

**NICE Update Bulletin August 2013 for guidance issued  
Wednesday 28<sup>th</sup> August 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>)

<b>Type</b>	<b>Guidance title and reference number</b>
<b>Technology Appraisals (TAs)</b>	<p><a href="#"><u>Breast cancer (HER2 negative, oestrogen receptor positive, locally advanced or metastatic) - everolimus (with an aromatase inhibitor) TA295</u></a></p> <p><b>Guidance recommendation</b></p> <p>1.1 Everolimus, in combination with exemestane, is <u>not recommended</u> within its marketing authorisation for treating postmenopausal women with advanced human epidermal growth factor receptor 2 (HER2) negative hormone-receptor-positive breast cancer that has recurred or progressed following treatment with a non-steroidal aromatase inhibitor.</p> <p>1.2 Women currently receiving everolimus for advanced breast cancer should be able to continue treatment until they and their clinician consider it appropriate to stop.</p>
<b>Clinical Guidelines (CGs)</b>	<p><a href="#"><u>Acute kidney injury: Prevention, detection and management of acute kidney injury up to the point of renal replacement therapy CG169</u></a></p> <p><b>Background information</b></p> <p>Acute kidney injury, previously known as acute renal failure, encompasses a wide spectrum of injury to the kidneys, not just kidney failure. The definition of acute kidney injury has changed in recent years, and detection is now mostly based on monitoring creatinine levels, with or without urine output. Acute kidney injury is increasingly being seen in primary care in people without any acute illness, and awareness of the condition needs to be raised among primary care health professionals.</p> <p>Acute kidney injury is seen in 13–18% of all people admitted to hospital, with older adults being particularly affected. The costs to the NHS of acute kidney injury (excluding costs in the community) are estimated to be between £434 million and £620 million per year, which is more than the costs associated with breast cancer, or lung and skin cancer combined. There have been concerns that suboptimal care may contribute to the development of acute kidney injury.</p> <p><b>The recommendations cover</b></p> <p>1.1 Assessing risk of acute kidney injury 1.2 Preventing acute kidney injury 1.3 Detecting acute kidney injury 1.4 Identifying the cause(s) of acute kidney injury 1.5 Managing acute kidney injury 1.6 Information and support for patients and carers</p> <p><b>The key priorities for implementation are</b></p> <ul style="list-style-type: none"> <li>Investigate for acute kidney injury, by measuring serum creatinine and</li> </ul>

comparing with baseline, in children and adults with acute illness if certain factors are likely or present: e.g. chronic kidney disease, heart failure, diabetes etc.

- **Before offering iodinated contrast agents to adults for emergency or non-emergency imaging, assess their risk of acute kidney injury. Be aware that increased risk is associated with certain factors.**
- **Assessing risk factors in adults having surgery**
- **Ongoing assessment of the condition of patients in hospital**
- **Detecting acute kidney injury**
- **Identifying the cause(s) of acute kidney injury**
- **Ultrasound** - When adults, children and young people have no identified cause of their acute kidney injury or are at risk of urinary tract obstruction, offer urgent ultrasound of the urinary tract (to be performed within 24 hours of assessment).
- **Referring to nephrology**- Discuss the management of acute kidney injury with a nephrologist or paediatric nephrologist as soon as possible and within 24 hours of detection when certain factors are present:
- **Information and support for patients and carers**

#### **[Autism: The management and support of children and young people on the autism spectrum CG170](#)**

The term autism describes qualitative differences and impairments in reciprocal social interaction and social communication, combined with restricted interests and rigid and repetitive behaviours, often with a lifelong impact.

In addition to these features, children and young people with autism frequently experience a range of cognitive, learning, language, medical, emotional and behavioural problems, including: a need for routine; difficulty in understanding other people, including their intentions, feelings and perspectives; sleeping and eating disturbances; and mental health problems such as anxiety, depression, problems with attention, self-injurious behaviour and other challenging, sometimes aggressive behaviour.

#### **The recommendations cover**

- 1.1 General principles of care
- 1.2 Families and carers
- 1.3 Specific interventions for the core features of autism
- 1.4 Interventions for behaviour that challenges
- 1.5 Interventions for life skills
- 1.6 Interventions for autism that should not be used
- 1.7 Interventions for coexisting problems
- 1.8 Transition to adult services

#### **The key priorities for implementation are**

- **Access to health and social care services**
- **Knowledge and competence of health and social care professionals**
- **Making adjustments to the social and physical environment and processes of care**
- **Psychosocial interventions**
- **Anticipating and preventing behaviour that challenges**
- **Psychosocial interventions for behaviour that challenges**
- **Pharmacological interventions for behaviour that challenges**

	<ul style="list-style-type: none"> <li>• Families and carers</li> <li>• Transition to adult services</li> </ul>
<b>Public Health Guidance</b>	None published so far this month
<b>Medical Technologies Guidance</b>	None published so far this month
<b>NICE Quality Standards</b>	<p><a href="#">Acute upper gastrointestinal bleeding QS38 (issued July 2013)</a></p> <p>This quality standard covers the management of acute upper gastrointestinal bleeding in adults and young people (16 years and older).</p> <p><a href="#">Attention deficit hyperactivity disorder QS39 (issued July 2013)</a></p> <p>This quality standard covers the diagnosis and management of attention deficit hyperactivity disorder (ADHD) in children aged 3 years and older, young people and adults</p> <p><a href="#">Psoriasis QS40</a></p> <p>This quality standard covers the assessment and management of psoriasis in children, young people and adults.</p> <p><a href="#">Familial hypercholesterolaemia QS41</a></p> <p>This quality standard covers the identification and management of heterozygous familial hypercholesterolaemia (FH) in adults, young people and children. Homozygous FH has been excluded from this quality standard because it has a low incidence and people with homozygous FH need specialist care.</p> <p><a href="#">Headaches in young people and adults QS42</a></p> <p>This quality standard covers the diagnosis and management of the most common primary headache disorders (tension-type headache, migraine and cluster headache) and medication overuse headache in adults and young people aged 12 years and older.</p> <p><a href="#">Smoking cessation - supporting people to stop smoking QS43</a></p> <p>This quality standard covers smoking cessation, which includes support for people to stop smoking and for people accessing smoking cessation services.</p>
<b>Interventional Procedures Guidance (IPGs)</b>	<p><a href="#">Endoscopic radiofrequency ablation for gastro-oesophageal reflux disease IPG461</a></p> <p><b>Recommendations</b></p> <p>1.1 The evidence on the safety of endoscopic radiofrequency ablation for gastro-oesophageal reflux disease (GORD) is adequate in the short and medium term but there is uncertainty about longer term outcomes. With regard to efficacy, there is evidence of symptomatic relief but objective evidence on reduction of reflux is inconclusive. <b>Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.</b></p> <p>1.2 Clinicians wishing to undertake endoscopic radiofrequency ablation for GORD should take the following actions.</p> <p>Inform the 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 endoscopic radiofrequency ablation for GORD.</p> <p><b>Description of the technology</b></p> <p>The procedure is usually performed with the patient under sedation. A guidewire with a flexible tip is passed through the endoscope and left in the stomach. A specially designed radiofrequency balloon catheter, consisting of an inflatable balloon-basket with 4 electrode needle sheaths, is inserted through the mouth over the guidewire and advanced to the gastro-oesophageal junction. The balloon is inflated to the diameter of the oesophagus and the electrodes are deployed to penetrate through the mucosa and</p>

	<p>deliver radiofrequency energy to the musculature of the lower oesophageal sphincter and the gastric cardia. Several cycles of approximately 1 minute of radiofrequency energy are delivered. These cause changes in the tissues of the lower oesophagus.</p> <p><a href="#">Translaryngeal tracheostomy IPG462</a></p> <p><b>Recommendations</b></p> <p>1.1 The evidence on the efficacy and safety of translaryngeal tracheostomy is adequate for use with normal arrangements for clinical governance, consent and audit.</p> <p>1.2 Clinicians wishing to undertake translaryngeal tracheostomy should receive specific training and should be experienced in using the procedure because carrying it out safely requires different skills to other methods of percutaneous tracheostomy insertion.</p> <p><b>Description of the technology</b></p> <p>Translaryngeal tracheostomy is a method for inserting a tracheostomy tube using direct endoscopic visualisation. It is usually carried out with the patient under general anaesthesia with muscle relaxation. The patient lies supine with the head extended, and the endotracheal tube is partially withdrawn to allow an endoscope to be passed into the trachea. A small introducer needle is inserted percutaneously between the second and third tracheal rings and visualised endoscopically as it enters the trachea. A metal guide wire is then passed through this needle into the trachea and pulled upwards and out through the mouth.</p> <p><a href="#">Insertion and use of implantable pulmonary artery pressure monitors in chronic heart failure IPG463</a></p> <p><b>Recommendations</b></p> <p>1.1 Current evidence on the safety and efficacy of the insertion and use of implantable pulmonary artery pressure monitors in chronic heart failure is limited in both quality and quantity. <b>Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research.</b></p> <p>1.2 Clinicians wishing to insert and use implantable pulmonary artery pressure monitors in chronic heart failure should take the following actions:</p> <p>Inform the clinical governance leads in their Trusts. Ensure that patients and their carers understand the uncertainty about the procedure's efficacy and safety 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 pulmonary artery pressure monitors inserted</p> <p><b>Description of the technology</b></p> <p>Insertion of implantable pulmonary artery pressure monitors is usually done under local anaesthesia. Using a percutaneous approach, commonly via the femoral vein, a passive radiofrequency sensor without batteries or leads is implanted into a distal branch of the pulmonary artery, with radiological guidance. The sensor is anchored within the artery. Data are downloaded in a secure format via an antenna linked to a computer in the patient's home. The antenna can be housed in a pillow on which the patient lies for this purpose. Data are then forwarded daily by the patient to a remote secure database from where the information can be accessed by the heart failure team.</p>
<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>	<b>None published so far this month</b>
<b>Diagnostics Guidance</b>	<p><a href="#">Intraoperative tests (RD 100i OSNA system and Metasin test) for detecting sentinel lymph node metastases in breast cancer DG8</a></p> <p><b>Recommendations</b></p> <p>1.1 Whole lymph node analysis using the RD-100i OSNA system <u>is recommended</u> as an option for detecting sentinel lymph node metastases during breast surgery in people with early invasive breast cancer who have a sentinel lymph node biopsy and in whom axillary lymph node dissection will be considered.</p>

1.2 The Metasin test **is not recommended** for detecting sentinel lymph node metastases in people with early invasive breast cancer in routine clinical NHS practice. The Metasin test shows promise and the development of robust evidence is recommended to demonstrate its utility in clinical practice.

**Description of the technology**

The RD-100i OSNA system (Sysmex UK) and the Metasin test (TIB MOLBIOL) are intraoperative molecular tests that are designed to indicate if cancer has spread to the lymph nodes in people diagnosed with invasive breast cancer. The RD-100i OSNA system analyses and amplifies mRNA from solubilised biopsy samples of sentinel lymph node tissue.

The time to results depends on the number of lymph nodes analysed, but the test takes approximately 30 to 45 minutes. This allows clinical decisions to be taken based on the test results during surgery.

**[Epidermal growth factor receptor tyrosine kinase \(EGFR-TK\) mutation testing in adults with locally advanced or metastatic non-small-cell lung cancer DG9](#)**

**1 Recommendations**

1.1 The tests and test strategies listed below are recommended as options for detecting epidermal growth factor receptor tyrosine kinase (EGFR-TK) mutations in the tumours of adults with previously untreated, locally advanced or metastatic non-small-cell lung cancer (NSCLC), when used in accredited laboratories participating in an external quality assurance scheme. The laboratory-developed tests should be designed to detect the mutations that can be detected by one of the CE-marked tests as a minimum.

- theascreen EGFR RGQ PCR Kit (CE-marked, Qiagen)
- cobas EGFR Mutation Test (CE-marked, Roche Molecular Systems)
- Sanger sequencing of samples with more than 30% tumour cells and theascreen EGFR RGQ PCR Kit for samples with lower tumour cell contents
- Sanger sequencing of samples with more than 30% tumour cells and cobas EGFR Mutation Test for samples with lower tumour cell contents
- Sanger sequencing followed by fragment length analysis and polymerase chain reaction (PCR) of negative samples.

1.2 There was insufficient evidence for the Committee to make recommendations on the following methods:

- high-resolution melt analysis
- pyrosequencing combined with fragment length analysis
- single-strand conformation polymorphism analysis
- next-generation sequencing
- theascreen EGFR Pyro Kit (CE-marked, Qiagen).

**Description of the technology**

Ten epidermal growth factor receptor tyrosine kinase (EGFR-TK) mutation methods for identifying adults with previously untreated, locally advanced or metastatic non-small-cell lung cancer (NSCLC) who may benefit from first-line treatment with EGFR-TK inhibitors were evaluated.

Three are CE-marked tests; 5 are laboratory-developed tests; and 2 are test strategies combining a CE-marked test and a laboratory-developed test.

**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 contribution**

<b>Title / link</b>	<b>Start date of consultation</b>	<b>Finish date of consultation</b>
<a href="#">Peripheral arterial disease: quality standard consultation</a>	06/08/2013	04/09/2013
<a href="#">PH32 Skin cancer prevention: information, resources and environmental changes: review proposal consultation</a>	23/08/2013	06/09/2013
<a href="#">Prostate cancer (update): guideline consultation</a>	16/07/2013	10/09/2013
<a href="#">Lung cancer (non small cell, non squamous) - pemetrexed (maintenance following pemetrexed &amp; cisplatin): appraisal consultation 2</a>	20/08/2013	11/09/2013
<a href="#">Insertion of prostatic urethral lift implants to treat lower urinary tract symptoms secondary to benign prostatic hyperplasia: interventional procedure consultation</a>	23/08/2013	20/09/2013
<a href="#">Electrochemotherapy for primary basal cell carcinoma and primary squamous cell carcinoma: interventional procedure consultation</a>	23/08/2013	20/09/2013
<a href="#">Subcutaneous implantation of a battery powered catheter drainage system for managing refractory and recurrent ascites: interventional procedure consultation</a>	23/08/2013	20/09/2013
<a href="#">Hysteroscopic morcellation of uterine fibroids: interventional procedure consultation</a>	23/08/2013	20/09/2013
<a href="#">Arthroscopic trochleoplasty for patellar instability: interventional procedure consultation</a>	23/08/2013	20/09/2013
<a href="#">Faecal incontinence: quality standard consultation</a>	23/08/2013	20/09/2013
<a href="#">Homecare: scope consultation</a>	27/08/2013	24/09/2013
<a href="#">Anxiety disorders: quality standard consultation</a>	27/08/2013	24/09/2013
<a href="#">Domestic violence and abuse - identification and prevention: guidance consultation</a>	02/08/2013	27/09/2013
<a href="#">Psychosis and schizophrenia in adults: guideline consultation</a>	20/08/2013	01/10/2013
<a href="#">Head injury: guideline consultation</a>	16/08/2013	04/10/2013
<a href="#">Osteoarthritis (update): guideline consultation</a>	15/08/2013	11/10/2013
<a href="#">Indicators process guide: Quality and outcomes framework, Clinical commissioning groups outcomes indicator set</a>	28/08/2013	30/11/2013

**Produced by**

**Andrew Williams (Clinical Effectiveness Technical Support  
Officer) NEW Devon CCG Clinical Effectiveness and Medicines  
Optimisation Team**

**For distribution Northern, Eastern and Western Devon CCG &  
South Devon and Torbay CCG**

**County Hall, Topsham Road, Exeter, EX2 4QL**

**Tel: 01392 26 7771**

**Email: [andrew.williams6@nhs.net](mailto:andrew.williams6@nhs.net)**