Northern, Eastern and Western Devon Clinical Commissioning Group
South Devon and Torbay Clinical Commissioning Group

NICE Update Bulletin April 2013 for guidance issued Wednesday 24th April 2013

Hyperlinks to the relevant NICE web page are included, to activate link hold down the CTRL key and left click on your mouse. Details are also available from the NICE website (**http://www.nice.org.uk**)

Type	Guidance title and reference number
Technology Appraisals (TAs)	**Omalizumab for treating severe persistent allergic asthma (review of technology appraisal guidance 133 and 201) TA278** **Guidance** 1.1 Omalizumab is recommended as an option for treating severe persistent confirmed allergic IgE-mediated asthma as an add-on to optimised standard therapy in people aged 6 years and older: • who need continuous or frequent treatment with oral corticosteroids (defined as 4 or more courses in the previous year), **and** • only if the manufacturer makes omalizumab available with the discount agreed in the patient access scheme. 1.2 Optimised standard therapy is defined as a full trial of and, if tolerated, documented compliance with inhaled high-dose corticosteroids, long-acting $beta_2$ agonists, leukotriene receptor antagonists, theophyllines, oral corticosteroids, and smoking cessation if clinically appropriate. 1.3 People currently receiving omalizumab whose disease does not meet the criteria in 1.1 should be able to continue treatment until they and their clinician consider it appropriate to stop. **Percutaneous vertebroplasty and percutaneous balloon kyphoplasty for the treatment of osteoporotic vertebral fractures TA279** **Guidance** 1.1 Percutaneous vertebroplasty, and percutaneous balloon kyphoplasty without stenting, are recommended as options for treating osteoporotic vertebral compression fractures only in people: • who have severe ongoing pain after a recent, unhealed vertebral fracture despite optimal pain management and • in whom the pain has been confirmed to be at the level of the fracture by physical examination and imaging. **The technologies:** **Percutaneous vertebroplasty** Vertebroplasty involves injecting bone cement into the vertebral body (the solid part of the vertebra), using local anaesthetic and an analgesic. Vertebroplasty aims to relieve pain in people with painful fractures and to strengthen the bone to prevent future fractures.

	Percutaneous balloon kyphoplasty without stenting Kyphoplasty involves inserting a balloon-like device (tamps) into the vertebral body, using local or general anaesthetic. The balloon is slowly inflated until it restores the normal height of the vertebral body or the balloon reaches its highest volume. When the balloon is deflated, the space is filled with bone cement, and a stent may or may not be placed. Kyphoplasty aims to reduce pain and curvature of the spine. **Rheumatoid arthritis (2nd line) - abatacept (rapid review of TA 234) TA280** **Guidance** 1.1 Abatacept in combination with methotrexate is recommended as an option for treating rheumatoid arthritis in adults whose disease has responded inadequately to 2 conventional disease-modifying anti-rheumatic drugs (DMARDs), including methotrexate, only if: • it is used in accordance with the recommendations for other biological DMARDs in "Adalimumab, etanercept and infliximab for the treatment of rheumatoid arthritis(NICE technology appraisal guidance 130)" and • the manufacturer provides abatacept with the discount agreed in the patient access scheme. 1.2 People currently receiving abatacept whose disease does not meet the criteria in section 1.1 should be able to continue treatment until they and their clinician consider it appropriate to stop. **Gout - canakinumab (terminated appraisal) TA281** NICE is unable to recommend the use in the NHS of canakinumab for treating gouty arthritis attacks and reducing the frequency of subsequent attacks because no evidence submission was received from the manufacturer of the technology. **Idiopathic pulmonary fibrosis - pirfenidone (TA282)** **Guidance** 1.1 Pirfenidone is recommended as an option for treating idiopathic pulmonary fibrosis only if: • the person has a forced vital capacity (FVC) between 50% and 80% predicted **and** • the manufacturer provides pirfenidone with the discount agreed in the patient access scheme. 1.2 Treatment with pirfenidone that is recommended according to 1.1 should be discontinued if there is evidence of disease progression (a decline in per cent predicted FVC of 10% or more within any 12 month period). 1.3 People currently receiving pirfenidone that is not recommended according to 1.1 should have the option to continue treatment until they and their clinician consider it appropriate to stop.
Clinical Guidelines (CGs)	**None published so far this month**
Interventional Procedures Guidance (IPGs)	**Occipital nerve stimulation for intractable chronic migraine IPG 452** **Guidance** 1.1 The evidence on occipital nerve stimulation (ONS) for intractable chronic migraine shows some efficacy in the short term but there is very little evidence about long-term outcomes. With regard to safety, there is a risk of complications, needing further surgery. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research. 1.2 Clinicians wishing to undertake ONS for intractable chronic migraine should take the following actions: • Inform the clinical governance leads in their Trusts.

- Ensure that patients understand the uncertainty about the procedure's safety and efficacy, and provide them with clear written information. In addition, the use of NICE's information for the public is recommended.

Outline of the procedure
2.2.1 ONS for intractable chronic migraine is usually done in 2 stages, although a single-stage procedure is sometimes used. In the first, trial stage, using local anaesthesia and usually with fluoroscopic guidance, electrodes are passed through a subcutaneous tunnel and placed over the occipital nerve(s) around the level of C1. Correct placement of electrodes is verified by intraoperative stimulation and patient feedback before they are sutured to subcutaneous tissue. A lead is tunnelled under the skin from the electrode to an exit site in the posterior cervical region, where it is connected by an external extension lead to a hand-held neurostimulator.

2.2.2 The second stage is carried out if the trial is successful. With the patient under general anaesthesia, an implantable neurostimulator is secured in a subcutaneous pocket, usually in the infraclavicular region or the abdominal wall. A lead is tunnelled from the electrode to the implantable neurostimulator. The patient uses a remote control to stimulate the occipital nerves when needed.

Prostate Artery Embolisation for Benign Prostatic Hyperplasia IPG 453

Guidance
1.1 Current evidence on the safety and efficacy of prostate artery embolisation for benign prostatic hyperplasia is inadequate in quantity and quality. Therefore, this procedure should only be used in the context of research.

1.2 Prostate artery embolisation for benign prostatic hyperplasia should only be undertaken following consideration of the patients by a multidisciplinary team that includes a urologist and an interventional radiologist.

Outline of the procedure
2.2.1The aim of prostate artery embolisation for benign prostatic hyperplasia is to reduce the blood supply of the prostate gland, causing some of it to undergo necrosis with subsequent shrinkage.

2.2.2 The procedure is usually performed with the patient under local anaesthetic and sedation. Using a percutaneous transfemoral approach, super-selective catheterisation of small prostatic arteries is done using microcatheters. Embolisation involves the introduction of microparticles to block these small prostatic arteries. Embolisation agents include polyvinyl alcohol (PVA), gelatin sponge and other synthetic biocompatible materials.

Insertion of a subcutaneous implantable cardioverter defibrillator for prevention of sudden cardiac death IPG 454

Guidance
Current evidence on the efficacy of the insertion of a subcutaneous implantable cardioverter defibrillator (ICD) for the prevention of sudden cardiac death in the short and medium term is adequate. Evidence on its safety in the short term is adequate but there are uncertainties about long-term durability. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

Outline of the procedure
An entirely subcutaneous ICD differs from a conventional ICD in that the lead is placed subcutaneously, rather than transvenously. The lead comprises 2 sensing electrodes and a shocking coil. The ICD senses cardiac signals, but the lead is not directly attached to the heart. Unlike a conventional ICD, the subcutaneous device is not designed to provide long-term pacing.

Corneal inlay implantation for correction of Presbyopia IPG 455

Guidance
1.1 The evidence for corneal inlay implantation for correction of presbyopia is limited in quantity and quality and comes predominantly from case series; there is some evidence of efficacy in the short term. In addition, there are reports that adverse effects occur

	frequently. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research. **Outline of the procedure** 2.2.1 Corneal inlay implantation aims to improve near visual acuity and increase depth of focus. It may particularly benefit people who find it difficult to use spectacles or contact lenses, for instance, those with limited dexterity. 2.2.2 The procedure is usually performed on the non-dominant eye, under topical anaesthesia. The patient fixates their eye on a light source on a surgical microscope so that the surgeon can identify the target position on the centre of the visual axis. Laser or microkeratome techniques are used to create either a lamellar corneal flap or a pocket within the corneal stroma. The flap or pocket is separated with a spatula and a special tool is used to position the inlay within it, at the marked centre of the axis. The flap or pocket self-seals, holding the inlay in place. Patients are normally prescribed corticosteroids and antibiotic eye drops in the short term and artificial tears for as long as needed. The inlay can be removed or replaced if needed.
Public Health Guidance	**None published so far this month**
Medical Technologies Guidance	**None published so far this month**
NICE Quality Standards	**Supporting people to live well with dementia QS30** This quality standard covers the care and support of people with dementia. It applies to all social care settings and services working with and caring for people with dementia. It should be read alongside the NICE Dementia quality standard (QS1) which covers care provided by health and social care staff in direct contact with people with dementia in hospital, community, home-based, group care, residential or specialist care settings. **Health and wellbeing of looked-after children and young people QS31** This quality standard defines best practice for the health and wellbeing of looked-after children and young people. NICE quality standards describe high-priority areas for quality improvement in a defined care or service area. This quality standard covers the health and wellbeing of looked-after children and young people from birth to 18 years and care leavers (including young people planning to leave care or under leaving care provisions). It applies to all settings and services working with and caring for looked-after children and young people, and care leavers, including where they live.
NICE Pathways	These pathways are not guidance in themselves but a way of displaying online the various guidance that exists around a subject.
Commissioning Guides	**None published so far this month**
Diagnostics Guidance	**None published so far this month**
Cancer Service Guidance	**None published so far this month**
Public health briefings for local government	**None published so far this month**

Current NICE consultations with links and start and finish dates for stakeholders to make contributions

Title / link	Start date of consultation	Finish date of consultation
Acute kidney injury: guideline consultation	14/03/2013	29/04/2013
Patient group directions: draft good practice guidance consultation	01/04/2013	29/04/2013
Epidermal growth factor receptor tyrosine kinase (EGFR-TK) mutation testing in adults with locally advanced or metastatic non-small-cell lung cancer: diagnostics consultation	09/04/2013	30/04/2013
Non Hodgkin´s lymphoma (relapsed refractory) - pixantrone monotherapy: appraisal consultation	11/04/2013	01/05/2013
Asthma - diagnosis and monitoring: scope consultation	10/04/2013	08/05/2013
Autism - management of autism in children and young people: guideline consultation	28/03/2013	10/05/2013
Heavy menstrual bleeding: quality standard consultation	15/04/2013	14/05/2013
Lower urinary tract symptoms (LUTS): quality standard consultation	15/04/2013	14/05/2013
Diabetic footcare (update of CG10 and CG119): scope consultation	17/04/2013	16/05/2013
Anaemia management in chronic kidney disease (update): scope consultation	25/04/2013	23/05/2013
Smoking cessation acute, maternity and mental health services: guideline consultation	05/04/2013	05/06/2013
Overweight and obese children and young people - lifestyle weight management services: guideline consultation	19/04/2013	18/06/2013

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