NICE Update Bulletin September 2014 for guidance issued Wednesday 24th September 2014

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)	**Lenalidomide for treating myelodysplastic syndromes associated with an isolated deletion 5q cytogenetic abnormality TA322** **Background** The myelodysplastic syndromes (MDS) are a diverse group of haematological disorders in which the bone marrow functions abnormally and insufficient numbers of mature blood cells are produced. Red blood cells, white blood cells and platelets may all be affected by MDS, resulting in life threatening disease, with anaemia and increased risk of bleeding and infections. MDS affect patients' quality of life due to debilitating symptoms such as fatigue and dyspnoea, treatment regimens involving hospitalisation with intravenous drug infusions and blood transfusions, and complications such as severe infections. **Recommendations** Lenalidomide is recommended as an option, within its marketing authorisation, that is for treating transfusion-dependent anaemia caused by low or intermediate-1 risk myelodysplastic syndromes associated with an isolated deletion 5q cytogenetic abnormality when other therapeutic options are insufficient or inadequate, with the following condition: • The drug cost of lenalidomide (excluding any related costs) for people who remain on treatment for more than 26 cycles (each of 28 days; normally a period of 2 years) will be met by the company. **The technology** Lenalidomide (Revlimid, Celgene) is a structural analogue of thalidomide. It has anti-neoplastic, anti-angiogenic, pro-erythropoeitic and immunomodulatory properties. **Financial factors** Lenalidomide is available in 21-day packs of 10 mg and 5 mg capsules at net prices of £3,780 and £3,570 respectively (excluding VAT; 'British national formulary' [BNF] edition 67). The cost of a 28-day cycle of treatment with 10 mg of lenalidomide (excluding VAT) is £3,780. Costs may vary in different settings because of negotiated procurement discounts. The company (Celgene) has agreed a standard patient access scheme with the Department of Health, in which the NHS pays for lenalidomide treatment for up to 26 monthly cycles. The company subsequently provides free of charge lenalidomide for those people who receive more than 26 monthly cycles.
Clinical Guidelines (CGs)	**Long-acting reversible contraception (update) CG30** The NICE clinical guideline on long-acting reversible contraception (LARC) offers best-practice advice for all women of reproductive age who may wish to regulate their fertility using LARC methods. It covers specific issues for the use of these methods during the menarche and before the menopause, and by particular groups, including women who have HIV, learning disabilities or physical disabilities, or are younger than 16 years. The addendum to NICE clinical guideline 30 updates the recommendations on progestogen-only subdermal implants in **section 1.5** of the guideline. The addendum also contains details of the methods and evidence used to update these recommendations. The progestogen-only subdermal implant Implanon, previously recommended in this guideline, is no longer available and has been replaced by Nexplanon. Nexplanon contains the same amount of the same drug as Implanon, but the summaries of product characteristics for the two devices are not identical. **Background information**

It is estimated that about 30% of pregnancies are unplanned. The effectiveness of the barrier method and oral contraceptive pills depends on their correct and consistent use. By contrast, the effectiveness of long-acting reversible contraceptive (LARC) methods does not depend on daily concordance. The uptake of LARC is low in Great Britain, at around 12% of women aged 16–49 in 2008–09, compared with 25% for the oral contraceptive pill and 25% for male condoms.

Expert clinical opinion is that LARC methods may have a wider role in contraception and their increased uptake could help to reduce unintended pregnancy. The current limited use of LARC suggests that healthcare professionals need better guidance and training so that they can help women make an informed choice. Health providers and commissioners also need a clear understanding of the relative cost effectiveness of LARC compared with other methods of fertility control. Enabling women to make an informed choice about LARC and addressing women's preferences is an important objective of this guideline.

LARC is defined in this guideline as contraceptive methods that require administration less than once per cycle or month. Included in the category of LARC are:

- copper intrauterine devices
- progestogen-only intrauterine systems
- progestogen-only injectable contraceptives
- progestogen-only subdermal implants
- combined vaginal rings – these are excluded from the original guideline because they did not have UK Marketing Authorisation at the time the original guideline was published in 2005.

The key priorities for implementation are

- Contraceptive provision
- Counselling and provision of information
- Training of healthcare professionals in contraceptive care

The recommendations in full cover

1.1 Contraception and principles of care

1.2 Copper intrauterine devices

1.3 Intrauterine system

1.4 Progestogen-only injectable contraceptives

1.5 Progestogen-only subdermal implants

Drug allergy: diagnosis and management of drug allergy in adults, children and young people CG183

This clinical guideline offers evidence-based advice on the diagnosis and management of drug allergy in adults, children and young people.

Background information

Major issues identified by this guideline include poor clinical documentation of drug allergy and a lack of patient information. Computerised primary care record systems are often unable to distinguish between intolerance and drug allergy and this can lead to a false label of drug allergy, particularly if the person's reaction took place many years previously and details about their reaction have been lost.

Diagnosing drug allergy can be challenging and there is considerable variation both in how drug allergy is managed and in access to specialist drug allergy services. This can lead to under diagnosis, misdiagnosis and self-diagnosis. This variation may be caused by insufficient awareness of available services or by a lack of local provision of drug allergy centres. In view of the variation in provision of care for people with drug allergy, the scope of this guideline identified a need for guidance to improve clinical management for people affected by drug allergy. This guideline has been developed for use by healthcare professionals at all levels of healthcare and offers best practice advice on the

diagnosis, documentation and communication of drug allergy in adults, children and young people.

The key priorities for implementation are

- Assessment
- Documenting and sharing information with other healthcare professionals
- Providing information and support to patients
- Non-specialist management and referral to specialist services

The recommendations in full cover

1.1 Assessment

1.2 Documenting and sharing information with other healthcare professionals

1.3 Providing information and support to patients

1.4 Non-specialist management and referral to specialist services

Dyspepsia and gastro-oesophageal reflux disease CG184

This guideline updates and replaces NICE clinical guideline 17 (published August 2004). It offers evidence-based advice on the care and treatment of adults (aged 18 and over) with symptoms of dyspepsia, symptoms suggestive of gastro-oesophageal reflux disease (GORD), or both.

New recommendations have been added about investigation and referral, Helicobacter pylori eradication therapy, specialist management, and surveillance of Barrett's oesophagus in people with dyspepsia.

Background information

Dyspepsia describes a range of symptoms arising from the upper gastrointestinal (GI) tract, but it has no universally accepted definition. The British Society of Gastroenterology (BSG) defines dyspepsia as a group of symptoms that alert doctors to consider disease of the upper GI tract, and states that dyspepsia itself is not a diagnosis. These symptoms, which typically are present for 4 weeks or more, include upper abdominal pain or discomfort, heartburn, gastric reflux, nausea or vomiting. Some of the costs associated with treating dyspepsia are decreasing, but the overall use of treatments is increasing. As a result, the management of dyspepsia continues to have potentially significant costs to the NHS.

The key priorities for implementation are

- Referral guidance for endoscopy
- Interventions for uninvestigated dyspepsia
- Interventions for gastro-oesophageal reflux disease (GORD)
- Interventions for peptic ulcer disease
- Referral to a specialist service
- Surveillance for people with Barrett's oesophagus

The recommendations in full cover

1.1 The community pharmacist

1.2 Common elements of care

1.3 Referral guidance for endoscopy

1.4 Interventions for uninvestigated dyspepsia

1.5 Reviewing patient care

1.6 Interventions for gastro-oesophageal reflux disease (GORD)

1.7 Interventions for peptic ulcer disease

1.8 Interventions for functional dyspepsia

1.9 Helicobacter pylori testing and eradication

	1.10 Laparoscopic fundoplication 1.11 Referral to a specialist service 1.12 Surveillance for people with Barrett's oesophagus **Bipolar disorder: the assessment and management of bipolar disorder in adults, children and young people in primary and secondary care CG185** This guideline updates and replaces NICE clinical guideline 38 (published July 2006). It offers evidence based advice on the care and treatment of children, young people and adults with bipolar disorder. **Background information** Bipolar disorder is a potentially lifelong and disabling condition characterised by episodes of mania (abnormally elevated mood or irritability and related symptoms with severe functional impairment or psychotic symptoms for 7 days or more) or hypomania (abnormally elevated mood or irritability and related symptoms with decreased or increased function for 4 days or more) and episodes of depressed mood. It is often comorbid with other disorders such as anxiety disorders, substance misuse, personality disorders and attention deficit hyperactivity disorder (ADHD). Since the publication of the previous guideline (NICE clinical guideline 38) in 2006, there have been some important advances in our knowledge of the care pathway and treatment approaches that are most likely to benefit people with bipolar disorder **The key priorities for implementation are** • Care for adults, children and young people across all phases of bipolar disorder • Recognising and managing bipolar disorder in adults in primary care • Managing mania or hypomania in adults in secondary care • Managing bipolar depression in adults in secondary care • Managing bipolar disorder in adults in the longer term in secondary care • Recognising, diagnosing and managing bipolar disorder in children and young people **The recommendations in full cover** 1.1 Care for adults, children and young people across all phases of bipolar disorder 1.2 Recognising and managing bipolar disorder in adults in primary care 1.3 Assessing suspected bipolar disorder in adults in secondary care 1.4 Managing crisis, risk and behaviour that challenges in adults with bipolar disorder in secondary care 1.5 Managing mania or hypomania in adults in secondary care 1.6 Managing bipolar depression in adults in secondary care 1.7 Managing bipolar disorder in adults in the longer term in secondary care 1.8 Monitoring physical health in secondary care 1.9 Promoting recovery and return to primary care 1.10 How to use medication 1.11 Recognising, diagnosing and managing bipolar disorder in children and young people
Public Health Guidance	**Exercise referral schemes to promote physical activity PH54** This guideline makes recommendations on exercise referral schemes to promote physical activity for people aged 19 and older. It is an update of recommendation 5 in 'Four commonly used methods to increase physical activity' (NICE public health guidance 2). It focuses on exercise referral schemes that try to increase physical activity

	among people who are inactive or sedentary and are otherwise healthy or who have an existing health condition or other risk factors for disease **The recommendations cover the areas of** • Exercise referral for people who are sedentary or inactive but otherwise healthy • Exercise referral for people who are sedentary or inactive and have a health condition or other health risk factors • Collating and sharing data on exercise referral schemes
Medical Technologies Guidance	**None published so far this month**
NICE Quality Standards	**Acute coronary syndromes (including myocardial infarction) QS68** This quality standard covers the diagnosis and management of acute coronary syndromes (including myocardial infarction) in adults aged 18 years and over. **Ectopic pregnancy and miscarriage QS69** This quality standard covers the diagnosis and initial management of ectopic pregnancy and miscarriage in women in their first trimester (up to 13 completed weeks of pregnancy). **Nocturnal enuresis (bedwetting) in children and young people QS70** This quality standard covers the assessment and management of nocturnal enuresis (bedwetting) in children and young people aged 18 years or younger.
Safe staffing guideline	**None published so far this month**
Interventional Procedures Guidance (IPGs)	**Assessing motility of the gastrointestinal tract using a wireless capsule IPG502** **Recommendations** 1.1 The evidence on assessing motility of the gastrointestinal tract using a wireless capsule raises no major safety concerns. There is evidence of efficacy in measuring gastrointestinal function but uncertainty about the clinical benefit of this, and about patient selection. **Therefore, this procedure should be used only with special arrangements for clinical governance, consent and audit or research.** 1.2 Clinicians wishing to assess motility of the gastrointestinal tract using a wireless capsule 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 the motility of the gastrointestinal tract assessed using a wireless capsule (see section 7.1). 1.3 NICE encourages further research into the use of a wireless capsule to assess motility of the gastrointestinal tract. Studies should include clear details of patient selection. They should report on the diagnostic accuracy of the procedure in different parts of the gastrointestinal tract, and should provide data on the clinical benefits of the procedure for patients **The procedure** The wireless capsule system consists of a single-use, non-digestible, wireless transmitting capsule, a receiver for acquiring and storing signals from the capsule and software for displaying data on a computer. While in the body, the capsule samples bowel contents and transmits data about pH, pressure and temperature to a portable receiver (worn by the patient) at regular intervals as it travels through the GI tract. The patient can record meals, sleep and bowel movements by pushing an event button on the receiver. The capsule is passed out of the bowel with the faeces. If not seen in the stool, loss of the recording signal or an abrupt temperature drop on the recording profile confirm exit of the capsule from the body

Combined endoscopic and laparoscopic removal of colonic polyps IPG503

1.1 Current evidence on the safety and efficacy of combined endoscopic and laparoscopic removal of colonic polyps is adequate. **Therefore this procedure may be used with normal arrangements for clinical governance, consent and audit.**

1.2 This procedure should be done only by teams experienced in laparoscopic colonic surgery and complex interventional endoscopy

The procedure

Combined endoscopic and laparoscopic removal of colonic polyps is used to excise polyps that are unsuitable or high-risk for endoscopic removal, without the need for open surgery or segmental laparoscopic resection. The procedure aims to provide enhanced visualisation and enable the colon to be manoeuvred and controlled during resection of the polyp.

Transcatheter valve-in-valve implantation for aortic bioprosthetic valve dysfunction IPG504

Recommendations

1.1 For patients with aortic bioprosthetic valve dysfunction for whom surgical aortic valve replacement (SAVR) is considered to be unsuitable the evidence on the safety and efficacy of valve-in-valve transcatheter aortic valve implantation (ViV-TAVI) is adequate. For these patients, ViV-TAVI may be used with normal arrangements for clinical governance, consent and audit. Details of all patients should be entered into the UK Central Cardiac Audit Database.

1.2 For patients with aortic bioprosthetic valve dysfunction for whom surgical aortic valve replacement (SAVR) is considered to be suitable but to pose a high risk (see sections 1.4, 1.5 and 1.6), the evidence on the safety and efficacy of valve-in-valve transcatheter aortic valve implantation (ViV-TAVI) is inadequate. For these patients, ViV-TAVI should only be used with special arrangements for clinical governance, consent and data collection or research. Details of all patients should be entered into the UK Central Cardiac Audit Database.

1.3 For patients with aortic bioprosthetic valve dysfunction for whom surgical aortic valve replacement (SAVR) is considered to be suitable and not to pose a high risk (see sections 1.5 and 1.6), the evidence on the safety and efficacy of valve-in-valve transcatheter aortic valve implantation (ViV-TAVI) is inadequate. For these patients, ViV-TAVI should only be used in the context of research. In addition, details of all patients should be entered into the UK Central Cardiac Audit Database.

1.4 Clinicians wishing to carry out valve-in-valve transcatheter aortic valve implantation (ViV-TAVI) for patients with aortic bioprosthetic dysfunction for whom surgical aortic valve replacement (SAVR) is considered to be suitable but to pose a high risk (see section 1.2) should take the following actions:

Inform the clinical governance leads in their NHS trusts.

- Ensure that patients understand the risk of death, and the uncertainty about the procedure's efficacy in the long term.
- Provide them with clear written information.

In addition, the use of NICE's information for the public is recommended.

Patient selection should be carried out by a multidisciplinary team including interventional cardiologists, cardiac surgeons, a cardiac anaesthetist and an expert in cardiac imaging. The multidisciplinary team should determine the risk level for each patient.

1.5 Valve-in-valve transcatheter aortic valve implantation (ViV-TAVI) is a technically challenging procedure that should only be done by clinicians and teams with special training and experience in complex endovascular cardiac interventions, including regular experience in the use of TAVI. Units doing this procedure should have both cardiac and vascular surgical support for emergency treatment of complications.

1.6 NICE encourages further research into valve-in-valve transcatheter aortic valve implantation (ViV-TAVI) for aortic bioprosthetic dysfunction. Comparative studies between ViV-TAVI and surgical aortic valve replacement (SAVR) for patients who are judged to have a low risk from SAVR should describe patient selection clearly and should report fully on complications and valve durability in the short and long term.

	1.7 NICE may review this procedure on publication of further evidence **<u>The procedure</u>** The procedure is done with the patient under general or local anaesthesia, with imaging guidance using fluoroscopy and usually transoesophageal echocardiography. Prophylactic antibiotics and anticoagulant medication are given before and during the procedure. Temporary peripheral extracorporeal circulatory support (usually through the femoral vessels) is sometimes used. A new prosthetic valve is mounted within a stent, which is either self-expanding or expanded using balloon inflation. It is delivered by a catheter across the failed bioprosthetic aortic valve.
NICE Pathways	These pathways are not guidance in themselves but a way of displaying online the various guidance that exists around a subject.
Commissioning Guides	**None published so far this month**

Diagnostics Guidance	**Atrial fibrillation and heart valve disease: self-monitoring coagulation status using point-of-care coagulometers (the CoaguChek XS system and the INRatio2 PT/INR monitor) DG14** **Background** NICE has assessed 2 point-of care coagulometers to help the NHS decide whether to use these products. They are called CoaguChek XS and InRatio2 PT/INR. Coagulometers monitor blood clotting in people taking long-term anti-blood clotting drugs (such as warfarin) to reduce their risk of blood clots. These tests allow people taking anti-blood clotting drugs to monitor blood clotting themselves. They can then change their dose in agreement with their health professional. Both coagulometers are recommended for use by people taking long-term anti-blood clotting therapy who have atrial fibrillation or heart valve disease, if they prefer and are able to effectively use this type of monitoring. People (and their carers) who will be using 1 of these devices should be given training, and their doctor should regularly assess self-monitoring. **Recommendations** 1.1 The CoaguChek XS system is recommended for self-monitoring coagulation status in adults and children on long-term vitamin K antagonist therapy who have atrial fibrillation or heart valve disease if: • the person prefers this form of testing and • the person or their carer is both physically and cognitively able to self-monitor effectively. 1.2 The InRatio2 PT/INR monitor is recommended for self-monitoring coagulation status in adults and children on long-term vitamin K antagonist therapy who have atrial fibrillation or heart valve disease if: • the person prefers this form of testing and • the person or their carer is both physically and cognitively able to self-monitor effectively. Although there is greater uncertainty of clinical benefit for the InRatio2 PT/INR monitor than for the CoaguChek XS system, the evidence indicates that the precision and accuracy of both monitors are comparable to laboratory-based INR testing. 1.3 Patients and carers should be trained in the effective use of the CoaguChek XS system or the INRatio2 PT/INR monitor and clinicians involved in their care should regularly review their ability to self-monitor. 1.4 Equipment for self-monitoring should be regularly checked using reliable quality control procedures, and by testing patients' equipment against a healthcare professional's coagulometer which is checked in line with an external quality assurance scheme. Ensure accurate patient records are kept and shared appropriately. 1.5 For people who may have difficulty with or who are unable to self-monitor, such as children or people with disabilities, their carers should be considered to help with self-monitoring.
Public health briefings for local government	**Health visiting LGB22** From October 2015, local authorities will build on current co-commissioning arrangements and take over full responsibility from NHS England for commissioning public health services for children up to the age of 5. The purpose of this briefing is to highlight NICE public health recommendations on health visiting that: • can help local authorities to improve the effectiveness of public health services commissioned to promote and protect the health and wellbeing of and reduce health inequalities among children aged 0–5 and their families • may support those responsible for delivering the Healthy Child Programme, including members of the health visiting team.

	Using evidence in practice LGB23 This briefing summarises the approach NICE takes to assessing what evidence to use as the basis of their public health recommendations. It provides an introduction to how to use evidence to inform decisions about public health issues ('evidence-informed' decision making). It may also be useful for people working in other local authority departments. People are persuaded by different types of evidence when making decisions. This varies between sectors – and among professionals within sectors. Health and social care professionals tend to use 'formal' evidence based on research and evaluation. They may also take into account other types of evidence including local views, community preferences, audit, or even the results of toxicological tests.

Current NICE consultations with links and start and finish dates for stakeholders to make contribution

Title / link	Start date of consultation	Finish date of consultation
Atypical haemolytic uraemic syndrome (aHUS) - eculizumab: evaluation consultation 2 (GID-ATYPICALHAEMOLYTICURAEMICSYNDROMEAHUSECULIZUMAB)	04/09/2014	25/09/2014
GORD in children: guideline consultation	31/07/2014	25/09/2014
Preventing the uptake of smoking by children and young people: review proposal consultation	15/09/2014	29/09/2014
Pancreatic adenocarcinoma (untreated, metastatic) - paclitaxel albumin-bound nanoparticles (with gemcitabine) [ID680]: appraisal consultation	09/09/2014	30/09/2014
Promoting physical activity in the workplace: 2nd review proposal consultation	17/09/2014	01/10/2014
Psychosis and schizophrenia in adults: quality standard consultation	08/09/2014	06/10/2014
Hepatitis C (chronic) - simeprevir [ID668]: appraisal consultation	18/09/2014	09/10/2014
Ulcerative colitis (moderate, severe) - infliximab (review TA140), adalimumab (review TA262) and golimumab (2nd line) [ID695]: Guidance consultation	18/09/2014	09/10/2014
Bladder cancer: guideline consultation	03/09/2014	15/10/2014
Ulcerative colitis (moderate, severe) - infliximab (review TA140), adalimumab (review TA262) and golimumab (2nd line) [ID695]: Guidance consultation	24/09/2014	15/10/2014
Mental health of people in prison: scope consultation	24/09/2014	22/10/2014
Sexually harmful behaviour among young people: scope consultation	24/09/2014	22/10/2014
Diabetes in pregnancy (update): guideline consultation	11/09/2014	23/10/2014
Workplace policy and management practices to improve the health of employees: guideline consultation	24/09/2014	11/11/2014

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