

North East London Evidence Based Interventions Policy

Procedures not routinely funded (Individual Funding Requests (IFR)) or funded only when specific criteria are met.

Barking & Dagenham, City & Hackney, Havering, Newham, Redbridge, Tower Hamlets, Waltham Forest Clinical Commissioning Group Boroughs (North East London CCG (NEL)

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Version Control

Date	Page no.	Policy	Ratified by	Reason for change
April 2021	36	Cataract surgery	North East London CCG Quality and Safety Committee	Purposes of clarity
April 2021	42	Interventional treatments for back pain	As above	Purposes of clarity
April 2021	19	Tonsillectomy	As above	Purposes of clarity
April 2021	12	Breast reduction and correction of breast asymmetry	As above	Purposes of clarity
April 2021	38	Injections for non-specific low back pain	As above	Purposes of clarity
April 2021	19	Rhinoplasty/Septoplasty/Rhinoseptoplasty (surgery to reshape the nose)	As above	Purposes of clarity
April 2021	13	Removal / revision of breast augmentation	As above	Purposes of clarity
November 2021	4	Age Threshold	NEL CCG Quality, Safety and Improvement Committee	Purposes of clarity

November 2021	31	Circumcision	As above	Based on clinical feedback
November 2021	18	Pinnaplasty/otoplasty (correction of significantly prominent ears)	As above	Removal of reference to 'bat ears'
November 2021	13	Removal / revision of breast augmentation	As above	Based on clinical feedback
November 2021	19	Tonsillectomy	As above	Wording changed to include children
November 2021		Hair Loss – Category 1 Procedures: IFR	As above	Removal based on provider feedback
November 2021		Replacement of existing policies on Chronic Sinusitis, Discectomy and Spinal Fusion with national EBI Wave 2 guidance	As above	To reflect latest national guidance
November 2021		National EBI Wave 2 except for 2D, 2U, 2W(i) & 2W(ii) (see below for reason for exclusions)	As above	To reflect latest national guidance
March 2024		To reflect change to NEL ICB		

Background

The NEL Evidence Based Interventions Policy (NEL EBI) is a list of treatments/interventions that are only funded by the NHS when a patient meets certain clinical threshold criteria. This policy applies to adult patients aged 18 and over only, unless specified otherwise in the body of text within each policy.

Policy development is an on-going process resulting from the publication of new evidence regarding clinical effectiveness. Policy reviews will be undertaken in response to NICE Guidance/Guidelines, health technology assessments etc.

This policy was first published in October 2019 after a rigorous clinically led programme which reviewed and incorporated where appropriate the latest national Evidence Based Interventions Programme¹ and the London Choosing Wisely Programme². The policy replaced the two existing Procedures of Limited Clinical Evidence Policies (POLCE) policies (Barking and Dagenham, Havering and Redbridge CCGs POLCE policy and the Waltham Forest, Tower Hamlets, Newham and Waltham Forest (WELC) POLCE policy).

Revisions to the single policy were made in April 2021 to take account of provider feedback.

In 2020 the Academy of Medical Royal Colleges consulted on a new wave of evidence based interventions https://www.aomrc.org.uk/ebi/resources/list-2-documents-resources/

After a review by local clinicians, the majority of those interventions have now been incorporated into this policy. There are however 3 interventions that clinicians decided not to adopt at this time. The first two as it was felt that in the context current waiting, applying this would have a detrimental impact on equality of access and waiting times.

- 1. Knee MRI should not be routinely used to initially investigate suspected meniscal tears in primary care (policy ref: 2U; table 2B)
- 2. Imaging for shoulder pain should be offered under the guidance of shoulder specialists where possible. (Policy Ref: 2W(i)(ii); Table: 2B)

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¹ https://www.aomrc.org.uk/ebi/

² https://www.healthylondon.org/our-work/london-choosing-wisely/

3. The third policy that has been put on hold relates to Adenoidectomy in Glue Ear (policy ref: 2D; table 2A) Local ENT consultants felt that this policy did not reflect the latest clinical evidence and this has been taken up with the national team for more discussion.

Purpose of the Policy

We know that some procedures are currently carried out on patients, where the evidence for intervention is not strong and more conservative approaches to the management of conditions would be more appropriate and present less risks than surgical intervention. We need to ensure that in making decisions on how we fund treatments, that our patients realise the best clinical and quality outcomes. Having a policy to govern these procedures that is adhered to will ensure that patients do not undergo unnecessary surgical interventions or procedures where clinical evidence is not strong or where in some cases carries significantly greater risk and cost, than alternative treatment options. Adherence to an effective policy will also ensure that surgical capacity is available for those patients that really need a procedure to be carried out that is supported by clinical evidence.

We need to continue to prioritise those services that deliver the greatest health gain for local people. By ceasing to make some services routinely available and putting in place criteria for accessing other services, we believe that will be able to protect the most important services so that they can be available when people need them whilst at the same time continuing to live within our financial means.

To achieve this aim, we will ensure the current NEL EBI Policy is:

- 1. Consistently applied across North East London Clinical Commissioning Group boroughs (Barking & Dagenham, City & Hackney, Havering, Newham, Redbridge, Tower Hamlets, and Waltham Forest) to avoid any postcode related inequity or inequality.
- 2. Presented using unambiguous language, which is easy for clinicians and patients to interpret.
- 3. Regularly reviewed, updated and reissued using the most up to date and validated evidence base.
- 4. Effectively and consistently communicated to health care professionals within the footprint.
- 5. An open and transparent process, adhering to local governance policies.

Where possible, references to the evidence/ guidelines underpinning individual clinical policies have been added to the relevant sections. However, it should be noted that an assumption is made that if National guidelines are updated that would impact upon this policy they will be taken into account when assessing eligibility for a particular treatment.

Securing NHS Funding

Category 1 - IFR (Not routinely funded) - The statement "NEL CCG will not routinely fund" means it is primarily a commissioning decision not to routinely fund. In these circumstances a clinician may still request funding for that treatment but this will only be approved if an Individual Funding Request (IFR) proves exceptional clinical need and is approved by the IFR panel (Please refer to IFR Policy).

A copy of the relevant IFR policy can be obtained from the IFR team by emailing at the following address:

For North East London CCG

Email: Nelcsu.ifr@nhs.net

Exceptional cases must have exceptional clinical circumstances supported by robust clinical evidence. We have defined exceptionality as an unusual clinical factor (or factor affecting the clinical condition) about the patient that suggests that they are

1. Significantly *different* to the general population of patients with the condition in question.

AND

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

The fact that a treatment is likely to be effective for a patient is not, in itself, a basis for exceptionality. For further information on clinical exceptionality please refer to the IFR policy or contact the IFR team in advance of completing an IFR application to discuss the appropriateness of pursuing funding?

Any procedures carried outside of the funding governance arrangements outlined above will be subject to challenge and carries a significant risk of non-payment to the provider.

Category 2 – interventions which should only be routinely commissioned or performed when specific criteria are met

These interventions are only routinely commissioned or performed when specific criteria is met. Clinicians will need to demonstrate that the patient meets the criteria set out in this policy. If the patient does not meet the relevant clinical criteria, but the clinician feels the patient has exceptional clinical circumstances, the request for funding should be taken through the IFR process.

Commissioners will use national and local datasets to determine which of these interventions may require closer monitoring through either a Prior Approval Process (Blueteq) or trust electronic solutions such as TCI forms with embedded criteria. The remaining interventions will be subject to light touch monitoring using benchmarking data or occasional audit.

The national EBI guidance is given contractual effect through provisions included at SC29.28-31. There is a requirement for the co-ordinating commissioner and the provider to agree clinically-appropriate goals for the annual number of procedures in each category to be undertaken. Material over-performance against the activity goals in-year should prompt review and action to ensure that EBI policy is being fully implemented. No individual patient should be prevented from accessing clinically appropriate treatment, in accordance with EBI guidance criteria, simply because the overall activity goal has been exceeded.

Any procedures carried outside of the funding governance arrangements previously outlined will be subject to challenge and carries a risk of non-payment to the provider.

Occasional retrospective audits - The frequency, scope and depth for any audits will be agreed with providers who will be given appropriate notice pending any such audits and or reviews. All providers will be asked to clarify any activity or procedure codes that fail to comply with those set out within the policy. These will be subject to challenge as is relevant and where appropriate challenged for non-payment.

Coding: CCGs and Providers will work collectively to agree, maintain and review coding as required to support policy implementation.

Equality statement

NEL CCG has a duty to have due regard for the need to reduce health inequalities in access to health services and health outcomes achieved as detailed in the Health and Social Care Act 2012. NEL CCG has committed to ensuring equality of access and non-discrimination, irrespective of age, gender, disability (including learning disability), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex (gender) or sexual orientation. In carrying out its functions, NEL CCG will have due regard to the different needs of protected equality groups, in line with the Equality Act 2010. This document is compliant with the NHS Constitution and the Human Rights Act 1998. This

applies to all activities for which they are responsible, including policy development, review and implementation.

NEL CCG completed an Equality Quality Impact Assessment (EQIA) and Full Quality Impact Assessment (fQIA) for the first version of this policy in November 19 and a further EQIA for the policy update published in December 2021. The Academy of Medical Royal Colleges undertook an Equalities Impact Assessments on Wave 1 and 2 guidance. These assessment can be found at this link. https://www.aomrc.org.uk/ebi/resources/list-2-documents-resources/

Exclusions to this policy

The policy does not apply to the following:

- Patients diagnosed with cancer or suspected of having cancer: diagnoses should be dealt with via a two-week wait referral and NOT via an Individual Funding Request (IFR) or Prior Approval (PA) application.
- Policies will not apply to those patients where the treatment is in relation to and outlined in their cancer pathway e.g. breast reconstruction following breast cancer.
- If Mental Health affects functionality (ability to undertake activities of daily living such that there is a sustained impact on health and/or patient safety) then it should be considered for funding. Although in such cases there should be a recommendation by a clinical psychologist and confirmation that mental health interventions have been exhausted or are compromised significantly.
- Children (aged under 18) unless otherwise stated within individual treatment/intervention policy.
- Emergency or urgent care.
- Where NHS England commission the service as part of specialist commissioning arrangements.
- If a clinician considers the need for referral/treatment on clinical grounds outside of the Prior Approval (PA) criteria, please refer to the CCG Individual Funding Request policy for further information.

In relation to the above exclusions, the provider should be able to demonstrate the clinical need either through the coding or as part of the patient record.

Implementation time scales

This policy will be used to assess all patients being referred for assessment or treatment from the date of implementation (one month after publication). The NEL EBI will be reviewed biennially (every 2 years). If required, formal Clinical Review Group (CRG) will be reinstated, and Nationally mandated policies will be adopted without further consultation.

Age Threshold

These policies apply to all adults aged 18 or over unless otherwise stated.

Category 1 Procedures: Individual funding request (IFR)

This list includes procedures that are not routinely commissioned by NEL CCG, and therefore funding is only available through an IFR panel. Only IFR applications that demonstrate <u>clear clinical exceptionality</u> will be processed. Please refer to the local IFR policy for further guidance before completing an application form.

Procedures	Speciality	Page No.
Acupuncture	Alternative therapy	8
Herbal medicines	Alternative therapy	8
Homeopathy	Alternative therapy	8
Excess skin excision from buttocks, thighs and arms	Bariatric surgery	9
Liposuction	Bariatric surgery	9
Surgery to correct divarification (or diastasis) of the abdominal rectus muscle	Bariatric surgery	9
Breast augmentation	Breast	11
Breast lift (mastopexy)	Breast	11
Male breast reduction (gynaecomastia)	Breast	11
2L Exercise ECG for screening for coronary heart disease (Treadmill test for heart disease)	Cardiology	13
Face lifts and brow lifts (rhytidectomy)	Dermatology & Skin	14
Hair transplantation	Dermatology & Skin	14
Repair of split ear lobes	Dermatology & Skin	14
Tattoo removal	Dermatology & Skin	14
Treatment for scarring and skin hyper- or hypo-	Dermatology & Skin	14
pigmentation	0,	
Surgical interventions for snoring in the absence of obstructive sleep apnoea	ENT	17
Double balloon enteroscopy for diagnostic purpose	Gastroenterology	22
All treatments for vascular lesions	General Surgery	27
Cosmetic genital procedures (labiaplasty – excluding Female Genital Mutilation (FGM) (refer to circumcision category 2 prior approval policy)	Gynaecology/Urology	30
Dilation & curettage (D&C) for heavy menstrual bleeding in women	Gynaecology/Urology	30
MRI guided ultrasound (MRgFUS) for uterine fibroids	Gynaecology/Urology	30
Non-medical circumcision	Gynaecology/Urology	30
Reversal of female sterilisation and reversal of	Gynaecology/Urology	30
Sacral nerve stimulation for faecal and urinary incontinence	Gynaecology/Urology	30
Varicocele	Gynaecology/Urology	30
White cell apheresis	Haematology	35
Ketogenic diet for epilepsy	Medicine	36
Laser surgery for short sightedness	Ophthalmology	36
Autologous chondrocyte (cartilage) implantation	Orthopaedics	38
Injections for non-specific low back pain	Orthopaedics	38
Knee arthroscopy for patients with osteoarthritis	Orthopaedics	38
Interventional treatments for back pain	Orthopaedics	38
Lumbar disc replacement	Orthopaedics	38
Ozone discectomy	Orthopaedics	38
2Z Helmet therapy for treatment of positional plagiocephaly/ brachycephaly in children (Helmets to reshape flat heads in babies) Individual Funding Request	Paediatrics	50
Manual therapies (osteopathy – outside of an MSK integrated service)	Physiotherapy	51

Category 2 Procedures: interventions which should only be routinely commissioned or performed when specific criteria are met

The following interventions are only routinely commissioned or performed when specific criteria are met. Clinicians will need to demonstrate that the patient meets the criteria set out in this policy. If the patient does not meet the relevant clinical criteria, but the clinician feels the patient has exceptional clinical circumstances, the request for funding should be taken through the IFR process.

Commissioners will use national and local datasets to determine which of the following interventions may require closer monitoring through either a Prior Approval Process (Blueteq) or trust electronic solutions such as TCI forms with embedded criteria. The remaining interventions will be subject to light touch monitoring using benchmarking data or occasional audit. These arrangements will be detailed in contracts with providers.

Procedures	Speciality	Page No.
2AA Pre-operative chest x-ray (Chest X-ray before an operation)	Anaesthetics	8
2BB Pre-operative ECG (Heart tracing (ECG) before an operation)	Anaesthetics	8
Bariatric Surgery	Bariatric surgery	9
2F Troponin test (Specialised blood tests (troponin) for investigation of chest pain)	Blood Test	10
2DD Liver function, creatinine kinase and lipid level tests – (Lipid lowering therapy) (Regular blood tests when taking cholesterol lowering tablets)	Blood Test	11
Breast reduction and correction of breast asymmetry	Breast	12
Nipple inversion	Breast	12
Removal / revision of breast augmentation	Breast	13
2A Diagnostic coronary angiography for low risk, stable chest pain (Invasive angiogram to investigate stable chest pain)	Cardiology	14
Excision of skin and subcutaneous lesions	Dermatology & Skin	14
Hair epilation	Dermatology & Skin	16
Keloid and other scar revision	Dermatology & Skin	16
Sympathectomy for severe hyperhidrosis (palmar, plantar, axillary)	Dermatology & Skin	17
Grommets for glue ear in children	ENT	18
Pinnaplasty/otoplasty (correction of prominent or bat ears)	ENT	18
Rhinoplasty/Septoplasty/Rhinoseptoplasty (surgery to reshape the nose)	ENT	19
Tonsillectomy	ENT	19
2C Surgical intervention for chronic rhinosinusitis	ENT	20
2M Upper GI endoscopy (Endoscopy to investigate gut problems)	Gastroenterology	22
2N Appropriate colonoscopy in the management of hereditary colorectal Cancer (Colonoscopy of the lower intestine)	Gastroenterology	24

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2X MRI scan of the hip for arthritis	Orthopaedics	47
Botulinum toxin (not cosmetic)	Other	49
Open MRI	Other	49

Detailed Procedure Criteria Guidance

Alternative therapies

Category 1 Procedures: Individual funding request (IFR)

Acupuncture
Herbal medicines
Homeopathy

Anaesthetics

Category 2 Procedures

2AA Pre-operative chest x-ray (Chest X-ray before an operation)

Criteria

Pre-operative chest radiographs should not be routinely performed in adult elective surgical patients. However, they may be appropriate in specific cohorts of patients, including when the following criteria apply:

- · Patients undergoing cardiac or thoracic surgery
- Patients undergoing organ transplantation or live organ donation
- At the request of the anaesthetist in:
- Those with suspected or established cardio-respiratory disease, who have not had a chest radiograph in the previous 12 months, and who are likely to go to critical care after surgery
- Those with a recent history of chest trauma
- Patients with a significant smoking history who have not had a chest radiograph in the previous
 12 months, or those with malignancy and possible lung metastases
- Those undergoing a major abdominal operation, who are at high risk of respiratory complications

2BB Pre-operative ECG (Heart tracing (ECG) before an operation)

Criteria

Pre-operative electrocardiograms should not be routinely performed in low risk, non-cardiac, adult elective surgical patients. However, they may be appropriately performed when the following criteria apply:

- Patients with an American Society of Anaesthesiologists (ASA) physical classification status of 3 or greater and no ECG results available for review in the last 12 months
- Patients with a history of cardiovascular or renal disease, or diabetes
- Patients with any history of potential cardiac symptoms (e.g. cardiac chest pain, palpitations, unexplained syncope or breathlessness) or a new murmur, that has not previously been investigated 71 Academy of Medical Royal Colleges EBI List 2 Guidance
- Patients over the age of 65 attending for major surgery. Where pre-operative tests are completed outside the centre in which surgery will be completed, avoid unnecessarily repeating these tests on admission and ensure appropriate transfer of images takes place.

Bariatric Surgery

Category 1 Procedures: Individual funding request (IFR)

Excess skin excision from buttocks, thighs and arms

Liposuction

Surgery to correct divarification (or diastasis) of the abdominal rectus muscle

Category 2 Procedures

Bariatric Surgery

Criteria

NEL CCG will fund bariatric surgery when all of the following criteria are met:

- They have a BMI of 40 kg/m2 or more, OR between 35 kg/m2 and 40 kg/m2 and other significant diseases (type 2 diabetes or high blood pressure) that could be improved if they lost weight AND
- All appropriate non-surgical measures have been tried but the person has not achieved or maintained adequate, clinically beneficial weight loss
 AND
- The person has been receiving or will receive intensive management in a tier 3 service
 AND
- The person is generally fit for anaesthesia and surgery AND
- The person commits to the need for long term follow up

For further details see NICE clinical guidance CG189:

https://www.nice.org.uk/guidance/cg189/chapter/1-recommendations

Blood Test

Category 2 Procedures

2F Troponin test (Specialised blood tests (troponin) for investigation of chest pain)

Criteria

In order to rule out suspected acute coronary syndrome (moderate or high risk of myocardial infarction) in people presenting with acute chest pain, NICE recommends early rule out using high-sensitivity troponin tests.

High-sensitivity troponin assays were developed to detect troponin in the blood at lower levels than non-high-sensitivity troponin assays. Using the high-sensitivity assays as part of an early rule-out protocol can reduce time to discharge. Guidance on early rule out of NSTEMI using high-sensitivity troponin assays recommends a 2-test strategy, typically on admission and at 3 hours. However, the committee concluded that there was insufficient evidence to recommend a specific test strategy and agreed that early rule-out protocols should be chosen according to local preference.

High-sensitivity troponin measurements should not be considered in isolation but interpreted alongside the clinical presentation, the time from onset of symptoms, the 12-lead resting ECG, pre-test probability of NSTEMI,

The possibility of chronically elevated troponin levels in some people and that 99th percentile thresholds for troponin I and T may differ between sexes.

If ACS is not suspected, high-sensitivity troponin test should not be used. For people at low risk of myocardial infarction only perform a second high sensitivity troponin test if the first troponin test at presentation is positive.

Diagnosis of myocardial infarction is the detection of a rise and/or fall of cardiac troponin with at least one value above the 99th percentile of the upper reference limit and at least one of the following:

- symptoms suggesting myocardial ischaemia
- new / presumed new significant ST-segment-T wave (ST-T) changes or new left bundle branch block (LBBB) development of pathological Q waves on the ECG
- imaging evidence of new loss of viable myocardium or new regional wall motion abnormality
- Identification of an intracoronary thrombus by angiography.

The appropriate use of high-sensitivity troponin testing should reduce the need for further investigation, result in shorter stays in hospital and overall result in cost-savings (if used in an early rule out clinical protocol). According to this recommendation, if acute coronary syndrome is suspected in a primary care setting, a referral should be made for prompt investigation and treatment.

This guidance applies to adults and children.

2DD Liver function, creatinine kinase and lipid level tests – (Lipid lowering therapy) (Regular blood tests when taking cholesterol lowering tablets)

Criteria

Creatine Kinase Testing — Creatine kinase should not be routinely monitored in asymptomatic people who are taking lipid modification therapy — Creatine kinase measurement is indicated: — Prior to lipid modification therapy initiation in patients who have experienced generalised, unexplained muscle pains or weakness (whether or not associated with previous lipid-monitoring therapy)

— If a patient develops muscle pains or weakness whilst on lipid modification therapy.

Liver Function Testing

- Baseline liver function should be measured before starting lipid modification therapy
- Liver function should be measured within 3 months of starting treatment and at 12 months, but not again unless clinically indicated
- Routine monitoring of liver function tests in asymptomatic people is not indicated after 12 months of initiating lipid lowering therapy
- ALT can be used as a measure of liver function.

Lipid Testing

- Measure full lipid profile by taking at least one lipid sample before starting lipid modification therapy. This should include measurement of total cholesterol, HDL cholesterol, non-HDL cholesterol and triglyceride concentrations. A fasting sample is not needed.
- Total cholesterol, HDL cholesterol and non-HDL cholesterol should be measured in all people who have been started on high-intensity statin treatment (both primary and secondary prevention, including atorvastatin 20 mg for primary prevention) at 3 months of treatment and aim for a greater than 40% reduction in non-HDL cholesterol.
- Consider an annual non-fasting blood test for non-HDL cholesterol to inform discussion at annual medication reviews.

Further details on creatine kinase, liver function and lipid testing during lipid lowering treatment are outlined in NICE guidance and ECS guidance for the management of dyslipidaemias: lipid modification to reduce cardiovascular risk.

Breast

Category 1 Procedures: Individual funding request (IFR)

Breast augmentation

Breast lift (Mastopexy)

Male breast reduction (gynaecomastia)

Category 2 Procedures

Breast reduction and correction of breast asymmetry

Criteria

Section 1: Bilateral breast reduction

NEL CCG will fund bilateral breast reduction when all of the following criteria are met:

1. The woman has received a full package of supportive care from their GP such as advice on weight loss and managing pain

AND

- 2. In cases of thoracic/ shoulder girdle discomfort, a physiotherapy assessment has been provided **AND**
- 3. 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

4. Breast reduction planned to be 500gms or more per breast or at least four cup sizes

5. Body mass index (BMI) is <27 and stable for at least 12 months

AND

6. Women must be provided with written information to allow them to balance the risks and benefits of breast surgery

AND

7. Women should be informed that smoking increases complications following breast reduction surgery and should be advised to stop smoking

AND

8. Women should be informed that breast surgery for hypermastia can cause permanent loss of lactation

Section 2: Unilateral breast reduction

This treatment 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. **NEL CCG** will fund unilateral breast reduction when all of the following criteria are met:

1. A difference of 150 - 200gms size as measured by a specialist

AND

2. Body mass index (BMI) is <27 and stable for at least 12 months

Additional information

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. The Association of Breast Surgery support contralateral surgery to improve cosmesis as part of the reconstruction process following breast cancer treatment.

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.

Nipple inversion

Criteria

Nipple inversion may occur as a result of an underlying breast malignancy and it is essential that this be excluded.

NEL CCG will fund surgical correction of nipple inversion when the following criteria is met:

The inversion has not been corrected by correct use of a non-invasive suction device after three
months of use.

Additional information

Idiopathic nipple inversion may be corrected by the application of sustained suction. Commercially available devices are available from major chemists or online without prescription. Best results are seen where this is used correctly for up to three months.

Removal / revision of breast augmentation

Criteria

Removal

NEL CCG will fund removal of breast implants when one of the following criteria are met for patients who have undergone cosmetic augmentation mammoplasty:

1. Breast disease

OR

2. Implants complicated by recurrent infections

OR

3. Implants with capsule formation that is associated with severe pain

OR

4. Implants with capsule formation that interferes with mammography

OR

5. Intra or extra capsular rupture of silicon gel-filled implants

Replacement

Replacement with a new prosthesis will only be considered where original implants were funded by the NHS for reconstruction i.e.: non-cosmetic purposes. Additional cosmetic surgery (e.g. mastopexy or bigger implants) should not be done at the same time as the reimplantation and will not be funded.

Cardiology

Category 1 Procedures: Individual funding request (IFR)

2L Exercise ECG for screening for coronary heart disease (Treadmill test for heart disease)

2L Exercise ECG for screening for coronary heart disease (Treadmill test for heart disease)

Criteria

Exercise ECG has no role in the screening of asymptomatic and low risk patients for coronary heart disease because it has a very low pre-test probability of identifying pathology. Risk calculators, such as Systematic Coronary Risk Evaluation (SCORE), are instead recommended to identify patients who are at greater risk of CHD.

Under the guidance of cardiologists, the test has a limited role for diagnosis in selected patients with symptoms suggestive of CHD, and/or where CHD has been diagnosed to confirm functional capacity or severity.

Category 2 Procedures

2A Diagnostic coronary angiography for low risk, stable chest pain (Invasive angiogram to investigate stable chest pain)

Criteria

When results of non-invasive functional imaging are inconclusive and patients are assessed as having low risk, stable cardiac pain, invasive coronary angiography (cardiac catheterisation) should be offered only as

third-line investigation.

Patients who have chest pain that is not an Acute Coronary Syndrome (ACS), but there is concern that it is due to an ischemic cause (stable angina) should, in the first instance, be offered a CT Coronary angiography (64 slice

or above).

This is based on:

- Clinical assessment indicating typical or atypical angina; or
- Clinical assessment indicates non-anginal chest pain but the 12-lead resting ECG shows ST-T changes or Q waves.

Significant coronary artery disease (CAD) found during CT coronary angiography is \geq 70% diameter stenosis of at least one major epicardial artery segment or \geq 50% diameter stenosis in the left main coronary artery.

If the CT coronary angiography is inconclusive, non-invasive functional imaging for myocardial ischemia should be considered in the following forms:

Stress echocardiography; or

First-pass contrast-enhanced magnetic resonance (MR) stress perfusion; or

- MR imaging for stress-induced wall motion abnormalities; or
- Fractional flow reserve CT (FFR-CT); or
- Myocardial perfusion scintigraphy with single photon emission computed tomography (MPS with SPECT).

Invasive coronary angiography should only be offered as third-line investigation when the results of non-invasive functional imaging are inconclusive.

Dermatology & Skin

Category 1 Procedures: Individual funding request (IFR)

Face lifts and brow lifts (rhytidectomy)

Hair transplantation

Repair of split ear lobes

Tattoo removal

Treatment for scarring and skin hyper- or hypo-pigmentation

Category 2 Procedures

Excision of skin and subcutaneous lesions

Criteria

This policy refers to the following benign lesions when there is diagnostic certainty and they do 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

NEL CCG will fund benign skin lesions which are listed above when one of the following criteria are met:

1. The lesion is unavoidably and significantly traumatised on a regular basis with evidence of this causing regular bleeding or resulting in infections such that the patient requires two or more courses of antibiotics (oral or intravenous) per year

OR

2. The lesion causes regular pain

OR

3. The lesion is obstructing an orifice or impairing field vision

OR

4. The lesion significantly impacts on function e.g. restricts joint movement

OR

5. The lesion causes pressure symptoms e.g. on nerve or tissue

OR

6. If left untreated, more invasive intervention would be required for removal

OR

7. Facial viral warts

OR

8. 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.

Referral to dermatology or plastic surgery:

- 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.
- This policy applies to all providers, including general practitioners (GPs), GPs with enhanced role (GPwer), independent providers, and community or intermediate services.

Hair epilation

Criteria

NEL CCG will fund hair epilation when either criteria 1(a) or criteria 1(b) AND 2 are met:

1(a). Have undergone reconstructive surgery leading to abnormally located hair-bearing skin to the face, neck, upper chest or hands (areas not covered by normal clothing)

OR

1(b). Are undergoing treatment for pilonidal sinuses to reduce recurrence for patients who do not meet these criteria

AND

2. Confirmation that the patient has not had more than six NHS/private treatments in the past

In the event that NHS funding is agreed up to a maximum of six treatments.

Additional information

An IFR application will ONLY be considered (for facial, neck or upper chest areas not covered by normal clothing) on completion of the relevant section explaining for the benefit of the IFR panel why the patient differs from the cohort of similarly hirsute patients such that they are likely to gain more health benefit from depilation which is not available to other similar patients.

Because NEL CCG do not fund maintenance treatment for hirsutism, it is not considered appropriate to commission an intervention whose effects are likely to be transitory and psychological distress would be likely to recur. Severe hirsutism due to an endocrine disorder may be referred to an endocrinology department but this is not an indication for NHS funding of epilation. NEL CCG will fund radiosurgery for the treatment of symptomatic trichiasis.

Keloid and other scar revision

Criteria

NEL CCG will not fund surgical procedures to re-fashion keloid scars for cosmetic purposes.

NEL CCG will fund symptomatic keloid scars when one of the following criteria are met:

1. Interferes with physical function

OR

2. Causes pain or itchiness for six months and is unrelieved by standard medication

Additional information

Corticosteroid injections and Haelan tape should be considered the first line treatment for keloid scars. The aim of injections and tape is to improve the appearance of the scar. Patients should be informed of the need to wear the tape for 12 hours daily for at least three months.

Patients should be informed that having surgery on a scar will in itself leave a new scar that will take up to two years to improve in appearance. If surgery is used to treat a hypertrophic scar, there is a risk that the scarring may be worse after the surgery.

Low-dose, superficial radiotherapy may reduce the recurrence rate of hypertrophic and keloid scars after surgery. Because of the possibility of long-term side effects, it is only reserved for the most serious cases. IFR applications should be submitted for this intervention describing the clinical exceptionality in any case.

Sympathectomy for severe hyperhidrosis (palmar, plantar, axillary)

Criteria

NEL CCG will fund sympathectomy when criteria 1(a) and 2 are met or 1(b) and 2 are met:

1(a). Significant focal hyperhidrosis and a one to two month trial of aluminium salts (under primary care supervision to ensure compliance) has been unsuccessful in controlling the condition

OR

1(b). Significant focal hyperhidrosis and intolerance of topical aluminium salts despite reduced frequency of application and use of topical 1% hydrocortisone

AND

2.All of the following conservative therapies have been tried and found to be unsuitable or unsuccessful:

- treatment of underlying anxiety if it is an exacerbating factor
- referral to a dermatologist for modified topical therapy
- prescription of oral anticholinergics (which block the effect of the nerves that stimulate the sweat glands)
- iontophoresis (for palmar or plantar hyperhidrosis) or botulinum toxin injections (for axillary hyperhidrosis)

Sympathectomy is an established intervention for this condition BUT should be considered only after all other non-invasive non-surgical treatment options have been tried and failed.

Additional Information

Compensatory sweating following sympathectomy is common and can be worse than the original problem. Patients should be made aware of this risk.

Ears, Nose & Throat (ENT)

Category 1 Procedures: Individual funding request (IFR)

Surgical interventions for snoring in the absence of obstructive sleep apnoea Criteria

Surgical interventions for snoring in the absence of obstructive sleep apnoea

Criteria

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.

Alternative Treatments

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.

Category 2 Procedures

Grommets for glue ear in children

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.

NEL CCG will fund grommets for glue ear when criteria 1, 2 and 3 are met. Or exclusively when either 4(a) or 4(b) are met:

- 1. All children must have had specialist audiology and ENT assessment **AND**
- 2. Persistent bilateral otitis media with effusion for at least three consecutive months **AND**
- 3. Hearing level in the better ear of 25-30dbHL or worse averaged at 0.5, 1, 2 & 4kHz OR exclusively in one of the following circumstances
- 4(a). 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 **OR**
- 4(b). 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

Additional information

This guidance does not apply to children with Down's Syndrome or Cleft Palate, who may be offered grommets after a specialist Multi-Disciplinary Team (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).

Pinnaplasty/otoplasty (correction of significantly prominent ears)

Criteria

NEL CCG will fund pinnaplasty/otoplasty when all of the following criteria are met:

1. The patient is under the age of 18 at the time of referral for significantly prominent ears **AND**

Where the prominence measures >30mm (using the measuring guide below)

Measuring guide

One of the most consistent methods for measuring the degree of prominence is the helical-mastoid (H-M) distance. Typically, the H-M distance is 18-20 mm. As the H-M distance increases, the ear is perceived to be increasingly prominent.

Measure from the posterior aspect of the Helix.

Prominence = H-M distance > 20mm

Pinnaplasty/otoplasty will only be considered in patients who have a >30mm prominence, unless there are other considerations e.g. in helping to retain hearing aids. In which case an IFR application would be required clearing setting out the patient's clinical exceptionality.

Rhinoplasty/Septoplasty/Rhinoseptoplasty (surgery to reshape the nose)

Criteria

NEL CCG will fund Rhinoplasty/Septoplasty/Rhinoseptoplasty (surgery to reshape the nose) when all of the following criteria are met:

Rhinoplasty, commonly known as a 'nose job', is a plastic surgery procedure for correcting and reconstructing the form, restoring the functions, and aesthetically enhancing the nose by resolving nasal trauma (blunt, penetrating, blast), congenital defect, respiratory impediment, or a failed primary rhinoplasty.

- a) Rhinoplasty, Septoplasty and Septorhinoplasty are not routinely commissioned for cosmetic reasons.
- b) Rhinoplasty, Septoplasty and Septorhinoplasty are restricted for non- cosmetic/other reasons.

The CCG will fund this treatment if the patient meets the following criteria:

- Documented medical problems caused by obstruction of the nasal airway AND all conservative treatments have been exhausted.
- Correction of complex congenital conditions e.g. Cleft lip and palate

The above criteria apply in cases resulting from trauma. For the purposes of this eligibility criteria, a medical problem is defined as a medical problem that continually impairs sleep and/or breathing.

This means (for patients who DO NOT meet the above criteria or require the procedure for cosmetic reasons) 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.

Tonsillectomy

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 Scottish Intercollegiate Guidelines Network (SIGN) guidance and supported by ENT UK commissioning guidance.

NEL CCG will fund tonsillitis when criteria 1 and 2 and one of criteria 3(a) or 3(b) or 3(c) are met:

Section 1

1. Sore throats are due to acute tonsillitis

AND

2. The episodes are disabling and prevent normal functioning

AND

3(a). Seven or more, documented, clinically significant, adequately treated sore throats in the preceding year

OR

3(b). Five or more such episodes in each of the preceding two years

OR

3(c). Three or more such episodes in each of the preceding three years

Section 2

There are a number of medical conditions where episodes of tonsillitis can be damaging to health or where 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. In these instances with prior approval, **NEL CCG will fund surgery when one of the following criteria are met:**

1. Acute and chronic renal disease resulting from acute bacterial tonsillitis

OR

2. As part of the treatment of severe guttate psoriasis

OR

Metabolic disorders where periods of reduced oral intake could be dangerous to health OR

4. PFAPA (Periodic fever, Apthous stomatitis, Pharyngitis, Cervical adenitis)

OR

5. Severe immune deficiency that would make episodes of recurrent tonsillitis dangerous

Additional information

Further information on the SIGN 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 a national randomised control trial is underway comparing surgery versus conservative management for recurrent tonsillitis in adults which may warrant review of this guidance in the near future.

The guidance applies to adults and children.

2C Surgical intervention for chronic rhinosinusitis (Surgery for sinusitis)

Criteria

Patients are eligible to be referred for specialist secondary care assessment in any of the following circumstances:

— A clinical diagnosis of CRS has been made (as set out in RCS/ENT-UK Commissioning guidance) in primary care and patient still has moderate / severe symptoms after a 3-month trial of intranasal steroids and nasal saline irrigation.

AND

— In addition, for patients with bilateral nasal polyps there has been no improvement in symptoms 4 weeks after a trial of 5-10 days of oral steroids (0.5mg/kg to a max of 60 mg)

OR

— Patient has nasal symptoms with an unclear diagnosis in primary care

OR

— Any patient with unilateral symptoms or clinical findings, orbital, or neurological features should be referred urgently / via 2-week wait depending on local pathways.

No investigations, apart from clinical assessment, should take place in primary care or be a prerequisite for referral to secondary care (e.g. X-ray, CT scan). There is no role for prolonged courses of antibiotics in primary care.

Patients can be considered for endoscopic sinus surgery when the following criteria are met: — A diagnosis of CRS has been confirmed from clinical history and nasal endoscopy and / or CT scan

AND

— Disease-specific symptom patient reported outcome measure confirms moderate to severe symptoms e.g. Sinonasal Outcome Test (SNOT-22) after trial of appropriate medical therapy (including counselling on technique and compliance) as outlined in RCS/ENT-UK commissioning guidance 'Recommended secondary care pathway'.

AND

— Pre-operative CT sinus scan has been performed and confirms presence of CRS. Note: a CT sinus scan does not necessarily need to be repeated if performed sooner in the patient's pathway.

AND

— Patient and clinician have undertaken appropriate shared decision making consultation regarding undergoing surgery including discussion of risks and benefits of surgical intervention.

OR

— In patients with recurrent acute sinusitis, nasal examination is likely to be relatively normal. Ideally, the diagnosis should be confirmed during an acute attack if possible, by nasal endoscopy and/or a CT sinus scan.

There are a number of medical conditions whereby endoscopic sinus surgery may be required outside the above criteria and in these cases they should not be subjected to the above criteria and continue to be routinely funded:

- Any suspected or confirmed neoplasia
- Emergency presentations with complications of sinusitis (e.g. orbital abscess, subdural or intracranial abscess)
- Patients with immunodeficiency
- Fungal Sinusitis
- Patients with conditions such as Primary Ciliary Dyskinesia, Cystic Fibrosis or NSAID-Eosinophilic Respiratory Disease (NSAID-ERD, Samter's Triad Aspirin Sensitivity, Asthma, CRS)
- Treatment with topical and / or oral steroids contra-indicated.
- As part of surgical access or dissection to treat non-sinus disease (e.g. pituitary surgery, orbital decompression for eye disease, nasolacrimal surgery)

There is a strong evidence base and expert consensus opinion to support the medical management of chronic rhinosinusitis with intranasal steroids and nasal saline irrigation as a first-line treatment. They are low cost and low risk, with newer generations of nasal steroids safe for long-term use owing to minimal systemic absorption.

There is also evidence to support the trial of oral steroids, but only when nasal polyposis is present. The benefits of oral steroids should be balanced against the risks when considering repeated courses. A Cochrane review has demonstrated the benefits of oral steroids can last up to three months; however the risks and side effects must be balanced against benefit for the patient with repeated courses.

There is evidence to support that when endoscopic sinus surgery is performed in appropriately selected patients (as outlined in the recommendation), it will lead to a significant and durable improvement in symptoms. There is also evidence that patients who undergo surgery early in their disease course will have a longer and more beneficial impact from the surgery. All national and international guidelines support consideration of endoscopic sinus surgery once appropriate medical therapy has failed.

It is important to note that there is currently a UK multidisciplinary randomised controlled trial (RCT) comparing medical therapy with surgery in the management of chronic rhinosinusitis (MACRO Trial: https://www.themacroprogramme.org.uk). he outcome of this trial may lead to modification of guidance for sinus surgery in due course.

Endoscopic sinus surgery is generally safe and low risk. Risks include bleeding, infection, scar tissue formation, and very rarely, orbital injury or cerebrospinal fluid leak (with associated risk of meningitis). Patients should be counselled that there is a risk of recurrent symptoms and that ongoing medical treatment is normally required to maintain symptom improvement after endoscopic sinus surgery.

This guidance applies to adults and children.

Gastroenterology

Category 1 Procedures: Individual funding request (IFR)

Double balloon enteroscopy for diagnostic purpose

Category 2 Procedures

2M Upper GI endoscopy (Endoscopy to investigate gut problems)

Criteria

Upper GI Endoscopy should only be performed if the patient meets the following criteria:

Urgent: (Within two weeks)

- Any dysphagia (difficulty in swallowing), to prioritise urgent assessment of dysphagia please refer to the Edinburgh Dysphagia Score OR
- Aged 55 and over with weight loss and any of the following:
 - Upper abdominal pain
 - Reflux Dyspepsia (4 weeks of upper abdominal pain or discomfort
 - Heartburn
 - Nausea or vomiting

- Those aged 55 or over who have one or more of the following:
 - Treatment resistant dyspepsia (as above), upper abdominal pain with low haemoglobin level (blood level) OR
 - Raised platelet count with any of the following: nausea, vomiting, weight loss, reflux, dyspepsia, upper abdominal pain OR
 - Nausea and vomiting with any of the following: weight loss, reflux, dyspepsia, upper abdominal pain.

For the assessment of Upper GI bleeding:

- For patients with haematemesis, calculate Glasgow Blatchford Score at presentation and any highrisk patients should be referred
- Endoscopy should be performed for unstable patients with severe acute upper gastrointestinal bleeding immediately after resuscitation
- Endoscopy should be performed within 24 hours of admission for all other patients with upper gastrointestinal bleeding.

For the investigation of symptoms:

- Clinicians should consider endoscopy:
 - Any age with gastro-oesophageal symptoms that are nonresponsive to treatment or unexplained
 - With suspected GORD who are thinking about surgery
 - With H pylori that has not responded to second- line eradication
 - Eradication can be confirmed with a urea breath test.

For management of specific cases H pylori and associated peptic ulcer:

— Eradication can be confirmed with a urea breath test, however if peptic ulcer is present repeat endoscopy should be considered 6-8 weeks after beginning treatment for H pylori and the associated peptic ulcer.

Barrett's oesphagus:

- Where available the non-endoscopic test called Cytosponge can be used to identify those who have developed Barrett's oesophagus as a complication of long-term reflux and thus require long term surveillance for cancer risk
- Consider endoscopy to diagnose Barrett's Oesophagus if the person has GORD (endoscopically determined oesphagitis or endoscopy negative reflux disease)
- Consider endoscopy surveillance if person is diagnosed with Barrett's Oesophagus.

Coeliac disease:

— Patients aged 55 and under with suspected coeliac disease and anti-TTG >10x reference range should be treated for coeliac disease on the basis of positive serology and without endoscopy or biopsy.

Surveillance endoscopy:

- Surveillance endoscopy should only be offered in patients fit enough for subsequent endoscopic or surgical intervention, should neoplasia be found. Many of this patient group are elderly and/or have significant comorbidities. Senior clinician input is required before embarking on long term endoscopic surveillance.
- Patients diagnosed with extensive gastric atrophy (GA) or gastric intestinal metaplasia, (GIM) (defined as affecting the antrum and the body) should have endoscopy surveillance every three years

— Patients diagnosed with GA or GIM just in the antrum with additional risk factors- such as strong family history of gastric cancer of persistent H pylori infection, should undergo endoscopy every three years.

Screening endoscopy can be considered in:

— European guidelines (2015) for patients with genetic risk factors / family history of gastric cancer recommend genetics referral first before embarking on long term screening. Screening is not appropriate for all patients and should be performed in keeping with European expert guidelines.

— Patients where screening is appropriate, for individuals aged 50 and over, with multiple risk factors for gastric cancer (e.g. H. Pylori infection, family history of gastric cancer - particularly in first degree relative -, pernicious anaemia, male, smokers).

Post excision of adenoma:

— Following complete endoscopic excision of adenomas, gastroscopy should be performed at 12 months and then annually thereafter when appropriate.

2N Appropriate colonoscopy in the management of hereditary colorectal Cancer (Colonoscopy of the lower intestine)

Criteria

Follow the British Society of Gastroenterology surveillance guidelines for colonoscopy in the management of hereditary colorectal cancer: https://www.bsg.org.uk/resource/guidelines-for-the-management-of-hereditarycolorectal-cancer.html.

Family history of CRC

For individuals with moderate familial CRC risk:

- Offer one-off colonoscopy at age 55 years
- Subsequent colonoscopic surveillance should be performed as determined by post-polypectomy surveillance guidelines.

For individuals with high familial CRC risk (a cluster of 3x FDRs with CRC across >1 generation):

Offer colonoscopy every 5 years from age 40 years to age 75 years.

Lynch Syndrome (LS) and Lynch-like Syndrome

For individuals with LS that are MLH1 and MSH2 mutation carriers:

— Offer colonoscopic surveillance every 2 years from age 25 years to age 75 years.

For individuals with LS that are MSH6 and PMS2 mutation carriers:

— Offer colonoscopic surveillance every 2 years from age 35 years to age 75 years.

For individuals with Lynch-like Syndrome with deficient MMR tumours without hypermethylation/BRAF pathogenic variant and no pathogenic constitutional pathogenic variant in MMR genes (and their unaffected FDRs), and no evidence of biallelic somatic MMR gene inactivation:

— Offer colonoscopic surveillance every 2 years from age 25 years to age 75 years.

Early Onset CRC (EOCRC)

For individuals diagnosed with CRC under age 50 years, where hereditary CRC symptoms have been excluded:

- Offer standard post-CRC colonoscopy surveillance after 3 years
- Then continue colonoscopic surveillance every 5 years until eligible for national screening.

Serrated Polyposis Syndrome (SPS)

For individuals with SPS:

- Offer colonoscopic surveillance every year from diagnosis once the colon has been cleared of all lesions >5mm in size
- If no polyps ≥ 10mm in size are identified at subsequent surveillance examinations, the interval can be extended to every 2 years.

For first degree relatives of patients with SPS:

- Offer an index colonoscopic screening examination at age 40 or ten years prior to the diagnosis of the index case
- Offer a surveillance colonoscopy every 5 years until age 75 years, unless polyp burden indicates an examination is required earlier according to post-polypectomy surveillance guidelines.

Multiple Colorectal Adenoma (MCRA)

For individuals with MCRA (defined as having 10 or more metachronous adenomas):

- Offer annual colonoscopic surveillance from diagnosis to age 75 years after the colon has been cleared of all lesions >5mm in size
- If no polyps 10mm or greater in size are identified at subsequent surveillance examinations, the interval can be extended to 2 yearly.

Familial Adenomatous Polyposis (FAP)

For individuals confirmed to have FAP on predictive genetic testing:

- Offer colonoscopic surveillance from 12-14 years
- Then offer surveillance colonoscopy every 1-3 years, personalised according to colonic phenotype.

For individuals who have a first degree relative with a clinical diagnosis of FAP (i.e. "at risk") and in whom a APC mutation has not been identified:

- Offer colorectal surveillance from 12-14 years
- Then offer every 5 years until either a clinical diagnosis is made and they are managed as FAP or the national screening age is reached.

MUTYH-associated Polyposis (MAP)

For individuals with MAP:

- Offer colorectal surveillance from 18-20 years, and if surgery is not undertaken, repeat annually. For monoallelic MUTYH pathogenic variant carriers:
- The risk of colorectal cancer is not sufficiently different to population risk to meet thresholds for screening and routine colonoscopy is not recommended.

Peutz-Jeghers Syndrome (PJS)

For asymptomatic individuals with PSJ:

- Offer colorectal surveillance from 8 years
- If baseline colonoscopy is normal, deferred until 18 years, however if polyps are found at baseline examination, repeat every 3 years.

For symptomatic patients, investigate earlier.

Juvenile Polyposis Syndrome (JPS)

For asymptomatic individuals with JPS:

- Offer colorectal surveillance from 15 years
- Then offer a surveillance colonoscopy every 1-3 years, personalised according to colorectal phenotype.

For symptomatic patients, investigate earlier.

For some patients with multiple risk factors for CRC, for example those with Lynch Syndrome and inflammatory bowel disease/multiple polyps, more frequent colonoscopy may be indicated. This needs to be guided by clinicians but with a clear scientific rationale linked to risk management.

20 Repeat Colonoscopy (Follow up colonoscopy of the lower intestine)

Criteria

Proposal Follow the British Society of Gastroenterology surveillance guidelines for post-polypectomy and post-colorectal cancer resection: https://www.bsg. org.uk/resource/bsg-acpgbi-phe-post-polypectomy-and-post-colorectalcancer-resection-surveillance-guidelines.html.

Risk Surveillance Criteria for Colonoscopy

Either of the following put individuals at high-risk for future colorectal cancer following polypectomy:

— 2 or more premalignant polyps including at least one advanced colorectal polyp (defined as a serrated polyp of at least 10mm in size or containing any grade of dysplasia, or an adenoma of at least 10mm in size or containing high-grade dysplasia); OR

5 or more premalignant polyps.

Surveillance colonoscopy after polypectomy

For individuals at **high-risk** and under the age of 75 **and** whose life expectancy is greater than 10 years:

Offer one-off surveillance colonoscopy at 3 years.

For individuals with no high-risk findings:

- No colonoscopic surveillance should be undertaken
- Individuals should be strongly encouraged to participate in their national bowl screening programme when invited.

For individuals not at high-risk who are more than 10 years younger than the national bowel screening programme lower age-limit, consider for surveillance colonoscopy after 5 or 10 years, individual to age and other risk factors.

Surveillance colonoscopy after potentially curative CRC resection:

- Offer a clearance colonoscopy within a year after initial surgical resection
- Then offer a surveillance colonoscopy after a further 3 years
- Further surveillance colonoscopy to be determined in accordance with the post-polypectomy highrisk criteria. 8. The number of interventions (415,262) represents colonoscopies for all indications, including those with symptoms and/or risk factors.

Surveillance after pathologically en bloc R0 EMR or ESD of LNPCPs or early polyp cancers:

- No site-checks are required
- Offer surveillance colonoscopy after 3 years
- Further surveillance colonoscopy to be determined in accordance with the post-polypectomy high-risk criteria.

Surveillance after piecemeal EMR or ESD of LNPCPs (large nonpedunculated colorectal polyps of at least 20mm in size):

- Site-checks at 2-6 months and 18 months from the original resection Once no recurrence is confirmed, patients should undergo post polypectomy surveillance after 3 years
- Further surveillance colonoscopy to be determined in accordance with the post-polypectomy highrisk criteria.

Surveillance where histological completeness of excision cannot be determined in patients with: (i) a non-pedunculated polyps of 10-19mm in size, or (ii) an adenoma containing high-grade dysplasia, or (iii) a serrated polyp containing any dysplasia:

- Site-check should be considered within 2-6 months
- Further surveillance colonoscopy to be determined in accordance with the post-polypectomy highrisk criteria

Ongoing colonoscopic surveillance:

— To be determined by the findings at each surveillance procedure, using the high-risk criteria to stratify risk — Where there are no high-risk findings, colonoscopic surveillance should cease but individuals should be encouraged to participate in the national bowel screening programme when invited.

General Surgery

Category 1 Procedures: Individual funding request (IFR)

All treatments for vascular lesions

Category 2 Procedures

Abdominoplasty

Criteria

NEL CCG will fund abdominoplasty following significant weight loss after bariatric surgery when criteria 1 is met or when criteria 2(a) and 2(b) are met:

Section 1: Following weight loss

1. Following non bariatric surgery weight loss have a stable BMI of less than 27 Kg/m2 for at least 24 months

OR

2(a). Following post bariatric surgery weight loss have a stable BMI of less than 27 Kg/m2 for at least 24 months

AND

2(b). Had their surgery at least two years previously

NEL CCG will fund abdominoplasty following significant weight loss after natural weight loss when one of criteria 3(a), 3(b) or 3(c) are met:

Section 2 have severe functional problems from excessive abdominal skin folds as defined as:

3(a). Severe difficulties with daily living (i.e. walking, dressing, toileting) which have been formally assessed, and for which abdominoplasty will provide a clear resolution

OR

3(b). Documented evidence of clinical pathology due to excess overlying skin e.g. recurrent infections or intertrigo which has led to ulceration requiring four or more courses of antibiotics in the 24 month period of stable weight

OR

3(c). Where overhanging skin makes it impossible to maintain care of stoma bags

Haemorrhoidectomy

Criteria

Often haemorrhoids (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.

NEL CCG will fund haemorrhoidectomy when one of the following criteria are met:

1. Do not respond to the non-operative measures outlined above

OR if the haemorrhoids are more severe

2. Recurrent grade 3 or grade 4 combined internal/external haemorrhoids with persistent pain or bleeding

OR

3. Irreducible and large external haemorrhoids

In cases where there is significant rectal bleeding the patient should be examined internally by a specialist.

Varicose veins

Criteria

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.

NEL CCG will fund varicose veins when one of the following criteria are met:

1. Symptomatic * primary or recurrent varicose veins

OR

2. Lower limb skin changes, such as pigmentation or eczema, thought to be caused by chronic venous insufficiency

OR

3. Superficial vein thrombophlebitis (characterised by the appearance of hard, painful veins) and suspected venous incompetence

OR

4. A venous leg ulcer (a break in the skin below the knee that has not healed within two weeks) **OR**

5. A healed venous leg ulcer.

*Symptomatic: "Veins found in association with troublesome lower limb symptoms (typically pain, aching, discomfort, swelling, heaviness and itching)." [NICE CG 168]

For patients whose veins are purely cosmetic and are not associated with any symptoms do not refer for NHS treatment.

Refer people with bleeding varicose veins to a vascular service immediately.

Do not offer compression hosiery to treat varicose veins unless interventional treatment is unsuitable.

2B Repair of minimally symptomatic inguinal hernia (Surgery for inguinal hernia)

Criteria

Minimally symptomatic inguinal hernia can be managed safely with watchful waiting after assessment. Conservative management should therefore be considered in appropriately selected patients.

In women, all suspected groin hernias should be urgent referrals.

https://www.aomrc.org.uk/ebi/clinicians/repair-of-minimally-symptomatic-inguinal-hernia/

2P ERCP in acute gallstone pancreatitis without cholangitis (Test of the gallbladder)

Criteria

Early ERCP in the treatment of acute gallstone pancreatitis, should only be performed if there is evidence of cholangitis or obstructive jaundice with imaging evidence of a stone in the common bile duct. Early ERCP refers to ERCP being performed on the same admission, ideally within 24 hours.

2Q Cholecystectomy (Removal of an inflamed gallbladder)

Criteria

For patients who are admitted to hospital with acute cholecystitis or mild gallstone pancreatitis, index laparoscopic cholecystectomy should be performed within that admission. These patients should have their gallbladders removed, ideally before discharge, to avoid further delay and prevent further potentially fatal attacks. If the patient is fit enough for surgery and same admission cholecystectomy will be delayed for more than 24 hours, it may be reasonable to make use of a virtual ward, where the patient can return home under close monitoring prior to undergoing surgery as soon as possible.

Otherwise patients diagnosed with acute cholecystitis should have their laparoscopic cholecystectomy on the same admission within 72 hours (NICE guidelines published in October 2014 state one week, but 72 hours is preferable). This guidance may not be applicable in patients with severe acute pancreatitis.

Surgery for these patients may be challenging and can be associated with a higher incidence of complications (particularly beyond 96 hours) and a higher conversion rate from laparoscopic surgery to open surgery. These patients should be operated on by surgeons with experience of operating on

patients with acute cholecystitis, or if not available locally, transfer to a specialist unit should be considered. Timely intervention is preferable to a delayed procedure, and, if the operation cannot be performed during the index admission it should be performed within two weeks of discharge.

2R Appendicectomy without confirmation of appendicitis (Tests to confirm appendicitis)

Criteria

Consider imaging of patients with the suspicion of acute appendicitis in a defined clinical pathway.

Where patients present with a high clinical suspicion of appendicitis, then imaging may not be necessary, but imaging can help identify which patients can be managed conservatively. If there is clinical doubt then imaging can reduce the negative appendicectomy rate. Most patients should have an ultrasound as the first-line investigation. If the diagnosis remains equivocal, a contrast-enhanced CT (CECT, preferably low dose) can be performed to give a definitive diagnosis prior to the patient returning to the surgical unit for a decision on management.

A pathway like this is dependent on the availability of an adequately skilled Radiologist (Consultant or Registrar) or Sonographer to perform the ultrasound assessment in a timely fashion. If this is not possible discretion should be used to proceed directly to limited dose CECT of the abdomen and pelvis.

This guidance applies to adults and children.

Gynaecology/Urology

Category 1 Procedures: Individual funding request (IFR)

Cosmetic genital procedures (Labiaplasty – excluding Female Genital Mutilation (refer to circumcision category 2 prior approval policy)

Dilation & curettage (D&C) for heavy menstrual bleeding in women (see below)

MRI guided ultrasound (MRgFUS) for uterine fibroids

Non-medical circumcision

Reversal of female sterilisation and reversal of vasectomy

Sacral nerve stimulation for faecal and urinary incontinence

Varicocele

Dilation & curettage (D&C) for heavy menstrual bleeding in women

Criteria

D&C should not be used for diagnosis or treatment for heavy menstrual bleeding in women because it is clinically ineffective.

Ultrasound scans and camera tests with sampling of the lining of the womb (hysteroscopy and biopsy) should be used to investigate heavy periods.

Medication and intrauterine systems (IUS) should be used to treat heavy periods.

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.

Category 2 Procedures

Bartholin's cysts

Criteria

NEL CCG will fund the surgical treatment of Bartholin's cysts which cause one of the following:

1. Significant pain

OR

2. Have become infected requiring anti-biotic treatment on at least two separate occasions

Circumcision

Criteria

NEL CCG will fund circumcision when one of the following criteria are met:

1. Phimosis seriously interfering with urine flow and/or associated with recurrent infection **OR**

2. Patients with discomfort and physical distress

OR

3. Paraphimosis

OR

4. Suspected cancer or balanitis obliterans

OR

5. Congenital urological abnormalities when skin is required for grafting and interference with sexual activity in adult males

OR

6. Recurrent, significantly troublesome episodes of infection beneath the foreskin

OR

7. To restore functional anatomy after female circumcision to facilitate childbirth where mutilation renders this hazardous

Female circumcision (Female Genital Mutilation) is prohibited under the Prohibition of Female Circumcision Act 1995.

Hysterectomy for menorrhagia (heavy menstrual bleeding)

Criteria

Based on NICE guidelines [Heavy menstrual bleeding: assessment and management [NG88] Published date: March 2018], 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.

NEL CCG will fund hysterectomy when criteria 1 and 3(a), 3(b) and 3(c) are met or 2 and 3(a), 3(b) and 3(c) are met:

Hysterectomy should be considered only when:

1. Where other treatment options have failed

OR

2. Where other treatment options are contradicted

OR

3a. there is a wish for amenorrhoea (no periods)

3b. the woman (who has been fully informed) requests it

AND

3c. the woman no longer wishes to retain her uterus and fertility

NICE guideline NG88 1.5 Management of HMB: 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.

NEL CCG will fund treatment for women with no identified pathology, fibroids less than 3 cm in diameter, or suspected or diagnosed adenomyosis when one of the following criteria are met:

1. 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.

OR

2. 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.

Be aware that progestogen-only contraception may suppress menstruation, which could be beneficial to women with HMB.

OR

3. 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, surgical options: second-generation endometrial ablation, hysterectomy.

OR

4. For women with submucosal fibroids, consider hysteroscopic removal

Treatments for women with fibroids of 3 cm or more in diameter

Consider referring women to specialist care to undertake additional investigations and discuss treatment options for fibroids of 3 cm or more in diameter.

If pharmacological treatment is needed while investigations and definitive treatment are being organised, offer tranexamic acid and/or NSAIDs.

Advise women to continue using NSAIDs and/or tranexamic acid for as long as they are found to be beneficial.

For women with fibroids of 3cm 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.

Be aware that the effectiveness of pharmacological treatments for HMB may be limited in women with fibroids that are substantially greater than 3cm in diameter.

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]

Consider second-generation endometrial ablation as a treatment option for women with HMB and fibroids of 3cm or more in diameter who meet the criteria specified in the manufacturers' instructions.

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.

Pre-treatment with a gonadotrophin-releasing hormone analogue before hysterectomy and myomectomy should be considered if uterine fibroids are causing an enlarged or distorted uterus.

2G Surgical removal of kidney stones (Removal of stones from the kidneys)

Criteria

Please refer to NICE NG118 (recommendation 1.5) for full details on the assessment and management of renal and ureteric stones: https://www.nice.org.uk/guidance/ng118/chapter/Recommendations.

Adult renal stones

<5mm: If asymptomatic consider watchful waiting

5-10mm: If not suitable for watchful waiting offer SWL as first-line treatment (unless contra-indicated or not targetable)

10-20mm: Consider SWL as first-line treatment if treatment can be given in a timely fashion. URS can also be considered if SWL is contraindicated or ineffective

Over 20mm (including staghorn): Offer percutaneous nephrolithotomy (PCNL) as first-line treatment

Adult ureteric stones

<5mm: If asymptomatic consider watchful waiting with medical therapy e.g. Alpha blocker for use with distal ureteric stones

5-10mm: Offer SWL as first-line treatment where it can be given in a timely fashion (unless contraindicated or not targetable)

10-20mm: Offer URS but consider SWL if local facilities allow stone clearance within 4 weeks.

2H Cystoscopy for men with uncomplicated lower urinary tract symptoms (Camera test of the bladder in men)

Criteria

Assessment of men with LUTS should focus initially on a thorough history and examination, complemented by use of a frequency – volume chart, urine dipstick analysis and International Prostate Symptom Score where appropriate. This assessment may be initiated in primary care settings.

Specialist assessment should also incorporate a measurement of flow rate and post void residual volume.

Cystoscopy should be offered to men with LUTS only when clinically indicated, for example, in the presence of the following features from their history:

- Recurrent infection
- Sterile pyuria

- Haematuria
- Profound symptoms
- Pain.

Additional contextual information may also inform clinical decision-making around the use of cystoscopy in men with LUTS. Such factors might include, but not be limited to:

- Smoking history
- Travel or occupational history suggesting a high risk of malignancy
- Previous surgery.

2l Surgical intervention for benign prostatic hyperplasia (Surgery for enlarged prostate)

Criteria

Only men with severe voiding symptoms, or in whom conservative management options and drug treatment have been unsuccessful, should be offered surgical intervention. Surgery is indicated (in healthy men) in complicated BPH i.e. chronic retention with renal impairment as evidenced by hydronephrosis and impaired GFR, and in most cases of acute retention secondary to BPH.

As such, a staged approach to managing voiding LUTS is recommended:

- 1. Conservative, or lifestyle interventions should be discussed.
- 2. Drug therapy should then be considered, in the context of more bothersome LUTS, or LUTS not responding to simple lifestyle interventions.
- 3. Where bothersome LUTS persist alongside high, or unchanged International Prostate Symptom Scores, or in the context of urinary tract infections, bladder stones or urinary retention, surgical intervention should be considered using a shared decision-making approach.

Men considering surgical intervention should be counselled thoroughly regarding alternatives to and outcomes from surgery. The quality of this counselling is deemed to be of major importance with respect to men's future experience and outcomes.

2CC Prostate-specific antigen (PSA) testing

Criteria

Where PSA testing is clinically indicated (see below), or requested by the man aged 50 and over, he should have a careful discussion about the potential risks and benefits of PSA testing which allows for shared decision making before a PSA test. Various tools are available to assist with shared decision making (see below).

PSA testing should be considered in asymptomatic men over age 40 who are at higher risk of prostate cancer if they are Black and/or have a family history of prostate cancer.

PSA testing should be considered when clinically indicated (ideally after counselling on the potential risks and benefits of testing) in men when there is clinical suspicion of prostate cancer, which may include the following symptoms:

- Lower urinary tract symptoms (LUTS), such nocturia, urinary frequency, hesitancy, reduced flow, urgency or retention.
- Erectile dysfunction.
- Visible haematuria.

— Unexplained symptoms that could be due to advanced prostate cancer (for example lower back pain, bone pain, weight loss).

PSA testing for prostate cancer is not recommended in asymptomatic men (unless they are at high risk of prostate cancer i.e. Black and/or family history) is not recommended. This is because the benefits have not been shown to clearly outweigh the harms. In particular, there is concern about the high risk of false positive results.

Where PSA test results are mildly raised above the age specific range for an individual patient, it may be appropriate to repeat the test within two to three months to monitor the trend.

Note: PSA testing for prostate cancer should be avoided if the man has:

— An active or recent urinary infection (PSA may remain raised for many months). — Had a prostate biopsy in the previous 6 weeks both of which are likely to raise PSA and give a false positive result.

Haematology

Category 1 Procedures: Individual funding request (IFR)

White cell apheresis

Category 2 Procedures

2EE Blood transfusion

Criteria

This guidance focuses on RBC transfusions for adults (or equivalent based on body weight for children or adults with low body weight) only.

Do not give RBC transfusions to patients with B12, folate or iron deficiency anaemia unless there is haemodynamic instability. If haemodynamic instability is present, treat this with transfusion of appropriate blood components (do not delay emergency transfusions).

Where, however, severe acute anaemia (Hb <70g/litre) exists that is symptomatic and prevents rehabilitation or mobilisation, those patients may benefit from a single unit of blood.

For adult patients (or equivalent based on body weight for children or adults with low body weight) needing RBC transfusion, suggest restrictive thresholds and giving a single unit at a time except in case of exceptions below.

Restrictive RBC transfusion thresholds are for patients who need RBC

transfusions and who do not:

- Have major haemorrhage or
- Have acute coronary syndrome or
- Need regular blood transfusions for chronic anaemia.

While transfusions are given to replace deficient red blood cells, they will not correct the underlying cause of the anaemia. RBC transfusions will only provide temporary improvement. It is important to investigate why patients are anaemic and treat the cause as well as the symptoms.

Note: Consider whether a dramatic fall in haemoglobin could be due to a severe haemolytic episode and not associated with any of the 3 exceptions. This would also be a possible indication to transfuse more than one unit at a time.

When using a restrictive RBC transfusion threshold, consider a threshold of 70 g/litre and a haemoglobin concentration target of 70–90 g/litre after transfusion.

For patients with acute coronary syndrome, a RBC transfusion threshold of 80 g/litre should be considered and a haemoglobin concentration target of 80–100 g/litre after transfusion.

For patients requiring regular transfusion for chronic anaemia, NICE advise defining thresholds and haemoglobin concentration targets for each individual.

This guidance applies to adults (or equivalent based on body weight for children or adults with low body weight) only.

Medicine

Category 1 Procedures: Individual funding request (IFR)

Ketogenic diet for epilepsy

Ophthalmology

Category 1 Procedures: Individual funding request (IFR)

Laser surgery for short sightedness

Category 2 Procedures

Cataract surgery

Criteria

This policy relates to cataract surgery only, as described in detail below.

The policy does not apply to:

- Patients with confirmed or suspected malignancy
- Patients with acute trauma or suspected infection
- Children under the age of 18

NEL CCG will fund cataract surgery when both of the following criteria are met:

- 1. Patient has a best corrected visual acuity of 6/9 or worse in either the first or second eye **AND**
- 2. Patient has impairment in lifestyle such as substantial effect on activities of daily living, leisure activities, and risk of falls

OR

NEL CCG will fund cataract surgery when the patient has any of the following ocular comorbidities:

- Glaucoma
- Conditions where cataract may hinder disease management or monitoring, including diabetic
 and other retinopathies including retinal vein occlusion, and age related macular degeneration;
 neuro-ophthalmological conditions (e.g. visual field changes); or getting an adequate view of
 fundus during diabetic retinopathy screening
- Occuloplastics disorders where fellow eye requires closure as part of eyelid reconstruction
- Corneal disease where early cataract removal would reduce the chance of losing corneal clarity (e.g. Fuch's corneal dystrophy or after keratoplasty)
- Corneal or conjunctival disease where delays might increase the risk of complications (e.g. cicatrising conjunctivitis)
- Severe anisometropia in patients who wear glasses
- Posterior subcapsular cataracts

AND

• The consultant treating the patient agrees that cataract surgery is in the best interests of the patient

Additional information

All patients should be given the opportunity to engage with shared decision making at each point in the pathway to cataract surgery (e.g. optometrists, GPs, secondary care), to ensure they are well informed about the treatment options available and personal values, preferences and circumstances are taken into consideration.

- Surgery is also indicated for management of cataract with coexisting ocular comorbidities. A
 full list of these ocular comorbidities can be found below.*
- Where patients have a best corrected visual acuity better than 6/9, surgery should still be
 considered where there is a clear clinical indication or symptoms affecting lifestyle. For NHS
 treatment to be provided, there needs to be mutual agreement between the provider and the
 responsible (i.e. Paying) commissioner about the rationale for cataract surgery prior to
 undertaking the procedure).

Chalazia removal

Criteria

NEL CCG will fund incision and curettage (or triamcinolone injection for suitable candidates) of chalazia when one of the following criteria have been met:

1. Has been present for more than six months and has been managed conservatively with warm compresses, lid cleaning and massage for four weeks

OR

2. Interferes significantly with vision

OR

3. Interferes with the protection of the eye by the eyelid due to altered lid closure or lid anatomy **OR**

4. Is a source of infection that has required medical attention twice or more within a six month time frame

OR

5. Is a source of infection causing an abscess which requires drainage

OF

6. If malignancy (cancer) is suspected e.g. Madarosis/recurrence/other suspicious features in which case the lesion should be removed and sent for histology as for all suspicious lesions

Surgery on the upper or lower eyelid (blepharoplasty)

Criteria

NEL CCG will fund surgery on the upper or lower eyelid when one of the following criteria are met:

1. Impairment of visual field(s) in the relaxed, non-compensated state where visual field test results show that eyelids impinge on visual fields reducing them to 1200 laterally and 400 vertically

OR

2. Patients who have severe headache as a result of frontalis muscle overaction when trying to overcome brow ptosis, upper eyelid ptosis or excess dermatochalasis should be allowed corrective surgery

Additional information

These procedures should only be carried out in the ophthalmology department under the care of an oculoplastic surgeon.

NEL CCG will not fund ptosis repair, upper eyelid blepharoplasty and brow lift for cosmetic reasons. This will include corrective surgery for patients who are dissatisfied with the cosmetic appearance post-surgery of any of the procedure mentioned above.

Orthopaedics

Category 1 Procedures: Individual funding request (IFR)

Autologous chondrocyte (cartilage) implantation

Injections for non-specific low back pain (see below for further guidance)

Knee arthroscopy for patients with osteoarthritis

Lumbar disc replacement (see back pain interventions below)

Ozone discectomy (see back pain interventions below).

Injections for non-specific low back pain

Criteria

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 not 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.

Note definition of non-specific low back pain according to NICE guidance: Low back pain that is not associated with serious or potentially serious causes has been described in the literature as 'non-specific', 'mechanical', 'musculoskeletal' or 'simple' low back pain. Alternative options are suggested in line with the National Back Pain Pathway. For further information, please see: https://www.nice.org.uk/guidance/ng59

Knee arthroscopy for patients with osteoarthritis

Criteria

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. ESCAPE pain), 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.

Category 2 Procedures:

Bunion surgery (Hallux Valgus)

Criteria

NEL CCG will fund bunion surgery where one of the following criteria are met:

1. Significant pain on walking not relieved by chronic standard analgesia

OR

2. Deformity such that fitting adequate footwear is difficult

OR

3. Overlapping or underlapping of adjacent toe(s)

OR

4. Hammer toes

OR

5. Recurrent or chronic ulceration

OR

6. Bursitis or tendinitis of the first metatarsal head

Functional electrical stimulation (FES) for foot drop

Criteria

NEL CCG will fund initiation or continuation of treatment when one of the following criteria are met:

The patient will have objectively demonstrated that the use of FES is still clinically appropriate by:

Initiation

1. Foot drop which impedes gait and evidence that this is not satisfactorily controlled using ankle-foot orthosis

OR

Continuation

2. Gait improvement from its use

Dupuytren's contracture release

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.

NEL CCG will fund intervention/treatment in the form of (collagenase injections, needle fasciotomy, fasciectomy and dermofasciectomy) when one of the following criteria are met:

1. Finger contractures causing loss of finger extension of 30° or more at the metacarpophalangeal joint or 20° at the proximal interphalangeal joint

OR

2. Severe thumb contractures which interfere with function

NEL CCG will fund, in line with NICE Guidance, collagenase when 1 or 2(a) and 2(b) of the following criteria are met:

1. Participants in the ongoing clinical trial (HTA-15/102/04)

OR

- 2. Adult patients with a palpable cord if:
- (a) 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

(b). needle fasciotomy is not considered appropriate, but limited fasciectomy is considered appropriate by the treating hand surgeon

Ganglion excision

Criteria

Section 1: Wrist ganglia

NEL CCG will fund wrist ganglia excision when 1 and 3 or 2 and 3 of the following criteria are met:

1. No treatment unless causing pain or tingling/numbness or concern (worried it is a cancer) **OR**

2. Aspiration if causing pain, tingling/numbness or concern

AND

3. Surgical excision only considered if aspiration fails to resolve the pain or tingling/numbness and there is restricted hand function

Section 2: Seed ganglia that are painful

NEL CCG will fund seed ganglia that are painful when one of the following criteria are met:

1. Puncture/aspirate the ganglion using a hypodermic needle

OR

2. Surgical excision only considered if ganglion persists or recurs after puncture/aspiration

Section 3: Mucous cysts

NEL CCG will fund mucous cysts when one of the following criteria are met:

 No surgery should be considered unless recurrent spontaneous discharge of fluid OR

2. Significant nail deformity

Surgical treatment of carpal tunnel syndrome

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 (8-12 weeks) term effectiveness)

OR

 Night splints (a support which prevents the wrist from moving during the night: not as effective as steroid injections)

NEL CCG will fund surgical treatment for carpal tunnel syndrome when 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 eight weeks

OR

2. A permanent (ever-present) reduction in sensation in the median nerve distribution **OR**

3. Muscle wasting or weakness of thenar abduction (moving the thumb away from the hand)

Nerve Conduction Studies if available are suggested for consideration before surgery to predict positive surgical outcome or where the diagnosis is uncertain.

Trigger finger

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:

 one or two steroid injections which are typically successful (strong evidence), but the problem may recur, especially in diabetics

OR

splinting of the affected finger for 3-12 weeks (weak evidence)

NEL CCG will fund trigger finger surgery when one of the following criteria are met:

1. The triggering persists or recurs after one of the above measures (particularly steroid injections) **OR**

2. The finger is permanently locked in the palm

OR

3. The patient has previously had two other trigger digits unsuccessfully treated with appropriate nonoperative methods

OR

4. Diabetics

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).

Treatment with steroid injections usually resolve troublesome trigger fingers within one week (strong evidence) but sometimes the triggering keeps recurring. Surgery is normally successful (strong evidence), provides better outcomes than a single steroid injection at one year and usually provides a permanent cure. Recovery after surgery takes two to four weeks. Problems sometimes occur after surgery, but these are rare (<3%).

Interventional treatments for back pain

Criteria

This policy relates to interventional treatments for back pain only as described in detail below and relates to people aged 18 and over.

Contained within this section are interventions that fall into both category 1 and 2.

For many patients, consideration of such treatments only arises after conservative management in primary care or specialist musculoskeletal services.

The following exclusions apply:

- Children (aged under 18)
- Patients thought to have/have cancer (including metastatic spinal cord compression)
- Patients with neurological deficit (spinal cord compression or cauda equina symptoms), fracture or infection

In ordinary circumstances, funding for interventional treatments for back pain is available for patients who meet the following criteria.

<u>Section 1: Epidurals</u> (Transforaminal epidurals and Interlaminar epidurals only) for radicular pain

NEL CCG will fund interventions for epidurals when criteria 1 and 2 and one of 3(a) or 3(b) are met:

- 1. The patient has radicular pain consistent with the level of spinal involvement **AND**
- 2. The patient has moderate-severe symptoms that have persisted for 12 weeks or more

AND either one of the following:

3(a). The patient has severe pain and advice, reassurance, analgesia and manual therapy ideally part of community Musculoskeletal (MSK) service has been undertaken. (Evidence that disc prolapses get better on their own)

AND/OR

3(b). The MRI scan (unless contraindicated) shows pathology concordant with the clinical diagnosis. A maximum of three epidural injections, within a 12 month period with objective with functional benefit demonstrable with each injection, will be funded

For patients with persisting symptoms after three injections, re-approval of treatment with epidural injections will be needed through the IFR panel. This may be older/frailer patients who derive medium term benefit but are unsuitable for or unwilling to have surgery.

Section 2: Spinal decompression

NEL CCG will fund interventions for spinal decompression when all of the following criteria are met:

1. The patient has radicular/claudicant leg pain consistent with the level of spinal involvement **AND**

2. The MRI scan (unless contraindicated) shows one or more areas of spinal stenosis whereby the pathology is concordant with the clinical diagnosis

AND

3. The patient has shown no sign of improvement despite conventional therapy for one year

Section 3: 2J Lumbar Discectomy (Spinal surgery for a slipped disc)

Patients presenting with radiculopathy who show objective evidence of clinical improvement within six weeks (e.g. VAS pain scores, ODI), are more likely than not to continue improving with non-operative treatment as the natural history of most intervertebral disc herniations is favourable.

Primary care management typically includes reassurance, advice on continuation of activity with modification, weight-loss, analgesia, manual therapy and screening patients who are high risk of developing chronic pain (i.e. STaRT Back).

Persistent symptoms may warrant onward referral to spinal services for consideration of interventional pain management injections (e.g. nerve root blocks / caudal epidural injections) or surgery.

In the presence of concordant MRI changes, Discectomy may be offered to patients with compressive nerve root signs and symptoms lasting three months (except in severe cases) despite best efforts with non-operative management.

Please note: This guideline is not intended to cover patients who demonstrate a deterioration in neurological function (e.g. objective weakness, sexual dysfunction, cauda equina syndrome). These patients require an urgent referral to an acute spinal centre for further evaluation and imaging, as non-operative treatment may lead to irreversible harm.

Section 4: Epidurolysis (See also NICE IPG 333)

NEL CCG will fund interventions for epidurolysis when all of the following criteria are met:

1. The patient has late onset radiculopathy post spinal surgery

AND

2. MRI Gadolinium-enhanced or dynamic epidurogram (unless contraindicated) findings are concordant to show adhesive radiculopathy

AND

3. Conservative management and epidural injections have failed

The specialist applying for funding must confirm that they are trained in the technique.

Subsequent epidurolysis treatments will require an IFR approval, including information about the nature and duration of benefit from initial treatment.

2Y Fusion surgery for mechanical axial low back pain (Surgery to fuse the bones in the back for back pain)

Spinal fusion is not indicated for the treatment of non-specific, mechanical back pain. The NICE exclusion criteria are:

- 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)
- scoliosis
- Pregnancy-related back pain
- Sacroiliac joint dysfunction
- Adjacent-segment disease
- Failed back surgery syndrome
- Spondylolisthesis.

Instead, spinal fusion is usually reserved for,

- Patients with a symptomatic spinal deformity (e.g. scoliosis)
- Instability (e.g. spondylolisthesis; trauma)
- An adjunct during spinal decompression surgery, where a more extensive exposure of the affected neurological structures is required and would otherwise render the spine unstable.

Primary care management typically includes reassurance, advice on continuation of activity with modification, weight-loss, analgesia, manual therapy and screening patients who are high risk of developing chronic pain (i.e. STaRT Back). Use combined physical and psychological programme for management of sub-acute and chronic low back pain e.g. Back Skills Training (BeST).

Lumbar Disc Replacement (Category 1)

Lumbar disc replacement surgery is not routinely funded

Acupuncture (Category 1)

Acupuncture for back pain is not routinely funded but can continue to be provided as part of existing physiotherapy packages of care.

Ozone Discectomy - (Category 1)

Ozone discectomy is not routinely funded

Medial Branch Blocks

Diagnostic Medial branch blocks, are only funded if performed in a Pain Service with a multidisciplinary team approach, only to be performed by doctors trained in Biopsychosocial Assessment.

2K Lumbar radiofrequency facet joint denervation (A procedure to numb nerves for low back pain)

Lumbar radiofrequency facet joint denervation (RFD) should only be offered in accordance with NICE Guideline NG59 which recommends it as an adjunct in the management of chronic low back pain only when non-operative treatment has failed, and the main source of pain is thought to arise from one or more degenerate facet joints.

2V Vertebral augmentation (vertebroplasty or kyphoplasty) for painful osteoporotic vertebral fractures (Procedures to build up brittle spine bones)

Criteria

Vertebroplasty (VP) or kyphoplasty (KP) should be offered as a treatment for painful osteoporotic vertebral fractures on a case-by-case basis.

As per advice in the NICE Technology Appraisal Guidance 279 (TAG 279), VP or KP may be considered:

- In cases where patients have 'severe (7/10 or greater on VAS scale) ongoing pain after a recent, unhealed vertebral fracture despite optimal pain management' and in particular hospitalised older people
- Where the acute vertebral fracture has been proven on imaging and correlates with the site of maximal pain on clinical examination
- The decision to treat should be taken after multidisciplinary team discussion
- The procedure should take place at a facility with access to spinal surgery services
- Processes for audit and clinical governance should be in place
- VP/KP must be performed in conjunction with additional measures to improve bone health.

NICE TAG 279 (https://www.nice.org.uk/guidance/ta279) delegates the eligible timeframe for intervention to the clinician. However, evidence from a 2016 randomised controlled trial (RCT) offers evidence that older patients (>60 years old) with fractures at most 6 weeks old and severe pain despite optimal pain management that benefit most from the procedure.

2S Low back pain imaging (Tests to investigate low back pain)

Criteria

Do not routinely offer imaging in a non-specialist setting for people with low back pain with or without sciatica in the absence of red flags, or suspected serious underlying pathology following medical history and examination.

Imaging in low back pain should be offered if serious underlying pathology is suspected. Serious underlying pathology includes but is not limited to: cancer, infection, trauma, spinal cord injury (full or partial loss of sensation and/or movement of part(s) of the body) or inflammatory disease.

Further information can be accessed at the relevant NICE guideline for these conditions. Patients presenting with low back pain and sciatica should be reviewed in accordance with the low back pain and sciatica guidance (https://www.nice.org.uk/guidance/ng59).

Patients presenting with low back pain without sciatica should be reviewed and if none of the above serious underlying pathology are suspected, primary care management typically includes reassurance, advice on continuation of activity with modification, weight loss, analgesia, manual therapy and reviewing patients who are high risk of 51 Academy of Medical Royal Colleges EBI - List 2 Guidance developing chronic pain (i.e. STaRT Back).

NICE guidelines recommend using a risk assessment and stratification tool, (e.g. STaRT Back), and following a pathway such as the National Back and Radicular Pain Pathway, to inform shared decision making and create a management plan.

Consider a combined physical and psychological programme for management of sub-acute and chronic low back pain (greater than 3 to 6 months duration) e.g. Back Skills Training (BeST).

Consider referral to a specialist centre for further assessment and management if required. Imaging within specialist centres is indicated only if the result will change management.

For further information please see the following NICE guidance:

- Low back pain and sciatica in over 16s: assessment and management (November 2016) https://www.nice.org.uk/guidance/ng59
- Low back pain and sciatica in over 16s: assessment and management (November 2016) Quality statement 2: Referrals for imaging https://www.nice.org.uk/guidance/qs155/chapter/Quality-statement-2-Referralsfor-imaging
- National Pathway of Care for Low Back and Radicular Pain https://www.nice.org.uk/guidance/ng59/resources/endorsed-resource-nationalpathway-of-care-for-low-back-and-radicular-pain-4486348909.

Shoulder decompression

Criteria

NEL CCG will fund arthroscopic subacromial decompression when:

1. The Arthroscopic subacromial decompression is for pure subacromial shoulder impingement

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.

2E Arthroscopic surgery for meniscal tears (Surgery to treat knee problems)

Criteria

The use of arthroscopic surgery to treat degenerate meniscal tears should follow published BASK guidelines <u>FLOW v10 (baskonline.com)</u>

This guidance applies to adults and children.

2T Knee MRI when symptoms are suggestive of osteoarthritis (Tests to investigate knee pain)

Criteria

In primary care, where clinical assessment is suggestive of knee OA, imaging is not usually necessary. If imaging is required than weight bearing radiographs are the first-line of investigation.

Patients with persistent symptoms should, after three to four months, be referred to secondary care and should have imaging of the knee to investigate for OA and/or other pathology.

Where imaging is necessary, in secondary care the first-line investigation of potential knee OA is weight bearing plain radiography. If the patient has a pattern of disease that allows surgical treatment to be adequately planned with plain radiographs, then MRI is not required.

However, there are a number of situations where MRI of the osteoarthritic knee can be useful:

- Patients who have severe symptoms but relatively mild OA on standard X-rays. In this situation the MRI offers more detail and can show much more advanced OA or Osteonecrosis within the knee
- In working up a patient for possible HTO or partial knee replacement an MRI can be a very useful investigation focusing on the state of the anterior cruciate ligament and state of the retained compartments.

In summary an MRI scan can be a useful investigation in the contemporary surgical management of osteoarthritis, giving critical information on the pattern of disease and state of the soft tissues. However, requesting an MRI scan when it is not indicated potentially prolongs further waiting times for patients, can cause unnecessary anxiety while waiting for specialist consultation and can delay MRI scans for appropriate patients.

The diagnosis of knee OA can be effectively made in primary care based upon the patient's history and physical examination. In particular, NICE recommends diagnosing osteoarthritis clinically, and without investigations, in patients who:

- Are 45 or over AND
- Have activity-related joint pain AND
- Has either no morning joint-related stiffness or morning stiffness that lasts no longer than 30 minutes.

It is important to exclude other diagnoses in some cases where there may be atypical features which may indicate alternative or additional diagnoses such as:

- A history of trauma
- History of cancer or corresponding risk factors
- Prolonged morning joint-related stiffness
- Rapid worsening of symptoms
- The presence of a hot swollen joint. Important differential diagnoses include gout, other inflammatory arthritides (for example, rheumatoid arthritis), septic arthritis and malignancy (bone pain).

In secondary care when surgical intervention for OA is being considered an MRI scan can offer valuable information about the pattern of disease within the knee. This includes planning for osteotomy around the knee for OA and for partial knee replacement, where in both cases information about the state of the preserved compartments and the anterior cruciate ligament are critical to the surgical plan.

A meta-analysis published in 2017 assessing the role of MRI in OA assessed 16 studies, which included 1220 patients. It found that MRI can detect OA with an overall high specificity and moderate sensitivity so better used to exclude OA than to confirm it. The study recommended that standard clinical algorithm for OA diagnosis, aided by radiographs is the most effective method for diagnosing OA.

The European League Against Rheumatism (EULAR) conducted a systematic review including 390 studies leading to seven recommendations concerning the use of imaging in peripheral joint OA as below:

- Imaging is not required to make the diagnosis in patients with typical presentation of OA. Level of evidence: III–IV. LOA (95% CI) 8.7 (7.9 to 9.4)
- In atypical presentations, imaging is recommended to help confirm the diagnosis of OA and/or make alternative or additional diagnoses. Level of evidence: IV. LOA (95% CI) 9.6 (9.1 to 10)
- Routine imaging in OA follow-up is not recommended. However, imaging is recommended if there is unexpected rapid progression of symptoms or change in clinical characteristics to determine if this relates to OA severity or an additional diagnosis. Level of evidence: III–IV. LOA (mean, 95% CI) 8.8 (7.9 to 9.7)
- If imaging is needed, conventional (plain) radiography should be used before other modalities. To make additional diagnoses, soft tissues are best imaged by US or MRI and bone by CT or MRI. Level

of evidence: III–IV. LOA (95% CI) 8.7 (7.9 to 9.6). — Consideration of radiographic views is important for optimising detection of OA features; in particular for the knee, weightbearing and patellofemoral views are recommended. Level of evidence: III. LOA (95% CI) 9.4 (8.7 to 9.9)

- According to current evidence, imaging features do not predict nonsurgical treatment response and imaging cannot be recommended for this purpose. Level of evidence: II–III. LOA (95% CI) 8.7 (7.5 to 9.7)
- The accuracy of intra-articular injection depends on the joint and on the skills of the practitioner and imaging may improve accuracy. Imaging is particularly recommended for joints that are difficult to access due to factors including site (e.g., hip), degree of deformity and obesity. Level of evidence: III–IV. LOA (95% CI) 9.4 (8.9 to 9.9).

2X MRI scan of the hip for arthritis

Criteria

Do not request a hip MRI when the clinical presentation (history and examination) and X-rays demonstrate typical features of OA. MRI scans rarely add useful information to guide diagnosis or treatment.

Requesting MRI scans further prolongs waiting times for patients. Importantly it can cause unnecessary anxiety while waiting for specialist consultation and can delay MRI scans for patients with diagnoses other than OA of the hip.

The diagnosis of hip OA can be effectively made based upon the patient's history and physical examination. NICE recommends diagnosing osteoarthritis clinically without investigations in patients who:

- Are 45 or over AND Have activity-related joint pain AND
- Have either no morning joint-related stiffness or morning stiffness that lasts no longer than 30 minutes.

It is important to exclude other diagnoses, especially when red flags are present. If imaging is necessary, the first-line investigation should be plain x-ray.

An MRI or urgent onward referral may be warranted in some circumstances. These include:

- Suggestions of infection, e.g. pyrexia, swollen and red joint, significant irritability, other risk factors of septic arthritis
- Trauma
- History or family history of an inflammatory arthropathy
- Mechanical, impingement type symptoms
- Prolonged and morning stiffness
- History of cancer or corresponding risk factors
- Suspected Osteonecrosis / Avascular necrosis of the hip
- Suspected transient osteoporosis Suspected periarticular soft tissue pathology e.g. abductor tendinopathy

Important differential diagnoses include inflammatory arthritis (for example, rheumatoid arthritis), femoro-acetabular impingement, septic arthritis and malignancy (bone pain).

A meta-analysis published in 2017 assessing the role of MRI in OA, assessed 16 studies which included 1220 patients. It concluded that MRI is more useful in excluding OA rather than diagnosing it. The study recommended that standard clinical algorithm for OA diagnosis, aided by radiographs is the most effective method for diagnosing OA.

The European League Against Rheumatism (EULAR) conducted a systematic review including 390 studies leading to seven recommendations concerning the use of imaging in peripheral joint OA as below:

- Imaging is not required to make the diagnosis in patients with typical presentation of OA. Level of evidence: III–IV. LOA (95% CI) 8.7 (7.9 to 9.4)
- In atypical presentations, imaging is recommended to help confirm the diagnosis of OA and/or make alternative or additional diagnoses. Level of evidence: IV. LOA (95% CI) 9.6 (9.1 to 10)
- Routine imaging in OA follow-up is not recommended. However, imaging is recommended if there is unexpected rapid progression of symptoms or change in clinical characteristics to determine if this relates to OA severity or an additional diagnosis. Level of evidence: III–IV. LOA (mean, 95% CI) 8.8 (7.9 to 9.7)
- If imaging is needed, conventional (plain) radiography should be used before other modalities. To make additional diagnoses, soft tissues are best imaged by US or MRI and bone by CT or MRI. Level of evidence: III–IV. LOA (95% CI) 8.7 (7.9 to 9.6)
- Consideration of radiographic views is important for optimising detection of OA features; in particular for the knee, weightbearing and patellofemoral views are recommended. Level of evidence: III. LOA (95% CI) 9.4 (8.7 to 9.9)
- According to current evidence, imaging features do not predict nonsurgical treatment response and imaging cannot be recommended for this purpose. Level of evidence: II–III. LOA (95% CI) 8.7 (7.5 to 9.7)
- The accuracy of intra-articular injection depends on the joint and on the skills of the practitioner and imaging may improve accuracy. Imaging is particularly recommended for joints that are difficult to access due to factors including site (e.g., hip), degree of deformity and obesity. Level of evidence: III–IV. LOA (95% CI) 9.4 (8.9 to 9.9)

Other

Category 2 Procedures

Botulinum toxin (not cosmetic)

Criteria

NEL CCG will not fund the use of Botulinum Toxin for cosmetic treatments.

Botulinum Toxin applications in oculoplastics

NEL CCG will fund the use Botulinum A by an oculoplastics specialist when one of the following criteria are met:

Section 1: Entropion

Botox will be commissioned by NEL CCG for patients with INVOLUTIONAL entropion who meet one of the following criteria:

1. Have a corneal ulcer/keratopathy secondary to entropion

OR

2. Where surgery is contraindicated due to medical co-morbidities not warranting cessation of anticoagulation

OR

3. Patient with advanced dementia, who is not fir for surgery under local, with or without sedation or general anaesthesia

Section 2: Corneal Ulcer/lagophthalmos

NEL CCG will fund corneal ulcer/lagophthalmos by an oculoplastics specialist when one of the following criteria are met:

Botox will be commissioned by NEL CCG for patients with corneal ulcer/ lagophthalmos who:

1. Have a corneal ulcer due to facial palsy and lagophthalmos to induce a protective ptosis **OR**

2. Have a corneal ulcer due to lagophthalmos secondary to eyelid retraction, trauma or proptosis to induce a protective ptosis

Botox treatment may need to be repeated after three to six months.

Prior approval is not required for the following treatments:

Blepharospasm

Botulinum A toxin is routinely funded and does not require prior approval for the treatment of blepharospasm.

For palmar or plantar hyperhidrosis, other procedures such as iontophoresis appear to be more effective and have fewer side effects and should be considered as initial treatment.

Botulinum A toxin is routinely funded and does not require prior approval for:

- 1. spasticity, hand and wrist disability associated with stroke, hemofacial spasm, spasmodic torticollis
- 2. severe hyperhidrosis, overactive bladder syndrome

Botulinum B toxin is routinely funded and does not require prior approval for:

- 1. spasmodic torticollis
- as alternative to Botulinum toxin A in presence of antibodies to Botulinum A.

Botulinum A will also be approved for treatment of migraine for patients who meet the criteria described in NICE TA 260 (https://www.nice.org.uk/guidance/ta260/chapter/1-Guidance):

- 1.1 Botulinum toxin type A is recommended as an option for the prophylaxis of headaches in adults with chronic migraine (defined as headaches on at least 15 days per month of which at least 8 days are with migraine):
 - that has not responded to at least three prior pharmacological prophylaxis therapies and
 - whose condition is appropriately managed for medication overuse.
- 1.2 Treatment with botulinum toxin type A that is recommended according to 1.1 should be stopped in people whose condition:
 - is not adequately responding to treatment (defined as less than a 30% reduction in headache days per month after two treatment cycles) or
 - has changed to episodic migraine (defined as fewer than 15 headache days per month) for three consecutive months.

Open MRI

Criteria

Claustrophobic patients

Most patients with claustrophobia can be successfully scanned using a conventional MRI scanner. **NEL CCG** will fund open MRI when 1(a) and 2 or 1(b) and 2 of the following criteria are met:

1(a). The patient has failed to tolerate a conventional scan using feet first

OR

1(b). Oral sedation approaches as appropriate

AND

2. Confirm that no other diagnostic tests are suitable. If more serious health problems preclude sedation, this will need to be detailed

Obese patients

Patients who are too large to fit within a conventional MRI scanner should be referred by a secondary care clinician to a bariatric MRI service.

Paediatrics

Category 1 Procedures: Individual funding request (IFR)

2Z Helmet therapy for treatment of positional plagiocephaly/ brachycephaly in children (Helmets to reshape flat heads in babies)
Individual Funding Request

2Z Helmet therapy for treatment of positional plagiocephaly/ brachycephaly in children (Helmets to reshape flat heads in babies) Individual Funding Request

Criteria

As clinically evidenced by the four major designated supra-regional craniofacial services in the UK (prior to the availability of Helmet therapy), the flattened area of the head usually self-corrects naturally, as a baby grows, develops and becomes more mobile with increased muscle strength, and spends less time lying in one position.

There is clear evidence and expert consensus that a helmet does not affect the natural course of skull growth and should not be used.

Helmets may be associated with significant risks such as pain, pressure sores and may adversely affect the bond between baby and parents. They are also expensive.

To reduce pressure on the flattened part of the head and encourage remoulding, the following simple interventions are suggested:

- 'Tummy time' Allow baby to spend time lying on their front while awake, supervised and playing.
- Change the position of toys / mobiles / cot in the room to encourage baby to move their head away from the flattened side
- Use a sling or a front carrier to reduce the amount of time baby spends lying on a firm flat surface
- Modify Parental lap "nursing" position to promote contact with less flattened side to parental chest.

All babies including those with non-synostotic/positional plagiocephaly or brachycephaly must be laid to sleep on their back. Sleeping in positions other than this is associated with an increased risk of Sudden Infant Death Syndrome or SIDS (formerly known as Cot Death). For the same reason, no pillows or props should be used to change a baby's sleeping position.

This guidance applies to children aged 2 years and under.

Physiotherapy

Category 1 Procedures: Individual funding request (IFR)

Manual therapies (osteopathy – outside of an MSK integrated service)