NICE Update Bulletin September 2015 issued 23rd September 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)	**Edoxaban for preventing stroke and systemic embolism in people with non-valvular atrial fibrillation TA355** **Recommendations** 1.1 Edoxaban is recommended, within its marketing authorisation, as an option for preventing stroke and systemic embolism in adults with non-valvular atrial fibrillation with one or more risk factors, including: • congestive heart failure • hypertension • diabetes • prior stroke or transient ischaemic attack • age 75 years or older. 1.2 The decision about whether to start treatment with edoxaban should be made after an informed discussion between the clinician and the person about the risks and benefits of edoxaban compared with warfarin, apixaban, dabigatran etexilate and rivaroxaban. For people considering switching from warfarin, edoxaban's potential benefits should be considered against its potential risks, taking into account the person's level of international normalised ratio (INR) control. **The technology** Edoxaban is an anticoagulant that directly inhibits factor X (factor Xa), which is a key component in the formation of blood clots. It is administered orally. Edoxaban has a marketing authorisation for the 'prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (NVAF) with one or more risk factors, such as congestive heart failure, hypertension, age 75 years or older, diabetes mellitus, prior stroke or transient ischaemic attack (TIA).' The summary of product characteristics states that the recommended dose is 60 mg once daily. The recommended dose is 30 mg once daily in people with one or more of the following clinical factors: moderate or severe renal impairment (creatinine clearance 15–50 ml/min); body weight of 60 kg or less; concomitant use of the P-glycoprotein inhibitors ciclosporin, dronedarone, erythromycin or ketoconazole. **Financial factors** Edoxaban costs £58.80 for a 28-tablet pack (60 mg or 30 mg) and the daily cost of treatment is £2.10 (excluding VAT). Costs may vary in different settings because of negotiated procurement discounts. The NICE costing statement says that 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. **Ruxolitinib for treating polycythaemia vera (terminated appraisal) TA356** **Recommendations** NICE is unable to make a recommendation about the use in the NHS of ruxolitinib for treating polycythaemia vera that is resistant to hydroxycarbamide or for people who cannot tolerate hydroxycarbamide because no evidence submission was received from Novartis Pharmaceuticals for the technology.

	Background information Novartis Pharmaceuticals was invited to submit evidence for this single technology appraisal for ruxolitinib in March 2015. The company informed NICE that the data used to support the marketing authorisation for ruxolitinib for treating polycythaemia vera were from a trial that only included people with splenomegaly. However, the marketing authorisation includes those with and without splenomegaly. The company stated that a trial comparing ruxolitinib with best supportive care is ongoing and includes people without splenomegaly. In addition this trial would capture the quality of life and resource data needed to better characterise the disease and the effect of ruxolitinib. The company explained that without data from this ongoing trial it would not be possible to develop a submission that would meet the standards necessary to ensure a proper appraisal. NICE has therefore terminated this single technology appraisal.
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)	**Coeliac disease: recognition, assessment and management NG20** **Background information** This guideline covers the recognition, assessment and management of coeliac disease in children, young people and adults. It updates and replaces NICE guideline CG86. Coeliac disease is an autoimmune condition associated with chronic inflammation of the small intestine, which can lead to malabsorption of nutrients. Dietary proteins known as glutens, which are present in wheat, barley and rye, activate an abnormal mucosal immune response. Clinical and histological improvements usually follow when gluten is excluded from the diet. Coeliac disease can present with a wide range of clinical features, both gastrointestinal (such as indigestion, diarrhoea, abdominal pain, bloating, distension or constipation) and non-gastrointestinal (such as fatigue, dermatitis herpetiformis, anaemia, osteoporosis, reproductive problems, neuropathy, ataxia or delayed puberty). Children may also present with features such as faltering growth, static weight or progressive weight loss. Although some people present with typical symptoms, others will initially experience few or no symptoms. Coeliac disease is a common condition. Population screening studies suggest that in the UK 1 in 100 people are affected. The complications of coeliac disease (which may or may not be present at diagnosis) can include osteoporosis, ulcerative jejunitis, malignancy (intestinal lymphoma), functional hyposplenism, vitamin D deficiency and iron deficiency. People with conditions such as type 1 diabetes, autoimmune thyroid disease, Down's syndrome and Turner syndrome are at a higher risk than the general population of having coeliac disease. First-degree relatives of a person with coeliac disease also have an increased likelihood of having coeliac disease. The treatment of coeliac disease is a lifelong gluten-free diet. Specific education and information, such as advice and education on alternative foods in the diet to maintain a healthy and varied intake, may increase the likelihood of adherence and a positive prognosis. These could be provided by a dietitian with experience in coeliac disease. However, access to specialist dietetic support is currently patchy in the UK.

The recommendations in full cover

- 1.1 Recognition of coeliac disease
- 1.2 Serological testing for coeliac disease
- 1.3 Referral of people with suspected coeliac disease
- 1.4 Monitoring in people with coeliac disease
- 1.5 Non-responsive and refractory coeliac disease
- 1.6 Information and support
- 1.7 Advice on dietary management

Financial factors

The NICE costing statement identifies some areas where additional expenditure may be required locally.

- Additional investment by laboratories to meet clinical pathology accreditation or ISO15189 accreditation standards
- Increased range of serological tests offered by laboratories.
- Improved access to specialist dietetic advice.
- Possible need for increased capacity to carry out annual reviews for around 530,000 people with coeliac disease

The NICE costing statement identifies a potential area for savings locally

- Possible use of human leukocyte antigen (HLA) DQ2/DQ8 testing in specialist settings (for example, in children and young people where a biopsy would require a general anaesthetic or people who have already withdrawn gluten from their diet, making them unsuitable for gluten challenge).

Home care: delivering personal care and practical support to older people living in their own homes NG21

Background information

Home care is one of several services that can be offered to people assessed as needing social care support. It can be funded by health or social care commissioners or by the person using services. Although the range and type of services that can be classed as home care varies, it usually encompasses:

- personal care, for example help to wash
- support with the activities of daily living, which might also include telecare (for example providing personal alarms)
- essential domestic tasks.

Home care services may also help people to stay independent and take part in social and other activities. A number of recent reports have identified significant concerns about the quality, reliability and consistency of home care services. A themed inspection of home care by the Care Quality Commission (Not just a number: Review of home care services) also highlighted some specific key areas for improvement.

The Department of Health asked NICE to develop a guideline to help address these issues (see the scope). The guideline was developed by a Guideline Committee following a detailed review of the evidence on home care. The Care Quality Commission uses NICE guidelines as evidence to inform the inspection process and NICE quality standards to inform ratings of good and outstanding.

This guideline focuses on older people receiving home care and their carers. The guideline does not cover younger adults (although many of the recommendations may also be relevant to younger adults). This is because the largest group of people using home care is older people.

This guideline considers how person-centred home care should be planned and

	delivered. It addresses how those responsible for managing, providing and commissioning home care should work together to deliver safe, high-quality home care services. These services should promote independence and support people to do the things that are important to them. This guideline has been developed in the context of a complex and rapidly evolving landscape of guidance and legislation, most notably the Care Act 2014. While the Care Act and other legislation describe what organisations must do, this guideline is focused on 'what works' in terms of how to fulfil those duties, and deliver support to older people using home care and their carers. **The recommendations in full cover** 1.1 Ensuring care is person centred 1.2 Providing information about care and support options 1.3 Planning and reviewing home care and support 1.4 Delivering home care 1.5 Joint working between health and social care 1.6 Ensuring safety and safeguarding people using home care services 1.7 Recruiting, training and supporting home care workers **Financial factors** The NICE costing statement states that there is significant variability in the commissioning and provision of home care in England. It is likely that implementing this guideline will have resource implications for local authority commissioners and for providers, and we advise them to assess these locally. The costing statement identifies areas for increased expenditure and savings **The recommendation areas that may have a significant resource impact are:** • Considering home care for people with low to moderate needs. • Ensuring home care visits are long enough, and shorter than half an hour only in defined circumstances. • Recruiting, training and supporting home care workers. **Potential areas for savings and benefits are:** • Local authorities may make savings if improved provision of home care avoids the need for high-intensity home care or residential care. • Clinical commissioning groups and NHS England may achieve savings if improved provision of home care avoids the need for hospital care or community health care. • Providers of home care may save costs associated with recruitment if retention of home care workers increases because of improved working practices and training.
Interventional Procedures Guidance (IPGs)	**Low-energy contact X-ray brachytherapy (the Papillon technique) for early-stage rectal cancer IPG532** **Recommendations** 1.1 In patients for whom surgery is not considered suitable, current evidence on the efficacy and safety of low-energy contact X-ray brachytherapy (CXB; the Papillon technique) for early-stage rectal cancer is adequate to support the use of this procedure, provided that **normal arrangements** are in place for clinical governance, consent and audit. 1.2 In patients for whom surgery is considered suitable, but who choose not to have an operation, the evidence on safety is adequate but the evidence on efficacy is inadequate. Therefore this procedure should only be used for these patients with special arrangements for clinical governance, consent and audit or research. 1.3 Clinicians wishing to do low-energy CXB in patients for whom surgery is considered suitable, but who choose not to have an operation, should take the following actions:

	• Inform the clinical governance leads in their NHS trusts. • Ensure that patients and their carers understand the alternative options for treatment and the uncertainty about this procedure's efficacy and provide them with clear written information. In addition, the use of NICE's information for the public is recommended. 1.4 Patient selection should be done by a colorectal cancer multidisciplinary team, including a clinical oncologist and a colorectal surgeon with expertise in local excision techniques. 1.5 Clinicians should enter details about all patients having low-energy CXB for early-stage rectal cancer onto the contact X-ray brachytherapy database. Clinical outcomes should also be reviewed locally. 1.6 NICE encourages further research into low-energy CXB for early-stage rectal cancer. Research should clearly describe details of patient selection and treatment intent. It should document adjunctive treatments and subsequent procedures. 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** Low-energy CXB for rectal cancer is usually delivered in a day-care setting. The patient is given an enema before treatment, to clear the bowel. Local anaesthesia and glyceryl trinitrate are applied to the anal sphincter to numb the area and relax the sphincter muscles. A sigmoidoscope is inserted to check the size and position of the tumour. A rigid endorectal treatment applicator is then inserted and placed in contact with the tumour. A contact X-ray tube is introduced into the applicator. The tube emits low-energy X-rays that only penetrate a few millimetres. This minimises damage to deeper tissues that are not involved in the cancer. If the tumour does not respond to low-energy CXB, or recurs after treatment, surgery may be performed.
Medical Technologies Guidance	**UroLift for treating lower urinary tract symptoms of benign prostatic hyperplasia MTG26** **Recommendations** 1.1 The clinical case for adopting the UroLift system for treating lower urinary tract symptoms of benign prostatic hyperplasia is supported by the evidence. The UroLift system relieves lower urinary tract symptoms while avoiding the risk to sexual function associated with transurethral resection of the prostate (TURP) and holmium laser enucleation of the prostate (HoLEP). Using the system reduces the length of a person's stay in hospital. It can also be used in a day-surgery unit. 1.2 The UroLift system should be considered as an alternative to current surgical procedures for use in a day-case setting in men with lower urinary tract symptoms of benign prostatic hyperplasia who are aged 50 years and older and who have a prostate of less than 100 ml without an obstructing middle lobe. 1.3 The primary cost drivers in the model were the cost of each implant and the number of implants used per treatment (the modelling assumed 4). Compared with monopolar and bipolar transurethral resection of the prostate (done as an inpatient procedure, which is most common), using the UroLift system in a day-surgery unit results in cost savings of around £286 and £159 per patient. There was uncertainty over the procedure duration in the model, but this made little difference to the cost case. **The technology** The UroLift system (NeoTract) is used to perform a prostatic urethral lift, a procedure that is an alternative to current standard surgical interventions such as transurethral resection of the prostate (TURP) and holmium laser enucleation (HoLEP). The UroLift system uses adjustable, permanent implants to pull excess prostatic tissue away so that it does not narrow or block the urethra. In this way, the device is designed to relieve symptoms of urinary outflow obstruction without cutting or removing tissue. The UroLift system comprises 2 single-use components: a delivery device and an implant. The delivery device consists of a hand-held pistol grip to which a needle-shaped probe is attached. Each UroLift implant consists of a superelastic nitinol capsular tab, a

polyethylene terephthalate monofilament, and a stainless steel urethral end-piece. A surgeon inserts the probe into the urethra until it reaches the prostatic urethra (the widest part of the urethral canal); a fine needle at the end of the probe deploys and secures an implant in a lobe of the prostate. One end of the implant is anchored in the urethra and the other is attached to the firm outer surface of the prostatic capsule, so pulling the prostatic lobe away from the urethra.

Financial Factors

The NICE costing statement for this guidance states that it is unlikely that the guidance will result in a significant change in resource use in the NHS. The key driver of the costs with the UroLift system is the number of devices used (implants) per procedure. Based on the economic model submitted by the company, each procedure needs 4 devices and at a cost of £330 each, the total cost per procedure is £1,320. The cost of the procedure in the economic model were closely aligned with the comparator treatments of TURP, HoLEP and Bi-TURP.

Virtual Touch Quantification to diagnose and monitor liver fibrosis in chronic hepatitis B and C MTG27

Recommendations

1.1 The case for adopting Virtual Touch Quantification (VTq) software to diagnose and monitor liver fibrosis is supported by the evidence. VTq is as accurate as transient elastography in diagnosing and staging liver fibrosis, and may offer other benefits in terms of imaging the liver and sampling selected areas to assess fibrosis and identify associated pathologies. By avoiding liver biopsies, it may also benefit people whose liver fibrosis needs monitoring. Cost savings through adopting VTq will be greater in hospitals in which liver biopsy is the primary method for diagnosing and monitoring liver fibrosis.

1.2 VTq should be considered as an option for people with chronic hepatitis B or C who need assessment of liver fibrosis.

1.3 Cost modelling suggests that using VTq is cost saving compared with transient elastography and liver biopsy, whether or not a compatible Siemens ultrasound machine needs to be purchased. Compared with transient elastography, the estimated overall cost saving for VTq is around £53 per person. This saving assumes that 10% of the ultrasound machine capacity would be used for VTq measurements, leaving 90% to be applied to other uses. Compared with liver biopsy, the corresponding saving is around £434 per person.

The technology

The VTq investigation comprises multiple measurements and is both non-invasive and painless.

The VTq software application uses acoustic radiation force impulse (ARFI) imaging technology to measure the elasticity of liver tissue. VTq is used in combination with a Siemens Acuson S2000 or S3000 ultrasound platform. Liver tissue can be damaged by inflammation, causing high levels of collagen to be deposited in the liver cells (fibrosis), which become stiff. ARFI imaging involves generating a shear wave by applying an acoustic 'push pulse' lateral to the area of interest identified during a conventional ultrasound scan. The speed of the shear wave is proportional to the stiffness of the tissue.

Financial Factors

The cost of the VTq software stated in the company's submission is £4,415. A compatible Siemens Acuson S2000 ultrasound system costs from £50,000 with annual maintenance costs, starting in year 2, from £2,000. The cost varies with the system configuration; the cost model includes typical values of £59,700 for the ultrasound system and £2,246 for the annual maintenance costs. All costs are excluding VAT.

According to the NICE costing statement for this technology for commissioners, increased use of VTq instead of transient elastography will mean little resource impact because VTq and TE come under the same Payments by Results tariff. However, using VTq may help reduce costs for surveillance ultrasound in people with chronic hepatitis. Using VTq instead of biopsy will also achieve savings.

Diagnostics Guidance	**None published so far this month**
NICE Quality Standards	**Secondary prevention after a myocardial infarction QS99** This quality standard covers secondary prevention after a myocardial infarction (MI), including cardiac rehabilitation, in adults (aged 18 years and over). It does not cover the diagnosis and management of myocardial infarction, which is covered by the quality standard on acute coronary syndromes (including myocardial infarction). In addition to the areas covered by this quality standard, the Quality Standards Advisory Committee identified the prescribing of high-dose high-intensity statins for secondary prevention as an area for quality improvement. The quality standard on cardiovascular risk assessment and lipid modification has a statement about this, which should be referred to for full details. Coronary revascularisation was also identified as an area for quality improvement; this area is covered in the quality standard on acute coronary syndromes (including myocardial infarction). **List of quality statements** Statement 1. Adults admitted to hospital with a myocardial infarction (MI) have an assessment of left ventricular function before discharge. Statement 2. Adults admitted to hospital with an MI are referred for cardiac rehabilitation before discharge. Statement 3. Adults admitted to hospital with an MI have the results of investigations and a plan for future treatment and monitoring shared with their GP. Statement 4. Adults referred to a cardiac rehabilitation programme after an MI have an assessment appointment within 10 days of discharge from hospital. Statement 5 (developmental). Adults referred to a cardiac rehabilitation programme after an MI are offered sessions during and outside working hours and the choice of undertaking the programme at home, in the community or in a hospital setting. **Cardiovascular risk assessment and lipid modification QS100** This quality standard covers identifying and assessing cardiovascular risk, and lipid modification for preventing cardiovascular disease, in adults (aged 18 years and over). **List of quality statements** Statement 1. Adults under 85 years with an estimated increased risk of cardiovascular disease (CVD) are offered a full formal risk assessment using the QRISK2 tool. Statement 2. Adults with a 10-year risk of CVD of 10% or more are assessed for secondary causes before any offer of statin therapy. Statement 3. Adults with a 10-year risk of CVD of 10% or more receive advice on lifestyle changes before any offer of statin therapy. Statement 4. Adults with a 10-year risk of CVD of 10% or more for whom lifestyle changes are ineffective or inappropriate, discuss the risks and benefits of starting statin therapy with their healthcare professional. Statement 5. Adults choosing statin therapy for the primary prevention of CVD are offered atorvastatin 20 mg. Statement 6. Adults with newly diagnosed CVD are offered atorvastatin 80 mg. Statement 7. Adults on a high-intensity statin who have side effects are offered a lower dose or an alternative statin.

	Statement 8. Adults on a high-intensity statin have a repeat measurement of lipids and liver transaminases after 3 months of treatment. Statement 9 (placeholder). Identifying people with an estimated increased risk.
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
Community engagement (update): draft guideline consultation	12/08/2015	24/09/2015
Healthcare-associated infections: quality standard consultation	28/08/2015	25/09/2015
Irritable bowel syndrome in adults: quality standard consultation	28/08/2015	25/09/2015
Radiofrequency ablation for symptomatic interdigital (Morton's) neuroma: consultation	28/08/2015	25/09/2015
Transapical transcatheter mitral valve-in-valve implantation for a failed surgically implanted mitral valve bioprosthesis in patients for whom open surgical valve implantation is unsuitable: consultation	28/08/2015	25/09/2015
Rheumatoid arthritis (standing committee A update): addendum consultation	01/09/2015	29/09/2015
Myeloma: draft guideline consultation	19/08/2015	01/10/2015
Breast cancer QS (update): topic engagement	18/09/2015	02/10/2015
Stroke (quality standards update): quality standard consultation	07/09/2015	05/10/2015
Gastric cancer (metastatic) - ramucirumab (after chemotherapy) [ID741]: appraisal consultation	15/09/2015	06/10/2015
Multiple myeloma - panobinostat (post 1 prior therapy) [ID663]: appraisal consultation	15/09/2015	06/10/2015
Home care: topic engagement	23/09/2015	08/10/2015
Idiopathic pulmonary fibrosis - nintedanib [ID752]: appraisal consultation	11/09/2015	09/10/2015
Motor Neurone Disease: draft guideline consultation	01/09/2015	13/10/2015
Motor neurone disease: topic engagement	01/09/2015	13/10/2015
Upper aerodigestive tract cancer: draft guideline consultation	03/09/2015	15/10/2015
Chronic heart failure in adults: quality standard consultation	17/09/2015	15/10/2015
Workplace health - older employees: draft guideline consultation	18/09/2015	19/10/2015
Antimicrobial resistance - changing risk-related behaviours in the general population: draft guideline consultation	08/09/2015	20/10/2015
Transition from children's to adults' services: draft guideline consultation	10/09/2015	22/10/2015

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