NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance

SCOPE

Endocuff Vision for endoscopic investigation

1 Technology

1.1 Description of the technology

Endocuff Vision is a single-use disposable device which fits over the end of most conventional colonoscopes and is designed to improve visualisation of the bowel during colonoscopy by increasing the total surface area of the visual field. Endocuff Vision has a row of flexible arms, hinged at the base, which are retracted during insertion and spread out during withdrawal. These arms push out the mucosal folds of the colon allowing more of the mucosal surface to be viewed. The company claims that this can also improve the stability of the colonoscope and control of the tip. The aim of improving visualisation is to enhance the identification of colonic polyps, specifically adenomas and adenocarcinomas, and increase the likelihood of complete excision as well as helping post-excision scar examination. Prior to using Endocuff Vision, users will need to complete a short training session. Endocuff Vision has been selected by NHS England for the Innovation and Technology Payment (ITP) 2018/19 scheme.

1.2 Regulatory status

The first Endocuff device was CE marked in August 2011 as a Class I sterile medical device and this was renewed for the successor product, Endocuff Vision, in August 2016. Endocuff Vision differs from Endocuff in having one row of longer (15 mm vs. 12 mm) arms instead of two shorter ones.

1.3 Claimed benefits

The benefits to patients claimed by the company through the use of Endocuff Vision in colonoscopy are:

- Significantly increased diagnostic yield: more cancerous and pre-cancerous polyps can be identified, potentially enabling earlier detection of cancer.
- More polyps are fully excised, which may reduce the need to refer patients to more specialist services for expert clinical care or open surgery, which may entail more travelling for the patient.
- Better evaluation of post-excision scars, which may reduce unnecessary repeat procedures and avoid tumour recurrence.
- Greater operator confidence in the colonoscopic procedure: patients may be given more accurate post-procedural information based on higher procedure sensitivity, allowing the correct post-procedural surveillance protocol to be followed and potentially reducing the risk of subsequent cancers or unnecessary procedures.
- Easier access to electrocoagulation for angiodysplasia, potentially reducing the number of repeat colonoscopies.

The benefits to the healthcare system claimed by the company are:

- Fewer missed cancers, which may be associated with the treatment of earlier cancers rather than advanced ones, resulting in fewer appointments, less chemotherapy, less radiotherapy, fewer additional tests, reduced in-patient time, less palliative treatment and less litigation.
- Through better removal of pre-malignant lesions, fewer cancers in the future with substantial savings in staff, consumables, surgery, and other treatments that would have been needed.
- More effective adenoma removals, polyp excisions and electrocoagulation, potentially leading to fewer recurrences or less need for open surgery, follow-ups, tests and treatment as listed above.

1.4 Relevant diseases and conditions

Endocuff Vision is intended for use in people undergoing colonoscopy:

- who have presented with unexplained change in bowel habit, iron deficiency or bleeding from the bowel (including those with positive faecal occult bloods (FOB) or faecal immunochemical test (FIT)). These are circumstances that suggest possible colorectal cancer
- to remove known polyps, which may be difficult to find, remove or ablate because of their size, position, or previous incomplete removal.

- for surveillance, following previous adenoma removal.

Colorectal (lower bowel) cancer is the fourth most common cancer, and the second most common cause of cancer death in the UK. Two-thirds of colorectal cancers develop in the colon – the remaining third develop in the rectum.

Colonoscopy is the standard procedure for the identification of colorectal cancer and pre-cancer. In 2015 41,804 new colorectal cancers were diagnosed (Cancer Research UK). Some cancers and precancerous polyps are missed at diagnostic colonoscopy; the likelihood of this happening is estimated to be between 6% and 8%, equating to between 1,896 - 2,528 missed cancers in England every year. Miss-rates are particularly high for small adenomas (less than 5 millimetres), for which the miss-rate has been estimated to be as high as 27%.

If a cancer is diagnosed within 6 months to 3 years (or 5 years, depending on the study design) of a negative diagnostic colonoscopy, it is referred to as an interval cancer. One study reported that 2.9% of all colorectal cancers diagnosed were interval cancers, and suggested that the majority of these (86%) could have been prevented. Studies conducted in the USA have found that around 6 to 7% of people undergoing colonoscopy subsequently developed interval cancers and that in some cases, these could be classed as missed by previous colonoscopy. There are clinical risk factors for the development of an interval cancer, such as proximal tumour location, increased co-morbidities, or a pre-existing diagnosis of diverticulitis. Procedural risk includes the procedure being undertaken by an endoscopist with a low adenoma detection rate (ADR), or by a non-specialist (not a

gastroenterologist). Under these circumstances, the relevant factors may relate to lack of experience or expertise.

1.5 Current management

The current NHS care pathway for a person undergoing colonoscopic investigation is described by several guidelines.

Bowel Cancer Screening Programme

The UK National Screening Committee recommendations on bowel cancer screening are currently under review and are expected to be completed by August 2018. Currently the NHS uses one of two methods to screen for bowel cancer:

- bowel scope screening (flexible sigmoidoscopy) is provided as a one-off bowel scope screening for people aged 55 years of age or older and is currently only available to people in England.

- faecal occult blood (FOB) home testing kits are automatically sent to all people aged 60 to 74 years who are registered with a GP. They can use the test at home and then post to a laboratory for testing. FOB tests will be sent to people in this age group every two years until they reach the maximum screening age.

People over 60 years with abnormal FOB test screening results will be offered a colonoscopy to check for polyps further up the bowel if repeat FOB tests are also abnormal. People with abnormal bowel scope screening results may also be offered a colonoscopy. People younger than 55 or older than 74 years may also receive screening but it is not routine practice to do so.

Symptomatic presentation

NICE guideline on suspected cancer: recognition and referral (lower gastrointestinal tract cancers) recommends that in general, a person presenting with symptoms suggestive of colorectal or anal cancer should be seen by a specialist service within 2 weeks. The guideline describes in detail

symptoms which should trigger a referral, especially in patients aged 40 years or older with unexplained weight loss, abdominal pain, rectal bleeding, iron-deficiency anaemia, changes in bowel habit or a lower abdominal or rectal mass.

NICE guideline on colorectal cancer: diagnosis and management: recommends that people with suspected colorectal cancer whose condition is being managed in secondary care should be advised that more than one investigation may be needed to confirm or exclude diagnosis. Colonoscopy should be offered to patients who do not have any major comorbidity to confirm diagnosis of colorectal cancer. If a lesion suspicious of cancer is detected a biopsy should be undertaken to obtain histological proof of diagnosis unless it is contraindicated. Other methods of diagnosis such as flexible sigmoidoscopy or computed tomographic colonography may be used.

NICE guideline on colorectal cancer prevention states that people with inflammatory bowel disease whose symptoms started over 10 years ago and who have ulcerative colitis (UC) (but not proctitis alone), people with Crohn's colitis involving more than one segment of colon and people with adenomas should be offered colonoscopic surveillance. The frequency of colonoscopic surveillance should be once every 1 to 5 years depending on the patient's risk of developing colorectal cancer.

The introduction of Endocuff Vision would leave the current patient pathway of care up to the time of colonoscopy unaltered. Endocuff Vision is designed to increase the diagnostic sensitivity of all colonoscopies, resulting in fewer false negatives and increasing the ADR and mean number of adenomas detected per procedure (MAP). By fully removing cancerous and pre-cancerous polyps at an earlier stage of the pathway, there is the potential to avoid the need for patients to undergo treatment for a more advanced cancer at a later stage. The British Society of Gastroenterology quality standards for colonoscopy aim for a minimal ADR of 15% for the UK all age population.

NICE diagnostic guidance recommends that in some circumstances virtual chromoendoscopy be used to assess polyps of 5 mm or less during

colonoscopy, instead of histopathology, to determine if the polyps are adenomatous or hyperplasia. NICE has also recommended that quantitative faecal immunochemical tests be used to guide referral for colorectal cancer in primary care.

2 Statement of the decision problem

	Scope issued by NICE
Population	People undergoing colonoscopy for suspected bowel cancer, for the removal of known polyps and for surveillance because of a higher than average risk of colorectal cancer in line with NICE guideline on colorectal cancer prevention.
Intervention	Colonoscopy with the addition of an Endocuff Vision device
Comparator(s)	Colonoscopy
Outcomes	The outcome measures to consider include: Procedural outcomes: •MAP, mean number of adenomas detected per procedure •ADR overall and ADR by location in the colon (right or left) •type of polyp (e.g. sessile serrated polyp) •size of polyp (diminutive, small and large) •overall procedure time (time to caecal intubation, time to withdrawal) •caecal intubation rates •number of repeat colonoscopies and sub-optimal examinations •polyp distribution in different parts of the colon Cancer diagnosis and management •incidence of subsequent interval cancers •rate of diagnosis of bowel cancer •referral rates for specialist treatment and rates of subsequent surgery, chemotherapy and radiotherapy •tumour recurrence after colonoscopic resection •rate of repeat colonoscopy after electrocoagulation for angiodysplasia Patient outcomes •patient comfort and experience •device-related adverse events for example complication rate (mucosal lacerations or major bleeding, perforation or loss of Endocuff Vision)
Cost analysis	Costs will be considered from an NHS and personal social services perspective. The time horizon for the cost analysis will be sufficiently long to reflect any differences in costs and consequences between the technologies being compared. Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which will include scenarios in which different numbers and combinations of devices are needed.
Subgroups to be considered	• People referred for colonoscopy through the NHS bowel cancer screening programme

	• People offered colonoscopic surveillance because they have had adenomas removed • People offered colonoscopy after reporting symptoms	
Special considerations, including those related to equality	Endocuff Vision cannot be used for small bowel investigations	
	Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristic?	Yes
	Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality?	No
	Is there anything specific that needs to be done now to ensure MTAC will have relevant information to consider equality issues when developing guidance?	No
	People with colonic strictures, acute diverticulitis and acute colitis cannot have colonoscopies and so cannot use Endocuff Vision; these people may be considered disabled if their condition has a substantial and long term adverse effect on their ability to carry out normal day to day activities for more than 12 months	

NICE may undertake, as part of this evaluation, additional technical assessment of issues including device compatibility.

3 Related NICE guidance

Published

Clinical guidelines

- Suspected cancer: recognition and referral (2015)
- Colorectal cancer: diagnosis and management (2011)
- Colorectal cancer prevention: colonoscopic surveillance in adults with ulcerative colitis, Crohn's disease or adenomas (2011)
- Improving outcomes in colorectal cancer (2004)

Technology appraisal guidance

- Trifluridine–tipiracil for previously treated metastatic colorectal cancer (2016)

- Aflibercept in combination with irinotecan and fluorouracil-based therapy for treating metastatic colorectal cancer that has progressed following prior oxaliplatin-based chemotherapy (2014)
- Cetuximab, bevacizumab and panitumumab for the treatment of metastatic colorectal cancer after first-line chemotherapy (2012)
- Bevacizumab in combination with oxaliplatin and either fluorouracil plus folinic acid or capecitabine for the treatment of metastatic colorectal cancer (2010)
- Cetuximab for the first-line treatment of metastatic colorectal cancer (2009)
- Bevacizumab and cetuximab for the treatment of metastatic colorectal cancer (2007)
- Laparoscopic surgery for colorectal cancer (2006)
- Capecitabine and oxaliplatin in the adjuvant treatment of stage III (Dukes' C) colon cancer (2006)
- Guidance on the use of capecitabine and tegafur with uracil for metastatic colorectal cancer (2003)

Interventional procedures guidance

- Low energy contact X-ray brachytherapy (the Papillon technique) for early stage rectal cancer(2015)
- Preoperative high dose rate brachytherapy for rectal cancer (2015)
- Transanal total mesorectal excision of the rectum (2015)
- Combined endoscopic and laparoscopic removal of colonic polyps (2014)
- Endoscopic submucosal dissection of lower gastrointestinal lesions (2010)
- Selective internal radiation therapy for non-resectable colorectal metastases in the liver (2011)
- Radiofrequency ablation for colorectal liver metastases (2009)
- Computed tomographic colonography (virtual colonoscopy) (2005)
- Complete cytoreduction for pseudomyxoma peritonei (Sugarbaker technique) (2004)

Diagnostic guidance

- Molecular testing strategies for Lynch syndrome in people with colorectal cancer (2017)
- Quantitative faecal immunochemical tests to assess symptomatic people who are at low risk of colorectal cancer in primary care (2017)
- Virtual chromoendoscopy to assess colorectal polyps during colonoscopy (2017)

Under development

NICE is developing the following guidance (details available from www.nice.org.uk):

Clinical guidelines

- Colorectal cancer: diagnosis and management (update). Expected publication date October 2019

Technology appraisal guidance

- Atezolizumab for treating metastatic colorectal cancer after 2 therapies Expected publication date TBC
- Nivolumab with ipilimumab for treating metastatic colorectal cancer with high microsatellite instability or mismatch repair deficiency. Expected publication date TBC

4 External organisations

4.1 Professional organisations

4.1.1 Professional organisations contacted for expert advice

At the selection stage, the following societies were contacted for expert clinical and technical advice:

- Association of Coloproctology of Great Britain and Ireland (ACPGBI)
- British Society of Gastroenterology
- Royal College of Surgeons

4.1.2 Professional organisations invited to comment on the draft scope

The following societies have been alerted to the availability of the draft scope for comment:

- Association of Coloproctology of Great Britain and Ireland
- British Society of Gastroenterology
- Royal College of Surgeons
- Royal College of Physicians
- British Society of Paediatric Gastroenterology, Hepatology and Nutrition.

4.2 Patient organisations

At the selection stage, NICE's Public Involvement Programme contacted the following organisations for patient commentary and alerted them to the availability of the draft scope for comment:

- Beating Bowel Cancer
- Bowel Cancer Information (Formerly Lynn's Bowel Cancer Campaign)
- Bowel Cancer UK
- Cancer Research UK
- Cancer Support UK
- CORE (Digestive Disorders Foundation)
- Helen Rollason Cancer Charity
- Help Adolescents With Cancer (HAWC)
- Independent Cancer Patients' Voice
- Macmillan Cancer Support
- Pelican Cancer Foundations
- Pelvic Pain Support Network
- Penny Brohn Cancer Care
- Tenovus