NICE National Institute for Health and Care Excellence

NICE guidance

FibroScan for assessing liver fibrosis and cirrhosis outside secondary and specialist care

HealthTech guidance

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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

This guidance replaces MIB216 and DG48.

1 Recommendations

This guidance does not evaluate use of FibroScan for wider use than what is currently recommended in national guidelines. For example, it does not evaluate use of FibroScan outside secondary and specialist care to allow widespread screening for early liver disease. The recommendation for its use outside secondary and specialist care does not affect who should have testing as recommended in national guidelines.

1.1 FibroScan is recommended as an option for assessing liver fibrosis or cirrhosis outside secondary and specialist care if:

- each FibroScan device is expected to be used for at least 500 scans per year, typically requiring use in locations which cover larger populations, such as community diagnostic hubs
- this is likely to improve access to testing for underserved groups
- it is used in accordance with national guidelines (see sections 2.3 to 2.5)
- a clear care pathway with guidance for healthcare professionals doing the test on what to do based on a FibroScan result is established locally through collaboration between primary or community care and secondary or specialist care providers
- there is training for healthcare professionals on how to do the test, and
- the company provides supporting materials to make sure people using the test continue to use it correctly.

Why the committee made these recommendations

Using FibroScan to assess liver fibrosis and cirrhosis outside secondary and specialist care has the potential to detect liver disease earlier. Providing tests at locations that are closer

to more people who need them may improve access and attendance at appointments. This may also reduce health inequalities for people from underserved groups (such as disabled people, people living in rural areas or people from lower socioeconomic backgrounds).

This assessment did not assess wider use of FibroScan than what is currently recommended in national guidelines (see sections 2.3 to 2.5). It only considered changing the location of testing and therefore FibroScan is only recommended for use outside secondary and specialist care in line with national guidelines. To maintain test performance, testing should be done as part of a clear care pathway. Also, training on doing the test should be provided and trained operators should use the device frequently to maintain their expertise.

There is some uncertainty about the overall long-term costs of using the test outside secondary and specialist care. But, it is likely that if each device is used frequently, the immediate costs of doing a test in the community will be lower than the cost of referring a person for testing in secondary or specialist care. So, FibroScan is recommended as an option for assessing liver fibrosis and cirrhosis outside secondary and specialist care.

2 The diagnostic test

Clinical need and practice

2.1 Liver fibrosis happens when persistent inflammation of the liver causes excessive scar tissue to build up in the organ and nearby blood vessels. The presence of scar tissue can impair overall liver function and limit blood flow which may lead to the death of liver cells. Advanced liver fibrosis can develop into cirrhosis, liver failure, portal hypertension and possibly needing a liver transplant. Liver fibrosis is caused by hepatitis, non-alcoholic fatty liver disease and alcohol-related liver disease.

2.2 Cirrhosis is a late-stage liver disease that happens when inflammation and fibrosis has spread throughout the liver and disrupts the shape and function of the liver. Cirrhosis usually develops silently after exposure to 1 or more risk factors such as alcohol misuse and hepatitis B or C which cause inflammation in the liver, or obesity. But, not everyone with inflammation of the liver will eventually develop cirrhosis. Untreated cirrhosis can cause liver failure, liver cancer or death.

2.3 NICE's guideline on assessing and managing cirrhosis in over 16s recommends using transient elastography to diagnose cirrhosis in people with hepatitis C, high alcohol consumption, diagnosed alcohol-related liver disease, or non-alcoholic fatty liver disease advanced fibrosis.

2.4 NICE's guideline on diagnosing and managing chronic hepatitis B recommends transient elastography as an initial test for liver disease in adults newly referred for assessment and for the annual reassessment of liver disease in adults who are not taking antiviral treatment.

2.5 NICE's guideline on assessing and managing non-alcoholic fatty liver disease states that the enhanced liver fibrosis test should be considered for people with non-alcoholic fatty liver disease to test for advanced liver fibrosis. Clinical experts highlighted that this test is not available everywhere, and FibroScan is often used instead of, or alongside, the enhanced liver fibrosis test. This is

consistent with the British Society of Gastroenterology's guidance on non-alcoholic fatty liver disease and guidance on diagnosing and monitoring non-alcoholic fatty liver disease published in the British Medical Journal.

The intervention

FibroScan used outside secondary and specialist care

2.6 FibroScan (Echosens) is a non-invasive medical device that assesses liver fibrosis and cirrhosis by measuring the degree of liver stiffness. It can distinguish normal liver or minimal fibrosis from cirrhotic livers.

2.7 FibroScan uses proprietary vibration-controlled transient elastography to quantify liver stiffness, which is essentially a measure of the extent of liver scarring.

2.8 There are multiple products in the FibroScan range with different features, but all measure liver stiffness using transient elastography. The full list of devices can be found in table 1 of the scope.

2.9 Different sizes of probes (small, medium or extra-large) are available. The device comes with a medium probe. Small and extra-large probes are optional extras. The extra-large probe is designed to enhance signal penetration through deeper tissues, reducing device failure rates in people with obesity.

2.10 In this assessment, the intervention is FibroScan used outside secondary and specialist care. The population tested included only those who would have FibroScan in line with current NHS practice. The assessment focused on where the test should be done, rather than who should have the test.

2.11 Submissions provided by the company were based on the cost of the FibroScan 430 Mini+ at £48,000 both within and outside of secondary and specialist care settings.

The comparator

FibroScan used in secondary or specialist care

2.12 The comparator is FibroScan used in the same way as the intervention, but in secondary or specialist care.

3 Committee discussion

The diagnostics advisory committee considered evidence on FibroScan for assessing liver fibrosis and cirrhosis from several sources, including an external assessment report and an overview of that report. Full details are in the project documents for this guidance.

Increased access to FibroScan may improve early detection of liver disease

3.1 Liver disease is a significant and growing cause of mortality in the UK and is often asymptomatic in early stages. Clinical experts explained that bringing FibroScan testing closer to people who need it improves attendance at appointments which could help with earlier detection of liver disease. They highlighted that there is a need to enable early detection of liver disease to reduce the number of cases being identified late in the disease course, and that fibrosis is reversible at early stages. Clinical experts commented that people generally have a positive experience with FibroScan and could be motivated by the test results to make behavioural changes that can reverse the course of their liver disease if detected early. But, they clarified that there was no evidence showing long-term behavioural change after FibroScan use.

There may be benefits to local testing

3.2 Patient experts reported that people often travel long distances to access FibroScan, especially in rural areas. Easier access to the test could reduce time and costs associated with this. It could help people attend the test in a more familiar environment. It could also help people with disabilities that make it difficult to travel. Patient experts commented that needing to travel longer distances could be a particular barrier for people from lower socioeconomic groups, who may be at higher risk of liver disease and typically die from the condition much earlier. The committee commented that the benefits outlined may not be seen if multiple appointments are needed to first do the scan and then separately deliver lifestyle advice. Clinical experts responded that lifestyle

interventions are often delivered by healthcare assistants or nurses, and that any advice needed based on a FibroScan result would be given in the same appointment as the scan was done (see section 3.12). Clinical experts further commented that the increasing prevalence of liver disease means that secondary care services risk being overwhelmed, and that moving some aspects of care like FibroScan testing to alternative settings could help manage the workload. The extent to which making FibroScan available outside of secondary and specialist care would improve access to testing depends on which locations testing is made available, and what transport links are available (compared with transport links to secondary or specialist care).

Clinical effectiveness

There is no data comparing the performance of FibroScan when used in alternative settings with its use in secondary or specialist care

3.3 There was no evidence comparing the performance of FibroScan for measuring liver fibrosis when it is used in alternative settings with when it is used in secondary or specialist care. At consultation on the draft guidance, the lack of published evidence was confirmed by the company.

Performance of FibroScan may depend on the experience of the user

3.4 Clinical experts explained that how well FibroScan works depends on the experience of the user. They stated that if FibroScan is used often enough to make sure it is being used correctly, performance between different care settings would be comparable.

There is no evidence on how often FibroScan would need to be used to maintain competence

3.5 The committee considered the level of use that would be needed for users to maintain competence with FibroScan. The company commented that it encouraged users to make sure that competency is validated in practice, but that it does not currently provide guidance on requirements for the level of use. Clinical experts highlighted that there is no independent accreditation scheme for users, and that this is also the case for tests done in secondary or specialist care. They explained that FibroScan users outside secondary or specialist care in their areas had close links with local hepatology departments which could provide support when needed. The company explained that pilot schemes in primary care networks typically saw 20 to 30 people a month. The committee noted that it is unclear how many FibroScan tests are currently done in the NHS (see section 3.11). Clinical experts highlighted that there is no clear evidence to define a number or frequency of tests that need to be done to achieve and maintain expertise. The committee considered that sufficient levels of use may not be achieved if the test was available in individual GP practice populations, but use in services that cover larger populations, such as community diagnostic hubs or across a primary care network, would likely mean the users do enough tests to be sure it is being used correctly. The committee concluded that if used outside secondary or specialist care, it would be important to make sure that operators used FibroScan often enough to be able to accurately use the test, and for centres to consider having an accreditation framework in place.

FibroScan can be done by any healthcare professional if they are suitably trained

3.6 Clinical experts commented that FibroScan is relatively simple to use, that it indicates if the test has not worked, and that all grades of staff can use the technology if appropriately trained. At consultation, the company proposed several measures they could introduce to make sure that user competency is maintained after the initial training. These included developing a competency checklist and framework for annual assessment, offering on-site assessment, developing online competency assessments, or getting continuing professional development accreditation for FibroScan training. The committee agreed these

would be valuable and would build confidence in test results. The committee concluded that if these measures were put in place, it would give reassurance that FibroScan assessment done outside secondary or specialist care would be done effectively.

With appropriate training and quality assurance, and frequent use, FibroScan can be done effectively outside secondary or specialist care

3.7 The committee recalled that there was no data directly comparing the performance of FibroScan tests done in, or outside, secondary or specialist care (see section 3.3). But, if the test was done in an alternative setting where appropriately trained operators do enough scans to maintain their expertise (see section 3.5), the committee concluded that it was likely that test performance could be maintained outside of secondary or specialist care, if there are ongoing measures to ensure quality such as those proposed by the company (see section 3.6).

There was concern that greater availability of FibroScan outside secondary and specialist care could lead to wider use

3.8 The committee recalled that the population in this assessment was restricted to those who would have FibroScan as in current NHS practice (see section 2.10). The test was only assessed for use in people it is already recommended for. It noted that performance of the test would depend on the population being tested, and that the value of testing would depend on the availability and effectiveness of interventions for the population tested, based on test results. Some consultation comments mentioned a potential benefit of FibroScan outside secondary or specialist care may be that it allows for wider screening for early liver disease. The committee noted that such use had not been assessed in this guidance and expressed concern that using FibroScan outside secondary or specialist care could lead to its use in a wider population than assessed, which could in turn affect its performance. It concluded that if recommended, the test should only be used as recommended in national guidelines (see sections 2.3 to

2.5).

FibroScan should be used as part of a clear care pathway

3.9 Clinical experts and committee members emphasised that clear guidance on what to do with the results of FibroScan is vital, particularly if testing is done outside a specialist setting. FibroScan done in alternative settings could reduce the number of unnecessary referrals to hepatology services. But, if there is uncertainty about what to do based on a result, a referral to specialist services, or contact with these services to ask advice, may still be made. Clinical experts highlighted that this could happen often if multiple conflicting test results (including FibroScan) were available. Liver pathways should be designed in agreement with primary and secondary care centres, and incorporate all tests used for detection and characterisation of liver disease, not just FibroScan. The committee concluded that establishing clear care pathways, with guidance for healthcare professionals on what to do based on a FibroScan result based on existing national guidelines, would be essential to ensure appropriate clinical management of liver disease in people who have FibroScan tests done outside secondary and specialist care settings.

Cost modelling

The long-term effects of testing outside secondary and specialist care on costs are uncertain

3.10 In the base-case analysis provided by the company, the economic model used a 1-year time horizon. The committee commented that this omits potential costs or cost savings that would only appear many years after testing, such as the costs of treating previously undetected liver disease. The committee noted that increased attendance at FibroScan appointments in primary or community care increased costs in the model, because more people were referred for follow-up appointments in hepatology. But, any potential cost savings or health benefits of greater detection of liver disease were not considered (see section 3.1). At consultation on the draft guidance, the company submitted a scenario analysis

with a 5-year time horizon, which estimated lower long-term costs of about £30 less per person if testing was done in primary or community care. The external assessment group (EAG) explained that the lower cost was because there were fewer people with missed liver disease if testing was done in primary or community care, because more people attended scans. The committee considered it was unclear what assumptions were made in the modelling to base this on. Company representatives were not able to provide further clarity in the committee meeting. The company's model did not allow people's liver disease to progress in the 5-year time period modelled. Clinical experts commented that this may not be appropriate for people with alcohol-related liver disease, whose condition can progress at a faster rate. The committee noted that the effect of lifestyle advice may differ depending on who provides it, for example a GP compared with a liver specialist, but experts said that there was no evidence on this. Clinical experts commented that referrals to hepatology services may increase after adopting FibroScan outside secondary and specialist care, but this may mean that more people who would benefit from specialist care are able to access it. Clinical experts also commented there was uncertainty about the long-term effect of using the test outside secondary or specialist care, for example, on levels of hospitalisation. The committee considered it plausible that testing in alternative settings could lead to longer term cost savings but thought that the company analysis did not allow this to be assessed. In advance of the third committee meeting, the company provided a revised model, and accompanying description, of the long-term implications of missing liver disease. This included allowing liver disease to progress within the modelled time period. This led to lower costs if FibroScan was done in primary or community care because increased attendance at scans was assumed to increase detection of liver disease and reduce progression to more severe stages. The EAG questioned the long-term costs used in the model because they came from a study of antiviral treatment for people with chronic hepatitis C (Wright et al. 2006). It suggested a study in which costs were related to managing non-alcoholic fatty liver disease (Tanajewski et al. 2017) as an alternative source. Some of the results from the updated model provided by the company for the third committee meeting, and further analyses run by the EAG using this model, did indicate that testing in primary or community care reduced long-term costs. Clinical experts said that earlier detection of liver disease could plausibly lead to cost savings. But, the committee also considered that costs could be higher in the long term (although potentially with accompanying improvements in health-related quality of life),

particularly if a time frame longer than the 5 years modelled was used. The committee concluded that there is considerable uncertainty about the long-term effect of FibroScan testing outside secondary or specialist care on costs.

There is uncertainty about the cost per scan in secondary care but the model likely underestimates this cost

3.11 The committee discussed the costs used in the original model submitted by the company, and the revised costs used by the EAG. The EAG removed a cost from the company's model for staff time to do and evaluate FibroScan in secondary or specialist care because this time was already incorporated within an existing cost used in the model. This meant that, using the figure proposed by the company for testing in this setting, the cost of doing FibroScan was greater per scan when done in primary or community care. Experts agreed that the staff costs of doing the scan would be included in the Health Resource Group (HRG) cost used by the company. The company used HRG bundled costs for ultrasound elastography to estimate the cost of FibroScan in secondary or specialist care, at £43.93 in the base case. This cost was also used by the EAG. The company highlighted that a scenario analysis done by the EAG in which a higher cost per use in secondary or specialist care (£61.98) was used, based on a weighted average of 2 different costs attributed to the HRG code, and suggested that this might be more appropriate. The EAG commented that the results of this scenario still indicated that using FibroScan outside secondary or specialist care was cost incurring. In their report, the EAG highlighted difficulties in evaluating the costs of doing FibroScan in the different settings that were a consequence of comparing a bundled HRG cost from secondary care with a cost obtained by micro-costing in a non-hospital setting, where a HRG code does not currently exist. The committee noted that the HRG code for ultrasound elastography was used only 3,561 times for outpatients in 2019 to 2020, which likely underestimated the number of FibroScan tests done in the NHS. Further scans may be done during outpatient appointments and recorded using other HRG codes, potentially at higher cost. At consultation, the company provided further analyses. Its base-case analysis kept the higher cost of testing in secondary care, including additional costs for staff time to do the test as well as the HRG code. Analyses using alternative costs were not cost neutral or cost saving for testing done in primary or community care. The company did not provide any further support for

their choice of cost used in the base case or rationale for the most appropriate choice of cost for the test in secondary care. The committee also questioned whether the full costs of a referral for testing in secondary or specialist care had been incorporated. Missed appointments were included as a separate cost in the model. A clinical expert commented that the cost of missed appointments was likely to already be captured in the cost of doing scans used in the company's model. If so, including an additional cost for missed appointments was not appropriate. Clinical experts noted that if a person misses an appointment in secondary care, they may need to restart the referral pathway to access FibroScan, incurring further cost. The committee concluded that there was still considerable uncertainty about the costs of testing in secondary care, and suggested further analysis to address this. In advance of the third committee meeting, the company provided further analyses. This included a micro-costing-based estimate of £40.61 for doing FibroScan in secondary care. The number of scans (610) used to determine this was from a survey of 4 NHS trusts. The EAG noted some limitations in the company's micro-costing approach but stated this was its preferred method for assessing costs. Clinical experts noticed that the company's micro-costing only included costs of doing FibroScan but not the costs of a referral for a hepatologist outpatient appointment that would happen in practice if a GP decided that the scan was needed. The EAG noted that the NHS reference cost for this appointment is £268 (cost in individual trusts may vary). The committee concluded that while there is uncertainty about the exact cost of testing, it is likely that the model underestimates the cost of doing FibroScan in secondary care.

The extent of use of FibroScan outside secondary or specialist care will affect cost per use

3.12 The committee noted that the cost the company has provided for FibroScan in primary or community care in their original submission is higher (£58.00 per scan, plus £10.50 for staff time to do the test and evaluate FibroScan result) than the HRG code cost used in the EAG's base case and scenario analysis for FibroScan in secondary or specialist care (see section 3.11). This was based on a fixed cost being charged by the company per scan, with no upfront cost for the machine. At consultation, the company submitted an alternative costing model in which the FibroScan device was purchased outright, which included a maintenance

contract over the assumed 7-year lifespan of the device. The average cost per scan, calculated assuming 500 scans per year being done based on Southampton clinical commissioning group use, was £34.29 plus staff time to do the test. The EAG did a threshold analysis and found that the device would have to be used at least 300 times a year for this model to be cheaper than the pay-per-scan model originally suggested. The company stated that their intended use of the tests outside secondary or specialist care is in hubs and diagnostic centres, rather than single GP practices, where use would be expected to be higher. The committee agreed that this usage may be achieved if the device was used in primary care networks or community diagnostic hubs (see section 3.7). But, it noted that only a single estimate of expected use in primary or community care had been provided by the company. The committee recalled that moving FibroScan testing outside secondary and specialist care would potentially move workload to other settings for activities that happen based on test results, such as lifestyle advice, and questioned whether the time taken by healthcare professionals to do this has been adequately captured in costs of doing the test outside secondary and specialist care. They further highlighted that even if a person is not referred to a specialist service after a test done outside this setting, advice from staff in these services may be sought. A clinical expert emphasised that community and primary care staff such as nurses and healthcare assistants are experienced in providing lifestyle and diet advice (see section 3.2) and that any advice could be given in the same appointment as the FibroScan test was done. The committee concluded that there was uncertainty about whether the costs of doing FibroScan outside secondary and community care used in the company's model were an accurate reflection of the true cost of testing. It further noted that if buying the FibroScan device outright, the cost per use would depend on the extent of use, and asked for further information to support estimates of expected use. In advance of the third committee meeting, the company provided further analysis. Using local real-world data and national data sources, the company estimated that 1 FibroScan device shared between 5 primary care networks would be used for 2,500 to 5,000 scans per year. The EAG considered the estimates based on real-world data more robust but stated that using 6 sources of information provided by the company, the EAG found only 1 example where FibroScan was used in as many as 500 to 1,000 people per year per primary care network. But of the 8 clinical experts consulted by the EAG, 5 said sharing 1 device between 5 primary care networks was plausible in some scenarios and all thought a single network would be able to do 500 scans per

year. The clinical experts attending the committee meeting supported this view. The committee noted that in its updated submissions, the company had provided the cost per FibroScan done in primary care based on buying the device outright and at least 500 scans per device being done per year (£44.79), rather than the cost per scan based on a pay-per-scan charging model as in its original submission (£58.00 per scan, plus £10.50 for staff time).

Using FibroScan in alternative settings is likely to cost less than doing the test in secondary care

3.13 There is still uncertainty about the true cost of doing a test both in secondary and specialist care (see section 3.11) or outside these settings (see section 3.12). The committee recalled that it is likely that the model underestimated the cost of testing in secondary care (see section 3.11). Higher cost of testing in this setting would make testing outside of secondary and specialist care more likely to be cost saving. The committee concluded that, based on buying FibroScan 430 Mini+ outright (see section 2.11) and an expected use of at least 500 scans per year per device as modelled by the company, the immediate costs related to a FibroScan test were likely to be lower outside of secondary and specialist care. The committee also recalled that making sure FibroScan was used enough outside secondary and specialist care was important to make sure operators do enough scans to maintain their expertise (see section 3.7).The committee further recalled that there is considerable uncertainty about the long-term effect on costs of using the test outside secondary and specialist care (see section 3.10). On balance, the committee concluded that there was enough certainty that the immediate costs of using FibroScan for assessing liver fibrosis and cirrhosis outside secondary and specialist care are likely to be lower than the cost of referring people for testing in secondary or specialist care to allow it to recommend use in this setting.

It would be beneficial to monitor the effect of FibroScan outside secondary and specialist care to make sure that the expected benefits are seen

3.14 The committee commented that it would be beneficial to monitor the effect of greater availability of FibroScan outside secondary and specialist care on relevant costs and outcomes to make sure that the proposed benefits are being achieved in practice in the NHS.

4 Diagnostics advisory committee members and NICE project team

Committee members

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

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

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.

NICE project team

Each diagnostics assessment is assigned to a team consisting of a technical analyst (who acts as the topic lead), a technical adviser and a project manager.

Jacob Grant
Topic lead (until July 2022)

Suvi Härmälä
Topic lead (from August 2022)

Thomas Walker
Technical adviser

Donna Barnes
Project manager (until April 2022)

Toni Gasse
Project manager (from May 2022)

Update information

Minor changes since publication

December 2025: Diagnostics guidance 48 has been migrated to HealthTech guidance 682. The recommendations and accompanying content remain unchanged.

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