

# NICE Update Bulletin November 2013 for guidance issued Wednesday 27<sup>th</sup> November 2013

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

<b>Type</b>	<b>Guidance title and reference number</b>
<b>Technology Appraisals (TAs)</b>	<p><a href="#"><u>Choroidal neovascularisation (pathological myopia) – ranibizumab TA298</u></a></p> <p><b><u>Recommendation</u></b></p> <p>Ranibizumab is recommended as an option for treating visual impairment due to choroidal neovascularisation secondary to pathological myopia when the manufacturer provides ranibizumab with the discount agreed in the patient access scheme.</p> <p><b><u>The technology</u></b></p> <p>Ranibizumab (Lucentis, Novartis) belongs to a class of drugs that blocks the action of vascular endothelial growth factor (VEGF)-A. By blocking the action of VEGF-A, ranibizumab prevents abnormal blood vessels developing, thereby limiting visual loss and improving vision.</p> <p><a href="#"><u>Leukaemia (chronic myeloid) – bosutinib TA299</u></a></p> <p><b><u>Recommendations</u></b></p> <p>1.1 Bosutinib is not recommended within its marketing authorisation for treating Philadelphia-chromosome-positive chronic myeloid leukaemia (CML).</p> <p>1.2 People currently receiving bosutinib that is not recommended for them in NICE guidance should be able to continue treatment until they and their clinician consider it appropriate to stop.</p> <p><b><u>The technology</u></b></p> <p>Bosutinib (Bosulif, Pfizer) is a second generation tyrosine kinase inhibitor that inhibits Abl-kinases including Bcr-Abl kinase. Bosutinib is administered orally. In March 2013 it received a conditional marketing authorisation for 'the treatment of adult patients with chronic phase (CP), accelerated phase (AP), and blast phase (BP) Philadelphia chromosome positive chronic myelogenous leukaemia (Ph+ CML) previously treated with 1 or more tyrosine kinase inhibitor(s) and for whom imatinib, nilotinib and dasatinib are not considered appropriate treatment options'.</p> <p><a href="#"><u>Hepatitis C (children and young people) - peginterferon alfa and ribavirin TA300</u></a></p> <p><b><u>Recommendation</u></b></p> <div style="border: 1px solid black; padding: 10px; margin: 10px 0;"> <p>This guidance updates and replaces:</p> <ul style="list-style-type: none"> <li>• section 1.7, bullet 2 only, of NICE technology appraisal guidance 75 (TA75) 'Interferon alfa (pegylated and non-pegylated) and ribavirin for the treatment of chronic hepatitis C'</li> <li>• part of section 1.6 of NICE technology appraisal guidance 106 (TA106) 'Peginterferon alfa and ribavirin for the treatment of mild chronic hepatitis C'.</li> </ul> </div> <p>Peginterferon alfa in combination with ribavirin is recommended, within its marketing authorisation, as an option for treating chronic hepatitis C in children and young people.</p> <p><b><u>The technology</u></b></p> <p>Peginterferon alfa-2a is administered subcutaneously once weekly. The dose depends on body surface area, and it should not be used in children with a body surface area of less than 0.71 m<sup>2</sup>.</p>

	<p><a href="#"><u>Diabetic macular oedema - fluocinolone acetonide intravitreal implant (rapid review of TA271) TA301</u></a></p> <p><b><u>Recommendation</u></b></p> <div style="border: 1px solid black; padding: 5px;"> <p>This guidance replaces NICE technology appraisal guidance 271 issued in January 2013.</p> <p>The review of fluocinolone acetonide intravitreal implant for treatment of chronic diabetic macular oedema after an inadequate response to prior therapy has resulted in a change in the guidance.</p> </div> <p>1.1 Fluocinolone acetonide intravitreal implant is recommended as an option for treating chronic diabetic macular oedema that is insufficiently responsive to available therapies only if:</p> <ul style="list-style-type: none"> <li>• the implant is to be used in an eye with an intraocular (pseudophakic) lens and</li> <li>• the manufacturer provides fluocinolone acetonide intravitreal implant with the discount agreed in the patient access scheme.</li> </ul> <p><b><u>The technology</u></b></p> <p>Fluocinolone acetonide intravitreal implant (Iluvien, Alimera Sciences) contains a corticosteroid that has anti-inflammatory and anti-vascular endothelial growth factor (anti-VEGF) properties. It is administered by intravitreal injection. The summary of product characteristics states that administration in both eyes concurrently is not recommended.</p> <p><a href="#"><u>Juvenile idiopathic arthritis (systemic) - canakinumab (terminated appraisal) TA302</u></a></p> <p>NICE is unable to make a recommendation about the use in the NHS of canakinumab for systemic juvenile idiopathic arthritis because no evidence submission was received from the manufacturer of the technology.</p>
<p><b>Clinical Guidelines (CGs)</b></p>	<p><a href="#"><u>Myocardial infarction: secondary prevention CG172</u></a></p> <p>This clinical guideline (published November 2013) updates and replaces NICE clinical guideline 48 (published May 2007). It offers evidence-based advice on secondary prevention for patients in primary and secondary care after an MI. New and updated recommendations on cardiac rehabilitation, lifestyle changes, drug therapy and communication of diagnosis and advice were included in 2013.</p> <p><b><u>Background information</u></b></p> <p>Myocardial infarction (MI) is one of the most dramatic presentations of coronary artery disease. It is usually caused by blockage of a coronary artery producing tissue death and consequently the typical features of a heart attack: severe chest pain, changes on the electrocardiogram (ECG), and raised concentrations of proteins released from the dying heart tissue into the blood.</p> <p><b><u>Key priorities for implementation</u></b></p> <p><b>Cardiac rehabilitation after an acute myocardial infarction (MI)</b></p> <ul style="list-style-type: none"> <li>• Offer cardiac rehabilitation programmes designed to motivate people to attend and complete the programme. Explain the benefits of attending. <b>[new 2013]</b></li> <li>• Begin cardiac rehabilitation as soon as possible after admission and before discharge from hospital. Invite the person to a cardiac rehabilitation session which should start within 10 days of their discharge from hospital. <b>[new 2013]</b></li> </ul> <p><b>Lifestyle changes after an MI</b></p> <ul style="list-style-type: none"> <li>• Advise people to eat a Mediterranean-style diet (more bread, fruit, vegetables and fish; less meat; and replace butter and cheese with products based on plant oils). <b>[2007]</b></li> <li>• Advise people to be physically active for 20–30 minutes a day to the point of slight breathlessness. Advise people who are not active to this level to increase their activity in a gradual, step-by-step way, aiming to increase their exercise capacity. They should start at a level that is comfortable, and increase the</li> </ul>

duration and intensity of activity as they gain fitness. [2007]

- Advise all people who smoke to stop and offer assistance from a smoking cessation service in line with [Brief interventions and referral for smoking cessation](#) (NICE public health guidance 1). [2007]

#### **Drug therapy**

- Offer all people who have had an acute MI treatment with the following drugs:
  - ACE (angiotensin-converting enzyme) inhibitor
  - dual antiplatelet therapy (aspirin plus a second antiplatelet agent)
  - beta-blocker
  - statin. [2007, amended 2013]
- Offer an assessment of left ventricular function to all people who have had an MI. [2013]
- Titrate the ACE inhibitor dose upwards at short intervals (for example, every 12–24 hours) before the person leaves hospital until the maximum tolerated or target dose is reached. If it is not possible to complete the titration during this time, it should be completed within 4–6 weeks of hospital discharge. [new 2013]
- Communicate plans for titrating beta-blockers up to the maximum tolerated or target dose – for example, in the discharge summary. [new 2013]

#### **Communication of diagnosis and advice**

- After an acute MI, ensure that the following are part of every discharge summary:
  - confirmation of the diagnosis of acute MI
  - results of investigations
  - incomplete drug titrations
  - future management plans
  - advice on secondary prevention. [2007, amended 2013]

#### **[Neuropathic pain - pharmacological management CG173](#)**

This clinical guideline updates and replaces Neuropathic pain – pharmacological management (NICE clinical guideline 96).

It offers evidence-based advice on the pharmacological management of neuropathic pain in non-specialist settings.

#### **Background information**

Neuropathic pain is very challenging to manage because of the heterogeneity of its aetiologies, symptoms and underlying mechanisms. There is often uncertainty regarding the nature and exact location of a lesion or health condition associated with neuropathic pain, particularly in non-specialist settings. Examples of common conditions that have peripheral neuropathic pain as a symptom are painful diabetic neuropathy, post-herpetic neuralgia, trigeminal neuralgia, radicular pain, post-surgical chronic neuropathic pain, and neuropathic cancer pain.

#### **The recommendations cover**

- Key principles of care
- Treatment for all neuropathic pain (except trigeminal neuralgia)
- Trigeminal neuralgia
- Treatments that should not be used

#### **Public Health Guidance**

#### **[Smoking cessation - acute, maternity and mental health services PH48](#)**

Stopping smoking at any time has considerable health benefits and for people using secondary care services, there are additional advantages including shorter hospital stays and fewer complications. Secondary care providers have a duty of care to protect the

	<p>health of, and promote healthy behaviour among, people who use, or work in, their services.</p> <p>This guidance aims to support smoking cessation, temporary abstinence from smoking and smoke free policies in all secondary care settings. It recommends:</p> <ul style="list-style-type: none"> <li>• Strong leadership and management to ensure premises remain smoke free.</li> <li>• All hospitals have an on-site stop smoking service.</li> <li>• Identifying people who smoke, offering advice and support to stop.</li> <li>• Providing intensive behavioural support and pharmacotherapy as an integral component of secondary care.</li> <li>• Integrating stop smoking support in secondary care with support provided by community-based services.</li> <li>• Ensuring staff are trained to support people to stop smoking while using secondary care services.</li> <li>• Supporting staff to stop smoking or to abstain while at work.</li> <li>• Ensuring there are no designated smoking areas or staff-facilitated smoking breaks for anyone using secondary care services.</li> </ul>
<p><b>Medical Technologies Guidance</b></p>	<p><b>None published so far this month</b></p>
<p><b>NICE Quality Standards</b></p>	<p><a href="#"><u>Surgical site infection (QS49)</u></a></p> <p>This quality standard covers the prevention and treatment of surgical site infection for adults, children and young people undergoing surgical incisions through the skin, in all healthcare settings.</p>
<p><b>Interventional Procedures Guidance (IPGs)</b></p>	<p><a href="#"><u>Negative pressure wound therapy for the open abdomen IPG467</u></a></p> <p><b>Recommendations</b></p> <div style="border: 1px solid black; padding: 5px; margin: 5px 0;"> <p>This document replaces previous guidance on negative pressure wound therapy for the open abdomen (interventional procedure guidance 322).</p> </div> <p>1.1 Current evidence on the safety and efficacy of negative pressure wound therapy (NPWT) for the open abdomen <b>is adequate to support the use of this procedure provided that normal arrangements are in place for consent, audit and clinical governance.</b></p> <p>1.2 NPWT for the open abdomen should only be carried out by healthcare professionals with specific training in the procedure: it should be done in accordance with the manufacturer's instructions when commercial products are used.</p> <p>1.3 NICE encourages further research into the role of NPWT for the open abdomen. Patient selection should be documented and research should report on efficacy outcomes such as impact on wound care and healing rates, and duration of hospital stay.</p> <p><b>The technology</b></p> <p>The aims of negative pressure wound therapy (NPWT) for the open abdomen include removing infected material and helping nursing care by reducing escape of fluid; its use may also influence the possibility of delayed primary closure.</p> <p>The systems and techniques used vary widely, but the underlying principle is that the abdominal contents are covered with a foam sponge or other porous dressing with a membrane between the sponge/dressing and the abdominal contents. The entire wound and surrounding skin are covered with an adhesive transparent membrane, which is perforated by a drainage tube attached to the suction system.</p> <p><a href="#"><u>Phrenic nerve transfer in brachial plexus injury IPG468</u></a></p> <p><b>Recommendations</b></p> <p>1.1 The limited quantity of evidence on the efficacy of phrenic nerve transfer in brachial plexus injury shows useful recovery of arm function in some patients, but there is very</p>

little information about long-term functional and quality-of-life outcomes, and evidence on safety shows some impairment of respiratory function. However, patients with brachial plexus injuries are often very disabled and treatment options may be limited. **Therefore, this procedure may be used with normal arrangements for clinical governance, consent and audit.**

1.2 During the consent process patients should be informed, in particular, that the procedure may not restore useful function in the arm and that it may compromise respiratory function.

1.3 Patient selection and treatment should only be carried out in units that specialise in the management of complex brachial plexus injuries and offer a full range of treatment options.

#### **The procedure**

The procedure is performed with the patient under general anaesthesia. The aim of the procedure is to re-innervate the target muscles and improve arm function.

#### **[Microwave ablation for treating primary lung cancer and metastases in the lung IPG469](#)**

#### **Recommendations**

1.1 There is evidence from imaging studies for the efficacy of microwave ablation for treating primary lung cancer and metastases in the lung, but evidence that the procedure improves clinical outcomes and quality of life is limited in quantity and quality. There is a risk of complications, including pneumothorax, which may have serious implications for patients with already compromised lung function. **Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit.**

1.2 Clinicians wishing to undertake microwave ablation for treating primary lung cancer and metastases in the lung should take the following actions.

- Inform clinical governance leads in their NHS 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.
- Audit and review clinical outcomes of all patients having the procedure.

1.3 Patient selection for microwave ablation for treating primary lung cancer and metastases in the lung should be carried out by a multidisciplinary team, which should normally include a thoracic surgeon, an oncologist and a radiologist.

1.4 This procedure should only be carried out by radiologists who regularly undertake image-guided interventional procedures.

1.5 NICE encourages further research into this procedure. Research studies should report details of patient selection and adverse events. Outcomes should include local tumour control, survival and quality of life.

#### **The procedure**

Microwave ablation aims to destroy tumour cells and create localised areas of tissue necrosis with minimal damage to surrounding normal tissues. The procedure can be performed using local anaesthesia and sedation or with the patient under general anaesthesia, usually by a percutaneous approach. A probe is advanced into each targeted lesion under imaging guidance and the tumour ablated by delivering high-frequency microwave energy

#### **[Ultra-radical \(extensive\) surgery for advanced ovarian cancer IPG470](#)**

#### **Recommendations**

1.1 Current evidence on the safety and efficacy of ultra-radical (extensive) surgery for advanced ovarian cancer is inadequate. Therefore this procedure **should not be done except with special arrangements for clinical governance, consent and audit or research** (with the objective of publishing outcomes for all patients having this procedure – see recommendation 1.5).

1.2 Clinicians wishing to undertake ultra-radical surgery for advanced ovarian cancer

should take the following actions:

- Inform the clinical governance leads in their NHS trusts.
- During the consent process, inform patients clearly about alternative treatment options, and about their benefits and risks compared with ultra-radical surgery for advanced ovarian cancer. Clinicians should provide patients with clear written information. In addition, the use of NICE's information for the public is recommended.
- Clinicians should submit data on all patients having this procedure to the national register when it becomes available and review clinical outcomes locally.

1.3 Selection of patients should be done by a specialist gynaecological cancer multidisciplinary team.

1.4 Ultra-radical surgery for advanced ovarian cancer should be done by collaboration between surgeons with appropriate expertise (such as specialists in gastrointestinal and hepatobiliary surgery) and/or by specialists in gynaecological cancer surgery with specific training in such extensive surgery. The procedure should only be done in specialised units with a regular practice in this type of surgery.

1.5 NICE encourages further research on this procedure, either in the form of research trials or in audits intended for publication (ideally by collaboration between units). Clinicians should ensure that details of patient selection and the precise extent of surgery are fully documented. Reported outcomes should include all complications, survival, and quality of life. Trials comparing complication rates, survival and quality of life against those of standard surgery and chemotherapy would be especially useful.

#### **The procedure**

The aim of ultra-radical surgery for advanced ovarian cancer is to remove all visible disease, with a view to improving survival compared with standard (radical) surgery. Extensive or ultra-radical surgery for advanced ovarian cancer is a development and extension of standard (radical) surgery. The precise differences between these procedures are not well defined, but some typical features of ultra-radical surgery include:

- stripping of the diaphragm
- extensive stripping of the peritoneum
- multiple resections of the bowel (excluding localised colonic resection)
- liver resection
- partial gastrectomy
- cholecystectomy
- splenectomy

#### **[Implantation of a duodenal-jejunal bypass sleeve for managing obesity IPG471](#)**

#### **Recommendations**

1.1 Current evidence on the safety and efficacy of implantation of a duodenal–jejunal bypass sleeve (DJBS) for managing obesity is limited in quality and quantity. **Therefore, this procedure should only be used in the context of research.**

1.2 Clinicians should review local clinical outcomes and enter details about all patients undergoing implantation of a DJBS for managing obesity onto the National Bariatric Surgery Register when the facility for this is available.

1.3 Well-controlled studies are needed to support the current limited evidence on weight loss in the short term. They should document patient selection, all complications (while the device is in place and after its removal) and technical problems associated with placing and removing the device.

#### **The procedure**

Endoscopic implantation of a duodenal–jejunal bypass sleeve (DJBS) is a minimally invasive procedure that has been used to promote weight loss in patients with obesity and with a view to improving comorbidities, including diabetes. The sleeve is positioned endoscopically (via the mouth). Using a delivery catheter, a capsule containing a single-use impermeable DJBS is positioned in the duodenal bulb just distal to the pylorus and is

	secured there. The sleeve is advanced distally into the jejunum. It extends approximately 60 cm down the small intestine and forms a barrier between food and the intestinal wall, delaying the mixing of digestive enzymes with the food.
<b>NICE Pathways</b>	These pathways are not guidance in themselves but a way of displaying online the various guidance that exists around a subject.
<b>Commissioning Guides</b>	None published so far this month
<b>Diagnostics Guidance</b>	None published so far this month
<b>Public health briefings for local government</b>	None published so far this month

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

<b>Title / link</b>	<b>Start date of consultation</b>	<b>Finish date of consultation</b>
<a href="#">Measuring fractional exhaled nitric oxide concentration in asthma - NIOX MINO, NIOX VERO and NObreath: diagnostics consultation</a>	07/11/2013	28/11/2013
<a href="#">Indicators process guide: Quality and outcomes framework, Clinical commissioning groups outcomes indicator set</a>	28/08/2013	30/11/2013
<a href="#">Multiple myeloma - bortezomib (induction therapy): appraisal consultation</a>	12/11/2013	03/12/2013
<a href="#">Non-Hodgkin's Lymphoma: scope consultation</a>	08/11/2013	05/12/2013
<a href="#">Obesity (update): scope consultation</a>	27/11/2013	11/12/2013
<a href="#">The geko device for venous thromboembolism prophylaxis: guidance consultation</a>	13/11/2013	11/12/2013
<a href="#">Overweight and obese adults - lifestyle weight management: guidance consultation</a>	16/10/2013	11/12/2013
<a href="#">Trauma services: scope consultation</a>	13/09/2013	11/12/2013
<a href="#">The Debrisoft monofilament debridement pad for use in acute or chronic wounds: guidance consultation</a>	14/11/2013	12/12/2013
<a href="#">Motor Neurone Disease: scope consultation</a>	15/11/2013	13/12/2013
<a href="#">Managing medicines in care homes: draft good practice guidance consultation</a>	18/11/2013	16/12/2013
<a href="#">Conduct disorders in children and young people: quality standard consultation</a>	19/11/2013	17/12/2013
<a href="#">Infection control: quality standard consultation</a>	19/11/2013	17/12/2013
<a href="#">Sickle cell crisis: quality standard consultation</a>	19/11/2013	17/12/2013
<a href="#">Lung cancer (non small cell, non squamous) - pemetrexed (maintenance following pemetrexed &amp; cisplatin): ACD3</a>	27/11/2013	18/12/2013
<a href="#">Hepatic encephalopathy - rifaximin (maintenance): ACD 2</a>	27/11/2013	18/12/2013
<a href="#">Extracorporeal membrane oxygenation (ECMO) for acute heart failure in adults: interventional procedures consultation</a>	21/11/2013	19/12/2013
<a href="#">Insertion of a magnetic-bead band for faecal incontinence: interventional procedures consultation</a>	21/11/2013	19/12/2013
<a href="#">Arthroscopic radiofrequency chondroplasty for discrete chondral defects of the knee: interventional procedures consultation</a>	21/11/2013	19/12/2013
<a href="#">Transoral carbon dioxide laser surgery for primary treatment of oropharyngeal malignancy: interventional procedures consultation</a>	21/11/2013	19/12/2013
<a href="#">NICE future public health quality standards and guidance - proposed topic list</a>	27/09/2013	20/12/2013
<a href="#">Pressure Ulcers: guideline consultation</a>	18/11/2013	06/01/2014



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