# NICE Update Bulletin November 2014 for guidance issued Wednesday 26th November 2014

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**)

| Type | Guidance title and reference number |
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| **Technology Appraisals (TAs)** | **Erythropoiesis-stimulating agents (epoetin and darbepoetin) for treating anaemia in people with cancer having chemotherapy (including review of TA142) TA323**<br><br>**Background**<br><br>This guidance replaces Epoetin alfa, epoetin beta and darbepoetin alfa for cancer treatment-induced anaemia (NICE technology appraisal guidance 142, issued in May 2008). The review of epoetin alfa, epoetin beta and darbepoetin alfa for cancer treatment-induced anaemia has resulted in a change in the guidance.<br><br>Anaemia can compromise the effect of treatment for cancer, reduce survival and cause symptoms that affect quality of life. Mild-to-moderate anaemia can cause headache, palpitations, tachycardia and shortness of breath. Chronic anaemia can damage organs. Severe fatigue is the most common symptom, and can lead to an inability to perform everyday tasks.<br><br>Approximately 60% of people with solid tumours who have chemotherapy develop anaemia, with a haemoglobin concentration of less than 110 g/litre. For haematological cancers, about 70% of people with lymphoma have anaemia after 3 to 4 cycles of chemotherapy.<br><br>**Recommendations**<br><br>1.1 Erythropoiesis-stimulating agents (ESAs -epoetin alfa, beta, theta and zeta, and darbepoetin alfa) are recommended, within their marketing authorisations, as options for treating anaemia in people with cancer who are having chemotherapy.<br><br>1.2 If different erythropoiesis-stimulating agents are equally suitable, the product with the lowest acquisition cost for the course of treatment should be used.<br><br>**The technology**<br><br>Epoetin alfa, beta, theta and zeta are recombinant human erythropoietin analogues used to shorten the period of symptomatic anaemia in people having cytotoxic chemotherapy. Epoetins are recommended for use when haemoglobin concentrations are 100 g/litre or lower, and target values up to 120 g/litre.<br><br>**Financial factors**<br><br>The commissioner for this technology are clinical commissioning groups. It is assumed by NICE that in current practice an estimated 20% of people who have chemotherapy will have a red blood cell transfusion (Mercante S 2000), around 1% have ESA's (NICE costing statement TA142 updated) and, in the remaining 79%, the disease can be managed with either chemotherapy dose adjustment or iron supplements.<br><br>It is assumed by NICE that in future practice 50% of people who develop anaemia will have a haemoglobin level of less than 100 g per litre and would have treatment with ESA's.<br><br>Several ESAs are available at substantially different costs, a 12 week course without discount or VAT ranges from £1,285 to £2,609. The overall change in costs on implementing the guideline, from the NICE costing template, is substantial at approximately £1.2 Million for NEW Devon CCG.<br><br>**Dual-chamber pacemakers for symptomatic bradycardia due to sick sinus syndrome without atrioventricular block (part review of technology appraisal guidance 88) TA324** |

**Background**

Bradycardia is a slow heart rate, defined as a heart rate of less than 60 beats per minute. Bradycardia can be caused by a range of factors. The most commonly identified causes of abnormal heart rhythms are age, ischaemic heart disease, heart valve disorders and heart failure. If untreated, symptomatic bradycardia may lead to fatigue, fainting, palpitations, dizziness, heart failure and an increased risk of mortality.

**Recommendations**

Dual-chamber pacemakers are recommended as an option for treating symptomatic bradycardia due to sick sinus syndrome without atrioventricular block.

**The technology**

Dual-chamber pacemakers are small battery-driven devices implanted in the chest with pacing leads inserted in the right atrium and ventricle. The pacing leads have sensors that detect the natural heartbeat and send that information to a small computer in the pacemaker. The pacemaker uses this data to send signals back to the heart to help it beat regularly. Dual-chamber pacemakers may be associated with a number of adverse reactions. The need for an additional lead in dual- compared with single-chamber pacemakers might lead to an associated increased risk of complications.

**Financial factors**

The commissioner for this technology are clinical commissioning groups. Providers are healthcare providers with cardiology services.

The acquisition cost of pacemakers depends on the particular model. The Association of British Healthcare Industries estimates an average cost of dual-chamber pacemaker devices of £1,265, and for single-chamber atrial pacemaker devices a price of £718. Costs may vary in different settings because of negotiated procurement discounts.

The NICE Committee concluded that in clinical practice, dual-chamber rather than single-chamber atrial devices were already being implanted for symptomatic bradycardia due to sick sinus syndrome without atrioventricular block in most of the patients. Therefore, they did not anticipate a significant impact on resources.

**Nalmefene for reducing alcohol consumption in people with alcohol dependence TA325**

**Background**

The summary of product characteristics states that a high drinking risk level is defined as alcohol consumption of more than 60 g (7.5 units) per day for men and more than 40 g (5 units) per day for women. The overall prevalence of alcohol dependence for adults in England is estimated to be around 6%. Alcohol dependence has a high probability of having a chronic and progressive course and has a large impact on individual health and on society, which rises with increasing alcohol consumption.

**Recommendations**

Nalmefene is recommended within its marketing authorisation, as an option for reducing alcohol consumption, for people with alcohol dependence:

- who have a high drinking risk level (defined as alcohol consumption of more than 60 g per day for men and more than 40 g per day for women, according to the World Health Organization's drinking risk levels) without physical withdrawal symptoms **and**
- who do not require immediate detoxification.

The marketing authorisation states that nalmefene should:

- only be prescribed in conjunction with continuous psychosocial support focused on treatment adherence and reducing alcohol consumption **and**
- be initiated only in patients who continue to have a high drinking risk level 2 weeks after initial assessment.

**The technology**

Nalmefene is an opioid receptor modulator

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| | **Financial factors**<br><br>The commissioners for this technology will be local authorities, clinical commissioning groups and NHS England.<br><br>Nalmefene is available as an 18 mg film-coated tablet and is priced at £42.42 for a pack of 14 tablets or £84.84 for a packet of 28 tablets (excluding VAT; 'British national formulary' [BNF], online April 2014). It is taken orally at a maximum dose of 1 tablet daily on an 'as-needed' basis. Costs may vary in different settings because of negotiated procurement discounts.<br><br>The conclusion of the NICE costing report is that the annual resource impact expected as a result of implementing the recommendations in the guidance is estimated to be £49,700 per 100,000 population at year 5 and approximately half of this cost in year 1 (using the standard assumptions in the costing model).<br><br>In year 1 uptake is assumed to be 20% market share rising steadily to 60% uptake in year 5. Costs are mainly due to psychological support approx £951 per annum and estimated £618 annual cost of nalmefene not including vat or discounts.<br><br>**Imatinib for the adjuvant treatment of gastrointestinal stromal tumours (review of NICE technology appraisal guidance 196) TA326**<br><br>**Background**<br><br>Gastrointestinal stromal tumours (GISTs) are rare connective tissue tumours. Although GISTs can occur along the length of the GI tract, the majority arise in the stomach (60–70%) or small intestine (25–35%). GISTs are associated with the overexpression of several tyrosine kinase growth receptors and the ligands that bind to them. Around 75–80% of GISTs have activating mutations in c-KIT (CD117).<br><br>**Recommendations**<br><br>1.1 Imatinib is recommended as an option as adjuvant treatment for up to 3 years for adults who are at high risk of relapse after surgery for KIT (CD117)-positive gastrointestinal stromal tumours, as defined by the Miettinen 2006 criteria (based on tumour size, location and mitotic rate).<br><br>1.2 People currently receiving treatment initiated within the NHS with imatinib that is not recommended for them by NICE in this guidance should be able to continue treatment until they and their NHS clinician consider it appropriate to stop.<br><br>**The technology**<br><br>Imatinib is a selective kinase inhibitor which binds to activated c-KIT receptors and blocks the cell signalling pathway, preventing uncontrolled cell proliferation.<br><br>**Financial factors**<br><br>The commissioner for this technology is NHS England.<br><br>At a dose of 400 mg per day, drug costs for a course of treatment would be approximately £20,700 for 1 year and £62,100 for 3 years.<br><br>The number of new people eligible for treatment with imatinib is around 170 per year for the population of England equating to approximately 3 people in NEW Devon CCG area. |
| **Clinical Guidelines (CGs)** | **Obesity: identification, assessment and management of overweight and obesity in children, young people and adults (CG189)**<br><br>**Background information**<br><br>Obesity is directly linked to a number of different illnesses including type 2 diabetes, fatty liver disease, hypertension, gallstones and gastro-oesophageal reflux disease (NICE guideline CG184), as well as psychological and psychiatric morbidities.<br><br>Different weight classes are defined based on a person's body mass index (BMI) as follows:<br><br>• healthy weight: 18.5–24.9 kg/$m^2$ |

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| | • overweight: 25–29.9 kg/m$^2$<br>• obesity I: 30–34.9 kg/m$^2$<br>• obesity II: 35–39.9 kg/m$^2$<br>• obesity III: 40 kg/m$^2$ or more.<br><br>The use of lower BMI thresholds (23 kg/m$^2$ to indicate increased risk and 27.5 kg/m$^2$ to indicate high risk) to trigger action to reduce the risk of conditions such as type 2 diabetes, has been recommended for black African, African-Caribbean and Asian (South Asian and Chinese) groups.<br><br>**The recommendations in full cover**<br><br>1.1 Generic principles of care<br><br>1.2 Identification and classification of overweight and obesity<br><br>1.3 Assessment<br><br>1.4 Lifestyle interventions<br><br>1.5 Behavioural interventions<br><br>1.6 Physical activity<br><br>1.7 Dietary<br><br>1.8 Pharmacological interventions<br><br>1.9 Continued prescribing and withdrawal<br><br>1.10 Surgical interventions<br><br>1.11 Bariatric surgery for people with recent-onset type 2 diabetes<br><br>1.12 Follow-up care<br><br>**Key priorities for implementation**<br><br>The guidance does not identify key priorities for implementation<br><br>**Financial factors**<br><br>NICE do not seem to have not produced a costing report or costing template for this guidance so it is difficult to assess financial implications of the guidance. If the guidance were implemented in full the costs would likely to be high because of the large number of patients involved. |
| **Public Health Guidance** | **Vitamin D: increasing supplement use among at-risk groups PH56**<br><br>This guideline aims to increase supplement use to prevent vitamin D deficiency among at-risk groups, as identified in 2012 by the UK Health Departments (Vitamin D – advice on supplements for at risk groups – letter from UK Chief Medical Officers Department of Health), and in 2007 by the Scientific Advisory Committee on Nutrition (Update on vitamin D).<br><br>Vitamin D is essential for skeletal growth and bone health. Severe deficiency can result in rickets (among children) and osteomalacia (among children and adults).<br><br>Dietary sources of vitamin D are limited. The main natural source is from the action of sunlight on skin. However, from mid-October to the beginning of April in the UK there is no ambient ultraviolet sunlight of the appropriate wavelength for skin synthesis of vitamin D. National surveys suggest that around a fifth of adults and 8 to 24% of children (depending on age and gender) may have low vitamin D status.<br><br>**The recommendations in full cover**<br><br>1 Increase access to vitamin D supplements<br><br>2 Clarify existing guidance<br><br>3 Develop national activities to increase awareness about vitamin D<br><br>4 Ensure a consistent multiagency approach<br><br>5 Increase local availability of vitamin D supplements for at-risk groups |

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| | 6 Improve access to Healthy Start supplements<br><br>7 Only test vitamin D status if someone has symptoms of deficiency or is at very high risk<br><br>8 Ensure health professionals recommend vitamin D supplements<br><br>9 Raise awareness among health, social care and other relevant practitioners of the importance of vitamin D<br><br>10 Raise awareness of the importance of vitamin D supplements among the local population<br><br>11 Monitor and evaluate the provision and uptake of vitamin D supplements<br><br>Commissioners of services related to the prevention of vitamin D deficiency include: local authorities, Public Health England, NHS England, and clinical commissioning groups. There are a range of possible providers, including primary care, secondary care and community services. |
| **Medical Technologies Guidance** | **Parafricta Bootees and Undergarments to reduce skin breakdown in people with or at risk of pressure ulcers MTG20**<br><br>**Recommendations**<br><br>1.1 Parafricta Bootees and Undergarments show potential to reduce the development and progression of skin damage caused by friction and shear in people with, or at risk of, pressure ulcers. **However, more evidence for their effectiveness in clinical practice is needed to support the case for routine adoption of Parafricta Bootees and Undergarments in the NHS**.<br><br>1.2 Research is recommended to address uncertainties about the claimed patient and system benefits of using Parafricta Bootees and Undergarments. This should take the form of comparative research against standard care, preferably carried out in a hospital. The research should include development of criteria to recognise people who would most benefit from the technology in both hospitals and community care. NICE will explore the development of appropriate further evidence, in collaboration with the technology sponsor and with clinical and academic partners, and will update this guidance if and when substantive new evidence becomes available.<br><br>**The technology**<br><br>Parafricta Bootees and Undergarments (APA Parafricta) are intended to reduce the potential for both the development and the progression of skin damage caused by friction and shear in people who have, or are at risk of developing, pressure ulcers, and in people with frail skin or those who have medical conditions in which skin frailty is a primary factor. Bootees provide protection for the heel and ankle, and Undergarments provide protection for the sacrum, buttocks and hips.<br><br>The items are made from proprietary Parafricta fabric which is designed to reduce the shear stress and friction associated with movement. This mechanism of action is different from current methods of pressure ulcer management or prevention, which aim to manage or prevent pressure ulcers by reducing or redistributing pressure.<br><br>**The ReCell Spray-On Skin system for treating skin loss, scarring and depigmentation after burn injury MTG21**<br><br>**Recommendations**<br><br>1.1 The ReCell Spray-On Skin system shows potential to improve healing in acute burns. **However, there is insufficient evidence on its use in clinical practice, particularly in relation to which patients might benefit most from its use, to support the case for its routine adoption in the NHS.**<br><br>1.2 Research is recommended to address uncertainties about the claimed patient and system benefits of the ReCell Spray-On Skin system. Clinical outcomes should include time to 95% healing, length of hospital stay, cosmetic appearance of the scar and function of the burned area, compared with standard care. As relevant databases and registers are available, the research might include analysis of data generated from these. NICE will explore the development of appropriate further evidence, in collaboration with the technology sponsor and with clinical and academic partners, and will update this guidance if and when new and substantive evidence becomes available<br><br>**The technology** |

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| | The ReCell Spray-On Skin system is a rapid, autologous cell harvesting, processing and delivery system for treating skin loss and preventing scarring and depigmentation in adults and children with burns.<br><br>ReCell Spray-On Skin is prepared by shaving skin from a donor site close to the burn. The donor skin is added to a proprietary enzyme solution in a processing unit and heated for 15–30 minutes to disaggregate the cells. The skin is then removed and scraped with a scalpel to develop a plume of cells. A suspension of the cells is prepared and delivered to the debrided burn using a spray applicator, or it can be dripped directly onto the site. The procedure is designed to be carried out by clinicians, without input from specialised laboratory staff. |
| **NICE Quality Standards** | **None published so far this month** |
| **Safe staffing guideline** | **None published so far this month** |
| **Interventional Procedures Guidance (IPGs)** | Telemetric adjustable pulmonary artery banding for pulmonary hypertension in infants with congenital heart defects IPG505<br><br>**Recommendations**<br><br>1.1 The evidence on the efficacy of telemetric adjustable pulmonary artery banding shows that the procedure can provide adjustable reduction of pulmonary artery flow in infants with congenital heart defects, but there are uncertainties about which infants will derive benefit from the procedure. The evidence on safety is limited in quantity. **Therefore the procedure should only be used with special arrangements for consent, audit or research and clinical governance**.<br><br>1.2 Clinicians wishing to undertake telemetric adjustable pulmonary artery banding for pulmonary hypertension in infants with congenital heart defects should take the following actions.<br><br>• Inform the clinical governance leads in their NHS trusts.<br><br>• Ensure that parents and carers 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.<br><br>• Enter details about all infants undergoing telemetric adjustable pulmonary artery banding for pulmonary hypertension associated with congenital heart defects onto the UK Central Cardiac Audit Database and review clinical outcomes locally.<br><br>1.3 Patient selection for telemetric adjustable pulmonary artery banding for pulmonary hypertension in infants with congenital heart defects should only be done in paediatric cardiac centres, by a multidisciplinary team experienced in managing infants and children with congenital heart defects.<br><br>1.4 Further research should focus on the extended use of telemetric adjustable pulmonary artery banding for ventricular retraining and for its use pending the resolution of ventricular septal defects. Data collection may provide useful information. NICE may review the procedure on publication of further evidence.<br><br>**The procedure**<br><br>Telemetric adjustable pulmonary artery banding is mainly used in infants with multiple or single ventricular septal defects and those needing left ventricular retraining for congenitally corrected transposition of the great arteries. An adjustable pulmonary artery band (which contains a micro motor) is fastened around the main pulmonary artery. Later adjustments to the band can be done in an outpatient setting, without the need for further surgery.<br><br>**Insertion of an annular disc implant at lumbar discectomy IPG506**<br><br>**Recommendations**<br><br>1.1 Current evidence on the safety and efficacy of insertion of an annular disc implant at |

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| | lumbar discectomy is limited in quantity and quality. Therefore, this procedure **should only be used with special arrangements** for clinical governance, consent and audit or research.<br><br>1.2 Clinicians wishing to undertake insertion of an annular disc implant at lumbar discectomy should take the following actions:<br><br>• Inform the clinical governance leads in their NHS trusts.<br><br>• Ensure that patients and their carers 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.<br><br>1.3 NICE encourages further research on insertion of an annular disc implant at lumbar discectomy, particularly comparative trials. All studies should report details of patient selection and recurrence rates.<br><br>1.4 Clinicians should enter details about all patients undergoing insertion of an annular disc implant at lumbar discectomy onto the British Spine Registry or a compatible international register, and review clinical outcomes locally.<br><br>**The procedure**<br><br>Insertion of an annular disc implant at lumbar discectomy aims to reduce the incidence of recurrent herniation and the degree of intervertebral disc collapse.<br><br>The device typically contains a metallic bone anchoring component and a woven polymer mesh. The bone anchoring component is inserted into one of the vertebral bodies adjacent to the discectomy site, and the woven mesh component is inserted into the annular disc defect, so covering the residual nucleus pulposus. |
| **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** |
| **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

| Title / link | Start date of consultation | Finish date of consultation |
|---|---|---|
| Dupuytren's contracture - collagenase clostridium histolyticum: appraisal consultation | 07/11/2014 | 28/11/2014 |
| The safe use and management of controlled drugs: scope consultation | 03/11/2014 | 01/12/2014 |
| Falls - assessment and secondary prevention in older people: quality standard consultation | 05/11/2014 | 03/12/2014 |
| Service guidance for improving outcomes for people with brain and other central nervous system tumours: surveillance review proposal | 19/11/2014 | 03/12/2014 |
| Nocturnal enuresis - the management of bedwetting in children and young people: surveillance review proposal | 21/11/2014 | 05/12/2014 |
| SherLock 3CG Tip Confirmation System for placement of peripherally inserted central catheters: consultation | 11/11/2014 | 09/12/2014 |
| Urinary tract infection in adults: quality standard consultation | 11/11/2014 | 09/12/2014 |
| Urticaria (chronic spontaneous, previously treated) - omalizumab [ID707]: appraisal consultation | 19/11/2014 | 10/12/2014 |
| Ulcerative colitis (moderate to severely active) - vedolizumab [ID691]: appraisal consultation | 26/11/2014 | 17/12/2014 |
| Cystic fibrosis: scope consultation | 20/11/2014 | 18/12/2014 |
| Implantation of Left Ventricular Assist Device (LVAD) for destination therapy: consultation | 20/11/2014 | 18/12/2014 |
| Insertion of a balloon device to disimpact an engaged fetal head prior to emergency caesarean section: consultation | 20/11/2014 | 18/12/2014 |
| Radiofrequency ablation for gastric antral vascular ectasia: consultation | 20/11/2014 | 18/12/2014 |
| Transanal total mesorectal excision of the rectum: consultation | 20/11/2014 | 18/12/2014 |
| Ultrasound enhanced catheter-directed thrombolysis for deep vein thrombosis: consultation | 20/11/2014 | 18/12/2014 |
| Ultrasound enhanced catheter-directed thrombolysis for pulmonary embolism: consultation | 20/11/2014 | 18/12/2014 |
| Osteoarthritis: quality standard consultation | 21/11/2014 | 19/12/2014 |
| Personality disorders (borderline and antisocial): quality standard consultation | 21/11/2014 | 19/12/2014 |
| Depression in children and young people (update): addendum consultation | 24/11/2014 | 22/12/2014 |
| Bronchiolitis in children: guideline consultation | 17/11/2014 | 05/01/2015 |
| Anaemia management in chronic kidney disease (update): guideline consultation | 17/11/2014 | 08/01/2015 |
| Suspected cancer: guideline consultation | 20/11/2014 | 09/01/2015 |

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