NICE Update Bulletin March 2014 for guidance issued Wednesday 26th March 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
Technology Appraisals (TAs)	**Colorectal cancer (metastatic) – aflibercept TA307** **Recommendations** 1.1 Aflibercept in combination with irinotecan and fluorouracil-based therapy **is not recommended** within its marketing authorisation for treating metastatic colorectal cancer that is resistant to or has progressed after an oxaliplatin-containing regimen. 1.2 People currently receiving aflibercept in combination with irinotecan and fluorouracil-based therapy for treating metastatic colorectal cancer that is resistant to or has progressed after an oxaliplatin-containing regimen should be able to continue treatment until they and their clinician consider it appropriate to stop. **The technology** Aflibercept is a recombinant human fusion protein that blocks the vascular endothelial growth factor (VEGF) pathway by preferentially binding to VEGF-A, VEGF-B and placental growth factor, which play an important role in the formation of new blood vessels in solid tumours (angiogenesis). By preventing these factors from activating their endogenous receptors, aflibercept interferes with the process by which blood vessels and capillaries expand into tumours (vascularisation) and so inhibits tumour growth. **Vasculitis (anti-neutrophil cytoplasmic antibody-associated) - rituximab (with glucocorticoids) TA308** **Recommendations** 1.1 Rituximab, in combination with glucocorticoids, **is recommended as an option** for inducing remission in adults with anti-neutrophil cytoplasmic antibody [ANCA]-associated vasculitis (severely active granulomatosis with polyangiitis [Wegener's] and microscopic polyangiitis), only if: • further cyclophosphamide treatment would exceed the maximum cumulative cyclophosphamide dose **or** • cyclophosphamide is contraindicated or not tolerated **or** • the person has not completed their family and treatment with cyclophosphamide may materially affect their fertility **or** • the disease has remained active or progressed despite a course of cyclophosphamide lasting 3–6 months **or** • the person has had uroepithelial malignancy. 1.2 People currently receiving treatment initiated within the NHS with rituximab 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. **The technology** Rituximab is a genetically engineered monoclonal antibody that depletes B cells by targeting cells bearing the CD20 surface marker. The summary of product characteristics states that limited data preclude any conclusions about the efficacy of subsequent courses of rituximab in people with granulomatosis with polyangiitis and microscopic polyangiitis. The summary of product characteristics also states that continued immunosuppressive therapy may be considered to prevent relapse, and may be especially appropriate in people at risk of relapse (for example, in people who have had previous relapses), but that the efficacy and safety of rituximab in maintenance therapy has not been established.

Clinical Guidelines (CGs)	**None published so far this month**
Public Health Guidance	**Contraceptive services with a focus on young people up to the age of 25 - PH51** **Background** According to the 2000/01 'National survey of sexual attitudes and lifestyles, the median age of first intercourse was 16 years for both men and women. It is estimated that between one-quarter and one-third of all young people have sex before they reach age 16. Among those leaving school at 16 with no qualifications, 60% of boys and 47% of girls had sex before they were 16. Among those aged 16–19, 7% of men and 10% of women reported using no form of contraception at first intercourse. Unprotected first sex was more likely for the youngest age groups. Access to contraceptive services is most problematic for people in disadvantaged communities. There is a 6-fold difference in teenage conception and birth rates between the poorest areas in England and the most affluent. There is a clear link between sexual ill-health, deprivation and social exclusion; unintended pregnancies can have a long-term impact on people's lives. **The recommendations in full cover** 1 Assessing local need and capacity to target services 2 Commissioning coordinated and comprehensive services 3 Providing contraceptive services for young people 4 Tailoring services for socially disadvantaged young people 5 Seeking consent and ensuring confidentiality 6 Providing contraceptive services after a pregnancy 7 Providing contraceptive services after an abortion 8 Providing school and education-based contraceptive services 9 Providing emergency contraception 10 Providing condoms in addition to other methods of contraception 11 Communicating with young people 12 Training and continuing professional development
Medical Technologies Guidance	**The Debrisoft monofilament debridement pad for use in acute or chronic wounds MTG17** **Recommendations** 1.1 **The case for adopting the Debrisoft monofilament debridement pad as part of the management of acute or chronic wounds in the community is supported by the evidence**. The available evidence is limited, but the likely benefits of using the Debrisoft pad on appropriate wounds are that they will be fully debrided more quickly, with fewer nurse visits needed, compared with other debridement methods. In addition, the Debrisoft pad is convenient and easy to use, and is well tolerated by patients. Debridement is an important component of standard woundcare management as described in Pressure ulcers (NICE clinical guideline 29) and Diabetic foot problems (NICE clinical guideline 119). 1.2 The Debrisoft pad is indicated for adults and children with acute or chronic wounds. The available evidence is mainly in adults with chronic wounds needing debridement in the community. The data show that the device is particularly effective for chronic sloughy wounds and hyperkeratotic skin around acute or chronic wounds. 1.3 The Debrisoft pad is estimated to be cost saving for complete debridement compared with other debridement methods. When compared with hydrogel, gauze and bagged larvae, cost savings per patient (per complete debridement) are estimated to be £99,

	£152 and £484 respectively in a community clinic and £222, £347 and £469 respectively in the home. **The technology** The Debrisoft monofilament debridement pad is a sterile, single-use pad for nurses and other healthcare professionals for use on adults and children to remove devitalised tissue, debris, and hyperkeratotic skin around acute or chronic wounds. Its dimensions are 10×10 cm and it consists of monofilament polyester fibres all orientated perpendicular to the base of the pad. The monofilament fibres are cut with angled tips designed to penetrate irregularly shaped areas and remove devitalised skin and wound debris. The Debrisoft pad is moistened, folded and then wiped across the wound with gentle pressure. Cellular debris, slough tissue, exudate and hyperkeratotic tissues become integrated into the monofilaments and are removed from the wound site. The Debrisoft pad is intended for use without analgesia, and the process takes, on average, 2–4 minutes. The NICE committee concluded that the use of the Debrisoft pad in community clinic or home settings could lead to quicker debridement, fewer nurse visits (3 instead of 9-12 for comparator treatments in the costing template) and possibly less discomfort for the patient compared with other debridement methods.
NICE Quality Standards	**Neonatal jaundice QS57** This quality standard covers the recognition and management of neonatal jaundice in newborn babies (both term and preterm) from birth to 28 days in primary care (including community care) and secondary care. It does not cover babies with jaundice who need surgery to correct the underlying cause, or the management of conjugated hyperbilirubinaemia in babies.
Interventional Procedures Guidance (IPGs)	**Extracorporeal membrane oxygenation (ECMO) for acute heart failure in adults IPG482** **Recommendations** 1.1 The evidence on the efficacy of extracorporeal membrane oxygenation (ECMO) for acute heart failure in adults is adequate but there is uncertainty about which patients are likely to benefit from this procedure, and the evidence on safety shows a high incidence of serious complications. Therefore, **this procedure should only be used with special arrangements for clinical governance, consent and audit or research.** 1.2 Clinicians wishing to undertake ECMO for acute heart failure in adults should take the following actions. • Inform the clinical governance leads in their NHS trusts. • 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. • Submit data on all adults undergoing ECMO for acute heart failure to the international Extracorporeal Life Support Organization register. 1.3 ECMO for acute heart failure in adults should only be carried out by clinical teams with specific training and expertise in the procedure. 1.4 NICE encourages further research into ECMO for acute heart failure. This should include clear documentation of patient selection and indications for the use of ECMO. Outcome measures should include survival, quality of life and neurological status. **The procedure** There are 2 main types of ECMO – venovenous and venoarterial. For acute heart failure in adults, the venoarterial method is used. Blood is withdrawn via the venous system (usually the femoral vein or right atrium) and pumped through an oxygenator, where gas exchange of oxygen and carbon dioxide takes place. It is then returned to the arterial system (usually the femoral artery or ascending aorta). Patients are given a continuous infusion of an anticoagulant, usually heparin, to prevent blood clotting in the external system. For patients with renal insufficiency, a haemofiltration unit may be integrated into

the circuit

Insertion of a magnetic bead band for faecal incontinence IPG483

1 Recommendations

1.1 Current evidence on the safety and efficacy of insertion of a magnetic bead band for faecal incontinence is limited in quantity and quality. The available evidence was considered in the context of the distress that faecal incontinence can cause and of the other treatment options, which may be limited. If further evidence supports the efficacy of this procedure, it has the potential to significantly improve quality of life for appropriately selected patients. Therefore **insertion of a magnetic bead band for faecal incontinence may be used with special arrangements for clinical governance, consent and audit**. NICE encourages the publication of outcomes on all patients, with specific consideration of entering all eligible patients into the HTA trial – 12/35/07.

1.2 Clinicians wishing to undertake insertion of a magnetic bead band for faecal incontinence should take the following actions.

- Inform the clinical governance leads in their NHS trusts.
- Ensure that patients understand the uncertainty about the procedure's efficacy (especially in the long term) and the risk of complications that may need removal of the band. They should inform them fully about other treatment options and about the value of research studies (when appropriate), and provide them with clear written information. In addition, the use of NICE's Information for the public is recommended.

1.3 Clinicians should offer all eligible patients entry into the HTA trial – 12/35/07. Data about all patients who do not enter the trial should be collected for local audit and review with a view to collaborative publication of outcomes.

1.4 The procedure should only be performed in units specialising in the assessment and treatment of faecal incontinence.

1.5 NICE will review the procedure when the results of the HTA trial are available. Research outcomes for any future studies should include disease-related quality of life.

The procedure

Insertion of a magnetic bead band for faecal incontinence aims to reinforce and improve the competence of the anal sphincter to prevent episodes of incontinence without creating obstruction, and with less morbidity than artificial bowel sphincter surgery. The magnetic bead band does not need to be adjusted once it has been inserted. The procedure is done with the patient under general anaesthesia, using stringent asepsis. A tunnel is created around the anal canal via an anterior incision in the perineal body. A sizing tool is inserted to assess the circumference of the anal canal and the size of implant needed. The sizing tool is then removed and the implant is placed circumferentially around the upper anal canal. Fluoroscopy may be used to confirm the correct position.

Transoral carbon dioxide laser surgery for primary treatment of oropharyngeal malignancy IPG484

Recommendations

1.1 Current evidence on the efficacy and safety of transoral carbon dioxide laser surgery for the primary treatment of oropharyngeal malignancy **is adequate to support the use of this procedure with normal arrangements for clinical governance, consent and audit**.

1.2 This procedure should only be carried out by clinicians who have been trained in the use of transoral carbon dioxide laser surgery in the oropharynx.

1.3 Patient selection for this procedure should be done by a multidisciplinary team in accordance with the NICE cancer service guidance on improving outcomes in head and neck cancers (CSGNH 2004).

1.4 Clinicians should enter details of all patients undergoing transoral carbon dioxide laser surgery for the primary treatment of oropharyngeal malignancy onto the Data for Head and Neck Oncology (DAHNO) database.

The procedure

	Transoral carbon dioxide laser surgery is a minimally invasive endoscopic approach for treating tumours in the oropharynx. It is usually performed under general anaesthesia, with the patient supine and tilted head-down. The carbon dioxide laser device is coupled to an operating microscope and the laser beam is used to excise the tumour completely, together with an adequate margin of tissue around it. Large tumours are removed in 2 or more pieces as a multiblock resection. **Faecal microbiota transplant for recurrent clostridium difficile infection IPG485** **Recommendations** 1.1 Current evidence on the efficacy and safety of faecal microbiota transplant for recurrent *Clostridium difficile* infection **is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit.** 1.2 This procedure should only be considered for patients with recurrent *C. difficile* infections that have failed to respond to antibiotics and other treatments. 1.3 Clinicians should ensure that a confidential record is kept of the donor and recipient of each faecal microbiota transplant. 1.4 NICE encourages further research into faecal microbiota transplant for *C. difficile* infection, specifically to investigate optimal dosage, mode of administration and choice of donor. **The procedure** Faecal microbiota transplants aim to restore a healthy balance of bacteria in the gut of people who have recurrent *Clostridium difficile* infections by introducing enteric bacteria from the faeces of healthy donors. Before the procedure, donors (who can be family members or unrelated) are screened for enteric bacterial pathogens, viruses and parasites. Donor faeces are taken and diluted with water, saline or another liquid such as milk or yogurt, and subsequently strained to remove large particles. The resulting suspension is introduced into the recipient's gut via a nasogastric tube, nasoduodenal tube, rectal enema or via the biopsy channel of a colonoscope. Recipients may receive a bowel lavage before transplantation, in order to reduce the *C. difficile* load in the intestines.
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	**Community engagement to improve health LGB16** This briefing summarises NICE's recommendations for local authorities and partner organisations on how community engagement approaches can be used to improve the planning and delivery of all services, including those that impact on health. It is particularly relevant to health and wellbeing boards. This includes local healthwatch organisations that sit on these boards. **Local government public health briefing on contraceptive services LGB17** This briefing summarises some of NICE's recommendations for local authorities and their partner organisations on contraceptive services (in particular, for under-25s) and on the general use of long-acting reversible contraception (LARC). It is particularly relevant to health and wellbeing boards

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
Delirium: Quality standard consultation	27/02/2014	27/03/2014
Feverish illness in children: quality standard consultation	27/02/2014	27/03/2014
Safe Midwifery Staffing for Maternity Settings: scope consultation	28/02/2014	28/03/2014
Technology Appraisal process guides consultation	06/01/2014	28/03/2014
Preoperative Tests (update): scope consultation	03/03/2014	31/03/2014
NICE BNF consultation	03/02/2014	31/03/2014
Tuberculosis (update): second call for evidence	04/03/2014	01/04/2014
Idiopathic Pulmonary Fibrosis: topic engagement exercise	19/03/2014	02/04/2014
Antimicrobial stewardship: scope consultation	05/03/2014	02/04/2014
Chronic kidney disease (update): guideline consultation	21/02/2014	04/04/2014
Multiple myeloma - bortezomib (induction therapy): Final appraisal determination	21/03/2014	04/04/2014
Multiple myeloma - lenalidomide (post bortezomib) (part rev TA171): Appraisal consultation	14/03/2014	04/04/2014
Hepatitis B: quality standard consultation	10/03/2014	07/04/2014
Pain and bleeding in early pregnancy: quality standard consultation	10/03/2014	07/04/2014
Advanced Breast Cancer: Addendum consultation	12/03/2014	09/04/2014
Varicose veins in the legs: quality standard conusltation	13/03/2014	10/04/2014
Radium-223 dichloride for treating metastatic hormone relapsed prostate cancer with bone metastases: Appraisal consultation	24/03/2014	11/04/2014
Oral health promotion approaches for dental health practitioners: Consultation on the draft scope	18/03/2014	15/04/2014
Intravenous fluid therapy in adults in hospital: Quality standard consultation	21/03/2014	22/04/2014
Powered microdebrider turbinoplasty for inferior turbinate hypertrophy : Interventional Procedures	24/03/2014	23/04/2014
Endoscopic radiofrequency ablation for squamous dysplasia of the oesophagus: Interventional Procedures	24/03/2014	23/04/2014
Endoscopic radiofrequency ablation for Barrett´s oesophagus with low grade dysplasia or no dysplasia : Interventional Procedures	24/03/2014	23/04/2014
Transition from children´s to adult services: scope consultation	25/03/2014	24/04/2014
Workplace health - older employees: consultation on the draft scope	26/03/2014	28/04/2014
Exercise referral schemes: Consultation on the draft guideline	19/03/2014	02/05/2014

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