

# NICE Update Bulletin July 2017

## (issued Wednesday 26 July 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>
Technology Appraisals (TAs)	<p><a href="#">Nivolumab for treating relapsed or refractory classical Hodgkin lymphoma TA462</a></p> <p><b><u>Recommendations</u></b></p> <p>1.1 Nivolumab is recommended, within its marketing authorisation, as an option for treating relapsed or refractory classical Hodgkin lymphoma in adults after autologous stem cell transplant and treatment with brentuximab vedotin, when the company provides nivolumab with the discount agreed in the patient access scheme.</p> <p><b><u>The technology</u></b></p> <p>Nivolumab is a human monoclonal antibody that blocks an immune checkpoint protein receptor called programmed cell death protein 1 (PD-1) to promote anti-tumour response.</p> <p><b><u>Financial factors</u></b></p> <p>This technology is commissioned by NHS England.</p> <p>NICE does not expect this guidance to have a significant impact on resources; it will be less than £5m per year in England (or £9,100 per 100,000 population). This is because the population size is small (less than 50 people per year in England).</p> <p><a href="#">Roflumilast for treating chronic obstructive pulmonary disease TA461</a></p> <p>This guidance replaces NICE technology appraisal guidance on roflumilast for the management of severe chronic obstructive pulmonary disease (TA244).</p> <p><b><u>Recommendations</u></b></p> <p>1.1 Roflumilast, as an add-on to bronchodilator therapy, is recommended as an option for treating severe chronic obstructive pulmonary disease in adults with chronic bronchitis, only if:</p> <ul style="list-style-type: none"> <li>• the disease is severe, defined as a forced expiratory volume in 1 second (FEV1) after a bronchodilator of less than 50% of predicted normal, and</li> <li>• the person has had 2 or more exacerbations in the previous 12 months despite triple inhaled therapy with a long-acting muscarinic antagonist, a long-acting beta-2 agonist and an inhaled corticosteroid.</li> </ul> <p>1.2 Treatment with roflumilast should be started by a specialist in respiratory medicine.</p> <p>1.3 These recommendations are not intended to affect treatment with roflumilast 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.</p>

### **The technology**

Roflumilast is an orally administered long-acting selective phosphodiesterase-4 enzyme inhibitor. It targets cells and mediators believed to be important in chronic obstructive pulmonary disease (COPD).

### **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 £5m per year in England (or £9,100 per 100,000 population). This is because the expected uptake of the technology is small because the therapy should only be started by specialists in secondary care, and the unit cost for the intervention is small.

### **[Adalimumab and dexamethasone for treating non-infectious uveitis TA460](#)**

#### **Recommendations**

1.1 Adalimumab is recommended as an option for treating non-infectious uveitis in the posterior segment of the eye in adults with inadequate response to corticosteroids, only if there is:

- active disease (that is, current inflammation in the eye) and
- inadequate response or intolerance to immunosuppressants and
- systemic disease or both eyes are affected (or 1 eye is affected if the second eye has poor visual acuity) and
- worsening vision with a high risk of blindness (for example, risk of blindness that is similar to that seen in people with macular oedema).

1.2 Stop adalimumab for non-infectious uveitis in the posterior segment of the eye in adults with inadequate response to corticosteroids if there is 1 of the following:

- new active inflammatory chorioretinal or inflammatory retinal vascular lesions, or both or
- a 2 step increase in vitreous haze or anterior chamber cell grade or
- worsening of best corrected visual acuity by 3 or more lines or 15 letters.

1.3 Dexamethasone intravitreal implant is recommended as an option for treating non-infectious uveitis in the posterior segment of the eye in adults, only if there is:

- active disease (that is, current inflammation in the eye) and
- worsening vision with a risk of blindness.

1.4 These recommendations are not intended to affect treatment with adalimumab and dexamethasone 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.

### **The technologies**

Adalimumab is a monoclonal antibody that reduces inflammation by inhibiting pro-inflammatory cytokine tumour necrosis factor-alpha. Dexamethasone intravitreal implant is a biodegradable corticosteroid implant that suppresses inflammation by inhibiting the expression of pro-inflammatory mediators.

### **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 £5m per year in England (or £9,100 per 100,000 population). This is because the eligible population size is small (around 450 people per year for adalimumab and around 380 people per year for dexamethasone) due to the optimisations made to the recommendations during development of the guidance.

### **Collagenase clostridium histolyticum for treating Dupuytren's contracture TA459**

#### **Recommendations**

1.1 People who meet the inclusion criteria for the ongoing clinical trial (HTA-15/102/04), comparing collagenase clostridium histolyticum (CCH) with limited fasciectomy, are encouraged to participate in the study.

1.2 For people not taking part in the ongoing clinical trial, CCH is recommended as an option for treating Dupuytren's contracture with a palpable cord in adults only if all of the following apply:

- There is evidence of moderate disease (functional problems and metacarpophalangeal joint contracture of 30° to 60° and proximal interphalangeal joint contracture of less than 30° or first web contracture) plus up to 2 affected joints.
- Percutaneous needle fasciotomy (PNF) is not considered appropriate, but limited fasciectomy is considered appropriate by the treating hand surgeon.
- The choice of treatment (CCH or limited fasciectomy) is made on an individual basis after discussion between the responsible hand surgeon and the patient about the risks and benefits of the treatments available.
- One injection is given per treatment session by a hand surgeon in an outpatient setting.

1.3 These recommendations are not intended to affect treatment with CCH that was started in the NHS before this guidance was published. Adults having treatment outside these recommendations may continue their current course 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**

Collagenase clostridium histolyticum (CCH) is indicated for treating Dupuytren's contracture in adults with a palpable cord.

#### **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 £5m per year in England (or £9,100 per 100,000 population). This is because collagenase clostridium histolyticum (CCH) represents a further treatment option to surgery.

CCH is marginally less expensive than its comparator options, limited fasciectomy and percutaneous needle fasciotomy. Expert opinion suggests the change in practice is likely to impact a small population because treatment with CCH is only recommended after other options are not considered appropriate by the surgeon.

## [Trastuzumab emtansine for treating HER2-positive advanced breast cancer after trastuzumab and a taxane TA458](#)

### **Recommendations**

1.1 Trastuzumab emtansine is recommended, within its marketing authorisation, as an option for treating human epidermal growth factor receptor 2 (HER2)-positive, unresectable, locally advanced or metastatic breast cancer in adults who previously received trastuzumab and a taxane, separately or in combination. Patients should have either received prior therapy for locally advanced or metastatic disease or developed disease recurrence during or within 6 months of completing adjuvant therapy. Trastuzumab emtansine is recommended only if the company provides it in line with the commercial access agreement with NHS England.

### **The technology**

Trastuzumab emtansine is an antibody-drug conjugate consisting of trastuzumab linked to maytansine, which is a cytotoxic agent. Because the antibody targets human epidermal growth factor receptor 2 (HER2), and HER2 is overexpressed in breast cancer cells, the conjugate delivers the toxin directly to the cancer cells.

### **Financial factors**

This technology is commissioned by NHS England.

NICE estimates that around 820 people in England with HER2 positive advanced breast cancer who previously received trastuzumab and a taxane are eligible for treatment with trastuzumab emtansine. Based on Cancer Drugs Fund (CDF) records, around 720 people currently have trastuzumab emtansine treatment. Uptake is not expected to change as a result of trastuzumab emtansine moving from the CDF into routine commissioning.

## [Carfilzomib for previously treated multiple myeloma TA457](#)

### **Recommendations**

1.1 Carfilzomib in combination with dexamethasone is recommended as an option for treating multiple myeloma in adults, only if:

- they have had only 1 previous therapy, which did not include bortezomib and
- the company provides carfilzomib with the discount agreed in the patient access scheme.

1.2 These recommendations are not intended to affect treatment with carfilzomib 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**

Carfilzomib is an irreversible proteasome inhibitor that binds to the N-terminal threonine site, causing degradation of the proteins in the cell. It is given intravenously.

### **Financial factors**

This technology is commissioned by NHS England. NICE estimates that around 2,200 people in England with multiple myeloma will be eligible for carfilzomib based on the recommendations in the guidance. Around 1,100 people will have carfilzomib each year from 2019/20, when uptake reaches a steady state.

## [Ustekinumab for moderately to severely active Crohn's disease after previous treatment TA456](#)

### **Recommendations**

- 1.1 Ustekinumab is recommended, within its marketing authorisation, as an option for treating moderately to severely active Crohn's disease, that is, for adults who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a TNF-alpha inhibitor or have medical contraindications to such therapies.
- 1.2 The choice of treatment between ustekinumab or another biological therapy should be made on an individual basis after discussion between the patient and their clinician about the advantages and disadvantages of the treatments available. If more than 1 treatment is suitable, the least expensive should be chosen (taking into account administration costs, dosage and price per dose).
- 1.3 Ustekinumab should be given until treatment failure (including the need for surgery) or until 12 months after the start of treatment, whichever is shorter. People should then have their disease reassessed in accordance with NICE's recommendations for infliximab and adalimumab for the treatment of Crohn's disease to see whether treatment should continue.

### **The technology**

Ustekinumab is a human monoclonal antibody that acts as a cytokine inhibitor by targeting interleukin-12 (IL-12) and interleukin-23 (IL-23).

### **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 £5m per year in England (or £9,100 per 100,000 population). This is because the technology is an option alongside current standard treatment options, the drugs are similarly priced and they do not think practice will change substantially as a result of this guidance.

## [Adalimumab, etanercept and ustekinumab for treating plaque psoriasis in children and young people TA455](#)

### **Recommendations**

- 1.1 Adalimumab is recommended as an option for treating plaque psoriasis in children and young people aged 4 years or older, only if the disease:
  - is severe, as defined by a total Psoriasis Area and Severity Index (PASI) of 10 or more and
  - has not responded to standard systemic therapy, such as ciclosporin, methotrexate or phototherapy, or these options are contraindicated or not tolerated.
- 1.2 Etanercept is recommended as an option for treating plaque psoriasis in children and young people aged 6 years or older, only if the disease:
  - is severe, as defined by a total PASI of 10 or more and
  - has not responded to standard systemic therapy, such as ciclosporin, methotrexate or phototherapy, or these options are contraindicated or not tolerated.
- 1.3 Ustekinumab is recommended as an option for treating plaque psoriasis in children and young people aged 12 years or older, only if the disease:

- is severe, as defined by a total PASI of 10 or more
- has not responded to standard systemic therapy, such as ciclosporin, methotrexate or phototherapy, or these options are contraindicated or not tolerated.

1.4 Stop etanercept treatment at 12 weeks, and adalimumab and ustekinumab treatment at 16 weeks, if the psoriasis has not responded adequately. An adequate response is defined as a 75% reduction in the PASI score from the start of treatment.

1.5 The choice of treatment should be made on an individual basis after discussion between the responsible clinician and the patient, or their parents or carers, about the advantages and disadvantages of the treatments available. Where a biosimilar product is available, start treatment with the least expensive option, taking into account administration costs, the dose needed and the product cost per dose.

1.6 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.

1.7 These recommendations are not intended to affect treatment with adalimumab, etanercept or ustekinumab that was started in the NHS before this guidance was published. Children and young 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. This decision should be made jointly by the clinician and the child or young person or the child's or young person's parents or carers.

### **The technologies**

Adalimumab is a fully human immunoglobulin G1 monoclonal antibody that inhibits the activity of tumour necrosis factor alpha (TNF-alpha).

Etanercept is a recombinant human TNF-alpha receptor fusion protein that inhibits the activity of TNF-alpha. Biosimilars for etanercept are also available.

Ustekinumab is a fully human monoclonal antibody that acts as a cytokine inhibitor by targeting interleukin-12 and interleukin-23.

### **Financial factors**

These technologies are commissioned by NHS England.

NICE does not expect this guidance to have a significant impact on resources; it will be less than £5m per year in England (or £9,100 per 100,000 population). Experts suggest that the number of people who will receive treatment is small and it is unlikely that current practice will change substantially as a result of this guidance.

### **[Daratumumab with lenalidomide and dexamethasone for treating relapsed or refractory multiple myeloma \(terminated appraisal\) TA454](#)**

NICE is unable to make a recommendation about the use in the NHS of daratumumab, with lenalidomide and dexamethasone, for treating relapsed or refractory multiple myeloma because no evidence submission was received from Janssen-Cilag. They will review this decision if the company decides to make a submission.

	<p><a href="#"><u>Bortezomib for treating multiple myeloma after second or subsequent relapse (terminated appraisal) TA453</u></a></p> <p>NICE is unable to make a recommendation about the use in the NHS of bortezomib for treating multiple myeloma after second or subsequent relapse because no evidence submission was received from Janssen-Cilag. They will review this decision if the company decides to make a submission.</p> <p><a href="#"><u>Ibrutinib for untreated chronic lymphocytic leukaemia without a 17p deletion or TP53 mutation (terminated appraisal) TA452</u></a></p> <p>NICE is unable to make a recommendation about the use in the NHS of ibrutinib for untreated chronic lymphocytic leukaemia without a 17p deletion or TP53 mutation because no evidence submission was received from Janssen-Cilag. They will review this decision if the company decides to make a submission.</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><a href="#"><u>Suspected cancer: recognition and referral NG12 (update)</u></a></p> <p>This guideline covers identifying children, young people and adults with symptoms that could be caused by cancer. It outlines appropriate investigations in primary care, and selection of people to refer for a specialist opinion. It aims to help people understand what to expect if they have symptoms that may suggest cancer.</p> <p><b>July 2017:</b> recommendation 1.3.4 was stood down as it has been superseded by newly-published NICE diagnostics guidance on quantitative faecal immunochemical tests to guide referral for colorectal cancer in primary care. Recommendation 1.3.1 was amended to remove a link to recommendation 1.3.4.</p> <p><a href="#"><u>Parkinson's disease in adults NG71</u></a></p> <p>This guideline covers diagnosing and managing Parkinson's disease in people aged 18 and over. It aims to improve care from the time of diagnosis, including monitoring and managing symptoms, providing information and support, and palliative care.</p> <p>The guideline includes recommendations on:</p> <ul style="list-style-type: none"> <li>• information and support</li> <li>• diagnosing Parkinson's disease</li> <li>• pharmacological management of motor symptoms</li> <li>• pharmacological management of non-motor symptoms</li> <li>• non-pharmacological management of symptoms</li> <li>• impulse control disorders</li> <li>• palliative care</li> </ul> <p><a href="#"><u>Constipation in children and young people: diagnosis and management CG99 (update)</u></a></p> <p>This guideline covers diagnosing and managing constipation in children and young people up to 18. It provides strategies to support the early identification and timely, effective treatment of constipation which will help improve outcomes for patients. It does not cover constipation caused by a specific condition.</p> <p><b>July 2017:</b> NICE updated the footnote to recommendation 1.1.4 to link to the newest NICE guideline on coeliac disease, and the footnotes in table 4 with manufacturer information that has changed since original publication.</p>

	<p>The following NICE Guideline was published at the end of June, after publication of the June bulletin:</p> <p><a href="#"><u>Air pollution: outdoor air quality and health NG70</u></a></p> <p>This guideline covers road-traffic-related air pollution and its links to ill health. It aims to improve air quality and so prevent a range of health conditions and deaths.</p> <p>This guideline recommends taking a number of actions in combination, because multiple interventions, each producing a small benefit, are likely to act cumulatively to produce significant change. It includes recommendations on:</p> <ul style="list-style-type: none"> <li>• planning</li> <li>• development management</li> <li>• clean air zones</li> <li>• reducing emissions from public sector transport services and vehicle fleets</li> <li>• smooth driving and speed reduction</li> <li>• walking and cycling</li> <li>• awareness raising</li> </ul>
<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>Hysteroscopic sterilisation by insertion of intrafallopian implants IPG587</u></a></p> <p>This guidance replaces NICE interventional procedures guidance on hysteroscopic sterilisation by tubal cannulation and placement of intrafallopian implants (IPG315).</p> <p><b><u>Recommendations</u></b></p> <p>1.1 Current evidence on the safety and efficacy of hysteroscopic sterilisation by insertion of intrafallopian implants is adequate to support the use of this procedure provided that <b>standard arrangements</b> are in place for clinical governance and audit.</p> <p>1.2 During the consent process, clinicians wishing to carry out hysteroscopic sterilisation by insertion of intrafallopian implants should ensure that women:</p> <ul style="list-style-type: none"> <li>• understand that additional contraception must be used until appropriate imaging has been done at about 3 months, to confirm procedural success, and that there is a small risk of pregnancy in the longer term</li> <li>• are informed that some women have reported chronic pain after the procedure</li> <li>• are provided with clear written information, including NICE's information for the public.</li> </ul> <p>1.3 The procedure should only be done by clinicians experienced in operative hysteroscopy and with specific training in the technique.</p> <p>1.4 All adverse events involving the medical devices used in this procedure should be reported to the Medicines and Healthcare products Regulatory Agency.</p> <p><b><u>The procedure</u></b></p> <p>Hysteroscopic sterilisation by insertion of intrafallopian implants is usually done with the patient under local anaesthesia, intravenous sedation or a combination of both. As with other forms of sterilisation, pregnancy should be ruled out before the procedure.</p>

A hysteroscope is inserted through the vagina and cervix. A flexible microinsert is then passed through the hysteroscope using a guidewire and placed into each fallopian tube. Depending on the specific device used, conception is prevented by occluding the fallopian tubes or by causing scar tissue to form which blocks them. The procedure is not intended to be reversible.

An alternative form of contraception should be used until an appropriate confirmation test is done (transvaginal ultrasound, X-ray or hysterosalpingogram) to evaluate microinsert location, or microinsert location and tubal occlusion, about 3 months after microinsert placement.

### **[Transcatheter aortic valve implantation for aortic stenosis IPG586](#)**

This guidance replaces NICE interventional procedures guidance on transcatheter aortic valve implantation for aortic stenosis (IPG421).

#### **Recommendations**

- 1.1 Current evidence on the safety and efficacy of transcatheter aortic valve implantation (TAVI) for aortic stenosis is adequate to support the use of this procedure provided that **standard arrangements** are in place for clinical governance, consent and audit.
- 1.2 Details of all patients should be entered into the UK TAVI registry. Adverse events should be reported to the Medicines and Healthcare products Regulatory Agency.
- 1.3 Patient selection should be carried out by an experienced multidisciplinary team, which must include interventional cardiologists experienced in the procedure, cardiac surgeons, an expert in cardiac imaging and, when appropriate, a cardiac anaesthetist and a specialist in elderly medicine. The multidisciplinary team should determine the risk level for each patient and the TAVI device most suitable for them.
- 1.4 During the consent process patients should be told about all treatment options and their advantages and disadvantages.
- 1.5 TAVI is a technically challenging procedure that should only be done in specialised centres and only by clinicians and teams with special training and experience in complex endovascular interventions. Units doing this procedure should have both cardiac and vascular surgical support for the emergency treatment of complications and subsequent patient care.

#### **The procedure**

Transcatheter aortic valve implantation (TAVI) aims to provide a less invasive alternative to open cardiac surgery for treating aortic stenosis, avoiding the need for sternotomy and cardiopulmonary bypass.

TAVI may be done with the patient under general anaesthesia or using local anaesthesia with or without sedation. Access to the aortic valve is most commonly transluminal, through a large artery (usually the femoral or subclavian artery; percutaneous or endovascular approach), or occasionally surgical, by a minithoracotomy with apical puncture of the left ventricle (transapical approach). The choice of access route (transluminal or transapical) depends on various patient-related factors including atherosclerotic disease in the arteries, which would make the transluminal approach impossible.

Initially the aortic valve ring may be dilated using a balloon catheter, which is advanced over a guidewire. The new prosthetic valve is manipulated into position and inserted inside the existing aortic valve.

[Laparoscopic insertion of a magnetic titanium ring for gastro-oesophageal reflux disease IPG585](#)

This guidance replaces NICE interventional procedures guidance on laparoscopic insertion of a magnetic bead band for gastro-oesophageal reflux disease (IPG431).

**Recommendations**

1.1 There are no major safety concerns about laparoscopic insertion of a magnetic titanium ring for gastro-oesophageal reflux disease (GORD). There is limited evidence of short-term efficacy, but evidence of long-term efficacy is inadequate in quality and quantity. Therefore, this procedure should only be used with **special arrangements** for clinical governance, consent, and audit or research.

1.2 Clinicians wishing to do laparoscopic insertion of a magnetic titanium ring for GORD should:

- Inform the clinical governance leads in their NHS trusts.
- Ensure that patients understand the uncertainty about the procedure's long-term efficacy and provide them with clear written information. In addition, the use of NICE's information for the public is recommended.
- Audit and review clinical outcomes of all patients having the procedure.

1.3 This procedure should only be done by a clinician trained in upper gastrointestinal laparoscopy and with expertise in plication procedures.

1.4 NICE encourages further research into laparoscopic insertion of a magnetic titanium ring for GORD, and may update the guidance on publication of further evidence. Long-term outcome data and comparative trials with other anti-reflux surgery would be helpful.

**The procedure**

The aim of laparoscopic insertion of a magnetic titanium ring for gastro-oesophageal reflux disease is to provide relief of reflux-related symptoms without impeding the ability to swallow, belch or vomit, and with less morbidity than traditional anti-reflux surgery.

The procedure is done with the patient under general anaesthesia. Using a laparoscopic approach, a specially designed sizing tool is loosely wrapped around the distal oesophagus to assess the size of implant needed. The sizing tool is then removed and the implant is placed so that it encircles the distal oesophagus at the gastro-oesophageal junction. The ends of the implant are secured together to hold it in place. Intraoperative endoscopy may be used to check that the implant is correctly positioned.

The implant consists of a ring of interlinked titanium beads, each with a weak magnetic force that holds the beads together to keep the distal oesophagus closed. When the patient swallows, the magnetic force is overcome, allowing the ring to open. After swallowing, magnetic attraction brings the beads together and the distal oesophagus is again closed.

**Medical Technologies Guidance**

None published so far this month.

**Diagnostics Guidance**

[Quantitative faecal immunochemical tests to guide referral for colorectal cancer in primary care DG30](#)

**Recommendations**

1.1 The OC Sensor, HM-JACKarc and FOB Gold quantitative faecal

immunochemical tests are recommended for adoption in primary care to guide referral for suspected colorectal cancer in people without rectal bleeding who have unexplained symptoms but do not meet the criteria for a suspected cancer pathway referral outlined in NICE's guideline on suspected cancer.

1.2 Results should be reported using a threshold of 10 micrograms of haemoglobin per gram of faeces. Companies should provide advice about the performance characteristics of the assays to laboratories, and ensure standardisation of results.

1.3 Commissioning groups adopting the OC Sensor, HM-JACKarc and FOB Gold should audit their outcomes and monitor the associated resource use.

1.4 There is currently not enough evidence to recommend the routine adoption of the RIDASCREEN haemoglobin or the RIDASCREEN haemoglobin/haptoglobin assay in primary care to guide referral for suspected colorectal cancer in people without rectal bleeding who have unexplained symptoms but do not meet the criteria for a suspected cancer pathway referral outlined in NICE's guideline on suspected cancer

### **The diagnostic tests**

Faecal immunochemical tests can detect small amounts of blood in stool samples and help GPs decide if people should be referred for more urgent tests.

The OC Sensor is a quantitative faecal immunochemical test. It comprises faecal sample collection tubes, latex reagent and buffer. The OC Sensor faecal sample collection tubes can hold 10 mg of faeces in 2 ml of buffer. The OC Sensor latex reagent contains latex particles coated with polyclonal antibodies for human haemoglobin. The antibodies bind with haemoglobin present in the faecal sample creating complexes that are detected using turbidimetry.

The HM-JACKarc system is a fully automated quantitative faecal immunochemical test system. It comprises faecal sample tubes, which incorporate a sample collection device (the Extel Hemo-auto MC A device) and can hold 2 mg of faeces in 2 ml of buffer, and latex agglutination reagent (Extel Hemo-Auto HS) and buffer (Extel Hemo-auto). The reagent contains latex particles that are coated in antibodies specific to human haemoglobin. The antibodies bind to haemoglobin present in the faecal sample creating complexes that are detected using turbidimetry.

The FOB Gold system is an automated quantitative faecal immunochemical test system. It comprises faecal sample collection tubes (the Sentifit pierce tube faecal collection device), which collect 10 mg of faeces in 1.7 ml of buffer, and latex agglutination reagent. The FOB Gold latex agglutination reagent contains polyclonal antibodies specific to human haemoglobin, which bind to haemoglobin present in the sample creating complexes that are detected using turbidimetry.

The RIDASCREEN haemoglobin test is an enzyme immunoassay (ELISA) for the quantitative determination of human haemoglobin in stool samples. The test is run on a microtitre plate using wells coated with polyclonal antibodies for human haemoglobin. The contents of each kit are enough for 96 tests. The instructions for the test suggest that it can be used with laboratory equipment other than the DSX automated ELISA system.

### **Financial factors**

This technology is commissioned by CCGs.

NICE recommends faecal immunochemical tests for routine adoption in primary care to guide referral for suspected colorectal cancer in people who have symptoms but are at low risk. The guidance may lead to savings at a local level from a reduction in the number of colonoscopies performed.

[New generation cardiac CT scanners \(Aquilion ONE, Brilliance iCT, Discovery CT750 HD and Somatom Definition Flash\) for cardiac imaging in people with suspected or known coronary artery disease in whom imaging is difficult with earlier generation CT scanners DG3 \(update\)](#)

**July 2017:** The guidance was updated following changes to the NICE clinical guideline on the assessment and diagnosis of chest pain of recent onset.

**Recommendations**

- 1.1 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%) in whom imaging with earlier generation CT scanners is difficult.
- 1.2 New generation cardiac CT scanners (Aquilion ONE, Brilliance iCT, Discovery 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.
- 1.3 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. There is currently not enough validation or clinical-outcome data to recommend the routine adoption of the InBody S10 or the MultiScan 5000 to guide fluid management in people with chronic kidney disease having dialysis in the NHS.

**The technologies**

Aquilion ONE, Brilliance iCT, Discovery CT750 HD and Somatom Definition Flash are new generation computed tomography (CT) scanners that have a variety of enhancements compared with earlier generation CT scanners. These enhancements, which vary among the four scanners, may include better temporal resolution, better spatial resolution and shorter acquisition times. It is claimed that the new generation CT scanners can better detect coronary artery stenosis in people with suspected or known coronary artery disease in whom imaging is difficult with earlier generation CT scanners. The acquisition cost of these scanners varies depending on local discounts but estimates range from £900,000 to £1.1 million.

**NICE Quality Standards**

[Low back pain and sciatica in over 16s QS155](#)

This quality standard covers the assessment and management of non-specific low back pain and sciatica in young people and adults aged 16 years and over. It describes high-quality care in priority areas for improvement.

[Chronic kidney disease in adults QS5 \(update\)](#)

This quality standard covers the assessment and management of chronic kidney disease in adults (aged 18 and over). It describes high-quality care in priority areas for improvement. It does not cover renal replacement therapy or acute kidney injury, which are covered by NICE's quality standards for renal replacement therapy services for adults and acute kidney injury.

**July 2017:** this quality standard was updated in response to an annual review, which identified changes in the areas for improvement for this topic.

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

<b>Title / link</b>	<b>End date of consultation</b>
<a href="#">Asthma - diagnosis and monitoring</a>	01/08/2017
<a href="#">Hepatitis B (chronic) : diagnosis and management</a>	02/08/2017
<a href="#">Flu vaccination: increasing uptake</a>	04/08/2017
<a href="#">Tests in secondary care to identify people at high risk of ovarian cancer</a>	09/08/2017
<a href="#">Vismodegib for treating basal cell carcinoma [ID1043]</a>	10/08/2017
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**Produced by**  
**Rebecca Heayn (Clinical Effectiveness Governance Manager),**  
**NEW Devon CCG Clinical Effectiveness and Medicines Optimisation Team**  
**County Hall, Topsham Road, Exeter, EX2 4QL**  
**For distribution Northern, Eastern and Western Devon CCG**  
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