NICE Update Bulletin November 2016
issued Wednesday 23rd November 2016

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)	**Nivolumab for previously treated advanced renal cell carcinoma TA417** **Recommendations** 1.1 Nivolumab is recommended, within its marketing authorisation, as an option for previously treated advanced renal cell carcinoma in adults, when the company provides nivolumab with the discount agreed in the patient access scheme. **The technology** Nivolumab (Opdivo, Bristol–Myers Squibb) is a human monoclonal antibody that blocks an immune checkpoint protein receptor called programmed cell death protein 1 (PD-1) to promote an anti-tumour response. Nivolumab as monotherapy is indicated for the treatment of advanced renal cell carcinoma after prior therapy in adults. Before the marketing authorisation was granted (April 2016), nivolumab was available in the NHS through the early access to medicines scheme. **Financial factors** This technology is commissioned by NHS England. Nivolumab provides an option for previously treated advanced renal cell carcinoma in adults at second line or third line. The current treatment options are axitinib or best supportive care from routine commissioning or everolimus available via the Cancer drugs fund (CDF). Before the marketing authorisation was granted (May 2016), nivolumab was available in the NHS through the early access to medicines scheme. Because nivolumab was made available in the NHS through the early access to medicines scheme, NHS England has indicated that this guidance will be implemented 30 days after final publication. **Dapagliflozin in triple therapy for treating type 2 diabetes TA418** **Recommendations** 1.1 Dapagliflozin in a triple therapy regimen is recommended as an option for treating type 2 diabetes in adults, only in combination with metformin and a sulfonylurea. 1.2 This guidance is not intended to affect the position of patients whose treatment with dapagliflozin in other triple therapy regimens was started within the NHS before this guidance was published. 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** Dapagliflozin (Forxiga, AstraZeneca) is a selective sodium–glucose cotransporter 2 (SGLT-2) inhibitor, which blocks the reabsorption of glucose in the kidneys and promotes excretion of excess glucose in the urine. Dapagliflozin has a UK marketing authorisation for treating type 2 diabetes mellitus to improve glycaemic control in adults: • as monotherapy: when diet and exercise alone do not provide adequate glycaemic control in people for whom 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

This technology is commissioned by CCGs. NICE does not expect this guidance to have an impact on resources because the technology is an option alongside current standard treatment options and the drugs are similarly priced.

Dapagliflozin in combination therapy for treating type 2 diabetes TA288 (update)

November 2016: Recommendation 1.3 was replaced by NICE technology appraisal guidance on dapagliflozin in triple therapy for treating type 2 diabetes (November 2016) – see above.

Apremilast for treating moderate to severe plaque psoriasis TA419

This guidance replaces NICE TA368 on apremilast for treating moderate to severe plaque psoriasis.

Recommendations

1.1 Apremilast is recommended as an option for treating chronic plaque psoriasis in adults whose disease has not responded to other systemic therapies, including ciclosporin, methotrexate and PUVA (psoralen and ultraviolet‑A light), or when these treatments are contraindicated or not tolerated, only if:

- the disease is severe, as defined by a total Psoriasis Area Severity Index (PASI) of 10 or more and a Dermatology Life Quality Index (DLQI) of more than 10
- treatment is stopped if the psoriasis has not responded adequately at 16 weeks; an adequate response is defined as:
  - a 75% reduction in the PASI score (PASI 75) from when treatment started or
  - a 50% reduction in the PASI score (PASI 50) and a 5-point reduction in DLQI from start of treatment
- the company provides apremilast with the discount agreed in the patient access scheme.

1.2 When using the DLQI, healthcare professionals should take into account any physical, sensory or learning disabilities, or communication difficulties, that could affect the responses to the DLQI and make any adjustments they consider appropriate.

1.3 This guidance is not intended to affect the position of patients whose treatment with apremilast was started within the NHS before this guidance was published. 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

Apremilast (Otezla, Celgene) is a small-molecule inhibitor of phosphodiesterase 4 (PDE4). Apremilast down-regulates the inflammatory response by modulating the expression of cytokines and mediators associated with psoriasis (including tumour necrosis factor [TNF]‑alpha and interleukin [IL]‑23).

It has a marketing authorisation 'for the treatment of moderate to severe chronic plaque psoriasis in adult patients who failed to respond to or who have a contraindication to, or are intolerant to other systemic therapy including ciclosporin, methotrexate or psoralen and ultraviolet‑A light (PUVA)'.

Financial factors

This technology is commissioned by CCGs.

Highly specialised technology guidance (HSTs)	**None published so far this month**
NICE Guidelines (NGs)	**Physical health of people in prison NG57** This guideline covers assessing, diagnosing and managing physical health problems of people in prison. It aims to improve health and wellbeing in the prison population by promoting more coordinated care and more effective approaches to prescribing, dispensing and supervising medicines. This guideline includes recommendations on assessing a person's health when they come into prison, managing and supervising medicines, promoting health and wellbeing in prison and how to manage health emergencies and support people with rapidly deteriorating health. Recommendations on ongoing mental health care will be included in NICE's guideline on mental health of adults in contact with the criminal justice system, due to publish in February 2017. **Diabetes (type 1 and type 2) in children and young people: diagnosis and management NG18 (update)** This guideline covers the diagnosis and management of type 1 and type 2 diabetes in children and young people aged under 18. The guideline recommends strict targets for blood glucose control to reduce the long-term risks associated with diabetes. **November 2016:** recommendations 1.2.115 and 1.3.52 were amended to add information on when eye screening should begin and referral for eye screening should happen. **Intrapartum care for healthy women and babies CG190 (update)** This guideline covers the care of healthy women and their babies during labour and immediately after the birth. It helps women to make an informed choice about where to have their baby. It also aims to reduce variation in areas of care such as fetal monitoring during labour and management of the third stage of labour. **November 2016:** NICE reviewed the evidence on the effectiveness of midwife-led continuity models and other models of care, and deleted a recommendation about team midwifery. **Hypertension in adults: diagnosis and management CG127 (update)** This guideline covers identifying and treating primary hypertension (high blood pressure) in people aged 18 and over. It aims to reduce the risk of cardiovascular problems such as heart attacks and strokes by helping healthcare professionals to diagnose hypertension accurately and treat it effectively. It also aims to reduce unnecessary treatment by improving the way blood pressure is measured. **November 2016:** a footnote about 2 MHRA drug safety alerts was added to recommendations in section 1.6 covering angiotensin-converting enzyme (ACE) inhibitors. These alerts cover ACE inhibitor use during pregnancy and breastfeeding. The following updated NICE Guidelines were published at the end of October, after publication of the October bulletin: **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.

	October 2016: Recommendation 1.3.19 and Table 1 were updated to remove reference to hip circumference percentile charts. A new recommendation has been added on providing information about olanzapine when choosing antipsychotic medication for children and young people with a first episode of psychosis. The evidence has been reviewed and no change made to the recommended action in 1 recommendation on choosing antipsychotic medication for children and young people with a first episode of psychosis.
Interventional Procedures Guidance (IPGs)	**Endoscopic transluminal pancreatic necrosectomy IPG567** **This guidance replaces NICE IPG411 on endoscopic transluminal pancreatic necrosectomy.** **Recommendations** 1.1 Current evidence on the safety of endoscopic transluminal pancreatic necrosectomy shows that there are serious but well-recognised complications. Evidence on efficacy is adequate to support the use of this procedure provided that **standard arrangements** are in place for clinical governance, consent and audit. 1.2 Patient selection should be done by a multidisciplinary team experienced in the management of the condition. 1.3 Endoscopic transluminal pancreatic necrosectomy should only be done in a specialist centre by a team experienced in the management of complex pancreatic disease. **The procedure** The usual surgical treatment for pancreatic necrosis is open or keyhole surgery to remove the dead tissue. In some patients, fluid collects that needs to be drained using an endoscope. NICE has looked at using endoscopic transluminal pancreatic necrosectomy as another treatment option. The aim of this procedure is to avoid open or keyhole surgery and the complications associated with them. This procedure is done using a general anaesthetic or sedation. An endoscope and surgical instruments are inserted through the mouth and into the stomach. The stomach is inflated using carbon dioxide. A small cut is made in the wall of the stomach and the opening is held open with a balloon. The instruments are passed through into the area of dead tissue. Fluid is drained and the dead tissue is removed. A stent may be left in place in the stomach wall to help further drainage. The procedure usually needs to be repeated, and other treatments may also be needed. **Percutaneous insertion of craniocaudal expandable implants for vertebral compression fracture IPG568** **Recommendations** 1.1 The evidence on percutaneous insertion of craniocaudal expandable implants for vertebral compression fracture raises no major safety concerns. Evidence on its efficacy is adequate. Therefore, this procedure may be used provided that **standard arrangements** are in place for clinical governance, consent and audit. 1.2 Patient selection and treatment should be done by a specialist multidisciplinary team that includes a radiologist and a spinal surgeon. 1.3 The procedure should be limited to patients whose pain is refractory to more conservative treatment. **The procedure** A vertebral compression fracture is a type of break in a bone in the spine in which the broken bone collapses. It can be caused by trauma, cancer or osteoporosis (thinning of the bones). Pain is the most common symptom. Initial treatment is conservative and includes pain killers and bed rest, and back braces to limit movement in the spine. People who still have pain after conservative treatment may need surgery to improve the structure of the spine.

	The aim of inserting a percutaneous craniocaudal expandable implant for a vertebral compression fracture is to strengthen the bone and increase its height, increase mobility and relieve pain. The implant is inserted with the patient lying on their front, and using a general, regional or local anaesthetic. An unexpanded implant is placed inside the affected level in the spine using x-ray guidance. It is then expanded with special instruments to restore the vertebral height. Bone cement is then injected into and around the implant. **Single-anastomosis duodeno-ileal bypass with sleeve gastrectomy for treating morbid obesity IPG569** **Recommendations** 1.1 Current evidence on the safety of single-anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S) for treating morbid obesity shows that there are well-recognised complications. Evidence on efficacy is limited in both quality and 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 SADI-S for treating morbid obesity should: • Inform the clinical governance leads in their NHS trusts. • Ensure that patients 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. 1.3 Clinicians should review local clinical outcomes and enter details about all patients having SADI-S for treating morbid obesity onto the National Bariatric Surgery Registry. 1.4 Patient selection should be done by a multidisciplinary team experienced in managing morbid obesity. 1.5 Treatment should be done by surgeons with specific training in the procedure, in centres with expertise in the treatment of morbid obesity. 1.6 NICE encourages further research into SADI-S for treating morbid obesity, particularly research examining long-term outcomes. NICE may update the guidance on publication of further evidence. **The procedure** Somebody has morbid obesity if their body mass index (BMI) is 40 or more, or if their BMI is 35 to 40 and they have significant health problems related to the obesity. People with morbid obesity are more likely to have other health problems like type 2 diabetes, coronary heart disease and high blood pressure. Weight loss reduces the risk of getting these conditions and also improves long-term survival. Morbid obesity is managed by lifestyle changes, including exercise and diet, and medication to reduce weight. If these don't work, then weight loss (bariatric) surgery is sometimes used. NICE has looked at using single-anastomosis duodenal-ileal bypass with sleeve gastrectomy as another surgical treatment option. Single-anastomosis duodeno-ileal bypass with sleeve gastrectomy for treating morbid obesity is usually done under a general anaesthetic by keyhole (laparoscopic) surgery. It involves 2 steps. First, a gastric sleeve is made by removing some of the stomach to make it smaller and into a tube shape. Then, the first part of the small intestine is shortened and joined to the last part of the small intestine. The procedure is permanent. Sometimes, the steps are done in 2 separate operations. The aim is to reduce the size of the stomach and small intestine to reduce the amount of food that is absorbed into the body. After surgery, patients have to eat a low-calorie diet. Multivitamins, calcium and iron supplements are prescribed when needed.
Medical Technologies Guidance	**None published so far this month**

Diagnostics Guidance	**High-throughput non-invasive prenatal testing for fetal RHD genotype DG25** **Recommendations** 1.1 High-throughput non-invasive prenatal testing (NIPT) for fetal RHD genotype is recommended as a cost-effective option to guide antenatal prophylaxis with anti-D immunoglobulin, provided that the overall cost of testing is £24 or less. This will help reduce unnecessary use of a blood product in pregnant women, and conserve supplies by only using anti-D immunoglobulin for those who need it. 1.2 Cost savings associated with high-throughput NIPT for fetal RHD genotype are sensitive to the unit cost of the test, additional pathway costs and implementation costs. Trusts adopting NIPT should collect and monitor the costs and resource use associated with implementing testing to ensure that cost savings are achieved. **Financial factors** This technology is commissioned by CCGs. Implementation of the guidance may lead to a reduction in drug and test costs for the provider.
NICE Quality Standards	**None published so far this month**

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Current NICE consultations with links and end dates for stakeholders to contribute

Title / link	End date of consultation
Irritable bowel syndrome in adults: diagnosis and management : Surveillance consultation	24/11/2016
Managing common infections : Draft scope consultation	28/11/2016
Multiple myeloma (treated) - carfilzomib [ID934] : Appraisal consultation	30/11/2016
Multiple myeloma - lenalidomide (post bortezomib) (part rev TA171) [ID667] : Appraisal consultation : 3	02/12/2016
Rehabilitation after critical illness : Topic engagement	05/12/2016
HIV testing : Topic engagement	05/12/2016
Low back pain : Topic engagement	06/12/2016
Pancreatic cancer - pegylated liposomal irinotecan hydrochloride trihydrate (after gemcitabine) [ID778] : Appraisal consultation : 1	06/12/2016
Asthma (eosinophilic) - reslizumab (after inhaled corticosteroids) [ID872] : Appraisal consultation	06/12/2016
Quantitative faecal immunochemical tests to assess symptomatic people who are at low risk of colorectal cancer in primary care : Diagnostics consultation	08/12/2016