# NICE Update Bulletin April 2016
# issued Wednesday 27th April 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 |
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| **Technology Appraisals (TAs)** | **Topotecan, pegylated liposomal doxorubicin hydrochloride, paclitaxel, trabectedin and gemcitabine for treating recurrent ovarian cancer TA389**<br><br>**Recommendations**<br><br>1.1 Paclitaxel in combination with platinum or as monotherapy is recommended within its marketing authorisation as an option for treating recurrent ovarian cancer.<br><br>1.2 Pegylated liposomal doxorubicin hydrochloride (PLDH) as monotherapy is recommended within its marketing authorisation as an option for treating recurrent ovarian cancer.<br><br>1.3 PLDH in combination with platinum is recommended as an option for treating recurrent ovarian cancer.<br><br>1.4 The following are **not** recommended within their marketing authorisations for treating the first recurrence of platinum-sensitive ovarian cancer:<br><br>• gemcitabine in combination with carboplatin<br>• trabectedin in combination with PLDH<br>• topotecan.<br><br>1.5 Topotecan is **not** recommended within its marketing authorisation for treating recurrent platinum-resistant or platinum-refractory ovarian cancer.<br><br>1.6 People whose treatment with gemcitabine in combination with carboplatin, trabectedin in combination with PLDH, or topotecan 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.<br><br>**The technologies**<br><br>Gemcitabine is a chemotherapeutic agent that inhibits DNA synthesis. It is a nucleoside analogue with anti-tumour activity against a number of solid tumours. Gemcitabine, in combination with carboplatin, has a UK marketing authorisation for the treatment of 'patients with locally advanced or metastatic epithelial ovarian carcinoma, in combination with carboplatin, in patients with relapsed disease following a recurrence-free interval of at least 6 months after platinum-based, first-line therapy'.<br><br>Paclitaxel is a cytotoxic anticancer drug that belongs to the taxane group of drugs. Taxanes prevent the formation of mitotic spindles, interfering with the process of cell division and resulting in cell death. Paclitaxel has a UK marketing authorisation 'for the treatment of metastatic carcinoma of the ovary after failure of standard, platinum containing therapy'.<br><br>Pegylated liposomal doxorubicin hydrochloride (PLDH) is an anthracycline – a group of cytotoxic antibiotics that inhibit DNA synthesis. They also interact with cell membranes, altering their function and generating cytotoxic chemicals. PLDH has a UK marketing authorisation for the treatment of advanced ovarian cancer in women for whom a first-line platinum-based chemotherapy regimen has failed. It has been studied in combination with carboplatin for the treatment of platinum sensitive ovarian cancer but this combination does not have a marketing authorisation.<br><br>Topotecan is a naturally derived chemotherapeutic agent that prevents DNA replication in cancer cells. It has a UK marketing authorisation for the treatment of women with |

'metastatic carcinoma of the ovary after failure of first-line or subsequent chemotherapy'.

Trabectedin is an anticancer agent that binds to the minor groove of the DNA and bends the helix to the major groove, which disrupts the cell cycle. It has a UK marketing authorisation, in combination with PLDH, for the treatment of women 'with relapsed platinum-sensitive ovarian cancer'.

**Financial factors**

Expert clinical opinion suggests that paclitaxel and PLDH are currently both in widespread use and topotecan is not widely used. It is unlikely that the guidance will result in a significant change in resource use in the NHS because it is considered that clinical practice will not change substantially as a result.

These technologies are commissioned by NHS England.

**Sacubitril valsartan for treating symptomatic chronic heart failure with reduced ejection fraction TA388**

**Recommendations**

1.1 Sacubitril valsartan is recommended as an option for treating symptomatic chronic heart failure with reduced ejection fraction, only in people:

- with New York Heart Association (NYHA) class II to IV symptoms and
- with a left ventricular ejection fraction of 35% or less and
- who are already taking a stable dose of angiotensin-converting enzyme (ACE) inhibitors or angiotensin II receptor-blockers (ARBs).

1.2 Treatment with sacubitril valsartan should be started by a heart failure specialist with access to a multidisciplinary heart failure team. Dose titration and monitoring should be performed by the most appropriate team member as defined in NICE's guideline on chronic heart failure in adults: management.

1.3 This guidance is not intended to affect the position of patients whose treatment with sacubitril valsartan 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**

Sacubitril valsartan has a UK marketing authorisation for 'the treatment of symptomatic chronic heart failure with reduced ejection fraction'. Before the marketing authorisation was granted, sacubitril valsartan was available in the NHS through the early access to medicines scheme. Sacubitril valsartan is an angiotensin receptor neprilysin inhibitor, including both a neprilysin inhibitor (sacubitril) and an angiotensin II receptor blocker (ARB; valsartan). Both sacubitril and valsartan lower blood pressure.

**Financial factors**

This technology is commissioned by CCGs.

Because sacubitril valsartan 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. Sacubitril valsartan is the first drug commissioned by CCGs to be approved under the early access to medicines scheme. Previously, all the other drugs available via the access to medicines scheme were cancer drugs and commissioned by NHS England.

**Abiraterone for treating metastatic hormone-relapsed prostate cancer before chemotherapy is indicated TA387**

**Recommendations**

1.1 Abiraterone in combination with prednisone or prednisolone is recommended, within its marketing authorisation, as an option for treating metastatic hormone-relapsed prostate cancer:

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| | • in people who have no or mild symptoms after androgen deprivation therapy has failed, and before chemotherapy is indicated<br>• only when the company rebates the drug cost of abiraterone from the 11th month until the end of treatment for people who remain on treatment for more than 10 months.<br><br>**The technology**<br><br>Abiraterone acetate is a selective androgen synthesis inhibitor that works by blocking cytochrome P450 17 alpha-hydroxylase. It blocks androgen production in the testes and adrenal glands, and in prostatic tumour tissue. Abiraterone is administered orally in combination with prednisolone or prednisone. It is indicated for treating 'metastatic castration resistant [hormone-relapsed] prostate cancer in adult men who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated'. It is also indicated for treating 'metastatic castration resistant prostate cancer in adult men whose disease has progressed on or after a docetaxel-based chemotherapy regimen'.<br><br>**Financial factors**<br><br>This technology is commissioned by NHS England.<br><br>Abiraterone will transfer out of the Cancer Drugs Fund into routine commissioning, which will have a budget impact for NHS England. |
| **Highly specialised technology guidance (HSTs)** | **None published so far this month** |
| **NICE Guidelines (NGs)** | **Controlled drugs: safe use and management NG46**<br><br>This medicines practice guideline covers systems and processes for using and managing controlled drugs safely in all NHS settings except care homes. It aims to improve working practices to comply with legislation and have robust governance arrangements. It also aims to reduce the safety risks associated with controlled drugs.<br><br>**This guideline includes recommendations:**<br><br>• for organisations on developing systems and processes, including governance arrangements, storage, stock checks, transportation and destruction and disposal<br>• for organisations on record keeping, risk assessment and reporting controlled drug-related incidents for organisations<br>• for health professionals on prescribing, obtaining and supplying, administering and handling controlled drugs<br>• for health professionals monitoring use, including governance and systems for reporting concerns and incidents.<br><br>**Routine preoperative tests for elective surgery NG45**<br><br>This clinical guideline covers routine preoperative tests for people aged over 16 who are having elective surgery. It aims to reduce unnecessary testing by advising which tests to offer people before minor, intermediate and major or complex surgery, taking into account specific comorbidities (cardiovascular, renal and respiratory conditions and diabetes and obesity). It does not cover pregnant women or people having cardiothoracic procedures or neurosurgery.<br><br>**This guideline includes recommendations on:**<br><br>• communication<br>• pregnancy testing<br>• sickle cell testing |

- HbA1c testing
- tests for people having minor surgery
- tests for people having intermediate surgery
- tests for people having major or complex surgery

**Depression in adults: recognition and management CG90 (update)**

**April 2016:** Recommendation 1.10.5.1 relating to transcranial magnetic stimulation has been deleted and replaced with a link to the NICE interventional procedure guidance on repetitive transcranial magnetic stimulation for depression (IPG542).

The following updated NICE Guideline was published at the end of March, after publication of the March bulletin:

**Workplace health: management practices NG13 (update)**

**March 2016:** NICE added recommendations about older employees, aged over 50 in paid or unpaid work.

**New Recommendations:**

(1.4.3) Offer older employees the same opportunities (including those identified in NICE's guideline on mental wellbeing at work) as younger employees.

(1.4.4) Treat each employee as an individual and avoid making stereotypical assumptions. For example, don't assume that an older employee may find learning new tasks difficult or that younger employees are less dependable.

(1.6.2) Consider helping employees to access screening and other health services to which they are entitled. This could include providing information about services such as cervical screening and eye tests and allowing time off to attend appointments.

(1.9.4) Line managers should offer older employees the same training and development opportunities as other employees.

(1.9.5) Offer or support older employees, in the same way as other employees, to undertake training if their job role changes.

(1.9.6) Tailor training programmes to meet employees' individual needs, learning style and ability. This could include providing:

- a training needs analysis
- work-based, practical on-the-job training
- mentoring or one-to-one sessions
- opportunities for reflection.

(1.9.7) Encourage and help employees, including older employees, who have few qualifications, or who may have received education and training some years ago, to make the most of learning and development opportunities. This includes giving them the necessary time off for training.

(1.10.5) Address the needs of older employees as part of a broad diversity policy to support retention of older employees. This should include recognising key life stages and life events and taking into account that caring responsibilities may change as people age. This policy could include:

- providing timely and appropriate support, for example, flexible working policies or carer's leave
- communicating working time options and eligibility clearly and without jargon, and providing information on the financial implications of flexible working if relevant
- planning and resourcing the policy effectively, including early liaison between HR and pensions fund staff if appropriate.

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| | (1.10.6) For each employee, identify and address issues affecting their health, wellbeing and ability to do their job. This includes the impact of shift work, and in particular of night working.<br><br>(1.10.7) Consider delivering a workplace health promotion programme incorporating both physical activity and diet. See NICE's pathways on physical activity and diet. |
| **Interventional Procedures Guidance (IPGs)** | **Percutaneous transforaminal endoscopic lumbar discectomy for sciatica IPG556**<br><br>**Recommendations**<br><br>1.1 Current evidence on the safety and efficacy of percutaneous transforaminal endoscopic lumbar discectomy for sciatica is adequate to support the use of this procedure provided that **standard arrangements** are in place for clinical governance, consent and audit.<br><br>1.2 Percutaneous transforaminal endoscopic lumbar discectomy for sciatica is a procedure that needs particular experience. Surgeons should acquire the necessary expertise through specific training and mentoring. It should only be done by surgeons who do the procedure regularly.<br><br>1.3 Details about all patients having percutaneous transforaminal endoscopic lumbar discectomy for sciatica should be entered onto the British Spine Registry.<br><br>**The procedure**<br><br>Percutaneous endoscopic lumbar discectomy procedures aim to preserve bony structures and cause less damage to paravertebral muscles and ligaments than open lumbar discectomy, allowing a shorter hospital stay and faster recovery. Percutaneous transforaminal endoscopic lumbar discectomy is done with the patient in the prone or lateral position using local or general anaesthesia.<br><br>Under fluoroscopic guidance, a needle is inserted through the skin and the appropriate intervertebral foramen into the disc. A small guidewire is placed through the needle and the needle is exchanged for a series of dilators to create a working channel through the muscles, to the ruptured disc. An endoscope and rongeurs are used for removal of the herniated disc fragments. A laser may also be used to aid removal of the disc.<br><br>**Percutaneous interlaminar endoscopic lumbar discectomy for sciatica IPG555**<br><br>**Recommendations**<br><br>1.1 Current evidence on the safety and efficacy of percutaneous interlaminar endoscopic lumbar discectomy for sciatica is adequate to support the use of this procedure provided that **standard arrangements** are in place for clinical governance, consent and audit.<br><br>1.2 Percutaneous interlaminar endoscopic lumbar discectomy for sciatica is a procedure that needs particular experience. Surgeons should acquire the necessary expertise through specific training and mentoring. It should only be done by surgeons who do the procedure regularly.<br><br>1.3 Details about all patients having percutaneous interlaminar endoscopic lumbar discectomy for sciatica should be entered onto the British Spine Registry.<br><br>**The procedure**<br><br>Percutaneous endoscopic lumbar discectomy aims to preserve bony structures and cause less damage to paravertebral muscles and ligaments than open discectomy, allowing a shorter hospital stay and faster recovery. An interlaminar approach provides an alternative to the transforaminal approach for treating central or centro-lateral disc extrusions, especially at the L5–S1 level where the transforaminal approach is difficult. Percutaneous interlaminar endoscopic lumbar discectomy is usually done with the patient in the prone position using local or general anaesthesia.<br><br>Under fluoroscopic guidance, a guidewire is inserted into the appropriate interlaminar space. Dilators are used to expose the ligamentum flavum and the ruptured disc is accessed through this ligament. An endoscope and rongeurs are used to remove the herniated disc fragments. A laser may also be used to aid removal of the disc. |

**Balloon pulmonary angioplasty for chronic thromboembolic pulmonary hypertension IPG554**

**Recommendations**

1.1 Evidence on the safety of balloon pulmonary angioplasty for chronic thromboembolic pulmonary hypertension shows the potential for serious but well-recognised complications. In relation to efficacy:

- For patients for whom pulmonary endarterectomy is considered to be unsuitable (because of comorbidities or the distribution of their arterial disease), 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.
- For patients for whom pulmonary endarterectomy is considered to be suitable, evidence on efficacy is inadequate, especially in the long term. Therefore, for these patients, this procedure should only be used with **special arrangements** for clinical governance, consent and audit or research.

1.2 Clinicians wishing to offer balloon pulmonary angioplasty for chronic thromboembolic pulmonary hypertension to patients for whom pulmonary endarterectomy would be suitable should:

- Inform the clinical governance leads in their NHS trusts.
- Ensure that patients understand the uncertainty about the procedure's efficacy, especially in the long term, 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 balloon pulmonary angioplasty for chronic thromboembolic pulmonary hypertension.

1.3 Patient selection and treatment should only be done in units specialising in the management of chronic thromboembolic pulmonary hypertension and which have timely access to services that are able to deal with any complications.

1.4 NICE encourages further research into balloon pulmonary angioplasty for chronic thromboembolic pulmonary hypertension. Details of patient selection, all complications, and subsequent treatments and interventions for pulmonary hypertension should be collected. Reports should include quality-of-life outcomes, long-term efficacy outcomes and survival. NICE may update the guidance on publication of further evidence.

**The procedure**

Balloon pulmonary angioplasty (BPA) aims to reduce pulmonary hypertension by dilating stenoses in the main or subsegmental pulmonary arteries. The procedure is usually done using a local anaesthetic, with the patient fully anticoagulated. A standard right heart catheterisation is done through the internal jugular vein or femoral vein. The stenosed and occluded arteries that need treatment are identified using selective pulmonary angiography. A balloon catheter is advanced through the stenosis or occlusion, over a guide wire. The balloon is then inflated to dilate each target artery. Between 1 and 6 segmental or subsegmental arteries may be treated during each BPA procedure. The procedure may be repeated until desired haemodynamic measurements are attained.

**Microwave ablation for liver metastases IPG553**

**Recommendations**

1.1 Current evidence on microwave ablation for treating liver metastases raises no major safety concerns and the evidence on efficacy is adequate in terms of tumour ablation. Therefore this procedure may be used provided that **standard arrangements** are in place for clinical governance, consent and audit.

1.2 Patient selection should be carried out by a hepatobiliary cancer multidisciplinary team.

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| | 1.3 Further research would be useful for guiding selection of patients for this procedure. This should document the site and type of the primary tumour being treated, the intention of treatment (palliative or curative), imaging techniques used to assess the efficacy of the procedure, long-term outcomes and survival.<br><br>**The procedure**<br><br>Microwave ablation aims to destroy tumour cells using heat, which creates localised areas of tissue necrosis with minimal damage to surrounding normal tissues.<br><br>The procedure can be done using local anaesthesia or with the patient under general anaesthesia, either percutaneously or during open or laparoscopic surgery. A probe is advanced into each targeted lesion under imaging guidance and the tumour is ablated by delivering high-frequency microwave energy. Multiple pulses of energy may be delivered during a session, and multiple probes can be used to treat larger tumours.<br><br>A variety of different microwave devices can be used for this procedure. |
| **Medical Technologies Guidance** | **None published so far this month** |
| **Diagnostics Guidance** | **None published so far this month** |
| **NICE Quality Standards** | **Antimicrobial stewardship QS121**<br><br>This quality standard covers the effective use of antimicrobials (antibacterial, antiviral, antifungal and antiparasitic medicines) to reduce the emergence of antimicrobial resistance (loss of effectiveness of antimicrobials).<br><br>It covers all settings, all formulations of antimicrobials (oral, parenteral and topical agents) and is for health and social care practitioners, organisations that commission, provide or support the provision of care, as well as people using antimicrobials and their carers.<br><br>**Venous thromboembolism in adults: diagnosis and management QS29 (update)**<br><br>This quality standard covers the diagnosis and treatment of venous thromboembolic diseases in adults, excluding pregnant women.<br><br>**April 2016:** Statement 4 describing the use of compression stockings has been removed. This is because the guidance from NICE has been updated and the advice on using compression stockings has changed. All other information remains the same.<br><br>**Antenatal care QS22 (update)**<br><br>This quality standard covers the antenatal care of all pregnant women up to 42 weeks of pregnancy, in all settings that provide routine antenatal care, including primary, community and hospital-based care.<br><br>The quality standard addresses routine antenatal care, including screening tests for complications of pregnancy, but it does not address the additional care needed to manage these complications if they arise in pregnancy (for example, gestational diabetes, pre-eclampsia and venous thromboembolism).<br><br>**April 2016:** The source recommendations and definitions for statement 6 on risk assessment – gestational diabetes have been updated to reflect changes to the NICE guideline on antenatal care in March 2016.<br><br>**Stroke in adults QS2 (update)**<br><br>This quality standard covers diagnosis and initial management, acute-phase care, rehabilitation and long-term management of stroke in adults (aged over 16 years).<br><br>**April 2016:** This quality standard has been updated and statements prioritised in 2010 replaced. |

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| | The following Quality Standards were published at the end of March, after publication of the March bulletin:<br><br>**Medicines Optimisation QS120**<br><br>This quality standard covers the safe and effective use of medicines for all people who take medicines, including people who are receiving suboptimal benefit from medicines.<br><br>It does not cover aspects of managing medicines specific to care home settings because this is covered by the NICE quality standard on medicines management in care homes (QS85).<br><br>**Anaphylaxis QS119**<br><br>This quality standard covers the care of adults, young people and children after emergency treatment for suspected anaphylaxis, including referral to a specialist allergy service.<br><br>**Food allergy QS118**<br><br>This quality standard covers the diagnosis, assessment and management of food allergy in children, young people and adults. Children and young people are those aged under 19. |
| **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 |
|---|---|---|
| Transition between inpatient mental health settings and community and care home settings: Draft guidance consultation | 16/03/2016 | 27/04/2016 |
| Extracorporeal carbon dioxide removal for acute respiratory failure: Interventional procedure consultation | 01/04/2016 | 29/04/2016 |
| Leukaemia (acute myeloid, over 30% blasts) - azacitidine [ID829] : Appraisal consultation | 08/04/2016 | 29/04/2016 |
| Hip fracture (update): Quality Standard consultation | 05/04/2016 | 04/05/2016 |
| Hyperglycaemia in acute coronary syndromes: management : Surveillance consultation | 20/04/2016 | 04/05/2016 |
| Low back pain and sciatica: Draft guidance consultation | 24/03/2016 | 05/05/2016 |
| Patient experience in adult NHS services: improving the experience of care for people using adult NHS services: Surveillance consultation | 26/04/2016 | 10/05/2016 |
| Multimorbidity: clinical assessment and management: Draft guidance consultation | 31/03/2016 | 12/05/2016 |
| Lung cancer (non-small cell, metastatic) - ramucirumab (after platinum chemotherapy) [ID838] : Appraisal consultation : 1 | 15/04/2016 | 16/05/2016 |
| Transition between inpatient hospital settings and community or care home settings for adults with social care needs : Quality Standard consultation | 18/04/2016 | 17/05/2016 |
| Single-anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S) for treating severe obesity: Interventional procedure consultation | 22/04/2016 | 20/05/2016 |
| Miniature lens system implantation for advanced age-related macular degeneration : Interventional procedure consultation | 22/04/2016 | 20/05/2016 |
| Epiduroscopic lumbar discectomy via the sacral hiatus for sciatica : Interventional procedure consultation | 22/04/2016 | 20/05/2016 |
| Preterm labour and birth: Quality Standard consultation | 26/04/2016 | 24/05/2016 |
| Older people with social care needs and multiple long-term conditions: Quality Standard consultation | 26/04/2016 | 24/05/2016 |
| Intravenous fluid therapy in children and young people in hospital: Quality Standard consultation | 26/04/2016 | 24/05/2016 |
| Preventing suicide in the community: Draft scope consultation | 27/04/2016 | 25/05/2016 |

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