NICE Update Bulletin May 2016
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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)	**Cabazitaxel for hormone-relapsed metastatic prostate cancer treated with docetaxel TA391** **Recommendations** 1.1 Cabazitaxel in combination with prednisone or prednisolone is recommended as an option for treating metastatic hormone-relapsed prostate cancer in people whose disease has progressed during or after docetaxel chemotherapy, only if: • the person has an eastern cooperative oncology group (ECOG) performance status of 0 or 1 • the person has had 225 mg/m2 or more of docetaxel • treatment with cabazitaxel is stopped when the disease progresses or after a maximum of 10 cycles (whichever happens first) • NHS trusts purchase cabazitaxel in pre-prepared intravenous-infusion bags, not in vials, and • the company provides cabazitaxel with the discount agreed in the patient access scheme. 1.2 When using ECOG performance status, healthcare professionals should take into account any physical, sensory or learning disabilities, or communication difficulties that could affect ECOG performance status and make any adjustments they consider appropriate. 1.3 This guidance is not intended to affect the position of patients whose treatment with cabazitaxel was started within the NHS before this guidance was published and whose treatment with cabazitaxel is not recommended in this NICE guidance. Treatment of those patients may continue without change to whatever funding arrangements were in place for them before this guidance was published until they and their NHS clinician consider it appropriate to stop. **The technology** Cabazitaxel (Jevtana, Sanofi) is an antineoplastic drug in a class of drugs known as taxanes, which includes paclitaxel and docetaxel. Taxanes disrupt the microtubular network essential for mitotic and interphase cellular functions, therefore inhibiting cell division and causing cell death. Cabazitaxel has a UK marketing authorisation for use 'in combination with prednisone or prednisolone for the treatment of patients with hormone refractory metastatic prostate cancer previously treated with a docetaxel-containing regimen'. It is administered by intravenous infusion. **Financial factors** This technology is commissioned by NHS England. Cabazitaxel has been available under the Cancer Drugs Fund (CDF) since April 2013. It is anticipated that there will be no significant change in overall NHS spending because the guidance results in funding for cabazitaxel moving from the CDF into routine commissioning.

	Canagliflozin, dapagliflozin and empagliflozin as monotherapies for treating type 2 diabetes TA390 **Recommendations** 1.1 Canagliflozin, dapagliflozin and empagliflozin as monotherapies are recommended as options for treating type 2 diabetes in adults for whom metformin is contraindicated or not tolerated and when diet and exercise alone do not provide adequate glycaemic control, only if: • a dipeptidyl peptidase-4 (DPP-4) inhibitor would otherwise be prescribed and • a sulfonylurea or pioglitazone is not appropriate. 1.2 Adults whose treatment with canagliflozin, dapagliflozin or empagliflozin as monotherapy 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 technologies** Canagliflozin (Invokana, Janssen), dapagliflozin (Forxiga, AstraZeneca) and empagliflozin (Jardiance, Boehringer Ingelheim and Lilly UK) are all selective sodium-glucose cotransporter 2 (SGLT-2) inhibitors, which block the reabsorption of glucose in the kidneys and promote excretion of excess glucose in the urine. Through this mechanism these drugs may help control glycaemia independently of insulin pathways. They all have UK marketing authorisations for treating type 2 diabetes to improve glycaemic control in adults: • as monotherapy: when diet and exercise alone do not provide adequate glycaemic control in people for whom the use of metformin is considered inappropriate due to intolerance or contraindications • as add-on combination therapy: with other glucose–lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control. **Financial factors** These technologies are commissioned by CCGs. It is unlikely that the guidance will result in a significant change in resource use in the NHS because the cost of the new technologies (SGLT-2 inhibitors) and existing technologies (DPP-4 inhibitors) is similar. **Donepezil, galantamine, rivastigmine and memantine for the treatment of Alzheimer's disease TA217 (update)** **May 2016:** This guidance has been partially updated by the NICE guideline on dementia.
Highly specialised technology guidance (HSTs)	**None published so far this month**
NICE Guidelines (NGs)	**Haematological cancers: improving outcomes NG47** This guideline covers integrated diagnostic reporting for diagnosing haematological cancer in adults, young people and children. It also covers staffing, facilities (levels of care) and multidisciplinary teams needed for adults and young people. It aims to improve care for people with suspected or diagnosed cancer by promoting best practice on the organisation of haematological cancer services. **This guideline includes recommendations on:** • integrated diagnostic reporting

	• staffing • isolation facilities • ambulatory care • multidisciplinary teams **Tuberculosis NG33 (update)** This guideline covers preventing, identifying and managing latent and active tuberculosis (TB) in children, young people and adults. It aims to improve ways of finding people who have TB in the community and recommends that everyone under 65 with latent TB should be treated. It describes how TB services should be organised, including the role of the TB control board. **May 2016:** Recommendation 1.2.1.1 was clarified to reflect the sequencing of tests. Reference to IGRA status was removed from recommendations 1.1.3.13; 1.1.3.16-18; 1.1.4.6; 1.1.4.8 and 1.6.1.4. **Psychosis and schizophrenia in children and young people: recognition and management CG155 (update)** This guideline covers recognising and managing psychosis and schizophrenia in children and young people. It aims to improve early recognition of psychosis and schizophrenia so that children and young people can be offered the treatment and care they need to live with the condition. **May 2016:** A new recommendation was added on providing information about olanzapine when choosing antipsychotic medication for children and young people with a first episode of psychosis. **Crohn's disease: management CG152 (update)** This guideline covers the management of Crohn's disease in children, young people and adults. It aims to reduce people's symptoms and maintain or improve their quality of life. **May 2016:** A new recommendation on inducing remission was added. **Jaundice in newborn babies under 28 days CG98 (update)** This guideline covers diagnosing and treating jaundice, which is caused by increased levels of bilirubin in the blood, in newborn babies (neonates). It aims to help detect or prevent very high levels of bilirubin, which can be harmful if not treated. **May 2016:** New recommendations were added on measuring and monitoring bilirubin levels and the type of phototherapy to use. **Dementia: supporting people with dementia and their carers in health and social care CG42 (update)** This guideline covers preventing, diagnosing, assessing and managing dementia in health and social care, and includes recommendations on Alzheimer's disease. It aims to improve care for people with dementia by promoting accurate diagnosis and the most effective interventions, and improving the organisation of services. **May 2016:** Recommendation 1.6.2.3 on prescribing medicines for Alzheimer's disease was reviewed and partially updated.
Interventional Procedures Guidance (IPGs)	**Transcutaneous electrical stimulation of the supraorbital nerve for treating and preventing migraine IPG559** **Recommendations** 1.1 Current evidence on transcutaneous electrical stimulation of the supraorbital nerve for treating and preventing migraine raises no major safety concerns. The evidence on efficacy is limited in quantity and quality. Therefore, this procedure should only be used with **special arrangements** for clinical governance, consent and audit or research.

1.2 Clinicians wishing to offer transcutaneous electrical stimulation of the supraorbital nerve for treating and preventing migraine 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 transcutaneous electrical stimulation of the supraorbital nerve for treating and preventing migraine (see section 7.2).

1.3 Patient selection should normally be done by clinicians in specialist headache clinics.

1.4 NICE encourages further research on transcutaneous electrical stimulation of the supraorbital nerve for treating and preventing migraine. Data should be collected for all patients not entered into controlled trials. Studies should describe clearly whether the procedure is used for treatment or prevention. They should include details of patient selection and the dose and frequency of use. Outcome measures should include the number and severity of migraine episodes, quality of life in the short and long term and any changes in medication. The development of any complications after starting treatment should be documented. NICE may update the guidance on publication of further evidence.

The procedure

Transcutaneous supraorbital nerve stimulation uses small electrical currents to stimulate the supraorbital nerve. It aims to relieve headache and, when used regularly, to reduce the severity and the frequency of migraine attacks.

Therapy is administered by the patient, using a small battery-operated device (a headband with a central button) connected to a self-adhesive electrode patch applied to the forehead above the eyebrows. When the device is activated, small electrical impulses stimulate the supraorbital nerves (branches of the ophthalmic nerve, the first division of the trigeminal nerve). The intensity of the electrical pulses increases periodically and this can be adjusted by the patient. Stimulation is applied for approximately 20 minutes daily.

The device can be used to treat acute migraine attacks and for prophylaxis between attacks.

Biodegradable subacromial spacer insertion for rotator cuff tears IPG558

Recommendations

1.1 Current evidence on the efficacy and safety of biodegradable subacromial spacer insertion for rotator cuff tears is limited in quantity and quality. Therefore, this procedure should only be used in the context of **research**.

1.2 Further research may include collaborative data collection and clinical trials. Patient selection should be clearly documented. Outcomes of interest include measures of shoulder function, pain relief and quality of life. All complications should be reported. Follow-up should ideally be for a minimum of 2 years.

The procedure

Biodegradable subacromial spacer insertion aims to improve pain symptoms and restore shoulder function in patients who have irreparable rotator cuff tears. The intention is to reduce subacromial friction by lowering the humeral head during shoulder abduction. It aims to be a less invasive and potentially safer alternative to tendon transfer or shoulder arthroplasty, with shorter procedure and rehabilitation times.

Biodegradable subacromial spacer insertion is done with the patient under general or regional anaesthesia. The subacromial space is visualised using either arthroscopy or minimal access open surgery. A surgical clearance of the damaged area is carried out. Measurements are made to determine the required size of the biodegradable spacer. The balloon-like spacer is then inserted into the subacromial space and inflated with saline solution. Once sufficient volume is reached, the balloon is sealed and left in situ.

	The balloon spacer is made from a biodegradable polymer and resorbs over a period of about 1 year. **Endovenous mechanochemical ablation for varicose veins IPG557** **Recommendations** 1.1 Current evidence on the safety and efficacy of endovenous mechanochemical ablation for varicose veins appears adequate to support the use of this procedure provided that **standard arrangements** are in place for consent, audit and clinical governance. Clinicians are encouraged to collect longer-term follow-up data. This replaces previous guidance on endovenous mechanochemical ablation for varicose veins (interventional procedure guidance 435). **The procedure** Endovenous mechanochemical ablation for varicose veins combines mechanical ablation with the use of sclerosing agents to close veins without the need for tumescent anaesthesia (infusion of a large volume of dilute local anaesthetic around and along the entire length of vein to be treated). The procedure is carried out using local anaesthesia at the catheter insertion site. Ultrasound imaging is used to identify the target vein, its diameter and the length of the section of vein to be treated. An infusion catheter with a motor drive is introduced percutaneously into the distal end of the target vein and, in the case of the great saphenous vein, the catheter tip is advanced to the saphenofemoral junction. A dispersion wire that extends through the catheter lumen is rotated to damage the epithelium and a sclerosant is infused simultaneously as the catheter is slowly pulled back through the vein. Patients are advised to wear compression stockings for about 2 weeks after the procedure.
Medical Technologies Guidance	**None published so far this month**
Diagnostics Guidance	**ImmunoCAP ISAC 112 and Microtest for multiplex allergen testing DG24** **Recommendations** 1.1 There is currently insufficient evidence to recommend the routine adoption of multiplex allergen testing, ImmunoCAP ISAC 112 or Microtest, to help diagnose allergy and predict the risk of an allergic reaction in people with allergy that is difficult to diagnose, when used with standard clinical assessment. 1.2 The ImmunoCAP ISAC 112 shows promise and further research is recommended on the clinical effectiveness of using it in people with allergy that is difficult to diagnose (see section 6.1). 1.3 Microtest is a new technology and further research by the company to show its clinical effectiveness is encouraged. 1.4 An allergy healthcare professional with appropriate expertise is needed to ensure the results of multiplex allergen tests are interpreted correctly. **PlGF-based testing to help diagnose suspected pre-eclampsia (Triage PlGF test, Elecsys immunoassay sFlt-1/PlGF ratio, DELFIA Xpress PlGF 1-2-3 test, and BRAHMS sFlt-1 Kryptor/BRAHMS PlGF plus Kryptor PE ratio) DG23** **Recommendations** 1.1 The Triage PlGF test and the Elecsys immunoassay sFlt-1/PlGF ratio, used with standard clinical assessment and subsequent clinical follow-up, are recommended to help rule-out pre-eclampsia in women presenting with suspected pre-eclampsia between 20 weeks and 34 weeks plus 6 days of gestation. When pre-eclampsia is not ruled-out using a PlGF-based test result, the result should not be used to diagnose (rule-in) pre-eclampsia.

	1.2 The Triage PlGF test and the Elecsys immunoassay sFlt-1/PlGF ratio, used with standard clinical assessment and subsequent clinical follow-up, show promise in helping to diagnose (rule-in) pre-eclampsia in women presenting with suspected pre-eclampsia between 20 weeks and 34 weeks plus 6 days of gestation. However, there is currently insufficient evidence to recommend their routine adoption for diagnosing pre-eclampsia in the NHS (see text box). Further research is recommended on using these tests in women with suspected pre-eclampsia to rule-in pre-eclampsia (see section 6.2). 1.3 The DELFIA Xpress PlGF 1-2-3 test and BRAHMS sFlt-1 Kryptor/BRAHMS PlGF plus Kryptor PE ratio are not recommended for routine adoption in the NHS. Further research by the companies is needed to show the clinical effectiveness of these tests, including diagnostic accuracy and analytical validity. This guidance only considers using PlGF-based testing to help diagnose suspected pre-eclampsia. NICE is aware of ongoing research linking low PlGF levels and high sFlt-1/PlGF ratios (positive test results) with placental disease, but placental disease is beyond the scope of this guidance. Therefore, the recommendations in this guidance do not consider using PlGF-based testing for conditions other than suspected pre-eclampsia and this guidance is not intended to give advice on diagnosing or managing placental disease. If placental disease is suspected, additional clinical surveillance may be needed.
NICE Quality Standards	**None published so far this month**
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
Autism spectrum disorder in under 19s: support and management : Surveillance consultation	18/05/2016	01/06/2016
Sickle cell disease: managing acute painful episodes in hospital : Surveillance consultation	19/05/2016	02/06/2016
Head and neck cancer : Topic engagement	20/05/2016	03/06/2016
Nivolumab for previously treated locally advanced or metastatic non-squamous non-small-cell lung cancer [ID900] : Appraisal consultation	12/05/2016	03/06/2016
Heavy menstrual bleeding (standing committee update) : Addendum consultation	12/05/2016	10/06/2016
Fertility (standing committee update) : Addendum consultation	12/05/2016	10/06/2016
Breast cancer (HER2 positive) - pertuzumab (neoadjuvant) [ID767] : Appraisal consultation	20/05/2016	13/06/2016
Increasing the uptake of HIV testing among people at higher risk of exposure : Draft guidance consultation	03/05/2016	15/06/2016
Supporting decision making for people who may lack capacity : Draft scope consultation	18/05/2016	15/06/2016
Brain tumours (primary) and brain metastases in adults : Draft scope consultation	18/05/2016	16/06/2016
Glaucoma: diagnosis and management (update) : Draft scope consultation	19/05/2016	16/06/2016
Lung cancer (non-small-cell, metastatic, squamous, untreated) - necitumumab [ID835] : Appraisal consultation	26/05/2016	17/06/2016
Endoscopic transluminal pancreatic necrosectomy : Interventional procedure consultation	20/05/2016	20/06/2016
Extracorporeal shockwave therapy for Achilles tendinopathy : Interventional procedure consultation	20/05/2016	20/06/2016
Severe mental illness and substance misuse (dual diagnosis) - community health and social care services : Draft guidance consultation	12/05/2016	23/06/2016
Children's attachment : Quality Standard consultation	21/05/2016	23/06/2016
Early and locally advanced breast cancer (update) : Draft scope consultation	26/05/2016	24/06/2016
Single-incision short sling (mesh) insertion for stress urinary incontinence in women : Interventional procedure consultation	26/05/2016	24/06/2016
Physical health of people in prison : Draft guidance consultation	16/05/2016	27/06/2016

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