



# Health Technologies Update Report

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**Report 2012/001**

April 2012



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# 1 Introduction

This report provides summaries of the Healthcare Improvement Scotland health technology assessment (HTA) programme outputs, outlining the technology under consideration, patient and comparator groups and highlights the key clinical and cost-effectiveness results and any patient/safety issues, where applicable.

It also presents information on the:

- National Institute for Health and Clinical Excellence (NICE) technology appraisals and medical technologies guidance published this period and information on the NICE forward work plan
- NICE interventional procedures published this period
- Scottish Intercollegiate Guidelines Network (SIGN) work programme.

NICE multiple technology appraisals (MTAs) are processed by Healthcare Improvement Scotland to establish whether the recommendations are valid for Scotland. For such MTAs, NHSScotland should take account of the NICE guidance and ensure that recommended drugs and treatments are made available to meet clinical need. All other NICE outputs are provided for information only.

The report is of interest to NHSScotland boards to inform their planning and decision making. The report may also be of interest to public partners, manufacturers and other health technology bodies.

## 2 Healthcare Improvement Scotland HTA programme

This section summarises the Healthcare Improvement Scotland HTA programme, to include HTAs, systematic reviews, evidence notes and technologies scoping reports published since the last report.

### 2.1 Systematic reviews

#### **Systematic Review 4: Brachytherapy to treat different types of cancer: an overview of the evidence; April 2012 (published December 2011)**

Full report available at:

[http://www.healthcareimprovementscotland.org/programmes/clinical\\_cost\\_effectiveness/shtg\\_systematic\\_reviews/brachytherapy.aspx](http://www.healthcareimprovementscotland.org/programmes/clinical_cost_effectiveness/shtg_systematic_reviews/brachytherapy.aspx)

**Description:** Brachytherapy can be used in the treatment of certain cancers. It involves placing a radiation source close to (intracavitary or intraluminal therapy) or into the tumour or treatment site (interstitial therapy). It can be used alone, or in combination with other therapies. High dose rate (HDR) brachytherapy uses radionuclides such as iridium-192 at dose rates of 20 cGy per minute or more. Low dose rate (LDR) brachytherapy can be practiced using a variety of sources (eg radium-226, cesium-137 and iodine-125) and is delivered at dose rates of 4–200 cGy per hour.

**Patient group(s):** Localised prostate cancer; palliation of dysphagia in oesophageal cancer; lung cancer; cervical and endometrial cancer; head and neck cancer; rectal cancer; breast cancer in women.

**Comparators:** Depending on the indication, treatment options include external beam radiotherapy (EBRT), surgery, high intensity focused ultrasound, cryotherapy and chemotherapy.

**Clinical effectiveness:**

**Prostate cancer:** NICE (2008) guidelines state that brachytherapy (LDR) alone is not recommended for men with high-risk localised cancer. However, it is presented as a treatment option for men with low-risk and intermediate-risk localised disease.

Observational studies suggest that for low-risk patients, biochemical recurrence-free survival after LDR brachytherapy is equivalent to that after EBRT or prostatectomy. Observational studies suggest that HDR brachytherapy in combination with EBRT may improve outcomes in patients with localised prostate cancer.

**Palliation of dysphagia in oesophageal cancer:** SIGN guidelines and a Cochrane review state that endoluminal brachytherapy is an option for patients with dysphagia from oesophageal cancer.

**Lung cancer:** The SIGN guideline recommends that brachytherapy may be useful in relieving malignant airway obstruction in patients with inoperable non small cell lung cancer (NSCLC) where standard EBRT has failed. Evidence from small randomised controlled trials (RCTs) suggests that EBRT alone is more effective for palliation of NSCLC symptoms than HDR endobronchial brachytherapy (EBB) alone, but there is insufficient evidence from RCTs that EBRT plus EBB is superior to EBRT alone. Uncontrolled observational studies of HDR brachytherapy with curative intent have recorded 2-year survival rates of 58% and 78%, and 5-year survival of 24% in patients with early stage NSCLC.

**Cervical and endometrial cancer:** SIGN guidelines on cervical cancer state that brachytherapy should be considered an essential component of radical radiotherapy or chemoradiotherapy. Current evidence suggests similar survival and complication rates with HDR and LDR brachytherapy for cervical cancer. Evidence from one randomised trial reported no significant difference in vaginal recurrence, disease-free and overall survival in patients with intermediate- to high-risk endometrial cancer receiving either brachytherapy or EBRT following surgery. A randomised trial comparing postoperative brachytherapy with surgery alone in low risk endometrial cancer reported no significant

difference in vaginal recurrence.

**Head and neck cancer:** The SIGN guidelines present 4 Grade D recommendations that: (1) Patients with small accessible (T1/2) tumours of the oral cavity and oropharynx may be treated by interstitial brachytherapy to a dose of 65-70 Gy at a dose rate of less than 0.55 Gy/hour. (2) Patients with small accessible recurrences in a previously irradiated region may be considered for interstitial brachytherapy in centres with appropriate facilities and expertise. (3) Early oropharyngeal cancer (stage I and II) patients with small accessible tumours may be treated by a combination of EBRT and brachytherapy in centres with appropriate expertise. (4) Patients with early oral cavity cancer may be treated by: surgical resection, where rim rather than segmental resection should be performed, where possible, in situations where removal of the bone is required to achieve clear histological margins; brachytherapy in accessible, well demarcated lesions.

**Rectal cancer:** NICE interventional procedures guidance advises that current evidence on the short-term safety of preoperative HDR brachytherapy for rectal cancer and its efficacy in reducing tumour bulk appears adequate. However, evidence about the advantages of the procedure as an adjunct to surgery and its effect on long-term survival is not adequate to support the use of this procedure without special arrangements for consent, audit and clinical governance.

**Breast cancer:** NICE guidance states that brachytherapy as the sole method of adjuvant radiotherapy for breast cancer after local excision raises no major safety concerns, although the limited evidence on efficacy means that this procedure should only be used in the context of research. No systematic review of randomised trial evidence was identified on the use of boost brachytherapy as an adjunct to conventional whole breast irradiation following surgery for breast cancer.

**Cost effectiveness:** For all the indications considered, there was insufficient evidence to draw conclusions on cost-effectiveness.

**Patient/safety issues:**

**Prostate cancer:** Low-level observational studies, mainly on LDR, reported on by NICE guidelines suggest that brachytherapy has a similar adverse event rate as prostatectomy and EBRT. Case series evidence suggests that there are lower rates of impotence and incontinence than seen with surgery or EBRT, but higher rates of obstructive and irritative urinary symptoms.

**Palliation of dysphagia in oesophageal cancer:** A general review article states that the major complications after brachytherapy are fistula formation (occurring in 3–10% of patients) and haemorrhage (in up to 5% of patients). Less severe complications include mild retrosternal pain and radiation oesophagitis.

**Lung cancer:** A systematic review of 18 prospective observational studies reported the main adverse effects associated with palliative HDR endobronchial brachytherapy to be radiation bronchitis (17%), fatal haemoptysis (10%), bronchial or tracheal stenosis (4%), bronchial necrosis or fistula formation (3%), pneumothorax (3%) and bronchial/tracheal spasm (2%).

**Cervical cancer:** Complications of HDR brachytherapy include diarrhoea, bleeding, colitis and cystitis, and also fistulae requiring surgery. There is also the possibility of long-term problems affecting the bowel, bladder and rectum. A Cochrane review comparing HDR and LDR brachytherapy reported more complications in the HDR arm, but most were not statistically significant.

**Endometrial cancer:** In one trial, patients receiving brachytherapy experienced fewer gastrointestinal complications but higher vaginal atrophy compared with EBRT. In another trial, dysuria, frequency and incontinence were slightly more common after vaginal irradiation compared to surgery.

**Head and neck cancer:** No clinical safety information was identified from systematic reviews and evidence-based guidelines.

**Rectal cancer:** Problems associated with preoperative brachytherapy include radiation ileitis, perianal skin problems, small bowel perforation, fistula formation, wound or

anastomotic dehiscence, small bowel obstruction, anastomotic stenosis, infection in the wound, and infection in the pelvis.

**Breast cancer:** A review of registry and case review data reported overall symptomatic seroma formation rate (12.7%), fat necrosis (2%), infection (4–9%), persistent pain (2%), significant telangiectasia (5%), acute skin reaction (12%), hyperpigmentation (16%), rib fracture (3%), and balloon catheter rupture (1%).

**Resource impact:** n/a

**Scottish context:**

**Is there existing advice in Scotland?**

Yes

No

NICE IPG132: Low dose rate brachytherapy for localised prostate cancer (2005):

<http://publications.nice.org.uk/low-dose-rate-brachytherapy-for-localised-prostate-cancer-ipg132>

NICE IPG174: High dose rate brachytherapy in combination with external-beam radiotherapy for localised prostate cancer (2006):

<http://publications.nice.org.uk/high-dose-rate-brachytherapy-in-combination-with-external-beam-radiotherapy-for-localised-prostate-ipg174>

NICE IPG160: High dose rate brachytherapy for carcinoma of the cervix (2006):

<http://publications.nice.org.uk/high-dose-rate-brachytherapy-for-carcinoma-of-the-cervix-ipg160>

NICE IPG201: Preoperative high dose rate brachytherapy for rectal cancer (2006):

<http://publications.nice.org.uk/preoperative-high-dose-rate-brachytherapy-for-rectal-cancer-ipg201>

NICE IPG268: Brachytherapy as the sole method of adjuvant radiotherapy for breast cancer after local excision (2008):

<http://publications.nice.org.uk/brachytherapy-as-the-sole-method-of-adjuvant-radiotherapy-for-breast-cancer-after-local-excision-ipg268>

SIGN 87: Management of oesophageal and gastric cancer (2006):

<http://www.sign.ac.uk/pdf/sign87.pdf>

SIGN 80: Management of patients with lung cancer (2005):

<http://www.sign.ac.uk/pdf/sign80.pdf>

SIGN 99: Management of cervical cancer (2008):

<http://www.sign.ac.uk/pdf/sign99.pdf>

SIGN 90: Diagnosis and management of head and neck cancer (2006):

<http://www.sign.ac.uk/pdf/sign90.pdf>

Two chapters of this review (breast and prostate) were published as separate Healthcare Improvement Scotland evidence notes (35 and 37).

[http://www.healthcareimprovementscotland.org/programmes/clinical\\_cost\\_effectiveness/shtg\\_-\\_evidence\\_notes/evidence\\_note\\_35.aspx](http://www.healthcareimprovementscotland.org/programmes/clinical_cost_effectiveness/shtg_-_evidence_notes/evidence_note_35.aspx)

[http://www.healthcareimprovementscotland.org/programmes/clinical\\_cost\\_effectiveness/shtg\\_-\\_evidence\\_notes/evidence\\_note\\_37.aspx](http://www.healthcareimprovementscotland.org/programmes/clinical_cost_effectiveness/shtg_-_evidence_notes/evidence_note_37.aspx)

**Current practice:**

National service

regional service

NHS board service

**NHS boards are advised:** No SHTG Advice Statement published.

## 2.2 Evidence notes

### Evidence note 37: The clinical and cost effectiveness of the use of brachytherapy to treat localised prostate cancer; June 2011 (published December 2011)

*In response to an enquiry from the Scottish Radiotherapy Advisory Group*

Evidence note available at:

[http://www.healthcareimprovementscotland.org/programmes/clinical\\_cost\\_effectiveness/shtg\\_evidence\\_notes/evidence\\_note\\_37.aspx](http://www.healthcareimprovementscotland.org/programmes/clinical_cost_effectiveness/shtg_evidence_notes/evidence_note_37.aspx)

**Description:** In prostate brachytherapy, radioactive ‘seeds’ are placed into the area of the prostate affected by the cancer. LDR or HDR treatments may be used. LDR brachytherapy involves the use of permanent implants, which emit a low dose of radiation over several months. The HDR approach involves the use of micro-catheters to deliver radioactive sources (typically iridium-192) directly into the target but, unlike the LDR method, the sources are removed after a short time (normally less than an hour).

**Patient group(s):** People with localised prostate cancer.

**Comparators:** Watchful waiting, active surveillance, radical prostatectomy, EBRT, high intensity focused ultrasound and cryotherapy.

**Clinical effectiveness:** NICE (2008) guidelines state that brachytherapy (LDR) alone is not recommended for men with high-risk localised cancer. However, it is presented as a treatment option for men with low-risk and intermediate-risk localised disease. Evidence from low-level observational studies suggests that at least for low-risk patients, biochemical recurrence-free survival after LDR brachytherapy is equivalent to that after EBRT or prostatectomy. Evidence from low-level observational studies suggests that HDR brachytherapy in combination with EBRT may improve outcomes in patients with localised prostate cancer. Two randomised trials support this conclusion, although it should be noted that in both of these the dose of EBRT used in the control arm was relatively low.

**Cost effectiveness:** A cost effectiveness study (Hummel et al, 2003), which considered costs and effects from an NHS perspective, was reported on in the NICE guideline. The authors developed a Markov model to explore the potential cost effectiveness of newer treatments (ie brachytherapy, 3-dimensional-conformal radiotherapy and cryotherapy) compared with standard treatments (ie watchful waiting, radical prostatectomy and radical radiotherapy). The model assumed that all the treatments were equally as effective as radical prostatectomy. The cost-effectiveness estimates were based on the impact of adverse events, resulting from different treatments, on quality-adjusted life years. The authors concluded that only cryotherapy appeared not to be cost effective compared with traditional treatments ‘owing to the associated high incidence of impotence’.

**Patient/safety issues:** Low-level observational studies, mainly on LDR, suggest that brachytherapy has a similar adverse event rate as prostatectomy and EBRT. Case series evidence suggests that there are lower rates of impotence and incontinence than seen with surgery or EBRT, but higher rates of obstructive and irritative urinary symptoms.

**Resource impact:** n/a

#### Scottish context:

**Is there existing advice in Scotland?**

Yes

No

NICE IPG132: Low dose rate brachytherapy for localised prostate cancer (2005):

<http://publications.nice.org.uk/low-dose-rate-brachytherapy-for-localised-prostate-cancer-ipg132>

NICE IPG174: High dose rate brachytherapy in combination with external-beam radiotherapy for localised prostate cancer (2006):

<http://publications.nice.org.uk/high-dose-rate-brachytherapy-in-combination-with-external-beam-radiotherapy-for-localised-prostate-ipg174>

**Current practice:**  
National service  regional service  NHS board service   
NHS boards are advised: No SHTG Advice Statement published.

**Evidence note 39: The clinical and cost effectiveness of long-term ventricular assist devices (VADs) as a bridge-to-transplant in adults; July 2011 (published March 2012)**

*In response to an enquiry from the NHS National Services Division*

Evidence note available at:

[http://www.healthcareimprovementscotland.org/programmes/clinical\\_cost\\_effectiveness/shtg\\_-\\_evidence\\_notes/evidence\\_note\\_39.aspx](http://www.healthcareimprovementscotland.org/programmes/clinical_cost_effectiveness/shtg_-_evidence_notes/evidence_note_39.aspx)

**Description:** VADs are mechanical pumps that provide circulatory support to the failing heart. VADs for long-term use have a pump that is implanted inside the body, connected by percutaneous leads to a portable control system and battery pack outside the body.

**Patient group(s):** adult heart transplant candidates who are too unwell to undergo the procedure or are unlikely to survive until a suitable donor heart becomes available.

**Comparators:** No VAD support.

**Clinical effectiveness:** There are no published randomised trials of VADs as bridge-to-transplant. There is evidence from observational studies of improvement in functional status and quality of life during VAD support, and improved survival to transplant with second generation compared with first generation devices.

**Cost effectiveness:** VAD support as bridge-to-transplant is not cost effective at currently accepted thresholds in the United Kingdom (UK).

**Patient/safety issues:** Implantation of contemporary VADs remains associated with serious adverse events.

**Resource impact:** Not assessed.

**Scottish context:**

**Is there existing advice in Scotland?** Yes  No

**Current practice:**

National service  regional service  NHS board service

**NHS boards are advised:** See [SHTG Advice Statement 001/12](#)

**Evidence note 41: What is the clinical and cost effectiveness of human papillomavirus (HPV) testing, followed by liquid-based cytology triage of positive results, in primary screening for cervical cancer? January 2012**

*In response to an enquiry from the Breast and Cervical Screening National Advisory Group HPV reference group*

Evidence note available at:

[http://www.healthcareimprovementscotland.org/programmes/clinical\\_\\_cost\\_effectiveness/shtg\\_-\\_evidence\\_notes/evidence\\_note\\_41.aspx](http://www.healthcareimprovementscotland.org/programmes/clinical__cost_effectiveness/shtg_-_evidence_notes/evidence_note_41.aspx)

**Description:** A review of published evidence to inform cervical screening policy in Scotland

**Patient group(s):** Women aged 20–60 years.

**Comparators:** No evidence was found on the comparator of interest, which was primary screening with liquid-based cytology (LBC); therefore evidence was included with conventional cytology as the comparator. Results are expected to be similar.

**Clinical effectiveness:** HPV testing using Hybrid Capture II (HC2) (QIAGEN, Gaithersburg, MD), followed by conventional cytology triage of positive results, is highly sensitive and highly specific in primary screening for cervical cancer. HPV testing triaged by conventional cytology is more sensitive than conventional cytology alone. In women older than 35 years, HPV testing triaged by conventional cytology is more specific than conventional cytology alone. There is a lack of evidence on specificity of HPV testing triaged by cytology applicable to women aged 20–35 years.

**Cost effectiveness:** A 5-year screening interval for HPV testing triaged by cytology may be cost effective compared with conventional cytology.

**Patient/safety issues:** The evidence suggests that primary HPV testing allows the screening interval to be safely extended to at least 6 years.

**Resource impact:** Any proposal to introduce HPV testing in the Scottish Cervical Screening Programme may require different management strategies to be identified for cohorts defined by vaccination status and age.

**Scottish context:**

**Is there existing advice in Scotland?** Yes  No

**Current practice:**

**National service**  **regional service**  **NHS board service**

**NHS boards are advised:** No SHTG Advice Statement published.

**Evidence note 42: High-risk human papillomavirus (HPV) testing as triage for women with mild or borderline cytology abnormalities; January 2012**

*In response to an enquiry from the Breast and Cervical Screening National Advisory Group HPV reference group*

Evidence note available at:

[http://www.healthcareimprovementscotland.org/programmes/clinical\\_\\_cost\\_effectiveness/shtg\\_-\\_evidence\\_notes/evidence\\_note\\_42.aspx](http://www.healthcareimprovementscotland.org/programmes/clinical__cost_effectiveness/shtg_-_evidence_notes/evidence_note_42.aspx)

**Description:** Within the Scottish Cervical Screening Programme women aged 20–60 years are offered routine screening by means of a smear test using LBC every 3 years. HPV triage is the use of HPV testing to discriminate women with low-grade cytology abnormalities who are at risk for cervical neoplasia and require referral to colposcopy from those not at risk who can return to routine screening. High-risk HPV testing utilises laboratory assays to detect the presence of any of a range of high-risk types of HPV in cervical cell samples.

**Patient group(s):** Women attending the Scottish Cervical Screening Programme who have low-grade squamous cell abnormalities or unsatisfactory smears.

**Comparators:** Women with low-grade abnormalities are currently offered repeat smears at regular intervals and referral to colposcopy after three consecutive borderline or two mild abnormality smears have been reported. Women with unsatisfactory smears are offered repeat smears at 3-monthly intervals and referral to colposcopy after three consecutive unsatisfactory results.

**Clinical effectiveness:** High-risk HPV triage has higher sensitivity and similar specificity compared with repeat smears for detection of high-grade cervical neoplasia in women with borderline abnormalities. High-risk HPV testing has similar sensitivity but lower specificity compared with repeat smears for detection of high-grade cervical neoplasia in women with mild abnormalities. There is limited evidence on the use of high-risk HPV testing to triage women with unsatisfactory smears.

**Cost effectiveness:** Pilot studies in the English screening programme suggest that HPV triage of low-grade cytology abnormalities is likely to be cost effective, and most cost effective if restricted to women aged 35 years and over, although there is considerable uncertainty around the accruable incremental cost and gains.

**Patient/safety issues:** HPV testing and positive test results can have adverse effects on women's psychological wellbeing. Introduction of high-risk HPV triage in a largely unvaccinated screening population is likely to increase colposcopy referral rates.

**Resource impact:** Not assessed.

**Scottish context:**

**Is there existing advice in Scotland?** Yes  No

**Current practice:**

**National service**  **regional service**  **NHS board service**

**NHS boards are advised:** No SHTG Advice Statement published.

## 2.3 Technologies scoping reports

<p><b>Technologies scoping report 1: What implications does the organisation of vascular services have for rates of amputation? December 2011</b>  <i>In response to an enquiry from the vascular services review steering group</i></p>
<p>Technologies scoping report available at:  <a href="http://www.healthcareimprovementscotland.org/programmes/clinical_cost_effectiveness/shtg_scoping_reports/scoping_report_1.aspx">http://www.healthcareimprovementscotland.org/programmes/clinical_cost_effectiveness/shtg_scoping_reports/scoping_report_1.aspx</a></p>
<p><b>Description:</b> A review of vascular services in Scotland is currently being undertaken. Consideration needs to be given to the extent to which the configuration of services affects patient outcomes. One aspect of this is how reconfiguration of vascular services might impact on rates of major limb amputation.</p>
<p><b>Patient group(s):</b> Patients using vascular services.</p>
<p><b>Comparators:</b> n/a</p>
<p><b>Clinical effectiveness:</b> Operational modeling using data from the 1990s showed that changes in the management of peripheral vascular disease in a devolved service to match the central hospital would be expected to reduce the number of major amputations and increase the proportion of more distal amputations, vascular reconstructions and angioplasties. There is evidence from case series that increased use of revascularisation procedures, including angioplasty, reduces rates of amputation. NICE guidelines recommend that inpatients with diabetic foot problems should be managed by a multidisciplinary foot care team.</p>
<p><b>Cost effectiveness:</b> Not assessed.</p>
<p><b>Patient/safety issues:</b> Not assessed.</p>
<p><b>Resource impact:</b> Not assessed.</p>

<p><b>Scottish context:</b>  <b>Is there existing advice in Scotland?</b>                      Yes <input type="checkbox"/>                      No <input checked="" type="checkbox"/></p>
<p><b>Current practice:</b>  <b>National service</b> <input checked="" type="checkbox"/>                      <b>regional service</b> <input type="checkbox"/>                      <b>NHS board service</b> <input type="checkbox"/></p>
<p><b>NHS boards are advised:</b> No SHTG Advice Statement published.</p>

**Technologies scoping report 2: What is the published evidence of an association between hospital volume and outcome in elective carotid endarterectomy surgery? December 2011**

*In response to an enquiry from the vascular services review steering group*

Technologies scoping report available at:

<http://www.healthcareimprovementscotland.org/his/idoc.ashx?docid=d7cfdc7e-b350-417b-89a6-5b5b94150d1e&version=-1>

**Description:** A review of published evidence to inform vascular service redesign in Scotland.

**Patient group(s):** Adults at risk of stroke from narrowing of the carotid artery.

**Comparators:** n/a

**Clinical effectiveness:** n/a

**Cost effectiveness:** n/a

**Patient/safety issues:** There is equivocal evidence of an association between hospital volume and outcome in carotid endarterectomy. Insufficient evidence was found to support a causal relationship. Surgeon factors such as volume, training and experience; and hospital factors such as case mix, bed capacity, critical care pathways, cardiac angiography, and a vascular recovery unit, may explain any relationship.

**Resource impact:** To address the question of causality will require examination of prospective studies over a period of centralisation of vascular services. If a volume–outcome relationship exists in carotid endarterectomy surgery, and is causal, then modelling can be used to determine the threshold for the number of procedures a vascular unit should undertake to achieve optimal outcomes.

**Scottish context:**

**Is there existing advice in Scotland?**

Yes

No

**Current practice:**

**National service**

**regional service**

**NHS board service**

**NHS boards are advised:** No SHTG Advice Statement published.

**Technologies scoping report 3: Is there a difference in operative mortality between endovascular aneurysm repair and open surgery in elective abdominal aortic aneurysm? December 2011**

*In response to an enquiry from the vascular services review steering group*

Technologies scoping report available at:

[http://www.healthcareimprovementscotland.org/programmes/clinical\\_cost\\_effectiveness/shtg\\_scoping\\_reports/scoping\\_report\\_3.aspx](http://www.healthcareimprovementscotland.org/programmes/clinical_cost_effectiveness/shtg_scoping_reports/scoping_report_3.aspx)

**Description:** A review of published evidence to inform vascular service redesign in Scotland.

**Patient group(s):** Adults with abdominal aortic aneurysm (AAA) who are fit for open surgery.

**Comparators:** Open surgical repair (OSR).

**Clinical effectiveness:** The published evidence indicates that operative mortality for endovascular aneurysm repair (EVAR) is around a third that of OSR.

**Cost effectiveness:** EVAR is unlikely to be cost-effective relative to OSR for most elective AAA patients, but it may be cost effective for patients at higher risk of operative mortality.

**Patient/safety issues:** NICE recommended EVAR as a potential treatment option in patients fit for surgery; the decision to be made jointly between doctor and patient taking account of aneurysm size and morphology; patient age, life expectancy and fitness for open surgery; and the short- and long-term benefits and risks of the procedures.

**Resource impact:** Not examined.

**Scottish context:**

**Is there existing advice in Scotland?**

Yes

No

NICE TA167: Endovascular stent-grafts for the treatment of abdominal aortic aneurysms (2009): <http://www.nice.org.uk/nicemedia/live/12129/43289/43289.pdf>

**Current practice:**

National service

regional service

NHS board service

**NHS boards are advised:** No SHTG Advice Statement published.

**Technologies scoping report 4: What is the published evidence of an association between hospital volume and operative mortality for surgical repair (open and endovascular) of unruptured and ruptured abdominal aortic aneurysms? December 2011**

*In response to an enquiry from the vascular services review steering group*

Technologies scoping report available at:

[http://www.healthcareimprovementscotland.org/programmes/clinical\\_cost\\_effectiveness/shtg\\_scoping\\_reports/scoping\\_report\\_4.aspx](http://www.healthcareimprovementscotland.org/programmes/clinical_cost_effectiveness/shtg_scoping_reports/scoping_report_4.aspx)

**Description:** Rollout of the AAA screening programme in Scotland in 2012 will facilitate surveillance of small aneurysms and timely operative repair of larger ones. Mortality rates for elective AAA repair are higher in the UK than in most other European countries. The Vascular Society of Great Britain and Ireland quality framework for vascular services aims to halve the UK mortality rate by 2013. The framework currently recommends that elective AAA repair should not be offered in hospitals undertaking <20 procedures per year. Assessment of the available evidence on the relationship between hospital volume (annual number of procedures) and operative mortality is needed to inform optimal reconfiguration of vascular services in Scotland.

**Patient group(s):** Patients with unruptured or ruptured AAA.

**Comparators:** n/a

**Clinical effectiveness:** The available evidence appears to support a hospital volume-outcome association for elective OSR, whereas the evidence from studies of ruptured aneurysm repair is inconsistent. Very little evidence relating to hospital volume and endovascular repair was identified. There was insufficient evidence to inform conclusions about the influence that other factors associated with high hospital volume, such as processes of care, might have on surgical mortality. The evidence reviewed was not sufficiently robust to determine a definite threshold for categorising hospitals as high or low volume, or an optimal hospital volume above which there is no reduction in mortality.

**Cost effectiveness:** Not assessed.

**Patient/safety issues:** Not assessed.

**Resource impact:** Not assessed.

**Scottish context:**

**Is there existing advice in Scotland?** Yes  No

**Current practice:**

**National service**  **regional service**  **NHS board service**

**NHS boards are advised:** No SHTG Advice Statement published.

**Technologies scoping report 5: In patients with severe medically refractory gastroparesis, how effective and cost effective is gastric electrical stimulation (GES) (Enterra™ device) in reducing symptoms, reducing requirement for nutritional support or hospitalisation and improving quality of life, when compared with medical or alternative surgical management? March 2012**

*In response to an enquiry from the West of Scotland Upper GI Surgery Unit, Department of Oesophagogastric Surgery, Glasgow Royal Infirmary*

Technologies scoping report available at:

[http://www.healthcareimprovementscotland.org/programmes/clinical\\_cost\\_effectiveness/shtg\\_scoping\\_reports/scoping\\_report\\_5.aspx](http://www.healthcareimprovementscotland.org/programmes/clinical_cost_effectiveness/shtg_scoping_reports/scoping_report_5.aspx)

**Description:** Low energy electrical stimuli are delivered to the stomach via a surgically implanted system that consists of two intramuscular leads and a neurostimulator.

**Patient group(s):** Patients with chronic, drug-refractory nausea and vomiting secondary to gastroparesis. Gastroparesis is a frequent complication of diabetes. It may also arise idiopathically or following gastric surgery.

**Comparators:** Medical management, major gastrointestinal surgery.

**Clinical effectiveness:** The evidence base consists mainly of uncontrolled observational studies. In these, GES is associated with clinically significant reductions in symptoms, reduced need for hospital admissions and improved quality of life. Two small RCTs have been inconclusive. An ongoing RCT is due to publish in 2013 and the results are likely to be influential.

**Cost effectiveness:** No good quality cost or cost effectiveness data was identified.

**Patient/safety issues:** Safety alerts concerning the risk of bowel perforation/obstruction and shocking sensations were identified. Device removal rate was around 10% in studies, this mainly associated with infection.

**Resource impact:** n/a

**Scottish context:**

**Is there existing advice in Scotland?** Yes  No

NICE IPG103: Gastroelectrical stimulation for gastroparesis (2004):

<http://publications.nice.org.uk/gastroelectrical-stimulation-for-gastroparesis-ipg103/guidance>

**Current practice:**

National service  regional service  NHS board service

**NHS boards are advised:** See [SHTG Advice Statement 002/12](#)

### 3 NICE Medical Technologies Advisory Committee (MTAC) guidance

NICE has introduced a new assessment programme known as the Evaluation Pathways Programme. This focuses specifically on the evaluation of innovative medical technologies including devices and diagnostics, with the guidance produced being known as medical technologies guidance and diagnostics guidance respectively. Topics are notified to the programme by manufacturer submissions.

The programme both complements and operates in conjunction with NICE's existing technology appraisal capacity, which continues to evaluate new pharmaceutical and biotechnology products. It is designed to help the NHS in England adopt efficient and cost-effective medical devices and diagnostics more rapidly and consistently. The 'case for adoption' recommendations are based on the claimed advantages of introducing the specific technology compared with current management of the condition. This 'case' is reviewed against the evidence submitted and expert advice. If the case for adopting the technology is supported, then the technology has been found to offer advantages to patients and the NHS England. The specific recommendations on individual technologies are not intended to limit use of other relevant technologies which may offer similar advantages.

This guidance has no status in NHSScotland and is therefore provided for information only.

#### 3.1 Medical technologies guidance (MTG) published November 2011 to February 2012

MTG Number	Date published	Title	NICE recommendations
<a href="#">8</a>	November 2011	<b>The VeriQ system for assessing graft flow during coronary artery bypass graft surgery</b>	<p>The case for adopting the VeriQ system in the NHS for assessing graft flow during coronary artery bypass graft surgery is supported by the evidence. The evidence suggests that intra-operative transit time flow measurement is effective in detecting imperfections that may be corrected by graft revision. This may reduce the incidence of graft occlusion and may reduce perioperative morbidity and mortality.</p> <p>The VeriQ system is associated with an estimated cost saving of £115 per patient compared with clinical assessment, when it is used routinely for assessing coronary artery bypass grafts during surgery.</p> <p>A <a href="#">costing template</a> is available to assist with implementation of this guidance in NHS England, but this may also be of interest to NHSScotland boards in their planning.</p>

MTG Number	Date published	Title	NICE recommendations
9	March 2012	<b>PleurX peritoneal catheter drainage system for vacuum assisted drainage of treatment-resistant recurrent malignant ascites</b>	<p>The case for adopting the PleurX peritoneal catheter drainage system in the NHS is supported by the evidence. The available clinical evidence suggests that the PleurX peritoneal catheter drainage system is clinically effective, has a low complication rate and has the potential to improve quality of life: it enables early and frequent treatment of symptoms of ascites, in the community, rather than waiting for inpatient treatment. The PleurX peritoneal catheter drainage system should be considered for use in patients with treatment-resistant, recurrent malignant ascites.</p> <p>The PleurX peritoneal catheter drainage system is associated with an estimated cost saving of £679 per patient when compared with inpatient large-volume paracentesis.</p> <p>A <a href="#">costing template</a> is available to assist with implementation of the guidance in NHS England, but this may also be of interest to NHSScotland boards in their planning.</p>

### 3.2 Forthcoming MTAC guidance

Title	Anticipated publication date
Pipeline embolisation device for treatment of complex intracranial aneurysms	March 2012
Mega soft patient return electrode for use during monopolar electro-surgery	July 2012
Watch BP Home A for the measurement of blood pressure and the diagnosis of atrial fibrillation	August 2012
EXOGEN Ultrasound bone Healing System to aid bone healing	December 2012
Evita Open Plus for the treatment of aneurysms and dissections of the thoracic aorta	To be advised
Levitronix CentriMag for the treatment of refractory cardiogenic shock or severe cardiopulmonary insufficiency in adult and paediatric patients	To be advised
SILK artery reconstruction device	To be advised
Ambu aScope for difficult and unexpected airway management	To be advised
OraQuick HCV Rapid Antibody Test	Not proceeding

### 3.3 Diagnostics guidance published November 2011 to February 2012

As part of the Evaluation Pathway, diagnostics technologies guidance is designed to help the NHS in England adopt efficient and cost-effective medical diagnostic technologies more rapidly and consistently.

The programme concentrates on pathological tests, imaging, endoscopy and physiological measurement, since these represent most of the investigations performed on patients. The types of products which might be included are medical diagnostic technologies that give greater independence to patients, and diagnostic devices or tests used to detect or monitor medical conditions. Diagnostic technologies may be used for various purposes: diagnosis, clinical monitoring, screening, treatment triage, assessing stages of disease progression, and risk stratification.

This guidance has no status in NHSScotland and is therefore provided for information only.

DTG number	Publication date	Title	NICE recommendation
<a href="#">2</a>	December 2011	<b>Elucigene FH20 and LIPOchip for diagnosis of familial hypercholesterolaemia</b>	<p>Elucigene FH20 and LIPOchip are not recommended for the confirmation of a clinical diagnosis in people with familial hypercholesterolaemia because greater health benefits can be achieved cost-effectively through the use of comprehensive genetic analysis.</p> <p>Elucigene FH20 and LIPOchip are not recommended for cascade testing relatives of people with confirmed familial hypercholesterolaemia because targeted sequencing is less expensive and can be used for all relatives with no loss in health benefits.</p>
<a href="#">3</a>	January 2012	<b>Computed tomography (CT) scanners for cardiac imaging - Somatom Definition Flash, Aquilion One, Brilliance iCT and Discovery CT750</b>	<p>New generation cardiac CT scanners (Aquilion ONE, Brilliance iCT, Discovery CT750 HD and Somatom Definition Flash) are recommended as an option for first-line imaging of the coronary arteries in people with suspected stable coronary artery disease (with an estimated likelihood of coronary artery disease of 10–29%, as described in 'Chest pain of recent onset' [NICE clinical guideline 95]) in whom imaging with earlier generation CT scanners is difficult.</p> <p>New generation cardiac CT scanners (Aquilion ONE, Brilliance iCT, Discovery</p>

			<p>CT750 HD and Somatom Definition Flash) are recommended as an option for first-line evaluation of disease progression, to establish the need for revascularisation, in people with known coronary artery disease in whom imaging with earlier generation CT scanners is difficult. CT scanning might not be necessary in situations in which immediate revascularisation is being considered.</p> <p>Service providers, working with commissioners and cardiac networks, should take into account the benefits of access to new generation cardiac CT scanners for use in the circumstances described in 1.1 and 1.2. They should do this when selecting CT scanners as part of medium term asset planning.</p>
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### 3.4 Forthcoming diagnostics guidance

Title	Anticipated publication date
SonoVue (sulphur hexafluoride microbubbles) contrast agent for contrast enhanced ultrasound (and other alternative technologies identified during scoping)	To be advised
Adjunctive colposcopy technologies for examination of the uterine cervix - DySIS, LuViva Advanced Cervical Scan, Niris Imaging System and Zilico APX-100	To be advised
E-ENTROPY (and alternative technologies identified during scoping) for monitoring the depth of anaesthesia	To be advised
Gene expression profiling and expanded immunohistochemistry tests to guide selection of chemotherapy regimes in breast cancer management	To be advised
SeHCAT (Tauroselcholic (75 Selenium) Acid) and other alternative technologies identified during scoping for the investigation of bile acid malabsorption and measurement of bile acid pool loss	To be advised
Xpert MTB/RIF assay (an alternative technologies identified during scoping) for detection of active pulmonary tuberculosis and multi-drug resistant tuberculosis	Currently suspended

## 4 NICE multiple technology appraisals

### 4.1 MTAs (drug) published November 2011 to February 2012

Since November 2011 NICE has published four drug MTAs. This section summarises those MTAs, including comparing the decisions for NICE with those from the Scottish Medicines Consortium (SMC), where relevant.

TA number	Date published	Drug	NICE decision	SMC decision	Implications for NHSScotland
<a href="#">TA241</a>	January 2012	<b>Dasatinib, high-dose imatinib and nilotinib for the treatment of imatinib-resistant chronic myeloid leukaemia (CML) (part review of NICE technology appraisal guidance 70), and dasatinib and nilotinib for people with CML for whom treatment with imatinib has failed because of intolerance</b>	<p>Nilotinib is recommended for the treatment of chronic or accelerated phase Philadelphia-chromosome-positive CML in adults: whose CML is resistant to treatment with standard-dose imatinib <b>or</b> who have imatinib intolerance <b>and</b> if the manufacturer makes nilotinib available with the discount agreed as part of the patient access scheme.</p> <p>Dasatinib is not recommended for the treatment of chronic, accelerated or blast-crisis phase CML in adults with imatinib intolerance or whose CML is resistant to treatment with standard-dose imatinib.</p> <p>High-dose imatinib is not recommended for the treatment of chronic, accelerated or blast-crisis phase Philadelphia-chromosome-positive CML that is resistant to standard-dose imatinib.</p> <p>People who are currently receiving dasatinib or high-dose imatinib for the treatment of CML should have the option to continue treatment until they and their clinicians consider it appropriate to stop.</p>	<p>Dasatinib (370/07) and nilotinib (440/08) have been accepted by SMC for restricted use in the chronic phase of CML only. High-dose imatinib has not been assessed by SMC for use in chronic myeloid leukaemia.</p>	<p>The NICE MTA guidance supersedes the SMC advice.</p>

TA number	Date published	Drug	NICE decision	SMC decision	Implications for NHSScotland
<a href="#">TA242</a>	January 2012	<b>Cetuximab, bevacizumab and panitumumab for the treatment of metastatic colorectal cancer after first-line chemotherapy: cetuximab (monotherapy or combination chemotherapy), bevacizumab (in combination with non-oxaliplatin chemotherapy) and panitumumab (monotherapy) for the treatment of metastatic colorectal cancer after first-line chemotherapy (review of technology appraisal 150 and part review of technology appraisal guidance 118)</b>	<p>Cetuximab monotherapy or combination chemotherapy is not recommended for the treatment of people with metastatic colorectal cancer that has progressed after first-line chemotherapy.</p> <p>Bevacizumab in combination with non-oxaliplatin (fluoropyrimidine-based) chemotherapy is not recommended for the treatment of people with metastatic colorectal cancer that has progressed after first-line chemotherapy.</p> <p>Panitumumab monotherapy is not recommended for the treatment of people with metastatic colorectal cancer that has progressed after first-line chemotherapy.</p> <p>People currently receiving cetuximab monotherapy or combination chemotherapy, bevacizumab in combination with non-oxaliplatin chemotherapy, or panitumumab monotherapy for the treatment of metastatic colorectal cancer that has progressed after first-line chemotherapy should have the option to continue treatment until they and their clinician consider it appropriate to stop.</p>	Cetuximab – not recommended (155/05). Bevacizumab not recommended (469/08). Panitumumab not recommended (486/08).	No important differences were identified for this NICE appraisal and Healthcare Improvement Scotland advises that the recommendations are as valid for Scotland as for England and Wales.

TA number	Date published	Drug	NICE decision	SMC decision	Implications for NHSScotland
<a href="#">TA243</a>	January 2012	<b>Rituximab for the first-line treatment of stage III-IV follicular lymphoma: (review of NICE technology appraisal guidance 110)</b>	Rituximab, in combination with cyclophosphamide, vincristine and prednisolone, cyclophosphamide, doxorubicin, vincristine and prednisolone, mitoxantrone, chlorambucil and prednisolone, or cyclophosphamide, doxorubicin, etoposide, prednisolone and interferon- $\alpha$ , is recommended as an option for the treatment of symptomatic stage III and IV follicular lymphoma in previously untreated people.	Accepted for restricted use within NHSScotland for the treatment of previously untreated patients with stage III to IV follicular lymphoma in combination with chemotherapy (493/08).	No important differences were identified for this NICE appraisal and Healthcare Improvement Scotland advises that the recommendations are as valid for Scotland as for England and Wales.
<a href="#">TA246</a>	February 2012	<b>Venom anaphylaxis - immunotherapy pharmlagen</b>	Pharmlagen is recommended as an option for the treatment of IgE-mediated bee and wasp venom allergy in people who have had: a severe systemic reaction to bee or wasp venom, <b>or</b> a moderate systemic reaction to bee or wasp venom and who have one or more of the following: a raised baseline serum tryptase, a high risk of future stings or anxiety about future stings. Treatment with Pharmlagen should be initiated and monitored in a specialist centre experienced in venom immunotherapy.	SMC has not issued advice on this medicine.	No important differences were identified for this NICE appraisal and Healthcare Improvement Scotland advises that the recommendations are as valid for Scotland as for England and Wales.

## 4.2 Forthcoming MTAs

To enable forward planning within NHSScotland, all ongoing NICE MTAs are listed below. When an MTA is published on the Healthcare Improvement Scotland website, the advice supersedes any existing SMC advice. NHSScotland should take account of the NICE MTA advice and ensure recommended drugs and treatments are made available to meet clinical need.

MTAs take around 60 weeks to complete and there are three key documents in the process which are issued for comment, in the undernoted sequence:

- The assessment report
- The appraisal consultation document (ACD)
- The final appraisal document (FAD).

Further information on all forthcoming MTAs is available on the NICE website <http://www.nice.org.uk/guidance/index.jsp?status=2&d-16544-p=1&action=byType&type=6>

<b>Breast cancer (metastatic hormone receptor) lapatanib and trastuzumab (with aromatase inhibitor) (first-line)</b>
<b>Anticipated publication date:</b> July 2012
<b>Appraisal status:</b> FAD has been the subject of an appeal, which was heard on 8 September 2011. The appeal resulted in a second ACD being issued on 14 February 2012.
<b>Preliminary advice:</b> Preliminary advice in second ACD is Lapatinib in combination with an aromatase inhibitor is not recommended for first-line treatment in postmenopausal women with metastatic hormone-receptor-positive breast cancer that overexpresses human epidermal growth factor receptor 2 (HER2).  Trastuzumab in combination with an aromatase inhibitor is not recommended for first-line treatment in postmenopausal women with metastatic hormone-receptor-positive breast cancer that overexpresses HER2.  Postmenopausal women currently receiving lapatinib or trastuzumab in combination with an aromatase inhibitor for the first-line treatment of metastatic hormone-receptor-positive breast cancer should have the option to continue treatment until they and their clinicians consider it appropriate to stop.
<b>SMC advice:</b> Lapatanib not recommended (768/12). Trastuzumab not recommended (386/07).
<b>Chronic myeloid leukaemia – dasatinib, nilotinib and standard dose imatinib within their licensed indications for the first line treatment of chronic myeloid leukaemia (including part-review of TA70)</b>
<b>Anticipated publication date:</b> May 2012
<b>Appraisal status:</b> ACD issued 6 December 2011 for 4 week consultation
<b>Preliminary advice:</b> Nilotinib is recommended as an option for the first-line treatment of chronic phase Philadelphia-chromosome-positive CML in adults if the manufacturer continues to make nilotinib available with the discount agreed as part of the patient access scheme.  Standard-dose imatinib is recommended as an option for the first-line treatment of adults with chronic phase Philadelphia-chromosome-positive CML.

Dasatinib is not recommended for the first-line treatment of chronic phase Philadelphia-chromosome-positive CML.
<b>SMC advice:</b> Nilotinib is accepted for use within NHSScotland (709/11). SMC has not issued advice on imatinib for this indication.
<b>Bone metastases from solid tumours – denosumab</b>
<b>Anticipated publication date:</b> June 2012
<b>Appraisal status:</b> Assessment Report issued 27 January 2012 for 4 week consultation
<b>Preliminary advice:</b> Not applicable
<b>SMC advice:</b> Advice following non submission issued in December 2011 (752/11), while outcome of the NICE MTA awaited.
<b>Cystic fibrosis - Colistimethate sodium powder and tobramycin powder for inhalation for pseudomonas lung infection</b>
<b>Anticipated publication date:</b> October 2012
<b>Appraisal status:</b> Final protocol issued on 16 February 2012
<b>Preliminary advice:</b> Not applicable
<b>SMC advice:</b> Advice for tobramycin due to be published 11 June 2012. No advice for colistimethate sodium powder.
<b>Severe persistent allergic asthma (review of TA133 and TA201) - Omalizumab</b>
<b>Anticipated publication date:</b> November 2012
<b>Appraisal status:</b> Final protocol issued 25 October 2011
<b>Preliminary advice:</b> Not applicable
<b>SMC advice:</b> Omalizumab is accepted for restricted use in NHSScotland (708/11) (611/10) (259/06).
<b>Implantable cardioverter defibrillators for the treatment of arrhythmias and cardiac resynchronisation therapy for the treatment of heart failure (review of TA95 and TA120)</b>
<b>Anticipated publication date:</b> September 2013
<b>Appraisal status:</b> Final protocol issued 17 February 2012
<b>Preliminary advice:</b> Not applicable
<b>SMC advice:</b> Not applicable
<b>Vertebral fractures – vertebroplasty and kyphoplasty</b>
<b>Anticipated publication date:</b> December 2012
<b>Appraisal status:</b> Final scope issued
<b>Preliminary advice:</b> Not applicable
<b>SMC advice:</b> Not applicable

## 5 NICE single technology appraisals (STAs)

Since April 2011 NICE has published 16 STAs. This section summarises those STAs, including comparing the decision for NICE with that from SMC, where relevant. STAs are not valid in Scotland and this section is for information only.

### 5.1 STAs published November 2011 to February 2012

TA number	Date published	Drug	NICE decision	SMC decision
<a href="#">219</a>	April 2011	Everolimus for the second line treatment of advanced renal cell carcinoma	Not recommended	Not recommended (595/10)
<a href="#">220</a>	April 2011	Golimumab for the treatment of psoriatic arthritis	Recommended	Not recommended (674/11)
<a href="#">221</a>	April 2011	Romiplostim for the treatment of chronic immune (idiopathic) thrombocytopenic purpura	Recommended	Accepted for restricted use (553/09)
<a href="#">222</a>	April 2011	Trabectedin for the treatment of relapsed ovarian cancer	Not recommended	Not accepted (634/10)
<a href="#">224</a>	n/a	Golimumab for the treatment of methotrexate-naive rheumatoid arthritis	Terminated appraisal	
<a href="#">225</a>	June 2011	Golimumab for the treatment of rheumatoid arthritis after the failure of previous disease modifying anti-rheumatic drugs	Recommended	Accepted for restricted use (733/11)
<a href="#">226</a>	June 2011	Rituximab for the first line treatment of follicular non-Hodgkins's lymphoma	Recommended	Accepted for restricted use (493/08)
<a href="#">237</a>	November 2011	Ranibizumab for macular oedema (diabetic)	Not recommended	Not recommended (711/11)

TA number	Date published	Drug	NICE decision	SMC decision
<a href="#">238</a>	December 2011	Tocilizumab for arthritis (juvenile idiopathic, systemic)	Recommended	Accepted (754/12)
<a href="#">239</a>	December 2011	Fulvestrant for breast cancer (metastatic)	Not recommended	Not recommended (114/04)
<a href="#">240</a>	December 2011	Panitumumab for colorectal cancer (metastatic)	Appraisal terminated	Not accepted (769/12)
<a href="#">244</a>	January 2012	Roflumilast for chronic obstructive pulmonary disease	Recommended only as part of a research study	Not accepted (635/10)
<a href="#">245</a>	January 2012	Apixaban (hip and knee surgery) – for venous thromboembolism	Recommended	Accepted (741/11)
<a href="#">247</a>	February 2012	Tocilizumab (rapid review of TA198) for rheumatoid arthritis	Recommended	Accepted for restricted use (593/09)
<a href="#">248</a>	February 2012	Exenatide (prolonged release) for type 2 diabetes	Recommended	Accepted for restricted use (748/11)
<a href="#">249</a>	March 2012	Dabigatran etexilate – atrial fibrillation	Recommended	Accepted (672/11)

## 5.2 Forthcoming STAs

Topic	Anticipated publication date	SMC decision
Vinflunine for transitional cell carcinoma of the urothelial tract	To be advised following appeal which was upheld. New FAD to be issued.	Not accepted (686/11)
Eribulin for breast cancer (advanced)	To be advised. FAD appealed and outcome awaited.	Not recommended (726/11)
Fingolimod for multiple sclerosis (relapsing-remitting)	To be advised. Second ACD issued 1 December 2011.	Not recommended (763/12)
Ranibizumab for macular oedema (retinal vein occlusion)	To be advised	Accepted for restricted use (732/11)
Ipilimumab for melanoma (stage III or IV)	To be advised	Submission received November 2011
Cabazitaxel for prostate cancer	To be advised. Appeal to be heard on 22 March 2012.	Not recommended (735/11)
Boceprevir for hepatitis C (genotype 1)	April 2012	Accepted (723/11)
Belimumab for systemic lupus erythematosus (active)	May 2012	Submission received November 2011
Rivaroxaban for atrial fibrillation (stroke prevention)	May 2012	Accepted for restricted use (756/12)
Telaprevir for hepatitis C (genotype 1)	June 2012	Accepted for experienced patients (742/11) and naive patients (743/11)
Botulinum toxin type A for migraine (chronic)	June 2012	Not recommended (692/11)
Erlotinib for lung cancer (non small cell, EGFR-TK mutation positive) (first-line)	June 2012	Not recommended (644/10)
Abiraterone for prostate cancer (metastatic, castration resistant) (following cytotoxic therapy)	June 2012	Not recommended (764/12)
Cetuximab for lung cancer (non small cell)	July 2012	None for this indication
Rivaroxaban for venous thromboembolism (treatment and long term secondary prevention)	July 2012	Accepted (755/12)

<b>Topic</b>	<b>Anticipated publication date</b>	<b>SMC decision</b>
Mannitol for cystic fibrosis	August 2012	None for this indication
Bevacizumab for breast cancer (metastatic) (first-line with capecitabine)	August 2012	None for this indication

## 6 NICE interventional procedure guidance (IPG)

This section summarises the NICE interventional procedure guidance published since the last report on the safety and efficacy of interventional procedures. Neither clinical nor cost effectiveness is considered. These are procedures used for diagnosis or treatment that involves one of the following:

- making a cut or a hole to gain access to the inside of a patient's body – for example, when carrying out an operation or inserting a tube into a blood vessel
- gaining access to a body cavity (such as the digestive system, lungs, womb or bladder) without cutting into the body – for example, examining or carrying out treatment on the inside of the stomach using an instrument inserted via the mouth
- using electromagnetic radiation (which includes X-rays, lasers, gamma-rays and ultraviolet light) – for example, using a laser to treat eye problems.

NHSScotland contributes to funding of the interventional procedures programme and the recommendations should be adopted in Scotland. Further information on all published IPGs is available from the NICE website (<http://www.nice.org.uk/Guidance/IP/Published>).

The NICE guidance on procedures is grouped into five categories.

- **Normal** - apply normal consent, audit and clinical governance arrangements
- **Special** - notify clinical governance leads, ensure patients understand the uncertainties and audit and review clinical outcomes of all patients having the procedure
- **Other** (see guidance) - includes additional recommendations, for example, on training, service delivery or data collection
- **Research only** - use only in the context of a research protocol
- **Do not use** - the procedure should not be used in the NHS.

IPG number	Date published	Title	Category
<a href="#">IPG413</a>	November 2011	Magnetic resonance image-guided transcutaneous focused ultrasound for uterine fibroids	Normal
<a href="#">IPG417</a>	January 2012	Breast reconstruction using lipomodelling after breast cancer treatment	Normal
<a href="#">IPG410</a>	November 2011	Closure of anorectal fistula using a suturable bioprosthesis plug	Special
<a href="#">IPG411</a>	November 2011	Endoscopic transluminal pancreatic necrosectomy	Special
<a href="#">IPG414</a>	November 2011	Single-port laparoscopic nephrectomy	Special
<a href="#">IPG416</a>	January 2012	Deep brain stimulation for refractory epilepsy	Special

<b>IPG number</b>	<b>Date published</b>	<b>Title</b>	<b>Category</b>
<a href="#">IPG418</a>	January 2012	Percutaneous transluminal radiofrequency sympathetic denervation of the renal artery for resistant hypertension	Special
<a href="#">IPG419</a>	January 2012	Bronchial thermoplasty for severe asthma	Special
<a href="#">IPG422</a>	March 2012	Incisionless otoplasty	Special
<a href="#">IPG421</a>	March 2012	Transcatheter aortic valve implantation for aortic stenosis	Other (see guidance)
<a href="#">IPG409</a>	November 2011	Balloon dilation of the Eustachian tube	Research only
<a href="#">IPG412</a>	November 2011	Drainage, irrigation and fibrinolytic therapy (DRIFT) for post-haemorrhagic hydrocephalus in preterm infants	Research only
<a href="#">IPG415</a>	December 2011	Epiretinal brachytherapy for wet age related macular degeneration	Research only
<a href="#">IPG420</a>	March 2012	Percutaneous venoplasty for chronic cerebrospinal insufficiency for multiple sclerosis	Research only

## 7 SIGN guidelines

The tables below lists forthcoming SIGN guidelines. Further information on SIGN guidelines is available from the SIGN website <http://www.sign.ac.uk/guidelines/index.html>

### Published guidelines

Guideline	Publication date
<a href="#">SIGN 126: Diagnosis and management of colorectal cancer</a>	December 2011

### Forthcoming guidelines

Guideline	Anticipated publication date
Antithrombotic therapy (update)	Spring 2012
Postnatal depression (update)	Spring 2012
Lung cancer (update)	Autumn 2012
Long term cancer survivors	Autumn 2012
Schizophrenia (update)	Winter 2012

SIGN is increasingly supporting implementation of its guidelines. As a result of this shift in focus, fewer new guidelines will be published in the future but for the ones that are produced, a range of implementation support activities will be delivered. These activities will include:

- improved dissemination processes
- more interactive website
- awareness raising through local clinical champions
- education and training modules linked to continuous professional development
- networking with professional networks
- linking with Scottish Government Health Directorate projects
- producing a range of implementation support resources, eg:
  - algorithms and care pathways
  - audit tools
  - clinical data sets
  - resource implications calculators
  - electronic decision support tools
  - slide sets
  - documentation templates.

For more information on these and other implementation resources, visit the SIGN website <http://www.sign.ac.uk/guidelines/implementation.html>.

## 8 Key terms/acronyms

Term	Definition/description
AAA	Abdominal aortic aneurysm
ACD	Appraisal consultation document
CML	Chronic myeloid leukaemia
CT	Computed tomography
EBB	Endobronchial brachytherapy
EBRT	External beam radiotherapy
EVAR	Endovascular aneurysm repair
FAD	Final appraisal determination
GES	Gastric electrical stimulation
HDR	High dose rate
HER2	Human epidermal growth factor receptor 2
HPV	Human papillomavirus
HTA	Health technology assessment
IPG	Interventional procedures guidance
LBC	Liquid-based cytology
LDR	Low dose rate
MTA(s)	Multiple technology appraisal(s)
MTAC	Medical Technologies Advisory Committee
MTG	Medical technologies guidance
NICE	National Institute for Health and Clinical Excellence
NSCLC	Non small cell lung cancer
RCT(s)	Randomised controlled trial(s)
SIGN	Scottish Intercollegiate Guidelines Network
SMC	Scottish Medicines Consortium
STA(s)	Single technology appraisal(s)
UK	United Kingdom
VADs	Ventricular assist devices

## 9 Glossary

The International Network of Agencies for Health Technology Assessment - Health Technology Assessment international glossary also provides a list of standard definitions used in HTA. It can be downloaded from [http://www.htaglossary.net/tiki-index.php?page=List all terms](http://www.htaglossary.net/tiki-index.php?page=List+all+terms)