NICE Update Bulletin June 2015 for guidance issued Thursday 04th June 2015

Guidance was not published during the period of the general election (April and May 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)	**Ustekinumab for treating active psoriatic arthritis (rapid review of TA313) TA340** **Recommendations** 1.1 Ustekinumab is recommended as an option, alone or in combination with methotrexate, for treating active psoriatic arthritis in adults only when: •treatment with tumour necrosis factor (TNF) alpha inhibitors is contraindicated but would otherwise be considered (as described in NICE technology appraisal guidance on etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis and golimumab for the treatment of psoriatic arthritis) or •the person has had treatment with 1 or more TNF–alpha inhibitors. Ustekinumab is recommended only if the company provides the 90 mg dose of ustekinumab for people who weigh more than 100 kg at the same cost as the 45 mg dose, as agreed in the patient access scheme. 1.2 Ustekinumab treatment should be stopped if the person's psoriatic arthritis has not shown an adequate response using the Psoriatic Arthritis Response Criteria (PsARC) at 24 weeks. An adequate response is defined as an improvement in at least 2 of the 4 criteria (1 of which must be joint tenderness or swelling score), with no worsening in any of the 4 criteria. As recommended in NICE technology appraisal guidance on etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis, people whose disease has a Psoriasis Area and Severity Index (PASI) 75 response but whose PsARC response does not justify continuing treatment should be assessed by a dermatologist to determine whether continuing treatment is appropriate on the basis of skin response (see NICE technology appraisal guidance on ustekinumab for the treatment of adults with moderate to severe psoriasis). 1.3 When using the Psoriatic Arthritis Response Criteria (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 People whose treatment with ustekinumab is not recommended in this NICE guidance, but was started within the NHS before this guidance was published, should be able to continue ustekinumab until they and their NHS clinician consider it appropriate to stop. **The technology** Ustekinumab is a monoclonal antibody that acts as a cytokine inhibitor by targeting interleukin-12 (IL-12) and interleukin-23 (IL-23). It is administered by subcutaneous injection. **Financial factors** The NICE costing statement states that Ustekinumab is an additional treatment option alongside current standard treatment options of golimumab, adalimumab, etanercept and infliximab, which are available at a similar cost. **Apixaban for the treatment and secondary prevention of deep vein thrombosis and/or pulmonary embolism TA341** **Recommendations** 1.1 Apixaban is recommended, within its marketing authorisation, as an option for

treating and for preventing recurrent deep vein thrombosis and pulmonary embolism in adults.

The technology

Apixaban is an anticoagulant which directly inhibits factor X (factor Xa), inhibiting thrombin formation and the development of thrombi (blood clots). It is administered orally. To treat deep vein thrombosis (DVT) or pulmonary embolism (PE), 10 mg apixaban should be taken twice a day for the first 7 days, followed by 5 mg twice a day for at least 3 months. For the prevention of recurrent disease, people who have completed 6 months of treatment for DVT or PE should take 2.5 mg twice a day.

Financial factors

There is no significant cost difference between apixaban and the other newer oral anticoagulants. The cost of providing apixaban is similar to dabigatran etexilate. Treatment with dabigatran etexilate requires initial treatment with LMWH. Apixaban does not require initial treatment with LMWH.

Obinutuzumab in combination with chlorambucil for untreated chronic lymphocytic leukaemia TA343

Recommendations

1.1 Obinutuzumab, in combination with chlorambucil, is recommended as an option for adults with untreated chronic lymphocytic leukaemia who have comorbidities that make full dose fludarabine based therapy unsuitable for them, only if:

- bendamustine based therapy is not suitable and
- the company provides obinutuzumab with the discount agreed in the patient access scheme.

1.2 People whose treatment with obinutuzumab 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 technology

Obinutuzumab is a type 2 glyco-engineered antibody that binds to the CD20 protein present on B cells (except stem or plasma cells) and causes cell death. Obinutuzumab plus chlorambucil has a UK marketing authorisation for 'the treatment of adult patients with previously untreated chronic lymphocytic leukaemia and with comorbidities making them unsuitable for full-dose fludarabine based therapy'. Obinutuzumab is administered as an intravenous infusion.

Financial factors

The company stated that a course of treatment costs £26,496 (£9,936 for cycle 1 and £3,312 for cycles 2–6, excluding VAT). The recommended dosage is 1,000 mg administered over days 1 and 2, 1,000 mg on day 8 and 1,000 mg on day 15 of treatment cycle 1, followed by 1,000 mg on day 1 of treatment cycles 2–6. The company has agreed a patient access scheme with the Department of Health that makes obinutuzumab available with a discount. The size of the discount is commercial in confidence

Ofatumumab in combination with chlorambucil or bendamustine for untreated chronic lymphocytic leukaemia TA344

Recommendations

1.1 Ofatumumab in combination with chlorambucil is recommended as an option for untreated chronic lymphocytic leukaemia only if:

- the person is ineligible for fludarabine based therapy and
- bendamustine is not suitable and
- the company provides ofatumumab with the discount agreed in the patient access scheme.

1.2 People whose treatment with ofatumumab is not recommended in this NICE

	guidance, but was started within the NHS before this guidance was published, should be able to continue ofatumumab until they and their NHS clinician consider it appropriate to stop. **The technology** Ofatumumab (Arzerra) is a fully human, monoclonal antibody that is targeted against the CD20 cell surface antigen of B-lymphocytes and causes cell death. It is administered by intravenous infusion. At the time of the appraisal, the marketing authorisation holder was GlaxoSmithKline; however, it is now marketed by Novartis. Ofatumumab in combination with chlorambucil or bendamustine has a marketing authorisation in the UK for treating chronic lymphocytic leukaemia in people who have not had prior therapy and who are not eligible for fludarabine-based therapy. **Financial factors** Assuming 6 cycles and no drug wastage, the mean cost of a treatment course for ofatumumab is £11,466 for 6,300 mg. The company has agreed a patient access scheme with the Department of Health that makes ofatumumab available with a discount. The size of the discount is commercial in confidence.
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)	**Anaemia management in people with chronic kidney disease NG8** **Background information** Blood haemoglobin (Hb) concentration serves as the key indicator for anaemia because it can be measured directly and has an international standard. A major cause of anaemia of chronic kidney disease (CKD) is a reduction in erythropoietin production due to kidney damage. Erythropoietin stimulates the bone marrow to produce red blood cells, and it is produced by the kidney in response to low tissue oxygen levels. Possible adverse effects of anaemia include reduced oxygen use, increased cardiac output, left ventricular hypertrophy, reduced cognition and concentration, reduced libido and reduced immune responsiveness. **The recommendations in full cover** 1.1 Diagnostic evaluation and assessment of anaemia 1.2 Managing anaemia 1.3 Assessment and optimisation of erythropoiesis 1.4 Monitoring treatment of anaemia of CKD **Financial factors** The NICE costing statement recommends that savings are anticipated nationally because of decreased testing costs, and more accurate diagnosis and treatment of anaemia in people with chronic kidney disease (CKD), which may avoid the need for hospital admissions. **Bronchiolitis in children NG9**

Background information

Bronchiolitis is the most common disease of the lower respiratory tract during the first year of life. It usually presents with cough with increased work of breathing, and it often affects a child's ability to feed. In primary care, the condition may often be confused with a common cold. The symptoms are usually mild and may only last for a few days, but in some cases the disease can cause severe illness.

The recommendations in full cover:

1.5 Assessment and diagnosis

1.6 When to refer

1.7 When to admit

1.8 Management of bronchiolitis

1.9 When to discharge

1.10 Key safety information for looking after a child at home

Financial factors

The NICE costing statement for this guidance states that the guideline might have additional costs but also additional savings at a local level as a result of variation in clinical practice across the country. Therefore, we encourage organisations to evaluate their own practices against the recommendations in the NICE guideline and assess costs and savings locally.

Violence and aggression: short-term management in mental health, health and community settings NG10

Background information

Violence and aggression refer to a range of behaviours or actions that can result in harm, hurt or injury to another person, regardless of whether the violence or aggression is physically or verbally expressed, physical harm is sustained or the intention is clear.

Violence and aggression are relatively common and serious occurrences in health and social care settings. Between 2013 and 2014 there were 68,683 assaults reported against NHS staff in England: 69% in mental health or learning disability settings, 27% against ambulance staff, 25% involving primary care staff and 26% involving acute hospital staff. Violence and aggression in mental health settings occur most frequently in inpatient psychiatric units and most acute hospital assaults take place in emergency department

Key priorities for implementation

- Anticipating and reducing the risk of violence and aggression
- Preventing violence and aggression
- Using restrictive interventions in inpatient psychiatric settings
- Managing violence and aggression in emergency departments
- Managing violence and aggression in community and primary care settings
- Managing violence and aggression in children and young people

Financial factors

The NICE costing statement recommends that the guideline might have resource implications at a local level as a result of variation in current practice across the country. Therefore organisations are encouraged to evaluate their own practices against the recommendations in the NICE guideline and assess costs locally.

Challenging behaviour and learning disabilities: prevention and interventions for people with learning disabilities whose behaviour challenges NG11

Background information

A learning disability is defined by 3 core criteria: lower intellectual ability (usually an IQ of

less than 70), significant impairment of social or adaptive functioning, and onset in childhood. Learning disabilities are different from specific learning difficulties such as dyslexia, which do not affect intellectual ability. Although the term 'intellectual disability' is becoming accepted internationally, 'learning disability' is the most widely used and accepted term in the UK and is therefore used in this guideline. The amount of everyday support a person with a learning disability needs will depend mostly on the severity of the disability. It is important to treat each person as an individual, with specific strengths and abilities as well as needs, and a broad and detailed assessment may be needed.

Key priorities for implementation

General principles of care

- Support and interventions for family members or carers
- Early identification of the emergence of behaviour that challenges
- Assessment of behaviour that challenges
- Psychological and environmental interventions
- Medication

The recommendations in full cover:

1.1 General principles of care

1.2 Physical healthcare

1.3 Support and interventions for family members or carers

1.4 Early identification of the emergence of behaviour that challenges

1.5 Assessment of behaviour that challenges

1.6 Behaviour support plan

1.7 Psychological and environmental interventions

1.8 Medication

1.9 Reactive strategies

1.10 Interventions for coexisting health problems

1.11 Interventions for sleep problems

Financial factors

The NICE costing statement for this guidance states that expert clinical opinion suggests current practice is highly variable and the guideline might have resource implications at a local level. Because the cost impact of the recommendations may vary, organisations are encouraged to evaluate their own practice against the recommendations in the NICE guideline and assess costs and savings locally.

Lower urinary tract symptoms in men: assessment and management CG97

Background information

Lower urinary tract symptoms (LUTS) comprise storage, voiding and post-micturition symptoms affecting the lower urinary tract. There are many possible causes of LUTS such as abnormalities or abnormal function of the prostate, urethra, bladder or sphincters. In men, the most common cause is benign prostate enlargement (BPE), which obstructs the bladder outlet. BPE happens when the number of cells in the prostate increases, a condition called benign prostatic hyperplasia. Other conditions that can cause LUTS include detrusor muscle weakness or overactivity, prostate inflammation (prostatitis), urinary tract infection, prostate cancer and neurological disease. This clinical guideline will advise on the effective evidence-based management of LUTS in men.

Key priorities for implementation

	• Initial assessment • Conservative management • Surgery for voiding symptoms • Providing information **The recommendations in full cover** 1.1 Initial assessment 1.2 Specialist assessment 1.3 Conservative management 1.4 Drug treatment 1.5 Surgery for voiding symptoms 1.6 Surgery for storage symptoms 1.7 Treating urinary retention 1.8 Alternative and complementary therapies 1.9 Providing information **Financial factors** The NICE costing reports states that the costing template produced to support this guideline enables organisations in England, Wales and Northern Ireland to estimate the impact locally and replace variables with ones that depict the current local position. A sample calculation using this template showed that additional costs of approximately £13,000 could be incurred for a population of 100,000.
Interventional Procedures Guidance (IPGs)	**Insertion of an epiretinal prosthesis for retinitis pigmentosa IPG519** **Recommendations** 1.1 Current evidence on the safety and efficacy of insertion of an epiretinal prosthesis for retinitis pigmentosa is limited in quality and quantity. Therefore, this procedure should only be used in the context of research. 1.2 NICE encourages further research on this technology. Outcomes should include the impact on quality of life and activities of day-to-day living, and durability of implants. NICE may update the guidance on publication of further evidence **The procedure** Insertion of an epiretinal prosthesis aims to restore perception of light, movement and shapes by surgically implanting an array of electrodes onto the retina. The electrodes emit electrical impulses to stimulate the sensory neurons of surviving retinal cells, which send visual information to the brain **Radiofrequency ablation for gastric antral vascular ectasia IPG520** **Recommendations** 1.1 Current evidence on radiofrequency ablation for gastric antral vascular ectasia raises no major safety concerns; however, evidence on its efficacy is inadequate in quantity. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research. 1.2 Clinicians wishing to undertake radiofrequency ablation for gastric antral vascular ectasia should take the following actions: • 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. • Audit and review clinical outcomes of all patients having radiofrequency

ablation for gastric antral vascular ectasia (see section 7.2).

1.3 The procedure should only be done by experienced interventional endoscopists with specific training in the technique.

1.4 NICE encourages further research into radiofrequency ablation for gastric antral vascular ectasia and collaborative publication of data from local audit. Patient selection should be clearly documented, including details of prior treatments. Outcomes should include success and duration of effect in controlling bleeding and the effect of this on the need for blood transfusion. All complications should be reported. NICE may update the guidance on publication of further evidence.

The procedure

The procedure is usually done with the patient under conscious sedation. A specially designed radiofrequency catheter is inserted into the gastric antrum under endoscopic guidance. The target area for treatment is identified, and the catheter electrode is positioned by manoeuvring the endoscope. The electrode is in the form of a plate, which allows a broad area to be treated in a few seconds by applying several pulses of radiofrequency energy.

Suture fixation of acute disruption of the distal tibiofibular syndesmosis IPG521

Recommendations

1.1 Current evidence on the efficacy and safety of suture fixation of acute disruption of the distal tibiofibular syndesmosis is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit.

The procedure

A small tunnel is drilled through the fibula and the tibia under image guidance. A polyethylene-based suture loop, threaded with an oblong metal button, is then inserted through the tunnel (and the vacant hole in a fracture fixation plate, if used) using a needle. After it has passed through the tibia, the button is pulled back so that it lies flat against the medial cortex of the tibia. The ends of the suture loop on the lateral side of the fibula are pulled tight against the fibula (or the fracture fixation plate) and secured by drawing a second metal button onto the surface of the fibula or the plate. Once both buttons are flush with the bone, a small knot is made with the free ends of the loop to secure the system and stabilise the joint. If additional stability is needed, a second suture loop can be inserted through the same or another tunnel.

Ultrasound-enhanced, catheter-directed thrombolysis for deep vein thrombosis IPG523

Recommendations

1.1 The evidence on ultrasound-enhanced, catheter-directed thrombolysis for deep vein thrombosis raises no major safety concerns over those of catheter-directed thrombolysis (CDT) alone. With regard to efficacy, evidence of any enhancement of thrombolysis over CDT alone is inadequate in 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 ultrasound-enhanced, catheter-directed thrombolysis (UE-CDT) for deep vein thrombosis (DVT) should:

- Inform the clinical governance leads in their NHS trust.
- 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 UE-CDT for DVT

1.3 NICE encourages further research comparing ultrasound-enhanced, catheter-directed thrombolysis for deep vein thrombosis against catheter-directed thrombolysis alone. Patient selection should be documented, including the duration and extent of thrombosis. The dose of thrombolytic agent used and the duration of thrombolysis should be reported, together with all complications. Outcome measures

	should include the success of thrombolysis (complete, partial or failed) and long-term sequelae. NICE may update the guidance on publication of further evidence. **The procedure** Ultrasound-enhanced, catheter-directed thrombolysis is an endovascular technique that uses high-frequency, low-energy ultrasound waves in combination with infusion of a thrombolytic drug, with the aim of accelerating plasmin-mediated thrombolysis. It aims to reduce treatment time, the dose of thrombolytic drug delivered and thrombolysis-related complications, compared with catheter-directed thrombolysis alone. **Ultrasound-enhanced, catheter-directed thrombolysis for pulmonary embolism IPG524** **Recommendations** 1.1 The evidence on ultrasound enhanced, catheter directed thrombolysis for pulmonary embolism raises no major safety concerns over those of catheter directed thrombolysis (CDT) alone. With regard to efficacy, evidence of any enhancement of thrombolysis over CDT alone is inadequate in 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 ultrasound enhanced, catheter directed thrombolysis (UE CDT) for pulmonary embolism (PE) 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 UE CDT for PE (see section 7.1). 1.3 NICE encourages further research into ultrasound enhanced, catheter directed thrombolysis for pulmonary embolism. Ideally this should include comparative studies against catheter directed thrombolysis alone. Patient selection should be documented. The dose of thrombolytic agent used and the duration of thrombolysis should be reported, together with all complications. Outcome measures should include the success of thrombolysis (complete, partial or failed) and long term sequelae. NICE may update the guidance on publication of further evidence. **The procedure** Ultrasound-enhanced, catheter-directed thrombolysis is an endovascular technique that uses high-frequency, low-energy ultrasound waves in combination with infusion of a thrombolytic drug, with the aim of accelerating plasmin-mediated thrombolysis. It aims to reduce treatment time, the dose of thrombolytic drug delivered and thrombolysis-related complications, compared with catheter-directed thrombolysis alone.
Medical Technologies Guidance	**None published so far this month**
Diagnostics Guidance	**Diagnosing prostate cancer: PROGENSA PCA3 assay and Prostate Health Index DG17** **Recommendations** 1.1 The PROGENSA PCA3 assay and the Prostate Health Index are not recommended for use in people having investigations for suspected prostate cancer, who have had a negative or inconclusive transrectal ultrasound prostate biopsy.

	<u>The procedure</u> The PROGENSA PCA3 assay (Hologic Gen-Probe) is an in vitro nucleic acid amplification test and is intended for the quantitative determination of prostate cancer antigen 3 (PCA3) ribonucleic acid (RNA) in urine. A digital rectal examination is performed, which releases prostate cells and RNA into the urinary tract,which are collected in a urine sample. Once collected, 2.5 ml of the sample is added to a transport tube containing a urine transport medium that triggers the breakdown of any remaining prostate cells and stabilises the RNA.
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
Developmental follow-up of pre-term babies: consultation on the draft scope	29/05/2015	26/06/2015
Electrical stimulation of the lower oesophageal sphincter (LES) for the treatment of gastro-oesophageal reflux disease (GORD): consultation	01/06/2015	26/06/2015
Insertion of a sub-retinal implant for retinitis pigmentosa: consultation	01/06/2015	26/06/2015
UroLift for treating lower urinary tract symptoms of benign prostatic hyperplasia: consultation	29/05/2015	26/06/2015
Short-term interventions for regaining independence: scope consultation	08/05/2015	05/06/2015
Macular degeneration: scope consultation	08/05/2015	08/06/2015
CG113 Anxiety: surveillance review proposal	01/06/2015	12/06/2015
Constipation (opioid-induced) - naloxegol: final appraisal determination	29/05/2015	12/06/2015
Secukinumab for treating moderate to severe plaque psoriasis: final appraisal determination	29/05/2015	12/06/2015
Preterm labour and birth: draft guideline consultation	01/06/2015	13/06/2015
Lung cancer (non-small cell) - nintedanib: final appraisal determination	02/06/2015	16/06/2015
Macular oedema (diabetic) - aflibercept: final appraisal determination	02/06/2015	16/06/2015
Macular oedema (diabetic) - dexamethasone intravitreal implant: final appraisal determination	02/06/2015	16/06/2015
Managing medicines for people receiving social care: scope consultation	15/05/2015	16/06/2015
Ankylosing spondylitis and axial spondyloarthritis (non-radiographic) - adalimumab, etanercept infliximab and golimumab (inc rev TA143 and TA233) ID694: appraisal consultation	29/05/2015	19/06/2015
Ovarian, fallopian tube and peritoneal cancer (BRCA 1 or 2, mutated, relapsed, platinum-sensitive) - olaparib (maintenance) [ID735]: appraisal consultation	01/06/2015	22/06/2015
Procalcitonin testing for diagnosing and monitoring sepsis (ADVIA Centaur BRAHMS PCT assay, BRAHMS PCT Sensitive Kryptor assay, Elecsys BRAHMS PCT assay, LIAISON BRAHMS PCT assay and VIDAS BRAHMS PCT assay)	03/06/2015	24/06/2015
Skin cancer - the VivaScope 1500 and 3000 systems for detecting and monitoring skin lesions: consultation	03/06/2015	24/06/2015
Endovascular aneurysm sealing for abdominal aortic aneurysm: consultation	29/05/2015	25/06/2015

Implantation of a corneal graft-keratoprosthesis combination for severe corneal opacity in wet blinking eyes: consultation	29/05/2015	25/06/2015
Antenatal and postnatal mental health: quality standard consultation	29/05/2015	26/06/2015
Bipolar disorder, psychosis and schizophrenia in children and young people: quality standard consultation	29/05/2015	26/06/2015
Challenging behaviour and learning disabilities: quality standard consultation	29/05/2015	26/06/2015
Prophylaxis against infective endocarditis (Standing Committee A update): addendum consultation	01/06/2015	29/06/2015
Sexual health - condom distribution schemes: consultation on the draft scope	03/06/2015	01/07/2015
Older people - independence and mental wellbeing: consultation on the draft guidance	29/05/2015	10/07/2015
Oral health promotion approaches for dental teams: consultation on the draft guideline	29/05/2015	10/07/2015
Children's attachment: draft guideline consultation	01/06/2015	13/07/2015
Intravenous fluids therapy in children: draft guideline consultation	01/06/2015	13/07/2015
Menopause: draft guideline consultation	01/06/2015	13/07/2015
Social care of older people with complex care needs and multiple long-term conditions: draft guideline consultation	01/06/2015	13/07/2015
Transfusion: draft guideline consultation	01/06/2015	13/07/2015
Tuberculosis (update): draft guideline consultation	01/06/2015	13/07/2015

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