Framework for clinical interventions that are targeted to deliver maximum health benefit

Interventions where Leeds North CCG, Leeds South & East CCG and Leeds West CCG believe a more targeted approach is needed to maximise cost effective health benefit

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Ratified by:	Leeds West CCG Assurance Committee on (date) Leeds North CCG Governance, Performance and Risk Committee on (date) Leeds South and East CCG Governance and Risk Committee on (date)
Name & Title of originator/author(s):	Drs Simon Stockill and Bryan Power, Medical Directors, LWCCG Dr Manjit Purewal, Medical Director LNCCG Dr David Mitchell, Medical Director LSECCG Dr Fiona Day, Consultant in Public Health Medicine, Leeds City Council
Name of responsible committee/individual:	Leeds West CCG Assurance Committee Leeds North CCG Governance, Performance and Risk Committee Leeds South and East CCG Governance and Risk Committee
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Produced on behalf of NHS Leeds West CCG, NHS Leeds North CCG and NHS Leeds South and East CCG

1 Introduction

Leeds Clinical Commissioning Groups (CCGs), Leeds North CCG, South and East CCG and Leeds West CCG are responsible for commissioning services to meet the needs of patients registered with their constituent practices. They are required to commission services which are evidence based, cost effective, improve health outcomes, reduce health inequalities and represent value for money for the taxpayer. Furthermore NHS Leeds CCGs are accountable for funding decisions to their constituent practices and populations.

The CCGs recognise that there are a number of clinical interventions which can be undertaken on a range of patients but where the intervention must be targeted to ensure most health benefit. Where possible Leeds CCGs follow a process by which the referring clinician can demonstrate treatment criteria are met without having to ask a panel to consider the request.

This document is intended as an aid to decision making. It should be used in conjunction with Leeds CCG policies on Individual Funding Requests and associated decision making frameworks, and also the Yorkshire and Humber Policy for the delivery of Fertility Treatment (or amended policy developed by CCGs).

Specialist services that are commissioned by NHS England http://www.england.nhs.uk/npc-crg/ are not covered by this framework. Leeds CCGs may choose to enter into shared policies with CCGs outside Leeds taking into consideration national guidance such as NICE interventional procedures and National Surgical Commissioning Centre Guides http://www.rcseng.ac.uk/providers-commissioners/nscc/commissioning-guides

2 Purpose

The purpose of the targeted clinical interventions framework is to enable officers of Leeds CCGs to exercise their responsibilities and to provide advice for General Practitioners, Clinicians and members of the public. The implementation of the framework will ensure that commissioning decisions are not taken in an ad-hoc manner without due regard to equitable access and good governance arrangements.

The CCGs IFR policy outlines the process for decision making with regard to targeted clinical interventions and seeks to improve consistency in this decision making process.

This framework covers all interventions (other than drugs and cosmetic interventions) where there is evidence that the intervention needs to be targeted to deliver the greatest health benefit. Where the patient falls outside the agreed criteria an individual funding request will need to be considered by the NCA panel.

Scope

The targeted clinical interventions framework is supported by a series of commissioning statements (appendix A). The current contents of appendix A represents examples and more will be added to the CCGs websites as commissioning statements are developed.

3 Framework Operation

This document is intended as an aid to decision making. It should be used in conjunction with Leeds CCG policies on Individual Funding Requests and associated decision making frameworks.

4 References

NHS Confederation. Priority setting priority overview
http://www.nhsconfed.org/Publications/Pages/Prioritysettingoverview.aspx accessed July 2013
NHS Confederation. Priority setting: legal considerations
http://www.nhsconfed.org/Publications/Pages/Prioritysettinglegal.aspx accessed July 2013

APPENDIX A

Specific interventions, interventional procedures and devices

What is an interventional procedure?

An interventional procedure is a procedure used for diagnosis or treatment that involves one of the following.

- Making a cut or a hole to gain access to the inside of a patient's body - for example, when carrying out an operation or inserting a tube into a blood vessel.
- Gaining access to a body cavity (such as the digestive system, lungs, womb or bladder) without cutting into the body - for example, examining or carrying out treatment on the inside of the stomach using an instrument inserted via the mouth.
- Using electromagnetic radiation (which includes X-rays, lasers, gamma-rays and ultraviolet light) - for example, using a laser to treat eye problems.

Interventional procedures and devices overarching policy

Leeds CCGs routinely commission interventional procedures where National Institute for Health and Care Excellence (NICE) guidance arrangements indicate "normal" or "offered routinely" or "recommended as option(s)" and the evidence of safety and effectiveness is sufficiently robust.

Leeds CCGs *do not* routinely commission interventional procedures where NICE guidance arrangement indicates "special", "other", "research only" and "do not use".

The commissioning statements for individual procedures are the same as those issued by NICE. (www.nice.org.uk).

An individual funding request (IFR) may be submitted for a patient who is felt to be an exception to the commissioning statements as per the Individual Funding Request Policy.

The CCGs accept there are clinical situations that are unique (five or fewer patients) where an IFR is appropriate and exceptionality may be difficult to demonstrate.

Whilst the Leeds CCGs are always interested in innovation that makes more effective use of resources, in year introduction of a procedure does not mean the CCGs will routinely commission the use of the procedure.

An individual funding request is not an appropriate mechanism to introduce a new treatment for a group or cohort of patients. Where treatment is for a cohort larger than five patients, that is a proposal to develop the service, the introduction of a new procedure should go through the usual business planning process. CCGs will not fund interventional procedures for cohorts over 5 patients introduced outside a business planning process.

Specific interventions

See appendices A(1) to A(21) below. Specific interventions defined as needing targeting to deliver maximum health benefit include:

- **Tonsillectomy** (Appendix A:1)
- **Otitis media with effusion (grommets)** (Appendix A:2)
- **Varicose veins**(Appendix A:3)
- **Headache**(Appendix A:4)
- **Sacral Nerve Stimulation** [SNS] (Sacral Nerve Neuromodulation) – this is now the responsibility of NHS England. (Appendix A:5)
- **Spinal Cord Stimulation** (neuromodulation) (Appendix A:6)
- **Anal/rectal skin tags**(Appendix A:7)

- **Carpal tunnel syndrome surgery**(Appendix A:8)
- **Cranial banding**(Appendix A:9)
- **Dupuytren's Contracture.** (Appendix A:10)
- **Haemorrhoid surgery**(Appendix A:11)
- **Heavy Menstrual Bleeding**(Appendix A:12)
- **Hernia Repair**(Appendix A:13)
- **Facet joint Procedures**(Appendix A:14)
- **Percutaneous Nucleoplasty for low back pain**(Appendix A:15)
- **Radiofrequency ablation**(Appendix A:16)
- **Spinal Epidural injections**(Appendix A:17)
- **TENS for Chronic Pain**(Appendix A:18)
- **Gastro-electrical stimulation for gastroparesis**(Appendix A:19)
- **Toric intraocular lens implant to correct astigmatism after cataract surgery**(Appendix A:20)
- **Erectile Dysfunction including penile prostheses** (Appendix A:21)

These are examples. Other specific interventions will be published on the CCGs websites in due course after approval by the relevant CCG Committees.

Appendix A (1)

Tonsillectomy Commissioning Policy

This policy is designed to clarify the agreements between the commissioners and providers regarding the commissioning of tonsillectomy.

It serves to agree the conditions which are automatically commissioned and those that require exception permission before they can proceed. There is an agreement that for commissioning to proceed, information must be provided by clinicians from levels 2, 3, or 4 (see below)

Definitions

Commissioner – Leeds CCGs
Providers – any hospital with a commissioning agreement with the CCGs, (including NHS and independent sector providers).

Level 2 – Primary care
Level 3 – Extended primary care intermediate services
Level 4 – Hospital services

Agreed conditions warranting tonsillectomy

The commissioners agree that tonsillectomy is appropriate in the following conditions:

- Recurrent acute tonsillitis where all the following criteria are met:
  - 7 or more clinically significant, adequately treated sore throats in the preceding 12 months, or
  - 5 or more episodes in each of the preceding two years, or
  - 3 or more in each of the preceding three years if the episodes of sore throat are disabling and prevent normal functioning
- In patient with recent history of peritonsillar abscess with previous history of recurrent tonsillitis
- Chronic tonsillitis for more than 6 months, associated with illness, halitosis and/or disruption to life
- Obstructive sleep apnoea in children
- As part of a palatal procedure for heavy snoring or sleep apnoea in adults
- Where malignancy is suspected

Supporting evidence

Sign Guidelines:
http://www.sign.ac.uk/pdf/qrg117.pdf

AETNA Clinical policy bulletins.
http://www.aetna.com/cpb/medical/data/400_499/0475.html

Appendix A (2)

Grommet Commissioning Policy

This policy is designed to clarify the agreements between the commissioners and providers regarding the commissioning of grommet insertion. It serves to agree the conditions which are automatically commissioned and those that require exception permission before they can proceed. There is an agreement that for commissioning to proceed, information must be provided by clinicians from levels 2, 3, or 4 (see below)

Definitions

Grommet Insertion – operation of insertion of ventilation tube or tympanostomy tube through the tympanic membrane. For the purpose of this document it should include all types of middle ear ventilation tube.

Commissioner – Leeds CCGs
Providers – any hospital with a commissioning agreement with the CCGs, (including NHS and independent sector providers).

Level 2 – Primary care
Level 3 – Extended primary care intermediate services
Level 4 – Hospital services

Agreed conditions warranting grommet insertion

The commissioners agree that grommet insertion is appropriate in the following conditions:

- Child has persistent (>3 months) documented otitis media with effusion with a hearing level in the better ear of 25db or worse averaged at 0.5, 1, 2, and 4 KHz
- Child has speech or language problems or child has developmental problems or child has significant behavioural problems and has persistent bilateral otitis media with effusion
- Severe otalgia in otitis media requiring admission, and unresolved with conservative treatment over 3 days
- In immunocompromised patients with otitis media where microbiologic specimens are required
- Complications of otitis media such as meningitis, facial nerve paralysis, coalescent mastoiditis, or brain abscess
- Child with recurrent acute otitis media more than 6 times in the previous 12 months
- Chronic retraction of the tympanic membrane
- Adults with otitis media with effusion where conservative management has failed over 6 weeks or where malignancy is suspected
- Autophony due to patulous eustachian tube
- As part of treatment for vestibular disorders either alone or with gentamicin

Supporting evidence

Sign Guidelines
http://www.sign.ac.uk/guidelines/fulltext/66/index.html

NICE
http://www.nice.org.uk/nicemedia/pdf/CG60NICEguideline.pdf

Appendix A (3)

Varicose Vein Commissioning Policy

This policy is designed to clarify the agreements between the commissioners and providers regarding the commissioning of varicose vein surgery. It serves to agree the conditions which are automatically commissioned and those that require exception permission before they can proceed. There is an agreement that for commissioning to proceed, information must be provided by clinicians from levels 2, 3, or 4 (see below)

Definitions

Varicose Vein surgery – operation of correction of venous damage due to incompetence (i.e., reflux) at the saphenofemoral junction or saphenopopliteal junction or greater saphenous vein or lesser saphenous vein is documented by Doppler or duplex ultrasound scanning.

Commissioner – Leeds CCGs
Providers – any hospital with a commissioning agreement with the CCGs, (including NHS and independent sector providers).
Level 2 – Primary care
Level 3 – Extended primary care intermediate services
Level 4 – Hospital services

Agreed conditions warranting Varicose Vein surgery

The commissioners agree that varicose vein surgery is appropriate in the following conditions:

- Itching, discomfort and aching of affected leg interfering with daily life associated with visible and or palpable varicose veins
- Skin changes eczema, haemosiderin deposition, lipodermatosclerosis, ulceration (please underline which are present)
- More than one episode of minor hemorrhage from a ruptured superficial varicosity
- A single significant hemorrhage from a ruptured superficial varicosity, especially if transfusion of blood was required
- Recurrent superficial thrombophlebitis following an unsuccessful trial of conservative treatment for a minimum of 6 months
- Severe and persistent pain and swelling interfering with activities of daily living and requiring repeat analgesic medication. Unsuccessful trial of conservative treatment for a minimum of 6 months
- recurrent varicosities following surgery

Supporting evidence

Aetna clinical policy bulletins http://www.aetna.com/cpb/medical/data/1_99/0050.html accessed July 2013

Randomised clinical trial, observational study and assessment of cost-effectiveness of the treatment of varicose veins (REACTIV trial**)** JA Michaels, WB Campbell, JE Brazier, JB MacIntyre, SJ Palfreyman, J

Ratcliffe and K Rigby *Health Technology Assessment* 2006; Vol. 10: No. 13
Shows that surgery for varicose veins is effective for severe varicose veins with reflux.

National Institute for Health and Care Excellence.CG 168 Varicose veins in the legs.
http://www.nice.org.uk/guidance/index.jsp?action=byID&o=14226 accessed July 2013

Appendix A (4)

Headache referral – neurology service

This policy is designed to clarify the agreements between the commissioners and providers regarding the commissioning of referral for headache. It serves to agree the conditions which are automatically commissioned and those that require exception permission before they can proceed. There is an agreement that for commissioning to proceed, information must be provided by clinicians from levels 2, 3, or 4 (see below)

Definitions

Headache – Headache is a pain in the head with the pain being above the eyes or the ears, behind the head (occipital), or in the back of the upper neck. Headache, like chest pain or back ache, has many causes. All headaches are considered primary headaches or secondary headaches. Primary headaches are not associated with other diseases. Examples of primary headaches are migraine headaches, tension headaches, and cluster headaches. Secondary headaches are caused by other diseases. The associated disease may be minor or major.

Commissioner – Leeds CCGs
Providers – any hospital with a commissioning agreement with the CCGs, (including NHS and independent sector providers).
Level 2 – Primary care
Level 3 – Extended primary care intermediate services
Level 4 – Hospital services

Agreed situations warranting headache referral

More Likely to need referral to a specialist	**Diagnostic guide:** Episodic tension type headache, Chronic tension type headache, Migraine, Analgesic overuse headache, Cluster headache, Suspicious headache *(see also 2 week referral guidance)* **Headache Symptoms:** *A symptom based guide to possible diagnosis:* (note: more than one type of headache may co-exist) **Episodic tension type headache:** *(affects 80% of the po* Typically bilateral, often band-like or pressure feeling, may have muscle tenderness, may be stress related. *(may respond to paracetamol or NSAID)* *(affects 3% of the population)* **Chronic tension-type headache** Occurs >15 days a month, may be unremitting and not respond to analgesia. May be related to stress or long standing neck problems *(may respond to amitriptyline)* *(affects 10% of the population)* **Migraine** Often unilateral, often throbbing, lasts up to a few days, may be aura, nausea or visual disturbance, or focal neurology such as paraesthesia of hand, arm or face for up to 60 minutes. *(If this lasts longer, always refer)* *(affects 5% of the population)* **Analgesic overuse headache** Typically daily, oppressive, worse on waking, worse on exertion. Consider if using over 3 tablets a day for over 3 days a week regularly. *(Ask patient to keep a headache/medication diary)* *(affects <1% of the population)* **Cluster headache** Strictly unilateral, severe/unbearable, around eye, often at night, may have red or watering eye, rhinitis, or blocked nose. Alcohol triggers. (*Refer **early** to specialist)* *(affects <1% of the population)* **Suspicious headache** New onset, qualitatively different, unusually severe and not responding to usual measures Persisting neurological signs, Optic disc changes Suspicion of malignancy, *(see 2 week referral guidance)* Meningism, acute neck stiffness, primary closed angle glaucoma, temporal arteritis or raised ESR without cause, suspected carbon monoxide poisoning *(Refer **Urgently** if any of the above are present)*	**More likely to be managed in primary care setting**

Supporting evidence

Headache (BMJ 2002; 325:881-886)
www.bash.org.uk (The British Association for the Study of Headache)
http://cks.nice.org.uk/ (clinical knowledge summaries, several guidelines on managing headaches and migraine)

Appendix A (5)

Sacral Nerve Stimulation [SNS] (Sacral Nerve Neuromodulation)

Sacral Nerve Stimulation/ Neuromodulation) for urinary and faecal incontinence is now the responsibility of NHS England.

Appendix A (6)

Spinal Cord Stimulation (SCS)

This policy is designed to clarify the agreements between the commissioners and providers regarding the commissioning of referral for Spinal Cord Stimulation (SCS) for chronic pain

It serves to agree the conditions which are automatically commissioned and those that require exception permission before they can proceed.

There is an agreement that for commissioning to proceed, information must be provided by clinicians from levels 2, 3, or 4 (see below)

Definitions

Stimulating the dorsal columns of the spinal cord with an implanted device (spinal cord stimulator) with the aim of modifying perception of neuropathic and ischaemic pain.

Commissioner – Leeds CCGs
Providers – any hospital with a commissioning agreement with NHS Leeds CCGs, (including NHS and independent sector providers).
Level 2 – Primary care
Level 3 – Extended primary care intermediate services
Level 4 – Hospital services

Criteria for treatment

Spinal cord stimulation will not be routinely funded for adults with chronic pain of ischaemic origin except in the context of research as part of a clinical trial. Individual funding requests may be considered where there are exceptional circumstances. Individual funding request is expected for patients with Refractory Angina and will be funded for patients that have been through the RA pathway and SCS is the recommended intervention following that pathway.

Spinal cord stimulation will be funded, following prior approval, for adults with chronic pain of neuropathic origin who continue to experience chronic pain (measuring at least 50 mm on a 0– 100 mm visual analogue scale) for at least 6 months despite appropriate conventional medical management, and who have had a successful trial (1 week or more) of stimulation as part of the assessment

It is expected that patients will meet the prior approval criteria set out below:

- In the vast majority of patients for whom this treatment is being considered, pain would be radicular (usually leg, and the presenting pain would be more than 50% leg pain).
- Appropriate medical management should include optimised medical therapy, psychological therapy, self-management and other therapies where appropriate
- The patient has been seen and correctly treated by a multi-disciplinary team, including a psychologist, physiotherapist, chronic pain clinical specialist to assess health functioning, identify and treat any physical or emotional /mental health issues. This will include ascertaining confidence in self-management skills and their implementation in daily life.
- The patient does not have treatable mental/emotional heath disorders which affect compliance or the outcome of the intervention e.g. depression, PTSD, anxiety disorders such OCD.

- It is expected that where there are different systems of equal effectiveness, the least costly system is used

Supporting evidence

Simpson EL, Duenas A, Holmes MW, Papaioannou D, Chilcott J. Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin: systematic review and economic evaluation. Health Technol Assess 2009;13(17).

Appendix A (7)

Surgery for Anal Skin Tags

This policy is designed to clarify the agreements between the commissioners and providers regarding the commissioning of referral for Anal skin tags.

It serves to agree the conditions which are automatically commissioned and those that require exception permission before they can proceed.

There is an agreement that for commissioning to proceed, information must be provided by clinicians from levels 2, 3, or 4 (see below)

Definitions

Hypertrophied papillae, also called anal skin tags, fibro epithelial polyps are common; they arise due to oedema, inflammation, fibrosis. They can protrude into anal canal. They are benign.

Commissioner – Leeds CCGs
Providers – any hospital with a commissioning agreement with NHS Leeds CCGs, (including NHS and independent sector providers).
Level 2 – Primary care
Level 3 – Extended primary care intermediate services
Level 4 – Hospital services

<table>
<tr><td></td><td></td></tr>
<tr><td>Treatment</td><td>Surgery for Anal Skin tags</td></tr>
<tr><td>For the treatment of</td><td>Anal/rectal skin tags</td></tr>
<tr><td>Background</td><td>Hypertrophied papillae, also called anal skin tags, fibro epithelial polyps are common; they arise due to oedema, inflammation, fibrosis. They can protrude into anal canal. They are benign. Their appearance is polypoid and they may resemble haemorrhoids. Microscopically they are projections of sub mucosa and overlying mucosa; squamous epithelium with central core of inflamed, oedematous, myxoid or fibrovascular stroma with thin walled vessels; 80% have large, multinucleated, CD34+ stellate cells, often with atypical nuclear features; frequent mast cells; no thick walled vessels, no organizing thrombi, no haemorrhage. Under the electron microscope they consist of fibroblastic and myofibroblastic stromal cells.

Urgent referral should take place in people with suspected malignancy

<table>
<tr><td>40 years of age and older</td><td>Rectal bleeding with a change in bowel habit towards looser stools and/or increased stool</td></tr>
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<tr><td></td><td>frequency persisting for 6 weeks or more.</td></tr>
<tr><td>60 years of age and older</td><td>Rectal bleeding persisting for 6 weeks or more without a change in bowel habit and without anal symptoms.
A change in bowel habit to looser stools and/or more frequent stools persisting for 6 weeks or more without rectal bleeding.</td></tr>
<tr><td>Of any age</td><td>A right abdominal mass consistent with involvement of the large bowel.
A palpable rectal mass (intraluminal and not pelvic; a pelvic mass outside the bowel would warrant an urgent referral to a urologist or gynaecologist).</td></tr>
<tr><td>Women (not menstruating)</td><td>Unexplained iron deficiency anaemia and haemoglobin 10 g/100 mL or less.</td></tr>
<tr><td>Men of any age</td><td>Unexplained iron deficiency anaemia and haemoglobin 11 g/100 mL or less.</td></tr>
</table></td></tr>
<tr><td>Commissioning position</td><td>Leeds CCGs do not routinely commission surgery for patients with anal skin tags where there is:

• Haemorrhoids, pruritis or solely a cosmetic problem

Referral for non-urgent assessment and treatment:

Leeds CCGs support referral where:

• There is a need to assess anal skin tags

• Where there are underlying pathologies such as inflammatory bowel disease

Leeds CCGs will commission surgery for patients with anal skin tags where this forms part of the treatment of an underlying pathology such as inflammatory bowel disease.</td></tr>
<tr><td>Summary of evidence/rationale</td><td>Kuehn HG,Gebbensleben O,Hilger Y,Rohde H Relationship between anal symptoms and anal findings. International Journal of Medical Sciences, 2009; 6: 1431-42

Bonheur JL,Braunstein J,Korelitz BI,Panagopoulos G Skin tags in inflammatory bowel disease: new observations and a clinical review. Inflammatory Bowel Diseases 2008; 14; 1236-9</td></tr>
</table>

Appendix A (8)

Surgery for Carpal Tunnel syndrome

This policy is designed to clarify the agreements between the commissioners and providers regarding the commissioning of referral for Carpal Tunnel syndrome.

It serves to agree the conditions which are automatically commissioned and those that require exception permission before they can proceed.

There is an agreement that for commissioning to proceed, information must be provided by clinicians from levels 2, 3, or 4 (see below)

Definitions

Carpal tunnel syndrome is a peripheral nerve entrapment caused by compression of the median nerve in the carpal tunnel.

Commissioner – Leeds CCGs
Providers – any hospital with a commissioning agreement with NHS Leeds CCGs, (including NHS and independent sector providers).
Level 2 – Primary care
Level 3 – Extended primary care intermediate services
Level 4 – Hospital services

Treatment	**CARPAL TUNNEL SYNDROME SURGERY**
For the treatment of	Median Nerve compression
Background	Carpal tunnel syndrome is a peripheral nerve entrapment caused by compression of the median nerve in the carpal tunnel. The carpal tunnel is an anatomical compartment of the hand; it is bounded on three sides by carpal bones which form an arch, and on the palmar side by the transverse carpal ligament. Intermittent or sustained high pressure within the tunnel (due to reduced dimensions of the tunnel or increased volume of its contents) produces ischaemia of the median nerve resulting in impaired nerve conduction causing paraesthesia and pain. Pressure on the nerve may lead to segmental demyelination producing more constant and severe symptoms occasionally associated with weakness and wasting. If axonal injury occurs secondary to prolonged ischaemia the nerve dysfunction may become irreversible.
Commissioning position	NHS Leeds CCGs will commission surgical intervention for Carpal Tunnel Syndrome where there is documented evidence that the patient has had or has declined access to conservative treatment with an injection and/or splint. Patients should only undergo electro-diagnostic testing where there is doubt about the underlying diagnosis prior to surgery. NHS Leeds CCGs will only commission standard open carpal tunnel release.
Summary of evidence/rationale	A detailed review of the evidence is available at http://cks.nhs.uk/carpal_tunnel_syndrome (accessed July 2013) In commissioning treatment for carpal tunnel syndrome Leeds CCGs have taken the following into account

	• Evidence from observational studies shows that symptoms resolve spontaneously in some people: good prognostic indicators were short duration of symptoms, a young age, and carpal tunnel syndrome due to pregnancy. • There is good evidence that surgical treatment relieves the symptoms of carpal tunnel syndrome (CTS) in about 75% of patients • Splinting is effective in about 37% of people in the short term. • There is moderate evidence that oral steroids may have significant short-term benefits in people with carpal tunnel syndrome, and limited evidence for ultrasound, yoga, and carpal bone mobilization. • There is good evidence that local corticosteroid injection provides improvement in symptoms in 70% of people with carpal tunnel syndrome. There is no good evidence on the recurrence rate and subsequent requirement for surgery in a primary care population cohort. • Standard open carpal tunnel release is as effective as endoscopic procedures for the short- and long-term relief of symptoms. • Electro-diagnostic testing unnecessary if symptoms are well defined

Appendix A (9)

Cranial Banding

This policy is designed to clarify the agreements between the commissioners and providers regarding the commissioning of cranial banding

It serves to agree the conditions which are automatically commissioned and those that require exception permission before they can proceed.

There is an agreement that for commissioning to proceed, information must be provided by clinicians from levels 2, 3, or 4 (see below)

Definitions

Treatment for brachycephaly and positional plagiocephaly includes the use of a rigid, plastic, foam lined orthosis (helmet). The procedure is known as cranial banding. The orthosis is custom made for each patient and applies pressures in particular areas to discourage growth in prominent areas and encourage growth in flattened parts of the skull.

Commissioner – Leeds CCGs
Providers – any hospital with a commissioning agreement with NHS Leeds CCGs, (including NHS and independent sector providers).

Level 2 – Primary care
Level 3 – Extended primary care intermediate services
Level 4 – Hospital services

Commissioning position

The following statement sets out the position of the Leeds CCGs in respect of commissioning cranial banding for the treatment of brachycephaly and positional plagiocephaly.

The evidence that cranial banding can be effective in the treatment of brachycephaly and positional plagiocephaly is inconclusive. Expert clinical opinion is not supportive of the treatment.

Cranial banding will not be routinely commissioned for patients in Leeds. The available evidence does not show cranial banding as a treatment for brachycephaly and positional plagiocephaly to be effective.

Cranial abnormalities

Positional plagiocephaly and brachycephaly refer to abnormal skull shape and symmetry, which arises in some infants due to pressure on the skull, either prior to birth or in the first months of life. Determinants appear to be limited head rotation, lower activity levels, and supine sleeping position.

Brachycephaly refers to a broad head, sometimes defined as having a large cephalic index (the ratio multiplied by 100 of the maximum breadth of the head to its maximum length). Plagiocephaly describes asymmetry of the head.

Prevalence of these deformities varies with age. In a prospective longitudinal study of their natural history Hutchinson found the prevalence of plagiocephaly and/or brachycephaly at six weeks 4, 8, 12, and 24 months was 16.0%, 19.7%, 9.2%, 6.8%, and 3.3% respectively. In this study cases were identified as having a cephalic index equal to or greater than 93%, and/or the oblique cranial length ratio equal or greater than 106%. Another estimate reported in the literature is 20% of infants having some deformity, with 1 in 65 being more severe cases.

The mid 2005 population estimates of 0-4 year olds in the Yorkshire and Humber Strategic Health Authority area is 286,900. The Hutchinson prevalence figures suggest that some 9,468 individuals may have plagiocephaly and/or brachycephaly at the age of 24 months. Alternatively, the estimate of 20% of infants (taken to be 0-1 year old) equates to 11,476 with some 175 having severe deformity. Overall it is suggested

that between 9,500 and 11,500 individuals may have plagiocephaly and/or brachycephaly with between 145 and 175 having severe deformity in the Yorkshire and Humber area.

Conservative therapies include positioning therapy, sometimes combined with physiotherapy, or cranial banding (helmets).

Cranial banding

Treatment for brachycephaly and positional plagiocephaly includes the use of a rigid, plastic, foam lined orthosis (helmet). The procedure is known as cranial banding. The orthosis is custom made for each patient and applies pressures in particular areas to discourage growth in prominent areas and encourage growth in flattened parts of the skull.

Typically the orthosis is worn constantly except for hygiene purposes. Regular checks are carried out to ensure the infant's skin is tolerating the device and to maintain normal ranges of neck movement. The helmet is checked once or twice a week and adjusted as necessary.

NICE was notified of the cranial banding procedure in February 2005. After due consideration, NICE determined that "this procedure does not fall within the remit of the Interventional Procedures Programme. This is because moulding helmets/cranial banding for plagiocephaly does not fall within the Institute's definition of an interventional procedure. Interventional procedures are those used for diagnosis or treatment that involves incision, puncture, entry into a body cavity or the use of ionising, electromagnetic or acoustic energy." As a result NICE will not be publishing guidance on the use of cranial banding.

Evidence base

As part of the Interventional Procedures Programme review of cranial orthoses, NICE identified a further unpublished (subsequently published) review (Bialocerkowski 2005) of conservative interventions for positional plagiocephaly.

The studies in the Bialocerkowski review were mostly case studies. Four were comparative studies. In none of these were participants randomised to treatment. Case series evidence suggested that positioning with or without physiotherapy may be effective. One study indicated that positioning was particularly effective in mildly affected infants. Similar evidence suggested that helmets may also be effective, particularly in infants with moderate to severe deformities. However the results of the comparative studies were inconclusive as to the benefit of one therapy over the other. Discrepancies in results may be due to differences in age, diagnostic technique, treatment methods and outcome measures. The author highlighted the lack of standard outcome measure to quantify skull shape or asymmetry. The main conclusion was: "further development of these outcome measures is required to quantify changes in skull shape and symmetry". In addition, reference was made to a 2002 article (Bridges SJ) that supported the view that positional plagiocephaly was a cosmetic problem.

The Institute for Clinical Systems Improvement (ICSI) Technology Report reported three non-randomised trials and one case series, all judged by ScHARR to be of poor quality. The overall conclusion was that, though the evidence is limited, the literature supports the use of cranial orthoses in infants before the age of 12 months. Positional therapy was considered to be effective only when employed in infants between the ages of two and four months.

NICE provided ScHARR with the evidence received as part of the consultation with clinical experts prior to the review being discontinued. Clinicians expressed scepticism about the efficacy of cranial orthoses and commented on the poor evidence available. They also considered that positional plagiocephaly spontaneously improved over time. The condition was generally considered both cosmetic and benign. Most clinicians believed that the demand for treatment would probably grow and could have a major impact on the NHS. Clinicians emphasised the need for community paediatric services to offer clear preventative advice to parents.

References

Hutchison, B. Lynne, Hutchison, Luke A. D., Thompson, John M. D., and Mitchell, Ed A. Plagiocephaly and Brachycephaly in the First Two Years of Life: A Prospective Cohort Study. Pediatrics 1-10-2004; 114 970-980.

Hutchison, B. Lynne, Hutchison, Luke A. D., Thompson, John M. D., and Mitchell, Ed A. Plagiocephaly and Brachycephaly in the First Two Years of Life: A Prospective Cohort Study. Pediatrics 1-10-2004; 114 970-980.

http://www.cranialtech.com/Treatment/treatment.html accessed July 2013

Bialocerkowski, A. E., Vladusic, S. L., and Howell, S. M. Conservative interventions for positional plagiocephaly: a systematic review. Dev.Med.Child Neurol. 2005; 47 563-570

Institute for Clinical Systems Improvement Cranial orthoses for deformational plagiocephaly. 2004

Appendix A (10)

Dupytren's contracture

This policy is designed to clarify the agreements between the commissioners and providers regarding the commissioning of dupuytren's contracture surgery

It serves to agree the conditions which are automatically commissioned and those that require exception permission before they can proceed.

There is an agreement that for commissioning to proceed, information must be provided by clinicians from levels 2, 3, or 4 (see below)

Definitions

Dupuytren's disease is a common and disabling fibroproliferative condition of the hand. It tends to strike patients in advancing age, causing progressive digital flexion contracture.

Commissioner – Leeds CCGs
Providers – any hospital with a commissioning agreement with NHS Leeds CCGs, (including NHS and independent sector providers).

Level 2 – Primary care
Level 3 – Extended primary care intermediate services
Level 4 – Hospital services

Commissioning position

Treatment	**DUPUYTREN'S CONTRACTURE SURGERY**
For the treatment of	**Dupuytren's Contracture.**
Background	Dupuytren's disease is a common and disabling fibroproliferative condition of the hand. It tends to strike patients in advancing age, causing progressive digital flexion contracture.
Commissioning position	NHS Leeds CCGs routinely commission: Referral and surgery where the patient does not fail the table top test NHS Leeds CCGs will not routinely commission repeat surgery for Dupuytren's contracture
Summary of evidence/rationale	Evidence available at http://www.bmj.com/cgi/content/extract/332/7538/397?ehom= (accessed July 2013)

Appendix A (11)

Haemorrhoids

This policy is designed to clarify the agreements between the commissioners and providers regarding the commissioning of haemorrhoid surgery

It serves to agree the conditions which are automatically commissioned and those that require exception permission before they can proceed.

There is an agreement that for commissioning to proceed, information must be provided by clinicians from levels 2, 3, or 4 (see below)

Definitions

Haemorrhoids are abnormally swollen vascular mucosal cushions that are present in the anal canal.

Commissioner – Leeds CCGs
Providers – any hospital with a commissioning agreement with NHS Leeds CCGs, (including NHS and independent sector providers).

Level 2 – Primary care
Level 3 – Extended primary care intermediate services
Level 4 – Hospital services

Commissioning position

<table>
<tr><td>Treatment</td><td colspan="2">HAEMORRHOID SURGERY</td></tr>
<tr><td>For the treatment of</td><td colspan="2">Haemorrhoids</td></tr>
<tr><td>Background</td><td colspan="2">Haemorrhoids are a common problem that will respond to conservative treatment. Haemorrhoids are abnormally swollen vascular mucosal cushions that are present in the anal canal. In the anus there are three vascular mucosal cushions, whose function is to help maintain anal continence]. These are typically described as being present at the left lateral, right posterior, and right anterior positions (i.e. at 3, 7, and 11 o'clock) but there is considerable individual variation. When these mucosal cushions become enlarged and symptomatic they are called haemorrhoids

Urgent referral should take place in people with suspected malignancy

<table>
<tr><td>40 years of age and older</td><td>Rectal bleeding with a change in bowel habit towards looser stools and/or increased stool frequency persisting for 6 weeks or more.</td></tr>
<tr><td>60 years of age and older</td><td>Rectal bleeding persisting for 6 weeks or more without a change in bowel habit and without anal symptoms.
A change in bowel habit to looser stools and/or more frequent stools persisting for 6 weeks or more without rectal bleeding.</td></tr>
<tr><td>Of any age</td><td>A right abdominal mass consistent with involvement of the large bowel.
A palpable rectal mass (intraluminal and not</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td></td><td><table>
<tr><td></td><td>pelvic; a pelvic mass outside the bowel would warrant an urgent referral to a urologist or gynaecologist).</td></tr>
<tr><td>Women (not menstruating)</td><td>Unexplained iron deficiency anaemia and haemoglobin 10 g/100 mL or less.</td></tr>
<tr><td>Men of any age</td><td>Unexplained iron deficiency anaemia and haemoglobin 11 g/100 mL or less.</td></tr>
</table></td></tr>
<tr><td>Commissioning position</td><td>Leeds CCGs will commission Haemorrhoid surgery in a patient with:
extremely painful, acutely thrombosed external haemorrhoids who present within 72 hours of onset for assessment, reduction or excision. (Excision under local anaesthetic effectively relieves pain.). In patients presenting after 72 hours home based conservative treatment is indicated.
internal haemorrhoids that have prolapsed and become swollen, incarcerated, and thrombosed (haemorrhoidectomy is likely to be needed).
People with perianal sepsis).
Referral for non-urgent assessment and treatment:
Leeds CCGs support referral where:
People with first- or second-degree haemorrhoids (or third-degree haemorrhoids that are quite small) that do not respond to 12 months conservative treatment that has been clearly documented in the GP notes.
People with third - degree haemorrhoids or fourth degree haemorrhoids that are either too large for non-operative measures or have not responded to them. (Haemorrhoidectomy may be appropriate.)
People with thrombosed haemorrhoids when bleeding is problematic, or there is chronic irritation or leakage.
Leeds CCGs do not routinely commission removal of anal skin tags</td></tr>
<tr><td>Summary of evidence/rationale</td><td>A detailed evidence base supporting the diagnosis and management of haemorrhoids is at http://cks.nhs.uk/haemorrhoids (accessed July 2013)</td></tr>
</table>

Appendix A (12)

Dilatation & Curettage for Heavy Menstrual Bleeding

This policy is designed to clarify the agreements between the commissioners and providers regarding the commissioning of D&C for Heavy Menstrual Bleeding

It serves to agree the conditions which are automatically commissioned and those that require exception permission before they can proceed.

There is an agreement that for commissioning to proceed, information must be provided by clinicians from levels 2, 3, or 4 (see below)

Definitions

Heavy menstrual bleeding (menorrhagia) is diagnosed when menstrual blood loss is considered excessive by the woman and is having a negative impact on her quality of life in terms of physical, emotional, or social well-being. It is often accompanied by other symptoms, such as menstrual pain (dysmenorrhoea).

Commissioner – Leeds CCGs
Providers – any hospital with a commissioning agreement with NHS Leeds CCGs, (including NHS and independent sector providers).

Level 2 – Primary care
Level 3 – Extended primary care intermediate services
Level 4 – Hospital services

Commissioning position

NHS Leeds CCGs do not routinely commission dilatation and curettage (D and C) as a diagnostic tool for heavy menstrual bleeding.

Treatment	**D&C**
For the treatment of	Heavy Menstrual Bleeding
Background	HMB is a common problem that will respond to treatments available in primary care. Heavy menstrual bleeding (menorrhagia) is diagnosed when menstrual blood loss is considered excessive by the woman and is having a negative impact on her quality of life in terms of physical, emotional, or social well-being. It is often accompanied by other symptoms, such as menstrual pain (dysmenorrhoea). ***Urgent referral*** (2 weeks) should be considered if there are any alarm symptoms or signs suggestive of gynaecological cancer, which include: • Persistent intermenstrual or postcoital bleeding. • An unexplained vulval lump or vulval bleeding due to ulceration. • A palpable abdominal mass that is not obviously uterine fibroids. • If there are clinical features of cervical cancer, an urgent referral should be made without the need for a smear test, and regardless of previous smear results.
Commissioning	Leeds CCGs routinely commissions:

position	***Elective referral*** where there are
	
	• Symptoms or signs suggestive of underlying pathology (structural or histological uterine abnormalities) or
	
	• Where there are no symptoms or signs suggestive of underlying pathology and there has been failure to control symptoms with:
	
	  ○ The levonorgestrel-releasing intrauterine system (LNG-IUS) or
	  ○ Tranexamic acid, nonsteroidal anti-inflammatory drugs (NSAIDs), or the combined oral contraceptive pill (COC) where the LNG-IUS is unsuitable or
	  ○ Oral norethisterone or long-acting progestogens if the other treatments are unsuitable and
	  ○ Where initial treatment was ineffective, switching to another pharmaceutical treatment (e.g. a progestogen), or using an additional drug (e.g. add tranexamic acid to an NSAID) has been considered.
	
	Leeds also routinely commissions:
	
	• Investigations in secondary care include endometrial biopsy, hysteroscopy, and/or pelvic ultrasound.
	
	NHS Leeds does **not** routinely commission dilatation and curettage (D and C) as a diagnostic tool for heavy menstrual bleeding.
	
	Surgery should be reserved for:
	
	• Use on the woman's request (following full counselling on the advantages and disadvantages).
	• Difficult-to-treat cases where pharmaceutical treatment has failed to be sufficiently effective or is contraindicated.

Summary of evidence/rationale	This policy is based on clinical guidelines on *Heavy menstrual bleeding*, published by the National Institute for Health and Care Excellence http://publications.nice.org.uk/heavy-menstrual-bleeding-cg44 Accessed July 2013

Appendix A (13)

Surgery for Hernia

This policy is designed to clarify the agreements between the commissioners and providers regarding the commissioning of surgery for hernia. It serves to agree the conditions which are automatically commissioned and those that require exception permission before they can proceed.

There is an agreement that for commissioning to proceed, information must be provided by clinicians from levels 2, 3, or 4 (see below)

Definitions

A hernia occurs when part of an internal organ or body part protrudes through an opening into another area where it ordinarily should not be located. There are many different types of hernias, but the most common is when a portion of the intestine protrudes through a weak area in the muscular wall of the abdomen. This causes an abnormal bulge under the skin of the abdomen, usually near the groin or the navel.

Hernias occur in various locations. Some hernias are present at birth, while others develop during adulthood. Hernias may enlarge due to increased pressure inside the abdomen, such as during straining, persistent coughing, obesity or pregnancy.

- Inguinal hernia. A portion of intestine or internal fat protrudes through a weakness in the inguinal canal. The inguinal canal is a natural passageway through the abdominal wall in the groin. In males, the inguinal canal contains the blood vessels that go to the testicle and the duct that carries sperm from the testicle. Inguinal hernias account for 75% of all hernias and are five times more common in males than females. They may be present in infants but can develop in adults also.

- Femoral hernia. This is a hernia through the passage that contains the large blood vessels (the femoral artery and vein) between the abdomen and the thigh. This type of hernia causes a bulge in the upper thigh just under the groin and is more common in women than men.

Commissioner – Leeds CCGs
Providers – any hospital with a commissioning agreement with NHS Leeds CCGs, (including NHS and independent sector providers).

Level 2 – Primary care
Level 3 – Extended primary care intermediate services
Level 4 – Hospital services

Commissioning position

Routinely commissioned for:

- Femoral Hernias
- Any groin hernia in women
- Men with a clinically palpable inguinal hernia and pain that limits daily activity
- Men with an irreducible hernia

Not routinely commissioned for:

Men with an asymptomatic or a minimally symptomatic inguinal hernia (discomfort or pain that does not restrict daily activity - adopt watchful waiting)
Men with groin pain and an ultrasound detected, but clinically impalpable, hernia (consider musculo-skeletal referral)

Not routinely commissioned:

Post-operative follow up low risk cases (ie no evidence of clinically significant haematoma, injury to the bowel or major blood vessels, deep infection, ischaemic orchitis, recurrence)

Background

Groin Hernias /Femoral Hernias in adults

- Significantly more femoral hernias need emergency surgery than inguinal hernias (36% vs. 5%)
- Women are more likely to need emergency surgery than men (17% vs. 5%)
- The elderly are not at increased risk of mortality after elective surgery
- Older patients are more likely to need emergency surgery than young patients
- Increased risk of post-operative mortality after emergency surgery

Watchful waiting is a safe and effective option for men with an asymptomatic or minimally symptomatic inguinal hernia (discomfort or pain that does not restrict daily activity).

What is the advantage of watchful waiting versus immediate operation for a minimally symptomatic hernia?

Avoidance of the risks of hernia surgery for the individual patients and costs for unnecessary surgery.

What are the risks of watchful waiting?

Acute incarceration/strangulation is a rare event - estimated at about 2 events 1000 patient-years. About 25% of watchful-waiting patients cross-over to surgery during the first two years - thereafter, the cross-over rate is estimated at 4%/year.

There does not appear to be any increase in technical complication in patient crossover to surgery after waiting; however, there is some concern that interval development/deterioration of an unrelated disease may increase the overall risks of surgery.

There is some literature on the concordance between radiological and surgical detection of groin hernias but no evidence that repair of a clinically impalpable hernia will improve groin pain.

Other considerations:

Minimally symptomatic inguinal hernias in elderly, infirm, frail men or limited decision-making capacity consider hernia repair to prevent complications but the evidence to support this is limited.

For initial repair the choice between open and laparoscopic repair is determined by the clinician and the patient. Repair of a recurrence should be a laparoscopic procedure (TAPP or TEP is a matter of clinical choice)

Supporting evidence

Swedish Hernia Registry data for 108,000 hernia repairs during 1992-2004. Ann Surg 2007;245:656-660

Patient reported outcomes http://www.hscic.gov.uk/catalogue/PUB10899 Accessed July 2013

Observation or Operation for Patients with an Asymptomatic Inguinal Hernia O'Dwyer et al. Ann Surg 2006;244:167-173. American study JAMA 2006;295:285-292

Fitzgibbons RJ Jr et al Watchful waiting vs repair of inguinal hernia in minimally symptomatic men: a randomized clinical trial. JAMA. 2006 Jan 18;295(3):285-92.

Laparosopic surgery for inguinal repair http://publications.nice.org.uk/laparoscopic-surgery-for-inguinal-hernia-repair-ta83 accessed July 2013

Laparoscopic Repair of Inguinal Hernias http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3140939/ accessed July 2013

Sevonius D, Gunnarsson U, Nordin P, et al. Repeated groin hernia recurrences. Ann Surg. 2009;249:516-518

Appendix A (14)

Facet Joint procedures for Chronic back pain

This policy is designed to clarify the agreements between the commissioners and providers regarding the commissioning of Facet Joint procedures for Chronic back pain.

It serves to agree the conditions which are automatically commissioned and those that require exception permission before they can proceed.

There is an agreement that for commissioning to proceed, information must be provided by clinicians from levels 2, 3, or 4 (see below)

Definitions

Facet or zygopophysial joints are common sources of chronic spinal pain accounting for approximately 15-45% of cases of chronic low back pain, 36-60% of chronic neck pain and
34-48% of cases of thoracic pain. Facet joint pain syndrome is poorly defined without clear clinical diagnostic criteria.

Facet joint procedures involve the instillation of analgesic and/or corticosteroid into the facet joint or around its nerve supply (ramus medialis of the ramus dorsalis) under fluoroscopic guidance. There are three types of procedures - intra-articular injections, medial branch blocks and percutaneous radiofrequency neurolysis of the medial branch nerves.

Commissioner – Leeds CCGs
Providers – any hospital with a commissioning agreement with NHS Leeds CCGs, (including NHS and independent sector providers).

Level 2 – Primary care
Level 3 – Extended primary care intermediate services
Level 4 – Hospital services

Commissioning position

Facet joints injections are not routinely commissioned for patients with (greater than 6 weeks and less than 12months – as set out in the NICE CG), persistent, nonspecific low back pain.

Leeds CCGs will fund medial branch blocks for the diagnosis and management of cervical, thoracic and lumbar back pain when all the following criteria are met:

- The patient is part of a comprehensive pain management programme including physiotherapy, psychosocial support, medication and patient education; AND
- A pain specialist or MSK Physician / GPSI (with back pain assessment, diagnostic and treatment skills) has assessed the patient and is of the opinion that facet joint is the most likely cause of pain; AND
- The pain has lasted for more than one year; AND
- The pain has resulted in documented moderate to significant impact on daily functioning (a loss of physical function of 50% or greater) AND
- All conservative management options (physiotherapy treatments and guided exercise programmes, pharmacotherapy including analgesia and muscle relaxants) have been tried and failed; AND
- Body Mass Index is less than 38kg/m2

Repeat injections are funded:

- In the diagnostic phase, patients may receive up to 2 injections at least 2- 6 weeks apart in a particular region of the spine (lumbar, cervical and thoracic).

- In the therapeutic phase, a maximum of 2 injections per year (6 months apart) are funded provided that providers have audit data showing:

    - Patient has been reviewed by a pain specialist or MSK Physician / GPSI and there is documentation to encourage self-care.
    - Repeat injection may be performed if there is documented evidence of a durable >50% pain relief
    - There has been greater than 50% reduction in symptoms for 3 months
    - Less pain medication
    - The patient remains within a comprehensive pain management programme.
    - Repeat injections where there has been a less than 50% objective response are not routinely funded.

Repeat injections where there has been a less than 50% objective response are not routinely funded.

Injections MUST be under radiological guidance. The procedure should be performed as per the best practice guidelines published by the Faculty of Pain Medicine of the Royal College of Anaesthetists and /or British Pain Society when these become available. Appropriate images should be stored for future reference.

Evidence base

Injection therapy for subacute and chronic low-back pain. Staal J et al. Cochrane Database of Systematic Reviews.
http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD001824/frame.html accessed July 2013

Boswell, Mark, V, Colson, James D., Sehgal, Nalini et al , 2007

Chou R, Atlas SJ, Stanos SP, Rosenquist RW. Nonsurgical interventional therapies for low back pain: a review of the evidence for an American Pain Society clinical practice guideline. Spine (Phila Pa 1976). 2009 May 1;34(10):1078-93.

Manchikanti L, Boswell MV, Datta S, Fellows B, Abdi S, Singh V, Benyamin RM, Falco FJ, Helm S, Hayek SM, Smith HS; ASIPP Comprehensive review of therapeutic interventions in managing chronic spinal pain. Pain Physician. 2009 Jul-Aug;12(4):E123-98.

NICE clinical guideline 88: Low back pain: Early management of persistent non-specific low back pain, 2009 http://publications.nice.org.uk/low-back-pain-cg88 accessed July 2013

Staal JB, de Bie RA, de Vet HC, Hildebrandt J, Nelemans P. Injection therapy for subacute and chronic low back pain: an updated Cochrane review. Spine (Phila Pa 1976). 2009 Jan 1;34(1):49-59.

Resnick DK, Choudhri TF, Dailey AT, et al; American Association of Neurological Surgeons/Congress of Neurological Surgeons. Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 13: Injection therapies, low-back pain, and lumbar fusion. J Neurosurg Spine. 2005;2(6):707-715.

American College of Occupational and Environmental Medicine (ACOEM). Neck and upper back complaints. Elk Grove Village, IL: American College of Occupational and Environmental Medicine (ACOEM); 2004.

Datta S, Lee M, Falco FJ, Bryce DA, Hayek SM. Systematic assessment of diagnostic accuracy and therapeutic utility of lumbar facet joint interventions. Pain Physician. 2009 Mar-Apr;12(2):437-60.

Falco FJ, Erhart S, Wargo BW, Bryce DA, Atluri S, Datta S, Hayek SM. Systematic review of diagnostic utility and therapeutic effectiveness of cervical facet joint interventions. Pain Physician. 2009 Mar-Apr;12(2):323-44.

Appendix A (15)

Percutaneous Nucleoplasty for Low Back Pain with Lower Limb Radicular Pain

This policy is designed to clarify the agreements between the commissioners and providers regarding the commissioning of Percutaneous Nucleoplasty for Low Back Pain with Lower Limb Radicular Pain.

It serves to agree the conditions which are automatically commissioned and those that require exception permission before they can proceed.

There is an agreement that for commissioning to proceed, information must be provided by clinicians from levels 2, 3, or 4 (see below)

Definitions

Chronic back pain is a common condition that affects a considerable proportion of the population. In the majority of individuals pain resolves spontaneously within several months.
However, for some people pain persists, despite specific causes of back pain such as herniated discs, osteoporosis and fractures being excluded. Increasingly this pain is being attributed to degeneration of the intervertebral disc, and referred to as discogenic back pain.
Degeneration of the intervertebral disc is a nearly universal phenomenon with ageing that is asymptomatic in most individuals, however internal disc disruption can be a major cause of pain and disability leading to diminished quality of life for many.

Percutaneous disc decompression using coblation is usually performed on an outpatient basis under local anaesthesia and sedation. Under fluoroscopic guidance, a needle is inserted into the affected disc. A probe-like device is then introduced into the disc. The device is heated up to 40–70°C, ablating the centre of the disc and creating a channel. After stopping at a pre-determined depth, the probe is then removed, coagulating the tissue as it is withdrawn. Around six channels are created during the procedure, the number of channels depending on the amount of tissue reduction required.

Commissioner – Leeds CCGs
Providers – any hospital with a commissioning agreement with NHS Leeds CCGs, (including NHS and independent sector providers).

Level 2 – Primary care
Level 3 – Extended primary care intermediate services
Level 4 – Hospital services

Commissioning position

Not routinely commissioned

Supporting evidence

NICE IPG 173 Percutaneous disc decompression using coblation for lower back pain
http://publications.nice.org.uk/percutaneous-disc-decompression-using-coblation-for-lower-back-pain-ipg173
accessed July 2013

Appendix A (16)

Radiofrequency ablation severe chronic pain in the lower back

This policy is designed to clarify the agreements between the commissioners and providers regarding the commissioning of Radiofrequency ablation severe chronic pain in the lower back

It serves to agree the conditions which are automatically commissioned and those that require exception permission before they can proceed.

There is an agreement that for commissioning to proceed, information must be provided by clinicians from levels 2, 3, or 4 (see below)

Definitions

Radiofrequency ablation is used to treat severe chronic pain in the lower (lumbar) back, cervical and thoracic spine where radio frequency waves are used to produce heat on specifically identified nerves supplying the facet joints on either side of the spine. By generating heat around the nerve, its ability to transmit pain signals to the brain is destroyed, thus ablating the nerve. The nerves to be ablated are identified through injections of local anaesthesia prior to the procedure. If the local anaesthesia injections provide temporary pain relief, then radiofrequency ablation is performed on the nerve(s) that responded well to the injections. Radiofrequency ablation is a minimally invasive procedure which is usually done in day-surgery clinics, and the patient is sent home shortly after completion of the procedure.

Commissioner – Leeds CCGs
Providers – any hospital with a commissioning agreement with NHS Leeds CCGs, (including NHS and independent sector providers).

Level 2 – Primary care
Level 3 – Extended primary care intermediate services
Level 4 – Hospital services

Commissioning position

Not routinely commissioned

Supporting evidence

NICE IPG83 Percutaneous intradiscal radiofrequency thermocoagulation for lower back pain http://publications.nice.org.uk/percutaneous-intradiscal-radiofrequency-thermocoagulation-for-lower-back-pain-ipg83 accessed July 2013

Appendix A (17)

Spinal Epidural injections for Nonspecific Low Back Pain, Radiculopathy, Spinal stenosis

This policy is designed to clarify the agreements between the commissioners and providers regarding the commissioning of Spinal Epidural injections for Nonspecific Low Back Pain, Radiculopathy, Spinal stenosis.

It serves to agree the conditions which are automatically commissioned and those that require exception permission before they can proceed.

There is an agreement that for commissioning to proceed, information must be provided by clinicians from levels 2, 3, or 4 (see below)

Definitions

Epidural injection (Transforaminal Epidural Steroid Injection, Interlaminar Epidural injection, Caudal epidural injection) for the management of spinal pain is one of the commonest interventions performed in many countries. Spinal pain is a common cause of chronic pain with lifetime prevalence 54-80%. Annual prevalence of chronic low back pain ranges from 15-45%. The most common type of complications are related to needle placement and drug administration including dural puncture, spinal cord trauma, subdural injections, abscess formation etc.

Commissioner – Leeds CCGs
Providers – any hospital with a commissioning agreement with NHS Leeds CCGs, (including NHS and independent sector providers).

Level 2 – Primary care
Level 3 – Extended primary care intermediate services
Level 4 – Hospital services

Commissioning position

Not routinely commissioned:

Epidural injections for non-specific low back pain

Commissioned providing certain criteria are met:

1. *Acute radiculopathy* when *ALL* of the following criteria are met:

- Aged 18 or over;
- The patient has radicular pain (below the knee for lower lumbar herniations, into the anterior thigh for upper lumbar herniations) consistent with the level of spinal involvement;
- Symptoms have persisted despite conservative treatment (e.g. analgesia, physical therapy etc) for at least 3 weeks

Patients may receive up to six injections 2-3 months apart provided there has been greater than 50% reduction in symptoms for six weeks. Repeat injections will only be funded following documentary evidence of a durable (6 weeks) clinically significant response (>50%) to a previous epidural injection (as measured on a Visual Analogue Pain Scale) and documented impact on quality of life as measured by Brief Pain Inventory or locally agreed questionnaire.

2. *Spinal stenosis* when *ALL* of the following criterion are met:

- The pain has lasted for more than one year;
- The pain has resulted in moderate to significant impact on daily functioning;

- The patient has had a physio trial of flexion exercise in the last 12m;
- The pain is of a type that becomes worse on walking or standing (the aim of treatment is to improve walking distance);
- All conservative management options (physiotherapy guided exercise, optimal pharmacotherapy including analgesia and muscle relaxants) have been tried and the patient's pain has not improved (>50% in VAS score and objective clinical assessment);
- Patient is within a tier 2 pain management programme (including physiotherapy, psychosocial support, medication and patient education).

Repeat injections will only be funded following documentary evidence of clinically significant response (>50%) to a previous epidural injection (as measured on a VAS scale, and in patient report of functioning and where the view of the treating clinician is that epidural injection is technically possible;

Injections MUST be under radiological guidance and per the best practice guidelines published by the Faculty of Pain Medicine of the Royal College of Anaesthetists and/or the British Pain Society. Appropriate images should be stored for future reference

Supporting Evidence

NICE CG 88 Low back pain: Early management of persistent non-specific low back pain
http://publications.nice.org.uk/low-back-pain-cg88/guidance#assessment-and-imaging
Accessed July 2013

Injection therapy for subacute and chronic low-back pain. Staal J et al. Cochrane Database of Systematic Reviews. http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD001824/frame.html Accessed July 2013

Khot A, Bowditch M, Powell J, Sharp D. The use of intradiscal steroid therapy for lumbar spinal discogenic pain: a randomized controlled trial. Spine. 2004; 29 (8):833-836

Chou R, Atlas SJ, Stanos SP, Rosenquist RW. Nonsurgical interventional therapies for low back pain: a review of the evidence for an American Pain Society clinical practice guideline. Spine (Phila Pa 1976). 2009 May 1;34(10):1078-93

Manchikanti L, Boswell MV, Datta S, Fellows B, Abdi S, Singh V, Benyamin RM, Falco FJ, Helm S, Hayek SM, Smith HS; ASIPP Comprehensive review of therapeutic interventions in managing chronic spinal pain. Pain Physician. 2009 Jul-Aug;12(4):E123-98.

Luijsterburg, P.A., Verhagen, A.P., Ostelo, R.W. et al. (2007a) Effectiveness of conservative treatments for the lumbosacral radicular syndrome: a systematic review. European Spine Journal 16(7), 881-899.

Abdi S, Datta S, Trescot A.M., et al. Epidural steroids in the management of chronic spinal pain: a systematic review. Pain Physician. 2007;10:185-212

North American Spine Society. Clinical Guidelines on the diagnosis and treatment of degenerative lumbar spinal stenosis,
2007.
Ghahreman A, et al. The efficacy of transforamenal injection of steroid for the treatment of lumbar radicular pain. Pain Medicine 2010; 11: 1149 – 1169

Appendix A (18)

TENS for Osteoarthritic pain in peripheral joints persisting for longer than 12 months

This policy is designed to clarify the agreements between the commissioners and providers regarding the commissioning of TENS for Osteoarthritic Musculoskeletal pain persisting for longer than 12 months.

It serves to agree the conditions which are automatically commissioned and those that require exception permission before they can proceed.

There is an agreement that for commissioning to proceed, information must be provided by clinicians from levels 2, 3, or 4 (see below)

Definitions

TENS is the application of electrical stimulation of varying frequency, intensity and pulse duration to the skin for pain relief. Different TENS modalities use varying combinations of frequency and intensity settings on the device to elicit pain relief. It is used in a variety of clinical settings to treat diverse acute and chronic pain conditions, although studies have produced varying results. TENS is popular with patients and health professionals of different disciplines, and is used widely in pain clinics across the UK, where it is considered as a first line intervention in the management of chronic pain.

Commissioner – Leeds CCGs
Providers – any hospital with a commissioning agreement with NHS Leeds CCGs, (including NHS and independent sector providers).

Level 2 – Primary care
Level 3 – Extended primary care intermediate services
Level 4 – Hospital services

Commissioning position

TENS is funded for selected patients who satisfy ALL of the following criteria:

- *Patient has osteoarthritis*
- *The patient has severe pain (assessed by a pain specialist using a Visual Analogue Scale) lasting at least 12 months.*
- *The pain results in significant impact on physical functioning*

TENS is NOT routinely funded for other pain indications

Source of evidence:
Claydon LS,Chesterton LS (2008) Does transcutaneous electrical nerve stimulation (TENS) produce 'doseresponses' ? A review of systematic reviews on chronic pain. Physical Therapy Reviews, 2008, vol./is.13/6(450-63), 1083-3196 (2008 Dec)
NICE guidance CG 88 (2009) Low back pain – early management of persistent non specific low back pain. (May 2009) http://publications.nice.org.uk/low-back-pain-cg88/guidance#assessment-and-imaging accessed July 2013
NICE guidance CG59 (2008) Osteoarthritis: The care and management of osteoarthritis in adults. Full guidance Feb 2008 http://publications.nice.org.uk/osteoarthritis-cg59/guidance
Accessed July 2013
Nnoaham KE,Kumbang (2008) Transcutaneous electrical nerve stimulation (TENS) for chronic pain. Cochrane Database of Systematic Reviews, 2008, vol./is. /3(CD003222), 1361-6137;1469-493X (2008)
Oosterhof J,Samwel HJ,de Boo TM,Wilder-Smith OH,Oostendorp RA,Crul B (2008) Predicting outcome TENS in chronic pain: a prospective, randomized, placebo controlled trial. Pain, May 2008, vol./is. 136/1-2(11-20), 0304-3959;1872-6623 (2008 May)
Rutjes AW,Nuesch E,Sterchi R,Kalichman L,Hendriks E,Osiri M,Brosseau L,Reichenbach. (2009) Transcutaneous electrostimulation for osteoarthritis of the knee.

Appendix A (19)

Gastro-electrical stimulation for gastroparesis

This policy is designed to clarify the agreements between the commissioners and providers regarding the commissioning of Gastro-electrical stimulation for gastroparesis

It serves to agree the conditions which are automatically commissioned and those that require exception permission before they can proceed.

There is an agreement that for commissioning to proceed, information must be provided by clinicians from levels 2, 3, or 4 (see below)

Definitions

Gastroparesis is a chronic disorder of the stomach in which food empties from the stomach much more slowly than normal (delayed gastric emptying) in the absence of any type of obstruction. The most common symptoms are nausea and protracted vomiting. Other symptoms include abdominal bloating, pain and, in severe cases, malnutrition. Gastroparesis is most commonly associated with type 1 diabetes. It can also occur after surgery or in association with other disorders such as anorexia nervosa and abdominal migraine. Gastroelectrical stimulation is an option for the treatment of patients with chronic, intractable (drug-refractory) nausea and vomiting secondary to gastroparesis. Other options include the palliative procedures of jejunostomy tube insertion for feeding, gastrostomy tube insertion for stomach decompression, and pyloroplasty to improve or facilitate gastric emptying

Commissioner – Leeds CCGs
Providers – any hospital with a commissioning agreement with NHS Leeds CCGs, (including NHS and independent sector providers).

Level 2 – Primary care
Level 3 – Extended primary care intermediate services
Level 4 – Hospital services

Commissioning position

Not routinely commissioned

Supporting evidence

NICE IPG103 Gastroelectrical stimulation for gastroparesis http://publications.nice.org.uk/gastroelectrical-stimulation-for-gastroparesis-ipg103/guidance Accessed July 2013

Appendix A (20)

Toric intraocular lens implant for astigmatism

This policy is designed to clarify the agreements between the commissioners and providers regarding the commissioning of Toric intraocular lens implant following cataract surgery in patients with astigmatism

It serves to agree the conditions which are automatically commissioned and those that require exception permission before they can proceed.

There is an agreement that for commissioning to proceed, information must be provided by clinicians from levels 2, 3, or 4 (see below)

Definitions

Toric IOLs refer to astigmatism correcting intraocular lenses used at the time of cataract surgery to decrease post-operative astigmatism.

Commissioner – Leeds CCGs
Providers – any hospital with a commissioning agreement with NHS Leeds CCGs, (including NHS and independent sector providers).

Level 2 – Primary care
Level 3 – Extended primary care intermediate services
Level 4 – Hospital services

Commissioning position

Not routinely commissioned as there is insufficient evidence to demonstrate safety, clinical and cost effectiveness.

Supporting evidence

Pichon Riviere A, Augustovski F, Garcia Marti S, Glujovsky D, Lopez A, Rey-Ares L, Bardach A, Regueiro A, Valanzasca P. Toric intraocular lenses. Centre for Reviews and Dissemination University of York http://www.crd.york.ac.uk/crdweb/ShowRecord.asp?LinkFrom=OAI&ID=32011000969#.UejcW8twa9I accessed July 2013

American Academy of Ophthalmology. Clinical Update: Cataract: Toric IOLs: Four Options for Addressing Residual Astigmatism. http://www.aao.org/publications/eyenet/201204/cataract.cfm accessed July 2013

American Academy of Ophthalmology. Clinical Update: Cataract Correcting Astigmatism during Cataract Surgery. http://www.aao.org/publications/eyenet/200506/cataract.cfm accessed July 2013

Laurendeau C, Lafuma A, Berdeaux G. Modelling lifetime cost consequences of toric compared with standard IOLs in cataract surgery of astigmatic patients in four European countries. Journal of Medical Economics 2009; 12(3): 230-237 reviewed by Centre for Reviews and Dissemination University of York http://www.crd.york.ac.uk/crdweb/ShowRecord.asp?LinkFrom=OAI&ID=22010000925#.UejaOctwa9I Accessed July 2013

National Institute for Health Research. Horizon scanning centre. Eye Disease: AcrySof® – a new intraocular lens for patients with cataracts and corneal astigmatism. Date of publication: 1st June 2010. http://www.hsc.nihr.ac.uk/topics/acrysof-r-intraocular-lens-for-patients-with-catar/ accessed July 2013.

Appendix A (21)

Erectile Dysfunction including Penile Prostheses

This policy is designed to clarify the agreements between the commissioners and providers regarding the commissioning of interventions for Erectile Dysfunction.

It serves to agree the conditions which are automatically commissioned and those that require exception permission before they can proceed.

There is an agreement that for commissioning to proceed, information must be provided by clinicians from levels 2, 3, or 4 (see below)

Definitions

Erectile dysfunction is defined as the persistent inability to attain and maintain an erection sufficient to permit satisfactory sexual performance. Some experts advise that symptoms lasting at least three months warrant evaluation and consideration of treatment.

Commissioner – Leeds CCGs
Providers – any hospital with a commissioning agreement with NHS Leeds CCGs, (including NHS and independent sector providers).

Level 2 – Primary care
Level 3 – Extended primary care intermediate services
Level 4 – Hospital services

Commissioning position

Leeds CCGs routinely commission services for erectile dysfunction in line with the Clinical Knowledge Summaries guidance provided by the National Institute for Health and Care Excellence, including

- Making a full assessment of physical, physiological, and psychological causes of erectile dysfunction
- Calculating and appropriately managing cardiovascular risk
- Providing advice on healthy lifestyle
- Treating people who require drug intervention with a phosphodiesterase-5 inhibitor
- Following-up to assess satisfaction with treatment
- Referring all men who cannot be adequately managed in primary care including for:
    - Emergency treatment of priapism to avoid permanent penile damage
    - Surgery if there are anatomical abnormalities (e.g. Peyronie's syndrome), or for insertion of a penile prosthesis.
    - Testosterone replacement if there is hypogonadism.
    - Medical treatments other than PDE-5 inhibitors if these are ineffective
    - Vacuum devices
    - Intracavernous injection therapy
    - Intraurethral alprostadil
    - Psychosexual counselling

Penile implants / prostheses are routinely funded for the treatment of severe organic erectile dysfunction (ED) with the following restrictions:

- as third line treatment ONLY following adequate trials of standard therapies (including oral PDE-5 inhibitors, testosterone replacement), vacuum constriction device, and intracavernous injection therapy and intraurethral alprostadil.
- ED is associated with one of the following medical conditions: Diabetes; Multiple Sclerosis ; Parkinson's Disease ; Poliomyelitis ; Prostate Cancer ; Prostatectomy ; Radical Pelvic Surgery ; Severe Pelvic Injury ; Renal Failure treated by dialysis or transplant ; Single Gene Neurological Disease ; Spinal Cord Injury ; Spina Bifida OR
- there is documented evidence the patient is suffering severe distress on account of their ED

- Appropriate risk factor modification and lifestyle changes such as losing weight, stopping smoking, reducing alcohol consumption, and increasing exercise should have been tried
- Psychological assessment has been done and has excluded a treatable underlying psychogenic cause.
- Urological assessment has been done and has excluded a treatable underlying physical abnormality.
- Endocrine assessment has been done and has excluded a treatable underlying hormonal cause.

Leeds CCGs do not routinely commission primary care interventions based in a hospital outpatient setting. Urology would be the usual referral option for men who cannot be managed in primary care, unless psychology services, endocrinology, or cardiovascular services are more appropriate.

Supporting evidence

Guidelines on the management of erectile dysfunction, British Society for Sexual Medicine (BSSM) Hackett et al, 2008.
http://www.bssm.org.uk/downloads/BSSM_ED_Management_Guidelines_2007.pdf

European Association of Urology 2009. Male Sexual Dysfunction: Erectile dysfunction and premature ejaculation. Wespes, E et al.
http://www.uroweb.org/fileadmin/tx_eauguidelines/2009/Full/Male_Sexual_Dysf.pdf

NICE CG 66 Type 2 Diabetes http://www.nice.org.uk/nicemedia/pdf/CG66FullGuideline0509.pdf

National Institute for Health and Care Excellence. Clinical Knowledge Summaries: Erectile Dysfunction http://cks.nice.org.uk/erectile-dysfunction#!topicsummary accessed August 2013

Appendix B: Version Control Sheet

Version	Date	Author	Status	Comment
Draft 2	18/7/13	J D Fear	Draft	Update plus add specific interventions
Draft 3	2/9/13	Fiona Day	Draft	Addition of erectile dysfunction interventions
Draft 4	9/9/13	Fiona Day	Draft	Amendment to section 2- removal of duplication. Removal of section on sacral nerve stimulation and replace with statement about NHS England as commissioner. Merger or erectile dysfunction with penile prostheses appendices. Addition of appendix numbers at start of appendix A to aid legibility.
Draft 5	11/9/13	Fiona day	Draft	Correction of typo plus formatting

Appendix C: Plan for Dissemination of Policy Documents
To be completed and attached to any document which guides practice when submitted to the appropriate committee for consideration and approval.

Acknowledgement: University Hospitals of Leicester NHS Trust.

Title of Policy:	Targeted clinical interventions to deliver maximum health benefit		
Date finalised:		Dissemination lead: Print name and contact details	
Previous policy already being used?	No		
If yes, in what format and where?	n/a		
Proposed action to retrieve out-of-date copies of the document:	n/a		
To be disseminated to:	How will it be disseminated, who will do it and when?	Paper or Electronic	Comments
Clinicians		Electronic	
Clinicians and patients		Electronic and Paper	
Panel Members		Electronic and paper	

Dissemination Record - to be used once policy is approved.

Date put on register / library of policy documents		Date due to be reviewed	

Disseminated to: (either directly or via meetings, etc)	Format (i.e. paper or electronic)	Date Disseminated	No. of Copies Sent	Contact Details / Comments
Via website				

Appendix D: Equality Impact Assessment

To ensure the Individual Funding Requests Policy for the Clinical Commissioning Groups in Leeds reflects due process for identifying the effect, or likely effect, of the policy on people with Equality Act protected characteristics – age, disability, gender reassignment, pregnancy and maternity, race, religion or belief, sex, sexual orientation - and that the policy demonstrates due regard to reducing health inequalities, addressing discrimination and maximising opportunities to promote equality the following steps have been taken.

The update to the policy results from the iterative refresh process, and the requirement to make changes to care as indicated by an evolving evidence-base. This means that access is broadened as more treatments and interventions become available without the need for an IFR. There is no change to the underlying principles of the policy. In order for an IFR to be approved according to the core principles for managing Individual Funding Requests, it must be demonstrated that the patient's case is exceptional.

The following consultation and engagement activities have been undertaken. The evidence-based policy has been circulated to all GPs and secondary care consultants for comment, and has been made available on the internet to the public, along with Plain English patient information leaflets. The core principles for managing Individual Funding Requests in Leeds have been made available online for twelve weeks and disseminated through Patient Advisory Groups and Patient Reference Groups along with a cascade through the Community and Voluntary Service network. Feedback from all these sources has been collected by the Clinical Commissioning Groups. There is also an open and transparent approach to the processes of the decision making panel with an established mechanism for appeals.