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 designed to fit over the end of most conventional colonoscopes 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 improve the stability of the colonoscope and control of the tip. It is intended that improved visualisation will enhance the identification of colonic polyps, specifically adenomas and adenocarcinomas, and increase the likelihood of complete excision as well as aiding post-excision scar examination.

1.2 Regulatory status

Endocuff was first CE marked in August 2011 and this was renewed for Endocuff Vision in August 2016. Endocuff Vision is a modified version of the first Endocuff and includes one row of longer (15 mm vs. 12 mm) arms instead of two.

1.3 Claimed benefits

The benefits to patients claimed by the company through the use of Endocuff Vision 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 the 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. There is some evidence that the incidence of colorectal cancer is falling as a result of the impact of population screening programmes (see later), greater public awareness and the increased removal of adenomas during colonoscopy.

Colonoscopy is the standard procedure for the identification of colorectal cancer and pre-cancer. In 2014, 41,265 new colorectal cancers were diagnosed. 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 NHS Bowel Cancer Screening Programme (BCSP) aims to increase the detection of bowel cancer at an early stage. There are different screening programmes in England, Wales and Northern Ireland. In England, people aged between 60 and 74 years are automatically offered screening every 2 years, using the faecal occult blood test (FOBt); people older than the maximum screening age may be screened on request. However, the NHS BCSP outside England does not currently accept requests for screening in patients older than 74 years of age.

Since 2013, some screening centres have been piloting a new screening test, known as “bowel scope screening”. This involves a one-off test offered to men and women at age 55 – a flexible sigmoidoscopy, which examines the lower part of the bowel, where most cancers are found. Bowel scope screening is a complementary procedure to the FOB testing. As of March 2015, about two-thirds of screening centres were beginning to offer this test to 55 year olds.

People with an abnormal screening result should be seen at a nurse-run clinic within one week and offered colonoscopy or an alternative imaging technique. People with normal screening results will be offered further FOB testing every 2 years until they reach the maximum local screening age.

Symptomatic presentation

NICE guideline NG 12 Suspected cancer: recognition and referral (lower gastrointestinal tract cancers) (2015) recommends that in general, a person presenting with symptoms suggestive of colorectal or anal cancer should be 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 CG 131: The diagnosis and management of colorectal cancer (2011) gives recommendations on the investigation and diagnosis of people with suspected colorectal cancer whose condition is being managed in secondary care. It is recommended that clinicians should:

- Advise the patient that more than one investigation may be necessary to confirm or exclude a diagnosis of colorectal cancer.
- Offer colonoscopy to patients without major comorbidity, to confirm a 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 (for example, patients with a blood clotting disorder).
- Offer flexible sigmoidoscopy then barium enema to patients with major comorbidity. If a lesion suspicious of cancer is detected a biopsy should be performed unless it is contraindicated.
- Consider computed tomographic (CT) colonography as an alternative to colonoscopy or flexible sigmoidoscopy then barium enema, if the local radiology service can demonstrate competency in this technique. If a lesion suspicious of cancer is detected on CT colonography, colonoscopy with biopsy should be offered to confirm the diagnosis, unless it is contraindicated.
- Offer patients who have had an incomplete colonoscopy, repeat colonoscopy, CT colonography (if the local radiology service can demonstrate competency in this technique), or barium enema.

NICE guideline CG 118:

In the case of adenomas, NICE CG 118 Colonoscopic surveillance for prevention of colorectal cancer in people with ulcerative colitis, Crohn's disease or adenomas (March 2011), recommends offering surveillance colonoscopy to people who have had adenomas removed and are at low, intermediate or high risk of developing colorectal cancer. Risk stratification

involves determined by the number and size of adenomas identified at removal:

- Low risk: 1-2 adenomas smaller than 10mm (no follow up colonoscopy or colonoscopy at 5 years)
- Intermediate risk: 3-4 adenomas smaller than 10mm or 1-2 adenomas where 1 is 10mm or larger (offer colonoscopy at 3 years)
- High risk: 5 or more adenomas smaller than 10mm or 3 or more adenomas where 1 is 10mm or larger (offer colonoscopy at 1 year)

CG 118 advises offering a repeat colonoscopic examination if any colonoscopy is incomplete, and considering whether a more experienced colonoscopist should undertake that repeat examination.

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. A 2014 study reported that each 1% increase in ADR is associated with a 3% decrease in the risk of subsequent cancer (hazard ratio, 0.97; 95% confidence interval: 0.96 to 0.98).

The British Society of Gastroenterology quality standards for colonoscopy state that at least 1 adenoma should be identified in 15% of cases referred for colonoscopy (15% ADR).

2 Reasons for developing guidance on Endocuff Vision for endoscopic investigation

- The committee recognised the potential advantage for Endocuff Vision colonoscopy to increase ADR. It noted that an increase in ADR is linked to the earlier detection of colorectal cancer and a possible reduction in the incidence of interval cancers

- The committee considered that there was some uncertainty about how many of the additional polyps detected using the Endocuff Vision were likely to predispose to malignancy.
- The committee was advised that publication of guidance on the Endocuff Vision may help to foster awareness and understanding of the technology amongst specialists, leading to increased adoption and a consequent increase in ADR.
- The committee noted that there is the potential for cost savings through the NHS adoption of Endocuff Vision through the avoidance of repeat colonoscopies, bowel resections and chemotherapy, and earlier detection and treatment of some colorectal cancers.
- The committee recognised that cost modelling would be needed to demonstrate that increased costs associated with the adoption of this technology are negated or outweighed by savings to the healthcare system from the avoidance of later-stage cancer treatment.

3 Statement of the decision problem

	Draft scope issued by NICE
Population	People undergoing colonoscopy for suspected bowel cancer, for the removal of known polyps and for surveillance following previous adenoma removal.
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, training time on using Endocuff Vision) •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	Comparator(s): 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 to a general practitioner
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 characteristics?	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 the condition has a severe effect on everyday life for more than 12 months.	

4 Related NICE guidance

Published

- Suspected cancer: recognition and referral (2015) NICE guideline NG12
- Colorectal cancer: diagnosis and management (2011) NICE guideline CG131
- Colorectal cancer prevention: colonoscopic surveillance in adults with ulcerative colitis, Crohn's disease or adenomas (2011) NICE guideline CG118
- Improving outcomes in colorectal cancer (2004) NICE cancer service guideline CSG5
- Trifluridine–tipiracil for previously treated metastatic colorectal cancer (2016) NICE technology appraisal guidance TA405
- Low energy contact X-ray brachytherapy (the Papillon technique) for early stage rectal cancer (2015) NICE interventional procedures guidance IPG532
- Preoperative high dose rate brachytherapy for rectal cancer (2015) NICE interventional procedures guidance IPG531
- Transanal total mesorectal excision of the rectum (2015) NICE interventional procedures guidance IPG514
- Combined endoscopic and laparoscopic removal of colonic polyps (2014) NICE interventional procedures guidance IPG503

- Aflibercept in combination with irinotecan and fluorouracil-based therapy for treating metastatic colorectal cancer that has progressed following prior oxaliplatin-based chemotherapy (2014) NICE technology appraisal guidance TA307
- Cetuximab, bevacizumab and panitumumab for the treatment of metastatic colorectal cancer after first-line chemotherapy (2012) NICE technology appraisal guidance TA242
- Endoscopic submucosal dissection of lower gastrointestinal lesions (2010) NICE interventional procedures guidance IPG335
- Bevacizumab in combination with oxaliplatin and either fluorouracil plus folinic acid or capecitabine for the treatment of metastatic colorectal cancer (2010) NICE technology appraisal guidance TA212
- Selective internal radiation therapy for non-resectable colorectal metastases in the liver (2011) NICE interventional procedures guidance IPG401
- Radiofrequency ablation for colorectal liver metastases (2009) NICE interventional procedures guidance IPG327
- Cetuximab for the first-line treatment of metastatic colorectal cancer (2009) NICE technology appraisal guidance TA176
- Bevacizumab and cetuximab for the treatment of metastatic colorectal cancer (2007) NICE technology appraisal guidance TA118
- Laparoscopic surgery for colorectal cancer (2006) NICE technology appraisal guidance TA105
- Capecitabine and oxaliplatin in the adjuvant treatment of stage III (Dukes' C) colon cancer (2006) NICE technology appraisal guidance TA100
- Computed tomographic colonography (virtual colonoscopy) (2005) NICE interventional procedures guidance IPG129
- Complete cytoreduction for pseudomyxoma peritonei (Sugarbaker technique) (2004) NICE interventional procedures guidance IPG56
- Guidance on the use of capecitabine and tegafur with uracil for metastatic colorectal cancer (2003) NICE technology appraisal guidance TA61

Under development

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

- Molecular testing strategies for Lynch syndrome in people with colorectal cancer NICE diagnostics guideline. Publication expected February 2017
- Quantitative faecal immunochemical tests to assess symptomatic people who are at low risk of colorectal cancer in primary care NICE diagnostics guideline. Publication expected April 2017
- Virtual chromoendoscopy to assess colorectal polyps during colonoscopy NICE diagnostics guideline. Publication expected May 2017
- Pembrolizumab for previously treated metastatic colorectal cancer that has high microsatellite instability or mismatch repair deficiency NICE technology appraisal guidance. Publication expected September 2017
- Colorectal cancer (metastatic) - cetuximab (review TA176) and panitumumab (part review TA240) (1st line) NICE technology appraisal guidance. Expected publication date: TBC

5 External organisations

5.1 Professional organisations

5.1.1 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

5.1.2 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.

5.2 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
- Action Cancer - NI
- Bladder and Bowel Foundation
- BME cancer.communities
- Bowel Cancer Information (Formerly Lynn's Bowel Cancer Campaign)
- Bowel Cancer UK
- Cancer Black Care
- Cancer Equality
- CancerHelp UK
- Helen Rollason Cancer Charity
- Independent Cancer Patients' Voice
- Macmillan Cancer Support
- Tenovus
- Ulster Cancer Foundation