NICE Update Bulletin August 2015 issued 26th August 2015

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)	**Vedolizumab for treating moderately to severely active Crohn's disease after prior therapy TA352** **Recommendations** 1.1 Vedolizumab is recommended as an option for treating moderately to severely active Crohn's disease only if: •a tumour necrosis factor‑alpha inhibitor has failed (that is, the disease has responded inadequately or has lost response to treatment) or •a tumour necrosis factor‑alpha inhibitor cannot be tolerated or is contraindicated. Vedolizumab is recommended only if the company provides it with the discount agreed in the patient access scheme. 1.2 Vedolizumab should be given as a planned course of treatment until it stops working or surgery is needed, or until 12 months after the start of treatment, whichever is shorter. At 12 months, people should be reassessed to determine whether treatment should continue. Treatment should only continue if there is clear evidence of ongoing clinical benefit. For people in complete remission at 12 months, consider stopping vedolizumab, resuming treatment if there is a relapse. People who continue vedolizumab should be reassessed at least every 12 months to decide whether continued treatment is justified. 1.3 People whose treatment with vedolizumab is not recommended in this NICE guidance, but was started within the NHS before this guidance was published, should be able to continue treatment until they and their NHS clinician consider it appropriate to stop. **The technology** Vedolizumab is a humanised IgG1 monoclonal antibody derived from a newly engineered cell line. It is targeted against α4β7 integrin, which is expressed on certain white blood cells. α4β7 integrin is responsible for recruiting these cells to inflamed bowel tissue. It is administered by intravenous infusion. The summary of product characteristics states that the recommended dosage of vedolizumab for treating Crohn's disease is 300 mg at 0, 2 and 6 weeks, then every 8 weeks thereafter. It further notes that people who have not shown a response may benefit from a dose at week 10. If no evidence of therapeutic benefit is seen by week 14, vedolizumab should not be continued. **Financial factors** The list price of vedolizumab is £2,050 per 300 mg vial (excluding VAT; British National Formulary, accessed online July 2015). The company has agreed a patient access scheme with the Department of Health The NICE costing statement encourages organisations to evaluate their own practices against the recommendations in the NICE guidance and assess costs using the local costing template. **Bevacizumab for treating relapsed, platinum-resistant epithelial ovarian, fallopian tube or primary peritoneal cancer (terminated appraisal) TA353** **Recommendations** NICE is unable to make a recommendation about the use in the NHS of bevacizumab for treating relapsed, platinum-resistant epithelial ovarian, fallopian tube or primary

	peritoneal cancer because no evidence submission was received from Roche Products for the technology. **Background information** Roche Products was invited to submit evidence for this single technology appraisal for bevacizumab in March 2015. Roche conceded that it would not be possible to demonstrate the cost effectiveness of bevacizumab for relapsed, platinum-resistant epithelial ovarian, fallopian tube or primary peritoneal cancer. Bevacizumab cannot be given special consideration as a treatment used at the end of life because the total population eligible for treatment across all its licensed indications is too large. NICE has therefore terminated this single technology appraisal. **Edoxaban for treating and for preventing deep vein thrombosis and pulmonary embolism TA354** **Recommendations** Edoxaban is recommended, within its marketing authorisation, as an option for treating and for preventing recurrent deep vein thrombosis and pulmonary embolism in adults. **The technology** Edoxaban is an anticoagulant that directly inhibits factor X (factor Xa), which is a key component in the formation of blood clots. Edoxaban has a marketing authorisation for the treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults. It is administered orally. The recommended dosage of edoxaban is 60 mg once daily, or 30 mg once daily in specific patient groups (people with renal impairment, low body weight [60 kg or less], or concomitant use of potent permeability glycoprotein [P‑glycoprotein] inhibitors), following treatment with a parenteral anticoagulant for at least 5 days. **Financial factors** Edoxaban costs £2.10 per 15-mg, 30-mg or 60-mg tablet (excluding VAT) and the daily cost of treatment is £2.10. Costs may vary in different settings because of negotiated procurement discounts. Edoxaban provides another option for treating and preventing deep vein thrombosis and pulmonary embolism in adults. Because it is an alternative to rivaroxaban, dabigatran etexilate and apixaban and the 4 drugs are similarly priced, NICE does not anticipate a significant impact on resources as a result of implementing the guidance.
Highly specialized technology guidance (HSTs)	**None published so far this month**

Note: From January 2015 NICE has decided to use a single set of methods and processes to develop all NICE guidelines, whether they are clinical, public health, social care, safe staffing or medicines practice.

Technology appraisals, interventional procedures, medical technologies and diagnostics guidance; and quality standards and advice products, are unaffected by this change.

NICE Guidelines (NGs)	**Antimicrobial stewardship: systems and processes for effective antimicrobial medicine use NG15** **Background information** The purpose of this guideline is to provide good practice recommendations on systems and processes for the effective use of antimicrobials

The benefits of reducing the use of antimicrobials include

- slow down the emergence of antimicrobial resistance
- ensure that antimicrobials remain an effective treatment for infection
- improve clinical outcomes for the population as a whole
- conserve healthcare resources.

This guideline includes recommendations on:

- antimicrobial stewardship programmes
- antimicrobial prescribing
- introducing new antimicrobials
- Communication
- Laboratory testing

The guideline does not cover:

- specific clinical conditions (although some evidence identified included patients with a specific infection such as community acquired pneumonia)
- named medicines
- public health awareness of antimicrobial resistance
- research into new antimicrobials
- immunisation and vaccination
- antimicrobial household cleaning products
- antimicrobial use in animals
- hand hygiene, decolonisation and infection prevention and control measures
- medicines adherence, except where there are specific issues for health and social care practitioners to address relating to antimicrobials
- access to medicines, including local decision-making for medicines not included on local formularies
- medicines shortages, including supply issues and discontinued medicines
- prescription charges
- waste medicines

Type 1 diabetes in adults: diagnosis and management NG17

Background information

Type 1 diabetes affects over 370,000 adults in the UK. It results from destruction of the cells that normally make insulin. Loss of insulin secretion results in high blood glucose and other metabolic and haematological abnormalities, which have both short-term and long-term adverse effects on health. Over years, type 1 diabetes causes tissue damage which, if not detected and managed early, can result in disability: blindness, kidney failure and foot ulceration leading to amputation, as well as premature heart disease, stroke and death. The risk of all of these complications is greatly reduced by treatment that keeps circulating glucose levels to as near normal as possible, reducing tissue damage. Disability from complications that are not avoided can often be prevented by early detection and active management.

NICE last produced a guideline on type 1 diabetes in 2004. Since then, life expectancy for adults living with type 1 diabetes has increased, but it remains significantly shorter than for people without diabetes. There remain important deficiencies in care provision, most adults with type 1 diabetes have HbA1c above target levels, and rates of diabetic ketoacidosis (the acute complication of insulin deficiency) and renal failure have increased. This update focuses on areas where new knowledge and treatment

opportunities have arisen in the last decade.

Key priorities for implementation identified by NICE include

- Education and information
- Blood glucose management
- Insulin therapy
- Awareness and management of hypoglycaemia
- Care of adults with type 1 diabetes in hospital

The recommendations in full cover

Blood glucose and plasma glucose

1.1 Diagnosis and early care plan

1.2 Support and individualised care

1.3 Education and information

1.4 Dietary management

1.5 Physical activity

1.6 Blood glucose management

1.7 Insulin therapy

1.8 Insulin delivery

1.9 Referral for islet or pancreas transplantation

1.10 Awareness and management of hypoglycaemia

1.11 Ketone monitoring and management of diabetic ketoacidosis (DKA)

1.12 Associated illness

1.13 Control of cardiovascular risk

1.14 Care of adults with type 1 diabetes in hospital

1.15 Managing complications

Financial factors

The NICE costing statement states that

There may be costs associated with:

- Offering all adults with type 1 diabetes a structured education programme.
- Supporting adults with type 1 diabetes to aim for a target HbA1c level of 48 mmol/mol (6.5%) or lower.
- Supporting adults with type 1 diabetes to test their blood glucose levels at least 4 times a day, and up to 10 times a day.

The recommendations may also result in some longer-term savings, such as:

- Possible savings of about £2,200 per person over 10 years from providing structured education with a DAFNE programme.
- Possible lifetime savings of about £3,500 per person through achieving an HbA1c level of 48 mmol/mol (6.5%) compared with 58.5 mmol/mol (7.5%).

Diabetes (type 1 and type 2) in children and young people: diagnosis and management NG18

Background information

Diabetes is a long-term condition that can have a major impact on the life of a child or young person, as well as their family or carers. In addition to insulin therapy, diabetes management should include education, support and access to psychological services, as detailed in this guideline. Preparations should also be made for the transition from

paediatric to adult services, which have a somewhat different model of care and evidence base.

Type 1 diabetes is becoming more common in the UK, and since 2004 type 2 diabetes is also being diagnosed with increasing frequency. The 2013–14 National Diabetes Audit identified 26,500 children and young people with type 1 diabetes and 500 with type 2. Much of the general care for type 2 diabetes is the same as for type 1 diabetes, although the initial management is different.

Since 2004 there have been major changes to the routine management of type 1 diabetes, in an attempt to achieve much stricter targets for blood glucose control to further reduce the long-term risks associated with the condition. This national guidance is the first for children and young people to recommend attempting to reach a glycated haemoglobin (HbA1c) level near the normal range and near normoglycaemia. This tight control may be achieved by intensive insulin management (multiple daily injections or insulin pump therapy) from diagnosis, accompanied by carbohydrate counting. Newer technology such as continuous subcutaneous glucose monitoring may also help children and young people to have better blood glucose control, although this is not currently recommended for all children and young people with type 1 diabetes.

Key priorities for implementation identified by NICE include

- Education and information for children and young people with diabetes
- Insulin therapy for children and young people with type 1 diabetes
- Dietary management for children and young people with type 1 diabetes
- Blood glucose and HbA1c targets and monitoring for children and young people with type 1 diabetes
- Hyperglycaemia, blood ketone monitoring and inter-current illness in children and young people with type 1 diabetes
- Psychological and social issues in children and young people with diabetes
- Diabetic kidney disease in children and young people with type 2 diabetes
- Diabetic ketoacidosis

The recommendations in full cover

- Diagnosis
- Type 1 diabetes
- Type 2 diabetes
- Diabetic ketoacidosis
- Service provision

Financial factors

Costs and savings may be incurred from implementing the recommendations for example cost of £1,000 - £2,500 for continuous glucose monitoring which may be offset by a reduction in costs of treating episodes of ketoacidosis.

Approximately 80% of paediatric units nationally fulfil the criteria to receive the best practice tariff, this could increase up to 100% resulting in increased costs to commissioners.

Diabetic foot problems: prevention and management NG19

Background information

The risk of foot problems in people with diabetes is increased, largely because of either diabetic neuropathy (nerve damage or degeneration) or peripheral arterial disease (poor blood supply due to diseased large- and medium-sized blood vessels in the legs), or both. Peripheral arterial disease affects 1 in 3 people with diabetes over the age of 50, and can also increase the risk of heart attack and stroke. Foot complications are

	common in people with diabetes. It is estimated that 10% of people with diabetes will have a diabetic foot ulcer at some point in their lives. A foot ulcer can be defined as a localised injury to the skin and/or underlying tissue, below the ankle, in a person with diabetes. Despite the publication of strategies on commissioning specialist services for preventing and managing diabetic foot problems, there is variation in practice in preventing and managing diabetic foot problems across different NHS settings, and amputation rates still vary up to fourfold in the UK. **Key priorities for implementation** • Care within 24 hours of a person with diabetic foot problems being admitted to hospital, or the detection of diabetic foot problems (if the person is already in hospital) • Care across all settings • Assessing the risk of developing a diabetic foot problem • Diabetic foot problems • Diabetic foot infection • Charcot arthropathy **The recommendations in full cover** 1.1 Care within 24 hours of a person with diabetic foot problems being admitted to hospital, or the detection of diabetic foot problems (if the person is already in hospital) 1.2 Care across all settings 1.3 Assessing the risk of developing a diabetic foot problem 1.4 Diabetic foot problems 1.5 Diabetic foot ulcer 1.6 Diabetic foot infection 1.7 Charcot arthropathy **Financial factors** Populating the NICE costing template with default values gives a net resource increase of £90K for NEW Devon CCG.
Interventional Procedures Guidance (IPGs)	**Transcranial direct current stimulation (tDCS) for depression IPG530** **Recommendations** 1.1 The evidence on transcranial direct current stimulation (tDCS) for depression raises no major safety concerns. There is some evidence of efficacy but there are uncertainties about the specific mode of administration, the number of treatments needed and the duration of effect. **Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.** 1.2 Clinicians wishing to do tDCS for depression should: •Inform the clinical governance leads in their NHS trusts. •Ensure that patients understand the uncertainty about the procedure's 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 tDCS for depression 1.3 NICE encourages further research into tDCS for depression, which should document how patients were selected and any other treatments they were having. It should describe the precise method and regime used for administering tDCS. Outcome measures should include the duration of effect. NICE may update the guidance on

	publication of further evidence. **The procedure** Transcranial direct current stimulation (tDCS) is a non-invasive method of electrical stimulation of the brain using a weak direct current applied to the scalp through electrodes. The patient, who remains awake and alert during the procedure, is usually seated while a portable battery-operated stimulator delivers a constant low-strength direct current to 2 saline-soaked sponge electrodes placed on the scalp. Treatment sessions typically last for about 20–30 minutes, and are repeated daily for several weeks. Treatment is usually delivered by a trained clinician, but it can also be self-administered by the patient. tDCS may be used alone or in addition to other treatments for depression **Preoperative high dose rate brachytherapy for rectal cancer IPG531** **Recommendations** 1.1 Current evidence on the safety of preoperative high dose rate brachytherapy for rectal cancer and its efficacy in reducing tumour size appears adequate. **However, there is no evidence that the procedure provides additional benefit when used as a boost to external beam radiotherapy**. Evidence on the clinical efficacy of the procedure if used without external beam radiotherapy 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 do preoperative high dose rate brachytherapy for rectal cancer 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 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 preoperative high dose rate brachytherapy for rectal cancer (see section 7.2). 1.3 Patient selection should be done by a colorectal cancer multidisciplinary team which includes a clinical oncologist and a colorectal surgeon with expertise in local excision techniques. 1.4 NICE encourages further research into preoperative high dose rate brachytherapy for rectal cancer. Trials should be designed to provide clear data on the efficacy of this procedure, whether or not other adjunctive treatments are used. Research should document adjunctive treatments and details of patient selection. Outcomes should include local recurrence, survival, disease-free survival and quality of life. NICE may update the guidance on publication of further evidence **The procedure** Before treatment the tumour size and stage are determined using imaging techniques. A 3-dimensional CT-based treatment planning system may be used to guide the positioning and dose of radiation. A rigid or flexible endorectal applicator is inserted into the rectum and used to deliver the radiation source to the tumour. The radioactive material is moved from the brachytherapy machine into the applicator and is left in place to deliver the correct dose of radiation to the tumour. A balloon may be placed over the applicator to displace the uninvolved rectal mucosa away from the radioactive material, to reduce toxicity.
Medical Technologies Guidance	**None published so far this month**

Diagnostics Guidance	**None published so far this month**
NICE Quality Standards	**None published so far this month but 2 published after the July bulletin was issued in late July** **Drug allergy: diagnosis and management (QS97)** This quality standard covers the diagnosis and management of drug allergy in adults, young people and children. It does not cover treatment of the acute phase, including anaphylaxis, because this will be covered by a separate quality standard. **Nutrition: improving maternal and child nutrition (QS98)** This quality standard covers improving nutrition before, during and after pregnancy (up to a year after birth) for women who may become pregnant, and for babies and pre-school children. It particularly focuses on low-income and other disadvantaged households. It does not cover population-based screening programmes or national maternal and child nutrition policies. It does not cover the nutrition and care of women and children with clinical conditions that require specialist advice, secondary dietary management or clinical therapeutic advice, for whom normal care would be inappropriate. For example, it does not cover women and children with diabetes, epilepsy or HIV, or the care of low birthweight babies
Commissioning Guides	**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	End date of consultation
Kidney transplantation (children, adolescents) - immunosuppressive regimens (review of TA99) [ID346]: appraisal consultation	06/08/2015	27/08/2015
Ovarian, fallopian tube and peritoneal cancer (BRCA 1 or 2, mutated, relapsed, platinum-sensitive) - olaparib (maintenance) [ID735]: appraisal consultation 2	06/08/2015	27/08/2015
Obesity - clinical assessment and management: topic engagement	14/08/2015	28/08/2015
Headaches (Standing Committee B update): addendum consultation	03/08/2015	01/09/2015
Service model for people with learning disabilities and challenging behaviour: consultation on the draft scope	15/07/2015	02/09/2015
Venous thromboembolic diseases - management (Standing Committee B update): addendum consultation	07/08/2015	04/09/2015
Diabetes in pregnancy: quality standard consultation	07/08/2015	07/09/2015
Drug misuse prevention: call for evidence	10/08/2015	07/09/2015
Pneumonia: quality standard consultation	07/08/2015	07/09/2015
Care and support of older people with learning disabilities: consultation on the draft scope	11/08/2015	08/09/2015
Care of the dying adult: draft guideline consultation	29/07/2015	09/09/2015
Intrapartum care for high risk women: scoping workshop, consultation and final scope	13/08/2015	11/09/2015
Obesity in Adults - prevention and lifestyle weight management programmes: quality standard consultation	17/08/2015	15/09/2015
Complex fractures: draft guideline consultation	07/08/2015	21/09/2015
Fractures: draft guideline consultation	07/08/2015	21/09/2015
Gastro-oesophageal reflux disease in children and young people: quality standard consultation	21/08/2015	21/09/2015
Major trauma services: draft guideline consultation	07/08/2015	21/09/2015
Major trauma: draft guideline consultation	07/08/2015	21/09/2015
Spinal injury assessment: draft guideline consultation	07/08/2015	21/09/2015
Abdominal aortic aneurysm: the scope	25/08/2015	23/09/2015
Community engagement (update): draft guideline consultation	12/08/2015	24/09/2015
Myeloma: draft guideline consultation	19/08/2015	01/10/2015

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