Guidance assessment consultation document for HTG10877 Technologies for diagnosing endometriosis in primary care

Guidance issue date July 2026

Guidance development process

NICE HealthTech guidance evaluates digital technologies, diagnostics and medical devices (including artificial intelligence). It provides evidence-based recommendations about how safe and effective these technologies are, and their cost effectiveness. The guidance supports healthcare professionals and commissioners to ensure that patients get the best possible treatments. NICE aims to promote innovations that meet the needs of patients and the healthcare system.

This guidance has been developed as early-use HealthTech guidance, for HealthTech products that could address an unmet need in the NHS and need more evidence to support routine use.

Find out more on the NICE webpage on HealthTech guidance.

NICE is producing this guidance on technologies for diagnosing endometriosis in primary care 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 the 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- The committee will then prepare the final draft guidance, which will go through a resolution process before the final guidance is agreed.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 technologies for diagnosing endometriosis in primary care. The recommendations in section 1 may change after consultation.

More details are available in NICE's HealthTech programme manual.

Key dates:

Closing date for comments: 24th July 2026

Second committee meeting: 12th August 2026

1 Recommendations

Can be used during the evidence generation period

1.1 Two technologies can be used in the NHS during the evidence generation period as options to diagnose endometriosis in primary care. The technologies are:

- EndoSure
- Endotest.

These technologies can only be used if the evidence outlined in the evidence generation plan for technologies for diagnosing endometriosis in primary care is being generated.

1.2 The technologies should only be used in primary care when endometriosis is suspected and:

- clinical (abdominal and pelvic) examination is normal, and
- imaging (transvaginal or transabdominal ultrasound) is either negative for endometriosis or inconclusive, or is declined or not suitable.

1.3 The companies are responsible for ensuring that data collection and analysis take place. They must confirm that agreements are in place to generate the evidence. NICE will contact the companies annually to confirm that evidence is being generated and analysed as planned. NICE may revise or withdraw the guidance if these conditions are not met.

1.4 At the end of the evidence generation period (3 years), the companies should submit the evidence to NICE in a format that can be used for decision making. NICE will review the evidence and assess if the technology can be routinely adopted in the NHS.

More research is needed

1.5 More research is needed on DotEndo to diagnose endometriosis in primary care before it can be funded by the NHS.

What this means in practice

Can be used during the evidence generation period

EndoSure and Endotest can be used as options in the NHS during the evidence generation period (3 years) and paid for using core NHS funding. During this time, more evidence will be collected to address any uncertainties. Companies are responsible for organising funding for evidence generation activities.

After this, NICE will review this guidance and the recommendations may change. Take this into account when negotiating the length of contracts and licence costs.

Potential benefits of use in the NHS during the evidence generation period

- **Access:** Variations in ultrasound expertise may affect the accuracy of diagnosing endometriosis in primary care. EndoSure and Endotest are not dependent on operator expertise and may help identify endometriosis not previously detected on ultrasound. This could reduce uncertainty for women, trans men and non-binary people with female reproductive organs who might otherwise remain undiagnosed. The technologies may offer an alternative, non-invasive method of diagnosis.
- **System benefit:** The technologies may enable earlier diagnosis and treatment of endometriosis in primary care, through management within primary care where appropriate or earlier referral to specialist services.
- **Patient outcomes:** Earlier diagnosis and treatment of endometriosis in primary care may enable people to get the support, treatment and care

that they need sooner, through either management in primary care or prompt referral to specialist services. This may help reduce symptom burden and improve quality of life. In addition, these technologies may be an alternative to transvaginal ultrasound if it is not suitable or declined, potentially improving patient experience.

- **Equality:** The technologies may support more equitable access to diagnosis for women, trans men or non-binary people with female reproductive organs for whom transvaginal ultrasound is not suitable or acceptable, by providing an alternative diagnostic option.

Managing the risk of use in the NHS during the evidence generation period

- **Costs:** Early economic modelling shows that EndoSure and Endotest could be cost effective over a long time horizon. But this is uncertain because of the lack of evidence on clinical benefits after using these tests and quality of life before and after diagnosis.
- **Clinical risk:** The diagnostic accuracy of the technologies in primary care (including false positives and false negatives) is unclear. The tests results could influence treatment decisions. This has potential risks of both overtreatment and undertreatment of endometriosis. The technologies should be used alongside standard practice and should not replace clinical judgement. Their impact on downstream patient outcomes is currently unknown.
- **Resources:** Implementation of the technologies in primary care may have resource implications. Both technologies require healthcare professionals to be trained in their use and interpretation, and in communicating results. EndoSure needs additional clinic space and time to undertake testing, while Endotest requires resources for sample collection. Positive test results from EndoSure and Endotest may

increase referrals to secondary care because more people could be diagnosed with endometriosis.

More research is needed

There is not enough evidence to support funding DotEndo in the NHS.

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

What evidence generation and research is needed

Evidence generation and more research is needed on the technologies':

- diagnostic accuracy, including their sensitivity, specificity, negative predictive value and positive predictive value, when used in primary care
- impact on the diagnostic pathway and resource use
- impact on patient-reported outcomes and patient experience
- associated training costs and cost savings associated with avoided downstream tests.

The evidence generation plan gives further information on the prioritised evidence gaps and outcomes, ongoing studies and potential real-world data sources. It includes how the evidence gaps could be resolved through real-world evidence studies.

Why the committee made these recommendations

It can take 4 to 10 years to confirm a diagnosis of endometriosis. These delays may result from late initial presentation, delays in the referral pathway, variation in expertise in transvaginal ultrasound in primary care, and long waiting times for gynaecology services. Delays in diagnosis lead to prolonged ill health and a condition that is more difficult to treat. Diagnostic tests in

primary care could enable earlier diagnosis of endometriosis, treatment in primary care if appropriate and earlier referral to gynaecology services.

Evidence on the diagnostic accuracy of these technologies is limited and varies between the technologies. All the studies are from secondary or tertiary care. Evidence from multiple studies suggests that EndoSure and Endotest have higher diagnostic accuracy than transvaginal ultrasound done in primary care. This would help identify endometriosis if transvaginal ultrasound results are negative or inconclusive, or if transvaginal ultrasound is not suitable or declined. There is no evidence on clinical outcomes or how these technologies could affect the diagnostic pathway or resource use. Despite this, the technologies have the potential to address a high unmet need in the NHS by enabling endometriosis diagnosis in primary care.

Early economic modelling suggests that EndoSure and Endotest are likely to be cost effective over a 60-year time horizon. So, they are recommended for use with evidence generation.

Economic modelling also suggests that DotEndo is likely to be cost effective over the same time horizon. But the evidence for DotEndo is insufficient because it comes from only 1 study of 100 people from 1 centre. So, more research is needed.

2 Information about the technologies

2.1 The 3 technologies for diagnosing endometriosis differ in their mechanisms: DotEndo is blood based, Endotest is saliva based and EndoSure is based on gastrointestinal myoelectrical activity (see table 1). The technologies can be used by healthcare professionals in primary care and are intended to be used alongside standard practice. Results from EndoSure are available immediately after testing, whereas Endotest and DotEndo require sample processing in a specialist laboratory that can analyse

microRNA biomarkers. All 3 technologies require an additional appointment to discuss the results with a healthcare professional.

Table 1 Overview of technology features

Technology name (company), regulatory status	Technology features and test processing	Intended age group	Cost
EndoSure (3PCM/Endosure) UK MDR class 2a	Measures gastrointestinal myoelectrical activity to detect abnormal electrical patterns in the gut caused by prostaglandins released by endometriosis tissue. Results are available immediately after testing	No lower or upper age limits specified	Test per person: £350 Implementation per person: • capital: £70.83 • training: £4.17 (Capital and training costs were assumed to be spread across 120 people)
Endotest (Ziwig) UK MDR class A, IVDR	Detects the presence of a 109-microRNA biomarker signature of endometriosis in saliva. Samples are sent to the company's centralised laboratory with sequencing capacity	18 to 43 years	Test per person: £1,381
DotEndo (DotLab) CE class C, IVDR expected in 2026	Quantifies endometriosis-specific microRNA biomarker levels in blood. Sample processing is not known, but laboratory analysis using polymerase chain reaction is needed	18 to 49 years	Test per person: £400

Abbreviations: CE, Conformité Européenne; IVDR, In Vitro Diagnostic Regulation; MDR, Medical Device Regulation.

Sustainability

2.2 For information, Ziwig's commitment to achieving net zero is published here: Ziwig's environmental responsibility. Ziwig did not disclose its Carbon Reduction Plan. Endosure and DotLab did not disclose their Carbon Reduction Plan for UK carbon emissions or their net zero commitment.

3 Committee discussion

The diagnostics advisory committee considered evidence on technologies for diagnosing endometriosis in primary care from several sources. This included evidence submitted by the companies, a review of clinical and cost evidence by the external assessment group, and responses from stakeholders. Full details are available in the project documents for this guidance.

The condition

3.1 Endometriosis is a chronic inflammatory disease in which tissue similar to the endometrial lining is present outside the uterus (womb). It is estimated that 10% of women and those assigned female at birth who are of reproductive age in the UK have endometriosis. The most common symptom of endometriosis is chronic pelvic pain. Other symptoms include:

- period-related pain that affects daily activities and quality of life
- deep pain during or after sexual intercourse
- period-related or cyclical gastrointestinal symptoms, in particular painful bowel movements
- period-related or cyclical urinary symptoms, in particular pain passing urine or blood in the urine
- subfertility or infertility associated with 1 or more of the above.

Current practice

3.2 NICE's guideline on endometriosis includes the following recommendations for diagnosis and referral in primary care:

- When endometriosis is suspected, offer an abdominal and pelvic (internal vaginal) examination.
- Regardless of the examination findings, offer a transvaginal ultrasound to all people with suspected endometriosis.
- If transvaginal ultrasound is declined or unsuitable, consider a transabdominal ultrasound of the pelvis.
- Ultrasound scans should be organised by the general practice.
- A normal abdominal or pelvic examination or ultrasound does not exclude endometriosis.
- Pharmacological treatment can start alongside the diagnosis and referral process if endometriosis is suspected.

3.3 NICE's guideline on endometriosis recommends referral to gynaecology services if:

- symptoms of endometriosis have a detrimental impact on activities of daily living
- initial treatment is not effective, not tolerated or contraindicated
- there are persistent or recurrent symptoms of endometriosis, or
- there are pelvic signs of endometriosis on examination but deep endometriosis is not suspected.

3.4 NICE's guideline on endometriosis recommends referral to a specialist endometriosis service (endometriosis centre) if there is suspected or confirmed:

- endometrioma
- deep endometriosis (including that involving the bowel, bladder or ureter), or

- endometriosis outside the pelvic cavity.

3.5 Specialist pelvic ultrasound or pelvic MRI (to assess the extent of deep endometriosis) may inform diagnosis in some cases. But if imaging findings are normal and endometriosis is still suspected, surgical laparoscopy should be considered to diagnose endometriosis.

Unmet need and innovative aspects

3.6 There is often a long wait for endometriosis to be diagnosed. There are delays in referral pathways and long waiting times for gynaecology services. Expertise in transvaginal ultrasound in primary care varies. This may result in lower diagnostic accuracy, leading to a missed or delayed diagnosis. There is also an unmet need for alternative, non-invasive diagnostic options.

3.7 The technologies may enable earlier diagnosis of endometriosis by providing an additional option in primary care. They do not rely on operator expertise for accuracy. Earlier decision making in the diagnostic pathway informed by the results of these tests may reduce delays to diagnosis and avoid unnecessary investigations. Earlier diagnosis and treatment in primary care could help prevent the endometriosis from becoming more severe.

Clinical effectiveness

Patient perspectives

3.8 Submissions from 2 patient organisations were presented to the committee. Common themes were that non-invasive tests were generally more acceptable and that the technologies may enable faster diagnosis, treatment and referrals.

3.9 The patient experts highlighted the importance of early and accurate diagnosis of endometriosis in primary care. They stated

that a presumptive diagnosis could lead to earlier access to effective treatment and improved quality of life. The technologies are not a complete solution, but they are a step towards enabling earlier diagnosis.

Healthcare professional perspective

3.10 The clinical experts highlighted that increased diagnosis of endometriosis in primary care could lead to more referrals to secondary care gynaecology or specialist endometriosis services. This could increase the burden on secondary care services. But, some referrals could be avoided if a diagnosis is made in primary care and the endometriosis can be subsequently managed there.

3.11 Imaging does not identify all types of endometriosis. This was also highlighted by the patient experts. Additional diagnostic options in primary care could support more informed decision making, particularly when people do not want to start treatment without a diagnosis.

3.12 The clinical experts thought the technologies could be used in women's health hubs but highlighted that service provision varies between hubs. Also, it was not clear if the services provided by women's health hubs would be standardised.

3.13 The clinical experts thought it was reasonable to expect the technologies to perform similarly in detecting endometriosis in primary care and in secondary care. But differences in endometriosis prevalence between settings may affect diagnostic accuracy. Despite this, the clinical experts considered that people could benefit from a diagnosis in primary care, even if it is presumptive.

Evidence base

3.14 The evidence base comprised:

- 9 published studies, including 1 cost-effectiveness study, 1 market analysis study and 1 study reporting clinician-reported outcomes
- 5 conference abstracts, including 1 that reported patient acceptability
- 5 unpublished studies.

The committee noted that the quantity and quality of studies for each technology varied. Diagnostic accuracy was the primary outcome in 16 of the studies. No studies reported any clinical outcomes, such as time to diagnosis, time to treatment, reduction in laparoscopy rates or quality of life. All peer-reviewed studies were done outside the UK.

3.15 The committee noted that the evidence for diagnostic accuracy for all 3 tests came from secondary or tertiary care, where the prevalence of endometriosis is higher than in primary care. There were multiple studies from different centres, as well as validation studies, for EndoSure and Endotest. There was a single-centre study with no validation for DotEndo.

EndoSure

3.16 There were 10 diagnostic accuracy studies for EndoSure (2 peer-reviewed, 3 conference abstracts, 5 unpublished), with sample sizes ranging from 8 to 286. Two peer-reviewed, prospective studies (of 50 and 154 people) reported sensitivity ranging from 91% to 96% and specificity from 95% to 96%. These sensitivity and specificity values were based on AI-derived modelling, incorporating area under the curve, symptom scores and age. The studies recruited women with suspected endometriosis who were awaiting laparoscopy in specialist centres. Both studies used

diagnostic laparoscopy, with visual identification of endometriosis and histological biopsy, as the reference standard. The tests were done before the diagnostic laparoscopy. The healthcare professionals and electroviscerography technicians were blinded to each other's results and to surgical findings.

3.17 A published conference abstract of 100 people reported that the majority (60%) preferred EndoSure over transvaginal ultrasound. But the committee noted that the setting was a specialised endometriosis centre, not primary care.

Endotest

3.18 There were 5 diagnostic accuracy studies for Endotest (3 peer reviewed, 2 conference abstracts), with sample sizes ranging from 200 to 1,000. Three peer-reviewed, prospective studies (of 200, 200 and 971 people) reported sensitivity ranging from 96% to 97.3% and specificity from 94.1% to 100%. The studies recruited women with signs and symptoms suggestive of endometriosis. All studies used diagnostic laparoscopy with histology or MRI as the reference standard. The external validation study used transvaginal ultrasound as a reference standard, as well as diagnostic laparoscopy or MRI. Saliva samples were collected before the MRI or diagnostic laparoscopy, and microRNA signature was assessed blinded to the surgical or imaging findings.

3.19 The committee acknowledged that a peer-reviewed survey of 141 German gynaecologists found limited support for using Endotest. But only 15% of those surveyed had actually used the test.

DotEndo

3.20 There was 1 peer-reviewed diagnostic accuracy study for DotEndo. This prospective study of 100 women reported sensitivity of 83% (specificity-optimised threshold) and 90% (balanced threshold), and

specificity of 96% (specificity-optimised threshold) and 90% (balanced threshold). The study recruited women with symptoms suggestive of endometriosis. Diagnostic laparoscopy, with visual confirmation and histological pathology, was used as the reference standard. Serum samples were collected before the diagnostic laparoscopy, and microRNA analysis was done blinded to the surgical findings.

Cost effectiveness

Conceptual model

3.21 The external assessment group developed a de novo health economic model in which the tests were positioned in primary care after a negative or inconclusive ultrasound, or when ultrasound was declined. It compared the technologies with current care in the NHS. A Markov model was used to represent the care pathway from initial presentation through to diagnosis and management. Decision trees were used to determine outcomes for people receiving either a single diagnostic test or multiple diagnostic tests, applied to the relevant proportions of the population. The model used a 60-year time horizon and monthly cycles.

Model parameters

3.22 The key clinical inputs to the model were the diagnostic accuracies of the technologies, informed by the most comprehensive evidence available for each technology.

3.23 The external assessment group explained that health-state utility benefits from having a presumptive or definitive diagnosis after a positive test result were based on assumptions because there was no available evidence. Baseline utility was derived from a French tertiary-care study, and utility changes associated with diagnosis were based on symptom severity rather than the effect of receiving

a diagnosis. The committee recalled that having a diagnosis would be beneficial to the person, even if it is presumptive.

Model results

3.24 The external assessment group's assessment showed that all technologies were cost effective at a willingness-to-pay threshold of £20,000 per quality-adjusted life year (QALY) gained in both the deterministic and probabilistic base cases and over the 60-year time horizon. The committee noted that the incremental QALYs (0.10 to 0.11) and net health benefit (0.07 to 0.11) appeared modest and were not realised in the short term. All the technologies also reduced the time to presumptive diagnosis compared with current practice (reduction of 1.44 years to 1.82 years) and the time to definitive diagnosis by 0.97 years to 1.22 years.

3.25 Results from one-way sensitivity analyses and scenario analyses changed the incremental cost-effectiveness ratios but not the overall interpretation. Lower prevalence of endometriosis was identified as a key cost driver, with lower prevalence associated with higher costs across all 3 technologies. Test specificity was a key driver of QALYs, with a lower specificity leading to a higher QALY gain in the model. The EAG explained that a lower specificity will produce more false-positive results. In the model, people with a positive test result were assumed to have a presumptive diagnosis, which is associated with higher utility than having no diagnosis. The committee discussed this assumption as a limitation.

Equality considerations

3.26 The committee was aware of potential equality issues related to endometriosis diagnosis, use of services and access to tests in certain population groups. These include:

- people with female reproductive organs who do not identify as women, including trans men and non-binary people
- young people (aged 12 to 17)
- women, trans men and non-binary people:
  - from ethnic minority backgrounds
  - who have a learning disability, or
  - who are uncomfortable with invasive diagnostic testing.

No evidence was identified that addressed any of the equality issues.

3.27 The committee was also aware of geographical variations in service delivery.

3.28 The committee noted that some populations may particularly benefit from using the technologies, including:

- women, trans men or non-binary people who find transvaginal ultrasound unacceptable, or for whom transvaginal ultrasound is not suitable
- women, trans men or non-binary people who do not have access to healthcare professionals in primary care with high levels of expertise in transvaginal ultrasound.

4 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

Tom Clutton-Brock

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 adviser, a project manager and an associate director.

Michael Kertanegara

Technical lead

Evan Campbell

Technical adviser

Lee Berry

Project manager

Emily Eaton Turner

Associate director

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