NICE Update Bulletin February 2017
issued Wednesday 22 February 2017

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Type	Guidance title and reference number
Technology Appraisals (TAs)	**Apremilast for treating active psoriatic arthritis TA433** This guidance replaces the previous NICE technology appraisal guidance on apremilast for treating active psoriatic arthritis (TA372). **Recommendations** 1.1 Apremilast, alone or in combination with disease-modifying antirheumatic drugs (DMARDs), is recommended as an option for treating active psoriatic arthritis in adults only if: • they have peripheral arthritis with 3 or more tender joints and 3 or more swollen joints and • their disease has not responded to adequate trials of at least 2 standard DMARDs, given either alone or in combination and • the company provides apremilast with the discount agreed in the patient access scheme. 1.2 Stop apremilast at 16 weeks if the psoriatic arthritis has not shown an adequate response using the Psoriatic Arthritis response Criteria (PsARC), defined as an improvement in at least 2 of the 4 PsARC criteria (including joint tenderness or swelling score) with no worsening in any criteria. If the disease has a Psoriasis Area and Severity Index (PASI) 75 response, a dermatologist should decide whether to continue treatment with apremilast after 16 weeks based on skin response. 1.3 When using the PsARC healthcare professionals should take into account any physical, sensory or learning disabilities, or communication difficulties that could affect a person's responses to components of the PsARC and make any adjustments they consider appropriate. 1.4 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 'alone or in combination with disease-modifying antirheumatic drugs (DMARDs), is indicated for the treatment of active psoriatic arthritis in adult patients who have had an inadequate response or who have been intolerant to a prior DMARD therapy'. **Financial factors** This technology is commissioned by CCGs. NICE says that this guidance is anticipated to be cost saving, although apremilast was seen to be not as effective as other drugs for this population. Apremilast is administered orally; therefore if there is movement from treatments that are infused there will be savings in the cost of administration. **Everolimus for advanced renal cell carcinoma after previous treatment TA432** This guidance is a Cancer Drugs Fund reconsideration of everolimus for the second-line treatment of advanced renal cell carcinoma (TA219). This guidance replaces TA219.

	Recommendations 1.1 Everolimus is recommended within its marketing authorisation as an option for treating advanced renal cell carcinoma that has progressed during or after treatment with vascular endothelial growth factor targeted therapy, only if the company provides it with the discount agreed in the patient access scheme. **The technology** Everolimus has a UK marketing authorisation for 'the treatment of patients with advanced renal cell carcinoma, whose disease has progressed on or after treatment with VEGF- [vascular endothelial growth factor] targeted therapy'. **Financial factors** This technology is commissioned by NHS England. No significant resource impact is anticipated; everolimus was previously available via the Cancer Drugs Fund.
Highly specialised technology guidance (HSTs)	**Migalastat for treating Fabry disease HST4** **Recommendations** 1.1 Migalastat is recommended, within its marketing authorisation, as an option for treating Fabry disease in people over 16 years of age with an amenable mutation, only if migalastat is provided with the discount agreed in the patient access scheme, and only if enzyme replacement therapy (ERT) would otherwise be offered. Criteria for starting and stopping ERT for Fabry disease are described in the UK adult Fabry disease standard operating procedures (Hughes et al. 2013). With the discount provided in the patient access scheme, migalastat has a lower total cost than ERT, and potentially provides greater health benefits than ERT. 1.2 The committee noted that there were important limitations and uncertainties in the evidence presented for migalastat, and that NICE has not evaluated ERT (agalsidase alfa and agalsidase beta) for treating Fabry disease. It encourages the company, NHS England and treatment centres to collect more evidence, particularly on the longer-term benefits of migalastat and ERT for treating Fabry disease, which should inform a future evaluation of the costs and benefits of all treatment options for Fabry disease. **The technology** Migalastat is an oral, small molecule drug designed to bind to the alpha-galactosidase A (alpha-gal A) enzyme as it is made, helping it to fold correctly and improving its function. Mutations that produce a form of alpha-gal A which responds to migalastat binding with a significant increase in function are known as amenable mutations. Migalastat is a lifelong treatment and has a marketing authorisation in the UK for 'long-term treatment of adults and adolescents aged 16 years and older with a confirmed diagnosis of Fabry disease (alpha-galactosidase A deficiency) and who have an amenable mutation'. **Financial factors** This technology is commissioned by NHS England.
NICE Guidelines (NGs)	**Drug misuse prevention: targeted interventions NG64** This guideline covers targeted interventions to prevent misuse of drugs, including illegal drugs, 'legal highs' and prescription-only medicines. It aims to prevent or delay harmful use of drugs in children, young people and adults who are most likely to start using drugs or who are already experimenting or using drugs occasionally. It does not cover broader activities, both population-level (universal) and targeted, that aim to build people's skills, resilience and ability to make positive decisions about their health and which address the wider determinants of health. For more information, see the NICE guidance on lifestyle and wellbeing. Additionally, this guideline does not cover treatment of drugs misuse (see the NICE guidelines on drug misuse: opioid detoxification and drug misuse: psychosocial interventions).

	This guideline includes recommendations on: • delivering drug misuse prevention activities as part of existing services • assessing whether someone is vulnerable to drug misuse • providing skills training for children and young people who are vulnerable to drug misuse • providing information to adults who are vulnerable to drug misuse • providing information about drug use in settings that people who use drugs or are at risk of using drugs may attend **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 focuses on women who give birth between 37 and 42 weeks of pregnancy ('term'). The guideline 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. **February 2017**: The evidence was reviewed on measuring fetal heart rate as part of initial assessment and on monitoring during labour. Some recommendations were changed and added in section 1.4 and section 1.10. **Osteoporosis: assessing the risk of fragility fracture CG146 (update)** This guideline covers assessing the risk of fragility fracture in people aged 18 and over with osteoporosis. It aims to provide guidance on the selection and use of risk assessment tools in the care of adults at risk of fragility fractures in all NHS settings. **February 2017**: The guideline was updated to correct reference to the WHO in relation to the FRAX tool. **Healthcare-associated infections: prevention and control in primary and community care CG139 (update)** This guideline covers preventing and controlling healthcare-associated infections in children, young people and adults in primary and community care settings. It provides a blueprint for the infection prevention and control precautions that should be applied by everyone involved in delivering NHS care and treatment. **February 2017**: A footnote was added to recommendation 1.1.4.2 linking to Health and Safety (Sharp Instruments in Healthcare) Regulations 2013. A footnote was also added to recommendations 1.4.3.1, 1.4.3.8, 1.4.4.1 and 1.4.4.11 linking to a safety alert on chlorhexidine. Other footnotes were updated with references to revised or replaced British Standards and other regulations. **Surgical site infections: prevention and treatment CG74 (update)** This guideline covers preventing and treating surgical site infections in adults, young people and children who are having a surgical procedure involving a cut through the skin. It recommends effective methods to use before, during and after surgery to minimise the risk of infection. **February 2017:** A footnote was added to recommendation 1.2.11 linking to related recommendations in the NICE guideline on caesarean section.
Interventional Procedures Guidance (IPGs)	**Trabecular stent bypass microsurgery for open-angle glaucoma IPG575** This guidance replaces NICE interventional procedures guidance on trabecular stent bypass microsurgery for open-angle glaucoma (IPG396). **Recommendations** 1.1 Current evidence on the safety of trabecular stent bypass microsurgery for open-angle glaucoma raises no major safety concerns. Evidence on efficacy is adequate in quality and quantity. Therefore, this procedure may be used provided that **standard arrangements** are in place for clinical governance, consent and audit.

	1.2 Trabecular stent bypass microsurgery for open-angle glaucoma should only be done by clinicians with specific training in the procedure. **The procedure** Open-angle glaucoma is an eye condition in which the nerve connecting your eye to your brain (the optic nerve) becomes damaged. It usually occurs when the fluid in the eye can't drain properly. This increases the pressure inside the eye, which puts pressure on the optic nerve. At first there are no symptoms but it causes sight problems and may lead to blindness. Treatment usually involves eye drops containing drugs that reduce the production, or increase the absorption, of fluid in the eye. Surgery aims to reduce pressure by increasing the drainage of fluid from the eye. NICE has looked at using trabecular stent bypass microsurgery as another treatment option. This procedure involves inserting a small tube (stent) into the eye. The aim is to improve drainage of fluid from the eye. Under local anaesthesia, a small cut is made in the side of the eye to gain access inside the eye. One or more stents are put into the eye. The procedure may be done at the same time as cataract surgery. **Lateral interbody fusion in the lumbar spine for low back pain IPG574** This guidance replaces NICE interventional procedures guidance on lateral (including extreme, extra and direct lateral) interbody fusion in the lumbar spine (IPG321). **Recommendations** Lateral interbody fusion in the lumbar spine for low back pain works well enough for use in the NHS. The evidence about how safe it is shows that there are serious but well-recognised complications. **The procedure** Chronic low back pain may result from changes in the spine caused by disease, age or injury. Treatments can include painkillers, drugs to reduce inflammation and manual therapy. If these do not work and severe pain stops the person doing their normal activities, surgery may be an option. Surgery may involve fixing parts of the spine (vertebrae) together, or inserting an artificial disc. NICE has looked at using lateral interbody fusion in the lumbar spine as another treatment option. The procedure is done under a general anaesthetic. The aim is to relieve pain by removing the damaged disc and fixing parts of the spine together. Using X-ray guidance a probe is inserted through a small cut in the person's side, level with the affected disc. A small cut is also sometimes made in the back so that the probe can be moved into the right place. Instruments inserted around the probe allow removal of the disc that is causing pain. A cage is then inserted to hold the 2 vertebrae in position. A piece of bone (a graft, usually taken from the hip) is placed between the vertebrae, sometimes supported by screws, plates or rods. The procedure can be done at more than 1 place in the spine during the same operation. It may take a few months for the person to be able to carry out their normal activities again.
Medical Technologies Guidance	**HeartFlow FFRCT for estimating fractional flow reserve from coronary CT angiography MTG32** **Recommendations** 1.1 The case for adopting HeartFlow FFR_{CT} for estimating fractional flow reserve from coronary CT angiography (CCTA) is supported by the evidence. The technology is non-invasive and safe, and has a high level of diagnostic accuracy. 1.2 HeartFlow FFR_{CT} should be considered as an option for patients with stable, recent onset chest pain who are offered CCTA as part of the NICE pathway on chest pain. Using HeartFlow FFR_{CT} may avoid the need for invasive coronary angiography and revascularisation. For correct use, HeartFlow FFR_{CT} requires access to 64-slice (or above) CCTA facilities.

	1.3 Based on the current evidence and assuming there is access to appropriate CCTA facilities, using HeartFlow FFR_{CT} may lead to cost savings of £214 per patient. By adopting this technology, the NHS in England may save a minimum of £9.1 million by 2022 through avoiding invasive investigation and treatment. **The technology** CCTA is a type of scan which shows detailed pictures of the heart and its blood vessels. HeartFlow FFR_{CT} is a computer program that uses images from the CCTA scan to estimate fractional flow reserve, or FFR. FFR can help to identify narrowed blood vessels and better inform future treatment. HeartFlow FFR_{CT} can only be used in hospitals with adequate CCTA facilities. However, using it may avoid the need for invasive procedures. **Financial factors** This technology is commissioned by CCGs. NICE has said that using HeartFlow FFR_{CT} as specified in the guidance is cost saving to the NHS. The level of savings depends on the availability of 64- slice (or above) coronary CT angiography facilities, which HeartFlow FFR_{CT} needs. Using HeartFlow FFR_{CT} may avoid the need for invasive coronary angiography and percutaneous coronary interventions. Fewer of these procedures will result in savings to commissioners and providers. **HumiGard for preventing inadvertent perioperative hypothermia MTG31** **Recommendations** 1.1 HumiGard shows promise for preventing hypothermia during abdominal surgery. There is, however, insufficient robust evidence to support the case for routine adoption, particularly on using HumiGard to avoid important adverse outcomes and on how it affects resource use in open and laparoscopic surgery. 1.2 Research is recommended on HumiGard compared with standard insufflation gases in patients having laparoscopic or open surgery alongside general measures to reduce the risk of perioperative hypothermia. Research should report on the comparative rate of surgical site infections and other complications associated with hypothermia and normothermia, as well as related resource use. **The technology** HumiGard is a device used to humidify and heat carbon dioxide gas, which is often used to fill the abdomen during keyhole surgery. Filling the abdomen with gas helps to maintain pressure and reduce the risk of complications. HumiGard can also be used in open surgery, using a specially made diffuser to surround the open surgical wound in warmed, humidified carbon dioxide gas. Warming this gas during both open and keyhole surgery can prevent patients' body temperatures from dropping too low (called perioperative hypothermia). HumiGard shows promise but there is not enough evidence to support its routine use in the NHS. NICE has recommended that more research be done on how well HumiGard works compared with standard insufflation gas.
Diagnostics Guidance	**Molecular testing strategies for Lynch syndrome in people with colorectal cancer DG27** **Recommendations** 1.1 Offer testing to all people with colorectal cancer, when first diagnosed, using immunohistochemistry for mismatch repair proteins or microsatellite instability testing to identify tumours with deficient DNA mismatch repair, and to guide further sequential testing for Lynch syndrome. Do not wait for the results before starting treatment. 1.2 If using immunohistochemistry, follow the steps in table 1.

Table 1 Steps in the immunohistochemistry testing strategy

Step 1	Do an immunohistochemistry 4-panel test for MLH1, MSH2, MSH6 and PMS2.	
Step 2	If the MLH1 immunohistochemistry result is abnormal, use sequential BRAF V600E and MLH1 promoter hypermethylation testing to differentiate sporadic and Lynch syndrome-associated colorectal cancers. First do a BRAF V600E test.	If the MSH2, MSH6 or PMS2 immunohistochemistry results are abnormal, confirm Lynch syndrome by genetic testing of germline DNA.
Step 3	If the BRAF V600E test is negative, do an MLH1 promoter hypermethylation test.	
Step 4	If the MLH1 promoter hypermethylation test is negative, confirm Lynch syndrome by genetic testing of germline DNA.	

1.3 If using microsatellite instability testing, follow the steps in table 2.

Table 2 Steps in the microsatellite instability testing strategy

Step 1	Do a microsatellite instability test.
Step 2	If the microsatellite instability test result is positive, use sequential *BRAF* V600E and *MLH1*promoter hypermethylation testing to differentiate sporadic and Lynch syndrome-associated colorectal cancers. First do a *BRAF* V600E test.
Step 3	If the *BRAF* V600E test is negative, do an *MLH1* promoter hypermethylation test.
Step 4	If the *MLH1* promoter hypermethylation test is negative, confirm Lynch syndrome by genetic testing of germline DNA.

1.4 Healthcare professionals should ensure that people are informed of the possible implications of test results for both themselves and their relatives, and ensure that relevant support and information is available. Discussion of genetic testing should be done by a healthcare professional with appropriate training.

1.5 Laboratories doing microsatellite instability testing or immunohistochemistry for mismatch repair proteins should take part in a recognised external quality assurance programme.

The technology

Lynch syndrome is an inherited condition caused by changes in some genes. People with Lynch syndrome have a higher risk of developing certain cancers, including colorectal cancer. There are ways to reduce the risks for some of these cancers, so it is important to know if people have the syndrome.

NICE has recommended that when a person is first diagnosed in the NHS as having colorectal cancer, either an immunohistochemistry (IHC) or microsatellite instability testing (MSI) test is routinely offered to check their tumour for changes that may mean they have Lynch syndrome. If changes are found, they will be offered further tests to confirm whether they have Lynch syndrome. If they do, they can be monitored for other cancers and their close relatives can also be offered testing for Lynch syndrome.

	Financial factors Services for testing for Lynch syndrome are commissioned by NHS England and CCGs. NICE has said that implementing the recommendations in the guidance will increase the number of people who have genetic testing for Lynch syndrome. This may increase use of pathology and genetic testing services. People with Lynch syndrome have an increased risk of cancer. It is anticipated that implementing this guidance will increase the numbers of screening tests for colorectal and endometrial cancers.
NICE Quality Standards	**Menopause QS143** This quality standard covers diagnosing and managing menopause in women, including women who have premature ovarian insufficiency (menopause before the age of 40, which can occur naturally or as a result of medical or surgical treatment). It describes high-quality care in priority areas for improvement. **Stable angina QS21 (update)** This quality standard covers diagnosing and managing stable angina in adults (aged 18 and over). It describes high-quality care in priority areas for improvement. **February 2017**: Statement 1 was updated to reflect changes to the NICE guideline on chest pain of recent onset.

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

Title / link	End date of consultation
Endoscopic full thickness removal of non lifting colonic adenoma : Interventional procedure consultation	27/02/2017
Infracoccygeal sacropexy using mesh to repair uterine prolapse : Interventional procedure consultation	27/02/2017
Infracoccygeal sacropexy using mesh to repair vaginal vault prolapse : Interventional procedure consultation	27/02/2017
Chronic obstructive pulmonary disease in over 16s: diagnosis and management (update) : Draft scope consultation	27/02/2017
Chronic obstructive pulmonary disease – roflumilast [ID984] : Appraisal consultation	28/02/2017
Breast cancer (early) - intrabeam radiotherapy system [ID618] : Appraisal consultation : 2	01/03/2017
Leukaemia (chronic myeloid, acute lymphoblastic) - ponatinib [ID671] : Appraisal consultation : 1	06/03/2017
Head injury: assessment and early management : Surveillance consultation	06/03/2017
Venetoclax for chronic lymphocytic leukaemia [ID944] : Appraisal consultation : 1	08/03/2017
Multiple frequency bioimpedance devices to guide fluid management in people with chronic kidney disease having dialysis : Diagnostics consultation : 1	08/03/2017
Indoor Air Pollution : Draft scope consultation	09/03/2017
Irritable bowel syndrome (diarrhoea) - eluxadoline [ID870] : Appraisal consultation	14/03/2017
Cabozantinib for treating renal cell carcinoma [ID931] : Appraisal consultation	14/03/2017
Primary hyperparathyroidism : Draft scope consultation	15/03/2017
Developmental follow-up of children and young people born preterm : Draft guidance consultation	03/04/2017
Child abuse and neglect : Draft guidance consultation	19/04/2017

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