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

NICE Update Bulletin September 2013 for guidance issued Wednesday 25th September 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)	**Lung cancer (non-small-cell, anaplastic lymphoma kinase fusion gene, previously treated) – crizotinib TA296** **1 Guidance** 1.1 Crizotinib is not recommended within its marketing authorisation, that is, for treating adults with previously treated anaplastic-lymphoma-kinase-positive advanced non-small-cell lung cancer. 1.2 People currently receiving crizotinib that is not recommended according to 1.1 should be able to continue treatment until they and their clinician consider it appropriate to stop.
Clinical Guidelines (CGs)	**Urinary incontinence: the management of urinary incontinence in women CG171** **Background information** Urinary incontinence (UI) is a common symptom that can affect women of all ages, with a wide range of severity and nature. While rarely life-threatening, incontinence may seriously influence the physical, psychological and social wellbeing of affected individuals. The impact on the families and carers of women with UI may be profound, and the resource implications for the health service considerable. UI is defined by the International Continence Society as 'the complaint of any involuntary leakage of urine'. UI may occur as a result of a number of abnormalities of function of the lower urinary tract or as a result of other illnesses, which tend to cause leakage in different situations. • Stress UI is involuntary urine leakage on effort or exertion or on sneezing or coughing. • Urgency UI is involuntary urine leakage accompanied or immediately preceded by urgency (a sudden compelling desire to urinate that is difficult to delay). • Mixed UI is involuntary urine leakage associated with both urgency and exertion, effort, sneezing or coughing. • Overactive bladder (OAB) is defined as urgency that occurs with or without urgency UI and usually with frequency and nocturia. Since the publication of the 2006 guideline, new methods of managing urinary incontinence have become available on the NHS. Botulinum toxin A and sacral nerve stimulation are also now more commonly used for treating OAB symptoms. Synthetic tape procedures have become increasingly popular for the treatment of stress urinary incontinence, and there have been reported improvements in the effectiveness and advances in the types of procedure offered since 2006. Updated guidance is needed to reflect these changes. New recommendations for 2013 sit alongside the original recommendations from the 2006 guideline. Urinary incontinence in neurological disease is outside the scope of this

	guideline but is covered in Urinary incontinence in neurological disease (NICE clinical guideline 148). **The recommendations cover** 1.1 Assessment and investigation 1.2 Lifestyle interventions 1.3 Physical therapies 1.4 Behavioural therapies 1.5 Neurostimulation 1.6 Alternative conservative management options 1.7 Pharmacological treatment 1.8 The multidisciplinary team (MDT) 1.9 Invasive procedures for OAB 1.10 Surgical approaches for SUI 1.11 Maintaining and measuring expertise and standards for practice **The key priorities for implementation are** • **History-taking and physical examination** • **Assessment of pelvic floor muscles** • **Bladder diaries** • **Percutaneous posterior tibial nerve stimulation** • **Absorbent products, urinals and toileting aids** • **General principles when using OAB drugs** • **Choosing OAB drugs** • **The multidisciplinary team (MDT)** • **Surgical approaches for SUI**
Public Health Guidance	**None published so far this month**
Medical Technologies Guidance	**None published so far this month**
NICE Quality Standards	**Atopic eczema in children QS44** This quality standard covers the management of atopic eczema in children from birth up to the age of 12 years. **Lower urinary tract symptoms QS45** This quality standard covers the diagnosis and management of lower urinary tract symptoms (LUTS) in men (18 years and older). **Multiple pregnancy QS46** This quality standard covers the management of twin and triplet pregnancies in the antenatal period.
Interventional Procedures Guidance (IPGs)	**Endoscopic bipolar radiofrequency ablation for the treatment of malignant biliary obstructions from cholangiocarcinoma or pancreatic adenocarcinoma IPG464** **1 Recommendations** 1.1 Current evidence on the safety and efficacy of endoscopic bipolar radiofrequency ablation for treating biliary obstructions caused by cholangiocarcinoma or pancreatic adenocarcinoma is inadequate in quantity and quality. Therefore, this procedure should only be used in the context of research.

1.2 Further research, in the form of comparative or observational studies, should document details of patient selection and should report all adverse events. Outcomes should include survival, quality of life, biliary patency and the need for further procedures.

1.3 Clinicians should consider entering patients with pancreatic adenocarcinoma into the EndoHPB 1001 trial.

Description of the technology
Unresectable malignant bile or pancreatic duct obstructions caused by cholangiocarcinoma or pancreatic cancer block the drainage of bile ducts that carry digestive juices from the gall bladder and pancreas to the small intestine. This causes bloating, abdominal pain and nausea. These patients are often managed by placing stents via an endoscope which help to keep the bile duct open and drain properly. However, many of these stents will eventually become blocked and need replacing which may be difficult. Endoscopic radiofrequency destruction which uses heat energy is a new method to clear the duct obstructions prior to stent insertion and for clearance of obstructed stents.

Insertion of endobronchial valves for lung volume reduction in emphysema IPG465

1 Recommendations

This guidance replaces previous guidance on bronchoscopic lung volume reduction with airway valves for advanced emphysema (interventional procedure guidance 318).

1.1 Current evidence on the efficacy of insertion of endobronchial valves for lung volume reduction in emphysema shows some clinical and quality-of-life benefits. However, this evidence includes data from patients who have and those who have not had assessment of collateral ventilation, which specialists now advise as fundamental to selection for treatment. Evidence of safety in the short term is adequate but the evidence of safety in the longer term is inadequate in quantity. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

1.2 Clinicians wishing to undertake insertion of endobronchial valves for lung volume reduction in emphysema should take the following actions.

- 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 insertion of endobronchial valves for lung volume reduction in emphysema.

1.3 Patient selection should be done by a multidisciplinary team experienced in the management of emphysema including a chest physician, a chest radiologist and a thoracic surgeon.

1.4 This procedure should only be carried out by clinicians with specific training and expertise in interventional bronchoscopy (including provision of sedation), who should perform their initial procedures with an experienced mentor.

1.5 NICE encourages further research into insertion of endobronchial valves for lung volume reduction in emphysema. Research should take the form of studies that allow comparison of the procedure with the natural history of the disease and other treatment options including surgery. The studies should define the criteria and techniques used for patient selection. Outcome measures should include lung function, dyspnoea score, exercise tolerance, quality of life and long-term safety.

Description of the technology
The aim of insertion of endobronchial valves for lung volume reduction in emphysema is to achieve atelectasis (closure of the lung resulting in reduced or absent gas exchange) of selected lung segments. Insertion of endobronchial valves is done with the patient under sedation or general anaesthesia. Using a delivery catheter passed through a bronchoscope, a synthetic valve is placed in the target location and fixed to the bronchial wall. The valve is designed to prevent air inflow during inspiration but to allow air and mucus to exit during expiration. Before the procedure, it is usual practice to assess the presence of collateral ventilation (when air enters a lobe of the lung through a passage

that bypasses the normal airway). A surrogate for this is CT scanning to assess the completeness of fissures. A functional approach, specially developed for use before insertion of airway valves, involves a specially designed balloon catheter with a flow sensor.

Photochemical corneal collagen cross linkage using riboflavin and ultraviolet A for keratoconus and keratectasia IPG466

1 Recommendations

> This guidance replaces previous guidance on photochemical corneal collagen cross-linkage using riboflavin and ultraviolet A for keratoconus (interventional procedure guidance 320).

Most of the published evidence on photochemical corneal collagen cross-linkage (CXL) using riboflavin and ultraviolet A (UVA) for keratoconus and keratectasia relates to the technique known as 'epithelium-off' CXL'. 'Epithelium-on (transepithelial) CXL' is a more recent technique and less evidence is available on its safety and efficacy. Either procedure (epithelium-off or epithelium-on CXL) can be combined with other interventions, and the evidence base for these combination procedures (known as 'CXL-plus') is also limited. Therefore, different recommendations apply to the variants of this procedure, as follows.

1.1 Current evidence on the safety and efficacy of epithelium-off CXL for keratoconus and keratectasia is adequate in quality and quantity. Therefore, this procedure can be used provided that normal arrangements are in place for clinical governance, consent and audit.

1.2 Current evidence on the safety and efficacy of epithelium-on (transepithelial) CXL, and the combination (CXL-plus) procedures for keratoconus and keratectasia is inadequate in quantity and quality. Therefore, these procedures should only be used with special arrangements for clinical governance, consent and audit or research.

1.3 Clinicians wishing to undertake epithelium-on (transepithelial) CXL, or the combination (CXL-plus) procedures should take the following actions:

- Inform the clinical governance leads in their NHS trusts.
- Ensure that patients and their parents or carers understand the uncertainty about the efficacy and safety of the procedures in the long term and provide them with clear information. In addition, the use of NICE's information for the public is recommended.
- Audit and review clinical outcomes of all patients having these procedures for keratoconus and keratectasia.

1.4 Patient selection for these procedures should include assessment of corneal thickness and consideration of the likelihood of disease progression.

1.5 The procedures should only be carried out by ophthalmologists with expertise in managing corneal disease and specific training in the use of ultraviolet light or by appropriately trained staff under their supervision.

1.6 NICE encourages further research into CXL using riboflavin and UVA for keratoconus and keratectasia, especially epithelium-on (transepithelial) CXL and the combination (CXL-plus) procedures. Details of the techniques used should be clearly described. Reported outcomes should include visual acuity, corneal topography and quality of life. Data on long-term outcomes for all types of CXL using riboflavin and UVA for keratoconus and keratectasia would be useful – specifically data about prevention of progression to corneal transplantation and about repeat procedures and their efficacy.

Description of the indications and technology

The indications

Keratoconus is a degeneration of the structure of the cornea in which the corneal surface thins and begins to bulge into a cone shape. This causes refractive error, which is usually a myopic shift and is often associated with astigmatism, leading to visual impairment. Iatrogenic keratoconus (for example, as a result of laser-assisted in situ keratomileusis [LASIK] surgery) is called keratectasia.

The procedures

	The CXL procedures are normally done as outpatient procedures using topical anaesthesia, and typically take 60–90 minutes. In epithelium-off CXL, the epithelium is first abraded with a blunt spatula to allow penetration of riboflavin into the corneal tissue. Riboflavin eye drops are applied to the corneal surface before the procedure and intermittently during the procedure. The corneal surface is exposed to UVA radiation: precise timings and treatment protocols vary. Postoperatively, topical antibiotics and anti-inflammatory drops are normally prescribed, with topical steroids if necessary. In some cases, a bandage contact lens may also be used for a few days. The procedure is done on 1 eye at a time and may also be repeated if needed. In epithelium-on (transepithelial) CXL, the corneal epithelial surface is left intact (or may be partially disrupted) and a longer riboflavin loading time is needed. Sometimes the procedure is used in combination with other interventions such as ICRS implantation, photorefractive keratectomy (PRK) or phakic intraocular lens (PIOL) implantation to improve visual acuity. These combination procedures are referred to as 'CXL-plus'. The mechanism of action of the CXL procedures is not fully understood: they may increase the number of 'anchors' that bond collagen fibres together and strengthen the cornea. This is expected to stop the progression of the disease but the duration of benefit is uncertain.
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	**Gene expression profiling and expanded immunohistochemistry tests for guiding adjuvant chemotherapy decisions in early breast cancer management: MammaPrint, Oncotype DX, IHC4 and Mammostrat DG10** **1 Recommendations** 1.1 Oncotype DX is recommended as an option for guiding adjuvant chemotherapy decisions for people with oestrogen receptor positive (ER+), lymph node negative (LN−) and human epidermal growth factor receptor 2 negative (HER2−) early breast cancer if: • the person is assessed as being at intermediate risk **and** • information on the biological features of the cancer provided by Oncotype DX is likely to help in predicting the course of the disease and would therefore help when making the decision about prescribing chemotherapy **and** • the manufacturer provides Oncotype DX to NHS organisations according to the confidential arrangement agreed with NICE. 1.2 NICE encourages further data collection on the use of Oncotype DX in the NHS. 1.3 MammaPrint, IHC4 and Mammostrat are only recommended for use in research in people with ER+, LN− and HER2− early breast cancer, to collect evidence about potentially important clinical outcomes and to determine the ability of the tests to predict the benefit of chemotherapy. The tests are not recommended for general use in these people because of uncertainty about their overall clinical benefit and consequently their cost effectiveness. The analysis leading to recommendation 1.1 was based on intermediate risk of distant recurrence being defined as a Nottingham Prognostic Index (NPI) score above 3.4. It is anticipated that an NPI score can be simply calculated from information that is routinely collected about people with breast cancer. Other decision-making tools or protocols are also currently used in the NHS and these may also be used to identify people at intermediate risk.

	Description of the technology Four tests available to the NHS were evaluated. Two are based on gene expression profiling: MammaPrint (Agendia) and Oncotype DX (Genomic Health). Two are based on immunohistochemistry (also known as protein expression profiling): IHC4 (academic sponsor – Royal Marsden Hospital and Queen Mary University, London) and Mammostrat (Clarient). These tests measure multiple markers within the tumour that may indicate how the tumour is likely to develop.
Public health briefings for local government	**Judging whether public health interventions offer value for money LGB10** This briefing summarises the economic and health benefits that can be gained from public health interventions and the methods that can be used to measure them. It is for local authorities and partner organisations. It is particularly relevant to health and wellbeing boards. **Tuberculosis in vulnerable groups LGB11** This briefing summarises NICE's recommendations for local authorities and partner organisations on identifying and managing tuberculosis (TB) in vulnerable people who may find it difficult to access services for diagnosis and treatment in traditional healthcare settings. This includes adults, young people and children from any ethnic background, regardless of migration status, whose social circumstances, language, culture or lifestyle (or those of their parents or carers) make it difficult to: • recognise the clinical onset of TB • access diagnostic and treatment services • self-administer treatment (or in the case of children and young people have treatment administered by a parent or carer) • attend regular appointments for follow-up. **Social and emotional wellbeing for children and young people LGB12** This briefing summarises NICE's recommendations for local authorities and partner organisations on social and emotional wellbeing for children and young people, specifically, vulnerable children aged under 5 years and all children in primary and secondary education. It is particularly relevant to health and wellbeing boards. Social and emotional wellbeing creates the foundations for healthy behaviours and educational attainment. It also helps prevent behavioural problems (including substance misuse) and mental health problems. That's why it is important to focus on the social and emotional wellbeing of children and young people. This is in line with the overarching goal of children's services, that is, to ensure all children have the best start in life (Fair society healthy lives). Promoting social and emotional wellbeing of children and young people will help local authorities and their local partners meet objectives outlined in the public health outcomes framework for England, 2013–2016.

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

Title / link	Start date of consultation	Finish date of consultation
Domestic violence and abuse - identification and prevention: guidance consultation	02/08/2013	27/09/2013
Autism in children, young people and adults: quality standard consultation	02/09/2013	30/09/2013
Psychosis and schizophrenia in adults: guideline consultation	20/08/2013	01/10/2013
Medicines optimisation: scope consultation	09/08/2013	04/10/2013
Head injury: guideline consultation	16/08/2013	04/10/2013
Metastatic spinal cord compression: quality standard consultation	11/09/2013	09/10/2013
Children and young people with cancer: quality standard consultation	06/09/2013	10/10/2013
Osteoarthritis (update): guideline consultation	15/08/2013	11/10/2013
Workplace policy and management practices to improve the health and wellbeing of employees: call for evidence	16/09/2013	14/10/2013
Multiple sclerosis (relapsing) - teriflunomide: appraisal consultation	18/09/2013	16/10/2013
Clinical guidelines proposed static list consultation	25/09/2013	23/10/2013
Needle and syringe programmes (update): guideline consultation	24/09/2013	05/11/2013
Indicators process guide: Quality and outcomes framework, Clinical commissioning groups outcomes indicator set	28/08/2013	30/11/2013
Trauma services: scope consultation	13/09/2013	11/12/2013

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