatments/Pages/Introduction.aspx

Intervention	**23. Removal of Benign or Congenital Skin Lesions**
Policy Statement	Removal of Benign skin lesions in secondary care are not routinely commissioned.
Rationale	Funding for Removal of Benign or Congenital Skin Lesions will not be authorised purely for cosmetic reasons. There is little evidence to suggest that removing benign skin lesions to improve appearance is beneficial. Risks of this procedure include bleeding, pain, infection and scarring. Though in certain specific cases as outlined by the criteria above, there are benefits for removing skin lesions, for example, avoidance of pain and allowing normal functioning **This policy refers to the following benign lesions when there is diagnostic** certainty and they do not meet the criteria listed below:

	• benign moles (excluding large congenital naevi) • solar comedones • corn/callous • dermatofibroma • lipomas • milia • molluscum contagiosum (non-genital) • epidermoid & pilar cysts (sometimes incorrectly called sebaceous cysts) • seborrhoeic keratoses (basal cell papillomata) • skin tags (fibroepithelial polyps) including anal tags • spider naevi (telangiectasia) • non-genital viral warts in immunocompetent patients • xanthelasmata • neurofibromata
Minimum Eligibility Criteria	**The benign skin lesions, which are listed above, must meet at least ONE of the following criteria to be removed:** • The lesion is unavoidably and significantly traumatised and on a regular basis with evidence of this causing regular bleeding or resulting in infections • If the cyst has become infected **AND** • Has not responded to 2 or more anti-biotics over a 3 month period *AND* • The cyst is beyond the scope of primary care to remove **AND** • The cyst is causing a functional impairment • The lesion bleeds in the course of normal everyday activity • The lesion causes regular pain • The lesion is obstructing an orifice or impairing field vision (for guidance on clinical criteria please refer to the Treatment policy for Upper and Lower Eyelid Surgery (Blepharoplasty). • The lesion significantly impacts on function e.g. restricts joint movement • The lesion causes pressure symptoms e.g. on nerve or tissue • If left untreated, more invasive intervention would be required for removal • Facial lesions > 1cm that cause significant disfigurement • Facial warts in all ages causing significant psychological impact • Facial spider naevi in children causing significant psychological impact Lipomas on the body > 5cms, or in a sub-facial position, with rapid growth and/or pain. These should be referred to Sarcoma clinic. **The following are *outside* the scope of this policy recommendation:** • Lesions that are suspicious of malignancy should be treated or referred according to NICE skin cancer guidelines. • Any lesion where there is diagnostic uncertainty, pre-malignant lesions (actinic keratoses, Bowen disease) or lesions with pre-malignant potential should be referred or, where appropriate, treated in primary care. • Removal of lesions other than those listed above. • The decision as to whether a patient meets the criteria is primarily with the referring clinician. If such lesions are referred, then the referrer should state that this policy has been considered and why the patient meets the criteria • Requests for treatment where a patient meets the criteria do not require prior approval or an IFR.

	• This policy applies to all Providers, including general practitioners (GPs), GPs with enhanced role (GPwer) independent providers and community or intermediate service.
Evidence for inclusion and threshold	References 1) Higgins JC, Maher MH, Douglas MS. Diagnosing Common Benign Skin Tumors. Am Fam Physician. 2015 Oct 1;92(7):601-7. PubMed PMID: 26447443. 2) Tan E, Levell NJ, Garioch JJ. The effect of a dermatology restricted-referral list upon the volume of referrals. Clin Exp Dermatol. 2007 Jan;32(1):114-5. PubMed PMID: 17305918.

Intervention	**24. Removal of Lipomata**
Policy Statement	Lipomata are fat deposits underneath the skin. They are usually removed on cosmetic grounds, although patients with multiple subcutaneous lipomata may need a biopsy to exclude neurofibromatosis. Removal of Lipomata in secondary care is restricted. The CCG will fund this treatment if the patient meets the minimum eligibility criteria below.
Rationale	This is because all removal of Lipomata that does not meet the criteria below is deemed to be cosmetic and does not meet the principles laid out in this policy.
Minimum Eligibility Criteria	The CCG will fund this treatment if the patient meets the following criteria: • suspected or proven malignancy (cancerous) **OR** • significant functional impairment caused by the lipoma **OR** • to provide histological evidence in conditions where there are multiple subcutaneous lesions **OR** • the lipoma is on the face (including pinna) or the neck and it has become infected or is causing functional impairment. Lipomas on other areas of the body should be referred back to primary care as agreed locally. For the purposes of the eligibility criteria, functional impairment is classed as a reduction in the ability to carry out an activity of daily living, e.g. the location of the lesion causes reduced movement resulting in interference with sleeping, eating, or walking.
	This means for patients who **DO NOT** meet the above criteria the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG
Evidence for inclusion and threshold	Information for commissioners of Plastic Surgery - referrals and guidelines in Plastic Surgery *Modernisation Agency (Action on Plastic Surgery) (2005)* NHS Modernisation Agency - Information for commissioners of Plastic Surgery - referrals and guidelines in Plastic Surgery (Action on Plastic Surgery) (2005) Weblink: http://northwestcsu.nhs.uk/BrickwallResource/GetResource/159f6308-bee1-413a-8da1-8098b0495cf6

Intervention	**25. Medical and Surgical treatment of Scars and Keloids**
Policy Statement	Unless one or more of the following criteria are met, refashioning or removal of scars/treatment and keloids will not normally be funded:

Minimum Eligibility Criteria	• For severe post burn cases or severe traumatic scarring or severe post- surgical scarring. • Revision surgery for scars following complications of surgery, keloid formation or other hypertrophic scar formation will only be commissioned where there is significant functional deformity or to restore normal function.

Intervention	**26. Botox Injection for the Ageing Face**
Policy Statement	Botox Injection for the face will not be funded.
Rationale	Botulinum toxin is not available for the treatment of facial ageing, excessive wrinkles or other cosmetic procedures.
Minimum Eligibility Criteria	It is acknowledged that treatment supported by Botox for respective Medical conditions are successful and often have a comprehensives evidence base to support this. For information on Botox treatments that are funded please refer to sections 64 and 65 of the policy.

Intervention	**27. Viral Warts**
Policy Statement	Treatment of viral warts in a secondary care setting will not be funded Only anal genital warts that have failed treatment within primary care setting will be funded.
Rationale	In adults and children, in the majority of cases of viral warts are self-limiting and treatment is not necessary. Primary treatment of warts is the responsibility of General Practitioners under the Essential Services section of their contract. Most viral warts will clear spontaneously or following application of topical treatments. Painful and persistent or extensive warts (particularly in the immune-suppressed patient) may need specialist assessment, usually by a dermatologist. Any intervention for viral warts should be limited to where there are significant functional problems. Cryotherapy is not recommended for use in children under the age of 6 and should be discouraged in older children.
Minimum Eligibility Criteria	• Only ano-genital warts that have failed treatment within primary care setting or Genito-Urinary Medicine (GUM) clinic.

Intervention	**28. Thread/ Telangiectasis/ Reticular veins**
Policy Statement	Treatment for Thread Veins / Telangiectasis will not be considered for funding.
Rationale	
Minimum Eligibility Criteria	Treatment for Thread Veins / Telangiectasis will not be considered for funding.

Intervention	**29. Rhinophyma**
Policy Statement	Surgical treatment of Rhinophyma is not routinely commissioned.
Rationale	This is because there is no cure for rhinophyma, although some treatments may control it. These treatments are deemed to be cosmetic and does not meet the principles laid out in this policy.
Minimum Eligibility Criteria	This means the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

Evidence for inclusion and threshold	Information for commissioners of Plastic Surgery - referrals and guidelines in Plastic Surgery *Modernisation Agency (Action on Plastic Surgery) (2005)* British Association of Dermatologists - Rhinophyma patient information leaflet Weblink: http://www.bad.org.uk/shared/get-file.ashx?id=2045&itemtype=document

Intervention	**30. Resurfacing Procedures: Dermabrasion, Chemical Peels and Laser Treatment**
Policy Statement	Resurfacing procedures including dermabrasion, chemical peels and laser treatment will not be funded:
Rationale	These procedures are deemed to be cosmetic and do not meet the principles laid out in this policy.

Intervention	**31. Other Cosmetic Procedures**
Policy Statement	Cosmetic interventions will not be funded.
Rationale	This is because 'Other Cosmetic Procedures' not specified in the Cosmetic Surgery policy but detailed in the Royal College of Surgeons 'Categorisation of Cosmetic Surgery' is deemed to be cosmetic and does not meet the principles laid out in this policy. For details of interventions – please refer to the Royal College of Surgeons 'Categorisation of Cosmetic Surgery'.
Minimum Eligibility Criteria	This means the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.
Evidence for inclusion and threshold	Information for commissioners of Plastic Surgery - referrals and guidelines in Plastic Surgery *Modernisation Agency (Action on Plastic Surgery) (2005)* Royal College of Surgeons - Cosmetic Surgery Categorisation Weblink: https://www.rcseng.ac.uk/surgeons/surgical-standards/working-practices/cosmetic- surgery/documents/cosmetic-surgery-categorisation-and-requirements/at_download/file NHS Choices – Ear Reshaping Weblink: http://www.nhs.uk/conditions/ear-reshaping/Pages/Introduction.aspx

Intervention	**32. Revision of Previous Aesthetic Surgery Procedures**
Policy Statement	**Revision surgery following previous NHS aesthetic surgery is not commissioned. The financial risk of revision surgery lies with the provider.** It is important to note revision of plastic surgery procedures originally performed in the private sector will not be funded. Referring clinicians should re-refer to the practitioner who carried out the original treatment.

Intervention	**33. Adenoidectomy**
Policy	*Adenoidectomy will not be funded as an isolated procedure; it will be funded only if undertaken in conjunction with Tonsillectomy or Grommets.
Rationale	An adenoidectomy is a quick operation to remove the adenoids – small lumps of tissue at the back of the nose, behind the palate. Adenoids are part of the immune system, which helps fight infection and protects the body from bacteria and viruses. Adenoids are only present in children. They start to grow from birth and are biggest when your child is approximately three to five years old.

	But by age seven to eight they start to shrink and by the late teens, are barely visible. By adulthood, the adenoids will have disappeared completely. The adenoids disappear because – although they may be helpful in young children – they're not an essential part of an adult's immune system.
Minimum Eligibility Criteria	*Adenoidectomy will not be funded as an isolated procedure; it will be funded only if undertaken in conjunction with Tonsillectomy or Grommets. (Please refer to relevant guidance/policy for Tonsillectomy and/or Grommets). *Please note – It is recognised there may be a small cohort of pre GCSE age children who do not grow out of enlarged adenoids and suffer nasal obstruction as a consequence, where surgery maybe clinically justified. Dudley CCG will consider surgery via the prior approval scheme for this small cohort of patients. Applications will need to demonstrate justification of surgery.
Evidence for inclusion and threshold	Royal College of Surgeons Commissioning Guide for Rhinosinusitis (2013): The Royal College of Surgeons of England and ENT UK (2013). Commissioning guide: Rhinosinusitis, Available from: http://www.rcseng.ac.uk/providers-commissioners/docs/rcseng-ent-uk-commissioning-guide-for-rhinosinusitis Robb PJ et al (2009), Tonsillectomy and adenoidectomy in children with sleep-related breathing disorders: consensus statement of a UK multidisciplinary working party, Annals of the Royal College of Surgeons of England, 91, 371-373. Available from: http://europepmc.org/articles/PMC2758429;jsessionid=MVfPN7W1Ky1PN4EiKikL.52

Intervention	**34. Insertion of Grommets for Glue Ear**
Policy	This is a surgical procedure to insert tiny tubes (grommets) into the eardrum as a treatment for fluid build-up (glue ear) when it is affecting hearing in children. Glue ear is a very common childhood problem (4 out of 5 children will have had an episode by age 10), and in most cases it clears up without treatment within a few weeks. Common symptoms can include earache and a reduction in hearing. Often, when the hearing loss is affecting both ears it can cause language, educational and behavioural problems. Please note this guidance only relates to children with Glue Ear (Otitis Media with Effusion) and SHOULD NOT be applied to other clinical conditions where grommet insertion should continue to be normally funded, these include: • Recurrent otitis media • Atrophic tympanic membranes • Access to middle ear for transtympanic instillation of medication Investigation of unilateral glue ear in adults
Rationale	In most cases glue ear will improve by itself without surgery. During a period of monitoring of the condition a balloon device (e.g. Otovent) can be used by the child if tolerated, this is designed to improve the function of the ventilation tube that connects the ear to the nose. In children with persistent glue ear, a hearing aid is another suitable alternative to surgery. Evidence suggests that grommets only offer a short-term hearing improvement in children with no other serious medical problems or disabilities.

	The NHS should only commission this surgery when the NICE criteria are met, as performing the surgery outside of these criteria is unlikely to derive any clinical benefit.
Minimum Eligibility Criteria	The NHS should only commission this surgery for the treatment of glue ear in children when the criteria set out by the NICE guidelines are met: • All children must have had specialist audiology and ENT assessment • Children should be <3 and >12 years as per NICE Guidance • For adults and children over 12 – funding will be considered on a clinically exceptional basis via Individual Funding Request submission • Persistent bilateral otitis media with effusion over a period of 3 months. Hearing level in the better ear of 25-30dbHL or worse averaged at 0.5, 1, 2, & 4kHz • Exceptionally, healthcare professionals should consider surgical intervention in children with persistent bilateral OME with a hearing loss less than 25-30dbHL where the impact of the hearing loss on a child's developmental, social or educational status is judged to be significant. • Healthcare professionals should also consider surgical intervention in children who cannot undergo standard assessment of hearing thresholds where there is clinical and tympanographic evidence of persistent glue ear and where the impact of the hearing loss on a child's developmental, social or educational status is judged to be significant. • The guidance is different for children with Down's Syndrome and Cleft Palate, these children may be offered grommets after a specialist MDT assessment in line with NICE guidance. • It is also good practice to ensure glue ear has not resolved once a date of surgery has been agreed, with tympanometry as a minimum. For further information, please see: https://www.nice.org.uk/Guidance/CG60 The risks to surgery are generally low, but the most common is persistent ear discharge (10-20%) and this can require treatment with antibiotic eardrops and water precautions. In rare cases (1-2%) a persistent hole in the eardrum may remain, and if this causes problems with recurrent infection, surgical repair may be required (however this is not normally done until around 8-10 years of age).
Management	For children with Down's Syndrome and Cleft Palate, these may be offered grommets after a specialist MDT assessment in line with NICE Guidance. Please see: https://www.nice.org.uk/Guidance/CG60
Evidence for inclusion and threshold	1) NICE Clinical Guideline 60 - Surgical Management Of OME http://guidance.nice.org.uk/CG60 2) Browning, G; Rovers, M; Williamson, I; Lous, J; Burton, MJ. Grommets (ventilation tubes) for hearing loss associated with otitis media with effusion in children. Cochrane Database of Systematic Reviews 2010, Issue 10. Art. No.: CD001801. DOI: 10.1002/14651858.CD001801.pub3

Intervention	**35. Routine Ear Irrigation**
Policy	Routine ear irrigation will not be funded in a Secondary Care setting.
Rationale	Routine ear syringing is not a procedure routinely carried out in a secondary care setting. Treatment should be delivered in primary care prior to referral to secondary care.

Minimum Eligibility Criteria	This will only be funded in clinically exceptional circumstances and clinicians will need to demonstrate exceptionality via an Individual Funding Request.
Evidence for inclusion and threshold	SIGN Guidance – Ear Care Best Practice Statement: http://www.healthcareimprovementscotland.org/previous_resources/best_practice_statement/ear_care.aspx

Intervention	**36. Adult Snoring Surgery (in the absence of OSA)**
Policy	Snoring is a noise that occurs during sleep that can be caused by vibration of tissues of the throat and palate. It is very common and as many as one in four adults snore, as long as it is not complicated by periods of apnoea (temporarily stopping breathing) it is not usually harmful to health, but can be disruptive, especially to a person's partner. This guidance relates to surgical procedures to remove, refashion or stiffen the tissues of the soft palate (Uvulopalatopharyngoplasty, Laser assisted Uvulopalatoplasty & Radiofrequency ablation of the palate) in an attempt to improve the symptom of snoring. Please note this guidance only relates to patients with snoring in the absence of Obstructive Sleep Apnoea (OSA) and should not be applied to the surgical treatment of patients who snore and have proven OSA who may benefit from surgical intervention as part of the treatment of the OSA. It is important to note that snoring can be associated with multiple other causes such as being overweight, smoking, alcohol or blockage elsewhere in the upper airways (e.g. nose or tonsils) and often these other causes can contribute to the noise alongside vibration of the tissues of the throat and palate.
Rationale	It is on the basis of limited clinical evidence of effectiveness, and the significant risks that patients could be exposed to, this procedure should no longer be routinely commissioned in the management of simple snoring. <u>Alternative Treatments</u> There are a number of alternatives to surgery that can improve the symptom of snoring. These include: • Weight loss • Stopping smoking • Reducing alcohol intake • Medical treatment of nasal congestion (rhinitis) • Mouth splints (to move jaw forward when sleeping) In two systematic reviews of 72 primary research studies there is no evidence that surgery to the palate to improve snoring provides any additional benefit compared to other treatments. While some studies demonstrate improvements in subjective loudness of snoring at 6-8 weeks after surgery; this is not longstanding (> 2years) and there is no long-term evidence of health benefit. This intervention has limited to no clinical effectiveness and surgery carries a 0-16% risk of severe complications (including bleeding, airway compromise and death). There is also evidence from systematic reviews that up to 58-59% of patients suffer persistent side effects (swallowing problems, voice change, globus, taste disturbance & nasal regurgitation). It is on this basis the interventions should no longer be routinely commissioned.

Minimum Eligibility Criteria	This means the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.
Evidence and References	References 1) Franklin KA, Anttila H, Axelsson S, Gislason T, Maasilta P, Myhre KI, Rehnqvist 2) N. Effects and side-effects of surgery for snoring and obstructive sleep apnoea-a systematic review. Sleep. 2009 Jan. 32(1):27-36 3) Main C, Liu Z, Welch K, Weiner G, Jones SQ, Stein K. Surgical procedures and non-surgical devices for the management of non-apnoeic snoring: a systematic review of clinical effects and associated treatment costs. Health Technol Assess 2009;13(3). https://www.ncbi.nlm.nih.gov/pubmed/19091167 4) Jones TM, Earis JE, Calverley PM, De S, Swift AC. Snoring surgery: A retrospective review. Laryngoscope. 2005 Nov 115(11): 2015-20. https://www.ncbi.nlm.nih.gov/pubmed/16319615

Intervention	**37. Tonsillectomy**
Policy	Unless the following criteria are met tonsillectomy for recurrent sore throats is not funded.
Rationale	Recurrent sore throats are a very common condition that presents a considerable health burden. In most cases they can be treated with conservative measures. In some cases, where there are recurrent, documented episodes of acute tonsillitis that are disabling to normal function, then tonsillectomy is beneficial, but it should only be offered when the frequency of episodes set out by the SIGN criteria are met. The surgery carries a small risk of bleeding requiring readmission to hospital (3.5%). A previous national audit quoted a 0.9% risk of requiring emergency surgery to treat bleeding after surgery but in a more recent study of 267, 159 tonsillectomies, 1.88% of patients required a return to theatre. Pain after surgery can be severe (especially in adults) for up to two weeks after surgery; this requires regular painkillers and can cause temporary difficulty swallowing. In addition to bleeding; pain or infection after surgery can require readmission to hospital for treatment. The Getting it Right First Time ENT report is due late 2018 and will present updated figures on readmission rates in relation to tonsillectomy. There is no alternative treatment for recurrent sore throats that is known to be beneficial, however sometimes symptoms improve with a period of observation.
Minimum Eligibility Criteria	The NHS should only commission this surgery for treatment of recurrent severe episodes of sore throat when the following criteria are met, as set out by the SIGN guidance and supported by ENT UK Commissioning Guidance: • Sore throats are due to acute tonsillitis **AND** • The episodes are disabling and prevent normal functioning **AND** • 7 or more documented clinically significant, adequately treated episodes in the preceding year; **OR** • 5 or more documented episodes in each of the preceding two years **OR** • 3 or more documented episodes in each of the preceding three years.

	There are a number of medical conditions where episodes of tonsillitis can be damaging to health or tonsillectomy is required as part of the on-going management. In these instances tonsillectomy may be considered beneficial at a lower threshold than this guidance after specialist assessment: Acute and chronic renal disease resulting from acute bacterial tonsillitis As part of the treatment of severe guttate psoriasis Metabolic disorders where periods of reduced oral intake could be dangerous to health PFAPA (Periodic fever, Apthous stomatitis, Pharyngitis, Cervical adenitis) Severe immune deficiency that would make episodes of recurrent tonsillitis dangerous Further information on the Scottish Intercollegiate Guidelines Network Guidance can be found here: http://www.sign.ac.uk/assets/sign117.pdf Please note this guidance only relates to patients with recurrent tonsillitis. This guidance should not be applied to other conditions where tonsillectomy should continue to be funded, these include: Obstructive Sleep Apnoea / Sleep disordered breathing in Children Suspected Cancer (e.g. asymmetry of tonsils) Recurrent Quinsy (abscess next to tonsil) Emergency Presentations (e.g. treatment of parapharyngeal abscess) It is important to note that national randomised control trial is underway comparing surgery versus conservative management for recurrent tonsillitis in adults in underway which may warrant review of this guidance in the near future. EMIS templates and guidance will aid GPs to refer only those cases that are appropriate. If a referral letter does not clearly indicate that the criteria is met, the referral will be rejected based on inadequate information.
Evidence for inclusion and threshold	References 1) Rubie I, Haighton C, O'Hara J, Rousseau N, Steen N, Stocken DD, Sullivan F, Vale L, Wilkes S, Wilson J. The National randomised controlled Trial of Tonsillectomy IN Adults (NATTINA): a clinical and cost-effectiveness study: study protocol for a randomised control trial. Trials. 2015 Jun 6;16:263. https://www.ncbi.nlm.nih.gov/pubmed/26047934 2) http://www.sign.ac.uk/assets/sign117.pdf 3) Osbourne MS, Clark MPA. The surgical arrest of post-tonsillectomy haemorrhage: Hospital Episode Statistics 12 years on. Annals RCS. 2018. May (100) 5: 406-408

Intervention	**38. Carpal Tunnel Syndrome**
Policy	Unless one or more of the minimum criteria are met, surgical treatment will not be funded.
Rationale	Carpal tunnel syndrome is very common, and mild cases may never require any treatment. Cases which interfere with activities or sleep may resolve or settle to a manageable level with non-operative treatments

	such as a steroid injection (good evidence of short-term benefit (12 weeks) but many progress to surgery within 1 year). Wrist splints worn at night (weak evidence of benefit) may also be used but are less effective than steroid injections and reported as less cost-effective than surgery. In refractory (keeps coming back) or severe case surgery (good evidence of excellent clinical effectiveness and long term benefit) should be considered. The surgery has a high success rate (75 to 90%) in patients with intermittent symptoms who have had a good short-term benefit from a previous steroid injection. Surgery will also prevent patients with constant wooliness of their fingers from becoming worse and can restore normal sensation to patients with total loss of sensation over a period of months. The hand is weak and sore for 3-6 weeks after carpal tunnel surgery but recovery of normal hand function is expected, significant complications are rare (≈4%) and the lifetime risk of the carpal tunnel syndrome recurring and requiring revision surgery has been estimated at between 4 and 15%.
Minimum Eligibility Criteria	Mild cases with intermittent symptoms causing little or no interference with sleep or activities require no treatment. Cases with intermittent symptoms which interfere with activities or sleep should first be treated with: • corticosteroid injection(s) (medication injected into the wrist: good evidence for short (**12 weeks**) term effectiveness) **OR** • night splints (a support which prevents the wrist from moving during the night: not as effective as steroid injections) **Surgical treatment** of carpal tunnel should be considered if one of the following criteria are met: • The symptoms significantly interfere with daily activities and sleep symptoms and have not settled to a manageable level with either one local corticosteroid injection and/or nocturnal splinting for a minimum **of 12 weeks**; **OR** • There is either: • **a permanent** (ever-present) reduction in sensation in the median nerve distribution; **OR** • muscle wasting or weakness of thenar abduction (moving the thumb away from the hand). • Supported by Nerve Conduction Studies
Evidence for inclusion and threshold	References 1) Atroshi I, Flondell M, Hofer M, Ranstam J. Methylprednisolone injections for the carpal tunnel syndrome: a randomized, placebo-controlled trial. Annals of internal medicine. 2013;159(5):309-17 2) Chesterton LS, Blagojevic-Bucknall M, Burton C et al. The clinical and cost- effectiveness of corticosteroid injection versus night splints for carpal tunnel syndrome (instincts trial): An open-label, parallel group, randomised controlled trial. Lancet. 2018, 392: 1423-33 3) Gerritsen AA, de Vet HC, Scholten RJ, Bertelsmann FW, de Krom MC, Bouter LM. Splinting vs surgery in the treatment of carpal tunnel syndrome: A randomized controlled trial. JAMA. 2002, 288: 1245-51

	4) Korthals-de Bos IB, Gerritsen AA, van Tulder MW et al. Surgery is more cost-effective than splinting for carpal tunnel syndrome in the Netherlands: Results of an economic evaluation alongside a randomized controlled trial. BMC Musculoskelet Disord. 2006, 7: 86 5) Louie D , Earp B & Philip Blazar P Long-term outcomes of carpal tunnel release: a critical review of the literature HAND (2012) 7:242–246 6) Marshall S, Tardif G, Ashworth N. Local corticosteroid injection for carpal tunnel syndrome. Cochrane Database Syst Rev. 2007(2):CD001554 7) Page MJ, Massy-Westropp N, O'Connor D, Pitt V. Splinting for carpal tunnel syndrome. Cochrane Database Syst Rev. 2012(7):CD010003 8) Shi Q, MacDermid JC. Is surgical intervention more effective than non- surgical treatment for carpal tunnel syndrome? A systematic review. J Orthop Surg Res. 2011;6:17 9) Stark H, Amirfeyz R. Cochrane corner: local corticosteroid injection for carpal tunnel syndrome. J Hand Surg Eur Vol. 2013;38(8):911-4 10) Royal College of Surgeons: https://publishing.rcseng.ac.uk/doi/10.1308/rcsbull.2017.28 11) 11.Verdugo RJ, Salinas RA, Castillo JL, Cea JG. Surgical versus non-surgical treatment for carpal tunnel syndrome. Cochrane Database Syst Rev. 2008(4):CD001552

Intervention	**39. Dupuytren's Disease**
Policy	Unless one or more of the minimum criteria are met, surgical treatment will not routinely be funded.
Rationale	Contractures left untreated usually progress and often fail to straighten fully with any treatment if allowed to progress too far. Complications causing loss, rather than improvement, in hand function occur more commonly after larger interventions, but larger interventions carry a lower risk of need for further surgery. Common complications after collagenase injection are normally transient and include skin breaks and localised pain. Tendon injury is possible but very rare. Significant complications with lasting impact after needle fasciotomy are very unusual (about 1%) and include nerve injury. Such complications after fasciectomy are more common (about 4%) and include infection, numbness and stiffness.
Minimum Eligibility Criteria	Treatment is not indicated in cases where there is no contracture, and in patients with a mild (less than 20°) contractures, or one which is not progressing and does not impair function An intervention (collagenase injections, needle fasciotomy, fasciectomy and dermofasciectomy) should be considered for: a. finger contractures causing loss of finger extension of 30° or more at the metacarpophalangeal joint or 20° at the proximal interphalangeal joint OR b. severe thumb contractures which interfere with function NICE concluded that collagenase should only be used for: Participants in the ongoing clinical trial (HTA-15/102/04) OR

	Adult patients with a palpable cord if: • there is evidence of moderate disease (functional problems and metacarpophalangeal joint contracture of 30° to 60° and proximal interphalangeal joint contracture of less than 30° or first web contracture) plus up to two affected joints **AND** • needle fasciotomy is not considered appropriate, but limited fasciectomy is considered appropriate by the treating hand surgeon
Evidence for inclusion and threshold	References 1) http://www.bssh.ac.uk/_userfiles/pages/files/Patients/Conditions/Elective/d upuytrens_disease_leaflet_2016.pdf 2) https://cks.nice.org.uk/dupuytrens-disease 3) Crean SM, Gerber RA, Le Graverand MP, Boyd DM, Cappelleri JC. The efficacy and safety of fasciectomy and fasciotomy for Dupuytren's contracture in European patients: a structured review of published studies. J Hand Surg Eur Vol. 2011;36(5):396-407. 4) Krefter C, Marks M, Hensler S, Herren DB, Calcagni M. Complications after treating dupuytren's disease. A systematic literature review. Hand surgery & rehabilitation. 2017, 36: 322-9. 5) NICE 2004. Needle fasciotomy for Dupuytren's contracture. https://www.nice.org.uk/guidance/ipg43 6) 6.NICE, 2017. Collagenase clostridium histolyticum for treating Dupuytren's contracture. : https://www.nice.org.uk/guidance/ta459, 7) Rodrigues JN, Becker GW, Ball C, Zhang W, Giele H, Hobby J, et al. Surgery for Dupuytren's contracture of the fingers. Cochrane Database Syst Rev. 2015(12):CD010143. 8) Scherman P, Jenmalm P, Dahlin LB. Three-year recurrence of Dupuytren's contracture after needle fasciotomy and collagenase injection: a two-centre randomized controlled trial. J Hand Surg Eur Vol. 2018;43(8):836-40. 9) Skov ST, Bisgaard T, Sondergaard P, Lange J. Injectable Collagenase Versus Percutaneous Needle Fasciotomy for Dupuytren Contracture in Proximal Interphalangeal Joints: A Randomized Controlled Trial. J Hand Surg Am. 2017;42(5):321-8 e3. 10) Stromberg J, Ibsen Sorensen A, Friden J. Percutaneous Needle Fasciotomy Versus Collagenase Treatment for Dupuytren Contracture: A Randomized Controlled Trial with a Two-Year Follow-up. J Bone Joint Surg Am. 2018;100(13):1079-86. 11) van Rijssen AL, Gerbrandy FS, Ter Linden H, Klip H, Werker PM. A comparison of the direct outcomes of percutaneous needle fasciotomy and limited fasciectomy for Dupuytren's disease: A 6-week follow-up study. J Hand Surg Am. 2006, 31: 717-25. 12) van Rijssen AL, ter Linden H, Werker PM. Five-year results of a randomized clinical trial on treatment in Dupuytren's disease: Percutaneous needle fasciotomy versus limited fasciectomy. Plast Reconstr Surg. 2012, 129: 469-77

Intervention	**40. Ganglion**

Policy	Most people live comfortably with ganglia and they often resolve spontaneously over time. Ganglion excision can be unnecessary, can cause complications, and recurrence is common following surgery. The complications may be similar to or worse than the original problem. Ganglia are cystic swellings containing jelly-like fluid which form around the wrists or in the hand. In most cases wrist ganglia cause only mild symptoms which do not restrict function, and many resolve without treatment within a year. Wrist ganglion rarely press on a nerve or other structure, causing pain and reduced hand function. Ganglia in the palm of the hand (seed ganglia) can cause pain when carrying objects. Ganglia which form just below the nail (mucous cysts) can deform the nail bed and discharge fluid, but occasionally become infected and can result in septic arthritis of the distal finger joint Ganglion excision should only be offered under the criteria outlined below.
Rationale	Most wrist ganglia get better on their own. Surgery causes restricted wrist and hand function for 4-6 weeks, may leave an unsightly scar and be complicated by recurrent ganglion formation. Aspiration of wrist ganglia may relieve pain and restore hand function, and "cure" a minority (30%). Most ganglia reform after aspiration but they may then be painless. Aspiration also reassures the patient that the swelling is not a cancer but a benign cyst full of jelly. Complication and recurrence are rare after aspiration and surgery for seed ganglia.
Minimum Eligibility Criteria	**Wrist ganglia** • no treatment unless causing pain or tingling/numbness or concern (worried it is a cancer); • surgical excision only considered if aspiration fails to resolve the pain or tingling/numbness and there is restricted hand function. **Seed ganglia that are painful** • puncture/aspirate the ganglion using a hypodermic needle • surgical excision only considered if ganglion persists or recurs after rupture. **Mucous cysts** • no surgery considered unless recurrent spontaneous discharge of fluid or significant nail deformity
Evidence for inclusion and threshold	1) Head L, Gencarelli JR, Allen M, Boyd KU. Wrist ganglion treatment: Systematic review and meta-analysis. J Hand Surg Am. 2015, 40: 546-53 e8. 2) Naam NH, Carr SB, Massoud AH. Intraneural Ganglions of the Hand and Wrist. J Hand Surg Am. 2015 Aug;40(8):1625-30. doi: 10.1016/j.jhsa.2015.05.025. PubMed PMID: 26213199. 3) http://www.bssh.ac.uk/_userfiles/pages/files/Patients/Conditions/Elective/ganglion_cyst_leaflet-2016.pdf

Intervention	**41. Trigger Finger**
Policy	Trigger digit occurs when the tendons which bend the thumb/finger into the palm intermittently jam in the tight tunnel (flexor sheath) through which they run. It may occur in one or several fingers and causes the finger to

	"lock" in the palm of the hand. Mild triggering is a nuisance and causes infrequent locking episodes. Other cases cause pain and loss and unreliability of hand function. Mild cases require no treatment and may resolve spontaneously. Trigger finger often resolves over time and is often a nuisance rather than a serious problem. If treatment is necessary steroid injection can be considered. Surgery should only be offered in specific cases according to NICE accredited guidelines by the British Society for Surgery to the Hand, where alternative measures have not been successful and persistent or recurrent triggering, or a locked finger occurs.
Rationale	Treatment with steroid injections usually resolve troublesome trigger fingers within 1 week (strong evidence) but sometimes the triggering keeps recurring. Surgery is normally successful (strong evidence), provides better outcomes than a single steroid injection at 1 year and usually provides a permanent cure. Recovery after surgery takes 2-4 weeks. Problems sometimes occur after surgery, but these are rare (<3%).
Minimum Eligibility Criteria	Mild cases which cause no loss of function require no treatment or avoidance of activities which precipitate triggering and may resolve spontaneously. Cases interfering with activities or causing pain should first be treated with: a. one or two steroid injections which are typically successful (strong evidence), but the problem may recur, especially in diabetics; **OR** b.. splinting of the affected finger for 3-12 weeks (weak evidence). **Surgery** should be considered if: • the triggering persists or recurs after one of the above measures (particularly steroid 2 injections); **OR** • the finger is permanently locked in the palm; **OR** • the patient has previously had 2 other trigger digits unsuccessfully treated with appropriate non-operative methods; Surgery is usually effective and requires a small skin incision in the palm, but can be done with a needle through a puncture wound (percutaneous release).
Evidence for inclusion and threshold	References 1) https://www.nhs.uk/conditions/trigger-finger/treatment/ 2) Amirfeyz R, McNinch R, Watts A, Rodrigues J, Davis TRC, Glassey N, Bullock J. Evidence-basedmanagementofadulttriggerdigits. J Hand Surg Eur Vol. 2017 Jun;42(5):473-480. doi: 10.1177/1753193416682917. Epub 2016 Dec 21. 3) British Society for Surgery of the Hand Evidence for Surgical Treatment (BEST). http://www.bssh.ac.uk/_userfiles/pages/files/professionals/BEST%20Guideli nes/BEST%20trigger%20finger%20PUBLISHED(1).pdf 4) Chang CJ, Chang SP, Kao LT, Tai TW, Jou IM. A meta-analysis of corticosteroid injection for trigger digits among patients with diabetes. Orthopedics. 2018, 41: e8-e14.

	5) Everding NG, Bishop GB, Belyea CM, Soong MC. Risk factors for complications of open trigger finger release. Hand (N Y). 2015, 10: 297-300. 6) Fiorini HJ, Tamaoki MJ, Lenza M, Gomes Dos Santos JB, Faloppa F, Belloti JC. Surgery for trigger finger. Cochrane Database Syst Rev. 2018 Feb 20;2:CD009860. doi: 10.1002/14651858.CD009860.pub2. Review. 7) Hansen RL, Sondergaard M, Lange J. Open Surgery Versus Ultrasound- Guided Corticosteroid Injection for Trigger Finger: A Randomized Controlled Trial With 1-Year Follow-up. J Hand Surg Am. 2017;42(5):359-66. 8) Lunsford D, Valdes K, Hengy S. Conservative management of trigger finger: A systematic review. J Hand Ther. 2017. 9) Peters-Veluthamaningal C, Winters JC, Groenier KH, Jong BM. Corticosteroid injections effective for trigger finger in adults in general practice: a double-blinded randomised placebo controlled trial. Ann Rheum Dis. 2008 Sep;67(9):1262-6. Epub 2008 Jan 7.

Intervention	**42. Autologous Cartilage Transplant**
Policy	Autologous Cartilage Transplant will not routinely be funded except as part of a randomised controlled trial.
Rationale	NICE guidance states that autologous chondrocyte implantation (ACI) is not recommended for the treatment of articular cartilage defects of the knee joint, except in the context of ongoing or new clinical studies that are designed to generate robust and relevant outcome data, including the measurement of health-related quality of life and long-term follow-up. Patients should be fully informed of the uncertainties about the long-term effectiveness and the potential adverse effects of this procedure.
Minimum eligibility criteria	Only considered as part of a randomised controlled trial or in clinically exceptional circumstances which can be demonstrated via an Individual Funding Request.
Evidence for inclusion and threshold	NICE Guidance TAG 16 (review) - Cartilage injury - autologous chondrocyte implantation: http://www.nice.org.uk/page.aspx?o=72659 National Public Health Service. *Autologous chondrocyte implantation for the ankle joints*. Cardiff: NPHS; 2006.

Intervention	**43. Knee Arthroscopy for patients with Osteoarthritis**
Policy	Arthroscopic washout of the knee is an operation where an arthroscope (camera) is inserted in to the knee along with fluid. Occasionally loose debris drains out with the fluid, or debridement, (surgical removal of damaged cartilage) is performed, but the procedure does not improve symptoms or function of the knee joint. Arthroscopic knee washout (lavage and debridement) should not be used as a treatment for osteoarthritis because it is clinically ineffective. Referral for arthroscopic lavage and debridement should not be offered as part of treatment for osteoarthritis, unless the person has knee osteoarthritis with a clear history of mechanical locking.

	More effective treatment includes exercise programmes (e.g. ESCAPEpain), losing weight (if necessary) and managing pain. Osteoarthritis is relatively common in older age groups. Where symptoms do not resolve after non- operative treatment, referral for consideration of knee replacement, or joint preserving surgery such as osteotomy is appropriate. For further information, please see: https://www.nice.org.uk/guidance/ipg230/evidence/overview-pdf-492463117 https://www.nice.org.uk/guidance/ipg230/chapter/1-Guidance https://www.nice.org.uk/donotdo/referral-for-arthroscopic-lavage-and-debridement-should-not-be-offered-as-part-of-treatment-for-osteoarthritis-unless-the-person-has-knee-osteoarthritis-with-a-clear-history-of-mechanical-locking-not http://www.escape-pain.org/ This means the CCG will only fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.
Rationale	NICE has reviewed the evidence for how well knee washout works for people with osteoarthritis. Seven clinical trials and three case studies have shown that knee wash out for people with osteoarthritis did not reduce pain nor improve how well their knees worked. There was a small increased risk of bleeding inside the knee joint (haemarthrosis) (2%) or blood clot in the leg (deep vein thrombosis) (0.5%).
Evidence and References	References 1) NICE guidance: https://www.nice.org.uk/guidance/ipg230/evidence/overview-pdf-492463117 2) NICE guidance: https://www.nice.org.uk/guidance/ipg230/chapter/1-Guidance 3) NICE guidance: https://www.nice.org.uk/donotdo/referral-for-arthroscopic-lavage-and-debridement-should-not-be-offered-as-part-of-treatment-for-osteoarthritis-unless-the-person-has-knee-osteoarthritis-with-a-clear-history-of-mechanical-locking-not 4) British Orthopaedic Association and the Royal College of Surgeons: https://www.rcseng.ac.uk/-/media/files/rcs/standards-and-research/commissioning/boa--painful-oa-knee-guide-final-2017.pdf 5) Siemieniuk Reed A C, Harris Ian A, Agoritsas Thomas, Poolman Rudolf W, Brignardello-Petersen Romina, Van de Velde Stijn et al. Arthroscopic surgery for degenerative knee arthritis and meniscal tears: a clinical practice guideline BMJ 2017; 357 :j1982 6) Brignardello-Petersen R, Guyatt GH, Buchbinder R, et al Knee arthroscopy versus conservative management in patients with degenerative knee disease: a systematic review BMJ Open 2017;7:e016114. doi: 10.1136/bmjopen-2017-016114` 7) Moseley JB, O'Malley K, Petersen NJ et al. (2002) A controlled trial of arthroscopic surgery for osteoarthritis of the knee. The New England Journal of Medicine 347: 81–8. 8) Hubbard MJS. (1996) Articular debridement versus washout for degeneration of the medial femoral condyle. Journal of Bone and Joint Surgery (British) 78-B: 217–19.

	9) Kalunian KC, Moreland LW, Klashman DJ et al. (2000) Visually-guided irrigation in patients with early knee osteoarthritis: a multicentre randomized controlled trial. Osteoarthritis and Cartilage 8: 412–18. 10) Chang RW, Falconer J, Stulberg SD et al. (1993) A randomized, controlled trial of arthroscopic surgery versus closed-needle joint lavage for patients with osteoarthritis of the knee. Arthritis & Rheumatism 36: 289–96. 11) Forster MC, Straw R. (2003) A prospective randomised trial comparing intra-articular Hyalgan injection and arthroscopic washout for knee osteoarthritis. The Knee 10: 291–3. 12) Jackson RW, Dieterichs C. (2003) The results of arthroscopic lavage and debridement of osteoarthritic knees based on the severity of degeneration: a 4- to 6-year symptomatic follow-up. Arthroscopy: The Journal of Arthroscopic and Related Surgery 19: 13–20. 13) Bernard J, Lemon M, Patterson MH. (2004) Arthroscopic washout of the knee – a 5-year survival analysis. The Knee 11: 233–5.

Intervention	**44. Elective Hip Surgery**
Policy	Referral for elective hip surgery should be considered for people with osteoarthritis who experience the following joint symptoms: • Pain • Stiffness • reduced function The NHS Hip Arthroplasty Surgery Decision Making Tool should be used when arthroplasty is being considered. Patients should be informed that the decision to have surgery can be a dynamic process and a decision to not undergo surgery does not exclude them from having surgery at a future point in time. Hip preserving operations include surgery for impingement and osteotomy for mal-alignment where there is the potential for developing early osteoarthritis, is best performed in centres undertaking high volumes of surgery on young adults' hips.
Rationale	As per NICE guidance, prosthesis should only be used if the evidence shows they require revision at a rate of less than 1 in 10 (10%) in 10 years.
Minimum Eligibility Criteria	Hip replacement/Hip Resurfacing Techniques is commissioned when a patient meets the following criteria; The patient has a BMI less than or equal 35 * supported by a primary care referral **AND** • Conservative means (e.g. Analgesics, NSAIDS, physiotherapy, advice on walking aids, home adaptations, curtailment of inappropriate activities and general counselling as regards to the potential benefits of joint replacement) have failed to alleviate the patients pain and disability **AND** • Pain and disability should be sufficiently significant to interfere with the patients' daily life and or ability to sleep/patients whose pain is so severe **AND** • Patient must accept and want surgery **OR**

	• The destruction of their joint is of such severity that delaying surgical correction would increase technical difficulty of the procedure. • *Patients with a BMI > 35 need to have ***documented evidence*** of completing a primary care weight reduction programme in order to ***attempt*** to reduce their BMI prior to referral. **Total Hip Replacement-** After appropriate diagnosis, consider total hip replacement when a patient meets **all** of the following: • Pain is inadequately controlled by medication • There is restriction of function • The quality of life is significantly compromised • There is narrowing of the joint space on radiograph **Hip Resurfacing Techniques**- (primary resurfacing arthroscopy of joint) Except in the following, metal on metal hip resurfacing techniques are not routinely funded: • Those who qualify for primary total hip replacements **AND** • are likely to outlive conventional primary hip replacements
	• Royal College of Surgeons Commissioning Guide for Painful Osteoarthritis of the Hip (2013) *http://www.rcseng.ac.uk/healthcare-bodies/docs/Painarisingfromthehipinadults.pdf* • NICE Clinical guideline Osteoarthritis CG59 (2008): **Effects of BMI** • Journal of Arthroplasty, 2013, 28(5), p714-721, A workgroup of the American Association of Hip and, Obesity and total joint arthroplasty: a literature based review (attached) "The morbidly obese (BMI >40) and the super obese (BMI >50) have complication profiles that may outweigh the functional benefits of total joint arthroplasty. These patients should be counseled regarding these risks prior to any surgical intervention. It is our consensus opinion that consideration should be given to delaying total joint arthroplasty in a patient with a BMI >40, especially when associated with other comorbid conditions, such as poorly controlled diabetes or malnutrition."

Intervention	**45. Knee Replacement Surgery**
Policy	Referral for joint replacement surgery should be considered for people with osteoarthritis who experience all of the following joint symptoms; • Pain • Stiffness • Reduced function
Minimum Eligibility Criteria	Knee Replacement surgery is commissioned for patients who fulfil ALL of the following criteria; • The patient has a BMI less than or equal 35*supported by a primary care referral **AND** • Conservative means (e.g. Analgesics, NSAIDS, physiotherapy, advice on walking aids, home adaptations, curtailment of inappropriate activities and general counselling as regards to the

	potential benefits of joint replacement) have failed to alleviate the patients pain and disability **AND** • Pain and disability should be sufficiently significant to interfere with the patients' daily life and or ability to sleep/patients whose pain is so severe **AND** • Patient must accept and want surgery **OR** • The destruction of their joint is of such severity that delaying surgical correction would increase technical difficulty of the procedure. * Patients with a BMI > 35 need to have ***documented evidence*** of completing a primary care weight reduction programme in order to ***attempt*** to reduce their BMI prior to referral
Evidence for inclusion and threshold	• Royal College of Surgeons Commissioning Guide for Painful Osteoarthritis of the Knee (2013) *http://www.rcseng.ac.uk/healthcare-bodies/docs/Painfulosteoarthritisoftheknee.pdf* • NICE Clinical guideline Osteoarthritis CG177 (2008): *http://www.nice.org.uk/guidance/cg177/resources/guidance-osteoarthritis-pdf* • Journal of Arthroplasty, 2013, 28(5), p714-721, A workgroup of the American Association of Hip and, Obesity and total joint arthroplasty: a literature based review • Saif Salih* and Paul Sutton (2013). Obesity, knee osteoarthritis and knee arthroplasty: a review. BMC Sports Science, Medicine and Rehabilitation:5(25) (http://www.biomedcentral.com/2052-1847/5/25) • http://www.westessexccg.nhs.uk/Downloads/Your%20NHS/Service%20Restriction%20Policies/Updated/Knee%20Replacement%20%20policy.pdf • http://www.northwestlondon.nhs.uk/_uploads/~filestore/9277007D-B6A0-4817-A767-5080E056A9E9/31%20Knee%20Replacement%20v3.pdf • http://www.cambsphn.nhs.uk/Libraries/Surgical_Threshold_Policies/PRIMARY_KNEE_REPLACEMENT_-_SEPT_2014_V7.sflb.ashx • http://www.shropshireccg.nhs.uk/download.cfm?doc=docm93jijm4n2001.pdf&ver=6416

Intervention	**46. Spinal Fusion for Chronic Low Back Pain**
Policy	Unless all of the following criteria are met Spinal Fusion for Chronic Low Back Pain will not routinely be funded.
Rationale	There is a body of evidence demonstrating that spinal fusion is no more clinically effective or cost-effective than a multi-disciplinary rehabilitation programme (physiotherapy, exercise and psychological input) for chronic (>1 year) degenerative back pain.
Minimum Eligibility Criteria	Unless the following criteria are met spinal fusion will not routinely be funded for chronic degenerative low back pain: • The patient has been assessed by a clinician trained in the diagnosis and management of chronic low back pain **AND** • The low back pain has lasted more than one year and is documented as significantly interfering with daily life (e.g. loss of function > 50% on EuroQol or BPI tool) **AND** • All conservative management functions, undertaken as part of a comprehensive pain management programme, have failed (physiotherapy guided exercise, maximal analgesia and muscle relaxants, psychological therapy)

Evidence for inclusion and threshold	NICE Clinical Guideline 88 - Low Back Pain

Intervention	**47. Joint Injections**
Policy	Wherever possible joint injections should be provided within a Primary Care setting. Joint injections in adults should not be done in a sterile theatre unless general anaesthetic or an image intensifier is required. They will routinely be funded as an outpatient procedure. (This policy statement relates only to adults (i.e. aged 19 and over), as it is recognised that children often require joint injections under general anaesthesia.)

Intervention	**48. Cholecystectomy for Gallstones**
Policy	The removal of the gallbladder for asymptomatic gallstones is regarded as a procedure of low clinical value and therefore not routinely funded by the Commissioner.
Rationale	Gallstones are small stones usually made of cholesterol that form in the gallbladder. In most cases they do not cause any symptoms. Gallstone disease is relatively straightforward to treat. The most widely used treatment is keyhole surgery to remove the gallbladder. Doctors refer to this as a laparoscopic cholecystectomy. Cholecystectomy is the surgical removal of the gall bladder. Prophylactic cholecystectomy is not indicated in most patients with asymptomatic gallstones. The removal of the gallbladder for asymptomatic gallstones is regarded as a procedure of low clinical value and therefore not routinely funded by the Commissioner. **Note:** Patients with suspected gallbladder carcinoma or severe complications should be referred / treated immediately, without delay.
Minimum Eligibility Criteria	**Guidance:** Cholecystectomy for Asymptomatic Gallstones is not routinely commissioned. The majority of people with gallbladder stones remain asymptomatic and require no treatment. For patients with symptoms follow Royal College of Surgeons guidance *Royal College of Surgeons Commissioning Guide: Gallstone disease (2013) and Best Practice Referral Guideline: https://www.rcseng.ac.uk/healthcare-bodies/docs/published-guides/gallstones/view* **RCS Commissioning Guide: Gallstone Disease** **High value care pathway for gallstone disease management** Patients with an incidental finding of stones in an otherwise normal gallbladder require no further investigation or referral. Most patients with symptomatic gallstones present with a self-limiting attack of pain that lasts for hours only. This can often be controlled successfully in primary care with appropriate analgesia, avoiding the

	requirement for emergency admission. When pain cannot be managed or if the patient is otherwise unwell (eg sepsis), he or she should be referred to hospital as an emergency. Further episodes of biliary pain can be prevented in around 30% of patients by adopting a low fat diet. Fat in the stomach releases cholecystokinin, which precipitates gallbladder contraction and might result in biliary pain. Patients with suspicion of acute cholecystitis, cholangitis or acute pancreatitis should be referred to hospital as an emergency. There is no evidence to support the use of hyoscine or proton pump inhibitors in the management of gallbladder symptoms. Antibiotics should be reserved for patients with signs of sepsis. There is no evidence of benefit from the use of non-surgical treatments in the definitive management of gallbladder stones (eg gallstone dissolution therapies, ursodeoxycholic acid or extracorporeal lithotripsy). **Best practice referral guidelines:** • Epigastric or right upper quadrant pain, frequently radiating to the back, lasting for several minutes to hours (often occurring at night) suggests symptomatic gallstones. These patients should have liver function tests checked and be referred for ultrasonography. • Confirmation of symptomatic gallstones should result in a discussion of the merits of a referral to a surgical service regularly performing cholecystectomies. • Following treatment for CBD stones with endoscopic retrograde cholangiopancreatography (ERCP) and sphincterotomy, removal of the gallbladder should be considered in all patients. However, in patients with significant co-morbidities, the risks of surgery may outweigh the benefits **Treatment is available for patients that are at high risk of the following**; • Patients with diabetes mellitus/transplant recipient patients/patients with cirrhosis who have been managed conservatively and subsequently develop symptoms • Where there is clear evidence of patients being at risk of gallbladder carcinoma • Confirmed episode of Gallstone induced pancreatitis • Confirmed episode of Cholecystiti • Episode of obstructive jaundice caused by biliary calculi
Evidence for inclusion and threshold	• NICE CG 188: http://www.nice.org.uk/guidance/cg188/resources/guidance-gallstone-disease-pdf

Intervention	**49. Male Circumcision**
Policy	Unless the following criteria is met circumcision will not be funded. N.B. Female genital circumcision is a separate issue. Any related activity would need to be in accordance with the Female Genital Mutilation Act 2003. The BMA's views on this issue are published in British Medical Association. Female genital mutilation. Caring for patients and child

	protection. London: BMA, 2001. An additional education resource is available from the Royal College of Nursing.
Rationale	Male circumcision is an operation to remove the foreskin (the skin covering the top of the penis). This policy only refers to male circumcision for medical reasons. Dudley CCG does not commission religious circumcision.

Minimum Eligibility Criteria	Circumcision will be funded in the following medical circumstances
	
	• Pathological phimosis
	• Relative indications for circumcision or other foreskin surgery include the following:
	  ○ Prevention of urinary tract infection in patients with an abnormal urinary tract
	  ○ Recurrent paraphimosis
	  ○ Trauma (e.g. zipper injury)
	  ○ Tight foreskin causing pain on arousal/ interfering with sexual function
	  ○ Congenital abnormalities

Evidence for inclusion and threshold	• The Royal College of Surgeons of England and British Associations of Urological Surgeons/ British Associations of Paediatric Surgeons/ British Associations of Paediatric Urologists (2013). Commissioning guide: Foreskin conditions. Available from: http://www.rcseng.ac.uk/providers-commissioners/docs/rcseng-baus-commissioning-guide-on-foreskin-conditions

Intervention	**50. Surgical Haemorrhoidectomy**
Policy	Numerous interventions exist for the management of haemorrhoids (piles). The evidence recommends that surgical treatment should only be considered for haemorrhoids that keep coming back after treatment or for haemorrhoids that are significantly affecting daily life. Changes to the diet like eating more fibre and drinking more water can often help with haemorrhoids. Treatments that can be done in clinic like rubber band ligation, may be effective especially for less severe haemorrhoids.
Rationale	Surgery should be performed, according to patient choice and only in cases of persistent grade 1 (rare) or 2 haemorrhoids that have not improved with dietary changes, banding or perhaps in certain cases injection, and recurrent grade 3 and 4 haemorrhoids and those with a symptomatic external component. Haemorrhoid surgery can lead to complications. Pain and bleeding are common and pain may persist for several weeks. Urinary retention can occasionally occur and may require catheter insertion. Infection, iatrogenic fissuring (tear or cut in the anus), stenosis and incontinence (lack of control over bowel motions) occur more infrequently.
Minimum Eligibility Criteria	Often haemorrhiods (especially early stage haemorrhoids) can be treated by simple measures such as eating more fibre or drinking more water. If these treatments are unsuccessful many patients will respond to outpatient treatment in the form of banding or perhaps injection. Surgical treatment should only be considered for those that do not respond to these non-operative measures or if the haemorrhoids are more severe, specifically:

	• Recurrent grade 3 or grade 4 combined internal/external haemorrhoids with persistent pain or bleeding; **OR** • Irreducible and large external haemorrhoids In cases where there is significant rectal bleeding the patient should be appropriately investigated by a specialist e.g. sigmoidoscopy.
Evidence for inclusion and threshold	References: 1) Watson AJM, Bruhn H, MacLeod K, et al. A pragmatic, multicentre, randomised controlled trial comparing stapled haemorrhoidopexy to traditional excisional surgery for haemorrhoidal disease (eTHoS): study protocol for a randomised controlled trial. Trials. 2014;15:439. doi:10.1186/1745-6215-15-439. 2) Watson AJM, Hudson J, Wood J, et al. Comparison of stapled haemorrhoidopexy with traditional excisional surgery for haemorrhoidal disease (eTHoS): a pragmatic, multicentre, randomised controlled 3) trial. Lancet (London, England). 2016;388(10058):2375-2385. doi:10.1016/S0140-6736(16)31803-7. 4) Brown SR. Haemorrhoids: an update on management. Therapeutic Advances in Chronic Disease. 2017;8(10):141-147. doi:10.1177/2040622317713957. 5) NHS website: https://www.nhs.uk/conditions/piles-haemorrhoids/ 6) Royal College of Surgeons: https://www.rcseng.ac.uk/- 7) /media/files/rcs/standards-and-research/commissioning/rcsacpgbirectalbleeding2017documentfinal_jan18 pdf 8) Health Technol Assess. 2016 Nov;20(88):1-150. The HubBLe Trial: haemorrhoidal artery ligation (HAL) versus rubber band ligation (RBL) for symptomatic second- and third-degree haemorrhoids: a multicentre randomised controlled trial and health-economic evaluation. Brown S et al.

Intervention	**51. Varicose Veins**
Policy	NICE has published detailed guidance on what treatment should be considered for varicose veins and when interventions for varicose veins (endothermal ablation, sclerotherapy or surgery) should be offered. Surgery is a traditional treatment that involves removal of the vein, patients can get recurrence of symptoms which may need further treatment. Treatments like endothermal ablation or ultrasound-guided foam sclerotherapy are less invasive than surgery and have replaced surgery in the management of most patients. However surgery is the most appropriate in some cases. Patients with symptomatic varicose veins should be offered treatment of their varicose veins. Compression hosiery is not recommended if an interventional treatment is possible.
Rationale	International guidelines, NICE guidance and NICE Quality standards provide clear evidence of the clinical and cost-effectiveness that patients with symptomatic varicose veins should be referred to a vascular service for assessment including duplex ultrasound. Open surgery is a traditional treatment that involves surgical removal by 'stripping' out the vein or ligation (tying off the vein), this is still a valuable technique, it is still a clinically and cost-effective treatment technique for

	some patients but has been mainly superseded by endothermal ablation and ultrasound guided foam sclerotherapy. Recurrence of symptoms can occur due to the development of further venous disease that will benefit from further intervention (see above). NICE guidance states that a review of the data from the trials of interventional procedures indicates that the rate of clinical recurrence of varicose veins at 3 years after treatment is likely to be between 10–30%. For people with confirmed varicose veins and truncal reflux NICE recommends: • Offer endothermal ablation of the truncal vein. • If endothermal ablation is unsuitable, offer ultrasound-guided foam sclerotherapy. • If ultrasound-guided foam sclerotherapy is unsuitable, offer surgery. • Consider treatment of tributaries at the same time • Do not offer compression hosiery to treat varicose veins unless interventional treatment is unsuitable. Complications of intervention include recurrence of varicose veins, infection, pain, bleeding, and more rarely blood clot in the leg. Complications of non-intervention include decreasing quality of life for patients, increased symptomatology, disease progression potentially to skin changes and eventual leg ulceration, deep vein thrombosis and pulmonary embolism.
Minimum Eligibility Criteria	1.1 Intervention in terms of, endovenous thermal (laser ablation, and radiofrequency ablation), ultrasound guided foam sclerotherapy, open surgery (ligation and stripping) are all cost effective treatments for managing symptomatic varicose veins compared to no treatment or the use of compression hosiery. For truncal ablation there is a treatment hierarchy based on the cost effectiveness and suitability, which is endothermal ablation then ultrasound guided foam, then conventional surgery. 1.2 Refer people to a vascular service if they have any of the following;- 1) Symptomatic * primary or recurrent varicose veins. 2) Lower-limb skin changes, such as pigmentation or eczema, thought to be caused by chronic venous insufficiency. 3) Recurrent Superficial vein thrombophlebitis (characterised by the appearance of hard, 4) painful veins) and suspected venous incompetence. 5) A venous leg ulcer (a break in the skin below the knee that has not healed within 2 weeks). 6) A healed venous leg ulcer. *Symptomatic: “Veins found in association with troublesome lower limb symptoms (typically pain, aching, discomfort, swelling, heaviness and itching).” For patients whose veins are purely cosmetic and are not associated with any symptoms do not refer for NHS treatment

	1.1 Refer people with bleeding varicose veins to a vascular service immediately. 1.2 Do not offer compression hosiery to treat varicose veins unless interventional treatment is unsuitable. For further information, please see: • https://www.nice.org.uk/guidance/qs67 • https://www.guidelinesinpractice.co.uk/nice-referral-advice-11-varicose- veins/300594.article • https://www.nice.org.uk/guidance/cg168
Evidence for inclusion and threshold	References 1) NICE Guidance: https://www.guidelinesinpractice.co.uk/nice-referral-advice- 11-varicose-veins/300594.article 2) NICE Guidance: https://www.nice.org.uk/guidance/cg168 3) NICE Quality Standard: https://www.nice.org.uk/guidance/qs67 4) Editor's Choice - Management of Chronic Venous Disease: Clinical Practice Guidelines of the European Society for Vascular Surgery (ESVS). Wittens C, Davies AH, Bækgaard N, Broholm R, Cavezzi A, Chastanet S, de WolfM, Eggen C, Giannoukas A, Gohel M, Kakkos S, Lawson J, Noppeney T, Onida S, Pittaluga P, Thomis S, Toonder I, Vuylsteke M, Esvs Guidelines Committee, Kolh P, de Borst GJ, Chakfé N, Debus S, Hinchliffe R, Koncar I, Lindholt J, de Ceniga MV, Vermassen F, Verzini F, Document Reviewers, De Maeseneer MG, Blomgren L, Hartung O, Kalodiki E, Korten E, Lugli M, Naylor R, Nicolini P, Rosales A Eur J Vasc Endovasc Surg. 2015 Jun;49(6):678-737. doi: 10.1016/j.ejvs.2015.02.007. Epub 2015 Apr 25. 5) The care of patients with varicose veins and associated chronic venous diseases: clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum. Gloviczki P1, Comerota AJ, Dalsing MC, Eklof BG, Gillespie DL, Gloviczki ML, Lohr JM, McLafferty RB, Meissner MH, Murad MH, Padberg FT, Pappas PJ, Passman MA, Raffetto JD, Vasquez MA, Wakefield TW; Society for Vascular Surgery; American Venous Forum. J Vasc Surg. 2011 May;53(5 Suppl):2S-48S. doi: 10.1016/j.jvs.2011.01.079.. 6) A Randomized Trial of Early Endovenous Ablation in Venous Ulceration.Gohel MS1, Heatley F1, Liu X1, Bradbury A1, Bulbulia R1, Cullum N1, Epstein DM1, Nyamekye I1, Poskitt KR1, Renton S1, Warwick J1, Davies AH1; EVRA Trial Investigators. N Engl J Med. 2018 May 31;378(22):2105-2114. doi: 10.1056/NEJMoa1801214. Epub 2018 Apr 24

Intervention	**52. Removal of Anal Skin Tags**
Policy Statement	Surgery for anal skin tags will only be performed if there is an urgent clinical need.
Rationale	Hypertrophied papillae, also called anal skin tags, fibro epithelial polyps are common; they arise due to oedema, inflammation, fibrosis. They can protrude into anal canal. They are benign. Their appearance is polypoid and they may resemble haemorrhoids. Microscopically they are projections of sub mucosa and overlying mucosa; squamous epithelium with central core of inflamed, oedematous, myxoid or fibrovascular stroma with thin walled vessels; 80% have large, multinucleated, CD34+ stellate cells, often with atypical nuclear features; frequent mast cells; no thick walled vessels, no organizing thrombi, no haemorrhage. Under the

	electron microscope they consist of fibroblastic and myofibroblastic stromal cells. *Urgent referral* should take place in people with suspected malignancy. For information on Haemorrhoidectomy, please refer to section 50 of the policy.
Minimum Eligibility Criteria	**Not** routinely commissioned surgery for patients with anal skin tags where there is: • Haemorrhoids, pruritis or solely a cosmetic problem • Referral for non-urgent assessment and treatment: This policy **supports** referral where: • Patients with anal skin tags where this forms part of the treatment of an underlying pathology such as inflammatory bowel disease.
Evidence for inclusion and threshold	Kuehn HG,Gebbensleben O,Hilger Y,Rohde H Relationship between anal symptoms and anal findings. International Journal of Medical Sciences, 2009; 6: 1431-42 Bonheur JL,Braunstein J,Korelitz BI,Panagopoulos G Skin tags in inflammatory bowel disease: new observations and a clinical review. Inflammatory Bowel Diseases 2008; 14; 1236-9

Intervention	**53. Hysterectomy for Heavy Menstrual Bleeding**
Policy	NICE recommends that hysterectomy should not be used as a first-line treatment solely for heavy menstrual bleeding (HMB). Heavy periods can be reduced by using medicines or intrauterine systems (IUS) or losing weight (if necessary).
Rationale	NICE's Guideline Development Group considered the evidence (including 2 reviews, four randomised control trials and one cohort study comparing hysterectomy with other treatments) as well as the views of patients and the public and concluded that hysterectomy should not routinely be offered as first line treatment for heavy menstrual bleeding. The Group placed a high value on the need for education and information provision for women with heavy menstrual bleeding. Complications following hysterectomy are usually rare but infection occurs commonly. Less common complications include: intra-operative haemorrhage; damage to other abdominal organs, such as the urinary tract or bowel; urinary dysfunction –frequent passing of urine and incontinence. Rare complications include thrombosis (DVT and clot on the lung) and very rare complications include death. Complications are more likely when hysterectomy is performed in the presence of fibroids (non-cancerous growths in the uterus). There is a risk of possible loss of ovarian function and its consequences, even if their ovaries are retained during hysterectomy. If oophorectomy (removal of the ovaries) is performed at the time of hysterectomy, menopausal-like symptoms occur.
Minimum Eligibility Criteria	Based on NICE guidelines [Heavy menstrual bleeding: assessment and management [NG88] Published date: March2018], hysterectomy should not be used as a first-line treatment solely for heavy menstrual bleeding.

	It is important that healthcare professionals understand what matters most to each woman and support her personal priorities and choices. Hysterectomy should be considered only when: • Other treatment options have failed or are contradicted **AND** • There is a wish for amenorrhoea (no periods) **AND** • The woman (who has been fully informed) requests it **AND** • The woman no longer wishes to retain her uterus and fertility. 1.13.1.1.1 NICE guideline NG88 1.5 Management of HMB 1.5.1 When agreeing treatment options for HMB with women, take into account: the woman's preferences, any comorbidities, the presence or absence of fibroids (including size, number and location), polyps, endometrial pathology or adenomyosis, other symptoms such as pressure and pain. 1.13.1.1.2 Treatments for women with no identified pathology, fibroids less than 3 cm in diameter, or suspected or diagnosed adenomyosis 1.5.2 Consider an LNG-IUS (levonorgestrel-releasing intrauterine system) as the first treatment for HMB in women with: no identified pathology or fibroids less than 3 cm in diameter, which are not causing distortion of the uterine cavity or suspected or diagnosed adenomyosis. 1.5.3 If a woman with HMB declines an LNG-IUS or it is not suitable, consider the following pharmacological treatments: non-hormonal: tranexamic acid, NSAIDs (non-steroidal anti-inflammatory drugs), hormonal: combined hormonal contraception, cyclical oral progestogens. 1.5.4 Be aware that progestogen-only contraception may suppress menstruation, which could be beneficial to women with HMB. 1.5.5 If treatment is unsuccessful, the woman declines pharmacological treatment, or symptoms are severe, consider referral to specialist care for: investigations to diagnose the cause of HMB, if needed, taking into account any investigations the woman has already had and alternative treatment choices, including: pharmacological options not already tried (see recommendations 1.5.2 and 1.5.3), surgical options: second-generation endometrial ablation, hysterectomy. 1.5.6 For women with submucosal fibroids, consider hysteroscopic removal. 1.13.1.1.3 Treatments for women with fibroids of 3 cm or more in diameter 1.5.7 Consider referring women to specialist care to undertake additional investigations and discuss treatment options for fibroids of 3 cm or more in diameter. 1.5.8 If pharmacological treatment is needed while investigations and

	definitive treatment are being organised, offer tranexamic acid and/or NSAIDs. 1.5.9 Advise women to continue using NSAIDs and/or tranexamic acid for as long as they are found to be beneficial. 1.5.10 For women with fibroids of 3 cm or more in diameter, take into account the size, location and number of fibroids, and the severity of the symptoms and consider the following treatments: pharmacological: non-hormonal: tranexamic acid, NSAIDs, hormonal: LNG-IUS, combined hormonal contraception, cyclical oral progestogens, uterine artery embolization, surgical: myomectomy, hysterectomy. 1.5.12 Be aware that the effectiveness of pharmacological treatments for HMB may be limited in women with fibroids that are substantially greater than 3 cm in diameter. 1.5.13 Prior to scheduling of uterine artery embolisation or myomectomy, the woman's uterus and fibroid(s) should be assessed by ultrasound. If further information about fibroid position, size, number and vascularity is needed, MRI should be considered. [2007] 1.5.14 Consider second-generation endometrial ablation as a treatment option for women with HMB and fibroids of 3 cm or more in diameter who meet the criteria specified in the manufacturers' instructions. 1.5.15 If treatment is unsuccessful: consider further investigations to reassess the cause of HMB, taking into account the results of previous investigations and offer alternative treatment with a choice of the options described in recommendation 1.5.10. 1.5.16 Pretreatment with a gonadotrophin-releasing hormone analogue before hysterectomy and myomectomy should be considered if uterine fibroids are causing an enlarged or distorted uterus. For further information, please see: https://www.nice.org.uk/guidance/ng88. https://www.nhs.uk/conditions/heavy-periods/#Causes
Evidence for inclusion and threshold	1) NICE guidance: https://www.nice.org.uk/guidance/ng88. 2) NHS website: https://www.nhs.uk/conditions/heavy-periods/#Causes 3) Hurskainen R, Teperi J, Rissanen P, et al. Clinical outcomes and costs with the levonorgestrel-releasing intrauterine system or hysterectomy for treatment of menorrhagia: randomized trial 5-year follow-up. JAMA: the journal of the American Medical Association 2004;291(12):1456–63. 4) Learman LA, Summitt Jr RL, Varner RE, et al. Hysterectomy versus expanded medical treatment for abnormal uterine bleeding: Clinical outcomes in the medicine or surgery trial. Obstetrics and Gynecology 2004;103(5 I):824–33. 5) Zupi E, Zullo F, Marconi D, et al. Hysteroscopic endometrial resection versus laparoscopic supracervical hysterectomy for menorrhagia: a prospective randomized trial. American Journal of Obstetrics and Gynecology 2003;188(1):7–12.

	6) Lethaby A, Hickey M, Garry R. Endometrial destruction techniques for heavy menstrual bleeding. Cochrane Database Syst Rev. 2005 Oct 19;(4):CD001501. Review. Update in: Cochrane Database Syst Rev. 2009;(4):CD001501. PubMed PMID: 16235284. 7) Hehenkamp WJ, Volkers NA, Donderwinkel PF, et al. Uterine artery embolization versus hysterectomy in the treatment of symptomatic uterine fibroids (EMMY trial): peri- and postprocedural results from a randomized controlled trial. American Journal of Obstetrics and Gynecology 2005;193(5):1618–29. 8) Pinto I, Chimeno P, Romo A, et al. Uterine fibroids: uterine artery embolization versus abdominal hysterectomy for treatment – a prospective, randomized, and controlled clinical trial. Radiology 2003;226(2):425–31.

Intervention	**54. Diagnostic Hysteroscopy for Menorrhagia**
Policy	Menorrhagia is menstrual blood loss which interferes with a woman's physical, emotional, social, and material quality of life, and which can occur alone or in combination with other symptoms. Hysteroscopy for Menorrhagia is not routinely commissioned by the CCG.
Rationale	There are a number of studies and systematic reviews examining the investigation and management of menorrhagia. The following policy statements for the funding of hysteroscopy in this condition are based upon 2007 NICE guidance.
Minimum Eligibility Criteria	Hysteroscopy is not routinely funded for the management of menorrhagia. N.B. It is recognised that hysteroscopy may be required to confirm placement of devices for ablative procedures, but it is anticipated that this will not attract additional funding.
Evidence for inclusion and threshold	**NICE Clinical guideline - Heavy menstrual bleeding CG44 (2007): http://www.nice.org.uk/guidance/cg44/resources/guidance-heavy-menstrual-bleeding-pdf**

Intervention	**55. Dilation and Curettage (D & C) for Heavy Menstrual Bleeding in Women**
Policy	NICE guidelines recommend that D&C is not offered as a diagnostic or treatment option for heavy menstrual bleeding, as there is very little evidence to suggest that it works to investigate or treat heavy periods. Ultrasound scans and camera tests, with sampling of the lining of the womb (hysteroscopy and biopsy), can be used to investigate heavy periods. Medication and intrauterine systems (IUS), as well as weight loss (if appropriate) can treat heavy periods.
Rationale	NICE guidelines recommend that D&C is not offered as a treatment option for heavy menstrual bleeding. There is very little evidence to suggest that D&C works to treat heavy periods and the one study identified by NICE showed the effects were only temporary. D&C should not be used to investigate heavy menstrual bleeding as hysteroscopy and biopsy work better. Complications following D&C are rare but include uterine perforation, infection, adhesions (scar tissue) inside the uterus and damage to the cervix.
Minimum Eligibility Criteria	D&C should not be used for diagnosis or treatment for heavy menstrual bleeding in women because it is clinically ineffective.

	UIltrasound scans and camera tests with sampling of the lining of the womb (hysteroscopy and biopsy) can be used to investigate heavy periods. Medication and intrauterine systems (IUS) can be used to treat heavy periods. For further information, please see: https://www.nice.org.uk/guidance/ng88 https://www.nhs.uk/conditions/hysteroscopy/#alternatives-to-hysteroscopy
Evidence and References	1) NICE guidance: https://www.nice.org.uk/guidance/ng88 2) NHS advice: https://www.nhs.uk/conditions/hysteroscopy/#alternatives-to-hysteroscopy 3) MacKenzie IZ, Bibby JG. Critical assessment of dilatation and curettage in 1029 women. Lancet 1978;2(8089):566–8. 4) Ben-Baruch G, Seidman DS, Schiff E, et al. Outpatient endometrial sampling with the Pipelle curette. Gynecologic and Obstetric Investigation 1994;37(4):260–2. 5) Gimpelson RJ, Rappold HO. A comparative study between panoramic hysteroscopy with directed biopsies and dilatation and curettage. A review of 276 cases. American Journal of Obstetrics and Gynecology 1988;158(3 Pt 1):489–92. 6) Haynes PJ, Hodgson H, Anderson AB, et al. Measurement of menstrual blood loss in patients complaining of menorrhagia. British Journal of Obstetrics and Gynaecology 1977;84(10):763–8.

Intervention	**56. Reversal of Male Sterilisation**
Policy	Reversal of male sterilisation is not commissioned.
Rationale	Reversal of male sterilisation is a surgical procedure that involves the reconstruction of the vas deferens. Sterilisation procedures are available on the NHS and couples seeking sterilisation should be fully advised and counselled that the procedure is intended to be permanent.
Minimum Eligibility Criteria	Male sterilisation is provided by the NHS as an irreversible procedure. This should be made clear to patients at referral and prior to treatment. Reversal of NHS sterilisation is not commissioned except in clinically exceptional circumstances and not to restore fertility.
Evidence for inclusion and threshold	Royal College of Obstetricians and Gynaecologists. Guideline summary - Male and Female Sterilisation, RCOG 1998.

Intervention	**57. Reversal of Female Sterilisation**
Policy	Reversal of female sterilisation is not commissioned.
Rationale	Reversal of sterilisation is a surgical procedure that involves the reconstruction of the fallopian tubes. One study of 85 women concluded that reversal of sterilisation is a safe and effective method of restoring fertility. Sterilisation procedures are available on the NHS and couples seeking sterilisation should be fully advised and counselled (in accordance with RCOG guidelines) that the procedure is intended to be permanent.
Minimum Eligibility Criteria	Reversal of Female sterilisation will not be funded.

	An Individual Funding Request may be submitted for consideration of the intervention, providing there is a clinical need, however, clinically exceptionality will need to be demonstrated. Funding is not available for restoration of fertility.
Evidence for inclusion and threshold	RCOG - Male and Female Sterilisation, Evidence-based Clinical Guideline Number 4 (Jan 2004) http://www.rcog.org.uk/files/rcog-corp/uploaded-files/NEBSterilisationFull060607.pdf

Intervention	**58. Routine Doppler Ultrasound Of Umbilical and Uterine Artery In Antenatal Care**
Policy	Routine doppler ultrasound of umbilical and uterine arteries will not routinely be funded for low risk pregnancies.
Rationale	Existing data does not provide conclusive evidence that the use of routine umbilical artery doppler ultrasound, or combination of umbilical and uterine artery doppler ultrasound in low-risk or unselected populations benefits either mother or baby. At present, doppler ultrasound examination should be reserved for use in high-risk pregnancies.
Minimum Eligibility Criteria	Routine doppler ultrasound of umbilical and uterine arteries will not routinely be funded for low risk pregnancies.
Evidence for inclusion and threshold	NICE Guidance CG 62: Antenatal care: routine care for the healthy pregnant woman: http://guidance.nice.org.uk/CG62

Intervention	**59. Back Pain - Non Specific, Specific & Chronic Back Pain**
Policy	Back Pain Back pain is a common problem that affects most people at some point in their life. The pain can be triggered by bad posture while sitting or standing, bending awkwardly, or lifting incorrectly. Back pain is not generally caused by a serious condition and; in most cases; it gets better within 12 weeks. It can usually be successfully treated by taking painkillers and keeping mobile In most cases, the pain disappears within six weeks but may come back (recur) from time to time. Chronic (persistent) pain develops in some cases and further treatment may then be needed. **Non Specific Back Pain without sciatica** NICE recommends that spinal injections should not be offered for non-specific low back pain. Alternative options like pain management and physiotherapy have been shown to work. **Chronic Back Pain** Chronic pain tends to be very difficult to manage because of its complex natural history, unclear aetiology and poor response to therapy. Chronic pain is characterised by pain which persists despite adequate time for healing. There is no clear definition but it is often defined as pain that has been present for more than 12 weeks.
Minimum Eligibility Criteria	For Non Specific Back Pain Spinal injections of local anaesthetic and steroid should not be offered for patients with non-specific low back pain.

	For people with non-specific low back pain the following injections should **no**t be offered: • facet joint injections • therapeutic medial branch blocks • intradiscal therapy • prolotherapy • Trigger point injections with any agent, including botulinum toxin • Epidural steroid injections for chronic low back pain or for neurogenic claudication in patients with central spinal canal stenosis • Any other spinal injections not specifically covered above Radiofrequency denervation can be offered according to NICE guideline (NG59) if all non-surgical and alternative treatments have been tried and there is moderate to severe chronic pain that has improved in response to diagnostic medical branch block. Epidurals (local anaesthetic and steroid) should be considered in patients who have acute and severe lumbar radiculopathy at time of referral. Alternative and less invasive options have been shown to work e.g. exercise programmes, behavioural therapy, and attending a specialised pain clinic. Alternative options are suggested in line with the National Back Pain Pathway. For further information, please see: https://www.nice.org.uk/guidance/ng59 **For Specific Back Pain** Interventional pain therapies should be part of comprehensive treatment by a multidisciplinary team (MDT) where there should be arrangements for on-going assessment following a trial of treatment to show evidence of response. Facet Joint Injections & Medial Branch Block or Spinal/Epidural injections should be part of comprehensive treatment by an MDT. • Diagnostic Facet Joint injections are only commissioned for the assessment of patients being considered for surgical management of chronic back pain performed by a clinician trained in back pain assessment, diagnosis and management as part of an MDT process. - This should be used as a screening tool to improve specificity if radiofrequency lesioning is being considered **OR** **One injection will be funded if a patient meets ALL of the following criteria;** • Pain lasting more than or equal to 12 months **AND** • Failed conservative treatment including maximum oral and topical analgesia **AND** • A Clinician trained in back pain assessment, diagnosis and management has assessed the patient and considers it would enable mobilisation and participation in rehabilitation as part of an MDT approach **AND**

	• Documented use of a standardised Pain and Quality Of Life (QOL) tool before and after procedure. Further injections will only be funded as part of a pain management pathway if significant improvement (50%) is seen on PAIN score & QOL score. **No more than a total of TWO injection sessions will be funded.** **Chronic Back Pain** Chronic pain tends to be very difficult to manage because of its complex natural history, unclear aetiology and poor response to therapy. Chronic pain is characterised by pain which persists despite adequate time for healing. There is no clear definition but it is often defined as pain that has been present for more than 12 weeks. Chronic pain is not simply a physical problem. It is often associated with severe and extensive psychological, social and economic factors. Apart from poor general physical health and disability there may also be depression, unemployment, and family stress. Many of these factors interact and the whole picture needs to be considered when managing individual patients. The impact of chronic pain on patients' lives varies from minor restrictions to complete loss of independence. **Eligibility Criteria** **Radiofrequency & Endothermal Ablation for Chronic Back Pain - Denervation of Lumbar Spine:** Radiofrequency denervation should be part of comprehensive treatment by a multidisciplinary team. There should be ongoing assessment following a trial of treatment to show evidence of response. • One diagnostic Medial Branch block will be funded. In the event of a positive outcome, *one further* diagnostic branch block will be funded prior to denervation techniques. Radiofrequency denervation should only be undertaken after a successful - >50% improvement on a validated scoring tool - following one set of diagnostic local anaesthetic blocks and as part of a MDT managed programme of care. Repeat radiofrequency procedure may only be offered to those patients with a previous successful response (as above) if the benefits of the procedure lasted for at least 6 months for a maximum of 2 treatments consistent with facet joint injections. Repeat radiofrequency denervation is only permitted at a minimum interval of 12 months. Therefore those patients who consistently experience less than 12 months relief following two radiofrequency procedures will not be offered further radiofrequency treatment

	Spinal Cord Stimulation for chronic back pain Spinal Cord Stimulation for Chronic pain of Neuropoathic or Ischaemic origin is **ONLY** commissioned in accordance with criteria NICE TA159
Rationale	NICE guidelines recommend that spinal injections should not be offered for non- specific low back pain. Radiofrequency denervation (to destroy the nerves that supply the painful facet joint in the spine) can be considered in some cases as per NICE guidance. Exclusion criteria for the NICE (NG59) include: Conditions of a non-mechanical nature, including; • Inflammatory causes of back pain (for example, ankylosing spondylitis or diseases of the viscera) • Serious spinal pathology (for example, neoplasms, infections or osteoporotic collapse) Neurological disorders (including cauda equina syndrome or mononeuritis) Adolescent scoliosis Not covered were conditions with a select and uniform pathology of a mechanical nature (e.g. spondylolisthesis, scoliosis, vertebral fracture or congenital disease) Other agreed exclusions by the GDG are: Pregnancy-related back pain, Sacroiliac joint dysfunction, Adjacent-segment disease, Failed back surgery syndrome, Spondylolisthesis and Osteoarthritis. NICE recommends the following approach for non-surgical invasive treatments for low back pain and sciatica in over 16s Spinal injections 1.3.1 Do not offer spinal injections for managing non-specific low back pain. Radiofrequency denervation 1.3.2 Consider referral for assessment for radiofrequency denervation for people with non-specific low back pain when non-surgical treatment has not worked for them and the main source of pain is thought to come from structures supplied by the medial branch nerve and they have moderate or severe levels of localised back pain (rated as 5 or more on a visual analogue scale, or equivalent) at the time of referral. 1.3.3 Only perform radiofrequency denervation in people with non-specific low back pain after a positive response to a diagnostic medial branch block. 1.3.4 Do not offer imaging for people with non-specific low back pain with specific facet join pain as a prerequisite for radiofrequency denervation.
Evidence for inclusion and threshold	1) NICE guidance: https://www.nice.org.uk/guidance/ng59, 2) United Kingdom Spine Societies Board: https://www.ukssb.com/improving- spinal-care-project

	3) Benyamin RM, Manchikanti L, Parr AT, Diwan S, Singh V, Falco FJ, et al.The effectiveness of lumbar interlaminar epidural injections in managing chronic low back and lower extremity pain. Pain Physician. 2012 Jul- Aug;15(4):E363-404. 4) Choi HJ, Hahn S, Kim CH, Jang BH, Park S, Lee SM, et al. Epidural steroid injection therapy for low back pain: a meta-analysis. Int J Technol Assess Health Care. 2013 Jul;29(3):244-53. 5) Cohen SP, Bicket MC, Jamison D, Wilkinson I, Rathmell JP. Epidural steroids: a comprehensive, evidence-based review. Reg Anesth Pain Med. 2013 May- Jun;38(3):175-200. 6) Royal College of Anaesthetists: https://www.rcoa.ac.uk/document-store/core-standards-pain-management-services-the-uk

Intervention	**60. Cataract Surgery**
Policy	A cataract is when the lens of an eye becomes cloudy and affects vision. Cataracts most commonly occur in older people and develop gradually. Cataracts can usually be treated with a routine day case operation where the cloudy lens is removed and is replaced with an artificial plastic lens (an Intraocular Implant).
Minimum Eligibility Criteria	Cataracts eye surgery is commissioned for both first and second eyes, when a patient meets the following criteria for each eye: • The patient should have sufficient cataract to account for the visual symptoms (6/9 or worse*) AND • Should affect the patient's lifestyle • Difficulty carrying out everyday tasks such as recognising faces, watching TV, cooking, playing sport/cards etc. • Reduced mobility, unable to drive or experiencing difficulty with steps or uneven ground. • Ability to work, give care or live independently is affected This information together with a report from a recent sight test should form the minimum data on the referral form. Other indications for cataract surgery include; facilitating treatment for **one or more** of the following; • Monitoring posterior segment disease e.g. diabetic retinopathy • Correcting anisometropia • Patient with Glaucoma who require cataracts surgery to contract intraocular pressure <u>Patients with Single Sight (Monocular Vision):</u> The indications for cataract surgery in patients with monocular vision and those with severe reduction in one eye e.g. dense amblyopia are the same as for patients with binocular vision, but the ophthalmologist should explain the possibility of total blindness if severe complications occur. *Please note: - Cataracts causing glare or starburst effect when driving, will be considered even if the visual acuity is better than 6/9
Evidence for inclusion and threshold	Health Information and Quality Authority (2013) Health Technology Assessment of Scheduled Surgical Procedures: Cataract Surgery. Available at: http://www.hiqa.ie/system/files/HTA-Cataract-Surgery-April13.pdf

	Royal College of Ophthalmology (2015) Commissioning Guide: Cataract Surgery. Available at: https://www.rcophth.ac.uk/wp-content/uploads/2015/03/Commissioning-Guide-Cataract-Surgery-Final-February-2015.pdf The Royal College of Ophthalmologists' National Ophthalmology Database shows that, for the period 2006-2010, 3%, 5% and 36% of eyes undergoing cataract surgery have preoperative visual acuities of better than or equal to 0.00, 0.18 and 0.30 logMAR respectively (equivalent to 6/6, 6/9 and 6/12 Snellen)9 indicating that before restrictions on access to cataract surgery based on visual acuity were commonplace, eyes with visual acuities of 6/9 or better accounted for less than 10% of cataract surgery. DVLA Driving Standards. Available at: https://www.gov.uk/driving-eyesight-rules

Intervention	**61. Laser Surgery for Short Sight (Myopia)**
Policy	Laser surgery for correction of short sight is not funded.
Rationale	Current evidence suggests that photorefractive (laser) surgery for the correction of refractive errors is safe and efficacious in appropriately selected patients. Refractive errors are usually corrected by wearing spectacles or contact lenses, and these treatments are currently not available on the NHS. Both have limitations and contact lens wear is associated with an increased risk of sight-threatening corneal infection. Surgical treatments have been developed to permanently improve refraction by re-shaping the cornea.
Minimum Eligibility Criteria	Laser surgery for correction of short sight will not routinely be funded
Evidence for inclusion and threshold	NICE IPG 164 - Photorefractive (laser) surgery for the correction of refractive errors.

Intervention	**62. Dental – Including Apicectomy, Dental Implants & Wisdom Teeth Removal**
Statement	These areas are now commissioned by NHS England, please contact the local NHSE area team for further information.

Intervention	**63. Botulinum Toxin Type A for Hyperhidrosis**
Policy	Botulinum Toxin for Hyperhidrosis is not routinely commissioned.
Rationale	Normal sweating helps to keep the body temperature steady in hot weather, during a high temperature (fever) or when exercising. Excessive sweating (hyperhidrosis) means sweating more than normal. Botulinum toxin injections works well for armpit sweating. Treatment consists of many small injections just under the skin in the affected areas. The Botulinum toxin stops the nerves in the skin that control the sweat glands from working. Botulinum toxin is not licensed to treat sweating of the palms and face. This is because there is a risk that the injections may stop some of the nearby small muscles of the hands or face from working. Botulinum toxin type A for hyperhidrosis is not routinely commissioned.

	This policy does not preclude individual patients being referred to the Individual Funding Request Panel where the referrer feels that the therapy may be appropriate and where the referrer can demonstrate that the patient's condition and presentation is clinically exceptional and significantly different from other cohort of patients.

Intervention	**64. Botulinum Toxin Type A - Spasticity**
Policy	Botulinum Toxin Type A will not be funded for the following treatments; • Cosmetic Reasons
Rationale	Spasticity is a significant feature of an upper motor neurone syndrome, which occurs quite commonly in many neurological conditions like stroke, multiple sclerosis, brain injury, cerebral palsy etc. It can lead to disabling complications like contractures and pressures sores, which in turn places a huge burden on the patient, family, social services and the NHS. [£10,551 for one pressure sore]. Prompt and effective management of spasticity by a multi-modal, multi-agency approach co-ordinated by an interdisciplinary team can prevent these complications. It is estimated that approximately one-third of stroke patients (van Kuijk et al 2007; Watkins et al 2002), 60% of patients with severe multiple sclerosis (MS) and 75% of patients with physical disability following severe traumatic brain injury will develop spasticity requiring specific treatment. Of these, approximately one-third may require treatment with Botulinum Toxin injections. (Verplancke et al 2005). BTA has been used for Management of spasticity since 1989 and its use is further recommended in the UK National Guidelines 2009. Effective management of spasticity using Botulinum Toxin injections can lead to benefits: • At impairment level: reduce pain; prevent pressure sores and contractures; improved seating etc. • At activity level: improved mobility; increase in an ability to use limbs for function like feeding, dressing, grooming; reduce carer burden and at participation level: improve self-esteem and self-image; facilitate social interaction etc. This should be supplemented by; a. Use of other pharmacological agents: oral anti-spasticity agents like baclofen, tizanidine etc, phenol nerve blockade b. Non-pharmacological interventions including effective management of noxious stimuli like constipation, bladder and skin issues c. Post injection goal-oriented therapy input and d. Liaising with and incorporating the support of allied agencies like Orthotics, Wheelchair services, Social Services etc. e. The clinical benefit can persist for many months (particularly when accompanied by an appropriate physical management regimen) but wears off gradually. Repeat injections generally follow a similar course. Experience in other neurological conditions has demonstrated that spasticity in adults may become biologically resistant to BTA as a result of antibody formation, especially with frequent, large dose injections (Greene and Fahn 1992, 1993; Hambleton and Moore1995).

	This has led to the general advice to avoid repeated injection at less than three month intervals. Although secondary non-response is theoretically an issue for the use of BTA in spasticity, it is rarely reported in practice. This may be because spasticity is often self-limiting in the course of natural recovery, e.g. following stroke or brain injury, so that long-term repeated injections are required for only a minority of patients.
Minimum Eligibility Criteria	Spasticity Botulinum Toxin Type A will be funded when medically necessary for Spasticity when the following criteria are met: 1. Spasticity due to a diagnosed neurological condition: a) Stroke b) Multiple Sclerosis [MS] c) Acquired Brain Injury- Traumatic and Non-Traumatic d) Acquired Spinal Injury: Traumatic and Non-traumatic e) Motor Neurone Disease [MND] f) Parkinson's disease g) Miscellaneous condition 2. Spasticity not responding to physical therapy and oral anti-spasticity agents 3. Focal spasticity and not generalised spasticity [therefore not needing systemic oral agents] 4. To improve function in upper and lower limbs 5. To facilitate therapy/ splinting/orthotics/positioning 6. To facilitate carer input/ reduce carer burden 7. To prevent severe complications which require expensive interventions like pressure sores, contractures etc 8. Reduce severe pain from spasticity in spite of optimal treatment with different pharmacological agents, positioning etc **Please Note:** funding will be approved on an ongoing basis however, the Provider will avoid repeated injection with intervals less than three months. **Note:** Patients who are not eligible for treatment under this policy may be considered on an individual basis where their GP or consultant believes clinically exceptional circumstances exist, that warrant deviation from the rule of this policy. Individual cases will be reviewed at the Individual Funding Request Panel upon receipt of a completed application form from the Patient's GP, Consultant or Clinician. Applications cannot be considered from patients personally.

Evidence for inclusion and threshold	• Royal College of Physicians **Spasticity in adults: management using botulinum toxin** National guidelines (2009): *https://www.rcplondon.ac.uk/sites/default/files/documents/spasticity-in-adults-management-botulinum-toxin.pdf*
	
	2.1 Patients should be selected for BT on the basis of:
	• focal or multifocal problems due to spasticity
	• a dynamic spastic component as opposed to contracture
	• clearly identified goals for treatment and anticipated functional gains
	• NICE Clinical guideline Spasticity **in children and young people** with non-progressive brain disorders CG145 (2012):
	
	1.5 Botulinum toxin type A
	
	General principles
	
	1.5.1 Consider botulinum toxin type A treatment in children and young people in whom focal spasticity of the upper limb is:
	
	• impeding fine motor function
	• compromising care and hygiene
	• causing pain
	• impeding tolerance of other treatments, such as orthoses
	• causing cosmetic concerns to the child or young person.
	
	1.5.2 Consider botulinum toxin type A[5] treatment where focal spasticity of the lower limb is:
	• impeding gross motor function
	• compromising care and hygiene
	• causing pain
	• disturbing sleep
	• impeding tolerance of other treatments, such as orthoses and use of equipment to support posture
	• causing cosmetic concerns to the child or young person.
	
	1.5.3 Consider botulinum toxin type A[5] treatment after an acquired non-progressive brain injury if rapid-onset spasticity is causing postural or functional difficulties.
	
	1.5.4 Consider a trial of botulinum toxin type A[6] treatment in children and young people with spasticity in whom focal dystonia is causing serious problems, such as postural or functional difficulties or pain.
	
	1.5.5 Do not offer botulinum toxin type A treatment if the child or young person:
	• has severe muscle weakness
	• had a previous adverse reaction or allergy to botulinum toxin type A
	• is receiving aminoglycoside treatment.
	
	1.5.6 Be cautious when considering botulinum toxin type A treatment if:
	• the child or young person has any of the following:
	  ○ a bleeding disorder, for example due to anti-coagulant therapy
	  ○ generalised spasticity

	○ fixed muscle contractures ○ marked bony deformity or • there are concerns about the child or young person's likelihood of engaging with the post-treatment adapted physical therapy programme (see recommendation 1.2.15). 1.5.7 When considering botulinum toxin type A treatment, perform a careful assessment of muscle tone, range of movement and motor function to: • inform the decision as to whether the treatment is appropriate • provide a baseline against which the response to treatment can be measured. A physiotherapist or an occupational therapist should be involved in the assessment. 1.5.8 When considering botulinum toxin type A treatment, give the child or young person and their parents or carers information about: • the possible benefits and the likelihood of achieving the treatment goals • what the treatment entails, including: ○ the need for assessments before and after the treatment ○ the need to inject the drug into the affected muscles ○ the possible need for repeat injections ○ the benefits, where necessary, of analgesia, sedation or general anaesthesia ○ the need to use serial casting or an orthosis after the treatment in some cases • possible important adverse effects (see also recommendation 1.5.10). 1.5.9 Botulinum toxin type A treatment (including assessment and administration) should be provided by healthcare professionals within the network team who have expertise in child neurology and musculoskeletal anatomy.

Intervention	**65. Complementary Medicines/Therapies**
Policy	**Complementary therapies listed below will not be funded.**
Rationale	Complementary and alternative therapy covers a wide range of therapies some of which lack evidence of effectiveness and are not supported by Dudley CCG. There is no national policy for the use of complementary and alternative therapies. Complementary and alternative therapies listed below are not routinely funded. Active release technique. Acupressure, Aimspro, AMMA therapy, Antineoplastons, Antineoplaston therapy and sodium Phenylbutyrate; Apitherapy; Applied kinesiology; Art therapy; Auto urine therapy;Bioenergetic therapy; Biofield Cancell (Entelev) cancer therapy; Bioidentical hormones;Carbon dioxide therapy; Cellular therapy; Chelation therapy for Atherosclerosis; Chung Moo Doe therapy; Coley's toxin; Colonic irrigation; Conceptual mind-body techniques; Craniosacral therapy; Cupping;

	Dance/Movement therapy; Digital myography; Ear Candling; Egoscue method; Electrodiagnosis according to Voll (EAV); Equestrian therapy; Essential Metabolics Analysis (EMA); Essiac; Feldenkrais method of exercise therapy; Flower essence; Fresh cell therapy; Functional intracellular analysis; Gemstone therapy; Gerson therapy; Glyconutrients; Graston technique; Greek cancer cure; Guided imagery; Hair analysis; Hako-Med machine (electromedical horizontal therapy); Hellerwork; Homeopathy; Hoxsey method; Humor therapy; Hydrazine sulphate; Hypnosis; Hyperoxygen therapy; Immunoaugmentive therapy; Infratronic Qi-Gong machine; Insulin potentiation therapy; Inversion therapy; Iridology; Iscador; Kelley/Gonzales therapy; Laetrile; Live blood cell analysis; Macrobiotic diet; Magnet therapy; Meditation/transcendental meditation; Megavitamin therapy; Meridian therapy; Mesotherapy; Misletoe therapy; Moxibustion (except for fetal breech presentation) - see MTH-68 vaccine; Music therapy; Myotherapy Neural therapy; Ozone therapy; Pfrimmer deep muscle therapy; Polarity therapy; (Poon's) Chinese blood cleaning; Primal therapy; Psychodrama; Purging; Qigong longevity exercises; Ream's testing; Reflexology (zone therapy); Reflex Therapy; Reiki; Remedial massage; Revici's guided chemotherapy;Rolfing (structural integration); Rubenfeld synergy method (RSM); 714-X (for cancer); Sarapin injections; Shark cartilage products ;Therapeutic Eurythmy-movement therapy; Therapeutic touch; Thought field therapy (TFT) (Callahan Techniques Training); Trager approach; Visceral manipulation therapy; Whitcomb technique; Wurn technique/clear passage therapy; Yoga.
Minimum Eligibility Criteria	This policy does not preclude individual patients being referred to the Individual Funding Request Panel where the referrer feels that the therapy may be appropriate and where the referrer can demonstrate that the patient's condition and presentation is clinically exceptional and significantly different from other cohort of patients. Funding requests are not required where particular therapies are commissioned as part of a wider treatment provided within a package of care.
Evidence for inclusion and threshold	The House of Commons Science and Technology Committee enquiry into the provision of homeopathic services within the NHS in 2009 recommended that homeopathic treatments should not be routinely available within the NHS. The committee report included a robust review of the evidence base for a variety of homeopathic treatments but found no evidence of effectiveness for any condition from published RCTs and systematic reviews. A previous report commissioned by the Association of Directors of Public Health in 2007 and more recent reviews by AETNA 3 are all consistent in confirming the lack of sufficient evidence of effectiveness of homeopathic treatments despite many years of research and hundreds of studies. There is some evidence of clinical benefit for some complementary therapies such as acupuncture, osteopathy, biofeedback and hypnotherapy for certain conditions. 1. Evidence Check 2: Homeopathy. House of Commons Science and Technology Committee Report. 2009-10. http://www.publications.parliament.uk/pa/cm200910/cmselect/cmsctech/45/45.pdf 2. Association of Public Health Report on the evidence for homeopathy (unpublished commissioned Report on the evidence for Homeopathy) 3. AETNA Clinical Policy Bulletin 0388. Complementary and Alternative Medicine. Last review date 05/04/2010. http://www.aetna.com/cpb/medical/data/300_399/0388.html

Intervention	66. Extracorporeal Shockwave Therapy for Refractory Plantar Fasciitis
Policy	Extracorporeal shockwave therapy for refractory plantar fasciitis will not be funded.
Rationale	Plantar fasciitis is characterised by chronic degeneration of the plantar fascia, which causes pain on the underside of the heel. It is usually caused by injury or biomechanical abnormalities and may be associated with microtears, inflammation or fibrosis. Conservative treatments include rest, application of ice, analgesic medication, non-steroidal anti-inflammatory drugs, orthotic devices, physiotherapy, eccentric training/stretching and corticosteroid injection. Extracorporeal shockwave therapy (ESWT) is a non-invasive treatment in which a device is used to pass acoustic shockwaves through the skin to the affected area. Ultrasound guidance can be used to assist with positioning of the device. Extracorporeal shockwave therapy may be applied in one or several sessions. Local anaesthesia may be used because high-energy ESWT can be painful. Different energies can be used and there is evidence that local anaesthesia may influence the outcome of ESWT. The evidence on extracorporeal shockwave therapy (ESWT) for refractory plantar fasciitis raises no major safety concerns; however, current evidence on its efficacy is inconsistent, therefore this procedure will not routinely be funded.
Minimum Eligibility Criteria	Extracorporeal shockwave therapy for refractory plantar fasciitis will not routinely be funded
Evidence for inclusion and threshold	NICE IPG 311- Extracorporeal shockwave therapy for refractory plantar fasciitis

Intervention	67. Extracorporeal Shockwave Therapy for Refractory Achilles Tendinopathy
Policy	Extracorporeal shockwave therapy for refractory Achilles tendinopathy will not be funded.
Rationale	Achilles tendinopathy is characterised by chronic degeneration of the Achilles tendon, and is usually caused by injury or overuse. Symptoms include pain, swelling, weakness and stiffness over the Achilles tendon and tenderness over the heel (insertional tendinopathy). Conservative treatments include rest, application of ice, non-steroidal anti-inflammatory drugs, orthotic devices, physiotherapy (including eccentric loading exercises) and corticosteroid injection. Surgery may be considered in some patients with refractory symptoms. Extracorporeal shockwave therapy (ESWT) is a non-invasive treatment in which a device is used to pass acoustic shockwaves through the skin to the affected area. Ultrasound guidance can be used to assist with positioning of the device. Extracorporeal shockwave therapy may be applied in one or several sessions. Local anaesthesia may be used because high-energy ESWT can be painful. Different energies can be used and there is evidence that local anaesthesia may influence the outcome of ESWT. The evidence on extracorporeal shockwave therapy (ESWT) for refractory Achilles tendinopathy raises no major safety concerns; however, current

	evidence on its efficacy is inconsistent, therefore this procedure will not routinely be funded.
Minimum Eligibility Criteria	Extracorporeal shockwave therapy for refractory Achilles tendinopathy will not be funded
Evidence for inclusion and threshold	NICE IPG 312 - Extracorporeal shockwave therapy for refractory Achilles tendinopathy.

Intervention	**68. Hyperbaric Oxygen Therapy**
Policy	Unless one or more of the criteria below are met Hyperbaric Oxygen Therapy will not be funded.
Rationale	Despite the increasing use of Hyperbaric Oxygen Therapy (HBOT) in a range of conditions there is very little evidence from clinical trials regarding its clinical effectiveness or cost effectiveness. In line with findings from the review of HBOT by NHS Quality Improvement. HBOT will be funded for conditions where there is a theoretical basis for its effectiveness, sufficient empirical evidence and clinical consensus.
Minimum Eligibility Criteria	Unless one or more of the criteria below are met Hyperbaric Oxygen Therapy will not be funded: **Emergency conditions** • Decompression illness – only for patients not covered by diver's insurance arrangements • Air and Gas Embolism • Acute Carbon monoxide poisoning **Other conditions** • Diabetic Lower Extremity Ulcers where all the conditions listed below are met: • Type I or II diabetes mellitus • Wounds/Ulcers classified as Wagner grade III only. • History of failed standard wound therapy for at least 30 days for a Wagner Grade 3 Wound/Ulcer i.e. failure of objective evidence of any improvement • For HBOT to continue at 30 day intervals, re-evaluation must show continued progression to healing • Radiation-induced Proctitis
Evidence for inclusion and threshold	The clinical and cost effectiveness of hyperbaric oxygen therap. HTA programme: HTA systematic review 2 – May 2008. NHS Quality Improvement Scotland

Intervention	**69. Inpatient Cognitive Behavioural Therapy (Residential Placements) for Chronic Fatigue Syndrome (CFS)/Myalgic Encephalomyelitis (ME)**
Policy	Cognitive Behavioural Therapy Residential Placements will not routinely be funded for Chronic Fatigue Syndrome/Myalgic Encephalomyelitis (CFS/ME). This policy excludes Fibromyalgia.
Rationale	Chronic Fatigue Syndrome/Myalgic Encephalomyelitis (CFS/ME) comprises a range of symptoms including fatigue, headache, sleep disturbance, difficulty in concentration and muscle pain. An individual's symptoms may vary in severity and there is variation between patients. Although many patients improve over time, others do not. The cause of CFS/ME is unknown. Many different interventions for CFS/ME have been investigated in clinical trials of

	varying quality. There is increasing evidence from good quality trials to support CBT and/or GET in the management of CFS/ME. CBT with or without GET is more effective than standard medical care and does not appear to be more expensive. There is evidence for effectiveness in both adults and children. There is currently insufficient evidence to support any other intervention in terms of clinical or cost effectiveness. This includes immunological treatments, anti-viral therapy, pharmacological treatments, dietary supplements, complementary or alternative medicine, multi-treatment regimes, buddy-mentor schemes, group therapy and 'low sugar low yeast' diets. There is currently no evidence relating to patients with severe CFS/ME (who are house or bed-bound)'. There is currently no evidence to support the use of in-patient or residential settings to deliver effective interventions for CFS/ME. There is currently no evidence to suggest that any group or sub-group of patients with CFS/ME will benefit particularly from any specific intervention or that patients who have failed to improve on one intervention may do better on another. *NOTES:* *1. Exceptional circumstances may be considered where there is evidence of significant health impairment and there is also evidence of the intervention improving health status.*
Minimum Eligibility Criteria	Cognitive Behavioural Therapy (Residential Placements) will not be funded for chronic fatigue syndrome.
Evidence for inclusion and threshold	The Treatment and Management of Chronic Fatigue Syndrome/Myalgic Encephalomyelitis in Adults and Children. Feb 2007. CRD, University of York. Chalder T et al. Inpatient treatment of CFS. Behavioural Cognitive Psychotherapy.1996;24:351-365 NICE clinical guideline 53 August 2007 Chronic fatigue syndrome/myalgic encephalomyelitis (or encephalopathy): diagnosis and management of CFS/ME in adults and children Fukuda et al (1994) *The Chronic Fatigue Syndrome: A Comprehensive Approach to Its Definition and Study* Annuls of Internal Medicine December 15, 1994 vol. 121 no. 12 953-959 Map of Medicine April 2011 (Appendix 1) Royal College of Paediatrics and Child Health (RCPCH). Evidence based guideline for the management of CFS/ME (Chronic Fatigue Syndrome/myalgic encephalopathy) in children and young people. London: RCPCH; 2004.

Intervention	**70. Inguinal Hernia Repair**
Policy	A hernia is defined as a protrusion of a sac of peritoneum, often containing intestine or other abdominal contents, from its proper cavity through a weakness in the abdominal wall. They usually present as a lump, and patients often experience pain or discomfort that can limit daily activities. In addition, hernias can present as a surgical emergency should the bowel strangulate or become obstructed due to the hernia. There are many different types of hernia; this policy relates to **inguinal** hernias only. **Please Note:** Patients need to be aware that surgery does not guarantee a successful, pain free outcome and there are both risks and benefits.

Minimum Eligibility Criteria	An inguinal hernia repair is commissioned where a patient meets **one or more** of the following; • irreducible and partially reducible inguinal hernias • patients who experience pain or discomfort that limits daily activities • patients with suspected strangulated or obstructed inguinal hernia should be referred as an emergency • all children <18 years with inguinal hernia (should be referred to a paediatric surgical provider) • all hernias in women (should be referred urgently) Note: Except for patients with minimally symptomatic inguinal hernias who have significant comorbidity (ASA 3 or 4) **AND** do not want to have surgical repair after appropriate information has been provided
Evidence for inclusion and threshold	Royal College of Surgeons (2013) Commissioning guide: Groin Hernia http://www.rcseng.ac.uk/healthcare-bodies/docs/published-guides/hernia http://www.britishherniasociety.org/patients/

Intervention	**71. Arthroscopic Shoulder Decompression for sub acromial shoulder pain**
Policy	Arthroscopic subacromial decompression for pure subacromial shoulder impingement should only offered in appropriate cases. To be clear, 'pure subacromial shoulder impingement' means subacromial pain not caused by associated diagnoses such as rotator cuff tears, acromio-clavicular joint pain, or calcific tendinopathy. Non-operative treatment such as physiotherapy and exercise programmes are effective and safe in many cases. For patients who have persistent or progressive symptoms, in spite of adequate non-operative treatment, surgery should be considered. The latest evidence for the potential benefits and risks of subacromial shoulder decompression surgery should be discussed with the patient and a shared decision reached between surgeon and patient as to whether to proceed with surgical intervention.
Rationale	Recruiting patients with pure subacromial impingement and no other associated diagnosis, a recent randomised, pragmatic, parallel group, placebo-controlled trial investigated whether subacromial decompression compared with placebo (arthroscopy only) surgery improved pain and function. While statistically better scores were reached by patients who had both types of surgery compared to no surgery, the differences were not clinically significant, which questions the value of this type of surgery. On the other hand, a more recent prospective randomised trial comparing the long term outcome (10 year follow up) of surgical or non-surgical treatment of sub acromial impingement showed surgery to be superior to non-surgical treatment. Other studies of limited quality identify certain patients with impingement syndrome that improve with surgical subacromial decompression if non-operative management fails. There is also some evidence to show the benefit of surgery when used selectively and applying national clinical guidelines.

	A review of the literature identified one further systematic review that looked at the effectiveness of surgery. The review was limited by the quality of evidence but their findings showed no difference between patients treated with surgery and those treated with non-surgical options. Healthcare professionals treating patients with subacromial pain should be familiar with the NICE approved commissioning and treatment guidelines for the management of subacromial pain. Risks associated with arthroscopic sub-acromial decompression are low but include infection, frozen shoulder, ongoing pain, potential damage to blood vessels or nerves and those associated with having a general anaesthetic.
Evidence for inclusion and threshold	1) Beard DJ, Rees JL, Cook JA, Rombach I, Cooper C, Merritt N, Shirkey BA, Donovan JL, Gwilym S, Savulescu J, Moser J, Gray A, Jepson M, Tracey I, Judge A, Wartolowska K, Carr AJ; CSAW Study Group. Arthroscopic subacromial decompression for subacromial shoulder pain (CSAW): a multicentre, pragmatic, parallel group, placebo-controlled, three-group, randomised surgical trial. Lancet. 2018 Jan 27;391(10118):329-338. doi: 10.1016/S0140-6736(17)32457-1. Epub 2017 Nov 20. PubMed PMID: 2) 29169668; PubMed Central PMCID: PMC5803129. 3) Dorrestijn O, Stevens M, Winters JC, van der Meer K, Diercks RL. Conservative or surgical treatment for subacromial impingement syndrome? A systematic review. J Shoulder Elbow Surg 2009; 18: 652–60. 4) Farfaras S, Sernert N, Rostgard Christensen L, Hallström EK, Kartus JT. Subacromial Decompression Yields a Better Clinical Outcome Than Therapy Alone: A Prospective Randomized Study of Patients With a Minimum 10-Year Follow-up. Am J Sports Med. 2018 May;46(6):1397-1407 5) Holmgren T, Björnsson Hallgren H, Öberg B, Adolfsson L, Johansson K. Effect of specific exercise strategy on need for surgery in patients with subacromial impingement syndrome: randomised controlled study. BMJ. 2012 Feb 20;344:e787. doi: 10.1136/bmj.e787 6) Magaji SA, Singh HP, Pandey RK. Arthroscopic subacromial decompression is effective in selected patients with shoulder impingement syndrome. J Bone Joint Surg Br. 2012 Aug;94(8):1086-9 7) Jacobsen JR, Jensen CM, Deutch SR. Acromioplasty in patients selected for operation by national guidelines. J Shoulder Elbow Surg. 2017 Oct;26(10):1854-1861. 8) https://www.boa.ac.uk/wp-content/uploads/2014/08/Subacromial-Shoulder- Commissioning-Guide_final.pdf