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NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Technology Appraisal

Capsule sponge tests for detection of Barrett's oesophagus and oesophageal cancer

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of capsule sponge tests within their indication for the detection of Barrett's oesophagus and oesophageal cancer in people with gastro-oesophageal reflux disease and risk factors, and surveillance in people who have a diagnosis of Barrett's oesophagus.

Background

Barrett's oesophagus is defined as an oesophagus in which any normal cells of the lower part of the oesophagus (distal squamous epithelium) have been replaced by cells like those lining the stomach and bowel (metaplastic columnar epithelium). This area has to be clearly visible endoscopically (more than 1 cm in length) above the gastro-oesophageal junction (the area where the esophagus connects to the stomach) and confirmed histopathologically from biopsies¹. Estimates suggest Barrett's oesophagus affects 1 to 2% of the adult population^{2,3}. However, it is difficult to obtain an exact estimate given that endoscopy is required to diagnose the condition.

People with Barrett's oesophagus may have no symptoms, or they may have symptoms of gastro-oesophageal reflux disease (GORD), which include:

- heartburn and indigestion
- chest pain
- discomfort in the upper part of the abdomen
- burping or coughing more when lying down.

Chronic reflux is a risk factor for developing Barrett's oesophagus. The risk of developing Barrett's oesophagus in this group reaches up to 10%⁴. The prevalence of Barrett's oesophagus among individuals with reflux is also higher compared with the general population, ranging between 3% and 14%⁵. Other risk factors for developing Barrett's oesophagus include older age, male sex, being overweight, smoking, having a hiatal hernia, White ethnicity and a family history of Barrett's oesophagus or oesophageal adenocarcinoma.

People with Barrett's oesophagus have a higher risk of developing oesophageal adenocarcinoma – an aggressive cancer with a poor prognosis when detected at a late stage. Of those with Barrett's, between 3 and 13% will develop oesophageal adenocarcinoma in their lifetime (but the annual incidence is less than 1%)⁶. Between April 2018 and March 2020, in England and Wales there were just over 14,700 diagnoses of oesophageal cancer and 74% of those were oesophageal adenocarcinomas⁷. The early detection of oesophageal adenocarcinoma is associated with improved survival.

Classifying Barrett's oesophagus

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There are several classifications of Barrett's oesophagus. Based on the length of the affected segment of the oesophagus it can be categorised into:

- short-segment Barrett's oesophagus (affected area of less than 3 cm)
- long-segment Barrett's oesophagus (affected area longer than 3 cm).

Barrett's oesophagus can also be staged as:

- non-dysplastic intestinal metaplasia
- intestinal metaplasia indefinite for dysplasia
- intestinal metaplasia with low-grade dysplasia
- intestinal metaplasia with high-grade dysplasia
- carcinoma.

Indefinite for dysplasia means that atypical changes are present, but it is unclear if they represent true dysplasia or changes due to inflammation.

Diagnosis of Barrett's oesophagus

Barrett's oesophagus is currently diagnosed via endoscopy following a GP referral to a gastroenterologist or other specialist in secondary care. [NICE's guideline on gastro-oesophageal reflux disease and dyspepsia in adults](#) notes that endoscopy should not be routinely offered to people with GORD, but should be considered based on the person's preferences and individual risk factors (for example, long duration of symptoms, increased frequency of symptoms, previous oesophagitis, previous hiatus hernia, oesophageal stricture or oesophageal ulcers, or male gender). [The British Society of Gastroenterology \(BSG\) guideline on the diagnosis and management of Barrett's oesophagus](#) also notes that endoscopy should be considered in people with chronic GORD symptoms and multiple risk factors (at least three of age over 50, White ethnicity, male sex or obesity).

[NICE's guideline on suspected cancer](#) currently recommends that non-urgent upper gastrointestinal endoscopy should be considered in people over 55 with: treatment-resistant dyspepsia; upper abdominal pain with low haemoglobin levels; raised platelet count with any of the following – nausea, vomiting, weight loss, reflux, dyspepsia or upper abdominal pain; or nausea or vomiting with any of the following – weight loss, reflux, dyspepsia or upper abdominal pain. This is to assess for both oesophageal and stomach cancer. This guideline also recommends urgent upper gastrointestinal endoscopy referral for people with dysphagia or people over 55 with weight loss and any of the following – upper abdominal pain, reflux or dyspepsia.

Surveillance of Barrett's oesophagus

The [BSG guidelines on the diagnosis and management of Barrett's oesophagus](#) and [NICE's guidelines on gastro-oesophageal reflux disease and dyspepsia in adults](#) and [Barrett's oesophagus and stage 1 oesophageal adenocarcinoma](#) recommend surveillance for people who have a diagnosis of Barrett's oesophagus, while taking into account:

- the presence of dysplasia
- the person's risk factors (for example, male sex, older age and the length of the Barrett's oesophagus segment)
- the person's individual preference.

The aim of surveillance of Barrett's oesophagus is to detect cancer or precancer at a stage when an intervention can be curative. Surveillance is done via a high-resolution white light upper gastrointestinal (GI) endoscopy procedure (also known as a

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gastroscopy) with histopathological assessment of biopsy samples. Biopsies should be taken following the Seattle biopsy protocol, which entails four-quadrant random biopsies for every 2 cm of Barrett's oesophagus in addition to targeted biopsies on visible lesions. The procedure is usually carried out in secondary care and includes sedation.

People with Barrett's oesophagus shorter than 3 cm, with intestinal metaplasia, should receive endoscopic surveillance every 3 to 5 years. This frequency is increased to every 2 to 3 years for people with Barrett's oesophagus that is 3 cm or longer. [NICE's guideline on Barrett's oesophagus and stage 1 oesophageal adenocarcinoma](#) and the [BSG guidelines](#) recommend that if the segment of Barrett's oesophagus is shorter than 3 cm, without intestinal metaplasia or dysplasia, a repeat endoscopy should be done to confirm the diagnosis. If the repeat endoscopy confirms the absence of intestinal metaplasia and dysplasia, discharge from surveillance is encouraged as the risks of endoscopy outweigh the benefits. In Barrett's oesophagus with indefinite dysplasia, [NICE's guideline on Barrett's oesophagus and stage 1 oesophageal adenocarcinoma](#) recommends consideration of endoscopic surveillance at 6 monthly intervals with dose optimisation of acid-suppressant medication. If no dysplasia is found after the repeat procedure, the surveillance strategy should follow the recommendation for non-dysplastic Barrett's oesophagus.

There are no formal stopping rules for surveillance of Barrett's oesophagus in the NHS. Clinical experts explained that people may only be removed from a surveillance list if the risks from any of the follow-up procedures outweigh the benefits.

Treatment of Barrett's oesophagus with low-grade dysplasia

Endoscopic radiofrequency ablation can be used as an option for treating Barrett's oesophagus with low-grade dysplasia (see [NICE's interventional procedures guidance on endoscopic radiofrequency ablation for Barrett's oesophagus with low-grade dysplasia or no dysplasia](#) and the [BSG guidelines on the diagnosis and management of Barrett's oesophagus](#)).

Treatment of Barrett's oesophagus with high-grade dysplasia

In Barrett's oesophagus with high-grade dysplasia, [NICE's guideline on Barrett's oesophagus and stage 1 oesophageal adenocarcinoma](#) recommends endoscopic resection of visible oesophageal lesions as a first-line treatment, followed by endoscopic ablation of any residual Barrett's oesophagus. Other treatment options include epithelial radiofrequency ablation (see [NICE's interventional procedures guidance on epithelial radiofrequency ablation for Barrett's oesophagus](#)) and photodynamic therapy (see [NICE's interventional procedures guidance on photodynamic therapy for Barrett's oesophagus](#)).

Treatment of oesophageal adenocarcinoma

If cancer is detected, then treatment is recommended. The type of treatment depends on the cancer stage. [NICE's guideline on Barrett's oesophagus and stage 1 oesophageal adenocarcinoma](#) and the [BSG guidelines](#) recommend endoscopic resection for early cancer (T1a adenocarcinoma confined to the mucosa). Clinical experts explained that some centres in the NHS also perform endoscopic resection of early adenocarcinomas that have extended into submucosa (T1b) if the submucosal invasion depth is less than 500 micrometer, there is no lymphovascular invasion and no poor tumour differentiation. However, surgical resection, radiotherapy and/or chemotherapy are generally recommended for early

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adenocarcinoma that has extended into submucosa (T1b), as well as for advanced (T2/3) and metastatic (T4) adenocarcinoma (see [NICE's guideline on Barrett's oesophagus](#) and [NICE's guideline on oesophago-gastric cancer](#)).

Unmet need

Upper GI endoscopy is both invasive and expensive and is usually done in secondary care. There is a need for a less invasive, quicker diagnostic test that can be done closer to a person's home. In addition, there is a substantial waiting list for endoscopy procedures, so in some NHS trusts the actual periods between surveillance endoscopies are longer than recommended in the guidelines. There may also be a delay in results being returned due to capacity constraints in non-urgent histopathological assessment. This means that some people on a surveillance programme may go unmonitored for longer than guidelines recommend and some people referred for a diagnostic endoscopy may experience a delay in getting the procedure. It is easier to treat Barrett's oesophagus before it progresses to cancer, as well as to treat the cancer in its early stage before it becomes advanced or metastatic. Therefore, detecting intestinal metaplasia, dysplasia and cancer earlier could lead to improved outcomes for patients.

The technology

A capsule sponge test (also known as "sponge-on-a-thread") is an oesophageal cell collection device used with biomarker tests to check for abnormal cells in the oesophagus. It is a small capsule-shaped device which is swallowed under clinical supervision, but without the need for sedation. The capsule is dissolvable and when swallowed, within 7 minutes, it expands into a small, rough-textured sponge in the person's stomach. The sponge is then withdrawn by pulling on the thread attached to it, collecting some of the cells lining the oesophagus. The most common side effect of the procedure is a sore throat, and this can be treated with appropriate conservative measures or simple analgesia. Transient nausea may also be experienced.

The sponge containing the exfoliated cells from the oesophagus is placed in a fixative and this sample is currently shipped using a secure courier network to a single central private laboratory in the UK which carries out the laboratory assessment. Samples are considered adequate if columnar cells are present. Three analyses (histological staining and 2 biomarker tests) are done on all samples (Table 1).

Table 1: Analyses done on oesophageal cell samples collected by the capsule sponge

Type of analysis	Biomarker	Interpretation	
		Detection of Barrett's oesophagus	Surveillance of Barrett's oesophagus
Haematoxylin and eosin (H&E) staining	Gastric cells	Quality control to show that the capsule reached the stomach	
	Cellular atypia		Positivity indicates inflammation, dysplasia or malignant changes

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Trefoil factor family 3 (TFF3) antibody test	TFF3	Positivity indicates the presence of intestinal metaplasia	Quality control (all samples are expected to be TFF3 positive)
Tumour protein 53 (p53) test	p53	Positivity indicates dysplasia or malignant changes	

The diagnostic results are shared with the requesting clinician within 14 working days from the day of sample receipt. The report received from the laboratory is uploaded onto the patient records and the responsible healthcare professional develops the follow-up plan.

In the context of detecting Barrett's oesophagus and oesophageal cancer, based on the diagnostic results:

- The presence of atypia (definite or of uncertain significance) and/or abnormal or equivocal p53 would indicate a need for a referral to an urgent endoscopy.
- The presence of intestinal metaplasia (TFF3 positive) with normal p53 and no atypia would indicate presence of Barrett's oesophagus and a need for a referral to a routine endoscopy for confirmation of this finding.
- If a sample is TFF3 negative or equivocal for intestinal metaplasia, with normal p53 and no atypia, the person is managed according to symptoms with appropriate safety netting.
- An insufficient sample would require repeat testing or an endoscopy as soon as feasible (within 3 months).

In the context of surveillance of Barrett's oesophagus, based on the diagnostic results:

- The presence of atypia (definite or of uncertain significance) and/or abnormal or equivocal p53 would indicate a need for a referral to an urgent endoscopy.
- If no atypia and normal p53 are found, clinical risk factors can be used to plan an appropriate surveillance interval.
- If a sample is TFF3 negative or equivocal for intestinal metaplasia, with normal p53 and no atypia, clinical judgement based on previous results and the length of the Barrett's oesophagus segment is needed to decide whether repeat testing is needed.
- An insufficient sample would require repeat testing or an endoscopy as soon as feasible (within 3 months).

These follow-up options are based on studies by [Pilonis et al. 2022](#) and [Tan et al. 2025](#) which derived those options based on a classification of the risk for dysplasia. The classification included 3 risk groups:

- High risk: atypia (definite or of uncertain significance) and/or abnormal or equivocal p53 with or without clinical factors
 - Tier 1: glandular atypia and aberrant p53 (very high risk)
 - Tier 2: any other combination of biomarker positive results
- Moderate risk: presence of clinical risk factors (Barrett's oesophagus segment length, age, and sex)
- Low risk: no positive biomarker or clinical risk factors.

The sections that follow describe the 2 included technologies. Both were available to the NHS at the time of writing this scope.

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EndoSign (Cyted Health)

The EndoSign technology consists of the EndoSign cell collection device and the EndoSign preservation kit. The former is CE-marked and UKCA marked as a Class I medical device under the EU MDR 2017/745 and the UK MDR SI 2002 No 618, as amended. The latter is CE-marked and UKCA marked as a Class A in-vitro diagnostic under the EU IVDR 2017/746 and the UK MDR SI 2002 No 618, as amended. The diagnostic assays are performed by Cyted Health's ISO15189 accredited histopathology laboratory which is regulated by the UK Accreditation Service.

In addition to the device components described above, EndoSign has a proprietary applicator to position the capsule on the back of the person's tongue. EndoSign's capsule is made from hydroxypropyl methylcellulose and the sponge is made from polyurethane. The company provides training to all healthcare professionals administering the technology. This includes both virtual and in-person training, including hands-on procedure simulation and supervised clinical practice of the procedure.

The technology is contraindicated for use in people with symptoms of dysphagia or other swallowing disorders, people with a previous endoscopic therapy or who have had a surgical procedure involving the stomach or oesophagus, people with a known or suspected anatomic abnormality of the oesophagus or stomach, women who are or may be pregnant, people with known or suspected portal hypertension, gastric or oesophageal varices and people on anti-thrombotic drugs which cannot be temporarily discontinued before and after the procedure.

In England, EndoSign is currently used in 18 sites for the detection of Barrett's oesophagus and in 30 sites for surveillance of Barrett's oesophagus.

Cytosponge (Medtronic)

The Cytosponge technology is CE-marked as a Class I medical device. Samples collected with Cytosponge are analysed in Cyted Health's histopathology laboratory. According to publicly available information, Cytosponge's capsule is made from vegetarian gelatine and the sponge is made from polyethylene.

The technology is contraindicated for use in people with symptoms of dysphagia or history of swallowing disorders, people with known or suspected anatomical abnormalities of the esophagus or stomach, people who have undergone esophageal or gastric dilation, ablation, biopsy, mucosal resection or other invasive medical procedures within the previous two months, as well as women who are or may be pregnant. Cytosponge should also not be used in people with known or suspected portal hypertension and/or gastric or esophageal varices and people on anti-thrombotic drugs that cannot be temporarily discontinued.

There is no publicly available information on the number of sites in England that use Cytosponge and whether the company provides any training to healthcare professionals administering the technology.

Place of the technologies in the care pathway

The capsule sponge test could be used as a less invasive alternative to upper GI endoscopy for:

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- detection of Barrett's oesophagus in people with multiple risk factors and GORD that persists despite recommended lifestyle and pharmacological management
- surveillance of Barrett's oesophagus.

This assessment will not consider the use of capsule sponge tests for population screening in people without risk factors and persistent GORD.

Innovative aspects

The capsule sponge test represents a minimally invasive approach for detection and surveillance of Barrett's oesophagus. Using a capsule sponge test does not require sedation and can be done in community and primary care settings with lower-grade staff, such as a nurse, rather than a trained endoscopist. It also requires only one healthcare professional to administer, whereas an endoscopy procedure requires at least 2 nurses and an endoscopist. The capsule sponge test generates fewer aerosols, so it can be administered in an office environment. Also, the test relies on laboratory analysis rather than visual inspection for the detection of pathologies.

Interventions	<ul style="list-style-type: none">• EndoSign• Cytosponge <p>If appropriate, in the context of surveillance, different testing schedules will be considered, including repeat capsule sponge testing only and alternating capsule sponge testing and surveillance endoscopy.</p>
Populations	<ul style="list-style-type: none">• People with gastro-oesophageal reflux disease that persists despite recommended lifestyle and pharmacological management strategies, and multiple risk factors (such as age over 55, family history of oesophageal adenocarcinoma), who do not have dysphagia or weight loss• People with Barrett's oesophagus with intestinal metaplasia and no or low-grade dysplasia who are on a surveillance programme
Subgroups	<p>If the evidence allows, the following subgroups may be considered:</p> <ul style="list-style-type: none">• People with short (less than 3 cm) and long (more than 3 cm) segments of Barrett's oesophagus• People at a higher risk of high-grade dysplasia or oesophageal adenocarcinoma
Comparators	The comparator for this assessment is high-resolution white light upper GI endoscopy with histopathological assessment of biopsy samples

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Outcomes	<p>The outcome measures to be considered include:</p> <p>Intermediate and clinical outcomes</p> <ul style="list-style-type: none">• Diagnostic accuracy of<ul style="list-style-type: none">○ TFF3 for intestinal metaplasia○ haematoxylin and eosin staining for atypia○ p53 for dysplasia or cancer• Diagnostic yield for intestinal metaplasia, dysplasia, cancer and other pathology• Procedure uptake• Procedure success• Time to do the procedure• Repeat procedures due to insufficient sample collected• Follow-up urgent endoscopies needed• Follow-up non-urgent (routine) endoscopies needed• Cancer-related mortality or survival• Adverse events• Time to intervention following an adverse event• Healthcare professional acceptability• Reduction in upper GI endoscopy wait times <p>Patient-reported outcomes</p> <ul style="list-style-type: none">• Health-related quality of life• Patient acceptability• Anxiety attributed to being on a waiting list <p>Costs and resource use</p> <ul style="list-style-type: none">• Cost of the technology (including the device and laboratory assessment)• Cost of follow-up upper GI endoscopy• Cost of treatment and management• Cost of training• Staff time at different specialisms and levels of pay• Staff cost at different specialisms and levels of pay• Health service use at different settings• Cost of health service use at different settings• Number of lost samples.
Setting	Community, primary, secondary and specialist care

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Economic analysis	<p>The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year.</p> <p>The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared.</p> <p>Costs will be considered from an NHS and Personal Social Services perspective.</p> <p>In 2023 NICE considered the clinical and cost-effectiveness of the capsule sponge test for surveillance of people with Barrett's oesophagus as part of the development of NG231. At the time, the guideline committee concluded that there was evidence of benefit of using the capsule sponge test to diagnose dysplasia and cancer, but the quality was not sufficient to support its use.</p>
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Other considerations	<p>Guidance will only be issued in accordance with the CE or UKCA marking.</p> <p>Implementation</p> <p>In the 2025/26 National Payment Scheme, the FF05Z tariff has been updated to support use of capsule sponge tests.</p> <p>The laboratory analyses for all capsule sponge tests done in the NHS are currently performed in a single laboratory by Cyted Health. This presents potential risks and capacity constraints, conditional on the extent of adoption of the technology. Some issues related to transportation from remote or hard-to-reach regions may also be present.</p> <p>Sustainability</p> <p>The capsule sponge is a single-use device. However, an endoscopy procedure also includes single-use plastic elements, water and other decontaminants, as well as an energy-intensive hospital environment. So, using the capsule sponge test has the potential to reduce waste and resource use. In addition, shifting care to primary and community care by using the capsule sponge test has the potential to reduce long-distance travel and so, associated emissions from transport.</p> <p>The BSG, Joint Accreditation Group (JAG) and Centre for Sustainable Health (CSH) (2022) published a <u>joint consensus on practical measures for environmental sustainability in endoscopy</u>. It states that GI endoscopy is highly resource intensive and contributes significantly to greenhouse gas emissions and waste generation and recommends that sustainable alternatives to conventional diagnostic endoscopy, such as the capsule sponge test, should be considered where clinically indicated.</p> <p>Patient preferences</p> <p>Some people may experience a mild sore throat after a capsule sponge test, but this can be managed with over-the-counter medicines. However, an upper GI endoscopy can also cause a sore throat and hoarseness, as well as bloating, gas or cramping (due to air introduced during the procedure) and sleepiness, dizziness, or grogginess (due to the sedation). Because sedation is not required for the capsule sponge test, travel to and from the healthcare centre may be easier. The capsule sponge test can be done in community and primary care, which may also reduce travel time.</p> <p>NHS endoscopy services are under considerable strain and there are long waiting lists for upper GI endoscopy. Waiting for medical tests can induce anxiety, especially if there is a potential risk of cancer. Having the option of accessing capsule sponge testing earlier than endoscopy could potentially reduce some of the 'waiting anxiety'. However, clear communication to the person would be needed around why the capsule sponge test is being offered, the nature of the procedure and the</p>
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	<p>potential benefits. Further tests including a follow-up endoscopy may be needed depending on the results. Some people may prefer to wait for an endoscopy.</p>
Equality considerations	<p>Condition prevalence and outcomes</p> <p>Barrett's oesophagus is more common in older people, men and in White people. Men are also at an increased risk of developing oesophageal adenocarcinoma. Incidence and mortality rates have been found to be higher among people who live in the most deprived areas. This may reflect increased exposure to risk factors in this group, such as smoking, alcohol consumption and obesity. In England and Wales, oesophageal cancer mortality rates are generally lower in non-White compared with White people. Sex and ethnicity are protected characteristics under the Equality Act 2010. People with cancer are also protected under the Equality Act 2010 from the point of diagnosis.</p> <p>Access to care</p> <p>The capsule sponge test can be administered in the primary and community care settings. This could improve access to care for people living in rural or remote areas, or those for whom travel is a limiting factor.</p> <p>The technology and procedure</p> <p>The technologies are contraindicated for use in women who are or may be pregnant. Pregnancy is a protected characteristic under the Equality Act 2010. They are also contraindicated for use in people with symptoms of dysphagia or other swallowing disorders, people with a known or suspected anatomic abnormality of the oesophagus or stomach, people with known or suspected portal hypertension, gastric or oesophageal varices, people on anti-thrombotic drugs which cannot be temporarily discontinued and people who have had a surgical or endoscopic procedure involving the stomach or oesophagus. In addition, some people may not be able to swallow the capsule even if they have no diagnosis of dysphagia or another swallowing disorder. Some of those people may be covered by the Equality Act 2010 if they are considered to have a disability.</p>
Related NICE recommendations	<p>Related NICE guidelines:</p> <p>NICE's guideline on suspected cancer: recognition and referral (2025) NICE guideline NG12.</p> <p>NICE's guideline on gastro-oesophageal reflux disease and dyspepsia in adults: investigation and management (2019) Clinical guideline CG184.</p> <p>NICE's guideline on Barrett's oesophagus and stage 1 oesophageal adenocarcinoma: monitoring and management (2023) NICE guideline NG231.</p>

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	<p>NICE's guideline on oesophago-gastric cancer: assessment and management in adults (2023) NICE guideline NG83.</p> <p>Related interventional procedures:</p> <p>NICE's interventional procedures guidance on epithelial radiofrequency ablation for Barrett's oesophagus (2010) NICE interventional procedures guidance IPG344.</p> <p>NICE's interventional procedures guidance on photodynamic therapy for Barrett's oesophagus (2010) NICE interventional procedures guidance IPG350.</p> <p>NICE's interventional procedures guidance on endoscopic radiofrequency ablation for Barrett's oesophagus with low-grade dysplasia or no dysplasia (2014) NICE interventional procedures guidance IPG496.</p>
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Questions for consultation

1. Is the proposed title for this assessment appropriate?
2. Are the proposed populations (in particular for the detection use case) described appropriately? Are there any other use cases (in addition to detection and surveillance) that should be considered?
3. Is the triage of patients according to the diagnostic results from a capsule sponge test (in particular for the detection use case) described appropriately (see page 5 of the scope)?
4. Are all the outcomes and costs suitable for inclusion in the assessment?
5. Do you consider that the use of capsule sponge tests can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?
Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.
6. NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if, in addition to the equality considerations in the decision problem table, the proposed remit and scope:
 - o could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which capsule sponge tests will be used;
 - o could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;
 - o could have any adverse impact on people with a particular disability or disabilities.
Please tell us what evidence should be obtained to enable the committee to identify and consider such impacts.
7. Are there any other stakeholders NICE should be aware of?

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NICE intends to appraise this technology through its Multiple Technology Appraisal (MTA) process. We welcome comments on the appropriateness of appraising this topic through this process. (Information on NICE's health technology evaluation processes is available at:

<https://www.nice.org.uk/process/pmg36/chapter/introduction-to-health-technology-evaluation>).

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