

## NICE Update Bulletin September 2017

Hyperlinks to the relevant NICE web page are included.

Details are also available from the NICE website (<http://www.nice.org.uk>)

<u>Type</u>	<u>Guidance title and reference number</u>
<b>Technology Appraisals (TAs)</b>	<p data-bbox="395 533 1445 600"><a href="#"><u>Cetuximab and panitumumab for previously untreated metastatic colorectal cancer TA439 (update)</u></a></p> <p data-bbox="395 613 1445 712"><b>September 2017:</b> this guidance was amended after a change to the commercial arrangements in August 2017. This change does not affect the cost effectiveness of cetuximab. Sections 1.3, 2 and 5.5 have been updated.</p> <p data-bbox="395 725 655 757"><b><u>Recommendations</u></b></p> <p data-bbox="395 770 1445 869">1.1 Cetuximab is recommended, within its marketing authorisation, as an option for previously untreated epidermal growth factor receptor (EGFR)-expressing, RAS wild-type metastatic colorectal cancer in adults in combination with:</p> <ul data-bbox="443 882 1166 958" style="list-style-type: none"> <li>• 5-fluorouracil, folinic acid and oxaliplatin (FOLFOX) or</li> <li>• 5-fluorouracil, folinic acid and irinotecan (FOLFIRI).</li> </ul> <p data-bbox="395 972 1445 1070">1.2 Panitumumab is recommended, within its marketing authorisation, as an option for previously untreated RAS wild-type metastatic colorectal cancer in adults in combination with:</p> <ul data-bbox="443 1084 644 1160" style="list-style-type: none"> <li>• FOLFOX or</li> <li>• FOLFIRI.</li> </ul> <p data-bbox="395 1173 1445 1272">1.3 The drugs are recommended only when the companies provide them with the discount agreed in the patient access scheme (for panitumumab) or commercial access agreement (for cetuximab).</p> <p data-bbox="395 1285 635 1317"><b><u>The technologies</u></b></p> <p data-bbox="395 1330 1445 1406">Cetuximab is a chimeric monoclonal IgG1 antibody that is specifically directed against epidermal growth factor receptor (EGFR).</p> <p data-bbox="395 1420 1445 1496">Panitumumab is a recombinant, fully human IgG2 monoclonal antibody that binds with high affinity and specificity to human EGFR.</p> <p data-bbox="395 1509 628 1541"><b><u>Financial factors</u></b></p> <p data-bbox="395 1554 1102 1585">These technologies are commissioned by NHS England.</p> <p data-bbox="395 1599 1445 1697">The Department of Health and Amgen have agreed that panitumumab will be available to the NHS with a patient access scheme which makes it available with a discount. The size of the discount is commercial in confidence.</p> <p data-bbox="395 1711 1445 1809">NHS England and Merck have agreed that cetuximab will be available to the NHS with a commercial access agreement. The details of this commercial access agreement are confidential.</p> <p data-bbox="395 1823 1445 1899"><a href="#"><u>Pembrolizumab for treating advanced melanoma after disease progression with ipilimumab TA357 (update)</u></a></p> <p data-bbox="395 1912 1445 2011"><b>September 2017:</b> this guidance was amended after a change to the commercial arrangements in August 2017. This change does not affect the cost effectiveness of pembrolizumab. Sections 1.1, 2.3 and 5.4 have been updated.</p>

**NHS organisations involved:**

Northern, Eastern and Western Devon Clinical Commissioning Group  
South Devon and Torbay Clinical Commissioning Group

## **Recommendations**

1.1 Pembrolizumab is recommended as an option for treating advanced (unresectable or metastatic) melanoma in adults only:

- after the disease has progressed with ipilimumab and, for BRAF V600 mutation-positive disease, a BRAF or MEK inhibitor and
- when the company provides pembrolizumab in line with the commercial access agreement with NHS England.

## **The technology**

Pembrolizumab is a humanised monoclonal antibody. It acts on the programmed cell death protein-1 immune checkpoint receptor pathway, blocking its interaction with ligand on the tumour cells. This allows reactivation of anti-tumour immunity.

## **Financial factors**

This technology is commissioned by NHS England.

The pricing arrangement considered during guidance development was that Merck Sharp & Dohme had agreed a patient access scheme with the Department of Health. This scheme provided a simple discount to the list price of pembrolizumab with the discount applied at the point of purchase or invoice.

After guidance publication in October 2015, the company agreed a commercial access agreement with NHS England that replaces the patient access scheme on equivalent terms. The financial terms of the agreement are commercial in confidence.

## **[Pembrolizumab for advanced melanoma not previously treated with ipilimumab TA366 \(update\)](#)**

**September 2017:** this guidance was amended after a change to the commercial arrangements in August 2017. This change does not affect the cost effectiveness of pembrolizumab. Sections 1.1, 2.3 and 5.4 have been updated.

## **Recommendations**

1.1 Pembrolizumab is recommended as an option for treating advanced (unresectable or metastatic) melanoma that has not been previously treated with ipilimumab, in adults, only when the company provides pembrolizumab in line with the commercial access agreement with NHS England.

## **The technology**

Pembrolizumab is a humanised monoclonal antibody. It acts on the programmed cell death protein-1 immune-checkpoint receptor pathway, blocking its interaction with ligand on the tumour cells. This allows reactivation of anti-tumour immunity.

## **Financial factors**

This technology is commissioned by NHS England.

The pricing arrangement considered during guidance development was that Merck Sharp & Dohme had agreed a patient access scheme with the Department of Health. This scheme provided a simple discount to the list price of pembrolizumab with the discount applied at the point of purchase or invoice.

After guidance publication in November 2015, the company agreed a commercial access agreement with NHS England that replaces the patient access scheme on equivalent terms. The financial terms of the agreement are commercial in confidence.

## [Pembrolizumab for treating PD-L1-positive non-small-cell lung cancer after chemotherapy TA428 \(update\)](#)

**September 2017:** this guidance was amended after a change to the commercial arrangements in August 2017. This change does not affect the cost effectiveness of pembrolizumab. Sections 1.1, 2 and 5.4 have been updated.

### **Recommendations**

1.1 Pembrolizumab is recommended as an option for treating locally advanced or metastatic PD-L1-positive non-small-cell lung cancer in adults who have had at least one chemotherapy (and targeted treatment if they have an epidermal growth factor receptor [EGFR]- or anaplastic lymphoma kinase [ALK]-positive tumour), only if:

- pembrolizumab is stopped at 2 years of uninterrupted treatment and no documented disease progression, and
- the company provides pembrolizumab in line with the commercial access agreement with NHS England.

1.2 This guidance is not intended to affect the position of patients whose treatment with pembrolizumab 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**

Pembrolizumab is a humanised monoclonal antibody that acts on the 'programmed death 1' protein (PD-1). The PD-1 protein is part of the immune checkpoint pathway, and blocking its activity may promote an anti-tumour immune response.

### **Financial factors**

This technology is commissioned by NHS England.

The pricing arrangement considered during guidance development was that Merck Sharp & Dohme had agreed a patient access scheme with the Department of Health. This scheme provided a simple discount to the list price of pembrolizumab with the discount applied at the point of purchase or invoice.

After guidance publication in January 2017, the company agreed a commercial access agreement with NHS England that replaces the patient access scheme on equivalent terms. The financial terms of the agreement are commercial in confidence.

## [Paclitaxel as albumin-bound nanoparticles with gemcitabine for untreated metastatic pancreatic cancer TA476](#)

### **Recommendations**

This guidance replaces NICE technology appraisal guidance 360 on paclitaxel as albumin-bound nanoparticles in combination with gemcitabine for previously untreated metastatic pancreatic cancer.

1.1 Paclitaxel as albumin-bound nanoparticles (nab-paclitaxel) with gemcitabine is recommended as an option for untreated metastatic adenocarcinoma of the pancreas in adults, only if:

- other combination chemotherapies are unsuitable and they would otherwise have gemcitabine monotherapy and
- the company provides nab-paclitaxel with the discount agreed in the patient access scheme.

1.2 This recommendation is not intended to affect treatment with nab-paclitaxel that was started in the NHS before this guidance was published. People having treatment outside this recommendation may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS clinician consider it appropriate to stop.

### **The technology**

Paclitaxel as albumin-bound nanoparticles with gemcitabine is indicated 'for the first-line treatment of adult patients with metastatic adenocarcinoma of the pancreas'.

### **Financial factors**

This technology is commissioned by NHS England.

NICE does not expect this guidance to have a significant impact on resources; it will be less than £5 million per year in England (or £9,100 per 100,000 population). This is because treatment is recommended for people for whom other combination chemotherapies are unsuitable and who would otherwise have gemcitabine monotherapy. NICE estimates that around 600 people in England will have nab-paclitaxel treatment. The list price of nab-paclitaxel has a discount that is commercial in confidence.

### **[Dimethyl fumarate for treating moderate to severe plaque psoriasis TA475](#)**

#### **Recommendations**

1.1 Dimethyl fumarate is recommended as an option for treating plaque psoriasis in adults, only if the disease:

- is severe, as defined by a total Psoriasis Area and Severity Index (PASI) of 10 or more and a Dermatology Life Quality Index (DLQI) of more than 10 and
- has not responded to other systemic therapies, including, ciclosporin, methotrexate and PUVA (psoralen and long-wave ultraviolet A radiation), or these options are contraindicated or not tolerated.

1.2 Stop dimethyl fumarate treatment at 16 weeks if the psoriasis has not responded adequately. An adequate response is defined as:

- a 75% reduction in the PASI score (PASI 75) from when treatment started or
- a 50% reduction in the PASI score (PASI 50) and a 5-point reduction in DLQI from when treatment started.

1.3 When using the PASI, healthcare professionals should take into account skin colour and how this could affect the PASI score, and make the clinical adjustments they consider appropriate.

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

1.5 These recommendations are not intended to affect treatment with dimethyl fumarate that was started in the NHS before this guidance was published. People having treatment outside these recommendations may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS clinician consider it appropriate to stop.

### **The technology**

Dimethyl fumarate is indicated 'for the treatment of moderate to severe plaque psoriasis in adults in need of systemic medicinal therapy'.

### **Financial factors**

This technology is commissioned by CCGs.

NICE does not expect this guidance to have a significant impact on resources; it will be less than £5 million per year in England (or £9,100 per 100,000 population).

This is because the technology is an option alongside current standard treatment options and they do not think practice will change substantially as a result of this guidance. Using the list price, dimethyl fumarate is cost saving for the NHS compared to biological treatment options and cost incurring compared to non-biological treatments.

### **[Sorafenib for treating advanced hepatocellular carcinoma TA474](#)**

#### **Recommendations**

This guidance is a Cancer Drugs Fund reconsideration of sorafenib for the treatment of advanced hepatocellular carcinoma (TA189). This guidance replaces TA189.

- 1.1 Sorafenib is recommended as an option for treating advanced hepatocellular carcinoma only for people with Child-Pugh grade A liver impairment, only if the company provides sorafenib within the agreed commercial access arrangement.
- 1.2 This recommendation is not intended to affect treatment with sorafenib that was started in the NHS before this guidance was published. People having treatment outside this recommendation may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS clinician consider it appropriate to stop.

#### **The technology**

Sorafenib is a multikinase inhibitor that inhibits tumour blood vessel development and tumour cell proliferation. It does this by inhibiting the Raf cascade, vascular endothelial growth factor and platelet-derived growth factor receptors of tumour cells, vascular endothelial cells and pericytes.

### **Financial factors**

This technology is commissioned by NHS England.

Sorafenib will be available to the NHS with a commercial access agreement which makes it available with a discount that is commercial in confidence.

The following NICE Technology Appraisals were published at the end of August, after publication of the August bulletin:

### **[Cetuximab for treating recurrent or metastatic squamous cell cancer of the head and neck TA473](#)**

#### **Recommendations**

- 1.1 Cetuximab in combination with platinum-based chemotherapy is recommended as an option for treating recurrent or metastatic squamous cell cancer of the head and neck in adults only:
  - if the cancer started in the oral cavity and
  - when the company provides the drug in line with the commercial access agreement with NHS England.
- 1.2 These recommendations are not intended to affect treatment with cetuximab that was started within the NHS before this guidance was published. People having treatment outside these recommendations may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS clinician consider it appropriate to stop.

### **The technology**

Cetuximab is a recombinant monoclonal antibody that blocks human epidermal growth factor receptor (EGFR). It inhibits the proliferation of cells that depend on EGFR activation for growth.

### **Financial factors**

This technology is commissioned by NHS England.

NICE does not expect this guidance to have a significant impact on resources; it will be less than £5 million per year in England (or £9,100 per 100,000 population). This is because the population size is small and fewer than 100 people per year will be treated in routine commissioning. The list price of cetuximab has a discount that is commercial in confidence.

### **[Obinutuzumab with bendamustine for treating follicular lymphoma refractory to rituximab TA472](#)**

### **Recommendations**

1.1 Obinutuzumab in combination with bendamustine followed by obinutuzumab maintenance is recommended for use within the Cancer Drugs Fund as an option for treating adults with follicular lymphoma that did not respond or progressed during or up to 6 months after treatment with rituximab or a rituximab-containing regimen, only if the conditions in the managed access agreement for obinutuzumab are followed.

### **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.

### **Financial factors**

This technology is commissioned by NHS England.

Obinutuzumab will be available to the NHS in line with the managed access agreement with NHS England. The commercial arrangements included in the managed access agreement will be operationalised as a patient access scheme, registered with the Department of Health. The Department of Health and Roche have agreed that obinutuzumab will be available to the NHS with a patient access scheme which makes it available with a discount. The size of the discount is commercial in confidence.

### **[Eluxadoline for treating irritable bowel syndrome with diarrhoea TA471](#)**

### **Recommendations**

1.1 Eluxadoline is recommended as an option for treating irritable bowel syndrome with diarrhoea in adults, only if:

- the condition has not responded to other pharmacological treatments (for example, ant motility agents, antispasmodics, tricyclic antidepressants) or
- pharmacological treatments are contraindicated or not tolerated, and
- it is started in secondary care.

1.2 Stop eluxadoline at 4 weeks if there is inadequate relief of the symptoms of irritable bowel syndrome with diarrhoea.

1.3 These recommendations are not intended to affect treatment with eluxadoline that was started in the NHS before this guidance was published. Adults having treatment outside these recommendations may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS clinician consider it appropriate to stop.

	<p><b><u>The technology</u></b></p> <p>Eluxadoline is an opioid receptor agonist and delta-opioid receptor antagonist that binds to opioid receptors in the digestive system and slows down the movement of food through the gut.</p> <p><b><u>Financial factors</u></b></p> <p>This technology is commissioned by CCGs.</p> <p>NICE concluded that eluxadoline would be started in secondary care and that the most appropriate population for eluxadoline included people whose condition had not responded to other pharmacological treatments, or when these treatments are contraindicated or not tolerated.</p> <p>NICE has estimated the annual costs of implementing this guidance for the population of England. The cost from year 2021/22 once steady uptake is reached, is equivalent to £11,300 per 100,000 population.</p>
<p><b>Highly specialised technology guidance (HSTs)</b></p>	<p>None published so far this month.</p>
<p><b>NICE Guidelines (NGs)</b></p>	<p><b><u><a href="#">Faltering growth- recognition and management of faltering growth in children NG75</a></u></b></p> <p>This guideline covers recognition, assessment and monitoring of faltering growth in infants and children. It includes a definition of growth thresholds for concern and identifying the risk factors for, and possible causes of, faltering growth. It also covers interventions, when to refer, service design, and information and support.</p> <p>The guideline includes recommendations on:</p> <ul style="list-style-type: none"> <li>• weight loss in the early days of life</li> <li>• faltering growth after the early days of life</li> <li>• organisation of care</li> <li>• information and support for parents and carers</li> </ul> <p><b><u><a href="#">Intermediate care including reablement NG74</a></u></b></p> <p>This guideline covers referral and assessment for intermediate care and how to deliver the service. Intermediate care is a multidisciplinary service that helps people to be as independent as possible. It provides support and rehabilitation to people at risk of hospital admission or who have been in hospital. It aims to ensure people transfer from hospital to the community in a timely way and to prevent unnecessary admissions to hospitals and residential care.</p> <p>The guideline includes recommendations on:</p> <ul style="list-style-type: none"> <li>• core principles of intermediate care, including reablement</li> <li>• supporting infrastructure</li> <li>• assessment of need for intermediate care</li> <li>• referral into intermediate care and entering the service</li> <li>• delivering intermediate care</li> <li>• transition from intermediate care</li> <li>• training and development</li> </ul>

### [Urinary tract infection in under 16s: diagnosis and management CG54 \(update\)](#)

This guideline covers diagnosing and managing first or recurrent upper or lower urinary tract infections in infants, children and young people. It aims to achieve more consistent clinical practice, based on accurate diagnosis and effective management.

**September 2017:** NICE reviewed the evidence for urine testing strategies for infants and children under 3 years and changed some recommendations in section 1.1.5.

### [Sepsis: recognition, diagnosis and early management NG51 \(update\)](#)

This guideline covers the recognition, diagnosis and early management of sepsis for all populations. The guideline committee identified that the key issues to be included were: recognition and early assessment, diagnostic and prognostic value of blood markers for sepsis, initial treatment, escalating care, identifying the source of infection, early monitoring, information and support for patients and carers, and training and education.

**September 2017:** NICE updated recommendation 1.4.3 to properly divide 2 bullet points. Table 3 and recommendations 1.4.9 and 1.9.2 were corrected to give oxygen saturation as less than 92% in air. Table 2 was amended to include tympanic temperature as a moderate risk factor. Table 3 was amended to add pallor of skin, lips or tongue as an intermediate to high risk factor, and recommendation 1.4.9 was amended to remove pale or flushed as an intermediate risk factor. Minor corrections for consistency were also made between the recommendations, tables and algorithms. The accompanying algorithms have also been redesigned to help with readability.

### [Depression in children and young people: identification and management CG28 \(update\)](#)

This guideline covers identifying and managing depression in children and young people aged between 5 and 18 years. Based on the stepped care model, it aims to improve recognition and assessment and promote effective treatments for mild, moderate and severe depression.

**September 2017:** NICE updated recommendation 1.1.5.4 to clarify the training needed for therapists. They also updated recommendation 1.4.1.1 to delete reference to a preferred questionnaire as this is no longer relevant. Footnotes 3, 5 and 6 were also updated to clarify the advice on marketing authorisation and licensed indications.

### [Psoriasis: assessment and management CG153 \(update\)](#)

This guideline covers assessing and managing psoriasis in adults, young people and children. It aims to improve long-term disease control and quality of life for people with psoriasis.

**September 2017:** NICE revised the guideline throughout to link to other NICE guidance (including technology appraisals) and some relevant non-NICE guidelines, as well as including new MHRA safety advice and updated licensing information.

### [Fertility problems: assessment and treatment CG156 \(update\)](#)

This guideline covers diagnosing and treating fertility problems. It aims to reduce variation in practice and improve the way fertility problems are investigated and managed.

**September 2017:** NICE stood down section 1.7 in this guideline as it has been superseded by publication of the NICE guideline on endometriosis.

	<p><a href="#"><u>Endometriosis: diagnosis and management NG73</u></a></p> <p>This guideline covers diagnosing and managing endometriosis. It aims to raise awareness of the symptoms of endometriosis, and to provide clear advice on what action to take when women with signs and symptoms first present in healthcare settings. It also provides advice on the range of treatments available.</p> <p>This guideline updates and replaces the recommendations on endometriosis in NICE's fertility problems guideline, which includes recommendations on fertility tests and treatments such as assisted reproduction.</p> <p>The guideline includes recommendations on:</p> <ul style="list-style-type: none"> <li>• organisation of care</li> <li>• information and support</li> <li>• endometriosis symptoms and signs</li> <li>• when to refer</li> <li>• diagnosing endometriosis</li> <li>• pharmacological management</li> <li>• surgical management</li> </ul>
<p><b>NICE Public Health Guidelines</b></p>	<p><a href="#"><u>Immunisations: reducing differences in uptake in under 19s PH21 (update)</u></a></p> <p>This guideline covers increasing immunisation uptake among children and young people aged under 19 years in groups and settings where immunisation coverage is low. It aims to improve access to immunisation services and increase timely immunisation of children and young people. It also aims to ensure babies born to mothers infected with hepatitis B are immunised.</p> <p><b>September 2017:</b> NICE added links to the online version of the Green Book, parts of recommendation 6 were removed to bring it in line with the incorporation of hepatitis B vaccination into the standard routine vaccinations for babies, and terminology throughout was updated to reflect current public sector structures for commissioning and delivery of immunisation services.</p> <p><a href="#"><u>Type 2 diabetes: prevention in people at high risk PH38 (update)</u></a></p> <p>This guideline covers how to identify adults at high risk of type 2 diabetes. It aims to remind practitioners that age is no barrier to being at high risk of, or developing, the condition. It also aims to help them provide those at high risk with an effective and appropriate intensive lifestyle-change programme to prevent or delay the onset of type 2 diabetes. The recommendations in this guideline can be used alongside the NHS Health Check programme.</p> <p><b>September 2017:</b> NICE reviewed the evidence for intensive lifestyle-change programmes and metformin for people at risk of type 2 diabetes. They added new recommendations on lifestyle-change programmes (recommendations 1.5.5 and 1.5.6) and changed the recommendation about offering metformin (recommendation 1.19.1).</p>
<p><b>NICE Medicines Practice Guidelines (MPGs)</b></p>	<p>None published so far this month.</p>
<p><b>Interventional Procedures Guidance (IPGs)</b></p>	<p><a href="#"><u>Intramuscular diaphragm stimulation for ventilator-dependent chronic respiratory failure caused by high spinal cord injuries IPG594</u></a></p> <p>This guidance replaces NICE interventional procedures guidance on intramuscular diaphragm stimulation for ventilator-dependent chronic respiratory failure due to neurological disease (IPG307).</p>

### **Recommendations**

1.1 Current evidence on intramuscular diaphragm stimulation for ventilator-dependent chronic respiratory failure caused by high spinal cord injuries shows that there are serious but well-recognised safety concerns. Evidence on efficacy is limited in quantity and quality. Therefore, this procedure should only be used in the context of **research**.

1.2 Further research should give details of patient selection, patient-reported outcomes and long-term effects including survival and quality of life. NICE may update the guidance on publication of further evidence.

### **The procedure**

The aim of intramuscular diaphragm stimulation is to make the diaphragm contract, strengthening it and allowing full or partial weaning from mechanical ventilation. This procedure needs intact phrenic nerve function, and avoids the need to access the phrenic nerve through the neck or thorax, as well as reducing the risk of phrenic nerve damage.

The procedure is done laparoscopically with the patient under general anaesthesia. A special probe is used to identify areas of the diaphragm where minimal electrical stimulation causes maximal diaphragm contraction (known as the 'motor points'). Two intramuscular electrodes are implanted on the abdominal surface of each hemi-diaphragm at the motor points. The electrode leads are tunnelled subcutaneously to an exit site in the chest where they are connected to an external battery-powered pulse generator. A reference electrode (anode) is also implanted and the leads tunnelled with the other electrodes. Intraoperative stimulation and voltage calibration tests are carried out to confirm adequate contraction of the diaphragm. After implantation the patient has a diaphragm conditioning programme, which involves progressive use of the system for increasing periods of time with gradual weaning from the ventilator.

### **[Intramuscular diaphragm stimulation for ventilator-dependent chronic respiratory failure caused by motor neurone disease IPG593](#)**

This guidance replaces NICE interventional procedures guidance on intramuscular diaphragm stimulation for ventilator-dependent chronic respiratory failure due to neurological disease (IPG307).

### **Recommendations**

1.1 Current evidence on intramuscular diaphragm stimulation for ventilator-dependent chronic respiratory failure caused by motor neurone disease suggests that there are serious long-term safety concerns. Evidence on efficacy is limited and therefore, this procedure **should not be used** to treat this condition.

### **The procedure**

The aim of intramuscular diaphragm stimulation is to make the diaphragm contract, strengthening it and allowing full or partial weaning from mechanical ventilation. This procedure needs intact phrenic nerve function, and avoids the need to access the phrenic nerve through the neck or thorax, as well as reducing the risk of phrenic nerve damage.

The procedure is done laparoscopically with the patient under general anaesthesia. A special probe is used to identify areas of the diaphragm where minimal electrical stimulation causes maximal diaphragm contraction (known as the 'motor points'). Two intramuscular electrodes are implanted on the abdominal surface of each hemi-diaphragm at the motor points. The electrode leads are tunnelled subcutaneously to an exit site in the chest where they are connected to an external battery-powered pulse generator.

A reference electrode (anode) is also implanted and the leads tunnelled with the other electrodes. Intraoperative stimulation and voltage calibration tests are carried out to confirm adequate contraction of the diaphragm. After implantation the patient has a diaphragm conditioning programme, which involves progressive use of the system for increasing periods of time with gradual weaning from the ventilator.

### [High-intensity focused ultrasound for symptomatic breast fibroadenoma IPG592](#)

#### **Recommendations**

- 1.1 The evidence on high-intensity focused ultrasound for symptomatic breast fibroadenoma raises no major safety concerns. Evidence on its efficacy is inadequate in quantity and quality. Therefore, this procedure should only be used with **special arrangements** for clinical governance, consent and audit or research.
- 1.2 Clinicians wishing to do high-intensity focused ultrasound for symptomatic breast fibroadenoma should:
  - 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 high-intensity focused ultrasound for symptomatic breast fibroadenoma (see section 7.1).
- 1.3 Patients should be informed about all the alternative treatment options, which could include conservative treatment.
- 1.4 Further research should include publication of patient-reported outcome measures and studies with long-term follow-up.

#### **The procedure**

High-intensity focused ultrasound for breast fibroadenomas is a minimally invasive thermoablative technique that can be done at an outpatient clinic under local anaesthesia and sedation. A focusing ultrasound device delivers the treatment and allows for simultaneous imaging of the treatment area. The technology uses sound waves that propagate through the tissues, generating local heat and inducing coagulative necrosis, protein denaturation and cellular destruction. A strong acute inflammatory response follows. Remodelling of the chronic inflammatory response lasts for up to 3 months and involves cellular regeneration, proliferation, migration and removal of debris.

Tumour size reduction should happen gradually with no need for further intervention.

### [Ab externo canaloplasty for primary open-angle glaucoma IPG591](#)

This guidance replaces NICE interventional procedures guidance on canaloplasty for primary open-angle glaucoma (IPG260).

#### **Recommendations**

- 1.1 Current evidence on the safety and efficacy of ab externo canaloplasty for primary open-angle glaucoma is adequate to support the use of this procedure provided that **standard arrangements** are in place for clinical governance, consent and audit.
- 1.2 Ab externo canaloplasty for primary open-angle glaucoma should only be done by clinicians with specific training in the procedure.

	<p><b><u>The procedure</u></b></p> <p>Ab externo canaloplasty is a surgical technique that aims to reduce intraocular pressure by improving drainage of aqueous fluid from the eye. It is done under local or general anaesthetic. A superficial hinged flap of sclera is made and a deeper flap excised, exposing the Schlemm's canal. An ultrasound imaging system is used to identify the canal and to visualise the surgical instruments when they are in the canal. A microcatheter with an illuminated tip is introduced into the canal and advanced around its entire circumference. As the catheter tip advances, viscoelastic fluid is injected into the canal to dilate it. When catheterisation of the entire canal is complete a suture is tied to the tip of the microcatheter and it is withdrawn, pulling the suture into the canal. The suture is cut, tied in a loop encircling the inner wall of the canal and tightened. This widens the canal. The superficial flap is sutured.</p>
<p><b>Medical Technologies Guidance</b></p>	<p>None published so far this month.</p>
<p><b>Diagnostics Guidance</b></p>	<p>None published so far this month.</p>
<p><b>NICE Quality Standards</b></p>	<p><b><u><a href="#">Urinary tract infection in children and young people QS36 (update)</a></u></b></p> <p>This quality standard covers diagnosing and managing urinary tract infection in infants, children and young people (under 16). It includes new and recurrent infections of the upper or lower urinary tract. It describes high-quality care in priority areas for improvement.</p> <p><b>September 2017:</b> The source guidance information and definitions section for statement 1 were updated to ensure alignment with the updated NICE guideline on urinary tract infection in under 16s.</p> <p><b><u><a href="#">Sepsis QS161</a></u></b></p> <p>This quality standard covers the recognition, diagnosis and early management of sepsis for all populations. It describes high-quality care in priority areas for improvement.</p> <p><b><u><a href="#">End of life care for infants, children and young people QS160</a></u></b></p> <p>This quality standard covers end of life care for infants, children and young people (from birth to 18 years) who have a life-limiting condition. Life-limiting conditions are those that are expected to result in an early death for the person. It also covers support for family members and carers. It describes high-quality care in priority areas for improvement.</p> <p><b><u><a href="#">Transition between inpatient mental health settings and community or care home settings QS159</a></u></b></p> <p>This quality standard covers transitions for children, young people and adults between mental health hospitals and their own homes, care homes or other community settings. It includes the period before, during and after a person is admitted to, and discharged from, a mental health hospital. It describes high-quality care in priority areas for improvement.</p> <p><b><u><a href="#">Rehabilitation after critical illness in adults QS158</a></u></b></p> <p>This quality standard covers adults with rehabilitation needs as a result of critical illness that required level 2 or level 3 critical care. It describes high-quality care in priority areas for improvement. It does not cover conditions for which published quality standards already include specialist rehabilitation after a critical care stay – such as head injury, myocardial infarction and stroke.</p>

**[HIV testing: encouraging uptake QS157](#)**

This quality standard covers interventions to improve the uptake of HIV testing among people who may have undiagnosed HIV. It focuses on increasing testing to reduce undiagnosed infection in people at increased risk of exposure. It describes high-quality care in priority areas for improvement.

It does not cover HIV testing in antenatal services as a universal antenatal screening programme is currently offered in England.

**[Physical health of people in prisons QS156](#)**

This quality standard covers assessing, diagnosing and managing physical health problems of adults aged 18 years and older in prisons or young offender institutes. It describes high-quality care in priority areas for improvement.

It does not cover people in immigration removal centres, people in police custody, NHS care provided for prisoners outside the prison service (for example in an acute hospital), end of life care, and dental management, other than self-care.

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

Title / link	End date of consultation
<a href="#">People's experience in adult social care services: improving the experience of care for people using adult social care services</a>	03/10/2017
<a href="#">Multiple Pregnancy (update)</a>	03/10/2017
<a href="#">Obinutuzumab for untreated advanced follicular lymphoma [ID1020]</a>	05/10/2017
<a href="#">Mental health of adults in contact with the criminal justice system</a>	05/10/2017
<a href="#">Attention deficit hyperactivity disorder (update)</a>	18/10/2017
<a href="#">Otitis media (acute): antimicrobial prescribing</a>	19/10/2017
<a href="#">Lymphoma (mantle cell, relapsed, refractory) - ibrutinib [ID753]</a>	19/10/2017
<a href="#">Stroke and transient ischaemic attack in over 16s: diagnosis and initial management (update)</a>	25/10/2017
<a href="#">Smoking cessation interventions and services</a>	01/11/2017
<a href="#">Lyme disease</a>	06/11/2017

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