NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HealthTech draft guidance

PillCam COLON 2 for investigating the colon

Guidance development process

NICE diagnostics guidance evaluates diagnostic tests and technologies. It provides evidence-based recommendations about how accurate and effective the tests are, as well as their costs. The guidance supports healthcare professionals and commissioners to choose the best diagnostic options to improve patient care. NICE aims to enhance the quality of diagnostic practices in the UK, leading to better health outcomes for patients.

Find out more on the NICE webpage on the diagnostics assessment programme.

NICE is producing this guidance on PillCam COLON 2 for investigating the colon in the NHS in England. The diagnostics advisory committee has considered the evidence and the views of clinical and patient experts.

This document has been prepared for consultation with the stakeholders. It summarises the evidence and views that have been considered, and sets out the recommendations made by the committee. NICE invites comments from the stakeholders for this evaluation and the public. This document should be read along with the evidence.

The committee is interested in receiving comments on the following:

- Has all of the relevant evidence been taken into account?
- Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?

- Are the recommendations sound and a suitable basis for guidance to the NHS?
- Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of age, disability, gender reassignment, pregnancy and maternity, race, religion or belief, sex or sexual orientation?

After consultation:

- Based on the consultation comments received, the committee may meet again.
- If committee meets again it will consider the evidence, this evaluation consultation document and comments from stakeholders.
- The committee will then prepare the final draft guidance, which will go through a resolution process before the final guidance is agreed.

Note that this document is not NICE's final guidance on PillCam COLON 2 for investigating the colon. The recommendations in section 1 may change after consultation.

More details are available in NICE's health technology evaluations: the manual.

Key dates:

Closing date for comments: 1 May 2025

Second committee meeting: 13 May 2025

1 Recommendations

1.1 More research is needed on PillCam COLON 2 for investigating the colon in adults with lower gastrointestinal signs or symptoms suggestive of colorectal cancer, before it can be funded by the NHS.

What research is needed

More research is needed on:

- diagnostic accuracy
- which subgroups have the lowest risk of needing a colonoscopy after PillCam COLON 2.

What this means in practice

There is not enough evidence to support funding PillCam COLON 2 in the NHS.

Access to PillCam COLON 2 should be through company, research or non-core NHS funding, and clinical or financial risks should be managed appropriately.

Why the committee made these recommendations

PillCam COLON 2 uses a small camera, swallowed in a capsule, to capture images of the colon (large bowel). It could be used as an alternative to colonoscopy or CT colonography to diagnose bowel conditions such as polyps and colorectal cancer. This may help reduce waiting lists and prioritise people who need further tests and treatment.

Evidence suggests that PillCam COLON 2 may reduce the number of colonoscopies. High quality evidence is limited because the studies do not reflect how the test would be used in clinical practice. Low quality evidence from 1 study suggests that PillCam COLON 2 may have high accuracy for diagnosing polyps.

Results from economic modelling suggest that PillCam COLON 2 is not cost effective compared with colonoscopy or CT colonography. But it is unknown whether PillCam COLON 2 may be cost effective when used in certain groups, such as people who have:

- had an incomplete colonoscopy
- low rates of needing colonoscopy after PillCam COLON 2.

So, more research is needed to determine if the technology is cost effective in these specific groups and which groups are more likely to not need colonoscopy after PillCam COLON 2.

3 Information about the technology

3.1 PillCam COLON 2 (Medtronic) is a type of colon capsule endoscopy, which provides direct visualisation of the colon to detect polyps and other abnormal bowel pathology. The technology consists of 3 components: the capsule, the recorder and sensors, and desktop software. The capsule is single use. The recorder is worn by the patient. The sensors are either worn on a sensor belt or a sensor array is attached directly to the patient. The belt or the array are worn for the duration that the capsule is within the body, and they receive data from the capsule. A single-use PillCam COLON 2 capsule costs £460.00 and the reusable sensor belt costs £307.28 per year, based on a 5-year contract.

3.2 The PillCam COLON 2 capsule is swallowed under clinical supervision after a bowel cleansing regimen started the day before. Additional booster medicines taken after the capsule has been swallowed help move it through the colon. After the capsule is excreted, raw data collected by the sensor belt or array is processed using PillCam desktop software. This is compiled into a video which can be uploaded to the secure PillCam Reader software for review. The user can play, rewind and fast-forward the

video and produce an interpretation that can be summarised in a patient report.

4 Committee discussion

The diagnostics advisory committee considered evidence on PillCam COLON 2 for investigating the colon from several sources. This included evidence submitted by Medtronic, a review of clinical and cost evidence by the external assessment group (EAG), and responses from stakeholders. Full details are available in the project documents for this guidance.

The condition

4.1 Colorectal polyps are small growths on the inner lining of the colon. Polyps are very common, affecting about 15% to 20% of the UK population aged 50 or over, and most people are unaware they have them. Polyps are not usually cancerous, but some may develop into adenomas (advanced polyps) which can be precancerous. People with adenomas have a higher risk of developing colorectal cancer if the adenomas are not removed. Colorectal cancer is the fourth most common cancer in the UK (see Cancer Research UK's webpage on cancer incidence for common cancers). There are approximately 44,000 new cases and 16,800 deaths per year, with over half of people diagnosed with colorectal cancer in England surviving at least 10 years after diagnosis (see Cancer Research UK's webpage on bowel cancer statistics). Early diagnosis improves survival.

Current practice

4.2 For people with symptoms that may suggest colorectal cancer, NICE's diagnostics guidance on quantitative faecal immunochemical testing (FIT) to guide colorectal cancer pathway referral in primary care recommends that:

- adults with a FIT result of 10 microgram/g or more should be referred using a suspected cancer pathway referral
- adults with a FIT result below 10 microgram/g should be referred to an appropriate secondary care pathway if there is a strong clinical concern of cancer because of ongoing unexplained symptoms. The referral would be for the most appropriate test or an appointment with a specialist.

4.3 People who have had high-risk findings on a previous colonoscopy may have follow-up surveillance colonoscopy or colorectal imaging after 3 years.

4.4 Colonoscopy is often used for diagnosing colorectal cancer. It can visualise the entire colon, and biopsies can be taken and examined histologically to confirm a diagnosis. Depending on the clinical situation, polyps may be removed when they are identified using cauterisation or a snare. Colonoscopy needs preparation of the colon using diet modification and laxatives and is most frequently done as an outpatient procedure. It is associated with very rare but serious complications, such as perforation of the bowel and heavy bleeding which may need a transfusion.

4.5 Colonoscopy may not be suitable for elderly people and those with comorbidities such as kidney disease. For these people, CT colonography may be used. Additionally, people who are unwilling to have a colonoscopy may have CT colonography. People having a CT colonography consume a contrast-based material, need air insufflation and are exposed to ionising radiation. If pathology is found then a follow-up colonoscopy, or flexible sigmoidoscopy if pathology is limited to the distal colon, may be needed.

4.6 After bowel polyps are removed, they are sent for laboratory testing. In rare cases, surgery may be needed to treat polyps by removing part of the bowel. If colorectal cancer is confirmed, NICE's guideline on colorectal cancer recommends further imaging

tests, such as CT or MRI, to stage the cancer and determine which treatment is needed. Colonoscopy may also find other bowel conditions such as Crohn's disease, ulcerative colitis and diverticulosis, which may need further treatment and follow up.

Unmet need

4.7 NHS endoscopy services are under considerable strain and in some areas there are long waiting lists for colonoscopy. Healthcare professionals have observed that many people on the suspected colorectal cancer referral pathway have no abnormal pathology found at colonoscopy. PillCam COLON 2 is indicated for use as an alternative to colonoscopy to help rule out polyps, colon cancer and other pathology, and to direct people who need a biopsy or polypectomy to therapeutic colonoscopy. This may help reduce waiting lists and aid early cancer detection by prioritising people who need further tests and treatment.

Clinical effectiveness

Diagnostic accuracy

4.8 The committee considered 1 study that included a population directly applicable to the scope. This study included people with symptoms who were referred for colonic investigation, based on NICE criteria before 2021. Sensitivity and specificity for detecting clinically significant polyps of 100% and 98% were reported in 66 people. This evidence was limited by there being a:

- small number of people
- low prevalence of polyps
- high risk of bias because of concerns arising from the unblinded interpretation of the diagnostic tests.

Also, the study only included a subset of the symptomatic population of interest to this evaluation, providing no data for

surveillance populations. The committee acknowledged the results and limitations of this evidence, accepting that further diagnostic accuracy evidence is needed to inform decision making.

4.9 Because of the scarcity of evidence identified in directly applicable populations, 5 studies including populations indirectly applicable to the scope were considered by the committee. The proportion of people within scope in these studies ranged from 64% to potentially as few as 11%. Pooled sensitivity and specificity estimates were lower than those seen in the directly applicable evidence. The EAG commented that the difference in diagnostic accuracy between mixed and within-scope populations was likely caused by potential differences in size and distribution of polyps between the groups, introducing uncertainty into the evidence. But it was unable to predict what impact this would have on diagnostic accuracy estimates. There was limited evidence available on the diagnostic accuracy of PillCam COLON 2 for adenomas and colorectal cancer. The committee acknowledged the limitations of the evidence but agreed that including this indirect evidence supports decision making. It concluded that further research should be done to reduce uncertainties in the diagnostic accuracy estimates.

Patient preference

4.10 The committee considered evidence on patient preference from 5 studies and testimony from a lay committee member with lived experience. Preference and satisfaction data for PillCam COLON 2 compared with colonoscopy and CT colonography was mixed. The committee noted that patient preference was likely to be influenced by the clinical situation. The committee acknowledged some points of dissatisfaction with PillCam COLON 2, including:

- the provision of information
- problems with the bowel preparation regimen

- pain and discomfort after swallowing the capsule
- the wait for results and a subsequent colonoscopy when needed
- the impact on daily life of both the bowel preparation regimen and wearing the sensor and recorder.

4.11 The committee considered that for some people there are potential barriers to having a colonoscopy. This includes people:

- who have previously had a negative experience of colonoscopy
- who have been sexually abused
- on anticoagulants that would need to be stopped before colonoscopy
- with certain religious or cultural beliefs.

The committee agreed that these groups would benefit from the option of a less-invasive test.

Ongoing studies

4.12 The committee discussed the ongoing ColoCap study being done in the UK, due to be published in 2027. The committee agreed that this study is likely to provide diagnostic accuracy and patient-preference evidence that is directly applicable to each of the 3 populations described in the decision problem.

Cost effectiveness

Model structure and inputs

4.13 The committee considered a health economic model that was developed to assess the cost effectiveness of PillCam COLON 2 compared with both colonoscopy and CT colonography. The model contained 6 separate populations: symptomatic FIT-positive patients, symptomatic FIT-negative patients, and post-polypectomy surveillance patients, each further split by whether they were willing to undergo colonoscopy or not. The committee was aware that the

polyp size categories identified in the literature for diagnostic accuracy did not directly align with those used in the long-term model, which introduces uncertainty.

Model results

4.14 Base-case results showed that PillCam COLON 2 was more costly and less effective than colonoscopy in all populations, resulting in it being dominated. Compared with CT colonography, PillCam COLON 2 was more costly and, depending on the population, either less effective or more effective. This led to it being dominated or having incremental cost effectiveness ratios (ICERs) ranging from £434,488 to £7,208,331 per quality adjusted life year gained, which are well above the range that NICE considers a cost-effective use of NHS resources. The committee noted that differences in quality-adjusted life years gained between tests was small, but that the difference in costs between them heavily contributed to the results. The committee noted that in all scenarios tested, PillCam COLON 2 was either dominated, or had a high ICER. This included an optimistic scenario that assumed a PillCam COLON 2 completion rate of 85% and equal diagnostic accuracy of PillCam COLON 2 and colonoscopy. The committee concluded that PillCam COLON 2 does not appear to be a cost-effective test when compared with either colonoscopy or CT colonography in any of the 6 modelled populations.

Colonoscopy capacity sparing

4.15 The model estimated that, in populations willing to have colonoscopy, using PillCam COLON 2 would result in large reductions in the number of colonoscopies, especially in symptomatic populations. The model estimated small reductions in the number of colonoscopies in populations which initially declined colonoscopy, noting that the only comparator in this population was CT colonography. Evidence from 2 studies identified in the

literature review also suggested that using PillCam COLON 2 would significantly reduce the number of colonoscopies needed. Notably, capacity-sparing estimates were highest in people with a negative FIT test result. The committee was concerned that interpretation of PillCam COLON 2 images may be done by the same endoscopists who perform colonoscopies. So, it was concerned whether benefits from colonoscopy capacity sparing would be realised in practice. The committee heard from clinical experts that interpretation of PillCam COLON 2 images by trained endoscopists does not take away from their colonoscopy capacity. So, PillCam COLON 2 could feasibly increase colon investigation capacity and reduce waiting times. Clinical experts noted that a partially complete PillCam COLON 2 investigation could be followed by flexible sigmoidoscopy to visualise the lower gastrointestinal tract, rather than a colonoscopy. Flexible sigmoidoscopy requires a less-intensive bowel preparation procedure and takes less time than a colonoscopy, potentially further freeing up endoscopist capacity. Additionally, the committee noted that colonoscopy is used for purposes beyond those included in the scope of this evaluation. Reducing the number of colonoscopies being done for colorectal cancer investigations could feasibly reduce waiting list times in these other populations. This may result in cost savings or improved health outcomes in these people. But, this was beyond the scope of this evaluation and could not be ascertained from the economic model.

Follow-up testing

4.16 The committee noted that the proportion of people who need colonoscopy or flexible sigmoidoscopy after a PillCam COLON 2 investigation was the key driver of the model results. This is because of the additional costs associated with further testing. In the model, if PillCam COLON 2 results in incomplete visualisation of the whole colon, people have a colonoscopy or flexible

sigmoidoscopy. Evidence from the literature review suggested large variations in the completion rates of PillCam COLON 2, ranging from 40% to 89%. The NHS England colon capsule endoscopy pilot study reported 70% completion rates. Clinical experts noted that some people are likely to have lower completion rates than others, for example, people with chronic constipation, people who are inactive and people with diabetes. Clinical experts noted that a learning curve exists for colon capsule endoscopy services. Improvements in completion rates, bowel cleansing rates, interpretation of findings and subsequent onward referral rates are likely to occur as centres gain experience in using the technology. Also, people with significant pathology found with PillCam COLON 2 need a therapeutic colonoscopy or flexible sigmoidoscopy. This means that a large proportion of people having PillCam COLON 2 need to have further investigation, incurring additional costs. Because of this, the committee concluded that PillCam COLON 2 is unlikely to be cost effective in people who are likely to have an incomplete test or are likely to have underlying pathology detected with PillCam COLON 2. It agreed that further research is needed to identify the populations who have the lowest risk of needing a colonoscopy after PillCam COLON 2.

Populations that could benefit most

4.17 The committee discussed subpopulations in which clinical and economic benefits may be seen. It considered this was likely in people who had an incomplete index test colonoscopy, because PillCam COLON 2 may allow complete visualisation of the colon. In current practice, this would need follow up with a CT colonography or a repeat colonoscopy. Clinical experts noted that CT colonography may not be suitable for everyone and that a repeat colonoscopy may not be possible. In this scenario, PillCam COLON 2 may be useful as an alternative test. Clinical experts

noted that in this situation, a patient could take the PillCam COLON 2 capsule immediately after the incomplete colonoscopy. This would reduce waiting time for a follow-up test and remove the need for an additional bowel cleansing regimen.

Equality considerations

4.18 The committee acknowledged that there was no data on whether socioeconomic status or ethnicity may impact patient preference or other outcomes in this assessment. The committee agreed that this was an important area for future research which may help to establish in which populations PillCam COLON 2 may provide most benefit.

5 Committee members and NICE project team

This topic was considered by NICE's diagnostics advisory committee, which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the technology to be evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of each committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Chair

Brian Shine

Chair, diagnostics advisory committee

NICE project team

Each evaluation is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the evaluation), a technical, a project manager and an associate director.

Toby Sands

Technical lead

Frances Nixon

Technical adviser

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Project manager

Lizzy Latimer

Associate director

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