NICE National Institute for Health and Care Excellence

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HealthTech draft guidance

Digital front door technologies to gather information for assessments for NHS Talking Therapies for anxiety and depression

April 2025

Guidance development process

NICE early value assessment (EVA) guidance provides recommendations on promising health technologies that have the potential to address national unmet need. NICE has assessed early evidence on these technologies to determine if earlier patient and system access in the NHS is appropriate while further evidence is generated.

EVA guidance recommendations are conditional while more evidence is generated to address uncertainty in their evidence base. NICE has included advice in this guidance on how to minimise any clinical or system risk of early access to treatment.

Further evidence will be generated over the next 3 years to assess if the benefits of digital front door technologies are realised in practice. NICE guidance will be reviewed to include this evidence and make a recommendation on the routine adoption of this technology across the NHS.

Find out more on the NICE webpage on early value assessment (EVA) for medtech.

Issue date: April 2025

NICE is producing this guidance on digital front door technologies 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 economic outcomes 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 digital front door technologies. The recommendations in section 1 may change after consultation.

Issue date: April 2025

More details are available in NICE's health technology evaluations: the manual and NICE's early value assessment interim process and methods statement.

Key dates:

Closing date for comments: 7 May 2025

1 Recommendations

1.1 Two digital front door technologies can be used in the NHS during the evidence generation period as options to gather information for assessments for NHS Talking Therapies for anxiety and depression in people 16 years and over. The technologies are:

- Limbic Access
- Wysa Digital Referral Assistant.

These technologies can only be used:

- if the evidence outlined in the evidence generation plan for Limbic Access and Wysa Digital Referral Assistant is being generated
- once they have appropriate regulatory approval including NHS England's Digital Technology Assessment Criteria (DTAC) approval.

1.2 The companies must confirm that agreements are in place to generate the evidence. They should contact NICE 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.

1.3 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 technologies can be routinely adopted in the NHS.

What evidence generation is needed

More evidence needs to be generated on digital front door technologies, including:

- the quality of the data collected
- their impact on clinical decision making in clinical assessments for NHS Talking Therapies for anxiety and depression
- their impact on administrative burden
- time saved
- feedback from people using the service
- costs including for training, promotion and digital safety assurance.

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.

What this means in practice

Limbic Access and Wysa Digital Referral Assistant can be used as an option 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.

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.

Why the committee made these recommendations

The evidence for Limbic Access and Wysa Digital Referral Assistant supports their use in gathering information for assessments for NHS Talking Therapies for anxiety and depression while further evidence is generated.

The clinical evidence on time savings and clinical impact with these technologies is limited, but suggests that they may improve outcomes and workflow. For example, any time saved may be used to discuss presenting problems and objectives in more detail with the healthcare ;professional during the assessment. This may result in a higher-quality clinical assessment, leading to identifying the correct treatment pathway more accurately. These technologies may also improve access to NHS Talking Therapies for anxiety and depression. This is because some people may prefer to use digital technology to access care rather than traditional routes. The risk associated with using these technologies is low. But more evidence is needed on their clinical effectiveness.

Early results from the economic evidence suggest that the technologies could be cost effective, even if only few minutes are saved for each assessment. More evidence is needed on the cost implications of using these technologies.

2 Information about the technologies

The digital front door technologies

2.1 Digital front door technologies are defined in the NHS Talking Therapies for anxiety and depression manual (2024) as ‘pre-assessment digital front doors, which can collect advance screening information about possible presenting problems that will help inform and facilitate the assessment’. NHS Talking Therapies for anxiety and depression (from now, NHS Talking Therapies) offer mental health support for mental health conditions. The manual also states that ‘it is important that problem descriptors are not allocated until a full healthcare professional-led assessment has taken place’. So, functions of technologies that go beyond that

of a digital front door, such as diagnosis (including assigning problem descriptors), treatment and remote monitoring, were not included in this early value assessment. Four technologies were identified for this early value assessment. Recommendations were made for 2 technologies. No recommendations were made for 2 technologies because:

- For AskFirst, there was no information to support its inclusion in this early value assessment. The company (Sensely) did not provide any information, and no relevant information was identified by the external assessment group.
- For Censeo Digital, the Medicines and Healthcare products Regulatory Agency (MHRA) issued a Field Safety Notice about Censeo Digital (Psyomics) on 22 January 2025. This advised its use should be stopped until it has been assessed by an Approved Body or Notified Body and determined to be compliant. The company has also informed NICE that the technology was no longer in the UK market as of the 24 February 2025, so is not available in the NHS.

Limbic Access

2.2 Limbic Access (Limbic) is a UKCA Class IIa artificial intelligence (AI) chatbot designed to help guide someone to the right service through a conversation and clinical decision making. It streamlines the referral and triage process for common mental health conditions like anxiety and depression. It collects key information, including:

- eligibility criteria
- contact details
- demographics
- presenting symptoms (minimum data set)

- assessment scores from the Patient Health Questionnaire 9 (PHQ-9), Generalised Anxiety Disorder-7 (GAD-7) and the Work and Social Adjustment Scale (WSAS)
- additional screening responses.

Limbic Access generates a clinical report summarising concerns, risk levels, clinical notes, disorder-specific measures and diagnosis predictors to aid healthcare professional assessments. It captures all the activity in a dashboard, providing insights into engagement, referrals and staff efficiency. It also suggests problem descriptors using anxiety disorder-specific measures, but this functionality is outside the scope for this topic. It is fully interoperable with cloud-based electronic health record (EHR) systems by enabling seamless data integration into these systems. Currently, it is used by about 40% of NHS Talking Therapies services. Limbic Access has no fixed costs, and its licensing fee is charged for each digital front door technology referral. The cost decreases as the volume increases, ranging from £6.59 to £4.20 (including VAT) for each referral.

Wysa Digital Referral Assistant (DRA)

2.3 Wysa DRA (Wysa) is a UKCA Class I AI-supported e-triage chatbot for NHS Talking Therapies services. It collects referral data, including demographic questions. If the referral is accepted, it gathers clinical information such as the PHQ-9 questionnaire, GAD-7 and WSAS, and other minimum data set elements. It provides immediate signposting for people who do not meet eligibility criteria based on age or GP location. The system flags people based on service-specific criteria for review by a healthcare professional while engaging users with mindfulness exercises during e-triage. Wysa DRA generates a report based on service-specific criteria for review by a healthcare professional. This summarises key findings and transfers referral data directly to the

NHS Talking Therapies EHR system, automatically creating a record when relevant data fields exist. The chatbot is currently live in several NHS Talking Therapies services. Wysa DRA has a one-time implementation and setup cost for each service of £10,180 (including VAT) in the first year. The licensing cost varies based on the number of digital front door technology referrals. The cost decreases as the volume increases, ranging from £3.90 to £1.39 (including VAT) for each referral.

3 Committee discussion

The diagnostics advisory committee considered evidence on digital front door technologies to gather information for assessments for NHS Talking Therapies for anxiety and depression (from now, NHS Talking Therapies) from several sources. This included evidence submitted by Limbic and Wysa, 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

3.1 Digital front door technologies are indicated for people over 16 years with suspected common mental health conditions, as specified in the NHS Talking Therapies for anxiety and depression manual (2024). Many people may experience more than 1 of these conditions.

Current practice

NHS Talking Therapies services pathway

3.2 The NHS Talking Therapies services pathway is divided into 5 steps in the NHS Talking Therapies manual: presentation, referral, pathway starts, assessment and next step. Referrals to NHS Talking Therapies can come from primary, secondary or community care, or through self-referral. Methods include paper forms, letters, phone calls, emails, online forms or digital front door

technology. Both people using the service and healthcare professionals can initiate referrals. Sometimes, professionals may guide people to self-refer and provide information on available methods, or help them in the process. The clinical experts highlighted that the referral process for assessments for NHS Talking Therapies in current practice varies between NHS Talking Therapies providers. While all referrals include information collection, the amount and type of information collected can vary.

Referral process

3.3 The referral process includes checking if a person is at risk from NHS Talking Therapies, or eligible or suitable for NHS Talking Therapies. This is also called triage or screening. Checking for risks and safeguarding issues, including self-harm, suicide or harm to others, is always prioritised. It is based on the person's presenting problems and medical history. If there are concerns about risk, a healthcare professional will contact the person to ensure safety, gather more information and direct them to appropriate services. Eligibility is based on GP location and age, with some services also available for young people aged 16 to 17 years. People for whom NHS Talking Therapies services are unsuitable are not offered an initial clinical assessment and are sent a letter explaining the referral rejection. The method of triaging people for assessments for NHS Talking Therapies varies, for example, it might include:

- doing eligibility checks at initial clinical assessments
- eligibility checks led by an administrator or healthcare professional before initial clinical assessments.

The comparator

3.4 The comparator for this early value assessment was the process of referring people to NHS Talking Therapies without using digital front door technologies.

Unmet need

3.5 In England, 1 in 6 people have a common mental health condition (like anxiety and depression) in any given week (McManus et al. 2016). The Five Year Forward View for Mental Health from 2016 set out that NHS England should increase access to evidence-based psychological therapies to reach 25% of people in need. This was so that at least 600,000 more adults with common mental health conditions could access NHS Talking Therapies services each year by 2020/21 (1.5 million in total). The NHS Long Term Plan then increased this to an additional 380,000 adults having access by 2023/24 (1.9 million in total).

Challenges

3.6 There are several challenges when accessing NHS Talking Therapies. One issue is the sharing of information. The quality of collected data before assessments for NHS Talking Therapies is often poor, which means that healthcare practitioners have to spend extra time gathering the necessary information during the actual assessments. Some services have to manually copy and paste information to populate fields. Also, manually entering referral details for people for clinical assessments for NHS Talking Therapies can be a burden for administrative staff. Another significant challenge is improving access to NHS Talking Therapies services. The committee noted that it is important to make it easier for people to refer themselves for assessments whenever they need to, rather than relying on referrals from healthcare providers. This could help more people get the support they need in a timely manner. Also, some people find face-to-face interactions uncomfortable, which can be a barrier to seeking help.

Innovative aspects

3.7 Digital front door technologies enable people to refer themselves for assessment at any time to access NHS Talking Therapies

services. They capture information at the point when people are seeking help by offering 24 hour access, 7 days a week, through web portals and mobile apps. Digital front door technologies also remove the need for face-to-face interactions, which could promote access for those who find this a barrier. Many incorporate artificial intelligence (AI) driven symptom checkers and have decision-support tools that automatically signpost people who are not eligible for other services. A key innovation is that they can interface with EHRs and improve clinical workflows by streamlining processes.

Clinical effectiveness

Evidence

3.8 The committee considered evidence from 10 sources for Limbic Access and 3 studies for Wysa Digital Referral Assistant (DRA). Data for Limbic Access was available from multiple sources including:

- 2 large UK-based peer-reviewed studies
- 1 validation study
- 2 company evaluation studies
- 1 short online survey of psychological wellbeing practitioners
- 1 evaluation of feedback responses from users of Limbic Access
- 1 research study about model training
- 2 NICE request for information responses.

Data for Wysa DRA was real-world experience from users reported in 3 Wysa NICE request for information responses. None of the data provided was comparative or sourced from published research studies. Most of the evidence came from routine data collected by NHS Talking Therapies services or company-reported data on the performance of their digital front door technologies. The evidence for patient-reported outcomes

was sourced from user responses to questions asked after completing referral information through a digital front door technology. Most studies were non-comparative, primarily evaluating the strengths and weaknesses of these technologies.

The extent to which the available clinical evidence is generalisable to all NHS Talking Therapies service providers is unclear. This is because the referral process and system for people to access initial assessment varies across NHS Talking Therapies services. The committee noted that it was not possible to synthesise the limited available clinical evidence because of the heterogeneity of the non-comparative data. The committee acknowledged that there was more evidence for Limbic Access than for Wysa DRA. But it noted that the overall quality of evidence assessed was broadly comparable for Limbic Access and Wysa DRA. This was because most of the information came either directly from the companies themselves, or from published data for which most of the authors were company affiliated. But the committee acknowledged that the published data (only available for Limbic Access) was in peer-reviewed studies.

Risks

3.9 The committee noted a lack of evidence on the impact for people unable to access the service or for people referred elsewhere. The clinical experts highlighted that triaging people out of the service without a formal clinical assessment does not align with the NHS Talking Therapies manual. They emphasised that the technology should prioritise collecting risk-related information rather than excluding individuals. The companies clarified that their technologies do not automatically exclude users. One clinical expert stated that it is the companies' responsibility to manage clinical risk by ensuring compliance with the Digital Clinical Safety Assurance process. This verifies that health information technology

used by healthcare professionals is safe and meets national standards. Also, the EAG addressed that digital front door technologies are an optional referral method because other pathways to NHS Talking Therapies assessments remain available. In addition, the evidence showed high levels of self-reported satisfaction among people using digital front door technologies to access NHS Talking Therapies. Also, the committee acknowledged that the technology is used to gather information to inform and help the healthcare professional when doing an assessment for NHS Talking Therapies. It does not make a clinical judgement independently from the healthcare professional. Based on these considerations, the committee concluded that digital front door technologies are low risk to use with further evidence generation.

Quality of clinical assessment for NHS Talking Therapies

3.10 The committee considered the potential benefits of using digital front door technologies to improve the quality of clinical assessments for NHS Talking Therapies. The clinical experts explained that data collection by less experienced staff in current practice is often poor, leading to over- or under-diagnosis. Digital front door technologies could enhance information gathering before assessment, helping healthcare professionals make more informed decisions during the initial clinical assessment. This could result in more accurate diagnoses and improved treatment pathway selection. But the clinical and patient experts also raised concerns that the AI-driven algorithms in some of these technologies may selectively present information to healthcare professionals, with unknown implications for clinical decision making. The committee discussed that further evidence comparing clinical assessment outcomes with and without digital front door technologies is needed. But the committee decided that the quality of the data collected by the technologies could be estimated pragmatically.

Time savings

3.11 The committee discussed the potential time savings from using digital front door technologies during initial clinical assessments. Both Limbic and Wysa reported that their technology can reduce assessment time. Limbic Access reportedly saves 12.7 minutes (data from a peer-reviewed study) and Wysa DRA reportedly saves between 16.0 and 21.0 minutes (data from the company's response) for each assessment. The EAG highlighted that a shorter assessment could have various affects, including:

- needing fewer healthcare professionals to complete the same number of assessments
- freeing healthcare professionals for other duties such as delivering treatment
- reallocating saved healthcare professional time to doing more initial assessments
- potentially reducing waiting times
- allowing for a more detailed discussion of people's presenting problems and objectives, leading to a more accurate and higher-quality clinical assessment.

The committee recognised that evidence on time savings was limited, and the net time saved remains uncertain. But it noted substantial potential for improving system efficiency.

Considerations of people using the service

3.12 The patient experts shared their experience of accessing NHS Talking Therapies and the impact of common mental health conditions. They highlighted that current services struggle to meet demand, leading to long waiting times for assessment and treatment. Delayed access can negatively affect relationships, employment, and mental wellbeing (for example, increasing suicidal thoughts) and reduce daily functioning. People using the service thought that digital front door technologies could offer

benefits such as faster access, improved identification of appropriate treatment pathways, and reduced duplication of information-sharing. But they were concerned about digital exclusion, literacy barriers and the affordability of technology, which may widen inequalities, particularly for vulnerable groups. Additional concerns included:

- risk to data privacy
- the risk of a technology making implicit judgments about a person's mental health condition based on their responses
- referrals or treatment pathways potentially being influenced without a formal clinical assessment
- potential misdirection to inappropriate services
- a lack of accuracy of AI-driven conclusions
- whether feedback from people using the service would be adequately considered
- whether these technologies might unintentionally exacerbate inequalities.

The committee emphasised the need for safeguards to ensure these technologies provide appropriate support to people using the service.

Survey results from people using the service

3.13 NICE developed a questionnaire for people who have used NHS Talking Therapies service. This was to elicit public responses on using a digital technology before clinical assessments for this service. NICE received a total of 433 responses to the questionnaire. The responses highlighted potential benefits and concerns. Most of the respondents were 25 to 59 years (73%). Women comprised 74% of the sample. Willingness to use digital technologies occurred in 82% of respondents. Reasons given included efficiency, convenience, flexibility and a sense of control over the information provided. But concerns were raised about data

privacy, risk of digital exclusion because of literacy and accessibility issues, and the impersonal nature of digital interactions. Also, 64% of respondents waited less than 3 months for an assessment, but 77% did not have any symptom management support while on the waiting list. When asked about information collection, 82% stated they were asked to provide details in advance, primarily through phone calls or digital platforms. Some respondents valued the structured approach of the digital technologies. Others expressed difficulty in talking about symptoms digitally, and said they preferred in-person interactions with healthcare professionals. The clinical experts noted that using digital front door technologies could reduce the need for phone calls to collect information, potentially saving time in the referral process. But the committee suggested that alternative referral methods to access NHS Talking Therapies services should still be available.

Economic evidence

Limitations

3.14 The EAG did not find any published economic evidence that met the its systematic literature review inclusion criteria for this early value assessment. So, there was insufficient evidence to compare standard referral practice to NHS Talking Therapies with and without digital front door technologies to:

- build a conceptual economic model
- generate any reliable economic results.

Certainty of results

3.15 To compare the benefits and costs of standard NHS pre-assessment referral practice to NHS Talking Therapies with and without digital front door technologies, the EAG did:

- an exploratory economic analysis

- a threshold analysis
- a scenario analysis.

Evidence supporting time savings during the initial clinical assessment with these technologies were limited. But the required time savings to offset the licence costs of Limbic Access or Wysa DRA are minimal. If there are no time savings, a very small quality-adjusted life year (QALY) gain of 0.0003 QALYs for each referral would be needed for either technology to be considered cost effective. This would be at a willingness-to-pay threshold of £20,000 for each QALY gained, assuming only licence costs are considered. Also, there is no quantitative data to support claims that digital front door technologies reduce administrative burden. The committee acknowledged the uncertainty in the economic findings because of the limited evidence. But it recognised the potential for these technologies to improve system efficiency.

Equality considerations

3.16 The committee noted that Limbic Access and Wysa DRA are designed to be accessible. This includes older people, people from minority backgrounds and disabled people. Some evidence shows that Limbic Access is effective at ease referrals from people with diverse gender identities and people from ethnic minority backgrounds who are typically underrepresented in mental healthcare. The clinical experts mentioned that, since the introduction of digital front door technologies, referrals from minority ethnic groups have increased. They also suggested that digital front door technologies may help reduce access barriers for some historically harder-to-reach populations.

The EAG highlighted that some people may not have access to a computer, smart phone or laptop. Also, people with low motivation

or cognitive challenges may disengage from digital platforms before their referral is complete. The committee noted the considerations raised by people using the service and people replying to the NICE questionnaire around the risk of digital exclusion because if to literacy and accessibility issues. Older adults or people with low digital literacy may face barriers to using digital front door technologies to access NHS Talking Therapies. There may also be issues for people with English as an additional language because translations may not be appropriate or the content culturally relevant. AI-based chatbots may be unable to interpret information provided by people with English as an additional language, leading to miscommunication. Marginalised populations, including those experiencing domestic violence or housing insecurity, may avoid using digital services because of concerns over confidentiality.

The clinical experts also noted that people whose first language is not English may face barriers when using digital front door technologies. They added that some people with anxiety, depression, or severe mental illness may struggle with engaging in digital interactions, particularly if they prefer face-to-face support. Also, people with severe physical disabilities may need adaptive technologies that are not always integrated into digital front door systems.

The committee agreed that, if NHS Talking Therapies services continue to provide multiple referral methods to access them, people attempting to access them are unlikely to be disadvantaged if digital front door technologies are introduced.

Evidence gap review

3.17 The committee agreed that there were evidence gaps for the technologies assessed in this early value assessment, including:

- Quality of the data collected: more evidence is needed to validate the quality of data collected by digital front door technologies and their potential to enhance the quality of clinical assessments in NHS Talking Therapies. Improving the quality of assessments could lead to better treatment decisions and more effective care pathways. The impact of these technologies on clinical decision making is unclear. Some outcomes will be collected through NHS Talking Therapies services. But the clinical experts emphasised the need for comparative studies assessing people referred using digital front door technologies compared with people referred through traditional routes. Also, evaluating the sensitivity and specificity of problem descriptors identified through clinical assessments would provide valuable insights into the reliability of these technologies in supporting clinical decision making.
- Acceptability: more data is needed on the completion rate of referrals through digital front door technologies. It is also needed on the acceptability of these technologies among healthcare professionals. This is important in evaluating their effectiveness and integration into NHS Talking Therapies services. Understanding both aspects is helpful for assessing the feasibility, usability and overall impact of digital front door technologies in improving access to NHS Talking Therapies.
- Resource and system impact: more information is needed on the impact on administrative burden and time saved by using digital front door technology to assess the net time saved. This will be helpful to understand wider system efficiencies.
- Reported outcomes from people using the service: more evidence is needed on feedback from people using the service about ease of access, usability, information clarity and relevance, comfort and privacy. This will help the committee understand how these technologies benefit people using the service.

- Costs: there was limited information on training, promotion, and digital safety assurance costs of digital front door technologies. The clinical experts highlighted that digital safety assurance costs can be significant. Additional cost data would help the committee better assess the overall value of these technologies.

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

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 adviser, a project manager and an associate director.

Ziqi Zhou
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ISBN: [to be added at publication]